Spero Awarded up to $54 Million by BARDA and DTRA to Support SPR994 Development

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- *Inter-agency collaboration among BARDA, DTRA, USAMRIID and Spero to fund further clinical development of product candidate SPR994*
- *Planned pivotal Phase 3 trial of SPR994 on track to initiate around year-end 2018*

CAMBRIDGE, Mass., July 16, 2018 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq:SPRO) (Spero), a multi-asset clinical-stage biopharmaceutical company focused on developing and commercializing novel antibiotics to treat multi-drug resistant bacterial infections, today announced that it was awarded funding of $15.7 million, with the potential for up to an additional $28.5 million over 5 years, from the Biomedical Advanced Research and Development Authority (BARDA). The funding will support the further clinical development of Spero's oral carbapenem product candidate, SPR994, for the treatment of complicated urinary tract infections (cUTIs) caused by antibiotic resistant Gram-negative bacteria. As part of the inter-agency collaboration with Spero, a series of studies to assess the efficacy of SPR994 in the treatment of infections caused by biodefense threats such as anthrax, plague and melioidosis will be conducted by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). In addition, the Defense Threat Reduction Agency (DTRA) will provide support up to $10 million to fund the nonclinical biodefense aspects of the inter-agency collaboration. The collaboration may also include a clinical trial in pneumonia patients, an indication for which tebipenem, SPR994's active pharmaceutical ingredient, is currently approved in Japan for pediatric use. Together, the two agencies will provide up to $54.2 million in total funding for the clinical development and biodefense assessment of SPR994, a portion of which is subject to the exercise of options by BARDA and Spero's achievement of specified milestones.

"We are honored to be the recipient of an award and to join BARDA and DTRA in this unique inter-agency collaboration. We look forward to advancing SPR994 through clinical development for public and biodefense use as we target public health needs caused by emerging drug-resistant infections," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "We believe the funding is a validation of the clinical potential of SPR994 across a broad treatment landscape, and of the ability of a small biotech company to work towards bringing these innovative therapies to patients in collaboration with our partners at BARDA and DTRA."

The award from BARDA commits $15.7 million of guaranteed initial funding and up to an additional $28.5 million over 5 years if BARDA exercises all of its options under the award. Additionally, DTRA will commit $1.25 million of initial support, and up to an additional $8.75 million upon the achievement of specified milestones.

About SPR994

SPR994 is Spero's novel investigational oral formulation of tebipenem, a carbapenem-class antibiotic marketed by Meiji Seika Pharma Co. Ltd. (Meiji) in Japan as Orapenem® since 2009 for common pediatric infections. Carbapenems are an important class of antibiotics because they have been demonstrated to be safe and effective against drug-resistant Gram-negative bacterial infections. Spero initiated a Phase 1 clinical trial of SPR994, designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study, in healthy subjects in October 2017. The trial is assessing the safety, tolerability, and pharmacokinetics of SPR994 to enable dose selection for Spero's planned pivotal Phase 3 clinical trial. Spero announced interim Phase 1 data from the trial in early July and expects to report final data from the MAD portion of the Phase 1 clinical trial in the third quarter of 2018. Pending discussions from a pre-Phase 3 meeting with the FDA, which Spero plans to request in the second half of 2018, Spero plans to initiate a pivotal Phase 3 clinical trial of SPR994 for the treatment of cUTI around year-end 2018 in support of a new drug application (NDA). In preclinical studies, SPR994 has shown potent antibiotic activity against Gram-negative bacteria, including *E. coli*-producing extended-spectrum beta-lactamases (ESBLs) and ESBL-producing *Klebsiella pneumoniae*, similar to IV-administered ertapenem. Approximately 1,200 subjects have been dosed with tebipenem in clinical and pharmacologic studies conducted by Meiji during its development of tebipenem in Japan. In addition, available post-marketing outcomes data report the safety and efficacy of tebipenem in 3,540 pediatric patients with pneumonia, otitis media or sinusitis, and these data are consistent with the safety profile of tebipenem as observed in the clinical trial conducted by Meiji.

About Spero

Spero is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multidrug-resistant ("MDR") bacterial infections.

Spero's lead product candidate, SPR994, is designed to be the first broad-spectrum oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.

Spero also has a platform technology known as its Potentiator Platform that it believes will enable it to develop drugs that will expand the spectrum and potency of existing antibiotics, including formerly inactive antibiotics, against Gram-negative bacteria. Spero's lead product candidates generated from its Potentiator Platform are two intravenous, or IV,-administered agents, SPR741 and SPR206, designed to treat MDR Gram-negative infections in the hospital setting.

Spero is also advancing SPR720, its novel oral therapy product candidate designed for the treatment of pulmonary non-tuberculous mycobacterial infection.

For more information, visit ***https://sperotherapeutics.com***.

About BARDA

The Biomedical Advanced Research and Development Authority (BARDA), an agency within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), provides a comprehensive, integrated, portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing infrastructure for vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear threats, pandemic influenza and emerging infectious diseases. For more information, visit ***https://www.phe.gov/about/barda/.***

About DTRA

The Defense Threat Reduction Agency (DTRA), an agency within the United States Department of Defense (DoD), is the official Combat Support Agency for countering weapons of mass destruction (chemical, biological, radiological, nuclear, and high explosives). DTRA's mission is to enable the DoD and the U.S. Government to prepare for and combat weapons of mass destruction, and has the responsibility to manage and integrate the DoD chemical and biological defense science and technology programs. DTRA's continued effort to enhance the combat support mission also advances public health services by developing innovative technologies that protect against biological threats. For more information, visit***http://www.dtra.mil/.***

About USAMRIID

The United States Army Medical Research Institute of Infectious Disease's mission is to provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents. Research conducted at USAMRIID leads to medical solutions—vaccines, drugs, diagnostics, and information—that benefit both military personnel and civilians. USAMRIID plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit ***http://www.usamriid.army.mil/.***

[The information contained in this press release does not necessarily reflect the position or the policy of the U.S. Government and no official endorsement should be inferred.]

Forward Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including statements regarding management's assessment of the results of such preclinical studies and clinical trials, the timing of clinical data, Spero's cash forecast and anticipated expenses, the sufficiency of its cash resources and the availability of additional non-dilutive funding from governmental agencies beyond any initially funded awards. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intent," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Spero's product candidates will advance through the preclinical development and clinical trial process on a timely basis, or at all; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether BARDA elects to exercise its options to provide Spero with additional funding and whether Spero achieves the milestones that are a precondition to its receipt of additional DTRA funding; and other factors discussed in the "Risk Factors" set forth in filings that we periodically make with the U.S. Securities Exchange Commission. The forward-looking statements included in this press release represent Spero's views as of the date of this press release. Spero anticipates that subsequent events and developments will cause its views to change. However, while Spero may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Spero's views as of any date subsequent to the date of this press release.

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