

# Toleranzia establishes a freeze-dried formulation of the TOL2 drug product

**Toleranzia AB ("Toleranzia" or the "Company") today announces that it has finalized the development of an optimized drug product formulation of its drug candidate TOL2. The new formulation, which comprises a freeze-dried TOL2 drug product with excellent characteristics, can be stored with extensive stability and reconstituted at a high active drug concentration.**

The formulation development program, initiated earlier this year, was based on material from the technical batch produced at 3P Biopharmaceuticals during late spring and has included extensive testing of different conditions to optimize TOL2 drug product characteristics. Multiple parameters such as pH, ionic strength, buffers, excipients, and concentrations of TOL2 have been varied in either a frozen or a freeze-dried format to obtain a final drug product with optimized properties for storage, reconstitution, and stability. The work has been completed by Toleranzia's Danish partners Bioneer and CMC Assist with excellent results.

The final formulated drug product comprises a freeze-dried TOL2 that can be stably stored and reconstituted at a high concentration of active drug. The long-term stability is currently being investigated to determine the drug product shelf life, which is expected to be at least two years – fully sufficient for the clinical program. In addition to this, freeze-dried TOL2 drug product has successfully been prepared from the technical batch, to be used in the GLP-toxicology study at Charles River Laboratories in France starting in mid-September.

*"I am very pleased to conclude that our Danish partners have conducted an exemplary formulation development program resulting in a final freeze-dried TOL2 drug product with excellent characteristics in terms of handling, storage, and stability. This freeze-dried drug product formulation has come to immediate use in the preparations of the GLP-toxicology study which we will initiate in mid-September together with our partner Charles River Laboratories in France," comments Charlotte Fribert, CEO of Toleranzia.*

## **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

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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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