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For immediate release

Johnson & Johnson submits regulatory applications to European Medicines Agency for TREMFYA® (guselkumab) for treatment of patients with ulcerative colitis and Crohn's disease

Submission included data from the Phase 3 QUASAR program in ulcerative colitis and the Phase 3 GALAXI program in Crohn's disease, which each achieved their primary endpoints[1,2]

Beerse, Belgium (May 1, 2024) – Janssen-Cilag International NV, a Johnson & Johnson company, today announced it has submitted applications to the European Medicines Agency (EMA) seeking to expand the Marketing Authorization Application for TREMFYA® (guselkumab) to include the treatment of adult patients with moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.

The submission included data from the Phase 3 QUASAR program in ulcerative colitis and the Phase 3 GALAXI program in Crohn's disease.[1,2,3,4,5] In the Phase 3 QUASAR induction and maintenance studies, guselkumab achieved each primary endpoint and showed statistically significant and clinically meaningful improvements relative to placebo in symptoms, measures of disease activity including stringent endpoints such as endoscopic normalization and histo-endoscopic mucosal healing, and patient-reported outcomes such as fatigue.[1,3,4] The safety results were consistent with the known safety profile of guselkumab in approved indications.[3,4,a]

In the Phase 3 GALAXI 2 and 3 studies, guselkumab achieved co-primary endpoints at Week 12 and demonstrated statistically significant and clinically meaningful improvements relative to placebo in corticosteroid free clinical remission and endoscopic response at Week 48.[2,5] Safety results were consistent with the known safety profile of guselkumab in approved indications.[2,5]

"People living with chronic, immune-mediated disease such as ulcerative colitis and Crohn's disease often spend a considerable amount of time cycling from one treatment to another in search of relief and sustained remission," said David Lee, MD, PhD, Global Therapeutic Area Head Immunology. "This submission is an important step in our mission to develop novel, effective therapies for the millions of people worldwide living with ulcerative colitis and Crohn's disease who are experiencing persistent and debilitating symptoms."

Guselkumab 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.[6] 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 ulcerative colitis and Crohn's disease.[7] Guselkumab is approved in the European Union (EU) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy and for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[6]

"Inflammatory bowel disease, which includes ulcerative colitis and Crohn's disease, affects as many as four million people in Europe annually," said Ludovic de Beaucoudrey, PhD, Senior Director, Therapeutic Area Lead, Immunology, Janssen-Cilag Limited, a company of Johnson & Johnson. "We look forward to working closely with the EMA during review of these applications and are deeply committed to rapidly innovating for those patients who live with immune-mediated diseases like ulcerative colitis and Crohn's disease where considerable needs remain."

Clinical data from the Phase 3 QUASAR induction study through 12 weeks were presented at the 2023 Digestive Disease Week Annual Meeting and results from the Phase 3 QUASAR maintenance study through 44 weeks will be presented at an upcoming medical meeting.[3] Clinical data from the long-term extension of the GALAXI Phase 2 study through three years were presented at United European Gastroenterology Week 2023 and results from the Phase 3 studies through 48 weeks will be presented at an upcoming medical meeting.[5] In March 2024, Johnson & Johnson submitted a supplemental Biologics License Application to the U.S. Food and Drug Administration seeking approval of guselkumab for treatment of adults with moderately to severely active ulcerative colitis.

Editor's Notes:

a. Guselkumab is not approved to treat ulcerative colitis or Crohn's disease.

ABOUT THE QUASAR PROGRAM (EudraCT 2018-004002-25)
QUASAR is a randomized, double-blind, placebo-controlled, parallel group, multicenter, seamless Phase 2b/3 program designed to evaluate the efficacy and safety of guselkumab, 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 [TNF]-alpha antagonists, vedolizumab, or tofacitinib).[1] QUASAR includes a Phase 2b dose-ranging induction study, a confirmatory Phase 3 induction study, a Phase 3 randomized withdrawal maintenance study, and a long-term extension study through a total of 5 years.[1] Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.[1]

ABOUT THE GALAXI PROGRAM (EudraCT 2017-002195-13)
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).[2] Each GALAXI study employed a treat-through design in which participants remained on the treatment to which they were initially randomized and includes a long-term extension study that will assess clinical, endoscopic, and safety outcomes with guselkumab through a total of five years.[2]

ABOUT ULCERATIVE COLITIS
Ulcerative colitis 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.[8] It is the result of the immune system's overactive response.[8] 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.[8]

ABOUT CROHN'S DISEASE
Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated four million people across Europe.[9] 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.[10] 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.[11]

ABOUT TREMFYA® (guselkumab)
Developed by Johnson & Johnson, 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.[6] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[7]

TREMFYA® is approved in the U.S., Canada, Japan, and a number of other countries for the treatment of adults with moderate to severe plaque psoriasis 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.[12,13,14] It is also approved in the EU for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy and for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[6]

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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