Acumen Announces First Patient Dosed in a Phase 1 Clinical Trial of ACU193, a Monoclonal Antibody that Selectively Targets Toxic Aβ Oligomers for the Treatment of Early Alzheimer's Disease

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ACU193 is the first monoclonal antibody to enter a clinical trial that was discovered and is being developed to selectively target toxic amyloid-beta oligomers (AβOs)

Enrollment of early Alzheimer's patients is ongoing in INTERCEPT-AD, the Phase 1 placebo-controlled, single- and multiple-dose clinical trial of ACU193

CHARLOTTESVILLE, Va. and CARMEL, Ind., Oct. 07, 2021 (GLOBE NEWSWIRE) -- Acumen Pharmaceuticals, Inc., a clinical stage biopharmaceutical company focused on the development of novel targeted therapeutics for Alzheimer's disease (AD), today announced dosing of the first patient in INTERCEPT-AD, the Phase 1 placebo-controlled, single- and multiple-dose clinical trial of ACU193, a monoclonal antibody that selectively targets toxic amyloid-beta oligomers (AβOs) for the treatment of early AD.

"We are very pleased to report this first clinical development milestone for ACU193," said Daniel O'Connell, President and CEO of Acumen. "We are encouraged by recent momentum and the breadth of scientific innovation that is being applied to Alzheimer's research. We believe ACU193 has distinct potential to address the continued unmet medical needs of people living with Alzheimer's disease."

ACU193 is a monoclonal antibody (mAb) discovered and developed based on its selectivity for AβOs, which Acumen believes are the most toxic and pathogenic form of Aβ, relative to Aβ monomers and amyloid plaques. AβOs have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic AβOs, ACU193 aims to directly address what a growing body of evidence indicates is a primary underlying cause of the neurodegenerative process in AD.

"We are all very excited about evaluating ACU193 in the INTERCEPT-AD trial," said Eric Siemers MD, Chief Medical Officer for Acumen. "Our goal for this Phase 1 clinical trial is to establish proof of mechanism for ACU193, including overall safety and tolerability, pharmacokinetics and target engagement. We have also incorporated standard clinical outcomes for AD as well as exploratory assessments. Based on ACU193's unique mechanism of action, we believe it has the potential for improved efficacy and for improved safety compared to other monoclonal antibodies in development."

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 immunotherapy drug, ACU193, a humanized monoclonal antibody that selectively targets toxic AβOs in a Phase I clinical trial involving early Alzheimer's disease patients.

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, as well as the expectations concerning 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. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 16, 2021, which is available on the SEC's website at www.sec.gov. 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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