Apogee Therapeutics Announces Results Up to 9 Months from Phase 1 Trial of APG777, its Novel Half-Life Extended Anti-IL-13 Antibody for the Treatment for Atopic Dermatitis and Other Inflammatory Diseases

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Pharmacokinetic data up to 9 months continue to support potential best-in-class profile, including a half-life of approximately 75 days, approximately three to five times that of currently approved treatments for moderate-to-severe AD

Key biomarker data from single doses of APG777 show near complete inhibition of pSTAT6 and sustained TARC inhibition up to 9 months

Proof-of-concept data from the ongoing APG777 Phase 2 clinical trial in patients with moderate-to-severe atopic dermatitis are expected in 2H 2025

APG777 has the potential to demonstrate improved clinical responses from greater exposures in induction and maintenance dosing of every 3- or 6-months

SAN FRANCISCO and WALTHAM, Mass., Oct. 24, 2024 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc., (Nasdaq: APGE), a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) and other I&I indications, today announced updated positive results from its ongoing Phase 1 clinical trial of APG777, a novel half-life extended anti-IL-13 antibody for the treatment for atopic dermatitis and other inflammatory diseases, in healthy volunteers up to nine months. These data will be presented at the American College of Allergy, Asthma & Immunology's (ACAAI) 2024 Annual Scientific Meeting, held in Boston from October 24-28, 2024.

Today's results build on the Phase 1 positive interim data announced in March 2024. This updated dataset includes findings from the 40 enrolled participants across three single-ascending dose (SAD) cohorts, now with nine months of follow-up, and two multiple-ascending dose (MAD) cohorts, now with six months of follow-up. Findings demonstrated that APG777, in single doses up to 1,200mg or multiple doses of 300mg, showed a well-tolerated safety profile. Pharmacokinetic (PK) data was consistent with what was previously reported, including a half-life of approximately 75 days, dose proportional increases in Cmax and AUC, and low variability. APG777's pharmacodynamic (PD) profile showed near complete inhibition of pSTAT6 and sustained TARC inhibition up to 9 months. These findings further support Apogee's ongoing Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD, with the potential for improved clinical responses from greater exposures in induction and significantly less frequent dosing in maintenance at every three or six months compared to every two-to-four week dosing with currently approved biologic therapies. The company expects to report 16-week topline data from Part A of the trial in the second half of 2025.

"Results from our Phase 1 trial of APG777 continue to support a potential best-in-class PK and PD profile of APG777, in particular a near-complete inhibition of pSTAT6 and sustained TARC inhibition out to nine months following a single dose," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "Furthermore, we are pleased to see that APG777 continues to be well tolerated, and with APG777's PK profile, we remain confident that we can achieve maintenance dosing of every 3- to 6- months in patients with moderate-to-severe AD. We are on track to report initial data from Part A of our Phase 2 clinical trial in patients with moderate to severe AD in the second half of next year. We look forward to sharing more on APG777 and providing an update on our progress across all programs as well as highlighting our combination strategy in further detail at our R&D Day on December 2nd."

Key Findings from the Phase 1 APG777 Results Up to 9 Months:

- Dose proportional PK was observed, with a half-life of ~75 days, approximately three to five times that of currently approved treatments for moderate-to-severe AD consistent with previously reported interim results.
    - APG777 demonstrated dose proportional increases in Cmax and AUC from 300mg up to 1,200mg across all SAD and MAD cohorts.
- Single and multiple doses of APG777 resulted in rapid and sustained effect on PD markers for up to nine months.
    - Single doses of APG777 showed rapid, near-complete inhibition of pSTAT6, one of the first downstream markers of IL-13 pathway inhibition, up to nine months (limit of available follow up in SAD cohort);
    - MAD cohorts showed similar inhibition of pSTAT6 through available follow-up. Single doses of APG777 suppressed TARC, an inflammatory mediator and the most strongly correlated biomarker to AD severity, with deep and sustained inhibition for up to nine months.
- APG777 was generally well-tolerated at doses up to 1,200 mg.
    - Treatment-emergent adverse events were generally mild-to-moderate and unrelated to APG777.
    - There were no serious adverse events or dose-dependent trends observed up to time of data cut.

Apogee's poster presentation from ACAAI can be found on the Publications page of the company website.

About APG777
APG777 is a novel, subcutaneous extended half-life monoclonal antibody targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD. In our head-to-head preclinical studies, APG777 demonstrated equivalent or better potency to lebrikizumab in the inhibition of IL-13 signaling. Based on its potentially best-in-class PK profile, APG777 has the potential for improved clinical responses from greater exposures of drug in induction and dosing as infrequently as once every three or six months. AD is a chronic inflammatory skin disorder which can lead to sleep disturbance, psychological distress, elevated infection risk and chronic pain, all of which significantly impact quality of life. Today's treatments are associated with many challenges, including frequent injection regimens that can lead to poor patient compliance. APG777 represents the first clinical-stage product candidate from the company's strategic collaboration with Paragon Therapeutics, Inc., an innovative discovery engine for biologics.

About Apogee
Apogee Therapeutics is a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest I&I markets, including for the treatment of AD, asthma, COPD 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, particularly APG777; its plans for current and future clinical trials; expected timing for release of data from Apogee's Phase 2 clinical trial of APG777 in AD; the potential clinical benefit, dosing schedule and half-life of APG777; plans for Apogee's other product candidates, and any other potential programs, including combination therapies. 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 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 study results; 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, 2023, filed with the SEC on March 5, 2024, Quarterly Report on 10-Q for the quarterly period ended June 30, 2024, filed with the SEC on August 12, 2024, and subsequent disclosure documents we 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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