Acumen Pharmaceuticals Announces First Subject Dosed in Phase 1 Study of Subcutaneous Sabirnetug (ACU193) for Early Alzheimer's Disease

July 29, 2024

NEWTON, Mass., July 29, 2024 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS), a clinical-stage biopharmaceutical company developing a novel therapeutic that targets soluble amyloid beta oligomers (AβOs) in the brain for the treatment of Alzheimer's disease (AD), today announced that the first subject has been dosed with a subcutaneous formulation of sabirnetug (ACU193) in a Phase 1 pharmacokinetic (PK) comparison study. The study plans to compare the PK between subcutaneous and intravenous administrations of sabirnetug in healthy volunteers.

Acumen's subcutaneous formulation of sabirnetug is co-formulated with Halozyme's proprietary ENHANZE ® drug delivery technology (recombinant human hyaluronidase enzyme, rHuPH20) that enables large volumes of subcutaneous injection with increased dispersion and absorption of co-administered therapies. ENHANZE® has been commercially validated in eight approved therapies.

"With a subcutaneous formulation of sabirnetug, we aim to provide a more convenient and accessible option for patients with Alzheimer's disease, which we believe will improve treatment adherence through enhanced flexibility for patients, caregivers and providers," said Daniel O'Connell, Chief Executive Officer of Acumen. "We are strongly committed to advancing the underlying science and innovation of Alzheimer's disease treatments, and we are excited about the potential of sabirnetug to make a meaningful impact on the lives of patients and their families."

Sabirnetug is the first humanized monoclonal antibody to clinically demonstrate selective target engagement of AβOs in AD patients. Soluble AβOs are a highly toxic form of Aβ that begin to accumulate before a clinical diagnosis of AD and are an early and persistent trigger of synaptic dysfunction and neurodegeneration. Acumen is developing sabirnetug as a potential next generation antibody treatment for early AD. The company is currently enrolling patients in the ALTITUDE-AD study, a Phase 2 clinical trial designed to evaluate the clinical efficacy and safety of intravenous sabirnetug in patients with early AD.

Topline results from the Phase 1 clinical trial INTERCEPT-AD indicated that intravenous administration of sabirnetug is well tolerated with a favorable overall safety profile, including low overall rates of ARIA-E. The trial showed compelling improvement of downstream biochemical biomarkers, evidence of target engagement supporting proof of mechanism, and statistically significant amyloid plaque reduction comparable to approved amyloid-directed therapies at similar time points.

For more information about Acumen Pharmaceuticals and its ongoing clinical trials, please visit www.acumenpharm.com.

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 Halozyme's ENHANZE ® Technology
Halozyme's commercially validated proprietary ENHANZE® drug delivery technology is based on its patented recombinant human hyaluronidase enzyme (rHuPH20). rHuPH20 has been shown to remove traditional limitations on the volume and delivery rates of biologics that can be delivered subcutaneously (just under the skin). By using rHuPH20, some biologics and compounds that are administered intravenously may instead be delivered rapidly in minutes subcutaneously. ENHANZE® may also benefit subcutaneous biologics by reducing the need for multiple injections.

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 of Acumen's product candidate, sabirnetug (ACU193), including a subcutaneous formulation of sabirnetug in a Phase 1 PK study, and Acumen's plans to complete a Phase 2 study 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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