A1M Pharma AB (publ), 556755-3226
Press release *2017-10-27*

A1M Pharma: First company in the world with large scale manufacturing of A1M under full GMP compliance for clinical studies

A1M Pharma, together with a leading European pharmaceutical manufacturer, have successfully manufactured the world's first large-scale batch of the active substance in the candidate drug ROSgard™ – based on a recombinant version of the endogenous protein A1M – in compliance with applicable GMP requirements.

The product is approved and released by the pharmaceutical manufacturer and the next step before clinical studies is the Fill & Finish process conducted by CordenPharma. Securing a large-scale manufacturing process in compliance with GMP is a prerequisite for clinical studies and the manufacturing of ROSgard™ for commercial use.

– It is very pleasing that we have reached this key milestone within the set time frame which means we are making great progress towards clinical studies. Securing a large scale manufacturing process in compliance with GMP has taken many years of intensive development work and has involved major investments. Besides representing a valuable and lasting asset in the company, this also means that the supply of material for future studies is now secured, says A1M Pharma's CEO Tomas Eriksson.

According to the regulatory requirements, manufacturing and control of the candidate drug must be in compliance with Good Manufacturing Practice (GMP) for the product to be used in humans. Since the last large-scale manufacturing of the active substance in the candidate drug – which was conducted for the GLP toxicology studies – selected stages in the manufacturing process have been optimized to increase the yield of the active substance in ROSgard™. The result shows that the candidate drug ROSgard™ has a high level of purity and meets the requirements for use in humans.

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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.