Acumen Pharmaceuticals Announces First Participant Dosed in Phase 2 Open-Label Extension Study of Sabirnetug in People with Early Alzheimer's Disease

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NEWTON, Mass., Nov. 17, 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 that the first participant has been dosed in the open-label extension (OLE) portion of its Phase 2 ALTITUDE-AD clinical trial evaluating sabirnetug (ACU193) in people with early Alzheimer's disease.

The open-label extension provides all participants who completed the 18-month placebo-controlled portion of ALTITUDE-AD with the opportunity to receive sabirnetug at 35 mg/kg administered intravenously once every four weeks for an additional 52 weeks. Clinical measures and safety monitoring will be the same as in the placebo-controlled portion of the study.

"Initiating the open-label extension study represents our ongoing commitment to the participants who have contributed in ALTITUDE-AD and provides us with valuable long-term safety and efficacy data," said Eric Siemers, M.D., Chief Medical Officer of Acumen Pharmaceuticals. "We expect the results of this study to supplement the broader data package supporting sabirnetug, and we look forward to gathering additional insights that will support our continued development of this potentially differentiated therapeutic approach."

Sabirnetug is the first humanized monoclonal antibody to demonstrate in AD patients selective target engagement of AβOs, a soluble and highly synaptotoxic form of amyloid-beta (Aβ) that accumulates early in AD and is a persistent trigger of synaptic dysfunction and neurodegeneration. In the Phase 1 INTERCEPT-AD trial, sabirnetug demonstrated a favorable safety profile with low overall rates of ARIA-E, evidence of target engagement, and positive effects on fluid and imaging biomarkers including reduction in amyloid plaques in the two groups of participants given the highest doses.

Acumen expects to report topline results from ALTITUDE-AD in late 2026.

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 people 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 542 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 people with early Alzheimer's disease, following positive results in its Phase 1 trial INTERCEPT-AD. Acumen is also investigating a subcutaneous formulation of sabirnetug using Halozyme's proprietary ENHANZE® drug delivery technology. Acumen is also collaborating with JCR Pharmaceuticals to develop an Enhanced Brain Delivery (EBD™) therapy for Alzheimer's disease utilizing a transferrin-receptor-targeting blood-brain barrier-penetrating technology. 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 "believes," "expects," "anticipates," "could," "should," "would," "seeks," "aims," "plans," "potential," "will," "milestone" 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 of Acumen's product candidate, sabirnetug (ACU193), including against other antibodies. These statements are based upon the current beliefs and expectations of Acumen 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.

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