

CINCLUS PHARMA ANNOUNCES POSITIVE FDA INTERACTION

Cinclus Pharma today announces that the company has completed a successful so-called end-of-phase-II meeting, with the US Food and Drug Administration (FDA) for the indication erosive gastroesophageal reflux disease (eGERD). The FDA broadly accepted Cinclus Pharma's proposal for the phase III program, including study design and primary endpoint for the studies. The positive outcome allows Cinclus Pharma to proceed with its phase III program.

"We are very pleased with the outcome of the meeting, which provided us with a clear and feasible regulatory roadmap to approval in the US. We now know what is required of us going forward, which allows us to continue to work on starting up our phase III program and other associated activities as soon as possible. There is a large need for more effective treatment for acid-related gastrointestinal diseases, and we notice that our P-CAB linaprazan glurate is very interesting for gastroenterologists", said Christer Ahlberg, CEO of Cinclus Pharma.

The purpose of this advisory meeting was to discuss the documentation for phase III and the planning of the study program needed for an approval. Among other things the meeting included discussions about the study design, the doses that Cinclus Pharma intends to conduct the studies with, and how the company is bridging from a previously used tablet formulation to a new, improved formulation.

Cinclus Pharma is now working to be able to include the first patients in the phase III studies. The intention is to recruit patients in the US, Europe and one additional region in 2024. By successfully conducting two randomized, double-blind, controlled studies involving approximately 1,000 patients each in 2024-2026, Cinclus Pharma plans to obtain market approval in 2027.

For additional information, please contact:

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

Charlotte Stjerngren, IR
Phone: +46 70 876 87 87
e-mail: charlotte.stjerngren@cincluspharma.com

About Cinclus Pharma

Cinclus Pharma Holding AB (publ) is a clinical stage pharma company developing small molecules for the treatment of gastric acid related diseases. Its drug candidate linaprazan glurate represents a novel class of drugs, Potassium Competitive Acid Blocker (P-CAB), and provides a fast-acting control of intragastric pH by a different mechanism of action than proton-pump inhibitors (PPIs). For more information, please visit www.cincluspharma.com

Attachments

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