



## **American Journal of Kidney Disease publishes review article of Alkaline Phosphatase**

*Leading journal presents case for AM-Pharma product to treat sepsis-associated acute kidney injury*

Bunnik, The Netherlands, 28 January 2014. AM-Pharma B.V., a biopharmaceutical company focused on the development of recAP (recombinant human Alkaline Phosphatase) for inflammatory indications, announces that the American Journal of Kidney Disease has published an *In Translation* feature entitled: *Alkaline phosphatase: a possible new treatment option for sepsis-associated acute kidney injury in critically ill patients.*

AJKD's *In Translation* is a recurring education feature that is an authoritative review of science with diagnostic or therapeutic implications in clinical practise in nephrology. The authors of the article, (abstract available at: [http://www.ajkd.org/article/S0272-6386\(13\)01636-3/abstract](http://www.ajkd.org/article/S0272-6386(13)01636-3/abstract)) are from Professor Pickkers' group, at the Department of Intensive Care Medicine, Nijmegen Institute for Infection, Inflammation and Immunity, Radboud University Nijmegen Medical Centre, The Netherlands.

He and his affiliates discuss the multi-factorial pathogenesis of sepsis-associated Acute Kidney Injury (AKI) and note that to be truly successful, an intervention would also need to address not a single but multiple targets.

They concluded that: "AP seems to be a promising new therapy for patients with sepsis-associated AKI because it restores an endogenously expressed protective enzyme that appears to exert a dual mechanism of action. AP may prevent the effects of inflammation and hypoxia, key events in the pathogenesis of sepsis-associated AKI. Therefore, AP seems to be a potent new treatment option for these patients."

The authors also noted that: "As inflammation and hypoxia are also involved in AKI induced by several other causes, including cardiac surgery and trauma, it would be of interest to further examine the therapeutic effects of AP in these additional clinical circumstances."

Commenting on the review paper, Erik van den Berg, CEO of AM-Pharma said, "It is satisfying and reassuring that an independent research group has come to similar conclusions to our research, on the potential of Alkaline Phosphatase to treat patients with a variety of AKI. We look forward to presenting further data on the clinical trials with recAP."

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## **Notes for Editors**

### **About AM-Pharma [www.am-pharma.com](http://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 lipopolysaccharides (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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