

Press Release – For Immediate Release

Data on Glenmark Pharmaceuticals' GBR 830, a First-in-Class, Investigational, Anti-OX40 Monoclonal Antibody in Development for the Treatment of Moderate-to-Severe Atopic Dermatitis, to be Presented at the Fall Clinical Dermatology Conference

Mahwah, NJ; October 18, 2018 – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that encore data from a Phase 2a, proof-of-concept study of GBR 830, an investigational treatment in development for moderate-to-severe atopic dermatitis (AD), will be presented at the Fall Clinical Dermatology Conference in Las Vegas. The poster, *GBR 830 induces progressive and sustained improvements in atopic dermatitis skin biomarkers and clinical parameters*, describes findings from this exploratory study, including evaluation of safety and the effect of the investigational drug on AD biomarkers, and provides the first clinical evidence of biological activity.

“Presentation of these data from a Phase 2a study of our lead biologic candidate, GBR 830, along with data that elucidate its mechanism, is part of our continued commitment to further analyze and characterize the unique profile and activity of this potential treatment for atopic dermatitis,” said Mahboob Rahman, President and Chief Medical Officer at Glenmark Pharmaceuticals. “We look forward to sharing further updates in the future, as the current and ongoing Phase 2b trial of GBR 830 progresses.”

The Phase 2a study randomized patients to receive two repeated doses of GBR 830 or placebo and assessed response at Day 29 and Day 71. In the Biological Activity Set of 40 patients (GBR 830 n=29; placebo n=11) who underwent lesional skin biopsy before and after treatment, GBR 830-treated patients exhibited a significant reduction from baseline in certain disease-related biomarker signatures compared to placebo. In the intent-to-treat population of all randomized subjects (GBR 830 n=46; placebo n=16), GBR 830-treated patients demonstrated a greater percentage change in Eczema Area and Severity Index 50 (EASI) versus placebo at Day 29 (44% vs. 23.0%) and Day 71 (78% vs. 38%). GBR 830-treated patients also demonstrated greater percentage change in EASI from baseline through Day 71 compared with placebo. In the study, GBR 830 was safe and well-tolerated. The most common treatment-emergent adverse events were headache and atopic dermatitis, with no meaningful differences observed between GBR 830- and placebo-treated patients (13% vs 25%, respectively; and 13% vs 12.5%, respectively).

Based on these results, the Phase 2b OXFORD study, **OX40 FOR Atopic Dermatitis**, was initiated in June 2018 and is ongoing.

In addition, a second poster entitled, *Targeting OX40 with GBR 830, an OX40 antagonist, inhibits T cell-mediated pathological response*, is being presented at the meeting. The poster describes data suggesting that GBR 830 has immunomodulatory capabilities in memory/chronic T helper cell-mediated pathological responses with no impact on primary antibody responses.

About GBR 830 in Atopic Dermatitis

GBR 830 is an investigational monoclonal antibody 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 activation of this 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 may inhibit the dual activities of OX40 and OX40L binding in both activated T cells and regulatory T cells, thus potentially reducing inflammation associated with symptoms of atopic dermatitis.

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 glenmarkpharma-us.com.

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