Last patient visit completed in Guard Therapeutics' clinical Phase 2 study AKITA

Guard Therapeutics [GUARD], a biotechnology company specializing in kidney diseases, announced today that the last patient's last visit (LPLV) in the clinical Phase 2 study AKITA has been completed. The study aims to evaluate the kidney protective effect of the investigational drug RMC-035 in relation to open heart surgery. This milestone means that all patients in the study have been followed up for 90 days after surgery. Top-line results from the study are expected to be communicated in the autumn of 2023 and will thus include the efficacy and safety of RMC-035 throughout the follow-up period.

The AKITA study is a randomized, double-blind, and placebo-controlled Phase 2 study of RMC-035 in patients undergoing open-heart surgery at increased risk to develop acute kidney injury (AKI). A total of 177 patients have been randomized and dosed in the study, providing a comprehensive dataset to analyze the efficacy and safety of RMC-035, as well as to perform predefined subgroup analyses, for example in patients with or without chronic kidney disease.

Originally, the study was estimated to include 268 dosed patients. This number was based on achieving a positive outcome with statistical significance for the study's primary (acute) efficacy endpoint, namely the incidence of AKI within 72 hours after the first dose administered during surgery. This efficacy endpoint is based on guidelines established by the scientific organization KDIGO (Kidney Disease: Improving Global Outcomes) and is a so-called surrogate measure for clinically relevant long-term effects, including irreversible loss of kidney function. On April 14th of this year, the company announced that patient recruitment for the AKITA study had been discontinued based on a recommendation from an independent Data Monitoring Committee (DMC). The decision was based on a predefined interim analysis that indicated a low likelihood of achieving the study's primary endpoint with statistical significance.

Several important secondary endpoints, which are critical for decisions regarding the continued development of RMC-035, were not part of the interim analysis. These include, in particular, changes in kidney function from baseline (before surgery) to days 30 and 90 after surgery, as well as serious kidney events according to the Major Adverse Kidney Events (MAKE) criteria at the same time points. MAKE is a composite endpoint that includes any of the following events: death, dialysis treatment, or a ≥25% reduction in eGFR (estimated glomerular filtration rate) compared to baseline. MAKE at 90 days is the expected primary endpoint required by the U.S. Food and Drug Administration (FDA) in a pivotal Phase 3 study.

The last patient has completed the study's last visit (LPLV). After complete data entry at all clinical sites, followed by verification and quality control, the database will be locked, and statistical analysis of the data will commence. The company expects to communicate top-line results from the study in the fall of 2023. These results will be instrumental for decision making regarding the continued development of RMC-035 in both heart surgery and the second development indication, kidney transplantation.

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. Currently, RMC-035 is being evaluated in the global Phase 2 clinical study AKITA for the treatment of AKI in open-heart surgery. A recent Phase 1b clinical study of RMC-035 in patients undergoing kidney transplantation was also completed.

About the AKITA study

AKITA is a global, randomized, double-blind, and placebo-controlled Phase 2 clinical study aimed at evaluating the kidney protective effect of the company's investigational drug, RMC-035, in patients at an increased risk of developing acute kidney injury (AKI) associated with open-heart surgery. The AKITA study involves approximately 30 investigational sites in both Europe and North America. The primary outcome measures of the study include the incidence of AKI within 72 hours after completion of heart surgery, according to the internationally recognized KDIGO guidelines, as well as the evaluation of the investigational drug's safety profile during a 90-day follow-up period. Top-line results from the AKITA study are expected to be available in the fall of 2023.

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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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