Guard Therapeutics establishes scientific advisory committee to support Phase 3 development of RMC-035

Guard Therapeutics today announced the formation of a new Scientific Advisory Committee comprising seven globally recognized experts in nephrology and drug development. The committee will play a pivotal role in advising on the company's late-phase development strategy and the design of the upcoming Phase 3 trial for RMC-035, a kidney protective therapy intended for use in open-heart surgery.

"We are glad and honored to collaborate with these internationally renowned clinicians, scientists, and clinical trialists," said Tobias Agervald, CEO of Guard Therapeutics.

"Their collective expertise will be instrumental in guiding us toward an optimal design for a pivotal Phase 3 study that aligns with regulatory and commercial goals while keeping patient perspectives at the forefront," Tobias Agervald added.

The committee members are:

Dr. Rinaldo Bellomo, MD, Professor of Intensive Care Medicine, University of Melbourne, Melbourne, Australia; Director of Intensive Care Research and Staff Specialist in Intensive Care at Austin Health; and Co-Director of the Australian and New Zealand Intensive Care Research Centre (ANZIC-RC).

Dr. Jay L Koyner, MD, Director of the Inpatient Dialysis Unit and ICU Nephrology at the University of Chicago Medical Center, USA, and Professor at the Department of Internal Medicine at the University of Chicago, USA.

Dr. Kathleen Liu, MD, PhD, MAS, Medical Director, Medical Intensive Care Unit and Apheresis Hemodialysis Unit, and Professor of Medicine and Anesthesia, University of California, San Francisco.

Dr. Vlado Perkovic, MD, PhD, Provost at the University of New South Wales, Sydney Australia; Scientia Professor at UNSW, and previously the Dean of the Faculty of Medicine and Health as well Professorial Fellow at The George Institute, Australia; and Staff Specialist in Nephrology at the Royal North Shore Hospital in Sydney.

Dr. Mitch Rosner, MD, FACP, Henry B. Mulholland Professor of Medicine and Chair, Department of Medicine at University of Virginia, USA.

Dr. Nicholas Selby, MD, Professor of Nephrology, University of Nottingham, UK.

Prof. Dr. Alexander Zarbock, MD, Director and Chairman of the Department of Anesthesiology, Intensive Care and Pain Medicine, University of Münster, Germany.

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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. 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.

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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