Johnson&Johnson

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For immediate release

Johnson & Johnson submits supplemental Biologics License Application to U.S. FDA seeking approval of TREMFYA® (guselkumab) for the treatment of adults with moderately to severely active ulcerative colitis

Submission is supported by data from the Phase 3 QUASAR program, which showed a significantly greater percentage of patients with moderately to severely active ulcerative colitis who received TREMFYA® achieved clinical remission at Week 44 compared with placebo

SPRING HOUSE, Pa. (March 11, 2024) – Johnson & Johnson today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of TREMFYA® (guselkumab) for treatment of adults with moderately to severely active ulcerative colitis (UC). The submission is based on results from the Phase 3 QUASAR program evaluating the efficacy and safety of TREMFYA® in the treatment of individuals living with moderately to severely active UC who had an inadequate response or intolerance to conventional therapy, prior biologics and/or JAK inhibitors.[1] The data show statistically significant and clinically meaningful improvements in symptoms, patient-reported outcomes such as fatigue and measures of disease activity including high bar endpoints such as endoscopic and histologic remission.[2,3] The safety results were consistent with the known safety profile of TREMFYA® in approved indications.[2,3,a]

“Despite advances in therapy, many people living with ulcerative colitis still experience inadequate response to or do not tolerate existing therapies,” said David Lee, MD, PhD, Global Therapeutic Area Head Immunology. “TREMFYA has the potential to be a new treatment option for patients. We look forward to working with the FDA in review of this application and remain focused on developing new therapies for those living with chronic autoimmune conditions, such as ulcerative colitis, who are experiencing persistent and debilitating symptoms.”

TREMFYA® is a dual-acting IL-23i that blocks IL-23 and binds to CD64, a receptor on cells that produce IL-23.[4] IL-23 is a cytokine secreted by activated monocyte/macrophages and dendritic cells that is known to be a driver of immune-mediated diseases including UC.[5] TREMFYA® was first approved in the U.S. in July 2017 for the treatment of adult patients with moderate-to-severe plaque psoriasis and was subsequently also approved for adults with active psoriatic arthritis in July, 2020.[4]

Clinical data from the Phase 3 QUASAR induction study through 12 weeks were presented at the 2023 Digestive Disease Week (DDW) Annual Meeting[2] and results from the Phase 3 QUASAR maintenance study through 44 weeks will be presented at an upcoming medical meeting.

Editor’s Notes:

a. TREMFYA® is not approved to treat UC.

ABOUT THE QUASAR STUDY (NCT04033445)
QUASAR is a randomized, double-blind, placebo-controlled, parallel group, multicenter, seamless Phase 2b/3 program designed to evaluate the efficacy and safety of TREMFYA®, a selective IL-23 inhibitor, in adult 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 and/or JAK inhibitors (i.e., tumor necrosis factor-alpha antagonists, vedolizumab, or tofacitinib).[1] QUASAR included a Phase 2b dose-ranging induction study, a confirmatory Phase 3 induction study, and a Phase 3 maintenance study. Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.[1]

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.[6] It is the result of the immune

system's overactive response.[6] Symptoms vary, but may include loose and more urgent bowel movements, rectal bleeding or bloody stool, persistent diarrhea, abdominal pain, loss of appetite, weight loss and fatigue.[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.[4] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[5] 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.[7,8,9,10]

TREMFYA® is approved in the U.S.,[4] Canada,[11] Japan[12] 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).[4] 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.[13]

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

IMPORTANT SAFETY INFORMATION[3]

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.

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.

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 a Johnson & Johnson companies.

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