

CINCLUS PHARMA HAS COMPLETED ALL PATIENT VISITS IN PHASE III HEEALING1 STUDY; TOPLINE RESULTS EXPECTED IN Q4 2026

Cinclus Pharma Holding AB (publ), a clinical-stage pharmaceutical company developing next-generation treatments for acid-related diseases, announced today that the last patient has completed the final safety follow-up visit four weeks after the end of the treatment period (Last Patient Last Visit) in the Phase III HEEALING1 study, marking the completion of all planned patient visits in the pivotal study. The Company continues to expect topline results in Q4 2026.

The milestone follows completion of the eight-week treatment period in September. With all planned patient visits now complete, the dataset will be prepared for the Q4 2026 topline readout.

Linaprazan glurate is a next-generation potassium-competitive acid blocker (PCAB) that demonstrated strong efficacy in the **Phase II LEED study**. In LEED, patients with moderate to severe erosive GERD achieved four-week healing rates of up to 93% with linaprazan glurate compared to 38% for lansoprazole.

Standard proton pump inhibitor (PPI) therapy fails to heal a significant proportion of patients with the most severe forms of erosive GERD, representing a substantial unmet medical need across an estimated 19 million patients worldwide.

Positive topline results would represent a key step toward regulatory submission, supporting commercialization in Europe through the licensing agreement with Zentiva and in the US, where Cinclus Pharma currently retains full commercial rights. The company's second Phase III study, HEEALING2, which will evaluate maintenance therapy as required by both the FDA and EMA, is planned to commence in both the US and Europe following the HEEALING1 topline readout.

"Many patients with severe erosive GERD do not achieve complete healing with current treatments. We believe linaprazan glurate has the potential to offer a better option for these patients," said Christer Ahlberg, CEO of Cinclus Pharma. "With all planned patient visits in HEEALING1 now complete, we remain on track to report topline results in Q4 2026. We are grateful to the patients, investigators and clinical teams who made the study possible."

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 includes

523 patients in eight European countries. 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.

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 has 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, with a substantial proportion failing to achieve complete healing. 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 completed all patient visits in Phase III HEEALING1 study; topline results expected in Q4 2026