

Guard Therapeutics announces positive top line results from the concluding study in the clinical phase 1 programme of ROSgard in healthy subjects

Guard Therapeutics today announced positive top line results from the concluding study in the clinical phase 1 programme in healthy subjects where the investigational drug ROSgard was administered in multiple ascending doses (MAD). ROSgard demonstrated good pharmacokinetic properties and a favourable safety profile. The company considers that this provides excellent conditions for continued development of the investigational drug within the field of acute kidney damage and is thus intensifying preparations in advance of forthcoming global patient studies.

Guard Therapeutics investigational drug ROSgard has been demonstrated in several pre-clinical studies to provide protection against cell and organ damage, including acute kidney damage, by counteracting oxidative stress and supporting regenerative processes. The investigational drug is being developed primarily to counteract kidney damage in connection with cardiac surgery. The company recently presented promising results from the SAD study (Single Ascending Doses) that was previously performed in subjects, which demonstrates among other things that ROSgard has a favourable effect on biomarkers that indicate a high risk of developing acute kidney damage after cardiac surgery.

"The positive results generated in the phase 1 programme mean that we now have an excellent foundation for the continued development of ROSgard. Based on these results, we are preparing an application to conduct a small phase 1b study in Germany, at the same time as we are planning for a subsequent global phase 2 study in patients who risk suffering kidney damage in connection with cardiac surgery", says Tobias Agervald, CEO of Guard Therapeutics.

In the next stage, Guard Therapeutics is planning follow-up bioanalyses based on data from the MAD study. The phase 1b study of ROSgard is planned to be conducted in Germany and is expected to comprise about 12 patients who are undergoing cardiac surgery. It is expected to commence during the final 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 2020-08-06 12:30 CEST.

Attachments

[Guard Therapeutics announces positive top line results from the concluding study in the clinical phase 1 programme of ROSgard in healthy subjects](#)