Vicore announces first patient enrolled in COMPANION; a digital therapeutic pivotal study for patients with pulmonary fibrosis

- **First randomized clinical investigation with a digital therapy (DTx) to address the psychological symptom burden in pulmonary fibrosis (PF) patients**
- **First patient enrolled in US pivotal study; readout expected Q4 2023**
- **Supports development of a strong holistic portfolio in rare lung disease**

Stockholm, December 5, 2022 – Vicore Pharma Holding AB (publ) ("Vicore"), a pioneer in the development of angiotensin II type 2 receptor agonists (ATRAGs), today launched the pivotal phase of COMPANION, the first clinical investigation of a digital cognitive behavioral therapy (dCBT) for patients with pulmonary fibrosis.

Patients with pulmonary fibrosis (PF) are given a poor prognosis, during which dyspnea, fatigue and cough gradually worsen. In a preceding study, it was shown that 63% of PF patients report treatable levels of anxiety[1]. Vicore's digital Cognitive Behavioral Therapy has the advantage of being accessible 24/7 and can be personalized to meet the patient's individual needs and schedule.

"Continuous access is important when providing psychological support for patients who have anxiety about leaving their homes due to the risk of infection or limitations due to their disease." Says Dr. Josh Solomon, MD of National Jewish Health, Denver, Colorado and Clinical Investigator of the study.

The COMPANION study[2] is a fully digitalized, randomized, controlled parallel-group clinical investigation to evaluate the impact of the digital therapy Almee™ on the psychological symptom burden in adults diagnosed with PF. Patients enrolled in the investigation will be randomized to Almee™ or a treatment-as-usual control group, for nine weeks. Outcomes will be patient- and clinician-reported measures of anxiety using validated questionnaires.

The COMPANION study, enrolling 250 patients across the US, is scheduled to complete in Q4 2023. Provided the result is positive, Almee™ will be submitted for FDA clearance as a prescription medical device to be launched in 2024 with the intention to treat the anxiety symptoms in patients with pulmonary fibrosis.

"Almee™ is an integral part of the Vicore development strategy for holistic and personalized treatment for rare lung disease and it addresses a clear unmet need in the PF population. This decentralized clinical investigation also gives us an opportunity to rethink the traditional clinical trial model while keeping the patient in focus," says Jessica Shull, Director of Digital Therapeutics at Vicore

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[1] Vicore data on file

[2] NCT05330312

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About Almee™, Vicore's digital therapeutic in pulmonary fibrosis (PF)

Almee™ (an investigational medical device pending FDA clearance) is a digital therapeutic (DTx) based on cognitive behavioral therapy (CBT) created to address the psychological impact of living with PF. Vicore is collaborating with Alex Therapeutics for the development of this medical device product.

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 PF patients.

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