Vicore Pharma recruits the first patient in the phase II Proof-of-Concept study in idiopathic pulmonary fibrosis

Gothenburg, November 16, 2020 – Vicore Pharma Holding AB (publ), a pharmaceutical company dedicated to developing innovative medicines for rare lung disorders, today announces that the first patient in the phase II idiopathic pulmonary fibrosis (IPF) study has been recruited in India.

Dr. Himanshu Pop Hale, Ace Hospital Pune, India, has recruited the first patient in the IPF phase II Proof-of-Concept study with C21 (VP01 project). "We are pleased to announce that we can now start our IPF trial despite the ongoing COVID-19 pandemic." says Anne Katrine Cohrt, Senior Director Clinical Operations at Vicore Pharma. In addition to India, the trial is approved in the UK and preparations are ongoing to expand the study into other countries as well.

Study design

The study is a phase II, multi-center, open-label, single-arm trial investigating the safety, effect on lung function and pharmacokinetics of C21 in 60 subjects with IPF. Patients will be treated with C21 twice daily for six months, with an option to continue treatment for another three months.

First-in-class molecule

C21, a first-in-class low molecular weight angiotensin II receptor type 2 (AT2R) agonist, activates the "protective arm" of the Renin-Angiotensin system (RAS). The primary indication for C21 is IPF, but it is also being studied in Raynaud's phenomenon in patients with systemic sclerosis as well as in acute COVID-19.

C21 has shown robust effects in multiple IPF disease models

The RAS is understood to play a role in regulation of fibrosis. C21 has previously shown effects in the bleomycin and monocrotaline pulmonary fibrosis/pulmonary hypertension (PH) models as well as in the severe Sugen-hypoxia PH model in the rat. In addition, C21 was recently shown to effectively inhibit TGFβ1, a key regulator of fibrosis, in lung tissue from an IPF patient undergoing lung transplantation.

The disease

IPF is a debilitating lung disease with a prognosis worse than most cancers. Today, there are two approved treatments for IPF, Ofev (nintedanib) and Esbriet (pirfenidone), which reduce the rate of progression by 50 percent, but with significant side effects and reduced quality of life.

For further information, please contact:

Carl-Johan Dalsgaard, CEO, tel: +46 70 975 98 63, carl-johan.dalsgaard@vicorepharma.com

This information was submitted for publication on November 16, 2020 at 08:00 CET.

About Vicore Pharma Holding AB (publ)

Vicore Pharma is a rare disease pharmaceutical company focused on rare lung disorders and related indications. The company currently has three drug development programs, VP01, VP02 and VP03.

The VP01 project aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (IPF), systemic sclerosis and COVID-19. The VP02 project is based on a new formulation and delivery route of an existing immunomodulatory compound (an "IMiD"). The VP02 project focuses on the underlying disease and the severe cough associated with IPF. Both projects are also being actively evaluated for other indications within the field of interstitial lung diseases which have a significant unmet need. The VP03 project includes follow-up molecules for C21.

The company's shares (VICO) are listed on Nasdaq Stockholm's main market. For more information, see www.vicorepharma.com.