

Alex Therapeutics presents results from digital therapeutic pilot study showing nearly 50% reduction in anxiety

- The Digital Therapeutic (DTx) was developed by DTx leader Alex Therapeutics using the proprietary “Alex DTx Platform”¹ in partnership with Vicore Pharma
- In the study patients with Idiopathic Pulmonary Fibrosis (IPF) and anxiety were given the DTx
- Safety, functionality, and user experience were all studied and found positive
- Average reduction in anxiety, GAD-7*, was 4.2 points
- Pivotal phase of study is to be launched in Q4, 2022

Stockholm, 13th October, 2022 - Alex Therapeutics is a DTx Software-as-a-medical-device (SaMD) manufacturer developing and licensing digital app-based therapies for multiple indications. Today they announce positive results from the pilot phase of a clinical study² for one of their digital therapies treating anxiety in patients with the rare disease IPF. Using GAD-7, anxiety symptoms were shown to have been reduced by an average of 4.2 points, a 49% reduction.

The Pilot study was a 4-week, single-arm, decentralized, open-label clinical investigation in 10 patients with self-reported anxiety related to idiopathic pulmonary fibrosis (IPF). The primary objective of the study was to test the functionality, user experience, and safety of the DTx, which were all found to be positive.

Additionally, the trial provided encouraging early indications of efficacy. The patient-reported Generalized Anxiety Disorder (GAD-7*) results showed an average score reduction of 4.2. A reduction in the GAD-7 score of ≥ 2 points is regarded as clinically meaningful. These results, together with the safety, functionality, and user experience indications suggest that the DTx could serve as a reliable resource for addressing the psychological impact of living with IPF.

“We’re very pleased with these early efficacy results for one of our anxiety Digital Therapeutics’. Even though the patient population is small it’s a positive indication heading into the next phase of the clinical trial. Digital Therapeutics have tremendous potential for treating depressive and anxiety symptoms in somatic diseases and we look forward to continuing our work in the space.” says John Drakenberg, CEO & co-founder of Alex Therapeutics.

The full DTx, AlmeeTM, to which patients in this pilot were given limited access, has been developed by Alex Therapeutics in collaboration with Vicore Pharma, an innovative clinical-stage pharmaceutical company developing innovative medicines for severe lung disorders such as idiopathic pulmonary fibrosis (IPF). Vicore Pharma will have an exclusive license to commercialize the AlmeeTM DTx, starting in the US.

“We’re pleased with these results and working with Alex; co-collaboration on a DTx is complex but it has been a successful partnership. We look forward to the pivotal phase and being one step closer to

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

² NCT05330312

providing another resource for people with PF." said Jessica Shull, Head of Digital Therapeutics at Vicore.

The pivotal phase of the clinical study will be initiated during Q4 of 2022. The full DTx, Almee™, will then undergo a US-based 9-week, randomized, controlled, parallel-group decentralized clinical investigation that will include 250 patients with all forms of pulmonary fibrosis (PF).

Alex announced strategic commercial partnership with Pfizer earlier in 2022

Earlier in 2022 Alex Therapeutics announced a strategic commercial partnership with world-leading pharmaceutical company Pfizer. The companies are collaborating to provide evidence-based, clinically validated digital therapeutics to patients, starting in Germany.

[Read the full press release here](#)

About Almee™

Almee™ is a Digital Therapeutic (DTx) developed by Alex Therapeutics in collaboration with Vicore Pharma. DTx products are medical devices subject to national regulations requiring clinical evidence. Almee™ is a digital Cognitive Behavioural Therapy, based on traditional CBT methodologies, specifically conceived and designed for the Pulmonary Fibrosis community.

About Alex Therapeutics

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 or follow us on [LinkedIn](#).

For further information, please contact:

Alex Therapeutics

Sebastian Blendow, COO & CFO

Upplandsgatan 7, 11123 Stockholm, Sweden

E-Mail: press@alextherapeutics.com

Website: www.alextherapeutics.com

For inquiries regarding partnerships, please contact:

Gergana Almquist, Ph.D., Global Partnership Manager

E-mail: partner@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. The VP03 program develops 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.

[Read the full Vicore Press release here](#)

***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.