Start of Toleranzia's planned clinical trial with TOL2 postponed due to global shortage of certain materials for production of the drug substance

Toleranzia AB (publ) today announces that the planned start of a first clinical study of its drug candidate TOL2 in patients with myasthenia gravis will be postponed until the second half of 2023 due to a continued global shortage of materials necessary for the purification of TOL2, which is also used in the prioritized manufacturing of covid-19 vaccines. The study was previously expected to be initiated before the end of 2022/23.

The production of covid-19 vaccines relies heavily on the same materials used in the production of TOL2 and other biologic drug substances. To address the global health threat from the pandemic, society has naturally chosen to prioritize access to these for vaccine manufacturing companies. This has led to material shortages and consequent production delays for pharmaceutical manufacturers around the world. In the case of Toleranzia, this is a delay in the supply of a separation material that is essential for the final GMP purification of TOL2 for use in the clinical trial.

Toleranzia's contract manufacturer, 3P Pharmaceuticals, has established all the steps in the scale-up and has carried out the cultivation of TOL2 at an industrial 1000-liter scale using a cultivation process that has been shown to be stably scalable and highly robust. However, due to the lack of materials for the purification process, the final GMP-grade purification of TOL2 has been postponed to the first quarter of 2023, with the result that the clinical trial in patients with myasthenia gravis is now expected to start in the second half of 2023.

"Like many other companies, Toleranzia continues to be impacted by the covid-19 pandemic. We fully understand, of course, that the development of vaccines to address the pandemic and its consequences is a top priority. Our drug concept to treat serious autoimmune diseases stands as strong as ever, even if the shortage of materials for the purification process of TOL2 means that the start of the first patient study will be postponed until 2023," says Toleranzia's CEO, Charlotte Fribert.

Toleranzia's drug candidates have the potential to teach the body's immune system to tolerate the endogenous substances that are mistakenly targeted in the development of severe autoimmune diseases. The company's most advanced drug candidate, TOL2, is being developed to cure myasthenia gravis - an autoimmune nerve and muscle disease that often leads to severe muscle weakness and a difficult life situation for the affected.

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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 alleviate or cure 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 Nasdaq First North Growth Market and Mangold Fondkommission AB, 08 503 015 50, CA@mangold.se, is the Company's Certified Adviser.

This information is information that Toleranzia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2021-11-11 16:10 CET.

Attachments

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