Vicore Pharma expands VP01 (C21) clinical program to enable functional read out

Vicore Pharma (publ) today announced that it will expand its clinical program of lead compound C21, for the treatment of idiopathic pulmonary fibrosis (IPF), to increase the likelihood of showing signals of functional effect and successfully advance C21 in its clinical development.

An expansion of the planned clinical phase IIa study in IPF patients – in number of patients, dose and also in treatment duration – is the result of a longer preclinical safety study that has recently been completed. This creates a number of important benefits in relation to the next development phase of C21, including the possibility of showing an efficacy signal in lung function, as measured by forced vital capacity (FVC), which will be an important endpoint for the future registration of C21.

“C21 is a very interesting compound that has the potential to be an effective treatment of IPF, which is a fatal disease with a high unmet medical need. But in order to succeed, we must ensure the clinical program is designed to provide the highest probability of success”, said Vicore Pharma’s CEO, Dr. Carl-Johan Dalsgaard.

“We have therefore taken the decision to redesign the Phase IIa study that was announced earlier this year to also include a more functional read out, including both efficacy and safety. The new design follows after a strategic review taking into account the results from the longer pre-clinical safety study.”

These data also give Vicore Pharma the opportunity to increase the exposure, and it will therefore help to identify new higher doses of C21 in man before selecting the most optimal dose regimen for the IPF study. The company expects to initiate the expanded program in January 2019 and the clinical phase IIa study in IPF patients is expected to start six months later.

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This information is information that Vicore Pharma Holding AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above, at 08:00 CET on September 10, 2018.

About Vicore Pharma Holding
Vicore Pharma AB is focused on the development of drugs for the treatment of interstitial lung diseases. The company’s two major development programs, VP01 (C21) and VP02 (IMiD), act through the AT2 receptor and is an immunomodulatory drug substance class being developed for local treatment, respectively. The company’s drug candidate C21 aims to improve the treatment of idiopathic pulmonary fibrosis (IPF), a rare disease for which C21 has been granted orphan drug designation both in the EU and the US. In addition, C21 is explored pre-clinically in a number of rare diseases where the AT2 receptor plays an important role. VP02 has in earlier experiments shown an effect in e.g. idiopathic pulmonary fibrosis with another administration form which, however, has limited its continued development. VP02 is being developed for local treatment in order to e.g. overcome such shortcomings. The company is based in AstraZeneca's Bioventurehub in Mölndal. The company's share (ticker: VICO) is listed on Nasdaq First North in Stockholm with Erik Penser Bank as Certified Adviser. For more information, see www.vicorepharma.com

About Idiopathic pulmonary fibrosis (IPF)
This disease affects the small alveoli and the lung tissue adjacent to the alveoli which are both subject to fibrotization and loss of function. The etiology of the disease is unknown but it is believed to be an exaggerated healing response to a minor insult and the end-result is general thickening and damage to the lung structure causing oxygen absorption impairment. The disease usually occurs at ages between 50-70 and the prevalence is approximately 14-42 cases per 100,000 inhabitants. The disease is progressive and five-year survival is around 30 percent.