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## Cyxone explores orphan drug designation for Rabeximod

Cyxone (publ), a Swedish biotechnology company in autoimmune diseases, today announced that the company's board of directors has decided to explore the possibilities of an orphan drug designation (ODD) of the drug candidate Rabeximod. An orphan drug status would mean that the drug candidate obtains a strengthened position under the Orphan Drug Act, as well as prevails under special regulatory frameworks designed to endorse development and shorten time to market. This is part of the continuous work to strengthen the control position of the company's own assets.

Kjell G. Stenberg, CEO of Cyxone, commented: "There is a real urge from pharma companies to target niche diseases, i.e. rare diseases, where also the willingness to pay significant amounts of money has increased. An orphan drug has the advantage that they are often very profitable as the product can be taken to market much faster with significantly lower development costs and risk. With widespread common illnesses, several hundreds of patients are usually required in a pivotal Phase 3 study while rare disease drugs can reach market approval based on a significantly smaller patient group, which further reduces costs and makes it slightly easier to find study participants. I think this is a great decision and I look forward to a very exciting future for our candidate Rabeximod."

Drug candidates that obtain an ODD receives, among other things, support from regulatory authorities in the design of clinical trials and support in the market approval application process. An orphan drug status also means reduced regulatory fees as well as market exclusivity of 10 years in Europe and 7 years in the US following market launch.

Cyxone is now initiating the evaluation of the possibilities of an ODD for Rabeximod. This is part of the company's strategy to strengthen the control position of the company's own assets, e.g. IP (intellectual property). More information will be shared with the market once possible.

## **Contact**

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## **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 clinical phase I program and Rabeximod for RA in clinical phase II program. Cyxone's Certified Adviser on the Nasdaq First North Growth Market is Mangold Fondkommission AB, +46 (0)8-503 015 50, ca@mangold.se. www.cyxone.com