# Vicore Initiates the Global, Randomized Phase 2b ASPIRE Trial Evaluating the Disease-Modifying Potential of Buloxibutid in Idiopathic Pulmonary Fibrosis

- ASPIRE is a global Phase 2b trial measuring change in FVC from baseline over 52 weeks, the established regulatory endpoint.
- ASPIRE will enroll 270 patients across 14 countries, including the United States, and will allow patients to remain on background nintedanib standard of care therapy.
- The advancement of buloxibutid into late-stage development is supported by a robust preclinical and translational dataset reflecting the potency of its potentially disease-modifying mechanism, consistent with data from the Phase 2a AIR trial, which demonstrated improvement in lung function over the 36-week study period.

**Stockholm, September 10, 2024 - Vicore Pharma Holding AB (STO: VICO), a clinical-stage biopharmaceutical company unlocking the potential of a novel class of drug candidates, angiotensin II type 2 receptor agonists (ATRAGs),** today announced initiation of the 52-week Phase 2b ASPIRE trial evaluating buloxibutid in IPF. The initiation follows clearance by the US Food and Drug Administration and other regulatory authorities to start the trial.

Buloxibutid is a first-in-class angiotensin II type 2 (AT2) receptor agonist that activates an upstream mechanism promoting alveolar integrity and function with corresponding downregulation of aberrant alveolar repair and fibrosis in IPF.

ASPIRE is a global 52-week Phase 2b, randomized, double-blind, placebo-controlled, parallel-group clinical trial designed to assess the efficacy and safety of buloxibutid in IPF patients who are either untreated or receiving background nintedanib standard of care. Participants will be randomized to receive one of two doses of buloxibutid (100 mg or 50 mg taken orally twice daily) or placebo. The primary endpoint is change from baseline in forced vital capacity (FVC), the registrational endpoint for IPF. Key secondary endpoints include safety, tolerability, and the proportion of patients with disease progression over the trial period. The trial is expected to enroll 270 patients from over 90 sites across 14 countries, including the United States. This trial was developed in collaboration with world leading pulmonologists, patient advocacy organizations, and an advisory panel of IPF patients and caregivers.

This Phase 2b trial will build on positive preclinical, translational, and clinical datasets, which suggest that buloxibutid protects type 2 alveolar epithelial cells, the progenitor cells responsible for maintaining alveolar homeostasis and promoting gas exchange in the lung. By promoting epithelial repair as well as reducing and resolving fibrotic tissue, buloxibutid has the potential to improve lung function, consistent with the effect seen in the Phase 2a AIR trial. In that trial, 36 weeks of treatment with buloxibutid improved FVC by an average of 216 mL from baseline, with a significant effect over the expected decline in untreated patients (n=28, $p<0.001$) [1,2]. Sixty-five percent of patients showed improved FVC, suggesting a robust treatment effect. Taken together with its excellent safety and tolerability profile, buloxibutid's Phase 2a trial results reflect disease-modifying potential.

"The initiation of this global Phase 2b trial marks an important milestone in the development of buloxibutid," said **Bertil Lindmark, MD PhD,** Chief Medical Officer of Vicore. "We are thrilled to build on our positive 36-week data from the Phase 2a AIR trial and are optimistic that buloxibutid has the potential to improve lung function and quality of life for patients with IPF."

Approximately three million people suffer from IPF worldwide. Current therapies are limited, often causing gastrointestinal side effects while only moderately slowing disease progression [3]. The current global market for nintedanib and pirfenidone is over $4 billion and continues to grow, despite modest benefit, poor tolerability, and the high discontinuation rates observed with these drugs [4]. If successful, buloxibutid has the potential to change standard treatment practices and provide a better tolerated, more effective therapy for patients.

"We are excited to advance buloxibutid to the Phase 2b ASPIRE trial, which will have a global footprint and include the accepted registrational endpoint," said **Ahmed Mousa**, Chief Executive Officer of Vicore. "Buloxibutid's disease-modifying tissue-repair mechanism and the encouraging results from the Phase 2a trial give us confidence that this drug has the potential to disrupt the current treatment paradigm and transform outcomes for IPF patients."

Vicore has engaged the contract research organization PSI to support the company in executing the Phase 2b ASPIRE study with the highest standards of quality and efficiency.

More information can be found at www.clinicaltrials.gov (identifier: NCT06588686) and at http://www.aspire-ipf.com/.

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***About Vicore Pharma Holding AB***
*Vicore is a clinical-stage pharmaceutical company unlocking the potential of a new class of drugs with disease-modifying potential. The company is advancing a portfolio of therapies in respiratory and fibrotic diseases, including idiopathic pulmonary fibrosis (IPF). Buloxibutid (C21) is a first-in-class orally available small molecule angiotensin II type 2 receptor agonist (ATRAG) recently completing a Phase 2a trial in IPF. Almee™ is an investigational digital therapeutic in clinical development that is based on cognitive behavioral therapy and created to address the psychological impact of living with pulmonary fibrosis. Almee has received Breakthrough Device Designation from the FDA, which the Company believes reflects its potential to have transformative impact. Using its expertise in ATRAG chemistry and biology, Vicore is further developing its pipeline with several new therapies across additional indications. The company's shares are listed on Nasdaq Stockholm's main market (VICO). www.vicorepharma.com*

1. Noble et al. Pirfenidone for idiopathic pulmonary fibrosis: analysis of pooled data from three multinational phase 3 trials. Eur Respir J. 47(1): 243–253 (2016)
2. Richeldi et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. Engl J Med. 370:2071-2082 (2014)

3. Maher et al. Global incidence and prevalence of idiopathic pulmonary fibrosis. Respiratory research 22, 197 (2021)
4. Dempsey et al. Adoption of the antifibrotic medications pirfenidone and nintedanib for patients with idiopathic pulmonary fibrosis. Ann Am Thorac Soc. 18, 7 (2021)

**Attachments**

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