Vicore's digital therapeutic for IPF patients shows nearly 50% anxiety reduction in pilot study

- **Analyses of safety, functionality and user acceptance was positive**
- **Reported decrease in anxiety scores for patients with pulmonary fibrosis**
- **COMPANION, a pivotal study in 250 patients with pulmonary fibrosis, to be initiated in Q4 2022**

Gothenburg, October 6, 2022 – Vicore Pharma Holding AB (publ) ("Vicore") pioneering development of angiotensin II type 2 receptor agonists (ATRAGs), today announces positive results for the pilot phase of the COMPANION study. Vicore's digital Cognitive Behavioral Therapy (CBT) therapy, Almee™; for patients with pulmonary fibrosis was safe, functional, user-friendly and reduced anxiety symptoms by 49% in patients with idiopathic pulmonary fibrosis (IPF).

The COMPANION Pilot study[1] was a four week, open-label, decentralized clinical investigation in 10 patients with self-reported symptoms of anxiety related to IPF. The primary objective of the study, to test the functionality, user experience and safety of the digital therapeutic (DTx), was met and preliminary efficacy results were encouraging; four weeks of using the DTx reduced GAD-7* scores by 4.2 points. A reduction in the GAD-7 score of ≥2 points is regarded as clinically meaningful.

These results indicate that the DTx could serve as a safe and reliable resource for IPF patients to address the psychological impact of living with a severe disease.

"Given the high incidence of anxiety in IPF patients and its potential impact on quality of life, the preliminary results are exciting. In light of the paucity of research exploring anxiety therapy in lung fibrosis, this study, and the soon to start pivotal study, represent major steps forward to improve the quality of life for patients suffering from lung fibrosis." said Maureen Horton, Principal Investigator of the COMPANION investigation, retired Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at the Johns Hopkins University School of Medicine and Co-Director of the Johns Hopkins Interstitial Lung Disease Clinic.

The pivotal phase of COMPANION will start in Q4, 2022, using a full implementation of the DTx product, Almee™. It will be a 9-week, randomized, controlled, decentralized clinical investigation including 250 patients with all forms of pulmonary fibrosis. Topline read-outs from the pivotal investigation are scheduled for 2023.

"This is the first clinical investigation of our DTx, developed in partnership with Alex Therapeutics. We are very pleased to see these results emerge from this small patient population in the pilot study. We have already learned much that will prove useful not only for the pivotal phase but also for our other clinical trials with C21 in IPF." said Jessica Shull, Head of Digital Therapeutics at Vicore.

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About Digital Therapeutics (DTx)

DTx products are clinically evaluated software, designed, built, and tested to treat a disease or condition. DTx are medical devices and subject to medical device regulations in the country of use. DTx products can be a stand-alone software, or used in conjunction with another therapy. As interest in DTx from pharmaceutical companies and medical professionals has grown, authorities in Europe and elsewhere have developed new assessment frameworks, requiring that digital therapeutics are shown to be clinically safe and effective before regulatory approval.

About Almee™, Vicore's digital therapeutic for pulmonary fibrosis

Almee™ (an investigational medical device pending FDA clearance) is a digital therapeutic (DTx) based on cognitive behavioral therapy (CBT) to address the psychological impact of living with pulmonary fibrosis. Almee™ will be evaluated through real-world pilots and clinical studies as well as secure regulatory approvals, according to national and international medical device development standards.

***About GAD-7**

GAD-7 is a self-administered patient questionnaire used as a screening tool and severity measure for generalised anxiety disorder (GAD). Spitzer RL, Kroenke K, Williams JB, et al; A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May 22;166(10):1092-7.

About Alex Therapeutics AB

Alex Therapeutics is a digital therapeutics (DTx) company that partners with pharmaceutical companies to create and license digital therapies. With the proven "Alex DTx Platform", expertise in patient-centric design, and evidence-based psychology, Alex Therapeutics is uniquely positioned to deliver safe and effective DTx Software-as-a-medical-devices (SaMDs) to the global market. The company has treated tens of thousands of patients, has clinically validated products, as well as overwhelmingly positive patient and partner testimonials. For more information, visit www.alextherapeutics.com.

About Vicore Pharma Holding AB (publ)

Vicore is an innovative Swedish clinical-stage pharmaceutical company dedicated to creating life-changing treatments in diseases where the Angiotensin II type 2 receptor (AT2R) has a central role for the disease pathology. 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. In the VP03 program new AT2 receptor agonists are developed. VP04 is a clinically validated digital therapeutic in development for IPF patients.

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