



Apogee Announces First Participants Dosed Ahead of Schedule in Phase 1 Trial of APG777, its Novel Half-life Extended Anti-IL-13 Antibody for the Treatment of Atopic Dermatitis and Other Inflammatory Diseases

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Preclinical data with APG777 demonstrate the potential for significantly improved dosing over standard of care, including the potential for every two- or three-month dosing

Initial subcutaneous pharmacokinetic and safety data from healthy volunteers anticipated in mid-2024

First product candidate to enter the clinic from the company's strategic collaboration with Paragon Therapeutics, Inc., an innovative discovery engine developing potentially best-in-class biologics

SAN FRANCISCO and WALTHAM, Mass., Aug. 07, 2023 (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 and other inflammatory and immunology (I&I) indications, today announced that it has initiated dosing of healthy volunteers in its first clinical trial for APG777, its lead product candidate being developed as a frontline treatment for moderate-to-severe AD and other inflammatory diseases. Initiation of this trial marks a milestone for the company and its approach. By targeting known biologic drivers of disease and utilizing advanced antibody engineering to develop product candidates with optimized properties such as improved half-life, Apogee aims to overcome the limitations of existing therapies for (I&I) diseases.

"The initiation of this Phase 1 study of APG777 represents an important advancement for Apogee, now a clinical-stage organization, and for our discovery research collaboration with Paragon, a pioneer in developing best-in-class biologics for a range of diseases," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "By leveraging known targets with differentiated monoclonal antibodies, Apogee has the potential to improve the course of treatment for multiple inflammatory disorders, and APG777 is just the start of our strategy to develop a broad pipeline of potentially best-in-class product candidates. I am proud of the Apogee team's rapid progress in advancing APG777 to this new stage, ahead of our initial timeline expectations."

APG777 is a novel, subcutaneous extended half-life monoclonal antibody targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD. In head-to-head preclinical studies, APG777 demonstrated equivalent or better potency to lebrikizumab in the inhibition of IL-13 signaling and exhibited significantly longer half-life with the potential to deliver dosing as infrequently as once every two to three 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.

The APG777 Phase 1 trial is a double-blind, placebo-controlled study in healthy volunteers and consists of a single-ascending dose (SAD) component and a multiple-ascending dose (MAD) component. The study is expected to enroll approximately 40 healthy adult subjects into three SAD and two MAD cohorts. The primary endpoint is safety and a key secondary endpoint is PK. We expect initial safety and PK data from this trial in mid-2024. Pending data from the Phase 1 trial, Apogee plans to initiate a randomized, placebo-controlled, 16-week Phase 2 clinical trial in patients with moderate-to-severe AD in 2024.

"Apogee is focused on delivering monoclonal antibody therapeutics with improved half-life and optimized potency, bioavailability, and manufacturability," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "APG777 is the first realization of these engineering efforts, with highly encouraging preclinical data that demonstrate APG777 has similar potency to current therapies, but with significantly longer half-life that could enable less frequent dosing. A new option providing dosing every two or three months could be a transformative change in the standard of care for moderate-to-severe AD patients."

About APG777

APG777 is a novel, subcutaneous extended half-life 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 preclinical studies, Apogee believes that APG777 can be dosed either every two or every three months in maintenance, which, if clinical trials are successful, would represent a significant improvement compared to first generation IL-13 antibodies that are dosed every two to four weeks. A Phase 1 clinical trial of APG777 in healthy volunteers is ongoing, and the company expects initial safety and pharmacokinetic data in mid-2024. Pending data from the Phase 1 trial, the company anticipates filing an IND application for a Phase 2 trial in AD, which would begin in 2024. Based on initial clinical data, the company may initiate a Phase 2 trial in asthma and plans to further evaluate opportunities to develop APG777 for other I&I indications, including alopecia areata (AA), chronic rhinosinusitis with nasal polyps (CRSwNP), chronic spontaneous urticaria

(CSU), eosinophilic esophagitis (EoE) and prurigo nodularis (PN).

About Paragon Collaboration

In February 2022, Apogee entered into an antibody discovery option and license agreement with Paragon Therapeutics, Inc. (Paragon). As part of the agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to Apogee. The collaboration currently includes three selected targets, IL-13, IL-4R α , and OX40L. Apogee has exercised its option for each research program and has been granted an exclusive, worldwide license to develop, manufacture and commercialize the antibodies and products directed to the selected targets. From time to time, Apogee can choose to add additional targets to the collaboration by mutual agreement with Paragon.

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) 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.

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 APG777, and potential additional indications for 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 Registration Statement on Form S-1, as amended, declared effective by the SEC on July 13, 2023, 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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