

## PRESS RELEASE

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### **NEW TWO-YEAR GUSELKUMAB DATA SHOW PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS ACHIEVED CONSISTENT RATES OF SKIN CLEARANCE**

*More than 80 percent of patients receiving guselkumab, including patients transitioned from HUMIRA® (adalimumab) to the anti-interleukin (IL)-23 monoclonal antibody, demonstrated PASI 90 and IGA 0/1 scores at week 100*

**Geneva, Switzerland, September 16, 2017** — Janssen Research & Development, LLC (Janssen) presented today new longer-term data from the open-label extension of the VOYAGE 1 trial demonstrating consistent rates of skin clearance with guselkumab treatment through week 100 among patients with moderate to severe plaque psoriasis receiving the subcutaneously administered anti-interleukin (IL)-23 monoclonal antibody.<sup>1</sup> The longer-term findings from the Phase 3 VOYAGE 1 study, presented at the 26<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress, showed more than 80 percent of patients receiving guselkumab, including those initially treated with placebo or the anti-tumor necrosis factor (TNF)-alpha agent adalimumab, achieved at least a 90 percent improvement in the Psoriasis Area Severity Index (PASI 90), or near complete skin clearance, and an Investigator's Global Assessment (IGA) score of cleared (0) or minimal disease (1) at week 100.<sup>1</sup> The findings, presented during an EADV late-breaker session, follow the recent European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommendation for approval of guselkumab, and the United States Food and Drug Administration (FDA) approval of guselkumab in July.

"These data show the rates of skin clearance with guselkumab were consistent at weeks 52 and 100 with every eight-week maintenance therapy. These important new findings contribute to the scientific evidence for targeting IL-23 in the treatment of moderate to severe plaque psoriasis," said Professor Chris Griffiths, Foundation Professor of Dermatology at the University of Manchester, UK, VOYAGE 1 study steering committee member. "Also noteworthy is that skin clearance rates in patients transitioned to guselkumab from adalimumab improved and the rates were consistent at weeks 52 and 100."

Results from the open-label extension of the Phase 3 VOYAGE 1 study showed that at week 100, among patients initially randomised to guselkumab, 82.4 percent achieved an IGA score of 0/1 (cleared or minimal disease) and 82.1 percent achieved a PASI 90 score (near complete skin clearance).<sup>1</sup> In addition, at week 100, 53.8 percent of patients achieved an IGA score of 0 and 49.0 percent of patients achieved a PASI 100 score.<sup>1</sup> These measures represent skin completely cleared of plaques and were consistent with PASI 100 and IGA 0 results demonstrated at week 52.<sup>1</sup> Among patients initially randomised to receive adalimumab and

transitioned to guselkumab at week 52, the proportion of patients achieving a PASI 90 score increased from 50.5 percent at week 52 to 81.1 percent at week 100, and the proportion of patients achieving an IGA 0/1 increased from 60.4 percent at week 52 to 84 percent at week 100.<sup>1</sup> The proportion of patients who achieved PASI 100 and IGA 0 scores increased from 24.0 percent and 27.3 percent, respectively, at week 52 to 51.6 percent and 55.6 percent, respectively, at week 100.<sup>1</sup> Results among patients initially randomised to placebo and crossed over to guselkumab at weeks 16 and 20 demonstrated consistent levels of skin clearance at weeks 52 and 100.<sup>1</sup>

Scores from the Psoriasis Symptoms and Signs Diary (PSSD), which evaluates patient-reported symptoms (i.e., itch, pain, stinging, burning and skin tightness) and signs (i.e., skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding), and the Dermatology Life Quality Index (DLQI), which assesses the impact of disease and disease improvement following therapy on study participants' quality of life, were consistent over the two-year period with guselkumab treatment.<sup>1</sup> Patients initially randomised to receive adalimumab therapy in VOYAGE 1 and crossed over to guselkumab demonstrated substantial improvement in PSSD and DLQI scores from week 48 to week 100.<sup>1</sup> The proportion of patients reporting PSSD symptom scores of 0 (0–10 scale where a higher score indicates more severe symptoms of psoriasis) improved from 23.1 percent at week 48 (during adalimumab treatment) to 41.8 percent at week 100 (during guselkumab treatment).<sup>1</sup> The proportion of patients reporting DLQI scores of 0/1 improved from 38.9 percent at week 48 (during adalimumab treatment) to 74.0 percent at week 100 (during guselkumab treatment).<sup>1</sup>

Through week 100, there were no disproportionate increases in rates of adverse events (AEs) compared with rates through week 48. Serious AE rates were low and remained stable. No cases of active tuberculosis, opportunistic infections or serious hypersensitivity reactions were reported.<sup>1</sup>

“We are committed to advancing innovative therapies for immune-mediated diseases, like psoriasis, as we seek to improve outcomes for patients,” said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. “We look forward to continued collaborations with regulators as we work to bring guselkumab to patients around the world who may benefit from this novel therapy.”

An additional eight abstracts presented during EADV 2017 reported on efficacy, safety and patient-reported outcome data from the guselkumab Phase 3 moderate to severe plaque psoriasis clinical development programme.

### **About VOYAGE 1**

The 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=837) were randomised to receive placebo at weeks 0, 4 and 12, followed by crossover to guselkumab at weeks 16 and 20 followed by every eight-week dosing (q8w); guselkumab 100 mg at weeks 0, 4 and 12, followed by q8w; or adalimumab 80 mg at week 0 and 40 mg at week 1, followed by every two-week dosing through week 47, with crossover to guselkumab q8w at week 52.<sup>2</sup> The co-primary endpoints of the study were the proportions of patients receiving guselkumab versus patients receiving placebo achieving IGA 0/1 (cleared/minimal disease) and PASI 90 response at week 16.<sup>2</sup> Secondary endpoints were assessed at weeks 16, 24 and 48, with safety monitoring throughout the study.<sup>2</sup> The open-label extension period started at week 52 and is currently ongoing. Results presented to date include findings through week 100 of the study.<sup>1</sup> Through week 48, non-responder imputation rules were used for missing data while after week 48, no missing data were imputed after the application of treatment failure rules. [VOYAGE 1](#) is part of a comprehensive guselkumab Phase 3 clinical development program that includes

two additional Phase 3 trials, [VOYAGE 2](#) and [NAVIGATE](#).<sup>2,3,4</sup>

### **About guselkumab**

Guselkumab is a human monoclonal antibody developed by Janssen that selectively blocks the protein interleukin (IL)-23 and is approved in the U.S. for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light). A Phase 3 program evaluating guselkumab in the treatment of active psoriatic arthritis is ongoing,<sup>5</sup> a Phase 3 study evaluating the efficacy of guselkumab compared with COSENTYX® (secukinumab) in the treatment of moderate to severe plaque psoriasis is underway<sup>6</sup> and a Phase 3 programme in Crohn's disease is planned.

The final European Commission (EC) decision on the approval of guselkumab is expected by the end of 2017. If approved by the EC, guselkumab will have the trade name TREMFYA®. Applications seeking approval in Japan and other countries are currently under review.

### **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.<sup>7</sup> The inconsistent nature of psoriasis means that even when plaques appear to subside, many patients still live in fear of their return.<sup>7</sup>

#### ***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.<sup>8</sup>

Psoriasis is also associated with several comorbidities including psoriatic arthritis; cardiovascular diseases; metabolic syndrome; chronic obstructive pulmonary disorder (COPD); and osteoporosis.<sup>9,10</sup> In addition, many individuals are faced with social exclusion, discrimination, and stigma because of their disease.<sup>11</sup>

### **About the Janssen Pharmaceutical Companies**

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](http://www.janssen.com/emea). Follow us on Twitter at <https://twitter.com/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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC and 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 in the section captioned "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](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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HUMIRA® is a registered trademark of AbbVie Inc. COSENTYX® is a registered trademark of Novartis AG.

## References

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