Toleranzia reports positive outcome from advisory meeting with the German Medicines Agency for the TOL2 development program

Toleranzia AB has successfully completed a scientific advisory meeting with the German Medicines Agency, Paul Ehrlich Institut (PEI), which confirmed Toleranzia's TOL2 program and the planned phase I/IIa study of the drug candidate in patients with myasthenia gravis.

At the end of January, Toleranzia held a scientific advisory meeting with the Paul-Ehrlich-Institut, PEI, the medical regulatory authority in Germany, and now PEI's final report from the meeting has been received. With this, Toleranzia has received positive feedback regarding the TOL2 program from the authorities in Sweden, Denmark and Germany, the three countries in which the clinical study in patients with myasthenia gravis (MG) is planned to be conducted. Similar to the two previous advisory meetings with the Swedish and Danish medical regulatory authorities, PEI provided broad support for the TOL2 program's development plan and the initial clinical phase I /IIa study. In addition to valuable advice on the clinical study, PEI also provided appropriate input on the design of the clinical trial application that is currently being prepared. Given the positive regulatory interactions with the Swedish, Danish and German regulatory authorities, Toleranzia is now planning to start the phase I/IIa study in the second half of this year.

The study is a multicenter, double-blind, first-in-human (FIH) study to evaluate the safety, clinical responses, and immune responses following single and repeated administrations of TOL2 in ascending doses in patients with MG. The study will start with a group of patients receiving treatment with TOL2 at increasing dose levels in a so-called "Single Ascending Dose" (SAD) part. After evaluation of safety and tolerability in this part, patients will receive multiple doses at increasing dose levels in a Multiple Ascending Dose (MAD) part. In this part, in addition to evaluating safety and tolerability, important measures of the therapeutic effect of TOL2 will be evaluated. Among other things, effectiveness will be measured via patient-registered questionnaires, an efficacy measure that regulatory authorities require to be used in phase III studies for the approval of a new drug.

"I am pleased to note that we have now held important advisory meetings with all pharmaceutical authorities in the countries where the clinical study is planned to be conducted, all with a positive outcome regarding the continued development of TOL2. We have received full support for the continued work to carry out the clinical development of TOL2 according to our plans and several valuable pieces of advice which will be naturally integrated into the program. Right now, we are in an intensive phase of finalizing the clinical trial application to ensure study start in the second half of 2024", comments Charlotte Fribert, CEO of Toleranzia.

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About Toleranzia AB (publ)
Toleranzia AB (publ) develops drugs that utilize the immune system's own power to treat autoimmune orphan diseases. The drugs, which target the cause of the disease, can cure or significantly alleviate the disease and not, like current treatments, only reduce the 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 Mangold Fondkommission AB, 08-503 015 50, CA@mangold.se, is the company's Certified Adviser.

Attachments

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