

## **CINCLUS PHARMA TO INITIATE HEEALING 1 PHASE III STUDY OF LINAPRAZAN GLURATE IN PATIENTS WITH EROSIVE GASTROESOPHAGEAL REFLUX DISEASE (GERD)**

**Cinclus Pharma Holding AB (publ), a clinical-stage pharmaceutical company developing the next generation of treatments for acid-related diseases, today announced the initiation of its Phase III HEEALING 1 study after receiving positive feedback from regulatory authorities. The study will evaluate linaprazan glurate for the treatment of Erosive Gastroesophageal Reflux Disease (GERD). The first patient is expected to be screened in September 2025, with topline results anticipated in 2026.**

The Phase 3 study HEEALING 1 (Healing of Erosive Esophagitis with unique Acid control using Linaprazan Glurate) will enroll approximately 500 patients across up to 100 clinical sites in seven European countries. The primary endpoint is to show superiority to the proton pump inhibitor lansoprazole in healing of patients with moderate to severe erosive GERD (LA grade C/D) after 4 weeks. Other endpoints will include healing and symptom relief for up to 8 weeks.

Cinclus and its commercial partner Zentiva see a strong potential for linaprazan glurate to become the first PCAB (potassium-competitive acid blocker) on the European market, representing a significant commercial opportunity in this area of high unmet need.

The company has also received feedback from the US Food and Drug Administration (FDA), permitting initiation of the study contingent on certain protocol adjustments. While the initial Phase 3 study will focus on Europe, Cinclus plans to extend development to the US through the second healing study, HEEALING 2, which will also evaluate maintenance therapy. This study is expected to begin as planned following the topline results of HEEALING 1.

"Initiating this Phase 3 study in collaboration with Zentiva marks a major and important milestone for both our company and the GERD community," said Christer Ahlberg, CEO of Cinclus Pharma. "By first initiating Europe and subsequently starting a US study, we are optimizing the path and the timing to market approval across all key regions. We see linaprazan glurate as having a strong potential to set a new standard in the treatment of severe erosive GERD."

Earlier this year, Cinclus Pharma entered into a strategic partnership and licensing agreement with Zentiva, a leading European pharmaceutical company, for the commercialization and manufacturing of linaprazan glurate in Europe. The total transaction value amounts to EUR 220 million, in addition to tiered royalties starting just below 20% and exceeding 20% at the highest sales levels. Part of this agreement is a milestone payment linked to the topline results of HEEALING 1, expected in H2 2026.

**For additional information, please contact:**

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**About Cinclus Pharma**

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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. Planning for phase III studies is currently underway, with an expected start 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](http://www.cincluspharma.com).

*This information is information that Cinclus Pharma Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-08-29 07:30 CEST.*

**Attachments**

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**Cinclus Pharma to initiate HEEALING 1 Phase III study of linaprazan glurate in patients with Erosive Gastroesophageal Reflux Disease (GERD)**