PRESS RELEASE
09 May 2023 08:00:00 CEST

CINCLUS PHARMA'S PHASE II EGERD STUDY IN ORAL PRESENTATION AT DDW

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 an abstract 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"), has been accepted as an oral presentation at Digestive Disease Week ("DDW"), a world leading gastro conference. The presentation is named: Linaprazan glurate is highly effective in treating moderate to severe erosive esophagitis: a double-blind, randomized, dose finding study.

"As only leading and novel research is selected for oral presentations, we are immensely proud of our data being selected for an oral presentation at DDW. It indicates that our P-CAB linaprazan glurate is highly interesting for the gastroenterology community and that there is a need for effective treatment for unmet medical needs in eGERD. The study results are stunning and a great achievement. We have taken an important step towards driving a paradigm shift in the treatment of gastric acid related diseases," said Christer Ahlberg, CEO of Cinclus Pharma.

As previously communicated, the primary objective of the LEED study is to support dose selection of linaprazan glurate for phase III studies, through central assessment of four-week to eight-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.

DDW, the world's premier meeting for physicians, researchers, and industry in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery, takes place May 6-9 in Chicago, IL, USA.

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.

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About linaprazan glurate

Linaprazan glurate is a prodrug of the P-CAB linaprazan, the main and active metabolite, developed originally by AstraZeneca. Linaprazan has been evaluated in 23 phase I studies and two phase II studies exposing a total of approximately 2,600 subjects to linaprazan. Linaprazan glurate is being developed for treatment of moderate to severe erosive gastroesophageal reflux disease (GERD). Linaprazan glurate has the potential to heal esophageal injuries and alleviate GERD symptoms more effectively than current pharmaceutical therapies including PPIs. The beneficial safety, efficacy and pharmacokinetic properties of linaprazan glurate was documented in a phase II study conducted in 2022.

About GERD

Gastroesophageal reflux disease (GERD) is a digestive disease that affects the lower esophageal sphincter (LES), the ring of muscle between the esophagus and stomach, causing retrograde flow of gastric content into the esophagus. This leads to erosions, acid regurgitations and heart burn. Approximately 133 million people of the adult population in the United States and the EU-30 suffer from reflux disease. The global acid reflux market is dominated by proton-pump inhibitors (PPIs). More than 20% of all GERD patients take PPIs off-label twice daily to overcome the incomplete symptom relief or supplement their treatment with over the counter-remedies. Despite frequent off-label prescription of high dosage PPIs, many patients still suffer from poor symptom control indicating a clear need for better drugs to treat GERD.

About Cinclus Pharma

Cinclus Pharma Holding AB (publ) is a clinical stage pharma company developing a small molecule for the treatment of gastric acid related and upper gastrointestinal diseases. Its leading drug candidate linaprazan glurate represents a new 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 oral presentation at DDW