



Vicore Pharma's drug candidate C21 dilates peripheral resistance vessels in fibrotic disease

Gothenburg, March 11, 2021 – Vicore Pharma Holding AB (publ), a pharmaceutical company developing innovative medicines for severe lung disorders such as idiopathic pulmonary fibrosis (IPF), today announces top line data from a phase II study of its oral angiotensin II type 2 receptor (AT2R) agonist C21 in patients with systemic sclerosis and Raynaud's phenomenon. In this mechanistic 12-person single-dose study, C21 did not reach the predefined area-under-curve endpoint but at the end of the measurement C21 treatment showed statistically significant evidence of restored skin temperature as a measure of dilated peripheral resistance vessels.

The trial (NCT04388176) assessed the effect of a single dose of highly specific AT2R agonist C21 on cold-induced vasoconstriction, so called Raynaud's phenomenon, in patients with systemic sclerosis. "The results of the phase II study show that C21 can directly increase blood flow in fibrotic tissue, an effect that is believed to be of benefit in IPF", says **Carl-Johan Dalsgaard, CEO of Vicore Pharma**. "This further differentiates C21 from competitors in pulmonary fibrosis".

The mechanistic study examined the role of the AT2R in acute improvement of blood flow in fibrotic tissues. Twelve patients with systemic sclerosis and Raynaud's phenomenon had both hands subjected to a challenge with cold water and the recovery periods on drug or on placebo were compared. Patients on C21 showed a robust and statistically significant ($p=0.04$) higher skin temperature 15 minutes after the cold challenge. "These findings are potentially very exciting and suggest that C21 increases blood flow in patients with microvascular disease" says **Professor Ariane Herrick, The University of Manchester and Salford Royal Hospital**, principal investigator for the study.

At the end of the 15-minute measurement period, the rate of temperature recovery in patients treated with C21 was still rising, strongly suggesting that the experimental design did not capture the full effect of C21. Consequently, the area under the 15 min temperature curve selected as primary endpoint was not met.

The new clinical results support the multi-faceted utility of C21 in the treatment of pulmonary fibrosis and related vasculopathies that would benefit not only from increased blood flow in fibrotic tissue (current trial), but also from the previously documented inhibition of the profibrotic growth factor TGF-beta1 in human IPF lung tissue *ex vivo*, as well as the reduced microvascular remodeling and pulmonary hypertension seen in relevant disease models *in vivo*.

C21 (VP01 program), a first in class AT2R agonist

C21 is a first in class orally available low molecular weight angiotensin II type 2 receptor (AT2R) agonist. It is under development for idiopathic pulmonary fibrosis (IPF) and was recently reported to show beneficial effects in COVID-19 in which a phase 3 study is currently being planned.

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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), pulmonary fibrosis in 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.