Apogee Therapeutics Announces Positive 16-Week Data from Phase 2 APEX Clinical Trial of APG777, its Potentially Best-in-Class Anti-IL-13 Antibody, in Moderate-to-Severe Atopic Dermatitis

July 7, 2025

APEX Part A met all primary and key secondary endpoints and exceeded trial objectives, including 71.0% decrease from baseline in EASI at Week 16

APG777 demonstrated EASI-75 of 66.9% (42.5% placebo-adjusted) at Week 16, the highest topline and placebo-adjusted efficacy of any biologic in a global study

Exposure-response relationship observed across multiple key endpoints; APEX Part B is testing higher exposures with readout accelerated and now anticipated mid-2026, enabling planned Phase 3 initiation in 2026

APEX Part A testing potentially best in class 3- or 6-month maintenance dosing with 52-week readout anticipated 1H 2026

APG777 was well tolerated with a favorable safety profile consistent with other agents in class

First patient dosed in APG279 (IL-13 + OX40L) Phase 1b head-to-head trial versus DUPIXENT with readout expected in 2H 2026

Management will host a conference call today at 8:00 a.m. ET

SAN FRANCISCO and BOSTON, July 07, 2025 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc., (Nasdaq: APGE), a clinical-stage biotechnology company advancing optimized, novel biologics with potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, today announced positive 16-week data from Part A of the Phase 2 APEX clinical trial of APG777, a potential best-in-class anti-IL-13 antibody, in patients with moderate-to-severe atopic dermatitis (AD).

“With two out of every three patients treated with APG777 achieving EASI-75 response at Week 16 in the Phase 2 APEX Part A trial, APG777 demonstrated the highest EASI-75 response rate both on a topline and placebo-adjusted basis for any biologic in a global study to date, reinforcing its potential best-in-class profile for patients with moderate-to-severe atopic dermatitis,” said Michael Henderson, M.D., Chief Executive Officer of Apogee. “APG777 has the potential to set a new standard of care by offering improved clinical responses with transformational quarterly or better maintenance dosing — benefitting patients, providers, and payers. Today’s results bring us closer to that vision, and we believe further de-risks APG777’s path to approval. In addition, I am excited for our two upcoming readouts to potentially even further improve on efficacy results — the accelerated APEX Part B testing higher exposures that is now expected to readout mid-2026, and the ongoing APG279 (IL-13 + OX40L) head-to-head trial against DUPIXENT expected to readout in the second half of 2026.”

“Today’s results from APEX Part A demonstrate strong efficacy results across all key endpoints,” said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. “In addition to these potentially best-in-class results, increased response rates were observed in patients with higher exposures, supporting our exposure-response hypothesis which we continue to further test in APEX Part B. Combined with a favorable safety profile, these findings reinforce APG777’s potential to deliver meaningful and durable benefit to patients while significantly reducing dosing frequency compared with existing agents. On behalf of the entire Apogee team, I’d like to extend our gratitude to the patients and physicians for their support in the successful execution of this important trial.”

APEX Phase 2 Part A Key 16-Week Results

The Phase 2 APEX clinical trial is a randomized, placebo-controlled study evaluating APG777 in patients with moderate-to-severe AD. Part A of the trial enrolled 123 adult patients who were randomized 2:1 to APG777 versus placebo and received an induction regimen dosing of 720mg at Weeks 0 and 2, followed by 360mg at Weeks 4 and 12. Patients benefiting from treatment continued maintenance dosing, evaluating 3- or 6-month dosing of APG777. The primary endpoint of Part A is mean percentage change in Eczema Area Severity Index (EASI) score from baseline at Week 16. Secondary endpoints include EASI-75, EASI-90, Validated Investigator Global Assessment (IGA) 0/1 and Itch Numeric Rating Scale (NRS) at Week 16.

Initial 16-week findings from APEX Part A include efficacy results, which compare favorably versus standard of care across endpoints as well as rapid onset of itch relief and lesion reduction, and a favorable safety profile consistent with its class:

- The trial met its primary endpoint, with APG777 showing significantly greater least squares mean percent change from baseline at Week 16 with an EASI reduction of 71.0% compared to placebo of 33.8% ($p < 0.001$).

- Highest absolute and placebo-adjusted EASI-75 of any biologic with 66.9% of participants treated with APG777 achieving

EASI-75 compared to 24.6% on placebo ($p < 0.001$)

- Pre-specified sensitivity analysis showed consistent results in both moderate and severe patients
- Additionally, an exposure-response relationship was observed, with patients in the two highest quartiles of exposures achieving the highest EASI-75 response at Week 16, 83.3% for quartile three and 89.5% for quartile four
  - APEX Part B is testing a higher dose of APG777, which is projected to achieve average exposures in line with the highest quartile of exposures from Part A

- Additional key secondaries were in line with standard of care, including vIGA 0/1 and EASI-90
  - vIGA 0/1 of 34.9% compared to placebo of 17.3% ($p < 0.05$)
  - EASI-90 of 33.9% compared to placebo of 14.7% ($p < 0.05$)
  - Patients in the highest quartile of exposures achieved the highest response, 63.2% vIGA 0/1 and 63.2% EASI-90 at Week 16
- Treatment of patients with APG777 led to rapid onset of itch relief and achieved statistically significant reduction by Week 1
  - 50.7% reduction of Itch NRS from baseline compared to 23.2% ($p < 0.01$)
- APG777 was well tolerated with a safety profile consistent with other agents in the class
  - Serious treatment-emergent adverse events (TEAEs) were rare for APG777-exposed patients (1.2% vs. 2.4% in placebo)
  - Discontinuation rate due to AEs was low for APG777-exposed patients (2.4%)
  - The most common TEAEs (occurring in ≥5% of patients in either treatment group) were non-infective conjunctivitis, upper respiratory tract infection, and nasopharyngitis, the latter two numerically lower in APG777 treated patients
  - There were 0 injection site reactions in the APG777 group

"The Phase 2 Part A results are exciting, with APG777 demonstrating promising efficacy results from only four injection days over the initial 16-week induction period," said Emma Guttman-Yassky, M.D., Ph.D., Waldman Professor of Dermatology and Immunology and Health System Chair of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City. "Despite meaningful advances in atopic dermatitis treatment, there remains a significant unmet need to reduce the injection burden for patients while continuing to improve patient outcomes. I look forward to seeing the first half-life extended antibody in AD progress and I am excited about Apogee's studies that are bringing this therapy closer to patients."

APEX Part B is a placebo-controlled dose optimization with approximately 280 patients randomized 1:1:1:1 to high, medium, or low dose APG777 versus placebo. Part B continues to enroll participants with readout expected in mid-2026. Data readout from the maintenance phase of APEX Part A, testing 3- and 6-month maintenance dosing, is expected in the first half of 2026.

Webcast Details
Apogee Therapeutics' live webcast of the Phase 2 APEX Part A results will begin today at 8:00 a.m. ET. The live webcast can be accessed via this link or the Investors section on the Company's website at https://investors.apogeetherapeutics.com/news-events/events. A replay of the webcast will be available following the call.

About Apogee
Apogee Therapeutics is a clinical-stage biotechnology company advancing optimized, novel biologics with potential for differentiated efficacy and dosing in the largest I&I markets, including for the treatment of Atopic Dermatitis (AD), asthma, Chronic Obstructive Pulmonary Disease (COPD), Eosinophilic Esophagitis (EoE) and other I&I indications. Apogee's antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties. APG777, the Company's most advanced program, is being initially developed for the treatment of AD, which is the largest and one of the least penetrated I&I markets. With four validated targets in its portfolio, Apogee is seeking to achieve best-in-class efficacy and dosing through monotherapies and combinations of its novel antibodies. Based on a broad pipeline and depth of expertise, the Company believes it can deliver value and meaningful benefit to patients underserved by today's standard of care. For more information, please visit https://apogeetherapeutics.com.

Forward Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, statements regarding: Apogee's plans for its current and future product candidates and programs; the expected timing of and results from its clinical trials, including 52-week maintenance data from Part A and the initial readout from Part B of its Phase 2 trial of APG777 in AD and initial readout from its Phase 1b trial of APG279 in AD; its planned clinical trial designs; its plans for current and future clinical trials, including the timing of initiation of a Phase 3 trial of APG777 in AD and potential path to regulatory approval; the potential clinical benefit and half-life, PK profile, dosing regimen, and treatment

outcomes of APG777 and APG279; and its planned business strategies. Words such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “develop,” “plan” or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Apogee believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Apogee’s filings with the U.S. Securities and Exchange Commission (the SEC)), many of which are beyond the Company’s control and subject to change. Actual or final results could be materially different. Risks and uncertainties include: global macroeconomic conditions and related volatility; expectations regarding the initiation, progress, and expected results of Apogee’s preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of Apogee’s clinical trials; the unpredictable relationship between preclinical study results and clinical trial results, including across different phases of clinical trials; the accuracy of cross-trial comparisons against products in the same class; the timing or likelihood of regulatory filings and approvals; liquidity and capital resources; and other risks and uncertainties identified in Apogee’s Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025, and subsequent disclosure documents Apogee has filed and may file with the SEC. Apogee claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. Apogee expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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