Guard Therapeutics presents positive clinical data with RMC-035 in patients undergoing kidney transplantation

Guard Therapeutics [GUARD] today announced positive results of the company's phase 1b clinical trial of the investigational drug RMC-035 in patients undergoing kidney transplantation. The study met its primary objective and demonstrated good pharmacokinetic properties of RMC-035 in this patient population and a favorable safety profile.

"We are pleased with the results and that the study achieved its primary goal. The data also provide an important basis for defining the dosing regimen in kidney transplantation with the treatment goal to improve kidney graft function both in the short and long term", said Guard Therapeutics' CEO, Tobias Agervald.

In the current open-label study all patients received treatment with RMC-035. Eight patients split into two different dose groups were included and treated in the study. RMC-035 was dosed once daily for five days (five doses in total) in the dose range of 0.3 to 0.6 mg/kg, with the first dose administered during the surgical procedure (kidney transplantation). RMC-035 exhibited good pharmacokinetic properties with plasma levels that are assessed to be pharmacologically active and consistent with predictions based on previous studies. The safety profile was favorable without any serious adverse effects associated with the study drug. Following the results of this pre-planned interim analysis no additional dose groups are planned in the study.

"Based on these results, we are now evaluating the next step in the development whilst awaiting 3-month follow-up data that will be available in May from all patients," Agervald continued.

"It has been exciting to lead this first study of RMC-035 in kidney transplantation. The protective mechanisms of the investigational drug fit this patient group well and based on the positive study results we look forward to the continued development of RMC-035 in kidney transplant patients with the principal goal of preventing or delaying the need for dialysis treatment or repeat kidney transplantation", said the study's principal investigator Johan Nordström, consultant transplant surgeon at Karolinska University Hospital.

Previous studies with RMC-035 have shown that kidney function plays an important role in the excretion of RMC-035 which affects the dosing strategy. Since patients undergoing kidney transplantation have very low or non-existent kidney function in connection with the transplant procedure, it is particularly important to identify adequate dose levels specifically in this patient group. The study results enable determination of the appropriate dose range in a future efficacy study.

In parallel to the ongoing phase 1b study in kidney transplantation, a large global phase 2 (AKITA) study is also underway with the aim of evaluating the kidney-protective effect of RMC-035 in connection with open heart surgery. An interim analysis based on 134 of 268 patients in total will

be carried out in April by an independent Data Monitoring Committee with the aim of providing a recommendation regarding the study's continued design.

About RMC-035
RMC-035 is a first-in-class investigational drug that consists of a recombinant and modified variant of the endogenous protein alpha-1-microglobulin. Its mechanism of action includes protection of cells and their mitochondria against injury caused by ischemia and elevated levels of the oxygen-binding and toxic protein heme. Robust treatment effects of RMC-035 have been observed in several different preclinical disease models. RMC-035 has a natural biodistribution to the kidneys and is primarily developed as an intravenous renal protective treatment in patients who are at high risk of developing acute kidney injury (AKI).

RMC-035 has received an IND approval from the US Food and Drug Administration (FDA) for the treatment of cardiac surgery associated acute kidney injury. The FDA has also granted RMC-035 Fast Track Designation for reducing the risk of an irreversible loss of kidney function, initiation of kidney replacement therapy or death following open-chest cardiac surgery in patients who are at increased risk for AKI. RMC-035 is currently being evaluated in the global Phase 2 clinical trial AKITA for the prevention and treatment of AKI in open heart surgery and in a Phase 1b study in kidney transplantation.

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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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