News Release

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The Majority of Adults with Moderately to Severely Active Crohn's Disease in a Phase 2 Study Achieved Clinical Remission and Corticosteroid-Free Remission Through 48 Weeks with TREMFYA® (guselkumab)

New long-term data show proportions of patients achieving clinical remission ranged from 57.4-73 percent across three TREMFYA dose groups in the Phase 2 GALAXI 1 study

The majority of patients in clinical remission were also in corticosteroid-free remission with rates ranging from 55.7-71.4 percent

Phase 3 GALAXI studies are continuing to enroll

SPRING HOUSE, PENNSYLVANIA, February 18, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new results from the Phase 2 GALAXI 1 clinical trial showing the majority (57.4-73 percent) of adults with moderately to severely active Crohn's disease (CD) who were treated with TREMFYA® (guselkumab) achieved clinical remission (Crohn's Disease Activity Index [CDAI]<150)[a] at week 48.[1] The week 48 results also show the majority (57.4-73 percent) of patients who achieved clinical remission with TREMFYA were free of

corticosteroid treatment.[1,b] TREMFYA is not currently approved for the treatment of CD in the U.S.[2] These data are being presented today as an oral presentation (OP24) at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO), taking place virtually from February 16-19.[1]

"These 48-week GALAXI 1 data represent a major step in the development of TREMFYA," said presenting study author Professor Silvio Danese, Director, Gastroenterology and Endoscopy, IRCCS Ospedale San Raffaele and University Vita-Salute San Raffaele, Milan, Italy.[c] "Further, remission was achievable for patients in this study without corticosteroids, which is important to note as avoidance of long-term steroid use is an important consideration when treating these patients."

Week 48 results show:[d]

- **Clinical remission:[a]** 63.9 percent of patients treated with TREMFYA 200 mg intravenous (IV)/100 mg subcutaneous (SC), 73 percent treated with TREMFYA 600 mg IV/200 mg SC and 57.4 percent treated with TREMFYA 1200 mg IV/200 mg SC achieved clinical remission.[1,a] With STELARA® (ustekinumab), which was used as a reference arm, 58.7 percent of patients achieved clinical remission.[1] The study was not powered to evaluate differences between treatment groups.[1]
- **Corticosteroid-free clinical remission:[b]** 59 percent of patients treated with TREMFYA 200 mg IV/100 mg SC, 71.4 percent treated with TREMFYA 600 mg IV/200 mg SC, and 55.7 percent treated with TREMFYA 1200 mg IV/200 mg SC, achieved corticosteroid-free clinical remission[b] (CDAI<150 and no corticosteroid therapy at week 48). The proportion of patients in the STELARA group was 58.7 percent.[1]
- **Patient-Reported Outcome (PRO)-2 remission:[e]** 57.4 percent of patients treated with TREMFYA 200 mg IV/100 mg SC, 69.8 percent treated with TREMFYA 600 mg IV/200 mg SC, and 50.8 treated with TREMFYA 1200 mg IV/200 mg SC achieved PRO-2 remission.[1,e] The proportion of patients in the STELARA group was 46 percent.[1]

All TREMFYA dose groups during the 48-week treatment period in GALAXI 1 had

comparable safety data, consistent with the known safety profile for TREMFYA in approved indications.[1,2] Key safety event rates were similar among the three dosing groups.[1] In the TREMFYA 200 mg IV/100 mg SC, 600 mg IV/200 mg SC, 1200 mg IV/200 mg SC and STELARA groups, adverse events (AEs) occurred in 71.2 percent, 80.8 percent, 69.9 percent, and 84.5 percent, respectively.[1] Serious adverse events (SAEs) occurred in 8.2 percent, 6.8 percent, 6.8 percent, and 12.7 percent, respectively.[1] No opportunistic infections, cases of tuberculosis, or deaths were reported in any group.[1] Infections[f] occurred in 34.2 percent, 41.1 percent, 34.2 percent, and 36.6 percent, respectively.[1] Serious infections occurred in 2.7 percent, 2.7 percent, 1.4 percent, and 1.4 percent, respectively.[1]

"With a life-long progressive condition like Crohn's disease, it's critical to investigate potential new treatment options with the understanding that remission is the ultimate goal," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "These new data underscore Janssen's continued commitment to investigating pathway science with TREMFYA in the development of additional therapies that can potentially address the multifaceted nature of immune-mediated diseases like Crohn's disease."

Janssen previously announced results from the 12-week interim analysis and top-line 48-week data from the GALAXI Phase 2 study.[3,4] Phase 3 clinical trials evaluating TREMFYA for the treatment of moderately to severely active CD are ongoing and actively enrolling participants. Learn more through the Janssen Global Trial Finder.

Editor's Notes:

a. Clinical remission is defined as a CDAI score of <150.[1]
b. Corticosteroid-free clinical remission is defined as a CDAI score <150 at week 48 and not receiving corticosteroids at week 48.[1]
c. Professor Danese is a paid consultant for Janssen. He has not been compensated for any media work.
d. Please see the 'About GALAXI 1' section below for further details regarding

the study design.

e. PRO-2 remission is defined as the unweighted CDAI component of daily average abdominal pain (AP) score ≤1 and the unweighted CDAI component of daily average stool frequency (SF) ≤3, and no worsening of AP or SF from baseline.[1]
f. Infections as assessed by the investigator.

About GALAXI 1 (NCT03466411; EudraCT 2017-002195-13)[5,6]

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).

Participants were randomized equally into five treatment arms, including treatment with TREMFYA dosed at 200, 600 or 1200 mg IV at weeks 0, 4 and 8, respectively; or treatment with the reference arm, STELARA, dosed at ~6 mg/kg IV at week 0 and then dosed at 90 mg 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.[7] All three induction doses of TREMFYA significantly improved CDAI scores from baseline as compared to placebo, with placebo-subtracted Least Squares Mean changes of 124.2 ($p<0.001$), 102.7 ($p<0.001$), and 108.7 ($p<0.001$) for the 200 mg IV, 600 mg IV, and 1200 mg IV groups, every four weeks, respectively. Additional key outcomes evaluated at week 12 include clinical remission (CDAI<150), clinical response (decrease from baseline in CDAI ≥100 or CDAI<150), PRO-2 remission (AP mean daily score ≤1 and mean daily stool frequency score ≤3), clinical biomarker response (clinical response and ≥50 percent reduction from baseline in C-reactive protein or fecal calprotectin), endoscopic response (≥50 percent improvement from baseline in the SES-CD), and safety in participants treated with TREMFYA compared with placebo.[7] Participants may

receive treatment through five years.

The 48-week analyses report the results of the 248 patients in the maintenance phase.[1] After completing 12 weeks of therapy, patients transitioned to their long-term maintenance treatments as follows: patients receiving TREMFYA 200 mg IV were shifted to TREMFYA 100 mg SC dose every eight weeks; patients receiving TREMFYA dosed at 600 mg IV or 1200 mg IV changed to TREMFYA 200 mg SC every four weeks; patients receiving STELARA continued with a 90 mg SC dose every eight weeks; placebo non-responders began STELARA IV followed by STELARA SC every eight weeks; and placebo responders continued on a placebo SC every four weeks.[1]

About Crohn's Disease

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans.[8] 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.[9] Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever.[10] There is currently no cure for CD.[11]

About TREMFYA® (guselkumab)[2]

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. 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 psoriasis (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 psoriatic arthritis (PsA). It is also approved in the European Union (EU) for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy, and alone or in combination with methotrexate (MTX) 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 (DMARD).

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 STELARA® (ustekinumab)[12]

STELARA is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways.[12,13] Janssen commercializes STELARA® in the U.S., EU, 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.[12]

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®, 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® 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® may also be more likely to get these infections.

Cancers

STELARA® 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®. 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® 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® 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 or call 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. 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 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 2, 2022, 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 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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