FOR EMEA MEDICAL AND TRADE MEDIA ONLY, EXCLUDING THE UK, GERMANY AND BENELUX

Media Contact:
Kevin Veninga
Mobile: +31 61526 8214
KVeninga@its.jnj.com

Investor Relations:
Christopher DelOrefice
Office: +1 (732) 524-2955

Jennifer McIntyre
Office: +1 (732) 524-3922

European Commission Approves Janssen's TREMFYA®▼ (guselkumab), a First-in-Class Treatment for Active Psoriatic Arthritis (PsA)

Guselkumab is the first selective IL-23 p19 subunit inhibitor licensed for both the treatment of PsA and plaque psoriasis

BEERSE, Belgium, November 25, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the European Commission (EC) has approved TREMFYA®▼ (guselkumab) for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

Guselkumab is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. It is already approved for the treatment of patients with moderate to severe plaque psoriasis. IL-23 is an important driver of the progression of inflammatory diseases including psoriasis and PsA, among others.[1]

PsA is a multifaceted, chronic, immune-mediated inflammatory disease that is progressive and is characterised by debilitating joint damage and inflammation, in addition to enthesitis, dactylitis, axial disease, and the skin lesions associated with psoriasis. The pain, stiffness and swelling of the joints and connective tissue can be severe and cause everyday tasks to become difficult.[2,3] In addition, more than half of people with PsA also live with another condition, such as cardiovascular disease, osteoporosis, inflammatory bowel disease or depression.[4,5] There is currently no known cure for PsA, and it is estimated that up to a third of the 14 million people living with psoriasis in Europe will go on to develop PsA.[6,7]

"Psoriatic arthritis is a progressive and debilitating disease and can have a huge impact not only on quality of life, but also on a person's mental health. We welcome the news that guselkumab is now approved for the treatment of psoriatic arthritis," said Jan Koren, President, European Federation of Psoriasis Patient Organisations (EUROPSO)*. "For patients, having more innovative treatment options available that improve the quality of life is good news, which we believe will bring hope to many patients in need of additional treatment options. We must now work to make this treatment accessible to patients across the European Union."

Approval for this new indication is based on results from the DISCOVER-1 and DISCOVER-2 Phase 3 clinical studies, which assessed safety and efficacy of guselkumab 100 mg q4w and q8w in adult patients with active PsA. DISCOVER-1 evaluated 381 participants with active PsA who had an inadequate response to standard therapies, including participants (~30 percent) previously treated with anti-tumour necrosis factor (TNF) alpha biologics.[8] DISCOVER-2 included 739 patients who were biologic-naïve only and had an inadequate response to standard therapies.[9] Data from these studies was published earlier this year in *The Lancet* (24-weeks; DISCOVER-1, DISCOVER 2).[8,9]

- The published results show that in both studies, at week 24, adult patients with active PsA achieved statistical significance in the primary endpoint of American College of Rheumatology (ACR) 20 percent improvement (ACR20)

response (DISCOVER-1: p<0.001; DISCOVER-2: p<0.001) in both q4w and q8w guselkumab groups (DISCOVER-1: n=255; DISCOVER-2: n=493) vs the placebo groups (DISCOVER-1: n=126; DISCOVER-2: n= 246).[10,11]

- In addition, significant improvements in quality of life scores (36-item short-form [SF36] physical component summary) were observed in the guselkumab groups vs the placebo groups in DISCOVER-1 (p<0.001 for both doses); in DISCOVER-2, significant improvements were observed in the q4w guselkumab group vs placebo group (p=0.0056 [q8w, p=0.068]).[10,11]
- In DISCOVER 2, inhibition of structural damage progression was measured radiographically and expressed as the mean change from baseline in the total modified van der Heijde-Sharp (vdH-S) score. At week 24, the guselkumab q4w group demonstrated statistically significantly less radiographic progression (p=0.006) and the guselkumab q8w group showed numerically less progression than placebo (p=0.068).[11] At week 52, the mean change from baseline in total modified vdH-S score was similar in the guselkumab q8w and q4w groups (mean scores of 0.97 and 1.07 respectively).[12]
- In addition, higher Psoriasis Area and Severity Index 75 percent improvement (PASI 75), PASI 90 and PASI 100 response rates were observed in the q4w and q8w guselkumab groups vs the placebo groups (in DISCOVER-1, all unadjusted p<0.001 with PASI 100 being p=0.0005 and in DISCOVER-2, all unadjusted p<0.001).[8,9]

In both studies, guselkumab was well-tolerated, and observed adverse events (AEs) were generally consistent with previous studies of guselkumab and current prescribing information. In DISCOVER-1 and -2, serious adverse events up to week 24 in q4w treatment arms (0 and 3 percent) and q8w treatment arms (3 and 1 percent) were similar to those in the placebo arms (4 and 3 percent). In DISCOVER-2, less than 1 percent of patients experienced serious infections following guselkumab treatment, and no patient experienced serious infections following guselkumab treatment in DISCOVER-1. There were no reported deaths in guselkumab-treated patients and no guselkumab-treated patient had inflammatory bowel disease, opportunistic infections such as tinea or candida, active tuberculosis or anaphylactic

or serum sickness-like reactions.[8,9]

"Guselkumab represents a new treatment option – the first in its class – for patients with psoriatic arthritis, in an area where additional treatment options are needed. The DISCOVER 1 and 2 studies, which this approval is based on, show the potential of guselkumab to improve skin and joint symptoms, including structural joint damage, which are all important elements of sustained management of psoriatic arthritis," said David M. Lee, M.D., Ph.D., Global Therapeutic Area Head, Immunology, Janssen Research & Development, LLC. "Today's approval marks an exciting breakthrough as we continue to reimagine what is possible in how immune-mediated diseases like active PsA are understood and treated."

This marketing authorisation follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), issued on 15 October.

**EUROPSO receives financial support from Janssen to support the organisation's work for people living with psoriatic disease. They have not been compensated for any media work.*

#ENDS#

About DISCOVER-1 (NCT03162796; EudraCT 2016-001163-37)[13,14]

DISCOVER-1 was a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab 100 mg q4w and q8w administered by subcutaneous (SC) injection in participants with active psoriatic arthritis PsA including those previously treated with biologic anti-TNF therapies. DISCOVER-1 evaluated 381 participants, continuing through approximately 1 year.[8]

The study consisted of a screening phase of up to 6 weeks, a blinded treatment phase of 52 weeks that included a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 52. It also included a safety follow-

up phase of 8 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). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)[15,16]

DISCOVER-2 is a randomised, double-blind, multicentre Phase 3 study evaluating the efficacy and safety of guselkumab 100 mg q4w and q8w administered by SC injection in participants with active PsA. DISCOVER-2 is evaluating 739 participants and continuing through approximately 2 years.

The study consists of a screening phase of up to 6 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. Efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker and pharmacogenomics evaluations are being performed in the study on a defined schedule.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterized 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 psoriasis.[3,17,18] In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[5] Studies show that up to 30 percent of the 14 million people in Europe living with psoriasis can also develop PsA.[6,7] 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.[19] Though the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[19]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is the first approved monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.[20] Guselkumab is approved as a prescription medicine in the EU, US, Canada, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from injections or pills (systemic therapy), or phototherapy (treatment using ultraviolet [UV] light).[20] In addition to this EU approval, it is also approved in the US, Canada, Japan, Brazil, Ecuador and Taiwan for the treatment of adult patients with active PsA.[20] IL-23 is an important driver of the pathogenesis of inflammatory immune-mediated diseases such as psoriasis and PsA.[1] 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 psoriasis and PsA, with 100 mg SC doses every 4 weeks considered in patients with PsA who are at high risk for joint damage according to clinical judgement.[20]

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

Important Safety Information[20]

Very common (≥10 percent) and common AEs (≥1 percent) in controlled periods of clinical studies with guselkumab were respiratory tract infections, increased transaminases, headache, diarrhoea, arthralgia and injection site reactions. Uncommon AEs (≥0.1 percent) observed were herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash. Most were considered to be mild and did not necessitate discontinuation of study treatment.

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.

▼ AEs should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected AEs related to this medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. AEs should also be reported to Janssen-Cilag Ltd on 01494 567447.

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 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 materialise, 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 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 29, 2019, 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.

# # #

References

1. Benson JM, *et al.* Discovery and Mechanism of Ustekinumab: A Human Monoclonal Antibody Targeting interleukin-12 and interleukin-23 for Treatment of Immune-Mediated Disorders. *MAbs* 2011;3:535–545.
2. Busse K, Liao W. Which Psoriasis Patients Develop Psoriatic Arthritis? *Psoriasis Forum* 2010;16(4):17–25.
3. Belasco J, Wei N. Psoriatic Arthritis: What is Happening at the Joint? *Rheumatol Ther* 2019;6(3):305–315.
4. Arthritis Foundation. Metabolic Comorbidities of Psoriatic Arthritis. Available at: https://www.arthritis.org/health-wellness/about-arthritis/related-conditions/other-diseases/metabolic-comorbidities-of-psoriatic-arthritis. Accessed November 2020.
5. Haddad A and Zisman D. Comorbidities in Patients with Psoriatic Arthritis. *Rambam Maimonides Med J* 2017;8(1):e0004.
6. Ogdie A and Weiss P. The Epidemiology Psoriatic Arthritis. *Rheum Dis Clin North Am* 2015;41(4):545–568.
7. Ortonne JP and Prinz JC. Alefacept: A Novel and Selective Biologic Agent for the Treatment of Chronic Psoriasis. *Eur J Dermatol* 2004;14:41–45.
8. Deodhar A, *et al.* Guselkumab in Patients with Active Psoriatic Arthritis who were Biologic-naive or had Previously Received TNFα Inhibitor Treatment (DISCOVER-1): a

Double-blind, Randomised, Placebo-controlled Phase 3 Trial. *The Lancet* 2020;395(10230):1115–1125.
9. Mease PJ, *et al*. Guselkumab in Biologic-naive Patients with Active Psoriatic Arthritis (DISCOVER-2): A Double-blind, Randomised, Placebo-controlled Phase 3 Trial. *The Lancet* 2020;395(10230):1126–1136.
10. Deodhar A, *et al.* Supplement to: Guselkumab in Patients with Active Psoriatic Arthritis who were Biologic-naive or had Previously Received TNFα Inhibitor Treatment (DISCOVER-1): a Double-blind, Randomised, Placebo-controlled Phase 3 Trial. *The Lancet* 2020; 395(10230):1115–1125.
11. Mease PJ, *et al*. Supplement to: Guselkumab in Biologic-naive Patients with Active Psoriatic Arthritis (DISCOVER-2): A Double-blind, Randomised, Placebo-controlled Phase 3 Trial. *The Lancet* 2020;395(10230):1126-36.
12. McInnes, I, *et al*. Efficacy and Safety of Guselkumab, an Interleukin-23p19-Specific Monoclonal Antibody, Through 1 Year in Biologic-naïve Psoriatic Arthritis Patients. *Arthritis Rheumatol* 2020 (October 11) doi: 10.1002/art.41553. [Epub ahead of print]
13. 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). Identifier: NCT03162796. Available at: www.clinicaltrials.gov/ct2/show/NCT03162796. Accessed November 2020.
14. Clincialtrialsregister.eu. A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis including those Previously Treated with Biologic Anti-TNFα Agent(s) Identifier 2016-001163-37. Available at: www.clinicaltrialsregister.eu/ctr-search/trial/2016-001163-37/DE. Accessed November 2020.
15. Clinicaltrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis (DISCOVER-2). Identifier: NCT03158285. www.clinicaltrials.gov/ct2/show/NCT03158285. Accessed November 2020.
16. Clinicaltrialsregister.eu. A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis. Identifier 2016-001224-63. Available at: www.clinicaltrialsregister.eu/ctr-search/trial/2016-001224-63. Accessed November 2020.
17. Creaky Joints. What is Enthesitis? Available at: https://creakyjoints.org/symptoms/what-is-enthesitis/. Accessed November 2020.
18. Creaky Joints. What is Dactylitis? Available at: https://creakyjoints.org/symptoms/what-is-dactylitis/. Accessed November 2020.
19. National Psoriasis Foundation. About Psoriatic Arthritis. Available at: www.psoriasis.org/about-psoriatic-arthritis. Accessed November 2020.
20. European Medicines Agency. TREMFYA Summary of Product Characteristics. 2020. Available at: www.medicines.org.uk/emc/product/9587/smpc. Accessed November 2020.