News Release

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TREMFYA® (guselkumab) Maintains Key Efficacy Endpoints Through Three Years for Adults with Moderately to Severely Active Crohn's Disease in a Phase 2 Study

Key efficacy endpoints of the long-term extension GALAXI study included clinical remission, patient-reported outcome remission, and endoscopic response

SPRING HOUSE, PENNSYLVANIA, October 16, 2023 – Janssen Pharmaceuticals, Inc., a Johnson & Johnson Company, today announced new data from the long-term extension (LTE) of the GALAXI Phase 2 study demonstrating the durable clinical and endoscopic efficacy of TREMFYA® (guselkumab), a selective IL-23 p19 inhibitor, in patients with moderate-to-severe Crohn's disease (CD), now through a total of three years.[1] Rates of clinical remission and endoscopic response were maintained through three years. The safety profile of TREMFYA was consistent with that of its currently approved indications.[1] These data are among Janssen's 17 oral and poster presentations at the United European Gastroenterology (UEGW) Week 2023 taking place in Copenhagen, Denmark, October 14-17, 2023.

"The results from the GALAXI long-term extension strengthen our confidence in TREMFYA's potential for patients with moderate-to-severe Crohn's disease," said

study author Anita Afzali, M.D., Division of Digestive Diseases, University of Cincinnati College of Medicine, Cincinnati, OH.[a] "These insights are especially helpful to physicians, as research continues investigating the efficacy and safety profile of TREMFYA for its use as a potential treatment option for their patients in need of lasting relief."

After completing the Week 48 Phase 2 GALAXI study, patients continued in the LTE to receive one of three maintenance regimens that were randomly assigned to the following treatment arms:[1]

- TREMFYA 100 mg subcutaneous (SC) every eight weeks (q8w)[1]
- TREMFYA 200 mg SC every four weeks (q4w)[1]
- STELARA® (ustekinumab) 90 mg SC q8w[1]

A summary of data from the GALAXI LTE at three years for all randomized patients is as follows:

Endpoint	Combined TREMFYA[b]	STELARA
Clinical remission[c]	54.1 percent (100/185)[1]	46.0 percent (29/63)[1]
PRO-2 remission[d]	51.4 percent (95/185)[1]	39.7 percent (25/63)[1]
Endoscopic response[e]	34.7 percent (61/176)[1]	19.4 percent (12/62)[1]

Both TREMFYA treatment arms demonstrated similar benefits in this study.[1] The study was not designed to evaluate efficacy differences between individual TREMFYA doses or TREMFYA versus STELARA.

Most infections were not serious and did not result in discontinuation, while incidence rates of serious adverse events (SAEs) and serious infections were generally low.[1] Most infections were mild to moderate in severity and resolved without discontinuation of treatment (65.8 versus 3.3 events per 100 patient-years).[2]

"Establishing the long-term efficacy and safety profile of TREMFYA is an important step as we work to bring relief and remission to the millions of people worldwide living with Crohn's disease," said Jan Wehkamp, MD, PhD, Vice President, Gastroenterology Disease Area Leader at Janssen. "We remain committed to researching and developing novel therapies, and to deepening our understanding of the interleukin (IL)-23 pathway with the goal of offering patients a range of treatment options that best fit their needs."

Further research is currently being conducted on TREMFYA for the treatment of patients with inflammatory bowel disease, which includes Phase 3 studies that are fully recruited and ongoing.[3]

TREMFYA® is not approved for the treatment of adults living with CD in the U.S.

Editor's Notes:

a. Dr. Anita Afzali is a paid consultant for Janssen. She has not been compensated for any media work.
b. Combined TREMFYA group includes the pooled 100 mg SC q8w and the 200 mg SC q4w data.[1]
c. Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score of <150 (primary efficacy analysis set (nonresponder imputation)).[1]
d. PRO-2 remission is defined as an abdominal pain (AP) mean daily score ≤1 and mean daily stool frequency (SF) score ≤3 and no worsening of AP or SF from baseline (primary efficacy analysis set (nonresponder imputation)).[1]
e. Endoscopic response is defined as ≥50 percent improvement from baseline in the Simple Endoscopic Score in Crohn's disease (SES-CD) (primary efficacy analysis set (nonresponder imputation)).[1]

About GALAXI 1 Long-Term Extension (NCT03466411; EudraCT 2017-002195-13)

GALAXI 1 is a double-blind, placebo-controlled, active-controlled, global, multicenter, Phase 2 dose-ranging study evaluating the efficacy and safety of TREMFYA in

participants with moderately to severely active CD with inadequate response/intolerance to conventional therapies (corticosteroids, immunosuppressives) and/or biologics (TNF antagonists, vedolizumab).[3,4] The GALAXI 1 long-term extension study is assessing clinical, endoscopic, and safety outcomes through 5 years in patients receiving maintenance therapy with TREMFYA.[4,5]

Upon completing the treat-through Week 48 Phase 2 study, patients who were deemed by the investigator to be benefitting from treatment were continued in the LTE with 1 of 3 previously assigned maintenance regimens: TREMFYA dosed at 100 mg subcutaneous (SC) every 8 weeks, TREMFYA dosed at 200 mg SC every 4 weeks (q4w), or STELARA dosed at 90 mg SC q8w.[4,5]

Key efficacy endpoints assessed at Week 144 included CD Activity Index (CDAI) clinical remission, patient-reported outcome (PRO)-2 remission, and endoscopic response.[4,5] Safety analyses included all treated patients. The Phase 2 study was not designed to evaluate efficacy differences between individual TREMFYA doses or between TREMFYA and STELARA.[4,5]

About Crohn's Disease (CD)

CD is one of the two main forms of inflammatory bowel disease (IBD), which affects an estimated three million Americans and an estimated two million people across Europe.[6,7] CD is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other environmental factors.[8] Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. There is currently no cure for CD.[9]

About TREMFYA® (guselkumab)

Developed by Janssen, 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.[10] IL-23 is an important driver of the pathogenesis of inflammatory diseases such as IBD, plaque psoriasis (PsO) and psoriatic arthritis (PsA). [10] TREMFYA is approved in the U.S., Canada, Japan and a number of other countries 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.[10] 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 disease-modifying antirheumatic drug therapy. [10]

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

IMPORTANT SAFETY INFORMATION[10]

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

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

Janssen Research & Development, LLC; Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC are Johnson & Johnson companies.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development of TREMFYA® (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, Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC 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, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Research & Development, LLC, Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC 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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