Guard Therapeutics phase 2 results published in leading scientific journal

Guard Therapeutics today announced that the renowned scientific journal eClinicalMedicine, part of Lancet Discovery Science, has published an article describing the main findings from the company's phase 2 clinical study AKITA with the drug candidate RMC-035, which is being evaluated for the treatment of kidney injury associated with open-heart surgery. The results form the basis for the continued clinical development program with RMC-035 and the design of the recently initiated phase 2b POINTER study.

The results published in eClinicalMedicine include a statistically significant and clinically relevant kidney-protective effect of RMC-035 compared to placebo in a stable phase after surgery. This effect is measured both as improved kidney function (estimated glomerular filtration rate, eGFR) at 90 days after surgery and as a reduction in Major Adverse Kidney Events (MAKE) at the same time point. MAKE is the expected primary efficacy endpoint in a future pivotal phase 3 study as required by regulatory authorities.

"We are very pleased to present the main results of the AKITA study in such a respected scientific journal as eClinicalMedicine. The publication validates the significance of the AKITA study and the efficacy signal observed for the first time in patients, associated with the completely new mechanism that RMC-035 represents," said Guard Therapeutics CEO Tobias Agervald.

The article, titled *Efficacy of therapeutic alpha-1-microglobulin in reducing kidney injury after cardiac surgery: a randomized placebo-controlled Phase 2 study*, was authored by Dr. Alexander Zarbock, the global principal investigator for the AKITA study and Professor of anesthesiology and intensive care medicine at the University Hospital of Münster, Germany. Co-authors are Tobias Agervald and Michael Reusch, CMO at Guard Therapeutics, as well as Nicolas Noiseux, David Mazer, Johannes Böhm, Maxime Laflamme, Klaus Matschke, Jan Burkert, Benoit de Varennes, Jan Vojacek, Jay L. Koyner, Dan Engelman and Matthias Thielmann.

"The results of the AKITA study are very exciting and indicate a potential breakthrough for the treatment of kidney injury associated with open-heart surgery. The concordance between improved renal function and the reduction of MAKE at a stable phase after surgery is very promising, as these endpoints reflect different ways of assessing the kidney-protective treatment effect. We look forward to the next development steps of RMC-035 and ultimately its potential to improve patient outcomes in the future," said Professor Zarbock.

The next step in the clinical program for RMC-035 is a phase 2b study (POINTER) aimed at optimizing the dose and identifying the exact target patient population prior to a pivotal phase 3 study. Patient recruitment was recently initiated and is expected to take approximately one year. Overall study results are anticipated to be available about 6 months after the completion of patient recruitment.

The article is now available online via the following link:
Efficacy and safety of therapeutic alpha-1-microglobulin RMC-035 in reducing kidney injury after cardiac surgery: a multicentre, randomised, double-blind, parallel group, phase 2a trial - ScienceDirect

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.

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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.

Attachments

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