Press release
Cyxone AB (publ)
559020-5471
15 December 2020

Cyxone has filed an IND in the US with Rabeximod following positive feed-back from pre-IND meeting with the FDA

Cyxone (publ.), a clinical stage biotech company developing first-in-class drugs for diseases of the immune system, announced today that the company has filed an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) pertaining to its drug candidate Rabeximod. The application follows on a productive pre-IND meeting with the authority, where valuable advice was received on *inter alia* the protocol for its imminent European Phase 2 clinical study in moderate Covid-19. The IND covers the development of Rabeximod in Covid-19 and other indications, such as rheumatoid arthritis, and is a prerequisite for a future validation of the company's five recent patent applications in the US market.

Cyxone recently held a constructive pre-IND meeting (type B meeting) with the FDA, and the authority's advice has been incorporated in the study protocol for the clinical study of Rabeximod in Covid-19, which is expected to be initiated shortly in Europe. The filing of an IND will enable participation of US medical centers in future clinical studies of Rabeximod in Covid-19, rheumatoid arthritis and potential other indications. The IND package is based upon the favorable safety profile of Rabeximod shown in previous Phase 1 and Phase 2a studies. In Covid-19, Rabeximod is positioned as an oral treatment of moderately diseased patients – a group that is not addressed by current standard of care therapeutics.

"Filing an IND with the FDA is an important step in the clinical development of Rabeximod. It is a quality stamp on our drug candidate and Covid-19 trial and would enable us to expand the clinical development to the United States. Even as vaccines are becoming available, safe and convenient treatments for Covid-19 will be required to lower the death toll of the current global health emergency and to be better prepared for future pandemics", said Cyxone's CEO, Tara Heitner.

Cyxone recently announced that the company had received regulatory approval to initiate a randomized, placebo controlled, double blind, Phase 2 clinical trial of Rabeximod in Poland. In parallel, the company has submitted a Clinical Trial Application in Slovakia and is preparing for submissions in additional countries. Rabeximod will be evaluated in patients suffering from moderate Covid-19 in need of oxygen treatment but not ventilation support. In the study, 300 patients will receive Rabeximod orally at one of two dose levels or placebo for 14 days after which Cyxone will evaluate the study outcome. Cyxone aims to announce top-line results from the study in the third quarter of 2021.

”We look forward to initiating the Phase 2 study in Covid-19 patients as soon as possible, to provide important information about the safety and efficacy of Rabeximod in an acute setting”, said Cyxone’s Chief Operating Officer, Malin Berthold.

Contact

Tara Heitner, CEO
Tel: +46 70 781 88 08
Email: tara.heitner@cyxone.com
Adelgatan 21
211 22 Malmö, Sweden

This contains such information that Cyxone AB is required to make public under the EU’s Market Abuse Regulation. The information was provided under the auspices of the above contact person for publication on 15 December 2020 at 09.25 CET.

About Cyxone

Cyxone AB (publ) (Nasdaq First North Growth Market: CYXO) develops disease modifying therapies for diseases such as rheumatoid arthritis and multiple sclerosis as well as treatments for virally induced acute respiratory disorders. Rabeximod is a Phase 2 candidate drug being evaluated for the management of rheumatoid arthritis and moderate Covid-19 infections. T20K is a Phase 1 candidate drug for treatment of multiple sclerosis. Certified Adviser is Mangold Fondkommission AB, +46 (0)8 503 015 50, ca@mangold.se. For more information, please visit www.cyxone.com