

Toleranzia AB starts production of finished drug product for clinical studies

Toleranzia AB announces today that the company has entered into an agreement with the contract manufacturer Curia (Scotland) Limited ("Curia") for the final manufacturing and packaging of the pharmaceutical product TOL2. Under the agreement, Curia will produce a finished freeze-dried and packaged pharmaceutical product of GMP quality for Toleranzia's upcoming clinical studies in patients with myasthenia gravis.

During the year, Toleranzia has developed a process for production of freeze-dried TOL2 with excellent properties regarding stability, storage capacity and handling, which is used in the company's ongoing GLP toxicology study of the drug candidate.

To produce a finished drug product in sufficient quantities and with a quality suitable to future clinical studies, collaboration with the contract manufacturer is initiated. The production will include approximately 3,000 packages of sterile, freeze-dried TOL2 of GMP quality. The product will be ready for distribution to clinical centers and subsequent administration of the drug candidate to patients in Toleranzia's upcoming studies in patients with the autoimmune disease myasthenia gravis.

"We are pleased to have entered into an agreement with Curia, which has all the expertise, experience and infrastructure required to successfully produce the final drug product in the required quantities and quality. The plan is to get started very quickly with the production of the pre-packaged drug product for our upcoming clinical study in patients with myasthenia gravis", comments Charlotte Fribert, CEO of Toleranzia.

The choice of partner is based on an extensive evaluation of other companies in the same industry, where Curia is a leading, international, well-established contract manufacturer with expertise and extensive experience in the manufacturing method developed by Toleranzia.

For further information, please contact

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About Toleranzia AB (publ)

Toleranzia AB (publ) develops drugs that utilize the immune system's own power to treat autoimmune orphan diseases. The drugs, which target the cause of the disease, can cure or significantly alleviate the disease and not, like current treatments, only reduce the symptoms.

They have the potential to be the first long-acting or curative treatments 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.

Attachments

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