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## News Release

**Media Contact:**

Brian Kenney  
Office: +1 215-628-7010  
Mobile: +1 215-620-0111  
[bkenney1@its.jnj.com](mailto:bkenney1@its.jnj.com)

Emily Bone  
Mobile: +44 7876 394360  
[ebone1@its.jnj.com](mailto:ebone1@its.jnj.com)

**Investor Contacts:**

Joseph J. Wolk  
Johnson & Johnson  
Office: +1 732-524-1142

Lesley Fishman  
Johnson & Johnson  
Office: +1 732-524-3922

### **NEW PHASE 3 DATA SHOW SIGNIFICANT EFFICACY VERSUS PLACEBO AND SUPERIORITY OF GUSELKUMAB VERSUS HUMIRA® IN TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS**

*Guselkumab, an anti-interleukin-23 monoclonal antibody, demonstrates significant efficacy compared with tumor necrosis factor blocker Humira® across all major study endpoints through 48 weeks of treatment*

**Vienna, Austria, October 1, 2016** — Janssen Research & Development, LLC (Janssen) announced today findings from the first of three pivotal Phase 3 studies evaluating guselkumab, a subcutaneously administered anti-interleukin (IL)-23 monoclonal antibody in late-stage development for the treatment of adults with moderate to severe plaque psoriasis. Data from the VOYAGE 1 trial showed significantly higher proportions of patients receiving guselkumab achieved cleared/minimal disease compared with patients receiving placebo, as defined by at least a 90 percent improvement in the Psoriasis Area Severity Index (PASI 90, near complete skin clearance) and an Investigator's Global Assessment (IGA) score of cleared (0) or minimal disease (1) at week 16, the study co-primary endpoints.<sup>1</sup> The VOYAGE 1 trial also included an active comparator arm evaluating guselkumab versus Humira® (adalimumab), and showed the superiority of guselkumab across major study endpoints and through 48 weeks of treatment.<sup>1</sup> These data were presented for the first time at the 25<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress and mark the first-ever results from a head-to-head study of an IL-23–targeted biologic therapy (guselkumab) compared with an anti-TNF- $\alpha$  treatment (adalimumab).

“Results from the VOYAGE 1 study showed high rates of skin clearance among patients with moderate to severe plaque psoriasis receiving guselkumab, and these responses were durable and maintained through week 48,” said Andrew Blauvelt, M.D., M.B.A., President of the Oregon Medical Research Center and lead study investigator.\* “Guselkumab also showed superior efficacy compared with adalimumab, with a separation in responses that was evident at week 16 and continued through the duration of the trial.”

In the VOYAGE 1 study, the co-primary endpoints were met at week 16, with 85.1 percent of patients receiving guselkumab 100 mg at weeks 0 and 4 and then every eight weeks achieving cleared (IGA 0) or minimal disease (IGA 1) compared with 6.9 percent of patients receiving placebo ( $P < 0.001$ ).<sup>1</sup> Nearly three-quarters of patients receiving guselkumab (73.3 percent) achieved a PASI 90 response, or near complete skin clearance, compared with 2.9 percent of patients receiving placebo ( $P < 0.001$ ).<sup>1</sup>

All major secondary endpoints in VOYAGE 1 achieved statistical significance in comparisons of guselkumab versus adalimumab administered subcutaneously at weeks 0 (80 mg), 1 (40 mg) and then 40 mg every other week ( $P < 0.001$  for all measures).<sup>1</sup> At week 16, following three injections of guselkumab and ten injections of adalimumab, significantly higher proportions of patients receiving guselkumab achieved IGA 0/1 and PASI 90 (85.1 percent and 73.3 percent, respectively) compared with patients receiving adalimumab (65.9 percent and 49.7 percent, respectively) ( $P < 0.001$ ).<sup>1</sup> At week 24, the proportion of patients who achieved a PASI 90 response was significantly higher in the guselkumab group compared with the adalimumab group (80.2 percent vs. 53.0 percent, respectively) ( $P < 0.001$ ).<sup>1</sup> Higher levels of skin clearance among the guselkumab group continued through weeks 24 and 48, with significantly more patients receiving guselkumab achieving IGA 0/1 and PASI 90, as well as measures of full skin clearance, as indicated by a 100 percent improvement in PASI score (PASI 100) or an IGA score of 0, compared with adalimumab ( $P < 0.001$ ).<sup>1</sup>

“The high and durable rates of response in skin clearance were associated with significant improvements in quality of life among patients treated with guselkumab,” said Professor Chris Griffiths, Foundation Professor of Dermatology at the University of Manchester and steering committee member.\* “Results from the VOYAGE 1 study show the promise of guselkumab as a potential therapeutic for plaque psoriasis, an immune-mediated disease.”

The Dermatology Life Quality Index (DLQI) assessed the impact of disease and disease improvement following therapy on study participants’ quality of life. At week 24, a score of 0/1, indicating no impact of psoriasis on health-related quality of life, was achieved by 60.9 percent of patients receiving guselkumab compared with 39.5 percent of patients receiving adalimumab ( $P < 0.001$ ).<sup>1</sup> Guselkumab-treated patients also showed substantial improvement at week 48 with 62.5 percent scoring a DLQI of 0/1 compared with 38.9 percent of adalimumab-treated patients ( $P < 0.001$ ).<sup>1</sup>

Through week 48 of the study, the proportions of patients reporting at least one AE were comparable between guselkumab (73.9 percent) and adalimumab (74.5 percent); the proportions of patients reporting serious AEs were also similar for guselkumab (4.9 percent) and adalimumab (4.5 percent).<sup>1</sup> Serious infections occurred in two patients receiving guselkumab and three patients receiving adalimumab.<sup>1</sup> Through week 48, there was one myocardial infarction in each of the guselkumab and adalimumab treatment groups, and two solid malignancies (one prostate and one breast cancer) were reported in patients receiving guselkumab.<sup>1</sup>

“We are committed to translating scientific progress into medicines for immune diseases like psoriasis where patients are (still) waiting for improved outcomes and treatment experiences,” said Newman Yielding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. “The results from the Phase 3 VOYAGE 1 study show marked differences in outcomes with guselkumab therapy through week 48 compared with placebo and adalimumab in the treatment of moderate to severe plaque psoriasis. We look forward to future data from the ongoing Phase 3 studies to further characterise the longer term efficacy and safety of this novel anti-IL-23 monoclonal antibody.”

### **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 adalimumab and placebo in adult patients 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; guselkumab 100 mg at weeks 0, 4 and 12, followed by every eight-week dosing; or adalimumab 80 mg at week 0 and 40 mg at week 1, followed by every two-week dosing.<sup>1</sup> The co-primary endpoints of the study were the

proportions of patients receiving guselkumab versus patients receiving placebo achieving cleared/minimal disease and PASI 90 response at week 16.<sup>1</sup> Secondary endpoints were assessed at weeks 24 and 48, with safety monitoring through week 48.<sup>1</sup> VOYAGE 1 is part of a comprehensive guselkumab Phase 3 clinical development program. Additional data analyses from VOYAGE 1, along with results from two other Phase 3 trials, VOYAGE 2 and NAVIGATE, are planned for future scientific congresses.

### **About Guselkumab**

Guselkumab is a human monoclonal antibody with a novel mechanism of action that targets the protein interleukin (IL)-23 and is in Phase 3 development as a subcutaneously administered therapy for the treatment of moderate to severe plaque psoriasis. A Phase 2 study evaluating guselkumab in the treatment of moderately to severely active psoriatic arthritis is also ongoing.

### **About Psoriasis**

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterised by raised, inflamed, red lesions, or plaques, which can cause physical pain.<sup>2</sup> It is estimated that as many as 125 million people worldwide have psoriasis, including 7.5 million Americans and 14 million Europeans.<sup>2-5</sup> The disease symptoms can range from mild, to moderate, to severe and disabling. It is estimated that nearly three percent of the world's population is living with psoriasis.<sup>5</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 <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 the development and potential benefits 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 Research & Development, LLC and 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action; 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 3, 2016, including in Exhibit 99 thereto, 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.

\*Compensated as study investigator or steering committee member.

## **References**

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