

## Vicore obtains significant new patent protection for C21 in the US

**Stockholm, May 23, 2023 – Vicore Pharma Holding AB (STO:VICO) (“Vicore”) today announces issuance of a new US patent protecting an improved C21 formulation based on enteric coated compositions. The drug candidate C21 is currently in a phase 2a trial in idiopathic pulmonary fibrosis (IPF).**

The patent provides strong protection in the US because the granted patent claims:

- relate to any form of enteric coating of C21; and
- are not limited to any specific disease

**Carl-Johan Dalsgaard, CEO of Vicore comments** *“This is a very important milestone for Vicore. By prolonging protection in the US to at least 2041, it substantially increases the commercial potential of C21 in IPF beyond current assumptions based on orphan drug status and data protection.”*

The United States Patent and Trademark Office (USPTO) today issued US Patent No. 11,654,115 entitled “New Delayed Release Composition for Peroral Administration.” The patent relates to a new invention that fundamentally improves C21 uptake through enteric coated tablets that dissolve only when reaching the small intestine. The patent protects any form of enteric coating of C21 and is expected to last at least until 2041. Corresponding patent applications have been filed in multiple jurisdictions in Europe and the rest of the world, including China and Japan.

**“We are very pleased that the USPTO has recognized the unique benefits of this technology” says Johan Raud, CSO of Vicore.** *“Importantly, the patent provides protection for C21 in all diseases.”*

In an interim analysis of the ongoing phase 2a trial, C21 has shown unmatched effects by increasing lung capacity in patients with IPF, a devastating disease which untreated results in a steady decline in lung capacity and a typical life expectancy of three to five years after diagnosis. C21 acts by preventing the scarring process characteristic of IPF, thereby restoring alveolar integrity and improving lung function.

**“In IPF alone, the potential value of this critical patent is material considering that the US IPF market represents \$2.8 bn in annual sales, despite the limitations of current therapies”, says Carl-Johan Dalsgaard.**

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**About the renin-angiotensin system (RAS) and angiotensin II type 2 receptor (AT2 receptor)**

*RAS is a hormone system that regulates several important physiological processes. In this system, the AT1 receptor is a well-established drug target with angiotensin receptor blockers (ARBs) as a drug class, while the AT2 receptor has been more elusive and difficult to study. The AT2 receptor is part of the body's resolution and repair system and is thought to be protective in several diseases connected to ageing and cell senescence, including idiopathic pulmonary fibrosis (IPF), chronic kidney disease and heart failure, as well as cognitive disorders. Stimulating the AT2 receptor has been shown to be effective in combating disease in numerous animal models and clinical validation is well advanced in lung disease. Stimulating the AT2 receptor also dilates small diseased resistance vessels in animals and in humans, resulting in locally increased blood flow. With C21 as the first-in-class highly selective small molecule AT2 receptor agonist (ATRAG) taken into clinical trials, the therapeutic benefit of targeting the AT2 receptor is becoming increasingly apparent. Vicore is developing C21 for rare lung diseases and has a series of new ATRAGs in development for other indications, the first of which (C106) is in clinical phase 1.*

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

*Vicore is an innovative Swedish clinical-stage pharmaceutical company unlocking the potential of a new class of drugs to stop disease progression and restore function. The company is establishing a portfolio in rare lung diseases including idiopathic pulmonary fibrosis (IPF) and pulmonary hypertension (PH). C21 is a first-in-class orally available small molecule angiotensin II type 2 receptor agonist (ATRAG) currently in a phase 2a study of IPF. C21 is protected by US and European Orphan Designation. A variety of patents have been filed to provide further protection for C21, out to 2040 and onwards. 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. Using its unique expertise in the ATRAG biology Vicore is further fuelling its pipeline with several new small molecule drug assets, with long patent life and for a variety of indications, some of which could be partnered while others may 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](http://www.vicorepharma.com).*

**Attachments**

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