Vicore provides update regarding Phase 1 study of C106

- **While no major safety signal was observed with C106, a reported increase in blood pressure represents a challenge to further development**
- **Learnings will be leveraged to advance follow-on molecules; preclinical characterization to date reflects favorable properties in these molecules**
- **Development of C21 continues as planned with significant clinical development to date without any blood pressure signal**

Stockholm, October 27, 2023 – Vicore Pharma Holding AB (publ), unlocking the potential of a new class of drug candidates, angiotensin II type 2 receptor agonists (ATRAGs), announced today that the Phase 1 study of C106 has concluded and that Vicore will not continue further development due to a transient increase in blood pressure observed at doses believed to be in the clinically effective range.

The Phase 1 study of C106 (NCT05427253), initiated in June 2022, was designed as a double-blind, placebo-controlled, randomized first-in-human study to evaluate safety, tolerability, and pharmacokinetics of single and multiple ascending oral doses of the drug candidate from 5 to 300 mg. While there were no major safety signals or tolerability concerns in the doses tested, an increase in blood pressure was observed at twice-daily doses of 140 mg and higher.

“The increase in blood pressure of C106, an angiotensin II type 2 receptor (AT2R) agonist, is believed to be due to an off-target effect on the angiotensin II type 1 receptor (AT1R).” said Johan Raud, MD, PhD, Vicore’s Chief Scientific Officer. “The clinical development of C106 to date will help us rigorously optimize and advance our follow-on ATRAGs, which have substantially higher AT2R-to-AT1R selectivity. C21, which has had no safety signals on blood pressure, also has substantially higher AT2R-to-AT1R selectivity than C106.”

“Due to the diseases and clinical profile of the patient populations where we would have advanced C106, even modest effects on blood pressure represents a challenge,” said Rohit Batta, MD, Vicore’s Chief Medical Officer. “We would like to thank the trial participants and clinical site that participated in this Phase 1 study. Looking ahead, we are excited to complete the Phase 2a AIR study of C21 in idiopathic pulmonary fibrosis (IPF) and are on track to initiate the Phase 2b ASPIRE trial for C21 in IPF in the first half of next year.”

For further information, please contact:
Ahmed Mousa, CEO
Phone: +1-607-437-0235
E-mail: ahmed.mousa@vicorepharma.com

This information was submitted for publication on October 27, 2023, at 08:00 CEST.

About Vicore Pharma Holding AB (publ)
Vicore is an innovative clinical-stage pharmaceutical company unlocking the potential of a new class of drug candidates to stop disease progression and restore function. 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) currently in a phase 2a study of IPF. C21 is protected by US and European orphan drug

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 fueling 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.

Attachments

Vicore provides update regarding Phase 1 study of C106