PRESS RELEASE
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CINCLUS PHARMA: FDA DETERMINES THAT A SINGLE PIVOTAL STUDY IS THE NEW STANDARD FOR MARKET APPROVAL IN THE US – POSITIVE FOR THE COMPANY'S PHASE III PROGRAM

Cinclus Pharma Holding AB (publ), a late#stage clinical pharmaceutical company developing next#generation treatments for acid#related gastrointestinal diseases, today announces that the FDA has clarified that a single pivotal study, instead of two, will become the new standard for drug approval in the US, even for common diseases. This confirms that Cinclus Pharma's current Phase III program for erosive GERD is considered a sufficient basis for a regulatory submission in the US.

Cinclus Pharma welcomes the clear guidance now presented by the U.S. Food and Drug Administration (FDA) in the *New England Journal of Medicine*. The agency clarifies that an adequate and well#controlled pivotal study complemented by supportive evidence will become the new standard for approval of all drugs, including those for common diseases, in the United States. This means that the FDA is moving away from the historically established requirement for two pivotal studies per indication.

"This announcement from the FDA is important for Cinclus Pharma and the development of linaprazan glurate. It confirms that the Phase III program we are currently running meets the requirements for a regulatory submission in both US and Europe, " says Christer Ahlberg, CEO of Cinclus Pharma.

Cinclus Pharma initiated its Phase III program for linaprazan glurate in autumn 2025 with an initial healing study in Europe, where two pivotal studies are still required for healing of erosive GERD. Topline results from this study are expected in H2 2026 and will support the US regulatory submission. The program will be completed with a second healing study, planned in both the US and Europe, where patients, after they are healed, will also be studied and evaluated for maintenance treatment as required by both the FDA and EMA. In other words, this program is designed for approval in both the US and Europe.

Linaprazan glurate is the next generation PCAB (potassium#competitive acid blocker), offering superior acid control compared with existing treatment options and addressing the medical needs of patients suffering from the more severe forms of erosive GERD.

Granting marketing authorization based on a single adequate and well-controlled study, in combination with confirmatory evidence, has previously been accepted for certain medicinal products on a case-by-case basis. The PCAB that has already received marketing authorization in the US did so on the basis of one pivotal Phase III study conducted in the US.

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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.cincluspharma.com**.

Attachments

Cinclus Pharma: FDA Determines That a Single Pivotal Study Is the New Standard for Market Approval in the US – Positive for the Company's Phase III Program