PRESS RELEASE
29 October 2024 07:30:00 CET

CINCLUS PHARMA AGREES ON PEDIATRIC INVESTIGATION PLAN (PIP) WITH EMA

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 European Medicines Agency's (EMA) Paediatric Commmittee (PDCO) on the company's Pediatric Investigation Plan (PIP). The regulatory agreement on a pediatric study plan is a pre-requisite for marketing 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.

"It is incredibly satisfying that our pediatric study plan has been agreed. It is a prerequisite for market approval in the EU, so it's really a milestone. In addition, an approved pediatric indication would of course also significantly increase our target population," said Christer Ahlberg, CEO of Cinclus Pharma.

The company's agreed PIP 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.

When a new medicine is developed for adult patients, that medicine must also be tested for potential application to pediatric patients. The sponsor must develop an overall plan to select the specific form or stage of the disease to be treated, to adapt the dosing and administration of the medicine for pediatric physiology, and to evaluate the safety and efficacy of the medicine in pediatric patients.

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 PIP to EMA in December 2023 and has been going through the regulatory review processes since then. The company's agreed PIP 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 Investigation Plan (PIP) with EMA