

A1M Pharma: ROSGard™ shows strong protective effect against renal damage in connection with radiation therapy in a preclinical long-term study

Preliminary data from the completed preclinical long-term study with an animal model clearly establish the strong protective effect against renal damage of the active substance in the candidate drug ROSGard™ in connection with radiation therapy. Clinical studies are scheduled to start in the beginning of 2018. The company's aim is to develop a pharmaceutical that will be administered in connection with each radiation therapy session in order to protect the kidneys and thereby enabling a more effective treatment.

The molecular targeted therapy PRRT, which is mainly used as a treatment for neuroendocrine tumours (NETs) that can spread to the gastrointestinal tract and the lungs, puts a heavy strain on the patient's kidneys with the risk of serious kidney injuries as a consequence. This limits the maximum radiation dose that can be used, both in separate radiation treatments and in total. The symptoms of possible kidney injuries often do not appear until several months after the radiation therapy session. A1M Pharma has therefore conducted two preclinical studies with the candidate drug ROSGard™ that is being developed to be administered in connection with each radiation therapy session in order to protect the kidneys from potential damage.

The first study focused on short-term kidney injuries. The final results from this study show that the radiation damage occurring within 8 days after the PRRT treatment was largely eliminated in the group who was administered with the active substance in ROSGard™ (RMC-035) in connection with the radiation therapy session.

The second study focused on long-term kidney injuries by monitoring the groups until 6 months after the radiation therapy session. This study has now been completed as well and the study data is currently being analysed. Although the analysis is not yet completed, the results clearly and unmistakably show that RMC-035 has a strong protective effect against renal damage.

The group in the long-term study that received radiation therapy without the active substance in ROSGard™ exhibited proteinuria, renal atrophy and death during the 6 months following the radiation therapy session. Within the group that was administered with the active substance in ROSGard™ together with the radiation treatment, these negative effects were heavily reduced and in some cases even prevented.

– These preclinical studies have established the strong protective effect against renal damage of the active substance in ROSGard™ in both the short and long term. This is a strong confirmation that we have something very valuable to offer within the market of radiation therapy, says A1M Pharma's Head of Development Eddie Thordarson

About PRRT – molecular targeted therapy

Peptide Receptor Radionuclide Therapy, PRRT, is a type of molecular targeted therapy used to treat tumours, commonly malignant tumours with the generic term neuroendocrine tumours or NETs. When aggressive, these tumours are fatal and can spread quickly to the gastrointestinal tract and the lungs. During PRRT treatment the patient is given a substance consisting of two parts, a tumour targeting peptide and a radioactive substance that breaks down the cell tissue. This powerful oxidation reaction creates waste products that end up in the kidneys. It is the harmful effects of these waste products that the active substance in A1M Pharma's candidate drug ROSGard™ is expected to eliminate and thus protect the kidneys. A renal protective treatment making this radiation treatment available for more patients or enabling an increase of the maximum radiation dose in connection with PRRT treatment, in separate sessions and/or in total, has the potential to reach the market relatively quickly considering the serious and fatal effects of NET cancer tumours.

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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 major surgery 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 diagnosis and 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.

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