AM-Pharma Increases Funding to €163m for Phase-III Trial of recAP in SA-AKI

- €23m [US$25.5m] equity provided mainly by US-based Cowen Healthcare Investments
- €24m [US$26.5m] finance facility provided by the European Investment Bank (EIB)
- Increased funding allows for finalization of all Marketing Authorization Application preparation activities

Utrecht, The Netherlands, 31 March 2020 – 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 additional funds of €47m [US$52m], increasing the total recent fundraising to €163m [US$176m].

This new capital will be used to support a multi-national pivotal Phase III trial of recAP in 1,400 patients with sepsis-associated-acute kidney injury (SA-AKI). It also allows the Company to fund the steps required to submit Marketing Authorization Applications following the trial's completion, including CMC validation and commercial manufacture.

€23m has been mainly provided by Cowen Healthcare Investments, an affiliate of Cowen Inc., which joins the existing investor syndicate of LSP and Andera Partners, Forbion, Ysios Capital, Kurma Partners, ID Invest Partners, BB Pureos Bioventures and Gilde Healthcare that raised an initial €116m in July 2019.

The additional €24m has been provided by the European Investment Bank (EIB), under the "Infectious Diseases Finance Facility" (IDFF) of the InnovFin – EU-Finance for Innovators program, which is financed from the EU's research and innovation program, Horizon 2020.

AKI is a devastating disease, with a high mortality rate which affects millions of patients worldwide and has no approved pharmacological treatments. The most important cause of AKI 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 SA-AKI. The Phase III trial in reCAP will be the largest clinical trial in SA-AKI, seeking to enroll up to 1,400 patients with SA-AKI at sites in approximately 12 countries.

Erik van den Berg, AM-Pharma's CEO commented: "This additional capital adds to the financing in July 2019, with the addition of the respected Cowen Healthcare Investments team to our international investor syndicate and support from the EIB. The Cowen team not only provides additional funds but also vast experience that can be drawn upon. We are also delighted with the award of funds from the EIB which is a great supporter of innovative medicines and will enable the building of our company."

He added, "The funds raised for our recAP Phase III trial is now at €163m which will also support further marketing application readiness activities. The support from our shareholders and the EIB highlights the urgent medical need in SA-AKI and recAP's potential to treat this indication. We look forward to working with our expanded investor syndicate and continuing work on recAP's path to market."

Tim Anderson at Cowen added "AM-Pharma has completed a robust 301 patient Phase II trial in SA-AKI, following a clear path based on regulatory feedback and the team has significant expertise in the field of acute kidney injury. We believe that recAP has the potential to be an important treatment option for AKI and other indications of high unmet medical need. We look forward to working with the team and the rest of the investors throughout the Phase III trial and beyond."

References

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2. Hoste EA, Bagshaw SM, Bellomo R, et al. Epidemiology of acute kidney injury in critically ill patients: the multinational AKI-EPI study. Intensive Care Med 2015;41:1411–23.

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For further information, please contact:

At the Company	For media enquiries	
AM-Pharma	**Instinctif Partners (UK/RoW)**	**LifeSpring Communications (NL)**
Erik van den Berg, CEO	Ashley Tapp/Phil Marriage	Leon Melens
e.vandenberg@am-pharma.com	+44 (0)20 7866 7923	+31 (0) 6 538 16 427
	AM-Pharma@instinctif.com	lmelens@lifespring.nl

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. 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 €240m 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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2. Murugan R. and Kellum J.A., (2011) Nat Rev Nephrol. Vol 7: 209-217
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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.

About Cowen Healthcare Investments

Cowen Healthcare Investments is an investment manager affiliated with Cowen Inc. Cowen Healthcare Investments manages a series of investment funds focused on investing in private healthcare companies across the biopharma, diagnostics and digital health sectors. Founded in 2012, the firm is headquartered in New York. Learn more at **www.cowen.com**.

Additional Financing Information related to the EU support via the EIB finance facility

Under Horizon 2020, the EU Research and Innovation Framework Programme for 2014-20, the 'Infectious Diseases Finance Facility (IDFF)' provides financial products ranging from standard debt to equity-type financing for amounts typically between EUR 7.5 million and EUR 75 million, to innovative players active in developing innovative vaccines, drugs, medical and diagnostic devices or novel research infrastructures for combatting infectious diseases. Project costs may include clinical trial costs, set-up of commercialization such as market access, development of prototypes or industrial roll out of novel equipment, pre-clinical R&D costs and working capital requirement. This facility is delivered directly by the EIB, which so far has made available EUR 241 million under the InnovFin IDFF.