

Guard Therapeutics receives approval to expand the global phase 2 study of ROSgard to Canada

Guard Therapeutics today announces that the Canadian health authority (Health Canada) has approved the company's application to conduct and include patients in Canada in the comprehensive phase 2 study of ROSgard, an investigational drug being developed for the prevention and treatment of acute kidney injury. This global study is planned to be conducted in Europe and North America and has since earlier been approved by the German medicines regulator.

The randomised, double-blind, placebo-controlled global phase 2 study of ROSgard is expected to include around 270 patients who are undergoing open heart surgery and are thus at risk of developing acute kidney injury. The lead investigator of the study is Prof. Dr. Alexander Zarbock at Münster University Hospital, Germany. Canadian study centres are expected to contribute significantly to the overall patient recruitment, and the study is planned to start in the first quarter of 2022. The company awaits local ethical approvals as a last step of the clinical trial application procedure before the study can start in Canada.

"The positive announcement from Health Canada now allows us to expand the global phase 2 study of our investigational drug ROSgard from Europe to North America. In parallel, clinical trial applications to include additional countries in the study are currently under evaluation", Guard Therapeutics' CEO, Tobias Agervald, says.

Among other properties, the investigational drug ROSgard has the ability to counteract severe oxidative stress, which is a common denominator for many types of acute kidney injury. In the initial clinical development phase Guard Therapeutics has chosen to give priority to treatment in connection with open heart surgery using a heart-lung machine. In case of a positive outcome, the global phase 2 study is expected to pave the way for a subsequent registrational study. There is also an option to expand the continued clinical programme to other segments, such as patients undergoing kidney transplants.

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About Guard Therapeutics

Guard Therapeutics is a pharmaceutical company that identifies and develops new therapies for diseases with a great medical need for more effective treatments. The company's clinical investigational drug ROSgard is being developed as a protective treatment against acute kidney injury with an initial focus on patients undergoing heart surgery. Guard Therapeutics is listed on Nasdaq First North Growth Market Stockholm.

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Attachments

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