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News Release

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New Phase 3 Data Show First-in-Class TREMFYA® (guselkumab) Achieved Complete Skin Clearance and Favourable Joint Efficacy in Adult Patients with Active Psoriatic Arthritis (PsA) Through Two Years

Data show more than 50 percent of adults with active PsA achieved complete skin clearance (PASI 100) and more than 70 percent achieved at least 20 percent improvement in joint symptoms (ACR 20)

These data mark the first and only long-term Phase 3 study results for a selective interleukin (IL)-23 inhibitor therapy in PsA, which include impact on radiographic progression through two years

BEERSE, Belgium, March 16, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced long-term data from the Phase 3 DISCOVER-2[a] study showing that the skin clearance, joint symptom relief, and safety of TREMFYA® (guselkumab) previously demonstrated through 24 weeks and one year (week 52) in adults with active psoriatic arthritis (PsA) continued through two years (week 112).[1,2] These findings also confirmed that the robust efficacy guselkumab demonstrated in patients at week 24 on physical function, physical aspects of health-related quality of life, and resolution of enthesitis[b] and dactylitis[c] was also seen through week 100.[1-8] In

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addition, the extent of radiographic progression[d] was studied through two years. These data will be presented virtually in abstract, poster, and video form during the Innovations in Dermatology: Virtual Spring Conference, March 16-20, 2021.[1,2] Guselkumab is the first and only IL-23 inhibitor therapy approved in the EU to treat both adults with active PsA and adults with moderate to severe plaque psoriasis (Pso).[9]

"PsA can be a chronically painful and debilitating disease, and many PsA patients are still searching for enduring relief of their symptoms," said Philip J. Mease,[e] M.D., of the Swedish Medical Center/Providence St. Joseph Health and the University of Washington in Seattle, Washington and presenting author. "These data, which show that the observed benefits of guselkumab in PsA continue through two years, represent positive news for physicians and patients alike."

Results showed that at week 100:[1,2]

- **Complete Skin Clearance:[2]** In patients who had clinically meaningful skin involvement[f] at baseline, 59 percent of those receiving guselkumab every four weeks (q4w) and 53 percent of those receiving guselkumab every eight weeks (q8w) achieved complete skin clearance (Psoriasis Area Severity Index [PASI] 100;[g] utilising non-responder imputation [NRI], with this method of analysis, subjects with missing data are assumed to be non-responders).
- **Joint Symptom Improvement:[2]** Among randomised patients, 76 percent of those receiving guselkumab 100 mg q4w and 74 percent of those receiving guselkumab 100 mg q8w achieved at least 20 percent improvement in the American College of Rheumatology (ACR 20) response criteria[h] (utilising NRI).[i]
- **Radiographic Progression**: From week 52-100, low rates of radiographic progression of joint damage were observed in patients receiving guselkumab q4w (0.75) and guselkumab q8w (0.46), which were both further numerically reduced from the results observed during weeks 0-52 (1.06, q4w; 0.99, q8w).[1,2] In the group of patients who crossed over from placebo to guselkumab q4w at week 24, mean changes in van der Heijde-Sharp (vdH-S)[j] scores were 1.12 from week 0-24 while receiving placebo, and 0.34 from week 24-52 and 0.13 from week 52-100 while receiving guselkumab q4w, indicating that further numerical improvements were also made through year two in this group.[1,2]

- **Durability:**[1,2] Robust joint and skin response rates and mean improvements from baseline in outcome measures were maintained through two years and around 90 percent of patients randomised to guselkumab q4w or q8w continued treatment with guselkumab through week 100.
- **Safety:**[1,2] No new safety signals were observed in the safety analysis conducted through week 112. Guselkumab safety in patients with active PsA through two years was comparable to safety at six months and one year and generally consistent with guselkumab safety in patients with moderate to severe plaque Pso.[10,11] Among the patients who received guselkumab q4w, guselkumab q8w and the patients who crossed over from placebo at q4w at week 24, there were 5.2, 6.1 and 6.0 serious adverse events per 100 patient-years; and 1.0, 2.2 and 2.6 serious infections per 100 patient-years, respectively. One patient in the cross over from placebo to q4w at week 24 group had an opportunistic infection, and no guselkumab-treated patient had anaphylactic/serum sickness reaction or active tuberculosis.

In addition, results showed 56 percent of guselkumab q4w patients and 55 percent of guselkumab q8w patients achieved at least 50 percent improvement in ACR score (utilising NRI).[2] Among patients who had clinically meaningful Pso at baseline, 62 percent of guselkumab q4w patients and 55 percent of guselkumab q8w patients achieved complete skin clearance as measured by the Investigator Global Assessment (IGA) score of 0 (utilising NRI).[2]

"PsA is a chronic inflammatory disease of the skin, joints, and soft tissue and therefore, sustained control of this inflammation is important to physicians and patients," said Alyssa Johnsen, M.D., Ph.D., Vice President, Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "These long-term study results further bolster our confidence in the ability of guselkumab to significantly improve the diverse manifestations of PsA over time."

Guselkumab is the first and only treatment approved both for adults with moderate to severe plaque Pso and for adults with active PsA that selectively inhibits IL-23, a

cytokine that is a key driver of the inflammatory immune response associated with the symptoms of these autoimmune diseases.[9,12]

Guselkumab was approved by the European Commission for adult patients with moderate to severe plaque Pso who are candidates for systemic therapy in November 2018 and in November 2020 for adults with active PsA who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.[9] The PsA approval was based on results from DISCOVER-1 and DISCOVER-2, which showed guselkumab reached each study's primary endpoint of ACR 20 response at 24 weeks.[13-16] Complete study results were previously published in *The Lancet.*[3,4]

DISCOVER-1 and DISCOVER-2 data showed guselkumab demonstrated improvements in multiple clinical outcomes of PsA including joint symptoms, skin symptoms, soft tissue inflammation, physical function, axial-related disease, fatigue as measured by Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) Scale,[k] and low rates of radiographic progression at week 52.[3-9,17]

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Footnotes:

a. In DISCOVER-2, patients were randomised to guselkumab 100 mg q4w or q8w for two years, or to placebo with crossover to guselkumab q4w at week 24 through two years.[15,16]
b. Enthesitis is defined as pain where the bone, tendon and ligament meet.[18]
c. Dactylitis is defined as severe inflammation of the finger and toe joints.[19]
d. Radiographic progression is measured by scoring the erosions and joint space narrowing in the hands and feet.[20]
e. Dr Mease is a paid consultant for Janssen. He has not been compensated for any media work.
f. Clinically meaningful defined as ≥3 percent body surface area psoriatic involvement and an IGA score of at least 2 at baseline.[15]
g. PASI 75/90/100 is defined as at least 75/90/100 percent improvement from baseline in the PASI score. The PASI score grades the amount of surface area on

each body region that is covered by Pso plaques and the severity of plaque redness, thickness, and scaliness.[21]

h. ACR 20/50/70 response is defined as both at least 20/50/70 percent improvement from baseline in the number of tender and number of swollen joints, and at least 20/50/70 percent improvement from baseline in three of the following five criteria: patient global assessment, physician global assessment, functional ability measure, visual analog pain scale, and erythrocyte sedimentation rate or C-reactive protein.[22]
i. ACR response rates at week 100 were determined post-hoc using NRI, which categorised patients who discontinued the study as non-responders from week 24 to 100.
j. Change in total vdH-S score is defined by change of score from baseline. The total vdH-S score combines erosion and joint space narrowing scores derived from radiographs of joints in hands and feet.[23]
k. FACIT-F scale is measured on a 4-point Likert scale (4 = not at all fatigued to 0 = very much fatigued)[24]

About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37)[13,14]

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 one or two biologic tumour necrosis factor inhibitors. DISCOVER-1 evaluated 381 participants and continued through approximately one year.

The study consisted of a screening phase of up to six weeks, a blinded active 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 included a safety follow-up phase of eight weeks after week 52 (week 52 to week 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; EudraCT 2016-001224-63)[15,16]

DISCOVER-2 was a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in bio-naïve patients with active PsA. DISCOVER-2 evaluated 739 participants and continued through approximately two years.

The study consisted of a screening phase of up to six weeks, a blinded active treatment phase (approximately 100 weeks) that included a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 100. It also included a safety follow-up phase of 12 weeks after the last administration of study agent. Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations were performed in the study on a defined schedule.

About 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 Pso.[18,19,25] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[26] Studies show up to 30 percent of people with Pso also develop PsA.[27,28] The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 30 and 50, but can develop at any time.[29] Nearly half of patients with PsA experience moderate fatigue and about 30 percent suffer from severe fatigue as measured by the modified fatigue severity scale.[30] Although the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in disease onset.[29]

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.[9] Guselkumab is approved as a prescription medicine in the EU for the treatment of adult patients with moderate to severe plaque Pso who are candidates for systemic therapy, and also has approved indications for the treatment of adult patients with moderate to severe plaque Pso in the US, Canada, Japan and a number of other countries worldwide.[9] Guselkumab, alone or in combination with methotrexate, is also approved in the EU for the treatment of adult patients with active PsA in those who have had an inadequate response or who have been intolerant to a

prior DMARD therapy, with additional PsA approvals in the US, Canada, Japan and a number of other countries worldwide.[9] IL-23 is an important driver of the pathogenesis of inflammatory immune-mediated diseases such as Pso and PsA.[31] In the EU, guselkumab is administered as a 100 mg SC injection once every 8 weeks, after starter doses at weeks 0 and 4 for both plaque Pso and PsA, with 100 mg SC doses every 4 weeks may be considered in patients with PsA who are at high risk for joint damage according to clinical judgement.[9]

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

Important Safety Information[9]

Very common (≥10 percent) and common (≥1 percent) adverse drug reactions (ADRs) in controlled periods of clinical studies with guselkumab were respiratory tract infections, increased transaminases, headache, diarrhoea, arthralgia and injection site reactions. Uncommon ADRs (≥0.1 percent) observed were herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash.

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.

ADRs should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected ADRs related to this medicinal product.

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 Janssen 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 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 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 materialize, 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 3, 2021, 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.

# # #

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