Guard Therapeutics receives IND approval from the FDA for RMC-035

Guard Therapeutics today announces that the U.S. Food and Drug Administration (FDA) has granted the company's Investigational New Drug (IND) application for the investigational drug RMC-035 (ROSgard). The approval enables expansion of the clinical development program for RMC-035 to the US, including the ongoing global and placebo-controlled Phase 2 study AKITA in cardiac surgery.

The investigational drug RMC-035 is being developed as an intravenous short-term treatment against acute kidney injury and is currently being evaluated in a comprehensive global Phase 2 study, AKITA, to document its renal protective effect in patients undergoing open heart surgery. The study is planned to include approximately 270 patients. In addition, a smaller Phase 1b study is underway in patients undergoing kidney transplantation.

"The U.S. Food and Drug Administration's approval of our IND application is an important milestone and a clear recognition of the preclinical and clinical data already generated for RMC-035. At the same time, the approval validates the design of the AKITA study and provides the opportunity to include study centers in the US, both within the AKITA study and in the continued clinical development program for our investigational drug", says Guard Therapeutics CEO, Tobias Agervald.

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About Guard Therapeutics

Guard Therapeutics is a Swedish biotech company that identifies and develops new therapies for diseases with a great medical need for more effective treatments. The company's investigational drug RMC-035 is being developed as a kidney protective treatment in connection with open heart surgery and kidney transplantation. 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 2022-10-10 08:20 CEST.

Attachments

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