Vicore announces FDA acceptance for pivotal phase 3 trial of C21 in COVID-19

Gothenburg, June 11, 2021 - Vicore Pharma Holding AB (publ) ("Vicore"), a rare disease pharmaceutical company developing innovative medicines for fibrotic lung disorders such as idiopathic pulmonary fibrosis (IPF), today announces that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for the company's lead asset, the orally available angiotensin II type 2 receptor (AT2R) agonist C21, for the treatment of COVID-19. The active IND enables initiation of US sites in Vicore's pivotal phase 3 trial, ATTRACT-3.

ATTRACT-3 trial is a randomized, double-blind, placebo-controlled, multinational, phase 3 trial that will include 600 adult patients hospitalized with COVID-19 requiring oxygen support but not mechanical ventilation. The primary objective is to evaluate the effect of C21 on recovery from COVID-19. Vicore's Phase 2 trial (ATTRACT) in COVID-19 showed that C21 significantly reduced the extended need for supplemental oxygen therapy, indicating faster recovery on C21 compared to placebo.

In ATTRACT-3, patients will be randomized to receive 100 mg C21 or placebo twice daily on top of standard of care (SoC) for 14 days and patients will be followed for 60 days. Trial preparations are currently ongoing in countries in North America, South and Central America, Europe, Africa and Asia. Topline results from ATTRACT-3 are expected during the first quarter of 2022.

"Morbidity and mortality in COVID-19 are still significant, particularly in moderate to severe disease, and our earlier trial indicates that C21 has the potential to improve respiratory outcomes and promote recovery in these patients," said Carl-Johan Dalsgaard, CEO of Vicore. "The FDA's acceptance of our first IND with C21 represents an important milestone in preparing our global phase 3 trial."

C21 in COVID-19 – improved respiratory outcomes

Results from the phase 2 ATTRACT study on 106 hospitalized patients with COVID-19, showed a significantly reduced risk for the need of supplemental oxygen (90% compared to placebo at day 14; P=0.003) and numerically fewer deaths and cases of patients requiring mechanical ventilation.

C21, a first-in-class AT2R agonist

C21 is a first-in-class, orally available, low molecular weight, angiotensin II type 2 receptor (AT2R) agonist that activates the "protective arm" of the renin-angiotensin system (RAS). The compound has shown robust effects in human idiopathic pulmonary fibrosis (IPF) lung slices and a phase 2 proof-of-concept study in IPF is currently ongoing. Given that AT2R agonism has therapeutic potential in several additional indications with significant unmet medical needs, Vicore has intensified the efforts to develop proprietary follow-up molecules with differentiated profiles.

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

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About Vicore Pharma Holding AB (publ)

Vicore is a rare disease pharmaceutical company focused on fibrotic lung disease and related indications. The company currently has four development programs, VP01, VP02, VP03 and VP04. VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (IPF) and COVID-19. VP02 is based on a new formulation and delivery route of thalidomide and focuses on the underlying disease and the severe cough associated with IPF. VP03 includes the development of new AT2R agonists. VP04 develops a clinically validated digital therapeutic for IPF patients.

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