



News Release

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New First-in-Class Phase 3 Data Demonstrate TREMFYA® (guselkumab) Maintained Skin Clearance Rates Through Nearly 5 Years of Continuous Use in Adult Patients with Moderate to Severe Plaque Psoriasis

Data from VOYAGE 1 open-label, long-term extension study show sustained efficacy response rates at week 252 and no new safety signals

First study of an IL-23 inhibitor treatment to demonstrate safety and efficacy throughout a nearly five-year period of use

SPRING HOUSE, PENNSYLVANIA, October 15, 2020 – The Janssen

Pharmaceutical Companies of Johnson & Johnson today announced new open-label extension data from the Phase 3 VOYAGE 1 study, which showed high rates of skin clearance with TREMFYA® (guselkumab) and no new safety signals in adult patients with moderate to severe plaque psoriasis through nearly five years of treatment.¹ At week 252 in the combinedⁱ TREMFYA group, 84 percent of patients achieved a Psoriasis Area Severity Index (PASI) 90 response (a 90 percent improvement in the

PASI score compared to baseline) and 82.4 percent achieved an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) (IGA 0/1).¹ Among patients in the combinedⁱ TREMFYA group, patients were either initially randomized to TREMFYA or to placebo with crossover to TREMFYA at week 16.¹ Safety outcomes were observed through 264 weeks with no new safety signals.¹ TREMFYA is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor.² These data are being presented at the 16th Annual Coastal Dermatology Symposium, which will be conducted virtually.¹

"Patients with psoriasis face a life-long struggle as a result of this complex and disabling chronic disease," said Chris Griffiths,ⁱⁱ M.D., Dermatology Centre, NIHR Manchester Biomedical Research Centre, Salford Royal NHS Foundation Trust, University of Manchester, Manchester, UK. "The VOYAGE 1 TREMFYA data are the first for an IL-23 p19 inhibitor to demonstrate skin clearance for the majority of patients through nearly five years of treatment and are encouraging for patients and physicians alike as they seek long-term treatment options."

In this Phase 3 trial, out of a total of 494 patients either randomized to TREMFYA at week 0 (n=329) or randomized to placebo and crossed over to receive TREMFYA at week 16 (n=165), 76.9 percent (380/494) continued on TREMFYA treatment through week 252. Through nearly five years of continuous TREMFYA use, PASI 90 response rates were steadily consistent based on the primary pre-specified Treatment Failure Rules (TFR). At week 52, PASI 90 response rates were 79.7 percent, 75.5 percent, and 80.6 percent based on TFR, Non-Responder Imputation (NRI), and As Observed (OBS) analyses, respectively; while corresponding rates at week 252 were 84.1 percent, 66.6 percent, and 86.6 percent. Similarly, PASI 100, IGA 0/1, and IGA 0 response rates were consistent from week 52 through week 252. Response rates were also consistent through week 252 in patients randomized to TREMFYA at week 0 (n=329). Of note, each patient may not have achieved response at each observation time point. At one year and thereafter, patients and

study investigators knew that all study participants were on TREMFYA, which may affect the results.¹

Safety findings were generally consistent with those previously observed.^{1,2}

Through the end of the safety assessment (week 264) for all patients (n=774) inclusive of the combinedⁱ TREMFYA group (n=494) and a group of patients initially treated with adalimumab who crossed over to TREMFYA (n=280), the proportion of patients reporting at least one adverse event (AE), serious AE, or discontinuation due to AEs were 87.7 percent, 16.4 percent, and 6.1 percent, respectively.¹

“We are excited to share these data demonstrating TREMFYA’s ability to help adults living with moderate to severe plaque psoriasis by providing sustained rates of clearance through nearly five years for the majority of patients,” said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC. “With remission as the ultimate goal, we are committed to continuing to apply the best science and disease insights to advancing therapies that improve the lives of patients.”

About Psoriasis

Psoriasis is an immune-mediated disease resulting in an overproduction of skin cells, which causes raised, red, scaly plaques that may be itchy or painful.³ It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.⁴ Nearly one-quarter of all people with psoriasis have cases that are considered moderate to severe.⁴ Living with psoriasis can be a challenge and impact life beyond a person’s physical health, including emotional health, relationships, and handling the stressors of life.⁵

About VOYAGE 1 (NCT02207231)⁶

This Phase 3, randomized, double-blind, placebo and active comparator-controlled trial with 837 patients was designed to evaluate the efficacy and safety of TREMFYA compared with placebo and adalimumab in adults with moderate to severe plaque psoriasis. Patients were randomized to receive placebo (n=174) at weeks 0, 4 and

12, followed by crossover to TREMFYA (n=165) at weeks 16 and 20 followed by every eight-week (q8w) dosing; TREMFYA 100 mg (n=329) at weeks 0, 4 and 12, followed by q8w dosing; or adalimumab 80 mg (n= 334) at week 0, followed by 40 mg at week 1, then dosing every two weeks through week 47, with crossover to TREMFYA q8w at week 52.

The co-primary endpoints of the study were the proportions of patients receiving TREMFYA vs. patients receiving placebo achieving IGA 0/1 (clear/almost clear) [73 percent vs. 3 percent, respectively; $p < 0.001$ vs. *placebo*] and PASI 90 [85 percent vs. 7 percent, respectively; $p < 0.001$ vs. *placebo*] at week 16. Secondary endpoints were assessed at weeks 16, 24 and 48, with safety monitoring throughout the study. Through week 48, NRI rules were used for missing data (after the application of TFR).

During the open-label extension period, which started at week 52, all patients continued open-label treatment with TREMFYA through week 252. Efficacy assessments included proportions of patients achieving PASI 90, PASI 100, IGA of 0/1, and IGA of 0. Efficacy was analyzed using prespecified TFR for the primary analysis, while NRI and OBS methodologies were used for the secondary analyses.

VOYAGE 1 and VOYAGE 2 are part of a comprehensive Phase 3 clinical development program for TREMFYA in psoriasis that includes an additional Phase 3 trial, NAVIGATE, and ECLIPSE, the first head-to-head Phase 3 study of an IL-23 inhibitor (TRMFYA) vs. an IL-17 inhibitor (secukinumab).^{7,8}

About TREMFYA® (guselkumab)²

Developed by Janssen, TREMFYA® (guselkumab) 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. TREMFYA is approved in the U.S., Canada, the European Union, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy

(treatment using ultraviolet [UV] light). It is approved in the U.S., Canada, Japan, Brazil, and Ecuador for the treatment of adult patients with active psoriatic arthritis. IL-23 is an important driver of the pathogenesis of immune-mediated inflammatory diseases such as psoriasis.⁹

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, or call 1-800-FDA-1088.

[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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal.

Janssen Research & Development, LLC is a part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

ⁱ *The combined group included patients who were initially randomized to receive TREMFYA at week 0 and patients who were initially randomized to placebo then crossed over to TREMFYA at week 16.*

ⁱⁱ *Dr. Griffiths is a paid consultant for Janssen. He was not compensated for any media work.*

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding ongoing and planned development efforts involving TREMFYA[®] (guselkumab) as a treatment for adult patients with moderate to severe plaque psoriasis. 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, 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 December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, 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.

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