Apogee Announces Dosing of First Patient in Phase 2 Atopic Dermatitis Trial of APG777, a Novel Subcutaneous Half-life Extended Anti-IL-13 Antibody for the Treatment of Atopic Dermatitis and Other Inflammatory Diseases

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Interim clinical data from APG777 Phase 1 healthy volunteers study exceeded all trial objectives and achieved a half-life of approximately 75 days with a potentially best-in-class profile

16-week proof-of-concept data from Part A of the Phase 2 trial expected in 2H 2025

Pipeline-in-a-product potential with a Phase 2 in asthma expected to initiate in 2025 and plans for additional indication expansion

SAN FRANCISCO and WALTHAM, Mass., May 15, 2024 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing differentiated biologics for the treatment of atopic dermatitis (AD), chronic obstructive pulmonary disease (COPD), asthma and other inflammatory and immunology (I&I) indications, today announced that it has initiated dosing in the Phase 2 trial of APG777 in patients with moderate-to-severe atopic dermatitis. APG777 is a novel, subcutaneously-administered half-life extended monoclonal antibody targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD.

“We are thrilled to begin patient dosing in our Phase 2 trial of APG777, marking a significant step forward in the advancement of this program and to further realizing the impact a fully-optimized antibody with extended half-life could have on the treatment of AD compared to other available biologics,” said Michael Henderson, MD, Chief Executive Officer of Apogee. “The initiation of this Phase 2 trial is supported by the highly encouraging results of our Phase 1 healthy volunteer trial that were reported earlier this year. With a potentially best-in-class pharmacokinetic profile, sustained pharmacodynamic responses, and well-tolerated safety profile, we believe APG777 could offer improved clinical responses with less frequent dosing than current standard of care. We look forward to the advancement of this trial and initial 16-week data in the second half of 2025.”

The APG777 Phase 2 clinical trial is a randomized, placebo-controlled, 16-week trial in patients with moderate-to-severe AD. The trial was designed to combine the typical Phase 2a and 2b portions of a clinical trial into a single protocol. Part A is expected to enroll approximately 110 patients randomized 2:1 to APG777 vs. placebo; patients receiving APG777 will receive induction regimen dosing of 720mg at weeks 0 and 2, followed by 360mg at weeks 4 and 12. Patients benefiting from treatment will continue to APG777 maintenance, which will evaluate 3- to 6-month dosing. Part B is a placebo-controlled dose optimization with approximately 360 patients randomized 1:1:1:1 to high, medium, or low dose APG777 vs. placebo. The primary endpoint of each part of the study is mean percentage changes in EASI score from baseline to Week 16.

In 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 pharmacokinetic (PK) profile, APG777 has the potential for improved clinical responses due to greater exposures of drug in induction while 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.

“Our Phase 2 trial features an innovative design, enabling us to run both proof-of-concept and dose optimization parts in the same study, which could significantly accelerate our timelines,” said Carl Dambkowski, MD, Chief Medical Officer of Apogee. “Importantly, based on APG777’s extended half-life and high-concentration formulation, we were able to establish a Phase 2 induction regimen designed to exceed lebrikizumab exposures by ~30-40% with potential for improved clinical responses (e.g. EASI-75, EASI-90, IGA 0/1). The optimized PK profile will further enable a dosing schedule of six injections during induction, compared to the 11 injections of lebrikizumab given during the same period, and ~70-90% fewer injections in maintenance compared to currently available therapies. This approach supports our mission to provide well-tolerated treatments that require less frequent injections for patients. We extend our gratitude to the sites, site staff, and patients participating in the study for their invaluable contributions to advancing our program and look forward to further realizing the impact that less frequent dosing and a potentially improved clinical response could bring to patients living with AD.”

About APG777
APG777 is a novel, subcutaneous half-life extended monoclonal antibody targeting IL-13 for the potential treatment of atopic dermatitis (AD). In head-to-head preclinical studies, APG777 showed equivalent or better potency to lebrikizumab in the inhibition of IL-13 signaling. AD is a chronic inflammatory skin disorder that affects approximately 40 million adults and 18 million children in the United States, France, Germany, Italy, Japan, Spain and the United Kingdom, 40 percent of which have moderate-to-severe disease. Based on initial clinical data, the company plans to initiate a Phase 2 trial in asthma and plans to further evaluate opportunities to develop APG777 for other I&I indications, including alopecia areata, chronic rhinosinusitis with nasal polyps, chronic spontaneous urticaria, eosinophilic esophagitis and prurigo nodularis.

About Apogee
Apogee Therapeutics is a clinical-stage biotechnology company seeking to develop differentiated biologics for the treatment of atopic dermatitis (AD), chronic obstructive pulmonary disease (COPD), asthma and other inflammatory and immunology indications with high unmet need. 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. The company’s two most advanced programs are APG777 and APG808, which are being initially developed for the treatment of AD and COPD, respectively. 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 www.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: the efficacy, safety, tolerability, PK and PD profile of APG777, the potential dosing regimen of APG777, the potential superiority of APG777 compared to current therapies, our expectations regarding plans for our current and future product candidates and programs, our plans for our current and future clinical trials, including our Phase 2 trial for APG777, our plans for clinical trial design, the anticipated timing of the initiation of and results from our clinical trials, including data from our Phase 2 trial of AP777, and the potential clinical benefit and half-life of APG777. 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 our preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of our 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 our Quarterly Report on 10-Q for the quarterly period ended March 31, 2024, filed with the SEC on May 13, 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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