Vicore's AIR study interim analysis suggests that C21 improves lung function in IPF patients

- FVC increased by an average +251 ml over baseline at 24 weeks
- Between 24 and 36 weeks, FVC was either stable or continued to increase
- C21 was safe and well tolerated
- Planning of a phase 2b study is being initiated
- A webcast presentation will be held at 14:00 CET (8 AM EST) today with more study details

Gothenburg, February 10, 2022 - Vicore Pharma Holding AB (publ) ("Vicore"), a clinical-stage pharmaceutical company developing medicines targeting the angiotensin II type 2 receptor (AT2R), today announces data from an interim analysis suggesting that C21 stabilizes disease and increases lung function in idiopathic pulmonary fibrosis (IPF) patients as quantified by standard FVC (Forced Vital Capacity) measurement.

An interim analysis of the phase 2 proof-of-concept study in IPF (the AIR[1] study) showed an initial stabilization of disease and then an increase in FVC up to the end of the study at 36 weeks. At the time of the interim analysis, there were 21 evaluable patients of which 13, 9 and 7 patients reached 12, 24 and 36 weeks of treatment, respectively. After 24 weeks, the increase in mean FVC was +251 ml, a considerable difference of 371 ml compared to the expected decline of 120 ml in 24 weeks in an untreated population. Five of the seven patients who completed both 24 and 36 weeks of C21 treatment showed continued improvement in FVC and two remained stable. Analysis of FVC slope values at 28, 32 and 36 weeks are statistically significant (p=0.016 at 36 weeks) compared to the expected mean for untreated patients. The study drug was well tolerated with no related serious adverse events, acute exacerbations, or gastrointestinal signals.

"This is very encouraging data", says Professor Toby Maher, clinical expert to Vicore *"to see stabilization in patients over 36 weeks is certainly not something we would expect to see by chance in a clinical trial and definitely warrants further assessment of C21 in IPF"*.

The AIR study is an open label single arm study in treatment naïve IPF patients in which 100 mg of C21 was administered twice daily for 24 weeks with an optional 12-week extension. The study is being conducted in the UK, India, Ukraine, and Russia. A correct diagnosis was secured by central reading of high-resolution computer tomography (HRCT). To assess lung volume, the gold standard for FVC measurements, the ERT system, was used at all sites.

"Based on the mechanism of action of C21, which has both vascular and antifibrotic characteristics, we were optimistic, but this exceeds our expectations" says Professor Joanna Porter, coordinating investigator in the AIR study.

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[1] NCT04533022

With these results, the company initiates the planning of AIR 2, a double-blind controlled phase 2 dose-finding study to confirm these results and accelerate the development of C21 in parallel to completing the AIR trial.

"Now that the interim analysis has shown both safety and a positive effect on lung function in this trial, we want to move as quickly as possible to the next stage to be able to bring this treatment to patients" says Rohit Batta, Chief Medical Officer of Vicore.

Webcast presentation
Vicore will host a webcast to present more details from the interim analysis at 14.00 CET (8:00 am EST) today that can be accessed via the link: https://financialhearings.com/event/44068

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

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) leading to resolution and regeneration following tissue damage. The compound is currently in a phase 2 proof-of-concept trial in IPF and in a pivotal phase 3 trial in COVID-19.

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This information is such 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 persons set out above on February 10, 2022 at 06:55 CEST.

About Vicore Pharma Holding AB (publ)
Vicore is a clinical-stage pharmaceutical company focused on developing innovative medicines in severe lung 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 COVID-19. VP02 is 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 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.