Acumen's ACU193, an Anti-Amyloid Beta Oligomer Antibody, Granted FDA Fast Track Designation for Alzheimer's Disease

October 24, 2022

CHARLOTTESVILLE, Va. and CARMEL, Ind., Oct. 24, 2022 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc. (NASDAQ: ABOS) today announced that ACU193, the first clinical-stage monoclonal antibody that selectively targets toxic soluble amyloid beta oligomers (AβOs), has been granted Fast Track designation for the treatment of early Alzheimer's disease by the U.S. Food and Drug Administration (FDA). ACU193 is currently being studied in the Phase 1 INTERCEPT-AD trial designed to assess safety and proof of mechanism of ACU193.

ACU193 is a humanized monoclonal antibody discovered and developed based on its selectivity for soluble AβOs, which scientific evidence shows are the most toxic and pathogenic form of Aβ, relative to Aβ monomers and amyloid plaques. Some types of 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, ultimately leading to cell death. ACU193 binds AβOs that bind to synapses, and due to its unique binding profile, ACU193 has potential to provide therapeutic benefit with low risk of amyloid-related imaging abnormalities (ARIA), because ACU193 blocks the toxic effects of AβOs without directly targeting amyloid plaques.

"We are encouraged to receive Fast Track designation for ACU193, reflecting its potential clinical utility to treat Alzheimer's disease," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "We look forward to collaborating with the FDA to advance the development of ACU193. Treating Alzheimer's disease ultimately requires therapies that target different components of the disease pathway, and we are developing ACU193 with the goal of providing patients with more treatment options."

The FDA Fast Track program is designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening conditions with the potential to fill an unmet medical need. The Fast Track designation allows Acumen to have more frequent engagement with the FDA to discuss development plans and clinical study design for ACU193 to ensure collection of appropriate data to support evaluation for approval.

About ACU193

ACU193 is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble 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 AD.

About INTERCEPT-AD

Approximately 62 individuals with early AD (mild cognitive impairment or mild dementia due to AD) are expected to be randomized into this double-blind, placebo-controlled, first-in-human study of ACU193. INTERCEPT-AD is designed to establish safety and proof of mechanism. It 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 is enrolling at 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 disease-modifying approach to treat Alzheimer's disease. 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," "would," "seeks," "aims," "plans," "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 Acumen's business and the therapeutic potential of Acumen's product candidate, ACU193, including its potential for improved safety and efficacy as compared to other monoclonal antibodies in development, and expectations with respect to the role of toxic soluble AβOs in the potential treatment of Alzheimer's disease. 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. 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 year ended December 31, 2021, filed with the SEC on March 28, 2022, which is available on the SEC's website at www.sec.gov, and its other documents subsequently filed with or furnished to 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.

Contacts:

Media:
AcumenPR@westwicke.com

Investors:
investors@acumenpharm.com