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News Release

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Results of Novel Clinical Study of Guselkumab and Golimumab Combination Therapy Show Adults with Moderately to Severely Active Ulcerative Colitis Maintained Higher Rates of Clinical and Histologic Remission and Endoscopic Normalisation at Week 38

The rate of clinical remission was 47.9 percent in patients who received combination induction therapy with guselkumab and golimumab compared with either treatment alone (31.0 percent and 20.8 percent, respectively) at 38 weeks[1]

BEERSE, BELGIUM, 10 October, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced data from an ongoing analysis of a Phase 2a clinical trial showing adults with moderately to severely active ulcerative colitis (UC) who received 12 weeks of combination induction therapy with guselkumab and golimumab, followed by a transition to guselkumab alone for maintenance, achieved a clinical remission rate[a] (based on the modified Mayo score [mMayo])[b] at week 38 of 47.9 percent, a higher rate than induction and maintenance treatment with either guselkumab alone (31.0 percent) or golimumab alone (20.8 percent).[1,2] The analyses were pre-specified but no adjustments were made for multiplicity. Patients had

comparable rates of adverse events (AEs) across the treatment groups.[1] Guselkumab alone, or the combination of guselkumab and golimumab are under clinical investigation and not approved for the treatment of adults with UC in EMEA.

The VEGA study is the first randomised controlled trial to evaluate the efficacy and safety of combination therapy with an interleukin (IL)-23p19 subunit antagonist (guselkumab) and a tumour necrosis factor-alpha (TNFα) antagonist (golimumab) in UC.[3,4] Detailed results were presented today as an oral presentation (OP087) at the United European Gastroenterology (UEG) Week taking place in-person in Vienna, Austria and virtually from October 8-11.[1]

"Exploring combinations of advanced therapies is an important step in continuing to innovate for the many patients living with ulcerative colitis," said Bruce E. Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai, Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and VEGA Steering Committee member.[c] "These new data from the VEGA trial build upon and affirm our initial 12-week findings showing the potential clinical benefit of combining guselkumab and golimumab in treating adults with moderately to severely active ulcerative colitis."

In the VEGA study, patients with moderately to severely active UC were randomised (1:1:1) to receive combination therapy with guselkumab and golimumab, guselkumab monotherapy, or golimumab monotherapy.[1] After endpoints were evaluated at week 12, patients in the monotherapy groups continued their initially assigned treatment, while patients randomised to the combination therapy group transitioned to guselkumab alone as a maintenance therapy.[1] Patients remained blinded and received their respective therapies through the final efficacy assessment at week 38.[1] Clinical remission[a,d] was assessed based on the modified Mayo score (mMayo),[b] as well as the total Mayo score.[e] Symptomatic remission,[f] endoscopic improvement,[g] endoscopic normalisation,[h] histologic remission,[i] and composite histologic-endoscopic endpoints[g,i] were also assessed at week 38 in an exploratory

analysis.[1] Safety was evaluated through week 50 (16 weeks after the final dose of study intervention at week 34).[1]

Patients who received combination therapy with guselkumab and golimumab followed by maintenance treatment with guselkumab achieved clinical remission[a] (mMayo[b]) at week 38 (47.9 percent [34/71]) versus 31.0 percent (22/71) and 20.8 percent (15/72) of patients who received guselkumab or golimumab alone, respectively (nominal p=<0.05).[1]

Rates of clinical remission[d] as defined by the total Mayo score[e] at week 38 were similar to those based on the mMayo,[a,b] with 43.7 percent (31/71) in the combination therapy followed by guselkumab group achieving this endpoint, compared to either the guselkumab or golimumab monotherapy groups, (31.0 percent [22/71] and 22.2 percent [16/72], respectively).[1]

Also, patients receiving combination therapy followed by guselkumab had the following outcomes at week 38:[1]

- Endoscopic improvement[g] and the composite histologic-endoscopic endpoint[g,i] were higher in patients who received combination therapy followed by treatment with guselkumab compared to patients who received guselkumab or golimumab alone.
- Endoscopic normalisation[h] and histologic remission[i] were higher in patients who received combination therapy followed by treatment with guselkumab compared to patients who received guselkumab or golimumab alone.

Patients receiving combination therapy followed by maintenance treatment with guselkumab and patients receiving treatment only with guselkumab monotherapy achieved the same rate of symptomatic remission[f] of 69 percent at week 38, which was greater than the golimumab monotherapy group of 59.7 percent.[1]

Rates of AEs were comparable through week 50 of the study.[1] Respectively, the combination therapy followed by guselkumab, guselkumab alone, and golimumab

alone groups had AE rates of 63.4, 64.8, and 76.4 percent and infection rates of 31.0, 23.9, and 31.9 percent.[1] All groups had the same serious AE rates of 5.6 percent and the same serious infection rates of 2.8 percent.[1] Overall, 13.1 percent of patients discontinued their treatment prior to the final dose of study intervention.[1]

"The 38-week VEGA data suggest the potential that guselkumab and golimumab combination therapy has in patients with moderately to severely active ulcerative colitis for whom previous conventional treatments have inadequately managed their disease or improved their well-being," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "We thank the patients who participated in the VEGA study, as their contribution helps us get closer to our goal of developing therapies that will bring meaningful improvements to patients with ulcerative colitis."

Janssen previously announced the 12-week data of patient outcomes from the VEGA study at the 17th Congress of the European Crohn's and Colitis Organisation on February 19, 2022.[2]

Editor's Notes:

a. Clinical remission (based on the mMayo) is defined as a stool frequency subscore of 0 or 1, where the stool frequency subscore has not increased from baseline, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1 with no friability present on endoscopy.[1]
b. Modified Mayo score consists of three of the four components of the full Mayo score: stool frequency, rectal bleeding, and endoscopic score. The physician global assessment score is not included.[5]
c. Dr Sands is a paid consultant for Janssen. He has not been compensated for any media work.
d. Clinical remission is defined as a Mayo score ≤2, with no individual subscore >1.[1]
e. The total Mayo score is the sum of four subscores – stool frequency, rectal bleeding, physician's global assessment, and endoscopy findings – that are scored from normal (0) to severe (3).[3]

f. Symptomatic remission is defined as Mayo stool frequency subscore of 0 or 1, where the stool frequency subscore has not increased from baseline, and a rectal bleeding subscore of 0.[1]
g. Endoscopic improvement is defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.[1]
h. Endoscopic normalisation is defined as an endoscopy subscore of 0.[1]
i. Histologic remission is defined as absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system.[1]

About VEGA (NCT03662542; EudraCT 2018-001510-15)

VEGA was a randomised, double-blind, active-controlled, parallel group, global multicentre Phase 2a proof-of-concept study evaluating the efficacy and safety of combination induction therapy with guselkumab and golimumab, followed by a transition to guselkumab monotherapy for maintenance, in patients with moderately to severely active UC as defined by a Mayo score of 6 to 12 inclusive and an endoscopy subscore of 2 or greater as determined by central read.[3,4]

Study participants were naïve to TNFα and had to be refractory or intolerant to conventional therapy (e.g. immunosuppressants and/or corticosteroids).[1] Participants were randomly assigned 1:1:1 to receive guselkumab monotherapy dosed at 200 milligrams (mg) intravenously (IV) at weeks 0, 4, and 8 followed by 100 mg every 8 weeks (q8w) subcutaneous (SC) (n=71); golimumab SC monotherapy dosed at 200 mg at week 0 followed by 100 mg SC at weeks 2, 6, and 10 followed by 100 mg every 4 weeks SC monotherapy (n=72); or a combination of 200 mg IV guselkumab plus 200 mg SC golimumab at week 0, 100 mg SC golimumab at weeks 2, 6, and 10, and 200 mg IV guselkumab at weeks 4 and 8 (n=71) followed by 100 mg guselkumab SC q8w thereafter.[1] After endpoints were evaluated at week 12, participants in the monotherapy groups continued their initially assigned treatment, while patients randomised to the combination group transitioned to guselkumab 100 mg SC q8w as a maintenance therapy.[1] Overall, 13.1% of patients discontinued treatment prior to week 34 (the final dose of study intervention.[1] The

participants remained blinded and received their respective therapies through week 34 with final efficacy assessments at week 38.[1]

The primary endpoint was clinical response at week 12, defined as a decrease from baseline in the Mayo score by 30 percent or more and 3 or more points, with either a decrease in rectal bleeding subscore of 1 or more or rectal bleeding subscore of 0 or 1.[3,4] The trial's major secondary endpoint was clinical remission at week 12, defined as Mayo score less than or equal to 2, with no individual subscore more than 1. No adjustments were made for multiple comparisons.[3,4] Other key endpoints evaluated at week 12 were clinical remission (based on components of the mMayo score), symptomatic remission, endoscopic improvement, endoscopic normalisation, histologic remission, composite histologic-endoscopic endpoints, and biomarker outcomes.[1]

About Ulcerative Colitis

UC affects up to 2.6 million people in Europe.[6] 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.[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 guselkumab

Developed by Janssen, guselkumab (which is marketed under the brand name 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.[9,10] 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.[9] 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.[11-13]

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).[9]

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.

About Golimumab

Golimumab (marketed under the brand name SIMPONI®), in combination with MTX, is a prescription medicine for adults with:[14]

- Moderate to severe, active rheumatoid arthritis (RA) when the response to DMARD therapy including MTX has been inadequate.
- Severe active and progressive RA not previously treated with MTX.
- Active and progressive PsA, alone or in combination with MTX, when the response to previous DMARD therapy has been inadequate.

Golimumab alone is also a prescription medicine for adults with:[14]

- Moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-

mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.

- Severe active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.
- Severe active non-radiographic axial spondyloarthritis with objective signs of inflammation, as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence, who have had an inadequate response to or are intolerant to nonsteroidal anti-inflammatory drugs.

Merck & Co., Inc. hold rights to market golimumab in the European Economic Area, the United Kingdom, Switzerland, Turkey, Russia, Serbia, Montenegro, Bosnia and Herzegovina, North Macedonia, and Albania. The Janssen Pharmaceutical Companies of Johnson & Johnson maintain marketing rights to golimumab in the U.S. and in all other countries or regions where golimumab is approved.

GOLIMUMAB IMPORTANT SAFETY INFORMATION

In controlled periods of clinical studies with golimumab, ADRs that consisted of upper respiratory tract infections were very common (≥10 percent); bacterial and viral infections, lower respiratory tract infections, bronchitis, sinusitis, superficial fungal infections, abscess, leukopenia, anaemia, allergic reactions, depression, insomnia, hypertension, dizziness, headache, paraesthesia, pyrexia, asthenia, injection site reactions, pruritus, rash, alopecia and dermatitis were common (≥1 to <10 percent); and sepsis, pyelonephritis, neoplasms, thrombocytopenia, pancytopenia, thyroid disorders, visual disorders, balance disorders, conjunctivitis, arrhythmia, ischaemic coronary artery disorders, bullous skin reactions, Pso, urticaria, cholelithiasis, hepatic disorders, interstitial lung disease, constipation, gastro-oesophageal reflux, breast and menstrual disorders were uncommon ADRs (≥0.1 percent to <1 percent).[14]

Please refer to the Summary of Product Characteristics for full prescribing information for golimumab: https://www.ema.europa.eu/en/documents/product-information/simponi-epar-product-information_en.pdf

ADRs should be reported. Guselkumab is subject to additional monitoring and it is, therefore, important to report any suspected ADRs related to this medicinal product. 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 guselkumab and golimumab product development. 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 2, 2022, 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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