Toleranzia's clinical trial application (CTA) for TOL2 approved in Germany while declined in Denmark

Toleranzia AB (the "Company" or "Toleranzia") today announces that the CTA, filed with the European Medicines Agency (EMA) for a clinical trial of the Company's investigational drug TOL2 in patients with myasthenia gravis, has now been approved in Germany while at the same time the Danish regulatory agency has declined it.

The CTA has now received conditional approval in both Sweden and Germany. The condition requires Toleranzia, in accordance with the commitment provided in the application, to provide data for bioburden, sterility and endotoxin level in the final drug product prior to starting the clinical trial. Toleranzia is analysing the response from Denmark to evaluate the possibility to appeal their decision. In parallel, the Company is continuing the already initiated work to include additional clinical trial sites in Germany to ensure timely patient recruitment.

Following the approval of Toleranzia`s CTA in Sweden and Germany, the Company is now working diligently to finalize the formulation of the previously produced Good Manufacturing Practice (GMP) batch of drug substance into a final lyophilized drug product. Toleranzia will then perform the release testing and deliver the data in accordance with the conditional approval to the EMA for their review and final approval. With the positive regulatory responses in Sweden and Germany and the work ahead to meet the conditional requirements, the enrollment of the first patients in the trial is expected to begin in Q3.

"We are excited to receive an approval from Germany which together with Sweden provides an adequate basis for conducting the multi-center trial. While I am of course disappointed about the negative outcome in Denmark, we are addressing this by including additional centers in Germany to maintain our planned timelines for patient recruitment. Once the conditional requirements are addressed and approved, we will be able to initiate the trial simultaneously in Sweden and Germany", comments Charlotte Fribert, CEO of Toleranzia.

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About Toleranzia AB (publ)
Toleranzia AB (publ) develops medicines that harness the power of the immune system to treat rare autoimmune diseases. The drugs, which target the cause of the disease, can cure or significantly alleviate the disease and not, like current treatments, just reduce symptoms. They

have the potential to be the first long-acting or curative treatments that act specifically on the underlying cause of the autoimmune orphan disease for which they are being developed. Toleranzia's shares are listed on Nasdaq First North Growth Market and Svensk Kapitalmarknadsgranskning AB, +46 (0)8 913 008, ca@skmg.se, is the company's Certified Adviser.

This information is information that Toleranzia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-02-20 15:57 CET.

Attachments

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