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# Cinclus Pharma receives approval of the International Nonproprietary Name (INN) linaprazan glurate for its lead drug candidate for the treatment of GERD.

**Stockholm, Sweden: Cinclus Pharma Holding AB ("Cinclus Pharma"), a biopharmaceutical company focused on the development of a novel treatment for severe gastroesophageal reflux disease ("GERD"), today announced that the World Health Organization (WHO) has designated linaprazan glurate as the International Nonproprietary Name (INN) for its lead drug candidate, formerly known as X842.**

Linaprazan glurate is a prodrug of the P-CAB linaprazan, developed originally by AstraZeneca in Sweden. Linaprazan was evaluated in 23 phase I, and two phase II studies respectively, including approximately 2,500 subjects, and was further supported by a full package of non-clinical data, showing the substance was effective and safe.

Cinclus has optimized linaprazan glurate for the treatment of Gastroesophageal reflux disease (GERD) with the potential to heal severe esophageal erosions and alleviate GERD symptoms more effectively, than current pharmaceutical therapies, including PPIs.

Following promising Phase I results Cinclus very recently announced the initiation of a Phase II dose ranging study with linaprazan glurate at multiple sites in the USA and Europe.

"The company is very pleased that the WHO has approved the INN, linaprazan glurate, which designation builds on the strong heritage of Astra Zeneca," stated Christer Ahlberg, CEO of Cinclus Pharmaceuticals. "This is another very important step towards bringing the product to market, as we look to complete Phase II and initiate our planned Phase III program next year. The INN will now be used in all our communications with stakeholders and the wider scientific community". he added. "There is a clear unmet need in this therapeutic area, as approximately 30% of patients treated with PPIs for GERD are not healed, and patients therefore continually seek medical alternatives "Christer concluded.

**For additional information, please contact:**

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**About Cinclus Pharma and its lead candidate drug X842**

Cinclus Pharma AB 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 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 management 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.cinclus pharma.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 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.