Guard Therapeutics receives approval from the Swedish Medical Products Agency to conduct a clinical study of RMC-035 in kidney transplantation

Guard Therapeutics today announces that the company has received approval from the Swedish Medical Products Agency (MPA) to start a clinical phase 1b study with the investigational drug RMC-035 (ROSgard) in patients undergoing kidney transplantation. Through the planned study, the company is thus expanding the clinical development program of RMC-035 into a second indication with significant need for kidney protective treatments. The study will include up to 12 individuals with the primary objective to evaluate the pharmacokinetic properties of RMC-035 in this patient population. The company is expected to present full study results in the first half of 2023.

Nearly 100,000 kidney transplantations are performed annually worldwide. In connection with kidney transplantation, especially with a deceased donor, tissue injury often occurs due to lack of oxygen because the organ is outside the body and without blood supply. Despite successful surgery, the injury often leads to a deterioration in the quality and function of the transplanted kidney both in the short and long term. If the transplanted kidney does not function properly after the transplantation, dialysis treatment is sometimes required, which also reduces the expected survival of the kidney and impairs the long-term prognosis.

Guard Therapeutics' investigational drug RMC-035 has in previous studies demonstrated high potential to prevent tissue injury related to limited oxygen supply, so called ischemia-reperfusion injuries. RMC-035 is currently being evaluated in a global Phase 2 study (AKITA) for the prevention and treatment of cardiac surgery associated acute kidney injury. Through the planned phase 1b study, the clinical development program is now expanding into another indication with significant unmet medical need and potential for orphan drug designation.

The Phase 1b study of RMC-035 is open-label and without control group, and is expected to include 8–12 patients undergoing kidney transplantation at the Karolinska University Hospital in Huddinge. Initially, eight patients will be enrolled in two dose groups, and after an interim pharmacokinetic analysis a decision will be made to possibly proceed to an optional third dose group. The primary endpoint includes key pharmacokinetic properties of RMC-035, and the results will form the basis for designing a potential subsequent Phase 2 (efficacy) study with the goal of improving renal function following deceased donor kidney transplantation. The study is expected to start in the third quarter this year and full study results to be available in the first half of 2023.

"We are pleased that the Medical Products Agency has approved our application to conduct this first clinical study of RMC-035 in patients undergoing kidney transplantation. In the United States alone, approximately 90,000 patients are currently on the waiting list to receive a new kidney, and every successful transplant therefore makes a big difference. We see a high potential of RMC-035 to limit potential tissue damage following kidney transplantation, and thus an opportunity to improve treatment for these patients with large unmet medical needs," said Guard Therapeutics CEO, Tobias Agervald.

For further information, please contact:

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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 clinical 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 2022-06-01 16:30 CEST.

Attachments

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