

Cyxone submits application to start first-in-human trial with T20K in MS

Cyxone (publ.), a Swedish biotech in autoimmune diseases, today announced that the company has set a date for the application submission for the start of clinical trials with T20K. On Monday May 27, an application to the relevant authorities to start a first-in-human, phase I, clinical trial with drug candidate T20K in multiple sclerosis (MS) will be submitted. The company will subsequently await a response from the authorities before the study can be initiated as planned during the second quarter of 2019.

The application to start the first-in-human clinical trial for T20K in MS will on Monday May 27 be submitted to the authorities in the Netherlands where the study will take place. Once reviewed and approved by the accredited Ethics Committee and Central Commission on Research Involving Human Subjects (CCMO), a response is sent to Cyxone and the phase I study can be initiated. The first-in-human trial is designed to be a double-blinded, single center study where T20K will be administrated to male healthy volunteers through infusion. The purpose of the trial is to evaluate the safety and tolerability of T20K in humans. The trial will be conducted in collaboration with the global clinical research organization (CRO) QPS, with their national division QPS Netherlands.

Kjell G. Stenberg, CEO of Cyxone, commented: “We are glad to be able to share this milestone as it means that our drug candidate is on the cusp of making history by hopefully, very soon, be tested in humans. We have a good partner by our side in QPS, which is a global leader in clinical development, with the purpose of giving our study the best prerequisites for success.”

“It is always a pleasure to contribute to the development of novel drugs that could help improve the lives of patients. On our side, we are fully prepared to start recruiting study participants as soon as the application has been approved by the relevant authorities and look forward to continuing this collaboration”, said Dr. Benjamin Chien, CEO of QPS.

T20K is in development as a novel form of multiple sclerosis (MS) treatment with prophylactic properties. This indicates that the substance could be used to mitigate or prevent MS episodes and potentially even delay the disease progression. Early disease intervention, such as this, is currently not targeted by treatments available. The company will announce a response from the appropriate authorities as soon as it has been received and make a further announcement once the clinical phase I trial commences.

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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 May 23, 2019 at 16.10 CET.

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 shortly 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