

Vicore's Phase 2b ASPIRE Trial of Buloxibutid in IPF Passes Pre-Planned Futility Analysis and Remains on Track for Mid-2027 Topline Results

Independent Data Monitoring Committee recommends ASPIRE continue without modification; no safety concerns identified

Fully enrolled 378-patient trial advances toward 52-week readout

Stockholm, Sweden & Cambridge, Mass., October 22, 2026 – Vicore Pharma Holding AB (Nasdaq Stockholm: VICO, Nasdaq US: VCRE), a biopharmaceutical company unlocking the potential of angiotensin II type 2 receptor agonists, today announced that the independent Data Monitoring Committee (iDMC) for the Phase 2b ASPIRE trial of buloxibutid in idiopathic pulmonary fibrosis (IPF) recommended that the trial continue without modification following a pre-planned futility analysis. In parallel, the iDMC conducted its regular safety and benefit-risk review of all available data and raised no concerns. ASPIRE continues as planned and remains on track to report 52-week topline results in mid-2027.

"Passing this futility analysis is an important milestone that allows ASPIRE to continue as designed. With 378 patients enrolled and a 52-week FVC primary endpoint, ASPIRE was built to generate a high-quality dataset, and our focus remains on disciplined execution through database lock and expected topline results in mid-2027," said Ahmed Mousa, Chief Executive Officer of Vicore Pharma. "Our cash runway into the second half of 2028 takes us beyond the readout and allows us to plan the next steps for the program and the company."

"The futility analysis was designed to protect patients and allow us to preserve the integrity of the trial, and we thank the iDMC for its independent review," said Bernt van den Blink, MD, PhD, Chief Medical Officer of Vicore Pharma. "We look forward to the final assessment of the efficacy and safety of buloxibutid next year. We are grateful to the patients, investigators and site staff whose commitment makes this trial possible."

The futility analysis assessed whether the trial should stop early for futility. The futility criteria were not met, and the iDMC recommended that the trial continue without modification. The analysis was conducted by an external statistician and reviewed by the iDMC, based on efficacy data from approximately the first 100 randomized patients who had completed 52 weeks of treatment or discontinued from the trial, representing around 27% of the enrolled patients. The analysis assessed the primary endpoint, the change from baseline in forced vital capacity (FVC) at Week 52, for the high dose of buloxibutid (100 mg twice daily) versus placebo. It used a conditional power approach, with a pre-specified threshold to consider stopping the trial for futility if conditional power was below 20%.

Vicore remains blinded to the trial data. To preserve trial integrity, no quantitative results, such as treatment effect estimates or conditional power values, were disclosed to the company.

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About Idiopathic Pulmonary Fibrosis (IPF)

IPF is a progressive and lethal fibrotic lung disease impacting approximately 250,000 people across the United States and Europe. The average life expectancy following diagnosis is 3–5 years, and currently approved therapies only slow the decline of lung function. While there are three antifibrotic therapies available today, a large proportion of patients do not initiate treatment, and those who do often discontinue due to limited efficacy and significant tolerability issues. With a growing patient population, there is a clear need for new disease-modifying treatments.

About the Phase 2b ASPIRE Trial

ASPIRE is an ongoing global 52-week Phase 2b, randomized, double-blind, placebo-controlled clinical trial designed to assess the efficacy and safety of buloxibutid in IPF patients who are either not currently on treatment or are receiving standard of care (nintedanib or nerandomilast). Participants are randomized to receive one of two doses of buloxibutid (50 mg or 100 mg taken orally twice daily) or placebo. The primary endpoint is change from baseline in forced vital capacity (FVC) at 52 weeks, the registrational endpoint for IPF. Secondary endpoints include safety, tolerability, and the proportion of patients with disease progression over the trial period. The trial completed enrollment in April 2026, with 378 patients randomized across over 100 sites in 14 countries, including the United States. Recruitment was completed ahead of schedule, positioning the company to report topline results in mid-2027.

About Vicore Pharma Holding AB

Vicore Pharma is a clinical-stage biopharmaceutical company unlocking the potential of a new class of drugs with disease-modifying potential in respiratory and fibrotic diseases, including idiopathic pulmonary fibrosis (IPF). The company's lead program, buloxibutid, is an oral small-molecule angiotensin II type 2 receptor agonist, which received Orphan Drug and Fast Track designations from the United States Food and Drug Administration and is currently being investigated in the global 52-week Phase 2b ASPIRE trial in IPF. Vicore Pharma is publicly listed on Nasdaq Stockholm (VICO) and Nasdaq US (VCRE). www.vicorepharma.com

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the ongoing Phase 2b ASPIRE clinical trial; the potential clinical benefits, safety, and efficacy of buloxibutid; clinical development timelines, including expected timing of topline data from the ASPIRE trial and continued development plans for buloxibutid, strategic and business plans, financial position and the anticipated cash runway. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties inherent in clinical development (including that interim or early data may not be predictive of later or final results and data from a small sample size

may not be indicative of results that may be observed in a larger group), clinical trial execution risks, the occurrence of adverse safety events, and references to those risks identified in the section entitled “Risk Factors” in Vicore Pharma’s filings with the U.S. Securities and Exchange Commission and discussed in Vicore Pharma’s Swedish filings and its press releases. Vicore Pharma cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Vicore Pharma disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Vicore Pharma’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

This information is information that Vicore Pharma Holding is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-10-22 18:50 CEST.

Attachments

[Vicore’s Phase 2b ASPIRE Trial of Buloxibutid in IPF Passes Pre-Planned Futility Analysis and Remains on Track for Mid-2027 Topline Results](#)