



## Vicore launches COMPANION, a clinical study investigating the benefit of digital therapy on anxiety in patients with idiopathic pulmonary fibrosis (IPF)

- First clinical study with a digital therapy (DTx) in patients with IPF to address the psychological symptom burden in this disease
- First patient enrolled in US pilot phase leading up to the US pivotal phase of the study with expected start in H2 2022
- DTx aims to form a part of a differentiated offering in rare lung disease

**Gothenburg, April 21, 2022 – Vicore Pharma Holding AB (publ) (“Vicore”), a clinical-stage pharmaceutical company, today announces the first patient enrolled in the pilot phase of COMPANION<sup>1</sup>, a clinical study of a digital cognitive behavioral therapy for patients with IPF.**

Patients with IPF have a life expectancy of three to five years, during which dyspnea, fatigue and cough gradually worsen and in a preceding study, it was shown that 63% of IPF patients report a moderate to severe level of anxiety<sup>2</sup>. Cognitive behavioral therapy (CBT) is a well-established method to help patients with the psychological burden caused by severe disease and a digital CBT has the advantage of being accessible around-the-clock and can be personalized to meet the patient’s needs.

COMPANION is a fully digitalized, randomized, controlled parallel-group clinical study to evaluate the impact of the digital therapy Almee™ on the psychological symptom burden in adults diagnosed with IPF. The COMPANION study consists of two phases; a pilot study designed to refine the interactive nature of the therapy session, followed by a pivotal study. The study will take place in the US and is expected to conclude in H1 2023, after which Vicore will seek FDA clearance for Almee™ as a medical device and is expected to be made available to patients in 2024. Almee™ is developed in collaboration with Alex Therapeutics AB\* and the COMPANION study is conducted using virtual clinical solutions developed by Curebase Inc\*.

*“We are very excited to have randomized our first patient in the pilot phase of the COMPANION study. This study will not only help to elucidate the effect of anxiety on IPF patients’ quality of life, it will also explore the benefits of cutting edge digital treatment.”* says Professor Maureen Horton, principal investigator of COMPANION, Johns Hopkins University.

*“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 IPF patient group. This decentralized clinical study 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.

### **For further information, please contact:**

Carl-Johan Dalsgaard, CEO

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<sup>1</sup> NCT05330312

<sup>2</sup> Vicore data on file



Phone: +46 70 975 98 63

E-mail: [carl-johan.dalsgaard@vicorepharma.com](mailto:carl-johan.dalsgaard@vicorepharma.com)

### **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 in IPF**

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 IPF. Vicore is collaborating with Alex Therapeutics for the development of this medical device product<sup>3</sup>. 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.

*\*For more information see [Alex Therapeutics AB](#) and [Curebase Inc](#) websites.*

*This information was submitted for publication on April 21, 2022 at 09:30 CET.*

### **About Vicore Pharma Holding AB (publ)**

*Vicore is a clinical-stage pharmaceutical company focused on developing innovative medicines in severe lung 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), pulmonary artery hypertension (PAH) and COVID-19. 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 IPF patients.*

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

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<sup>3</sup> <https://vicorepharma.com/investors/press-releases/press/?releaseID=92C77E493C3A21FD>