# Guard Therapeutics reports positive top-line results from phase 1 study of ROSgard in individuals with renal impairment

**Guard Therapeutics today announced positive top-line results from a phase 1 study of its investigational drug ROSgard in individuals with renal impairment. The main aim of the study was to characterize the pharmacokinetic properties and safety profile of ROSgard in patients with renal impairment. The company believes that these results, together with previously reported positive results from a clinical phase 1 programme in healthy subjects, provide an excellent foundation for continued development of ROSgard in the area of acute kidney injury.**

Guard Therapeutics' investigational drug ROSgard has been shown in several preclinical studies to protect against cell and organ damage, including acute kidney injury, by counteracting oxidative stress and supporting regenerative processes. The investigational drug is initially being developed to prevent kidney injury in connection with cadiac surgery.

In the study, ROSgard was administered in single doses to individuals with varying degrees of renal function. Interim results from the study have previously been reported for individuals with mild to moderate renal impairment (eGFR ≥45 mL/min). In the concluding part, individuals with more severe impairment of renal function were included (eGFR 15-44 mL/min). Overall, the results confirm a favourable safety profile as well as a clear association between renal impairment, prolonged plasma elimination time and higher exposure (AUC). The results provide important guidance for dosing strategies in future patient studies.

A more comprehensive analysis of the study results will be presented at a later time.

"We are pleased to announce positive top-line results which show that ROSgard has a favourable pharmacokinetic profile and is well tolerated also in people with renal impairment. The study results provide a strengthened foundation for continued clinical development. We are now intensifying preparations for our first study in patients undergoing cardiac surgery and an upcoming global phase 2 programme," Tobias Agervald, CEO of Guard Therapeutics, says.

An initial study in the primary target group for treatment – patients undergoing cardiac surgery with a high risk of developing acute kidney injury – is planned to be carried out in Germany and is expected to begin in the fourth quarter of 2020, subject to the necessary regulatory approvals.

**For further information, please contact:**

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## About Guard Therapeutics

Guard Therapeutics' investigational drug ROSgard has been documented in several preclinical studies to protect against cell and organ damage, including acute kidney damage, by counteracting oxidative stress and supporting regenerative processes. 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 2020-09-28 08:25 CEST.*

## Attachments

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