# AM-Pharma Raises €116m [$133m] to Conduct Pivotal Phase III Trial of recAP in Acute Kidney Injury

- Financing co-led by new investors LSP and Andera Partners, with participation of existing investors Forbion, Ysios Capital, Kurma Partners, ID Invest Partners, BB Pureos Bioventures and Gilde Healthcare
- Proceeds to be used for the 1,400-patient international pivotal Phase III trial of recombinant human Alkaline Phosphatase (recAP) in patients with sepsis-associated acute kidney injury (SA-AKI)
- AKI is a devastating disease, with a high mortality rate and no approved pharmacological treatments

**Bunnik, The Netherlands, 16 July 2019** – AM-Pharma B.V. ('AM-Pharma, the Company'), a clinical stage biopharmaceutical company, leading in the development of a treatment for acute kidney injury (AKI) with its innovative recombinant human Alkaline Phosphatase therapeutic (recAP) today announces that it has raised €116m [$133m] from a European syndicate of new and existing investors. These new funds will be used to carry out a multi-national pivotal Phase III trial of recAP in 1,400 patients with sepsis-associated acute kidney injury (SA-AKI). Last year AM-Pharma reported promising results from its STOP-AKI Phase II clinical trial, which demonstrated significant improvements in survival and kidney function.

The financing round was co-led by new investors LSP and Andera Partners, and includes founding investor Forbion together with other existing investors, Ysios Capital, Kurma Partners, ID Invest Partners, BB Pureos Bioventures and Gilde Healthcare.

AKI is a devastating disease, with a high mortality rate and no approved pharmacological treatments. The most important cause of AKI, which affects millions of patients worldwide, is sepsis. [1,2] AM-Pharma was awarded Fast Track designation by the US Food and Drug Administration in 2016 and recAP has the potential to be a first-in-class medicine for AKI.

The results of AM-Pharma's adaptive Phase II STOP-AKI study of recAP in 301 sepsis patients with AKI, demonstrated a significant relative reduction in mortality of more than 40% in the treatment group compared to the placebo group. Whilst the primary endpoint – short term kidney function – was missed, long-term kidney function was significantly improved. Throughout the study, recAP was shown to be safe and well tolerated. These results were published in the Journal of the American Medical Association (JAMA).[3]

This new capital will be used to support the largest ever clinical trial in SA-AKI, seeking to enroll up to 1,400 patients with SA-AKI at multiple sites in approximately 12 countries. Following recent discussions with regulatory authorities in the US and Europe, AM-Pharma plans to submit market authorization applications following the successful completion of this upcoming single pivotal Phase III study.

Erik van den Berg, AM-Pharma's CEO commented: "Raising this amount of capital from highly experienced life sciences venture capital firms LSP and Andera Partners, with continued support from our existing investors, highlights the urgent medical need in AKI and the potential of recAP as a life-saving treatment. We look forward to working with our expanded investor syndicate and to initiating the Phase III trial."

Martijn Kleijwegt, Managing Partner at LSP added "We have been following the AM-Pharma story for some time and are delighted to have the opportunity to co-lead this financing round. With its promising Phase II

recAP data published last year, this is an exciting time to support the Company as it is poised and ready to start the Phase III clinical study. recAP has the potential to become the first pharmacological treatment and a blockbuster first-line therapy for critically ill patients with SA-AKI."

Raphaël Wisniewski, Partner at Andera Partners added "We were very impressed with the concept-to-clinic work that AM-Pharma has carried out. This includes the development and cGMP manufacture of recAP, gaining an understanding of its mechanism of action, designing and running an adaptive Phase II clinical trial and, most importantly, its positive impact on patients with SA-AKI. On this journey AM-Pharma has matured from a start-up to a clinical-stage biopharmaceutical company with an in-depth understanding of the underlying and complex causes of AKI. We look forward to these valuable insights translating to future treatment for patients with renal and other diseases of high unmet medical need."

AM-Pharma's Board of Directors will consist of Martijn Kleijwegt and Felice Verduyn van Weegen from LSP, Raphael Wisniewski from Andera, Remi Droller from Kurma and Geert-Jan Mulder from Forbion.

**References**


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**Notes to Editors**

**About AM-Pharma**

AM-Pharma is a clinical stage biopharmaceutical company, leading in the development of a treatment for acute kidney injury (AKI) with its innovative recombinant human Alkaline Phosphatase therapeutic (recAP). AKI affects millions of patients worldwide. It is a devastating disease with high mortality rate and no approved pharmacological treatments. AM-Pharma reported positive results from a Phase II study of recAP in patients with sepsis associated AKI (SA-AKI) and the Company is preparing to initiate a pivotal Phase III trial of recAP in patients with SA-AKI. AM-Pharma is also exploring the development of recAP for other indications including ulcerative colitis (UC), necrotizing enterocolitis (NEC) and hypophosphatasia (HPP). Founded in 2001, AM-Pharma is a private company that is based in the Netherlands. The Company is backed by a strong syndicate of international investors, both Venture Capital funds and Corporate Venture Funds, and has raised over €195m in equity and debt to date.
Find out more about us online at: **www.am-pharma.com**.

**About Acute Kidney Injury (AKI)**

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 40-60% of critical care admissions. Depending on the severity and cause of renal injury, mortality ranges from 10% to as high as 60%. 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. Currently the only treatment options are dialysis and supportive care. No drugs are approved to treat this condition. Typically, these patients are treated in Intensive Care Units, often with support of nephrologists.[1,2,3,4]

**References**


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**AKI – recAP Mechanism of Action**

Acute Kidney Injury (AKI) is a severe inflammation and damage of the kidney resulting in a sudden drop in kidney function, which can sometimes result in complete kidney failure. AM-Pharma has discovered that one key function of the enzyme Alkaline Phosphatase (AP) is to protect organs against inflammation and tissue damage.

AP acts as a detoxifying agent by removing phosphate from extracellular substrates. The dephosphorylation of pro-inflammatory substances like lipopolysaccharides (LPS) and extracellular ATP plays an important anti-inflammatory role. Research has shown that ATP dephosphorylation has a double effect in protecting against kidney injury. When the pro-inflammatory ATP is dephosphorylated the resulting adenosine further reduces inflammation through the activation of the immunosuppressive adenosine A2a receptor pathway (A2aR).

**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. recAP is highly stable and active and has a dual mechanism of action via dephosphorylation of lipopolysaccharides (LPS) and extracellular ATP. AM-Pharma has shown that treatment of patients with exogenous AP not only reduces local and systemic inflammation but also protects the kidney against further damage.

Awarded fast track designation by the US Food and Drug Administration in 2016, recAP has the potential to be a first-in-class medicine. The results of an adaptive Phase II STOP-AKI study of recAP in 301 sepsis patients with AKI were published in 2018 in the prestigious Journal of the American Medical Association (JAMA). recAP demonstrated a significant relative reduction in mortality of more than 40% in the treatment group compared to the placebo group without any safety observations of concern. AM-Pharma is now preparing for the pivotal Phase III study of recAP in patients with sepsis associated kidney injury.