Apogee Therapeutics Announces First Participants Dosed in Phase 1 Clinical Trial of APG333, its Novel Half-Life Extended TSLP Antibody for the Treatment of Respiratory and Broader I&I Conditions

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Interim safety and pharmacokinetic data from Phase 1 healthy volunteers trial anticipated in 2H 2025

APG777 + APG333 can potentially address key drivers of respiratory diseases more broadly versus monotherapy

Preclinical proof-of-concept achieved for APG777 + APG333 combination with clinical trial planning underway in asthma and COPD

SAN FRANCISCO and WALTHAM, Mass., Dec. 10, 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), eosinophilic esophagitis (EoE) and other I&I indications, today announced that it has initiated dosing of healthy volunteers in its clinical trial of APG333, a novel, subcutaneous (SQ) half-life extended monoclonal antibody targeting thymic stromal lymphopoietin (TSLP), which is being evaluated initially as a treatment for people living with asthma, COPD and broader I&I conditions.

"The initiation of the APG333 Phase 1 clinical trial marks our fourth program to enter clinical trials in less than 18 months and represents an important step in our pipeline evolution, as we continue to establish the building blocks for our combination strategy," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "TSLP is a clinically validated target that plays an important role in both Type 2 and Type 3 inflammation, the primary drivers of inflammatory respiratory conditions. Based on its mechanism, it has the potential to broadly address obstructive respiratory diseases, including for the approximately half of patients with low Type 2 inflammatory respiratory diseases who currently have fewer treatment options. We plan to initially explore APG333 for the treatment of asthma, with the ultimate goal of leveraging this investigational therapy in combination with APG777, a combination approach that could optimally address respiratory and broader I&I diseases."

The APG333 Phase 1 clinical trial is designed as a double-blind, placebo controlled, first-in-human, single-ascending dose trial in healthy volunteers. The study will evaluate the safety, tolerability and pharmacokinetics (PK) of APG333 and is expected to enroll approximately 32 healthy adults into 4 cohorts. Apogee expects interim data from the trial in the second half of 2025.

In preclinical studies, the combination of APG777 + APG333 has been shown to drive broader and deeper inhibition of inflammation centrally with deeper impact on local airway responses compared to approved or in-development biologics, with the potential for a significantly less frequent dosing schedule.

About APG333
APG333 is a novel, SQ extended half-life mAb targeting TSLP, a key driver of Type 2 and Type 3 inflammation in eosinophilic and non-eosinophilic conditions. TSLP is an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of I&I indications. 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 novel biologics with potential for differentiated efficacy and dosing in the largest I&I markets, including for the treatment of AD, asthma, COPD, 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, its plans for current and future clinical trials, including a Phase 1 clinical trial for APG333; Apogee's plans for clinical trial design; the anticipated timing of the initiation of and results from Apogee's clinical trials, including data from Apogee's Phase 1 clinical trial of APG333; and the potential clinical benefit and half-life of APG333 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 September 30, 2024, filed with the SEC on November 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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