PRESS RELEASE
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CINCLUS PHARMA INCLUDES THE LAST PATIENT IN ITS PHASE II EGERD STUDY

Cinclus Pharma Holding AB (publ), a biopharmaceutical company focused on the development of a novel treatment for gastroesophageal reflux disease ("GERD"), today announces that the last patient has been included in the company's phase II study of the company's leading drug candidate linaprazan glurate.

The study includes a total of 248 patients with severe erosive GERD (eGERD). The goal is to find the optimal dose for future phase III studies, based on healing of erosive esophagitis after four weeks.

"Patient recruitment in our phase II clinical trial conducted in the United States and Eastern Europe has recovered well after the pandemic, despite the crisis caused by the invasion of Ukraine. Thanks to hard work from the entire organization, we have now included the last patient. Thus, we have taken another important step towards driving a paradigm shift in the treatment of gastric acid related diseases," said Christer Ahlberg, CEO of Cinclus Pharma.

Now follows about two months of treatment of the last patient before the study closes. Validation and analysis are expected during the month and topline results of expected studies in October. The study results will form the basis for the study design of the upcoming registration-based phase III studies that are expected to begin in 2023.

Linaprazan glurate is a prodrug and belongs to the class P-CAB and is being developed for the treatment of severe GERD. Effective P-CAB is the new treatment regimen that is expected to replace the proton pump inhibitors (PPIs), and Cinclus Pharma's goal is to make linaprazan glurate best in class and to achieve a paradigm shift in the care of gastric acid related diseases. Thanks to the unique properties of linaprazan glurate, Cinclus Pharma has the chance to develop a drug that is clearly differentiated and well positioned in relation to other P-CABs and PPIs.

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About Cinclus Pharma and its lead candidate drug linaprazan glurate

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 is a fast-acting regulator of intragastric pH by a different mechanism of action than proton-pump inhibitors (PPIs). The beneficial safety and pharmacokinetic properties of linaprazan glurate have been documented in phase I studies. The Phase 2 study is ongoing in Europe and the US. Linaprazan glurate is a prodrug of the P-CAB linaprazan, developed originally by AstraZeneca. Linaprazan has been evaluated in 23 phase I, and two phase II studies in a total of approximately 2,500 subjects. Linaprazan glurate is being developed for treatment of severe Gastroesophageal reflux disease (GERD) and has the potential to heal esophageal injuries and alleviate GERD symptoms more effectively than current pharmaceutical therapies including PPIs.

Based on epidemiological data, the estimated size of this target population is 18.5 million and carries a Blockbuster potential (estimated sales exceeding USD 1 bn). The Company's management team has extensive experience from the pharmaceutical industry with special focus on the GI pharmaceutical area with experience from AstraZeneca and Novartis. For more information www.cinclus pharma.com

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. About 175 million people of the adult population in North America and Europe suffer from reflux disease. The global acid reflux market is dominated by proton-pump inhibitors (PPIs). On average 5-10% of eGERD Grades A and B and approximately 30% of patients with eGERD1) Grades C and D are unhealed after eight weeks on PPIs, and 78% of all GERD patients experience nocturnal symptoms despite PPIs - resulting in quality-of-life issues. More than 20% of all GERD patients take PPIs 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 severe GERD.
1) Erosive GERD

Attachments

Cinclus Pharma includes the last patient in its phase II eGERD study