PRESS RELEASE
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CINCLUS PHARMA RECEIVES QIDP DESIGNATION

Cinclus Pharma Holding AB (publ), a biopharmaceutical company focused on the development of a novel treatment for gastroesophageal reflux disease (GERD), today announces that the US Food and Drug Administration (FDA) has granted a Qualified Infectious Disease Product (QIDP) designation for the company's leading drug candidate linaprazan glurate for the treatment of Helicobacter pylori (H. pylori) infection allowing an additional five years of U.S. data exclusivity given that linaprazan glurate receives a marketing approval for the indication.

The QIDP designation is intended to encourage development of new drugs for the treatment of serious or life-threatening infections. Under FDA's Generating Antibiotic Incentives Now (GAIN) Act, a QIDP designation allows for fast-track status and priority review, potentially leading to a shorter New Drug Application (NDA) review time by the FDA, and, if approved, an additional five years of U.S. data exclusivity on top of the standard exclusivity period.

"We are very pleased to receive QIDP designation from the FDA for linaprazan glurate and are looking forward to working with the FDA to rapidly make this P-CAB, linaprazan glurate, available to patients. We are planning for phase III studies in *H. pylori* and GERD and are excited to get this important recognition from the FDA, potentially giving us a total of ten years of US data exclusivity from registration, the same as in EU," said Christer Ahlberg, CEO of Cinclus Pharma.

The work to finalize the phase II clinical trial with linaprazan glurate for the treatment of severe erosive GERD (eGERD) that has been conducted in the USA and Europe is currently ongoing. The top-line result will be presented during the fall 2022. The study results will form the basis for the study design of the upcoming pivotal phase III studies on GERD and *H. pylori* infection that are expected to begin in 2023.

About *H. pylori* infection
H. pylori is a bacterial pathogen that continues to be a major health problem worldwide. The World Health Organization has listed *H. pylori* among the sixteen antibiotic-resistant bacteria posing the greatest threat to human health. Linaprazan glurate has demonstrated superior gastric acid suppression over PPIs and will facilitate the antibiotic efficacy and subsequently improving the eradication rate of *H. pylori* infection.

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About Cinclus Pharma and its lead candidate drug linaprazan glurate

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 is a fast-acting regulator of intragastric pH by a different mechanism of action than proton-pump inhibitors (PPIs). The beneficial safety and pharmacokinetic properties of linaprazan glurate have been documented in phase I studies. The Phase 2 study is ongoing in Europe and the US. Linaprazan glurate is a prodrug of the P-CAB linaprazan, developed originally by AstraZeneca. Linaprazan has been evaluated in 23 phase I, and two phase II studies in a total of approximately 2,500 subjects. Linaprazan glurate is being developed for treatment of severe Gastroesophageal reflux disease (GERD) and has the potential to heal esophageal injuries and alleviate GERD symptoms more effectively than current pharmaceutical therapies including PPIs.

Based on epidemiological data, the estimated size of this target population is 18.5 million and carries a Blockbuster potential (estimated sales exceeding USD 1 bn). The Company's management team has extensive experience from the pharmaceutical industry with special focus on the GI pharmaceutical area with experience from AstraZeneca and Novartis. For more information www.cinclupharma.com

About GERD

Gastroesophageal reflux disease (GERD) is a digestive disease that affects the lower esophageal sphincter (LES), the ring of muscle between the esophagus and stomach, causing retrograde flow of gastric content into the esophagus. This leads to erosions, acid regurgitations and heart burn. About 175 million people of the adult population in North America and Europe suffer from reflux disease. The global acid reflux market is dominated by proton-pump inhibitors (PPIs). On average 5-10% of erosive GERD (eGERD) grades A and B and approximately 30% of patients with eGERD grades C and D are unhealed after eight weeks on PPIs, and 78% of all GERD patients experience nocturnal symptoms despite PPIs - resulting in quality-of-life issues. More than 20% of all GERD patients take PPIs twice daily to overcome the incomplete symptom relief or supplement their treatment with over the counter-remedies. Despite frequent off-label prescription of high dosage PPIs, many patients still suffer from poor symptom control indicating a clear need for better drugs to treat severe GERD.

Attachments

Cinclus Pharma receives QIDP designation