AM-Pharma presents preclinical data on mode-of-action for recAP in Acute Kidney Injury at ASN meeting

Data shows recAP to increase glomerular filtration rate and creatine clearance

Bunnik, The Netherlands, 13 November 2014. AM-Pharma B.V., a biopharmaceutical company focused on the development of recAP (recombinant human Alkaline Phosphatase) for inflammatory indications, today presents further preclinical data on its drug candidate recAP, at the American Society of Nephrology (ASN) meeting Kidney Week in Philadelphia, PA, USA. The research was conducted by Professor Bruce A. Molitoris, MD FASN, and his team at the Indiana University School of Medicine, Indianapolis, IN, USA. RecAP is currently in clinical development for Acute Kidney Injury (AKI).

The research presented in the ASN poster used two-photon microscopy fluorescence imaging to monitor kidney function in rat models of Ischemia-Reperfusion Injury-induced AKI. At 24 hours post-AKI induction, the study quantified both plasma creatinine (PCr) levels and Glomerular Filtration Rate (GFR).

The results show in Sprague-Dawley rats that clamping of the renal pedicle and contralateral nephrectomy induced a significant rise in PCr from ~0.4 ml/dL prior to AKI induction to 3.2 ± 0.59 mg/dL after 24 h. Treatment results showed that over a wide dose range (50-2000 U/kg) a single intravenous administration of recAP significantly reduced PCr (1.7 ± 0.65 mg/dl at 500 U/kg) ($p<0.01$). Similarly, in Munich-Wistar Frömter rats, PCr rose from t 0.38 ± 0.04 mg/dL to to 2.28 ± 0.64 mg/dL post-AKI and a single dose of 1000 U/kg recAP limited PCr to 0.82 ± 0.15 mg/dL ($p<0.003$). Also, control AKI rats demonstrated a GFR of 0.09 ± 0.09 ml/min, compared to 0.75 ± 0.29 ml/min in recAP treated rats ($p<0.003$).

“The data in these AKI models show that recAP is able to maintain glomerular filtration and creatinine clearance, both key parameters for assessing kidney function, thereby indicating the potential treatment effect of recAP in acute kidney injury,” said Erik van den Berg, CEO of AM-Pharma. “Further elucidating recAP's mode-of-action is extremely valuable as we move towards commercialisation and seeking regulatory approval for the product.”

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Notes to 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 (AKI) and a Phase II trial in Ulcerative Colitis (UC), AM-Pharma developed an innovative recombinant form of human Alkaline Phosphatase. This recombinant Alkaline Phosphatase (recAP) will be used in future trials and for commercialisation. AM-Pharma raised €29.2M in Q4 2011, enabling the Company to finalise the GMP production, toxicology studies, Phase I in healthy volunteers and the start of Phase II in AKI patients. The Company raised a further €12.2M in September 2014 for the completion of Phase II development of recAP in AKI patients and continued development of an oral formulation of recAP for UC patients.

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 USD2.6 billion could be achieved with an effective drug treatment.

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 optimised 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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