

Toleranzia announces successful large-scale production of drug candidate TOL2

Toleranzia AB ("Toleranzia" or the "Company") today announces that it has successfully manufactured and evaluated a pilot batch of its drug candidate TOL2 at the contract manufacturer 3P Biopharmaceuticals (3P). In the execution of the pilot batch, all steps of the manufacturing process have been carried out on a large scale with satisfactory results. The company will now move forward with the development of TOL2 and conduct a toxicology study as the final step prior to the start of clinical trials in patients with myasthenia gravis.

Toleranzia concludes after the evaluation that all steps in the purification process of the pilot batch have been in accordance with expectations and requirements. The pilot batch resulted in a higher yield of pure TOL2 after the last step of the process than expected. A detailed mass spectrometric analysis is now being carried out to validate the quality of the purified material.

The material from the pilot batch will be used mainly for the remaining formulation work. With the positive data from the pilot batch Toleranzia is now advancing the manufacturing program to produce two additional large-scale batches of TOL2, one technical batch for the regulatory GLP toxicology study and thereafter one GMP batch for the clinical trial in patients.

CEO Charlotte Fribert comments:

- We are pleased that all the steps implemented in the large-scale manufacturing process for the pilot batch of TOL2 turned out well, despite the significant challenges posed by the covid-19 pandemic for the production of biologics. The significantly better than expected yield after the final purification step is encouraging and supports that the manufacturing process will yield adequate quantities of the drug candidate for the clinical trial in patients.

For further information, please contact:

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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.

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Attachments

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