Guard Therapeutics provides in-depth information on phase 2 clinical trial

Guard Therapeutics today provides an update on the plan for the company's global, clinical phase 2 study of ROSgard in patients undergoing open heart surgery with additional risk factors to develop acute kidney injury. The study aims to evaluate the renal protective treatment effect of ROSgard based on several outcome measures, and is anticipated to provide a comprehensive data set to support further clinical development including the design of a subsequent registration study. The phase 2 study is called AKITA and is expected to provide blinded interim results in the first quarter of 2023 at topline results during the later part of 2023. Guard Therapeutics CEO, Tobias Agervald, presents the study design in a video interview that is available via link further down in this press release.

The Phase 2 AKITA study is a randomized, double-blind and placebo-controlled trial and is conducted in patients undergoing open heart surgery and who are at increased risk of developing acute kidney injury (AKI). The study was opened for patient recruitment in Canada and Germany by the end of the first quarter 2022, and the first patient has already completed their study treatment. The principal investigator of the study is Prof. Dr. Alexander Zarbock at the University Hospital of Münster, Germany. During the second quarter of 2022, it is planned to expand patient recruitment in additional European countries. The company also intends to include trial centers in the US during the second half of 2022. The goal is to include a total of approximately 270 patients, half of whom will receive active treatment and half placebo.

When 50% of the patients have completed their study treatment an independent and blinded interim analysis of the treatment effect is planned based on prespecified efficacy endpoints, including the incidence of AKI in each treatment group. Based on a number of predefined criteria regarding the treatment effect, the study can either continue according to plan, be expanded to a total of around 350 patients or be terminated prematurely. The outcome of this interim analysis is expected to be available during the first quarter 2023, and topline results of the full study are expected to be communciated during the later part of 2023.

In the study, patients will receive a starting dose adjusted to their kidney function before surgery. Patients with an estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m2 will receive 0.65 mg/kg and patients with eGFR above this level will initially be treated with 1.3 mg/kg. The first dose will be given during surgery and four additional doses will be given over the next two days. Patients will be closely monitored during hospitalization up to one week after end-of-treatment and then undergo additional follow-up visits at 30 and 90 days after surgery.

The primary endpoint is the presence of AKI within 72 hours of the first dose according to guidelines established by the scientific organization Kidney Disease: Improving Global Outcomes (KDIGO). Additional secondary outcome measures will be included, such as AKI within seven days after surgery, severity and duration of AKI, integrated renal function in the first three and seven days after surgery, change in renal function from screening (prior to surgery) up to seven days and at 30 and 90 days after surgery, respectively, and incidence of major adverse kidney events

(MAKE) at 30 and 90 days after surgery. MAKE is a composite endpoint of death, dialysis treatment after surgery or >25% reduction in eGFR compared to the baseline (screening) value before surgery. Both the primary endpoint and the secondary endpoints will have an impact on the interpretation of the results and the design of a subsequent pivotal study. Thus, there is no formal requirement that the primary endpoint is met in order to take the project to the next study if clinically relevant effects are observed and there is consistency between different outcome measures.

The investigational drug ROSgard has the ability to counteract severe oxidative stress – a common denominator for many different types of AKI. Guard Therapeutics has chosen to prioritize treatment in connection with open heart surgery and use of a heart-lung machine in the initial clinical development phase.

Guard Therapeutics CEO Tobias Agervald presents the study design in a video interview that can be seen here: https://youtu.be/Git_Gt-L68o

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 pharmaceutical company that identifies and develops new therapies for diseases with a great medical need for more effective treatments. The company's clinical investigational drug ROSgard is being developed as a protective treatment against acute kidney injury with an initial focus on patients undergoing heart surgery. 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

Guard Therapeutics provides in-depth information on phase 2 clinical trial