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PRESS RELEASE

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EUROPEAN COMMISSION APPROVES TREMFYA® (GUSELKUMAB) FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN THE EUROPEAN UNION

Janssen's guselkumab is the first biologic to be approved that selectively blocks interleukin (IL)-23

Beerse, Belgium, Thursday 23 November 2017 – Janssen-Cilag International NV announced today that the European Commission (EC) has approved TREMFYA® (guselkumab) for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.[1] Guselkumab is the first biologic that selectively blocks interleukin (IL)-23, a key driver of the immune inflammatory response in psoriasis.[2,3,4,5]

"*We are delighted guselkumab will now be available to patients in Europe,*" said Kris Sterkens, Company Group Chairman, Janssen Europe, Middle East and Africa (EMEA). "*With 14 million people in the region affected by this often painful and potentially disabling disease, we must continue the fight to help improve the lives of those affected. We are proud to be introducing an innovative new option to help address the continued needs of people living with plaque psoriasis.*"

Guselkumab is a self-injectable (following training) treatment for psoriasis. Treatment requires two starter doses, one initially and the other four weeks later, followed by a maintenance dose once every eight weeks (q8w) thereafter.[3,4]

The EC approval is based on data from three Phase III clinical studies. The VOYAGE 1 and 2 trials, which compared guselkumab with placebo and HUMIRA® (adalimumab), showed high levels of skin clearance after just 16 weeks, with at least a 90% reduction in Psoriasis Area and Severity Index score (PASI 90) in 73.3% and 70.0% of patients receiving guselkumab, compared with 49.7% and 46.8% in patients receiving adalimumab, respectively ($P<0.001$).[2,3]

The NAVIGATE trial evaluated patients who did not achieve a response of cleared or minimal disease (Investigator's Global Assessment [IGA] score of 0 or 1) by week 16 when treated with STELARA® (ustekinumab), and were then randomised to either switch to guselkumab or continue on ustekinumab.[4] The guselkumab group benefited significantly from the switch, with a significantly higher mean number of visits at which patients achieved an IGA score of 0 or 1 and at least a 2-grade improvement from week 28 through week 40 (relative to week 16), compared to the ustekinumab group (1.5 *vs* 0.7; $P<0.001$).[4]

During the clinical development programme for guselkumab in psoriasis there were no clear signals of increased risk of malignancy, major cardiovascular events or serious infections, including tuberculosis and the re-activation of latent tuberculosis.[2,3,4] Adverse events reported in at least 5% of guselkumab-treated patients during the first 16 weeks in the VOYAGE 1 and 2 trials included: nasopharyngitis,

upper respiratory tract infection, injection site erythema, headache, arthralgia, pruritus and back pain. The types of adverse events reported remained generally consistent through 48 weeks of treatment.[2,3]

Marketing authorisation follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), issued on 14 September 2017.[6] This approval allows for the marketing of TREMFYA® (guselkumab) in all 28 member states of the European Union as well as the European Economic Area countries (Norway, Iceland and Liechtenstein). Janssen received US FDA approval of guselkumab for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy in July 2017.[7]

*** Ends ***

Information for Editors

About guselkumab

VOYAGE 1, VOYAGE 2 and NAVIGATE studies

- VOYAGE 1 was a Phase III, multicentre, randomised, double-blind, placebo- and active comparator- controlled study, including 837 patients. It included a placebo-controlled period (weeks 0–16), after which patients taking placebo crossed over to receive guselkumab through week 48, and an active comparator-controlled period comparing guselkumab with adalimumab (week 0–48).[2] At week 48, patients randomised to guselkumab at week 0 and those who crossed over from placebo to guselkumab at week 16 continued to receive guselkumab q8w; patients randomised to adalimumab at week 0 also switched to guselkumab q8w at week 48.[8] Beginning at week 52, all patients began receiving open-label guselkumab. This study will continue for a total of 5 years.

- VOYAGE 2 was a Phase III, multicentre, randomised, double-blind, placebo- and active comparator-controlled study, including 992 patients. It consisted of a placebo-controlled period (weeks 0–16), an active comparator-controlled period (weeks 0–28), and a randomised withdrawal and retreatment period (weeks 28–72).[3] Beginning at week 76, all patients began receiving open-label guselkumab. This study will also continue for a total of 5 years.

- NAVIGATE was a Phase III, multicentre, randomised, double-blind study, including 871 patients. All patients received open-label ustekinumab treatment (patients weighing ≤100 kg: 45 mg, patients weighing >100 kg: 90 mg) at weeks 0 and 4. At week 16, patients with an inadequate response to ustekinumab (IGA score ≥2) were randomised in a double-blinded fashion to receive guselkumab at weeks 16, 20, and every 8 weeks thereafter through week 44, or to continue ustekinumab at week 16 and every 12 weeks thereafter through week 40. The final safety follow up visit was at week 60.[4]

Lifecycle development

Phase III studies are being undertaken to evaluate the efficacy and safety of guselkumab for patients with psoriatic arthritis.[9] A Phase III comparator study (the ECLIPSE study) is underway to evaluate the efficacy of guselkumab versus Cosentyx® (secukinumab), an IL-17A inhibitor, in patients with moderate to severe plaque psoriasis.[10]

About Psoriasis

What it is

The most common form of psoriasis is plaque psoriasis, usually resulting in areas of thick, red or inflamed skin covered with silvery scales which are known as plaques.[11] The inconsistent nature of psoriasis means that even when plaques appear to subside, many patients still live in fear of their return.[12]

Impact

Psoriasis can cause great physical and psychological burden. A study comparing psoriasis to other prominent conditions found its mental and physical impact comparable to that seen in cancer, heart disease and depression.[13]

Psoriasis is also associated with several comorbidities including psoriatic arthritis, cardiovascular diseases, metabolic syndrome, chronic obstructive pulmonary disorder (COPD) and osteoporosis.[14,15] In addition, many individuals are faced with social exclusion, discrimination, and stigma because of their disease.[16]

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/emea. Follow us on Twitter: @JanssenEMEA.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development and potential availability in Europe of 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 or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," 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. Neither 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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