NEWS RELEASE

Phase 2b Findings Published In The New England Journal Of Medicine Demonstrate Significant Efficacy Of Guselkumab In Treatment Of Moderate To Severe Plaque Psoriasis

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Spring House, Pa., July 8, 2015 - Results published today in The New England Journal of Medicine from a Janssen Research & Development, LLC (Janssen)-sponsored Phase 2b trial showed up to 86 percent of patients with moderate to severe plaque psoriasis receiving guselkumab (CNTO 1959) achieved a Physician's Global Assessment (PGA) score of cleared psoriasis or minimal psoriasis at week 16, the study's primary endpoint. The X-PLORE study showed significantly higher levels of efficacy for all guselkumab doses at week 16 when compared with the placebo group, and responses were maintained through week 40 of the study. The trial also included an active comparator arm, which showed several guselkumab dosage regimens provided better response rates compared with the anti-tumor necrosis factor (TNF)-alpha agent, adalimumab (Humira®). Guselkumab is an investigational human monoclonal antibody that targets the protein interleukin (IL)-23, and is currently in Phase 3 development as a subcutaneously administered therapy for the treatment of moderate to severe plaque psoriasis.

"The Phase 2b guselkumab study results show that blockade of IL-23 resulted in significant skin clearance, and improvements continued through week 40 with every eight- or twelve-week maintenance treatment," said Professor Kristian Reich, Ph.D., M.D, Dermatologikum Hamburg, Hamburg, Germany, study investigator. "These findings provide important insights into the role of IL-23 in the pathogenesis of psoriasis and the potential therapeutic benefit of guselkumab. Findings from the Phase 3 guselkumab studies will provide greater insights into the efficacy and safety profile of this novel monoclonal antibody."

X-PLORE is a Phase 2b, randomized, placebo- and active comparator-controlled, parallel-group, multicenter dose-ranging seven-arm study in which participants received subcutaneous injections of either placebo, guselkumab (five dose groups: 5 mg at weeks 0, 4 then every 12 weeks; 15 mg every eight weeks; 50 mg at weeks 0, 4 then every 12 weeks; 100 mg every eight weeks; and 200 mg at weeks 0, 4 then every 12 weeks) or adalimumab (80 mg initial dose, followed by 40 mg every other week starting one week after initial dose).

At week 16, significantly higher proportions of guselkumab-treated patients achieved PGA 0 (cleared psoriasis) or 1 (minimal psoriasis) compared with patients receiving placebo across all dose groups: 34 percent (5 mg); 61 percent (15 mg); 79 percent (50 mg); 86 percent (100 mg); 83 percent (200 mg); 7 percent (placebo group) [$P = 0.002$ for 5 mg; $P < 0.001$ for all other doses]. According to major secondary endpoints, at week 16, significantly higher proportions of patients receiving guselkumab achieved at least a 75 percent or 90 percent improvement in the Psoriasis Area Severity Index (PASI 75 or PASI 90, respectively): 44 percent and 34 percent, respectively (5 mg); 76 percent and 34 percent, respectively (15 mg); 81 percent and 45 percent, respectively (50 mg); 79 percent and 62 percent, respectively (100 mg); and 81 percent and 57 percent, respectively (200 mg), compared with 5 percent and 2 percent, respectively (placebo group) [$P < 0.001$]. Patients in all guselkumab groups achieved significantly greater decreases (improvement) in Dermatology Life Quality Index (DLQI) score from baseline to week 16 compared with placebo ($P \leq 0.008$).

After week 16, the proportions of guselkumab-treated patients achieving a PGA score of 0 or 1, PASI 75 and PASI 90 remained consistent or showed additional improvement. Moreover, complete clearance (PGA 0 and PASI 100) was observed in 62 percent and 54 percent, respectively, of patients in the guselkumab 100 mg dose group after 40 weeks of continuous treatment.

Guselkumab at doses of 50 mg, 100 mg and 200 mg showed higher efficacy when compared with the adalimumab treatment group. Significantly greater proportions of patients in the guselkumab 50 mg, 100 mg and 200 mg groups achieved a PGA score of 0 or 1 at week 16 compared with the adalimumab group (58 percent). Similarly, significantly greater proportions of guselkumab-treated patients in the 50 mg (71 percent), 100 mg (77 percent) and 200 mg (81 percent) groups achieved a PGA score of 0 or 1 at week 40 than the adalimumab-treated group (49 percent).

"The guselkumab Phase 2b study shows the potential of targeting IL-23 alone, an important, specific cytokine active in immune-mediated diseases," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We recently completed enrollment for the guselkumab Phase 3 clinical program and remain committed to advancing the understanding and treatment of psoriasis for both patients and physicians."

Through week 16, the placebo-controlled period, adverse events (AEs) were reported in 50 percent of patients

receiving guselkumab (combined groups), 56 percent of patients receiving adalimumab and 52 percent of patients receiving placebo; 1 percent, 2 percent and 2 percent of patients reported at least one serious AE in these respective groups. Serious infections occurred in two patients treated with guselkumab (appendicitis, lung abscess).

Between week 16 and week 52, AEs were reported in 49 percent of patients receiving guselkumab (combined groups) and 61 percent of patients receiving adalimumab; 2 percent and 3 percent reported at least one serious AE in these respective groups. No additional serious infections occurred in guselkumab-treated patients; one serious infection occurred in a patient treated with adalimumab (pneumonia). There were no cases of tuberculosis or opportunistic infections. One guselkumab-treated patient reported a malignancy (cervical intraepithelial neoplasia III, including carcinoma in situ). Three major adverse cardiovascular events were reported in guselkumab-treated patients (one fatal myocardial infarction [MI], one nonfatal MI, one cerebrovascular accident), all of whom had multiple pre-existing cardiovascular risk factors.

About X-PLORE

X-PLORE, a Phase 2b, randomized, placebo- and active comparator-controlled, parallel-group, multicenter dose-ranging study, investigated subcutaneous injections of five doses of guselkumab compared with placebo and adalimumab in patients with moderate to severe plaque psoriasis, defined by a PASI greater than or equal to 12, PGA greater than or equal to 3 and body surface area (BSA) involvement of at least 10 percent, who are candidates for systemic or phototherapy. Patients (n=293) were randomized in the seven-arm study to receive placebo, guselkumab (five dose groups: 5 mg at weeks 0, 4 then every 12 weeks; 15 mg every eight weeks; 50 mg at weeks 0, 4 then every 12 weeks; 100 mg every eight weeks; and 200 mg at weeks 0, 4 then every 12 weeks), or adalimumab (80 mg initial dose, followed by 40 mg every other week starting one week after initial dose). The primary endpoint was the proportion of patients who achieve a Physician's Global Assessment (PGA) score of cleared (0) or minimal (1) at week 16. A PGA score indicates a physician's assessment of the severity of psoriasis, with 0 indicating no psoriasis (clear of disease) and 5 indicating most severe disease. Secondary endpoints include at least a 75 percent or 90 percent improvement in psoriasis as measured by the Psoriasis Area Severity Index (PASI 75 or PASI 90) at week 16.

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 clinical development as a subcutaneously administered therapy for the treatment of moderate to severe plaque psoriasis.

About Psoriasis

Psoriasis, a chronic, immune-mediated disease that results from the overproduction of skin cells, affects 125 million people worldwide, including nearly 7.5 million Americans.[1] Plaque psoriasis often results in patches of thick,

red or inflamed skin covered with silvery scales known as plaques. These plaques can crack and bleed, and often show up on the scalp, knees, elbows and lower back.[2] 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 and nearly one-quarter of those people have cases that are considered moderate to severe.[1]

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care.

Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen.com for more information. Follow us on Twitter at **www.twitter.com/JanssenUS**.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; 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 description 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 28, 2014, 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. 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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References

1. National Psoriasis Foundation. Statistics. **https://www.psoriasis.org/cure_known_statistics**. Accessed June 16, 2015.

2. National Psoriasis Foundation. About Psoriasis. **http://psoriasis.org/about-psoriasis**. Accessed June 16, 2015.

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