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PRESS RELEASE

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JANSSEN RECEIVES CHMP POSITIVE OPINION FOR GUSELKUMAB RECOMMENDING APPROVAL FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN THE EUROPEAN UNION

Pending approval, guselkumab will be the first biologic that selectively blocks interleukin (IL)-23

Beerse, Belgium, 15 September 2017 – Janssen-Cilag International NV announced today that the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorisation in the European Union for the use of guselkumab in the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.[1] Psoriasis is a chronic, painful, disfiguring and disabling disease for which there is no cure.[2] It is also the most common immune system related skin disorder, affecting approximately 14 million people across Europe.[3]

"*People living with plaque psoriasis bear a tremendous physical and emotional burden due to the painful and visible nature of the disease, and there is a real need to improve upon current treatment options*," said José Antonio Burón Vidal, Vice President, Medical Affairs, Europe, Middle East and Africa (EMEA). "*We are pleased guselkumab may soon be available to adults living with moderate to severe plaque psoriasis in Europe, because the evidence shows this novel therapeutic offers significant and lasting efficacy for patients in need of alternative treatment options."*

The EU filing is based primarily on data from three Phase III clinical studies:

- The VOYAGE 1 and 2 trials demonstrated the superior efficacy of guselkumab across all primary and major secondary endpoints compared with placebo and Humira® (adalimumab). Results showed high levels of skin clearance after just 16 weeks, with a 90% reduction in Psoriasis Area and Severity Index (PASI 90) score in 73.3% and 70.0% of patients receiving guselkumab, compared with 49.7% and 46.8% of patients receiving adalimumab in the VOYAGE 1 and 2 trials, respectively ($P<0.001$). In addition, data showed sustained efficacy with every-8-week dosing following two starter doses at weeks 0 and 4. Guselkumab was shown to be generally well-tolerated in patients with psoriasis for a full year, with discontinuation rates due to adverse events comparable to placebo through 16 weeks and to adalimumab through 1 year.[4,5]
- The majority of patients receiving guselkumab for 16 weeks in the VOYAGE 1 and 2 studies achieved a score of 0 or 1 on the widely-used patient-reported outcome tool, the Dermatology Life Quality Index (DLQI), indicating that their psoriasis had no impact on their health-related quality of life. In the VOYAGE 1 study, this result was achieved by a significantly greater proportion of patients receiving guselkumab (62.5%) through week 48, compared with 38.9% of patients treated with adalimumab ($P<0.001$).[4]
- The Psoriasis Symptoms and Signs Diary (PSSD) is a validated patient-reported outcome tool used to assess symptoms and signs of moderate to severe psoriasis. In the VOYAGE 1 and 2 trials, 27.0% and 27.3% of patients receiving guselkumab, respectively, achieved a symptom score of zero (symptom-free) at week 16 compared with <1% of patients in the placebo groups

and 16.5% and 15.0% in the adalimumab groups. In addition, 20.2% and 20.9% of patients receiving guselkumab in the VOYAGE 1 and 2 trials, respectively, achieved a sign score of zero (sign-free) at week 16, compared with 0% of patients in the placebo groups and 11.7% and 10.4% of patients in the adalimumab groups.[4,5]

- The NAVIGATE trial demonstrated that patients who did not achieve a response of cleared or minimal disease (Investigator's Global Assessment score of 0 or 1) by week 16 when treated with STELARA® (ustekinumab), significantly benefited when switched to guselkumab. Among randomised patients, the guselkumab group had 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; $P<0.001$).[6]

Guselkumab is the first treatment to selectively target IL-23, a key driver of the immune inflammatory response in psoriasis.[4,5,6,7] Additional findings from the guselkumab Phase III clinical development programme are currently being presented at the 26th European Academy of Dermatology and Venereology (EADV) congress (13–17 September, Geneva, Switzerland). This includes late breaking two-year efficacy and safety data from the VOYAGE 1 trial.

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 re-activation of latent tuberculosis.[4,5,6] Adverse events reported in at least 1% of guselkumab-treated patients during the first 16 weeks in the VOYAGE 1 and 2 trials included: nasopharyngitis (common cold symptoms), upper respiratory tract infections, headache, arthralgia (joint pain), injection site reactions, hypertension, diarrhea, gastroenteritis, fatigue, back pain and cough. The type of adverse events reported, remained consistent through 48 weeks of treatment.[4,5]

Following this positive opinion, a final decision from the European Commission (EC) is expected later this year. If approved by the EC, guselkumab will have the trade name TREMFYA®.

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.[8]

*** 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).[4]

- 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 randomized withdrawal and retreatment period (weeks 28–72).[5]

- NAVIGATE was a Phase III, multicentre, randomised, double-blind study, including 871 patients. All patients received open-label ustekinumab (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 (Investigator's Global Assessment [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.[6]

Treatment regimen
The self-injectable (following training) treatment requires two starter doses, one at the beginning of treatment and the other four weeks later, followed by one dose once every eight weeks thereafter. [4,5,6]

Additional efficacy
VOYAGE 2 demonstrated that patients had a significantly better chance of achieving PASI 90 with guselkumab treatment compared with adalimumab. Of those unable to achieve this response with adalimumab (n=112), 66.1% did so after switching to guselkumab.

In addition to the current guselkumab clinical programme, the ECLIPSE study will be evaluating the efficacy and safety of guselkumab in comparison with the IL-17A inhibitor, Cosentyx® (secukinumab).[9]

Future indications
Phase III studies are also being undertaken to evaluate the efficacy and safety of guselkumab for patients with psoriatic arthritis, and a Phase 3 programme in Crohn's disease is planned.[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.[11]

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.[12]

Psoriasis is also associated with several comorbidities including psoriatic arthritis; cardiovascular diseases; metabolic syndrome; chronic obstructive pulmonary disorder (COPD); and osteoporosis.[13,14] In addition, many individuals are faced with social exclusion, discrimination, and stigma because of their disease.[2]

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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