

## **Clinical study investigating Alex Therapeutics' and Vicore's standalone digital therapy (DTx) treating anxiety in patients with idiopathic pulmonary fibrosis (IPF) has launched in the US**

- **The DTx, Almee™, under clinical study was built on Alex Therapeutics proprietary “Alex DTx Platform”<sup>1</sup>**
- **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 US pivotal phase of the study**
- **The DTx is developed by Alex Therapeutics in collaboration with Vicore Pharma (“Vicore”). Vicore is responsible for the clinical validation and commercialisation of the DTx**

**Stockholm, April 21, 2022 - Alex Therapeutics, a Digital Therapeutics (DTx) Software as a Medical Device (SaMD) manufacturer, today announces the first patient enrolled in the pilot phase of the COMPANION<sup>2</sup> 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. 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 Alex will seek FDA clearance for Almee™ as a medical device and is expected to be made available to patients in 2024. Almee™ has been developed by Alex Therapeutics in collaboration with Vicore Pharma<sup>3</sup>, who are responsible for leading the clinical validation of the DTx and the subsequent commercialisation. The COMPANION study is conducted using virtual clinical solutions developed by Curebase Inc<sup>4</sup>.

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<sup>1</sup> <https://alextherapeutics.com/dtx-platform>

<sup>2</sup> NCT05330312

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

<sup>4</sup> <https://www.curebase.com/>

*“We’re excited to have begun the first the first step in clinically validating our Digital Therapeutic for IPF patients. This clinical pilot study, conducted using a decentralized clinical trial model, will provide invaluable clinical insights ahead of the larger pivotal phase of the study. Its been a pleasure working with Vicore and Curebase in launching this study and we look forward to continuing our collaboration.” - John Drakenberg Renander, CEO at Alex Therapeutics*

*“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.” - 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” - Jessica Shull, Director of Digital Therapeutics at Vicore.*

[Read Vicore press release here](#)

## **Press**

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## **About Alex Therapeutics**

Alex Therapeutics is a digital therapeutics (DTx) company based in Stockholm which designs and develops Software-as-a-Medical-Devices (SaMDs). With the proven “Alex DTx Platform”, expertise in artificial intelligence and evidence-based psychology, Alex Therapeutics is uniquely positioned to deliver cutting-edge and reliable DTx products. The company has treated tens of thousands of patients, has experience with clinical validation, and overwhelmingly positive patient testimonials. For more information, visit [www.alextherapeutics.com](http://www.alextherapeutics.com) or follow us on [LinkedIn](#).

**About Almee™, Vicore and Alex Therapeutics’ 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. Alex Therapeutics is collaborating with Vicore for the clinical validation and commercialisation of the medical device product. 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 Vicore Pharma Holding AB (publ)***

Vicore Pharma is a rare disease pharmaceutical company focused on fibrotic lung disease and related indications. 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 COVID-19. VP02 is based on 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 AT2R 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).

### **About IPF**

Patients diagnosed with IPF have a life expectancy of 3-5 years, during which their symptoms of severe shortness of breath, fatigue, and cough only worsen. Currently there are limited treatment options for IPF, even for symptomatic relief. The need to plan daily routines around the debilitating respiratory symptoms of IPF deepens anxiety and depression, particularly in patients experiencing a noticeable exacerbation in physical symptoms.

### **About Digital Therapeutics**

Digital therapeutics (DTx) are clinically proven medical treatments delivered digitally to patients. In recent years, interest in using software to treat various conditions has increased greatly, with a growing body of scientific literature documenting the effectiveness of DTx. They can be used either as standalone treatments or together with medication or other devices, are highly scalable and readily personalized. 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.