Toleranzia's clinical trial application (CTA) for TOL2 approved in Sweden

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 been approved in Sweden.

The clinical trial will be a double-blind, randomized, placebo-controlled, first-in-human (FIH) Phase I/IIa trial in patients with generalized myasthenia gravis receiving single or multiple doses of increasing amounts of TOL2 to assess safety, tolerability, and preliminary efficacy of the investigational drug.

The application is approved with the condition that Toleranzia, prior to starting the clinical trial, provides the data for bioburden, sterility and endotoxin level in the clinical trial material in accordance with the commitment provided in the application. These data are pending the completion of the large-scale manufacturing of lyophilized TOL2 drug product for the trial, which is ongoing by Toleranzia's contract manufacturing partner.

Toleranzia has submitted its CTA to the EMA for authorization in Sweden, Denmark and Germany. Since the three countries' respective decisions are not notified simultaneously, the outcomes from Denmark and Germany are still pending. Awaiting these decisions, the regulatory approval in Sweden already permits the Company to initiate the first clinical trial of TOL2 in Sweden once all preparation activities have been completed.

"We are immensely pleased to announce the approval of the CTA by the Swedish Medical Products Agency. It marks a significant milestone for our Company and a critical step forward in the continued development of TOL2. In addition to the positive response from the Swedish regulators, we are expecting the decisions from Denmark and Germany shortly", comments Charlotte Fribert, CEO, 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 2025-02-08 19:25 CET.

Attachments

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