Press release
Cyxone AB (publ)
559020-5471
August 01, 2019

Cyxone's T20K shows favorable safety and tolerability in first-in-human trial

Cyxone (publ), a Swedish biotech in autoimmune diseases, today announced that the clinical phase I trial with drug candidate T20K successfully achieved its purpose of confirming T20K's safety and tolerability in humans. There were no reports of serious adverse events in this infusion study. T20K, which is under development for the treatment of multiple sclerosis (MS), will as a next step in the development program be prepared as an oral formulation followed by a further clinical phase I study.

The first-in-human study, so-called clinical phase I trial, achieved its objective of determining T20K's safety and tolerability in humans. By measuring the amount of substance in the study subjects' blood, T20K's pharmacokinetic values could be determined. These results, the pharmacokinetic values, provides knowledge of what the human body does to T20K, referring to the movement of the substance into, through, and out of the body. No serious adverse events were reported in the study; one study subject reported a mild and transient headache.

Kjell G. Stenberg, CEO of Cyxone, commented: "There is always an element of uncertainty when taking a new substance to man despite successful testing in several animal species. To our great delight, the results were far above our expectations already after the first, lowest, dose level reinforcing our conviction of T20K's exceptional potential."

The clinical phase I study was planned to comprise one cohort of eight healthy male volunteers receiving a very low dose of T20K, 0.005 mg per kilo, if it was not possible to measure the level of T20K in the blood at this stage, a second cohort with a higher dose level would follow. Based on the results from the first dose level achieving the study objective, a higher dose level will not need to be studied.

The next steps for the T20K clinical development program will be focused on moving towards an oral substance formulation followed by a further clinical phase I study using the developed oral formulation.

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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 August 1, 2019 at 17.35 CET.

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About T20K
T20K is in development as a novel form of multiple sclerosis (MS) treatment with prophylactic properties. Results from preclinical studies demonstrate that the candidate could be used to mitigate or even prevent MS episodes and potentially even delay the disease progression. Early disease intervention, such as this, is currently not targeted by the treatments available. Additionally, the candidate has demonstrated a low toxicity level and could, due to its favorable absorption and distribution in the body, be administrated at low doses on a bi-weekly or even monthly basis.

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 a clinical phase I program 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