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For immediate release

TREMFYA® (guselkumab) demonstrates superiority versus STELARA® (ustekinumab) in Phase 3 Crohn's disease program

Data from GALAXI 2 & 3 showed TREMFYA® was superior to STELARA ® in all pooled endoscopic endpoints

Washington, D.C. (May 21, 2024) – Johnson & Johnson today announced the first Phase 3 results for TREMFYA® (guselkumab) in adult patients with moderately to severely active Crohn's disease (CD), which demonstrated superiority of both subcutaneous (SC) maintenance doses (200 mg every 4 weeks [q4w] and 100 mg every 8 weeks [q8w]) versus placebo and ustekinumab.[1] Data showed that both maintenance doses of TREMFYA® met the composite co-primary endpoints compared to placebo in each individual study.[1,b] In results versus ustekinumab, both doses of TREMFYA® demonstrated statistically significant and clinically meaningful differences on all prespecified pooled endoscopic endpoints.[1] These findings were featured as a late-breaking oral presentation (Abstract #1057b) at Digestive Disease Week (DDW) 2024.[1]

The GALAXI 2 (n=508) and GALAXI 3 (n=513) studies were the first-ever double-blind registrational head-to-head clinical trials to demonstrate superiority versus ustekinumab in CD.[1] A summary of select data from the 48-week pooled, multiplicity-controlled endpoints is as follows:[1]

	Endpoint	**TREMFYA® 200mg SC q4w versus ustekinumab**	**TREMFYA® 100mg SC q8w versus ustekinumab**	**Ustekinumab**
Endoscopic endpoints	Endoscopic response[d]	52.7% (p<0.001)	47.9% (p=.009)	37.1%
	Endoscopic remission[e]	37.2% (p=0.001)	33.2% (p=0.024)	24.7%
	Clinical remission and endoscopic response	47.3% (p<0.001)	41.6% (p=0.049)	33.7%
	Deep remission[f]	33.8% (p=0.002)	29.7% (p=0.040)	22.3%
Clinical endpoint	Clinical remission[g]	70.3% (p=.058)	65.4% (p=.512)	62.9%

"These results are promising for those who continue to experience persistent and debilitating symptoms and offer the possibility of guselkumab as a future-first advanced therapy or after failure of other advanced therapies that may deliver the lasting remission patients deserve to relieve the burden of disease," said Remo Panaccione, M.D., Professor of Medicine, University of Calgary and lead study investigator.[a] "The GALAXI program demonstrates the potential of guselkumab and this targeted IL-23 approach for rapid and sustained efficacy in the treatment of Crohn's disease."

TREMFYA® has a well-studied safety profile and years of patient experience in approved indications and earlier inflammatory bowel disease trials. In the GALAXI program, the safety profile was consistent with that of the currently approved indications.[1] Through Week 48, the number of patients with at least one or more (≥1) adverse events (AE), ≥1 serious AEs, and AEs leading to discontinuation were similar across patients who received TREMFYA®, placebo, or ustekinumab.[1] The proportions of patients with serious infections and AEs of interest were low.[1]

"The Phase 3 GALAXI program, comprised of two rigorous, double-blind studies with secondary endpoints comparing TREMFYA to ustekinumab, reiterate our dedication to addressing the needs of patients with Crohn's disease and our deep scientific expertise in inflammatory bowel disease and focused innovation in the IL-23 pathway," said David Lee, M.D., Ph.D., Global Therapeutic Area Head Immunology, Johnson & Johnson Innovative Medicine. "These findings demonstrate the

promise of TREMFYA for patients living with moderately to severely active Crohn's disease compared to conventional and advanced therapies."

This year, Janssen-Cilag International NV, a Johnson & Johnson company, announced submission of applications to the European Medicines Agency (EMA) seeking to expand the Marketing Authorization Application for TREMFYA® to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) and moderately to severely active CD. Additionally, Johnson & Johnson submitted regulatory applications seeking the approval of TREMFYA® for the treatment of adults with moderately to severely active UC in countries or regions including the United States and Europe.

Editor's Notes:

a. Dr. Panaccione is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.
b. TREMFYA® is not currently approved to treat Crohn's disease.
c. Design in which patients in the active treatment arms remained on the therapy to which they were initially randomized, regardless of clinical response at Week 12, with the exception of nonresponders in the placebo arm, who crossed over to blinded ustekinumab treatment.[1]
d. 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]
e. Endoscopic remission is defined as an endoscopy subscore of 0.[1]
f. Deep remission endpoint consists of clinical remission and endoscopic remission together.[1]
g. Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score of <150 (primary efficacy analysis set (nonresponder imputation)).[1]

ABOUT THE GALAXI PROGRAM (NCT03466411)

GALAXI is a randomized, double-blind, placebo-controlled, active-controlled (ustekinumab), global, multicenter Phase 2/3 program designed to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active Crohn's disease with inadequate response/intolerance to conventional therapies (immunomodulators, corticosteroids) and/or biologics (TNF antagonists, vedolizumab).[2] GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3).[1] Each GALAXI study employed a treat-through design in which participants remained on the treatment to which they were initially randomized, reflecting real-world clinical practice, and includes a long-term extension study that will assess clinical, endoscopic, and safety outcomes with guselkumab through a total of five years.[1]

ABOUT CROHN'S DISEASE

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans and an estimated four million people across Europe.[3,4] Crohn's disease 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 Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. There is currently no cure for Crohn's disease.[6]

ABOUT TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first approved fully-human, dual-acting monoclonal antibody that blocks IL-23 by binding to the p19 subunit of IL-23 and binding to CD64, a receptor on cells that produce IL-23.[7] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[7] Findings for dual acting are limited to in vitro studies that demonstrate guselkumab binds to CD64, which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model. The clinical significance of this finding is not known.[8,9,10,11]

TREMFYA® is approved in the U.S.,[7] Canada,[12] Japan[13] and a number of other countries for the treatment of adults with moderate-to-severe plaque psoriasis (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 psoriatic arthritis (PsA).[7] 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.[14]

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®.

IMPORTANT SAFETY INFORMATION

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

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 use 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 JOHNSON & JOHNSON

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JNJInnovMed. Janssen Research & Development, LLC and Janssen Biotech, Inc. 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 TREMFYA®. 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/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, 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. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. 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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