NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

September 30, 2025

Orphan Drug Designation granted to Buloxibutid
for the Treatment of Idiopathic Pulmonary Fibrosis in Japan

Kyoto, Japan, September 30, 2025 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that the Ministry of Health, Labor and Welfare (MHLW) has granted Orphan Drug Designation to buloxibutid（NS-421/C21）for the treatment of idiopathic pulmonary fibrosis (IPF). In February 2024, Nippon Shinyaku signed an exclusive license agreement with Vicore Pharma Holding AB (publ) (Vicore; Headquarters: Stockholm, Sweden; CEO: Ahmed Mousa) for the development and sale of this drug candidate in Japan.

Under Japan's Orphan Drug Designation system, drug candidates are reviewed and designated if they target fewer than 50,000 patients domestically and address serious diseases with high medical needs. This designation provides various incentives to support development.

IPF is one of the idiopathic interstitial pneumonias, a serious chronic lung disease designated as an intractable disease by the MHLW. IPF is characterized by progressive fibrosis in the lungs, leading to symptoms such as respiratory impairment, dry cough, and pulmonary hypertension. It is a progressive lung disease with a poor prognosis, predominantly affecting men over 50 years of age. The average survival period after diagnosis is 3 to 5 years, and acute exacerbations can cause rapid progression to respiratory failure. The treatment options for IPF are very limited, with only a few anti-fibrosis drugs available. Therefore, there is a high unmet medical need for effective therapies.

Buloxibutid is a first-in-class, orally administered, small-molecule angiotensin II type 2 receptor agonist (ATRAG). Vicore is developing it overseas for the treatment of IPF. A Phase IIa study (AIR study) showed tolerability and stabilization or improvement in respiratory function in treatment naïve IPF patients. An overseas global Phase IIb study (ASPIRE study) has been ongoing since 2024. Buloxibutid was granted Orphan Drug Designation by the European Commission in 2016 and by the U.S. Food and Drug Administration (FDA) in 2017 and further received Fast Track Designation by the FDA in 2025.

At Nippon Shinyaku, we are committed to developing innovative new therapies for intractable and rare diseases with a sense of mission. We will continue our efforts to accelerate the development of buloxibutide to provide IPF patients with a new treatment option as soon as possible.

About Vicore Pharma Holding AB (publ)

Vicore 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 an angiotensin II type 2 receptor agonist being advanced globally as a potentially disease-modifying treatment for IPF. It is currently being investigated in the global 52-week Phase IIb ASPIRE trial. The company's shares (VICO) are listed on Nasdaq Stockholm's main market. For more information, see https://vicorepharma.com/.

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