

Guard Therapeutics presents positive follow-up analysis from phase 1 study of ROSgard

Guard Therapeutics (Nasdaq First North Growth Market: GUARD) has today presented follow-up results from a previously completed phase 1 study of ROSgard in single ascending doses (SAD). In particular, the results show that the investigational drug has a favourable effect on a well established biomarker that is used to predict onset of acute kidney injury after cardiac surgery. The study was conducted in healthy subjects.

The investigational drug ROSgard is a synthetic form of the endogenous protein alpha-1 microglobulin, which is tasked with keeping the body free from the toxic reactive substances generated by oxidative stress. These substances can cause serious damage to cells and tissues. Even in healthy individuals there is a certain background level of cellular stress, which can be measured using biomarkers.

An exploratory biomarker analysis conducted after the completion of the SAD study shows that no increased cellular stress or damage to kidney cells occurs during treatment with ROSgard, which supports the positive safety data reported previously. A significant reduction of IGFBP-7 ($p < 0.05$) was also observed as well as a smaller non-significant reduction of TIMP-2, two biomarkers indicating acute kidney cell stress that are included in the FDA-approved diagnostic test NephroCheck, which is used to predict onset of acute kidney injury after cardiac surgery.

"The results of these exploratory analyses are based on data from healthy subjects and must of course be confirmed in future patient studies, but we consider them to be very promising and believe they could be a first indication that ROSgard exerts a protective effect in humans", Tobias Agervald, CEO of Guard Therapeutics, says.

ROSGard is being developed as a preventive treatment for acute kidney injury. Currently, the final stage of the phase 1a programme is underway, where the investigational drug is being administered in multiple ascending doses (MAD). A parallel study is being conducted in individuals with impaired kidney function. If the phase 1 programme produces positive results, the company is planning to conduct an initial smaller study in patients undergoing cardiac surgery that will start in the fourth quarter of 2020.

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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 2020-07-08 10:50 CEST.

Attachments

[Guard Therapeutics presents positive follow-up analysis from phase 1 study of ROSgard](#)