Apogee Therapeutics Announces Positive 16-Week Part B Induction Dose Optimization Results from Phase 2 APEX Trial of Zumilokibart in Moderate-to-Severe Atopic Dermatitis

May 27, 2026

APEX Part B met all primary and secondary endpoints with high statistical significance; mid-dose zumilokibart planned to advance into Phase 3 trials in moderate-to-severe atopic dermatitis (AD) in 2H 2026

Zumilokibart was well tolerated with a safety profile consistent with other agents in class

Strategic financing collaboration with Blackstone Life Sciences announced today expected to provide funding through commercialization of zumilokibart in AD, asthma, and EoE

Results support pipeline-in-a-product potential for zumilokibart with asthma and eosinophilic esophagitis (EoE) trial plans shared today

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

SAN FRANCISCO and BOSTON, May 27, 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 16-week data from Part B of the Phase 2 APEX clinical trial of zumilokibart (APG777), a potential best-in-class anti-IL-13 antibody, in patients with moderate-to-severe AD. The trial met its primary and secondary endpoints with high statistical significance including 65.9% of patients treated with mid-dose zumilokibart achieving EASI-75 (41.9% placebo adjusted). Based on these dose optimization results and subject to regulatory interactions, Apogee plans to move forward with the mid-dose, which achieved the best clinical activity of the three doses tested and was well-tolerated, in its Phase 3 trials.

"We are thrilled by the strength and consistency that zumilokibart demonstrated across all endpoints from today's APEX Part B induction results, which we believe could set a new standard of care for patients. Today's results help clear our path to advance zumilokibart into the Phase 3 trials planned for the second half of this year and we look forward to engaging with regulatory agencies." said Michael Henderson, M.D., Chief Executive Officer of Apogee. "Zumilokibart has the potential to move the bar on disease control and dosing based on both today's data as well as the robust APEX Part A maintenance results that showed continued improvement in efficacy over 52 weeks with every 3- and 6- month dosing. Beyond AD, we are excited to develop zumilokibart's pipeline-in-a-product potential and plan to commence Phase 2 studies in EoE in the second half of 2026 and asthma in the first half of 2027."

"Patients with atopic dermatitis and their physicians want therapies that provide durable and deeper disease control with less frequent dosing. The APEX Part B results align extremely well with these patient-centric goals, particularly the achievement of very low disease activity, or vLDA, with simultaneous robust improvement in lesion and itch benefit in more than one fifth of mid-dose patients, which are results not seen with any biologic to date," said Ruth Ann Vleugels, MD, MPH, MBA, Heidi and Scott C. Schuster Distinguished Chair in Dermatology and Director, Atopic Dermatitis Program at Mass General Brigham and Professor of Dermatology, Harvard Medical School. "The Part B induction data demonstrated that zumilokibart delivered robust efficacy within the first 16 weeks with significantly fewer injections versus the current standard-of-care. Together with Part A data demonstrating that zumilokibart can be dosed every 3 to 6 months in maintenance with continuous and even enhanced efficacy, we are seeing a strong clinical profile that offers what dermatologists are looking for in clinical practice for our patients."

APEX Phase 2 Part B 16-Week Results

The Phase 2 APEX clinical trial is a randomized, placebo-controlled study evaluating zumilokibart in patients with moderate-to-severe AD. In Part B, 346 adult patients were dosed after being randomized 1:1:1:1 to high-, mid- or low-dose zumilokibart versus placebo. The primary endpoint is the proportion of patients who achieve an Eczema Area and Severity Index (EASI) percent score reduction of at least 75 (EASI-75) at Week 16. Secondary endpoints include Validated Investigator's Global Assessment (IGA) 0/1, EASI-90, Itch Numeric Rating Scale (I-NRS ≥4), EASI-100, and Very Low Disease Activity (vLDA; EASI-90 + I-NRS 0/1) at Week 16.

- The trial met its primary endpoint, with mid- and high-doses of zumilokibart demonstrating comparable efficacy and both doses outperforming low dose and placebo with EASI-75 scores at Week 16:
    - High dose: 61.6% achieved EASI-75 ($p<0.001$ vs placebo)
    - Mid dose: 65.9% achieved EASI-75 ($p<0.001$ vs placebo)
    - Low dose: 50.5% achieved EASI-75 ($p<0.001$ vs placebo)
    - Placebo: 23.4% achieved EASI-75

- Mid-dose zumilokibart met key secondary endpoints at Week 16:
  - IGA 0/1 response in 46.0% of patients, compared to 10.9% in the placebo arm (p<0.001)
  - EASI-90 response in 47.4% of patients, compared to 9.3% in the placebo arm (p<0.001)
  - I-NRS ≥4 reduction from baseline in 50.5% of patients, compared to 13.9% in placebo arm (p <0.001)
  - EASI-100 response in 16.5% of patients, compared to 3.4% in the placebo arm (p<0.01)
  - vLDA response in 20.6% of patients, compared to 4.5% in the placebo arm (p<0.01)

- Zumilokibart was well tolerated, with a safety profile generally consistent with other agents in the class.
  - The most common treatment-emergent adverse events (TEAEs) in zumilokibart-treated patients were nasopharyngitis, headache, and noninfective conjunctivitis.
  - For the planned Phase 3 dose (mid dose), the pooled conjunctivitis rate (all conjunctivitis preferred terms) was 10.6%, compared to 15.1% for the low dose and 20.7% for the high dose.

"The APEX Part B results demonstrated meaningful improvements across all lesional and itch endpoints, achieved with just four dosing days during induction versus nine with the current standard-of-care," said Carl Dambkowski, M.D., Chief Medical Officer of Apogee. "Importantly, these results underscore the potential for a significant reduction in treatment burden for patients while delivering robust clinical activity. We are grateful to the patients and investigators whose participation made this study possible."

"In the APEX Phase 2 Part B study, the improvements in both skin outcomes and itch in the induction period are particularly encouraging given the replicability from prior studies" said Jonathan I. Silverberg, M.D., Ph.D., MPH, Professor of Dermatology at The George Washington University School of Medicine and Health Sciences. "These findings suggest the potential for sustained disease control with less frequent dosing, an important goal in managing this chronic condition."

Based on results from the APEX clinical program, Apogee plans to initiate Phase 3 trials of zumilokibart for moderate-to-severe atopic dermatitis in the second half of 2026, pending regulatory interactions. Apogee has also disclosed planned trial designs for its asthma and eosinophilic esophagitis (EoE) programs, further supporting zumilokibart's potential as a pipeline-in-a-product opportunity across multiple I&I diseases.

About the ADventure Phase 3 trials in AD
The ADventure 1 and ADventure 2 trials are randomized, placebo-controlled, replicate Phase 3 monotherapy trials evaluating zumilokibart in patients with moderate-to-severe atopic dermatitis (EASI ≥16, vIGA ≥3, BSA ≥10%). Each study is expected to enroll approximately 400 patients and includes a 16-week induction period followed by maintenance through Week 52. In maintenance, patients will receive dosing every three or six months. The co-primary endpoint is EASI-75 and IGA 0/1 at Week 16, with additional assessment at Week 52.

The ADventure TCS Phase 3 trial will evaluate zumilokibart in combination with background topical corticosteroids in patients with moderate-to-severe atopic dermatitis (EASI ≥16, vIGA ≥3, BSA ≥10%). The randomized, placebo-controlled study is expected to enroll approximately 400 patients and includes a 16-week induction period and maintenance through Week 52. The co-primary endpoint is EASI-75 and IGA 0/1 at Week 16, with longer-term outcomes assessed at Week 52.

About the ASPIRE Phase 2b trial in Asthma
The ASPIRE Phase 2b trial is a randomized, placebo-controlled study evaluating multiple dosing regimens of zumilokibart in patients with moderate-to-severe asthma with elevated Type 2 biomarkers and a history of exacerbations. The study is designed to be potentially registrational and is expected to enroll approximately 500 patients randomized across dosing intervals of every three, six, or twelve months, or placebo. The primary endpoint is annualized exacerbation rate at Week 52, with additional assessments of lung function and symptoms.

About the ELEVATE Phase 2a trial in Eosinophilic Esophagitis (EoE)
The ELEVATE Phase 2a trial is an open-label, proof-of-concept study evaluating zumilokibart in patients with EoE. The study is expected to enroll approximately 30 to 50 patients and will assess dosing every three or six months. The primary endpoint is histologic response, including reductions in eosinophil counts, with additional evaluation of endoscopic findings and patient-reported outcomes.

Webcast Details
Apogee Therapeutics' live webcast of the APEX Phase 2 Part B results 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 zumilokibart
Zumilokibart (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 the APEX Phase 2 Part A 52-week trial, zumilokibart demonstrated potential to maintain and deepen clinical responses with as little as every 3- and 6-month dosing. 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. Zumilokibart has pipeline-in-a-product potential with proof-of-concept demonstrated in asthma, and with expansion plans in asthma, EoE, and other I&I indications.

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, Chronic Obstructive Pulmonary Disease (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, 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 and EoE. 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 expectations regarding: Apogee's plans for its current and future product candidates, programs, and clinical trials, including expansion of zumilokibart into additional indications; the anticipated timing of initiation of its clinical trials, including the Phase 2b trial of zumilokibart in asthma, the Phase 2a trial of zumilokibart in eosinophilic esophagitis (EoE), and the Phase 3 ADventure program for zumilokibart in AD; the expected timing of results from its clinical trials, including the 52-week readout from Part B and the 2-year follow-up from Part A of our Phase 2 trial of zumilokibart in AD, and 16-week readouts from the Phase 3 ADventure program; the expectation that the APEX Phase 2 Part B 16-week results will support commencement of a Phase 3 trial in zumilokibart; its planned clinical trial designs, including anticipated enrollment and dosing regimens; the potential clinical benefit, dosing regimen, safety and efficacy profiles and treatment outcomes of zumilokibart, including its potential to be a best-in-class therapy and new standard of care in AD, and any other product candidates, including combination therapies; its planned 2029 launch timeline for zumilokibart in AD; the pipeline-in-a-product potential for zumilokibart; and its planned business strategies; expected timing for future pipeline updates, regulatory decisions, BLA filing for zumilokibart in AD, and potential commercialization; its expectations regarding the time period over which Apogee's capital resources will be sufficient to fund its anticipated operations; and estimates of market size. 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 Apogee 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 Apogee'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 applicability of clinical study results to actual outcomes; 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, 2025, filed with the SEC on March 2, 2026, 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