Half of the patients dosed in the Phase 2 AKITA study

Guard Therapeutics [GUARD] today announced that 134 of the planned 268 patients have been dosed in the global randomized, double-blinded and placebo-controlled Phase 2 clinical trial (AKITA). The AKITA study has been designed to evaluate the kidney-protective effects of the investigational drug RMC-035 in conjunction with open heart surgery. An interim analysis will be conducted by an independent Data Monitoring Committee (DMC) who will provide a recommendation in April regarding the continuation of the study.

"It is gratifying that the patient recruitment to the AKITA study is proceeding according to plan. With half of the patients included, we now look forward to receiving the DMC recommendation regarding the remaining part of the study, while the recruitment of additional patients continues unabated", said Tobias Agervald, CEO of Guard Therapeutics.

Based on the current patient data, an interim analysis will be conducted that will form the basis for the external and independent DMC recommendation on the continuation and potential modification of the study. The interim analysis consists of two parts: an analysis of safety data and a separate evaluation of the study's primary and several secondary endpoints. To preserve the validity and data integrity of the study, unblinded study results will be reviewed by the DMC only, whereas Guard Therapeutics will receive the DMC recommendation (according to the alternatives below) without disclosure of any results from the analysis.

Based on the efficacy data analysis, the DMC recommendation can result in three different outcomes: 1) that the study continues according to plan with unchanged study protocol, 2) that the study is expanded to include a total of 348 patients with the purpose to increase the probability that the primary endpoint will be statistically significant, or 3) that the study is terminated prematurely. There is also a possibility of modifying the inclusion criteria in the study.

The interim analysis is planned to be conducted during the first quarter of 2023, while the outcome of the DMC recommendation is expected to be available in April 2023. Patient recruitment will continue until further notice.

The top-line results from the complete study are expected to be available at the turn of the year 2023/2024 and will form the basis for a subsequent pivotal study.

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), which means that RMC-035 may be administered to patients in clinical studies in the US. 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 and in a Phase 1b study in kidney transplantation.

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. An interim evaluation that is blinded for the company will be conducted when half of the patients have been included in the study. Preliminary top-line results are expected at the turn of the year 2023/2024. The results from the AKITA study are expected to form the basis for a subsequent pivotal study.

For further information, please contact:

Tobias Agervald, CEO
Telephone: +46 8 670 65 51
E-mail: info@guardtherapeutics.com

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.

Attachments

Half of the patients dosed in the Phase 2 AKITA study