Guard Therapeutics provides more information on the development strategy for RMC-035

Guard Therapeutics [GUARD], a biotechnology company specializing in kidney diseases, today announced further information regarding the development strategy for the investigational drug RMC-035. An advisory meeting with the U.S. Food and Drug Administration (FDA) will be requested to explore dose optimization and the framework for a future registrational trial for the prevention of kidney injury in open-heart surgery. The development strategy is based on the recent top-line results of the Phase 2 AKITA study, which demonstrated statistically significant and clinically relevant long-term kidney-protective effects of RMC-035 after open-heart surgery.

As a first step, the company plans to engage with the FDA concerning AKITA study results and subsequent development steps. To facilitate this, Guard Therapeutics is seeking an advisory meeting which is anticipated to take place around the turn of the year 2023/24 based on standard timelines.

"We are highly motivated by the efficacy results of the Phase 2 AKITA study. To advance RMC-035 in the clinical development towards an approved medication, it is now crucial to promptly present these results to the FDA and seek its guidance regarding the upcoming development steps in open-heart surgery," said Dr. Michael Reusch, Chief Medical Officer at Guard Therapeutics. "We look forward to engaging in a fruitful dialogue with the FDA to establish a continued scientifically sound and efficient development plan".

The company intends to proceed as planned to determine the optimal dose of RMC-035. Based on the clear kidney-protective effects of RMC-035 in the AKITA study, alternative development paths will also be evaluated with the aim of reducing the time and cost to market approval. This includes the possibility of obtaining a so-called Breakthrough Therapy designation - an FDA program aimed at expediting the development and review of drugs targeting serious or life-threatening conditions.

More details regarding the clinical plan are expected to be communicated after the planned advisory meeting with the FDA.

After determining the optimal dose in open-heart surgery, the company also intends to advance RMC-035 in the kidney transplantation indication into the next clinical development phase. With demonstrated proof-of-concept and an established dose in open-heart surgery, there are potential opportunities to proceed directly to a pivotal phase 2b/3 study in 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 increased risk of AKI. Recent top-line results from the Phase 2 study AKITA demonstrated a statistically significant and clinically relevant 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 recently 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.

Attachments

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