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A1M Pharma announces positive top-line results from a phase 1a study of ROSgard

A1M Pharma today announced that the results from the initial part of a phase 1a study show that the investigational drug ROSgard™ has a good safety profile and that plasma concentrations that are expected to have a therapeutic effect were achieved. ROSgard is being developed as a potential new treatment for prevention of acute kidney injury in cardiac surgery.

The study evaluated the safety profile and pharmacokinetic properties of ROSgard after single ascending doses in healthy subjects. The results show that single doses of ROSgard are well tolerated with favourable pharmacokinetic characteristics. Plasma concentrations that are expected to have a therapeutic effect were achieved and no serious side effects were reported.

The results form the basis for the next stage of development, where the company plans to study multiple ascending doses of ROSgard in healthy subjects. The aim is to document the safety and pharmacokinetics of the dosage regimen that is intended to be used clinically to protect patients' kidneys during the critical period after cardiac surgery. The study, which requires separate regulatory approval, is expected to take approximately three months to complete.

"Taking a drug candidate from the laboratory environment to the first study in humans is an important milestone and value-creating step. The available data today indicate that ROSgard has both a good safety profile and favourable pharmacokinetics at exposure levels which are predicted to be clinically relevant. We are now looking forward to obtaining data for the specific dosage regimen that we believe will protect the kidneys in patients undergoing cardiac surgery. Our goal is to initiate the first study in patients already next year," Tobias Agervald, CEO of A1M, says.

Data from multiple non-clinical experiments support that ROSgard can prevent acute kidney injury by reducing oxidative stress. As soon as the ongoing phase 1a study in healthy volunteers has been completed, A1M Pharma plans to conduct a small phase 1b study in the target population of patients undergoing cardiac surgery who are at risk of developing acute kidney injury. This is considered to be an attractive indication based on ROSgard's mechanism of action and the available non-clinical data. Access to patients is good, the treatment duration is short and there are well defined clinical endpoints that are accepted by the regulatory authorities.

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About A1M Pharma

A1M Pharma's investigational drug ROSgard™ – based on the endogenous protein alpha-1-microglobulin – has in several non-clinical studies been documented to reduce acute kidney injury caused by oxidative stress by protecting exposed tissue and supporting regenerative processes. A1M Pharma is listed on Nasdaq First North Growth Market Stockholm. The company's Certified Advisor is Erik Penser Bank AB, tel. +46 (0)8-463 83 00, certifiedadviser@penser.se.

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