Acumen Pharmaceuticals Presents Innovative Trial Screening Advancements Utilizing pTau217 Assay in Phase 2 Study of Sabirnetug for Early Alzheimer's Disease at the 17th Annual Clinical Trials on Alzheimer's Disease Conference

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- *Late-breaking presentation highlights the pTau217 assay as an effective and efficient tool to screen participants for ALTITUDE-AD that reduces unnecessary amyloid PET scans and lumbar puncture procedures for those who are not eligible*

NEWTON, Mass., Oct. 31, 2024 (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 presented updated data on a validated research-use plasma pTau217 assay to screen potential participants in the ongoing Phase 2 ALTITUDE-AD clinical trial of sabirnetug, at the 17th Annual Clinical Trials on Alzheimer's Disease (CTAD) conference. The study found that this enrichment screening approach is resulting in a higher proportion of participants who meet the amyloid PET or CSF-based inclusion criteria compared to Acumen's Phase 1 INTERCEPT-AD trial, which did not use this approach. Furthermore, the enrichment approach is resulting in a more efficient participant selection process that reduces unnecessary amyloid PET scans or lumbar puncture (LP) procedures among people who are not eligible to continue in screening.

"The pTau217 screening assay enrichment approach is an important part of the clinical trial process for Alzheimer's treatments because it could spare patients from invasive lumbar punctures and unnecessary radiation exposure with an amyloid PET scan," said Todd Feaster, Psy.D., Senior Clinical Research Scientist at Acumen Pharmaceuticals and the study presenter. "We are encouraged to see that our screening strategy is performing as intended and streamlining the trial enrollment process overall. Screening assays like this can reduce burden for patients, clinical trial investigators and their staff and foster a more compassionate and sustainable clinical trial experience."

ALTITUDE-AD is a Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy and safety of sabirnetug. The study drug will be evaluated in approximately 540 adults ages 50 to 90 years. Thus far, the study is enrolling at 75 sites across the U.S., Canada, EU and U.K. Acumen expects to complete enrollment in the first half of 2025.

One key eligibility criterion in ALTITUDE-AD and other clinical trials for amyloid-targeting therapies is the confirmation of cerebral amyloid accumulation by either PET scan or CSF, which can be more burdensome and time-intensive than a blood biomarker assay. However, plasma concentrations of the biomarker pTau217 are a strong indicator of AD pathology. While not a diagnostic, the pTau217 assay is being used at U.S. trial sites as an enrichment approach – a first step to help identify potential clinical trial participants with the highest likelihood of having amyloid in the brain as confirmed by a subsequent PET scan or CSF.

The pTau217 assay is an effective tool for classifying participants most likely to be eligible for the ALTITUDE-AD study. The study established a pTau217 threshold of ≥0.15 pg/mL, which was designed for enrichment purposes in this study of early AD and was not intended as a diagnostic cut-point. To date, more than half of potential ALTITUDE-AD study participants have been excluded from the study because of a plasma p-tau217 test result <0.15 pg/mL. Overall, 74% of participants with p-tau217 ≥0.15 pg/mL met study amyloid burden eligibility requirements following confirmatory assessment with amyloid PET scan or CSF Aβ42/40. In contrast, 40% of participants met study amyloid burden eligibility requirements in the Phase 1 INTERCEPT-AD trial when amyloid PET was used as the initial screening tool.

"The study is not only a testament to our commitment to advancing a next-generation treatment for Alzheimer's disease but also our commitment to pioneering clinical trial designs that provide an improved patient experience," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "We are pleased with the pace of enrollment in ALTITUDE-AD thus far. This swift progress underscores the strong interest in our approach and desire to bring more innovative solutions to those affected by Alzheimer's."

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 will enroll approximately 540 individuals with early Alzheimer's disease (mild cognitive impairment or mild dementia due to AD). The global study is currently ongoing at multiple investigative sites located in the United States, Canada, the United Kingdom, and the European Union. 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 effectiveness of the pTau217 assay, the therapeutic potential and potential clinical efficacy of Acumen's product candidate, sabirnetug (ACU193), and enrollment in the Phase 2 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.

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