

Press Release – For Immediate Release

## Glenmark Pharmaceuticals Announces Initiation of a Phase 2b Trial of GBR 830, a First-in-Class, Investigational, Anti-OX40 Monoclonal Antibody for the Treatment of Moderate-to-Severe Atopic Dermatitis

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**Mumbai, India; April 17, 2018** – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced the initiation of a Phase 2b clinical trial of GBR 830, a novel, investigational treatment for moderate-to-severe atopic dermatitis. The trial's primary endpoint will assess the efficacy of GBR 830, compared to placebo. Secondary and exploratory trial endpoints include additional measures of efficacy, safety and pharmacodynamics. Trial enrollment is expected to begin in June 2018.

*"The results of the Phase 2a trial completed last year demonstrated that GBR 830 was well-tolerated, and suggested signals of efficacy in the treatment of moderate-to-severe atopic dermatitis," said Fred Grossman, President and Chief Medical Officer at Glenmark Pharmaceuticals. "We are very pleased to rapidly advance the GBR 830 development program in atopic dermatitis as there is a need for effective and well-tolerated treatments."*

The Phase 2b, double-blind, placebo-controlled multicenter trial will randomize approximately 392 patients across four dosing arms of GBR 830 and placebo. The trial's primary endpoint will assess the effectiveness of GBR 830, compared to placebo, on reducing the severity of atopic dermatitis as measured by Investigator's Global Assessment (IGA). Secondary efficacy measures include patients with a greater than 75% improvement in disease severity, as measured by the Eczema Area and Severity Index (EASI), along with other measures including disease activity using validated assessment tools such as EASI response, and Scoring Atopic Dermatitis (SCORAD). The trial will also assess safety, and biomarkers relevant to the disease and unique mechanism of GBR 830.

*"The initiation of this trial is a meaningful milestone in pursuit of a potentially new treatment for a disease with significant unmet need," said Kurt Stoeckli, President and Chief Scientific Officer at Glenmark Pharmaceuticals. "It is also an exciting step for the many scientists who contributed to the discovery of GBR 830, Glenmark's first new biologic entity developed in-house at Glenmark."*

In addition to moderate-to-severe atopic dermatitis, Glenmark is evaluating the potential for conducting studies with GBR 830 for the treatment of other inflammatory autoimmune conditions where dysregulation of OX40 overexpression is implicated in disease activity. Preparations for a clinical trial assessing GBR 830 for the treatment of systemic lupus erythematosus (SLE) are currently underway.

### 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 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 inhibits 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](http://glenmarkpharma-us.com).