

## **A1M Pharma re-submits application to the Swedish Medical Products Agency to conduct clinical trial with ROSgard™**

**A1M Pharma announces that the company has re-submitted the application to the Swedish Medical Products Agency (Läkemedelsverket) to conduct a clinical phase I study with ROSgard™ – a candidate drug that has shown a protective effect against kidney injuries in connection with oxidative stress in several preclinical studies. Upon approval, the phase I study is scheduled to start in Q4 2018.**

A1M Pharma submitted an application to conduct a clinical phase I study in healthy volunteers to the Swedish Medical Products Agency on January 31, 2018. Following a request for more information from the agency, A1M Pharma has been working intensively to complete a renewed application. When finalizing the information requested, A1M Pharma decided to switch contract manufacturer for the production and packaging of the candidate drug ROSgard. This was done following production disturbances at the former contract manufacturer. A1M Pharma's new manufacturing partner for the candidate drug has now successfully implemented the production of ROSgard in compliance with good manufacturing practice (GMP).

Data from the new production has been included in the re-submission of the application to initiate a phase I study to evaluate the safety profile of ROSgard. A new application processing period at the Swedish Medical Products Agency of up to 60 days has begun.

The submitted application concerns the administration of ROSgard in single and ascending doses (SAD - Single Ascending Dose) to document the drug candidate's safety, tolerability and pharmacokinetics. The scheduled phase I study will be conducted together with the contract research company CTC in Uppsala, Sweden.

### **For more information, please contact**

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### **About A1M Pharma**

Several preclinical studies indicate that A1M Pharma's candidate drug, ROSgard™ – based on the 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 Adviser at Nasdaq First North is Erik Penser Bank AB, +46 8-463 80 00.

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