

# RAPT Therapeutics Reports Positive Topline Results from Phase 1b Trial of RPT193 Monotherapy in Atopic Dermatitis

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- Improvements demonstrated in all key exploratory efficacy endpoints percent change in EASI, EASI-50, vIGA and pruritis NRS at four weeks following once-daily oral treatment with RPT193
  - Further improvement in percent change in EASI, EASI-50 and vIGA observed with RPT193 two weeks after end of treatment
    - RPT193 was well tolerated with no serious adverse events
    - RAPT plans to advance RPT193 to Phase 2b clinical trial in atopic dermatitis
      - Management to host webcast conference call today at 8:30 a.m. ET

SOUTH SAN FRANCISCO, Calif., June 14, 2021 (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 oncology and inflammatory diseases, today announced positive topline results from its randomized placebo-controlled Phase 1b clinical trial of RPT193 as monotherapy in 31 patients with moderate-to-severe atopic dermatitis (AD). After four weeks of treatment, patients with moderate-to-severe AD who received RPT193 showed a 36.3% improvement from baseline in the Eczema Area and Severity Index (EASI) score, a standard measure of disease severity, compared to 17.0% in the placebo group. Notably, in the two-week period following the end of treatment, the RPT193 group showed continued improvement and further separation from placebo with a 53.2% improvement in EASI at the six-week time point compared to 9.6% in the placebo group. This continued improvement may be related to RPT193's mechanism of action, which is upstream of other agents targeting cytokines or signaling pathways.

"These data strongly support the potential of RPT193 as a safe, once-daily, oral treatment for patients with atopic dermatitis which would be an attractive therapeutic alternative ahead of injectable drugs," said Brian Wong, M.D., Ph.D., President and CEO of RAPT Therapeutics. "We look forward to advancing RPT193 to a Phase 2b trial in atopic dermatitis and a Phase 2a trial in asthma."

Emma Guttman-Yassky, M.D., Ph.D., the Waldman Professor of Dermatology and System Chair Department of Dermatology at the Icahn School of Medicine at Mount Sinai, and member of RAPT's Scientific Advisory Board, added, "I am very excited about these results as they not only demonstrate clinically meaningful improvement after just four weeks of treatment, but also further improvement for two weeks after completion of treatment. This may suggest that this novel mechanism of action targeting CCR4 on Th2 cells could have prolonged, disease-modifying effects, which could differentiate it from other agents. Along with being an oral drug that seems to have promising clinical activity and a well-tolerated safety profile, RPT193 could fill a high unmet medical need for AD patients."

#### Key Findings from the Phase 1b Study

In the Phase 1b study, 21 patients with moderate-to-severe atopic dermatitis were treated with 400 mg of RPT193, administered orally once a day for four weeks, while 10 patients received placebo. The RPT193 group showed clear improvement in key efficacy measures compared to placebo at the end of the four-week treatment period, including improvement in the Eczema Area and Severity Index (EASI) score, validated Investigator Global Assessment (vIGA) and pruritis Numerical Rating Scale (NRS):

- Patients treated with RPT193 achieved a 36.3% improvement in EASI score from baseline compared with a 17.0% improvement in patients in the placebo group
- 42.9% of patients treated with RPT193 achieved a 50% improvement in EASI score (EASI-50) compared with 10.0% in the placebo group
- 4.8% of patients treated with RPT193 achieved a vIGA score of 0/1 and at least a two-point improvement over baseline compared with 0.0% in the placebo group; and
- 45.0% of patients treated with RPT193 achieved at least a four-point reduction in the pruritus NRS score, compared with 22.2% in the placebo group

Patients were also evaluated for exploratory endpoints at six weeks (two weeks after the end of treatment). At six weeks, the patients treated with RPT193 showed further improvement in EASI score and vIGA:

Patients treated with RPT193 achieved a 53.2% improvement in EASI score from baseline compared with a 9.6%

- 61.9% of patients treated with RPT193 achieved EASI-50 compared with 20.0% in the placebo group; and
- 14.3% of patients treated with RPT193 achieved a vIGA score of 0/1 and at least a two-point improvement over baseline compared with 0.0% in the placebo group

Based on exploratory statistical analyses, the difference between RPT193 and placebo on the percent change in EASI score and EASI-50 was statistically significant at Day 43 (p < 0.05). No other endpoints or timepoints achieved statistical significance.

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. The overall safety profile of RPT193 to date, including the Phase 1b study and the previously reported blinded safety data from our Phase 1a study in healthy volunteers, suggests RPT193 is a well-tolerated oral drug that would not require any laboratory safety monitoring.

In addition to the topline data reported today, RAPT intends to report additional data and analyses in a future publication or at an upcoming medical conference.

Based on the efficacy and safety data observed in the Phase 1b study, RAPT plans to initiate a dose-ranging Phase 2b study in patients with moderate-to-severe AD and is also planning a Phase 2a study in asthma.

#### About the Phase 1a/1b Study of RPT193

The Phase 1b study reported today is part of RAPT's first-in-human Phase 1a/1b trial of RPT193. The Phase 1b portion of the trial is a randomized, double-blind, placebo-controlled study examining RPT193 as monotherapy in patients with moderate-to-severe AD. The study was conducted at multiple sites in the United States and enrolled 31 patients with moderate-to-severe AD who had an inadequate response to, or were intolerant of, topical corticosteroids. The primary endpoint of the Phase 1b study is safety. Secondary and exploratory endpoints include pharmacokinetics, biomarkers and clinical efficacy as evaluated by multiple measurements, including percent change in the Eczema Area and Severity Index (EASI) score, the validated Investigator Global Assessment (vIGA) and pruritis Numerical Rating Scale (NRS). The Phase 1b trial was not powered to achieve statistical significance for any particular endpoint.

The Phase 1a portion of the Phase 1a/1b trial was a standard single and multiple dose-escalation study in healthy volunteers. The data from the Phase 1a study demonstrated pharmacokinetics and pharmacodynamics that support once-daily oral dosing with RPT193, and blinded safety data supported initiation of the Phase 1b portion of the trial.

#### Conference call and webcast details

RAPT will host a conference call accompanied by a slide presentation today, Monday, June 14, 2021, at 8:30 a.m. ET. The live webcast and audio archive of the presentation is available on the RAPT Therapeutics website at https://investors.rapt.com/events-and-presentations. The call can be accessed by dialing (833) 672-0665 (domestic) or (929) 517-0344 (international) and referring to conference ID 4696044. The webcast replay will be available for 30 days.

# 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. Preliminary 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 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 inflammatory diseases, including atopic dermatitis, asthma, chronic urticaria, allergic rhinitis, chronic rhinosinusitis and eosinophilic esophagitis.

### **About Atopic Dermatitis**

Atopic dermatitis is a 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.

## 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 oncology and inflammatory diseases. Utilizing its proprietary discovery and development engine, RAPT 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, FLX475 and RPT193, each targeting C-C motif chemokine receptor 4 (CCR4), for the treatment of cancer and inflammation, respectively. RAPT 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 interpretations of the topline results from the Phase 1b clinical trial of RPT193, clinical development progress including the anticipated advancement of RPT193 to a Phase 2b trial in atopic dermatitis as well as Phase 2 trials in other indications and the potential of

RPT193 to treat atopic dermatitis or other inflammatory diseases. 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, 2021, 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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