



Acumen Pharmaceuticals to Present Deeper Insights from First-in-Human Phase 1 Study of ACU193 for Early Alzheimer's During Symposium at the 16th Annual Clinical Trials on Alzheimer's Disease (CTAD)

October 4, 2023

- *Expanded analyses from robust Phase 1 INTERCEPT-AD trial exploring novel target engagement (dose-related), amyloid plaque reduction, and ARIA levels observed with ACU193 administration to be included in a symposium on Friday, October 27*
- *New data from additional exploratory analyses of ACU193 to also be presented in four virtual and in-person poster presentations*

CHARLOTTESVILLE, Va. and INDIANAPOLIS, Oct. 04, 2023 (GLOBE NEWSWIRE) -- [Acumen Pharmaceuticals, Inc.](#) (NASDAQ: ABOS), a clinical-stage biopharmaceutical company developing a novel therapeutic that targets soluble amyloid beta oligomers (A β O) for the treatment of Alzheimer's disease (AD), today announced that it will present deeper insights and new exploratory findings from its Phase 1 INTERCEPT-AD trial evaluating ACU193, the first clinical-stage A β O-directed antibody therapy for early AD, at the 16th Annual Clinical Trials on Alzheimer's Disease (CTAD) conference taking place in Boston and online from October 24-27, 2023. INTERCEPT-AD was selected to be featured in a symposium on Friday, October 27, and data from exploratory analyses of the Phase 1 trial will also be shared in two in-person and two virtual poster presentations.

Decades of research have shown that soluble A β O are a highly toxic form of A β , based on their propensity to bind to neurons, disrupt synapses and contribute to tau hyper-phosphorylation. ACU193 is the first clinical-stage antibody designed to selectively bind A β O, inhibiting their ability to disrupt synaptic function, while potentially offering improved safety and clinical benefit over existing amyloid-directed therapies. In July of this year, Acumen announced topline results from its INTERCEPT-AD trial which demonstrated that ACU193 was well-tolerated with a compelling overall safety profile, meeting the primary objective of this Phase 1 study in both single and multiple doses in 60 participants with early AD.

"Following Acumen's announcement of positive topline results from the Phase 1, first-in-human trial of ACU193, we are excited to present more extensive insights into the trial data and novel target engagement of ACU193," said Daniel O'Connell, President and Chief Executive Officer of Acumen. "This deeper dive into our Phase 1 results offer further support that ACU193 may offer a differentiated, next-generation treatment to help address unmet needs of people living with Alzheimer's disease."

Additional analyses from the INTERCEPT-AD study will be presented as a late-breaking scientific session symposium on Friday, October 27, 2023, at 9:25 a.m. ET.

Late-Breaking Symposium:

INTERCEPT-AD phase 1 insights and findings from the investigation of ACU193, a monoclonal antibody targeting soluble A β oligomers

Date/Time: Late Breaking Symposium 7, Friday, October 27, 9:25 a.m. ET

Chair: Diana Kerwin, M.D. Kerwin Medical Center, Dallas, TX

- Presentation 1: Determination of Target Engagement at Various Doses of ACU193 in INTERCEPT-AD
 - Presenting Author: Mirjam Trame, Pharm.D., Ph.D., Vice President, Cetera Drug Development Solutions
- Presentation 2: Reduction in Amyloid Plaque Load at Higher Doses of ACU193 in INTERCEPT-AD
 - Presenting Author: Eric Siemers, M.D., Chief Medical Officer, Acumen Pharmaceuticals
- Presentation 3: Characteristics of Participants in INTERCEPT-AD Who Did or Did Not Develop ARIA with ACU193
 - Presenting Author: Stephen Salloway, M.D., M.S., Alpert Medical School of Brown University

In addition to the symposium, Acumen will also present in-person posters detailing clinical trial diversity and participant exit interview data from the study, as well as virtual posters detailing additional pharmacokinetic and target engagement findings.

In-Person Poster Presentations:

- **Poster #LP 008:** Incorporating the Study Participant's Voice into Early Development of ACU193 for Early Alzheimer's Disease: A Qualitative Interview Study Following Participation in the INTERCEPT-AD Study
- **Poster #P003:** Recruitment and Eligibility of a Diverse Study Population in INTERCEPT-AD: A phase I trial of A β oligomer-targeting ACU193 in early Alzheimer's disease

Virtual Poster Presentations:

- **Poster #LP 034:** INTERCEPT-AD: ACU193 CSF pharmacokinetics in early Alzheimer's disease
- **Poster #LP 033:** ACU193-sA β O Complex Measurement in CSF: Additional Analyses Using a Sensitive Assay of Target Engagement for the sA β O-Selective Antibody ACU193 in INTERCEPT-AD

About ACU193

ACU193 is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble A β O_s, which Acumen believes are the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β O_s have been observed to be potent neurotoxins that bind to neurons, inhibit synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A β O_s, ACU193 aims to directly address a growing body of evidence indicating that soluble A β O_s are 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) enrolled in 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. 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 Indianapolis, IN, is a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (A β O_s) for the treatment of Alzheimer's disease (AD). Acumen's scientific founders pioneered research on A β O_s, 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, ACU193, a humanized monoclonal antibody that selectively targets toxic soluble A β O_s, following positive topline results 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 Acumen's business, and the therapeutic potential of Acumen's product candidate, ACU193, including against other antibodies, and the anticipated timeline for reporting additional data from 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 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, including Acumen's most recent Quarterly Report on Form 10-Q. 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.

Investors:

Alex Braun
abraun@acumenpharm.com

Media:

Jessica Laub
ICR Westwicke
AcumenPR@westwicke.com