

# Vicore Reports Positive Results for the Pivotal Study of its Digital Therapy for Patients with Pulmonary Fibrosis

- The COMPANION pivotal study met the primary endpoint and demonstrated significantly reduced anxiety in patients with pulmonary fibrosis.
- Almee™ is the first digital therapy to address the psychological symptom burden of living with pulmonary fibrosis.

**Stockholm, January 4, 2024 – Vicore Pharma Holding AB (publ), unlocking the potential of a new class of drug candidates, angiotensin II type 2 receptor agonists (ATRAAGs), today announced positive results of the COMPANION study ([NCT05330312](#)), investigating the efficacy of Almee™, a 9-week digital cognitive behavioral therapy (CBT) accessed through a smartphone or tablet.**

The study met its primary endpoint, change from baseline in GAD-7 anxiety scores, with a statistically significant 2.7-point improvement of anxiety symptoms in the group treated with Almee compared to control, where a change in GAD-7 score of more than 1.8 points is considered clinically meaningful[1]. The GAD-7 scale is widely used in clinical practice as an assessment tool for anxiety; scoring ranges from 0 to 21 with four levels spanning minimal anxiety (0 to 4) to severe (15 to 21). The observed 2.7-point improvement reflects promising efficacy in reducing anxiety levels and offering tangible relief to individuals coping with pulmonary fibrosis (PF). Quality of life, measured by the K-BILD[2], was a key secondary endpoint and improved by 4.4 points compared to control, and the K-BILD psychological domain improved by 6.5 points.

The COMPANION study enrolled 108 participants from across the United States in a randomized, controlled, parallel-group clinical investigation evaluating the impact of Almee on the psychological symptom burden in adults diagnosed with pulmonary fibrosis. Living with a deadly disease for which there is currently no curative treatment available has a negative impact on mental health and quality of life[3]; the aim of Almee is to provide personalized and accessible psychological support for these patients.

*"It is very encouraging to see a digital CBT demonstrating a clear clinical benefit for individuals suffering from the mental health burden that accompanies pulmonary fibrosis,"* said COMPANION study Principal Investigator Dr. Maureen Horton, Professor of Pulmonary and Critical Care Medicine Johns Hopkins University School of Medicine, retired. *"Providing behavior-modifying tools that enhance quality of life represents a new addition to a comprehensive treatment approach for patients living with this devastating disease."*

*"We're so pleased to see these positive results in the COMPANION pivotal study,"* said Ahmed Mousa, Chief Executive Officer of Vicore, *"and believe that Almee can play a key role in combination with molecular therapies to address the suffering of individuals with pulmonary fibrosis in a holistic way."*

Vicore plans to present full results from the COMPANION study at a conference in 2024. The company will seek to advance Almee in partnership with the developers of approved and late-stage molecular therapies for the treatment of pulmonary fibrosis, spearheading the continued development of innovation in improved therapy with software-molecular combination therapies.

Almee is subject to medical device regulation in the United States and Europe and is developed in partnership with Alex Therapeutics.

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

*Vicore is an innovative clinical-stage pharmaceutical company unlocking the potential of a new class of drugs with disease-modifying potential. The company is establishing a portfolio in respiratory diseases, including idiopathic pulmonary fibrosis (IPF). C21 is a first-in-class orally available small molecule angiotensin II type 2 receptor agonist (ATRAG) currently in phase 2a development for IPF. Almee™ (an investigational medical device in clinical development) is a digital therapeutic based on cognitive behavioral therapy created to address the psychological impact of living with pulmonary fibrosis. Using its unique expertise in ATRAG chemistry and biology, Vicore is further fueling its pipeline with several new therapies across additional potential indications. 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 Alex Therapeutics**

*Alex Therapeutics, a digital health company, partners with pharmaceutical companies to help patients with disease and treatment-specific challenges through clinically validated apps. With its proven, scalable technology platform, as well as expertise in patient-centric design and evidence-based behavior change, Alex Therapeutics treats patients and supports healthcare professionals globally. Alex Therapeutics, alongside its partners, has extensive experience in multi-jurisdiction Software-as-a-Medical-Device (SaMD) regulatory processes, including CE and FDA approval, as well as clinical evidence generation for SaMDs. For more information, visit [www.alextherapeutics.com](http://www.alextherapeutics.com)*

[1] Kounali D, Button KS, Lewis G, Gilbody S, Kessler D, Araya R, Duffy L, Lanham P, Peters TJ, Wiles N, Lewis G. How much change is enough? Evidence from a longitudinal study on depression in UK primary care. *Psychol Med.* 2022 Jul;52(10):1875-1882. doi: 10.1017/S0033291720003700. Epub 2020 Nov 3. PMID: 33138872; PMCID: PMC9340848.

[2] King's Brief Interstitial Lung Disease (KBILD) is a 15-item validated health-related quality of life (HRQOL) questionnaire. Nolan CM, Birring SS, Maddocks M, Maher TM, Patel S, Barker RE, Jones SE, Walsh JA, Wynne SC, George PM, Man WD. King's Brief Interstitial Lung Disease questionnaire: responsiveness and minimum clinically important difference. *Eur Respir J.* 2019 Sep 5;54(3):1900281. doi: 10.1183/13993003.00281-2019. PMID: 31221807.

[3] Yohannes, AM (2020) Depression and anxiety in patients with interstitial lung disease, *Expert Review of Respiratory Medicine*, 14:9, 859-862, DOI: 10.1080/17476348.2020.1776118

**Attachments**

[Vicore Reports Positive Results for the Pivotal Study of its Digital Therapy for Patients with Pulmonary Fibrosis](#)