

CINCLUS PHARMA COMPLETES IMP MANUFACTURING FOR PHASE III

Cinclus Pharma, a clinical-stage pharmaceutical company developing molecules for the treatment of acid-related diseases, announces today that the manufacturing of the Investigational Medicinal Product (IMP), to be used for the company's upcoming phase III study of linaprazan glurate for eGERD, has been successfully completed. Thus, the company is following its time plan for recruiting the first patient in 2025.

"This is the first time we are manufacturing our new formulation on a large scale, which is an important milestone to be able to start our phase III studies, especially given that it is a new formulation that has not been manufactured on a large scale before. Today's announcement bodes well for the future as the batch size is representative of a commercial batch and secures the coming commercial manufacturing. This also means that we are on track to be able to recruit the first patient in 2025," said Christer Ahlberg, CEO of Cinclus Pharma.

The manufacturing was done by Cinclus Pharma's partner, the Swiss company Lonza, one of the world's leading contract development and manufacturing organizations (CDMO), at its site in Florida, USA.

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About linaprazan glurate

Linaprazan glurate has been developed by Cinclus Pharma and is a prodrug of the P-CAB linaprazan, the main and active metabolite, originally developed by AstraZeneca. Linaprazan and linaprazan glurate have been evaluated in more than 30 phase I and two phase II studies, exposing over 3,000 individuals to linaprazan or linaprazan glurate. Linaprazan glurate is being developed for the treatment of severe gastroesophageal reflux disease (GERD). Linaprazan glurate has the potential to heal erosions in the esophageal mucosa caused by leaked stomach acid and to alleviate GERD symptoms more effectively and rapidly than current pharmaceutical treatments, including proton pump inhibitors (PPI). The favorable safety, efficacy, and pharmacokinetic properties of linaprazan glurate have been documented in several phase I and one phase II study. Planning for the initiation of the phase III program is underway, with an expected study start in 2025.

About GERD

Gastroesophageal reflux disease (GERD) is a digestive disorder that affects the lower esophageal sphincter (LES), the ring of muscle between the esophagus and the stomach, causing a backflow of stomach contents into the esophagus. This leads to erosions, acid reflux, and heartburn caused by stomach acid. Approximately 133 million adults in the US and EU-30 suffer from GERD. The global market for acid reflux is dominated by proton pump inhibitors (PPI). To heal the most vulnerable patients with the most severe erosions, acid control must be maintained around the clock. Overall, about 10 million patients in the EU and the US suffer from the most severe form of eGERD. Many of these are not helped by the current standard treatment, indicating a clear need for better medications to treat GERD. Linaprazan glurate is developed to meet these patients' needs.

About Cinclus Pharma

Cinclus Pharma Holding AB (publ) is a clinical late stage pharma company developing a small molecule for the treatment of gastric acid-related diseases and disorders of the upper gastrointestinal tract. Its drug candidate linaprazan glurate represents a novel class of drugs, Potassium-Competitive Acid Blockers (P#CAB), and provides a fast-acting control of intragastric pH by a different mechanism of action than proton pump inhibitors (PPIs), with unique capacity to deliver acid control, pH>4, around the clock. For more information, please visit www.cincluspharma.com.

Attachments

Cinclus Pharma completes IMP manufacturing for phase III