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NEWS RELEASE

TREMFYA® (guselkumab) long-term data show sustained clinical and endoscopic remission in ulcerative colitis through 3 years

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More than 80% of those treated with TREMFYA® were in clinical remission and more than 50% were in endoscopic remission at Week 140 of the QUASAR long-term extension study, showing lasting disease control for patients

78% of patients achieved intestinal healing at both the tissue and visual level (histo-endoscopic mucosal improvement)

STOCKHOLM, Feb. 21, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new long-term data from the QUASAR long-term extension (LTE) study showing that TREMFYA® (guselkumab) sustained clinical, endoscopic, and histologic outcomes through Week 140 in adults with moderately to severely active ulcerative colitis (UC). These data are among the 30 company-sponsored abstracts being presented at the European Crohn's and Colitis Organisation (ECCO) 2026 conference.

At Week 140, 80.8% of patients taking TREMFYA® were in clinical remission[a]. Additionally, 78.6% of patients achieved histo-endoscopic mucosal improvement (HEMI)[b], and 53.6% of patients were in endoscopic remission[c], respectively.[d] Approximately 89% of eligible study participants combined completed treatment through Week 140. Nearly all participants who achieved clinical remission at Week 140 were corticosteroid-free for at least eight weeks.[1]

The study also showed that of those in clinical remission at Week 44, 87.5% maintained clinical remission through Week 140. Efficacy was sustained regardless of prior biologic and/or JAK inhibitor treatment history, and no new safety concerns were observed.[1]

"Ulcerative colitis is a lifelong condition that can significantly impact patients' overall health and they need treatment options that remain effective and well-tolerated over time," said Laurent Peyrin-Biroulet, MD, PhD, study investigator.[e] "The QUASAR long-term study shows the sustained ability of TREMFYA to deliver durable results, with consistent outcomes regardless of previous biologic or JAK inhibitor treatment. With high study retention and no new safety concerns over this extended time period, the data strengthen confidence in the long-term use of TREMFYA in ulcerative colitis."

"These findings highlight the endoscopic outcomes that can be achieved with TREMFYA, raising expectations for what is possible for patients with ulcerative colitis," said Esi Lamousé-Smith, MD, PhD, Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson. "Patients who achieve endoscopic remission experience fewer flare-ups and are less likely to need steroids or require surgery over time. We are energized by these findings and remain focused on delivering treatments that help more patients achieve meaningful, lasting disease control."

TREMFYA® is the first and only approved, dual-acting monoclonal antibody that blocks IL-23 while also binding to CD64, a receptor on cells that produce IL-23. IL-23 is a cytokine secreted by activated monocyte/macrophages and dendritic cells that is known to be a driver of immune-mediated diseases. Findings are based on in vitro studies.[2 3 4 5 6]

TREMFYA® has received U.S. Food and Drug Administration (FDA) and European Commission (EC) approval for both SC and IV induction options for the treatment of adults with moderately to severely active Crohn's disease and U.S. FDA approval for both SC and IV induction options for the treatment of adults with moderately to severely active ulcerative colitis. TREMFYA® is approved by the EC for the treatment of adult patients with moderately to severely active ulcerative colitis and is currently administered via an IV induction regimen, followed by a SC maintenance regimen.

Two other Johnson & Johnson-sponsored abstracts were selected as Top 10 oral abstracts by ECCO, highlighting continued commitment to providing treatment options to those with inflammatory bowel disease:

- Results from the Phase 2b ANTHEM-UC study of icotrokinra, the first targeted oral peptide that selectively blocks the interleukin-23 receptor, demonstrating its impact on systemic and tissue biomarkers of inflammatory burden in UC.[7]
- Primary safety results from the UNITI Jr study of STELARA® (ustekinumab) showing that it was effective and well-tolerated, with no new safety signals, in treating pediatric patients with Crohn's disease.[8]

For a full list of all Johnson & Johnson data being presented at ECCO visit: **https://www.jnj.com/innovativemedicine/immunology/gastroenterology**.

Editor's Notes:

a. Clinical remission was defined as a Mayo stool frequency subscore of 0 or 1 and not increased from induction baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopic subscore (MES) of 0 or 1.
b. Histo-endoscopic mucosal improvement was defined as a combination of endoscopic improvement and histologic improvement (neutrophil infiltration in <5% of crypts, no crypts destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system.
c. Endoscopic remission (normalization) was defined as a MES of 0.
d. As observed. Data were analyzed using 2 methods: 'nonresponder imputation' (NRI) accounting for patients with treatment failure or missing data, and 'as observed'. NRI results were consistent with as observed.
e. Dr. Laurent Peyrin-Biroulet is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

About the QUASAR Program (**NCT04033445**)

QUASAR is a randomized, double-blind, placebo-controlled, parallel group, multicenter, Phase 2b/3 program designed to evaluate the efficacy and safety of TREMFYA® in adults with moderately to severely active ulcerative colitis who had an inadequate response or intolerance to conventional therapy (e.g., thiopurines or corticosteroids), prior biologics (TNF antagonists or vedolizumab) and/or JAK inhibitors (tofacitinib). QUASAR included a Phase 2b dose-ranging induction study, a confirmatory Phase 3 induction study, and a Phase 3 randomized withdrawal maintenance study. In the Phase 3 induction study, patients received either TREMFYA® 200 mg or placebo by IV infusion at Weeks 0, 4, and 8. In the Phase 3 maintenance study, patients received a SC maintenance regimen of either TREMFYA® 200 mg q4w, TREMFYA® 100 mg q8w, or placebo. The ongoing long-term extension study provides an additional 4 years of treatment. Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.[9]

About ANTHEM-UC (NCT06049017)

ANTHEM-UC is a Phase 2b multicenter, randomized, placebo-controlled, dose-ranging study to evaluate the efficacy and safety of icotrokinra (JNJ-77242113, JNJ-2113) in patients with moderately to severely active ulcerative colitis who had an inadequate response or intolerance to conventional therapy (e.g., thiopurines or corticosteroids), prior biologics (TNF antagonists or vedolizumab) and/or ozanimod or approved JAK inhibitors. The study is evaluating three once-daily dosages of icotrokinra taken orally. Participants who complete the Week 28 assessments and have achieved clinical response at Week 28 and who, in the opinion of the investigator, will continue to benefit from treatment with study intervention will continue in the 48-week long term extension (LTE) period and receive the same treatment up to Week 76.[10]

About UNITI JR (NCT04673357)

UNITI-Jr is a randomized, double-blind Phase 3 study evaluating the efficacy, safety, and pharmacokinetics of ustekinumab in 48 pediatric patients (aged 2-17) with moderately to severely active Crohn's disease (defined by a Pediatric Crohn's Disease Activity Index [PCDAI] score >30) through 52 weeks of treatment (8 weeks of induction and 44 weeks of maintenance treatment).1,3 The study included an open-label induction treatment with a single ustekinumab intravenous dose of approximately 6mg/kg followed by a randomized double-blind subcutaneous maintenance regimen of 90mg administered either every 8 weeks or every 12 weeks.

About Ulcerative Colitis

Ulcerative colitis (UC) is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus. It is the result of the immune system's overactive response. Symptoms vary but may typically include loose and more urgent bowel movements, rectal bleeding or bloody stool, persistent diarrhea, abdominal pain, loss of appetite, weight loss, and fatigue.[11]

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.[12] [13] 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.[14] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Currently no cure is available for Crohn's disease.[15]

About TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first fully-human, dual-acting monoclonal antibody designed to neutralize inflammation at the cellular source by blocking IL-23 and binding to CD64 (a receptor on cells that produce IL-23). Findings for the dual-acting mechanism 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.

TREMFYA® is a prescription medicine approved in the U.S. to treat:

- adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.
- adults with moderately to severely active Crohn's disease.

TREMFYA® is approved in Europe, Canada, Japan, and a number of other countries for the treatment of adults with moderate-to-severe plaque psoriasis, adults with active psoriatic arthritis, adults with moderate-to-severe Crohn's disease and adults with moderate-to-severe ulcerative colitis.

The legal manufacturer for TREMFYA® is Janssen Biotech, Inc.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®. For more information, visit: **www.tremfya.com**.

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to precisely block the IL-23 receptor[16], which underpins the inflammatory response in moderate-to-severe plaque psoriasis, ulcerative colitis and offers potential in other IL-23-mediated diseases.[17] [18] Icotrokinra binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, precise inhibition of IL-23 signaling in human T cells.[19] The license and collaboration agreement established between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc., a Johnson & Johnson company, in 2017 enabled the companies to work together to discover and develop next-generation compounds that ultimately led to icotrokinra.[20]

Icotrokinra was jointly discovered and is being developed pursuant to the license and collaboration agreement between Protagonist and Johnson & Johnson. Johnson & Johnson retains exclusive worldwide rights to develop icotrokinra in Phase 2 clinical trials and beyond, and to commercialize compounds derived from the research conducted pursuant to the agreement against a broad range of indications.[21] [22] [23]

Icotrokinra is being studied in the pivotal Phase 3 ICONIC clinical development program in moderate-to-severe plaque psoriasis, active psoriatic arthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.

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:

o fainting, dizziness, feeling lightheaded (low blood pressure)
o swelling of your face, eyelids, lips, mouth, tongue or throat
o trouble breathing or throat tightness
o chest tightness
o skin rash, hives
o 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:

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o fever, sweats, or chills
o muscle aches
o weight loss
o cough
o warm, red, or painful skin or sores on your body different from your psoriasis
o diarrhea or stomach pain
o shortness of breath
o blood in your phlegm (mucus)
o burning when you urinate or urinating more often than normal

- Liver problems. With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA®. Your healthcare provider may stop treatment with TREMFYA® if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:

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o unexplained rash
o vomiting
o tiredness (fatigue)
o yellowing of the skin or the whites of your eyes
o nausea
o stomach pain (abdominal)
o loss of appetite
o dark urine

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. Pregnancy Registry: If you become pregnant during treatment with TREMFYA®, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA®. You can enroll by visiting **www.mothertobaby.org/ongoing-study/tremfya-guselkumab**, by calling **1-877-311-8972**, or emailing **MotherToBaby@health.ucsd.edu**. The purpose of this registry is to collect information about the safety of TREMFYA® during pregnancy.
- 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: respiratory tract infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, stomach pain, 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**.

Dosage Forms and Strengths: TREMFYA® is available as 100 mg/mL and 200 mg/2mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

WHAT IS STELARA® (ustekinumab)?

STELARA® is a prescription medicine used to treat:

- adults and children 6 years of age and older with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years of age and older with active psoriatic arthritis.
- adults with moderately to severely active Crohn's disease.
- adults with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

STELARA® 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. Some people have serious infections during treatment with STELARA®, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your healthcare provider should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment

Before starting STELARA®, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:

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o fever, sweats, or chills
o muscle aches
o cough
o shortness of breath
o blood in phlegm
o weight loss
o warm, red, or painful skin or sores on your body
o diarrhea or stomach pain
o burning when you urinate or urinate more often than normal
o 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 healthcare provider 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 healthcare provider 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 healthcare provider if you have any new skin growths.

Serious Allergic Reactions

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

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. Tell your healthcare provider right away if you get any symptoms of PRES during treatment with STELARA®, including: headache, seizures, confusion, and vision problems.

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 healthcare provider right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before you use or receive STELARA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections or cancers.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your healthcare provider 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 are being treated with STELARA® should avoid receiving live vaccines. Tell your healthcare provider 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 avoid receiving 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 healthcare provider should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. STELARA® can pass into your breast milk.
- talk to your healthcare provider about the best way to feed your baby if you receive STELARA®.

Tell your healthcare provider 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 healthcare provider and pharmacist when you get a new medicine.

When prescribed STELARA®:

- Use STELARA® exactly as your healthcare provider tells you to. The healthcare provider will determine the right dose of STELARA®, the amount for each injection, and how often it should be given. Be sure to keep all scheduled follow-up appointments.
- STELARA® is intended for use under the guidance and supervision of your healthcare provider. In children, it is recommended that STELARA® be administered by a healthcare provider. If your healthcare provider decides that you or a caregiver may give your injections of STELARA® at home, you or a caregiver should receive training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® until you have been shown how to inject STELARA® by a healthcare provider.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, influenza, 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 read the full **Prescribing Information** and **Medication Guide** for STELARA® and discuss any questions you have with your doctor.

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.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to 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 Johnson & Johnson. Risks and uncertainties include, but are not limited to: competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and 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 most recent Annual Report on Form 10-K, 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**, **www.investor.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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