

Toleranzia concludes manufacturing of a technical batch of drug candidate TOL2

Toleranzia AB ("Toleranzia" or the "Company") today announces that it has successfully manufactured a technical batch of TOL2. The material from the technical batch is derived from the second manufacturing of TOL2 at a large scale and will be used for the upcoming pivotal GLP-toxicology study prior to the start of clinical trials in patients with myasthenia gravis. The technical batch produced the same high yield of purified TOL2 as that obtained in the pilot batch produced at the end of 2022.

After initial evaluation, Toleranzia concludes that the second large-scale batch of TOL2, which was at 1000 L scale, mirrored the pilot batch and also resulted in a high yield of pure TOL2. All parameters examined so far confirm the robustness of the manufacturing process at a 1000 L scale.

This material will be mainly used for the GLP-toxicology studies. With two large-scale batches successfully completed, Toleranzia will now move ahead to manufacture a third large-scale GMP batch of TOL2 for the clinical trials in myasthenia gravis patients.

"With the second large-scale batch of TOL2 successfully manufactured we are excited that we, in partnership with our contract manufacturer 3P, now have an efficient and robust large-scale manufacturing process in place. We look forward to start producing GMP material, the final step before initiating clinical development of TOL2," comments Charlotte Friberg, CEO of Toleranzia.

Toleranzia's drug candidate TOL2 is in development for the treatment of myasthenia gravis (MG), an autoimmune disease in which the body's immune system destroys the acetylcholine receptors in skeletal muscle. This leads to an impaired signal transmission between nerve and muscle which results in severe muscle weakness, a hallmark of MG. Based on Toleranzia's unique concept of antigen-specific tolerance-induction, TOL2 acts effectively to halt the uncontrolled immune destruction and re-establish self-tolerance towards the body's acetylcholine receptors. TOL2 has been shown to restore tolerance and normalize muscle function in preclinical models of MG.

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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

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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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