Apogee Therapeutics Announces Positive Interim Phase 1 Results from Healthy Volunteer Trial of APG333, its Novel Half-Life Extended TSLP Antibody

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Interim Phase 1 results for APG333 exceeded trial objectives, demonstrated a half-life of approximately 55 days, and suppressed key biomarkers for 6 months following a single dose, supporting potential 3- and 6- month dosing

Results support development of a quarterly or less frequently dosed co-formulation of APG273 (APG777+APG333) for respiratory indications

APG333 was well tolerated across all cohorts with doses of up to 1,000 mg

SAN FRANCISCO and BOSTON, Nov. 10, 2025 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing optimized, novel biologics with potential for best-in-class profiles in the largest inflammatory and immunology (I&I) markets, today announced positive interim Phase 1 results from its first-in-human study of APG333, which demonstrated data supporting potential 3- and 6-month dosing based on a half-life of approximately 55 days across doses tested. Additionally, APG333 was well tolerated across all cohorts, with doses up to 1,000 mg.

"Today's positive results show that our engineered antibody approach continues to deliver durable activity, which may enable less frequent dosing versus currently available agents, potentially improving adherence and outcomes for patients. This milestone represents another important step forward for our pipeline in the evolution of I&I treatments," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "The extended PK and favorable tolerability profile of APG333 underscores Apogee's potential to advance a quarterly or better dosing combination of APG777 and APG333, designed to address key drivers of respiratory diseases more broadly than a monotherapy."

The APG333 Phase 1 clinical trial was designed as a double-blind, placebo-controlled, first-in-human, single-ascending dose study in healthy volunteers. It evaluated the safety, tolerability and PK of APG333 in 32 healthy adults across four cohorts. Key results include:

- APG333 demonstrated an optimized PK profile, including a half-life of approximately 55 days, supporting potential for APG273 (APG777+APG333) every 3-month or better dosing.
    - Key biomarkers of eosinophils and IL-5 showed depth of suppression in line with TSLP analogs and durability out to 6 months (limit of available follow up).
- APG333 was well tolerated across the four cohorts, with doses of up to 1,000 mg.
    - The most common treatment-emergent adverse events (TEAEs) occurring in ≥10% of APG333 treated participants were headache and upper respiratory tract infection.
    - TEAEs were generally mild and self-limited and there were no dose dependent trends in TEAEs seen.
    - There were no Grade 3 TEAEs related to study drug or serious adverse events. No adverse events led to study discontinuation.

"We are encouraged by these initial results, which further highlight the potential of TSLP inhibition, a clinically validated target that plays an important role in promoting immune cell recruitment and activation," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "APG333's PK profile supports the potential for dosing two to four times a year, a significant advancement over the current standard of care. These data unlock our combination of APG777 and APG333, which together demonstrated suppression of complementary pathways implicated in obstructive airway disease and may enable quarterly or less frequent dosing, expanding options for patients with limited available treatments."

About APG333
APG333 is a novel, SQ extended half-life mAb targeting TSLP, an epithelial cell-derived cytokine that has emerged as an attractive, clinically validated target for the treatment of I&I indications because the target plays an important role in promoting immune cell recruitment and activation. In addition, a TSLP-targeting mAb may be used in combination with other mAbs for potentially greater efficacy in broader populations. TSLP inhibition has been clinically validated, with one approved product on the market for the treatment of severe asthma without biomarker or phenotype restrictions.

About Apogee
Apogee Therapeutics is a clinical-stage biotechnology company advancing optimized, novel biologics with potential for best-in-class profiles in the largest I&I markets, including for the treatment of Atopic Dermatitis (AD), asthma, Eosinophilic

Esophagitis (EoE), Chronic Obstructive Pulmonary Disease (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 profiles 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; its planned clinical trial designs; its plans for current and future clinical trials; and the potential clinical benefit and half-life, PK profile and dosing regimen, and treatment outcomes of APG273 (APG777+APG333). 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, 2024, filed with the SEC on March 3, 2025, Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025, filed with the SEC on August 11, 2025, and subsequent disclosure documents Apogee 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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