

Swedish Medical Products Agency grants A1M Pharma permission to start a clinical Phase I study of ROSgard™

A1M Pharma announces today that the Swedish Medical Products Agency has granted permission to start a clinical Phase I study of ROSgard™ – a drug candidate developed to prevent Acute Kidney Injury (AKI) in connection with primarily heart surgery. The Phase I study is expected to start during the first quarter of 2019, which is in line with the updated development plan that A1M Pharma recently presented.

The Swedish Medical Products Agency grants A1M Pharma permission to start a Phase I study with the drug candidate ROSgard™. In the first part of the study, which is estimated to take six months to complete, healthy volunteers will receive Single Ascending Doses. Subsequently, a follow-up Phase I study with Multiple Ascending Doses is planned. The first part of this study is expected to commence during the first quarter of 2019 and the second part during the second half of 2019.

– It is encouraging that the Swedish Medical Products Agency has granted clearance to start clinical studies with ROSgard™. This means that we can proceed with preparations for the study in accordance to our recently communicated development plan. There are today no effective therapies to prevent acute kidney injuries that arise in connection with heart surgery and there is considerable commercial potential for a new drug within this indication, says A1M Pharma's CEO Tomas Eriksson.

Over two million heart surgical operations are conducted globally every year – primarily operations on coronary vessels and cardiac valves. New studies indicate that the risk to develop acute kidney injuries in connection with these operations can be closer to 30 per cent. Acute kidney injuries in connection with heart surgery are expected to be an indication where there are good possibilities to quickly see clinical efficacy. Moreover, the regulatory development is well-defined and the commercial potential is considerable.

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About A1M Pharma

Several preclinical studies indicate that A1M Pharma's candidate drug ROSgard™ - based on endogenous protein Alpha-1-Microglobulin – restores impairments to kidney function by repairing damaged tissues and protecting against oxidative stress. A1M Pharma is listed on Nasdaq First North Stockholm. A1M Pharma's Certified at Nasdaq First North is Erik Penser Bank AB, +46 8-463 80 00.

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