

## Guard Therapeutics' application to conduct a phase 2 clinical trial of ROSgard is approved by the German medicines regulator

**Guard Therapeutics announces today that the German medicines regulator, the Federal Institute for Drugs and Medical Devices (BfArM), has approved the company's application to conduct a comprehensive clinical phase 2 study of ROSgard, an investigational drug being developed for the prevention and treatment of acute kidney injury. The global study is planned to be conducted in Europe and North America under the guidance of Prof. Dr. Alexander Zarbock at Münster University Hospital, Germany.**

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 study is planned to start in the first quarter of 2022 and German study centres are expected to recruit a significant proportion of the total number of patients. The company awaits ethical approval of the study as a last step in the German clinical trial application procedure before the study can start.

"The positive announcement from the German medicines regulator is the first regulatory approval of this comprehensive global phase 2 study of ROSgard and is an important milestone that supports our plan to start the study in the first quarter of 2022. The approval also reflects the quality of the documentation we have generated so far for our investigational drug and our ability to meet the strict regulatory requirements defined in the regulatory process for obtaining a trial permit," 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.

**For further information, please contact:**

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## About Guard Therapeutics

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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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