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AM?Pharma receives FDA fast track designation for recAP in Acute Kidney Injury, and reports completion of first stage in Phase II trial

Tuesday, April 26, 2016 - 08:00am

Bunnik, The Netherlands, 26 April 2016. AM?Pharma B.V., a biopharmaceutical company focused on the development of recAP (recombinant human Alkaline Phosphatase) for inflammatory diseases, announces that it has received fast track designation from the U.S. Food and Drug Administration (FDA) for recAP to treat Acute Kidney Injury (AKI). Additionally, the Company reports that the interim analysis on the first stage of the adaptive Phase II trial in AKI has been successfully completed.

The fast track designation helps facilitate the development and expedite the review process of drugs designed to treat severe conditions and fulfill an unmet medical need.1 This status also enables a continuous dialogue with the FDA on the clinical and regulatory development of recAP.

Within the Phase II study, an independent data monitoring committee has completed its interim analysis of the first 120 patients recruited to the trial. The outcome is the selection of the best of the three doses that were investigated in the first stage of the study. In the second stage of the clinical trial, an additional 170 patients will be recruited in two arms of 85 patients each, where patients will receive either the selected recAP dose or placebo.

The study is the largest to date investigating treatment of AKI, and will recruit a minimum of 290 patients in more than 70 sites across Western Europe and North America. Results from the study are expected in 2017.

“Both the fast track designation and the completion of the interim analysis indicate the positive progress of recAP and potentially shorten the time to bring the product to patients,” said Erik van den Berg, CEO of AM? Pharma. “We look forward to continuing our interactions with the regulatory agencies for fast development of recAP to address this unmet medical need in Acute Kidney Injury.”

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1 U.S. Food and Drug Administration; available at
http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm

Notes to Editors

About AM?Pharma 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 strong results from Phase II trials with bovine Alkaline Phosphatase in AKI and UC, AM?Pharma developed an innovative recombinant form of human Alkaline Phosphatase (recAP), which is currently in Phase II development for sepsis?associated AKI. In May 2015, AM?Pharma signed a deal with Pfizer, which made an upfront payment of $87.5 million for a minority equity interest, and exclusive option to acquire the Company, with additional potential payments of up to $512.5 million upon option exercise and potential launch of any product that may result from the agreement.

About Acute Kidney Injury
Acute Kidney Injury (AKI) involves inflammatory processes in the kidney which can lead to complete loss of renal function. Hospital?acquired AKI affects annually around 3 million patients in Europe, the US and Japan, and is associated with mortality in roughly 700,000 patients. 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, hospitals spend around $10 billion each year on managing this major 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.1,2,3

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, which is highly stable and active. It is in Phase II development for the potential treatment of AKI, with the potential to be developed for HPP. An oral formulation has been developed for the treatment of UC. The enzyme is produced by cGMP manufacture for preclinical and clinical trial supply and commercialization.

1 Murugan R. and Kellum J.A., (2011) Nat Rev Nephrol. Vol 7: 209-217
2 Heung M. and Chawla L., (2014) Nephron Clin Pract. Vol 127: 30-34
3 Chertow et al., (2005) J Am Soc Nephrol. Vol 16: 3365-3370 Soc Nephrol. Vol 16: 3365-3370 –

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