

Study results with Guard Therapeutics' RMC-035 in kidney transplantation confirm previously positive data analysis

Guard Therapeutics [GUARD], a biotechnology company specialized in kidney diseases, today announced the full results from the company's Phase 1b clinical study of the investigational drug RMC-035 in patients undergoing kidney transplantation. The study results confirm the previously positive preliminary data analysis and demonstrate favorable pharmacokinetic properties of RMC-035 without any serious adverse effects associated with the investigational drug.

"It is encouraging that the final study results confirm our previous promising observations, providing us a clear path forward for the dosing of RMC-035 in kidney transplantation. We are now looking forward to the results of our ongoing Phase 2 study in cardiac surgery as a decision-making basis for the next development step of RMC-035," said Tobias Agervald, CEO of Guard Therapeutics.

All eight patients in the study received treatment with RMC-035. The open-label study without a control arm aimed to evaluate the pharmacokinetics and safety of RMC-035 in the context of kidney transplantation. RMC-035 was administered once daily for five days, with a total of five doses, within the dosage range of 0.3 to 0.6 mg/kg. The first dose was administered during the surgical procedure, i.e., the kidney transplantation itself.

In parallel, a global Phase 2 study (AKITA) is underway to evaluate the kidney-protective effect of RMC-035 in patients undergoing open-heart surgery. Top-line results from the AKITA study are expected to be available during the autumn in 2023 and will form the basis for the continued clinical development of RMC-035 in both heart surgery and kidney transplantation.

About RMC-035

RMC-035 represents a completely new class of drugs (first-in-class) and consists of a recombinant and modified variant of the endogenous protein alpha-1-microglobulin. The investigational drug has the ability to protect cells and their mitochondria from damage caused by oxygen deprivation and elevated levels of the oxygen-binding and toxic protein heme. Promising treatment effects of RMC-035 have been observed in various preclinical disease models. RMC-035 has a natural affinity for the kidneys and is primarily being developed as an intravenous kidney-protective treatment for patients at high risk of developing acute kidney injury (AKI).

RMC-035 has received an Investigational New Drug (IND) approval from the U.S. Food and Drug Administration (FDA) for the treatment of AKI in open-heart surgery. Additionally, RMC-035 has been granted Fast Track Designation by the FDA to reduce the risk of irreversible loss of kidney function, the need for dialysis treatment, or death after open-heart surgery in patients at elevated risk of AKI. Currently, RMC-035 is being evaluated in the global Phase 2 study AKITA for the treatment of AKI in open-heart surgery. The patient recruitment for the AKITA study was

terminated in accordance with the study protocol in April 2023 after a prespecified blinded interim analysis, which indicated a low likelihood of achieving the study's primary (acute) endpoint, i.e., occurrence of AKI within 72 hours after surgery. Additional clinically relevant efficacy endpoints, including change in kidney function in the stable phase after surgery and MAKE (i.e., composite of either death, dialysis or $\geq 25\%$ decline in estimated glomerular filtration rate (eGFR)) by day 30 and 90, have not yet been analyzed. Top-line results from the AKITA study are anticipated to be available in the fall of 2023.

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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, www.skmg.se.

Attachments

[Study results with Guard Therapeutics' RMC-035 in kidney transplantation confirm previously positive data analysis](#)