Results from Guard Therapeutics' Phase 1b study in cardiac surgery published in Kidney International Reports

Guard Therapeutics [GUARD] today announced that the results from its Phase 1b clinical trial of RMC-035 in patients undergoing open heart surgery have been published in the scientific journal Kidney International Reports. The Phase 1b study met its primary objective and has formed the basis for the company's ongoing Phase 2 clinical trial AKITA.

"The now published results reflect our previous communication that the investigational drug RMC-035 is safe and well tolerated with a favorable pharmacokinetic profile in the initial target patient population, with biomarker data that support the protection of kidney cells in connection with open heart surgery. The publication in a reputable and peer-reviewed scientific journal is a clear validation of the project and strengthens our conviction that RMC-035 has the potential to become the first treatment option to reduce the risk of developing acute kidney injuries in broader patient groups", said Guard Therapeutics' CEO, Tobias Agervald.

The lead author of the article, titled *"Recombinant alpha-1-microglobulin (RMC-035) to prevent AKI in cardiac surgery patients",* is Dr. Raphael Weiss at the University Hospital of Münster who was also a clinical investigator and treating physician in the study.

"It is exciting to see the promising results of this early Phase 1b study. We are now looking forward to the results of the AKITA study where the efficacy of RMC-035 can be assessed based on hard clinical endpoints", said Dr Weiss.

The primary objective of the Phase 1b study, which included a total of 12 patients, was to evaluate the safety and pharmacokinetic properties of RMC-035 in patients undergoing open heart surgery. Results from the study were reported in September 2021.

The kidney-protective effects of RMC-035 in conjunction with open heart surgery is currently being evaluated in the large global Phase 2 study AKITA. An interim analysis based on 134 of the planned 268 subjects will be conducted by an independent Data Monitoring Committee (DMC) who will provide a recommendation in April regarding the continuation of the study.

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), which means that RMC-035 may be administered to patients in clinical studies in the US. 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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