

## **CINCLUS PHARMA ANNOUNCES SCREENING OF FIRST PATIENT IN HEEALING 1 PHASE III TRIAL EVALUATING LINAPRAZAN GLURATE FOR THE TREATMENT OF EROSIIVE GERD**

**Cinclus Pharma Holding AB (publ), a late-stage clinical pharmaceutical company developing next-generation treatments for acid-related diseases, today announced the screening of the first patient with erosive gastroesophageal reflux disease (GERD) in its Phase III clinical trial of linaprazan glurate.**

"The initiation of our Phase III program marks a significant milestone in the development of linaprazan glurate. Current preclinical and clinical data have demonstrated strong potential, and this study will be essential in evaluating the efficacy and safety of linaprazan glurate in a broader patient population. We are excited to have started the study and look forward to the insights it will generate.", says Kajsa Larsson, Chief Medical Officer at Cinclus Pharma.

"Screening the first patient in our Phase III program represents an important achievement for Cinclus Pharma underscoring our commitment to advancing therapies for acid-related disorders, and marking our transition into a late-stage clinical company. We believe linaprazan glurate could set a new standard in this treatment landscape thanks to its unique 24hr acid control. With full funding beyond the topline results next year, we are well-positioned to advance the program.", says Christer Ahlberg, CEO, Cinclus Pharma.

### **About the HEEALING Study**

The pivotal HEEALING 1 study is designed to confirm the efficacy of linaprazan glurate in patients with erosive GERD. The randomized, double-blind trial will compare 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 will enroll approx. 500 patients across up to 100 clinical sites in seven European countries. Participants will 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 HEEALING 1 study are expected in H2 2026. The second healing study, HEEALING 2, that will also evaluate maintenance therapy is planned to commence in both the US and Europe following the topline results of HEEALING 1.

### **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. 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.

#### **For additional information, please contact:**

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Christer Ahlberg, CEO  
Phone: +46 70 675 33 30  
e-mail: [christer.ahlberg@cincluspharma.com](mailto:christer.ahlberg@cincluspharma.com)

Henrik Vikström, IR  
Phone: +46 70 952 80 06  
e-mail: [henrik.vikstrom@cincluspharma.com](mailto:henrik.vikstrom@cincluspharma.com)

## 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. 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](http://www.cincluspharma.com).

## Attachments

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**Cinclus Pharma announces screening of first patient in HEEALING 1 Phase III trial evaluating linaprazan glurate for the treatment of erosive GERD**