PRESS RELEASE
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CINCLUS PHARMA RECEIVES REGULATORY SUPPORT – EMA PROVIDES POSITIVE FEEDBACK ON CMC FOR LINAPRAZAN GLURATE

Cinclus Pharma Holding AB (publ), a late#stage clinical pharmaceutical company developing next#generation treatments for gastric acid#related diseases, today announced that the European Medicines Agency (EMA) has provided positive feedback following scientific advice regarding Chemistry, Manufacturing and Controls (CMC) for the drug candidate linaprazan glurate.

EMA's advice confirms that the company's planned CMC approach is well aligned with the requirements for the upcoming marketing authorization application. The agency clarified the expected supplementary data and considered the overall manufacturing strategy appropriate, further strengthening Cinclus Pharma's regulatory readiness going forward.

"The feedback from EMA represents another important step in our progression. In October, we received similar input from the FDA regarding our CMC plans, and it is encouraging to see both agencies now providing consistent support for our strategy. This positive feedback reinforces the view that Cinclus Pharma is well positioned to advance linaprazan glurate toward the market in a safe and efficient manner," says Christer Ahlberg.", CEO of Cinclus Pharma.

CMC guidance is a central component of the regulatory process and ensures that manufacturing methods, quality systems, and control strategies meet regulatory standards. Early engagement with regulatory authorities enables companies to identify and address potential challenges in the development process.

Cinclus Pharma continues to advance its development activities according to plan and intends to maintain close dialogue with both EMA and FDA in the upcoming stages of 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 regulatory support – EMA provides positive feedback on CMC for linaprazan glurate