FDA provides positive feedback to Guard Therapeutics regarding the continued development plan for RMC-035

Guard Therapeutics [GUARD], a biotechnology company specializing in kidney diseases, today announced that the United States Food and Drug Administration (FDA) has provided positive feedback regarding the continued development of the company's leading drug candidate RMC-035 in open-heart surgery. The next developmental step includes a phase 2b study with the aim of identifying an optimal dosage of RMC-035. The phase 2b study is also expected to enable the most efficient design of a subsequent pivotal phase 3 study.

"It is gratifying and of great significance that we have received positive feedback from the FDA and established a comprehensive and optimal development plan for RMC-035. The outcome of the meeting with the FDA is a clear validation of our phase 2 clinical data and strengthens our confidence in RMC-035 as a new unique preventive treatment for kidney injuries, initially in patients undergoing heart surgery. With significant experiences from the AKITA-study of enrolling and treating patients, we now look forward to initiating and conducting the phase 2b study as quickly as possible," said Guard Therapeutics CEO Tobias Agervald.

The advisory meeting with the FDA was based on the results of the recently completed randomized, double-blind, and placebo-controlled phase 2 study AKITA with RMC-035. The study included a total of 177 patients who underwent open-heart surgery with an increased risk of developing kidney injuries. The study results showed a clinically relevant and statistically significant improvement in kidney function compared to placebo at 90 days after surgery, both as measured by change in kidney function (estimated glomerular filtration rate, eGFR) over time and the number of kidney-related events according to a composite outcome measure (major adverse kidney events, MAKE), including death, dialysis treatment or at least a 25% loss of eGFR compared to baseline.

In line with standard drug development practice, the next step is to conduct a phase 2b study aimed at identifying an optimal dosage for RMC-035 in a subsequent pivotal study. The phase 2b study will be randomized, double-blind and placebo controlled, and, like the AKITA study, include patients undergoing open-heart surgery who are at increased risk of developing kidney injuries in connection with the procedure. The study is expected to include a total of approximately 160 patients divided into two different dose arms of RMC-035 (60 mg and 30 mg) as well as a control arm (placebo). The primary endpoint is change in eGFR from study start to 90 days after surgery, which corresponds to the planned follow-up period of the study. Patient recruitment is expected to begin in the third quarter of 2024 and continue for approximately one year. Study results are expected to be available approximately 6 months after completion of patient recruitment.

RMC-035 has previously been awarded a Fast Track Designation by the FDA. This designation means opportunities for faster development and a shorter registration process for RMC-035, as well as the opportunity for more frequent guidance from the FDA. Based on the current dialogue with the FDA, and assuming positive results in the planned phase 2b study, the company plans to subsequently conduct a single pivotal phase 3 study with an endpoint reflective of an irreversible loss of kidney function, and to discuss the potential for a study design that allows for accelerated approval.

The company plans to host a research and development update at the end of January and present next development steps in more detail. More information will be shared shortly.

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 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.

This information is information that Guard Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-01-15 07:45 CET.

Attachments

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