

# Positive results show that C21 can become an important complement to COVID-19 vaccines

Gothenburg, December 21, 2020 – Vicore Pharma Holding AB (publ), a pharmaceutical company dedicated to developing innovative medicines for severe lung disorders, today reports an expanded data analysis to follow up the encouraging top line data from the ATTRACT study reported on December 8, 2020. The data show restoration of lung function in COVID-19 with the company's oral lead candidate drug C21, suggesting that C21 can become an important complement to vaccines to combat the COVID-19 pandemic. A webcast presentation will be held today at 15:00 CET (9:00 am EST).

With COVID-19 increasing world-wide, with more than 600,000 new cases and 10,000 deaths registered per day, there is an urgent need for a safe oral effective therapy as an important complement to the recently launched vaccine efforts.

"The critical incident in COVID-19 that makes this disease different to a common cold is the progression to the distal airways with respiratory distress and subsequent need for oxygen supplementation", said **Carl-Johan Dalsgaard, CEO of Vicore Pharma.** "Our data clearly show that C21 can restore lung function on top of steroids and normalize gas exchange. A safe oral medication with such properties can become an important complement to vaccines to combat the pandemic".

# **Updated summary of results**

- C21 gradually lowered the risk for patients needing oxygen supplementation with reductions
  of 40% (p=0.057) at the end of the 7-day treatment and 57% (p=0.014) at day 8 after start of
  treatment.
- At the end of the trial, about a week after the last dose of C21, the effect was even more pronounced, with only one patient in the C21 group still needing oxygen supplementation compared to 11 patients in the placebo group a reduction by >90% (p<0.002).
- In the subgroup of patients needing oxygen supplementation (about 30 patients per treatment group), C21 produced a greater **reduction of CRP** (C-reactive protein) than in the placebo group, an effect that was **statistically significant** at the predefined 10% level.
- As reported on December 8, there was a clear trend for C21 reducing the number of patients
  needing mechanical ventilation and a trend for C21 reducing mortality. The data also showed
  that the treatment was safe and well tolerated.

The reduced need for oxygen supplementation indicates that C21 stops virus-induced pathological processes in the distal airways and thereby restores lung function. The improvement developed gradually and became more pronounced after the treatment period, and the results suggest that C21 may also be capable of preventing respiratory damage caused by the virus, and in doing so the development of COVID-19.



# Webcast presentation

Vicore Pharma will host a webcast to present more about the outcome of the study at 15.00 CET (9:00 am EST) today that can be accessed via the link: <a href="https://financialhearings.com/event/13570">https://financialhearings.com/event/13570</a>

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) with a follow up after 7-10 days. According to data analyzed to date, the treatment groups were well balanced regarding age, sex and concomitant medications. Importantly, the vast majority of patients received corticosteroid treatment.

# 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 Pharma 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 - <a href="https://www.lifearc.org/funding/COVID-19-funding-2/">https://www.lifearc.org/funding/COVID-19-funding-2/</a> - 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.

**Ends** 

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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 <a href="https://www.vicorepharma.com">www.vicorepharma.com</a>.