

PRESS RELEASE, April 24, 2019

**Cinclus Pharma announces news on the further development of X842 and secures financing through a directed share issue of SEK 28 million, to prepare initiation of clinical Phase 2 study**

**Cinclus Pharma Holding AB (“Cinclus Pharma”) today announced that it has completed a directed share issue of SEK 28 million to prepare initiation of a clinical Phase 2 study for its lead compound X482, for the treatment of severe erosive Gastroesophageal reflux disease (eGERD). Following the completion of the share issue, Cinclus Pharma further strengthened its equity position by converting a SEK 10 million debt into shares under a previously issued convertible loan.**

The Phase 2 study will be conducted at sites in Europe and the US. This randomized double blind, active comparator, dose-finding study will target 300 - 400 patients with severe eGERD, with a primary objective of demonstrating superior healing rates after four weeks compared to PPI. The plan is to conclude the study within 12 months after study start.

The fully subscribed share issue attracted a number of well-known investors within the Swedish Biotech and healthcare space, including Recipharm Venture Fund.

“We are very excited that we have been able to attract such strong and committed investors. Thanks to them, we have sufficient funding to prepare the next step in our accelerated development and clinical program for the treatment of severe eGERD, where there is a significant unmet medical need,” said Kjell Andersson, CEO and co-founder of Cinclus Pharma. “We are very glad to be able to join the funding of Cinclus Pharma with a strategic investment, where we hope that we also can contribute with industrial expertise in pharmaceutical development and manufacturing to a very interesting project,” said Carl-Johan Spak, Senior Vice President at Recipharm AB.

A Phase 1 study, which was concluded in 2018, showed that X842 was safe and well tolerated. Intra-gastric acidity, the strongly validated biomarker for healing of eGERD, was maintained above pH 4 for 24 hours after a single dose. The abstract of the study was selected as “Poster of Excellence” at the United European Gastroenterology Week in November 2018, which is the largest annual meeting in Europe, focused on GI related diseases. Such level of acid control indicates that close to 100% healing rate of eGERD is potentially achievable. The trial was an open label, single and multiple oral dose study in healthy volunteers receiving different dose regimens. Participants were allocated to treatment with increasing doses of X842, given as a single dose and multiple doses for five days.

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### **About GERD**

Gastroesophageal reflux disease (GERD) is a digestive disorder that affects the lower esophageal sphincter (LES), the ring of muscle between the esophagus and stomach. Many people suffer from heartburn or acid regurgitation caused by GERD. About 175 million people of the adult population in US and Europe suffer from reflux disease. The global acid reflux market – worth \$12-14bn - 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 impaired quality of life. More than 20% of the 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 or symptomatic GERD, and in particular therapies with an effect that is sustained for >24 hours.

### **About X842**

X842 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. X842 belongs to the P-CAB class that competitively inhibits the H<sup>+</sup>, K<sup>+</sup>-ATPase in the parietal cell and thereby controls gastric acid secretion. X842 is a prodrug of linaprazan, with comprehensive data from 25 Phase I studies including more than 600 subjects. Furthermore, two Phase II studies including 2,973 patients showed that linaprazan was well tolerated, with a fast onset of action and full effect at first dose. However, linaprazan was quickly eliminated from the body and had too short duration of acid inhibition. In comparison, X842 has a longer half-life in the body, shows total control of the gastric acid production, and is tailored for patients with severe eGERD.

### **About Cinclus Pharma**

The Swedish based company Cinclus Pharma Holding AB is the 100% owner of Cinclus Pharma AG, a research-based biotech company, based in Basel, Switzerland. It develops small molecules for the treatment of gastric acid related diseases. Its lead candidate, X842, has successfully completed a Phase I clinical trial. The company have an experienced management team with deep knowledge in the different aspects of drug development and business development, coming from both the multinational sector as well as the Biotech sector. The management team is highly experienced in the GI area (AstraZeneca, Glaxo and Novartis). [www.cincluspharma.com](http://www.cincluspharma.com).