Guard Therapeutics receives regulatory EU approvals to include patients in its Phase 2b study POINTER

Guard Therapeutics announced today that, through the European application procedure, the company has received authorization from regulatory authorities and ethics committees in Spain, Germany, and the Czech Republic to include patients in the clinical Phase 2b study POINTER with the drug candidate RMC-035 as a kidney-protective treatment in open-heart surgery.

"We are very pleased with the swift and positive response from the relevant authorities, which means that all approvals required to start the study are now in place in the countries where the study is planned to be conducted," said Guard Therapeutics CEO, Tobias Agervald.

In April, the federal Canadian institution Health Canada was the first authority to approve the company's application to include patients in the POINTER study. Patient enrollment is expected to begin shortly at several investigational sites in Canada and in the coming months in Europe, and to continue for about a year.

The POINTER study is a randomized, double-blind, and placebo-controlled Phase 2b study of RMC-035 with the main purpose of establishing an optimal dosing regimen and precise target group for treatment prior to a pivotal Phase 3 study. The study is expected to include a total of approximately 160 patients distributed across two different dose arms of RMC-035 (60 mg and 30 mg) and a control arm (placebo). The study's primary endpoint is change in renal function (estimated glomerular filtration rate, eGFR) from study start to 90 days after surgery, which corresponds to the planned follow-up period of the study participants. Overall study results are expected to be available approximately 6 months after completion of patient recruitment.

About the indication – kidney injury in open heart surgery

The company's drug candidate RMC-035 aims to counteract kidney injury that occurs in connection with open heart surgery and ultimately to reduce the risk of an irreversible loss of kidney function and future end-stage kidney disease that requires dialysis treatment or a kidney transplant.

Open heart surgery carried out using a heart-lung machine mainly includes coronary artery by-pass graft (CABG) with or without surgery of the heart valves or the aortic root. This type of surgery often causes significant damage to the kidneys. An important cause of a such damage is reduced blood flow to and oxygenation of the kidneys (ischemia-reperfusion injury). Hemolysis is another contributing cause, meaning that red blood cells are damaged, which in turn gives rise to kidney injury due to harmful breakdown products of the oxygen-carrying substance hemoglobin. Hemolysis occurs when blood is circulated outside the body, via the heart-lung machine, and following blood transfusions that are often given in connection with the procedure. Additionally, as a result of lack of oxygen and hemolysis, a secondary inflammation often occurs which contributes to an ongoing injury process in the kidneys with the risk of scarring and permanent loss of kidney function.

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 elevated risk of AKI. Recent top-line results from the Phase 2 study AKITA demonstrated a statistically significant and clinically relevant favorable 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.

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, www.skmg.se.

Attachments

Guard Therapeutics receives regulatory EU approvals to include patients in its Phase 2b study POINTER