# Pfizer Acquires Minority Interest in AM-Pharma; Secures Option to Acquire Company

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Option May Be Exercised Based on Phase II Trial Results for Recombinant Human Alkaline Phosphatase

AM?Pharma B.V., a privately held Dutch biopharmaceutical company focused on the development of recombinant human Alkaline Phosphatase (recAP) for inflammatory diseases, and Pfizer Inc. (NYSE:PFE) announced today that Pfizer has acquired a minority equity interest in AM-Pharma and secured an exclusive option to acquire the remaining equity in the company. The option becomes exercisable upon completion of a Phase II trial of recAP in the treatment of Acute Kidney Injury (AKI) related to sepsis. There are no drugs currently approved for this condition and the only treatment option is dialysis and supportive care. Results from the current Phase II trial for recAP are expected in the second half of 2016. Under the terms of the agreement, Pfizer has made an upfront payment of \$87.5 million for the minority equity interest and exclusive option, with additional potential payments of up to \$512.5 million upon option exercise and potential launch of any product that may result from this agreement. Other terms of the transaction were not disclosed.

"Pfizer is committed to advancing the science to address the high unmet medical need in Acute Kidney Injury," said Mikael Dolsten, M.D., Ph.D., president, Worldwide Research and Development at Pfizer. "Clinical data for recAP show the potential to uniquely address Acute Kidney Injury in the setting of sepsis, and we look forward to working with our partners at AM-Pharma as we aim to accelerate the development of recAP into a potential first-in-class treatment for patients."

Erik van den Berg, CEO of AM-Pharma added: "This agreement is a significant step for AM-Pharma, and we welcome Pfizer as a shareholder and dedicated partner. This deal not only provides good shareholder value, but provides the next step in the development of recAP as a potential treatment for patients with Acute Kidney Injury and other inflammatory diseases."

Ropes & Gray LLP and De Brauw Blackstone Westbroek N.V. acted as legal advisors to Pfizer, and Dechert LLP and Clifford Chance LLP acted as legal advisors to AM-Pharma.

#### **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 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 commercialization. Since inception, the company has raised €67 million from a syndicate of international investors including Inventages, Forbion

Capital Partners, Gilde Healthcare, Ysios Capital, Kurma biofund, IDInvest Partners, BB Biotech Ventures, Abbvie and Shire. The most recent financing round in September 2014 was €12.2 million, for the completion of a Phase II study of recAP in AKI patients, as well as continued development of an oral formulation of recAP for UC patients.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

## **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 under development for testing the potential treatment of AKI, with the potential to be developed for hypophosphatasia. An oral formulation may be developed for the treatment of ulcerative colitis. The enzyme is produced by cGMP manufacture for preclinical and clinical trial supply and commercialization.

## Pfizer Disclosure Notice

The information contained in this release is as of May 11, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's acquisition of a minority equity interest in AM-Pharma and an exclusive option to acquire the remaining equity, as well as about a product candidate, recAP, including the potential benefits thereof, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when new drug applications may be filed in any jurisdictions for recAP; whether and

when such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of recAP; the ability to realize the anticipated benefits of the acquisition; other business effects, including the effects of industry, economic, political or regulatory conditions; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at <a href="https://www.sec.gov">www.pfizer.com</a>.

- 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

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