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News Release

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New Phase 3b Psoriatic Arthritis (PsA) Data Show First-in-Class TREMFYA® (guselkumab) Achieved Robust Joint Symptom Improvement and Complete Skin Clearance in Patients with Inadequate Response to Tumour Necrosis Factor Inhibition (TNFi-IR)

57.7 percent achieved ≥20 percent improvement in joint symptoms (ACR20) and 53.4 percent achieved complete skin clearance (PASI 100) at one year in COSMOS, the first study of a selective interleukin (IL)-23 inhibitor in a true TNFi-IR patient population

Of 34 Janssen abstracts at the European League Against Rheumatism (EULAR) E-Congress, many present efficacy and safety data for guselkumab in treating adults with active PsA

BEERSE, BELGIUM, June 2, 2021 – Today the Janssen Pharmaceutical Companies of Johnson & Johnson announced new efficacy and safety data for first-in-class TREMFYA® (guselkumab), including data from the first study evaluating a selective IL-23 inhibitor in adult patients with active PsA all of whom had demonstrated inadequate response or intolerance to tumour necrosis factor inhibition (TNFi).[1] In the COSMOS Phase 3b study, significantly higher proportions of patients treated with guselkumab showed joint symptom improvement and

complete skin clearance versus placebo at week 24 in this true TNFi-IR[a] patient population, which is often more difficult to treat.[1,2] These results are among the 34 scientific abstracts Janssen is presenting from the Company's rheumatology portfolio at the EULAR E-Congress, many of which feature guselkumab, the only selective IL-23 inhibitor therapy approved in the EU to treat adults with moderate to severe plaque psoriasis (Pso) who are candidates for systemic therapy, as well as adults with active PsA who have had an IR or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.[3]

PsA is a chronic, progressive, immune-mediated disease characterised by pain, stiffness, and swelling in and around both peripheral and axial joints as well as itch and discomfort from skin lesions.[4] People living with PsA can also suffer from sleep disorders, fatigue, stress, and depression.[5,6] Janssen data shared at EULAR show the severity of skin and joint symptoms of active PsA was significantly associated with a higher loss of work productivity and impact on daily activity outside of work.[7,8]

"The diverse manifestations, varying natural history, and potential severity of PsA mean that delivering treatments that are safe and have long-term effectiveness is challenging. A number of patients do not reach treatment targets of remission or low inflammation with available therapies. In particular, patients may either not respond well to TNFi, or respond but have a loss of response over time," said study investigator Laure Gossec, M.D., Ph.D., Professor of Rheumatology in Pitie-Salpetriere Hospital and Pierre & Marie Curie University in Paris, France.[b] "These COSMOS data reinforce guselkumab as a therapeutic option with an alternative mechanism of action for adult patients with PsA when their disease management is complex because they have not responded to one or more therapies."

COSMOS (Presentation #OP0230) results show:

- **Robust Joint Symptom Improvement:** 44.4 percent of patients who received guselkumab vs 19.8 percent of patients who received placebo achieved at least 20 percent improvement in the American College of

Rheumatology criteria (ACR20)[c] at week 24, the study's primary endpoint.[1] ACR20 response rates increased at one year (57.7 percent of guselkumab patients at week 48 utilising non-responder imputation [NRI]; with this method of analysis, patients with missing data were considered non-responders).[1] Guselkumab was also superior to placebo in percentage of patients achieving ACR50 and improvement in physical function (Health Assessment Questionnaire Disability Index [HAQ-DI])[d] and general health outcomes (Short Form [SF]-36 and Physical Component Summary [PCS] scores).[1,e] Mean improvement in physical function increased at one year, with higher resolution rates of enthesitis and dactylitis seen as well (soft tissue inflammation measured by the Leeds Enthesitis Index [LEI][f] and Dactylitis Severity Score [DSS] respectively).[1]

- **Complete Skin Clearance:** At week 24, the proportion of patients with ≥3 percent body surface area psoriatic involvement and an Investigator's Global Assessment (IGA)[g] score of ≥2 at baseline achieving complete skin clearance (100 percent improvement in Psoriasis Area Severity Index [PASI])[h] was significantly higher among those receiving guselkumab than those receiving placebo (30.8 percent vs 3.8 percent).[1] At one year (week 48), PASI 100 response rates increased to 53.4 percent of patients receiving guselkumab (utilising NRI).[1]
- **Established Safety Profile:** Guselkumab demonstrated a consistent safety profile with low rates of adverse events (AEs) leading to discontinuation and serious AEs (SAEs).[1] Through week 56, for patients randomized to guselkumab who received at least one administration of drug, there were 149.3 AEs, 6.2 SAEs, and 3.6 AEs leading to treatment discontinuation per 100 patient years.[1] Moreover, there were 39.7 infections and 0.5 serious infections per 100 patient years.[1]

Guselkumab efficacy and safety findings across additional abstracts (presentation numbers cited within) are also being presented:

- **Rapid and Durable Joint Symptom Improvement and Complete Skin Clearance:**

- In the DISCOVER-2 PsA trial, the robust response rates seen at week 24 for joint symptoms (ACR20/50/70), skin clearance (PASI 90/100), improved physical function (HAQ-DI) and enthesitis and dactylitis resolution persisted through two years, even when long-term response rates were conservatively estimated using NRI.[9] 88 percent of patients who received guselkumab (652/739) completed week 100 of the study, with low rates of radiographic progression of joint structural damage observed from week 52-100 **(POS1027)**.[9]
- In DISCOVER-1 and -2, guselkumab demonstrated meaningful improvements in individual components of the ACR criteria as early as week four. At early study time points, both patients and physicians were able to discern improvements in signs and symptoms of arthritis that rapidly followed (within one assessment) reductions in systemic inflammation based on C-reactive protein levels **(AB0525)**.[10]
- In a post hoc analysis of pooled data from DISCOVER-1 and -2 patients with axial symptoms and imaging-confirmed sacroiliitis, guselkumab resulted in numerically lower mean scores for all six Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[i] components compared with placebo as early as week eight and through week 24, with mean scores maintained at week 52 using NRI **(AB0524)**.[11]

- **Established Safety Profile:**
  - Pooled data from the active PsA trials, DISCOVER-1 and -2, and the Pso trials, VOYAGE 1 and 2, showed the guselkumab safety profile was generally consistent between patients with PsA and Pso through one year. Decreased neutrophil counts and elevations in hepatic transaminases – generally mild, transient and without sequalae – were somewhat more common in PsA than Pso patients **(AB0528)**.[12] Through one year of follow-up with guselkumab treatment in pooled DISCOVER-1 and -2 and VOYAGE 1 and 2 data, gastrointestinal-related SAE rates were low. There were no reported cases of uveitis, opportunistic infections, or new onset/exacerbation of inflammatory

bowel disease in guselkumab-treated patients. No new safety concerns were identified through one year **(POS1031)**.[13]

- **Physical, Social and Work Activity:**
  - In an assessment of DISCOVER-2, observed mean T-scores showed improvement from baseline to week 24 in guselkumab-treated patients vs placebo across all seven domains of The Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29)[j] instrument: anxiety, depression, fatigue, pain interference, physical function, sleep disturbance, and social participation. Maintenance of improvements in these health-reported outcomes was seen through week 52 **(POS1029)**.[14]
  - In patients with active PsA who were working at baseline, improvement in work productivity and non-work activity was greater with guselkumab vs placebo at week 24, and these improvements were sustained through week 52. Improvements demonstrated may result in yearly indirect savings in costs associated with work productivity **(POS1026)**.[7]

"These results further our understanding of the efficacy of guselkumab to treat the varied manifestations of PsA," said Alyssa Johnsen, M.D., Ph.D., Vice President and Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "People with PsA live with joint, skin and soft tissue symptoms, but also experience impacts on physical function and social and psychological wellbeing. We are committed to continuing our research in PsA in order to advance therapeutic options that may help more patients reach their treatment goals."

Later this year, Janssen will dose its first patient in the APEX (NCT04882098) study. APEX is a newly initiated Phase 3b trial with long-term extension through three years to further assess the efficacy of guselkumab on the inhibition of radiographic progression of joint structural damage in patients with active PsA.[15]

Abstracts can be accessed on the EULAR 2021 website at: http://scientific.sparx-ip.net/archiveeular

Footnotes:

a. TNFi-IR was defined by the presence of active PsA despite previous treatment with either one or two anti-TNF alpha agents or a lack of benefit of an anti-TNF alpha therapy. This was documented in the participant history by the treating physician, after at least 12 weeks of etanercept, adalimumab, golimumab, or certolizumab pegol therapy (or biosimilars) and/or at least a 14-week dosage regimen (i.e. at least four doses) of infliximab (or biosimilars).[16]

b. Dr Gossec is a paid consultant for Janssen. She has not been compensated for any media work.

c. ACR20/50/70 response is defined as both at least 20/50/70 percent improvement from baseline in the number of tender and 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 (HAQ-DI), visual analogue pain scale, and erythrocyte sedimentation rate or C-reactive protein.[17]

d. HAQ-DI is a patient questionnaire that assesses physical function and disability across rheumatic diseases.[18]

e. SF-36 is a set of generic, coherent, and easily administered quality-of-life measures that rely upon patient self-reporting.[19]

f. LEI is an assessment of periarticular soft tissue tenderness in patients,[20] and DSS is a composite assessment that measures tenderness and digit circumference.[21]

g. 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). IGA Pso response was defined as an IGA score of 0 (cleared) or 1 (minimal) with a ≥2 reduction in IGA score from baseline.[22]

h. 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.[23]

i. BASDAI is a six-question diagnostic test using a 0-10 rating scale to assess the severity of the symptoms of ankylosing spondylitis. A major clinical response (BASDAI 50) is defined as a ≥50 percent improvement in symptoms.[24]

j. PROMIS-29 contains four items for each of seven domains and one pain intensity item; 28 items are scored on a five-point Likert-type scale, and pain intensity is rated from 0-10.[14] The raw score of each domain is converted to a standardised T-score, with norms based on a general population mean score=50 and a standard deviation (SD)=10. Higher scores in anxiety, depression, fatigue, pain interference, and sleep disturbance indicate more severe symptoms; higher physical function and social participation scores indicate better health outcomes.[14] Changes ≥5 points (1/2 SD of T-score) are considered clinically meaningful. Analyses were performed using both observed (mean scores/changes, effect sizes) and imputed clinically meaningful response (whereby change from baseline was set to 0 at week 24/52 for patients who had missing data or at week 24 for patients who met treatment failure criteria prior to week 24).[14]

More 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.[4,5,25,26] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[5,6] Studies show up to 30 percent of people with Pso also develop PsA.[5,27] 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.[5] 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.[28] 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.[4]

About COSMOS (NCT03796858; EudraCT 2018-003214-41)[16,29]

COSMOS was a Phase 3b, multicentre, randomised, double-blind, placebo-controlled study to evaluate the safety and efficacy of guselkumab in 285 patients with active PsA and IR to TNFi therapy. The primary endpoint was ACR20 response at week 24. Participants were randomised (2:1) to receive guselkumab 100 mg at weeks 0, 4, and q8w thereafter, or placebo. The study included two periods: a 24-week double-blind, placebo-controlled period for the primary analysis of the efficacy and safety of guselkumab, compared with placebo and a 32-week active-treatment and safety follow-up period for additional analysis of the efficacy and safety of guselkumab. Through week 48, NRI rules were used for missing data (after the application of treatment failure rules [TFR]). Safety was monitored throughout the study to week 56.

About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37)[30,31]

DISCOVER-1 was a Phase 3, multicentre randomised, double-blind, placebo-controlled 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 TNFi. DISCOVER-1 evaluated 381 participants who were treated and followed through approximately one year. The primary endpoint was ACR20 response at week 24. In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70; resolution of soft tissue inflammation, i.e., enthesitis and dactylitis; improvement in physical function; skin clearance (IGA); fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue Scale); disease activity (Disease Activity Index for PsA, Minimal Disease Activity, Very Low Disease Activity and remission determined using Disease Activity Index for PsA) and general health outcomes (SF-36 PCS and MCS). Through week 48, NRI rules were used for missing data (after the application of TFR).

The study consisted of a screening phase of up to six weeks and a blinded treatment phase of 52 weeks, which 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 the study agent at week 48). Efficacy, safety,

pharmacokinetics, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)[32,33]

DISCOVER-2 was a Phase 3, multicentre, randomised, double-blind, placebo-controlled 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 for DISCOVER-1 and -2 was ACR20 response at week 24 and the data were previously presented at scientific congresses and published in *The Lancet*.[34] In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70; resolution of soft tissue inflammation, i.e., enthesitis and dactylitis; improvement in physical function; skin clearance (IGA); fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue Scale); disease activity (Disease Activity Index for PsA, Minimal Disease Activity, Very Low Disease Activity and remission determined using Disease Activity Index for PsA), and general health outcomes (SF-36 PCS and MCS). DISCOVER-2 also assessed changes in structural damage as a key secondary endpoint (using the PsA-modified van der Heijde-Sharp score). Through week 48, NRI rules were used for missing data (after the application of TFR).

The study consisted of a screening phase of up to six weeks and a blinded treatment phase of approximately 100 weeks, which 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 the 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.

A network meta-analysis of all targeted, advanced therapies approved for PsA published in *Rheumatology* included DISCOVER-1 and -2 data and showed that

guselkumab demonstrated favorable arthritis efficacy comparable to IL-17a and SC TNF inhibitors while offering better PASI response relative to many other treatments.[35]

About VOYAGE 1 (NCT02207231; EudraCT 2014-000719-15)[36,37]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial with 837 patients was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque Pso. Patients were randomised to receive placebo at weeks 0, 4 and 12, followed by crossover to guselkumab at weeks 16 and 20 and then q8w dosing; guselkumab 100 mg at weeks 0, 4 and 12, followed by q8w dosing; or adalimumab 80 mg (n=334) at week 0, followed by 40 mg at week 1, then dosing every two weeks (q2w) through week 47, with crossover to guselkumab q8w at week 52.

The co-primary endpoints of the study were the proportions of patients receiving guselkumab vs patients receiving placebo achieving IGA 0/1 (clear/almost clear skin) and PASI 90 at week 16. Secondary endpoints were assessed at weeks 16, 24 and 48, with safety monitoring throughout the study. Through week 48, NRI rules were used for missing data (after the application of TFR).

During the open-label extension period, which started at week 52, all patients continued open-label treatment with guselkumab through week 252. Efficacy assessments included proportions of patients achieving PASI 90, PASI 100, IGA 0/1, and IGA 0 (clear skin). Efficacy was analysed using prespecified TFR for the primary analysis, while NRI and as observed (OBS) methodology were used for the secondary analyses.

About VOYAGE 2 (NCT02207244; EudraCT 2014-000720-18)[38,39]

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 at weeks

0, 4 and q8w thereafter; placebo at weeks 0, 4, and 12 followed by crossover to guselkumab 100 mg at week 16; or adalimumab 80 mg at week 0, 40 mg at week 1, then 40 mg 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. Through week 48, NRI rules were used for missing data (after the application of TFR). 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.

Co-primary endpoints of the study were proportions of patients receiving guselkumab vs patients receiving placebo achieving IGA 0/1 (clear/almost clear) and PASI 90 at week 16. Additional efficacy assessments included proportions of patients achieving PASI 75, PASI 100, and IGA 0 (clear skin) responses; a Dermatology Life Quality Index score of 0/1; and a Psoriasis Signs and Symptoms Diary score of 0, as well as changes in baseline in SF-36, Hospital Anxiety and Depression Scale and the Work Limitations Questionnaire scores. Efficacy was analysed using pre-specified TFRs, NRI, and OBS methodology.

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.[3] 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.[3] 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 IR 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.[3] IL-23 is an important driver of the pathogenesis of inflammatory immune-mediated diseases

such as Pso and PsA.[40] 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.[3]

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

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.[3] Uncommon ADRs (≥0.1 percent) observed were herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash.[3]

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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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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