Guard Therapeutics presents additional AKITA results at leading U.S. nephrology conference

Guard Therapeutics (publ) today announced that additional results from the Phase 2 AKITA study with the company's drug candidate RMC-035 will be presented at the scientific conference Kidney Week 2025 organized by the American Society of Nephrology (ASN), in Houston, TX, USA. The new results are based on post hoc analyses of the previously completed and reported study and provide deeper insights into the potential of RMC-035 to preserve kidney function after open-heart surgery.

"We look forward to sharing additional important insights from the AKITA study with the world's leading nephrology experts," said Tobias Agervald, CEO of Guard Therapeutics. "With topline results from the subsequent Phase 2b POINTER study expected in the fourth quarter, our commitment is to advance RMC-035 as a first-in-class therapy for acute kidney injury and to contribute to improved care for both patients with pre-existing kidney disease and those at risk."

The AKITA study was the first to evaluate the kidney-protective effect of RMC-035 in patients undergoing open-heart surgery who were at high risk of developing acute kidney injury (AKI). The primary results demonstrated a statistically significant and clinically meaningful improvement in kidney function at 90 days post-surgery in the group treated with RMC-035 compared with placebo.

The new analyses of the AKITA study will be presented by its lead investigator, Professor Alexander Zarbock, University Hospital Münster, Germany, as two poster presentations titled:

- *Efficacy of RMC-035 in Reducing MAKE90 in Patients With and Without AKI After Cardiac Surgery: Post Hoc Analysis of the AKITA Study*
- *Kidney Function Following Open-Chest Cardiac Surgery: Post Hoc Analysis of the AKITA Study*

The congress will be held November 5–9 in Houston, TX, USA. Further details, including time and session, will be made available on the company's and ASN's websites as the congress approaches.

For more information about the ASN conference, please visit: American Society of Nephrology | Kidney Week - Home

For further information, please contact:

Tobias Agervald, CEO
Telephone: +46 8 670 65 51
E-mail: info@guardtherapeutics.com

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 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

Guard Therapeutics presents additional AKITA results at leading U.S. nephrology conference