



## **News Release**

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## **Janssen Reports Positive Topline Week 48 Phase 2 Results for TREMFYA® (guselkumab) in Adults With Moderately to Severely Active Crohn's Disease**

*The Phase 3 GALAXI 2 and 3 studies are continuing to enroll*

**SPRING HOUSE, PENNSYLVANIA, November 17, 2021** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced topline results from the Phase 2 GALAXI 1 clinical trial which showed rates of clinical remission (Crohn's Disease Activity Index [CDAI]<150) previously reported at week 12 increased at week 48 among adults with moderately to severely active Crohn's disease (CD) treated with TREMFYA® (guselkumab).<sup>1</sup> At week 48, 65 percent of patients receiving TREMFYA achieved clinical remission. TREMFYA is under investigation and not currently approved for the treatment of CD in the U.S.<sup>2</sup>

Janssen [previously announced](#) week 12 interim analyses from the 48-week, double-blind, placebo-controlled, multicenter Phase 2 dose-ranging GALAXI 1 study. The

primary endpoint of the Phase 2 study is change from baseline in CDAI scores at week 12 in patients treated with TREMFYA compared to placebo.<sup>3</sup> Overall, all TREMFYA treatment groups during the 48-week treatment period in GALAXI 1 had comparable safety data, consistent with the known safety profile for TREMFYA.

“We look forward to sharing the comprehensive GALAXI 1 48-week results at an upcoming scientific medical meeting while we continue to progress and enroll patients in the pivotal Phase 3 GALAXI 2 and 3 studies,” said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC.

The 48-week GALAXI 1 results mark the first long-term data evaluating TREMFYA in moderately to severely active CD.<sup>2</sup> Phase 3 clinical trials evaluating TREMFYA for the treatment of moderately to severely active CD and moderately to severely active ulcerative colitis are ongoing and enrolling participants. Learn more through the [Janssen Global Trial Finder](#).

### **About GALAXI 1<sup>2</sup>**

GALAXI 1 is a double-blind, placebo-controlled, 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 (corticosteroid, immunosuppressives) and/or biologics (TNF antagonists, vedolizumab).

Participants 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 the reference arm, ustekinumab, dosed at ~6mg/kg IV at week 0 and then dosed at 90 mg subcutaneously (SC) at week 8; or IV placebo. Comparison with placebo was not conducted beyond week 12.

The primary endpoint of the Phase 2 GALAXI 1 study is change from baseline in CDAI scores at week 12. Additional key outcomes evaluated at week 12 include

clinical remission (CDAI<150), clinical response (decrease from baseline in CDAI  $\geq$ 100 or CDAI<150), Patient Report Outcome (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 percent reduction from baseline in C-reactive protein or fecal calprotectin), endoscopic response ( $\geq$ 50 percent improvement from baseline in the SES-CD), and safety in participants treated with TREMFYA compared with placebo. Participants may receive treatment through five years.

### **About Crohn's Disease (CD)**

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans.<sup>4</sup> 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.<sup>5</sup> Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever.<sup>6</sup> There is currently no cure for CD.<sup>7</sup>

### **About TREMFYA® (guselkumab)<sup>2</sup>**

Developed by Janssen, TREMFYA 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. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque psoriasis (PsO) and active psoriatic arthritis (PsA).<sup>8</sup> TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque PsO who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA. 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.

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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

### **About STELARA® (ustekinumab)<sup>9</sup>**

STELARA® is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the interleukin (IL)-12 and IL-23 pathways. Janssen commercializes STELARA® in the U.S., European Union, and in countries around the world. STELARA® is approved in the U.S. for the treatment of: 1) adults and children six years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; 2) adult patients (18 years or older) with active psoriatic arthritis, used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active CD; 4) adult patients (18 years and older) with moderately to severely active UC.

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

### **IMPORTANT SAFETY INFORMATION**

STELARA® (ustekinumab) is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects including:

### **Serious Infections**

STELARA® may lower your ability to fight infections and may increase your risk of infections. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.

### **Before starting STELARA®, tell your doctor if you:**

- think you have an infection or have symptoms of an infection such as:
  - fever, sweats, or chills
  - muscle aches
  - cough
  - shortness of breath
  - blood in phlegm
  - weight loss
  - warm, red, or painful skin or sores on your body
  - diarrhea or stomach pain
  - burning when you urinate or urinate more often than normal
  - feel very tired
- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

**After starting STELARA<sup>®</sup>, call your doctor right away** if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. STELARA<sup>®</sup> can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take STELARA<sup>®</sup> may also be more likely to get these infections.

### **Cancers**

STELARA<sup>®</sup> may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA<sup>®</sup>. Tell your doctor if you have any new skin growths.

### **Posterior Reversible Encephalopathy Syndrome (PRES)**

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.

### **Serious Allergic Reactions**

Serious allergic reactions can occur. Stop using STELARA<sup>®</sup> and get medical help right away if you have any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

### **Lung Inflammation**

Cases of lung inflammation have happened in some people who receive STELARA<sup>®</sup> and may be serious. These lung problems may need to be treated in a



hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

**Before receiving STELARA®, tell your doctor about all of your medical conditions, including if you:**

- have any of the conditions or symptoms listed above for serious infections, cancers, or PRES.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your doctor if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can cause serious problems. **You should not receive the BCG vaccine during the one year before receiving STELARA® or one year after you stop receiving STELARA®.**
- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your doctor should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk.
- talk to your doctor about the best way to feed your baby if you receive STELARA®.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the

medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

**When prescribed STELARA®:**

- Use STELARA® exactly as your doctor tells you to.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that STELARA® be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.

**Common side effects of STELARA® include:** nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain, and joint pain. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

**Please click to read the full [Prescribing Information](#) and [Medication Guide](#) for STELARA® and discuss any questions you have with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call [1-800-FDA-1088](tel:1-800-FDA-1088).**

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**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](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://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 TREMFYA® (guselkumab) product development. 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 January 3, 2021, 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](http://www.sec.gov), [www.jnj.com](http://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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## References

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