PRESS RELEASE
16 October 2023 08:00:00 CEST

CINCLUS PHARMA'S PHASE II EGERD STUDY IN TWO PRESENTATIONS AT UEG

Cinclus Pharma Holding AB (publ) ("Cinclus Pharma"), a pharma company focused on the development of a novel treatment for gastroesophageal reflux disease ("GERD"), today announces that two abstracts from the company's phase II study, LEED, on its leading drug candidate linaprazan glurate, developed for the treatment of moderate to severe erosive GERD ("eGERD"), are being presented at the leading gastro conference United European Gastroenterology ("UEG") which is held in Copenhagen 14 – 17 October 2023. One of the abstracts focuses on linaprazan glurate's effectiveness, the other one on its safety.

"Since only leading and new research is selected by the UEG, we are incredibly proud that our data is presented not just once, but twice. It indicates that our P-CAB linaprazan glurate is very interesting for gastroenterology and that there is a need for effective treatment for unmet medical needs in eGERD. We are moving forward with the goal of bringing about a paradigm shift in the treatment of gastric acid related diseases," said Christer Ahlberg, CEO of Cinclus Pharma.

The abstract with a focus on effect; "Linaprazan glurate is very effective in the treatment of moderate to severe erosive esophagitis: a double-blind, randomized, dose-finding study" was presented on 15 October.

The abstract with a focus on safety; "Linaprazan glurate is well tolerated in the treatment of patients with erosive esophagitis: a double-blind, randomized, dose-finding study" will be presented at 8.30 on 16 October.

United European Gastroenterology (UEG) is Europe's leading non-profit organization for excellence in digestive health. The organization is an umbrella for multidisciplinary gastroenterology and has over 50,000 members. The UEG Week conference is organized every year, this year in Copenhagen 14–17 October.

As previously communicated, the primary objective of the LEED study was to support the dose selection of linaprazan glurate for phase III studies, through central assessment of the four-week endoscopic healing of eGERD. For Cinclus Pharma's primary patient population, patients with moderate to severe eGERD, the highest four-week healing rate in a linaprazan glurate dosing group was 89%, compared to 38% in the lansoprazole group.

More about the Linaprazan glurate Erosive Esophagitis Dose Ranging (LEED) study
The LEED trial was randomized, double-blind study conducted in the United States and Europe on patients with erosive esophagitis (eGERD). Patients were divided into two cohorts, one with patients having moderate to severe eGERD (Los Angeles (LA) classification grades C or D) and one with patients having milder eGERD (LA grades A or B) and preceding history of at least eight weeks healing course with proton pump inhibitor (PPI).

The primary objective of the study was to support dose selection of linaprazan glurate for the phase III program in eGERD, assessed as four-week endoscopic healing rates of eGERD, with safety and tolerability as secondary objectives. The number of patients needed for measuring efficacy was based on the patient cohort with moderate to severe eGERD.

In total, 248 patients were randomized to four weeks double-blind treatment with either one of the four dose levels of linaprazan glurate or the active comparator lansoprazole, a PPI in the approved eGERD healing dose, followed by four weeks open-label treatment with lansoprazole healing dose. Healing was defined as no presence of esophageal erosions, i.e., no erosive damage to the esophageal mucosa.

A retrospective central review of the endoscopy findings was performed after four weeks, and 162 patients with eGERD were available for evaluation of the primary endpoint. All enrolled 248 patients were included in the safety analysis.

For patients with moderate to severe eGERD, LA grades C or D, the highest four-week healing rate in a linaprazan glurate dosing group was 89%, compared to 38% in the lansoprazole group. While the study was not powered to demonstrate significance towards the comparator lansoprazole, the average healing rate in all C and D patients treated with linaprazan glurate was significantly higher than the healing rate in the lansoprazole group in a conservative post-hoc analysis (Fisher's exact test, mean harmonic p-value <0.05).

For all patients treated with linaprazan glurate, the mean healing rate was 80% compared to 69% in the lansoprazole treated group. For patients with milder eGERD, LA grades A or B, the highest four-week healing rate in a linaprazan glurate dosing group was 91%, compared to 81% in the lansoprazole group. Linaprazan glurate was generally well tolerated and safety data was comparable to that of lansoprazole, with the most reported adverse event being COVID-19, occurring in 4% of the total study population.

PRESS RELEASE
16 October 2023 08:00:00 CEST

For additional information, please contact:

Christer Ahlberg, CEO
Phone: +46 70 675 33 30
e-mail: christer.ahlberg@cinclusphar ma.com

Charlotte Stjerngren, IR
Phone: +46 70 876 87 87
e-mail: charlotte.stjerngren@cinclusphar ma.com

About Cinclus Pharma

Cinclus Pharma Holding AB (publ) is a clinical stage pharma company developing small molecules for the treatment of gastric acid related diseases. Its drug candidate linaprazan glurate represents a novel class of drugs, Potassium Competitive Acid Blocker (P-CAB), and provides a fast-acting control of intragastric pH by a different mechanism of action than proton-pump inhibitors (PPIs). For more information, please visit **www.cinclusphar ma.com**

Attachments

Cinclus Pharma's phase II eGERD study in two presentations at UEG