News Release

Media contact:
Kevin Veninga
+316 1526 8214
kveninga@its.jnj.com

Investor relations:
Christopher DelOrefice
+1 732 524 2955

Lesley Fishman
+1 732 524 3922

Janssen Seeks to Expand Use of TREMFYA®▼ (guselkumab) in the Treatment of Adults with Active Psoriatic Arthritis

If approved, guselkumab will be the first selective IL-23 p19 subunit inhibitor for people in the European Union with active psoriatic arthritis

BEERSE, BELGIUM, 23 October, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a Type II Variation Application to the European Medicines Agency (EMA) seeking first-in-class approval of TREMFYA®▼(guselkumab) for the treatment of adult patients with active psoriatic arthritis (PsA). If approved, this will be the second approved indication for guselkumab in the European Union.

Guselkumab is a human monoclonal antibody against the p19 subunit of interleukin (IL)-23, which is an important driver of the pathogenesis of immune-mediated inflammatory diseases such as psoriasis and PsA.[1,2]

It is estimated that up to a third of the 14 million people who are living with psoriasis in Europe will also develop PsA, a chronic, immune-mediated inflammatory disease characterised by both joint inflammation and the skin lesions associated with psoriasis.[3,4,5] 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 age.[6]

"This submission to the EMA is an important milestone for people with psoriatic arthritis, who currently have limited treatment options that improve the signs and symptoms of the condition," said Alyssa Johnsen, M.D. Ph.D., Vice President, Rheumatology Disease Area Leader, Janssen Research & Development, LLC. *"With this filing, we hope to offer clinicians a new and innovative treatment option for people living with psoriatic arthritis."*

This regulatory submission is based on data from the Phase 3 DISCOVER-1 and DISCOVER-2 studies. The DISCOVER programme comprises the first-ever Phase 3 studies evaluating a human monoclonal antibody targeting the p19 subunit of IL-23 in patients with active PsA, and the results have been submitted for presentation at an upcoming medical meeting.

"Psoriatic arthritis is a complex disease causing considerable distress to those afflicted and their families. It is believed to be caused by both genetic and environmental factors," said Professor Iain McInnes,* Muirhead Professor of Medicine and Director of the Institute of Infection Immunity and Inflammation, University of Glasgow. *"Although treatment options for PsA have improved dramatically over the past 15 years, a significant unmet need still exists, with only half of patients achieving more than a 20 percent improvement in joint symptoms in randomised clinical trials. Moreover, too few patients enjoy an acceptable quality of life. New treatment options with different mechanisms of action are urgently needed to improve outcomes."*

Guselkumab was previously approved in the European Union for the treatment of adult patients with moderate to severe plaque psoriasis in November 2017

and has also been approved in the U.S., Canada, Japan and several other countries worldwide.

In the phase 2a study of guselkumab in PsA, guselkumab was generally well tolerated during approximately 1 year of exposure.[7] 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.[8,9]

During clinical development of guselkumab in psoriasis, guselkumab was generally well-tolerated.[8,9,10,11] 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).[2]

# # #

*Professor Iain McInnes is a paid consultant for Janssen. He has not been compensated for any media work.

About psoriatic arthritis

Psoriatic arthritis is a chronic, immune-mediated inflammatory disease characterised by both joint inflammation and the skin lesions associated with psoriasis.[5] 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.[6] Although the exact cause of psoriatic arthritis is unknown, genes, the immune system and environmental factors are all believed to play a role in disease onset.[3,5,12]

About the DISCOVER trial programmes[13,14]

Both DISCOVER trials are randomised, double-blind, multicentre Phase 3 studies designed to evaluate the efficacy and safety of TREMFYA administered by subcutaneous injection in patients with active PsA compared to placebo. DISCOVER-1 evaluates 381 participants, including those previously treated with anti-TNF therapy, and is planned to continue through approximately 1 year. DISCOVER-2 includes 739 biologic-naïve participants and is planned to continue through approximately 2 years. The data from both the DISCOVER trials have been submitted for presentation at an upcoming medical meeting.

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is a human monoclonal antibody against the p19 subunit of IL-23.[2] 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.[1] The guselkumab development programme includes two Phase 3 programmes evaluating TREMFYA in the treatment of active psoriatic arthritis.

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

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 authorization holder for TREMFYA© in the EU, and Janssen Research & Development, LLC is 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 submission of a Group Type II Variation Application to the European Medicines Agency (EMA) seeking approval of TREMFYA® (guselkumab) for the treatment of adult patients with active psoriatic arthritis (PsA). 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] Hueber and McInnes (2007) Immune regulation in psoriasis and psoriatic arthritis--recent developments. *Immunol Lett*;114:59–65
[2] 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 October 2019.
[3] 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 October 2019.
[4] Ortonne J.P. *et al.* (2004) Alefacept: a novel and selective biologic agent for the treatment of chronic plaque psoriasis. *European Journal of Dermatology*;14:41–45.
[5] Versus Arthritis. Psoriatic Arthritis. Available at: https://www.versusarthritis.org/about-arthritis/conditions/psoriatic-arthritis/. Last accessed October 2019.
[6] National Psoriasis Foundation. About Psoriatic Arthritis. Available at: https://www.psoriasis.org/about-psoriatic-arthritis. Last accessed October 2019.
[7] 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.
[8] 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.
[9] 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.
[10] 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.
[11] 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.
[12] Gladman D.D *et al* (2005) Psoriatic arthritis: epidemiology, clinical features, course and outcome. *Ann Rheum Dis*;64(Suppl II):ii14–ii17.
[13] 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 October 2019.
[14] 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?term=NCT03158285&rank=1. Last accessed October 2019.