Guard Therapeutics granted FDA Fast Track designation for RMC-035

Guard Therapeutics today announces that the U.S. Food and Drug Administration (FDA) has granted RMC-035 (ROSgard) 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 acute kidney injury. FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs aimed at treating serious conditions which have a large unmet medical need, with the goal to provide patients earlier access to such drugs.

The investigational drug RMC-035 is being developed as an intravenous short-term treatment against acute kidney injuries (AKI) and is currently being evaluated in a comprehensive global Phase 2 study (AKITA) to document its renal protective effect in patients undergoing open cardiac surgery. In addition, a Phase 1b study is underway in patients undergoing kidney transplantation.

"AKI remains a large unmet medical need and is associated with significant short-term and long-term morbidity and mortality. It is a serious condition which affects patients' lives and consumes significant health care resources including prolonged post-operative intensive care and hospitalization time and, in the longer perspective, management of chronic complications like the possible transition to chronic kidney disease and accelerated progression towards end-stage renal disease as well as cardiovascular disease. RMC-035 is a new investigational drug targeting central disease pathways causing AKI and is a novel promising therapeutic strategy in the management of AKI" says Professor Jay L. Koyner, University of Chicago, Department of Internal Medicine, Section of Nephrology.

Tobias Agervald, CEO of Guard Therapeutics, says: "It is gratifying that our investigational drug is granted Fast Track designation by the FDA. AKI is a serious clinical problem, and we are pleased that the FDA recognizes the large medical need in the field. It also provides the opportunity to a closer dialogue with the agency and support in the continued development of our innovative investigational drug for the treatment of AKI associated with cardiac surgery, which in turn can lead to a faster way to market".

About Fast Track designation

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions that address an unmet medical need, by providing a therapy where none exists or providing a therapy which potentially may be better and shows some advantage over available therapies. Fast Track designation includes opportunities for more frequent meetings with the FDA to discuss trial design, development plans, data needed to support drug approval, submission of a New Drug Application (NDA) on a rolling basis and eligibility for accelerated approval and priority review, if relevant criteria are met.

About RMC-035

RMC-035 (ROSgard) is a first-in-class investigational drug that consists of a synthetic 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. 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 conjunction wiht 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 to be presented in the fourth quarter of 2023. The AKITA study is 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.

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 2022-11-08 08:05 CET.

Attachments

Guard Therapeutics granted FDA Fast Track designation for RMC-035