# Vicore Pharma announces Last Patient Last Visit in the mechanistic phase II study with C21 in systemic sclerosis

**Gothenburg, December 15, 2020 – Vicore Pharma Holding AB (publ), a pharmaceutical company dedicated to developing innovative medicines for serious lung disorders, today announces that the last patient has completed the final visit in the mechanistic phase II study of Raynaud's phenomenon in systemic sclerosis patients.**

- The study has been closed with 12 patients having completed the study
- Top line data is estimated to be available in February 2021

"After reassuring that the statistical power is sufficient to pick up the signal we are looking for in the study, we decided to stop recruitment after 12 subjects having completed the trial", says Carl-Johan Dalsgaard, CEO Vicore Pharma. "We are very pleased that we have been able to complete the patient enrollment in these difficult times, and we look forward to presenting top line data in February 2021".

**Study design and purpose**
The trial is designed to study the effect of a single dose of C21 on cold-induced vasoconstriction, so called Raynaud's phenomenon (RP), in patients with systemic sclerosis (SSc). It may shed light on the AT2 receptor's role in acute improvement of blood flow in affected tissues. If the results are positive, the study will further support that C21 may also have beneficial effects on the pulmonary vascular pathology often seen in patients with SSc related pulmonary fibrosis as well as in idiopathic pulmonary fibrosis (IPF). The original study was planned to recruit up to 16 patients but due to the challenges caused by COVID-19 it was decided to stop at the minimally required patient number.

**About Systemic Sclerosis (SSc)**
SSc is a disease with a substantial involvement of angiotensin II and upregulation of the angiotensin II type 2 receptor (AT2R - the target for C21) which is known to mediate both anti-fibrotic and beneficial vascular effects in several models of pulmonary fibrosis and pulmonary hypertension.

SSc is a rare and severe chronic autoimmune disease affecting skin as well as inner organs such as the lung and kidney. There is no cure for the disease and severe cases are treated with potent immunomodulatory drugs or, in some cases, autologous stem cell transplantation, nevertheless challenges and unmet medical need persists. The prevalence of SSc is estimated at 7-34 and 14-44 per 100,000 individuals in Europe and North America, respectively. The incidence is estimated to be 1-2 and 1-6 per 100,000 individuals in Europe and North America, respectively. SSc is 3-4 times more common in women than in men. It is estimated that 20 percent of the SSc patient population have the severe diffuse form. Between 30 and 50 percent of patients also suffer from interstitial lung disease.

**C21 (VP01 program), 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). It is further under development for idiopathic pulmonary fibrosis (IPF) and was recently reported to show beneficial effects in COVID-19 patients.

**For further information, please contact:**
Carl-Johan Dalsgaard, CEO, tel: +46 70 975 98 63, carl-johan.dalsgaard@vicorepharma.com

*This information was submitted for publication on December 15, 2020, at 08:00 CET*

***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.*

*VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (IPF), systemic sclerosis and COVID-19. VP02 is based on a new formulation and delivery route of an existing immunomodulatory compound (an "IMiD"). VP02 focuses on the underlying disease and the severe cough associated with IPF. VP01 and VP02 are also being actively evaluated for other indications within the field of interstitial lung diseases which have a significant unmet need. VP03 includes follow-up molecules for VP01.*

*The company's shares (VICO) are listed on Nasdaq Stockholm's main market. For more information, see www.vicorepharma.com.*