

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 14, 2021

RAPT Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38997
(Commission
File Number)

47-3313701
(IRS Employer
Identification No.)

561 Eccles Avenue
South San Francisco, CA
(Address of Principal Executive Offices)

94080
(Zip Code)

(650) 489-9000
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value per share	RAPT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 8.01 OTHER EVENTS

On June 14, 2021, RAPT Therapeutics, Inc. (“RAPT” or the “Company”) issued a press release announcing positive topline results from its Phase 1b clinical trial of RPT193 in patients with moderate to severe atopic dermatitis. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

During a conference call and webcast scheduled to be held at 8:30 a.m. Eastern Time on June 14, 2021, the Company’s management will discuss the results from its Phase 1b clinical trial of RPT193 in atopic dermatitis. The slide presentation for the conference call and webcast is furnished as Exhibit 99.2 hereto and is incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	<u>Press Release titled “RAPT Therapeutics Reports Positive Topline Results from Phase 1b Trial of RPT193 in Atopic Dermatitis” dated June 14, 2021.</u>
99.2	<u>RAPT Therapeutics, Inc. Investor Presentation.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RAPT Therapeutics, Inc.

Dated: June 14, 2021

By: /s/ Rodney Young
Rodney Young
Chief Financial Officer



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

- *Improvements demonstrated in all key exploratory efficacy endpoints - percent change in EASI, EASI-50, vIGA and pruritus 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 – 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 pruritus 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% improvement in patients in the placebo group
- 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 pruritus 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.

Investor Contact:

Sylvia Wheeler
swheeler@wheelhousesa.com

Media Contact:

Aljanae Reynolds
areynolds@wheelhousesa.com



Transforming the Treatment of Cancer and Inflammation

June 14, 2021

RPT193 Topline Results

Legal Disclaimers

Statements in this Presentation that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding RAPT Therapeutics, Inc.'s (the "Company," "we," or "us") research and clinical development plans, including the planned initiation of a Phase 2b dose-ranging study of RPT193 in patients with moderate-to-severe atopic dermatitis and a planned Phase 2a trial in patients with asthma, interpretations of the topline results from the Phase 1b clinical trial of RPT193; current and future drug candidates; business strategy and plans; regulatory pathways; and our ability to complete certain milestones. Words such as "believe," "anticipate," "plan," "expect," "will," "may," "upcoming," "milestone," "potential," "target" or the negative of these terms or similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based on the current beliefs of the Company's management with respect to future events and trends and are subject to known and unknown risks and uncertainties, including those described in the "Risk Factors" section of our most recent Form 10-Q filed with the Securities and Exchange Commission, that may cause our actual performance or achievements to be materially different from any future performance or achievements expressed or implied by the forward-looking statements in this Presentation. These forward-looking statements should not be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that any assumptions on which such forward-looking statements have been made are correct or exhaustive or, in the case of such assumptions, fully stated in the Presentation. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this Presentation is given. Although we believe that the beliefs and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Presentation.

This Presentation discusses drug candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of any drug candidates for any use for which such drug candidates are being studied.

Summary

- Topline data from a placebo-controlled double-blinded Phase 1b trial examining 400 mg oral RPT193 as monotherapy for 4 weeks in 31 patients with moderate-to-severe atopic dermatitis*
 - Efficacy: RPT193 demonstrates clear improvement over placebo on all key exploratory endpoints
 - At Day 29: EASI [36.3% vs. 17.0%], EASI-50 [42.9% vs. 10.0%], vIGA 0/1 [4.8% vs. 0.0%], and pruritis NRS-4 [45.0% vs. 22.2%]
 - Further improvement observed during the 2-week follow up period to Day 43: EASI [53.2% vs. 9.6%][†], EASI-50 [61.9% vs. 20.0%][†], and vIGA 0/1 [14.3% vs. 0.0%]
 - Safety: Overall safety profile to date suggests a well-tolerated oral drug that would not require laboratory safety monitoring
 - No SAEs reported; all AEs reported were mild or moderate in intensity
- The clear clinical benefit combined with the favorable safety profile and oral convenience would support positioning ahead of approved and late-stage therapies
- A 16-week Phase 2b dose-ranging study in patients with moderate-to-severe AD will be initiated

* Initial topline data and analyses are being reported today. Additional analyses are ongoing and full datasets will be incorporated as part of a future publication or at a medical conference.

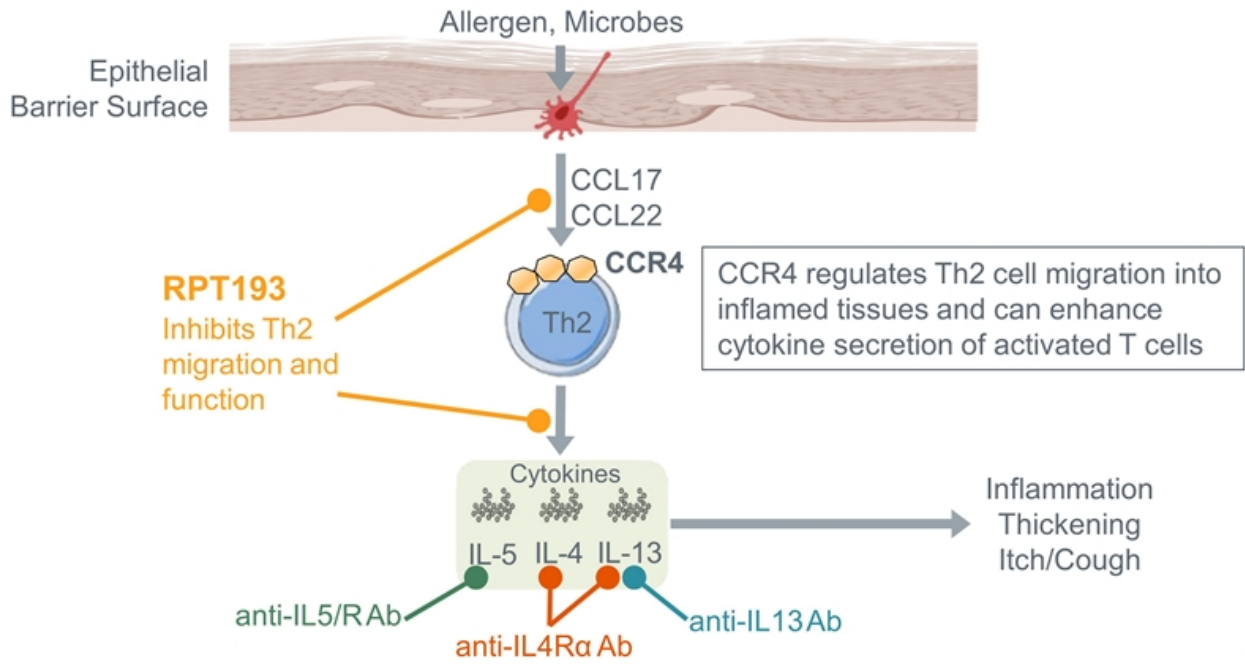
[†] Difference between RPT193 and placebo on the EASI and EASI-50 score was statistically significant at Day 43 ($p < 0.05$). No other endpoints or timepoints achieved statistical significance.

Atopic Dermatitis Represents a Major Market Opportunity

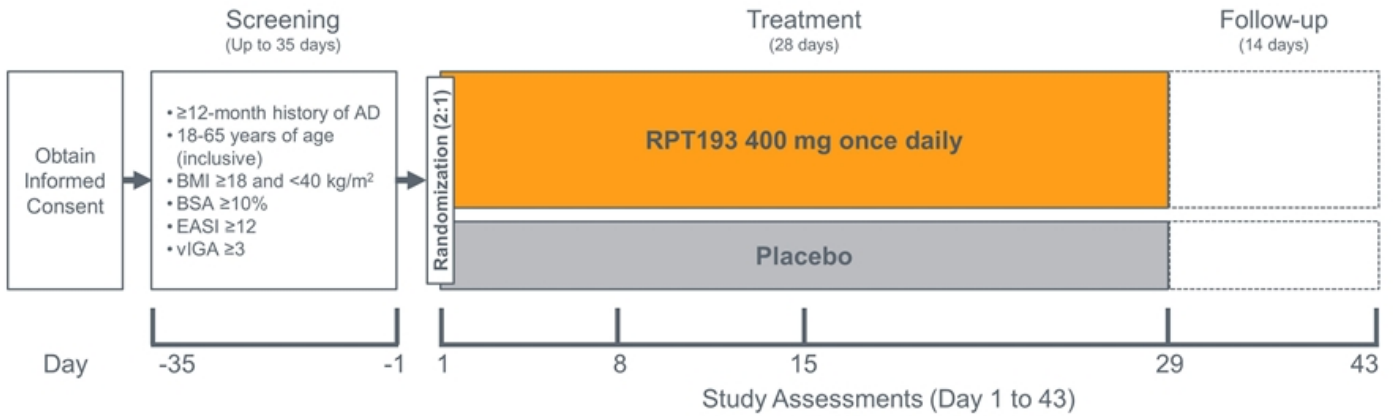
- Atopic dermatitis (AD) is a common disease affecting ~19M adults and ~10M children in the US
- \$24B market by 2029*
- While the injectable Dupixent® (dupilumab) provides an important option, a well-tolerated, effective, oral drug that does not require laboratory safety monitoring remains a high unmet need in these patients
- RPT193, a highly potent and selective oral C-C chemokine receptor type 4 (CCR4) antagonist, has the potential to address this need
- Novel mechanism of action – upstream of current agents targeting cytokines and the JAK pathway – designed to target the specific type of inflammation that drives allergic disease, without broadly suppressing the immune response

* Decision Resources Guide May 2021; EU, US, and Japan market

RPT193 Acts on a Validated Upstream Pathway in Atopic Dermatitis and Asthma



Phase 1b Trial Explores RPT193 Activity in Patients with Moderate-to-Severe Atopic Dermatitis



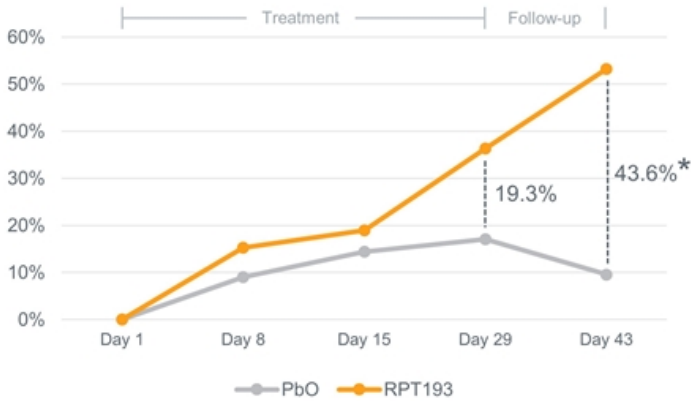
- Enrolled 31 patients into a double-blind, randomized trial with 2:1 allocation of RPT193 to placebo
- Monotherapy study: steroid and immunosuppressant washout period; rescue steroids not permitted through Day 43
- Trial was not powered for any specific endpoint
- Exploratory endpoints include: EASI, Pruritus Numerical Rating Scale (NRS), and vIGA
- Data presented are from the Intent to Treat dataset

Phase 1b Baseline Demographics

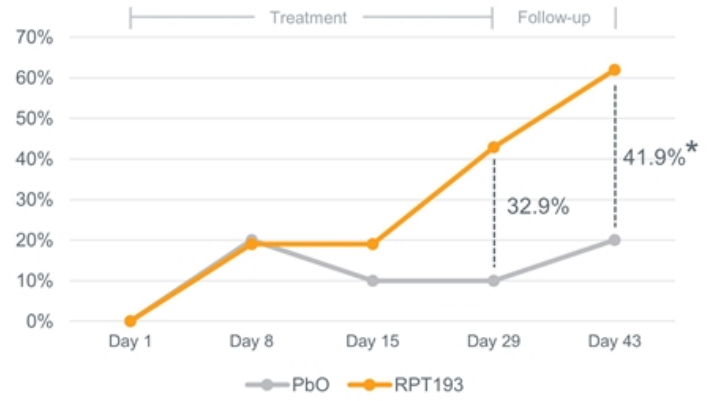
	Placebo	RPT193
N	10	21
Age, Mean (Range)	35.8 (22-64)	41.0 (19-63)
Female, n (%)	4 (40.0%)	12 (57.1%)
Baseline Characteristics		
EASI, Mean (Range)	21.07 (13.6-45.5)	18.49 (12-30)
BSA, Mean (Range)	24.5 (10-61)	23.3 (11-55)
vIGA 3, n (%)	8 (80.0%)	18 (85.7%)
Peak NRS, Mean (Range)	7.3 (3-10)	6.9 (3-10)
Peak NRS \geq 4, n (%)	9 (90.0%)	20 (95.2%)

RPT193 Differentiated from Placebo for EASI and EASI-50 at Day 29 with Further Improvement at Day 43

% Improvement in EASI

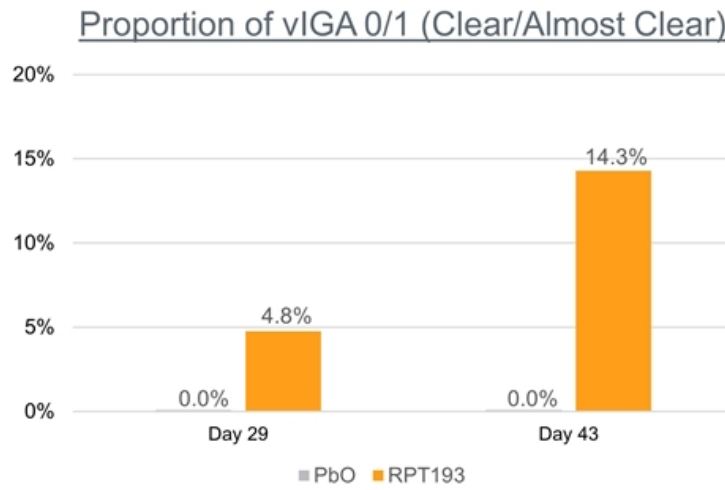


Proportion of EASI-50

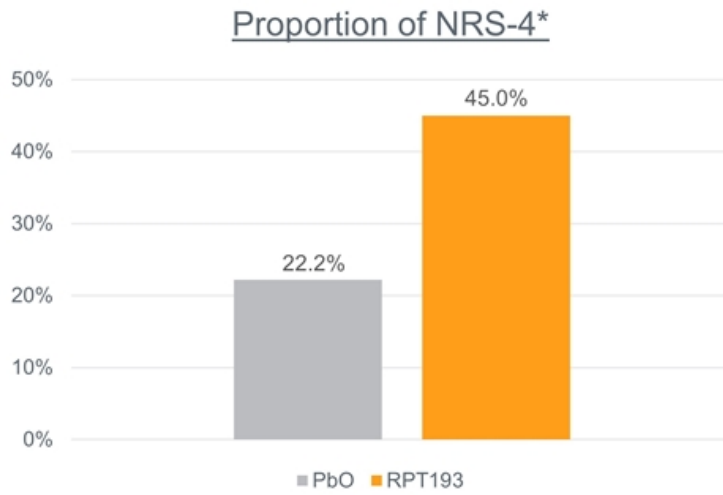


*p < 0.05

RPT193 Differentiated from Placebo for vIGA Clear/Almost Clear at Day 29 with Further Differentiation at Day 43



RPT193 Demonstrates Clinically Meaningful Improvement in Itch Compared to Placebo at Day 29

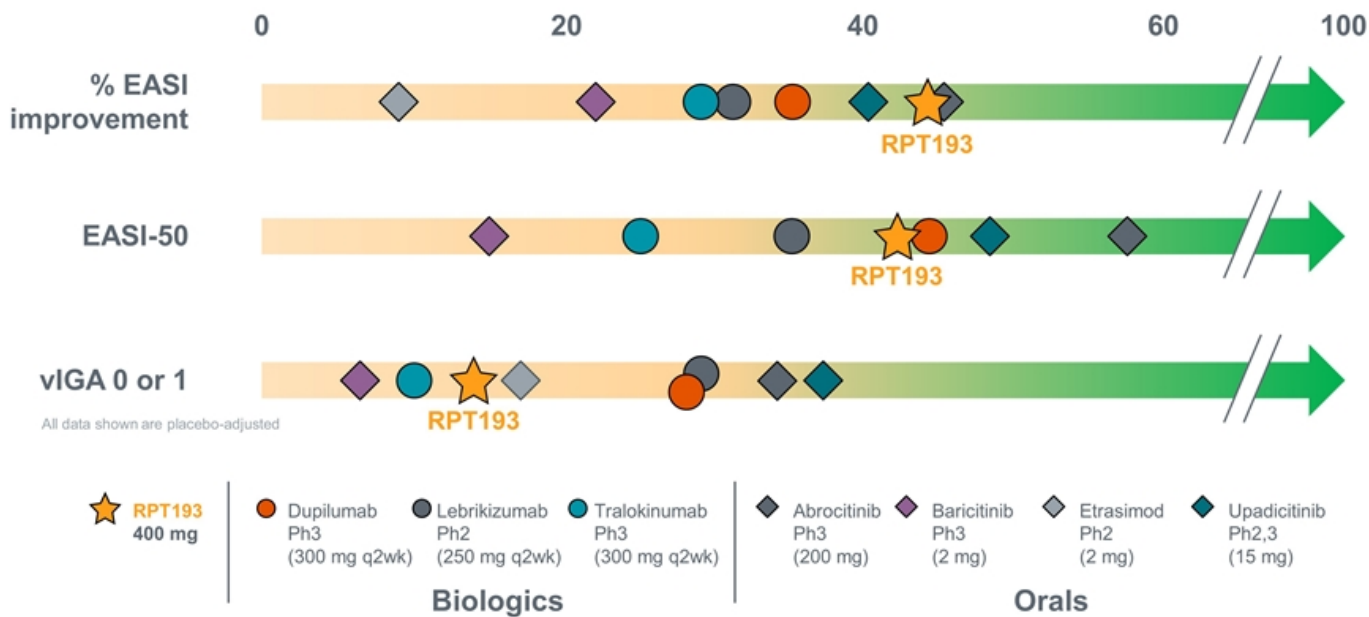


*At least a 4-point improvement among patients with a baseline pruritis NRS ≥ 4

Safety

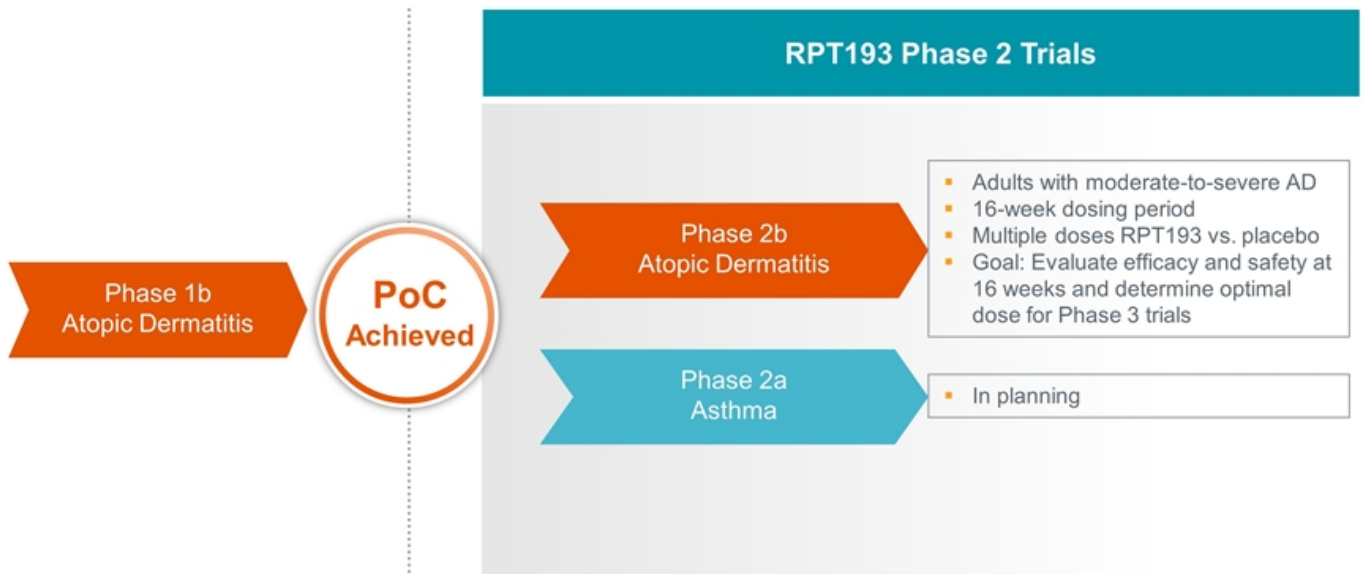
- No SAEs reported
- All AEs reported were mild or moderate in intensity
- No clinically significant safety laboratory abnormalities observed
- Overall safety profile to date suggests a well-tolerated oral drug that should not require laboratory safety monitoring

RPT193 6-Week Efficacy Compared to Other Drugs at 12-16 Weeks*



* Comparisons are based on published data and relative properties of other agents and do not reflect a head-to-head comparative study or clinical trial

Next Steps for RPT193 Program



Conclusion

- Data from this Phase 1b study in patients with atopic dermatitis demonstrate clear benefit in key exploratory clinical endpoints including EASI and vIGA
- Continued deepening of responses through the 2-week follow-up period suggests higher levels of efficacy could be achieved in longer studies
- Profile suggests an effective, well-tolerated oral molecule without the need for laboratory safety monitoring, with potential positioning ahead of injectables
- Next step: 16-week Phase 2b study in patients with moderate-to-severe AD
- Planning a Phase 2a study in patients with asthma



Thank You

