



Acumen Pharmaceuticals to Present Sabirnetug (ACU193) Fluid Biomarker and Target Engagement Analyses from Phase 1 INTERCEPT-AD Study in Early Alzheimer's at the AD/PD™ 2024 Annual Meeting

February 21, 2024

- Oral presentation to explore drug effect of sabirnetug (ACU193) on key cerebrospinal fluid biomarkers in early AD
- Poster presentation to showcase method used to develop a first-of-its-kind assay to measure target engagement of an A β O-selective antibody
 - On track to initiate a Phase 2 trial evaluating sabirnetug in the first half of 2024
- Sabirnetug is the nonproprietary name for ACU193 now accepted by the United States Adopted Name (USAN) Council and the International Nonproprietary Names (INN) Programme

CHARLOTTESVILLE, Va., Feb. 21, 2024 (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 be presenting biomarker data and target engagement methods in an oral and poster presentation, respectively, at the upcoming International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD), taking place March 5-9, 2024, in Lisbon, Portugal, and online.

Acumen's sabirnetug (ACU193) is the first humanized monoclonal antibody to demonstrate selective target engagement of A β O, a soluble and highly toxic form of A β that accumulates early in AD and triggers synaptic dysfunction and neurodegeneration. Positive topline results from 62 participants in the Phase 1 INTERCEPT-AD trial (NCT04931459) showed sabirnetug to be well-tolerated with a favorable overall safety profile. Study findings including statistically significant, dose-related amyloid plaque reduction comparable to approved and in-review amyloid-directed therapies at similar time points, low overall levels of ARIA-E, and pharmacokinetic data that confirmed proof-of-mechanism, support sabirnetug's potential to offer differentiated safety and efficacy as a next-generation treatment for early AD.

"We're proud to have generated one of the most robust Phase 1 datasets in the AD space to-date from INTERCEPT-AD and look forward to presenting key findings from some of our extensive exploratory analyses at this year's AD/PD meeting," said Daniel O'Connell, Chief Executive Officer of Acumen. "Fluid biomarkers are of particular interest in the AD field and will continue to advance our understanding of the therapeutic potential of differentiated mechanisms that target soluble, non-plaque forms of A β . Our initial findings from the Phase 1 study are promising and sabirnetug's effect on biomarkers will be further explored in our Phase 2 trial to be initiated in the first half of this year."

ACU193 lowers cerebrospinal fluid (CSF) neurogranin and pTau181 levels in INTERCEPT-AD Phase 1 study in early AD

In an oral presentation, Acumen will share results from an assessment of CSF biomarkers associated with AD pathology before and after drug exposure in the INTERCEPT-AD study. Effects of sabirnetug on both neurogranin and pTau181 levels in CSF in this Phase 1 study are consistent with downstream pharmacologic effects of the drug. Presentation details as follows:

- Presenter: Erika Cline, PhD, Manager, Bioanalytical Methods, Acumen Pharmaceuticals
- Session: Therapeutic Interventions in AD and PD
- Date & time: Friday, March 8, 3:20 p.m. - 3:35 p.m. WET (Lisbon, UTC+0)
- Location: Auditorium V

Target engagement in INTERCEPT-AD: Development of a novel assay measuring ACU193-amyloid beta oligomer complexes in human CSF

Acumen will also present a poster detailing its method for developing the first assay to directly measure target engagement of A β O by an immunotherapy (as measured by sabirnetug (ACU193)-A β O complex in CSF) in the INTERCEPT-AD trial. Presentation details as follows:

- Presenter: Erika Cline, PhD, Manager, Bioanalytical Methods, Acumen Pharmaceuticals
- Poster number: P0304 / #1684
- Poster topic: Theme A: β -Amyloid Diseases / A03.b. Drug Development, Clinical Trials: Amyloid Clearance
- Date & time: Wednesday, March 6 and Thursday, March 7, on-demand

Sabirnetug is the nonproprietary name for ACU193 accepted by USAN and INN.

About Sabirnetug (ACU193)

Sabirnetug (ACU193) is a humanized monoclonal antibody (mAb) discovered and developed based on its selectivity for soluble A β O, which are a highly toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β O 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, sabirnetug aims to directly address a growing body of evidence indicating that soluble A β O are a primary underlying cause of the neurodegenerative process in Alzheimer's disease. Sabirnetug 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 was 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 sabirnetug 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 sabirnetug. The INTERCEPT-AD study consisted of single-ascending-dose (SAD) and multiple-ascending-dose (MAD) cohorts and was designed to evaluate the safety, tolerability, pharmacokinetics (PK), and target engagement of intravenous doses of sabirnetug. More information can be found on www.clinicaltrials.gov, NCT identifier NCT04931459.

About Acumen Pharmaceuticals, Inc.

Acumen, headquartered in Charlottesville, VA, with additional offices in Indianapolis, IN and Newton, MA, is a clinical-stage biopharmaceutical company developing a novel therapeutic that targets toxic soluble amyloid beta oligomers (A β Os) for the treatment of Alzheimer's disease (AD). Acumen's scientific founders pioneered research on A β Os, 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 A β Os, following positive 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 "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 of Acumen's product candidate, sabirnetug (ACU193), Acumen's preparations with respect to its plans to initiate a Phase 2 study, and Acumen's potential to receive regulatory approval for and bring sabirnetug to patients living with AD. 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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