AM-Pharma presents positive data from recAP preclinical study at ASN meeting

Data shows anticipated reduction in inflammation and tissue injury in Acute Kidney Injury models

Bunnik, The Netherlands; Atlanta, GA, 8 November 2013. AM-Pharma B.V., a biopharmaceutical company focused on the development of recAP (recombinant human Alkaline Phosphatase) for inflammatory indications, today presents preclinical data on its drug candidate recAP in an Acute Kidney Injury (AKI) setting, at the American Society of Nephrology (ASN) meeting Kidney Week in Atlanta, GA, USA. The research was conducted by Prof. Dr. Can Ince and his team at the Department of Translational Physiology, Academic Medical Center, University of Amsterdam, the Netherlands.

In the study, AKI was induced in rats through either ischemia-reperfusion (I-R) or by LPS injection. The rats were instrumented to enable real-time quantification of systemic and local haemodynamics, oxygenation and inflammatory responses during the initiation of disease and for 3 hours post treatment.

The control group developed signs of mild AKI (I-R model) or severe AKI (LPS model), whereas the subjects that received a single dose of recAP at 1000 U/kg demonstrated significant inhibition of various parameters of renal inflammation (iNOS, IL-6 – $p<0.001$, leukocyte infiltration $p<0.05$) and tissue damage (L-FABP, NGAL – $p<0.001$, Bax – $p<0.01$).

Furthermore, treatment with recAP was found to be associated with improvement of renal blood flow and renal vascular resistance, without affecting systemic haemodynamics.

Commenting on the study, Erik van den Berg, CEO of AM-Pharma said, “We have seen similar results to these in the past with our bovine form of Alkaline Phosphatase. As such it is very encouraging to see that recAP, our recombinant human Alkaline Phosphatase, is also demonstrating strong, immediate pharmacological effects that include the suppression of acute inflammation and inhibition of tissue injury in this model of AKI.”

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Notes for Editors

About AM-Pharma www.am-pharma.com
AM-Pharma is a biopharmaceutical company focused on the preclinical and clinical development of Alkaline Phosphatase as protective treatment of acute kidney injury and inflammatory bowel diseases. AM-Pharma is based in Bunnik, The Netherlands. Based on the strong results of the Phase II trials with bovine Alkaline Phosphatase in Acute Kidney Injury and a Phase II trial in Ulcerative Colitis – a form of inflammatory bowel disease – AM-Pharma developed an innovative recombinant form of human Alkaline Phosphatase. This recombinant Alkaline Phosphatase will be used in future trials and for commercialization. AM-Pharma raised €29.2M in Q4 2011, enabling AM-Pharma to finalize the GMP production and the development through phase II.

About Acute Kidney Injury
Acute Kidney Injury (AKI) involves an inflammatory process in the kidney which can lead to complete loss of renal function. Hospital-acquired AKI affects annually around 2 million patients in Europe, US and Japan, of which around 700,000 patients die. It occurs in as many as 4% of hospital admissions and 40% of critical care admissions. Depending on the severity and cause of renal injury, mortality ranges from 10% to as high as 70%. In the US alone, around USD10 billion is spent each year on managing this big medical problem. The most important causes of AKI are sepsis, cardiovascular surgery, exposure to nephrotoxic drugs and trauma. AKI patients that need dialysis have the worst prognosis. Currently the only treatment option is dialysis and supportive care. No drugs are approved to treat this condition. Typically these patients are treated in Intensive Care, often with support of nephrologists. Due to the large number of patients suffering from AKI, the high medical need, worldwide annual sales of over USD2 billion could be achieved with an effective drug treatment.

About Alkaline Phosphatase
Alkaline Phosphatase (AP) is an enzyme that is naturally present in humans on epithelial cells of the gastrointestinal tract, kidney, liver and lungs. An important role of AP is the dephosphorylation of proinflammatory substances like lipopolysacharides (LPS) and extra-cellular ATP. The anti-inflammatory characteristics of AP was firstly published by Professor Poelstra and his group at Groningen University, the Netherlands. AM-Pharma has since shown that treatment with exogenous AP not only reduces local and systemic inflammation but also protects the kidney against further damage.

About recAP
AM-Pharma's therapeutic candidate, recAP (recombinant Alkaline Phosphatase), is a proprietary recombinant human AP constructed from two naturally occurring human isoforms of the AP enzyme. This hybrid is highly stable and active, and has been optimized for treating inflammatory conditions. It is being developed as an injectable for the treatment of Acute Kidney Injury and an oral formulation for Ulcerative Colitis. The enzyme is being produced by cGMP manufacture for preclinical and clinical trial supply and commercialisation.

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