Press release
Cyxone AB (Publ.)
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Cyxone will leverage IND and use FDA pre-review for Covid-19 phase 2 trial

Cyxone AB (publ) announces today that the company is expecting to communicate top-line results from a recently concluded Phase 2 trial of its drug candidate Rabeximod in Covid-19 patients during the fourth quarter. The results were previously slated for the third quarter. The postponement is due to the company's decision to leverage the U.S. Food and Drug Administration (FDA) initiative to pre-review the statistical analysis plan for the clinical trial, whereby the exact timing of the results will depend on the process and discussion required with the FDA. This is an extraordinary opportunity provided by the authority to expedite the development of safe and efficacious Covid-19 treatments.

The FDA has decided to offer advisory reviews of the statistical analysis plans for all Investigational New Drug (IND) registered clinical trials in Covid-19. Therefore, before conducting final statistical analysis Cyxone has chosen to welcome this initiative from the authority to conduct an additional review to secure a to secure a high integrity of the data before final readout.

A clinical Phase 2 trial of Rabeximod in approximately 90 Covid-19 patients has recently been concluded. All study data has been successfully collected from the study centers, and a statistical analysis plan has been put in place for the upcoming review by the FDA. This process is estimated to be completed in approximately 6-8 weeks, whereafter the study results can be processed to allow a presentation of the top line data on the drug candidate's safety and efficacy profile.

"The opportunity to let the FDA perform a pre-review of the statistical analysis plan for Covid-19 trial demonstrates the agency's active involvement in the development of treatments that can ease the burden of this devastating pandemic. We believe that the potential to add value to our Phase 2 study will increase by FDA's input on the data analysis. We hope this will facilitate an interest and engagement in Cyxone's Covid-19 project in later interactions with regulatory bodies. Increasing the data integrity further outweighs the slight delay that this additional process will have on the analysis of top-line results," comments Tara Heitner, CEO, Cyxone.

Rabeximod is also being developed as a potential new treatment for rheumatoid arthritis, where planning of a Phase 2b study is well underway.

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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 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