Vicore Pharma reports positive top line data from the ATTRACT clinical study in patients with COVID-19

Oral C21 treatment demonstrates significant clinical improvement on top of corticosteroids

Gothenburg, December 08, 2020 – Vicore Pharma Holding AB (publ), a pharmaceutical company dedicated to developing innovative medicines for severe lung disorders, today announces positive top line data from the ATTRACT COVID-19 trial with C21 (VP01). A webcast presentation will be held today at 15:00 CET (9 am EST).

The ATTRACT study was a randomized, double-blind and placebo-controlled trial investigating the efficacy of oral C21 compared with placebo in 106 hospitalized COVID-19 patients with signs of an acute respiratory infection but not requiring mechanical ventilation. Many of these patients go on to experience respiratory distress, as manifested by the need for supplemental oxygen, often leading to acute respiratory failure if the disease progresses. The need for oxygen treatment reflects progress of the infection to the lower airways where gas exchange occurs.

Topline results:

- **C21 reduced the risk of needing oxygen** at the end of treatment **by 40 %**, an effect that was **statistically significant** (p=0.057) at the 10% level as predefined in the Statistical Analysis Plan.
- There was a clear trend for **C21 reducing number of patients needing mechanical ventilation**, with four patients in the placebo group compared to one in the C21 group.
- There was also a **trend for C21 reducing mortality**, with three deaths in the placebo group compared with one in the C21 group.
- **C21 was well tolerated** in this population of severely sick patients.

Vicore Pharma will continue to analyze the data from the study and more information will be presented in due course.

“Given the nature and scale of this study, we are surprised to see such a clear and significant clinical benefit for C21”, says **Carl-Johan Dalsgaard, CEO of Vicore Pharma**, “and given the severity and duration of the pandemic, an oral C21 formulation with an excellent safety and tolerability profile could become an important and convenient early treatment of COVID-19, fulfilling a huge medical need. In addition, these results bode well for our ongoing study in idiopathic pulmonary fibrosis (IPF) as well as for future studies in larger indications where activation of AT2R may have a role to play”.

Dr. Reema Kashiva, Principal Investigator at Noble Hospital and Research Centre, Pune, India, said: “Given the severity of COVID-19, it is encouraging to see promising clinically meaningful results such as the impact of C21 on oxygen use, suggesting potential utility of this medicine on shifting the treatment paradigm of this aggressive disease.”

Webcast presentation

Vicore Pharma will host a webcast to present more about the outcome of the study at 15.00 CET (9 am EST) today that can be accessed via the link: https://financialhearings.com/event/13550

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

Study design

In the ATTRACT study (Angiotensin II Type Two Receptor Agonist COVID-19 Trial), a randomized, double-blind and placebo-controlled trial, a total of 106 hospitalized patients with a diagnosis of coronavirus SARS-CoV-2 infection (confirmed by polymerase chain reaction test) and signs of an acute respiratory infection but not requiring mechanical ventilation were recruited. The patients were randomized to receive oral treatment with C21 (100 mg b.i.d., n=51) or placebo (n=56) for seven days on top of standard of care (physician's choice). The treatment groups were well balanced regarding age and sex. According to the currently available data, at least 100 of the 106 patients were treated with glucocorticoids.

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 IPF lung slices, and a phase II proof of concept study in IPF has recently started. Given that AT2R agonism has therapeutic potential in a number of additional indications with significant unmet needs, Vicore has intensified the efforts to develop proprietary follow-up molecules with different profiles.

LifeArc funding

The ATTRACT study received £1.5 million in funding from the UK charity LifeArc - Coronavirus (COVID-19) Therapeutics - https://www.lifearc.org/funding/COVID-19-funding-2/ - a £10 million fund launched on 20 March 2020 to support research and testing of therapeutics that could be rapidly deployed to help address COVID-19.

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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), 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.