



Cyxone announces forward looking drug development strategy with focus on Rabeximod in Rheumatoid Arthritis trial

Cyxone AB (CYXO), a clinical-stage company developing transformative therapies in the autoimmune area to improve patient outcomes, today provided a forward-looking strategy.

Rabeximod in Rheumatoid Arthritis

Rheumatoid arthritis (RA) is chronic disease, affecting more than 20 million patients globally, that require convenient rest-of-the-life treatment with as few side-effects and drug interactions as possible. There is still a large unmet need for new oral therapies with novel modes of action to give rheumatologists real alternatives to current therapies. Over 40% of patients don't respond to the first line oral treatment methotrexate while 25% of diagnosed patients do not tolerate it. Second-line biologics such as TNF alpha inhibitors can provide great efficacy, but only 30% of patients respond well. Finally, the safety of oral JAK-inhibitors, a drug class that raised expectations within the specialist community when being launched eleven years ago have caused concern among the American and European authorities. The US Food and Drug Administration (FDA) have announced safety concerns regarding the JAK-inhibitors. The European Medicines Agency's (EMA) safety committee, [PRAC](#), started a review of the safety of these drug therapies in February, this year.

Cyxone is developing an alternative first-in-class oral therapy, Rabeximod, with a new mode of action for the millions of patients suffering from rheumatoid arthritis (RA) that are underserved by current therapies. Rabeximod with its favorable safety and tolerability profile is positioned as a second line oral therapeutic following methotrexate failure to delay the need for patients to move to more invasive and complex biologics and other injectibles. Cyxone's vision is to enable patients to keep disease in remission with an effective, oral, easy to take and tolerate once a day tablet for many years. Feedback to date confirms there is a large market interest from rheumatologists, patients and strategic partners for a such an approach.

Cyxone is currently focusing on preparations for the Rabeximod in RA phase 2b study, which will be initiated later in 2022.

The company has used first part of 2022 to adjust to the new market climate caused by the war in Ukraine and implement an optimized clinical trial design to be resource efficient. Alternative countries in Eastern Europe have been identified to replace Ukraine and Russia, which were the primary countries to be included, and the initial projection for patient enrolment in H1 2022 is thus pushed out to later this year.

T20K in Multiple Sclerosis

With the focus on the RA trial, the T20K program has been moved to a lower priority.

T20K has progressed in 2021-2022 with positive data generated in preclinical models for T20K and the T20K combination therapy with kappa opioid receptor agonist (KORa). Preclinical studies have shown that T20K is effective as both an oral and subcutaneous administered drug. Preclinical studies have been conducted to support the new T20K/KORa combination therapy patent and have thus expanded the potential therapeutic use of T20K to a wider MS patient population. As



Cyxone implements the new optimized strategy current activities will be completed and additional studies will be put on hold to allocate all resources to the lead program in RA.

Rabeximod in Covid-19

In 2021 Cyxone completed a Covid-19 trial in 92 patients. Topline results were reported in December 2021 and secondary endpoints results in April 2022. While encouraging trends emerged, no statistical significance in primary or secondary endpoints was reported. This result is consistent with other RA drugs that were tested as treatments for Covid-19 and has no implications for the upcoming RA trial.

After careful consideration the company has decided not to work further on Covid- 19 for the following reasons:

- The focus on RA indication which offers at least a 10-fold greater commercial opportunity.
- The market and business attractiveness are less urgent with more options available for Covid-19 patients today.
- Difficulty in running a phase 2 trial as a monotherapy and risk of inconclusive results.
- Lack of statistical significance.

Uplisting process

Cyxone has previously announced plans for an uplisting to the main market in Q1 of this year. However, the political instability in Europe and other events have caused uncertainty in the market and the company has decided to wait until a time when it will most benefit the company and its shareholders.

CEO Tara Heitner comments:

“Cyxone continues to push its lead program forward while implementing optimized strategies in the company to withstand the political instability currently impacting the biotech sector. During the first quarter and in recent weeks we have taken steps to streamline our lead program - a phase 2b clinical trial for Rabeximod in treatment of moderate to severe RA patients. We have implemented trial design optimization for the phase 2b RA trial, to accelerate patient enrolment, increase likelihood of success and to be resource efficient. We have also relocated our clinical sites to politically stable countries. With a strong and focused development team, agile and efficient organization, and additional financial resources secured in January 2022, we are well positioned to execute our drug development strategy to deliver on important upcoming clinical milestones.”

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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

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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