News Release

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Media Contacts:
Brian Kenney
Office: +1 215 628 7010
Mobile: +1 215 620 0111

Emily Bone
Mobile: +44 7876 394360
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 RESULTS FROM SECOND PHASE 3 STUDY SHOW SIGNIFICANT EFFICACY OF GUSELKUMAB AND SUPERIORITY VERSUS HUMIRA® IN TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

Additional Phase 3 Study Data Show Significant Efficacy of Guselkumab in Patients Experiencing Inadequate Response to STELARA® in the Treatment of Moderate to Severe Plaque Psoriasis

Orlando, Florida, 3 March 2017 — Janssen Research & Development, LLC (Janssen) announced today new findings from two pivotal Phase 3 studies reporting the efficacy and safety of guselkumab in the treatment of adults with moderate to severe plaque psoriasis.[1–3] Data from the VOYAGE 2 study showed that patients treated with guselkumab experienced significant improvements in skin clearance and other measures of disease activity compared with placebo, and significantly greater improvements compared with the anti-tumor necrosis factor (TNF)-alpha treatment Humira® (adalimumab).[1–2] VOYAGE 2 is the second Phase 3 study to demonstrate superior efficacy of guselkumab versus adalimumab following VOYAGE 1.[4] Data from a third Phase 3 study (NAVIGATE) showed that patients who had an inadequate response following treatment with the anti-interleukin (IL)-12/23 monoclonal antibody (mAb) STELARA® (ustekinumab) and who then switched to guselkumab, showed significantly greater improvements in skin clearance compared with patients who continued to receive ustekinumab.[3] These Phase 3 data are being presented at the 2017 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Florida, 3–7 March.[1–3] Guselkumab, a subcutaneously administered anti-IL-23 mAb, is currently under review by health authorities in the US and EU for the treatment of adults living with moderate to severe plaque psoriasis.

VOYAGE 2: Efficacy and safety of guselkumab compared with adalimumab for the treatment of moderate to severe plaque psoriasis

In the VOYAGE 2 study, the co-primary endpoints were met at week 16, with 84.1% of patients receiving guselkumab 100 mg at weeks 0 and 4 and then every 8 weeks achieving an Investigator's Global Assessment (IGA) score of cleared (0) or minimal (1) disease compared with 8.5% of patients receiving placebo ($P < 0.001$).[1] In addition, 70.0% of patients receiving guselkumab achieved a Psoriasis Area Severity Index (PASI) 90 score (near complete skin clearance) compared with 2.4% of patients receiving placebo ($P < 0.001$).[1]

Major secondary endpoints in VOYAGE 2 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 (all $P <$

0.001).[1] At week 16, following three injections of guselkumab and ten injections of adalimumab, significantly higher proportions of patients receiving guselkumab versus adalimumab achieved IGA 0/1 (84.1% versus 67.7%, respectively) and PASI 90 (70.0% versus 46.8%, respectively).[1] Guselkumab continued to demonstrate superiority versus adalimumab at week 24 for both the IGA 0/1 and PASI 90 scores.[1] Among other secondary endpoints, significantly higher proportions of patients receiving guselkumab compared with adalimumab achieved Dermatology Life Quality Index (DLQI) scores of 0/1 (indicating no impact of psoriasis on health-related quality of life) and PASI 100 scores (complete skin clearance) at week 24.[1] Additionally, at week 16 and 24, 34.1% and 44.2% of patients receiving guselkumab achieved PASI 100 responses, respectively.[1]

“The majority of patients treated with guselkumab achieved high levels of skin improvement at week 16, while this was rarely seen in patients receiving placebo; a difference that was highly significant. Higher rates in efficacy in major secondary endpoints comparing guselkumab with adalimumab were also demonstrated and significant,” said Kristian Reich, Ph.D., M.D., Dermatologikum Hamburg, VOYAGE 2 study investigator. “These findings are consistent with the previously presented Phase 3 VOYAGE 1 study results and further demonstrate the important role of selectively targeting IL-23 in an immune-mediated disease like plaque psoriasis.”

Through week 16, the placebo-controlled period, 44.8%, 47.6% and 48.4% of patients receiving placebo, guselkumab and adalimumab, respectively, reported at least one adverse event (AE).[1] Serious AEs were reported in 1.2% of patients receiving placebo, 1.6% of patients receiving guselkumab and 2.4% of patients receiving adalimumab.[1] Serious infections occurred in one patient receiving placebo, one patient receiving guselkumab and two patients receiving adalimumab.[1] During this period, no malignancies were reported, and one major adverse cardiovascular event (MACE) was reported (in the adalimumab group).[1]

Through week 28, the active comparator period, 58.3% of patients receiving guselkumab and 62.9% of patients receiving adalimumab reported at least one AE. Serious AEs were reported in 3.6% of patients receiving guselkumab and 3.6% of patients receiving adalimumab. Infections and infections requiring treatment were also comparable between guselkumab and adalimumab groups.[1] Three serious infections each were reported in the guselkumab and adalimumab groups. One malignancy of prostate cancer in the guselkumab group and two non-melanoma skin cancers (one squamous cell carcinoma in the guselkumab group and one basal cell carcinoma in the placebo to guselkumab group) were reported.[1] Two MACE were reported (one myocardial infarction each in the guselkumab and adalimumab groups).

NAVIGATE: Efficacy and safety of switching to guselkumab in moderate to severe plaque psoriasis patients with an inadequate response to ustekinumab

The NAVIGATE study evaluated the efficacy and safety of guselkumab in patients who continued to experience mild to severe skin symptoms (IGA of 2 or more) following 16 weeks of treatment with ustekinumab.[3] Patients who switched to guselkumab consistently showed greater improvement in their psoriasis between weeks 28 and 40, compared with patients who continued to receive ustekinumab, having twice as many office visits with at least a 2 point improvement in IGA from week 16, and an IGA score of 0 or 1, the study’s primary endpoint (1.5 and 0.7 respectively; $P < 0.001$).[3] Guselkumab also demonstrated superiority across major secondary endpoints in comparisons with ustekinumab.[3] Major secondary endpoints included the number of visits that patients achieved a PASI 90 response or IGA score of 0 between weeks 28 and 40, and the proportion of patients that achieved an IGA score of 0 or 1 with at least a 2 point improvement from week 16 at week 28 (all $P \leq 0.001$).[3] In addition, a significantly higher proportion of patients in the guselkumab group achieved an IGA score of 0 or 1 and at least a 2 point improvement from week 16 at week 52, and a PASI 90 response at weeks 28 and 52, compared with ustekinumab (all $P < 0.001$).[3]

“Findings from NAVIGATE showed treatment with guselkumab provided significant benefit to patients who were not achieving clear or almost clear skin with ustekinumab treatment,” said Richard Langley, MD, FRCPC, Professor, Division of Clinical Dermatology & Cutaneous Science, Department of Medicine, Dalhousie University, NAVIGATE study investigator. “These data show the effectiveness of guselkumab in patients who had an inadequate response to treatment with ustekinumab and provide further insights into the therapeutic profile of guselkumab in this patient population.”

PHGB/IMM/0217/0003
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Through week 60, AEs were reported in 64.4% of patients receiving guselkumab and 55.6% of patients receiving ustekinumab.[3] Serious AEs were reported in 6.7% of patients receiving guselkumab and 4.5% in patients treated with ustekinumab, including three myocardial infarctions (two from the guselkumab-treated group and one from the ustekinumab-treated group) and two malignancies (bladder carcinoma and a fatal squamous cell carcinoma of the neck, both in the guselkumab-treated group).[3] A serious infection occurred in one patient receiving guselkumab.[3]

Results through week 48 for both the ongoing VOYAGE 1 and VOYAGE 2 studies were recently published in the *Journal of the American Academy of Dermatology*.[5,6] Together with NAVIGATE, these three Phase 3 studies comprise the comprehensive clinical development programme evaluating guselkumab in the treatment of moderate to severe plaque psoriasis.

“At Janssen, we are committed to building upon our understanding of psoriasis and bringing forward innovative therapies that continue to meet the needs of people living with immune-mediated diseases like psoriasis,” said Newman Yeilding, MD, Head of Immunology Development, Janssen Research & Development, LLC. “Data from the Phase 3 VOYAGE 2 and NAVIGATE studies continue to demonstrate the potential that guselkumab may offer patients and physicians, and we are committed to working with health authorities around the world on our current and future applications.”

About VOYAGE 2

The Phase 3 VOYAGE 2 trial is a randomised, double-blind, placebo- and active-comparator controlled study with randomised withdrawal and retreatment from weeks 28 to 76, data that will be presented in the future.[1,7] The trial is designed to evaluate the safety and efficacy of guselkumab compared with placebo and adalimumab and of guselkumab maintenance therapy compared with withdrawal of therapy in adult patients with moderate to severe plaque psoriasis.[1,7] Patients (n=992) were randomised to receive subcutaneous (SC) injections of guselkumab 100 mg at weeks 0, 4, 12 and 20; placebo at weeks 0, 4, and 12 with crossover to guselkumab at weeks 16 and 20 or adalimumab 80 mg at week 0, followed by 40 mg at week one and every two weeks through to week 23.[1,7]

About NAVIGATE

The Phase 3 NAVIGATE trial was a randomised, double-blind, multicentre study evaluating the efficacy and safety of guselkumab compared with ustekinumab in adult patients with moderate to severe plaque psoriasis who had an inadequate response to treatment with ustekinumab.[3,8] Patients (n=871) received SC injections of ustekinumab 45 mg or 90 mg (based on weight) at weeks 0 and 4 during open-label treatment.[3,8] At week 16, patients (n=268) with an IGA score greater than or equal to 2 were considered inadequate responders and were randomised to receive guselkumab 100 mg at weeks 16 and 20 and then every eight weeks through week 44, or to continue on ustekinumab every 12 weeks through to week 40; patients (n=585) who achieved an IGA score of 0/1 at week 16 continued to receive ustekinumab every 12 weeks through week 40.[3,8] Safety results were monitored through to week 60.[3,8]

About guselkumab

Guselkumab is a human monoclonal antibody with a novel mechanism of action that specifically targets the protein interleukin (IL)-23 and is currently under review by health authorities in the US and EU as a subcutaneously administered therapy for the treatment of adults living with moderate to severe plaque psoriasis. Results of a Phase 2 study evaluating guselkumab in the treatment of patients with active psoriatic arthritis were presented for the first time at the 2016 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting and will also be presented at the AAD Annual Meeting 2017. A Phase 3 programme evaluating the efficacy and safety of guselkumab for the treatment of active psoriatic arthritis is planned.

About ustekinumab

In the European Union, ustekinumab is approved for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen plus ultraviolet A (PUVA), and is also indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older who are inadequately controlled by or are intolerant to other systemic therapies or phototherapies. In addition, ustekinumab is approved alone or in combination with

MTX for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. In November 2016, the European Commission approved ustekinumab for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha antagonist or have medical contraindications to such therapies.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to ustekinumab, which is currently approved for the treatment of moderate to severe plaque psoriasis in 89 countries, paediatric psoriasis in 39 countries, psoriatic arthritis in 79 countries and Crohn's disease in 33 countries.

Important safety information

For complete European Union (EU) prescribing information, please visit: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000958/human_med_001065.jsp&mid=WC0b01ac058001d124

About Psoriasis

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterised by raised, inflamed, scaly, red lesions, or plaques, which can cause itching and physical pain.[9] It is estimated that as many as 125 million people worldwide have psoriasis,[10] including 14 million Europeans,[11] and approximately 20% of people affected have cases that are considered moderate to severe.[12]

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. Follow us at Twitter.com/JanssenEMEA.

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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 the potential benefits, and plans for continued development, 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, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Research & Development, LLC 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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PHGB/IMM/0217/0003
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