

Toleranzia runs GMP manufacturing of drug candidate TOL2 for clinical study

Toleranzia AB ("Toleranzia" or the "Company") today announces that it has successfully completed the manufacturing steps of the GMP process for the TOL2 drug substance to be used in the company's first clinical study. Both the upstream and the downstream steps have been run as planned, demonstrating an effective and robust process in line with that of the previous technical batches.

Since starting the 1000 L full-scale GMP manufacturing of TOL2 drug substance in the beginning of August, both the upstream fermentation step and downstream purification process have been finalized as planned. All process parameters and specifications assessed so far meet set requirements fully, in line with those obtained in the two previous technical batches. Following this interim report, Toleranzia is awaiting a report with a full set of TOL2 product analyses currently performed at 3P. When all specifications are met, the GMP manufacturing will be completed and large-scale GMP-grade TOL2 drug substance will be ready for final formulation, packaging, and labeling into a finished TOL2 drug product with GMP quality. The GMP-grade drug product will subsequently be shipped to participating clinical centers in the upcoming clinical study in myasthenia gravis patients.

"After an intense period of activities over the summer months to finalize all detailed preparations for the GMP manufacturing of TOL2, the work at 3P was started in early August with on-site representation and overview by Toleranzia project management. Today, I am pleased to report that the process has been running smoothly and efficiently, fully according to plans and set requirements. With just the final product analyses pending, it is extremely satisfactory to advance towards a critical milestone in the TOL2 product development program, which takes us an important step closer to the start of our clinical study in patients with myasthenia gravis, a severe and debilitating disease currently lacking a safe and effective disease-specific treatment," comments Charlotte Fribert, CEO of Toleranzia.

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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

[Toleranzia runs GMP manufacturing of drug candidate TOL2 for clinical study](#)