Vicore submits clinical trial application for phase II trial with C21 in IPF

Gothenburg, March 30, 2020 – Vicore Pharma, a pharmaceutical company dedicated to developing innovative medicines for rare lung disorders, today announces submission of the clinical trial application (CTA) for a proof-of-concept study with its proprietary compound C21 in patients with IPF (idiopathic pulmonary fibrosis) to the UK regulatory agency MHRA.

The phase II clinical study in patients with IPF will be a six months single arm open label study which will compare the effect of C21 to the well documented linear decline of lung function in untreated patients. It will also be possible to, on an individual basis, extend the trial period for an additional three months, up to a total of nine months, allowing further collection of meaningful data.

As previously communicated, the updated study design, provides stronger statistical power to detect a treatment effect. This is feasible since the validated endpoint, FVC (forced vital capacity), a measurement of lung volume, is an objective and consistent measure of disease progression which decreases with approximately 120 ml per six months.

“The extension from three to six months has a dramatic effect on the statistical power which will increase our chances of capturing any treatment effect. The study will provide interpretable data that will give us the confidence to design future studies for patients. Furthermore, it is significantly more attractive for patients to participate in a study without a placebo group as they are certain to be treated with the active substance”, says Rohit Batta, CMO of Vicore Pharma.

“This is a clever and patient friendly design that will indicate whether C21 works in IPF. IPF continues to have a high unmet need and new treatments are desperately needed”, says Professor Joanna Porter, University College of London, Chief Investigator of the trial.

IPF is a debilitating lung disease with a prognosis worse than most cancers. There are no existing treatments that can reverse the fibrosis or cure IPF. Vicore anticipates recruitment of patients to the trial to start in Q3 2020. The study will include approximately 60 patients and it will be performed in the UK with the possibility to expand to additional countries.

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About Vicore Pharma Holding AB (publ)
Vicore Pharma is a rare disease pharmaceutical company focused on interstitial lung diseases and related indications. The company currently has two drug development programs, VP01 and VP02.

VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (“IPF”) and pulmonary fibrosis in systemic sclerosis (“SSc”). 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.

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