Toleranzia reports positive feedback from meeting with the Danish Medicines Agency

Toleranzia AB has successfully completed a scientific advisory meeting with the Danish Medicines Agency, DKMA, on the preclinical status and the company's plans for the clinical development of the drug candidate TOL2.

At the end of November, Toleranzia participated in a scientific advisory meeting with DKMA regarding the company's upcoming clinical studies of TOL2. The outcome of the meeting is of central importance as Denmark is one of the countries where the upcoming clinical study in patients with myasthenia gravis will be conducted.

During the meeting, DKMA expressed broad support for the quality requirements set for the drug substance TOL2, the design of the ongoing toxicology study, and the company's plans for the initial clinical phase I/IIa study. In addition, DKMA also provided valuable advice on the continued clinical development of TOL2, including questions related to patient recruitment.

"The meeting with the Danish Medicines Agency was particularly important for us, as it was the first time we were able to present data on the drug substance and the design of the ongoing GLP toxicology study with TOL2. It is therefore gratifying to note that the views expressed by the DKMA provide full support for the continued work to carry out the clinical development of TOL2 according to our plans", comments Charlotte Fribert, CEO of Toleranzia.

A similar meeting will be held in January 2024 with the Medicines Agency in Germany, which is the second country for the Phase I/IIa study.

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About Toleranzia AB (publ)
Toleranzia AB (publ) develops drugs that harness the power of the immune system for the treatment of autoimmune orphan diseases. The drugs, which target the cause of the disease, can cure or significantly alleviate the disease and not, like current treatments, merely reduce the symptoms. They have the potential to be the first long-acting or curative therapies that act specifically on the underlying cause of the autoimmune orphan disease for which they are being developed. Toleranzia's shares are listed on the 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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