

CINCLUS PHARMA ACHIEVES KEY PHASE III MILESTONE: LAST PATIENT SCREENED IN HEEALING1 STUDY

Cinclus Pharma Holding AB (publ), a clinical pharmaceutical company developing next-generation treatments for gastric acid-related diseases, today announced the successful completion of screening of patients in the pivotal Phase III HEEALING1 trial evaluating linaprazan glurate in erosive gastroesophageal reflux disease (GERD). The company is on track to deliver topline results in Q4 2026.

Linaprazan glurate is a next-generation potassium-competitive acid blocker (PCAB) that demonstrated strong efficacy in the **Phase II LEED study** (Linaprazan glurate Erosive Esophagitis Dose Ranging). In patients with moderate to severe erosive GERD, linaprazan glurate achieved four-week healing rates of up to 93% compared to 38% for comparator lansoprazole, a standard proton pump inhibitor (PPI). These results are particularly relevant given that standard PPI therapy fails to heal a significant proportion of the most severe patients, representing a substantial unmet medical need in an estimated 19 million patients worldwide.

“Data from our previous preclinical and clinical studies have demonstrated significant potential for linaprazan glurate. The HEEALING1 study is designed to confirm those results in a larger, well-powered patient population, and we look forward to presenting the study results,” said Kajsa Larsson, Chief Medical Officer of Cinclus Pharma.

Following the completion of screening, after reaching the target number of screened patients, Cinclus Pharma is on track to deliver topline data in Q4 2026, marking an important step toward a potential regulatory submission and subsequent commercialization. The company’s second Phase III study, HEEALING2, which will also evaluate maintenance therapy, is the final study before submission for approval and is planned to commence in both the US and Europe following the HEEALING1 readout.

“HEEALING1 has enrolled on schedule and we remain on track to report topline results before year-end. The unmet medical need in severe erosive GERD is well-documented, and our Phase II data give us strong confidence in linaprazan glurate’s ability to deliver meaningfully better outcomes for this patient population. We view the upcoming topline readout from the study as a key clinical milestone for Cinclus Pharma,” said Christer Ahlberg, CEO of Cinclus Pharma.

About the HEEALING1 Study

The pivotal HEEALING1 (Healing of Erosive Esophagitis with unique Acid control using Linaprazan Glurate) study is designed to confirm the efficacy of linaprazan glurate in

patients with erosive GERD. The randomized, double-blind trial compares linaprazan glurate to the current standard of care, a proton pump inhibitor (PPI), with a primary focus on superior healing rates, faster healing time, and improved symptom control. The trial enrolls approximately 500 patients in eight European countries. Participants undergo an up to eight-week treatment period. The primary endpoint is superiority to the proton pump inhibitor lansoprazole in healing of patients with moderate to severe erosive GERD (LA grade C/D) after 4 weeks. Secondary endpoints include healing and symptom relief for up to 8 weeks.

Top-line results from the HEEALING1 study are expected in Q4 2026. The second healing study, HEEALING2, which will also evaluate maintenance therapy, and represents the final study prior to regulatory submission, is planned to commence in both the US and Europe following the topline results of HEEALING1.

About Linaprazan Glurate

Linaprazan glurate is a next-generation of potassium competitive acid blockers (PCAB) with a unique acid control inhibiting profile that enables enhanced healing and symptom relief in patients with severe forms of acid-related diseases. It is a prodrug of linaprazan, designed to optimize pharmacokinetics by providing sustained acid suppression with lower peak plasma concentrations.

Phase II data for linaprazan glurate have demonstrated robust healing efficacy, particularly in patients with severe erosive GERD. In the randomized, double-blind LEED study, linaprazan glurate achieved healing rates of up to 93% at four weeks in patients with LA grade C/D disease, compared to just 38% for lansoprazole. In patients with only partial response after 8 weeks of PPI treatment, linaprazan glurate showed 100% healing after 4 weeks of treatment in the best dosing group.

About Erosive GERD

Erosive GERD is a severe form of GERD characterized by visible erosions or ulcerations in the esophageal lining, typically confirmed via endoscopy. Severity is graded from A to D using the Los Angeles Classification system, with grades C and D representing the most extensive mucosal injury.

Patients with severe erosive GERD often experience more persistent symptoms, slower healing, and a reduced response to conventional PPI therapy. This population represents a significant unmet medical need, with an estimated 19 million patients affected globally, including over 10 million in Europe and the US. In patients with LA grade C/D disease, healing rates with PPIs at four weeks can be as low as 30–40%, underscoring the need for more effective treatment options.

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About Cinclus Pharma

Cinclus Pharma Holding AB (publ) is a late-stage clinical pharmaceutical company developing drugs for the treatment of acid-related diseases and disorders of the upper gastrointestinal tract. The company's leading drug candidate is linaprazan glurate, a prodrug of P-CAB linaprazan, which was originally developed by AstraZeneca. Linaprazan glurate has the potential to heal erosions in the esophageal mucosa and relieve symptoms of gastroesophageal reflux disease (GERD) more effectively than current treatments like proton pump inhibitors (PPI). The safety and efficacy of linaprazan and linaprazan glurate have been documented in over 30 phase I and two phase II studies involving more than 3,000 participants. The first Phase III study commenced in 2025. GERD affects approximately 133 million adults in the US and EU, and there is a significant need for new drugs to treat the most severe cases: around 10 million patients. Linaprazan glurate is developed to meet these needs. For more information, visit www.cincluspharma.com.

Attachments

Cinclus Pharma Achieves Key Phase III Milestone: Last Patient Screened in HEALING1 Study