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A1M Pharma to use experienced European CRO partner for preclinical toxicology studies

A1M Pharma has signed an agreement with Research Toxicology Centre, a leading European contract research organization with over 40 years of industry experience, as CRO partner for the company's preclinical toxicology studies. The practical preparations for the studies have now been initiated, fully in accordance with the company's development plan.

In order to secure the best possible partner for the company's toxicology studies within treatment of preeclampsia, A1M Pharma evaluated a number of European contract research organizations (CROs). The company decided on the Italian Research Toxicology Centre (RTC) with over 40 years of industry experience and specialist knowledge in the type of studies A1M Pharma is preparing to perform.

A1M Pharma and RTC have signed an agreement for these studies and initiated the practical preparations, such as the transfer process as well as establishing and validating bioanalytical methods.

"It is very satisfying that we have signed an agreement with RTC as CRO partner for the toxicology studies with our candidate drug RMC-035 for treatment of preeclampsia. We have done a very thorough evaluation of potential CRO partners, and RTC was undoubtedly the most suited partner based on our needs and specification of requirements. To get this agreement into effect and initiate the practical preparations according to plan is an important step towards our clinical phase I study", says A1M Pharma´s Development Manager Eddie Thordarson.

The studies that are covered in the agreement are A1M Pharma's planned preclinical toxicology studies with the company's candidate drug RMC-035 within treatment of preeclampsia. The agreement with RTC enables A1M Pharma to obtain complete toxicity and safety data required to initiate clinical studies in humans. Initially non-GLP studies will be conducted, which is covered within the company's current financial framework, and then the studies will progress into the GLP phase. The estimated completion date for these studies is Q1 2017 and Q4 2017, respectively.

"I am pleased that A1M Pharma has selected us as their CRO partner for their toxicology studies with their candidate drug RMC-035. Our extensive experience and knowledge in this area will be of great benefit for this project. We are also specifically looking forward to working with A1M Pharma within preeclampsia treatment, an important and exciting research area", says Germano Oberto, General Manager and Scientific Director at Research Toxicology Centre.

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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, reporting and archiving. 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 Research Toxicology Centre
RTC is a leading European Contract Research Organization with more than four decades of worldwide experience, providing a broad selection of services within non-clinical studies to pharmaceutical companies and other health-related organizations. RTC's Headquarters are based in Pomezia, Rome, Italy and the company has 150 employees. All studies are performed according to international guidelines and regulations. RTC can support the Client from a very early stage of the project, providing a full range of experimental and consultancy services, in order to offer a tailored approach in the preclinical development process. Scientific and technological expertise, combined with skills in project management and communication, may qualify RTC as the partner of choice for any product development.

About A1M Pharma
A1M Pharma develops a diagnostic method and treatment for pre-eclampsia, a condition that affects around 10 million pregnant women worldwide each year. This disorder is responsible for 76,000 maternal and 500,000 infant deaths each year and it is the cause of 15 % of all premature births. Currently, there is no effective diagnostic method or curative treatment for impaired kidney function associated with pre-eclampsia. The only option is therefore to terminate pregnancy by inducing delivery which leads to premature infants and substantial health care costs. Several studies indicate that A1M Pharma's candidate drug, the protein A1M (alpha-1-microglobulin), restores the impaired kidney function by repairing damaged tissue and protect against oxidative stress. New findings indicate that the cells within the heart are protected in a similar way. Apart from the connection with pre-eclampsia, kidney injury is a condition often accompanying major surgery and transplantation and the company is therefore also developing a treatment for the closely related indication acute kidney injury. Acute kidney injury that can lead to permanent kidney damage affects 12 million people every year.