Toleranzia secures access to materials for largescale manufacturing of drug candidate TOL2

Toleranzia AB (publ) ("Toleranzia" or the "Company") today announces that the Company has taken additional steps to secure access to the materials required to complete the scale-up of production and large-scale manufacturing of its drug candidate TOL2. The shortage of materials caused by the COVID-19 pandemic has previously led to significant uncertainty as to when the first batch of TOL2 for the clinical trial could be produced. Now that the Company has succeeded in finding an additional supplier and has ordered, on behalf of its production partner 3P Biopharmaceuticals, all the purification material needed for the large-scale production, the prospects of being able to start the study in the second half of 2023 in accordance with the communicated schedule are strengthened.

Toleranzia announced in November 2021 that the start of the Company's planned first clinical study of its drug candidate TOL2 will be delayed due to a lack of materials for large-scale production. The shortage was due to the fact that the material necessary for the purification of TOL2 is also used in the production of vaccines against COVID-19.

Since then, Toleranzia has been evaluating options to complete production as quickly as possible. Analyses carried out by the company show unequivocally that the purification material from the Uppsala-based company Bio-Works is of a very high quality, fully comparable to that of other suppliers. As Bio-Works can also guarantee short delivery times, Toleranzia has placed an order, securing the supply of the entire requirement of the critical purification material for the large-scale purification process, for delivery to its manufacturing partner 3P Biopharmaceuticals.

"In addition to being able to use this time to optimize the upcoming clinical trial with TOL2, it is gratifying and a relief that we have now been able to find and evaluate an alternative supplier that will ensure our material needs for the large-scale production of TOL2. Our partner 3P Biopharmaceuticals will now be able to continue the scale-up of production and we are working focused to start the clinical trial in the second half of 2023 as planned," said Toleranzia's CEO, Charlotte Fribert.

For further information, please contact:

Charlotte Fribert - CEO, Toleranzia Tel: +46 763 19 98 98 Email: <u>charlotte.fribert@toleranzia.com</u>

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

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