PRESS RELEASE
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CINCLUS PHARMA AGREES ON PEDIATRIC STUDY PLAN WITH FDA

Cinclus Pharma, a clinical-stage pharmaceutical company developing molecules for the treatment of acid-related diseases, today announces that it has reached an agreement with the US Food and Drug Administration (FDA) on the company' s initial Pediatric Study Plan (iPSP). The regulatory agreement on a pediatric study plan is a prerequisite for market approval of a new medicine for adult patients, such as linaprazan glurate. It also provides an opportunity for an expanded approval for use in children.

"The agreement on our pediatric study plan with the FDA is a prerequisite for market approval in the US, so it's really a milestone. Now that we have agreed with both the EMA and the FDA, we have taken an important step towards making linaprazan glurate available to patients, thereby fulfilling a large unmet need. Furthermore, an approved pediatric indication would significantly increase the target population for linaprazan glurate," said Christer Ahlberg, CEO of Cinclus Pharma.

The company's agreed iPSP mainly includes a clinical efficacy and safety trial where approximately 100 pediatric patients will be treated with linaprazan glurate on the same treatment schedule as in the company's phase III trials in adult eGERD patients. The study plan is essentially the same as Cinclus Pharma recently agreed with the European Medicines Agency (EMAs) Pediatric Committee (PDCO).

A regulatory agreement of a pediatric study plan must be obtained before a sponsor may submit a Marketing Authorization Application for approval to commercialize a new medicine for adult patients. Cinclus Pharma submitted its proposed iPSP to FDA in December 2023 and has been going through the regulatory review processes since then. The company's agreed iPSP includes a deferral under which the pediatric efficacy and safety trial is anticipated to be undertaken after a Marketing Authorization Application has been submitted.

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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. 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.cinclusphar ma.com**.

Attachments

Cinclus Pharma agrees on pediatric study plan with FDA