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Janssen Receives CHMP Positive Opinion for Expanded Use of TREMFYA®▼ (guselkumab) in the Treatment of Active Psoriatic Arthritis (PsA) in the European Union (EU)

If approved, guselkumab will be the first selective interleukin (IL)-23 p19 subunit inhibitor licensed for both the treatment of PsA and moderate to severe plaque psoriasis

BEERSE, BELGIUM, October 16, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the expanded use of TREMFYA®▼ (guselkumab) for the treatment of adult patients with active psoriatic arthritis (PsA) in the European Union (EU). Guselkumab is currently approved in the EU for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[1]

Guselkumab is a monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. IL-23 is an important driver in the pathogenesis of inflammatory diseases such as PsA, psoriasis and others.[2]

"This positive opinion brings us closer to the addition of guselkumab to the drug armoury for the management of psoriatic arthritis, which is of critical importance for patients. Psoriatic arthritis is an impactful, multifaceted and currently incurable disease," said Professor Iain McInnes,[i] Muirhead Professor of Medicine and Director of the Institute of Infection Immunity and Inflammation, University of Glasgow. "Long-term control of the diverse symptoms in joints, skin and soft tissue is required. If approved, guselkumab would be a welcome addition to our therapeutic options in the management of this disease."

PsA is a chronic, immune-mediated, inflammatory disease that is progressive and is characterised by debilitating joint damage and inflammation, in addition to enthesitis, dactylitis, axial disease, and the skin lesions associated with psoriasis.[3] There is no known cure, and it is estimated that up to a third of the 14 million people who are living with psoriasis in Europe will also go on to develop PsA.[4,5]

The CHMP positive opinion is based on data from DISCOVER-1 and DISCOVER-2, two first-in-class Phase 3 clinical studies, that demonstrated the efficacy and safety of guselkumab 100 mg q4w and q8w for the treatment of active PsA in adult patients. Data from these studies were recently published in *The Lancet* in March 2020.[6,7]

DISCOVER-1 evaluated 381 participants with active PsA who had an inadequate response to standard therapies, including participants (~30 percent) previously treated with anti-tumour necrosis factor (TNF) alpha biologics.[6] DISCOVER-2 included 739 patients who were biologic-naïve only and had an inadequate response to standard therapies.[7]

Results published in *The Lancet* showed that in both studies, at week 24, the primary endpoints of American College of Rheumatology (ACR) 20 percent improvement (ACR20) achieved statistical significance (DISCOVER-1: $p<0.0001$; DISCOVER-2: $p<0.0001$) in both q4w and q8w guselkumab groups (DISCOVER-1: n=255; DISCOVER-2: n=493) vs the placebo groups (DISCOVER-1: n=126; DISCOVER-2: n= 246). Significant improvements in quality of life scores (36-item short-form [SF36] physical component summary) were also observed in the

guselkumab groups vs the placebo groups in DISCOVER-1 ($p<0.0001$ for both doses); in DISCOVER-2, significant improvements were observed in the q4w guselkumab group vs placebo group ($p=0.0056$ [q8w, $p=0.068$]). In addition, higher Psoriasis Area and Severity Index 75 percent improvement (PASI 75), PASI 90, and PASI 100 response rates were observed in the guselkumab groups vs the placebo groups (in DISCOVER-1, all unadjusted $p<0.0001$ with PASI 100 being $p=0.0005$ and in DISCOVER-2, all unadjusted $p<0.0001$).[6,7]

In both studies, guselkumab was generally well tolerated through study completion, and observed adverse events (AEs) were generally consistent with previous studies of guselkumab and the current Summary of Product Characteristics.[1] In DISCOVER-1 and -2, serious adverse events up to week 24 in q4w treatment arms (0 and 3 percent) and q8w treatment arms (3 and 1 percent) were similar to those in the placebo arms (4 and 3 percent). In DISCOVER-2, less than 1 percent of patients experienced serious infections following guselkumab treatment, and no patient experienced serious infections following guselkumab treatment in DISCOVER-1. There were no reported deaths in guselkumab-treated patients and no guselkumab-treated patient developed inflammatory bowel disease, opportunistic infections such as tinea or candida, active tuberculosis or anaphylactic or serum sickness-like reactions.[6,7]

“We are excited to be one step closer to bringing guselkumab to both patients living with psoriatic arthritis, as well as to the doctors who treat them,” said David M. Lee, M.D., Ph.D., Global Therapeutic Area Head, Immunology, Janssen Research & Development, LLC. “Guselkumab reinforces our broad commitment to developing first-in-class treatments for patients living with psoriatic arthritis and other immune-mediated diseases.”

Guselkumab was first approved by the European Commission on 23 November 2017 for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[1] Guselkumab is approved in the EU, US, Brazil, Canada, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet [UV] light).[1] It is approved in the US, Canada, Japan, Brazil and

Ecuador for the treatment of adult patients with active PsA. A final decision from the European Commission (EC) regarding PsA indication expansion is expected later this year.

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About DISCOVER-1 (NCT03162796)[8]

DISCOVER-1 was a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by subcutaneous (SC) injection in participants with active PsA, including those previously treated with biologic anti-TNF therapies. DISCOVER-1 evaluated 381 participants and continued through approximately 1 year.[6]

The study consisted of a screening phase of up to 6 weeks, a blinded treatment phase of 52 weeks that included a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 52. It also includes a safety follow-up phase of 8 weeks after week 52 (week 52 to 60; 12 weeks from the last administration of study agent [at week 48] through to the final visit in the safety follow-up phase). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285)[9]

DISCOVER-2 is a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in participants with active PsA. DISCOVER-2 is evaluating 739 participants and continuing through approximately 2 years.[7]

The study consists of a screening phase of up to 6 weeks, a blinded treatment phase (approximately 100 weeks) that includes a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 100. It also includes a safety follow-up phase of 12 weeks after the last administration of study agent. Efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker and pharmacogenomics evaluations are being performed in the study on a defined schedule.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterised by peripheral joint inflammation, enthesitis (pain where the bone, tendon and ligament meet), dactylitis (severe inflammation of the finger and toe joints), axial disease, and the skin lesions associated with psoriasis.[3,10,11] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[12] Studies showed that up to 30 percent of people with psoriasis also develop PsA.[4] The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 30–50, but can develop at any time.[13] Though the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset and of the disease.[13]

About TREMFYA® (guselkumab)

Developed by Janssen, 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.[1] Guselkumab is approved in the EU, US, Canada, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet [UV] light).[1] It is approved in the US, Canada, Japan, Brazil and Ecuador for the treatment of adult patients with active PsA. IL-23 is an important driver of the pathogenesis of inflammatory immune-mediated diseases such as psoriasis.[2] In psoriasis guselkumab is administered as a 100 mg SC injection once every 8 weeks, after starter doses at weeks 0 and 4.[1]

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

Important Safety Information[1]

Very common (≥10 percent) and common AEs (≥1 percent) in controlled periods of clinical studies with guselkumab were upper respiratory infections, gastroenteritis, herpes simplex infections, tinea infections, headache, diarrhoea, urticaria, arthralgia, and injection site reactions. Uncommon AEs (≥0.1 percent)

were hypersensitivity, anaphylaxis and rash. Most were considered to be mild and did not necessitate discontinuation of study treatment.

Please refer to the Summary of Product Characteristics for full prescribing information for guselkumab: https://www.ema.europa.eu/en/medicines/human/EPAR/tremfya#product-information-section.

▼ AEs should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected AEs 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. AEs should also be reported to Janssen-Cilag Ltd on 01494 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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/emea.
Follow us at www.twitter.com/JanssenEMEA.

Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU, and Janssen Research & Development, LLC are members 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 ongoing and planned development efforts involving TREMFYA® (guselkumab) as a treatment for adult

patients with active psoriatic arthritis. 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 December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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.

[i]*Professor Iain McInnes is a paid consultant for Janssen. He has not been compensated for any media work.*

# # #

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