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News Release

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New Phase 3 First-in-Class TREMFYA®▼ (guselkumab) Data Show Durability of Joint Efficacy, Including Low Rates of Structural Damage Progression, and a Demonstrated Safety Profile in Adults with Active Psoriatic Arthritis (PsA)

Guselkumab inhibited radiographic progression versus placebo and maintained low rates of progression through two years in biologic-naïve active PsA patients

Guselkumab is the first and only selective interleukin (IL)-23 inhibitor therapy approved for moderate to severe plaque psoriasis (Pso) and active PsA

BEERSE, BELGIUM, November 1, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today six new analyses of Phase 3 data from the DISCOVER-1 and DISCOVER-2 clinical trials, which demonstrate TREMFYA®▼ (guselkumab) provided low rates of radiographic progression[a] versus placebo and substantial and durable improvements in joint signs and symptoms, axial symptoms,[b]

enthesitis,[c] dactylitis,[d] and pain among adult patients with active psoriatic arthritis (PsA).[1,2,3,4] Data also showed a safety profile consistent between adults with active PsA through two years and adults with moderate to severe plaque psoriasis (Pso) through five years.[5,6] These data, which represent the most comprehensive results to date for a selective interleukin (IL)-23 inhibitor therapy in the active PsA adult patient population, are among 39 abstracts Janssen will present at the American College of Rheumatology (ACR) Convergence, November 3-9, 2021. Guselkumab is the first and only selective IL-23 inhibitor therapy approved in the EU to treat adults with moderate to severe plaque Pso who are candidates for systemic therapy, as well as adults with active PsA who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.[7]

"The symptoms of psoriatic arthritis can vary from patient to patient, making it difficult to select appropriate treatments," said Philip Mease, M.D., Director of Rheumatology Research at the Swedish Medical Center/Providence St. Joseph Health and Clinical Professor at the University of Washington School of Medicine.[e] "These data reinforce the important therapeutic role of guselkumab and provide useful insights for healthcare professionals treating patients who experience the various symptoms of active psoriatic arthritis, including peripheral arthritis, enthesitis, dactylitis, axial symptoms, and structural joint damage."

Data from the abstracts being presented show:

- **Durable Improvements in Joint Disease:**
    - Mean changes in radiographic scores from week 52-100 indicated guselkumab was associated with low rates of radiographic progression, a key indicator of structural damage, through two years in DISCOVER-2, which enrolled biologic-naïve patients with active PsA at increased risk of structural damage.[4] Guselkumab patients achieving clinical response across several global measures of disease activity or normalised physical function at week 100 had lower mean changes in total PsA-modified van der Heijde Sharp (vdH-S)[f] scores compared with non-responders, emphasizing the relationship between achievement of stringent clinical response criteria with

guselkumab and prevention of radiographic progression, a key indicator of disease modification (POSTER #1050677).[4]

- Guselkumab provided durable improvements in symptoms of axial involvement through week 100 in patients with active PsA and investigator- and imaging-confirmed sacroiliitis[g] from the DISCOVER-2 trial, with substantial proportions of patients achieving and maintaining clinically meaningful improvement in ankylosing spondylitis disease activity score (POSTER #1050685).[2] Among PsA patients with axial symptoms and sacroiliitis (via investigator-confirmed imaging) in the DISCOVER-1 and -2 trials, guselkumab treatment resulted in lower mean scores for all six components of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[h] compared with placebo as early as week 8 and through week 24, with mean scores maintained at week 52 (POSTER #1056731).[8]
- Data from DISCOVER-2 showed that guselkumab dosing every eight weeks resolved enthesitis and dactylitis through week 100 in 70 percent and 83 percent of biologic-naïve PsA patients, respectively.[3] In patients who had both dactylitis and enthesitis at baseline, guselkumab-treated patients showed significant correlations between resolution of each condition at week 24, 52, and 100, with nearly 90 percent of patients with enthesitis resolution also achieving dactylitis resolution at weeks 52 and 100 (POSTER #1050684).[3]
- In DISCOVER-2, guselkumab also provided consistent and durable improvements in patient-reported pain across several measures, including the 0-10 cm Visual Analogue Scale for Pain[i] employed in the ACR, Disease Activity in Psoriatic Arthritis (DAPSA), the Minimal Disease Activity (MDA) response criteria, Bodily Pain Intensity reported via the 36-Item Short-Form Health Survey (SF-36);[j] and spinal and peripheral joint pain reported as a component of BASDAI (in the subgroup of DISCOVER-2 patients with investigator- and imaging-confirmed sacroiliitis).[1] Patients receiving guselkumab reported approximately twice the improvement in these pain measures compared with patients receiving placebo at week 24, and these improvements were maintained or increased at weeks 52 and 100 in

DISCOVER-2, as well as through one year of DISCOVER-1, which also enrolled tumour necrosis factor (TNF) inhibitor-experienced patients.[1]

- Among 748 guselkumab-treated patients across DISCOVER-1 and -2, substantial proportions achieved meaningful improvement in pain as early as week 4 with 32 percent of patients achieving ≥20 percent improvement and 33 percent achieving ≥50 percent improvement at week 16.[1] Patient-reported pain is an important factor for further evaluation as an early and sensitive indicator of treatment effect in patients with active PsA (POSTER #1050694).[1]

- **Established Safety Profile:**
  - The analysis of data from guselkumab treatment through two years and five years of follow-up in the pooled PsA[k] and pooled Pso trials, respectively, showed a guselkumab safety profile consistent between patients with active PsA and moderate to severe Pso (POSTER #1050675).[5]
  - Across the guselkumab Phase 2 and Phase 3 trials, incidence rates of serious adverse events (SAEs); gastrointestinal-related SAEs; and adverse events of interest including candidiasis, uveitis, and opportunistic infections were low, or no cases were reported (POSTER #1050676).[6]

"The consistent improvements across multiple measures of disease and the demonstrated safety profile support the use of guselkumab as an effective treatment for people living with psoriatic arthritis," said Alyssa Johnsen, M.D., Ph.D., Vice President and Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "We are pleased to contribute to the scientific and clinical understanding of this important indication in order to help more patients manage the challenges of living with psoriatic arthritis."

These further analyses of long-term data from DISCOVER-2 complement the comprehensive results of two-year data from DISCOVER–2 recently published in *Arthritis & Rheumatology*.[9] This manuscript presents the final clinical efficacy, radiographic progression, and safety results of the two-year DISCOVER-2 trial, the first such completed with a selective IL-23 inhibitor in PsA.[9] Our continued

commitment to advancing guselkumab for the treatment of active PsA is demonstrated by the guselkumab PsA clinical development program, which currently includes three studies in Phase 3b or Phase 4 testing.

Editor's Note:

a. Radiographic progression is a key indicator of structural damage, which includes erosion and joint space narrowing.[10]
b. Axial symptoms in PsA include back and neck stiffness that lasts longer than 30 minutes and neck or back pain that improves with activity and worsens after prolonged inactivity.[11]
c. Enthesitis in PsA is inflammation where the bone, tendon and ligament meet.[12]
d. Dactylitis in PsA is severe inflammation of the finger and toe joints.[13]
e. Dr Mease is a paid consultant for Janssen. He was not compensated for any media work.
f. The total PsA-modified vdH-S score is a composite score of structural damage that ranges from 0-528 and measures the number and size of joint erosions and the degree of joint space narrowing in the hands and feet.[10]
g. Sacroiliitis is inflammation of one or both of the sacroiliac joints, which are situated on each side of the spine and connect the sacrum to the ilium. Sacroiliitis symptoms include pain in the lower back, buttocks, hips, or groin, and may extend down one or both legs and feet.[14]
h. BASDAI is a patient-reported outcome measure of disease activity originally developed for ankylosing spondylitis and used in axial PsA. The questionnaire assesses the patient-reported severity of fatigue, spinal pain, peripheral joint pain, localised tenderness, quantity, and duration of morning stiffness using a 0–10 numeric rating scale (NRS) or 10 cm visual analogue scale (VAS) with symptoms ranging from "none" to "very severe."[15]
i. The Visual Analogue Scale (VAS) for Pain is a continuous scale comprised of a horizontal or vertical line, usually 10 cm (100 mm) in length, anchored by two verbal descriptors, one for each symptom extreme. For pain intensity, the scale

is most commonly anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 10 [or 100 on a 100-mm scale]).[16]

j. SF-36 is a set of quality-of-life measures used for patient self-reporting. The SF-36 includes one multi-item scale that assesses eight health concepts: limitations in physical activities because of health problems; limitations in social activities because of physical or emotional problems; limitations in usual role activities because of physical health problems; bodily pain; general mental health (psychological distress and well-being); limitations in usual role activities because of emotional problems; vitality (energy and fatigue); and general health perceptions.[17]

k. Guselkumab safety in PsA was assessed by pooling data across the one-year Phase 2, one-year DISCOVER-1, and two-year DISCOVER-2 randomised control trials.[6]

About Psoriasis (Pso)

Pso is an immune-mediated disease resulting in an overproduction of skin cells, which causes raised, red, scaly plaques that may be itchy or painful.[18] It is estimated that more than 125 million people worldwide live with the disease.[19] Nearly one-quarter of all people with Pso have cases that are considered moderate to severe.[19] Living with Pso can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[20]

About Psoriatic Arthritis (PsA)

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 fingers and toes), axial disease, and the skin lesions associated with Pso.[21,22,23] Patients with PsA also often present with comorbidities, such as obesity, cardiovascular diseases, anxiety and depression.[24] Studies show up to 30 percent of people with Pso also develop PsA.[25] 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.[25] 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.[26] 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.[27]

About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37)[28,29]

DISCOVER-1 is 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 TNF inhibitors. DISCOVER-1 evaluated 381 participants who were treated and followed through approximately one year.[1] The primary endpoint was response of American College of Rheumatology (ACR) 20 at week 24 and primary endpoint data were previously presented at scientific congresses. In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70; resolution of soft tissue inflammation, enthesitis and dactylitis; improvement in physical function; skin clearance (Investigator's Global Assessment [IGA] score), and general health outcomes (SF-36 Physical Component Summary [PCS] and Mental Component Summary [MCS] scores).

The study consisted of a screening phase of up to six weeks, a blinded treatment phase of 52 weeks that included a placebo-controlled period from week 0 to week 24 and a blinded active treatment period from week 24 to week 52. It also included a safety follow-up phase through week 60 (i.e., approximately 12 weeks from the last administration of study agent at week 48). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)[30,31]

DISCOVER-2 is a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in biologic-naïve patients with active PsA. DISCOVER-2 evaluated 739 participants who were treated and followed through approximately two years.[1] The primary endpoint was response of ACR20 at week 24 and primary endpoint data was previously presented at scientific

congresses. In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70; resolution of soft tissue inflammation, enthesitis and dactylitis; improvement in physical function; skin clearance (IGA), and general health outcomes (SF-36 PCS and MCS scores). DISCOVER-2 also assessed changes in structural damage as a key secondary endpoint (vdH-S score).

The study consisted of a screening phase of up to six weeks, a blinded treatment phase of approximately 100 weeks that included a placebo-controlled period from week 0 to week 24 and a blinded active treatment period from week 24 to week 100. It also included a safety follow-up phase through week 112 (i.e., approximately 12 weeks after the last administration of study agent at week 100). Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations were performed in the study on a defined schedule.

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.[7] IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque Pso and active PsA.[32]

Guselkumab is approved in the EU for the treatment of moderate to severe plaque Pso in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[7] 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.[7]

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

GUSELKUMAB IMPORTANT SAFETY INFORMATION

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.[7] Uncommon ADRs (≥0.1 percent) observed were herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash.[7]

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

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 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.

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Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU; and Janssen Research & Development, LLC each are a 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 TREMFYA® (guselkumab) 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 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 behavior 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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