



News Release

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Janssen Announces New Three-Year TREMFYA® (Guselkumab) Data Demonstrates Stably Maintained Rates of Skin Clearance in Patients with Moderate to Severe Plaque Psoriasis

At the three-year mark, patients receiving TREMFYA® in clinical studies continue to show stably maintained PASI 90 and IGA 0/1 responses

Las Vegas, Nev., October 19, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today new long-term data from the open-label period of the VOYAGE 1 clinical trial demonstrating that stably maintained rates of skin clearance with TREMFYA® treatment achieved from week 52 (1 year) were maintained through week 156 (3 years) among adult patients with moderate to severe plaque psoriasis. TREMFYA® is the first anti-interleukin (IL)-23 monoclonal antibody that was approved by the U.S. Food and Drug Administration (FDA) and is administered by subcutaneous injection. The findings, presented at the 37th Fall Clinical Dermatology Conference in Las Vegas, Nevada, showed nearly 83 percent of patients receiving TREMFYA® in the Phase 3 VOYAGE 1 study maintained at least a 90 percent improvement in the Psoriasis Area Severity Index (PASI 90) response (near complete skin clearance), and an Investigator’s Global Assessment (IGA) score of cleared (0) or minimal disease (1) at week 156.

“These findings are impressive as they demonstrate consistency in high rates of skin clearance with guselkumab treatment at weeks 48, 100 and 156 with every eight-week maintenance therapy,” said Andrew Blauvelt, M.D., MBA, President, Oregon Medical Research Center, and VOYAGE 1 study steering committee member.* “In the management of moderate to severe plaque psoriasis, including symptom relief as well as skin clearance, it is essential that we continue to evaluate the impact of treatments with long-term data like those presented today. The VOYAGE 1 findings help further our understanding of the long-term impact of targeting IL-23 with guselkumab in the treatment of plaque psoriasis.”

Results from the open-label extension of the VOYAGE 1 Phase 3 clinical study showed that at week 156, in the combined group of patients initially randomized to TREMFYA® or to placebo with crossover to TREMFYA® at week 16, 82.1 percent achieved an IGA score of 0/1 (cleared or minimal disease), 96.4 percent achieved a PASI 75 score, and 82.8 percent achieved a PASI 90 score.

At week 156, 53.1 percent of patients achieved an IGA score of 0 and 50.8 percent of patients achieved a PASI 100 response. These measures represent skin completely cleared of psoriasis plaques and are consistent with PASI 100 and IGA 0 results demonstrated at week 100.

Responses based on the Psoriasis Symptoms and Signs Diary (PSSD) were consistent at week 100 and week 156 as well. This tool evaluates patient-reported symptoms (i.e., itch, pain, stinging, burning and skin tightness) and signs (i.e., skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The percentage of patients reporting a PSSD symptom score of 0 was 40.2 at week 100 and 40.4 at week 156.

Of the 494 patients in the combined TREMFYA® and placebo crossover to TREMFYA® group, the percentages of patients reporting adverse events (AEs), serious AEs, infections, and serious infections through week 48 were 70.9 percent, 4.3 percent, 50.2 percent and 0.6 percent, respectively, and through week 100 were 80.0 percent, 9.1 percent, 61.1 percent and 1.2 percent, respectively. Among the same patient group, the percentages of events reported

through week 156 were 86.2 percent, 13.4 percent, 67.8 percent and 2.2 percent respectively. No cases of active tuberculosis, opportunistic infections or serious hypersensitivity reactions were reported among TREMFYA-treated subjects.

“We are very pleased and excited by these results. The data adds to the growing body of safety and efficacy evidence with the use of TREMFYA over a three-year period,” said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. “As a part of our commitment to developing innovative therapies for chronic, immune-mediated disease like psoriasis, we have been focusing on generating long-term data so that patients and physicians can be more informed when making treatment decisions.”

About VOYAGE 1

This Phase 3, randomized, double-blind, placebo and active comparator-controlled trial was designed to evaluate the efficacy and safety of TREMFYA[®] compared with placebo and adalimumab in adults with moderate to severe plaque psoriasis. Patients (n=837) were randomized to receive placebo at weeks 0, 4 and 12, followed by crossover to TREMFYA[®] at weeks 16 and 20 followed by every eight-week (q8w) dosing; TREMFYA[®] 100 mg at weeks 0, 4 and 12, followed by q8w dosing; or adalimumab 80 mg at week 0 and 40 mg at week 1, followed by every two-week dosing 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[®] versus patients receiving placebo achieving IGA 0/1 (cleared/minimal disease) [73% vs 3% *P*<0.001 vs placebo] and PASI 90 [85% vs 7% *P*<0.001 vs placebo] responses at week 16. Secondary endpoints were assessed at weeks 16, 24 and 48, with safety monitoring throughout the study. The open-label extension period started at week 52 and is currently ongoing. Results presented to date include findings through week 156 of the study. Through week 48, non-responder imputation rules were used for missing data while after week 48, no missing data were imputed after the application of treatment failure rules.

[VOYAGE 1](#) is part of a comprehensive TREMFYA[®] Phase 3 clinical development program that includes two additional Phase 3 trials, [VOYAGE 2](#) and [NAVIGATE](#).

About TREMFYA® (guselkumab)

TREMFYA® is a human monoclonal antibody developed by Janssen that selectively blocks the protein interleukin (IL)-23 and is approved in the U.S., Canada, 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 or UV light). Ongoing trials include: Phase 3 program evaluating TREMFYA in the treatment of active psoriatic arthritis, Phase 3 study evaluating the efficacy of TREMFYA compared with Cosentyx® (secukinumab) in the treatment of moderate to severe plaque psoriasis, and a Phase 2b program in Crohn's disease.

TREMFYA is a trademark of Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

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

TREMFYA® may cause serious side effects, including infections. TREMFYA® is a prescription medicine that 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

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, and herpes simplex infections.

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.

075142-170622

About Psoriasis

Psoriasis is a chronic, inflammatory autoimmune disorder that results in the overproduction of skin cells, characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain. It is estimated that as many as 125 million people worldwide have psoriasis, including more than 8 million Americans and 14 million Europeans.¹⁻⁷ The disease symptoms can range from mild, to moderate, to severe and disabling. It is estimated that nearly three percent of the world's population is living with psoriasis.⁵

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. 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 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in 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. Neither 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.

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

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