



## **AM-Pharma starts Adaptive Phase II trial of recAP in Acute Kidney Injury**

*Adaptive trial, largest ever intervention study in AKI*

Bunnik, The Netherlands, 20 January 2015. AM - Pharma B.V., a biopharmaceutical company focused on the development of recAP (recombinant human Alkaline Phosphatase) for inflammatory diseases, has recruited the first 3 patients into its Phase II trial of recAP in sepsis-associated Acute Kidney Injury (AKI). The clinical trial is now underway in 9 countries, and will involve 50 sites.

The primary objective of the trial is to determine the most effective dose of recAP and to establish proof-of-concept in ameliorating AKI through measuring kidney function, and to confirm the favourable safety data from previous trials.

The adaptive Phase II trial has two-stages and will recruit a total of 290 patients. In the first stage 120 patients will be evaluated to identify and select the most effective dose out of three different doses of recAP. In the second stage an additional 170 patients will be recruited in two arms of 85 patients each, receiving either the best dose of recAP as identified in stage one, or placebo.

In both stages of the trial, the effect on kidney function during the first 7 days following therapy will be measured by creatinine clearance rate, a sensitive marker of kidney function. The trial will also record the incidence and duration of renal replacement therapy (dialysis) over 28 days, and prevention of chronic kidney disease.

In addition to the kidney specific measurements, the trial will measure non-kidney related clinical parameters such as the duration of intensive care (ICU) and hospital stay, and patient's quality of life.

"The design of this trial results from close collaboration with various international experts and regulators, and builds on the previous positive Phase I data with recAP and also the Phase II data we collected in clinical trials with bovine Alkaline Phosphatase," said Erik van den Berg, CEO of AM-Pharma. "It was great news therefore that the FDA approved the IND within 30 days. The adaptive trial is expected to provide essential information and clear guidance on how to progress recAP in its further development and regulatory approval."

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### **Notes to 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 recAP (recombinant Human Alkaline Phosphatase) as a treatment of Acute Kidney Injury (AKI), Ulcerative Colitis (UC) and Hypophosphatasia (HPP). Based on the strong results of the Phase II trials with bovine Alkaline Phosphatase in AKI and UC, AM - Pharma developed an innovative recombinant form of human Alkaline Phosphatase (recAP), which will be used in future trials and for commercialisation. In Q4 2011, the Company raised €29.2M, and in September 2014, raised a further €12.2M for the completion of Phase II study of recAP in AKI patients, as well as 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 USD2.7 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 AKI and HPP, and an oral formulation for UC. The enzyme is being produced by cGMP manufacture for preclinical and clinical trial supply and commercialisation.

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