PRESS RELEASE
13 February 2026 08:00:00 CET

CINCLUS PHARMA RECEIVES POSITIVE ASSESSMENT OF ITS NONCLINICAL DEVELOPMENT PLAN FROM THE FDA

Cinclus Pharma Holding AB (publ), a late#stage clinical pharmaceutical company developing next#generation treatments for gastric acid#related diseases, today announced that the US Food and Drug Administration (FDA) has provided a positive assessment of the company's nonclinical development plan for its drug candidate linaprazan glurate following a scientific advice meeting.

During the meeting, the FDA expressed its support for Cinclus Pharma's nonclinical program, including the toxicology studies required ahead of a future New Drug Application (NDA). The Agency concluded that, based on the current information, there is no need for additional toxicological studies of linaprazan glurate.

"The FDA's positive assessment is a clear confirmation of the quality of our research and nonclinical program. The fact that the Agency does not see a need for any further toxicology studies brings both time and resource efficiencies and represents an important step toward our goal of offering patients a new and much#needed treatment.", says Christer Ahlberg, CEO of Cinclus Pharma.

The meeting, which focused on key elements of the nonclinical program, represents an important component of the regulatory process. Its purpose is to ensure that Cinclus Pharma has the nonclinical data required by the authorities to complete the remaining clinical studies ahead of a future NDA submission. The company will now advance its development activities as planned while maintaining close dialogue with the FDA throughout the upcoming steps in the process.

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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.cinclusphar ma.com**.

Attachments

Cinclus Pharma receives positive assessment of its nonclinical development plan from the FDA