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Media contacts:
Kevin Veninga
Mobile: +31 61526 8214
kveninga@its.jnj.com

Investor contacts:
Chris DelOrefice
Office: +1 732 524 2955

Lesley Fishman
Office: +1 732 524 3922

TREMFYA®▼ (guselkumab), a First-in-Class IL-23 p19 Subunit Inhibitor, Meets Primary Endpoints of Superior ACR20 Responses versus Placebo at Week 24 in Phase 3 Psoriatic Arthritis Studies

Findings from the DISCOVER-1 and DISCOVER-2 studies are presented, for the first time, at the 2019 American College of Rheumatology and Association of Rheumatology Professionals Annual Meeting

These are the first Phase 3 results evaluating p19-specific interleukin (IL)-23 inhibition in active psoriatic arthritis

BEERSE, BELGIUM, 11 November, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced 24-week Phase 3 data showing a significantly greater proportion of patients with active psoriatic arthritis (PsA) treated with TREMFYA®▼ (guselkumab) achieved at least a 20 percent improvement in disease signs and symptoms

(American College of Rheumatology ACR20 response) compared to placebo.[1,2] These findings represent the primary endpoints of the DISCOVER-1 and DISCOVER-2 Phase 3 studies, which were designed to evaluate the efficacy and safety of investigational use of guselkumab for the treatment of adult patients with active PsA.[1,2] These results were presented as part of an oral plenary session (abstract 0807) and a late-breaking poster session (abstract L13), respectively, at the American College of Rheumatology and Association of Rheumatology Professionals (ACR/ARP) 2019 Annual Meeting taking place 8-13 November in Atlanta.[1,2] Janssen presented a total of 30 abstracts at the meeting.

"*People living with psoriatic arthritis cope with symptoms like pain, joint swelling, and irreversible joint damage that may interfere with their daily activities*," said Atul Deodhar*, M.D., MRCP, FACP, FACR, Professor of Medicine, Oregon Health & Science University and study steering committee member. "*These data show guselkumab as a potential treatment option to help patients living with this serious disease*."

The data presented at ACR are the first Phase 3 study results in active PsA evaluating a human monoclonal antibody against the p19 subunit of IL-23. DISCOVER-1 evaluated 381 participants with active PsA who had an inadequate response to standard therapies, including participants previously treated with anti-tumour necrosis factor (TNF) alpha biologics.[3] DISCOVER-2 evaluated 739 participants with active PsA who were biologic naïve and had an inadequate response to standard therapies.[4]

Results from DISCOVER-1 show that at Week 24, 59 percent of adult patients with active PsA receiving guselkumab every 4 weeks (q4w) and 52 percent of patients receiving guselkumab at weeks 0, 4 and every eight weeks thereafter (q8w) achieved an ACR20 response compared to 22 percent of patients receiving placebo (both $p<0.001$). Among patients who had a ≥3 percent body surface area (BSA) affected with psoriasis, and an Investigator Global Assessment (IGA) score of ≥2 at baseline, 75 percent of patients receiving guselkumab q4w and 57 percent of patients receiving guselkumab q8w achieved an IGA score of 0 (Cleared) or 1 (Minimal) and a $\geq$2 grade reduction, compared to 15 percent of patients receiving placebo (both $p<0.001$).[1]

Results from DISCOVER-2 show that at Week 24, 64 percent of adult, biologic naïve patients with active PsA receiving guselkumab q4w or q8w achieved an ACR20 response, compared to 33 percent of patients receiving placebo (both $p<0.001$).[2] Among patients who had a ≥3 percent BSA affected with psoriasis, and an IGA score of ≥2 at baseline, 69 percent receiving guselkumab q4w and 71 percent receiving guselkumab q8w achieved an IGA score of 0 or 1, and a $\geq$2 grade reduction from baseline, compared to 19 percent of patients receiving placebo (both $p<0.001$).[2] Patients with active PsA receiving guselkumab q4w showed significantly reduced radiographic damage progression vs. placebo at Week 24.[2]

In DISCOVER-1 and DISCOVER-2, observed adverse events (AEs) were generally consistent with previous studies of guselkumab and current prescribing information.[5,6,7,8,9,10]

Data from the DISCOVER programme formed the basis of the recent supplemental Biologics License Application submission to the U.S. Food and Drug Administration for approval of guselkumab on 13 September, 2019 and the validated filing to the European Medicines Agency (EMA) for approval of guselkumab in the European Union on 11 October, 2019 for adult patients with active psoriatic arthritis.[11]

"*We are passionate about the development of therapies, such as guselkumab, since patients are still struggling with active psoriatic arthritis and need new treatment options*," said Alyssa Johnsen, M.D., Ph.D., Vice President, Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "*These results from the DISCOVER programme represent a major step in the development of guselkumab as a treatment for psoriatic arthritis*."

The DISCOVER studies also evaluated multiple secondary endpoints, including ACR50/70 response, resolution of soft tissue inflammation (enthesitis and dactylitis), disease activity

(DAS-28 CRP), improvement in physical function (HAQ-DI), and general health outcomes (SF-36 PCS and MCS).[1,2]

In the Phase 2a study of guselkumab in PsA, guselkumab was generally well tolerated during approximately 1 year of exposure.[5] The incidence of adverse events, including infections, was similar across both treatment groups. Few serious adverse events were reported, discontinuation was infrequent, and serious infections were rare. The safety outcomes in this Phase 2a study were generally consistent with those observed in clinical trials investigating guselkumab in psoriasis.[6,7]

During clinical development of guselkumab in psoriasis, guselkumab was generally well tolerated.[6,7,8,9] The very common and common adverse events associated with guselkumab are as follows: upper respiratory infection (very common, ≥1/10), and arthralgia, diarrhoea, gastroenteritis, headache, herpes simplex infections, injection site erythema, tinea infections and urticaria (common, ≥1/100 to <1/10). Injection site pain, hypersensitivity and rash have been reported as uncommon adverse events (≥1/1,000 to <1/100).[5]

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* Atul Deodhar is a paid consultant for Janssen. He has not been compensated for any media work.

About DISCOVER-1 (NCT03162796)

DISCOVER-1 is a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by subcutaneous injection in participants with active psoriatic arthritis including those previously treated with biologic anti-TNF alpha agent(s).[3] DISCOVER-1 is evaluating 381 participants and continuing through approximately one year.[3]

The study consists of: a screening phase of up to six weeks, a blinded treatment phase of 52 weeks that includes a placebo-controlled period from Week 0 to Week 24 and an active treatment period from Week 24 to Week 52, and a safety follow-up phase of eight 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).[3] Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations are being performed in the study on a defined schedule.[3]

About DISCOVER-2 (NCT03158285)

DISCOVER-2 is a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab administered by subcutaneous injection in subjects with active psoriatic arthritis.[4] DISCOVER-2 is evaluating 739 participants and continuing through approximately two years.[4]

The study consists of: a screening phase of up to six 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, and a safety follow-up phase of 12 weeks after the last administration of study agent.[4] Efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker and pharmacogenomics evaluations are being performed in the study on a defined schedule.[4]

About psoriatic arthritis

Psoriatic arthritis is a chronic, immune-mediated inflammatory disease characterised by both joint inflammation and the skin lesions associated with psoriasis.[12,13] It is estimated that up to a third of the 14 million people who are living with psoriasis in Europe will also develop PsA.[14,15] The disease causes pain, stiffness and swelling in and around the joints and commonly appears between the ages of 30 and 50, but can develop at any time.[16] Although the exact cause of psoriatic arthritis is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[13,14,17]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is a human monoclonal antibody against the p19 subunit of IL-23.[5] Guselkumab was granted marketing authorisation in the European Union and is approved in the U.S., Canada, Japan and several other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy). IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and psoriatic arthritis.[18]

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

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 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 the Phase 3 DISCOVER-1 and

DISCOVER-2 studies. 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-Cilag International NV, 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 30, 2018, 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.

[1] Deodhar A, *et al*. (2019) Guselkumab, an Anti-interleukin-23p19 Monoclonal Antibody, in Patients with Active Psoriatic Arthritis Who Were Biologic-Naïve or Prior TNFα Inhibitor-Treated: Week 24 Results of a Phase 3, Randomized, Double-blind, Placebo-controlled Study. Available at: https://acrabstracts.org/abstract/guselkumab-an-anti-interleukin-23p19-monoclonal-antibody-in-patients-with-active-psoriatic-arthritis-who-were-biologic-naive-or-prior-tnf%ce%b1-inhibitor-treated-week-24-results-of-a-phase-3-rando/. Last accessed November 2019.
[2] Mease PJ, *et al*. (2019) Guselkumab, an Anti-interleukin-23p19 Monoclonal Antibody, in Biologic-naïve Patients with Active Psoriatic Arthritis: Week 24 Results of the Phase 3, Randomized, Double-blind, Placebo-controlled Study. Available at: https://acrabstracts.org/abstract/guselkumab-an-anti-interleukin-23p19-monoclonal-antibody-

in-biologic-naive-patients-with-active-psoriatic-arthritis-week-24-results-of-the-phase-3-randomized-double-blind-placebo-controlled-stud/. Last accessed November 2019.
[3] Clinicaltrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti -Tumor Necrosis Factor (TNF) Alpha Agent(s) (Discover-1). Available at: https://clinicaltrials.gov/ct2/show/NCT03162796. Last accessed November 2019.
[4] Clinicaltrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03158285 . Last accessed November 2019.
[5] Deodhar A, *et al.* Efficacy and safety of guselkumab in patients with active psoriatic arthritis: a randomised, double-blind, placebo-controlled, phase 2 study. *Lancet* 2018; 391:2213-24.
[6] Reich K, *et al*. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the Phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. *J Am Acad Dermatol* 2017;76(3):418–31.
[7] Blauvelt A, *et al.* Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *J Am Acad Dermatol* 2017;76(3):405–17.
[8] Reich K, *et al.* Guselkumab versus secukinumab for the treatment of moderate-to-severe psoriasis (ECLIPSE): results from a phase 3, randomised controlled trial. *Lancet* 2019; 394(10201):831–39.
[9] Langley R, *et al*. Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: results of the randomized, double-blind, phase III NAVIGATE trial. *Br J Dermatol* 2017;178(1):114–23.
[10] European Medicines Agency. Tremfya Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf. Last accessed November 2019.
[11] BusinessWire. Janssen Seeks to Expand Use of TREMFYA®▼ (guselkumab) in the Treatment of Adults With Active Psoriatic Arthritis. Available at: https://www.businesswire.com/news/home/20191022006172/en/Janssen-Seeks-Expand-TREMFYA%C2%AE%E2%96%BC-guselkumab-Treatment-Adults/. Last accessed November 2019.
[12] National Psoriasis Foundation. Types of psoriatic arthritis. Available at: https://www.psoriasis.org/psoriatic-arthritis/classification-of-psoriatic-arthritis. Last accessed November 2019.
[13] Versus Arthritis. Psoriatic Arthritis. Available at: https://www.versusarthritis.org/about-arthritis/conditions/psoriatic-arthritis/. Last accessed November 2019.
[14] Ogdie A, *et al*. The Epidemiology Psoriatic Arthritis. *Rheum Dis Clin North Am*. 41(4) 545-568. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4610151/pdf/nihms-710337.pdf. Last accessed November 2019.
[15] Ortonne JP, *et al.* Alefacept: a novel and selective biologic agent for the treatment of chronic plaque psoriasis. *European Journal of Dermatology* 2004;14:41–45.
[16] National Psoriasis Foundation. About Psoriatic Arthritis. Available at: https://www.psoriasis.org/about-psoriatic-arthritis. Last accessed November 2019.
[17] Gladman DD, *et al.* Psoriatic arthritis: epidemiology, clinical features, course and outcome. *Ann Rheum Dis* 2005;64(Suppl II):ii14–ii17.
[18] Hueber and McInnes. Immune regulation in psoriasis and psoriatic arthritis-recent developments. *Immunol Lett* 2007;114:59–65