

Toleranzia submits a clinical trial application (CTA) for the drug candidate TOL2 for the treatment of myasthenia gravis

Toleranzia AB (the "Company" or "Toleranzia") today announces that it has filed a CTA with the European Medicines Agency (EMA) for a Phase I/IIa trial with the Company's drug candidate TOL2 in patients with the autoimmune disease myasthenia gravis.

The trial will be a multi-center, placebo-controlled, first in human (FiH) study in myasthenia gravis patients receiving one or more doses of increasing amounts of TOL2 (in the so-called single and multiple ascending dose parts of the study) to evaluate the safety, tolerability and preliminary efficacy of TOL2. Clinical centers in Sweden, Denmark and Germany will participate in the trial, which will be managed by Toleranzia's partner Clinical Trial Consultants (CTC).

Large-scale manufacturing of lyophilized TOL2 drug product for the trial is currently ongoing at Curia Global in Scotland, and labelling, storing and distribution of the drug to participating clinics will be managed by Toleranzia's partner ClinStorage AB.

"With this clinical trial application for TOL2, Toleranzia reaches its most important milestone to date, and I am very grateful for all the hard work that our employees and partners have put in to achieve this. Following regulatory approval, we are ready and eager to start the clinical trial as soon as possible in patients with myasthenia gravis, a patient group that is in great need of safer and more effective treatments", comments Charlotte Fribert, CEO, 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 Mangold Fondkommission AB, 08-503 015 50, CA@mangold.se, is the company's Certified Adviser.



Attachments

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