Guard Therapeutics announces completion of data collection in Phase 2b POINTER study

Guard Therapeutics (publ) today announced that the last patient in its ongoing Phase 2b clinical trial, POINTER, has successfully completed the final scheduled follow-up visit 90 days after surgery (last patient last visit). The study is evaluating the company's drug candidate, RMC-035, as a kidney-protective treatment for patients undergoing open-heart surgery.

"We are very pleased that data collection progressed according to plan during the summer, allowing the study to be completed ahead of schedule," said Tobias Agervald, CEO of Guard Therapeutics. "With all data collected, we now look forward to the upcoming readout in the fourth quarter."

A total of 170 patients were randomized and treated at 19 clinical sites across Europe and Canada. The purpose of the study is to evaluate the efficacy and safety of RMC-035 in preserving kidney function after surgery in patients at high risk of acute kidney injury – a common and serious complication of open-heart surgery.

Following completion of data collection, work is now underway to finalize all data, after which the study can be unblinded and the results analyzed. The overall results are expected to be available and communicated during the fourth quarter of 2025.

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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 (ticker: GUARD).

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

About the POINTER study

The POINTER study is a randomized, double-blind, placebo-controlled Phase 2b trial of RMC-035 designed to evaluate its efficacy and safety as a kidney-protective treatment in open-heart surgery, and to determine the optimal dosing regimen and target patient population ahead of a registrational Phase 3 study.

The study includes a total of 170 patients randomized to two RMC-035 dose groups (60 mg and 30 mg) and a control group (placebo) in a 2:2:3 allocation. The primary efficacy endpoint is the change in renal function (eGFR) from baseline to Day 90 after surgery. Major Adverse Kidney Events (MAKE) at Day 90 after surgery is a secondary efficacy endpoint, defined as death, dialysis, or ≥25% loss of eGFR compared with baseline.

Data from the two RMC-035 dose groups will be pooled and compared with placebo in the primary efficacy analyses. Baseline kidney function was used as a stratification factor to ensure that patients with and without chronic kidney disease were evenly distributed across all treatment arms.

Patient recruitment for the study was completed during the second quarter of 2025, and the overall study results are expected to be available in the fourth quarter.

About RMC-035

The company's lead candidate 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 from the U.S. Food and Drug Administration (FDA) for administration to patients in clinical studies. 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 beneficial effect of RMC-035 compared with placebo on long-term kidney outcomes in this patient population. Based on these results, a subsequent Phase 2b study, POINTER, was initiated.

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

About the indication – kidney injury in open-heart surgery

The company's lead 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.

Attachments

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