Guard Therapeutics closes its phase 2 clinical trial AKITA following DMC recommendation

Guard Therapeutics [GUARD] today announces that an external and independent Data Monitoring Committee (DMC) recommends termination of the ongoing phase 2 clinical trial AKITA. The recommendation is based on a planned interim analysis regarding both efficacy and safety of the investigational drug RMC-035 using data from half of the total planned 268 patients.

The AKITA study is a global, randomized, double-blind and placebo-controlled phase 2 study and aims to evaluate the kidney-protective effect of RMC-035 in conjunction with open heart surgery.

The company has decided to follow the DMC recommendation, which means that further patient recruitment is discontinued and that the study is terminated prematurely because the probability of achieving the study's main objectives is considered low. The recommendation is based on an analysis of both efficacy and safety data.

"We will now analyze the unblinded results and make our own more comprehensive analyses of the study results and then decide upon next steps", says Guard Therapeutics' CEO, Tobias Agervald.

The company has so far only received the DMC recommendation regarding the continuation of the study, but no unblinded data.

About RMC-035
RMC-035 is a first-in-class investigational drug that consists of a recombinant and modified variant of the endogenous protein alpha-1-microglobulin. Its mechanism of action includes protection of cells and their mitochondria against injury caused by ischemia and elevated levels of the oxygen-binding and toxic protein heme. Robust treatment effects of RMC-035 have been observed in several different preclinical disease models. RMC-035 has a natural biodistribution to the kidneys and is primarily developed as an intravenous renal protective treatment in patients who are at high risk of developing acute kidney injury (AKI).

RMC-035 has received an IND approval from the US Food and Drug Administration (FDA) for the treatment of cardiac surgery-associated AKI. The FDA has also granted RMC-035 Fast Track Designation for reducing the risk of an irreversible loss of kidney function, initiation of kidney replacement therapy or death following open-chest cardiac surgery in patients who are at increased risk for AKI. RMC-035 is currently being evaluated in the global Phase 2 clinical trial AKITA for the prevention and treatment of AKI in open heart surgery. Positive results of the ongoing Phase 1b study in kidney transplantation were announced on 20 March 2023.

About AKITA
AKITA is a global, randomized, double-blind and placebo-controlled Phase 2 clinical trial

evaluating the renal protective effect of the company's investigational drug RMC-035 in patients at increased risk of developing acute kidney injury (AKI) in open heart surgery. The AKITA study is planned to include 268 patients at up to 30 trial centers in both Europe and North America. The primary outcome measures of the study include the occurrence of AKI at 72 hours after surgery according to the internationally accepted KDIGO guidelines and evaluation of the safety profile of RMC-035 during a 90-day follow-up period.

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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, tel. +46 11 32 30 732, ca@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 2023-04-14 08:30 CEST.

Attachments

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