Acumen Pharmaceuticals Completes Enrollment of ALTITUDE-AD, a Phase 2 Clinical Trial of Sabirnetug (ACU193) in Early Alzheimer's Disease

March 26, 2025

NEWTON, Mass., March 26, 2025 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), a clinical-stage biopharmaceutical company developing a novel therapeutic that targets soluble amyloid beta oligomers (AβOs) for the treatment of Alzheimer's disease (AD), today announced the completion of enrollment in its ALTITUDE-AD Phase 2 trial of sabirnetug (ACU193) in patients with early Alzheimer's disease. Acumen completed enrollment ahead of schedule and plans to report topline results, including efficacy and safety data, in late 2026.

"We are pleased to complete enrollment for our Phase 2 ALTITUDE-AD trial of sabirnetug," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "Achieving this milestone is a testament to the significant interest in our approach from both patients and the scientific community, and we are grateful to all the participants, investigators and trial sites, and our clinical team for enabling us to complete enrollment efficiently. We look forward to sharing topline results in late 2026 and advancing sabirnetug as a next-generation treatment for Alzheimer's disease."

Sabirnetug is the first humanized monoclonal antibody to demonstrate in AD patients selective target engagement of AβOs, a soluble and highly toxic form of Aβ that accumulates early in AD and is a persistent trigger of synaptic dysfunction and neurodegeneration. The Phase 1 INTERCEPT-AD clinical trial demonstrated sabirnetug was generally well-tolerated with low overall rates of ARIA-E. The trial also showed dose- and exposure-dependent target engagement and statistically significant amyloid plaque reduction compared to placebo at higher dose multiple-ascending dose cohorts evaluated in the study.

ALTITUDE-AD (NCT06335173) is a Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial that enrolled 542 patients with early AD at sites in the United States, Canada, the European Union and the United Kingdom. The study participants were randomized to receive one of two dose levels of sabirnetug (35mg/kg or 50mg/kg once every four weeks) or placebo. The primary endpoint is change from baseline in the Integrated Alzheimer's Disease Rating Scale (iADRS) at 18 months. Secondary endpoints include the Clinical Dementia Rating – Sum of Boxes scale (CDR-SB), ADAS-Cog13, ADCS-ADL and various AD biomarkers. Standard safety measures and MRIs will also be assessed. Participants who completed the double-blind portion of the study will have the opportunity to continue into an open-label extension.

About Sabirnetug (ACU193)

Sabirnetug (ACU193) is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble amyloid beta oligomers (AβOs), which are a highly toxic and pathogenic form of Aβ, relative to Aβ monomers and amyloid plaques. Soluble AβOs have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble AβOs, sabirnetug aims to address the hypothesis that soluble AβOs are an early and persistent underlying cause of the neurodegenerative process in Alzheimer's disease (AD). Sabirnetug has been granted Fast Track designation for the treatment of early AD by the U.S. Food and Drug Administration and is currently being evaluated in a Phase 2 study in patients with early AD.

About ALTITUDE-AD (Phase 2)

Initiated in 2024, ALTITUDE-AD is a Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy and safety of sabirnetug (ACU193) infusions administered once every four weeks in slowing cognitive and functional decline as compared to placebo in participants with early Alzheimer's disease. The study has enrolled approximately 540 individuals with early Alzheimer's disease (mild cognitive impairment or mild dementia due to AD) at multiple investigative sites located in the United States, Canada, the European Union and the United Kingdom. More information can be found on www.clinicaltrials.gov, NCT identifier NCT06335173.

About Acumen Pharmaceuticals, Inc.

Acumen Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (AβOs) for the treatment of Alzheimer's disease (AD). Acumen's scientific founders pioneered research on AβOs, which a growing body of evidence indicates are early and persistent triggers of Alzheimer's disease pathology. Acumen is currently focused on advancing its investigational product candidate, sabirnetug (ACU193), a humanized monoclonal antibody that selectively targets toxic soluble AβOs, in its ongoing Phase 2 clinical trial ALTITUDE-AD (NCT06335173) in early symptomatic Alzheimer's disease patients, following positive results in its Phase 1 trial INTERCEPT-AD. The company is headquartered in Newton, Mass. For more information, visit www.acumenpharm.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Any statement describing Acumen's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Words such as "potential," "will" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements include statements concerning the therapeutic potential and potential clinical efficacy of Acumen's product candidate, sabirnetug (ACU193), and the timing of topline results for the ALTITUDE-AD trial. These statements are based upon the current beliefs and expectations of Acumen's management, and are subject to certain factors, risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing safe and effective human therapeutics. Such risks may be amplified by the impacts of geopolitical events and macroeconomic conditions, such as rising inflation and interest rates, supply disruptions and uncertainty of credit and financial markets. These and other risks concerning Acumen's programs are described in additional detail in Acumen's filings with the Securities and Exchange Commission ("SEC"), including in Acumen's most recent Annual Report on Form 10-K, and in subsequent filings with the SEC. Copies of these and other documents are available from Acumen. Additional information will be made available in other filings that

Acumen makes from time to time with the SEC. These forward-looking statements speak only as of the date hereof, and Acumen expressly disclaims any obligation to update or revise any forward-looking statement, except as otherwise required by law, whether, as a result of new information, future events or otherwise.

Investors:
Alex Braun
abraun@acumenpharm.com

Media:
Jon Yu
ICR Healthcare
AcumenPR@icrhealthcare.com