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Anti-Interleukin-23 Monoclonal Antibody Guselkumab Shows Significant Efficacy in Treatment of Moderate to Severe Plaque Psoriasis

Results from Phase 2b X-PLORE Study through Week 40 Report Efficacy of Guselkumab across Multiple Dosing Regimens and Compared with Adalimumab

DENVER, March 24, 2014 - New findings presented for the first time at the 2014 Annual Meeting of the American Academy of Dermatology (AAD) 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 or minimal at week 16, the study's primary endpoint. The Phase 2b Janssen Research & Development, LLC (Janssen)-sponsored X-PLORE study demonstrated significantly higher levels of efficacy at all doses of guselkumab studied at week 16 when compared with the placebo group. Similar proportions of patients achieving a PGA score of cleared or minimal were observed at week 40 of the study. The trial also included an adalimumab arm. Guselkumab is an investigational human monoclonal antibody with a novel mechanism of action that targets the protein interleukin (IL)-23, and is being developed as a subcutaneously administered therapy for the treatment of moderate to severe plaque psoriasis.

"The efficacy of guselkumab in the treatment of moderate to severe plaque psoriasis looks promising according to these Phase 2b study results," said Kristina Callis Duffin, M.D., Assistant Professor of Dermatology, University of Utah School of Medicine, study investigator. "As a practicing dermatologist, I look forward to understanding how investigational therapies like guselkumab may meet the needs of patients with psoriasis in the future."

Patients participating in the Phase 2b, randomized, placebo- and active comparator-controlled, parallel-group, multicenter dose-ranging 7-arm X-PLORE study received subcutaneous injections of either placebo, guselkumab (five dose groups: 5 mg at weeks 0, 4 then every 12 weeks; 15 mg every 8 weeks; 50 mg at weeks 0, 4 then every 12 weeks; 100 mg every 8 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 the primary endpoint of a Physician Global Assessment (PGA) score of cleared (0) or minimal (1) compared with patients receiving placebo across all dose groups: 34 percent (5 mg at weeks 0, 4 then every 12 weeks); 61 percent (15 mg every 8 weeks); 79 percent (50 mg at weeks 0, 4 then every 12 weeks); 86 percent (100 mg every 8 weeks); 83 percent (200 mg at weeks 0, 4 then every 12 weeks); 7 percent (placebo group) [$P = 0.002$ for 5 mg; $P < 0.001$ for all other doses]. 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.

Significantly higher proportions of patients receiving guselkumab achieved at least a 75 percent improvement in psoriasis as measured by the Psoriasis Area Severity Index (PASI 75) at week 16: 44 percent (5 mg at weeks 0, 4 then every 12 weeks); 76 percent (15 mg every 8 weeks); 81 percent (50 mg at weeks 0, 4 then every 12 weeks); 79 percent (100 mg every 8 weeks); and 81 percent (200 mg at weeks 0, 4 then every 12 weeks), compared with 5 percent of patients receiving placebo ($P < 0.001$). At week 16, PASI 90 responses, or at least 90 percent improvement in psoriasis, were also reported in significantly higher proportions of guselkumab-treated patients: 34 percent (5 mg at weeks 0, 4 then every 12 weeks); 34 percent (15 mg every 8 weeks); 45 percent (50 mg at weeks 0, 4 then every 12 weeks); 62 percent (100 mg every 8 weeks); and 57 percent (200 mg at weeks 0, 4 then every 12 weeks), compared with 2 percent of patients receiving placebo ($P < 0.001$). In the adalimumab treatment group at week 16, 58 percent, 70 percent and 44 percent of patients achieved PGA scores of 0 or 1, PASI 75 response and PASI 90 response, respectively.

Beyond week 16, the proportions of patients achieving a PGA score of 0 or 1, a PASI 75 response and a PASI 90 response remained consistent or showed additional improvement over time for guselkumab through the final dosing visit at week 40.

"Within the past decade, Janssen has advanced the scientific understanding of psoriasis and therapeutic options for the treatment of this complex, immune-mediated disease," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We look forward to progressing guselkumab into Phase 3 development based on the findings from the X-PLORE study and we remain focused and committed to advancing the treatment of psoriasis."

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). No malignancies or major adverse cardiovascular events (MACE) were observed in any group.

Through week 52, AEs were reported in 66 percent of patients receiving guselkumab (combined groups) and 72 percent of patients receiving adalimumab; 3 percent and 5 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 MACE 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 XPLORE

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 twelve weeks; 15 mg every eight weeks; 50 mg at weeks 0, 4 then every 12 weeks; 100 mg every 8 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. Secondary endpoints include at least a 75 percent improvement in psoriasis as measured by the Psoriasis Area Severity Index (PASI 75) at week 16.

About Guselkumab (CNTO 1959)

Guselkumab is a human monoclonal antibody with a novel mechanism of action that targets the protein interleukin (IL)-23, and is in clinical development as a subcutaneously administered therapy for the treatment of moderate to severe plaque psoriasis. Guselkumab is also being investigated for the treatment of active rheumatoid arthritis in a Phase 2 study.

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 may occur anywhere on the body.[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.

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(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including regarding plans for further clinical development of guselkumab. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC or Johnson & Johnson. Risks and uncertainties include, but are not limited to, technological advances, new products and patents attained by competitors; challenges and difficulties inherent in new product development, including obtaining regulatory approvals; manufacturing difficulties or delays; and trends toward health care cost containment. A further list and description of risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013 and in its subsequent reports on Form 10-Q and Form 8-K. 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 statements as a result of new information or future events or developments.)

References

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