Press release
Cyxone AB (publ)
559020-5471
1 April 2022

Safety confirmation and observed trends in Covid-19 study build further confidence in Cyxone's rheumatoid arthritis program

Cyxone AB (publ), the Swedish biotech company that develops disease modifying therapies for diseases such as rheumatoid arthritis (RA) confirms the previously demonstrated favorable safety and tolerability profile for its drug candidate Rabeximod, in the Clinical Study Report from its exploratory phase 2 study in Covid-19 patients. Other observations include a trend showing patients that were given Rabeximod, in comparison to the placebo group, had a higher rate of early release from the hospital. Exploratory endpoints analysis indicated modulation of disease relevant cytokine biomarkers by Rabeximod compared to the placebo group. These results are encouraging and will be further investigated in the upcoming RA trial. The study also supported the dose selection for the upcoming RA study.

All together the safety and the observed trends support and build confidence for the upcoming rheumatoid arthritis program phase 2b study which is the current focus for the company.

"I am pleased to see that Rabeximod is safe and well tolerated in this group of Covid-19 infected patients and I am very encouraged by the additional supportive observations. Safety and tolerability are crucial in all our clinical work. Data from this trial adds to the data we have collected historically in patients with rheumatoid arthritis, our primary indication for Rabeximod. We will now focus our resources for Rabeximod in the upcoming phase 2b study regarding rheumatoid arthritis. I'm proud that Cyxone took on the challenge and contributed to the global work of finding a drug for Covid-19," comments CEO Tara Heitner.

Cyxone's phase 2 Covid-19 study – in brief

The phase 2 Covid-19 study was carried out during the pandemic in 2020 and 2021, in order to support the global effort in identifying a drug for a new and unexplored severe disease. The study was designed in accordance with FDA's guidelines for Covid-19 studies. Rabeximod was tested on top of standard of care dexamethasone (placebo arm). The combination was compared to dexamethasone treatment alone. Top-line data was presented December 6th 2021. No statistical significant benefit between treatment and placebo arms was observed mainly due to a high placebo effect, meaning that most patients responded well to standard of care dexamethasone. The final data analysis concludes that Rabeximod is well tolerated in patients and the majority of reported adverse events were mild to moderate and assessed as not related to study drug. Overall, at this stage the benefit to risk profile remains favorable. The phase 2 Covid-19 study included 92 patients. The intended inclusion criteria were patients diagnosed with Covid-19 who exhibited moderate symptoms (having difficulty breathing, signs of pneumonia, potentially requiring oxygen but not requiring mechanical ventilation). The patients were randomized to three arms, Rabeximod 15 mg o.d (n=30), 30 mg o.d (n=30) or placebo (n=32) and constituting two types of patients (with and without oxygen therapy), receiving treatment in an inpatient and outpatient fashion. The treatment period was 14 days, the endpoint 28 days and all patients were followed up for 60 days.

Contact

Tara Heitner, CEO
Tel: +46 (0)70 781 88 08
Email: tara.heitner@cyxone.com

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 FNCA Sweden AB, +46(0)8-528 00 399, info@fnca.se. For more information, please visit www.cyxone.com