

CINCLUS PHARMA APPOINTS PSI AS CRO FOR ITS EGERD PHASE III PROGRAM

Cinclus Pharma (“the Company”) announced today that Swiss-based global company PSI CRO will serve as the clinical research organization (CRO) for the phase III program of the Company’s lead drug candidate, linaprazan glurate, for the treatment of erosive gastroesophageal reflux disease (eGERD).

The program will involve approximately 500 patients at nearly 100 sites across Europe and the USA. Recruitment of the first patient is planned for 2025, with the first readout of healing data expected in 2026.

Linaprazan glurate is a new drug developed to provide effective, fast, and long-lasting symptom relief in patients with erosive gastroesophageal reflux disease. It has shown superior results to standard-of-care in previous clinical studies and is expected to offer an improved treatment option for patients suffering from this chronic disease.

"We are very pleased to initiate this strategic partnership with PSI," said Christer Ahlberg, CEO of Cinclus Pharma. "After a comprehensive evaluation process involving more than ten different CROs, it became clear that PSI has the experience and expertise needed to conduct our phase III program for eGERD successfully. Their global presence, experience in the GI field, and strong track record, not least in timely delivery, make them the optimum partner. We look forward to taking the next step in the development of linaprazan glurate together with PSI to be able to offer a new and effective treatment for patients with severe erosive GERD."

"Gastrointestinal disease is a key focus for PSI, a passion we share with the pioneers in GERD treatment at Cinclus Pharma and our global network of over 4,000 experienced GI sites," said Kasia Moscicka, Head of Feasibility at PSI. "We are proud to leverage this dedication to help advance Cinclus Pharma's clinical program and bring hope to patients affected by erosive GERD worldwide."

About PSI

PSI is a privately-owned, full-service clinical research organization (CRO) operating globally. PSI's global reach supports clinical trials across multiple countries and continents and specializes in the planning and execution of global pivotal registration clinical trials. With an exceptionally high repeat and referral business rate combined with minimal staff turnover, PSI is committed to being the best CRO in the world as measured by its employees, customers, investigators, and vendors. Global headquarters are located in Switzerland at 113a Baarerstrasse, Zug 6300. www.psi-cro.com.

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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 appoints PSI as CRO for its eGERD phase III program