Acumen Pharmaceuticals Announces Topline Results from Phase 1 Study of Subcutaneous Formulation of Sabirnetug in Healthy Volunteers

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- *Weekly subcutaneous administration of sabirnetug was well-tolerated in the Phase 1 study*
- *Systemic exposure following subcutaneous administration supports further clinical development*
- *Development of sabirnetug delivered subcutaneously has the potential for decreased treatment burden and increased patient convenience*

NEWTON, Mass., March 19, 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 topline results from its Phase 1 study comparing pharmacokinetics (PK) between subcutaneous (SC) and intravenous (IV) formulations of sabirnetug in healthy volunteers. Weekly SC administration of sabirnetug was well-tolerated with systemic exposure supporting further clinical development.

"We are pleased that the results of our initial clinical study support further clinical development of sabirnetug administered subcutaneously, underscoring the potential for increasing patient convenience of this formulation relative to intravenous treatment," said Daniel O'Connell, Chief Executive Officer of Acumen. "The timely completion of this study highlights the strength of our clinical team and partners, and our commitment to advancing our clinical pipeline efficiently and effectively. Based on these data, we believe that further development of subcutaneous sabirnetug as a more convenient administration option for patients is warranted."

The Phase 1 study in healthy volunteers enrolled 12 subjects who received single IV doses of 2,800 mg and 16 subjects who received four weekly SC doses of 1,200 mg. The most frequently reported adverse events included injection site reactions (62.5%), all of which were mild (Grade 1) in severity and resolved. No other safety signals were identified. Importantly, SC administration of sabirnetug produced sufficient systemic exposure to enable further clinical studies of SC dosing.

Sabirnetug is the first humanized monoclonal antibody to clinically demonstrate selective target engagement of AβOs in patients with AD. The SC formulation of sabirnetug is co-formulated with Halozyme's proprietary ENHANZE® drug delivery technology (recombinant human hyaluronidase enzyme, rHuPH20) that enables large volume SC injection with increased dispersion and absorption of co-administered therapies. ENHANZE® has been commercially validated as a component of nine approved therapies.

The Phase 2 ALTITUDE-AD study of IV sabirnetug is currently ongoing.

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, UK, and the European Union. More information can be found on www.clinicaltrials.gov, NCT identifier NCT06335173.

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 and potential clinical efficacy of Acumen's product candidate, sabirnetug (ACU193) and its subcutaneous formulation. l. 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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