Acumen Pharmaceuticals Presents Patient Experience and Biomarker Data from Phase 1 INTERCEPT-AD Study at the Alzheimer's Association International Conference (AAIC®) 2024

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NEWTON, Mass., July 28, 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 new findings from its Phase 1 INTERCEPT-AD study of sabirnetug (ACU193). The research highlights the experiences of patients in the clinical trial to inform development of future trials, biomarker data to support sabirnetug's mechanism of action, and an ultra-sensitive method of measuring small amounts of sabirnetug in cerebrospinal fluid (CSF). The posters will be presented at the Alzheimer's Association International Conference (AAIC®) 2024 taking place in Philadelphia and online from July 28-Aug. 1, 2024.

Sabirnetug is the first humanized monoclonal antibody to demonstrate in patients with early symptomatic AD 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 symptomatic AD.

"These findings from our Phase 1 study of sabirnetug highlight not only the strength of the study design with participants having early symptomatic AD but also continue to support the potential for sabirnetug as a best-in-class treatment," said Eric Siemers, M.D., Chief Medical Officer of Acumen. "Our research reflects our focus on incorporating the patient voice into drug development, provides further support for the mechanism of action of sabirnetug, and includes developing powerful tools for drug development with an assay that can measure even small amounts of sabirnetug bound to toxic soluble amyloid beta oligomers in patients in our clinical trials. These insights can help us as we advance clinical studies of sabirnetug, including our ongoing Phase 2 study. As recently approved therapies for Alzheimer's gain traction, we have an opportunity to advance a next-generation treatment that has the potential to optimize the benefit-risk ratio compared to first-generation disease-modifying treatments for AD."

Understanding the Patient Experience in INTERCEPT-AD

Acumen is putting patients first by incorporating the patient voice in drug development. Acumen conducted exit interviews in a subset of patients from the INTERCEPT-AD trial to understand their experience with MCI and mild AD and expectations for treatment. Acumen also obtained feedback on topics such as the decision-making process preceding trial enrollment and the overall trial experience, and examined the results by participant gender to guide planning for future clinical trials. Participants reported a broad array of symptoms consistent with AD, most frequently difficulty with memory or cognitive functioning. Nearly every participant desired treatment that would keep the disease from getting worse or slow progression. Additionally, participants wanted a new treatment that would help them maintain the ability to recognize loved ones and maintain or improve communication abilities.

Sabirnetug Lowers CSF Levels of Synaptic Biomarkers

The study revealed that three administrations of sabirnetug significantly lowered CSF levels of both pre- and post-synaptic proteins, consistent with its proposed mechanism of action to inhibit synaptic binding of AβOs. VAMP2, a biomarker associated with synaptic injury, was significantly lowered in all multiple ascending dose cohorts and appeared to be the biomarker most sensitive to sabirnetug in this study. Acumen is planning to evaluate longer-term changes in biomarkers and their relationship to clinical outcomes in the ongoing 18-month Phase 2 clinical trial ALTITUDE-AD to further support sabirnetug's mechanism of action.

Developing a Highly Sensitive Assay to Detect Sabirnetug in CSF

Acumen developed an ultra-sensitive assay to detect total levels of sabirnetug, both bound and unbound, in CSF. The assay demonstrated sensitivity, accuracy and precision, selectivity, specificity, dilutional linearity, and stability of the method. This development will aid in the accurate quantification of total drug exposure of sabirnetug in clinical trials since only a small fraction of peripherally-administered monoclonal antibodies typically move from blood to the brain.

The Phase 2 clinical trial ALTITUDE-AD (NCT06335173) is designed to evaluate the clinical efficacy and safety of sabirnetug in patients with early 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.

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 INTERCEPT-AD (Phase 1)
Completed in 2023, INTERCEPT-AD was a Phase 1, U.S.-based, multi-center, randomized, double-blind, placebo-controlled clinical trial evaluating the safety and tolerability, and establishing clinical proof of mechanism, of sabirnetug in patients with early Alzheimer's disease (AD). Sixty-five individuals with early symptomatic AD (mild cognitive impairment or mild dementia due to AD) enrolled in this first-in-human study of sabirnetug. The INTERCEPT-AD study consisted of single-ascending-dose (SAD) and multiple-ascending-dose (MAD) cohorts and was designed to evaluate the safety, tolerability, pharmacokinetics (PK), and target engagement of intravenous doses of sabirnetug. More information can be found

on www.clinicaltrials.gov, NCT identifier NCT04931459.

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) intravenous 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 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). 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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