PRESS RELEASE
16 June 2025 07:30:00 CEST

CINCLUS PHARMA SECURES EMA AND FDA PEDIATRIC STUDY WAIVERS FOR LINAPRAZAN GLURATE IN H. PYLORI INFECTION

Cinclus Pharma AB (publ), a clinical-stage pharmaceutical company developing next generation treatments for acid-related diseases, today announced that the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) have granted exemption from the requirement to conduct pediatric studies with linaprazan glurate for the treatment of *Helicobacter pylori* (*H. pylori*) infection.

In addition to treating eGERD, linaprazan glurate can in combination with antibiotics potentially be used to treat infections caused by *H. pylori*, a bacterium found in the stomach. *H. pylori* infection is a globally prevalent bacterial infection that affects more than half of the world's population and is associated with gastritis, ulcers and gastric cancer. The WHO lists *H. pylori* as one of the antibiotic-resistant bacteria that poses the greatest threat to human health.

Today, *H. pylori* infection is treated with acid-inhibiting drugs in combination with two or three antibacterial agents. Antibiotic resistance in these treatments is high and increasing, which is seen as a major problem. Cinclus Pharma's linaprazan glurate, with its unique acid control properties, has potential to be at least as effective or better than current standard treatments while requiring only a single narrow spectrum antibiotic - thereby reducing the antibiotic use and the risk of resistance.

The EMA and FDA waivers remove all requirements for pediatric studies, which would otherwise have been mandatory to obtain market approval in the EU and the US respectively for the treatment of *H. pylori* infection.

"These regulatory waivers represent a meaningful milestone for Cinclus Pharma, streamlining the potential development of linaprazan glurate in *H. pylori* and enabling us to pursue this significant market opportunity more efficiently. With a differentiated profile and reduced reliance on antibiotics, linaprazan glurate has the potential to redefine the treatment paradigm for *H. pylori* infection. A potential approval for *H. pylori* infection would extend the data exclusivity of linaprazan glurate from 5 to 10 years in the US and from 10 to 11 years in Europe.", says Christer Ahlberg, CEO of Cinclus Pharma.

Cinclus Pharma has full global commercial rights outside China for linaprazan glurate for the treatment of *H. pylori* as this indication was not part of the recently announced agreement with Zentiva for the commercialization and manufacture of linaprazan glurate on the European market.

PRESS RELEASE
16 June 2025 07:30:00 CEST

For additional information, please contact:

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

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

Attachments

Cinclus Pharma secures EMA and FDA pediatric study waivers for linaprazan glurate in H. pylori infection