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A1M Pharma reports positive results from its GLP toxicology study – now able to finalize application to initiate clinical studies

A1M Pharma announces that the company's preclinical GLP toxicology study with the active substance in the candidate drug ROSgard™ has been successfully completed, including an established dose that is now being used to calculate the doses in the company's planned clinical safety studies in humans. The company has now gathered all of the required preclinical data needed to finalize the application for initiating clinical studies with ROSgard™. The clinical program is scheduled to start in the first quarter of 2018, in line with the previously communicated plan.

– Being able to report positive results from the completed GLP toxicology study represents a key milestone in the company's history, and the results are very encouraging. In perfect alignment with our plan, we are now completing the application to initiate clinical studies, says A1M Pharma's Head of Development Eddie Thordarson.

The study design of the GLP toxicology study was rigorous and challenging, with daily injections in two different animal species during 28 consecutive days.

– By conducting such thorough safety studies in collaboration with our CRO partner, gives us great flexibility when designing our planned clinical studies. This is important to emphasize as we are designing our clinical program to eventually include kidney and bone marrow protection during radiation therapy as well as a treatment for preeclampsia, explains Eddie Thordarson.

Establishing how much of the active substance in a candidate drug that is deemed safe to be given to humans is based on the No Observed Adverse Effect Level, NOAEL. Determining this level is a key factor in the design of A1M Pharma's clinical safety study in healthy volunteers, scheduled to start in the first quarter of 2018.

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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 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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