

Guard Therapeutics reports positive results from phase 1b study

Guard Therapeutics today presents positive results from a clinical phase 1b study of the potentially kidney-protecting biological investigational drug ROSgard in connection with open heart surgery. The study fulfilled its primary objective – to confirm ROSgard's favourable safety and tolerability profile in the patient population for which treatment is initially intended. In addition, explorative analyses of several well-established biomarkers indicate that ROSgard potentially has the ability to protect kidney cells from injury associated with heart surgery. The company is now continuing its preparations for a comprehensive clinical phase 2 study.

The phase 1b study was conducted mainly for the purpose of evaluating the investigational drug's safety and tolerability profile and its pharmacokinetic properties in 12 patients who underwent extensive open-chest heart surgery and had additional risk factors for acute kidney injury (AKI). The study results show that ROSgard was well tolerated and no side effects attributed to the investigational drug were reported. Pharmacokinetic analyses showed desirable blood concentrations of ROSgard, providing support for the dosing regimen intended to be used in the planned phase 2 study. No patients developed autoantibodies to the drug substance, which could have led to unwanted immunological reactions.

The study also followed five well-established biomarkers in the urine that are considered to reflect the presence and degree of stress and damage to the kidney cells. An explorative analysis of measurements performed during or immediately after surgery – a critical time window for the occurrence of kidney injury – showed a general trend in favour of ROSgard compared with placebo for these biomarkers. Despite the limited number of patients, a statistically significant difference ($p < 0.05$) was achieved for one of the biomarkers: L-FABP (liver fatty acid binding protein). Overall, these results provide further support for the scientific hypothesis that ROSgard may protect renal tissue in connection with heart surgery.

Based on the positive study results, the company has decided to continue its development of ROSgard and is now preparing an application for the start of a comprehensive phase 2 study in the same indication that is planned to start around the turn of the year 2021/2022.

"Following the positive results from the phase 1b study of ROSgard, the project risk is significantly reduced. Despite the limited number of patients in the study, we have by measuring a number of biomarkers for kidney injury been able to capture possible early signals of an effect of the treatment. We can now with greater confidence continue our preparations for the next step in the clinical development of our unique investigational drug, which has the potential to reduce the problem of acute kidney injury in broad patient groups," 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, where nearly 40 per cent of all patients are estimated to develop some form of acute kidney injury. There is also an option to expand the continued clinical programme to other segments, such as patients undergoing kidney transplants. The global market for acute kidney injury, which covers a wide variety of patient groups, is estimated at between SEK 250 and 300 billion and is expected to grow further in the future.

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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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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 2021-09-15 07:30 CEST.

Attachments

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