Vicore Pharma receives regulatory approval to start phase II clinical trial with VP01 (C21) in patients with IPF

Gothenburg, May 5, 2020 – Vicore Pharma Holding AB (publ), a pharmaceutical company dedicated to developing innovative medicines for rare lung disorders, today announces the approval by the UK regulatory agency (MHRA[1]) of the clinical trial application (CTA) for a phase II study with its proprietary compound VP01 (C21) in patients with IPF (idiopathic pulmonary fibrosis).

Approximately five weeks after submitting the CTA, Vicore Pharma has received approval from the MHRA to start the study. In addition to the MHRA approval, a favourable opinion from the ethics committee is also required before the study can enroll patients. Depending on the COVID-19 situation, Vicore Pharma anticipates that patient recruitment may start during the third quarter of 2020.

The phase II clinical study in patients with IPF will be a six months single arm open label study including up to 60 patients. The study will compare the observed treatment effect of VP01 on lung function as measured by FVC[2], an objective measure, to the well documented linear decline of lung volume in untreated patients. Subject to individual assessments, it may also be possible for patients to extend their treatment periods up to a total of nine months, allowing for further collection of efficacy and safety data.

"The study will provide a strong foundation for designing the continued clinical program which will hopefully lead to the approval of VP01, addressing a severe and devastating disease. We confidently believe that one of the advantages of this study design is the patient centric approach, removing the placebo lottery and subsequently aiding a more efficient recruitment", says Carl-Johan Dalsgaard, CEO of Vicore Pharma.

The disease

IPF is a debilitating lung disease with a prognosis worse than most cancers. There are no existing treatments that can cure IPF or reverse the fibrosis and survival after diagnosis is estimated to be an average of five years. Today there are two approved treatments for IPF, Ofev (nintedanib) and Esbriet (pirfenidone) which reduce the rate of progression by up to 50 percent, but with significant side effect profiles which negatively impact quality of life.

First in class molecule

VP01 (C21) is a first in class small molecule and an agonist of the Angiotensin II type 2 receptor that promotes anti-inflammatory and antifibrotic effects in a number of lung disease models.

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[1] MHRA stands for "The Medicines and Healthcare products Regulatory Agency"
[2] FVC stands for "Forced Vital Capacity" and measures the total amount of air exhaled during the forced expiratory volume (FEV) test.

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 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.