A1M Pharma AB (publ), 556755-3226
Press release *2017-02-10*

A1M Pharma has successfully conducted large scale manufacturing of the active substance in ROSGard™ and initiates GLP toxicology studies

A1M Pharma's manufacturing partner has successfully and completely within the set time frame manufactured the first large scale batch of the active substance in the candidate drug ROSGard™. After conducted tests that verified good quality and a high level of purity, A1M Pharma has decided to use this batch in the upcoming GLP toxicology studies.

During 2016, A1M Pharma has performed an up-scaling of the manufacturing process for the active substance in the company's candidate drug ROSGard™, together with a leading European manufacturer. During 2016, the first large scale manufacturing of a so-called development batch was performed by directly, without any intermediate steps, scaling up the manufacturing process with a scale-up factor 100 to a level sufficient for GLP toxicology studies as well as the company's upcoming clinical studies.

Tests of the batch in question have now been conducted and all the parameters regarding the quality of the substance, including the level of purity, shows that the large scale manufacturing process works very well. The company has therefore decided to use this batch for the upcoming GLP toxicology studies. These studies will form the basis for the application to initiate a clinical phase I study.

"To achieve a successful large scale manufacturing of the active substance in ROSGard™ with sufficient quality and quantity for our further toxicology studies and clinical studies right away is a great success for A1M Pharma. I am proud that we have achieved one of the most important milestones on our way towards clinical studies", says A1M Pharma's Head of Development Eddie Thordarson.

A1M Pharma, together with the company’s manufacturing partner, will now optimize selected stages in the manufacturing process with the aim of increasing the yield of the active substance. Apart from this, the only difference going into GMP manufacturing will be the implementation of stricter requirements for documentation.

Eddie Thordarson points out that the step from large-scale manufacturing of the active substance to a finished candidate drug is a lot less complicated than what has been achieved so far.

"Since the active substance is already in its final formulation, the step from active substance to a finished candidate drug that can be used in clinical studies is mainly a matter of achieving the appropriate dilution for the proper concentration, followed by aseptic filling.

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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 tissue and protecting against oxidative stress. Kidney injury is a condition which often occurs in connection with preeclampsia and major surgery 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 diagnosis and 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.