



## **News Release**

### **Media Contact:**

Craig Stoltz  
Mobile: +1 (215) 986-1975

### **Investor Contact:**

Raychel Kruper  
Office: +1 (732) 524-6164

## **TREMFYA® (guselkumab) Real-World Data Analyses Show Greater Treatment Persistence Than IL-17s in Both Bio-naïve and Bio-experienced Patients Living With Moderate to Severe Plaque Psoriasis**

*Additional post-hoc analysis of TREMFYA showed improvements in scalp psoriasis and quality-of-life measures at week 48*

**SPRING HOUSE, PENNSYLVANIA, March 17, 2023** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data, showing that initiation of TREMFYA® (guselkumab) was associated with greater treatment persistence<sup>a</sup> compared to secukinumab or ixekizumab in bio-naïve and bio-experienced patients<sup>b</sup> living with moderate to severe plaque psoriasis (PsO), based on pairwise analyses<sup>c</sup> of real-world data.<sup>1,2</sup> Additionally, in a post-hoc analysis of Phase 3 VOYAGE 2 clinical trial results, TREMFYA demonstrated durable clinical efficacy, itch relief and quality-of-life improvements in patients living with scalp PsO.<sup>3</sup> TREMFYA is the first and only fully human selective interleukin (IL)-23 inhibitor therapy approved in the U.S. for adults with moderate to severe plaque PsO.<sup>4</sup> These study results are among 14 company-sponsored abstracts being

presented by Janssen at the 2023 American Academy of Dermatology (AAD) Annual Meeting in New Orleans, LA.

Analysis of real-world data from the IBM MarketScan Research Databases from July 13, 2017, to May 1, 2021, showed TREMFYA was associated with greater persistence (i.e., longer median time to index treatment discontinuation) compared to secukinumab and ixekizumab among bio-naïve patients:<sup>1</sup>

- The TREMFYA cohort showed 2.20 times (at 12 months) and 2.28 times (at 18 months) longer persistence versus the secukinumab cohort, and 1.84 times (at 12 months) and 1.86 times (at 18 months) longer persistence versus the ixekizumab cohort.<sup>1</sup>
- 2,202 and 2,772 patients were identified for pairwise analysis of the TREMFYA versus secukinumab cohorts, and 2,241 and 2,007 patients for pairwise analysis of the TREMFYA versus ixekizumab cohorts, respectively.<sup>1</sup>

Analysis of real-world data from the IBM MarketScan Research Databases from July 13, 2017, to May 1, 2021, showed TREMFYA was associated with greater persistence compared to secukinumab and ixekizumab among bio-experienced patients:<sup>2</sup>

- The TREMFYA cohort showed 2.00 times (at 12 months) and 2.04 times (at 18 months) longer persistence versus the secukinumab cohort, and 1.76 times (at 12 months) and 1.67 times (at 18 months) longer persistence versus the ixekizumab cohort.<sup>2</sup>
- 1,314 and 3,294 patients were identified for pairwise analysis of the TREMFYA and secukinumab cohorts, and 1,564 and 2,667 patients for pairwise analysis of the TREMFYA and ixekizumab cohorts, respectively.<sup>2</sup>

“These persistency real-world results potentially indicate that TREMFYA is associated with better long-term control of the symptoms associated with PsO compared with secukinumab and ixekizumab, irrespective of whether patients were bio-naïve or bio-experienced,” said Steven Feldman, M.D., Ph.D., dermatologist at the Wake Forest University School of Medicine.<sup>d</sup> “Increasing our understanding of

real-world data can improve clinical practice, leading to benefits for our patients. These critical insights help us make better treatment decisions for, and with, our patients living with PsO.”

In a post-hoc analysis<sup>e</sup> of the Phase 3 VOYAGE 2 clinical trial, which compared TREMFYA with placebo and with adalimumab in patients with moderate to severe plaque PsO, TREMFYA demonstrated durable clinical efficacy, changes in mean Psoriasis Symptoms and Signs Diary (PSSD) itch scores<sup>f</sup> and quality-of-life improvements in adult patients with scalp PsO:<sup>3</sup>

- Among TREMFYA responders (patients achieving at least 90 percent improvement from baseline in Psoriasis Area and Severity Index [PASI 90] score)<sup>3,9</sup> remaining on treatment, mean scalp-specific Investigator Global Assessment (ss-IGA)<sup>h</sup> score rapidly improved from 2.9 at week 0 to 0.2 at week 24, and 0.3 at week 48.<sup>3</sup>
- Changes in mean PSSD itch scores and Dermatology Life Quality Index scores paralleled changes in mean ss-IGA scores for all cohorts.<sup>3</sup>

“These new data underscore Janssen’s commitment to provide efficacious and long-lasting treatments for people living with PsO, which may also proactively contribute to their overall well-being,” said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Stronghold, Janssen Research & Development, LLC. “Up to 80 percent of people living with PsO have scalp involvement, and it significantly impacts quality of life.<sup>5</sup> These results continue to show the important role TREMFYA plays in the management of moderate to severe plaque PsO, including difficult-to-treat areas such as the scalp.”

#### **Editor’s Notes:**

- a. Persistence was defined based on gaps between days of treatment supply over twice the labelled dosing interval: >120 days for TREMFYA or >60 days for secukinumab/ixekizumab.<sup>1,2</sup>
- b. Adults with moderate to severe plaque PsO initiated (index date) on TREMFYA, secukinumab, or ixekizumab between July 13, 2017, and May 1,

2021, were identified in the IBM MarketScan Research Databases. Bio-naïve patients had no claims for biologics 12 months pre-index date.<sup>1</sup> Bio-experienced patients had  $\geq 1$  claim for a biologic other than TREMFYA, secukinumab, and ixekizumab 12 months pre-index date.<sup>2</sup>

- c. These analyses compared real-world persistence between pairs of patients from each cohort. Cohorts were balanced for potential confounders using entropy balancing, and persistence was compared using Cox proportional hazard models (TREMFYA versus secukinumab, TREMFYA versus ixekizumab).<sup>1,2</sup> Results may not be generalized to the uninsured or patients with non-commercial insurance. Prescription fills do not guarantee the medication was taken as prescribed. Results may be subject to residual confounding.<sup>1,2</sup>
- d. Dr. Steven Feldman is a paid consultant for Janssen. He has not been compensated for any media work.
- e. This post-hoc analysis explored scalp responses as measured by ss-IGA during TREMFYA treatment and withdrawal in patients with scalp involvement (as indicated at screening) who were randomized to TREMFYA 100 mg at week 0 and week 4, then every 8 weeks. At week 28, PASI 90 responders were re-randomized to continue (n=159) or discontinue (n=164) TREMFYA; non-responders continued TREMFYA (n=84).<sup>3</sup>
- f. The PSSD is a validated patient-reported outcome tool used to assess symptoms and signs of moderate to severe plaque PsO.<sup>6</sup> PSSD itch scores were not scalp-specific.<sup>3</sup>
- g. The PASI score grades the amount of surface area on each body region that is covered by PsO plaques and the severity of plaques for their redness, thickness, and scaliness.<sup>7</sup>
- h. ss-IGA assesses scalp PsO lesions for degree of redness, thickness, and scaling on a 5-point scale, with 0 indicating absence of disease and 4 indicating severe disease.<sup>8</sup>

**About VOYAGE 2 (NCT02207244; EudraCT 2014-000720-18)**<sup>9,10</sup>

This Phase 3, randomized, double-blind, placebo- and active comparator-controlled

clinical trial was designed to evaluate the efficacy and safety of TREMFYA compared with placebo and adalimumab in adults with moderate to severe plaque PsO.<sup>9</sup> Patients (N=992) were randomized to receive subcutaneous injections of TREMFYA 100 mg (n=496) at weeks 0, 4, and every 8 weeks (q8w) thereafter; placebo (n=248) at weeks 0, 4, and 12 followed by crossover to TREMFYA 100 mg at week 16; or adalimumab 80 mg (n=248) at week 0, 40 mg at week 1, then 40 mg every 2 weeks (q2w) until week 23.<sup>11</sup> Weeks 28-72 incorporated a randomized withdrawal study design.<sup>11</sup> During the open-label period (weeks 76-252), all patients received TREMFYA 100 mg q8w.<sup>9</sup> Physician- and patient-reported outcomes were assessed.<sup>11</sup> Efficacy was analyzed using prespecified treatment failure rules (patients discontinuing due to lack of efficacy, worsening of PsO, or use of a prohibited treatment were considered non-responders).<sup>11</sup> Data were combined for patients randomized to TREMFYA and for those originally randomized to placebo who later crossed over to TREMFYA at week 16.<sup>11</sup> Patients were treated and followed for up to 264 weeks.<sup>9</sup>

Co-primary endpoints of the study were proportions of patients receiving TREMFYA versus placebo achieving IGA 0/1 (clear/almost clear) (84 vs 9 percent, respectively [P<0.001 vs placebo]) and PASI 90 (70 vs 2 percent, respectively [P<0.001 versus placebo]) at week 16.<sup>11</sup> Additional efficacy assessments included proportions of patients achieving PASI 75, and PASI 100 responses, as well as IGA score of 0, Dermatology Life Quality Index score of 0/1, PSSD score of 0, SF-36, the Hospital Anxiety and Depression Scale, and the Work Limitations Questionnaire.<sup>11</sup> Efficacy was analyzed using pre-specified treatment failure rules, non-responder imputation, and as observed methodology.<sup>11</sup>

### **About Plaque Psoriasis (PsO)**

Plaque PsO is an immune-mediated disease resulting in an overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.<sup>12</sup> It is estimated that eight million Americans and more than 125 million people worldwide live with the disease.<sup>13</sup> Nearly one-quarter of all people with plaque PsO have cases that are considered moderate to severe.<sup>13</sup> Living with plaque PsO can be a

challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.<sup>14</sup>

### **About TREMFYA® (guselkumab)<sup>4</sup>**

Developed by Janssen, TREMFYA is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.<sup>4,15</sup> IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque PsO and active psoriatic arthritis (PsA).<sup>4</sup> TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque PsO who are candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.<sup>4,16,17</sup> It is also approved in the EU for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior conventional synthetic disease modifying antirheumatic drug therapy.<sup>15</sup> Guselkumab is being investigated in Phase 2/3 clinical trials in both adults with moderately to severely active Crohn's disease (EudraCT 2017-002195-13) and adults with moderately to severely active ulcerative colitis (EudraCT 2018-004002-25).<sup>18,19</sup>

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA®.

### **IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about TREMFYA®?**

**TREMFYA® is a prescription medicine that may cause serious side effects, including:**

- **Serious Allergic Reactions.** Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)

- swelling of your face, eyelids, lips, mouth, tongue or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching
- **Infections.** TREMFYA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

- fever, sweats, or chills
- muscle aches
- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

**Do not take TREMFYA®** if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

**Before using TREMFYA®, tell your healthcare provider about all of your medical conditions, including if you:**

- have any of the conditions or symptoms listed in the section **“What is the most important information I should know about TREMFYA®?”**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**What are the possible side effects of TREMFYA®?**

**TREMFYA® may cause serious side effects. See “What is the most important information I should know about TREMFYA®?”**

**The most common side effects of TREMFYA® include:** upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, and bronchitis.

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

**Please read the full [Prescribing Information](#), including [Medication Guide](#) for TREMFYA®, and discuss any questions that you have with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

cp-82626v3

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal) and [www.twitter.com/JanssenUS](https://www.twitter.com/JanssenUS).

Janssen Research & Development, LLC; Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

### **Cautions Concerning Forward-Looking Statements**

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding TREMFYA<sup>®</sup> (guselkumab). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC or any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of

obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

# # #

## **References**

---

<sup>1</sup> Zhdanova M, et al. Long term psoriasis control with guselkumab versus secukinumab and ixekizumab among bio-naïve patients: analysis of drug persistence in large claims database. Presented at AAD 2023, March 17-21.

<sup>2</sup> Zhdanova M, et al. Long term psoriasis control with guselkumab versus secukinumab and ixekizumab among bio-experienced patients: analysis of drug persistence in large claims database. Presented at AAD 2023, March 17-21.

<sup>3</sup> Sonkoly E, et al. Guselkumab in patients with scalp psoriasis: A post hoc analysis of the VOYAGE 2 trial. Presented at AAD 2023, March 17-21.

<sup>4</sup> Food and Drug Administration. TREMFYA<sup>®</sup> Prescribing Information. Horsham, PA. 2017. Available at: <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf>. Accessed March 2023.

<sup>5</sup> Blakely K, et al. Management of scalp psoriasis: current perspective. *Psoriasis (Auckl)*. 2016;6:33-40. doi: 10.2147/PTT.S85330. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683126>. Accessed March 2023.

<sup>6</sup> Papp KA, et al. Patient-reported symptoms and signs of moderate-to-severe psoriasis treated with guselkumab or adalimumab: Results from the randomized VOYAGE 1 trial. *J Eur Acad Dermatol Venereol*. 2018;32(9):1515-1522. Published online April 10, 2018. doi: 10.1111/jdv.14910.

<sup>7</sup> Thompson Jr, D. How the Psoriasis Area and Severity Index Works. *Everyday Health*. Available at: <https://www.everydayhealth.com/psoriasis/living-with/how-the-pasi-index-works>. Accessed March 2023.

<sup>8</sup> Foley P, et al. Efficacy of Guselkumab Compared with Adalimumab and Placebo for Psoriasis in Specific Body Regions. *JAMA Dermatol*. 2018;154(6):676-683. Available at: <https://jamanetwork.com/journals/jamadermatology/fullarticle/2681556>. Accessed March 2023.

- 
- <sup>9</sup> Clinicaltrials.gov. A Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis With Randomized Withdrawal and Retreatment (VOYAGE 2). Identifier NCT02207244. <https://www.clinicaltrials.gov/ct2/show/NCT02207244>. Accessed March 2023.
- <sup>10</sup> EU Clinical Trials Register. A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator controlled Study Evaluating the Efficacy and Safety of Guselkumab for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis with Randomized Withdrawal and Retreatment. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-000720-18/results>. Accessed March 2023.
- <sup>11</sup> Reich K, *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 III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. *J Am Acad Dermatol.* 2017;76(3):418-431.
- <sup>12</sup> National Psoriasis Foundation. About Psoriasis. Available at: <https://www.psoriasis.org/about-psoriasis>. Accessed March 2023.
- <sup>13</sup> National Psoriasis Foundation. Psoriasis Statistics. Available at: <https://www.psoriasis.org/content/statistics>. Accessed March 2023.
- <sup>14</sup> National Psoriasis Foundation. Life with Psoriasis. Available at: <https://www.psoriasis.org/life-with-psoriasis/>. Accessed March 2023.
- <sup>15</sup> European Medicines Agency. TREMFYA Summary of Product Characteristics. Last Updated July 2022. Available at: [https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf). Accessed March 2023.
- <sup>16</sup> Japan Pharmaceuticals and Medical Devices Agency. Tremfya Report on the Deliberation Results. Available at: <https://www.pmda.go.jp/files/000234741.pdf>. Accessed March 2023.
- <sup>17</sup> The Canadian Agency for Drugs & Technologies in Health. TREMFYA Prescribing Information. Available at: [https://pdf.hres.ca/dpd\\_pm/00042101.PDF](https://pdf.hres.ca/dpd_pm/00042101.PDF). Accessed March 2023.
- <sup>18</sup> EUClinicalTrialsRegister.eu. A Phase 2/3, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-002195-13/GB>. Accessed March 2023.
- <sup>19</sup> EUClinicalTrialsRegister.eu. A Phase 2b/3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-004002-25/SE>. Accessed March 2023.