News Release

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New First-in-Class Phase 3 Data Demonstrate TREMFYA®▼ (guselkumab) Maintained Skin Clearance Rates Through Nearly 5 Years of Continuous Use in Adult Patients with Moderate to Severe Plaque Psoriasis

Data from VOYAGE 1 open-label, long-term extension show sustained efficacy response rates at week 252 and no new safety signals

First study of an IL-23 inhibitor treatment to demonstrate safety and efficacy throughout a nearly five-year period of use

BEERSE, BELGIUM, 15 October, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new open-label extension data from the Phase 3 VOYAGE 1 study, which showed high rates of skin clearance with TREMFYA®▼ (guselkumab) and no new safety signals in adult patients with moderate to severe plaque psoriasis through nearly five years of treatment.[1,2] At week 252 in the combined* guselkumab group, 84 percent of patients achieved a Psoriasis Area Severity Index (PASI) 90 response (a 90 percent improvement in the PASI score compared to baseline) and 82.4 percent achieved an Investigator's Global

Assessment (IGA) score of 0 (clear) or 1 (almost clear) (IGA 0/1).[1] Among patients in the combined* guselkumab group, patients were either initially randomised to guselkumab or to placebo with crossover to guselkumab at week 16.[1] Safety outcomes were observed through 264 weeks with no new safety signals.[1,2] 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.[2] These data are being presented at the 16th Annual Coastal Dermatology Symposium, which will be conducted virtually.[1]

“Patients with psoriasis face a life-long struggle as a result of this complex and disabling chronic disease," said Chris Griffiths,** M.D., Dermatology Centre, University of Manchester, Manchester, UK. “The VOYAGE 1 guselkumab data are the first for an IL-23 p19 inhibitor to demonstrate skin clearance for the majority of patients through nearly five years of treatment and are encouraging for patients and physicians alike as they seek long-term treatment options.”

In this Phase 3 trial, out of a total of 494 patients either randomised to guselkumab at week 0 (n=329) or randomised to placebo and crossed over to receive guselkumab at week 16 (n=165), 76.9 percent (380/494) continued on guselkumab treatment through week 252. Through nearly five years of continuous guselkumab use, PASI 90 response rates were steadily consistent based on the primary pre-specified Treatment Failure Rules (TFR). At week 52, PASI 90 response rates were 79.7 percent, 75.5 percent, and 80.6 percent based on TFR, Non-Responder Imputation (NRI), and As Observed (OBS) analyses, respectively; while corresponding rates at week 252 were 84.1 percent, 66.6 percent, and 86.6 percent. Similarly, PASI 100, IGA 0/1, and IGA 0 response rates were consistent from week 52 through week 252. Response rates were also consistent through week 252 in patients randomised to guselkumab at week 0 (n=329). Of note, each patient may not have achieved response at each observation time point. At one year and thereafter, patients and study investigators knew that all study participants were on guselkumab, which may affect the results.[1]

Safety findings were generally consistent with those previously observed and the current Summary of Product Characteristics.[1,2] Through the end of the safety assessment (week 264) for all patients (n=774) inclusive of the combined* guselkumab group (n=494) and a group of patients initially treated with adalimumab who crossed over to guselkumab (n=280), the proportion of patients reporting at least one adverse event (AE), serious AE, or discontinuation due to AEs were 87.7 percent, 16.4 percent, and 6.1 percent, respectively.[1] Very common (≥10 percent) and common AEs (≥1 percent) 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 reactions. Uncommon AEs (≥0.1 percent) observed were hypersensitivity, anaphylaxis and rash.[2]

“We are excited to share these data demonstrating guselkumab’s ability to help adults living with moderate to severe plaque psoriasis by providing sustained rates of clearance through nearly five years for the majority of patients,” said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC. “With remission as the ultimate goal, we are committed to continuing to apply the best science and disease insights to advancing therapies that improve the lives of patients.”

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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.[3] The inconsistent nature of psoriasis means that even when plaques appear to subside, patients can have ongoing concerns over their return.[4]

Impact

Approximately 14 million people in Europe are living with psoriasis, which often leads to a great physical and psychological burden.[5] 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.[6] Psoriasis is also associated with several comorbidities including psoriatic arthritis, cardiovascular diseases, metabolic syndrome, chronic obstructive pulmonary disorder (COPD) and osteoporosis.[7] In addition, many individuals face social exclusion, discrimination and stigma because of their disease.[8]

About VOYAGE 1 (NCT02207231)[1]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial with 837 patients was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque psoriasis. Patients were randomised to receive placebo (n=174) at weeks 0, 4 and 12, followed by crossover to guselkumab (n=165) at weeks 16 and 20 followed by every eight-week (q8w) dosing; guselkumab 100 mg (n=329) at weeks 0, 4 and 12, followed by q8w dosing; or adalimumab 80 mg (n= 334) at week 0, followed by 40 mg at week 1, then dosing every two weeks through week 47, with crossover to guselkumab q8w at week 52.

The co-primary endpoints of the study were the proportions of patients receiving guselkumab vs. patients receiving placebo achieving IGA 0/1 (clear/almost clear) [73 percent vs. 3 percent *p<0.001 vs placebo*] and PASI 90 [85 percent vs. 7 percent *p<0.001 vs placebo*] at week 16. Secondary endpoints were assessed at weeks 16, 24 and 48, with safety monitoring throughout the study. Through week 48, NRI rules were used for missing data (after the application of treatment failure rules).

During the open-label extension period, which started at week 52, all patients continued open-label treatment with guselkumab through week 252. Efficacy assessments included proportions of patients achieving PASI 90, PASI 100, IGA of

0/1, and IGA of 0. Efficacy was analysed using prespecified TFR for the primary analysis, while NRI and OBS methodologies were used for the secondary analyses.

VOYAGE 1 and VOYAGE 2 are part of a comprehensive Phase 3 clinical development program for guselkumab in psoriasis that includes an additional Phase 3 trial, NAVIGATE, and ECLIPSE, the first head-to-head Phase 3 study of an IL-23 inhibitor (guselkumab) vs. an IL-17 inhibitor (secukinumab).[9,10]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.[2] Guselkumab is approved in the European Union (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).[2] It is approved in the US, Canada, Japan, Brazil and Ecuador for the treatment of adult patients with active psoriatic arthritis.[2] IL-23 is an important driver of the pathogenesis of inflammatory immune-mediated diseases such as psoriasis.[11] In psoriasis, guselkumab is administered as a 100 mg subcutaneous injection once every 8 weeks, after starter doses at weeks 0 and 4.[2]

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

Important Safety Information[2]

Very common (≥10 percent) and common AEs (≥1 percent) 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 reactions. Uncommon AEs (≥0.1 percent) were hypersensitivity, anaphylaxis 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.
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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.

**The combined group included patients who were initially randomized to receive TREMFYA at week 0 and patients who were initially randomized to placebo then crossed over to TREMFYA at week 16.*
***Professor Griffiths is a paid consultant for Janssen. He was not compensated for any media work.*

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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 materialize, 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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