

Guard Therapeutics completes successful pre-IND meeting with FDA

Guard Therapeutics today announces that the company has completed a pre-IND meeting with the US Food and Drug Administration and has received positive feedback on its planned clinical development programme for its investigational drug ROSgard. This is an important validation of the quality of the project and is a significant step towards an application to include American study centres in future clinical studies (Investigational New Drug Application, IND).

Guard Therapeutics investigational drug ROSgard has been demonstrated in several pre-clinical studies to provide protection against cell and organ damage, including acute kidney damage, by counteracting oxidative stress and supporting regenerative processes. The investigational drug is being developed primarily to counteract kidney damage in connection with cardiac surgery.

The main purpose of the pre-IND meeting was to discuss the overall clinical development plan for ROSgard and to identify any need for further preclinical or clinical studies prior to submitting an IND application. Based on FDA recommendations, Guard Therapeutics estimates that no further studies will be required prior to an IND application beyond the already planned phase 1b study in patients undergoing cardiac surgery.

"The positive response from the FDA to our plans for continued clinical development of ROSgard is a clear seal of quality on the data generated so far in our pharmaceutical project and confirms our ability to design a trial program that meets the strict requirements of one of the world's most respected regulatory authorities," Tobias Agervald, CEO of Guard Therapeutics, says.

The company is planning to submit an IND application to the US regulator after completing a phase 1b study in patients undergoing heart surgery. An approved IND application is a requirement for conducting clinical studies with a new drug candidate in the United States.

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About Guard Therapeutics

Guard Therapeutics' investigational drug ROSgard has been documented in several preclinical studies to protect against cell and organ damage, including acute kidney damage, by counteracting oxidative stress and supporting regenerative processes. Guard Therapeutics is listed on Nasdaq First North Growth Market Stockholm.

Certified Adviser is Svensk Kapitalmarknadsgranskning AB, tel. +46 11 32 30 732, ca@skmg.se.

This information is information that Guard Therapeutics 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 2020-12-29 08:30 CET.

Attachments

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