

First patient in Europe dosed in the clinical phase 2b POINTER study

Guard Therapeutics today announced that the first patient in Europe was dosed in the phase 2b POINTER study with the drug candidate RMC-035 as a kidney-protective treatment in open-heart surgery.

"After study initiation in Canada according to plan, we have now also started to enroll patients for the POINTER study in Europe. A total of 14 clinics in Germany, the Czech Republic and Spain will be involved in the patient recruitment to the study," said Guard Therapeutics CEO, Tobias Agervald.

The first patient in Europe was dosed in Germany at the University Hospital Carl Gustav Carus in Dresden under the leadership of principal investigator Professor Klaus Matschke.

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 $\geq 25\%$ 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.

An independent Data Safety Monitoring Committee (DSMC) will conduct interim safety reviews based on data from one-third and two-thirds of the planned number of patients, respectively. The results of these analyses will be blinded to Guard Therapeutics.

Patient recruitment began in late August 2024 and is expected to last for approximately one year. The overall study results are expected to be available about six months after completion of patient enrollment.

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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. 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.

Attachments

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