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New Phase 3 Data for TREMFYA®▼ (guselkumab), a First-in-Class IL-23 p19 Subunit Inhibitor, Show Consistent, High Levels of Skin Clearance Through Four Years in Adult Patients with Moderate to Severe Plaque Psoriasis

New analyses of the VOYAGE 1 Phase 3 head-to-head data show a higher proportion of patients treated with guselkumab reported symptom-free and sign-free status through 48 weeks versus adalimumab

BEERSE, BELGIUM, June 15, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new long-term plaque psoriasis data for TREMFYA®▼ (guselkumab), a first-in-class treatment showing consistent, high levels of skin clearance at week 100 and week 204 (four years).[1,2]

In the open-label extension of VOYAGE 2, at four years, 80 percent of patients who were treated with guselkumab 100 mg every 8 weeks (q8w), achieved at least 90

percent improvement in the Psoriasis Area and Severity Index (PASI 90) score. At four years, the proportion of patients who achieved an Investigator's Global Assessment (IGA) score of clear (0) or minimal disease (1) was 82 percent, and 51 percent of patients achieved PASI 100, or complete clearance of their psoriasis plaques.[2] These data are being shared online as an accepted poster (P15300) by the American Academy of Dermatology, which conducted its annual congress virtually.[2]

Guselkumab is the first monoclonal antibody that selectively binds to the p19 subunit of IL-23, and inhibits its interaction with the IL-23 receptor, to have been approved by the European Commission.[1]

VOYAGE 2 endpoints also included patient-reported outcome measures, including the Dermatology Life Quality Index (DLQI)[a] and the Psoriasis Symptoms and Signs Diary (PSSD)[b].[3] At four years, 69 percent of patients achieved a DLQI score of 0 or 1 (indicating no impact of skin disease on health-related quality of life), 40 percent reported a PSSD symptom score of 0, and 27 percent reported a PSSD sign score of 0 (reflecting symptom- and sign-free status, respectively).[2]

"Psoriasis patients are often burdened by physical pain and discomfort, and providing long-term relief from the disease is also important in alleviating the related impact to patients' quality of life," said Kristian Reich[i], M.D., Ph.D., Professor of Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Germany, and lead investigator of the VOYAGE 2 study. "Results from the VOYAGE 2 study demonstrate guselkumab as an efficacious therapy through four years, providing patients who may be experiencing chronic psoriatic symptoms with a long-term treatment option."

The safety profiles observed for guselkumab and adalimumab in VOYAGE 2 were consistent with the known safety profiles seen in the respective registration trials

and current prescribing information. As in the current prescribing information, very common (>10%) and common adverse events (AEs; >1%) in controlled periods of clinical studies with guselkumab were upper respiratory infections, gastroenteritis, herpes simplex infections, tinea infections, headache, diarrhoea, urticaria, arthralgia and injection site erythema. Most were considered to be mild and did not necessitate discontinuation of study treatment.[1] No new safety signals were identified at four years in the presented analyses.[2]

Symptom- and Sign-Free versus Adalimumab at 48 Weeks

Separately, data from the randomised, placebo-controlled, head-to-head, Phase 3 VOYAGE 1 trial comparing patient-reported outcomes between those being treated with guselkumab and those being treated with adalimumab are also being shared online as a poster (P15287). The findings show that at week 48, approximately 42 percent of guselkumab-treated patients and 23 percent of adalimumab-treated patients were symptom-free, as demonstrated by a PSSD symptom score of 0, and 36 percent vs 19 percent (both $p<0.001$), respectively, were sign-free, as demonstrated by a PSSD sign score of 0. Also, through week 48, patients treated with guselkumab experienced numerically more time free from symptoms like itching and pain, and signs like cracked and scaly skin, compared with patients treated with adalimumab.[4]

"The four-year patient-reported outcomes in the VOYAGE programme are particularly noteworthy because they show that the efficacy data for guselkumab translates into nearly 70 percent of patients reporting that their skin disease had no negative impact on their health-related quality of life and approximately 40 percent of patients reporting that they were symptom-free," said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC. "These findings are indicative of the consistent and durable skin clearance possible for adults living with moderate to severe plaque psoriasis."

Initial four-year efficacy analyses from VOYAGE 1 were presented at the 2019 Fall Clinical Dermatology congress.[5] These new data from VOYAGE 2 are consistent with and complement those findings.

#ENDS#

[i] *Dr. Reich is a paid consultant for Janssen. He has not been compensated for any media work.*

Key definitions

[a] The Dermatology Life Quality Index is a patient questionnaire that assesses the effect of a skin disease on quality of life in ten activities of daily life over the previous week.[3]

[b] The Psoriasis Symptoms and Signs Diary is used to track the severity of five symptoms (itch, skin tightness, burning, stinging, and pain) and six signs (dryness, cracking, scaling, shedding/flaking, redness, and bleeding) of psoriasis. It is a patient-reported assessment.[3]

About VOYAGE 2[3]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque psoriasis. Patients (N=992) were randomised to receive subcutaneous (SC) injections of guselkumab 100 mg (n=496) at weeks 0, 4 and every 8 weeks (q8w) thereafter; placebo (n=248) at weeks 0, 4, and 12 followed by crossover to guselkumab 100 mg at week 16; or adalimumab 80 mg (n=248) at week 0, 40 mg at week 1, then 40 mg q2w until week 23. Weeks 28–72 incorporated a randomised withdrawal study design. During the open-label period (weeks 100–204), patients received guselkumab 100 mg q8w. Physician- and patient-reported outcomes were assessed. Efficacy was analysed using pre-specified treatment failure rules beginning at week 76 (patients were considered non-responders after discontinuing

due to lack of efficacy, worsening of psoriasis, or use of a prohibited treatment). Data were combined for patients randomised to guselkumab and for those originally randomised to placebo who later crossed over to guselkumab at week 16. This study will continue for a total of five years.

Efficacy assessments included proportions of patients achieving PASI 75, PASI 90 and PASI 100 responses, as well as IGA scores of 0/1 and 0, a DLQI score of 0/1, and a PSSD score of 0. Efficacy was analysed using pre-specified treatment failure rules, non-responder imputation, and as observed methodology.

About VOYAGE 1[6]

VOYAGE 1 is a Phase 3, multicentre, randomised, double-blind, placebo- and active comparator-controlled study, with 837 patients. It included a placebo-controlled period (weeks 0–16), after which patients receiving placebo crossed over to receive guselkumab through week 48, and an active comparator-controlled period comparing guselkumab with adalimumab (week 0–48). Patients randomised to guselkumab at week 0 and those who crossed over from placebo to guselkumab at week 16 continued to receive guselkumab q8w through week 48. Beginning at week 52, all patients began receiving open-label guselkumab treatment. This study will continue for a total of five years.

VOYAGE 1 and VOYAGE 2 are part of a comprehensive guselkumab Phase 3 clinical development programme in psoriasis that includes an additional Phase 3 trial, NAVIGATE, as well as ECLIPSE, which is a Phase 3 study of guselkumab vs secukinumab.[7,8]

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.[9] The inconsistent nature of psoriasis means that even when plaques appear to subside, patients can have ongoing concerns over their return.[10]

Impact

Approximately 14 million people in Europe are living with psoriasis, which often leads to a great physical and psychological burden.[11] Mental health issues are common among people with psoriasis, and the impact it can have on quality of life is comparable with diabetes and cancer.[12] Psoriasis is also associated with several comorbidities including psoriatic arthritis, cardiovascular diseases, metabolic syndrome, chronic obstructive pulmonary disorder (COPD) and osteoporosis.[13] In addition, many individuals are faced with social exclusion, discrimination and stigma because of their disease.[14]

About TREMFYA® (guselkumab)[1]

Developed by Janssen, guselkumab is the first approved monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. Guselkumab is approved as a prescription medicine in the European Union (EU), U.S., 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). It is approved as a prescription medicine in Japan and Brazil for the treatment of adult patients with active psoriatic arthritis. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and psoriatic arthritis.[15] Guselkumab is administered as a 100 mg SC injection once every 8 weeks, after starter doses at weeks 0 and 4 in the treatment of adults with moderate to severe plaque psoriasis.

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

Important Safety Information

Very common (>10%) and common AEs (>1%) in controlled periods of clinical studies with guselkumab were upper respiratory infections, gastroenteritis, herpes simplex infections, tinea infections, headache, diarrhoea, urticaria, arthralgia and injection site erythema. 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.medicines.org.uk/emc/medicine/34321

▼ 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 +44 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.
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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 moderate to severe plaque psoriasis. 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.

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