Chronic Disease Coalition

Oregon Prescription Drug Affordability Board (PDAB)
350 Winter St. NE Room 410
Salem, OR

March 13, 2024

Chair Patterson, Vice Chair Bailey, and members of the board,

On behalf of the Chronic Disease Coalition, thank you for the opportunity to provide our thoughts and feedback as the PDAB evaluates the affordability of proven treatments for psoriasis, psoriatic arthritis, Crohn's disease, and other chronic conditions.

Headquartered in Portland, the Chronic Disease Coalition is a national nonprofit organization dedicated to raising the patient voice and perspective in healthcare policymaking. The coalition was founded in 2015 to advocate for people living with long-term or lifelong health conditions. Our patient advisors and partners represent common diseases (e.g., diabetes, kidney disease, arthritis), rare diseases (e.g., Guillain-Barré syndrome, hypoparathyroidism), and many other conditions whose scale and scope are still not understood.

We have provided comment to this board before, and will continue to highlight patients' critical need for consumer-level cost controls and continued innovation in medicine. Especially as the board contemplates upper payment limits, it is critical to recognize how limits affect the treatments and cures that patients depend on.

- To be clear, regardless of whether a chronic disease is rare or common, chronic disease patients are extremely cost-sensitive; we also recognize the state's interests in controlling costs. Those are not, however, interchangeable policy mechanisms.
- Chronic disease patients need more access to better treatments, and any action to address pricing must consider its potential impact on similar medications and the landscape of treatment development.
- Impacting the prices of a few life-saving drugs could inadvertently affect costs across other categories and slow the development of future treatments.
- All new treatments only come from the private sector, and the next generation of patients deserves the next generation of cures.

Additionally, while the PDAB rightfully considers manufacturer prices as a starting point for discussions on affordability, it's crucial to recognize that list prices don't reflect patient costs, and that there are other ways of protecting patients. Achieving meaningful progress requires a holistic approach that includes proven reforms directly benefiting patients. The CDC was proud to support two bipartisan bills that passed this year in the Oregon Legislature — HB 4149 and HB 4113 — that enhance transparency of PBM practices and address copay accumulator programs, respectively. By prioritizing reforms like these bills that offer immediate and tangible benefits to patients, we can collectively advance the cause of more accessible and effective healthcare.

Sincerely,

Nathaniel Brown
Director of Advocacy
nathaniel@chronicdiseasecoalition.org
(971) 219.5561

December 18, 2023

SUBMITTED VIA EMAIL TO: pdab@dcbs.oregon.gov

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405

Re: Oregon Prescription Drug Subset List

Dear Members of the Oregon Prescription Drug Affordability Board,

On behalf of Takeda Pharmaceuticals America, Inc. ("Takeda"), I am writing concerning the December 13, 2023 meeting of the Oregon Prescription Drug Affordability Board ("PDAB"), during which the PDAB revised the final subset of prescription drugs for affordability review. We appreciate the opportunity to provide written feedback and respectfully ask that Vyvanse® (lisdexamfetamine dimesylate) be removed from the prioritized subset and not subject to the affordability review process because numerous generic versions of Vyvanse, covering all dosage forms and strengths of the product, have been approved and launched beginning in August 2023.

Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments in our core therapeutic and business areas, including rare diseases, gastrointestinal and inflammation, plasma-derived therapies, oncology, neuroscience and vaccines. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline.

Takeda has been monitoring Oregon's implementation of the PDAB Statute. At the December 13 meeting, the Board voted to approve the staff recommendation to remove the Creon group, Albuterol Sulfate group, Symbicort group, and Suboxone group from the prescription drug subset list. This recommendation was based on further consideration of OAR 925-200-0010(4), which states that the board shall consider, "For brand-name drugs and biological products, whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product." Continued inclusion of Vyvanse on the prioritized subset of prescription drugs for affordability review would be inconsistent with the Board's decision during the meeting to exclude those drugs with generic competition from consideration for affordability review. Currently, nine generic versions of lisdexamfetamine dimesylate, covering in total all dosage forms and strengths of Vyvanse, launched beginning in August 2023, with additional generics approved by the Food and Drug Administration (FDA).[1]

Vyvanse is approved for the treatment of attention deficit hyperactivity disorder (ADHD) and moderate to severe binge eating disorder (BED) in adults. Patent protection covering Vyvanse and the associated pediatric regulatory exclusivity expired in the U.S. in August 2023. Since that time, Vyvanse has experienced generic competition from multiple manufacturers that have launched AB-rated generic versions of lisdexamfetamine dimesylate. Given that the PDAB has excluded from consideration and

[1] FDA Orange Book, https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm

Takeda Pharmaceuticals America, Inc.
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(202) 649-4000

affordability review drugs that have approved and marketed generic drugs, we respectfully ask that Vyvanse also be excluded from consideration and affordability review.

Thank you for considering our comments. Should you have any questions, please contact me at kirsten.powell@takeda.com.

Sincerely,

Kirsten Powell
Vice President, Public Policy & Reimbursement
U.S. Public Affairs
Takeda Pharmaceuticals America, Inc.

From: JP
Sent: Wednesday, March 13, 2024 4:50 PM
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Subject: Rising health care costs.

To Whom it may concern:

Since you drove right through Eugene/Springfield on your way south, I decided to weigh in. There is more than one way to approach the high cost of drugs /medical care and you should look at all of them.

1. *To get a prescription for drugs, you first must have testing to support the diagnosis. Paying out of pocket through Life Line Screening is the only way you can get tested around here in my experience*. Trying to get your PCP to follow up on LLS testing is proving to be a major problem. Many have turned to alternative care but UHC won't cooperate with alternative medicine doctors.

2. *United Health care owns the largest clinic in the Eugene/Springfield area, Oregon Medical group. The state voluntarily let a monopoly like this happen and that is not conducive to good medical care.* (Why? I can spell it out for you if you need me too.) This clinic is known for its lack of care and that hasn't changed since United Health care bought it. ***OMG tries and get rid of senior citizens but sadly its the only choice most seniors have.***

3. *Medicare keeps reducing the number of procedures and drugs it will cover. Medicare Advantage plans follow their lead. Even if you have medical insurance, that doesn't mean what you need is covered. For some reason, we don't have the good Medicare Advantage plans here*. Be sure and factor that UHC doesn't cover name brand drugs and generic drugs made in China seemingly have no active ingredients, or worse, they may contain dangerous additives.

Seniors may be the only tax payers left around here so you might want to consider them when you think about high drug costs.

Best Regards
J Petersen

From: Cathy Sutor-Giles
Sent: Saturday, March 23, 2024 10:37 AM
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Subject: Prolia Shots for Osteoporosis...

Dear Board Members,

I've had to restart Prolia shots again. I don't want to restart them but my Dr says I need to for my **Osteoporosis**. **Each shot (twice a year) is $6,691.47. My portion with my insurance is $283.58.** I don't understand why Prolia is SO expensive!!

PLEASE address this medication for what they're charging!! I think it's really out-of-bounds and shouldn't be this high!!

I'm retired and on a fixed income. This is a big hit financially for me as all my other bills have been going up too.

Sincerely,
Cathy Sutor-Giles

abbvie

March 26, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drugs for Affordability Review – Removal of Skyrizi®

Dear Members of the Oregon Prescription Drug Affordability Board:

AbbVie appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board (PDAB). As explained below, we object to the inclusion of Skyrizi® on the list of drugs that are subject to an affordability review and respectfully request that Skyrizi® immediately be removed from the list. The inclusion of Skyrizi® on the list of drugs that are subject to an affordability review is inconsistent with the plain language of Oregon Revised Statutes (ORS) § 646A.694(2), which excludes drugs with orphan designations from affordability review.

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care.

I. Background on Skyrizi®

Skyrizi® (Risankizumab-rzaa) is a prescription interleukin-23 antagonist that, in certain circumstances, is indicated to treat adults with moderate to severe plaque psoriasis, active psoriatic arthritis, and moderate to severe Crohn's disease.[1] Skyrizi® was first approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate-to-severe plaque psoriasis in adults in April 2019.[2] Since the initial approval, AbbVie has continued to sponsor research on the use of Skyrizi® to meet unmet patient needs, including for rare diseases.

In 2016, the FDA granted an orphan designation to AbbVie for risankizumab (the active ingredient in Skyrizi®) for the "[t]reatment of pediatric Crohn's disease."[3] Pediatric Crohn's

[1] *Skyrizi®*, https://www.skyrizi.com/.
[2] ABBVIE, Press Release: AbbVie Expands Immunology Portfolio in the U.S. with FDA Approval of SKYRIZI™ (risankizumab-rzaa) for Moderate to Severe Plaque Psoriasis (Apr. 23, 2019), https://news.abbvie.com/2019-04-23-AbbVie-Expands-Immunology-Portfolio-in-the-U-S-with-FDA-Approval-of-SKYRIZI-TM-risankizumab-rzaa-for-Moderate-to-Severe-Plaque-Psoriasis.
[3] FDA, *Search Orphan Drug Designations and Approvals: Risankizumab*, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=544716. We acknowledge that the active ingredient as identified in the Skyrizi label differs from the way the generic name appears in FDA's orphan database (Risankizumab-rzaa vs. Risankizumab). However, "Risankizumab" (orphan designation) and "Risankizumab-rzaa" (generic name) are the same drug. The difference is due to a biologics naming convention change that post-dates when AbbVie first obtained the orphan designation. In 2017, FDA modified its naming

disease is a "rare, inflammatory bowel disease characterized by severe, chronic inflammation of the intestinal wall or any portion of the gastrointestinal tract."[4] At the time that AbbVie obtained this orphan designation, risankizumab had not yet been approved for marketing for any indication and thus had not been assigned a proprietary name. Upon approval of the biologics license application (BLA) in 2019, AbbVie launched risankizumab with the brand name Skyrizi®. Although FDA's orphan database does not identify risankizumab with a brand name, the designation does in fact apply to Skyrizi. This is made clear in FDA's decision to exempt Skyrizi® from certain Pediatric Research Equity Act (PREA) requirements because of its orphan designation. In the Skyrizi® approval letter, FDA explicitly states "[b]ecause this drug product for this indication has an orphan drug designation, you are exempt from this requirement."[5] Moreover, although Skyrizi® is not yet approved for pediatric Crohn's disease, consistent with post-marketing commitments for Skyrizi®,[6] AbbVie currently is sponsoring a Phase 3, multi-center study to assess the pharmacokinetics, efficacy, and safety of Skyrizi® in pediatric participants with moderately to severely active Crohn's disease. The study began in December 2023, and is estimated to be completed in April 2029.[7]

II. Skyrizi® is Statutorily Ineligible to be Selected for an Affordability Review

On December 13, 2023, the Oregon PDAB selected Skyrizi® (including Skyrizi Pen®) and certain other drug products for an affordability review.[8] The Oregon PDAB law is clear, however, that an orphan-designated drug *cannot* be selected for an affordability review. Therefore, as an orphan-designated drug, Skyrizi® must be removed from the list of drugs subject to an affordability review.

ORS § 646A.694(1) provides that each calendar year, the PDAB will identify nine drugs and at least one insulin product, from lists provided by the Department of Consumer and Business Services, that may create affordability challenges for healthcare systems or patients in the state. However, under ORS § 646A.694(2), a "drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review" by the PDAB. Skyrizi® is a "drug that is designated by [FDA]

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conventions for biological products to add a "distinguishing suffix that is devoid of meaning and composed of four lowercase letters" to the nonproprietary name for biological products licensed under the Public Health Service Act. *See* FDA, *Nonproprietary Naming of Biological Products, Guidance for Industry* (Jan. 2017), https://www.fda.gov/files/drugs/published/Nonproprietary-Naming-of-Biological-Products-Guidance-for-Industry.pdf. FDA's naming convention change happened after AbbVie received an orphan designation for risankizumab (November 29, 2016), but before it was first approved for marketing (April 23, 2019) (under the brand name Skyrizi®). This explains why the "rzaa" suffix is appended to the "risankizumab" approved generic name for Skyrizi®, as appears in the Prescribing Information and other labeling materials.

[4] RARE DISEASES, *Pediatric Crohn's Disease*, https://rarediseases.org/rare-diseases/pediatric-crohns-disease/.

[5] Letter from FDA to AbbVie, Inc. Re: Supplement Approval (June 16, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/761105Orig1s016ltr.pdf ("Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.").

[6] Letter from FDA to AbbVie, Inc. Re: Supplement Approval (June 16, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/761105Orig1s016ltr.pdf.

[7] CLINICAL TRIALS, *A Study to Assess Adverse Events, Change in Disease Activity, and How Intravenous and Subcutaneous Risankizumab Moves Through the Body of Pediatric Participants With Moderately to Severely Active Crohn's Disease*, https://clinicaltrials.gov/study/NCT05995353?term=m16-194&rank=1.

[8] OREGON PRESCRIPTION DRUG AFFORDABILITY BOARD, *Prescription Drugs for Affordability Review (Approved by the Board on Dec. 13, 2023)*, https://dfr.oregon.gov/pdab/Documents/OR-PDAB-RX-insulin-list.pdf.

. . . under 21 U.S.C. 360bb, as a drug for a rare disease or condition," in this case, pediatric Crohn's disease. Therefore, under the plain text of the law, Skyrizi® "is not subject to the review" and immediately must be removed from the list.

In November 2023, the Board removed drugs that have both orphan-designated indications and non-orphan indications from the list of drugs eligible to be selected for affordability review,[9] but the Board did not remove Skyrizi® from the list. Based on our review of the Board meeting materials, the Board seems to be unaware that Skyrizi® has an orphan designation. For example, in the October 2023 meeting materials, while certain drugs are marked as having "Orphan and Non-Orphan" designations per the FDA, the materials incorrectly state that Skyrizi® has no orphan designations.[10] Because Skyrizi® has an orphan designation for the treatment of pediatric Crohn's disease, the drug is not eligible for an affordability review under Oregon's PDAB law. Therefore, like other drugs with "Orphan and Non-Orphan" designations, Skyrizi® should have been removed from the list, and must now be removed and not subject to an affordability review.

III. ORS § 646A.694 Does Not Permit the Oregon PDAB to Select Non-Rare Indications of an Orphan Drug

On July 19, 2023, the Oregon PDAB voted to approve a rule implementing the statutory orphan drug exclusion. Oregon Administrative Rule (OAR) § 925-200-0020(2)(n) provides that "[a] prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications." This rule became effective August 1, 2023.

The statute, however, does not distinguish between different indications of an orphan drug, as OAR § 952-200-0020(2)(n) does. Under the statute, if a "drug" has an orphan designation, then that "drug" is ineligible for an affordability review. Thus, the statute categorically excludes any drug with an orphan designation from affordability review, regardless of whether the drug has non-orphan indications. If the Oregon legislature intended to distinguish between indications of an orphan drug, it would have made that clear in the statutory language of ORS § 646A.694(2), but it did not.

Oregon case law supports that when a statute uses plain and unambiguous language, it should be presumed that the law intends exactly what the words imply.[11] Moreover, ORS § 174.010 provides that "[i]n the construction of a statute, the office of the judge is simply to ascertain and declare what is, in terms or in substance, contained therein, not to insert what has been omitted, or to omit what has been inserted." Therefore, both case law and Oregon law on statutory

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[9] *Oregon Prescription Drug Affordability Board November 15, 2023*, https://www.youtube.com/watch?v=6Gk2182MFZw&t=6385s, at 1:34:45.

[10] OREGON PRESCRIPTION DRUG AFFORDABILITY BOARD, *Agenda: October 18, 2023*, https://dfr.oregon.gov/pdab/Documents/20231018-PDAB-document-package.pdf, at 39.

[11] *See, e.g.*, *Clark v. Eddie Bauer LLC*, 371 Or. 177, 185 (Or. 2023) ("Because the words of a statute are the best evidence of the legislature's intent, we give 'primary weight to the [statute's] text and context.' *State ex rel. Rosenblum v. Nisley*, 367 Or. 78, 83, 473 P.3d 46 (2020). In considering that statutory text, we give words of common usage their ordinary meaning. *Gaines*, 346 Or. at 175, 206 P.3d 1042."); *see also State v. Buck*, 200 Or. 87 (Or. 1953) ("It is well recognized that when the language of an act is unambiguous the intent of the legislature must be gained from the language used.").

interpretation direct that the application of a statute should follow the plain language of the statute.

While the PDAB did not apply OAR § 925-200-0020(2)(n) this year due to operational complexities with determining utilization of different indications, if followed, this rule would violate the plain language of the statute, which unambiguously excludes orphan-designated drugs from being eligible for affordability review. For these reasons, the PDAB should repeal OAR § 925-200-0020(2)(n), because it directly conflicts with ORS § 646A.694(2).

Moreover, AbbVie is concerned that OAR § 925-200-0020(2)(n) would disincentivize innovators from conducting further research on drugs that treat rare diseases. This undermines the clear intent of the statute to encourage innovation by allowing manufacturers to explore different indications for drugs that treat rare diseases. Subjecting orphan-designated drugs to a burdensome affordability review would deter innovation of such drugs for smaller patient populations and that save patient lives.

IV. Conclusion

Thank you for this opportunity to provide our comments on the list of drugs subject to an affordability review and our significant concerns with the inclusion of Skyrizi®. Accordingly, Skyrizi® must be removed from the list immediately. Please contact Emily Donaldson at emily.donaldson@abbvie.com with any questions.

Sincerely,

Hayden Kennedy
Vice President, Global Policy & U.S. Access Strategies
Government Affairs
On behalf of AbbVie Inc.

Johnson&Johnson

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March 28, 2024

VIA ELECTRONIC FILING

Oregon Division of Financial Regulation
ATTN: Oregon Prescription Drug Affordability Review Board
PO Box 14480
Salem, OR 97309

RE: April 17, 2024 Oregon Prescription Drug Affordability Board Meeting and Review of TREMFYA® (guselkumab)

Dear members of the Oregon Prescription Drug Affordability Board:

We write to provide the Prescription Drug Affordability Review Board (the "Board") information on TREMFYA® (guselkumab), which was recently selected for an "Affordability Review" under Senate Bill 844.

At Johnson & Johnson (J&J), for more than 130 years, cutting-edge technologies and expert insight have helped us understand and address the serious health problems of today and unlock the potential medicines of tomorrow. We apply rigorous science and compassion to confidently address the most complex diseases of our time. We also recognize these medicines can only have an impact if patients can access them. We work tirelessly to improve access for patients across Oregon.

As the Board conducts its Affordability Reviews, we urge it to consider the entire drug supply chain ecosystem and the complex ways in which each part impacts patient affordability. Out-of-pocket costs are a function of insurance plan benefit design, which is determined by the patient's insurer. Insurers may negotiate with manufacturers for rebates which reduce the plan's overall expenses, but which often are not directly shared with patients. When patients are left with high out-of-pocket costs, they may look to manufacturer patient assistance programs for additional support. Through J&J's patient assistance programs, the majority of commercially insured patients are eligible to pay $5 or less to fill their TREMFYA® prescription. Furthermore, for any patient unable to afford their medications, J&J's Patient Assistance Foundation provides free product to those who qualify. In 2022 across our portfolio, J&J has provided more than 1.16 million patients with help to afford their medicines through our patient support programs.[1]

Our submission focuses on five key areas, along with an appendix with additional clinical information for TREMFYA®:

1. Context for the Growth of TREMFYA® in Oregon
2. Clinical and Real-World Evidence Overview for A Broad Range of Patients, Including A Clinical Trial Across All Skin Tones in Psoriasis
3. Patient Copayment Support
4. Cost Information
5. Economic Impact of Treatment

The information provided within this submission is intended to help policymakers and other stakeholders develop a better understanding of the prescription drug supply chain, the clinical value of TREMFYA® for patients in Oregon, and how we support affordable access to our products.

As one of the nation's leading healthcare companies, we have a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access, and health equity as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop and bring to market medicines that are safe, effective, and accessible. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Thank you,

Blasine Penkowski

Chief Strategic Customer Officer

Johnson & Johnson Healthcare Systems

What Matters to Oregon Patients:

Immune-related diseases may be chronic, debilitating, and distressing for patients. Psoriasis is a life-altering disease that affects as many as 7.5 million Americans, with up to 20% of patients experiencing moderate to severe disease. Patients with psoriasis can develop psoriatic lesions, which cause pain and itching, and 78% of patients experience nail involvement as well.[2,3] These physical discomforts, combined with the potential psychological effects of disease, may interfere with everyday activities and negatively impact an individual's quality of life (*See **Appendix Section 1** for example figures of the severity of psoriasis for patients at baseline prior to treatment in the VISIBLE study)*.

Psoriatic arthritis is a chronic, immune-mediated inflammatory disease which impacts an estimated 1.5 million Americans, and for approximately 85% of patients, their psoriatic arthritis is preceded by psoriasis. Psoriatic arthritis is characterized by peripheral joint inflammation, enthesitis (pain where the bone, tendon, and ligament meet), dactylitis (severe inflammation of the finger and toe joints), axial disease, and the skin lesions associated with psoriasis. The disease causes pain, stiffness, and swelling in and around joints.[4-8]

TREMFYA® delivers significant value to Oregon patients, providing a treatment option for adults with moderate to severe plaque psoriasis (PsO) and adults with active psoriatic arthritis (PsA) that is effective and has a well-established safety profile. These factors must be considered in evaluating patient affordability.

Context for the Growth of TREMFYA® in Oregon

TREMFYA® was listed by the Oregon PDAB as the drug with the 25th highest spend increase in 2022. The spend growth for TREMFYA® observed in Oregon was driven not by significant price increases, but rather by an increased number of Oregonians benefiting from treatment in 2022. This was following the 2020 FDA approval for use in active PsA and increased use as a first-line treatment in moderate to severe PsO. In 2022, the entire dermatology market had a year-over-year growth in volume of 21%, and specifically the IL-23 inhibitor (IL-23i) product class had a growth in volume of 58%.[9] This growth is indicative of prescriber comfort and familiarity with this class of products. In fact, the net price of TREMFYA® decreased in the marketplace during this same time period.[1]

Clinical and Real-World Evidence Overview for a Broad Range of Patients, Including A Clinical Trial Across All Skin Tones in Psoriasis

TREMFYA® is a fully human IL-23i indicated for adult patients with moderate-to-severe plaque PsO who are candidates for systemic therapy or phototherapy, and also for adult patients with active PsA.[10] TREMFYA® (100mg) is administered via subcutaneous injection at weeks 0 and 4, and every 8 weeks thereafter, for a total of 8 injections for year 1 and 6 injections in subsequent years.[10] TREMFYA® has been characterized across several clinical trials, with five years of clinical data in moderate to severe plaque PsO[abc] and two years in active PsA[def] (*See footnotes for select efficacy and safety data and the full Prescribing Information for TREMFYA® here for more information)*.[10-16] Post-hoc analyses have been conducted to characterize the efficacy of TREMFYA® for specific patients, taking into account body weight, prior therapy, and patients who have not received a biologic therapy prior to TREMFYA®(*See **Appendix Section 2** for select data)*.[17-20g-j] Across both

moderate to severe plaque PsO and active PsA, TREMFYA® has a robust clinical profile with proven efficacy and well-defined safety.

Additionally, several real-world evidence studies demonstrate that patients with PsO and PsA receiving TREMFYA® experience significantly better persistence on therapy versus comparators.[kl] Patients with PsO who were persistent on TREMFYA® for 18 months experienced significant improvements in disease activity measures and subsequent improvements in activity and productivity.[mn] Patients with PsA who were persistent on TREMFYA® for 6 months experienced significant improvement in peripheral joint disease, skin disease, and patient-reported pain (*See footnotes and* ***Appendix Section 3*** *for select data)*.[21-27mo]

For patients of color with PsO, there are additional challenges including delayed diagnosis due to limited medical research and education gaps, as well as underrepresentation in clinical trials. This has led to a lack of data and barriers to optimal care for skin of color patients.[28-32] In a study of African American and Caucasian patients with PsO and PsA, African American patients with PsO reported greater quality of life and psychological impacts from their disease compared with Caucasian patients, and biologic treatment was less frequently used in African American patients with PsO than in Caucasian patients (13% vs 46%, $P<0.0001$).[33]

In 2022, J&J initiated VISIBLE, a first-of-its-kind, phase 3b, multicenter, randomized, double-blind, placebo-controlled study, evaluated the efficacy and safety of TREMFYA® for adults with moderate to severe plaque PsO across all skin tones. Week 16 results have been presented at recent congresses (*See* ***Appendix Section 1*** *for additional information on the VISIBLE study)*.[34,35p] VISIBLE has generated an extensive collection of PsO clinical images across skin tones and provides further understanding of post-inflammatory pigmentation to assist providers in discussing the diagnosis and treatment journey with their patients.[31,36]

J&J continues to invest in ongoing research and development for TREMFYA® (guselkumab). Guselkumab is being investigated to bolster the evidence for existing and additional patient populations with immune-mediated disease across a multitude of J&J-sponsored trials.[37]

Patient Copayment Support

TREMFYA® is affordable for most Oregonians, and 90% of TREMFYA® use is by commercially insured patients.[38] Through J&J's patient assistance programs, the majority of commercially insured patients are eligible to pay $5 or less to fill their TREMFYA® prescription. Furthermore, for any patient unable to afford their medications, J&J's Patient Assistance Foundation provides free product to those who qualify. Patient out-of-pocket cost varies and is determined by health plan design; J&J advocates that health plans pass along their savings to patients and offers these assistance programs directly to patients to support affordability. Given the economic and patient outcomes evidence we are presenting in this submission, TREMFYA® delivers significant clinical value to Oregon patients providing a safe and effective option to treat the chronic, debilitating, and distressing immune-related diseases of PsO and PsA.

Cost Information

The list price of a medicine is a starting point that is ultimately reduced to a net price, the amount a manufacturer receives after negotiating and providing rebates, discounts and/or fees to different parts of the healthcare system. J&J negotiates with private insurance companies, pharmacy benefit managers (PBMs) and entities where medications are dispensed or administered (e.g., hospitals, clinics and private physician practices). In addition, mandatory or statutory price reductions are provided through government programs. Government programs (e.g., Medicare, Medicaid, etc.) receive prices reduced by both private negotiations and statutory discounts. Vigorous private market negotiations throughout the system result in lower net prices for commercial payers and government programs. To put this into context, in 2022, the rebates, discounts and/or fees we provided to the different parts of the healthcare system totaled $39 billion dollars. This equates to nearly 58 cents of every dollar of our gross sales going back into the healthcare system.[1]

In the face of inflationary pressures, American families and businesses experienced the fastest growth in prices in nearly 40 years in 2022. Yet, commercial insurers, PBMs, and government payers paid lower net prices for J&J's medicines for the sixth year in a row. Net prices for J&J's medicines declined by 3.5%, and nearly 20% when compounded over the past six years.[1]

While commercial insurers pay lower net prices, many patients do not directly benefit from these lower prices and continue to pay higher out-of-pocket costs. Patients pay higher out-of-pocket costs because their cost-sharing amount, set by their insurance plan, is often based on the initial list price, not the negotiated lower net price the commercial insurer pays.

At the same time patients continue to pay higher out-of-pocket costs, commercial insurers and PBMs are implementing more restrictive utilization management programs. Utilization management is the use of administrative mechanisms (e.g., prior authorization) and financial mechanisms (e.g., patient cost sharing) to control or restrict patient access to healthcare. One such example is the increasing use of exclusion lists, which are designed to block patients from accessing a medicine that their own doctor has prescribed. Since 2014, these exclusion lists have grown more than 961% to include more than 1,156 unique products.[1] Exclusion lists are also being leveraged with specialty drugs, which could disproportionately affect patients with very serious and specialized treatment needs. Utilization management programs also include expanded tiered lists with varying cost sharing, prior authorization, non-medical switching and step therapy.

Economic Impact of Treatment

PsO: Clinical studies have demonstrated considerable physical, social, and psychological burdens associated with psoriatic diseases. The cumulative effects of psoriatic disease can contribute to decrements in patients' self-esteem, daily activities, social relationships, and ability to work.[39-42] Additionally, the incidence of comorbid conditions, such as obesity, heart disease, diabetes mellitus, hypertension, malignancy, hyperlipidemia, anxiety, and depression are increased in patients with PsO.[43-50] By not adequately managing PsO, musculoskeletal symptoms can be exacerbated, increasing disease burden for the patient.[51] In a commercially insured population, PsO patients with treated anxiety and depression incurred a

substantial economic burden, primarily driven by greater use of medical services.[52] In a recent systematic review, which showed the cost impact of comorbidities in PsO, the cost of PsO per year in the US was estimated to be $112 billion, with $36 billion due to medical comorbidities.[53] Additionally, annual indirect costs due to total work productivity loss per patient is reported to be $9,591.[54] In a retrospective cohort study, treatment with IL-12/23 inhibitors or IL-23 inhibitors was associated with reduced risk of progression to inflammatory arthritis as compared to treatment with tumor necrosis factor inhibitors.[55] PsO patients with lower disease severity (as measured by BSA% affected) self-report higher levels of satisfaction with treatment, less productivity loss, and a better quality of life (QOL) than patients with higher disease severity.[56]

PsA: Several real-world studies comparing patients with and without psoriatic diagnoses have documented the substantial healthcare costs and high comorbidity burden associated with PsA. Compared with patients without PsA or PsO, patients with PsA incur $20,733 more in annual per patient direct healthcare costs. Another analysis demonstrated that patients with PsA have 3.9x higher total annual direct healthcare costs versus patients without PsA.[4] Patients with PsA have higher rates of non-PsA associated comorbidities than patients free of PsA and PsO.[57] Although indirect cost is generally challenging to estimate, a recently published systematic review and meta-analysis of 8 studies estimated the average annual indirect cost for PsA ranged from $1,694 to $50,271 per patient (in 2013 USD).[58] In an analysis of MarketScan Commercial Claims and Encounters Database and Health and Productivity Management Database between 2009 and 2020, patients with PsA cost on average 1.9x and 1.4x more than patients without PsA in terms of short-term disability and non-recreational work absences (sick, disability, leave, family medical leave, or other), respectively.[59]

Summary

TREMFYA® has a robust clinical profile with proven efficacy and well-defined safety profile through five years in moderate to severe plaque PsO[abc] and two years in active PsA[def], and real-world persistence on therapy has been observed in several studies for both PsO and PsA.[10-14,16,21-25kl] The ongoing, first-of-its-kind VISIBLE clinical study creates an opportunity to generate data for patients with skin of color and create an enduring library of PsO images to support patient-provider discussions into the future.[34,35p]

TREMFYA® was listed by the Oregon PDAB as the drug with the 25th highest spend increase in 2022. This spend growth was driven not by significant price increases, but because an increased number of Oregonians are benefiting from treatment with TREMFYA® following the FDA approval of the active PsA indication in 2020. In fact, our net price of TREMFYA® decreased in the marketplace during the same period.[1]

The complexity of the healthcare system does not allow patients to benefit from direct cost savings observed by commercial insurers, PBMs, and government payers. While net prices for J&J's medicines declined for the 6th year in a row, patients are facing higher out-of-pocket costs. We as J&J have a responsibility to engage with stakeholders such as the Oregon PDAB to address these gaps in affordability, access, and health equity.

J&J offers multiple options to provide financial assistance directly to patients, including patient assistance programs and the Patient Assistance Foundation, in order to support the accessibility and affordability of our products.

We are committed to ensuring TREMFYA® is available and accessible to patients with immune-related diseases, both now and into the future. Our research and development programs are ongoing to explore TREMFYA® for existing and additional patient populations with high disease burden and significant unmet needs.

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[a]VOYAGE 1 (N=837) and VOYAGE 2 (N=992) were phase 3, multicenter, double-blind, placebo-controlled, active comparator trials evaluating the efficacy and safety of TREMFYA® 100 mg subcutaneous injection at Weeks 0, 4, and 12, then q8w in adult patients with moderate to severe plaque PsO who were candidates for phototherapy and/or systemic therapy. Co-primary endpoints in both trials were PASI 90 and IGA 0/1 at Week 16.[10,60,61]

[b]In VOYAGE 1, at Week 16, PASI 90 for TREMFYA® (n=329) versus placebo (n=174): 73% (n=241/329) vs 3% (n=5/174), *P*<0.001, and IGA 0/1 for TREMFYA® versus placebo: 85% (n=280/329) vs 7% (n=12/174), *P*<0.001. At Week 252, PASI 90 for TREMFYA® (n=391) was 84%, and IGA 0/1 was 82%. In VOYAGE 2, at Week 16, PASI 90 for TREMFYA (n=496) versus placebo(n=248): 70% (n=347/496) vs 2% (n=6/248), *P*<0.001, and IGA 0/1 for TREMFYA® versus placebo: 84% (n=417/496) vs 8% (n=21/248), *P*<0.001. At Week 252, PASI 90 for TREMFYA® (n=560) was 82%, and IGA 0/1 (TREMFYA® n=559) was 85%. Results at Week 16 are calculated by non-responder imputation. Results at Week 252 are calculated by treatment failure rules from an open-label extension. These data include patients who crossed over from placebo to receive TREMFYA® at Week 16.[10,62]

[c]Pooled safety, Week 16, % [events/100 PYs of follow-up], TREMFYA® (n=823) vs Placebo (n=422): adverse events: 49.2 [330.1] vs 46.7 [316.9]; serious adverse events: 1.9 [6.3] vs 1.4 [4.7]; infections: 23.2 [97.9] vs 21.3 [86.4]; serious infections: 0.1[0.4] vs 0.2 [0.8]. Pooled safety data from VOYAGE 1 and VOAGE 2 through 5 Years (Week 264) for TREMFYA®, events/100 PYs of follow-up, n=1721: adverse events: 149.4; serious adverse events: 5.0; infections: 60.6; serious infections 0.9. Data at Year 5 include all patients exposed to TREMFYA® in VOYAGE 1 and VOYAGE 2. [10,63]

[d]DISCOVER 1 (N=381; bio-naïve population [69%] and bio-experienced population: ≤2 TNFα inhibitors [31%]) and DISCOVER 2 (N=739; bio-naïve population) were phase 3, multicenter, double-blind, placebo-controlled trials evaluating the efficacy and safety of TREMFYA® 100 mg subcutaneous injection at Weeks 0, 4, and 12, then q8w in adult patients with active PsA despite standard therapies. The primary endpoint in both trials was ACR20 at Week 24.[10]

[e]DISCOVER 1 ACR20 results for TREMFYA® vs placebo: At Week 24: 52% (66/127) vs 22% (28/126); *P*<0.0001. At Week 52: 60% (76/127) of patients receiving TREMFYA® q8w. DISCOVER 2 ACR20 results for TREMFYA® (n=248) vs placebo (n=246): At Week 24: 64%(n=159/248) vs 33% (n=81/246), *P*<0.0001. Patients with missing data were considered nonresponders. At Week 52, ACR20 for TREMFYA®: 75% (n=185/248). At Week 100, ACR20 for TREMFYA: 74% (n=183/248). After Week 24, the study was open label with blinded dosing interval, which may have affected results. Prespecified as-observed analysis from Week 24 to Week 100 from DISCOVER 2 and from Week 24 to Week 52 from DISCOVER 1 are not shown.[10,13,64,65]

[f]Pooled safety, Week 24, % [events/100 PYs of follow-up], TREMFYA® (n=375) vs Placebo (n=372): adverse events: 48.5 [257.3] vs 47.3 [220.0]; serious adverse events: 1.9 [4.0] vs 3.2 [9.3]; infections: 19.5 [58.3] vs 20.7 [58.5]; serious infections: 0.3 [0.6] vs 0.8 [4.1]. In DISCOVER 2 only through Week 112 (2 Years) for TREMFYA®, events/100 PYs of follow-up, n=248: adverse events: 158.0; serious adverse events: 6.1; infections: 40.5; serious infections 2.2. [10,15,63] Data at Year 2 (Week 112) include patients exposed to TREMFYA® in DISCOVER 2 only.

[g]ECLIPSE (N=1048) was a phase 3, multicenter, randomized, double-blind, comparator-controlled study in patients (≤18 years of age) with moderate to severe plaque psoriasis, defined by an IGA≥3, PASI ≥12, and BSA involvement of at least 10%, who were candidates for or previously received either systemic therapy or phototherapy. 1048 patients were randomized in a 1:1 ratio into parallel TREMFYA (n=534) or active comparator (n=514) treatment groups. The study was conducted at 142 sites in 9 countries. TREMFYA 100mg was administered subcutaneously q8w, after weeks 0 and 4, through week 44, and the active comparator was administered through week 44. The last dosing visit was week 44 and patients were followed for an additional 12 weeks with a final safety visit at week 56.[17-19]

[h]In ECLIPSE, at week 48, PASI 90 for TREMFYA versus secukinumab: 84% (n=451/534) vs 70% (360/514), 14.2 treatment difference 95% CI (9.2-19.2); *P*<0.0001 for noninferiority and superiority. Efficacy findings from the ECLIPSE trial were further evaluated in post hoc analyses by baseline body weight and body mass index and prior psoriasis medication history. [17]

[i]COSMOS was a phase 3b, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of TREMFYA in adult patients with active PsA who demonstrated inadequate response to 1-2 TNF inhibitors. The primary endpoint was an ACR20 response at week 24. Patients with missing data or who met treatment failure (TF) criteria through week 24 (defined as discontinuation of study agent and/or study participation for any reason, initiation or increase in the dose of allowed conventional synthetic DMARDs (csDMARDs) or oral corticosteroids for PsA, initiation of protocol-prohibited medications/therapies for PsA or met

early escape [EE] criteria) were considered nonresponders. In the EE-correction analysis, 12 patients in the guselkumab group did not meet any other TF criteria (ie, introduction/change in dose of concomitant therapy) through week 24 and their response was included with other patients in the guselkumab group; 8 patients in the placebo group received guselkumab as EE therapy at weeks 16 and 20, met TF criteria, and were considered nonresponders. Through week 44, 88% of patients treated with guselkumab 100 mg completed the study. [20]

[j]In COSMOS, at week 24, the primary endpoint for ACR20 response rates in the TREMFYA group was 44.4% (84/189) vs 9.8% (19/96) of placebo-treated patients (P<0.001). Efficacy findings from the COSMOS trial were further evaluated in post hoc analyses by body weight and prior and concomitant medications. [20]

[k]Health claims data from the IBM® MarketScan® Research Database were used to describe treatment persistence among patients with PsO who initiated TREMFYA® versus Otezla® (apremilast), Cosentyx®(secukinumab), and Taltz® (ixekizumab). Patients were included for evaluation between January 1, 2016 and October 31, 2021. The index date was first observed claim for studied biologic, and the baseline period included 12-month before the index date. The follow-up period spanned the index date until the earliest end of data availability or end of continuous health plan eligibility. 3,379 and 10,087 patients were identified for TREMFYA® versus Otezla® comparison, 3,516 and 6,066 patients were identified for TREMFYA® versus Cosentyx® comparison, and 3,805 and 4,674 patients were identified for TREMFYA® versus Taltz® comparison. TREMFYA® was associated with almost three times greater persistence than Otezla® (apremilast) at 18 months after therapy initiation. Persistence probability at 18 months of follow-up was 59.3% for TREMFYA® versus 25.5% for Otezla® (*P*<0.001). TREMFYA® was associated with approximately two times greater persistence compared to Cosentyx® (secukinumab) at 18 months after therapy initiation. Persistence probability at 18 months of follow-up was 61.5% for TREMFYA® versus 33.4% for Cosentyx® (*P*<0.001). TREMFYA® was associated with almost two times greater persistence than Taltz® (ixekizumab) at 18 months after therapy initiation. Persistence probability at 18 months of follow-up was 60.7% for TREMFYA® versus 42.6% for Taltz® (*P*<0.001). These results may not be generalized to the uninsured or patients with non-commercial insurance, prescription fills do not account for whether medication was taken, and results may be subject to residual confounding.[21,22]

[l]Health claims data from the IQVIA® Health Plan Claims Data were used to compare on-label treatment persistence among patients with active PsA newly initiated on TREMFYA® versus first use of a subcutaneous TNF inhibitor (TNFi). Patients were included for evaluation between July 14, 2019 and September 30, 2022. The index date was 1st TREMFYA® or SC TNFi claim during intake period, and ≥12 months of continuous health insurance eligibility was required before index date. 526 patients comprised the TREMFYA® cohort and 1,953 patients comprised the SC TNFi cohort, including Humira® (adalimumab) (n=1,339), Enbrel® (etanercept) (n=400), Cimzia® (certolizumab pegol) (n=159), and SIMPONI® (SC golimumab) (n=55). Inverse probability weights were used to obtain a balanced sample. Weights were estimated using a multivariable logistic regression model. Weighted Cox proportional hazard model was used to compare risk of discontinuation between the TREMFYA® and SC TNFi cohorts. Models were adjusted for baseline use of biologic disease modifying anti-rheumatic drugs. Primary analysis was conducted based on a 2x duration of time between administration per label. TREMFYA® was associated with approximately 3x greater persistence than SC TNFis at 12 months. The percentage of patients with on-label persistence at 12 months was: TREMFYA® (72%) vs SC TNFi (44%) (Hazard Ratio 2.97, 95% CI [2.36, 3.74]; *P*<0.001), despite the TREMFYA® cohort comprising a higher proportion of biologic-experienced pts at baseline (52% vs 17%). Results may not be generalizable to non-commercially insured patients in the United States or patients outside of the United States. Claims data do not ensure treatments are taken as prescribed. Treatment effectiveness and reasons for discontinuation could not be assessed using claims data. Days of supply in pharmacy claims data can be inaccurate due to coverage restrictions. Imputation is a valid approach commonly used for claims-based persistence analysis; however, it may occasionally lead to misclassifications.[23]

[m]Results may not be generalized to the uninsured or patients with noncommercial insurance. Prescription fills do not account for whether medication was taken. Results may be subject to residual confounding.[24,25]

[n]The CorEvitas Psoriasis Registry was utilized to evaluate the long-term effectiveness of TREMFYA® on patient-reported outcomes, health-related quality of life, work productivity loss, and activity impairment in real-world patients with moderate to severe plaque PsO who persistently received TREMFYA® for 18-24 months between July 2017 and September 2021. Of 183 patients, 77 were bio-naïve and 106 were bio-experienced. Select results include: (baseline versus follow up at 18-24 months; mean change in work productivity and activity impairment): absenteeism baseline versus follow-up (n=106), 4.3 versus 0.6; presenteeism baseline versus follow-up (n=105), 15.9 versus 4.0; work productivity loss baseline versus follow-up (n=104), 17.1 versus 4.5; activity impairment baseline versus follow-up (n=180), 24.4 versus 6.4. Because the data source is a US/Canadian registry, the results may not be generalizable to all patients with moderate to severe plaque psoriasis outside of the US/Canada. Psoriasis patients who were persistent on TREMFYA® for 18-24 months were included, therefore results are not generalizable to other patient populations.[25]

[o]TREMFYA® was assessed in patients with active PsA with persistent TREMFYA® use at the 6-month visit from CorEvitas PsA/SpA Registry data. Eligible patients had a 6-month visit (within a 5- to 9-month window following guselkumab initiation) occurring on or before March 31, 2023. The primary endpoint was mean change (95% CI) in Clinical Disease Activity Index for PsA score (cDAPSA) at 6 months. The major secondary endpoints included Physician Global Assessment (PGA) of PsA and PsO, Patient Pain (Patient-Reported Pain), and percent body surface area (BSA) with PsO. Changes in continuous outcomes from baseline (guselkumab initiation) to 6 months are reported as mean (95% CI). Each measure was evaluated only among patients with data at both timepoints. Paired t-tests determined whether changes were statistically significantly different from 0 (α=0.05). 90 patients persisted

on TREMFYA® at 6 months on labeled dose (90/114; 78.9%). At baseline, persistent TREMFYA® users were on average biologic-experienced, with long-standing PsA and active peripheral joint and skin disease, moderate pain, and moderate disease activity. TREMFYA® significantly improved disease activity at 6 months versus baseline as assessed by cDAPSA (baseline versus 6-month follow-up, 21.6% (N=75) versus 16.1% (N=75), *P*<0.001). TREMFYA® significantly improved disease activity at 6 months vs BL in PGA, Patient Pain, and % BSA with PsO (baseline versus 6-month follow-up, PGA: 41.3% [N=82] versus 22.4% [N=82], *P*<0.001; Patient Pain: 58.1% [N=87] versus 48.9% [N=87], *P*<0.001; Percent BSA with PsO, 8.0% [N=79] versus 2.9% [N=79], *P*<0.001). Limitations of the study included: modest sample size, the study may not be generalizable outside of the US, patient selection based on requirement for TREMFYA® persistence at a 6-month follow-up visit may introduce time and selection bias, limited details are available regarding end of treatment exposure (eg, a small subset of patients identified as non-persisters may have still been exposed to TREMFYA® at the follow-up visit). [27]

[P]First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).[66]

REFERENCES

1. Janssen US 2022 US Pricing Transparency Report. https://transparencyreport.janssen.com/?gclid=CjwKCAjwy7CKBhBMEiwA0Eb7ar8Sf4f1eeJBlS5L0GCm5NuADJ-zUhil87alo2SBn18NfI_tjymU8RoC4zYQAvD_BwE

2. National Psoriasis Foundation. About Psoriasis. Available: http://www.psoriasis.org/about-psoriasis. Accessed April 6th, 2017.

3. Jong E de, Seegers B, Gulinck M, et al. Psoriasis of the nails associated with disability in a large number of patients: results of a recent interview with 1728 patients. *Dermatology*. 1996;193(4):300-303.

4. Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. *J Am Acad Dermatol*. 2013;69(5):729-735.

5. Mease PJ, Armstrong AW. Managing Patients with Psoriatic Disease: The Diagnosis and Pharmacologic Treatment of Psoriatic Arthritis in Patients with Psoriasis. *Drugs*. 2014;74(4):423-441.

6. Husted JA, Tom BD, Schentag CT, et al. Occurrence and correlates of fatigue in psoriatic arthritis. *Ann Rheum Dis*. 2009;68(10):1553.

7. Belasco J, Wei N. Psoriatic Arthritis: What is happening at the Joint? *Rheumatol Ther*. 2019;6(3):305-315.

8. National Psoriasis Foundation. About psoriatic arthritis. Available at: https://www.psoriasis.org/about-psoriatic-arthritis. Accessed February 22, 2021.

9. IQVIA NPA/DDD August 2023.

10. TREMFYA (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.;https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf.

11. Reich K, Armstrong AW, Langley RG, et al. Maintenance of response through up to 5-years of continuous guselkumab treatment of psoriasis in the VOYAGE 2 phase 3 trial. Poster presented at: American Academy of Dermatology; April 23-25, 2021; E-Congress.

12. Deodhar A, Helliwell P, Boehncke W, et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naive or had previously received TNFα inhibitor treatment (DISCOVER-1): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1115-1125.

13. Ritchlin CT, Helliwell PS, Boehncke WH. Guselkumab, an inhibitor of the IL-23p19 subunit, provides sustained improvement in signs and symptoms of active psoriatic arthritis: 1 year results of a phase III randomised study of patients who were biologic-naïve or TNFα inhibitor-experienced. *RMD Open*. 2021;7(1):e001457.

14. Mease PJ, Rahman P, Gottlieb AB, et al. Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1126-1136.

15. McInnes IB, Rahman P, Gottlieb AB, et al. Long-term efficacy and safety of guselkumab, a monoclonal antibody specific to the p19 subunit of interleukin-23, through 2 Years: results from a phase 3, randomized, double-blind, placebo-controlled study conducted in biologic-naive patients with active psoriatic arthritis. *Arthritis Rheumatol*. 2022;74(3):475-485.

16. Reich K, Gordon KB, Strober BE, et al. Five-year maintenance of clinical response and health-related quality of life improvements in patients with moderate-to-severe psoriasis treated with guselkumab: results from VOYAGE 1 and VOYAGE 2. *Br J Dermatol*. 2021;185(6):1146-1159.

17. Reich K, Armstrong AW, Langley RG, et al. Guselkumab versus secukinumab for the treatment of moderate-to-severe psoriasis (ECLIPSE): results from a phase 3, randomised controlled trial. *Lancet*. 2019;394(10201):831-839.

18. Blauvelt A, Armstrong AW, Langley RG, et al. Efficacy of guselkumab versus secukinumab in subpopulations of patients with moderate-to-severe plaque psoriasis: results from the ECLIPSE study. *J Dermatol Treat*. 2022;33(4):2317-2324.

19. Blauvelt A, Vender R, Spelman L, et al. Efficacy of guselkumab versus secukinumab in patients with moderate-to-severe plaque psoriasis in subgroups defined by previous psoriasis medication history: results from the ECLIPSE study. Poster presented at: 28th European Academy of Dermatology and Venereology (EADV) Congress; October 9-13, 2019; Madrid, Spain.

20. Coates LC, Gossec L, Theander E, et al. Efficacy and safety of guselkumab in patients with active psoriatic arthritis who are inadequate responders to tumour necrosis factor inhibitors: results through one year of a phase IIIb, randomised, controlled study (COSMOS). *Ann Rheum Dis*. 2022;81(3):359-369.

21. Fitzgerald T, Zhdanava M, Pilon D, et al. Long term psoriasis control with guselkumab versus apremilast: analysis of drug persistence and other treatment patterns in large claims database. Poster presented at: European Academy of Dermatology and Venereolgy (EADV) Congress; September 7-11, 2022; Milano, Italy.

22. Zhdanava M, Fitzgerald T, Pilon D, et al. Long term psoriasis control with guselkumab versus secukinumab and ixekizumab: analysis of drug persistence in large claims database. Poster presented at: European Academy of Dermatology and Venereology (EADV) Congress; September 7-11, 2022; Milano, Italy.

23. Walsh J, Lin I, Zhao R, et al. Comparison of on-label treatment persistence in real-world patients with psoriatic arthritis receiving guselkumab versus subcutaneous TNF inhibitors. Poster presented at: Congress of Clinical Rheumatology West (CCR West); September 7-10, 2023; San Diego, California.

24. Strober B, Fitzgerald T, Janak J, et al. Long-term effectiveness up to 24 months of guselkumab on disease severity in the CorEvitas Psoriasis Registry. Poster presented at: Dermatology Spring Conference; April 27-30, 2022; Scottsdale, AZ.

25. al AA et. Long-term effectiveness up to 24 months of guselkumab on patient-reported outcomes in the CorEvitas Psoriasis Registry. Armstrong AW, et al. Poster presented at: Maui Derm NP + PA Summer; June 22-25 2022; Colorado Springs, CO.

26. Mease PJ, Gladman DD, Poddubnyy D, et al. Efficacy of guselkumab on axial-related symptoms through up to 2 years in adults with active psoriatic arthritis in the phase 3, randomized, placebo-controlled DISCOVER-2 study. *Rheumatol Ther*. 2023;10(6):1637-1653.

27. Mease PJ, Ogdie A, Tesser J, et al. Six-month persistence and multi-domain effectiveness of guselkumab in adults with psoriatic arthritis: real-world data from the CorEvitas Psoriatic Arthritis/Spondyloarthritis registry. *Rheumatol Ther*. 2023;10(6):1479-1501.

28. Bhosle MJ, Kulkarni A, Feldman SR, et al. Quality of life in patients with psoriasis. *Health and Quality of Life Outcomes*. 2006.

29. Reddy V, Myers B, Chan S, et al. A review of current phase III clinical trials of plaque psoriasis: under-representation of nonwhite participants and need for reform. *Br J Dermatol*. 2021;184:348-350.

30. Kaufman BP, Alexis AF. Psoriasis in Skin of Color: Insights into the Epidemiology, Clinical Presentation, Genetics, Quality-of-Life Impact, and Treatment of Psoriasis in Non-White Racial/Ethnic Groups. *Am J Clin Dermatol*. 2018;19:405-423.

31. Janssen announces TREMFYA® (guselkumab) demonstrates significant skin clearance in first-of-its-kind prospective, large-scale study dedicated to people of color living with moderate to severe plaque psoriasis. 3/6/2024. https://www.jnj.com/media-center/press-releases/janssen-announces-tremfya-guselkumab-demonstrates-significant-skin-clearance-in-first-of-its-kind-prospective-large-scale-study-dedicated-to-people-of-color-living-with-moderate-to-severe-plaque-psoriasis

32. S S, C N, T B. Racial disparities in clinical trials of biologic treatments for psoriatic arthritis. *J Am Acad Dermatol*. 2022;87(4):910-912.

33. GS K, S Q, J R, et al. Psoriasis and psoriatic arthritis in African-American patients--the need to measure disease burden. *Clin Rheumatol*. 2014;34(10):1753-1759.

34. McMichael A, Gold LS, Soung J, et al. VISIBLE: guselkumab demonstrated rapid and significant scalp psoriasis clearance in participants with moderate-to-severe plaque psoriasis across all skin tones. Poster presented at: Fall Clinical Dermatology Conference; October 19-22, 2023; Las Vegas, NV.

35. Alexis A, McMichael A, Bhutani T, et al. VISIBLE cohort B: guselkumab demonstrates significant scalp clearance at week 16 in participants with moderate-to-severe scalp psoriasis across all skin tones. Poster presented at: Maui Derm Hawaii; January 22-26, 2024; Maui, HI.

36. Data on File. VISIBLE images; 2024.

37. National Library of Medicine. National Center for Biotechnology Information. ClinicalTrials.gov. March 26th, 2024. https://clinicaltrials.gov/search?term=guselkumab&lead=Janssen&aggFilters=status:rec%20act&page=3&rank=23&limit=10

38. IQVIA LAAD through Jan-Dec 2023.

39. G K, J K, M L, et al. The impact of psoriasis on quality of life, results of a 1998 National Psoriasis Foundation patient-membership survey. *Arch Dermatol*. 2001;137(3):280-284.

40. Vardy D, Besser A, Amir M, et al. Experiences of stigmatization play a role in mediating the impact of disease severity on quality of life in psoriasis patients. *British Journal of Dermatology*. 2002;147:736-742.

41. AW E, Y L, P D, et al. Common burden of chronic skin diseases? Contributors to psychological distress in adults with psoriasis and atopic dermatitis. *British Journal of Dermatology*. 2005;152(6):1275-1281.

42. J K. Population-based epidemiologic study of psoriasis with emphasis on quality of life assessment. *Dermatol Clin*. 1992;14(3):485-496.

43. Henseler T, Christophers E. Disease concomitance in psoriasis. *J Am Acad Dermatol*. 1995;32(6):982-986.

44. Herron MD, Hinckley M, Hoffman M, et al. Impact of obesity and smoking on psoriasis presentation and management. *Arch Dermatol*. 2005;141:12.

45. Gelfand JM, Berlin J, Voorhees AV. Lymphoma rates are low but increased in patients with psoriasis results from a population-based cohort study in the United Kingdom. *Arch Dermatol*. 2003;139(11):1425-1429.

46. Gelfand JM, Shin DB, Neimann AL, et al. The Risk of Lymphoma in Patients with Psoriasis. *J Investig Dermatol*. 2006;126(10):2194-2201.

47. Gelfand J, Troxel A, Lewis J, et al. The risk of mortality in patients with psoriasis: results from a population-based study. *Arch Dermatol*. 2007;143(12):1493-1499.

48. Cai Q, Teeple A, Shrivastava S, et al. Trends in prevalence of psychiatric comorbidities among patients with moderate to severe psoriasis. Poster presented at: Fall Clinical Dermatology Conference; October 18-21; Las Vegas, NV.

49. Pilon D, Teeple A, Zhdanava M. The economic burden of psoriasis with high comorbidity among privately insured patients in the United States [poster]. *J Med Econ*. 2018;22(2):196-203.

50. CA E, HW L, B S. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. 2019;81:775-804.

51. Merola JF, Patil D, Egana A, et al. Prevalence of musculoskeletal symptoms in patients with psoriasis and predictors associated with the development of psoriatic arthritis: Retrospective analysis of a US claims database. *Dermatol Ther (Heidelb)*. 2023;13(11):2635-2648.

52. Cai Q, Teeple A, Wu B, et al. Economic burden of comorbid anxiety and depression among patients with moderate to severe psoriasis. Presentation presented at: Fall Clinical Dermatology Conference; October 18-21; Las Vegas, NV.

53. Brezinski E, Dhillon J, Armstrong A. Economic burden of psoriasis in the United States: a systematic review. *JAMA Dermatol*. 2015;151(6):651-658.

54. Villacorta R, Teeple A, Lee S, et al. A multinational assessment of work-related productivity loss and indirect costs from a survey of patients with psoriasis. *Br J Dermatol*. 2020;183(3):548-558.

55. Singla S, Putman M, Liew J, et al. Association between biological immunotherapy for psoriasis and time to incident inflammatory arthritis: a retrospective cohort study. *Lancet Rheumatol*. 2023;5:e200-e207.

56. Lucas J, Teeple A, Hetherington J, et al. Assessing the relationship between disease severity and patient-reported outcomes in psoriasis patients in the US. Presentation presented at: Fall Clinical Dermatology Conference; October 18-21, 2019; Las Vegas, NV.

57. Merola J, Dennis N, Chakravarty S. Healthcare utilization and costs among patients with psoriasis and psoriatic arthritis in the USA-a retrospective study of claims data from 2009 to 2020. *Clin Rheumatol*. 2021;40(10):4061-4070.

58. Kawalec P, Malinowski K. The indirect costs of psoriatic arthritis: systematic review and meta-analysis. *Expert Rev Pharmacoecon Outcomes Res*. 2015;15(1):125-132.

59. Orbai A, Reddy S, Villacorta R. Work absenteeism and disability associated with psoriatic arthritis and psoriasis in the US. *Value in Health*. 2020;23 (Suppl):S238-S239.

60. Blauvelt A, Papp K, Griffiths C, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: results from the phase 3, double-

blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *J Am Acad Dermatol*. 2017;76(3):405-417.

61. Reich K, Armstrong A, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: results from the phase 3, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial [published correction appears in J Am Acad Dermatol. 2017;76(6):1226.]. *J Am Acad Dermatol*. 2017;76(3):418-431.

62. K Reich, KB Gordon, BE Strober, et al. Five-year maintenance of clinical response and improvements in health-related quality of life in patients with moderate-to-severe psoriasis treated with guselkumab: results from VOYAGE 1 and VOYAGE 2. *Br J Dermatol*. 2021;185(6):1146-1159.

63. Data on File. Data on file. Janssen Biotech, Inc.;

64. Mease PJ, Rahman P, Gottlieb AB, et al. Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1126-1136.

65. McInnes IB, Rahman P, Gottlieb AB, et al. Long-term efficacy and safety of guselkumab, a monoclonal antibody specific to the p19 subunit of interleukin-23, through two years: results from a phase 3, randomized, double-blind, placebo-controlled study conducted in biologic-naïve patients with active psoriatic arthritis. *Arthritis Rheumatol*. 2022;74(3):475-485.

66. Janssen Research & Development, LLC. Study of guselkumab in skin of color participants with moderate-to-severe plaque and/or scalp psoriasis (VISIBLE). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). https://clinicaltrials.gov/study/NCT05272150. Accessed January 25, 2024.

APPENDIX

Section 1: Select Moderate to Severe Plaque PsO Patient Images and the VISIBLE Clinical Study

Section 2: Select Additional Clinical Data for TREMFYA® in Moderate to Severe Plaque PsO and Active PsA

Section 3: Select Real-World Evidence for TREMFYA® in Moderate to Severe Plaque PsO

APPENDIX

Section 1: Select Moderate to Severe Plaque PsO Patient Images and the VISIBLE Clinical Study

Innovations of VISIBLE

In Plaque Psoriasis Patients With Skin of Color

TREMFYA® (guselkumab) Indication, Dosing, and Administration[1]

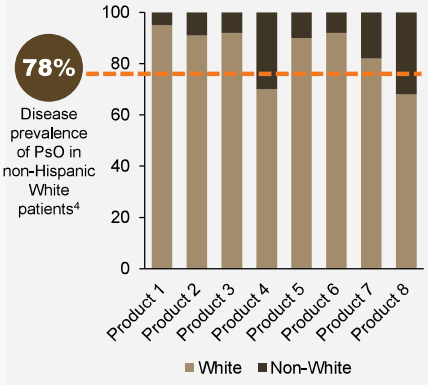
TREMFYA® is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and adults with active psoriatic arthritis. TREMFYA® 100 mg is administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter. TREMFYA® is intended for use under the guidance and supervision of a physician. TREMFYA® may be administered by a healthcare professional, or a patient may self-inject after proper training in subcutaneous injection technique. **See VOYAGE 1 and VOYAGE 2 study designs below**.

In Plaque Psoriasis Patients Across All Skin Tones

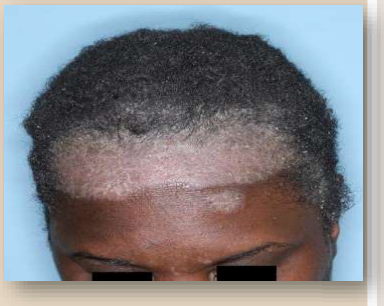
UNMET NEED

Representation in psoriasis clinical trials	Patients with scalp psoriasis in clinical trials	Postinflammatory pigmentation from psoriasis
Historically, people of color are underrepresented in psoriasis trials[2]	~80% of patients with psoriasis have scalp involvement[5]	Postinflammatory dyspigmentation (PID) makes recognizing treatment success challenging[2]

The majority of phase 3 psoriasis clinical trials with biologic therapies prior to May 2020 enrolled ~86% White participants[3]

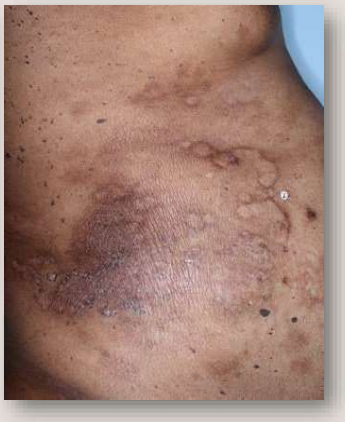


Scalp Psoriasis



Scalp psoriasis presents unique treatment challenges in the skin of color community due to hair texture variations and social/cultural hair styling practices.[6,7]

Postinflammatory Dyspigmentation



SOLUTION

VISIBLE is a phase 3b, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of TREMFYA® in moderate to severe plaque psoriasis patients with skin of color[8,9]

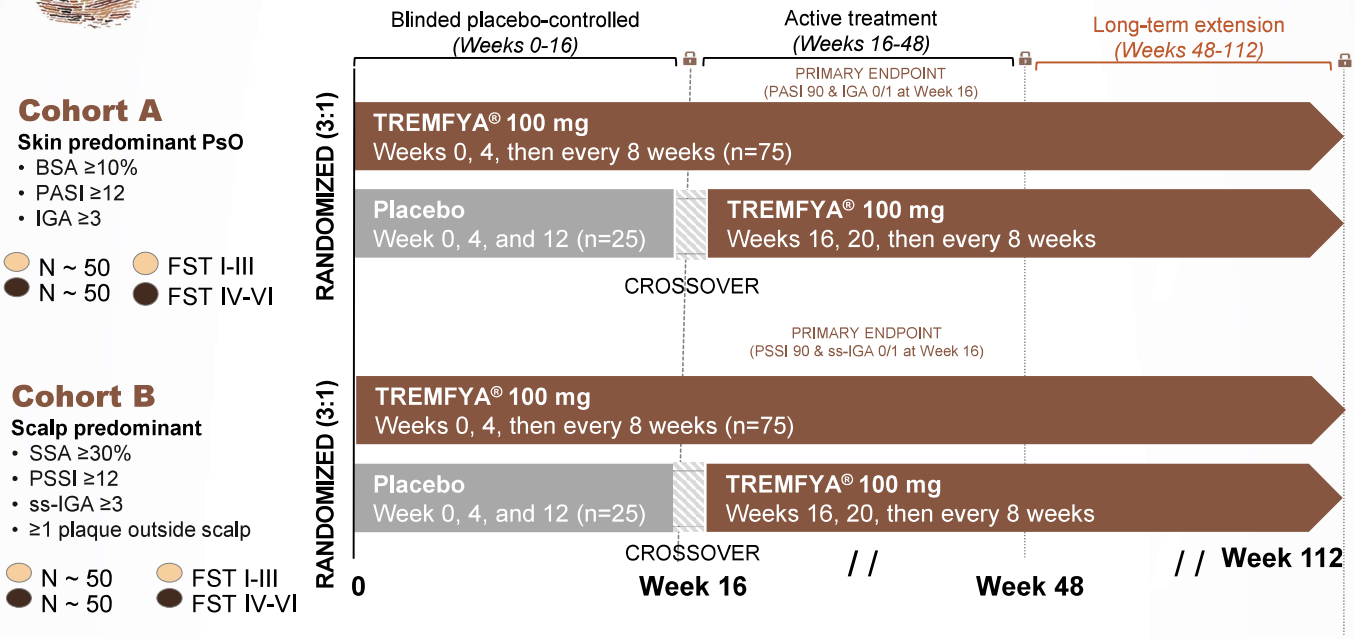
Inclusive of all FST (anyone who self-identified as non-white race/ethnicity)	Inclusive of a dedicated scalp psoriasis cohort	Examines PID in psoriasis through 2 years

Photos are Janssen-owned blinded data from NCT05272150.

In patients with moderate to severe plaque and/or scalp psoriasis

VISIBLE Study Design[8,9]

First large-scale, prospective study dedicated to the evaluation of psoriasis and treatment outcomes in patients with skin of color across all skin tones, utilizing a combination of objective clinician-reported and patient-reported parameters

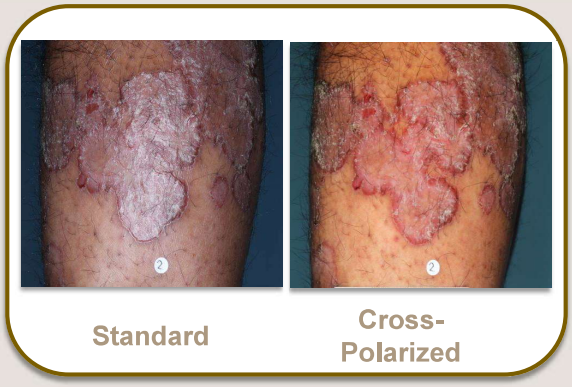


In patients with moderate to severe plaque and/or scalp psoriasis

VISIBLE is collecting data on:[10]

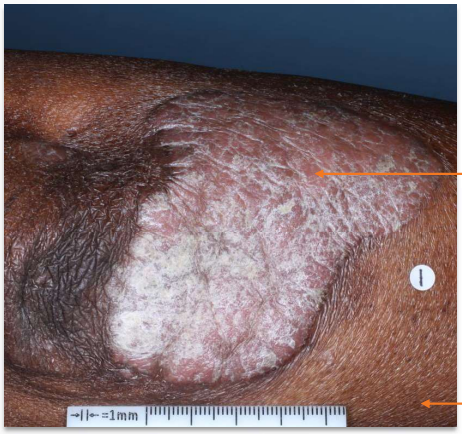
- **Postinflammatory Dyspigmentation**
- **Enhanced Clinical Photos**
- **Biomarkers**
  - Serum + plasma
  - Optional skin biopsy & tape strips
  - Optional pharmacogenomics
- **Comorbidities** — e.g. Hs-CRP, HgbA1c, lipid panel
- **Psoriatic Arthritis** — PEST and PSAID12

Cross-polarized Photography Enhances Erythema[10]



Images are Janssen-owned blinded data from NCT05272150.

Colorimetry Can Be Used to Differentiate Between Involved and Uninvolved Psoriatic Skin



Lesional Skin

L: 37 a: 10 b: 17

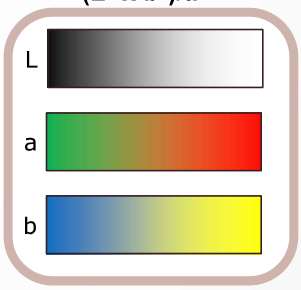
(L* x b*)/a* = 62.9

Normal Skin

L: 37 a: 13 b: 7

(L* x b*)/a* = 19.9

(L* x b*)/a*[11]



This device has been used in additional research studies.[12-16]
This figure including images and values is for illustrative purposes only and (L* x b*)/a* values are Janssen-owned, blinded data from NCT05272150.

Innovations in the VISIBLE study include:

- Represents inclusion of skin of color patients across all skin tones to provide additional data in a population historically underrepresented in psoriasis trials
- 2-year data on post inflammatory dyspigmentation (PID) from psoriasis with objective measurements like colorimetry, enhanced cross-polarized photography in addition to both clinician and patient reported outcomes
- Deep dive into comorbidities with lab and biomarker assessments, optional tape strips/biopsies and pharmacogenomic studies to appreciate mechanisms behind how psoriasis may present across various skin tones
- Comprehensive training of investigators with central review of participant photos to ensure consistent evaluation across all skin tones producing a large database of photos for future patient and provider education

BSA, body surface area; FST, Fitzpatrick skin type; HgbA1c, glycated hemoglobin; hs-CRP, high-sensitivity C-reactive protein; IGA, Investigator's Global Assessment; PASI, Psoriasis Area Severity Index; PEST, Psoriasis Epidemiology Screening Tool; PsAID, Psoriatic Arthritis Impact of Disease; PsO, psoriasis; PSSI, Psoriasis Scalp Severity Index; ss-IGA, scalp specific IGA; SSA, scalp surface area.

TREMFYA ISI[1]

1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.
2. Kaufman BP, et al. *Am J Clin Dermatol.* 2018;19(3):405-423.
3. Reddy V, et al. *Brit J Dermatol.* 2021;184:348-350.
4. Armstrong AW, et al. *JAMA Dermatology.* 2021;157(8):940-946.
5. Yan D, et al. *Dermatology Online Journal.* 2018;24(7):1-3.
6. Yadav G, et al. *Dermatol Ther (Heidelb).* 2022;12:2401-2413.
7. Zamperion A, et al. *G Ital Dermatol Venereol.* 2015;150:309-316.
8. Alexis A, et al. SID Annual Meeting. March 2022.
9. Alexis A, et al. AAD Annual Meeting. March 2023.
10. Data on file. Janssen Biotech, Inc.
11. Ly BCK et al. *J Investig Dermatol.* 2020;140:3-12.
12. Li X, et al. *J. Biophotonics.* 2019;12:e201800442.
13. Kanellis V. *Biophys Rev.* 2019;11:843-849.
14. Farshi S, et al. *J Dermatolog Treat.* 2018 Mar;29(2):182-189.
15. Baquie M, et al. *Skin Res Technol.* 2014 May;20(2):218-27.
16. Anbar TS, et al. *Skin Res Technol.* 2019;25(4):512-516.
17. Blauvelt A, et al. *J Am Acad Dermatol.* 2017;76:405-417.
18. Reich K, et al. *J Am Acad Dermatol.* 2017;76:418-431.

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TREMFYA® (guselkumab) is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated
in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

WARNINGS AND PRECAUTIONS (Continued)

Pre-Treatment Evaluation for Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating treatment with TREMFYA®. Initiate treatment of latent TB prior to administering TREMFYA®. Monitor patients for signs and symptoms of active TB during and after TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection.

Immunizations

Prior to initiating TREMFYA®, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common (≥1%) adverse reactions associated with TREMFYA® include upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.

The overall safety profile observed in patients with psoriatic arthritis is generally consistent with the safety profile in patients with plaque psoriasis, with the addition of bronchitis and neutrophil count decreased.

Please read the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

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VOYAGE 1 and VOYAGE 2 Study Designs

VOYAGE 1 (n=837) and VOYAGE 2 (n=992) were phase 3, multicenter, double-blind, placebo-controlled trials in adult patients with moderate to severe plaque PsO. Patients were randomized to TREMFYA® 100 mg SC injection at Weeks 0, 4, and 12, then every 8 weeks (q8w); placebo at Weeks 0, 4, and 12, followed by crossover to TREMFYA® at Week 16, Week 20, and q8w; or active comparator through Week 47 (VOYAGE 1) or Week 23 (VOYAGE 2). In VOYAGE 1, patients initially randomized to active comparator entered a washout period after their final dose at Week 47 and entered open-label TREMFYA® from Week 52-252. VOYAGE 2 incorporated a randomized withdrawal and re-treatment from Week 28-72, followed by open-label TREMFYA® from Week 76-252. Safety was assessed through Week 264. The co-primary endpoints in VOYAGE 1 and VOYAGE 2 were PASI 90 and IGA 0/1 at Week 16. ss-IGA was also evaluated.[17, 18]

BACK

VISIBLE

Study of TREMFYA® (guselkumab) in Skin of Color (SOC) Participants With Moderate-to-Severe Plaque and/or Scalp Psoriasis (PsO)*: Week 16 Results

*Patients with scalp PsO in Cohort B is defined by scalp surface area ≥30%, PSSI≥12 and ss-IGA≥3 and at least one plaque outside of the scalp at screening and at baseline.

PSSI=Psoriasis Scalp Severity Index; ss-IGA=scalp-specific Investigator's Global Assessment.

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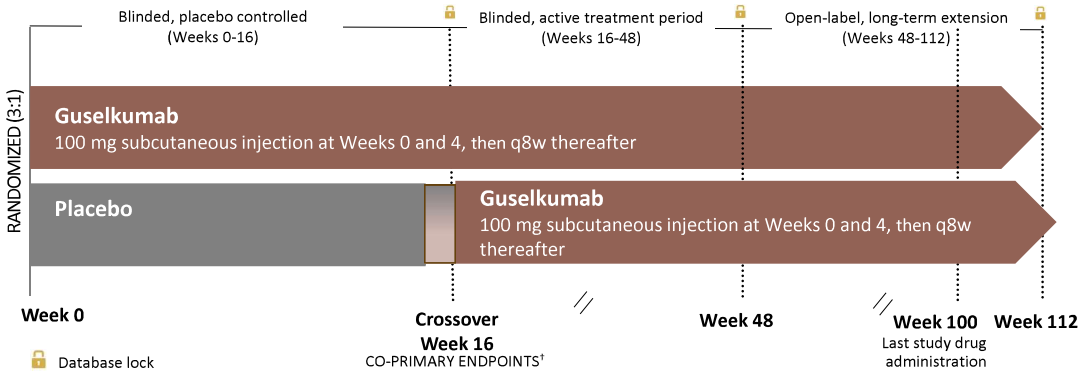
VISIBLE—a Clinical Study Evaluating Adults With Moderate to Severe Plaque PsO Across All Skin Tones*

VISIBLE is an ongoing phase 3b, multicenter, randomized, double-blind, placebo-controlled study (N=211)[1-4]



Selected Inclusion Criteria

- ≥18 years of age
- Self-identify as non-white
- Patients with all Fitzpatrick skin types I-VI were eligible for enrollment in both cohorts (>50% of patients enrolled were Fitzpatrick skin type IV-VI)
  - Colorimetry was used to assess Fitzpatrick skin type
- **Cohort A:** Moderate to severe body plaque PsO (BSA ≥10%, PASI ≥12, and IGA ≥3
- **Cohort B:** Moderate to severe scalp PsO (SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 PsO plaque outside the scalp)
  - Trial ongoing; Week 16 data not yet available
- Biologic-naïve and –experienced patients included

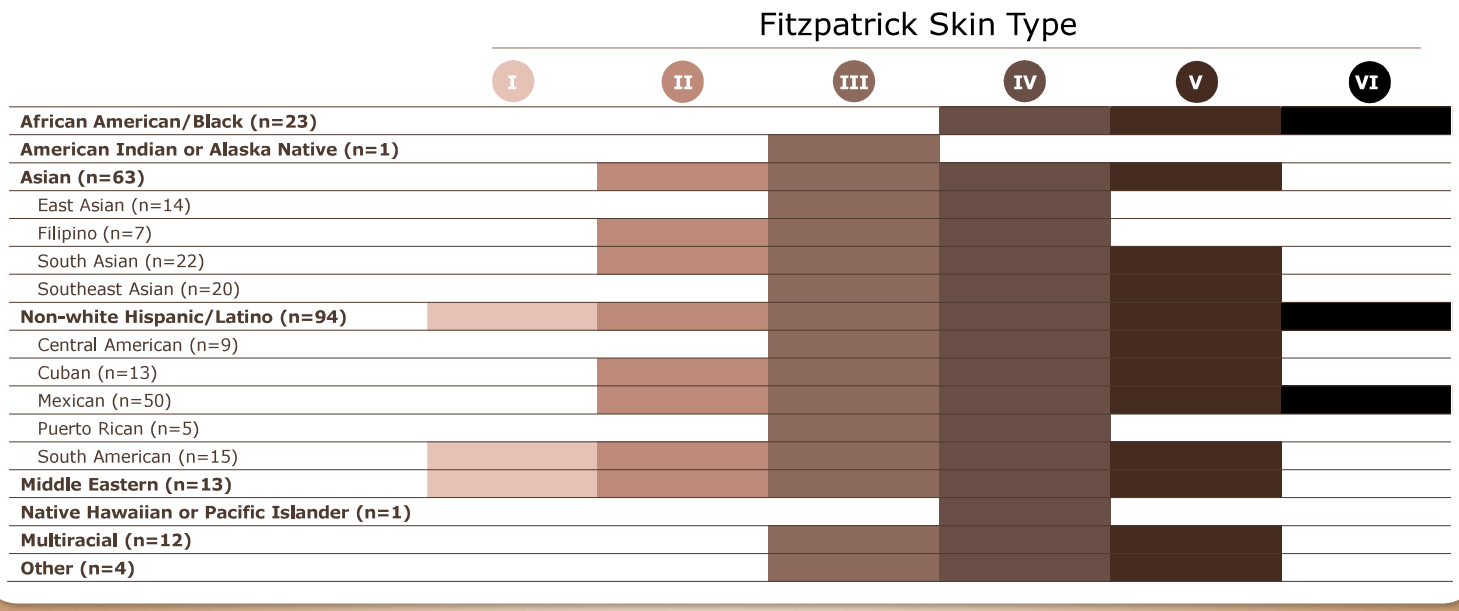
*Refers to patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI). †Co-primary endpoints=Cohort A: PASI 90 and IGA 0/1 at Week 16; Cohort B: PSSI 90 and ss-IGA 0/1 at Week 16. BSA=body surface area; IGA= Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PsO=psoriasis; PSSI=psoriasis scalp severity index; q8w=every 8 weeks; SSA=scalp surface area; ss-IGA=scalp-specific Investigator's Global Assessment.

1. Alexis A, et al. SID Annual Meeting. March 2022.
2. Alexis A, et al. AAD Annual Meeting. March 2023.
3. Clinicaltrials.gov https://clinicaltrials.gov/study/NCT05272150. Accessed: 10/11/23.
4. Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

Range of Self-identified Backgrounds and FST Enrolled in VISIBLE

Cohort A & Cohort B (N=211)



FST=Fitzpatrick skin type.
Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

VISIBLE Participant Cohort A Baseline Characteristics

	Placebo (n=26)	TREMFYA® (guselkumab) (n=77)	Total (n=103)
Age, years			
Mean ± SD	42.3 ± 15.7	44.7 ± 11.8	44.1 ± 12.9
Median	38.0	44.0	43.0
Weight, kg			
Mean ± SD	95.7 ± 27.2	94.5 ± 29.0	94.8 ± 28.4
Median	89.0	85.3	86.0
BMI, kg/m²			
Mean ± SD	32.7 ± 8.5	32.6 ± 8.9	32.6 ± 8.8
Median	30.7	30.4	30.4
% with scalp psoriasis at baseline	80.8%	79.2%	79.6%
% with psoriatic arthritis at baseline	30.7%	25.9%	27.2%
Psoriasis disease duration, years			
Mean ± SD	14.9 ± 8.8	14.9 ± 11.0	14.9 ± 10.5
Median	14.8	13.1	13.7

BMI=body mass index.
Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

VISIBLE Participant Cohort A Baseline Disease Characteristics

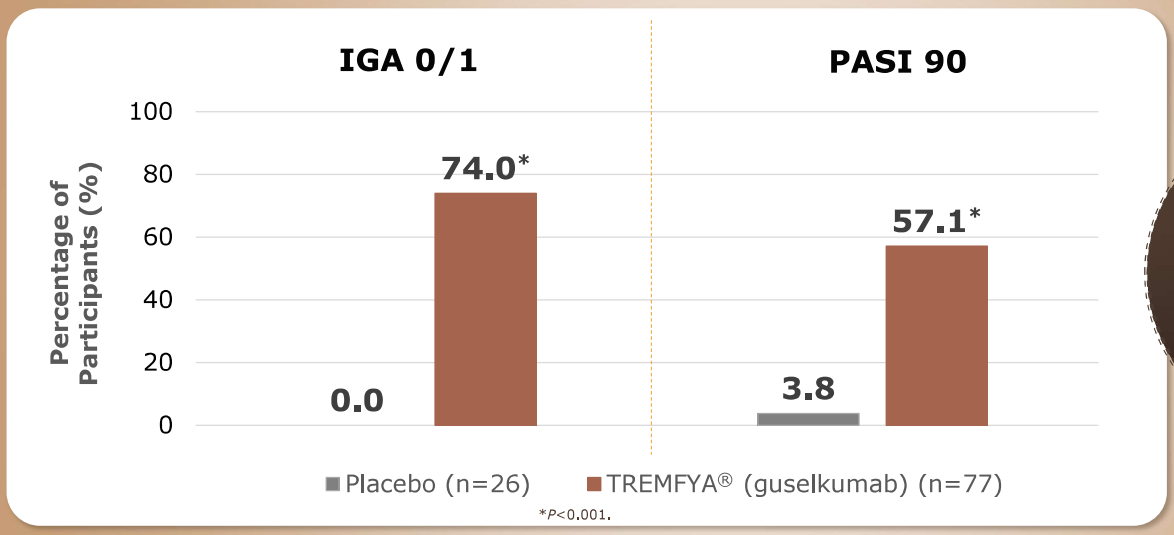
	Placebo (n=26)	TREMFYA® (guselkumab) (n=77)	Total (n=103)
BSA, % involvement			
Mean ± SD	26.1 ± 15.9	27.0 ± 20.4	26.8 ± 19.3
Median	20.5	20.0	20.0
PASI score (0-72)			
Mean ± SD	19.8 ± 6.2	21.2 ± 9.9	20.8 ± 9.1
Median	19.2	18.0	18.0
IGA score, n (%)			
Moderate (3)	21 (80.8%)	57 (74.0%)	78 (75.7%)
Severe (4)	5 (19.2%)	20 (26.0%)	25 (24.3%)
Topicals, ever used, n (%)	19 (73.1%)	61 (79.2%)	80 (77.7%)
Phototherapy, ever used, n (%)*	6 (23.1%)	14 (18.2%)	20 (19.4%)
Nonbiologic systemic therapy, ever used, n (%)†	6 (23.1%)	12 (15.6%)	18 (17.5%)
Biologics, ever used, n (%)‡	8 (30.8%)	22 (28.6%)	30 (29.1%)

*Includes PUVA, UVB. †Includes PUVA, methotrexate, cyclosporine, acitretin. ‡Includes etanercept, infliximab, adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab.
BSA=body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PUVA=psoralen plus ultraviolet A; UVB=ultraviolet B.
Data on file. Janssen Biotech, Inc.

Co-primary Endpoints

In participants with moderate to severe plaque psoriasis

IGA Score of 0/1 and PASI 90 Response at Week 16 (NRI)



Major Secondary Endpoint:

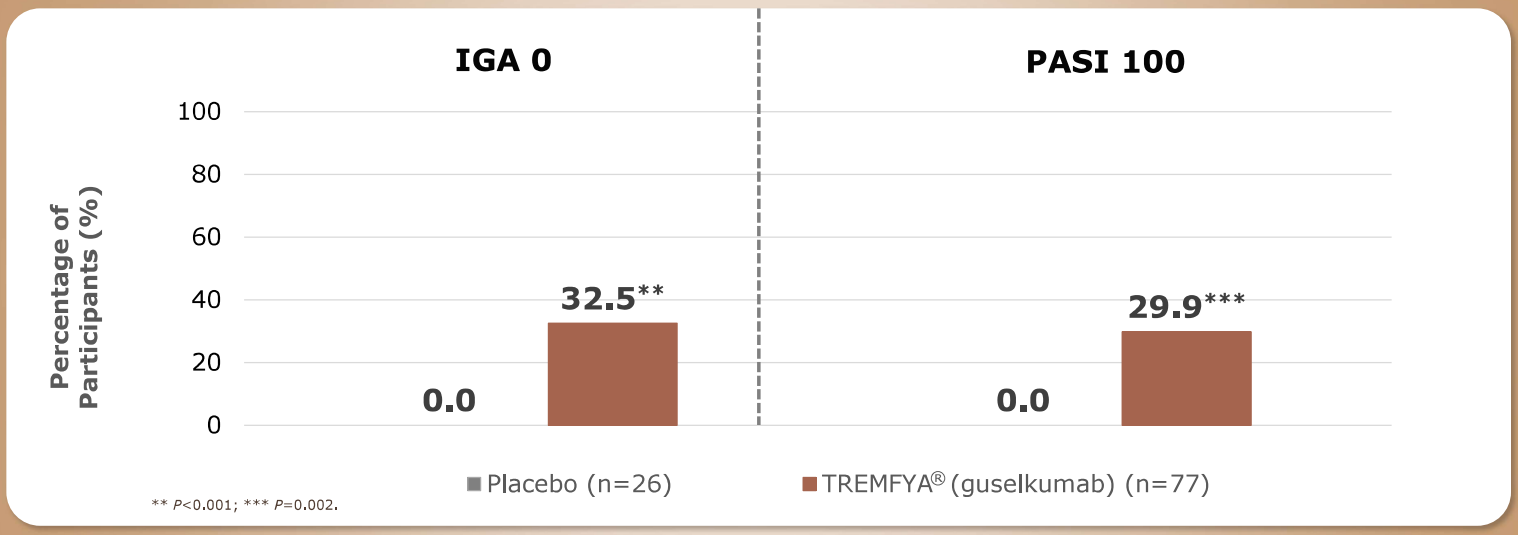
The median time to PASI 90 for patients treated with TREMFYA® is 13.2 weeks

Patients who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to Week 16 were considered nonresponders. Patients with missing data were considered nonresponders.
IGA=Investigator's Global Assessment; NRI=nonresponder imputation; PASI=Psoriasis Area and Severity Index. *P*-values are based on Cochran-Mantel-Haenszel (CMH) test stratified Fitzpatrick skin type (Type I-III/Type IV-VI) and represent the comparisons with placebo.
Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

Major Secondary Endpoints

IGA Score of 0 and PASI 100 Response at Week 16 Across All Skin Tones (NRI)*



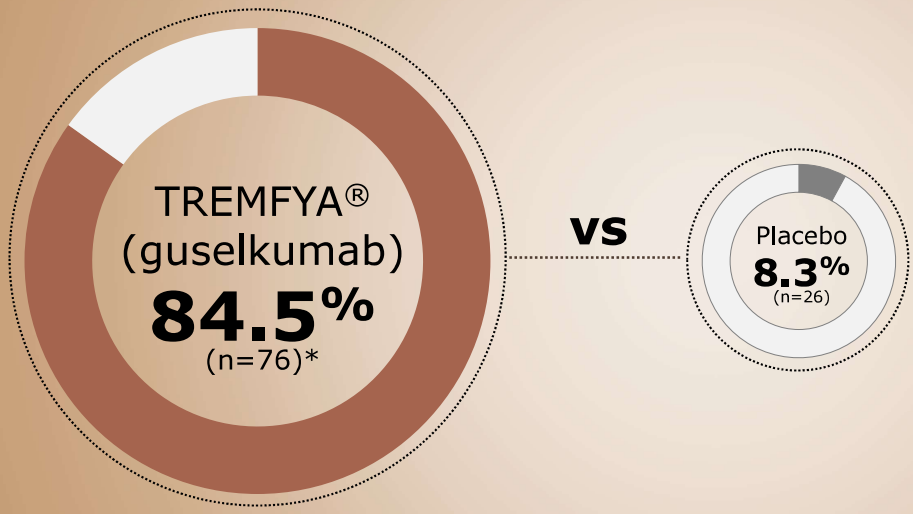
** *P*<0.001; *** *P*=0.002.

*Self-identified skin of color patients across the entire spectrum of the Fitzpatrick scale were included.
Patients who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to Week 16 were considered nonresponders. Patients with missing data were considered nonresponders.
IGA=Investigator's Global Assessment; NRI=nonresponder imputation; PASI=Psoriasis Area and Severity Index. *P*-values are based on Cochran-Mantel-Haenszel (CMH) test stratified Fitzpatrick skin type (Type I-III/Type IV-VI) and represent the comparisons with placebo.
Data on file. Janssen Biotech, Inc.

Major Secondary Endpoint

In participants with moderate to severe plaque psoriasis

Mean % PASI Improvement From Baseline at Week 16



Mean PASI improvement is an assessment of the average percentage improvement from baseline in psoriatic signs of redness, thickness, scaling, and body surface area of involvement.

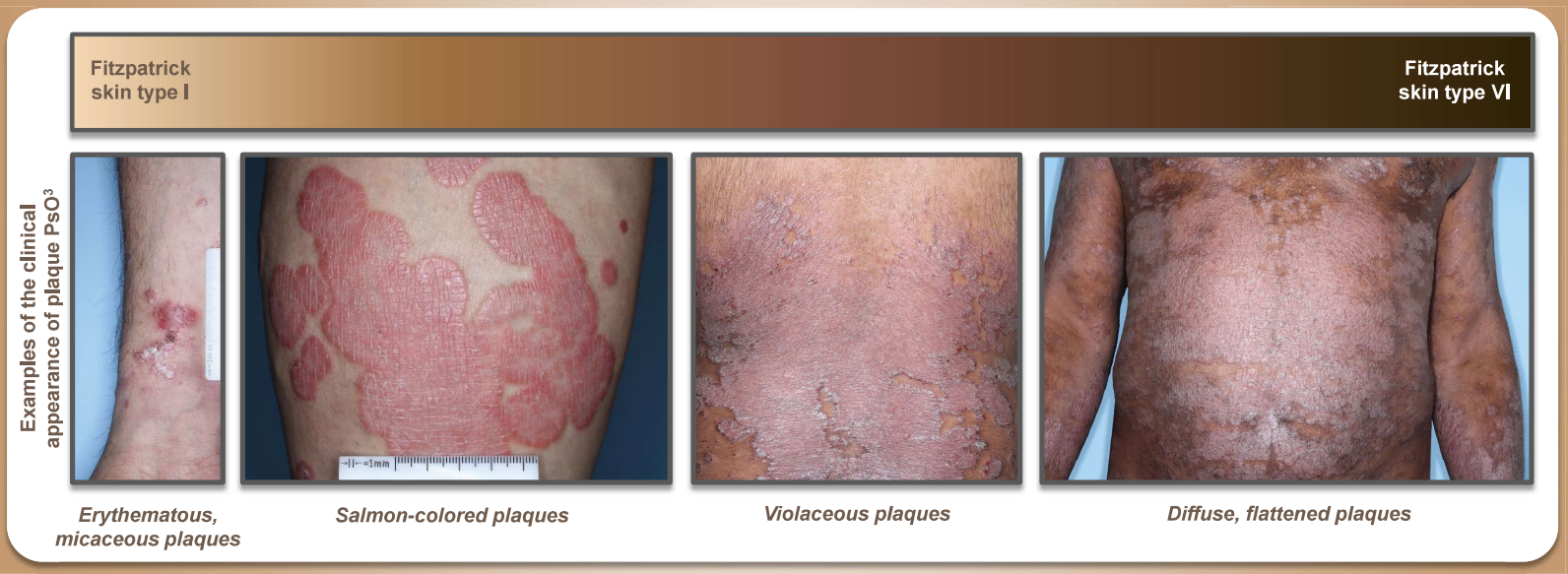
*$P<0.001$ vs placebo. The least squares means and P-values were based on Mixed-Effect Model Repeated Measures (MMRM).

Patients who discontinued study agent due to lack of efficacy, or worsening of PsO, or who initiated a protocol-prohibited PsO treatment prior to Week 16 were considered as zero change. Patients with missing data were not explicitly imputed; they were accounted for in the analysis model.

PASI=Psoriasis Area and Severity Index.
Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

Patients With Plaque PsO Can Have Different Skin Tones, Affecting Disease Presentation[1,2]



1. Kaufman BP, Alexis AF. *Am J Clin Dermatol.* 2018;19(3):405-423.
2. Hermann AE, et al. *HCA Healthc J Med.* 2022;3(3):139-144.
3. Data on file. Janssen Biotech, Inc.

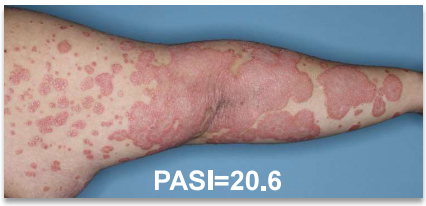
Images are Janssen owned from blinded trial: NCT05272150.

In participants with moderate to severe plaque psoriasis

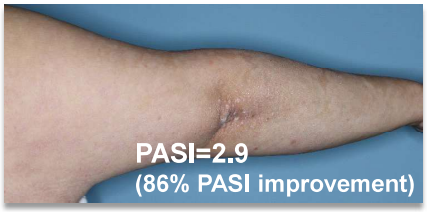
Clinical Photographs From the VISIBLE Study

Fitzpatrick skin type III*

BASELINE



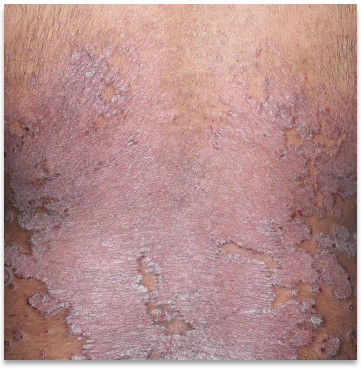
WEEK 16



Images are Janssen owned from blinded trial: NCT05272150.

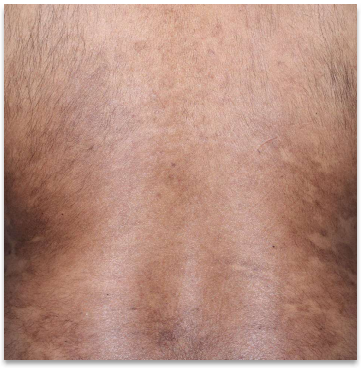
Fitzpatrick skin type IV*

BASELINE



PASI=41.5

WEEK 16



PASI=1.6
(96% PASI improvement)

Patients treated with TREMFYA® with moderate to severe plaque PsO from the VISIBLE study. Individual results may vary.

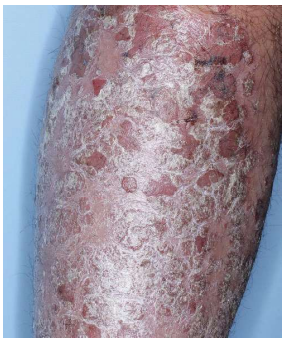
*Fitzpatrick skin type was assessed by colorimetry.
PASI=Psoriasis Area and Severity Index.
Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

PASI 0 Response Across Skin Tones*

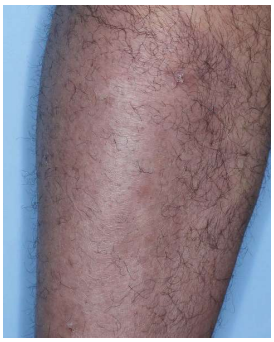
Fitzpatrick skin type II†

BASELINE



PASI=20.1

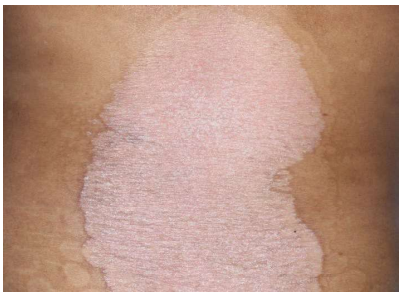
WEEK 16



PASI=0
(100% PASI improvement)

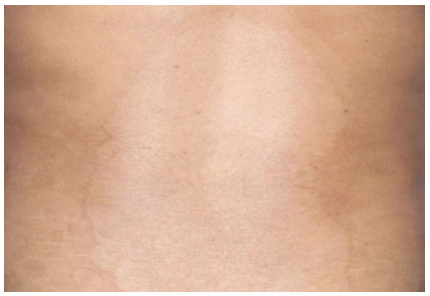
Fitzpatrick skin type V†

BASELINE



PASI=31

WEEK 16



PASI=0
(100% PASI improvement)

Patients treated with TREMFYA® with moderate to severe plaque PsO from the VISIBLE study. Individual results may vary.

Images are Janssen owned from blinded trial: NCT05272150.

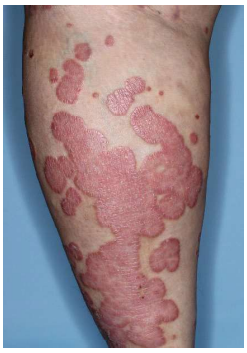
PASI=Psoriasis Area and Severity Index.
*Refers to patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
†Fitzpatrick skin type was assessed by colorimetry.
Data on file. Janssen Biotech, Inc.

In participants with moderate to severe plaque psoriasis

PASI Response Across Skin Tones*

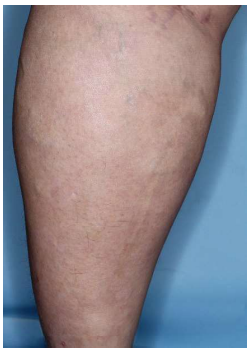
Fitzpatrick skin type III†

BASELINE



PASI=20.6

WEEK 16

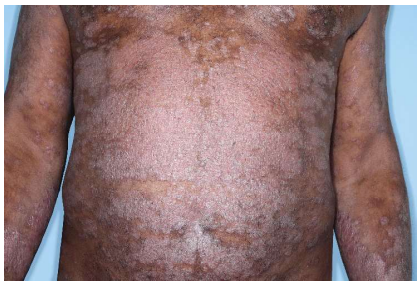


PASI=2.9

(86% PASI improvement)

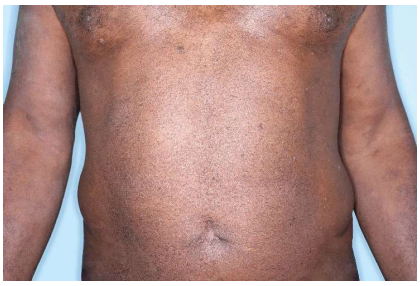
Fitzpatrick skin type VI†

BASELINE



PASI=45.1

WEEK 16



PASI=9.6

(79% PASI improvement)

Patients treated with TREMFYA® with moderate to severe plaque PsO from the VISIBLE study. Individual results may vary.

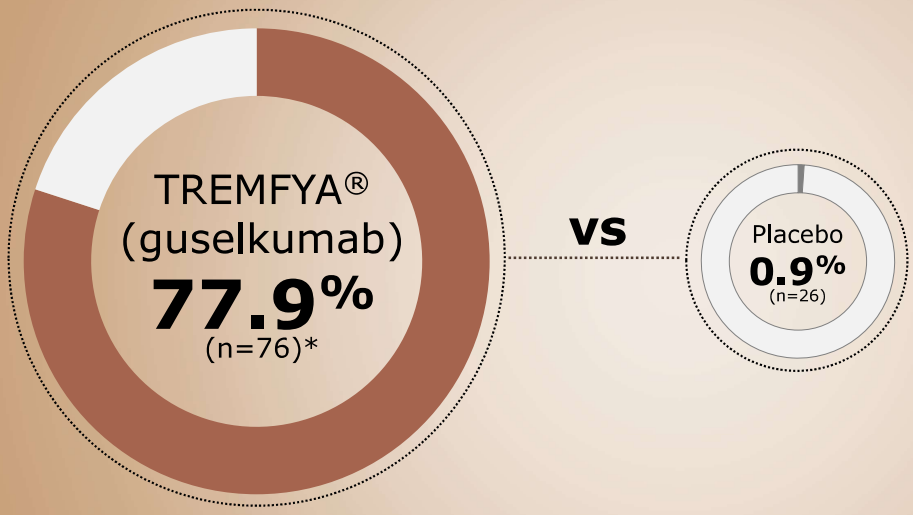
Images are Janssen owned from blinded trial: NCT05272150.

PASI=Psoriasis Area and Severity Index.
*Refers to patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
†Fitzpatrick skin type was assessed by colorimetry.
Data on file. Janssen Biotech, Inc.

Major Secondary Endpoint

In participants with moderate to severe plaque psoriasis

Mean % BSA Improvement From Baseline at Week 16



Mean BSA improvement is an assessment of the average percentage improvement from baseline in BSA involvement.

*P<0.001 vs placebo. The least squares means and P-values were based on Mixed-Effect Model Repeated Measures (MMRM).

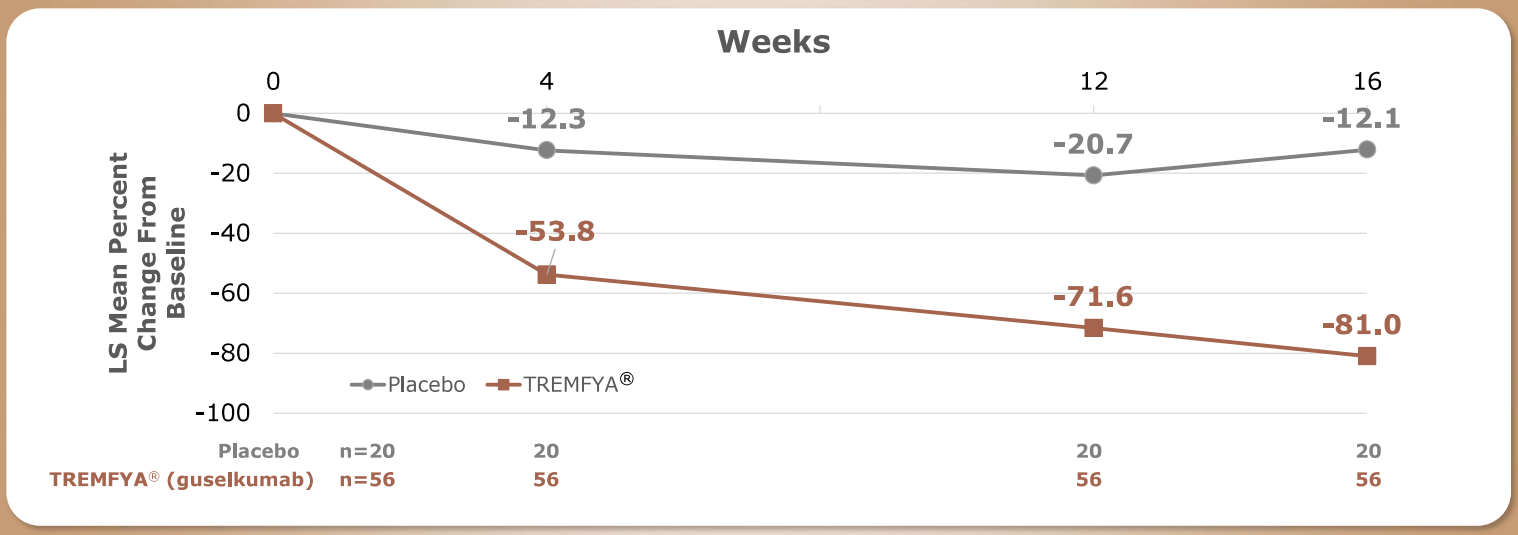
Patients who discontinued study agent due to lack of efficacy, or worsening of PsO, or who initiated a protocol-prohibited PsO treatment prior to Week 16 were considered as zero change. Patients with missing data were not explicitly imputed; they were accounted for in the analysis model.

BSA=body surface area.
Data on file. Janssen Biotech, Inc.

Other Prespecified Secondary Endpoint

In participants with moderate to severe plaque psoriasis

LS Mean Percent Change From Baseline in PSSI Through Week 16, Among Those With Baseline Scalp Psoriasis and ss-IGA Score ≥2



Baseline ss-IGA: moderate scalp PsO TREMFYA® (59%) vs. Placebo (62%); severe scalp PsO TREMFYA® (16.4%) vs. Placebo (4.8%).
Baseline mean PSSI score (0-72): TREMFYA® (20.3±14.6) vs. Placebo (19.6±9.4).

Patients who discontinued study agent due to lack of efficacy, worsening of PsO, or initiated a protocol prohibited PsO treatment prior to Week 16 were considered as zero change. Patients with missing data were not explicitly imputed. They were accounted for in the analysis model. PSSI=Psoriasis Scalp Severity Index; ss-IGA=scalp-specific Investigator's Global Assessment.

1. Data on file. Janssen Biotech, Inc. 2. McMichael A, et al. Fall Clinical Dermatology Conference; October 2023.

In participants with moderate to severe plaque psoriasis

Week 16 Select Safety Data Across All Skin Tones*

	Placebo (n=26)	TREMFYA® (guselkumab) (n=77)
Average duration of follow-up (weeks)	16.0	16.1
≥1 AE	5 (19.2%)	29 (37.7%)
≥1 SAE	0	0
≥1 AE leading to discontinuation of study agent†	0	1 (1.3%)
Deaths	0	0
Malignancy	0	0
Active TB	0	0
MACE	0	0

†Participant discontinued due to impetigo and atopic dermatitis.
Data shown are n (%), unless otherwise indicated. Participants are counted only once for any given event, regardless of the number of times they actually experienced the event. Adverse events are coded using MedDRA version 25.1. Week 16 dose is not counted among the number of study agent administrations.
AE=adverse event; MACE-major adverse cardiovascular events; SAE=serious adverse event; TB=tuberculosis; TEAE=treatment-emergent adverse event.
Data on file. Janssen Biotech, Inc.

APPENDIX

Section 2: Select Additional Clinical Data for TREMFYA® in Moderate to Severe Plaque PsO and Active PsA

ECLIPSE[1-3]

Subgroup Analysis by Body Weight and Body Mass Index

Efficacy findings from the ECLIPSE trial were further evaluated in post hoc analyses by baseline body weight and body mass index. Patients were categorized by body weight quartile (Q1, ≤74 kg; Q2, >74 to ≤87 kg; Q3, >87 to ≤100 kg; and Q4, >100 kg) and by body mass index (BMI) category (normal, <25 kg/m2; overweight, ≥25 to <30 kg/m2; and obese, ≥30 kg/m2). Data were analyzed using non-responder imputation (patients with missing data were considered non-responders) after applying treatment failure rules (patients were considered non-responders after discontinuing treatment for lack of efficacy, or an adverse event of psoriasis worsening, or after initiating a prohibited psoriasis treatment). At baseline, mean body weight was 89 kg in both guselkumab and secukinumab treatment groups. In the guselkumab group, 41.8% of patients were obese, and in the secukinumab group, 44.0% of patients were obese. Subgroup analysis findings for proportions of patients achieving PASI 90, PASI 100, IGA 0/1, or IGA 0 response at week 48 are provided below.

Table. PASI 90 and PASI 100 Response Rates at Week 48 by Baseline Body Weight Quartile[a]

	Guselkumab vs Secukinumab			
	Q1 (≤74 kg)	**Q2 (>74 to ≤87 kg)**	**Q3 (>87 to ≤100 kg)**	**Q4 (>100 kg)**
PASI 90 Patients, % Difference, % (95% CI)	86.7% vs 75.6% 11.1% (0.9, 21.3)	89.1% vs 73.0% 16.0% (6.0, 26.0)	80.3% vs 71.0% 9.3% (–1.9, 20.6)	82.1% vs 61.3% 20.9% (9.4, 32.3)
PASI 100 Patients,% Difference, % (95% CI)	58.7% vs 56.1% 2.6% (–10.0, 15.3)	66.4% vs 51.8% 14.6% (2.0, 27.2)	59.1% vs 47.6% 11.5% (–1.4, 24.4)	50.0% vs 38.7% 11.3% (–1.4, 24.0)

Abbreviations: CI, confidence interval; PASI, Psoriasis Area and Severity Index; Q, body weight quartile.
[a]Results by body weight quartile were available for 534 patients in the guselkumab group (Q1, n=143; Q2, n=119; Q3, n=132; Q4, n=140) and for 512 patients in the secukinumab group (Q1, n=123; Q2, n=141; Q3, n=124; Q4, n=124).

Table. PASI 90 and PASI 100 Response Rates at Week 48 by Baseline Body Mass Index[a]

	Guselkumab vs Secukinumab		
	Normal (<25 kg/m²)	**Overweight (≥25 to <30 kg/m²)**	**Obese (≥30 kg/m²)**
PASI 90 Patients, % Difference, % (95% CI)	88.1% vs 75.2% 12.8% (2.2, 23.5)	84.1% vs 73.4% 10.6% (1.6, 19.7)	82.5% vs 65.3% 17.2% (8.8, 25.6)
PASI 100 Patients, % Difference, % (95% CI)	64.2% vs 57.8% 6.4% (–6.8, 19.5)	61.4% vs 53.7% 7.7% (–3.2, 18.5)	52.5% vs 40.4% 12.0% (2.4, 21.6)

Abbreviations: CI, confidence interval; PASI, Psoriasis Area and Severity Index.
[a]Results by body mass index category were available for 533 patients in the guselkumab group (normal, n=134; overweight, n=176; obese, n=223) and for 511 patients in the secukinumab group (normal, n=109; overweight, n=177; obese, n=225).

Figure. Proportion of Patients Achieving IGA 0/1 or IGA 0 at Week 48 by Baseline Body Weight Quartile

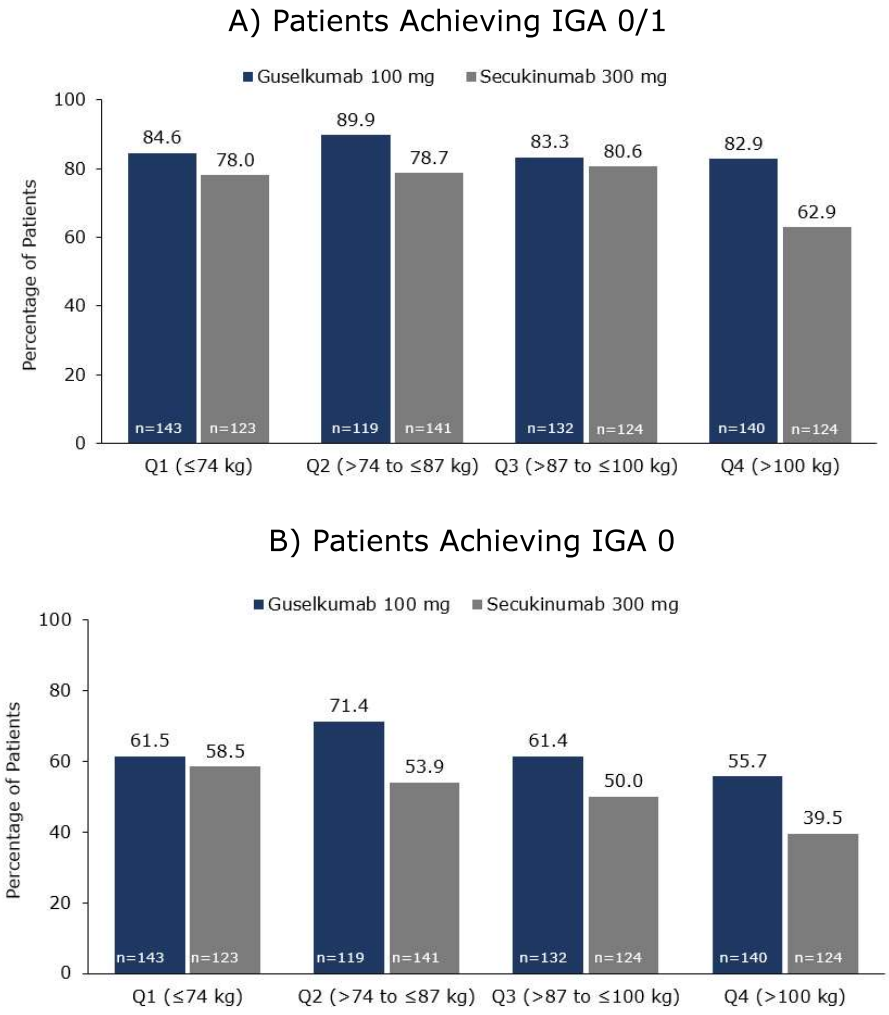
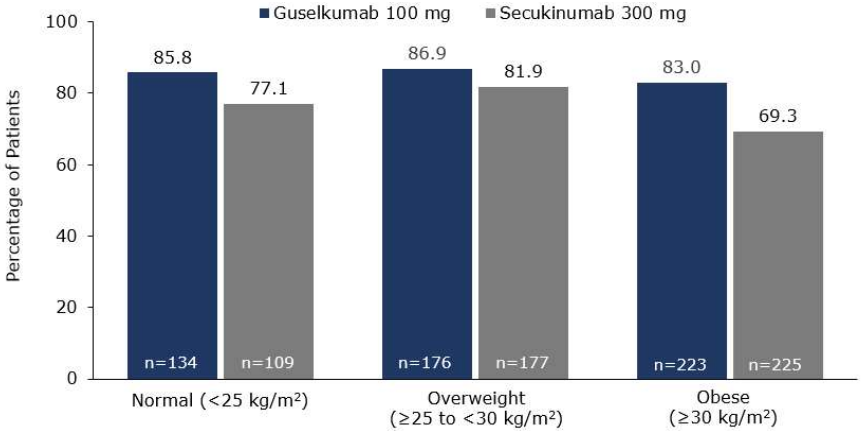
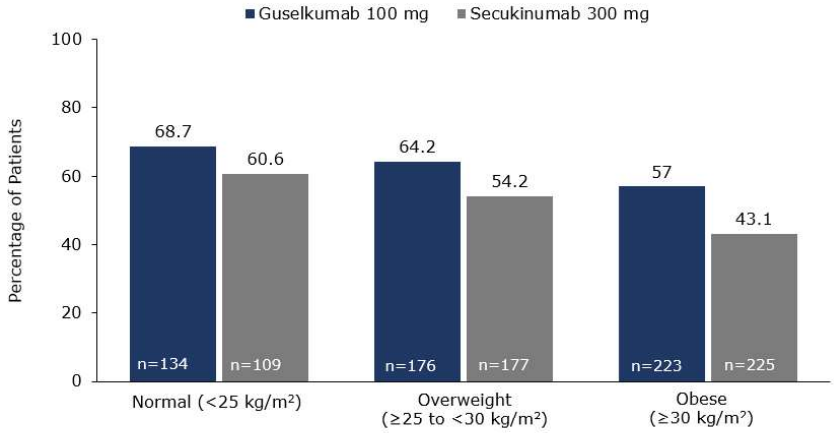


Figure. Proportion of Patients Achieving IGA 0/1 or IGA 0 at Week 48 by Baseline Body Mass Index

A) Patients Achieving IGA 0/1



B) Patients Achieving IGA 0

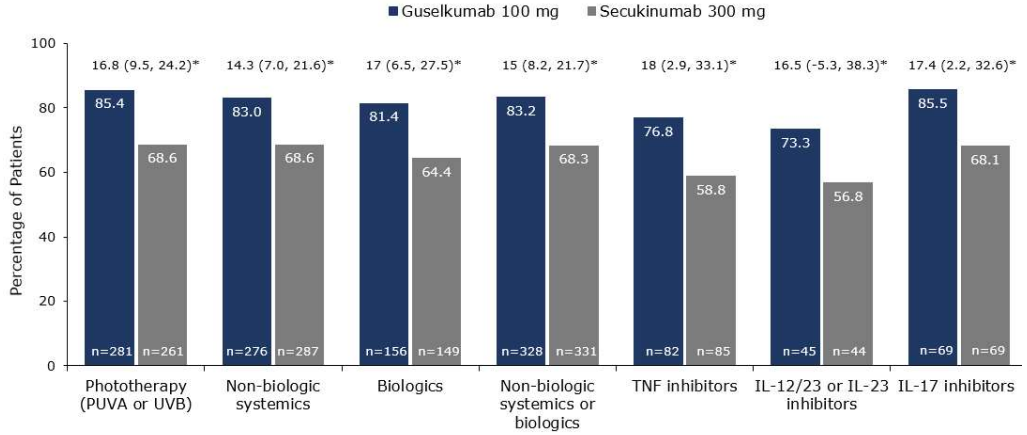


Subgroup Analysis by Prior Psoriasis Medication History

(Blauvelt A et al. Presented at the 2019 Congress of the European Academy of Dermatology and Venereology, P1635)

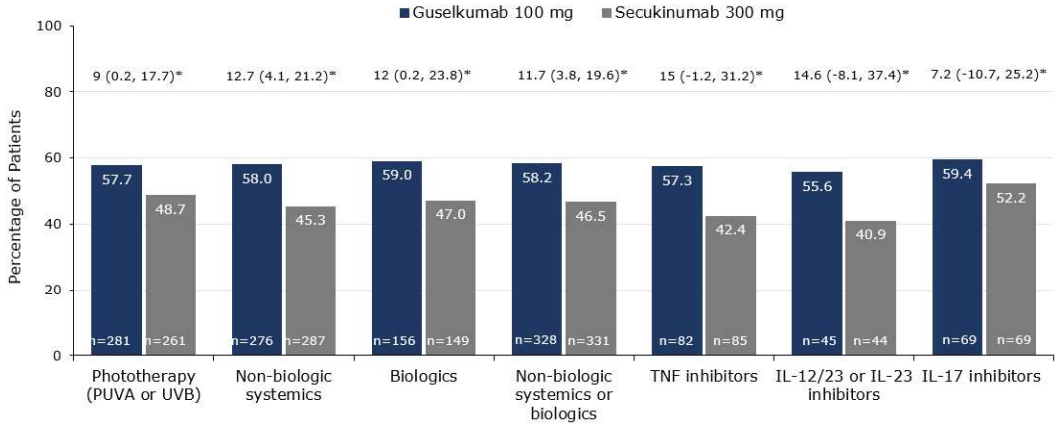
Efficacy findings from the ECLIPSE trial were further evaluated in post hoc analyses by previous psoriasis treatment, including history of treatment with phototherapy (psoralen plus ultraviolet A [PUVA] or Ultraviolet B [UVB]), nonbiologic systemic therapy, and/or biologic therapy (TNF inhibitors, IL-12/IL-23 inhibitors, IL-23 inhibitors, IL-17 inhibitors, alefacept, efalizumab). Subgroup analysis findings for proportions of patients achieving PASI 90, PASI 100, or IGA 0 response at Week 48 are provided in Figures 10–12.

Figure. Proportions of Patients Achieving PASI 90 Response at Week 48 by Previous Baseline PsO Treatment



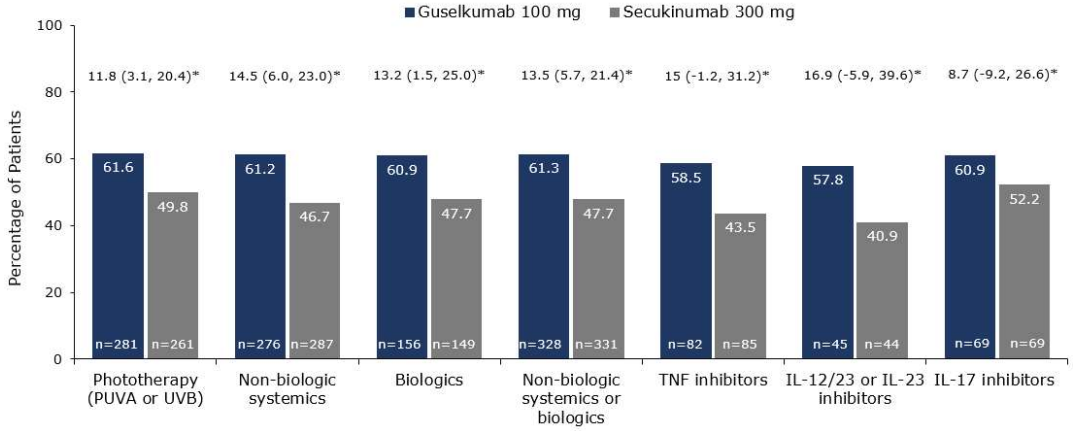
*Represents treatment difference (95% confidence interval)
IL=interleukin; PUVA=Psoralen plus Ultraviolet A; TNF=tumor necrosis factor; UVB=Ultraviolet B

Figure. Proportion of Patients Achieving PASI 100 Response at Week 48 by Previous Baseline PsO Treatment



*Represents treatment difference (95% confidence interval)
IL=interleukin; PUVA=Psoralen plus Ultraviolet A; TNF=tumor necrosis factor; UVB=Ultraviolet B

Figure. Proportions of Patients Achieving IGA 0 Score at Week 48 by Previous Baseline PsO Treatment



*Represents treatment difference (95% confidence interval)
IL=interleukin; PUVA=Psoralen plus Ultraviolet A; TNF=tumor necrosis factor; UVB=Ultraviolet B

Safety Outcomes

Key safety findings are summarized in Table. Key Safety Events Through Week 56. No cases of active tuberculosis or opportunistic infections were reported during the study.

Table. Key Safety Events Through Week 56

	Guselkumab (n = 534)	Secukinumab 300 mg (n = 511)
Mean (standard deviation) duration of follow-up, weeks	54.9 (6.7)	53.7 (9.2)
Patients with ≥1 AE, n (%)	416 (78%)	417 (82%)
Common Aes, n (%)[a]		
Nasopharyngitis	118 (22%)	125 (24%)
Upper respiratory tract infection	83 (16%)	92 (18%)
Headache	49 (9%)	48 (9%)
Arthralgia	30 (6%)	25 (5%)
Back pain	29 (5%)	18 (4%)
Diarrhea	27 (5%)	20 (4%)
Discontinued study drug because of AE, n (%)	10 (2%)	12 (2%)
Patients with ≥1 serious AE, n (%)	33 (6%)	37 (7%)
Overall infections, n (%)	313 (59%)	331 (65%)
Requiring treatment	118 (22%)	147 (29%)
Serious infections	6 (1%)	5 (1%)
Candida infections, n (%)[b]	12 (2%)	29 (6%)
Tinea infections, n (%)[c]	9 (2%)	23 (5%)
Worsening of psoriasis, n (%)	4 (1%)	11 (2%)
Crohn's disease, n (%)[d]	0	3 (1%)
Malignancy, n (%)	7 (1%)	4 (1%)

NMSC[e]	6 (1%)	2 (<1%)
Other malignancies[f]	1 (<1%)	2 (<1%)
MACE, n (%)[g]	0	1 (<1%)

Abbreviations: AE, adverse event; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer.
[a]Occuring in ≥5% of patients in any treatment group.
[b]Candida infections included the AE terms: oral candidiasis, vulvovaginal candidiasis, skin candida, candida infection, balanitis candida, and vulvovaginal mycotic infection.
[c]Tinea infections included the following AE terms: tinea pedis, tinea cruris, fungal skin infection, body tinea, dermatophytosis, and onychomycosis.
[d]One (<1%) was a new-onset AE of Crohn's disease, 1 (<1%) a new-onset serious AE of Crohn's disease, and 1 (<1%) an AE of worsening of Crohn's disease in a patient who had not disclosed a history of Crohn's disease at screening; all cases were established by colonoscopy.
[e]NMSC were basal cell caricnomas (n=3 [<1%] in the guselkumab group, n=2 [<1%] in the secukinumab group) and squamous cell carcinomas (n=3 [<1%] in the guselkumab group).
[f]Other malignancies were 1 breast cancer in the guselkumab group, and 1 lung cancer and 1 mycosis fungoides in the secukinumab group.
[g]MACE is defined as an investigator-reported nonfatal myocardial infarction, nonfatal stroke, or cardiovascular death; the 1 MACE reported in the secukinumab group was a cerebrovascular accident.

COSMOS [4]

In the COSMOS study, ACR20 response rates for TREMFYA vs placebo were consistent across subgroups defined by baseline patient and disease characteristics such as body weight and by prior and concomitant medications (nbDMARDs, oral corticosteroids, NSAIDs, prior TNFi, reason for prior TNFi discontinuation). See Table. ACR20 Response at Week 24 by Baseline Characteristics.

Table. ACR20 Response at Week 24 by Baseline Characteristics

Parameter, n (%)	GUS 100 mg (n=189)	Placebo (n=96)	OR (95% CI)
All patients	84 (44.4)	19 (19.8)	3.2 (1.8-5.8)
Sex			
Male	42 (48.8)	10 (19.2)	4.0 (1.8-9.0)
Female	42 (40.8)	9 (20.5)	2.7 (1.2-6.1)
Body weight (kg)			
≤90	55 (45.1)	8 (17.0)	4.0 (1.7-9.3)
>90	29 (43.3)	11 (22.4)	2.6 (1.2-6.0)
Non-biologic DMARDs at baseline			
Yes	57 (47.5)	14 (23.3)	3.0 (1.5-6.0)
MTX	52 (49.5)	11 (22.0)	3.5 (1.6-7.5)
No	27 (39.1)	5 (13.9)	4.0 (1.4-11.5)
Oral corticosteroids at baseline			
Yes	16 (48.5)	6 (28.6)	2.4 (0.7-7.6)
No	68 (43.6)	13 (17.3)	3.7 (1.9-7.2)
NSAIDs at baseline			

Parameter, n (%)	GUS 100 mg (n=189)	Placebo (n=96)	OR (95% CI)
Yes	46 (43.8)	8 (16.3)	4.1 (1.8-9.6)
No	38 (45.2)	11 (23.9)	2.6 (1.2-5.9)
Prior TNF inhibitor			
1	79 (47.3)	18 (21.2)	3.3 (1.8-6.1)
2	5 (22.7)	1 (9.1)	2.9 (0.3-28.9)
Reason for prior TNF inhibitor discontinuation			
Inadequate efficacy	70 (44.0)	17 (21.5)	2.9 (1.5-5.3)
Intolerance	14 (46.7)	2 (11.8)	6.6 (1.3-33.8)

Abbreviations: ACR20, ≥20% improvement from baseline in the American College of Rheumatology Criteria; CI, confidence interval; CRP, C-reactive protein; GUS, guselkumab; MTX, methotrexate; NSAID, non-steroidal anti-inflammatory drug; OR, odds ratio; TNF, tumor necrosis factor.

- The results for the primary and secondary endpoints are summarized in Table. Summary of Primary and Select Secondary Endpoints at Week 24 and Week 48.

Table. Summary of Primary Endpoint at Week 24 and Week 48

	Week 24			Week 48	
	Placebo n=96	GUS 100 mg n=189	*P* Value	Placebo→ GUS 100 mg n=51[a]	GUS 100 mg n=189
Primary Endpoint					
ACR20, %	19.8	44.4	<0.001[b]	54.9	57.7
EE correction[c]	-	48.1	-	-	-

Abbreviations: ACR20/50/70, ≥20%/50%/70% improvement from baseline in the American College of Rheumatology Criteria; DSS, Dactylitis Severity Score; EE, early escape; GUS, guselkumab; HAQ-DI, Health Assessment Questionnaire-Disability Index; LEI, Leeds Enthesitis Index; LS, least squares; SF-36 PCS, 36-item Short-Form Health Survey Physical Component Summary; PASI100, 100% improvement from baseline in Psoriasis Area and Severity Index; q8w, every 8 weeks.
[a]Efficacy results for the placebo→guselkumab 100 mg q8w group at week 48 include patients who did not enter early escape and crossed over to guselkumab at week 24 (those who entered early escape at week 16 were considered nonresponders at subsequent timepoints).
[b]Adjusted for multiplicity.
[c]EE-correction analysis was conducted to address 20 patients incorrectly routed to EE and considered non-responders in the primary analysis.
[d]Resolution of dactylitis (DSS=0; range, 0-60) or enthesitis (LEI score=0; range, 0-6) determined in patients with dactylitis or enthesitis, respectively, at baseline.

Safety

- The most common AEs in patients treated with guselkumab through week 24 included nasopharyngitis (5%) and upper respiratory tract infection (4%), with similar incidence in the placebo group (5% and 3%, respectively).
- Through week 24, SAEs and serious infections occurred in 3.7% and 0.5% of patients in the guselkumab group (n=189), respectively. In the placebo group (n=96), SAEs and serious infections occurred at 3.1% and 0%, respectively.

- Overall, the safety profile was similar through weeks 24 and 56, with no opportunistic infections, active tuberculosis, anaphylactic/serum sickness-like reaction, confirmed inflammatory bowel disease, or death was reported.
- Through week 56, there was no increase in adverse event rates in the guselkumab group. The safety results are presented in Table. Summary of Safety Results Through Week 56.

Table. Summary of Safety Results Through Week 56

AEs, Events/100 PY (95% CI)	Placebo[a]	Placebo→GUS 100 mg q8w		GUS 100 mg q8w[d]		All GUS 100 mg q8w[e]
	Weeks 0-24	Weeks 16-56[b]	Weeks 24-56[c]	Weeks 0-24	Weeks 24-56	Weeks 0-56
Patients, n	96	45	45	189	174	279
Total follow-up, PY	28.1	32.9	27.2	87.7	107.6	255.4
AEs	369.8 (302.2-448.1)	127.5 (91.9-172.4)	143.3 (101.9-195.9)	229.2 (198.6-263.2)	81.8 (65.6-100.8)	144.9 (130.5-160.4)
SAEs	10.7 (2.2-31.2)	6.1 (0.7-21.9)	7.4 (0.9-26.5)	8.0 (3.2-16.5)	4.7 (1.5-10.8)	6.3 (3.6-10.2)
AEs leading to study agent discontinuation	7.1 (0.9-25.7)	0 -	0 -	4.6 (1.2-11.7)	2.8 (0.6-8.2)	2.7 (1.1-5.7)
Infections	99.6 (66.2-143.9)	30.4 (14.6-55.9)	29.4 (12.7-57.9)	63.9 (48.2-82.9)	19.5 (12.1-29.8)	37.2 (30.1-45.5)
Serious infections	0 -	0 -	3.7 (0.1-20.5)	1.1 (0.03-6.4)	0 -	0.8 (0.1-2.8)

Abbreviations: AE, adverse event; CI, confidence interval; GUS, guselkumab; PY, patient-years; q8w, every 8 weeks; SaE, serious adverse event.
[a]AEs that occurred during placebo treatment in placebo-randomized patients.
[b]AEs that occurred during guselkumab treatment in placebo randomized patients who crossed over to guselkumab prior to week 24.
[c]AEs that occurred in placebo randomized patients who crossed over to guselkumab at week 24.
[d]Includes guselkumab-randomized patients who received an early escape placebo injection at week 16.
[e]AEs that occurred in all patients who received at least 1 administration of guselkumab, including those randomized to placebo.

REFERENCES

1. Reich K, Armstrong AW, Langley RG, et al. Guselkumab versus secukinumab for the treatment of moderate-to-severe psoriasis (ECLIPSE): results from a phase 3, randomised controlled trial. *Lancet*. 2019;394(10201):831-839.

2. Blauvelt A, Armstrong AW, Langley RG, et al. Efficacy of guselkumab versus secukinumab in subpopulations of patients with moderate-to-severe plaque psoriasis: results from the ECLIPSE study. *J Dermatol Treat*. 2022;33(4):2317-2324.

3. Blauvelt A, Vender R, Spelman L, et al. Efficacy of guselkumab versus secukinumab in patients with moderate-to-severe plaque psoriasis in subgroups

defined by previous psoriasis medication history: results from the ECLIPSE study. Poster presented at: 28th European Academy of Dermatology and Venereology (EADV) Congress; October 9-13, 2019; Madrid, Spain.

4. Coates LC, Gossec L, Theander E, et al. Efficacy and safety of guselkumab in patients with active psoriatic arthritis who are inadequate responders to tumour necrosis factor inhibitors: results through one year of a phase IIIb, randomised, controlled study (COSMOS). *Ann Rheum Dis*. 2022;81(3):359-369.

APPENDIX

Section 3: Select Real-World Evidence for TREMFYA® in Moderate to Severe Plaque PsO

Poster 69

Long-term effectiveness up to 24 months of guselkumab on disease severity in the CorEvitas Psoriasis Registry

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INTRODUCTION

- Guselkumab is an IL-23 inhibitor approved for moderate-to-severe plaque PsO and active PsA[1]
- In clinical trials, guselkumab has demonstrated improvement in clinical disease activity through five years (VOYAGE 1 and VOYAGE 2)[2-5]
- Studies are needed to determine the long-term effectiveness of guselkumab in a real-world setting

OBJECTIVE

- To evaluate the long-term effectiveness on clinical disease activity among patients with moderate to severe plaque psoriasis in the CorEvitas Psoriasis Registry with persistent use of guselkumab for 18-24 months

METHODS

Study Setting

- The CorEvitas Psoriasis Registry[6] is a prospective, multicenter, non-interventional registry, launched in April 2015, for patients with psoriasis under the care of a dermatologist
- The Registry collects data from both physicians (dermatologists) and patients at the time of outpatient clinical dermatological encounters
- Registry inclusion criteria
  - Be at least 18 years of age
  - Provide written informed consent for participation in the registry
  - Have started on or switched to an eligible systemic psoriasis treatment at enrollment or within the previous 12 months of the date of enrollment

Study Population

- Enrolled in the CorEvitas Psoriasis Registry between July 2017 and September 2021
- Adult patients with a history of plaque psoriasis
- Patients with at least moderate disease severity, defined as Body Surface Area (BSA) ≥3% and Investigator Global Assessment (IGA) ≥3, at index visit
- No discontinuation of guselkumab prior to the start of the 18-24-month study window
- CorEvitas visit 18-24 months post guselkumab initiation

Study Outcomes

- Investigator's Global Assessment (IGA) [IGA 0, IGA 0/1, Mean change in IGA]
- Psoriasis Area Severity Index (PASI) [PASI 90, PASI 100, Mean change in PASI]
- Body Surface Area (BSA) [Mean change in BSA]
- National Psoriasis Foundation (NPF) Acceptable Response (BSA ≤ 3% or ≥75% improvement from baseline) and Target Response (BSA ≤ 1%)

METHODS

Covariates

- Demographic characteristics; Health behavior and lifestyle characteristics; History of comorbidities; Disease characteristics; Psoriasis treatment characteristics

Statistical Analysis

- Covariates including demographics, health behaviors and lifestyle characteristics, disease characteristics, and patient reported outcomes were described at the index visit
- Means and standard deviations (SD) or frequencies and percentages were reported for baseline sociodemographic, disease characteristics, and disease severity measures
- Disease response measures at the 18-24-month follow-up visit were summarized using percentages and 95% confidence intervals (CI), each measure estimated from a one-sample proportion interval estimation
- The change in each continuous outcome from baseline was reported with a mean and SD, along with a 95% CI
- A paired t-test was used to compare the change in the outcomes from 0 (i.e., no change)
- Results were reported for the overall sample and separately for patients that were biologic-naïve and biologic-experienced at the index visit

RESULTS

- 183 patients were included in this study with a median duration of guselkumab use of 20 months (Interquartile Range = [19, 22])
- For continuous outcomes, all measures indicated improvement from guselkumab initiation to the 18-24-month follow-up visit
- The majority of patients were biologic-experienced (n = 106; 58%) with a mean age of 49 years (SD = 15.3), White (n = 147; 80%), male (n = 108; 59%), and had a mean disease duration of 16.1 years (SD = 13.4) (Table 1)
- Most patients achieved clinically meaningful skin clearance and NPF treatment targets at 18-24-month follow-up (Figure 1a & 1b)
  - IGA 0/1 (n = 126; 69.2% [95% CI: 62.0%, 75.8%])
  - IGA 0 (n = 76; 41.8% [95% CI: 34.5%, 49.3%])
  - PASI 90 (n = 105; 57.7% [95% CI: 50.2%, 65.0%])
  - PASI 100 (n = 78; 42.9% [95% CI: 35.6%, 50.4%])
  - NPF Acceptable Response (n = 159; 87.4% [95% CI: 81.6%, 91.8%])
  - NPF Target Response (n = 122; 67.0% [95% CI: 59.7%, 73.8%])
- Changes in disease activity (Figure 2):
  - PASI (n=182; mean -9.7 [95%CI: -10.8, -8.6])
  - IGA (n=182; mean -2.2 [95%CI: -2.4, -2.0])
  - BSA (n=182; mean -14.2 [95%CI -16.4, -12.0])

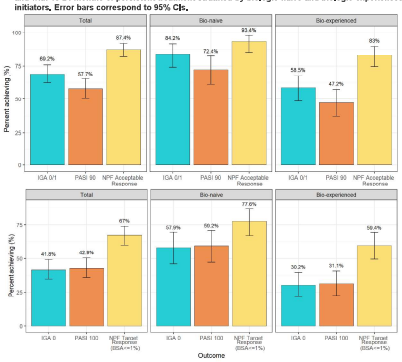
RESULTS

Table 1. Patient characteristics at index visit for guselkumab initiators with moderate to severe psoriasis who were persistent users for 18-24 months, stratified by bio-naïve and bio-experienced initiators

Characteristics	Total (N = 183)	Bio-naive (N = 77)	Bio-experienced (N = 106)
Age (years), mean (SD)	48.9 (15.3)	48.0 (16.1)	49.5 (14.7)
Sex-male, n (%)	108 (59%)	42 (55%)	66 (62%)
Race-White, n (%)	147 (80%)	65 (84%)	82 (77%)
Body Mass Index (BMI, kg/m^2), mean (SD)	32.0 (7.2)	30.6 (6.8)	33.0 (7.3)
Psoriasis duration (years), mean (SD)	16.1 (13.4)	13.4 (14.1)	18.1 (12.6)
BSA (% involvement), mean (SD)	16.5 (15.7)	16.0 (12.6)	16.8 (17.6)
IGA, mean (SD)	3.3 (0.4)	3.3 (0.5)	3.2 (0.4)
PASI (Score:0-72), mean (SD)	11.3 (7.8)	10.8 (5.9)	11.7 (9.0)
Previous Biologics ≥2	77 (42%)	—	77 (73%)

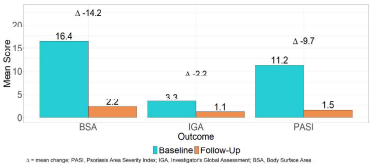
BSA, Body Surface Area, IGA, Investigator's Global Assessment, PASI, Psoriasis Area Severity Index

Figure 1a & 1b. Disease activity response for guselkumab initiators with moderate to severe psoriasis and with 18-24 months of persistent treatment stratified by biologic-naive and biologic-experienced initiators. Error bars correspond to 95% CIs.



IGA, Investigator's Global Assessment, PASI, Psoriasis Area Severity Index, NPF, National Psoriasis Foundation

Figure 2. Mean change of disease activities for guselkumab initiators with moderate to severe psoriasis who were persistent users for 18-24 months.



Δ = mean change; PASI, Psoriasis Area Severity Index; IGA, Investigator's Global Assessment; BSA, Body Surface Area

STRENGTHS AND LIMITATIONS

- To our knowledge, this is the first long-term real-world assessment of effectiveness of guselkumab in a North American psoriasis patient population
- Because the data source is a US/Canadian registry, the results may not be generalizable to all patients with moderate to severe plaque psoriasis outside of the US/Canada
- Psoriasis patients who were persistent on guselkumab for 18-24 months were included, therefore results are not generalizable to other patient populations

CONCLUSIONS

The majority of patients with psoriasis who were persistent on guselkumab for 18-24 months achieved meaningful and durable improvement in skin clearance. Durable long-term effectiveness was achieved irrespective of prior treatment history, although numerically greater improvements are observed in biologic-naive versus biologic-experienced patients, indicating the potential need for earlier intervention to maximize treatment outcomes. Understanding individual patient characteristics associated with both long-term persistence and effectiveness is warranted to appropriately target therapies to individual patient needs.

DISCLOSURES, ACKNOWLEDGEMENTS, & REFERENCES

DISCLOSURES: BS, Consultant (honoraria) for AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol Myers Squibb, Connect Biopharma, Dermavant, Equillium, Janssen, Leo Pharma, Eli Lilly, Maruho, Meiji Seika Pharma, and Mindera; AA, Consultant, advisor, and investigator for AbbVie, Janssen Pharmaceuticals Inc., Novartis Pharmaceuticals Corp, Eli Lilly, Regeneron Pharmaceuticals, Sanofi Genzyme, Leo Pharma, Science 37 Inc., Modernizing Medicine, and Ortho Dermatologics; TF, KR, OC, DC, RT, Employees of Janssen Scientific Affairs and shareholders of Johnson & Johnson; JJ, Employee and shareholder, CorEvitas, LLC; AS, HK, MM, Employees of CorEvitas, LLC; ACKNOWLEDGEMENTS: Support for thirdparty writing assistance for this poster, furnished by Michelle Karpman, PhD, editing by Leslie Whitehead and Blessing Dube, MPH of CorEvitas, LLC, and was funded by Janssen Global Services, LLC. Horsham, PA, USA. This study is sponsored by CorEvitas, LLC. CorEvitas has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, Inc., Arena, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Chugai, Eli Lilly and Company, Genentech, Gilead Sciences, Inc., GlaxoSmithKline, Janssen Pharmaceuticals, Inc., UCB Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Regeneron Pharmaceuticals, Inc., Sanofi, Sun Pharmaceutical Industries Ltd, and UCB S.A. The authors would like to thank all the investigators, their clinical staff, and patients who participate in the CorEvitas Psoriasis Registry. REFERENCES: 1. Tremfya [guselkumab]. Prescribing Information for Psoriasis and Psoriatic Arthritis. Janssen Biotech, Inc.; 2021, Accessed 2/14/22. https://www.tremfya.com; 2. Griffiths et al. J Drugs Dermatol. 2018 Aug 1;17(8):826-832; 3. Armstrong et al. Am J Clin Dermatol. 2018 Feb;20(1):155-164; 4. Griffiths et al. J Dermatolog Treat. 2020 Jul 15:1-0; 5. Reich et al. Br J Dermatol. 2021 Dec;185(6):1144-1159; 6. Strober et al. J Am Acad Dermatol. 2019;81(2):323-332.

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March 27, 2024

VIA ELECTRONIC DELIVERY
Oregon Prescription Drug Affordability Review Board
Labor & Industry Building
350 Winter Street NE
Salem, OR 97309-0405

Care of: pdab@dcbs.oregon.gov

Re: Selection of Cosentyx® for Affordability Review

Dear Oregon Prescription Drug Affordability Board ("Board"):

Novartis Services, Inc. submits this letter on behalf of Novartis Pharmaceuticals Corporation and its affiliates referred to collectively herein as "Novartis." We appreciate the opportunity to comment on the Board's selection of Cosentyx® (secukinumab) for affordability review pursuant to *OR. Rev. Stat. § 646A.693 - 646A.697*.

Novartis provides health care solutions that address the evolving needs of patients and societies worldwide. We are a focused medicines company concentrated on the core therapeutic areas of cardiovascular disease, immunology, neuroscience, and oncology. At Novartis, we are united by a single purpose to reimagine medicine to improve and extend lives. Through innovative science and technology, we address some of society's most challenging health care issues. We work to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our vision is to be the most valued and trusted medicines company in the world.

At Novartis, we believe everyone should have access to the medicines they need. When we determine the prices for our medicines, we consider the value that these medicines provide to patients as well as health care systems and society at large.

Cosentyx is a proven medicine that has been studied clinically for more than 17 years and used to treat more than 1 million patients globally since its approval by the FDA in 2015.[1] The medicine is backed by strong evidence supporting its

[1] Data on file. COSENTYX Patient Reach. Novartis Pharmaceuticals Corp; January 2023.

safety and efficacy for patients across multiple autoimmune diseases, including moderate to severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS), radiographic axial spondyloarthritis (nr-axSpA), juvenile idiopathic arthritis, and moderate to severe hidradenitis suppurativa.[2,3,4,5,6,7,8] We believe Cosentyx is an important treatment option, and we offer a variety of programs to provide broad, affordable access for eligible patients. We remain confident in the value of Cosentyx and are committed to supporting those who can benefit from it.

Below we briefly summarize why the Board should recognize that Cosentyx is affordable:

- Cosentyx is a proven medicine backed by robust evidence.
- Oregon patients have broad, affordable access to Cosentyx today. Eligible patients with commercial health coverage can access Cosentyx at a cost as low as zero dollars with the Novartis co-pay support program.[9]
- Many other moderate-income, lower-income, and underinsured patients pay nothing for Cosentyx via the Novartis Patient Assistance Foundation.
- The average net price of Cosentyx to payers has been nearly flat over the past five years. When adjusted for inflation, the average net price has declined.
- Cosentyx provides value to the broader health care system. This is particularly clear when compared to therapeutic alternatives.

We have significant concerns with the methodologies, data, and approach to stakeholder engagement used by the Board in its work, and fear these may yield an erroneous and unreliable result in affordability reviews. A determination that Cosentyx may present affordability challenges despite facts and data

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[2] Baraliakos X, Braun J, Deodhar A, et al. Long-term efficacy and safety of secukinumab 150 mg in ankylosing spondylitis: 5-year results from the phase III MEASURE 1 extension study. RMD Open. 2019;5:e001005.
[3] Bissonnette R, Luger T, Thaçi D, et al. Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to-severe psoriasis through 5 years of treatment (SCULPTURE Extension Study). J Eur Acad Dermatol Venereol. 2018;32:1507-1514.
[4] Mease PJ, Kavanaugh A, Reimold A, et al. Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Psoriatic Arthritis: Final 5-year Results from the Phase 3 FUTURE 1 Study. ACR Open Rheumatol. 2020;2:18-25.
[5] Data on file. CAIN457F2310 (MEASURE 1 and 2): Pooled Safety Data. Novartis Pharmaceuticals Corp; July 23, 2018.
[6] Data on file. CAIN457F2310 and CAIN457F2305 summary of 5-year clinical safety in (ankylosing spondylitis). Novartis Pharmaceuticals Corp; May 2019.
[7] Data on file. CAIN457F2312 Data Analysis Report. Novartis Pharmaceuticals Corp; November 2008.
[8] McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet 2015;386:1137-46.
[9] IQVIA Claim Data FY 2022, 2023.

demonstrating otherwise would raise serious concerns, and we urge you to reject that premise.

Our detailed comments are provided below.[10]

A. Cosentyx Is a Proven Medicine for Patients Backed by Robust Evidence.

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years of age and older who are candidates for systemic therapy or phototherapy. Cosentyx is also indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.

Affecting 7.5 million Americans, psoriasis is a chronic autoimmune inflammatory disease characterized by thick and oftentimes extensive skin plaques that cause itching, scaling, and pain. Psoriasis can negatively impact patients' quality of life, both psychosocially and physically.[11]

However, psoriasis is not simply a skin disease. Up to 41% of patients with certain types of psoriasis may also have psoriatic arthritis, which - through destructive inflammation - can lead to irreversible joint damage if not properly treated.[12]

In clinical trials, Cosentyx has been shown to help achieve clear skin in plaque psoriasis and help stop progressive joint damage and improve physical function in patients with psoriatic arthritis. Cosentyx generally starts working in as little as 3 to 4 weeks with positive results observed up through 5 years.[13]

Cosentyx is also approved for active ankylosing spondylitis and active non-radiographic axial spondyloarthritis – two inflammatory arthritis conditions that affect the spine - as well as active enthesitis-related arthritis (ERA). Additionally, in 2023, Cosentyx was approved as the first new biologic treatment in nearly a

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[10] Novartis is making this submission in accordance with the procedures provided by Oregon law and to show that Cosentyx is not unaffordable for Oregon customers. Novartis, however, has significant concerns about the legality of the Oregon statute that established the PDAB and by making this submission does not waive its rights with regard to any legal challenge to that statute.

[11] Armstrong A, Mehta M, et al. Psoriasis Prevalence in Adults in the United States. JAMA Dermatol. 2021 Aug; 157(8): 1–7. doi: 10.1001/jamadermatol.2021.2007.
National Psoriasis Foundation. About Psoriasis. https://www.psoriasis.org/about-psoriasis/. Accessed September 27, 2023.

[12] Rech J, Sticherling M, et al. Psoriatic arthritis epidemiology, comorbid disease profiles and risk factors: results from a claims database analysis. Rheumatol Adv Pract. 2020; 4(2): rkaa033. doi: 10.1093/rap/rkaa033.

[13] Cosentyx Prescribing Information. East Handover, NJ: Novartis Pharmaceuticals Corp; July 2023.
Cosentyx.com. Results with Cosentyx. https://www.cosentyx.com/psoriatic-arthritis/treatment-results. Accessed September 27, 2023.

decade for adults with moderate to severe hidradenitis suppurativa (HS), a painful and often debilitating inflammatory skin condition.

We have ongoing development programs for Cosentyx in other areas of high unmet need such as giant cell arteritis (GCA) a condition that can cause pain and swelling in blood vessels.

B. Cosentyx Is Affordable for Oregonians and the Health Care System.

At its core, the question of whether Cosentyx is "affordable" for Oregonians has a simple answer: the drug is affordable because eligible Oregon patients with commercial health coverage can access Cosentyx at a cost as low as zero dollars with the assistance of the Cosentyx Co-pay Card Program.[14] Additionally, pursuant to state and federal regulations, patients who access prescription drugs, including Cosentyx, through Oregon's Medicaid program pay a nominal amount, and potentially even nothing, out-of-pocket.[15]

Furthermore, the health plans that pay a portion of the cost of Cosentyx benefit from heavily discounted prices. The complicated interplay of drug pricing and rebates throughout the supply chain and the selective use of pricing data can complicate what should be a straight-forward analysis of affordability.

Chief among these complicating factors is a reliance on "list" prices as a proxy for patient costs and affordability. A patient or health plan rarely if ever pays the list price of a drug. In Oregon, as in the rest of the United States, where third-party payers and government health care programs negotiate the price of drugs they buy, Novartis works with third parties to negotiate significant rebates and other price concessions on our medicines. The vast majority of patients, too, enjoy significant assistance even beyond the net price of Cosentyx and their insurance coverage through the Cosentyx Co-Pay Program or the charitable assistance of the Novartis Patient Assistance Foundation (NPAF). These programs further reduce the costs patients pay, in many cases to as little as $0[16].

Ultimately, to accurately determine the affordability of Cosentyx to Oregon consumers, the Board must use the actual amounts paid by patients and the net, not list, price paid by payers.

Cosentyx is Affordable for Oregon Patients.

For patients, the most significant hallmark of "affordability" is the price they pay out-of-pocket. Patients judge the cost of a medicine not by reference to

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[14] Novartis.com, Paying for Cosentyx, https://www.cosentyx.com/all/treatment-cost

[15] Oregon Health Plan, What to Do If You Are Asked to Pay for a Prescription, https://www.oregon.gov/oha/hsd/ohp/pages/prescriptions.aspx#:~:text=The%20Oregon%20Health%20Plan%20(OHP,they%20give%20them%20to%20you.., Accessed February 25, 2024.

[16] IQVIA Claim Data FY 2022, 2023.

complicated gross or net price formulas, but by how much they must pay out-of-pocket to access their medication.

Novartis negotiates with third-party payers for affordable coverage for patients and provides a suite of programs to help address any residual affordability challenges once coverage is determined by payers. Through our Patient Assistance website[17], we help patients find programs that may provide savings or resources that can help them access Cosentyx or any other Novartis prescription medication. We do this because Novartis believes that medicines should be available to all who need them.

Novartis has a co-pay assistance program in the US that helps thousands of patients with commercial health coverage access our medicines for as little as zero cost to them. In 2023, 64% of Oregon patients accessing Cosentyx through their commercial coverage used a Cosentyx co-pay card.[18] In 2022, 65% of these patients used a Cosentyx co-pay card.[19] Manufacturer co-pay card programs play a critical role in helping eligible commercially-insured patients satisfy the cost-sharing requirements dictated by their health insurance coverage. Alarmingly, insurers and pharmacy benefit managers are increasingly subjecting this assistance to accumulator adjustment programs, which prevent co-pay card amounts from counting toward a patient's deductible and out-of-pocket maximum.

Nineteen states, the District of Columbia, and Puerto Rico have enacted laws banning accumulator adjustment programs in state-regulated commercial plans. Oregon is considering taking similar action to protect patients, which we strongly support.[20] According to a recent report, 5 out of 6 health insurers in Oregon and 83% of the plan options on the Oregon Health Insurance Marketplace use accumulator adjustment programs.[21] Any affordability determination by the Oregon PDAB must take into account these health insurer tactics that result in Oregonians paying more out-of-pocket for a necessary medication than they should.

Additionally, our "Covered Until You're Covered Program" is available for eligible patients taking Cosentyx in subcutaneous form who have commercial insurance, a valid prescription for Cosentyx, and a denial of insurance coverage based on a prior authorization request. The program provides Cosentyx for free to eligible

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[17] Novartis.com. Patient Assistance. https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance. Accessed September 21, 2023.
[18] IQVIA Claim Data FY 2023, SP Dispense Data FY 2023.
[19] IQVIA Claim Data FY 2022, SP Dispense Data FY 2022.
[20] The Oregon legislature passed House Bill 4113 on March 5, 2024, and sent the bill to the governor for consideration.
[21] AIDS Institute, https://aidsinstitute.net/documents/TAI-2024-Report-2.27.pdf, Accessed March 8, 2024.

patients for up to two years, or until they receive insurance coverage approval, whichever occurs first.[22]

Further, for patients who are uninsured or under-insured (commercially-insured or in government-funded insurance programs), NPAF provides Novartis treatments at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage.[23] NPAF is an independent, 501(c)(3) non-profit, non-commercial entity. Patients who cannot afford the cost of their Novartis medication may be eligible to receive it from NPAF at no cost. Income and affordability guidelines vary by drug but are generally well above federal poverty levels.[24]

In 2021, NPAF provided more than $4 billion in free medicines to more than 127,000 patients in the U.S., covering 71 medicines from our portfolio. Over the last five years, through NPAF, medications valued at $13.5 billion have been made available to 445,000 patients at no cost.[25]

We caution the Board against relying on data from third-party sources, including the state's All Payer All Claims Reporting program, that purports to indicate a patient out-of-pocket cost for Cosentyx. That cost may well have been borne by Novartis or the NPAF through the mechanisms described above.

Oregon Payers Benefit From Significant – And Growing – Discounts on Cosentyx.

Payers such as commercial insurers routinely negotiate rebates and other price concessions from the Novartis list price. These rebates and price concessions lower the final "net" price of the drug significantly below the initial list price. Payers and employers in turn can pass these rebates and price concessions on to patients by reducing their out-of-pocket costs, or use them in other ways, such as for lowering premiums, applying the discount to administrative costs, or other uses.

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[22] The Covered Until You're Covered Program requires the submission of an appeal of a coverage denial within the first 90 days of enrollment in order to remain eligible. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Novartis.com Cosentyx Connect. https://www.cosentyx.com/psoriatic-arthritis/cosentyx-connect-personal-support-program. Accessed March 7, 2024.

[23] Novartis.com. Patient Assistance. https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance. Accessed March 8, 2024.

[24] *Id.*

[25] Novartis in Society 2021 US Report, available at https://www.novartis.com/us-en/sites/novartis_us/files/2022-03/220211-novartis-in-society-report-2021_0.pdf.

The continuing gap between list and net prices generated by this practice fuels increasing confusion about the real price paid for drugs by the health care system. While industry critics focus on the rise in wholesale acquisition cost (WAC), also known as the list or gross price, the reality is that price increases are often outpaced by rebates and price concessions to third-party payers and other channel intermediaries (e.g., wholesalers, pharmacies). Oregon, unlike some states, does not require payers and intermediaries to share these rebates and price concessions with patients.

Novartis rebates and price concessions to payers are important not just to understanding why Cosentyx is *currently* affordable to patients, but also why the Cosentyx net price has remained essentially flat over time, and actually declined when adjusted for inflation, despite WAC price increases over the same period. It is critical that the Board base its affordability determination on the net price. The Board must take account of these rebates and price concessions, which are a significant component of the affordability of Cosentyx.

Notably, between January 2018 and January 2023, inflation, measured by the CPI, was 21%. By our estimate this means the Cosentyx net price declined over this timeframe when adjusted for inflation. Additionally, the net price of Cosentyx represents a greater discount off the gross price, or WAC, than many therapeutic alternatives.[26]

It is therefore concerning that the initial affordability reviews released and considered by the Board heavily relied on WAC and spending metrics that did not take price concessions into account. Subsequently, the Board has released affordability review reports that claim to incorporate price concessions reported by Oregon's commercial insurance carriers, but it is unclear if that data fully incorporates the growing range of rebates and fees that manufacturers provide carriers, PBMs, and related entities (e.g., GPOs or "rebate aggregators"). The Board's refusal to provide a mechanism for manufacturers to submit data confidentially means manufacturers cannot provide commercially sensitive data that would provide a complete picture on net pricing.

In reviewing Cosentyx, we urge the Board to look beyond list price and consider the numerous ways in which Cosentyx is made more affordable to the health care system and offsets other costs that would be incurred in its absence.

Cosentyx is an Effective Drug for Multiple Indications that Provides Value to the Broader Health Care System.

[26] Based on Novartis analysis that utilized Analysource for WAC comparisons and SSR Health for discount comparisons.

In evaluating a drug's affordability, the Board must take account of its "relative financial effects on health, medical, or social services costs."[27] In this regard, Cosentyx should be recognized as effectively treating multiple indications that would otherwise significantly limit patient health and impose major costs on the state.

The major indications for which Cosentyx is used[28] are associated with significant economic burden. We strongly urge the Board to consider the value Cosentyx provides in reducing the direct and indirect costs of these diseases to the workforce, communities, and overall health care system as described below.

Psoriasis:

Total direct and indirect costs associated with the disease have been estimated at $11.3 billion annually. [29]

A claims database from 31 self-insured employers (representing 5.1 million employees, their spouses, and dependents) during the period from 1998 to 2005 was used to evaluate both the direct medical and indirect work-loss costs associated with psoriasis.[30] After multivariate adjustment, psoriasis patients demonstrated significantly higher direct and indirect costs compared to other patients.[31] Approximately 40% of the total cost burden was associated with work loss (i.e., indirect costs).[32]

Cosentyx is effective in relieving this burden. A health economic model was developed to demonstrate the cost-effectiveness of Cosentyx for patients with plaque psoriasis. The patient population of interest included adults diagnosed with moderate-to-severe plaque psoriasis who are candidates for systemic or biologic therapy. The model demonstrated that the cost per responder was lower for Cosentyx 150 mg and 300 mg than some leading therapeutic alternatives.[33]

Psoriatic Arthritis (PsA):

The total direct costs of PsA in the US have been estimated at $1.9 billion annually.[34] There are limited data on the indirect costs (e.g., lost productivity and

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[27] OAR 925-200-0020-(1)-(j)

[28] For this analysis, Novartis focuses on its approved indications for treatment of psoriasis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, non-radiographic axial spondyloarthritis, and hidradenitis suppurativa.

[29] NPF, National Psoriasis Foundation Statistics [Online]. 2015b. Available: http://www.psoriasis.org/research/science-of-psoriasis/statistics [Accessed November 17, 2015].

[30] Fowler, J.F., Duh, M.S., Rovba, L., Buteau, S., et al. 2008. The impact of psoriasis on health care costs and patient work loss. *J Am Acad Dermatol.* 59(5), 772-780.

[31] *Id*.

[32] *Id*.

[33] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.

[34] Lee, S., Mendelsohn, A. & Sarnes, E. 2010. The burden of psoriatic arthritis: a literature review from a global health systems perspective. P T. 35(12), 680-689.

absenteeism) attributable to PsA in the US; however, it was reported that total indirect costs account for approximately 52% to 72% of total costs.[35] The costs increase with deterioration of disease activity and decline in physical function.[36]

A health economic model explored the cost-effectiveness of Cosentyx for patients with psoriatic arthritis (PsA). The patient population of interest included adults diagnosed with PsA who are candidates for biologic therapy or apremilast. Cosentyx 150 mg and 300 mg had a lower cost per responder than some leading therapeutic alternatives.[37]

Ankylosing Spondylitis (AS):

A health economic model explored the cost-effectiveness of Cosentyx for patients. The patient population of interest included adults with active AS treated with a biologic. The cost per responder was lower for Cosentyx 150 mg than another leading therapeutic alternative.[38]

Non-radiographic axial Spondyloarthritis (nr-axSpA):

The economic impact of work limitations related to *nr-axSpA* is substantial and compounded by the typically young age at diagnosis.[39] Patients treated with Cosentyx showed substantial reduction in work-related impairment, measured through mean change in the Work Productivity and Activity Impairment (WPAI) from baseline to Week 52.[40]

Juvenile Idiopathic Arthritis (JIA):

Several studies have found that patients with JIA of all types have higher health care resource utilization and health care costs than patients without JIA.[41] [42] [43] As one of the most common chronic conditions in children, JIA places a sizable burden on the pediatric healthcare system and can result in a substantial economic burden for patients and their families. JIA includes several disorders in

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[35] *Id*.
[36] *Id*.
[37] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[38] *Id.*
[39] Strand, V. and Singh, J. A. 2017a. Patient Burden of Axial Spondyloarthritis. *Journal Of Clinical Rheumatology : Practical Reports On Rheumatic & Musculoskeletal Diseases*. 23(7): 383-391.
[40] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[41] Krause ML, Zamora-Legoff JA, Crowson CS, Muskardin TW, Mason T, Matteson EL. Population-based study of outcomes of patients with juvenile idiopathic arthritis (JIA) compared to non-JIA subjects. *Semin Arthritis Rheum*. 2017;46(4):439-443.
[42] Kumar N, Ramphul K, Ramphul Y, et al. Children hospitalized for juvenile arthritis in the United States. Reumatologia. 2021;59(4):270-272.
[43] Marshall A, Gupta K, Pazirandeh M, Bonafede M, McMorrow D. Treatment patterns and economic outcomes in patients with juvenile idiopathic arthritis. Clinicoecon Outcomes Res. 2019;11:361-371.

children involving inflammation of the joints. Cosentyx is approved to treat two of those disorders: ERA and juvenile PsA.[44]

Hidradenitis suppurativa (HS)

Patients with HS have higher rates of hospital emergency department use and higher mean emergency department costs than healthy individuals and patients with psoriasis.[45] Even compared with patients with severe psoriasis, rates of inpatient care and emergency department use are higher for patients with HS.[46] In a retrospective cohort study analyzing indirect costs, patients with HS were found to have more days of work loss (184 vs 77), higher annual total indirect costs ($2925 vs $1483) and lower annual income ($54,925 vs $62,357) than healthy controls. [47]

Cosentyx helps adults with moderate to severe HS find relief at 16 weeks, including at least a 50% reduction in the number of inflammatory bumps and abscesses and no increase in the number of abscesses or draining tunnels.[48] Cosentyx can help reduce flares in adults with moderate to severe HS. In 1 of 2 clinical trials, 75% of adults taking Cosentyx had zero flares at week 16.[49] In the second trial the same results were not seen. A flare was defined as a greater than 25% increase in the number of inflammatory bumps and abscesses, with a minimum increase of 2 inflammatory bumps or abscesses.[50]

C. The Board Should Address the Methodological and Implementation Issues With Its Processes.

Any determination by the Board that a drug may present affordability challenges would be a momentous step, and should come only after a deliberate, transparent, and cautious process. Reflecting that gravity, the Board must correct the many methodological concerns that remain with its process and that prevent the public from having confidence in the Board's conclusions.

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[44] Angeles-Han ST, Ringold S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Screening, Monitoring, and Treatment of Juvenile Idiopathic Arthritis-Associated Uveitis. *Arthritis Care Res (Hoboken)*. 2019;71(6):703-716.
[45] Khalsa, A., Liu, G., & Kirby, J.S. 2015. Increased utilization of emergency department and inpatient care by patients with hidradenitis suppurativa. J Am Acad Dermatol. 73(4), 609-614.
[46] *Id*.
[47] Tzellos, T., Yang, H., Mu, F., Calimlim, B., & Signorovitch, J. 2019. Impact of hidradenitis suppurativa on work loss, indirect costs and income. Br J Dermatol. 181(1), 147-154.
[48] Cosentyx 300mg every 4 weeks (after 5 initial weekly doses). In the 2 clinical trials, 41% and 43% of adults taking COSENTYX 300 mg every 4 weeks (after 5 initial weekly doses) achieved at least a 50% reduction in the number of inflammatory bumps and abscesses, with no increase in the number of abscesses and/or draining tunnels at 16 weeks vs 29% and 26% taking placebo.

Unfortunately, the Board's process to date has revealed that many issues have yet to be firmly resolved. The lack of clarity and resolution threatens to render its process, actions, and decisions arbitrary and methodologically suspect.

We support the comments made by our trade associations PhRMA, BIO, and the Oregon Bioscience Association regarding areas demanding improvement. Novartis would like to bring the Board's attention specifically to the following gaps:

The Board Has Not Defined What Constitutes "Affordability Challenges to the Health Care System" or "High Out-of-Pocket Costs for Patients."

The Board is required in its affordability analysis to determine if a drug "may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon." Yet, neither the Board nor the legislation authorizing its review clearly define what "affordability challenges to the health care system" or "high out-of-pocket costs for patients" mean.

This striking gap leaves Novartis and the public with no understanding of what principles the Board is applying to reach its ultimate conclusions, and no means of verifying that the Board's analysis has been conducted correctly. Compounding this uncertainty is that the Board's regulations detail at great length the types of factors the Board might consider in its analysis, without specifying the relative weight or impact of any one factor. This negatively impacts the ability of Novartis and the public to provide meaningful input.

Ultimately, the Board appears to be making an *ad hoc* determination of whether a drug may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon without clearly articulating what those thresholds would look like.

The Board's Processes for Selecting Drugs and Conducting Affordability Reviews Has Been Arbitrary and Confusing.

It is of paramount importance that stakeholders clearly understand the Board's process for selecting drugs for affordability reviews and conducting reviews. Otherwise, stakeholders, especially the patients whom the Board is seeking to help, will struggle to meaningfully engage in a process that could have significant ramifications them.

Unfortunately, the Board's process for selecting drugs for an affordability review has been confusing even for the closest observers. After the Board initially selected the subset of drugs it intends to subject to an affordability review on October 18, 2023, it revised that list twice, on November 15 and December 13, 2023, without any indication that earlier lists were drafts or subject to revision. Further, these revisions appeared, at times, arbitrary and not based on the

Board's criteria for selecting drugs for an affordability review outlined in OAR 925-200-0010.

Challenges with the Board's process have continued with the release of affordability reviews. The Board released its affordability reviews for insulin products on January 10, 2024, and then, without any indication that the reviews were subject to change, released revised affordability reviews on January 19, 2024.

These changes have sown widespread confusion amongst stakeholders as to which decisions and documents constitute final actions by the Board as well as about the affordability review process more broadly.

The Board Has Not Meaningfully Engaged with Stakeholders When Conducting Affordability Reviews.

More concerning than the Board's unclear process for selecting and reviewing drugs has been the Board's almost total lack of *proactive* outreach to stakeholders. While it is commendable that stakeholders can submit written comments at any time and verbal comments during Board meetings, the Board does not appear to have made any effort to *solicit* input from patients, caregivers, individuals with scientific and medical training, manufacturers, or other stakeholders. For example, the Board did not survey or hold listening sessions for patients or health care providers or meet with manufacturers prior to conducting affordability reviews. The result of these missed opportunities is apparent based on the fact that the affordability reviews released so far include little or no input from patients, health care providers, or groups that represent them. A more proactive approach to stakeholder engagement could have provided much needed context for affordability reviews.

As previously mentioned, the Board's efforts to gather information for affordability reviews are also hamstrung by the lack of a mechanism for manufacturers to submit commercially sensitive information. The Board has not developed a process or provided guidance in its Public Comment Policy on how manufacturers can confidentially submit such data. Additionally, there is not an opportunity for the Board to discuss commercially sensitive data or meet with manufacturers in executive session, which could have been another opportunity for manufacturers to provide important data for affordability reviews.

Finally, it is problematic that there is limited opportunity outside of verbal public comment at Board meetings for stakeholders to offer input on affordability reviews once they are released. The Board releases a drug's affordability review report shortly before a meeting and then deliberates and votes on whether the drug may present affordability challenges during that same meeting. There is not a chance for stakeholders to submit written comments on affordability review

reports before they are final and voted on by the Board, leaving little recourse to identify and correct inaccurate information in the reports.

Conclusion

For the reasons detailed above, Cosentyx is affordable to patients and the health care system, and the Board should reject the premise that it is not. We welcome the opportunity to answer any questions you may have about the information provided above. Please contact me at courtney.piron@novartis.com.

Sincerely,

Courtney Piron
US Country President
Head, US Public Affairs

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

April 12, 2024

Oregon Prescription Drug Affordability Board
Labor & Industry Building
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments - Oregon Prescription Drug Affordability Board (PDAB)

Dear Members of the Oregon Prescription Drug Affordability Board:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is grateful for the opportunity to submit public comments throughout this process. We hope the board will consider these statements as you continue forward with your drug affordability reviews.

About AiArthritis. AiArthritis is a leader in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand how important it is to be able to access safe, efficacious, and affordable treatments. As patients living with heterogeneous conditions, we also understand there is no one-size-fits-all drug - even for those diagnosed with the same disease. Through lived experience, we also know that disrupting continuity of care often leads to uncontrolled disease, comorbidities, and significantly decreased rates of remission.

About the Ensuring Access through Collaborative Health (EACH) and the Patient Inclusion Council (PIC) Coalition. AiArthritis leads a national coalition of patient organizations and affiliated groups (EACH) and a coordinating patient and caregiver group (PIC), that work together and independently to ensure patient needs are considered first in government drug affordability review processes. Additionally, both groups offer our expertise, guidance, and collaboration in any way possible to help the Board. The PIC, led by people diagnosed with diseases treated by drugs under review - and who are also experts in education, policy, and research - can assist in a variety of ways, including focus group question design, moderating, and analysis.

Patient and Patient Organization Involvement in the Process. We appreciate and acknowledge the board taking steps to provide additional opportunities for patient engagement by holding a series of community forums during April and May. We hope that the board will utilize these forums to speak directly with patients to better understand the real issues that impact patients' ability to access treatment regimens and maintain their health. Additionally, we have heard from partners in Oregon that there is potential to hold patient focus groups. We applaud such a step and offer the board our support and resources - as well as from the coalitions we manage - to assist in all aspects of the process.

During the town halls, focus groups, or other methods of data collection, we encourage the board to go beyond general comments and instead drill down to gather and understand specific affordability issues patients face. This will help uncover if the list price of drugs is the problem or if patient issues stem from other circumstances, such as insurance protocols like utilization management, their ability to access manufacturer assistance programs, narrow pharmacy networks, or other issues brought on by our complex healthcare system. This type of due diligence can help save costs, in part, by determining if the issues outlined can even be addressed by board policies.

Finally, as patients share their stories, we hope that there will be opportunities for substantive discussion and two-way exchanges, so board members and staff can gain the necessary clarity and context of their responses. We also encourage recording this information in a way that is transparent and offers the public - including those, like

AiArthritis and affiliated coalitions - who are skilled in patient-research data assessment to help them analyze and better understand the results.

Revised Drug Review Process. We look forward to learning more about the revised drug review process during the upcoming meeting and urge the board to keep the following principles in mind for any reviews or policy changes:

Focus on Patient Outcomes. Immune conditions, including multiple sclerosis and Crohn's disease, can be incredibly debilitating and keep those diagnosed from maintaining normal functions and daily routines. Worsened health conditions can result in more frequent doctor visits, the need for invasive medical interventions, and hospitalizations. Patients who identify and maintain effective treatments can resume their normal daily lives. It cannot be understated that the medications under review are life-changing for the patients they treat. Therefore, we urge the committee to keep patient impact at the forefront of deliberations of these drugs.

Prevent Impeding Patient Access. As the board proceeds with review of drugs that specifically treat immune disorders, we would like to emphasize the importance of maintaining unrestricted access to broad treatment options for patients with complex conditions.

- Patients with complex and chronic conditions often spend years identifying treatments that work for them – it is typical for a patient to try and fail at multiple treatments before finding one that is most effective for them personally.
- Treatments can work for a specific patient for multiple years but then become less effective, forcing a change in therapies.
- Over the course of a lifetime of maintaining a chronic disease, many patients will face switching medications multiple times as their selected treatment becomes less effective to them personally.
- Treatments that are classified as therapeutic alternatives are not guaranteed to work for every patient.

Therefore, it is critical that health policies do not impede access to treatments or lead to fewer options for patients.

Avoid Unintended Consequences to Patients. Reviewing only a handful of medications can create further inequities, picking winners and losers among patients and patient populations. Additionally, focusing solely on the price of drugs ignores the many complicated factors that are known to drive costs up for patients by oversimplifying a very complex healthcare process. It can increase utilization management, lead to fewer treatment options, and create more barriers to accessing life-changing medications patients need.

We appreciate all opportunities to collaborate with the board and invite you to lean on us for additional information or guidance as needed. We appreciate every opportunity given to patients that enables us to have a voice in matters involving our healthcare. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson

Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

670 Maine Ave SW WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

April 13, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: April 17, 2024 Agenda and Meeting Materials Related to Affordability Reviews

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing to comment on the agenda and discussion materials for the Oregon Prescription Drug Affordability Board's (the "Board's") April 17, 2024 meeting (the "Meeting Materials").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. As discussed further below, PhRMA has a number of questions and concerns about the draft revised affordability review template and draft generic drug report included in the Meeting Materials.[2]

I. Draft Revisions to Affordability Review Template

The Board's Meeting Materials include draft revisions to its affordability review template.[3] PhRMA provides the below comments to the Board's draft revisions:

- First, PhRMA recognizes the expanded list of affordability criteria in the draft revised template, which now reflects the criteria enumerated in the PDAB Statute and the Board's implementing regulations.[4] As in our prior comments, PhRMA urges the Board to consistently and comprehensively consider all statutorily and regulatorily required criteria in its affordability review process.[5]

- Second, the draft revised template includes reporting of a "PBM Concession" as an element of the "Breakdown of … gross to net costs" for each drug under review, but it is not clear to what data

[1] *See* Board, Meeting Materials (Apr. 17, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20240417-PDAB-document-package.pdf.
[2] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.
[3] Meeting Materials at 6 *et seq*.
[4] *Compare id.* at 11–17 *with* PDAB Statute § 646A.694(1)(a)–(m) *and* Or. Admin. R. 925-200-0020(1).
[5] *See* Letter from PhRMA to Board (Feb. 17, 2024) ("'Agencies are creatures of statute' and their actions 'may also be circumscribed the agency's own regulations.' The Board cannot fail to consistently consider statutorily required factors or ignore its own regulatory requirements without a valid explanation for why doing so is permissible under applicable laws and regulations. Likewise, the Board cannot simply recite facts and information without 'fully explain[ing] why those facts lead it to the decision it makes.'") (citations omitted).

element this refers.[6] Large PBMs negotiate on behalf of health plan sponsors and manage benefits for covering tens of millions of patients, leveraging their market power to obtain substantial discounts and rebates on brand medicines. In exchange for their services, PBMs typically retain a percentage of the discounts and rebates paid by manufacturers and/or are paid a fee by health plans. Manufacturers pay rebates directly to PBMs, which pass them on, in whole or in part, to health plans or employers according to the terms of the client's agreement with the PBM. Given this dynamic, PhRMA requests clarification about what "PBM Concession" refers to and how the Board intends to consider this information as part of the affordability review process.

- Third, the draft revised template also includes fields for "Information from manufacturers," which include certain information about drug indications, clinical efficacy, and clinical safety.[7] Some of this information, such as contraindications or common side effects, is readily available in the prescribing information and patient labeling for a given drug. However, other information may not be readily available or known to manufacturers despite being included in the "Information from manufacturers" field. PhRMA requests clarification of how the Board intends to gather such information and from what sources if certain information is not readily available to or known by manufacturers.[8]

- Fourth, the draft revised template includes fields for "input from specified stakeholders," including patients and caregivers, individuals with scientific or medical training, safety net providers, and payers.[9] Consistent with our prior comments about the Board's regulations, PhRMA asks for clarification about the information the Board intends to collect from payers.[10] Specifically, it is not clear whether the information regarding the "[c]ost of the prescription drug to the payer" will be net of rebates or other discounts. We also recommend that the Board collect information that allows it to more broadly understand the full range of factors that drive patient affordability and out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and copay accumulator adjustment and maximizer programs) and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurance plans that the PBMs and plans are not sharing directly with patients at the point of sale.[11] These factors are determined by plans and their PBMs, and the Board should give

[6] Meeting Materials at 18 (Figure 3). The Meeting Materials further describe this item as the "Discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices." *Id*.

[7] *Id.* at 24–25. We note that the corresponding statutory and regulatory criteria referred to by this section of the draft revised template, ORS § 646A.694(1)(L) and Or. Admin. R. 925-200-0020(1)(L), specifically refer to "Any information a manufacturer chooses to provide" and not information drawn from public sources or other means.

[8] *See id.* at 25 (citing ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L) and indicating the "information [would be] provided from manufacturers and information with sources from contractors").

[9] *Id.* at 26–27 (outlining specific information to be collected from each stakeholder category, paralleling the factors described in Or. Admin. R. 925-200-0020(k)).

[10] *See* Letter from PhRMA to Board (May 14, 2023), 4.

[11] *Id.* As PhRMA has previously described, accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year. Copay maximizer programs are insurance benefit designs that generally restructure a patient's cost sharing obligations for a particular drug to equal the full value of manufacturer cost sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost sharing for some plans by designating medications as non-Essential Health Benefits. *See* Letter from PhRMA to Board (May 14, 2023), 4.

due weight to their impact in contributing to the inability of Oregonians to afford their health care.[12]

Fifth, and finally, with respect to "input from specified stakeholders," PhRMA is concerned about the lack of clarity about data collected from safety net providers.[13] In gathering and considering information from safety net providers, the Board must guard against release of confidential and proprietary information related to the 340B Program, such as 340B pricing data, that is protected from disclosure under federal law.[14] Information from safety net providers should be considered in light of the specific context surrounding the federal 340B program. The 340B program was intended to help vulnerable patients gain better access to medicines at certain qualifying safety-net clinics and hospitals. Instead, the program has been abused by covered entities and their contract pharmacies seeking to profit off the "spread" between the discounted 340B price that covered entities pay for 340B drugs and the higher amount they receive from patients and payers for the same drugs, while often not passing on any portion of that spread to patients to reduce their out-of-pocket costs for their medicines.[15] We ask that the Board revise data collection procedures to clarify how the data collected from safety net providers participating in the federal 340B program will be used in conducting affordability reviews, particularly in light of the federal protections for 340B pricing information, and how this information will be considered in determining a drug's affordability for payers and patients given the fact that 340B discounts are often not being passed on directly to lower patients' costs for their medicines.

II. Draft Generic Drug Report

The Meeting Materials include a draft "Report for the Oregon Legislature Generic Drug Report Pursuant to Senate Bill 844."[16] PhRMA has significant concerns about the accuracy and reliability of the draft report, which incorporates significant misinformation regarding the practices of branded drug manufacturers.

[12] We reiterate that the Board should incorporate specific protections for the confidentiality of this information consistent with its obligations under federal and state law. *See, e.g.*, Letter from PhRMA to Board (Feb. 11, 2023), at 7-8 (outlining PhRMA's confidentiality concerns in additional detail, and explaining the confidentiality obligations of the Board under state and federal law). See also Letter from PhRMA to Board (June 23, 2023), 3.

[13] Meeting Materials at 26-27.

[14] The federal Medicaid statute protects the pricing data that manufacturers report to the Centers for Medicare & Medicaid Services ("CMS") under the Medicaid Drug Rebate Program ("MDRP"), information which is used to calculate rebates under the 340B Program. The Medicaid statute makes clear that "information disclosed by manufacturers or wholesalers under [the Medicaid statute] ... is confidential and shall not be disclosed by the Secretary ... or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, [or] prices charged for drugs by such manufacturer or wholesaler," except under limited circumstances described in the statute that are not applicable here. 42 U.S.C. § 1396r–8(b)(3)(D). Further, manufacturers that participate in the 340B Program enter into a Pharmaceutical Pricing Agreement ("PPA") with the Department of Health and Human Services ("HHS"). The PPA contains a confidentiality provision that generally prohibits disclosure of information provided by the manufacturers under the 340B Program. HHS, PPA § V, https://www.hrsa.gov/sites/default/files/hrsa/opa/pharmaceutical-pricing-agreement-example.pdf.

[15] Independent government watchdog groups have reported that when disproportionate share hospitals (DSHs) use contract pharmacies, it is common for pharmacies to not pass through 340B discounts to uninsured patients. *See* OIG, Contract Pharmacy Arrangements in the 340B Program, Feb. 2014, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp; GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, Jul. 2018, https://www.gao.gov/products/gao-18-480; GAO, Information About Hospitals That Received an Eligibility Exception as a Result of COVID-19, May 2023, https://www.gao.gov/products/gao-23-106095.

[16] Meeting Materials at 31 *et seq.*

PhRMA also asks that the Board clarify the extent to which the draft report was prepared by, and may reflect the specific views of, a third party contractor rather than the reasoned determination of the Board itself.[17]

Due to the limited time provided by the Board to submit written comments for consideration at the March meeting, PhRMA intends to provide a more comprehensive response to the draft report at a subsequent date.[18] Consistent with PhRMA's prior comments, we emphasize that America's biopharmaceutical research ecosystem is the global leader in the development of innovative medicines, allowing patients in the U.S. to access new medicines faster than the rest of the world. This is the result of a carefully balanced policy environment that includes robust intellectual property protections that foster investment in groundbreaking research and development, while also promoting access for patients and the sustainability of the U.S. health care system.[19]

* * *

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns with the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[17] *See* Letter from PhRMA to Board (June 20, 2022), 1-3 (describing necessary safeguards regarding potential conflict of interest or bias in the Board's independent contractors).
[18] We reiterate our concerns from prior comment letters regarding the short timeframe provided by the Board to review the Board's meeting materials and provide substantive comments. *See* Letter from PhRMA to Board (July 31, 2022), 2-3.
[19] *See* Letter from PhRMA to Board (Nov. 23, 2022) (responding to presentation by Mr. Tahir Amin of the Initiatives for Medicines, Access & Knowledge (I-MAK)).

April 12, 2024

Via email (pdab@dcbs.oregon.gov)

Labor & Industry Building
ATTN: Oregon Prescription Drug Affordability Review Board
350 Winter Street NE
Salem, OR 97309

Re: Genvoya Affordability Review

Dear Members of the Prescription Drug Affordability Review Board ("the Board"):

I am writing on behalf of Gilead Sciences, Inc. ("Gilead"), concerning the Board's selection of Genvoya® for an affordability review. Genvoya is affordable to payers and patients and poses no affordability concerns for any aspect of the healthcare systems operating in Oregon. Approximately 90% of patients' monthly claims for Genvoya in Oregon had $5 or less in final out-of-pocket costs in 2022,[1] and 99% of insured individuals in Oregon had coverage for Genvoya in 2023.[2] Just last month, the Colorado Prescription Drug Affordability Review Board ("Colorado PDAB")—applying criteria similar to those laid out in the Oregon statute—determined unanimously[3] that Genvoya is *not* unaffordable.[4]

HIV is an infectious disease and currently not curable. It is critical to avoid HIV treatment disruptions that could increase the risk of an individual's illness and death, transmission, and development of resistant forms of the virus. We are deeply concerned that Genvoya has been selected for an affordability review—and should the Oregon PDAB gain the necessary authority and choose to set an upper payment limit ("UPL") on the drug—this would have negative implications for access to HIV therapy, clinical outcomes in those living with HIV, and public health in Oregon.

Below we summarize high-level considerations for the Board as it pursues its review process for Genvoya. Gilead will submit a more detailed document with information related to Genvoya's affordability and accessibility by the October 6 requested deadline.

[1] IQVIA's Longitudinal Access and Adjudication Data. Data on file with Gilead.
[2] MMIT data, August 2023.
[3] One member recused.
[4] Video recording: Colorado PDAB Meeting (Feb. 16, 2024) (on the Colorado PDAB website)

I. **Genvoya is already affordable and accessible for Oregonians with HIV.**
II. **Affordability reviews are a step towards imposing a UPL, which would have an adverse impact on patient access and affordability.**
III. **Barriers in patient access to lifesaving medicines, leading to disruptions in HIV treatment and detectable viral load, will lead to worse clinical outcomes, including death, increased risk of HIV transmission, and costly healthcare resource utilization.**
IV. **Treatment disruptions would disproportionately affect vulnerable populations.**
V. **The Board should ensure engagement from people with HIV and manufacturers and facilitate rational and reasonable decisions.**
VI. **Imposition of a UPL based on a determination of unaffordability would raise legal concerns.**

Our detailed comments follow.

I. Genvoya is already affordable and accessible for Oregonians with HIV.

Genvoya is affordable and widely accessible for people with HIV in Oregon across all payer types. The latest formulary coverage data across all payer types shows Genvoya is accessible and affordable to patients: 99% of Oregonians with insurance have coverage for Genvoya and approximately 90% of monthly claims for Genvoya in Oregon had $5 or less in final out-of-pocket costs in 2022.[5] In addition, 97% of those covered individuals are not required to go through utilization management before obtaining Genvoya.[6] This is important because utilization management includes techniques such as prior authorization[7] and step therapy[8] which can limit an individuals' ability to obtain the medicine they and their doctor determined was best for them. Moreover, patient out-of-pocket costs are substantially mitigated through an established network of care assistance programs, including Oregon's Ryan White AIDS Drug Assistance Program (CAREAssist)[9] and manufacturer programs such as Gilead's Advancing Access® Patient Support Program, which substantially reduce patients' out-of-pocket expenses. CAREAssist receives funding through Ryan White and enables low-income people with HIV (defined as having an income at or below 550% of the federal poverty level) to obtain FDA-approved HIV medications, including Genvoya.[10] In addition, Gilead's Advancing Access supports patient

[5] IQVIA's Longitudinal Access and Adjudication Data. Data on file with Gilead.
[6] MMIT data, August 2023
[7] Prior authorization is a requirement imposed by an insurer under which a patient must demonstrate that they need the medicine prior to the insurer providing coverage.
[8] Step therapy is a requirement imposed by an insurer whereby a patient must try another drug before they can obtain coverage for the medicine their doctor prescribed.
[9] Oregon Health Authority. CAREAssist: Oregon's AIDS Drug Assistance Program. Available at: https://www.oregon.gov/oha/ph/diseasesconditions/hivstdviralhepatitis/hivcaretreatment/careassist/pages/index.aspx
[10] Ibid.

affordability for eligible patients through a co-pay coupon card, which helps with out-of-pocket costs, and a patient assistance program which provides Gilead HIV treatments for free.[11]

Oregon's publicly available data fail to show that Genvoya is unaffordable to payers or for any aspect of the healthcare systems operating in Oregon.[12] Given the immense cost savings Genvoya creates by reducing future expensive treatments, it strains credulity to assert that Genvoya creates affordability concerns for Oregon's health systems. Under the review criteria Oregon has established, which appear to be similar to the criteria considered by the Colorado PDAB, the state should follow the conclusion of the Colorado PDAB that Genvoya is "not unaffordable."

Gilead will submit a more detailed document with information related to Genvoya's affordability and accessibility by the October 6 requested deadline.

II. Affordability reviews are a step towards imposing a UPL, which would have an adverse impact on patient access.

While the Board does not currently have authority to set a UPL for any drugs, we expect that the Board will recommend that the legislature provide UPL authority, and then apply that authority to any drugs that it has deemed unaffordable. This would be particularly problematic for Genvoya because HIV is a potentially deadly and uncurable infectious disease, for which untested price setting policies are likely to cause significant harm to patients and public health.

Experience from government price setting policies implemented in other countries in the Organization for Economic Co-operation and Development (OECD) provides evidence that policies like UPLs do, in fact, reduce patients' ability to access new medicines. On average, patients in other OECD countries that rely on various forms of pharmaceutical price-setting, have access to only 29% of new medicines, while patients in the United States have access to 85%.[13] Given the profoundly negative impact that state actions disrupting Genvoya treatment for patients who rely on the drug to suppress their HIV virus, we urge Oregon to affirm the data showing that Genvoya is affordable and widely accessible for people with HIV in Oregon.

[11] Advancing Access. https://www.gileadadvancingaccess.com/
[12] State of Oregon Department of Consumer and Business Services. Prescription Drug Price Transparency Program results and recommendations – 2023. Updated March 29, 2024. https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf.
[13] Richard Kane. PhRMA. New global analysis shows patient access challenges around the world. April 12, 2023. https://phrma.org/en/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world.

III. Barriers in patient access to lifesaving medicines, leading to disruptions in HIV treatment and detectable virus, will lead to worse clinical outcomes, including death, and costly healthcare resource utilization.

Any public policy that introduces new access barriers to HIV treatments or interrupts care for patients currently virally suppressed on therapy will result in new HIV infections. Patient and provider choice of therapy for HIV is critical because adherence to effective treatment can reduce the amount of HIV in the body to an undetectable level. This not only improves that patient's individual health and well-being but also has the added public health benefit of preventing sexual transmission of the HIV virus. The U.S. Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV states that "selection of a regimen should be individualized" for a particular patient based on factors such as virologic efficacy, toxicity, potential adverse effects, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, and childbearing potential.[14] Researchers at the National Institutes of Health found that maintaining an undetectable viral load for at least six months results in people with HIV having no risk of sexually transmitting HIV to partners.[15] In contrast, delays in initiating HIV treatment, gaps that might occur as a patient switches from one regimen to another, or relegating a person living with HIV to a suboptimal or less tolerated treatment regimen will negatively impact their ability to adhere to treatment and remain virally suppressed.[16]

Drug resistance is another serious consequence that can occur when HIV treatment is disrupted. Resistance can lead to treatment failure and may eliminate any further treatment from the class of drugs that the resistance impacts. Treatment failure requires patients to switch to alternative treatment regimens that may be less optimal for the individual, potentially resulting in either poor outcomes for the patient and/or increased health resource utilization. Partial adherence to treatment regimens, where patients take some of their HIV medications but not all, can occur when people living with HIV are switched off a single-tablet treatment regimen. Compared to multi-tablet regimens, single-tablet regimens offer simplicity and convenience due to lower pill burdens and once-daily dosing. Therefore, single-tablet regimens eliminate the risk of selective nonadherence to components of the regimens.[17] Partial adherence poses a significant public

[14] HHS, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, G-4 (Mar. 23, 2023), https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv

[15] Eisinger RW, Dieffenbach CW, Fauci AS. HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable. *JAMA*. 2019 Feb 5;321(5):451-452.

[16] Yuan Y, et al. "Determinants of discontinuation of initial highly active antiretroviral therapy regimens in a US HIV-infected patient cohort." HIV Med. 2006 Apr;7(3):156-62. doi: 10.1111/j.1468-1293.2006.00355.x.

[17] Cutrell J, Bedimo R. Single-Tablet Regimens in the Treatment of HIV-1 Infection. Fed Pract. 2016 Apr;33(Suppl 3):24S-30S. PMID: 30766212; PMCID: PMC6375416.

health threat and can lead directly to the development of treatment resistant forms of the virus.[18] In addition, the drug-resistant form of the virus can then be spread to and infect other patients, which further undermines efforts to end the HIV epidemic.[19]

Reductions in viral suppression would not only result in worse health outcomes, treatment failures and higher healthcare costs, but also increased HIV transmission rates to other Oregonians by people that are not virally suppressed.[20,21] All of these results would drive up healthcare costs for Oregon. Avoiding just one new HIV infection can reduce lifetime healthcare costs – which for many patients may be borne partly or entirely by Medicaid – by $850,557 on average; annual and cumulative healthcare costs were up to seven times higher for people living with HIV compared to those without HIV.[22]

IV. Treatment disruptions would disproportionately affect vulnerable populations.

The PDAB should recognize that pursuing price-setting policies specifically for HIV treatments like Genvoya risks disproportionately impacting care for disadvantaged people with HIV, as those individuals are most likely to suffer from disruptions in care. HIV disproportionately impacts socially marginalized and disenfranchised populations, particularly sexual minorities, and communities of color.[23] People with HIV suffer disproportionately high irrational negative behaviors and judgements (stigma) while seeking care, resulting in more opportunity to avoid care. Additional barriers to receiving the care chosen with providers could further exacerbate the risk of disconnection to care. Therefore, state actions disrupting care for HIV create additional barriers that would disproportionately harm some of the most vulnerable groups in Oregon who already face barriers that limit their ability to access and adhere to treatment. As an example, Black people represent 2.0% of Oregon's population but accounted for 7.9% of all people with HIV in the state and 7.9% of new HIV diagnoses in 2021. As another example, Hispanic/Latinx people represent 14% of Oregon's population, yet account for 16.4% of all people with HIV in the state and 26.2% of new diagnoses in the same year.[24] As of 2021, 72% of Black people with

[18] Von Wyl V, Klimkait T, Yerly S, Nicca D, Furrer H, et al., Adherence as a Predictor of the Development of Class-Specific Resistance Mutations: the Swiss HIV Cohort Study, 8 *PLoS ONE* e77691 (2013).
[19] Guyer B, et al., AMCP NEXUS, Abstract #17 (2010).
[20] Von Wyl V, Klimkait T, Yerly S, et al. Adherence as a predictor of the development of class-specific resistance mutations: the Swiss HIV Cohort Study. *PLoS One*. 2013;8(10):e77691. Published 2013 Oct 16. doi:10.1371/journal.pone.0077691
[21] Bangsberg DR, Acosta EP, Gupta R, et al. Adherence-resistance relationships for protease and non-nucleoside reverse transcriptase inhibitors explained by virological fitness. *AIDS*. 2006;20(2):223-231. doi:10.1097/01.aids.0000199825.34241.49
[22] Cohen JP, Beaubrun A, Ding Y, Wade RL, Hines DM. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. *Pharmacoecon Open*. 2020;4(4):687-696.
[23] Pellowski J., Kalichman S., Matthews K., et. al., (2013). A pandemic of the poor: social disadvantage and the U.S. HIV epidemic. *The American psychologist*, *68*(4), 197–209. doi.org/10.1037/a0032694
[24] AIDSVu.org. Local Data: United States. Accessed from https://aidsvu.org/local-data/united-states/.

diagnosed HIV in Oregon were virally suppressed compared to 75% of Hispanic/Latinx people and 79% of White people with HIV.

In part because of these disparities in social determinants of health and the nature of HIV, it is even more important to ensure that individuals can work with their providers to select the treatment that is most appropriate for them. Individualized treatment allows for maximization of clinical benefits, including: increasing the likelihood of adherence and persistence that can improve the opportunity for consistent viral suppression, significantly decreased rates of hospitalization and lower healthcare costs,[25] reduced risk of treatment discontinuation, and avoidance of adverse consequences such as drug resistance and transmission of HIV.[26] As introduced in Section III above, DHHS guidelines on HIV recognize the importance of patient and provider choice, stating "Regimens should be tailored for the individual patient to enhance adherence and support long-term treatment success. Considerations when selecting an [antiretroviral] regimen for an individual patient include potential side effects, patient comorbidities, possible interactions with concomitant medications, results of pretreatment genotypic drug-resistance testing, and regimen convenience."[27] For these reasons, it is critical to reduce or eliminate all manner of barriers to receiving effective treatment and care for HIV, not add new challenges by introducing unnecessary price-setting mechanisms.

V. The Board should adopt a process that will ensure engagement from people with HIV and manufacturers and facilitate rational and reasonable decisions.

In making its affordability decisions, the Board should follow procedures that allow for meaningful engagement by people living with HIV, manufacturers, and other stakeholders. Gilead offers an important perspective about Genvoya's affordability and the ease of access to Genvoya for people with HIV in Oregon. Moreover, Gilead stands to be directly affected by the Board's Genvoya affordability determination. Yet so far, the Board has failed to provide people with HIV or manufacturers a meaningful opportunity to participate in its decision-making process. Indeed, the Board's publicly announced plan for soliciting input on the development and recommendation of UPL approaches indicates that the Board views its "constituents" as limited

[25] Sutton S, et al., Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy, 36 *Pharmacotherapy* 385-401 (2016); Sutton S, et al., Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks, 22 American Journal of Managed Care 242-48 (2016).

[26] Yager J, et al., Relationship Between Single Tablet Antiretroviral Regimen and Adherence to Antiretroviral and Non-Antiretroviral Medications Among Veterans' Affairs Patients with Human Immunodeficiency Virus, 31 *AIDS Patient Care and STDs* 370-76 (2017); Cohen C, et al.; Association of Partial Adherence (PA) To Antiretroviral Therapy With Hospitalizations and Healthcare Costs in an HIV Population, 15 Journal of the International AIDS Society 18060 (2012); Bangsberg DR, et al., Adherence-Resistance Relationships For Protease And Non-Nucleoside Reverse Transcriptase Inhibitors Explained By Virological Fitness, 20 *AIDS* 223-32 (2006).

[27] HHS, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, Treatment Goals (Jan. 28, 2016), https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/treatment-goals?view=full.

to "carriers, hospitals/health systems, 340B covered entities, and pharmacies."[28] If the Board denies manufacturers and patients an opportunity to respond to other stakeholders' or Members' comments about their medicines, the Board risks making a decision without all relevant information and potential consequences. For example, we note from previous experience that substantial data errors, limitations, and misinformed assumptions have been used in drug board analyses, which lead to erroneous conclusions. The Board has already acknowledged that its data may be flawed, which can result in decisions that are not rational, fair, or supported by substantial evidence. During the January 26, 2024, meeting, for example, then-Vice Chair Shelley Bailey recognized that the Board lacks sufficient information about discounts, rebates, and the contractual relationships between different parties for the Board to know actual prices to the system or payors.[29] Gilead will provide this information as part of its forthcoming detailed submission. It would be arbitrary for the Board to disregard that information and instead rely on its incomplete cost data.

Stakeholders, particularly patients and manufacturers, are uniquely able to identify such errors and offer corrections and more complete data. Failing to reach accurate, reasonably informed conclusions would undermine the Board's obligation to engage in rational decision-making and deprive manufacturers of a meaningful hearing and increase the risk of an erroneous determination.

The Board should also ensure that its procedures are adequate to allow the voices of people with HIV to be heard. While anecdotes should not take precedence over robust affordability data, to date, the Board has not established any process for people to share their experiences other than through general public comment. Given the stigma often associated with HIV and the socio-economic barriers that confront many people with HIV, this process is inadequate for considering the affordability of HIV medicines. HIV not only impacts those in marginalized communities but remains a marginalizing disease itself. Many people living with HIV have not disclosed their condition to their families or friends; they may be reticent to seek care in HIV-specific settings and may be anxious as they take necessary steps to seek care, even when they present to a pharmacy to pick up their prescription. Stigma and fear of disclosure likely play a role in an individual's decision whether to engage in public comment opportunities where anonymity might not be able to be maintained. Without addressing these potential barriers to providing public input, the Board cannot expect significant engagement from people living with HIV unless it offers a specific pathway that will ensure anonymity and ease of access.

Finally, the Board should ensure that it applies a consistent standard to each drug it reviews. Although the statute permits the Board to consider many different affordability factors, conducting reviews in an *ad hoc* manner, or relying on different factors for each drug would

[28] Oregon Prescription Drug Affordability Board. April 17, 2024 Meeting Agenda at 47. Available at https://dfr.oregon.gov/pdab/Documents/20240417-PDAB-document-package.pdf
[29] Video recording: Board Rescheduled Regular Meeting at 42:05 (Jan. 26, 2024) (on the Board's website).

exceed the Board's discretion and be arbitrary and unfair. Unfortunately, to date, the Board's drug-selection process has been lacking and subject to procedural bias. The statute requires the Board to "identify nine drugs and at least one insulin product" that may pose affordability concerns.[30] As a result of beginning this process with only 12 drugs, the Board apparently must find 75% (9 of 12) of these drugs unaffordable, meaning that the Board may be forced to designate a drug as unaffordable even when the evidence indicates the drug is affordable. For example, if the Board decides that the first three drugs reviewed in sequence do not pose affordability challenges, then Oregon law requires that the remaining 9 drugs must be deemed unaffordable in order to meet Oregon's statutory mandate. Therefore, because of the statutory requirement to identify nine drugs as unaffordable, depending on how many drugs the Board finds unaffordable in its earlier reviews, drugs that are arbitrarily reviewed later, such as Genvoya, may be systemically disadvantaged due to the Board's processes and statutory constraints.

VI. Imposition of a UPL based on a determination of unaffordability would raise legal concerns.

Should the Board acquire authority to impose a UPL for drugs it finds unaffordable, setting a UPL for Genvoya would conflict with federal patent law and related federal exclusivity laws designed to encourage the development of new medicines, in violation of the Constitution's Supremacy Clause. These laws establish a comprehensive framework that encourages companies like Gilead to develop innovative therapies like Genvoya by providing them limited periods during which they hold the exclusive right to market their medicines. Setting a UPL that eliminates or reduces the risk-reward that Congress intended to provide would impermissibly second-guess Congress's determination, with unforeseeable effects on future investment—significantly undercutting Congress's goals.

Depending on its implementation, a UPL could also impermissibly regulate out-of-state transactions or interfere with the nationwide market for prescription drugs; undermine the interconnected web of federal drug-purchasing and insurance programs, including those applying specifically to HIV; or impermissibly displace federal standards governing Medicare Part D.

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[30] Or. Rev. Stat. Ann. § 646A.694(1).

In conclusion, Genvoya plays a crucial role in Oregon's goals to end the HIV epidemic and remains demonstrably affordable and widely accessible for people with HIV in Oregon. To avoid disrupting the many patients using Genvoya to suppress their HIV virus, it is important that the PDAB not pursue unnecessary price-setting mechanisms for Genvoya. If you have any questions or wish to notify Gilead about future PDAB actions, please do not hesitate to contact me at kristie.banks@gilead.com.

Sincerely,

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc

Carissa Kemp, American Diabetes Association

Thank you for the opportunity to comment on the discussion of the affordability of glucagon-like peptide (GLP-1) agonists. These medications are essential for people with type 2 diabetes as ways to lower their blood glucose and help them manage their diabetes. In particular GLP-1 can result in large benefits both in lowering blood glucose and body weight.

The American Diabetes Association (ADA) has been the leading organization advocating for people with diabetes for more than eight decades. Much of this work centers around access and affordability of care. People with diabetes must have access to medications and tools they need to manage the disease. Managing diabetes requires a holistic, multifaceted, person-centered approach that accounts for the complexities associated with diabetes and the complications and comorbidities people with diabetes are at risk for across an individual's life span. The American Diabetes Association *Standards of Care* recommends that person-specific factors for treatment should be individualized for achieving glycemic goals and should consider weight goals, the individual's risk for hypoglycemia, and the individual's history of risk factors for cardiovascular, kidney, liver, and other comorbidities and complications of diabetes.[1]

The ADA *Standards of Care* recommends that pharmacologic therapy be started at the same time type 2 diabetes is diagnosed and that approaches that provide the efficacy to achieve treatment goals should be considered. In general, higher-efficacy approaches have a greater likelihood of achieving glycemic goals, with the following having a very high efficacy for glucose lowering: the GLP-1 RAs dulaglutide and semaglutide. Weight management is a distinct treatment goal, along with glycemic management in individuals with type 2 diabetes, as it has multifaceted benefits, including improved glycemic management, reduction in hepatic steatosis, and improvement in cardiovascular risk factors. The glucose-lowering treatment plan should therefore consider approaches that support weight management goals, with semaglutide and tirzepatide currently having the highest weight loss efficacy among agents approved for glycemic management.[2]

While we share concerns over cost and wanting to ensure that patients can afford their medication, we must also balance that with ensuring access to treatment and minimizing barriers to care. We encourage the committee to take steps to ensure that the discussion, decisions, and policy-recommendations are patient-centered and do not result in access issues for patients.

Ensuring people with diabetes have access to the treatment and tools necessary to manage their disease can help them reduce the risk of developing devastating and costly complications including cardiovascular disease, kidney disease, and amputations. Protecting access to these medications and interventions to control diabetes can create cost savings and are ultimately cost-effective.[3] The ADA *Standards of Care* highlights the importance of weight loss, which can be achieved through the use of the medications, to reduce A1C and fasting glucose and may promote sustained diabetes remission.[4] The 2024 *Standards of Care* recommends that GLP-1 as preferred pharmacotherapy for obesity management in people with diabetes because of the greater weight loss efficacy.[5] We respectfully encourage the

[1] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[2] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2909081/
[4] https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention
[5] https://diabetesjournals.org/care/article/47/Supplement_1/S5/153943/Summary-of-Revisions-Standards-of-Care-in-Diabetes

committee to take the efficacy of these medications into account along with the cost-savings from preventing complications that increase the burden on both the patients and the health care system.

If you have any questions please contact me at ckemp@diabetes.org.

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February 21, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon PDAB Prescription Drug Affordability Review Process

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for the opportunity to provide feedback on the Board's approach and process for conducting drug affordability reviews. Genentech has been following the Board's meetings and communications closely to understand the Board's views and how we can best engage to share information relevant to the Board's processes. We previously submitted written comments to the Board in October and November 2023 regarding the Board's processes and operations. This comment letter focuses on our most recent observations and concerns.

As an initial matter, **we are concerned with the current vacancies on the Board, especially given the January 26, 2024 public resignation of Chairman Akil Patterson.** Senate Bill 192 (2023) established an eight-member board, to be appointed by the Governor and confirmed by the Senate. Although a majority of the Board (five members) shall constitute a quorum, the current three vacancies reduce the diversity of perspectives that would enrich the Board's discussions and drug affordability review process in contrast to what would be expected with a fully-seated Board. In contrast to other state Boards, Oregon's statute did not establish a stakeholder advisory council to guide the Board's decision making, which further emphasizes the need for the Board itself to represent varied perspectives. To ensure the Board's discussions and drug affordability reviews benefit from a diversity of experience, we strongly suggest that the Board consider further delaying its drug affordability reviews until the full Board is seated and can be fully informed of the operations and actions of the Board.

While we understand the Board's efforts have been previously delayed and there are statutory deadlines of which to be mindful, the decisions before the Board should not be rushed nor taken lightly. Discussions and following decisions regarding a drug's affordability, even in the absence of an Upper Payment Limit, could have implications in and beyond Oregon. As such, it is critical the Board invests the appropriate time and resources to this process, even if it results in a delay in fulfilling the Board's duties.

In addition to the aforementioned issue of an incomplete Board, we continue to have significant concerns about the Board's processes, limited stakeholder engagement and outreach, and an acknowledged lack of access to critical data which can impact the assessment of a drug's

affordability. We are providing feedback on the following three concerns and ask the board to address these shortcomings before proceeding with any future drug affordability reviews.

1. **The Board's general approach, meeting operations, and lack of clear processes for stakeholder engagement continues to create confusion. The Board should provide a well documented, transparent and consistent approach to data review, stakeholder engagement, and consideration of data factors to support a fair assessment of affordability across diseases and treatments.**

2. **Stakeholder engagement efforts have been severely limited and may adversely impact the Board's decision making. The Board should invest more time soliciting stakeholder feedback as part of a robust review process prior to making decisions on drug affordability.**

3. **The Board continues to rely on a limited set of data elements, and has deprioritized data from manufacturers which would provide a more complete picture of drug affordability. The Board should ensure complete review of draft affordability reports and manufacturer-submitted data prior to making a decision on a drug's affordability.**

The following will provide more detail on these concerns and offer necessary remedies for the Board's immediate consideration.

1. ***The Board's general approach, meeting operations, and lack of clear processes for stakeholder engagement continues to create confusion. The Board should provide a well documented, transparent and consistent approach to data review, stakeholder engagement, and consideration of data factors to support a fair assessment of affordability across diseases and treatments.***

We have commented previously on the lack of clarity that has resulted from the Board's interaction and decisions during their Board meetings. There have been numerous meetings, including the Board's most recent meeting on January 26, 2024, where the Board's action items and decisions were not immediately clear - neither to the Board members themselves, nor to those attending the meeting. For example, during the affordability review of Tresiba and Tresiba FlexTouch, more than one Board member appeared to be unsure of the actual task the Board was performing in conducting the affordability review and required the eventual clarification from staff to specify the action and decision that was before the Board. This exchange highlights that the Board's approach could benefit from increased clarity and direction in the decisions to be made at each meeting, by whom the decision must be made, and the instructions for doing so. The speed at which the Board has sought to advance through their required actions may also be contributing to a lack of clarity in operational processes and decision making. <u>We believe these issues can be addressed with more robust meeting materials and a summary at the start of each meeting that clearly outlines the decisions before the board, and the expected outcomes of those decisions.</u>

Moreover, it is critical the Board establish predictable and reliable processes for all forms of engagement with manufacturers and other stakeholders. Each affordability review undertaken by the Board should follow the same procedures and adhere to a consistent approach to provide confidence in a fair and equitable review process. It was extremely unexpected to witness the Board engage in a question and answer dialogue with a representative of the drug manufacturer during an affordability review on January 26, given no prior notice of this possibility. As an engaged manufacturer, we have asked for, and would welcome the opportunity to have a dialogue with the board about the value of our medicines in an appropriate forum. However, all stakeholders, including manufacturers, should be afforded the benefit of preparation for such engagement and dialogue. We urge the Board to reconsider its current processes and make the necessary adjustments to ensure the review process is predictable and consistent for manufacturers and all other interested stakeholders and allows for a meaningful exchange of information.

2. ***Stakeholder engagement efforts have been severely limited and may adversely impact the Board's decision making. The Board should invest more time soliciting stakeholder feedback as part of a robust review process prior to making decisions on drug affordability.***

OAR 925-200-0020 indicates as part of conducting drug affordability reviews, the Board ***will seek*** input from patients and caregivers and individuals who possess scientific or medical training related to the drug under review. While we appreciate the Board has provided instructions for written and oral stakeholder comments, the Board has not undertaken efforts that fairly and openly ***seek input*** from critical stakeholders whose lived experience and expertise should be highly valued in this process.

The Board's outlined processes for conducting drug affordability reviews have alloted for extremely limited time for live stakeholder engagement - just 20 minutes of public comment per drug. Although stakeholders can submit written comments to the Board in advance of their drug affordability review deliberations, it remains unclear if these comments are being thoroughly reviewed by the Board in advance. This is particularly disconcerting as the Board weighted information from patients and caregivers at 8.6 out of 10 in level of importance, yet has made what appears to be limited effort to engage patients and their caregivers, actively solicit their input, or ensure patients are aware that a medicine they may be taking is undergoing an affordability review by the Board.

Stakeholder engagement tactics undertaken by Boards in other states have included focus groups, open public surveys, and direct stakeholder meetings. Boards are also partnering with patient organizations that represent the impacted community to engage those with lived experience and solicit their input. To align with the Board's weighting of input from patients and caregivers as highly important, we strongly urge the Board to adopt these or other tactics to immediately seek stakeholder feedback.

3. ***The Board continues to rely on a limited set of data elements, and has deprioritized data from manufacturers which would provide a more complete picture of drug***

affordability. The Board should ensure complete review of draft affordability reports and manufacturer-submitted data prior to making a decision on a drug's affordability.

In addition to allotting only 20 minutes for public comment during an affordability review, the Board has also dedicated only 20 minutes to reviewing the draft drug affordability report and discussing its contents. Once again, this is an extremely limited amount of time to dedicate to what is the primary directive of the Board. In fact, during the January 26 reviews, staff spent approximately two minutes highlighting the data, primarily the cost tables, in each drug's draft affordability report, and did not review the clinical sections of the report. The report was only discussed in more depth if a question or comment was raised by a Board member. This approach does not adequately review the substantial data required to be part of a drug affordability review, nor does it allow for thoughtful discussion by the Board on each required data element. As a best practice, we ask the Board to reconsider and revise the time allotted to each drug affordability review to ensure all required data elements are fully discussed and considered. For example, in instances where clinical outcomes associated with a drug may have substantial impact on a patient's total cost of care, or cost to the healthcare system, it will be essential for these data to be appropriately reviewed and thoughtfully considered. Furthermore, we urge the Board to reevaluate the weighting of data and information shared by a drug manufacturer. In many instances, a drug manufacturer is the most robust source of data associated with clinical outcomes, cost offsets, and/or other data essential to determining a drug's value and affordability. This data should not be discounted, nor deprioritized, as it currently has been in the Board's weighting exercise. An overly narrow, and subjective, approach to considering data in the affordability review fails to recognize many of the drug characteristics that drive overall treatment value and shape patient and physician choice of treatment that should contribute and assist in the Board's assessment of drug affordability.

Due to the aforementioned concerns, **we ask the Board to allow for a fully-appointed Board to be present for the remaining drug affordability reviews, and provide time for the staff and Board to remedy and improve upon the deficiencies with the current affordability review process.**

We continue to welcome the opportunity to engage with the Board and its staff on these concerns. If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

AIMEDALLIANCE

February 25, 2024

Oregon Prescription Drug Affordability Board
Labor & Industry Building
350 Winter Street NE
Salem, OR 97309

Re: Call for Inclusion of Patient Voice and Lived Experience in Drug Review Process

Dear Members of the Oregon Prescription Drug Affordability Board:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the opportunity to comment on the Oregon Prescription Drug Affordability Board's affordability review process. Aimed Alliance urges the Board to consider the following recommendations:

1. **Prioritize patient voice and lived experience in the drug review process;**
2. **Ensure the drug review processes embraces diverse community perspectives; and**
3. **Adopt an exclusion for rare disease drugs.**

I. Introduction

The escalating costs of healthcare in the United States poses a significant challenge for healthcare consumers nationwide. In response to this pressing issue, numerous states have introduced legislation establishing prescription drug affordability boards (PDABs) aimed at addressing the prices of prescription medications and ensuring equitable access to affordable drugs. Typically, these boards are tasked with setting upper payment limits (UPLs) for specific prescription drugs.[1]

As PDABs undertake the task of reviewing drug affordability, it is imperative that they uphold their commitment to ensuring prescription drug affordability for *healthcare consumers.* This commitment is essential for enhancing healthcare accessibility, alleviating financial burdens, advancing public health outcomes, and promoting equity within the healthcare system.

II. Oregon's PDAB Should Prioritize Patient Access and Affordability

As advocates for patient-centric health care policies, Aimed Alliance urges the Board to consider the role of the patient voice and lived experience in the drug review process. Involving patients in the decision-making process can provide insights into disease management, access challenges, treatment preferences, and other pertinent considerations associated with various prescription drugs.[2]

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[1] Aimed Alliance, *Enacted Prescription Drug Affordability Boards*, https://aimedalliance.org/wp-content/uploads/2024/01/AA-PDAB-Enacted-Chart-Jan-2024.pdf.
[2] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECHNOLOGY INFORMATION 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.

Moreover, research consistently highlights the benefits of actively involving patients in healthcare decisions. For instance, studies demonstrate engage patients has a positive effect on improving health outcomes, enhancing satisfaction with the care experience, lowering costs, improving quality of care, and increasing accessibility.[3] By incorporating patients in the drug review process, the Board can help ensure that their voices are heard and their needs are recognized.[4] It also enables the Board to access a wealth of firsthand knowledge, that may not be documented in empirical data, that is essential for making well-informed and patient-centered decisions.[5]

Aimed Alliance also encourages the Board to ensure that the drug review process incorporates a multitude of diverse community perspectives. Recognizing the unique needs and challenges faced by different communities is crucial to fostering inclusivity and equity within the decision-making processes.[6] For instance, individuals living in rural areas confront significant barriers to accessing health care due to sparse provider availability and extended travel distances to seek care, while individuals in more urbanized areas may experience different access challenges.[7]

Importantly, in Oregon, 16 percent of the state, approximately 660,000 residents, live in rural areas.[8] For many, the nearest clinic is located more than 100 miles away.[9] In these areas, financial hardship and limited access to health care services impact health care access and the ability to manage chronic conditions, significantly impacting overall health outcomes for residents.[10] Thus, it is imperative that the Board takes into account these complex realities when evaluating drug access and affordability in Oregon.

By actively seeking input from a broad range of stakeholders, including patients, caregivers, and community representatives, the Board can develop a fair and comprehensive drug review framework. In recognizing the multifaceted challenges faced by patients and caregivers, it is imperative that the Board also acknowledge its shared responsibility in engaging these communities. Patients and caregivers must manage work and family commitments, treatment regimens, and financial strains—all while striving to navigate complex healthcare systems to care for themselves or their loved ones. Therefore, the onus cannot solely rest on consumers to advocate for their needs; the Board must actively reach out and involve these stakeholders in the decision-making process. To ensure these efforts reach the intended communities, the Board

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[3] *Id.*; Lisa Baumann, et al., *Public and patient involvement in health policy decision-making on the health system level – A scoping review*, 126 HEALTH POL. 1023-38 (Oct. 2022), https://www.sciencedirect.com/science/article/pii/S0168851022001919.
[4] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECH. INFO. 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.
[5] *Id.*
[6] *Improving Cultural Competence to Reduce Health Disparities for Priority Populations*, EFFECTIVE HEALTH CARE, https://effectivehealthcare.ahrq.gov/products/cultural-competence/research-protocol (Jul. 8, 2014).
[7] *Why Health Care Is Harder to Access in Rural America,* U.S. Gov. ACCOUNTABILITY OFF., (May 16, 2023), https://www.gao.gov/blog/why-health-care-harder-access-rural-america.
[8] *Id.*
[9] *Id.*
[10] *Id.*

should engage local stakeholders and leaders who are already connected, trusted, and working within these communities.

Lastly, the process of engagement must extend beyond the initial review stage. Once the Board establishes a UPL, the Board should continuously monitor how the UPL impacts access and affordability. Establishing clear channels for consumers to voice concerns regarding any access barriers stemming from pricing policies is critical to ensuring equitable access to essential medications. By fostering a culture of transparency and responsiveness, the Board can effectively address emerging challenges following adoption of the UPL.

III. Rare Disease Exclusion

Aimed Alliance urges the Board to consider creating an exclusion for rare disease drugs within the drug review framework. Patients with rare diseases often face significant challenges in accessing life-saving medications due to the substantial research and development costs involved, coupled with the relatively small patient populations they serve.[11] In fact, the development of drugs for rare diseases is particularly scarce; with the U.S. Food and Drug Administration (FDA) reporting that, of the approximately 7,000 known rare diseases, less than 10 percent have an FDA-approved treatment available.[12] Given the high prices and limited treatment options for rare diseases, the establishment of a UPL by the Board carries heightened significance in this context and could decrease access to these treatments, and disincentivize investment and research into rare disease treatments. Therefore, Aimed Alliance urges the Board to recognize the unique challenges confronting patients with rare disease and consider creating an exclusion for rare disease drugs from the drug review process.

IV. Conclusion

In conclusion, Aimed Alliance encourages the Oregon Prescription Drug Affordability Board to champion a drug review process that centers on patient voice and lived experience, embraces diverse community perspectives, and excludes rare disease drugs from consideration. We appreciate the opportunity to comment on this issue and commend the Oregon Prescription Drug Affordability Board for its efforts to improve access to affordable prescription drugs for the residents of Oregon.

Sincerely,

Ashira Vantrees
Counsel

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[11] Takeya Adachi et al., *Enhancing Equitable Access to Rare Disease Diagnosis and Treatment around the World: A Review of Evidence, Policies, and Challenges*, 20 INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH (Mar. 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10049067/.

[12] *Rare Disease Cures Accelerator*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/drugs/regulatory-science-research-and-education/rare-disease-cures-accelerator#:~:text=However%2C%20of%20the%20approximately%207%2C000,and%20progression%20of%20each%20disease. a

Feb 29, 2024

Chair Deb Patterson
Senate Committee on Health Care
900 Court St. NE, S-411,
Salem, Oregon 97301

Chair Rob Nosse
House Committee on Behavioral Health and Health Care
900 Court St. NE, H-472
Salem, Oregon 97301

Dear Chair Patterson and Chair Nosse:

As organizations representing patients, people with disabilities and older adults, we are writing with regard to our concerns about the implementation of the State Prescription Drug Affordability Board and the need for oversight from legislators. When the bill creating the board passed, we were assured that its processes would be transparent, provide for robust engagement of patient and disability stakeholders and avoid reference to discriminatory evidence related to the effectiveness and value of treatments being evaluated. We have been very disappointed. At this stage, it is now clear that our efforts to engage the board members and staff in addressing our concerns are not working. As you know, the board itself is not operating at full capacity and is trying to recruit new members.[1] Therefore, we urge the legislature to pause the board's activities and initiate legislative oversight of the board's implementation.

On December 4, 2023, several organizations reached out to the board to ask it to address our concerns about board representation, the lack of engagement opportunities for expert advisors living with a condition treated by the selected drugs for review, the transparency of its deliberations, including its use of measures such as the quality-adjusted life year (QALY) and equal value of life year gained (evLYG) to measure the effectiveness and value of treatments, and finally the need to emphasize patients in affordability reviews. To date, we have not received a response or been given an opportunity to meet. In fact, their processes have only gotten worse. Our prior letter to the board is provided to you as an addendum to this letter.

We continue to be concerned that the board's meetings do not welcome patient input. The board's agenda does not provide any guidance on the information being sought from patients to help in their deliberations. The time allotted for patient input is very limited and does not provide for a robust back and forth discussion between the board members and concerned patients and people with disabilities. It is not clear to us what information is being considered by the board and on which patients and people with disabilities could be providing input. The affordability review timeframes for each treatment under consideration are very short during the meetings with little engagement opportunity. There is not a separate dedicated engagement opportunity for patients and

[1] https://dfr.oregon.gov/pdab/Documents/20240131-PDAB-applicant-summary.pdf

and people with disabilities related to each drug being reviewed, which is highly inconsistent with the process in other states. In summary, the board process is confusing and instills little confidence that its conclusions will accurately represent the effectiveness and value of treatments under consideration.

The lack of public testimony to-date is a strong indicator that the current process is not working. In the December meeting, public comment was limited to 1 minute per person.

The legislation creating the board, SB 844, stated, "The board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition." The legislation also listed several criteria focused on the patient experience of accessing drugs being evaluated, including "health inequities for communities of color," "impact on patient access" and "estimated average patient copayment or other cost-sharing," yet the affordability review seems less focused on patient affordability than costs borne by the state. We share concerns about health system costs, but do not want the board's work to be at the expense of patients for whom existing therapeutic alternatives may not be the most clinically effective. We want to understand how the board is defining existing therapeutic alternatives and whether they are as effective as the treatments being reviewed. It is insufficient for the state to conclude less expensive alternatives are just as effective without hearing from patients. The goal of this process should be to ensure patients have access to the treatment that is most effective to treat their disease or condition. This requires a robust feedback loop and dedicated time to engaging patients and people with disabilities, including time for the board to respond, ask questions and solicit additional information.

Additionally, when the legislature passed SB 844, patients and people with disabilities were assured that QALYs and similar measures were barred from the board's consideration. Yet, the Institute for Clinical and Economic Review (ICER), an entity that calls QALYs the gold standard and that has developed the similar evLYG measure, as well as associated pro-QALY entities such as the Program on Regulation, Therapeutics, and Law (PORTAL), are deeply engaged in the board's work. Therefore, it is of the utmost importance for the evidence under consideration by the board to be transparent to the public to allow for patients and people with disabilities to weigh in with the board if consideration of certain evidence may be in conflict with its statute. We have shared these concerns with the board, yet we continue to be kept in the dark about the underlying evidence that may support its decisions.

In closing, we hope that the legislature will consider our concerns, pause the board's implementation, and conduct much-needed oversight of its activities. Thank you for your consideration and efforts to advance a health system that is equitable and allows for patients to affordably access the most clinically effective treatment.

Sincerely,

Organizations:
AiArthritis
ALS Northwest
Biomarker Collaborative

Caring Ambassadors Program
Cystic Fibrosis Research Institute
Exon 20 Group
ICAN, International Cancer Advocacy Network
MET Crusaders
National Bleeding Disorders Foundation
Pacific Northwest Bleeding Disorders
Partnership to Improve Patient Care
PD-L1 Amplifieds
The Bonnell Foundation: Living with cystic fibrosis
The ALS Association
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum

Individuals:
Laura Bonnell
Mary Canton
Lance Christian
Joy Krumdiack
Robbie Thurman-Noche

cc: Governor Kotek
Members of the Oregon Legislature
TK Keen, DCBS
Ralph Magrish, DCBS
PDAB committee

March 5, 2024

VIA ELECTRONIC FILING

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK appreciates the opportunity to participate in the February 2024 meeting and further appreciates the Board's decision not to include Shingrix on the list of prescription drugs that may create affordability challenges for patients in the state.

As you know, Shingrix is a vaccine indicated for prevention of herpes zoster (i.e., shingles) in adults aged 50 years and older and in adults aged 18 years and older who are or will be at increased risk due to immunodeficiency or immunosuppression caused by known disease or therapy. It is the only vaccine available to prevent shingles, and it is widely available without patient cost-sharing, as mandated by federal law.[1]

Upon review of the Board's Affordability Review Report, we want to clarify one datapoint used in the assessment of Shingrix. Page 8 of the Shingrix report states that "the package wholesale acquisition cost (WAC) for Shingrix (NDC 58160-0823-11) was $1,834.06 as of 12/31/2023." GSK would like it represented in the final PDAB affordability review report that the cited amount refers to the WAC of the total package, and that each package of Shingrix contains ten single-dose vials, resulting in a WAC per dose of $183.41.

Thank you again for your consideration and for the opportunity to engage with the Board. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

[1] Commercial plans: 42 U.S.C. §30gg-13(a)(2); Medicare Part B: 42 U.S.C. §1395x(s)(10) and 42 C.F.R. 410.57; Medicare Part D: 42 U.S.C. §1395w-102(e); Medicaid/Children's Health Insurance Program (CHIP): 42 U.S.C. §300gg-13(a)(2) (Medicaid Expansion) and 42 U.S.C. §1396o-1 (Traditional Medicaid)