

Press Release

For Immediate Release

Glenmark Pharmaceuticals Reports Positive Data in a Phase 2a Study of GBR 830 for the Treatment of Patients with Atopic Dermatitis

GBR 830 is an Investigational, First-in-Class, Anti-OX40 Monoclonal Antibody

Mumbai, India; August 01, 2017: Glenmark Pharmaceuticals, a global pharmaceutical company, today announced positive data from a Phase 2a study of GBR 830, an investigational, anti-OX40 monoclonal antibody, in atopic dermatitis (AD), a common and serious chronic skin disease. The study evaluated the safety, biological and clinical activity, and pharmacokinetics of GBR 830, relative to placebo, in adults with moderate-to-severe AD with history of inadequate response to topical therapies. Based on the results of this Phase 2a study, Glenmark is firmly committed to advancing GBR 830 for patients with AD and plans to initiate a Phase 2b trial in the first half of calendar year 2018.

In this Phase 2a study, a total of 31 patients were evaluated following the last study visit. Patients were assessed on multiple endpoints after receiving two doses with two viable biopsies. In the GBR 830 cohort, 17 out of 23 patients experienced at least a 50% reduction in their Eczema Area and Severity Index (EASI) scores at day 57 compared to baseline, a key secondary endpoint of the study. Although not powered for statistical differences between GBR 830 versus placebo, data from this analysis suggest clinically meaningful improvement of symptoms that is continuous and sustained, with consistency observed between biological and clinical response.

“Atopic dermatitis can have a severe impact on quality of life. There is an unmet need for safe and more durable therapies for people suffering from atopic dermatitis,” said Dr. Fred Grossman, President and Chief Medical Officer at Glenmark Pharmaceuticals. “GBR 830 is a novel, antagonistic monoclonal antibody that is designed to selectively target OX40 receptors to reduce inflammation in atopic dermatitis. We are pleased with the outcome of our Phase 2a study and look forward to rapidly advancing GBR 830.”

About the Phase 2a Study

This Phase 2a double-blind, placebo-controlled study, randomized 62 patients (3:1) with moderate-to-severe atopic dermatitis (AD) to evaluate the safety, biological and clinical activity, and pharmacokinetics of GBR 830 over 12 weeks. Patients were randomized to receive two doses of GBR 830. The study population included adult males (52 percent) and adult females (48 percent) with chronic, moderate-to-severe AD as defined by: Eczema Area and Severity Index (EASI) score; Scoring of Atopic Dermatitis (SCORAD); Investigator’s Global Assessment (IGA); and a history of inadequate response to topical therapies. Improvement in clinical response over time reflected in the EASI 50 was also supported by EASI 75, SCORAD and IGA clinical scales. The overall safety profile of GBR 830 was similar to that of placebo. The most common treatment-related adverse event was headache, with no clinically meaningful differences between GBR 830 and placebo (4 percent and 6 percent, respectively).

Glenmark plans to submit these data for presentation at upcoming scientific meetings and publication in a peer-reviewed journal.

About GBR 830 in Atopic Dermatitis

GBR 830 is designed to inhibit OX40, a costimulatory immune checkpoint receptor expressed on activated T cells and memory T cells. Costimulatory signals are essential for T cell activity and binding between OX40 and OX40L is a biomarker for the severity of autoimmune diseases. The pathway leads to conversion of activated T cells into memory T cells, which promotes inflammation. In addition, regulatory T cells also contribute to inflammation, and OX40 signaling by these cells downregulates immune suppressing functions. It is believed that GBR 830 inhibits the dual activities of OX40 and OX40L binding in both activated T cells and regulatory T cells, thus reducing inflammation associated with symptoms of atopic dermatitis.

About Atopic Dermatitis

Atopic dermatitis (AD), also known as eczema, is a chronic skin disease caused by allergic reactions. Characterized by dry, itchy skin, AD affects nearly 18 million Americans and accounts for as many as 1 in 5 dermatology visits. Most often, AD occurs in infants and children, with 65 percent of patients developing symptoms in the first year of life, and 90 percent of patients developing symptoms before the age of 5.

The cause of AD isn't clear, but it affects the skin's ability to hold moisture. In affected people, skin becomes dry, itchy, and easily irritated. Most people who have AD have a personal or family history of allergies, such as hay fever (allergic rhinitis) or asthma. Mild AD affects a small area of skin and may be itchy only once in a while. Moderate and severe AD affect larger areas of skin and are itchy more often, and at times the itch may be intense.

About Glenmark Pharmaceuticals

About Glenmark Pharmaceuticals Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 countries. Glenmark has a diverse pipeline with several compounds in various stages of clinical development, primarily focused in the areas of oncology, respiratory disease, and dermatology. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information, visit www.glenmarkpharma.com.

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