AM-Pharma returns to clinic with Phase I trial of new recombinant human Alkaline Phosphatase to treat Acute Kidney Injury

Trial to reaffirm safety seen in previous Phase I & II trials of bovine Alkaline Phosphatase

Bunnik, The Netherlands, 23 September 2013. AM-Pharma B.V., a biopharmaceutical company focused on the development of recombinant human Alkaline Phosphatase (AP) for inflammatory indications is pleased to announce that the first subjects have entered a Phase I trial of its recombinant AP (recAP) to treat Acute Kidney Injury (AKI).

This is a significant milestone in the progress of AM-Pharma, as it re-enters the clinic with its new recombinant AP product. The Company previously presented strong, positive, Phase II data on an enzymatically comparable bovine extracted AP, which showed that AKI patients on AP had improved renal function, reduced length of stay in intensive care, and that AP was safe and well tolerated.

The Phase I study of recAP consists of 50 healthy volunteers, aims to confirm safety and tolerability, and investigate the pharmacology including enzyme activity in serum – a key indicator of the drug's therapeutic potential.

Recruitment to the trial will close in December 2013, with the results reporting in early 2014. Confirmation of the results seen in the previous bovine AP trials will enable the Company to seek approval for Phase II development in Q2 2014.

Erik van den Berg, CEO of AM-Pharma said, "We are delighted to be re-entering the clinic with our recombinant Alkaline Phosphatase, recAP. Our previous, statistically significant and clinically-relevant, studies of bovine AP have shown the product to be a very promising, safe, and effective treatment for Acute Kidney Injury – a multi-billion dollar market for which there are no current drugs. We believe recAP has favourable characteristics over the bovine form, and with scalable production makes for a commercially viable 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 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 commercialization.

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