JSR Life Sciences

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KBI Biopharma Enters Commercial Manufacturing Agreement with AM-Pharma to Prepare for the Commercial Launch of Lead Program in Acute Kidney Disease

Agreement supports future commercial manufacturing for AM-Pharma's recombinant alkaline phosphatase program

Utrecht, The Netherlands and DURHAM, NC – June 17, 2021 – KBI Biopharma, Inc. (KBI), a JSR Life Sciences company, and AM-Pharma, an emerging leader focused on the development of therapeutics that protect organ function in patients with severe medical conditions, have signed a commercial manufacturing agreement to advance AM-Pharma's recombinant human Alkaline Phosphatase (recAP) program towards commercialization. AM-Pharma is developing recAP for the potential treatment of Sepsis-Associated Acute Kidney Injury (SA-AKI).

SA-AKI is a devastating disease affecting hundreds of thousands of patients worldwide with high mortality rates and no approved pharmacological treatments.

Under the terms of the new commercial manufacturing agreement, KBI Biopharma will conduct drug substance manufacturing alongside the ongoing process characterization and validation work. The commercial manufacturing agreement will provide drug substance and regulatory support for the Phase III REVIVAL study and potential BLA filing. Based on the clinical results, KBI will continue to support drug substance manufacturing and release for commercial use.

"We have a successful history with KBI Biopharma and are looking forward to working together to advance our lead program through to commercial launch," stated Erik van den Berg, Chief Executive Officer, AM-Pharma. "Acute kidney disease remains a critical unmet need and we look forward to working with KBI to help patients who are in need of treatment options."

KBI will conduct manufacturing and validation in its existing facilities. AM-Pharma and KBI Biopharma began collaborating on the recAP program in 2011 when KBI performed initial process development and cGMP manufacturing for early clinical use.

“We are proud to have grown alongside our partners and to play an integral role in the development and manufacture of therapies that represent true advances to the treatment landscape for patients in need,” said KBI President and CEO Dirk Lange. “The analytics and cGMP capabilities of our facilities are strongly suited for AM-Pharma’s product launch requirements. We look forward to continuing our collaboration on the recAP program as it advances toward the treatment of acute kidney disease.”

About recAP

AM-Pharma’s therapeutic candidate is a proprietary recombinant human Alkaline Phosphatase (recAP) constructed from two naturally occurring human isoforms of the AP enzyme. The Company’s compound 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.

About AM-Pharma

AM-Pharma’s purpose is to save and improve the lives of patients confronted with severe medical conditions. Our initial focus is sepsis-associated acute kidney injury, the cause of death for hundreds of thousands of people hospitalized each year. Our proprietary recombinant human alkaline phosphatase has the potential to become the first treatment for sepsis-associated acute kidney injury and is now in a global pivotal Phase III clinical trial. We are a dedicated team driven to bring treatment options to severely ill patients, their families and acute care professionals. Find out more about us online at: www.am-pharma.com.

About KBI Biopharma, Inc.

KBI Biopharma, a JSR Life Sciences Company, is an award-winning biopharmaceutical contract services organization providing fully integrated, accelerated drug development and biomanufacturing services to pharmaceutical and biotechnology companies globally. With each of our 300+ client partners, we have worked closely to personalize and rapidly accelerate their drug development programs. Built upon a foundation of world-class analytical capabilities, we deliver efficient process development and clinical and commercial cGMP manufacturing services for mammalian, microbial, and cell therapy programs. We have locations in Durham and Research Triangle Park (NC), Boulder and Louisville (CO), The Woodlands (TX), and Leuven, Belgium. More information is available at www.kbibiopharma.com

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