PRESS RELEASE
21 October 2025 08:00:00 CEST

CINCLUS PHARMA RECEIVES POSITIVE FDA FEEDBACK ON CMC MEETING

Cinclus Pharma Holding AB (publ), a late-stage clinical pharmaceutical company developing the next-generation treatments for acid-related diseases, today announced that it received positive feedback from a recent Chemistry, Manufacturing, and Controls (CMC) meeting with the U.S. Food and Drug Administration (FDA), supporting continued advancement of its lead product candidate, linaprazan glurate.

The FDA provided clear guidance and alignment with Cinclus Pharma's proposed CMC strategy preparation for the upcoming new drug application (NDA) submission during the meeting. The agency did not raise concerns about the proposed strategy, reinforcing the company's confidence in its manufacturing approach and regulatory preparedness.

"We are very encouraged by the outcome of the CMC meeting with the FDA. This feedback represents an important milestone in our regulatory journey and supports our commitment to advancing linaprazan glurate to patients as efficiently and safely as possible.", says Christer Ahlberg, CEO at Cinclus Pharma.

The CMC meeting is a critical part of the regulatory pathway. During this meeting, the FDA evaluates whether the company's activities and plans are suitable for establishing reliable manufacturing processes and quality control systems. In other words, it assesses the overall readiness to produce a drug consistently and safely. These meetings are designed to identify and resolve any potential issues early in the development process, ensuring that the drug meets the agency's rigorous standards for quality and compliance.

The company remains on track with its development timeline and plans to continue close engagement with the FDA as the development continues.

For additional information, please contact:

Christer Ahlberg, CEO
Phone: +46 70 675 33 30
e-mail: **christer.ahlberg@cinclusphar ma.com**

Henrik Vikström, IR
Phone: +46 70 952 80 06
e-mail: **henrik.vikström@cinclusphar ma.com**

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 FDA feedback on CMC meeting