Acumen Pharmaceuticals Completes Enrollment in Phase 1 Trial of ACU193, First Monoclonal Antibody Developed to Selectively Target Toxic Aβ Oligomers in Patients with Early Alzheimer's Disease

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Topline results including safety and proof-of-mechanism data expected in third quarter of 2023

CHARLOTTESVILLE, Va. and CARMEL, Ind., Feb. 13, 2023 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS) ("Acumen" or the "Company"), 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 the completion of enrollment in its Phase 1 INTERCEPT-AD trial of ACU193 in patients with early Alzheimer's disease. Acumen is on track to report topline results, including safety and proof-of-mechanism data, in the third quarter of 2023, which is earlier than previously expected.

"Today's announcement marks an important milestone for Acumen and the Alzheimer's community as we continue to explore ACU193 as a potential therapeutic option for people with early Alzheimer's disease," said Daniel O'Connell, President and Chief Executive Officer of Acumen Pharmaceuticals. "ACU193 builds on decades of scientific evidence that points to the role of soluble amyloid beta oligomers as primary and persistent toxins in Alzheimer's pathology. By targeting toxic oligomers, we hope to expand the understanding of targets beyond deposited amyloid plaques which we believe could provide patients with safer and more effective treatment options."

The Phase 1 INTERCEPT-AD trial enrolled 65 subjects across 17 active sites in the United States. This randomized, placebo-controlled Phase 1 trial is designed to assess safety and proof of mechanism of ACU193. The trial was initiated based on encouraging nonclinical studies of ACU193 that support the selective targeting of AβOs.

ACU193 is the first clinical-stage monoclonal antibody developed to selectively target soluble AβOs, which are among the most toxic and pathogenic forms of Aβ relative to Aβ monomers and deposited amyloid plaque. Toxic soluble AβOs have been found to interact within synapses, which leads to altered neuronal function, and can initiate and perpetuate the process of neurodegeneration.

For more information on INTERCEPT-AD (NCT04931459), please visit www.clinicaltrials.gov.

About ACU193

ACU193 is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble amyloid beta oligomers (AβOs), which Acumen believes are the most 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, ACU193 aims to directly address what a growing body of evidence indicates is a primary underlying cause of the neurodegenerative process in Alzheimer's disease. ACU193 has been granted Fast Track designation for the treatment of early Alzheimer's disease by the U.S. Food and Drug Administration.

About INTERCEPT-AD

INTERCEPT-AD is 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 ACU193 in patients with early Alzheimer's disease (AD). Sixty-five individuals with early AD (mild cognitive impairment or mild dementia due to AD) have been randomized into this first-in-human study of ACU193. The INTERCEPT-AD study consists of single-ascending-dose (SAD) and multiple-ascending-dose (MAD) cohorts and is designed to evaluate the safety, tolerability, pharmacokinetics (PK), and target engagement of intravenous doses of ACU193. The study has completed enrollment across multiple investigative sites located in the United States. More information can be found on www.clinicaltrials.gov, NCT identifier NCT04931459.

About Acumen Pharmaceuticals, Inc.

Acumen, headquartered in Charlottesville, VA, with clinical operations based in Carmel, IN, 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 primary triggers of Alzheimer's disease pathology. Acumen is currently focused on advancing its investigational product candidate, ACU193, a humanized monoclonal antibody that selectively targets toxic soluble AβOs 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 "believes," "expects," "anticipates," "could," "should," "would," "seeks," "aims," "plans," "potential," "will," "milestone" 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, ACU193, as well as the expectations concerning the timing of data for the INTERCEPT-AD trial. These statements are based upon the current beliefs and expectations of Acumen 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 the COVID-19 pandemic, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and future filings with the SEC, including Acumen's Quarterly Report on Form 10-Q for the quarter ended and September 30, 2022. 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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