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A1M Pharma report successful scientific advice meeting with Swedish Medical Products Agency regarding initial development program

In accordance with the previously communicated plan for development, A1M Pharma and the Swedish Medical Products Agency recently held a scientific advice meeting regarding the company's drug development program. The meeting was held in preparation ahead of scaling up of drug manufacture and future clinical trials.

A1M Pharma intends to maintain a continuous dialogue with the relevant regulatory authorities to ensure that the company's development projects comply with demands placed by regulatory authorities. This first meeting with the Swedish Medical Products Agency focused on the design of A1M Pharma's safety evaluation studies and the initial clinical development program for the treatment of pre-eclampsia.

"The positive and constructive meeting with the Medical Products Agency covered a number of aspects of the drug development process relating to recombinant A1M (rA1M). On the basis of the Agency's comments, we consider that our plans to continue pre-clinical trials, including toxicology studies, are sufficient to allow us to begin trials in humans with rA1M in accordance with our development plan," commented Tomas Eriksson, CEO of A1M Pharma.

The Swedish Medical Product Agency offers scientific advice to companies active in pharmaceutical development and aims to promote open dialogue regarding development projects. However, the advice given by the Agency at this early development stage does not constitute a prior assessment of the documentation with respect to the approval of a medical product for sale.

"In addition to covering pre-clinical documentation, we also discussed the planned design of our initial studies in healthy volunteers and women suffering from pre-eclampsia. The Medical Products Agency provided us with valuable feedback and insightful perspectives," commented Tomas Eriksson, CEO of A1M Pharma

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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.