RAPT Therapeutics Announces Initiation of Phase 2a Trial of RPT193 in Patients with Moderate-to-Severe Asthma

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SOUTH SAN FRANCISCO, Calif., March 29, 2023 (GLOBE NEWSWIRE) -- RAPT Therapeutics, Inc. (Nasdaq: RAPT), a clinical-stage, immunology-based therapeutics company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology, today announced that it has initiated its global 14-week randomized, double-blind, placebo-controlled Phase 2a clinical trial to evaluate the efficacy and safety of RPT193 as an oral, once-daily monotherapy in patients with moderate-to-severe asthma.

“We are excited by the potential of RPT193 as a well-tolerated, once-daily, oral treatment for patients with asthma,” said Brian Wong, M.D., Ph.D., President and CEO of RAPT. “Following promising results from our Phase 1b trial in atopic dermatitis, where RPT193 demonstrated clinically meaningful improvement in signs and symptoms of the disease, we see asthma as the next pillar in our pipeline-in-a-product strategy. We look forward to generating proof-of-concept in this indication.”

About the Phase 2a Trial of RPT193 in Asthma
The global multicenter Phase 2a trial will assess the efficacy and safety of RPT193 in adult patients with moderate-to-severe Type 2-high asthma whose disease is partially controlled by standard medications. Type 2-high asthma is characterized by an eosinophilic airway infiltrate and the overexpression of Th2 cytokines such as IL-4, -5 and -13. The Phase 2a trial is initially focused on patients with Type 2-high asthma as RPT193 has been shown to selectively inhibit the migration of Th2 cells into inflamed tissues by blocking CCR4.

The double-blind, placebo-controlled study will compare 400 mg once-daily RPT193 to placebo in approximately 100 patients randomized 1:1. The primary endpoint is the proportion of patients who experience a loss of asthma control.

Patients enrolled in the trial will enter a run-in period of approximately 28 days with standardized regimens of inhaled corticosteroids (ICS) and long-acting beta agonists (LABA). Following this run-in period, patients will receive either RPT193 or placebo for 14 weeks during which time background ICS and LABA is gradually tapered such that patients will receive only RPT193 or placebo as monotherapy for the final 3-4 weeks of the study, depending on their pre-screening medication dosages. Patients will be followed throughout the 14-week treatment period and monitored for loss of asthma control, which is defined as meeting any of the following criteria: 1) a significant reduction in morning peak expiratory flow on two consecutive days; 2) a significant increase in reliever inhalations on two consecutive days; 3) a significant increase in the dose of ICS; 4) an asthma exacerbation requiring systemic corticosteroids; or 5) an asthma exacerbation that requires hospitalization or an emergency room visit.

About RPT193
RPT193 is a small molecule oral therapy in development for the treatment of atopic dermatitis and asthma. RPT193 is a CCR4 antagonist designed to selectively inhibit the migration of Th2 cells into inflamed tissues In allergic inflammatory diseases such as atopic dermatitis and asthma, chemokines recruit Th2 cells via CCR4 into inflamed tissues, where the Th2 cells secrete proteins known to drive the inflammatory response, and patients with atopic dermatitis and asthma express higher levels of CCR4 ligands compared with healthy individuals; 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 inflammatory diseases, including atopic dermatitis, asthma, chronic spontaneous urticaria, alopecia areata, prurigo nodularis, chronic rhinosinusitis with nasal polyps, allergic rhinitis and eosinophilic esophagitis.

About Asthma
Asthma is a chronic inflammatory disease of the airways characterized by intermittent airway obstruction, swelling and hyperproduction of mucus, which can result in coughing, wheezing and difficulty breathing. Type 2 asthma, which is driven by overactive Th2 cells, is triggered by the inhalation of allergens, including dust, pollen and dander, or by viral or bacterial infections. An estimated 25.2 million individuals in the United States have asthma, with Type 2 asthma the most common subtype, constituting approximately 80% of asthmatic children and approximately 60% of asthmatic adults.

Standard treatment of asthma includes inhaled corticosteroids and inhaled beta agonists as first-line therapies. A number of biologics can be prescribed for patients with asthma who are uncontrolled by standard treatments. While these therapies are generally effective, they are administered via injection or infusion and their targets are downstream of CCR4, presenting a market opportunity for an oral, upstream alternative.

About RAPT Therapeutics, Inc.
RAPT Therapeutics is a clinical stage immunology-based therapeutics company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology. Utilizing its proprietary discovery and development engine, the company is developing highly selective small molecules designed to modulate the critical immune drivers underlying these diseases. RAPT has discovered and advanced two unique drug candidates, RPT193 and FLX475, each targeting C-C motif chemokine receptor 4 (CCR4), for the treatment of inflammation and cancer, respectively. The company is also pursuing a range of targets that are in the discovery stage of development.

Forward-Looking Statements
This press release contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties

and other factors that may cause our actual results, performance or achievements to be materially different from any future performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about the therapeutic potential of RPT193 to treat asthma and other inflammatory diseases, RAPT's Phase 2a clinical trial of RPT193, the design thereof and the generation of data therefrom, and other statements that are not historical fact. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, preliminary data and trends may not be predictive of future data or results, may not demonstrate safety or efficacy or lead to regulatory approval by the FDA or other regulatory agencies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, the timing and results of unexpected litigation or other disputes, and the sufficiency of RAPT's cash resources. Detailed information regarding risk factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in RAPT's Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 14, 2023 and subsequent filings made by RAPT with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. RAPT disclaims any obligation to update these forward-looking statements.

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