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First clinical study successfully completed with X842, an innovative promising treatment for severe erosive GERD

The Basel, Switzerland-based biotech company Cinclus Pharma AG today announced that it has successfully completed the first clinical Phase 1 study of its lead compound X842, for the treatment of severe erosive Gastroesophageal reflux disease (Erosive GERD Grade C and D).

The study showed that X842 was safe and well tolerated. The strongly validated biomarker for healing of erosive GERD (eGERD), intragastric acidity, was possible to maintain above pH 4 for 24 hours after a single dose. Such acid control indicates that 100% healing rate of eGERD is 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.

In the US and Europe, 20-40% of adult population suffer from reflux disease. The acid reflux market – worth $12-14bn - is dominated by proton-pump inhibitors (PPIs). Approximately 30% of the patients with severe eGERD – more than 14 million people - are unhealed after eight weeks on PPIs, and 78% of all GERD patients experience nocturnal symptoms despite PPIs - resulting in an impaired quality of life.

“The unmet medical need among patients with severe eGERD is well known and demands new therapeutic approaches. In the study, our lead candidate X842 showed total gastric acid control, and we believe this can become a superior treatment of severe eGERD compared to current therapies”, commented Kjell Andersson, CEO and co-founder of Cinclus Pharma.

Cinclus Pharma plans to initiate a clinical Phase 2 study in Europe and the US in Q2 2018. This randomized double blind, active comparator study with four treatment arms will target approximately 310 patients with severe eGERD, with a primary objective of demonstrating superior healing rates after four weeks. The plan is to have the study completed in Q4 2019.

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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).

Approximately 30% of patients with severe eGERD 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.

About Cinclus Pharma
Cinclus Pharma AG is a research- based biotech company, based in Basel, Switzerland and 100% owned by the Swedish based company Cinclus Pharma Holding AB. It develops small molecules for the treatment of gastric acid related diseases. Its lead candidate, X842, recently 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 and Novartis).

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