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News Release

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First Phase 3 TREMFYA® (guselkumab) Data in Inflammatory Bowel Disease Show Positive Induction Results Among Patients with Moderately to Severely Active Ulcerative Colitis

Late-breaking data from the Phase 3 QUASAR Induction Study show statistically significant and clinically meaningful improvements among ulcerative colitis patients, including bio-naïve patients and those who have experienced treatment failure with advanced therapies

BEERSE, BELGIUM, 9 May, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new efficacy and safety data from the Phase 3 QUASAR Induction Study evaluating the investigational use of guselkumab in adults with moderately to severely active ulcerative colitis (UC)[a] who had an inadequate response or intolerance to conventional[b] and/or advanced therapies.[1,c] The data show

statistically significant and clinically meaningful improvements across symptomatic and histo-endoscopic outcome measures[1]. Safety data were also consistent with the known safety profile of guselkumab in approved indications.[1] These data, which were accepted as a late-breaking oral presentation to the Digestive Disease Week® (DDW) Annual Meeting, comprise one of Janssen's 17 oral and poster presentations at the conference taking place in Chicago, Illinois, 6-9 May 2023.

"Many people living with ulcerative colitis, especially those who have had inadequate response to other treatments, live with uncertainty and continue to experience debilitating symptoms," said study author Jessica R. Allegretti, M.D., M.P.H., Medical Director, Crohn's and Colitis Center at the Brigham and Women's Hospital, Boston, MA, USA.[d] "These Phase 3 data represent an important step in the advancement of a new treatment for moderately to severely active ulcerative colitis, as researchers continue to investigate therapeutic options that have the potential to provide relief for individuals at all stages of disease."

QUASAR Phase 3 Induction Study Outcomes (Abstract #913b):[1]

Among 701 patients[e] randomised 3:2 to receive intravenous (IV) guselkumab 200 mg or placebo at Weeks 0, 4, and 8, and observed through Week 12, results demonstrate:

- A significantly greater proportion of patients treated with guselkumab compared with placebo (22.6 percent versus 7.9 percent, $p<0.001$, $\Delta^f=14.9$ percent) achieved clinical remission[g] at Week 12, the study's primary endpoint[1]
- At Week 4, 22.6 percent of patients receiving guselkumab achieved symptomatic remission[h] versus 12.9 percent placebo ($p<0.001$, $\Delta=9.9$ percent). At Week 12, 49.9 percent of patients achieved symptomatic remission versus 20.7 percent placebo ($p<0.001$, $\Delta=29.4$ percent)[1]
- Compared to placebo, a greater proportion of guselkumab-treated patients at Week 12 achieved:
    - Clinical response[i] (61.5 percent versus 27.9 percent placebo [$p<0.001$, $\Delta=33.8$ percent])[1]

    - Endoscopic improvement[j] (26.8 percent versus 11.1 percent placebo [p<0.001, Δ=16.0 percent])[1]
    - Histo-endoscopic mucosal improvement[k] (23.5 percent versus 7.5 percent placebo [p<0.001, Δ=16.2 percent])[1]
    - Endoscopic normalisation[l] (15.0 percent versus 5.0 percent placebo [nominal p<0.001, Δ=10.1 percent])[1]
- Frequencies of treatment-emergent adverse events (AEs) in guselkumab-treated patients were generally comparable to placebo[1]
- There were numerically fewer serious AEs (2.9 percent guselkumab versus 7.1 percent placebo) and AEs leading to discontinuation (1.7 percent guselkumab versus 3.9 percent placebo) in guselkumab-treated patients compared with placebo[1]
- Overall, safety results through Week 12 were consistent with the known safety profile of guselkumab in approved indications[1]

"Results from the QUASAR study offer insights into the potential utility of guselkumab for people living with this lifelong chronic condition and reinforce the known safety profile of guselkumab observed in approved indications," said Kavitha Goyal, M.D., Head of Global Medical Affairs, Gastroenterology, Janssen Global Services, LLC. "Janssen continues to investigate IL-23 pathway science with guselkumab for treatment of complex immune-mediated diseases like ulcerative colitis, so that healthcare providers can have a range of treatment options that best fit patients' needs and can bring them closer to the goal of remission."

Further research is currently being conducted on guselkumab for the treatment of patients with inflammatory bowel disease, which includes ongoing Phase 3 trials in Crohn's disease (2017-002195-13, 2020-006165-11) and UC (2018-004002-25, 2002-000365-41).[2,3,4,5]

Guselkumab is not approved for the treatment of adults living with UC in the European Union (EU).[6]

Editor's Notes:

a. Defined as a baseline modified Mayo score of 5 to 9, inclusive of a rectal bleeding subscore ≥1 and an endoscopy subscore ≥2 evaluated during central review of video endoscopy[1]
b. i.e., thiopurines or corticosteroids[1]
c. i.e., tumour necrosis factor-alpha antagonists, vedolizumab or tofacitinib[1]
d. Dr. Allegretti is a paid consultant for Janssen. Dr. Allegretti has not been compensated for any media work.
e. Mean age, 40.5 years; female, 43.1 percent; mean UC duration, 7.5 years; mean modified Mayo score, 6.9; Mayo endoscopy subscore of 3 indicating severe disease, 67.9 percent; median faecal calprotectin, 1641.0mg/kg; median C-reactive protein, 4.2mg/L; baseline oral corticosteroid use, 43.1 percent. Baseline demographic and disease characteristics were balanced across the two treatment groups. While half of the patients were receiving a biologic for the first time, approximately 50 percent of patients had a prior failure to advanced therapies for UC, and nearly half (47.4 percent) of these patients failed two or more advanced therapy classes, reflecting highly refractory disease.[1]
f. Adjusted treatment difference based on Wald statistic with Cochran-Mantel-Haenszel weight[1]
g. Clinical remission: A Mayo stool frequency subscore of 0 or 1 and not increased from baseline, a Mayo rectal bleeding subscore of 0 and a Mayo endoscopy subscore of 0 or 1 with no friability present on the endoscopy[1]
h. Symptomatic remission: A stool frequency subscore of 0 or 1 and not increased from baseline and a rectal bleeding subscore of 0[1]
i. Clinical response: A decrease from baseline in the modified Mayo score by ≥30 percent and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1[1]
j. Endoscopic improvement: An endoscopy subscore of 0 or 1 with no friability present on the endoscopy[1]
k. Histo-endoscopic mucosal improvement: Achieving a combination of histologic improvement (neutrophil infiltration in <5 percent of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue according to the Geboes

grading system, i.e., Geboes score ≤3.1) and endoscopic improvement (endoscopy subscore of 0 or 1, with no friability present on the endoscopy) [1]

l. Endoscopic normalisation: An endoscopy subscore of 0[1]

About Digestive Disease Week® (DDW)

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers, and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from 6-9 May, 2023. The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About the QUASAR Study (NCT04033445;[7] EudraCT2018-004002-25)

The QUASAR study is designed to answer scientific questions pertaining to the efficacy and safety of guselkumab in the treatment of moderately to severely active UC.[7] Overall, the study evaluates long-term guselkumab treatment. Efficacy, safety, pharmacokinetics, immunogenicity and biomarkers are assessed at specified time points.[7] The QUASAR Phase 3 Induction Study is a randomised, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy and safety of guselkumab, an interleukin-23 p19 subunit antagonist, as induction therapy in patients with moderately to severely active UC who had an inadequate response or intolerance to conventional (i.e., thiopurines or corticosteroids) and/or advanced therapies (i.e., tumour necrosis factor-alpha antagonists, vedolizumab or tofacitinib).[1]

About Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD) is an umbrella term for two conditions – Crohn's disease (CD) and ulcerative colitis (UC) – that cause chronic inflammation of the gastrointestinal (GI) tract.[8] Prolonged inflammation results in damage to the GI

tract.[8] The exact cause of IBD is unknown but may be the result of the immune system's response to environmental triggers or genetic predisposition.[8] Symptoms may vary but may include persistent diarrhoea, abdominal pain, rectal bleeding, bloody stool, weight loss and fatigue.[8]

About Ulcerative Colitis

Ulcerative Colitis (UC) affects up to 2 million people in Europe.[9] It 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.[10] It is the result of the immune system's overactive response.[11] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[10]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab 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.[6,12] Guselkumab is approved in the EU for the treatment of moderate to severe plaque psoriasis (Pso) in adults who are candidates for systemic therapy, and alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[6] It is also 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.[12,13,14]

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

GUSELKUMAB IMPORTANT SAFETY INFORMATION

In controlled periods of clinical studies with guselkumab, adverse drug reactions (ADRs) that consisted of respiratory tract infections were very common (≥10 percent); increased transaminases, headache, diarrhoea, arthralgia, and injection site reactions were common (≥1 to <10 percent); and herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash were uncommon ADRs (≥0.1 percent to <1 percent).[6]

Please refer to the Summary of Product Characteristics for full prescribing information for guselkumab in Pso and PsA: https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf

ADRs should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. ADRs should also be reported to Janssen-Cilag Ltd on +44 (0) 1494 567447.

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 & Retina, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/EMEA.
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Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU, and Janssen Research & Development, LLC are each 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 product development of TREMFYA® (guselkumab). 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 materialise, 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 behaviour 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 1, 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 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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