Cyxone makes further strides with Rabeximod phase IIb trial by signing CRO EGeen Inc.

Cyxone (publ), a Swedish biotech in autoimmune diseases, today announced that the company has signed an agreement with EGeen Inc., a clinical research organization (CRO), for conducting its upcoming clinical phase IIb trial with Rabeximod in rheumatoid arthritis (RA) in select Eastern European countries. Cyxone is now, together with several partners, finalizing the necessary applications for permission to run its phase IIb multicenter study in both Western and Eastern Europe. The first application has been submitted and the remaining, up to eight, applications are expected to be submitted within the next six months.

Cyxone has partnered with a number of companies bringing the specific expertise and knowledge required for the clinical phase II study during next few years. Cyxone’s clinical phase IIb trial in Eastern Europe with Rabeximod in RA will be conducted by EGeen Inc., a global full-service clinical research organization (CRO). EGeen has lengthy experience of conducting trials in Eastern Europe including filing submissions to regulatory bodies, selecting and training investigate sites, and monitoring data gathering during the trial. There are, however, a number of companies bringing the specific expertise needed for this clinical development. The CRO Sourcia, a long-term partner of Cyxone’s, is managing the clinical phase IIb study overall as well as conducting the clinical operations in select Western European countries. Sourcia is responsible for the preparation of the clinical phase IIb trial managing the development of critical documentation such as the study protocol, investigator’s brochure, patient consent form, case report form and Investigational Medicinal Product Dossier (IMPD). EGeen is also involved in the preparations by ensuring localized documentation and liaising with regulatory authorities locally in the select Eastern European countries.

Kjell G. Stenberg, CEO of Cyxone, commented: “Preparing for a clinical phase IIb trial requires intense work, why I am very pleased that we have highly-reputed and specialized partners such as EGeen and Sourcia supporting Cyxone in this. It gives me great confidence moving forward with our preparations of the trial and soon enough starting patient recruitment.”

The preparations ahead of a clinical trial is comprehensive and time-consuming, especially a multinational study given the different language and documentation requirements, why the first application for permission to start the phase IIb trial was submitted already in the beginning of July 2019 in Poland. Submissions in up to eight additional countries, including Estonia, Ukraine, Georgia and the Netherlands, will follow within the next six months. In parallel, further processes such as procuring suitable statisticians and analysts for the study data, selecting investigational sites and drug manufacturer with manufacturing authorization in Europe have been completed or are currently underway.

Cyxone will announce the response from the appropriate authorities once received and make further announcements as the preparations of the clinical phase IIb trial with Rabeximod in RA advances.
This press release contains forward-looking statements that constitute subjective estimates and forecasts about the future. Assessments about the future are only valid on the date they are made and are, by their nature, similar to research and development work in the biotech field, associated with risk and uncertainty. In light of this, actual outcomes may differ substantially from what is described in this press release.

**About the clinical phase IIb trial**

The clinical phase IIb trial with Rabeximod in RA is a multi-center, randomized, double-blind, placebo-controlled clinical trial where patients with moderate to severe RA, who have previously been treated with methotrexate with inadequate response, will be treated with Rabeximod for 24 weeks. The aim of the study is to confirm Rabeximod’s therapeutic effect as well as good safety and tolerability.

**About Rabeximod**

Rabeximod is an oral drug candidate in development for the treatment of moderate to severe active rheumatoid arthritis (RA) for patients who have previously been treated with methotrexate with inadequate response. The candidate has demonstrated a therapeutic effect in a placebo-controlled clinical phase II study in RA comprising more than 200 patients. The study was designed to measure the effect of Rabeximod after 12 weeks of treatment, although a statistically significant effect was only achieved four weeks after the stipulated study time (in week 16). The upcoming planned clinical phase IIb trial aims to confirm the effect with a 24-week study.

**About Cyxone**

Cyxone AB is a clinical stage biotech company with a portfolio of immunomodulating drugs for the treatment of autoimmune diseases such as multiple sclerosis (MS) and rheumatoid arthritis (RA). The company’s drug portfolio is based on two technological pillars in the form of oral molecules and cyclotide-based drugs that inhibit key processes in the body’s cells that are typically associated with various immune-related disorders. Cyxone’s technologies have the potential to address an unmet need and provide new effective and safe medicines that can improve the quality of life for patients affected by autoimmune diseases. The company has two drug candidates, T20K for MS in clinical phase I and Rabeximod for RA in clinical phase II-program. Cyxone’s Certified Adviser on the Nasdaq First North is Mangold Fondkommission AB, +46 (0)8-503 015 50, ca@mangold.se, www.cyxone.com