Vicore provides an update on the ATTRACT-3 COVID-19 trial

- **ATTRACT-3 did not meet its primary endpoint, reduction of all-cause mortality at 60 days**
- **Lack of effect explained by new virus mutations**
- **No safety signals detected**
- **The company will focus the development of C21 for the treatment of IPF and PAH**

Gothenburg, September 15, 2022 – Vicore Pharma Holding AB (publ) ("Vicore"), a clinical-stage pharmaceutical company developing medicines targeting the angiotensin II type 2 receptor (AT2R), today announces the top-line data from the ATTRACT-3 trial in hospitalized COVID-19 patients.

In ATTRACT-3[1], a global phase 3 trial, 272 hospitalized patients in need of oxygen supplementation were treated with 100 mg C21 twice daily or matching placebo for 14 days. The primary endpoint, reduction in overall mortality at 60 days was not met, nor were the secondary efficacy endpoints related to disease progression and discharge. Vicore will discontinue further clinical development of C21 in COVID-19.

In the phase 2 ATTRACT trial[2], conducted when the wild-type SARS-COV-2 virus was causing COVID-19, C21 treatment resulted in a significant restoration of lung function as well as a reduction of long-term lung injury. The wild-type virus was unique in that it infected alveolar epithelial cells deep into the lung parenchyma, resulting in a distinct clinical pattern and a pathogenesis very similar to idiopathic pulmonary fibrosis (IPF)[3]. In contrast, the later virus mutations, and especially the Omicron variant that became predominant during the ATTRACT-3 trial period, reproduces more superficially in the bronchial mucosa in the upper airways giving rise to a much milder disease[4,5].

This change of virus characteristics could not be foreseen and explains the differences in disease pattern and why targeting alveolar integrity and function with C21 was not effective in treating the disease or to reduce mortality in the ATTRACT-3 trial.

"*The development of SARS-COV-2 virus to less severe and more contagious mutations has completely changed the clinical picture from a life-threatening disease to a more flu-like or even ordinary upper respiratory tract infection"* says Maureen Horton, retired Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at the Johns Hopkins University School of Medicine and Co-Director of the Johns Hopkins Interstitial Lung Disease Clinic.

"We are of course disappointed by the efficacy results but encouraged by the safety. These new findings strengthen the view that C21 acts by stimulating alveolar epithelial cells which is critical in the treatment of IPF, and explain why it was efficacious in COVID-19 caused by the wild type virus," says Carl-Johan Dalsgaard, CEO of Vicore.

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[1] NCT04880642
[2] NCT04452435
[3] Sinha et. al. The Lancet eBiomedicine vol 82, 2022. DOI: https://doi.org/10.1016/j.ebiom.2022.104185
[4] Lamers et. al. bioRxiv 2022. DOI: https://doi.org/10.1101/2022.01.19.476898
[5] Hui et. al. Nature vol 603, 2022. DOI: https://doi.org/10.1038/s41586-022-04479-6

Vicore will now concentrate the development of C21 on its on-going clinical program for the treatment of IPF and pulmonary arterial hypertension (PAH).

About angiotensin II type 2 receptor agonists (ATRAGs)

The AT2R is part of the body's regeneration and repair system and is suggested to be involved in several diseases connected to ageing and cell senescence, including idiopathic pulmonary fibrosis, chronic kidney disease, heart failure as well as cognitive disorders. Stimulating the AT2R has been shown to be effective in combatting disease in numerous models and clinical validation is well advanced in acute and chronic lung disease. Stimulating AT2R also dilates small diseased resistance vessels in animals and in humans, resulting in locally increased blood flow. In the lungs, the AT2R is highly expressed in the alveolar epithelium while it is absent in the bronchial mucosa.

About the ATTRACT-3 trial

ATTRACT-3 is a randomized, double-blind, placebo-controlled, multinational, phase 3 trial with 272 adult patients hospitalized with COVID-19 requiring oxygen support but not mechanical ventilation. The primary endpoint is all-cause mortality up to day 60. Patients were randomized to receive 100 mg C21 or placebo twice daily on top of standard of care for 14 days and be followed for 60 days.

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About Vicore Pharma Holding AB (publ)
Vicore is a clinical-stage pharmaceutical company focused on developing innovative medicines in severe diseases where the Angiotensin II type 2 receptor (AT2R) plays an important role. 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 pulmonary artery hypertension (PAH). VP02 is a new formulation and delivery route of thalidomide and focuses on the underlying disease and the severe cough associated with IPF. The VP03 program develops new AT2 receptor 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.