# Apogee Therapeutics Announces First Participants Dosed in Phase 1 Trial of APG808, its Novel Half-life Extended IL-4Rα Antibody for the Treatment of Chronic Obstructive Pulmonary Disease (COPD) and Other Inflammatory Diseases

March 25, 2024 11:00 AM EDT

*Preclinical data with APG808 demonstrate the potential for improved dosing over other treatment options in development, including the potential for dosing every six- or eight- weeks compared to dosing every two weeks for other biologics in development*

*Second product candidate to enter the clinic following positive interim results from Phase 1 Healthy Volunteer Trial for APG777, which exceeded all of its trial objectives*

*Interim subcutaneous safety and pharmacokinetic data from healthy volunteers anticipated in 2H 2024*

SAN FRANCISCO and WALTHAM, Mass., March 25, 2024 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing differentiated biologics for the treatment of atopic dermatitis (AD), COPD, asthma and other inflammatory and immunology (I&I) indications, today announced that it has initiated dosing of healthy volunteers in its first clinical trial for APG808, a novel subcutaneous (SQ) extended half-life monoclonal antibody (mAb) targeting IL-4Rα, which is being developed as a treatment for people living with moderate-to-severe COPD, asthma and other I&I diseases.

“On the heels of announcing positive interim data from our Phase 1 APG777 clinical trial, the initiation of the APG808 Phase 1 healthy volunteer trial represents another important advancement for Apogee’s portfolio of differentiated and optimized biologics,” said Michael Henderson, M.D., Chief Executive Officer of Apogee. “Launching our second clinical program, ahead of initial timeline expectations, brings us one step closer to providing potentially best-in-class biologics designed to significantly improve therapeutic options for patients with I&I diseases and further builds our track record of execution.”

APG808 is a novel, SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding and femtomolar affinity for IL-4Rα as compared to a first-generation mAb, DUPIXENT, and has demonstrated similar inhibition to DUPIXENT across three in vitro assays, which measure downstream functional inhibition of the IL-13/IL-4 pathway (pSTAT6 induction, inhibition of TF-1 proliferation, and inhibition of TARC secretion). COPD is a progressive respiratory disease that is estimated to affect approximately 10 percent of the global population 40 years of age and older. Despite recent advancements in COPD treatment, a significant number of people continue to suffer and die from the disease.

The APG808 Phase 1 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 APG808 and is expected to enroll approximately 32 healthy adults into four cohorts. Apogee expects interim data from the trial in the second half of 2024, and, pending positive results from the Phase 1 trial and following the submission of an IND or foreign equivalent, plans to initiate a potential Phase 1b trial in asthma with a data readout in the first half of 2025 and a randomized, placebo-controlled Phase 2 clinical trial in patients with moderate-to-severe COPD in 2025.

“By targeting known biologic drivers of disease and utilizing advanced antibody engineering such as improved half-life, Apogee aims to overcome limitations of existing therapies for I&I diseases,” said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. “We demonstrated the potential benefits of optimizing antibody properties with APG777 and now hope to do the same with APG808, which, in head-to-head preclinical studies, demonstrated similar potency to current therapies but with a significantly longer half-life. Importantly, this points to potentially less frequent dosing for patients with COPD, which could significantly improve quality of life.”

**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 chronic obstructive pulmonary disease (COPD), asthma and other inflammatory and immunology indications. APG808 has similar binding and femtomolar affinity for IL-4Rα as compared to a first generation mAb, DUPIXENT, and has demonstrated similar inhibition to DUPIXENT across three in vitro assays which measure downstream functional inhibition of the IL-13/IL-4 pathway (pSTAT6 induction, inhibition of TF-1 proliferation, and inhibition of TARC secretion). COPD is a progressive respiratory disease that is estimated to affect approximately 10 percent of the global population 40 years of age and older. Despite recent advancements in COPD treatment, a significant number of people continue to suffer and die from the disease. A Phase 1 clinical trial of APG808 in healthy volunteers is ongoing, and the company expects interim safety and pharmacokinetic data in the second half of 2024. Pending data from the Phase 1 trial, the company plans to initiate a potential Phase 1b trial in asthma with a data readout in in the first half of 2025 and a randomized, placebo-controlled Phase 2 clinical trial in patients with moderate-to-severe COPD in 2025.

**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, our expectations regarding plans for our current and future clinical trials, plans for clinical trial design, the anticipated timing of the initiation of and results from our clinical trials, potential clinical benefit and half-life of APG808, and potential additional indications for APG808 and our other programs. 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, including those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 5, 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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