Acumen Pharmaceuticals, Inc. and Halozyme Enter Global Collaboration and License Agreement to Develop Subcutaneous Formulation of ACU193 with ENHANZE® Technology

November 6, 2023

Expect to initiate Phase 1 development in mid-2024 to compare pharmacokinetics of subcutaneous form to intravenous form of ACU193

CHARLOTTESVILLE, VA. and INDIANAPOLIS, IN., Nov. 06, 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 a global non-exclusive collaboration and license agreement with Halozyme Therapeutics Inc. ("Halozyme"). The collaboration will provide Acumen access to Halozyme's ENHANZE ® drug delivery technology, based on a recombinant human hyaluronidase PH20 enzyme (rHuPH20), for the development of a subcutaneous formulation of ACU193, the first clinical-stage AβO-targeting antibody. ENHANZE® has been commercially validated in seven approved therapies, with global collaborations covering more than 60 therapeutic targets.

Acumen intends to explore using ENHANZE® with ACU193 and plans to initiate Phase 1 development in human subjects in mid-2024 to compare the pharmacokinetics (PK) of a subcutaneous form of ACU193 to the intravenous (IV) form. Acumen recently completed the Phase 1 INTERCEPT-AD trial in patients with early AD, which demonstrated robust, dose dependent target engagement for ACU193 and additionally produced amyloid plaque reduction following three administrations of ACU193 at 25 mg/kg or 60 mg/kg. At or near a three-month timepoint, ACU193 reduced amyloid plaque to a comparable level as that observed with administration of LEQEMBI®.

Under the terms of the agreement, in return for an upfront payment to Halozyme and other considerations, Acumen will receive non-exclusive rights to ENHANZE®. Acumen is obligated to make future payments to Halozyme, subject to achievement of specified development, regulatory and sales-based milestones. Halozyme will also be entitled to receive royalties on sales of commercialized medicines using the ENHANZE® technology.

"We are thrilled to partner with Halozyme, the market leader in rapid subcutaneous drug delivery technology, and look forward to working closely with their team to advance a subcutaneous formulation of ACU193," said Daniel O'Connell, President and Chief Executive Officer. "Acumen is a patient-driven organization, and with the recent momentum of subcutaneous administration of Alzheimer's therapies, we look forward to being able to provide another treatment option that has the potential to broaden patient access and decrease treatment burden."

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 (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 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 AβOs, 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.

Acumen Forward-Looking Statement

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, Acumen's ability to achieve its strategic goals, the therapeutic potential of Acumen's product candidate, ACU193, with and without the ENHANZE ® technology, and Acumen's obligations under the Agreement. 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. 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.

LEQEMBI® is a registered trademark of Eisai R&D Management Co., Ltd.

CONTACTS:

Investors:
Alex Braun
abraun@acumenpharm.com

Media:
AcumenPR@westwicke.com