First US patient dosed in Guard Therapeutic's Phase 2 AKITA study

Guard Therapeutics [GUARD] today announced that the first patient in the US has been dosed with study drug in the ongoing global Phase 2 clinical trial AKITA. The main study objective is to evaluate the kidney-protective effect of RMC-035 in patients who are at increased risk of developing acute kidney injury in connection with open heart surgery.

"Following the FDA's clearance of our IND application, it is gratifying that inclusion of patients in the AKITA study also has started in the US. With additional high-quality investigational sites activated, we are accelerating patient recruitment and raising awareness of our kidney-protective treatment concept ahead of a potential future product launch in the US. We look forward to the outcome of the blinded interim evaluation in April that will be conducted by an independent Data Monitoring Committee based on the treatment of half of the planned number of patients in the study. Our goal is to be able to present topline results at the turn of the year", said Guard Therapeutics' CEO Tobias Agervald.

RMC-035, which represents a completely new class of drugs (first-in-class), can protect cells and their mitochondria against injury caused by oxygen deficiency and elevated levels of the oxygen-binding and toxic protein heme. RMC-035 is currently being evaluated in the AKITA study for the prevention of acute kidney injury in open heart surgery and in a Phase 1b study in kidney transplantation.

The dosing of the first patient in the US in the AKITA study took place at Indiana Ohio Heart, Fort Wayne, Indianapolis. Patient recruitment is already ongoing in several European countries and in Canada and continues according to plan.

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.

About AKITA

AKITA is a global, randomized, double-blind and placebo-controlled Phase 2 clinical trial evaluating the renal protective effect of the company's investigational drug RMC-035 in patients at increased risk of developing acute kidney injury (AKI) in open heart surgery. The AKITA study is planned to include 268 patients at up to 30 trial centers in both Europe and North America. The primary outcome measures of the study include the occurrence of AKI at 72 hours after surgery according to the internationally accepted KDIGO guidelines and evaluation of the safety profile of RMC-035 during a 90-day follow-up period. An interim evaluation that is blinded for the company will be conducted when half of the patients have been included in the study. The outcome of the interim analysis is expected to be available in April 2023, and preliminary top-line results of the full study are expected at the turn of the year 2023/2024. The AKITA study is expected to form the basis for a subsequent pivotal study.

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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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