Toleranzia seeks a scientific advice meeting with the Danish Medicines Agency

Toleranzia AB (the "Company" or "Toleranzia") today announces that the company has decided to apply for a scientific advice meeting with the Danish regulatory agency DKMA following their unfavorable opinion on the Clinical Trial Application (CTA) for TOL2.

As previously communicated, the CTA for TOL2 was approved in Sweden and Germany but not in Denmark. After further contact with the DKMA, Toleranzia has decided not to appeal their decision but instead request a follow-up scientific advice meeting with the objective to address any unclarities in the CTA which may have affected the outcome of the CTA review by DKMA. Depending on the outcome of the advice meeting, a new CTA may be submitted to the DKMA.

Toleranzia is not depending on participation from Denmark for maintaining the patient recruitment timelines in the clinical trial thanks to the opportunity to include additional clinical centers in Germany. Work to contact these centers has already been initiated. A continued partnership with the clinic and clinical expertise in myasthenia gravis at Rigshospitalet in Copenhagen is nevertheless considered valuable for the study.

"We are seeking a scientific advice meeting with the DKMA with the aim to provide clarification of any ambiguity which may have influenced DKMA in reaching their decision. With this, we hope to provide a reinforced foundation for a positive outcome from DKMA following a potential reapplication in Denmark. Alongside our continued close collaboration with our clinical centers in Sweden and Germany, we are also looking forward to the inclusion of additional participating clinics in Germany", comments Charlotte Fribert, CEO of Toleranzia.

For further information, please contact
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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.

Attachments

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