PRESS RELEASE

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Ziccum reports good progress in the project for inhalable mRNA/LNP

Ziccum AB (publ) ('Ziccum') has an ongoing project with Copenhagen University to engineer inhalable solid dosage forms of mRNA/LNP. At the production stage, all primary development objectives have been met. The project has reached the phase of animal testing, with several trials completed with good results.

The two main objectives of the study involve engineering of inhalable dry powder particles of mRNA /LNP materials with the precise activity and structure characteristics required for inhalation, and to then test the effectiveness of delivery to the lungs in animal studies. Through the efforts in this project, Ziccum is aiming to build a strong case for pharmaceutical companies that have an ambition to develop inhalable mRNA/LNP, an area that is rapidly becoming of high interest in respect to new vaccines and treatments.

The project is executed in collaboration with Copenhagen University together with Professor Camilla Foged, who is an international authority in vaccine design and delivery. Model messenger-RNA used in the project is formulated in lipid nanoparticles (LNPs). Production of dry powders based on these fragile LNP-formulations has been considered very challenging or even impossible with conventional manufacturing methods.

As reported earlier this year, Ziccum has generated an encouraging set of trial formulations with the precise desired powder properties for inhalation. These results have now been further complemented. Today, Ziccum can also report on several positive findings achieved in the project, as described below.

First stage: endpoints met and further complemented

The desired outcome in stage 1 related to particle morphology, structure and mass median aerodynamic diameter (MMAD). These are important metrics that describe the dry particle's ability to 'fly' as an aerosol. The results demonstrate that LaminarPace® successfully produces inhalable particles with the correct MMAD and morphology.

These are very important results: other techniques to obtain dry powder have not generated materials of reliable quality, let alone with any acceptable particle characteristics. For example, freeze-drying will typically only produce a sticky cake of material. Now, additional formulation excipient compositions have been investigated in the project, for further advancement regarding delivery performance parameters.

Second stage: advanced in-vivo testing in good progress
The purpose of administering dry powder LaminarPace® material to mice is to verify that the active drug ingredient is correctly delivered to the mucosal barrier, transported through this barrier and resulting in the desired therapeutic effect. The mRNA activity is monitored with advanced image analysis of the fluorescence that is generated upon correct drug delivery effect.

The scope in this experimental stage has included one trial with intra-muscular injection in mice, where the LaminarPace® material has excellent initial results, fully preserving the mRNA activity. A second animal trial has verified the delivery of LaminarPace® material to the lung via aerosol inhalation, showing correct delivery and uptake, demonstrating the desired therapeutic effect for the LaminarPace® material. The third animal study, currently on-going, is testing this also with dry powder materials.

Ziccum CEO Ann Gidner: "Having the ability to accomplish mRNA delivery through inhalation is a unique argument for LaminarPace®. Since the world-wide deployment of mRNA-based Covid vaccines, there has been a rapidly increasing interest in RNA-based drugs that are suitable for delivery by inhalation. This has resulted in multiple new business dialogues for Ziccum. With the current progress, we see several important topics to pursue further".

To achieve inhalable Biopharmaceuticals and RNA/LNP treatments
Inhalable solid dosage forms of biological drugs and vaccines are of great interest to the pharmaceutical industry. Solid dosage forms may offer increased storage stability compared to liquid formulations, simplified handling and patient convenience, and very significant cost savings. Currently, there are no existing inhalable mRNA/LNP therapies on the market. The main reason is that the elevated temperatures of conventional drying methods are not applicable for processing of mRNA/LNP materials, since the active substances are highly sensitive to changes in temperature and other factors causing molecular stress. Ziccum's technology LaminarPace® is applied at room temperature with minimal stress factors, enabling a very gentle treatment compared to other methods.

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About Ziccum

Ziccum is developing LaminarPace®, a unique drying method for biopharmaceuticals and vaccines based on mass transfer, not heat transfer. The technology is offered by licensing to vaccine and biologics developers and manufacturers in the global pharmaceutical industry. By reducing drying stress to the active ingredient, LaminarPace® uniquely enables particle-engineered, thermostable dry powder biopharmaceuticals which can be easily handled and transported and are highly suitable for novel administration routes. The technology has been successfully applied to mRNA, peptides, proteins, antibodies, lipids and enzymes as well as excipients and adjuvants, and is well suited for industrial application. Ziccum is listed on the Nasdaq First North Growth Market.

Attachments

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