



News Release

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TREMFYA® (guselkumab) Induces Clinical and Endoscopic Improvements in Patients with Moderately to Severely Active Crohn's Disease based on Interim Results from Phase 2 Study

Interim analyses from GALAXI 1 study presented as an oral presentation at the United European Gastroenterology (UEG) Week Virtual 2020 Congress

These are the first data evaluating TREMFYA in moderately to severely active Crohn's disease

SPRING HOUSE, PENNSYLVANIA, October 12, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced Phase 2 interim data from the GALAXI 1 study, which showed TREMFYA® (guselkumab) demonstrated results at week 12 in adult patients with moderately to severely active Crohn's disease (CD) with inadequate response or intolerance to conventional therapies and/or biologics.¹ At 12 weeks, TREMFYA induced significantly greater improvements compared to placebo across key clinical and endoscopic outcome measures, with a safety profile consistent with approved indications.¹ TREMFYA is not currently approved for the treatment of CD in the U.S.²

These new data are being presented today as an oral presentation (Abstract OP089) at the 28th United European Gastroenterology (UEG) Week, which is conducting its annual congress virtually.¹

“While there have been substantial treatment breakthroughs in Crohn’s disease, there are still patients who are not gaining benefit from any of the currently approved mechanisms of action for their symptoms,” said lead study investigator William J. Sandbornⁱ, M.D., Chief of Gastroenterology, Professor of Medicine, University of California, San Diego, who is delivering the oral presentation virtually at UEG Week. “I am encouraged by these early data, which show that TREMFYA across three different dosing groups induced a significant response in key clinical and endoscopic outcome measures in Crohn’s disease.”

GALAXI 1 evaluated the efficacy and safety of TREMFYA compared with placebo in CD. The interim analyses reported results through week 12 from the first 250 patients enrolled. Approximately 50 percent of patients had previously failed biologic therapy; and baseline disease characteristics were consistent with moderately to severely active CD (Crohn’s Disease Activity Index [CDAI], mean 306.6; Simple Endoscopic Score for Crohn’s Disease [SES-CD], median 11.0). Patients were randomized equally into five treatment arms, including treatment with TREMFYA dosed at 200, 600 or 1200 mg intravenously (IV) at weeks 0, 4 and 8, respectively; or treatment with ustekinumab dosed at ~6mg/kg IV at week 0 and then dosed at 90 mg subcutaneously (SC) at week 8; or placebo.¹

At week 12, there were significantly greater reductions from baseline in the CDAI observed in each TREMFYA group (200, 600 or 1200 mg IV doses) compared with placebo (Least Squares [LS] means: -154.1, -144.3, -149.5 versus -36.0, respectively; all $p < 0.001$). A significantly higher proportion of patients assigned to each TREMFYA dose achieved clinical remission compared with placebo (CDAI < 150): 54.0 percent, 56.0 percent, 50.0 percent, respectively, versus 15.7 percent ($p < 0.001$). Among conventional therapy failures, 61.6 percent in the TREMFYA-combined group versus 18.5 percent treated with placebo achieved clinical remission at week 12. Among patients who had previously failed biologic therapy, 45.5 percent in the TREMFYA-combined group compared with 12.5 percent in the placebo group achieved clinical remission at week 12.¹

Furthermore, at week 12, a significantly higher proportion of patients treated with TREMFYA achieved clinical response ($p < 0.001$), patient reported outcome (PRO)-2 remission ($p < 0.001$), clinical-biomarker response ($p < 0.001$), and endoscopic response ($p < 0.001$) compared with patients treated with placebo. Endoscopic healing is an important outcome for long-term disease control; 37.3 percent of patients in the TREMFYA-combined group compared with 11.8 percent in the placebo group achieved endoscopic response after only 12 weeks of induction treatment ($p < 0.001$).¹

“For patients living with moderately to severely active Crohn’s disease, including those who have not had an adequate response or have intolerance to other therapies, these results show that TREMFYA may play an important role as a new treatment option pending results from the ongoing registration trials,” said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “Although more research is needed, we are encouraged by the data and the potential role for selective IL-23 inhibition in helping patients manage their Crohn’s disease symptoms and treating the underlying disease process.”

TREMFYA demonstrated a safety profile consistent with that established from prior clinical trials across approved indications. Observed adverse events (AEs) were generally similar amongst treatment groups and placebo through week 12. In the TREMFYA 200, 600, 1200 mg IV and placebo treatment groups, serious AEs occurred in 4 percent, 4 percent, 2 percent and 4 percent, and serious infections occurred in 2 percent, 0 percent, 0 percent and 0 percent of patients, respectively. There were no reported deaths in TREMFYA-treated patients, and no TREMFYA-treated patient had active tuberculosis, serious hypersensitivity reactions or malignancies.¹

About the GALAXI 1 trial^{1,3}

GALAXI 1 is a double-blind, placebo-controlled, multicenter Phase 2 dose-ranging study evaluating the efficacy and safety of TREMFYA® (guselkumab) in patients with moderately to severely active Crohn’s disease with inadequate response/intolerance to conventional therapies (corticosteroid, immunosuppressive) and/or biologics (TNF antagonist,

vedolizumab). Patients will receive treatment through up to 3 years.

Interim analyses at week 12 evaluated the key outcomes of change in CDAI score from baseline, clinical remission (CDAI<150), clinical response (decrease from baseline in CDAI \geq 100 or CDAI<150), PRO-2 remission (abdominal pain mean daily score \leq 1 and mean daily stool frequency score \leq 3), clinical biomarker response (clinical response and \geq 50% reduction from baseline in C-reactive protein or fecal calprotectin), endoscopic response (\geq 50% improvement from baseline in the SES-CD), and safety in patients treated with TREMFYA compared with placebo. The efficacy and safety of the reference arm (ustekinumab) compared with placebo was also evaluated and demonstrated.

About Crohn's disease (CD)

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated 3 million Americans.⁴ 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.⁵ Symptoms of CD can vary but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever.^{5,6} There is currently no cure for CD.⁶

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.² 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).² 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.⁷

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.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the Phase 2 Week 12 interim study of TREMFYA® (guselkumab) in Crohn's disease. 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, and 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.

ⁱDr William J. Sandborn is a paid consultant for Janssen. He has not been compensated for any media work.

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References

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