



FLX Bio Highlights Preclinical Atopic Dermatitis and Asthma Data for FLX193 at the American Association of Immunologists (AAI) Annual Meeting 2019

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-- FLX193 Presents Potentially Attractive Alternative to Treatment with Injectable Biologics or Topical Corticosteroids --

SOUTH SAN FRANCISCO, Calif.--([BUSINESS WIRE](#))--FLX Bio, Inc., a clinical-stage, immunology-focused biopharmaceutical company, today announced researchers presented preclinical data for its lead inflammatory disease compound demonstrating the mechanism of action for FLX193 and its potential as an oral treatment for patients with allergic disease including atopic dermatitis and allergic asthma. The data were presented Saturday, May 11, 2019 at the American Association of Immunologists (AAI) Annual Meeting, Immunology 2019™.

During the AAI meeting, researchers from FLX presented data showing dose-dependent inhibition of overactive Type 2 helper T cells (Th2), immune cells known to cause allergic inflammation and play a critical role in the pathogenesis of atopic dermatitis and asthma. In addition, in models of both atopic dermatitis and asthma, FLX193 demonstrated anti-inflammatory efficacy comparable to an anti-IL-13 antibody (currently in later stage clinical development as an injectable therapeutic) which reflects a clinically validated mechanism in atopic dermatitis as well as the ability to reduce inflammatory cells at the site of inflammation.

In inflammatory diseases including atopic dermatitis and asthma, chemokines (CCL17 and CCL22) bind to the CCR4 receptor on the surface Th2 cells and recruit these cells to inflamed tissues. Once Th2 cells enter tissues such as the skin or the airways in the lung, they secrete proteins known to drive the inflammatory response.

"Taken together, this series of encouraging preclinical data confirm that FLX193, an orally bioavailable small molecule inhibitor of CCR4, reduces inflammation associated with an allergic response such as in asthma or atopic dermatitis, and may be an attractive alternative to treatment with injectable biologics or topical corticosteroids," said Dirk Brockstedt, Ph.D., senior vice president of biology at FLX Bio. "Based on these positive results, we intend to enroll healthy volunteers in a Phase 1 single and multiple dose escalation clinical study in 2019, initiating a Phase 1b study quickly thereafter in patients with moderate to severe atopic dermatitis with proof-of-concept results anticipated by mid-2020."

About FLX193

FLX193 is a small molecule CCR4 inhibitor that blocks the recruitment of inflammatory immune cells, known as Th2 cells, which are clinically implicated in inflammatory disorders. FLX's preclinical pharmacology and toxicology results suggest efficacy similar to clinically validated mechanisms in inflammatory disease models, with a once daily oral dosing projected and a safety profile consistent with chronic dosing in humans. FLX is developing FLX193 for the treatment of a broad range of allergic inflammatory diseases, the first of which is atopic dermatitis, a chronic, inflammatory skin disease characterized by skin barrier disruption and immune dysregulation. The company believes that inhibition of CCR4 has the potential to bring therapeutic benefit to patients with a broad spectrum of inflammatory diseases, including asthma, chronic urticaria, chronic rhinosinusitis, allergic conjunctivitis and eosinophilic esophagitis.

About FLX Bio

FLX Bio is a clinical stage immunology-based biopharmaceutical company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in oncology and inflammatory diseases. Utilizing our proprietary discovery platform, we develop highly selective small molecules that are designed to modulate the fundamental immune responses underlying these diseases. FLX has rapidly discovered and advanced two drug candidates each uniquely targeting CCR4, including our lead oncology drug candidate, FLX475, in now in clinical development and our lead inflammation drug candidate, FLX193, expected to enter the clinic in atopic dermatitis in the second half of 2019.

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