Vicore announces new data from the IPF AIR trial further strengthening the benefit-risk profile of C21

- The new results show stabilization of disease already from week 6 and confirm the unprecedented increase in lung function over time
- Vicore will accelerate clinical development
- Invitation to conference call on November 4 at 13:00 CET/8:00 am EST

Stockholm, November 3, 2022 – Vicore Pharma Holding AB (publ) ("Vicore" or the "Company"), a pioneer in the development of angiotensin II type 2 receptor agonists (ATRAGs), provides a new interim analysis of the ongoing AIR trial, a phase 2a study in idiopathic pulmonary fibrosis (IPF).

The AIR trial[1] is a multi-center open label single arm 24-week trial with the addition of a 12-week extension study evaluating the safety and efficacy of the AT2R agonist (ATRAG) C21 in patients with IPF. After an interim analysis of 41 patients, the previously reported strong effect on lung function is reinforced still without safety concerns, suggesting a strong benefit-risk profile. The new dataset shows a stabilization of lung capacity already at week 6 and, as already seen in the previous interim analysis, a subsequent increase of forced vital capacity (FVC) from week 18 to 36. The increase was more pronounced in IPF patients without end-stage destruction of lung parenchyma as documented by high resolution computer tomography (HRCT).

Conference call

Vicore will host a conference call together with Prof. Toby Maher to present more details from the interim analysis on Friday, November 4th at 13:00 CET (8:00 am EST) which is accessible via the link: https://lifesci.rampard.com/WebcastingAppv5/Events/eventsDispatcher.jsp?Y2lk=MjA2Mw==

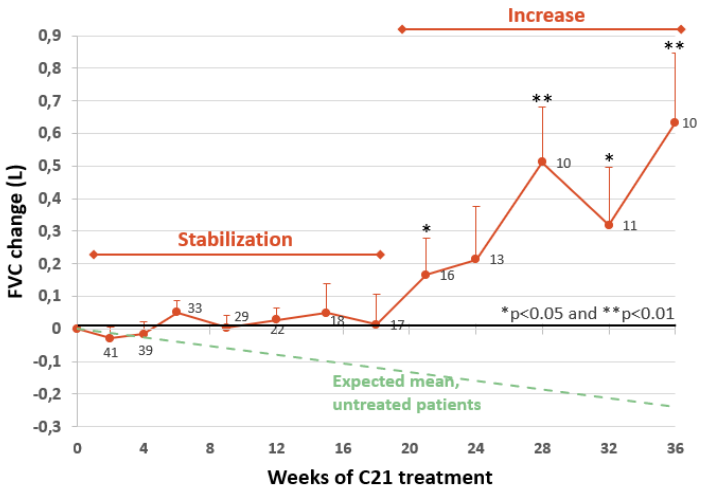
The presentation will be available after the webcast on: https://vicorepharma.com/investors/events-presentations/

After 12 weeks of treatment with C21, an increase in FVC of 28 mL from baseline was seen (n=22). In untreated patients, a decline of about 80 mL and 120 mL is generally observed at 12 and 24 weeks, respectively [2]. After 24 weeks of treatment with C21, the increase in FVC was 213 mL (n=13), and at week 36 the increase was 633 mL (n=10), compared to baseline. At weeks 21, 28, 32 and 36, linear regression analysis showed statistical significance vs. the expected mean for untreated patients ($p<0.05$ for weeks 21 and 32; $p<0.01$ for weeks 28 and 36). The results are illustrated in the figure below.

[1] ClinicalTrials.gov - NCT04533022

[2] Richeldi et al. N Engl J Med 365(12):1079-87, 2011. doi: 10.1056/NEJMoa1103690

Mean change (±SEM) from baseline in FVC over time, observed values



"We are very pleased to see that the new results from the AIR trial show even greater patient benefit than in the first interim analysis. To be able to stop disease progression with a safe and well tolerated drug would be a major step forward in the treatment of IPF and if the increase in FVC holds true in future trials, it would suggest that C21 has disease modifying effects" says Carl-Johan Dalsgaard, CEO of Vicore.

IPF is a lethal lung disease affecting ~200,000 individuals in the Western world, which if left untreated leads to death within three to five years[3]. The two IPF drugs that are on the market today do not improve FVC in IPF patients and typically reduce the rate of decline by about 50% and for many patients comes at a price of serious gastrointestinal side effects. IPF is a disease where insufficient alveolar repair is the cause of the progressive scarring [4] and because C21 is believed to stimulate the progenitor cells responsible for maintaining alveolar integrity, AT2R activation represents a novel mechanism to address this devastating disease.

"The AIR data continues to look very encouraging" says Professor Toby Maher, Keck School of Medicine at University of Southern California *"To see these long-term effects with stabilization over 36 weeks and even an increase in lung capacity is something we would not expect to see by chance in a clinical trial, and definitely warrants further assessment of C21".*

Given the exceptional data, Vicore is now in discussions with advisers and clinical experts on the design of the next IPF trial, which if data remain robust, may serve as substantial evidence of effectiveness. The company is pleased to announce that it has formed a global advisory committee focused on providing strategic guidance and support during the execution of the next trial. Committee members include world-renowned experts in IPF such as Professors Kevin Flaherty, Tamera Corte, Michael Kreuter and Toby Maher, together with patient advocacy representation.

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[3] Raghu et al. Chest. 154:1359-1370, 2018. doi: 10.1016/j.chest.2018.08.1083

[4] Martinez et al. Nat Rev Dis Primers 3:17074, 2017. doi: 10.1038/nrdp.2017.74

"This is an important and exciting moment for the IPF community, and I'm glad that Vicore is capitalising on decades worth of experience in developing ATRAGs and favoring a patient-centric approach" said Kevin Flaherty, Professor of Medicine in the Division of Pulmonary & Critical Care Medicine, Department of Internal Medicine at the University of Michigan.

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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 November 3, 2022 at 17.40 CET.

About the phase 2a trial in IPF (AIR)

The main purpose of this therapeutic exploratory trial is to investigate the safety and efficacy of C21 in treatment-naïve patients with IPF. The trial is an open-label, single-arm trial in which C21 is given orally twice daily as monotherapy for 24 weeks with an option to continue treatment for another 12 weeks. Patients with IPF have a well-characterized decline in lung function. Effect of C21 on lung function, measured by change from baseline in FVC, is investigated and interpreted in the light of the well-documented natural history of IPF. The trial has multiple centers with regulatory approvals obtained in the UK, India, Ukraine and Russia. The trial is paused in Ukraine and Russia due to the conflict. The first patient was recruited in November 2020. In February 2022, Vicore performed the first interim analysis showing an initial stabilization of disease and then an increase in FVC up to the end of the study at 36 weeks.

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. 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.