RAPT Therapeutics Announces Initiation of First-in-Human Phase 1 Study of RPT193

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-- Once-Daily, Orally Administered CCR4 Antagonist Blocks Recruitment of Th2 Inflammatory Immune Cells --

-- Potential to Treat Allergic Inflammatory Diseases Including Atopic Dermatitis --

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--RAPT Therapeutics, Inc., a clinical-stage immunology-based biopharmaceutical company developing oral small molecules for oncology and inflammatory diseases, today reported the initiation of its first-in-human Phase 1 clinical trial for RPT193, an orally-administered small molecule CCR4 antagonist that is designed to selectively inhibit the migration of type 2 T helper cells, or Th2 cells, into allergically-inflamed tissues. RAPT is developing RPT193 initially for the treatment of atopic dermatitis, and subsequently plans to expand clinical development into allergic asthma and other allergic inflammatory diseases.

“The onset of atopic dermatitis often occurs during childhood and can persist into adulthood,” commented Emma Guttmann-Yassky, M.D., Ph.D., of the Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York. “The estimated U.S. adult prevalence of atopic dermatitis is seven percent of adults, with 20-30% of these having disease characterized as moderate to severe. There is a true need for a safe and effective oral therapeutic to address this growing need.”

RAPT’s Phase 1 study of RPT193 is enrolling both healthy volunteers and patients with moderate to severe atopic dermatitis at multiple sites in North America and Europe. Initial cohorts of healthy volunteers in the Phase 1a single ascending dose portion of the study were dosed with RPT193 or placebo beginning in August. Preliminary safety, pharmacokinetic and pharmacodynamic data to date from these initial cohorts supports once-daily oral dosing with RPT193 and dose escalation continues as planned. After completing the Phase 1a single and multiple ascending dose cohorts of healthy volunteers, RAPT will enroll the Phase 1b double-blind, placebo-controlled portion of the study in patients with moderate to severe atopic dermatitis (AD). The endpoints of the Phase 1b study include safety, pharmacokinetics, and exploratory endpoints including biomarkers and efficacy as evaluated by multiple measurements, including the Eczema Area and Severity Index (EASI). Preclinical studies of RPT193 demonstrated its ability to block the migration of mouse and human Th2 cells *in vitro* as well as inhibit inflammation in models of atopic dermatitis and asthma.

“Building on our preclinical results, we anticipate clinical proof-of-concept results from the Phase 1b portion of our RPT193 study by mid-2020, and if positive, we intend to continue further development in atopic dermatitis and expand our clinical development into additional Th2-driven allergic indications such as allergic asthma, chronic rhinosinusitis, eosinophilic esophagitis, skin rash and conjunctivitis,” said Brian Wong, M.D., Ph.D., president and CEO of RAPT Therapeutics.

About RPT193

RPT193 is a small molecule oral therapy in development for the treatment of atopic dermatitis and other allergic inflammatory diseases. RPT193 is a CCR4 antagonist designed to selectively inhibit the migration of Th2 cells into allergically-inflamed tissues, effectively “turning down” an overactive immune response. RPT193 blocks CCR4, a receptor highly expressed on Th2 cells. In allergic inflammatory diseases, including AD, chemokines recruit Th2 cells via CCR4 into 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. The role of Th2 cells has been clinically validated by injectable biologics targeting this pathway. Patients with atopic dermatitis express higher levels of CCR4 ligands compared with healthy humans; these ligands also correlate with the severity of disease. RAPT believes that by inhibiting CCR4, RPT193 has the potential to bring therapeutic benefit to patients across a broad spectrum of additional allergic inflammatory diseases, including asthma, chronic urticaria, allergic conjunctivitis, chronic rhinosinusitis and eosinophilic esophagitis.

About Atopic Dermatitis

Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by skin barrier disruption and immune dysregulation. Patients with AD have chronically inflamed skin lesions that cause, among other disabilities, debilitating pruritus (itch), which can severely impair quality of life. While there are marketed injectable products for the treatment of AD, RAPT believes based on its preclinical pharmacology and Good Laboratory Practice toxicology results, if confirmed in clinical trials, combined with the convenience of once daily oral dosing, RPT193, if approved by the FDA, could fill an unmet medical need for the treatment of allergic disorders.

In addition to AD, a number of allergic diseases are characterized by an inflammatory response to cytokines produced by Th2 cells. These diseases include allergic asthma, chronic urticaria, chronic rhinosinusitis, allergic conjunctivitis and eosinophilic esophagitis.

About RAPT Therapeutics, Inc.

RAPT Therapeutics (formerly 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 its proprietary discovery and development engine, the company is developing highly selective small molecules designed to modulate the critical immune responses underlying these diseases. In its first four years since inception, RAPT has discovered and advanced two unique drug candidates, each targeting C-C motif chemokine receptor 4. The company’s lead oncology drug candidate, FLX475, reached the clinic in just two and a half years with its lead inflammation drug candidate, RPT193, also in the clinic. The company is also pursuing a range of targets, including general control nonderepressible 2

and hematopoietic progenitor kinase 1, that are in the discovery stage of development.

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