

A1M Pharma submits application to the Swedish Medical Products Agency to conduct clinical phase I study with ROSgard™

A1M Pharma announces that the company has submitted an application to the Swedish Medical Products Agency (Läkemedelsverket) to conduct a clinical phase I study in healthy volunteers with the candidate drug ROSgard™. The study is the starting point of the company's own clinical trials, and it will be followed by clinical studies where patients undergoing PRRT radiation therapy will be administered with ROSgard™ to prevent damages on their kidneys and bone marrow.

"This application summarizes the results of a truly solid and successful preclinical program, which has demonstrated that ROSgard™ has a strong safety profile and shows a strong therapeutic effect in our chosen indications. Another key component in the application is the description of our large-scale and quality certified manufacturing processes, says A1M Pharma's Head of Development Eddie Thordarson.

The Swedish Medical Product Agency's policy is to notify their decision within 60 days when they have received and started processing an application to conduct a clinical study.

"We will initiate this clinical safety study, the first in which ROSgard™ is administered to humans, immediately upon approval by the Swedish Medical Product Agency. At that time, we will also present more details regarding the study design", says Eddie Thordarson.

For more information, please contact:

*Tomas Eriksson, CEO
Telephone: +46 46-286 50 30
Email: te@a1m.se*

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 tissue and protecting against oxidative stress. Kidney injury is a condition which often occurs in connection with preeclampsia and which often limits the possibilities of using radiation therapies as a treatment for cancer. The company's two indications are kidney protection in connection with Peptide Receptor Radionuclide Therapy (PRRT) - a targeted radiation therapy for cancer - with the aim of opening the possibility of increasing treatment levels and so fight metastatic cancer more effectively as well as treatment of preeclampsia. Every year, over 12 million people are affected by acute kidney injuries that can lead to permanent kidney damage. Preeclampsia affects around 10 million pregnant women worldwide and is responsible for 76,000 maternal and 500,000 infant deaths each year. A1M Pharma is listed on Nasdaq First North Stockholm since 20 June 2017. A1M Pharma's Certified Adviser at Nasdaq First North is Erik Penser Bank AB, +46 8-463 80 00.

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