



RAPT

THERAPEUTICS

RAPT Therapeutics Announces Initiation of Phase 2b Trial of RPT193 in Patients with Moderate-to-Severe Atopic Dermatitis

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SOUTH SAN FRANCISCO, Calif., May 23, 2022 (GLOBE NEWSWIRE) -- RAPT Therapeutics, Inc. (Nasdaq: RAPT), a clinical-stage, immunology-based biopharmaceutical company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology, today announced it has initiated its 16-week randomized, double-blind, placebo-controlled Phase 2b clinical trial to further evaluate the efficacy and safety of RPT193 as monotherapy in patients with moderate-to-severe atopic dermatitis (AD).

"We are excited to advance RPT193 into this Phase 2b trial in atopic dermatitis," said Brian Wong, M.D., Ph.D., President and CEO of RAPT. "Our Phase 1b trial results support the potential of RPT193 as a safe, once-daily, oral treatment for AD that would be an attractive therapeutic alternative ahead of injectable drugs. Moreover, the clinical results were supported by our recently reported biomarker data. We are encouraged by the potential of RPT193 for patients with AD and other inflammatory diseases and we plan to expand development of RPT193 into a Phase 2a trial in asthma in the second half of this year."

Last year, RAPT reported that in the Phase 1b trial, RPT193 demonstrated clear benefit over placebo in key exploratory efficacy measures at the end of the four-week treatment period (Day 29), including the Eczema Area and Severity Index (EASI) score, validated Investigator Global Assessment (vIGA), pruritus Numerical Rating Scale (NRS) and body surface area (BSA). By the end of the study, which included a two-week follow-up period (Day 43), RPT193 demonstrated improvement in EASI, EASI-50, EASI-75, EASI-90, vIGA and BSA. In a post-hoc statistical analysis comparing RPT193-treated patients to placebo-treated patients, the improvements in EASI, EASI-50 and BSA at Day 43 were statistically significant. RPT193 was well tolerated in the Phase 1b study. No serious adverse events were reported, and all adverse events reported were mild or moderate in intensity. In March 2022, biomarker data from the Phase 1b trial presented at the American Academy of Dermatology Annual Meeting demonstrated statistically significant improvements in the transcriptomic profile in the skin of RPT193-treated patients that correlated with key efficacy measures.

About the Phase 2b Trial of RPT193

The U.S. based Phase 2b trial is designed to assess the efficacy and safety of multiple-dose levels of RPT193 as monotherapy in patients with moderate-to-severe AD. The randomized, double-blind, placebo-controlled study will compare three oral dose levels of RPT193 (50, 200 and 400 mg once daily) to placebo with a treatment duration of 16 weeks. The co-primary endpoints for the trial are the percent change in the EASI from baseline at week 16 and incidence of treatment emergent adverse events. Key secondary endpoints include the percentage of patients achieving a vIGA score of 0 or 1 at week 16, the percentage of patients achieving EASI-75, defined as a 75% reduction in EASI from baseline to week 16, and the percent change from baseline in the Peak Pruritus Numerical Rating Scale (PP-NRS) from an itch daily e-diary at week 16. Furthermore, given maximum clinical benefit in the four-week Phase 1b trial was observed two weeks after cessation of treatment, patients in the Phase 2b trial will be followed for an additional eight weeks beyond the 16-week treatment period to understand whether sustained responses and/or further improvement in clinical parameters are observed beyond the treatment period.

About RPT193

RPT193 is a small molecule oral therapy in development for the treatment of atopic dermatitis and other inflammatory diseases. RPT193 is designed to selectively inhibit the migration of Th2 cells into inflamed tissues by blocking CCR4, a receptor highly expressed on Th2 cells. Preclinical data suggest that RPT193 also has the potential to modulate Th2 cell function by lowering the secretion of Th2 cytokines upon stimulation. In allergic inflammatory diseases such as AD, chemokines recruit Th2 cells via CCR4 into inflamed tissues, where the Th2 cells 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 AD 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 inflammatory diseases, including AD, asthma, chronic spontaneous urticaria, allergic rhinitis with nasal polyps, chronic rhinosinusitis and eosinophilic esophagitis.

About Atopic Dermatitis

Atopic dermatitis is a highly prevalent chronic, inflammatory skin disease characterized by skin barrier disruption and immune dysregulation. Patients with AD have chronically inflamed skin lesions that can cause debilitating pruritus (itch), which can severely impair quality of life. While there is a marketed injectable product for the treatment of AD, RAPT believes RPT193, if approved, could fill an unmet medical need for the treatment of inflammatory disorders with the convenience of once-daily oral dosing. There are approximately 19 million adults and approximately 10 million children affected by AD in the United States.

About RAPT Therapeutics, Inc.

RAPT Therapeutics 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 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipate,” “could,” “expect,” “look forward,” “target,” “will,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify 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, the design for the Phase 2b trial of RPT193 in atopic dermatitis, clinical development progress, including the anticipated advancement of RPT193 to a Phase 2a trial in asthma or other indications, and the potential of RPT193 to treat AD or other inflammatory diseases. 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, clinical trial site activation or enrollment rates that are lower than expected, unanticipated or greater than anticipated impacts or delays due to the COVID-19 pandemic, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 11, 2022, 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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