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News Release

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**New Phase 3 TREMFYA® (guselkumab) Results in Ulcerative Colitis Show a
77 Percent Overall Clinical Response Rate and Early Symptom
Improvement**

Data from the QUASAR induction study of adults with moderate to severely active ulcerative colitis show clinically meaningful results at Weeks 12 or 24

Additional data show symptomatic response as early as one week after the first induction dose, with symptomatic improvements increasing through Week 12

BEERSE, BELGIUM, 23 October 2023 –Janssen Pharmaceuticals, Inc., a Johnson & Johnson Company, today announced new data from the QUASAR Phase 3 Induction Study demonstrating the efficacy and safety profile of guselkumab, a selective IL-23 p19 inhibitor, in patients with moderately to severely active ulcerative colitis (UC) through 24 weeks.¹ High rates of clinical response^a were observed at Weeks 12 or

24, with no new safety signals observed compared to the safety profile of guselkumab in its approved indications.¹

Symptomatic response^b and improvements in patient-reported outcomes of rectal bleeding and absolute stool number were observed as early as one week after a single IV induction dose, with symptomatic response evident in more than two-thirds of patients at Week 12.² These data are among Janssen's 20 oral and poster presentations at the American College of Gastroenterology (ACG) Annual Scientific Meeting, taking place in Vancouver, Canada, 20-25 October 2023.

"Ulcerative colitis is a complex immune-mediated disease that can cause a wide range of often-debilitating symptoms," said study author Jessica R. Allegretti, M.D., Medical Director, Crohn's and Colitis Center at the Brigham and Women's Hospital, Boston, MA, USA.^c "Results from the QUASAR studies support the potential of guselkumab as a durable and fast-acting treatment option."

QUASAR Cumulative Clinical Response Results Through Week 24:

- At Week 12, clinical response was achieved by a significantly higher percentage of guselkumab-treated patients (61.5 percent [259/421]) versus placebo (27.9 percent [78/280]).¹
- Among guselkumab-treated patients who were not in clinical response to IV induction therapy at Week 12 and who then received subcutaneous treatment for an additional 12 weeks, 55 percent (66/120) achieved clinical response at Week 24.¹
- Cumulative clinical response at Week 12 or 24 was achieved by 77.2 percent (325/421) of patients randomised to guselkumab at baseline.¹ Patients with or without a history of inadequate response/intolerance to biologics and JAK inhibitors benefited from continued treatment with subcutaneous guselkumab through Week 24.¹

QUASAR Cumulative Safety Results Through Week 24:

- Safety findings through the final safety visit were consistent with Week 12 results; no new safety signals were identified.¹
- The most frequent adverse events among guselkumab-treated patients (n=586) were COVID-19 (7.2 percent), anaemia (5.1 percent), and worsening UC (4.6 percent).¹

QUASAR Early Symptomatic Response Data: Week 1 Through Week 12:

- As early as Week 1 and increasing through Week 12, greater symptomatic improvements were seen in patients treated with guselkumab compared with placebo with treatment differences for guselkumab versus placebo evident across outcomes.²

Percentage of Patients Achieving Early Symptomatic Response ^{2,b}		
	guselkumab-treated patients	Placebo-treated patients
Week 1 (p<0.01)	28.3 percent	18.9 percent
Week 2 (p<0.01)	34.0 percent	23.6 percent
Week 4 (p<0.01)	53.2 percent	30.0 percent
Week 8 (p<0.01)	66.0 percent	39.6 percent
Week 12 (p<0.01)	71.7 percent	35.0 percent

Percentage of Patients with Stool Frequency Subscores of 0 or 1 ^{2,d}		
	guselkumab-treated patients	Placebo-treated patients
Week 2 (p<0.05)	26.1 percent	18.2 percent
Week 4 (p<0.001)	41.3 percent	25.4 percent
Week 8 (p<0.001)	53.4 percent	29.6 percent
Week 12 (p<0.001)	60.1 percent	31.8 percent

Percentage of Patients with Rectal Bleeding Subscores of 0 ^{2,e}		
	guselkumab-treated patients	Placebo-treated patients
Week 2 (p<0.110)	24.2 percent	19.3 percent
Week 4 (p<0.001)	36.8 percent	22.9 percent
Week 8 (p<0.001)	55.8 percent	33.2 percent
Week12 (p<0.001)	64.6 percent	28.6 percent

“Guselkumab continues to show that it has the potential to provide people living with ulcerative colitis with early, clinically meaningful results,” said Jan Wehkamp, MD, PhD, Vice President, Gastroenterology Disease Area Leader at Janssen. “We are committed to ongoing research of guselkumab in inflammatory bowel disease to give those living with the condition and providers more treatment options that fit their needs and help them achieve remission.”

Further research is currently being conducted on guselkumab for the treatment of patients with inflammatory bowel disease, which includes ongoing Phase 3 studies that are fully recruited and ongoing.³

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

Editor’s Notes:

- a. Clinical response was defined as 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
- b. Symptomatic response was defined as a decrease from induction baseline in the symptomatic Mayo score (sum of the stool frequency and the rectal bleeding subscores) by ≥ 30 percent and ≥ 1 point, with either a ≥ 1 point

decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.²

- c. Dr. Allegretti is a paid consultant for Janssen. She has not been compensated for any media work.
- d. A stool frequency subscore of 0 or 1 is indicative of normalisation or near normalisation of bowel habits.²
- e. Rectal bleeding subscores of 0 is indicative of resolution of rectal bleeding.²

About the QUASAR Study (NCT04033445; EudraCT 2018-004002-25)

The QUASAR study is designed to evaluate the efficacy and safety of guselkumab in the treatment of moderately to severely active UC. Overall, the study evaluates long-term guselkumab treatment.^{4,5} Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.^{4,5} 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, a selective IL-23 p19 inhibitor, 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).^{4,5,6}

About Ulcerative Colitis (UC)

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.⁷ It is the result of the immune system's overactive response.⁷ Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.⁸

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.^{4,9} 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.⁴ 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.^{9,10,11}

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).⁴

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 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 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, Janssen-Cilag International NV, 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, or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen-Cilag International NV, nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

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References

1. Rubin, D, *et al.* Cumulative Response to Guselkumab Through Week 24 of Induction in Patients with Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 QUASAR Induction Study. Presented at the American College of Gastroenterology Annual Scientific Meeting, October 20-25.
2. Lichtenstein, G, *et al.* Early Symptomatic Improvement With Guselkumab Induction Treatment in Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 QUASAR Induction Study. Presented at the American College of Gastroenterology Annual Scientific Meeting, October 20-25.
3. National Institutes of Health: Clinicaltrials.gov. A Study of Guselkumab Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (ASTRO). Identifier: NCT05528510. Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT05528510>. Accessed October 2023.
4. European Medicines Agency. TREMFYA Summary of Product Characteristics. Available at: <https://www.medicines.org.uk/emc/medicine/34321>. Accessed October 2023.
5. National Institutes of Health: Clinicaltrials.gov. A Study of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis (QUASAR). Identifier: NCT04033445. Available at: <https://clinicaltrials.gov/ct2/show/NCT04033445>. Accessed October 2023.
6. EU Clinical Trials Register: Clinicaltrialsregister.eu. A Phase 2b/3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis (QUASAR).

Identifier: 2018-004002-25. Available at:

<https://www.clinicaltrialsregister.eu/ctrsearch/trial/2018-004002-25/SE>. Accessed October 2023.

7. Crohn's & Colitis Foundation. What is Ulcerative Colitis? Available at: <https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis>. Accessed October 2023.
8. Crohn's & Colitis Foundation. Signs and Symptoms of Ulcerative Colitis. Available at: <http://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/symptoms>. Accessed October 2023.
9. US Food and Drug Administration. TREMFYA Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761061s007lbl.pdf. Accessed October 2023.
10. The Canadian Agency for Drugs & Technologies in Health. TREMFYA Prescribing Information. Available at: https://pdf.hres.ca/dpd_pm/00042101.PDF. Accessed October 2023.
11. Japan Pharmaceuticals and Medical Devices Agency. Tremfya Report on the Deliberation Results. Available at: <https://www.pmda.go.jp/files/000234741.pdf>. Accessed October 2023.