Apogee Therapeutics Announces Positive Interim Results from Phase 1b Trial of Zumilokibart (APG777), its Potentially Best-in-Class Anti-IL-13 Antibody, in Patients with Mild-to-Moderate Asthma and Highlights 2026 Anticipated Milestones and Outlook

January 6, 2026

Phase 1b interim results of zumilokibart (APG777) in asthma demonstrated rapid and durable suppression of FeNO (key biomarker of Type 2 inflammation) through 16 weeks for all patients
- Suppression of FeNO through 32 weeks for patients with available follow up
- Results reinforce continued development in asthma testing every 3- or 6-month dosing

Successful expansion of zumilokibart beyond dermatology confirms its pipeline-in-a-product potential across I&I indications

Zumilokibart in atopic dermatitis (AD) advancing in Phase 2 APEX trials with goal of Phase 3 initiation by end of 2026:
- Part A maintenance (52-week) data readout expected in Q1 2026 with potential to establish best-in-class every 3- or 6-month dosing profile
- Part B enrollment completed ahead of schedule and exceeded enrollment target with a total of 347 patients; 16-week induction data readout on track for Q2 2026

Serial innovation in AD advances with APG279 Phase 1b expanded to approximately 80 patients with readout on track for 2H 2026 based on strong enrollment

Strong cash position of $913 million with runway into 2H 2028 supports advancement toward potential launch of zumilokibart in 2029

Management will host a conference call at 8:00 a.m. ET

SAN FRANCISCO and BOSTON, Jan. 06, 2026 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing optimized, novel biologics with potential for best-in-class profiles in the largest inflammatory and immunology (I&I) markets, today announced positive interim data from the Phase 1b trial of zumilokibart (APG777) in patients with mild-to-moderate asthma and highlighted upcoming 2026 milestones. The company recently received approval for the International Non-proprietary Name (INN) of zumilokibart for APG777. Zumilokibart is a novel, half-life extended anti-IL-13 antibody.

“2025 was a foundational year for Apogee, setting the stage for a potentially transformational 2026 as we plan to deliver multiple significant clinical data readouts for our monotherapy and combination programs and enter Phase 3 development,” said Michael Henderson, M.D., Chief Executive Officer of Apogee. “With today’s positive readout in patients with mild-to-moderate asthma, we are excited to advance zumilokibart in asthma and seek to further derisk its pipeline-in-a-product potential. We look forward to reporting three clinical readouts for atopic dermatitis in 2026, which we expect to further solidify the potential for our portfolio of best-in-class monotherapy and combination treatments. Apogee is well capitalized and positioned to execute on its strategic vision of transforming the standard of care for people living with I&I conditions.”

Zumilokibart (APG777) Phase 1b Positive Interim Results in Mild-to-Moderate Asthma

Today, the company announced interim results from its Phase 1b double-blind, placebo-controlled trial evaluating the safety and tolerability of zumilokibart in 19 adult patients with mild-to-moderate asthma and a fractional exhaled nitric oxide (FeNO) baseline greater or equal to 25 parts per billion (ppb) which represents an enriched Type 2 inflammation population. The trial also evaluated FeNO suppression, a key biomarker of Type 2 inflammation. Participants received a single dose of 720 mg of zumilokibart or placebo on day 1.

In the trial, zumilokibart demonstrated:

- Favorable safety profile; zumilokibart was well-tolerated in patients with mild-to-moderate asthma.
    - The only treatment-emergent adverse event (TEAE) observed in more than one patient was gastroesophageal reflux disease (GERD; 2 patients). There were no Grade 3 or higher TEAEs or serious adverse events.
    - No conjunctivitis, injection site reactions, or anti-drug antibodies (ADAs) were observed.
- Robust and durable suppression of FeNO, a biomarker of Type 2 inflammation that has shown the strongest correlation with exacerbations in asthma, following a single dose.

- Maximum absolute mean FeNO reduction of 45 ppb (60% decrease from baseline) after single dose.
- Durable FeNO suppression through 16 weeks for all patients.
- Suppression of FeNO through 32 weeks for patients with available follow up, supporting potential for 3- or 6-month dosing.

- Positive trends observed in forced expiratory volume in one second (FEV1) and across Type 2 biomarkers for all available data. FEV1 is a pharmacodynamic measure of lung function. Further data from the study will be shared at upcoming medical conferences.

“This first dataset of zumilokibart in asthma is very promising and showcases the potential of this treatment to help a new patient population,” said Mario Castro, M.D., M.P.H. Chief of Pulmonary, Critical Care, and Sleep Medicine, University of Kansas. “We need new treatment options for these patients, especially those that are more convenient with the less frequent administration. These data, in particular the deep and durable FeNO suppression, highlight the promise of this drug for asthma patients with Type 2 inflammation, and I look forward to continued evaluation of zumilokibart in upcoming studies.”

“The results from this study further emphasize the versatility of zumilokibart across Type 2 inflammatory diseases, now spanning both dermatology and respiratory indications,” said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. “With a favorable safety profile, as well as durable FeNO suppression, zumilokibart has the potential to serve as a foundational therapy – both as a monotherapy and in combination. Further, in patients in the APEX Phase 2 Part A trial with comorbid asthma or sinusitis, we saw improvement in asthma and sinusitis, as measured by improvements in ACQ-5 and SNOT-22, respectively, solidifying zumilokibart’s potential to broadly impact Type 2 inflammatory diseases. Based on these results, we look forward to advancing and sharing our plans later this year to further evaluate zumilokibart in the ASPIRE asthma trial. I would like to thank the patients and physicians for their support in the successful execution of this Phase 1b trial.”

Anticipated 2026 Key Milestones

Establish potential best-in-class profile for zumilokibart in future $50B+ atopic dermatitis market

- Phase 2 APEX Part A (52-week) maintenance data readout – expected Q1 2026
- Phase 2 APEX Part B (16-week) induction data readout – expected Q2 2026
  - The trial completed enrollment ahead of schedule and exceeded its target with a total of 347 patients, driven by strong interest from physicians and patients.
- Initiation of Phase 3 trial – expected 2H 2026 enabling potential launch in 2029

Execute on expansion indications for zumilokibart in treating I&I diseases beyond atopic dermatitis

- Reported positive interim data readout today of zumilokibart Phase 1b clinical trial in mild-to-moderate asthma in Type 2 inflammation patients
  - Multiple potential blockbuster expansions in dermatology, respiratory and GI with prioritization to start ASPIRE asthma trial.

Continue serial innovation in atopic dermatitis with novel combinations

- Phase 1b head-to-head clinical trial of APG279 (APG777+APG990) vs. DUPIXENT for moderate-to-severe AD readout remains on track – expected 2H 2026
  - Trial upsized from approximately 50 to 80 patients due to strong patient enrollment.
  - APG279 is Apogee’s first-in-class fixed dose combination targeting both IL-13 and OX40L.

With these readouts, Apogee expects to generate data across monotherapy and combination programs in 2026, setting the stage for potential initiation of Phase 3 trials and a potential 2029 launch of zumilokibart in AD, as well as continued expansion across the company’s portfolio. As of September 30, 2025, Apogee had total cash of $913 million (pro forma cash, cash equivalents, marketable securities, and long-term marketable securities includes $588.9M as of September 30, 2025, plus proceeds before expenses, of $324.3M from October 2025 equity financing) with cash runway into the second half of 2028.

Webcast Details
Apogee Therapeutics’ live webcast of the positive interim data results of zumilokibart Phase 1b trial in mild-to-moderate asthma will begin today at 8:00 a.m. ET. The live webcast can be accessed via this link or the Investors section on the Company’s website at https://investors.apogeetherapeutics.com/news-events/events. A replay of the webcast will be available following the call.

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. Zumilokibart (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, as well as asthma. 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: the potential for zumilokibart (APG777) in asthma; Apogee's plans for its current and future product candidates and programs; the anticipated timing of its clinical trials, including the APEX 52-week Part A in AD, APEX 16-week Part B in AD, APG279 Phase 1b head-to-head readout against DUPIXENT in AD, the potential Phase 3 trial of zumilokibart and the potential launch of zumilokibart; its planned clinical trial designs; its plans for current and future clinical trials; the potential clinical benefit and half-life, PK profile and dosing regimen, and treatment outcomes of zumilokibart and APG279; the potential to expand zumilokibart for other indications; Apogee's other product candidates, including combination therapies, and any other potential programs; its planned business strategies; potential market sizes; and its expectations regarding the time period over which Apogee's capital resources will be sufficient to fund its anticipated operations. 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, 2024, filed with the SEC on March 3, 2025, Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, filed with the SEC on May 12, 2025, Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025, filed with the SEC on August 11, 2025, Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, filed with the SEC on November 10, 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.

Investor Contact:
Noel Kurdi
VP, Investor Relations
Apogee Therapeutics, Inc.
Noel.Kurdi@apogeetherapeutics.com

Media Contact:
Dan Budwick
1AB Media
dan@1abmedia.com