

PRESS RELEASE
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Cinclus Pharma raises SEK 250 million for the continued development of a novel treatment against gastroesophageal reflux disease

Cinclus Pharma Holding AB (“Cinclus Pharma”) announced today that the company has successfully completed a financing round of SEK 250 million to fund the further clinical development of X842 – a clinical-stage drug candidate for the treatment of gastroesophageal reflux disease (GERD). The Fourth Swedish National Pension Fund (AP4) joined as a new major shareholder through the issue, which was also subscribed by, among others, the current shareholders Bengt Julander, Jonas Sjögren and Recipharm Venture Fund. X842 has the potential to alleviate GERD symptoms and heal esophageal injuries more effectively than current pharmaceutical therapies.

Gastroesophageal reflux disease (GERD) is a common medical condition characterized by regurgitation of gastric acid from the stomach into the esophagus. This can lead to severe pain and mucosal erosions. Currently available GERD treatments are not sufficiently effective to maintain a normal esophageal pH over the course of a full day. Among patients treated with proton pump inhibitors (PPIs) such as Losec® or Nexium®, about 40 percent experience unsatisfactory symptom alleviation. More than 35 percent of patients who suffer from severe esophageal erosions (grade C and D esophagitis) are not healed despite high dosage treatment with PPIs.

Cinclus Pharma’s drug candidate X842 represents a novel class of pharmaceuticals (Potassium Competitive Acid Blockers, P-CAB), which utilizes a different mode of action to modulate and control the release of gastric acid, as compared to PPIs. This novel approach provides a better way to alleviate symptoms and promote healing of the fretted mucosal lining. X842 is based on a substance initially developed by AstraZeneca that has been proven safe and well-tolerated in studies including over 2 500 individuals. The favorable safety profile and pharmacokinetic characteristics of X842 has been demonstrated in a Phase 1 clinical study.

The proceeds from the financing round will be used to perform a phase 2 clinical trial, which is expected to start in the second half of 2020, as well as operating costs and other key activities necessary to make the project ready for a pivotal phase 3 clinical trial program.

“The high level of interest from reputed and long-term investors provides us with the opportunity to bring our unique drug candidate, X842, all the way to a pivotal phase 3 clinical program. The introduction of Losec and other proton pump inhibitors in the 1980s and the 1990s was a major step forward in the treatment of GERD. However, there is potential to help significantly more patients to a better life by developing even more efficient drugs”, says Kjell Andersson, CEO at Cinclus Pharma.

Cinclus Pharma estimates that a superior pharmaceutical for the treatment of severe esophagitis (grade C and D), and other patient groups where PPIs are not sufficiently effective, may have a blockbuster potential.

Carnegie Investment Bank AB (publ) has acted as sole financial advisor to the company in the transaction.

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To the editors

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.

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 North America 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⁺, K⁺-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.