

Press Release

For Immediate Release

Glenmark Pharmaceuticals Reports Positive Results from a Phase 3 Trial of GSP 301, Mometasone/Olopatadine Fixed-Dose Combination Nasal Spray, in Seasonal Allergic Rhinitis

GSP 301 is Glenmark's leading candidate for the company's first New Drug Application with the U.S. Food & Drug Administration

Mumbai, India; March 30, 2017: Glenmark Pharmaceuticals, a global pharmaceutical company, today announced positive results for GSP 301, an investigational fixed-dose combination of mometasone furoate (25 mcg) and olopatadine hydrochloride (665 mcg) administered twice-daily as a nasal spray being studied for the treatment of seasonal allergic rhinitis. These results are from a recently completed Phase 3 trial assessing the efficacy and safety of GSP 301 combination therapy versus mometasone, olopatadine or placebo.

“We continue to advance our respiratory pipeline and are pleased to report positive results of GSP 301 in seasonal allergic rhinitis,” said Fred Grossman, D.O., President and Chief Medical Officer at Glenmark Pharmaceuticals. “The number of people affected by seasonal allergic rhinitis is steadily growing, and there are limited FDA-approved combination treatments,¹ therefore there is a need for additional, potentially effective treatment options.”

This Phase 3, U.S.-based trial was a four-arm, double-blind, randomized, parallel group, active and placebo-controlled study that enrolled 1,176 adults and adolescents 12 years of age and older for 14-days of twice daily treatment with GSP 301, mometasone (a corticosteroid), olopatadine (a histamine H1-receptor agonist) or placebo. All trial arms utilized the same vehicle and nasal spray delivery system. The primary endpoint was change from baseline in average morning and evening patient-reported 12-hour reflective Total Nasal Symptom Score (rTNSS). Secondary endpoints include safety and tolerability.

In the trial treatment with GSP 301 demonstrated statistically significant and clinically meaningful improvement from baseline in average morning and evening patient-reported rTNSS, compared to placebo ($p < 0.001$), olopatadine ($p = 0.028$), and mometasone ($p = 0.019$). All investigational treatments administered in the trial were well-tolerated, and showed no meaningful differences in reported adverse events (AEs) across study arms. The most common AE occurring in at least 2 percent of patients was dysgeusia.

Data from this trial have not yet been published. Glenmark will be submitting these data for presentation at upcoming scientific meetings and publication in a peer-reviewed journal.

About Seasonal Allergic Rhinitis

According to the most recent data, over 17 million adults and 6 million children in the United States are affected by seasonal allergic rhinitis, also called hay fever, every year.^{2,3} It is the primary diagnosis in over 11 million doctor's visits and is estimated to affect more than seven percent of adults aged 18 and over in the United States.^{4,5} As of January 2017 the annual value of the U.S. nasal spray market was \$1.3 billion.⁶

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's current respiratory pipeline is aimed at addressing the global public health burden of allergic rhinitis, asthma, and COPD, and includes four investigational treatments across the disease spectrum and devices. 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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