Vicore Pharma gets regulatory approval to start phase II clinical trial with VP01 (C21) in patients with COVID-19, SARS CoV-2 infection

Gothenburg, April 28, 2020 – Vicore Pharma Holding AB (publ), a pharmaceutical company dedicated to developing innovative medicines for rare lung disorders, today announces the approval by the UK regulatory agency (MHRA[1]) of the clinical trial application (CTA) for a phase II study with the proprietary compound VP01 (C21) in patients with COVID-19, SARS CoV-2 infection.

Only four weeks after submitting a Letter of Intent to file a CTA to start the process, Vicore Pharma has completed the submission and gained approval from the agency to start the study.

The study, named ATTRACT (Angiotensin II Type Two Receptor Agonist Covid-19 Trial), is targeting hospitalized patients treated with basic respiratory care, but not mechanical ventilation. These patients have an intense inflammatory drive in the lungs which can lead to acute respiratory failure if it progresses.

VP01, a first in class low molecular weight angiotensin II receptor type 2 (AT2R) agonist, activates the "protective arm" of the renin angiotensin system (RAS). It is under development for idiopathic pulmonary fibrosis (IPF) and is also being studied in Raynaud's phenomenon in patients with systemic sclerosis.

Internal preclinical findings with VP01 suggest that it may be useful in the treatment of COVID-19.

The RAS is understood to play a role in the development of COVID-19 because angiotensin II (ANG II) is upregulated and contributes to the inflammatory reaction in the lungs. Moreover, the protective arm of the RAS is disarmed by SARS-CoV-2 which binds to the enzyme ACE2 and thereby inhibits the conversion of ANG II to endogenous protective molecules stimulating the AT2R. Because VP01 directly stimulates the AT2R, the belief is that VP01 could bypass the negative effects of viruses like SARS-CoV-2 on the protective RAS functions.

"To test the concept of an AT2R agonist in COVID-19 is innovative and represents a completely new approach to the disease" says Professor Joanna Porter, London University College, Chief Investigator of the trial.

The study will be a randomized, double-blind, placebo-controlled trial in approximately 100 COVID-19 patients with moderately severe disease requiring basic respiratory support, but not mechanical ventilation. The study will investigate the efficacy on respiratory failure and functional outcomes.

"Thanks to a dedicated in-house team and the efforts of our clinical research organization, Orphan Reach, we have managed to get this trial through to approval in record time" says Mimi Flensburg, VP Clinical Development of Vicore Pharma.

[1] MHRA stands for "The Medicines and Healthcare products Regulatory Agency"

Vicore Pharma will host a webcast to present more about the study and the background at 14.00 (CET) today. The webcast can be accessed via the link:
https://financialhearings.com/event/12879

The presentation will be available before the webcast at:
https://vicorepharma.com/investors/events-presentations/

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

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 two drug development programs, VP01 and VP02.

VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis ("IPF") and pulmonary fibrosis in systemic sclerosis ("SSc"). VP02 is based on a new formulation and delivery route of an existing immunomodulatory compound (an "IMiD"). VP02 focuses on the underlying disease and the severe cough associated with IPF. VP01 and VP02 are also being actively evaluated for other indications within the field of interstitial lung diseases which have a significant unmet need.

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