

Guard Therapeutics research published in American Journal of Physiology – Renal Physiology

Guard Therapeutics today announced that the scientific journal American Journal of Physiology – Renal Physiology has published an article summarizing important preclinical results of the company's clinical drug candidate RMC-035. The results consistently demonstrate positive effects of RMC-035 in a large number of models for kidney injury and provide clear support for its continued clinical development as a renal protective treatment in open-heart surgery.

"It is very gratifying that our extensive and solid work with RMC-035 in kidney injuries is being noticed by the scientific community. Taken together, the preclinical studies provide important information regarding the treatment effect, biodistribution and mechanisms of RMC-035 across a wide range of experimental evaluations. The findings are also well aligned with the results of our phase 2 trial AKITA showing clinically relevant kidney protective effects of RMC-035 in open-heart surgery patients," said Tobias Agervald, CEO of Guard Therapeutics.

The article, titled *Therapeutic alpha-1-microglobulin ameliorates kidney ischemia reperfusion injury*, was authored by Tobias Agervald and Peter Gilmour, Head of Preclinical Science at Guard Therapeutics, as well as Mikhail Burmakin, Magnus Gram, Nelli Shushakova, Ruben M. Sandval and Bruce A. Molitoris.

"We are pleased to have contributed to the research on RMC-035 and its beneficial effect on the kidneys observed in numerous preclinical trials. We look forward to following the further development of RMC-035 towards a new drug," said Professor Bruce Molitoris, Indiana University, Indianapolis, USA.

The current research results, which were published in an online version of the American Journal of Physiology – Renal Physiology, mainly include effect studies in so-called ischemia-reperfusion injury that occurs in the kidneys in connection with heart surgery. Overall, favorable treatment effects of RMC-035 were demonstrated based on analyses of a large number of outcome measures, including kidney function (GFR), kidney injury markers in the blood (creatinine and urea), albuminuria (protein in urine), cell injury markers in urine (NGAL, KIM-1), inflammation (IL-6) and protection of the cell's mitochondria. A careful mapping also demonstrated specific uptake of RMC-035 in the so-called proximal tubular cells of the kidneys, which is advantageous given that these are the primary cells affected by the initial kidney injury occurring in association with heart surgery.

Guard Therapeutics now intends to continue the clinical program of RMC-035 in heart surgery, and recently received approval by Health Canada to enroll patients in Canada to its phase 2b clinical trial POINTER. Patient recruitment is expected to begin in the third quarter of 2024 and last for around one year. Overall study results are expected to be available approximately 6 months after

completion of patient recruitment.

The unedited article is now available online via the following link:

<https://journals.physiology.org/doi/abs/10.1152/ajprenal.00067.2024>

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.

Press Release
27 May 2024 11:00:00 CEST



Attachments

[Guard Therapeutics research published in American Journal of Physiology – Renal Physiology](#)