Apogee Therapeutics Announces Positive Interim Results from the Phase 1b Trial of APG808, its Novel Half-life Extended IL-4Rα Antibody, in Patients with Mild-to-Moderate Asthma

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Multiple doses of APG808 resulted in rapid suppression of FeNO, a biomarker of Type 2 inflammation associated with exacerbations in asthma, with a robust maximal FeNO decrease from baseline of 53%

APG808 demonstrated the potential for durable disease control in asthma with sustained FeNO decrease from baseline of 50% at 12 weeks

APG808's optimized formulation and potential best-in-class pharmacokinetic (PK) profile, combined with robust and sustained FeNO suppression through 12 weeks, support the potential for transformative dosing every 2-months or longer, compared to the current biweekly standard of care

APG808 was well tolerated with a favorable safety profile consistent with the anti-IL-4Rα class

Phase 1b proof-of-concept data validates Apogee's approach to designing potentially best-in-class biologics and builds on Apogee's track record of execution

SAN FRANCISCO and BOSTON, May 12, 2025 (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, eosinophilic esophagitis (EoE), chronic obstructive pulmonary disease (COPD) and other I&I indications, today announced positive interim data from its Phase 1b trial of APG808, a novel half-life extended IL-4Rα antibody, in patients with mild-to-moderate asthma.

“Today’s results from the APG808 Phase 1b trial mark a significant milestone in its clinical development, as APG808 demonstrated a favorable safety profile and encouraging initial efficacy in patients with asthma,” said Michael Henderson, M.D., Chief Executive Officer of Apogee. “With its potential best-in-class PK profile, APG808 could substantially improve clinical outcomes for patients with asthma over the biweekly current standard of care and enable dosing as infrequently as every two months or longer. We believe today’s progress reinforces our ability to soundly execute and build a leading I&I company poised to redefine treatment paradigms for patients worldwide.”

The Phase 1b double-blind, placebo-controlled, multiple-dose trial evaluated the safety and tolerability of APG808 in 22 adult patients with mild-to-moderate asthma. The trial also evaluated fractional exhaled nitric oxide concentration (FeNO), TARC, and pSTAT6. Participants were randomized 3:1, receiving 600mg of APG808 or placebo on day 1 and day 29.

Key results include:

- Multiple dose regimen of APG808 was well tolerated in asthmatic patients through 12 weeks of available follow-up.
    - The most common treatment-emergent adverse events (TEAEs) observed were headache, injection site erythema, and upper respiratory tract infections.
    - There were no Grade 3 TEAEs or severe adverse events. No adverse events led to study discontinuation.
- Multiple doses of APG808 resulted in rapid suppression of FeNO, a biomarker of Type 2 inflammation that is associated with exacerbations in asthma, with a maximal robust FeNO decrease from baseline of 53% and sustained FeNO decrease from baseline of 50% at 12 weeks. APG808 also demonstrated sustained and near-complete reduction in pSTAT6 as well as deep reduction of TARC maintained through 12 weeks, two key Type 2 inflammatory biomarkers.
- APG808's optimized formulation and potential best-in-class PK profile along with durable FeNO suppression out to 12-weeks support potential for 2-month or longer maintenance dosing.

About APG808
APG808 is a novel, subcutaneous extended half-life monoclonal targeting IL-4Rα, a target with clinical validation across eight Type 2 allergic diseases, for the potential treatment of asthma, COPD and other inflammatory and immunology indications. In preclinical studies, APG808 has similar binding and femtomolar affinity for IL-4Rα as compared to DUPIXENT and has demonstrated similar inhibition to DUPIXENT. Asthma is one of the most common non-communicable diseases and, for a substantial number of

patients, has an impact on quality of life and is estimated to affect 40 million adults and 12 million children in the United States, France, Germany, Italy, Japan, Spain and the United Kingdom, with prevalence rates of 5% to 8% in many countries. APG808 Phase 1 results demonstrated a potential best-in-class PK profile supporting the potential for every two- to three- month maintenance dosing.

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, EoE, 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 planned clinical trial designs; the potential clinical benefit, PK profile and dosing regimen, and treatment outcomes of APG808; the potential for APG808 to improve clinical outcomes for patients with asthma over current standard of care, and Apogee's ability to execute on 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 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 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 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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