Guard Therapeutics announces positive outcome from first independent safety data review in Phase 2b POINTER study

Guard Therapeutics announced today that an independent Data Safety Monitoring Committee (DSMC) has completed its first planned review of safety data and has recommended that the Phase 2b clinical study POINTER continue as planned. The committee reviewed safety data from 67 patients, corresponding to more than one-third of the planned number of patients in the study, which evaluates the drug candidate RMC-035 as a kidney protective treatment in open-heart surgery.

"We are very pleased with the committee's recommendation. Patient recruitment for the study will now continue according to the existing study protocol, and in the second quarter of 2025, we expect to present the results of the next safety review, which will include data from about two-thirds of the total planned patients," said Guard Therapeutics' CEO, Tobias Agervald. "Meanwhile, recruitment is progressing very well, and we have now enrolled half of the planned number of patients in the study."

Patient recruitment is expected to be completed in Q3 2025, with the overall study results anticipated approximately six months after recruitment is finalized.

This information is information that Guard Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-02-27 18:30 CET.

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About Guard Therapeutics

Guard Therapeutics is a Swedish clinical-stage biotechnology company that identifies and develops new therapies for diseases with a large unmet medical need, focusing on different forms of kidney disease. The company's candidate drugs are based on the endogenous protein alpha-1-microglobulin. Guard Therapeutics is listed on Nasdaq First North Growth Market Stockholm

Certified Adviser is Svensk Kapitalmarknadsgranskning AB, www.skmg.se.

About the indication – kidney injury in open-heart surgery

The company's drug candidate RMC-035 aims to counteract kidney injury that occurs in connection with open-heart surgery and ultimately to reduce the risk of an irreversible loss of kidney function and future end-stage renal disease that requires dialysis treatment or a kidney transplant.

Open-heart surgery using a heart-lung machine typically involves coronary artery bypass grafting (CABG), with or without concurrent heart valve or aortic root surgery. This procedure often leads to significant kidney damage, primarily due to ischemia-reperfusion injury, where blood flow and oxygen supply to the kidneys are reduced. Another contributing factor is hemolysis, the breakdown of red blood cells, which releases harmful byproducts of hemoglobin that can damage the kidneys. Hemolysis occurs during extracorporeal blood circulation through the heart-lung machine, as well as following blood transfusions, which are commonly administered during the procedure. Additionally, the lack of oxygen and the effects of hemolysis often trigger a secondary inflammatory response, exacerbating kidney injury and increasing the risk of scarring and permanent loss of kidney function.

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. Favorable treatment effects of RMC-035 have been observed in several 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 obtained an Investigational New Drug (IND) clearance by 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.

Results from the Phase 2 AKITA study, which enrolled 177 patients, demonstrated a statistically significant and clinically relevant favorable effect of RMC-035 on long-term kidney outcomes in this patient population.

RMC-035 is currently evaluated in the POINTER study, a randomized, double-blind and placebo-controlled Phase 2b study with the main objective of establishing an optimal dosing regimen and exact target patient population for a future pivotal Phase 3 study.

In addition to its evaluation in open-heart surgery, RMC-035 was also assessed in a Phase 1b clinical study involving patients undergoing kidney transplantation.

About the POINTER study

The POINTER study is a randomized, double-blind and placebo-controlled phase 2b study of RMC-035 with the main objective of establishing an optimal dosing regimen and exact target patient population for a future pivotal phase 3 study.

The study is expected to enroll a total of approximately 160 patients, of which at least 30% with chronic kidney disease defined as eGFR (estimated glomerular filtration rate) less than 60 mL/min /1.73m2. Patients will be distributed across two different dose arms of RMC-035 (60 mg and 30 mg) and one control arm (placebo) in a 2:2:3 ratio. Renal function before surgery is also a so-called stratification factor, which means that patients with and without chronic kidney disease will be distributed evenly between all treatment arms.

The study's primary endpoint is change in eGFR from study entry to 90 days post-surgery, which corresponds to the study's planned follow-up time. Major Adverse Kidney Events (MAKE) at 90 days post-surgery is a secondary endpoint consisting of either death, dialysis treatment, or ≥ 25% loss of eGFR compared to pre-surgery. Data from the two dose arms with RMC-035 will be pooled and compared against placebo in the primary efficacy analyses.

Attachments

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