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A1M Pharma has successfully conducted preclinical toxicology/safety studies within preeclampsia

A1M Pharma has successfully and according to plan conducted the first part of the company's toxicology/safety studies with the pharmaceutical compound in the company's candidate drug ROSGard™. In the studies, a maximum tolerated dose (MTD) has been established in two different animal models. These results will be used to establish the dosage levels to be used in the GLP-compliant toxicology studies.

On the way towards clinical studies within treatment of preeclampsia, A1M Pharma is conducting several preclinical toxicology/safety studies. The first part, which aims to establish the maximum tolerated dose in two different animal models, has now successfully been conducted within the communicated time frame.

"I am very pleased to say that we have conducted this first step within our toxicology/safety program in a good way and completely within the set time frame", says A1M Pharma's Head of Development Eddie Thordarson.

During the next part of the toxicology/safety studies, which has already been initiated, the goal is to collect data from repeated administration of the pharmaceutical compound. This step is expected to be completed during Q1 2017, after which the collected amount of data will form the basis of the GLP-compliant toxicology/safety studies that are scheduled for initiation during Q2 2017. Completed GLP-compliant toxicology/safety studies are required in order to initiate clinical studies.

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About GLP (Good Laboratory Practice)
Good Laboratory Practice, abbreviated GLP, is a quality system applied to non-clinical safety studies within pharmaceutical development with the purpose of securing the integrity of such studies. Completed safety studies in compliance with GLP is a requirement before initiating clinical studies in humans. GLP embodies a set of principles concerning the organizational process as well as the prevailing conditions at a non-clinical safety study, including planning, performing, monitoring, recording, archiving and reporting. Non-clinical safety studies that are not conducted in compliance with this quality system are called non-GLP. In Sweden, Läkemedelsverket is the authority responsible for the supervision of GLP compliance.

About A1M Pharma
A1M Pharma develops a diagnostic method and a novel treatment for the damaging effects of pre-eclampsia, a condition that affects around 10 million pregnant women worldwide. This disorder is responsible for 76,000 maternal and 500,000 infant deaths each year. It is also the cause of 15 per cent of all premature births. Currently, there is no predictive diagnostic method or treatment for impairments to kidney function associated with pre-eclampsia. In serious cases, doctors are forced to terminate the pregnancy which leads to premature infants and results in a substantial health care cost burden. 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 is often associated with major surgery and with cancer treatments using radiation therapies. The company is therefore also developing a treatment for these acute kidney injuries. The first indication is kidney protection in connection with PRRT – a targeted radiation therapy for cancer – with the aim of opening the possibility of increasing treatment levels and so fight the cancer more effectively. Every year, over 12 million people are affected by acute kidney injuries that can lead to permanent kidney damage.

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