Press Release
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Buloxibutid Receives Orphan Drug Designation in Japan for the Treatment of Idiopathic Pulmonary Fibrosis

Stockholm, September 30, 2025 – Vicore Pharma Holding AB (STO: VICO), unlocking the potential of a novel class of drugs, angiotensin II type 2 receptor agonists (ATRAGs), today announced that Japan's Ministry of Health, Labor and Welfare (MHLW) has granted Orphan Drug designation to buloxibutid for the treatment of idiopathic pulmonary fibrosis (IPF).

Buloxibutid is a first-in-class angiotensin II type 2 receptor agonist that activates an upstream mechanism to drive alveolar repair, resolve fibrosis, and promote pulmonary vascular function. In February 2024, Vicore entered into an exclusive licensing agreement with Nippon Shinyaku to develop and commercialize buloxibutid in Japan.

The designation is intended to support the development of promising therapies for rare diseases with high unmet need and can provide incentives such as reduced consultation and review fees, and extended market exclusivity upon approval in Japan.

"This milestone underscores the significant unmet medical need in IPF and reinforces the potential of buloxibutid to offer significant improvement over existing therapies," said **Bertil Lindmark**, Chief Medical Officer of Vicore. "We look forward to working closely with our partners at Nippon Shinyaku and with the MHLW to support the development of buloxibutid in Japan."

Buloxibutid was granted Orphan Drug designation by the European Commission in 2016 and by the United States Food and Drug Administration (FDA) in 2017, as well as Fast Track designation by the FDA in 2025.

Buloxibutid is being evaluated in the global Phase 2b ASPIRE trial for the treatment of IPF. More information can be found at www.aspire-ipf.com.

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About Vicore Pharma
Vicore Pharma Holding AB is a clinical-stage pharmaceutical 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 a first-in-class oral small molecule angiotensin II type 2 receptor agonist, which has received Orphan Drug and Fast Track designation from the United States Food and Drug Administration and is currently being investigated in the global 52-week Phase 2b ASPIRE trial in IPF.

The company is publicly listed on the Nasdaq Stockholm exchange (VICO). www.vicorepharma.com

About Nippon Shinyaku
Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim

to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (www.nippon-shinyaku.co.jp /english) for products or detailed information.

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 two anti-fibrotic 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 receiving background nintedanib standard of care. Participants are 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, the registrational endpoint for IPF. Secondary endpoints include safety, tolerability, and the proportion of patients with disease progression over the trial period. The trial will enroll 270 patients from approximately 100 sites across 14 countries, including the United States.

Attachments

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