Vicore Pharma submits Letter of Intent for a clinical trial application for a phase II study in patients with COVID-19, SARS CoV-2 infection

Gothenburg, March 31, 2020 – Vicore Pharma, a pharmaceutical company dedicated to developing innovative medicines for rare lung disorders, today announces the submission of a Letter of Intent to file a clinical trial application (CTA) to the UK regulatory agency (MHRA[1]) for a phase II study with its proprietary compound C21 in patients with COVID-19, SARS CoV-2 infection.

Together with the Letter of Intent, Vicore Pharma has submitted the first regulatory documents for initial review in a rolling submission, as recently agreed with the MHRA. The formal application will be submitted as soon as all necessary documents are available, with a decision by the MHRA expected to follow shortly thereafter.

C21, a first in class low molecular weight angiotensin II receptor type 2 (AT2R) agonist, belongs to the "protective arm" of the renin angiotensin system (RAS), and is under development for idiopathic pulmonary fibrosis (IPF) and is also being studied in systemic sclerosis. Internal preclinical findings with C21 and the fact that the RAS plays a key role in the development of COVID-19 suggested that C21 could have a role in the treatment of the disease. This prompted Vicore Pharma to initiate a dialogue with the MHRA who invite initiatives to explore treatments for COVID-19.

There is a good scientific rationale for studying C21 as a potential treatment of COVID-19. It has recently been shown that the SARS CoV-2 virus utilizes the enzyme ACE2, which is part of RAS, for entry into the cell. This inactivates the ACE2 enzyme, creating an imbalance in the local RAS, leading to acute lung injury. Given that ACE2 generates the natural ligands for AT2R, Vicore Pharma believes that, by acting directly on the AT2R, C21 may suppress inflammatory mediators and bypass the way by which the virus incapacitates the system.

"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 proposed study will be a randomized, double blind, placebo controlled study in approximately 50 COVID-19 patients with a moderately severe disease, requiring oxygen support, but not mechanical ventilation. The study will investigate the efficacy on respiratory failure as measured by capacity to oxygenize the blood circulation.

"In these critical times, it is important to explore new opportunities to combat one of the worst pandemics in modern history," says Carl-Johan Dalsgaard, CEO of Vicore Pharma, "and we are pleased to collaborate with the clinical research organization, Orphan Reach, who has taken on this mission with very short notice".

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

Vicore will host a webcast to present more about the study and the background at 14.00 (CET) today that can be accessed via the link:
https://financialhearings.com/event/12848

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

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This information is information that Vicore Pharma Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above, at 08:00 CET on March 31, 2020

About Vicore Pharma Holding AB (publ)
Vicore Pharma is a rare disease pharmaceutical company focused on interstitial lung diseases 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.