Acumen Pharmaceuticals Announces First Patient Dosed in ALTITUDE-AD, a Phase 2 Clinical Trial of Sabirnetug (ACU193) in Early Alzheimer's Disease

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CHARLOTTESVILLE, Va., May 08, 2024 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), 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), today announced that the first patient has been dosed with sabirnetug (ACU193) in the ALTITUDE-AD Phase 2 clinical trial designed to evaluate the clinical efficacy and safety of sabirnetug in patients with early AD.

"Today marks a significant milestone for Acumen and the Alzheimer's community as we begin the Phase 2 trial of sabirnetug," said Daniel O'Connell, Chief Executive Officer of Acumen. "Sabirnetug is at the forefront of the next generation of Alzheimer's therapies, with encouraging Phase 1 results supporting its novel mechanism of action and selectivity for toxic amyloid beta oligomers. These results have led to a high level of investigator and patient interest in sabirnetug's therapeutic potential and a strong start to the trial."

ALTITUDE-AD (NCT06335173) is a Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial currently enrolling at sites in the United States and Canada, with plans for additional study centers in Europe and the UK. The study will enroll approximately 540 people with early AD who will be randomized to receive one of two dose levels of sabirnetug (35mg/kg or 50mg/kg once every four weeks) or placebo. Dose levels were determined to approach maximal target engagement based on modeling conducted from INTERCEPT-AD Phase 1 study results. The primary endpoint will be change from baseline in the Integrated Alzheimer's Disease Rating Scale (iADRS) at 18 months. Secondary endpoints will 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 complete the double-blind portion of the study will have the opportunity to continue into an open-label extension.

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. Acumen is developing sabirnetug as a potential best-in-class antibody treatment for early AD.

Positive topline results from 62 participants in the Phase 1 INTERCEPT-AD trial (NCT04931459) showed sabirnetug to be well-tolerated with a favorable overall safety profile. The trial showed statistically significant, dose-related amyloid plaque reduction comparable to approved and late-stage amyloid-directed therapies at similar time points, low overall rates of ARIA-E, and evidence of target engagement that validated proof of mechanism. The results thus far support sabirnetug's potential to offer differentiated safety and efficacy as a next-generation treatment for early AD.

Additionally, Acumen expects to initiate a Phase 1 bioavailability study to support a subcutaneous dosing option of sabirnetug in mid-2024, as announced in November 2023.

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 was previously evaluated in a Phase 1 study in patients with early AD.

About ALTITUDE-AD (Phase 2)

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 will enroll approximately 540 individuals with early Alzheimer's disease (mild cognitive impairment or mild dementia due to AD). The global study is currently enrolling at multiple investigative sites located in the United States and Canada with plans for additional sites in Europe and the UK. More information can be found on www.clinicaltrials.gov, NCT identifier NCT06335173.

About Acumen Pharmaceuticals, Inc.

Acumen, headquartered in Charlottesville, VA, with additional offices in Indianapolis, IN and Newton, MA, 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, following positive results in INTERCEPT-AD, a Phase 1 clinical trial involving early Alzheimer's disease patients. 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 of

Acumen's product candidate, sabirnetug (ACU193), Acumen's preparations with respect to its plans to initiate and complete a Phase 2 study, and Acumen's plans to initiate a study of subcutaneous administration of sabirnetug. 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.

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