FOR MEDICAL AND TRADE MEDIA ONLY

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JANSSEN REPORTS TOP-LINE PHASE 3 RESULTS FOR TREMFYA® (GUSELKUMAB) IN ADULTS WITH ACTIVE PSORIATIC ARTHRITIS

Data are part of the DISCOVER 1 and 2 programme, the first Phase 3 studies to evaluate a selective IL-23 p19 inhibitor in the treatment of psoriatic arthritis

HORSHAM, PENNSYLVANIA, 14 June, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced top-line results from the Phase 3 DISCOVER 1 and 2 studies, which evaluated the efficacy and safety of guselkumab compared to placebo in adult patients with active moderate to severe psoriatic arthritis (PsA). Both studies met their primary endpoints of American College of Rheumatology 20% improvement (ACR20), and the safety profiles observed for guselkumab in the DISCOVER programme were consistent with previous studies of guselkumab and current prescribing information.[1]

The DISCOVER programme comprises the first-ever Phase 3 studies evaluating an IL-23 p19 inhibitor for the treatment of psoriatic arthritis, and data will be presented at upcoming scientific medical meetings. Data from the two DISCOVER

studies will serve as the basis of submissions to the U.S. Food and Drug Administration and European Medicines Agency seeking approval of guselkumab as a treatment for psoriatic arthritis, which are anticipated for later this year.

The DISCOVER programme consists of DISCOVER-1 and DISCOVER-2, two randomised, double-blind, multicentre Phase 3 studies designed to evaluate efficacy and safety of subcutaneous guselkumab in patients with active PsA compared to placebo. In addition to the primary endpoint of ACR20 response at week 24, multiple secondary endpoints were assessed that included ACR50/70, resolution of soft tissue inflammation (enthesitis and dactylitis), disease activity (DAS-28 CRP), improvement in physical function (HAQ-DI), skin clearance (IGA), and quality of life (SF-36 PCS and MCS). DISCOVER-2 also assessed effect on structural damage (vdH-S) as a key secondary endpoint.[1]

DISCOVER-1 included 381 participants, including participants previously treated with biologic anti-TNF biologics. The study continues through 52 weeks. DISCOVER-2 included 739 bio-naive participants and continues through 100 weeks.

#ENDS#

About Psoriatic Arthritis (PsA)

PsA is a chronic, immune-mediated inflammatory disease characterised by both joint inflammation and the skin lesions associated with psoriasis.[2] It is estimated that one third of the 125 million people who are living with psoriasis worldwide will also develop PsA.[3] 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.[2] 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.[2]

About guselkumab[4]

On 10 November 2017, TREMFYA® (guselkumab) was granted market authorisation in the European Union (EU) for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy).[4]

Guselkumab is the first psoriasis treatment licensed in the EU to selectively target IL-23, a key driver of the immune inflammatory response in psoriasis.[5,6,7,8] Guselkumab is a subcutaneous, self-injectable treatment for psoriasis (following training). Treatment requires two starter doses, one initially and the other four weeks later, followed by a maintenance dose once every eight weeks (q8w) thereafter.[5,6,9]

Ongoing trials include: two Phase 3 programmes evaluating guselkumab in the treatment of active PsA and a Phase 2b programmes in Crohn's disease, and two Phase 2 programmes – one for the treatment of ulcerative colitis and the other for the treatment of hidradenitis suppurativa.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA® which is currently approved in the US, Canada and the EU.

Prescribing and safety information

For complete EU prescribing and safety information, please visit: https://www.medicines.org.uk/emc/medicine/34321

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 new study data on guselkumab. 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 and Janssen Research & Development, LLC. 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 30 December, 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.

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[1] Janssen Pharmaceutical Companies of Johnson & Johnson. Data on file (2019)
[2] Mayo Clinic. Psoriatic Arthritis. http://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/home/ovc-20233896. Accessed June 2019.
[3] International Federation of Psoriasis Associations. Our Cause: Psoriasis. Available at: https://ifpa-pso.com/our-cause/. Accessed June 2019.
[4] European Medicines Agency. Tremfya 100mg solution for injection. 2017. Available at: https://www.medicines.org.uk/emc/medicine/34321. Accessed June 2019.
[5] 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.
[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] 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* 2018;178(1):114–23.
[8] Bachelez, H. Interleukin 23 inhibitors for psoriasis: not just another number*. The Lancet* 2017;390(10091):208–10.
[9] ClinicalTrials.gov. A Study to Evaluate the Comparative Efficacy of CNTO 1959 (Guselkumab) and Secukinumab for the Treatment of Moderate to Severe Plaque-type Psoriasis (ECLIPSE). Identifier NCT03090100. Available at: https://clinicaltrials.gov/ct2/show/NCT03090100. Accessed June 2019.