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News Release

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New Phase 3 Data Showed First-in-Class TREMFYA® (guselkumab) Provided Durable Complete Skin Clearance Through 5 Years in Moderate to Severe Plaque Psoriasis (Pso) and Robust Joint Improvement Through 52 Weeks in Active Psoriatic Arthritis (PsA)

Skin clearance rates were maintained at five years with 55.5 percent of patients achieving an Investigator's Global Assessment score of 0 and 53 percent achieving Psoriasis Area Severity Index 100 response in VOYAGE 2

Guselkumab, the first and only selective interleukin (IL)-23 inhibitor therapy approved for both Pso and PsA, improved overall PsA disease activity as evaluated by composite disease activity scores, and PsA axial symptoms as evaluated by the Bath Ankylosing Spondylitis Disease Activity Index in DISCOVER-1 and -2

BEERSE, BELGIUM, April 23, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new Phase 3 data which showed TREMFYA® (guselkumab) sustained durable, complete skin clearance rates in a majority of adults with moderate to severe plaque psoriasis (Pso) through five years (252 weeks),[a] and improved disease activity and axial symptoms in adults with active psoriatic arthritis (PsA) through one year (52 weeks).[1,2,3] These data are being presented at the American Academy of Dermatology (AAD) Virtual Meeting Experience (VMX) 2021, where Janssen will present a total of 22 abstracts. Guselkumab is the first and only selective interleukin

(IL)-23 inhibitor therapy approved in the EU to treat both adults with moderate to severe plaque Pso and adults with active PsA.[4]

"People living with psoriatic disease can face a lifetime of physical pain and discomfort, which places a significant burden on their lives," said Kristian Reich,[b] M.D., Ph.D., Professor of Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Germany, and lead author of the VOYAGE 2 study. "The signs and symptom improvements seen with guselkumab are noteworthy for both patients who live with fear of disease recurrence and their physicians, as these data add to a growing body of evidence for this first-in-class IL-23 inhibitor treatment for moderate to severe plaque psoriasis and active psoriatic arthritis."

Results show:

- **Durable and Complete Skin Clearance Rates:** In the Pso trial VOYAGE 2 (POSTER #27859), 55.5 percent of patients in the guselkumab group[c] achieved an Investigator's Global Assessment (IGA)[d] score of 0, indicating complete skin clearance, and 53 percent achieved a Psoriasis Area Severity Index (PASI)[e] 100 skin clearance response (PASI 100) at week 252.[1] Additionally, in the same trial, 82 percent achieved a PASI 90 skin clearance response and 85 percent achieved an IGA score of 0/1 (clear/almost clear).[1] High efficacy rates were maintained through five years of guselkumab treatment based on analyses using pre-specified treatment failure rules (patients discontinuing due to lack of efficacy, worsening of Pso, or use of a prohibited treatment were considered non-responders).[1]
- **Robust Joint Symptom Improvement:** Guselkumab 100 mg every four weeks and every eight weeks improved PsA disease activity in joints and across multiple domains through week 52 in both PsA trials, DISCOVER-1 and -2, as measured by the Disease Activity Index for PsA, Minimal Disease Activity, Very Low Disease Activity, and remission determined using Disease Activity Index for PsA (POSTER #27038).[2] Differences in response rates associated with composite indices between guselkumab and placebo were seen as early as week eight and increased over time through week 52.[2] In addition, data from a separate abstract

show guselkumab is the first IL-23 inhibitor to provide sustained improvements in PsA axial symptoms based on change from baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[f] score and percentage of patients achieving a BASDAI 50 response through week 52 (POSTER #27851).[3]

- **Established Safety Profile**: Across both Pso trials, VOYAGE 1 and 2, 78.4 percent of patients (n=1,349/1,721) with moderate to severe plaque Pso treated with guselkumab continued treatment through week 252 (7,166 patient-years of follow-up).[5] This comprehensive safety analysis of VOYAGE 1 and 2 showed a consistent safety profile for guselkumab from year one through year five with low rates of adverse events (AEs) leading to discontinuation, and serious AEs (POSTER #28095).[5] Through week 264, for patients in the guselkumab, adalimumab to guselkumab crossover and combined guselkumab groups[c] there were 5.18, 4.55 and 5.01 serious AEs; 0.97, 0.52 and 0.85 serious infections; 0.31, 0.42, 0.34 nonmelanoma skin cancers (NMSC); and 0.50, 0.31, 0.45 other malignancies per 100 patient-years of follow-up, respectively.[5] In both studies, guselkumab was well-tolerated, and observed AEs were generally low and consistent with previous studies of guselkumab and summary of product characteristics.[1,4,5]

"The durable response rates seen in the majority of patients enrolled in the VOYAGE and DISCOVER trials further demonstrate the important role that guselkumab has in helping patients with their moderate to severe plaque psoriasis and their active psoriatic arthritis and add to the volume of scientific insights provided by the comprehensive guselkumab research programme," said Lloyd S. Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC.

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Footnotes:

a. VOYAGE 2 included a randomised withdrawal phase and some patients had treatment interrupted; all resumed treatment by week 76. Starting at 76 weeks and thereafter, patients and study investigators knew that all study participants were on guselkumab.[1]

b. Dr Reich is a paid consultant for Janssen. He was not compensated for any media work.
c. The guselkumab group included patients who were initially randomised to receive subcutaneous (SC) injections of 100 mg guselkumab at weeks 0, 4, and every 8 weeks (q8w) thereafter, and patients who were initially randomised to placebo then crossed over to 100 mg SC guselkumab at week 16. The adalimumab to guselkumab crossover group included patients who were initially randomised to receive 80 mg adalimumab SC injection at week 0, 40 mg at week one and then 40 mg q2w through week 47 (VOYAGE 1) or week 23 (VOYAGE 2). This group then crossed over to guselkumab 100 mg q8w at week 52 (VOYAGE 1), or crossed over to placebo withdrawal at week 28 and guselkumab retreatment upon loss of ≥50 percent of PASI improvement or to guselkumab 100 mg at weeks 28 and 32, then q8w (VOYAGE 2). The combined guselkumab group includes the guselkumab group and adalimumab to guselkumab crossover group, as defined above.[5]
d. Investigator's Global Assessment (IGA Score) is a five-point scoring system used to characterise Pso severity. Scores range from 0 to 5 and represent cleared (0), almost clear (1), mild (2), moderate (3), severe (4) and very severe (5).[6]
e. PASI 75/90/100 responses are defined as at least 75/90/100 percent improvement in the PASI score from baseline. The PASI score grades the amount of surface area covered by Pso plaques in each body region, and the degree of plaque redness, thickness, and scaliness.[7]
f. BASDAI consists of a 0-10 scale (0 being no problem and 10 being the worst problem) which is used to answer six questions pertaining to the major symptoms of ankylosing spondylitis: fatigue, spinal pain, joint pain, enthesitis, morning stiffness and duration of morning stiffness.[8]

About Psoriasis

What it is

The most common form of Pso is plaque Pso, usually resulting in areas of thick, red or inflamed skin covered with silvery scales which are known as plaques.[9] The inconsistent

nature of Pso means that even when plaques appear to subside, patients can have ongoing concerns over their return.[10]

Impact

Approximately 14 million people in Europe are living with Pso, which often leads to a great physical and psychological burden.[11] Mental health issues are common among people with Pso, and the impact it can have on quality of life is comparable with diabetes and cancer.[12] Pso is also associated with several comorbidities including PsA, cardiovascular diseases, metabolic syndrome, chronic obstructive pulmonary disorder (COPD) and osteoporosis.[13] In addition, many individuals face social exclusion, discrimination and stigma because of their disease.[14]

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.[15-17] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[18] Studies show up to 30 percent of people with Pso also develop PsA.[19,20] 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.[21] 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.[22] 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.[21]

About VOYAGE 2 (NCT02207244; EudraCT 2014-000720-18)[23,24]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque Pso. Patients (N=992) were randomised to receive SC injections of guselkumab 100 mg (n=496) at weeks 0, 4 and every 8 weeks (q8w) thereafter; placebo (n=248) at weeks 0, 4, and 12 followed by crossover to guselkumab 100 mg at week 16; or adalimumab 80 mg (n=248) at week

0, 40 mg at week 1, then 40 mg every 2 weeks (q2w) until week 23. Weeks 28-72 incorporated a randomised withdrawal study design. During the open-label period (weeks 76-252), all patients received guselkumab 100 mg q8w. Physician- and patient-reported outcomes were assessed. Efficacy was analysed using pre-specified treatment failure rules (patients discontinuing due to lack of efficacy, worsening of Pso, or use of a prohibited treatment were considered non-responders). Data were combined for patients randomised to guselkumab and for those originally randomised to placebo who later crossed over to guselkumab at week 16. Patients were treated and followed for up to 264 weeks.

Efficacy assessments included proportions of patients achieving PASI 75, PASI 90 and PASI 100 responses, as well as IGA scores of 0/1 and 0, a Dermatology Life Quality Index (DLQI) score of 0/1, a Psoriasis Signs and Symptoms Diary (PSSD) score of 0, the 36-Item Short-Form Health Survey (SF36), Hospital Anxiety and Depression scale (HADs) and the Work Limitations Questionnaire (WLQ). Efficacy was analysed using pre-specified treatment failure rules, non-responder imputation, and as observed methodology.

VOYAGE 2 is part of a comprehensive Phase 3 clinical development program for guselkumab in Pso that includes VOYAGE 1, NAVIGATE, and ECLIPSE, the first head-to-head Phase 3 study of an IL-23 inhibitor (guselkumab) vs. an IL-17 inhibitor (secukinumab).[25-27]

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

DISCOVER-1 was a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in participants with active PsA, including those previously treated with one or two tumour necrosis factor (TNF) inhibitors. DISCOVER-1 evaluated 381 participants who were treated and followed through approximately one year. The primary endpoint was response of American College of Rheumatology (ACR) 20 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 (36-Item Short-Form Health Survey [SF-36] Physical Component Summary [PCS] and Mental Component Summary [MCS]).

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 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 who were treated and followed through approximately two years. The primary endpoint was response of ACR 20 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). DISCOVER-2 also assessed changes in structural damage as a key secondary endpoint (van der Heijde-Sharp 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.[4] 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.[4] 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 disease-modifying anti-rheumatic drug (DMARD) therapy, with additional PsA approvals in the US, Canada, Japan and a number of other countries worldwide.[4] IL-23 is an important driver of the pathogenesis of inflammatory immune-mediated diseases such as Pso and PsA.[32] 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.[4]

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

Important Safety Information[4]

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 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.
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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 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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