

Guard Therapeutics presents late breaking clinical trial abstract at ASN Kidney Week 2023

Guard Therapeutics (GUARD), a biotechnology company specializing in kidney diseases, today announced that its late breaking clinical trial abstract has been selected for presentation at the American Society of Nephrology (ASN) Kidney Week in Philadelphia, Pennsylvania, in November 2023. The abstract includes results from the Phase 2 clinical study AKITA evaluating the company's leading candidate drug RMC-035 as a kidney protective therapy in open-heart surgery.

The abstract, titled *Results of a randomized placebo-controlled double-blind adaptive Phase 2 study (AKITA) evaluating RMC-035 for the prevention of AKI in patients undergoing cardiac surgery*, will be presented at a late-breaking clinical trial poster session on November 2. The main author of the abstract is Professor Dr Alexander Zarbock, Münster University Hospital.

The abstract includes the recently announced results from the Phase 2 clinical study AKITA, which demonstrated statistically significant and clinically relevant long-term kidney-protective effects of RMC-035 after open-heart surgery.

"We are pleased to be presenting important clinical trial results of RMC-035 at such a large and reputable conference as the ASN Kidney Week. The results represent a potential breakthrough in the protection of kidney function in open-heart surgery and we are looking forward to advancing RMC-035 in the clinical development towards an approved medication," said Tobias Agervald, CEO at Guard Therapeutics.

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 protects 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 undergoing open-heart surgery at high risk of developing kidney injury.

RMC-035 has obtained an Investigational New Drug (IND) clearance by the U.S. Food and Drug Administration (FDA) for the treatment of acute kidney injury (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 increased risk of AKI. Recent top-line results from the Phase 2 study AKITA demonstrated a statistically significant and clinically relevant favorable effect of RMC-035 on long-term kidney outcomes in this patient population. In addition to open-heart surgery, a second development program with RMC-035 was initiated with a recently completed Phase 1b clinical study in patients undergoing kidney transplantation.

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About Guard Therapeutics

Guard Therapeutics is a Swedish biotech company that identifies and develops new therapies for diseases with a great medical need for more effective treatments. The company's investigational drug RMC-035 is being developed as a kidney protective treatment in connection with open heart surgery and kidney transplantation. Guard Therapeutics is listed on Nasdaq First North Growth Market Stockholm.

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

Attachments

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