

First kidney transplant recipient dosed with Guard Therapeutics' investigational drug RMC-035

Guard Therapeutics today announces that the first patient has been dosed in a Phase 1b clinical trial of the investigational drug RMC-035 (ROSGard) in kidney transplantation. The company has thus achieved an important milestone by expanding the clinical development program to a second indication where RMC-035 has the potential to protect against acute kidney injuries. Full study results are expected to be available in the first half of 2023.

Guard Therapeutics' investigational drug RMC-035 has in preclinical studies demonstrated favorable treatment effects in several models of acute kidney injury, for example linked to oxygen deficiency (so-called ischemia-reperfusion injuries). The efficacy of RMC-035 is already being evaluated in a comprehensive global Phase 2 study (AKITA) to demonstrate its ability to prevent and treat acute kidney injury in patients undergoing open heart surgery.

The current Phase 1b study of RMC-035 is open-label, without control group, and will include 8–12 patients undergoing kidney transplantation at Karolinska University Hospital in Huddinge. Initially, eight patients will be enrolled in two sequential dose groups, after which an interim analysis of the pharmacokinetic properties of RMC-035 will be conducted. Based on the outcome of this analysis, a potential third dose group may be evaluated. The primary endpoint of the study includes key pharmacokinetic properties of RMC-035, and the results will inform on the design of a potential subsequent Phase 2 study aimed at improving renal function in kidney transplant recipients.

"The Phase 1b study marks the start of an expansion of the clinical development program for RMC-035 to another area with a high need for novel and improved therapies. Based on the mechanism of action of our investigational drug, we see significant opportunities to counteract specific kidney injuries that occur in relation to kidney transplantation and that often leads to both short-term and long-term medical complications in patients, even after successful transplantation", 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.

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Attachments

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