Vicore Announces FDA Breakthrough Device Designation for AlmeeTM, a Digital Therapy for Patients with Pulmonary Fibrosis

- AlmeeTM is the first digital therapy to address anxiety and quality of life in patients living with pulmonary fibrosis (PF).
- AlmeeTM has shown effectiveness in reducing anxiety symptoms and improving health-related quality of life in the COMPANION study as reported earlier this year, driving a 2.7-point increase in GAD-7 score and a 4.4 improvement in KBILD score

Stockholm, March 19, 2024 – Vicore Pharma Holding AB (publ), unlocking the potential of a new class of drug candidates, angiotensin II type 2 receptor agonists (ATRAGs), today announced FDA Breakthrough Device Designation status for AlmeeTM, a 9-week digital cognitive behavioral therapy (CBT), to be used as an adjunct treatment of anxiety symptoms related to PF.

The FDA Breakthrough Devices Program designates those medical devices that are evaluated as providing a more effective treatment for life-threatening or irreversibly debilitating diseases. Breakthrough designation reflects the effectiveness of this new therapy compared to treatment as usual for anxiety associated with pulmonary fibrosis and demonstrates the impactful nature of this digital therapy.

Almee is a patient-facing tool based on CBT principles accessed via a smartphone or tablet. The COMPANION study on Almee demonstrated a 2.7-point improvement over control in GAD-7 (generalized anxiety disorder scale) and a 4.4 improvement in KBILD (King's Brief Interstitial Lung Disease) total score for quality of life.

PF affects approximately 250,000 people in the United States[1], with increasing incidence[2]. Currently available therapies only slow the progression of this devastating and fatal disease. The physical burden of PF drives psychological impact with studies showing that 60% of patients with PF report having anxiety[3].

"Breakthrough designation sets Almee apart as an innovative and effective tool for PF patients, and it supports our ambition to help patients with pulmonary fibrosis by improving quality of life," said Ahmed Mousa, Chief Executive Officer of Vicore.

Vicore plans to present Almee and the COMPANION study at a pulmonology conference in 2024.

The company is seeking to advance Almee in partnership with the developers of approved and late-stage molecular therapies for the treatment of pulmonary fibrosis. "Almee represents the future of healthcare and is poised to deliver significant patient impact as an example of innovation in digital-molecular combination therapies," said Jessica Shull, PhD, Director of Digital Health at Vicore.

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 AlmeeTM
Almee was developed in collaboration with Alex Therapeutics and is a software built for patients to be used on smartphones or tablets. The application includes psychological exercises based on CBT principles, and other interactive methodologies designed to increase beneficial actions and thoughts and improve anxiety and quality of life.

About the COMPANION trial
The trial was an open randomized study in 110 patients who were not on cognitive behavioral therapy but could be on anxiolytic or anti-depressant therapy or both. Positive topline data in the study was reported in January 2024. The measurements were focused on anxiety using validated instruments like GAD-7, and on quality of life using the K-BILD questionnaire. The study was analyzed using predefined criteria and analysis methods.

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.

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

[1] www.pulmonaryfibrosis.org/understanding-pff/about-pulmonary-fibrosis/what-is-pulmonary-fibrosis
[2] Pergolizzi JV Jr, LeQuang JA, Varrassi M, Breve F, Magnusson P, Varrassi G. What Do We Need to Know About Rising Rates of Idiopathic Pulmonary Fibrosis? A Narrative Review and Update. Adv Ther. 2023 Apr;40(4):1334-1346. doi: 10.1007/s12325-022-02395-9. Epub 2023 Jan 24. PMID: 36692679; PMCID: PMC9872080.

[3] van Manen MJ, Kreuter M, van den Blink B, Oltmanns U, Palmowski K, Brunnemer E, et al. What patients with pulmonary fibrosis and their partners think: a live, educative survey in the Netherlands and Germany. ERJ Open Res. 2017;3:00065–2016

Attachments

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