Press Release
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Vicore receives Innovation Passport designation by the UK regulatory agency MHRA for C21 in IPF

Stockholm, March 29, 2023 – Vicore Pharma Holding AB (publ) ("Vicore"), unlocking the potential of a new class of drugs - angiotensin II type 2-receptor agonists (ATRAGs), today announces that the UK MHRA (Medicines and Healthcare products Regulatory Agency) has awarded Vicore Innovation Passport designation for C21 in idiopathic pulmonary fibrosis (IPF), a life-threatening and seriously debilitating condition.

- C21 recognized by MHRA as an innovative and potentially important medicine for the treatment of IPF
- Innovation Passport designation aims to accelerate time to market and facilitate patient access to innovative medicines
- Reduces development risks through the opportunity for extended support from regulatory and other stakeholders

The Innovation Passport is the entry point to the UK Innovative Licensing and Access Pathway (ILAP), aiming to accelerate time to market and facilitate patient access. C21 meets the ILAP qualifying criteria as an innovative medicine with potential benefit to patients with IPF – a rare life-threatening disease for which there is a significant patient and public health need[1].

"We are very pleased to see that the MHRA recognizes the potential benefits of C21 in IPF. The latest interim analysis of the phase 2a trial in IPF (AIR) shows at least a true stabilization over time of the disease and we are committed to bringing C21 to patients in need as soon as possible." says Carl-Johan Dalsgaard, CEO of Vicore.

Vicore has a strong history of collaboration with the scientific community, regulators, and patient representatives. The Innovation Passport designation provides a unique opportunity to further strengthen this multi-stakeholder collaboration. A toolkit supports the advancement of a product through to regulatory approval and can accelerate time to market.

"We look forward to exploring the opportunities to partner with MHRA, NICE (National Institute for Health and Care Excellence) and patient stakeholders in the UK through this innovative pathway" says Karin Eklund Vanderpol, Head of Regulatory Affairs at Vicore.

About ILAP, Innovation Passport and Target Development Profile

ILAP (Innovative Licensing and Access Pathway) was established in January 2021 to support innovative approaches to the safe, timely and efficient development of medicines to improve patient access. The Innovation Passport is granted by the ILAP Steering Group, consisting of representatives from MHRA (Medicines and Healthcare products Regulatory Agency), NICE (National Institute for Health and Care Excellence), SMC (Scottish Medicines Consortium) and AWTTC (All Wales Therapeutics and Toxicology Centre). The ILAP provides companies with opportunities for enhanced regulatory and other stakeholder input and includes access to a co-created Target Development Profile (TDP). The TDP toolkit supports the advancement of a product through to regulatory approval and patient access by creating a roadmap and identifying key areas for engagement.

About C21 – first-in-class ATRAG (angiotensin II type 2 receptor agonist)

C21 is an innovative, first-in-class, orally available, selective, small molecule ATRAG under development for the treatment of IPF (idiopathic pulmonary fibrosis). C21 has orphan drug designation in IPF both in Europe and the US. The novel and multimodal mechanism of action of C21 targets the underlying fibrosis in IPF by stimulating the protective arm of the renin-angiotensin system (RAS). Consequently, there is an effect in terms of promoting alveolar repair and maintenance of alveolar integrity thereby reducing fibrosis formation, stabilising disease, and increasing lung capacity.

About the phase 2a trial in IPF (AIR)

The main purpose of this therapeutic exploratory trial is to investigate the safety and efficacy of C21 in treatment-naïve patients with IPF. The trial is an open-label, single-arm trial in which C21 is given orally twice daily as monotherapy for 24 weeks with an option to continue treatment for another 12 weeks. Patients with IPF have a well-characterized decline in lung function. The effect of C21 on lung function, measured by change from baseline in FVC, is investigated. The trial has multiple centers with regulatory approvals obtained in the UK, India, Ukraine and Russia. The trial is paused in Ukraine and Russia due to the ongoing conflict. In November 2022, Vicore presented an interim analysis of 41 patients, further confirming the previous results with a stabilization of lung capacity already at week 6 and, as also seen in the previous interim analysis, a subsequent increase of lung capacity from weeks 18 to 36. The increase was more pronounced in IPF patients without end-stage destruction of lung parenchyma as documented by high resolution computer tomography (HRCT).

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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 AT2 (angiotensin II type 2) receptor has a central role in stopping and reversing disease pathology. The company is establishing a portfolio in rare lung diseases including idiopathic pulmonary fibrosis (IPF) and pulmonary arterial hypertension (PAH). C21 is a first-in-class orally available small molecule angiotensin II type 2 receptor agonist (ATRAG). Almee™ (an investigational medical device in clinical development) is a digital therapeutic (DTx) based on cognitive behavioral therapy (CBT) created to address the psychological impact of living with pulmonary fibrosis. Inhaled IMID is a new formulation and delivery route of thalidomide targeting the severe cough associated with IPF. With our unique expertise in the ATRAG biology we fuel our pipeline with several new assets with long patent life for a variety of diseases, some of which could be partnered while others can be taken to the market by Vicore.

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

[1] Innovative Licensing and Access Pathway. Guidance. Available at: https://www.gov.uk/guidance/innovative-licensing-and-access-pathway .

Attachments

Vicore receives Innovation Passport designation by the UK regulatory agency MHRA for C21 in IPF