

CINCLUS PHARMA HAS REACHED ENROLLMENT TARGET IN PHASE III HEEALING1 STUDY – TOPLINE RESULTS EXPECTED Q4 2026

Cinclus Pharma Holding AB (publ), a clinical pharmaceutical company developing next-generation treatments for acid-related diseases, today announced that the randomization target has been reached in HEEALING1, the company's pivotal Phase III study evaluating linaprazan glurate for the treatment of erosive gastroesophageal reflux disease (GERD).

HEEALING1 is a randomized, double-blind study that has, as of today, randomized 521 patients, exceeding the protocol-specified target of 501 patients. A few additional patients are currently in screening and are expected to be randomized over the coming days. The primary endpoint is superiority to lansoprazole in healing of moderate to severe erosive GERD (LA grade C/D) after four weeks, with secondary endpoints assessing healing and symptom relief at up to eight weeks of treatment.

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

"Reaching the enrollment target in HEEALING1 is an important step for our program and for the more severe GERD-patients who currently have few effective treatment options. The study is designed to confirm in a large, well-powered population what our Phase II data have already shown, and we look forward to reporting those results later this year," said Kajsa Larsson, Chief Medical Officer of Cinclus Pharma.

"The completion of enrollment in HEEALING1 represents an important operational achievement for Cinclus Pharma and keeps us on track to report topline results in Q4 2026. Severe erosive GERD remains an area of significant unmet medical need, and we believe linaprazan glurate has the potential to meaningfully improve treatment outcomes. As we now turn our focus to study completion and data readout, we look forward to the next stage in the program's development," said Christer Ahlberg, Chief Executive Officer of Cinclus Pharma.

The company's second and final Phase III study for the main indication erosive GERD, HEEALING2, will also evaluate maintenance therapy and is planned to commence in both the US and Europe following the HEEALING1 topline readout.

About the HEEALING1 Study

The pivotal HEEALING1 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 primary focus on superior healing rates, faster healing time, and improved symptom control. The trial has randomized 521 patients in eight European countries. Participants undergo an 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 will 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, that will also evaluate maintenance therapy 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 has Reached Enrollment Target in Phase III HEEALING1 Study – Topline Results Expected Q4 2026