Spero Therapeutics Announces Exercise of $15.9 Million Option by BARDA for Tebipenem HBr Development

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CAMBRIDGE, Mass., Feb. 05, 2020 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), a multi-asset clinical-stage biopharmaceutical company focused on identifying, developing and commercializing treatments in high unmet need areas involving multi-drug resistant (MDR) bacterial infections and rare diseases, announced today that the Biomedical Advanced Research and Development Authority (BARDA) has exercised its first contract option for additional committed funding pursuant to its existing contract with Spero. Specifically, the option exercise provides Spero with $15.9 million in reimbursement for the further development of tebipenem HBr. Spero's lead product candidate, tebipenem HBr, is an oral carbapenem currently being evaluated in a pivotal Phase 3 clinical trial for the treatment of complicated urinary tract infections (cUTI), with top-line data expected in the third quarter of 2020.

The option was exercised under Spero's existing 2018 contract with BARDA, which provides for reimbursement to Spero of up to $46.8 million for qualified expenses for tebipenem HBr development over a five-year period. Total committed funding under the BARDA award to date is $34.0 million, inclusive of this first contract option being exercised. There is a second option exercisable by BARDA for the remaining $12.7 million of funding, subject to specified milestones being achieved under the award agreement. Furthermore, the Defense Threat Reduction Agency (DTRA) provides up to $10.0 million, in addition to the total potential award from BARDA, to cover the cost of the nonclinical biodefense aspects of the collaboration program for tebipenem HBr. Together, the two agencies will provide up to $56.8 million in total funding for the clinical development and biodefense assessment of tebipenem HBr, a portion of which is subject to the exercise of options by BARDA and Spero's achievement of specified milestones.

The $15.9 million contract option exercise announced today is expected to support the funding of specified manufacturing activities required for approval of tebipenem HBr, including API validation batch manufacturing and stability studies. Additionally, the option is expected to support the funding of several non-clinical and clinical development activities relating to tebipenem HBr, including a Phase 1 bronchoalveolar lavage (BAL) study in healthy subjects to assess lung exposure of tebipenem HBr, an important assessment to support a biodefense indication as well as evaluation in lung infections. Tebipenem HBr has demonstrated preclinical activity in murine lung models of Gram-negative bacterial infections and its active pharmaceutical ingredient is also currently approved in Japan for the treatment of pediatric pneumonia. As a result of this option exercise, and together with support from DTRA, Spero intends to progress tebipenem HBr into non-human primate efficacy studies in one or more models of biothreat disease. Spero anticipates initiating a Phase 1 BAL clinical trial of tebipenem HBr in healthy subjects in the third quarter of 2020.

"We look forward to our continued relationship with BARDA and DTRA and appreciate their support as we work to advance tebipenem HBr to treat the serious unmet need of multi-drug resistant infections," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "The tebipenem HBr Phase 1 BAL study will be important to our long-term strategy as we look towards new indications, including pneumonia, and to position tebipenem HBr as an effective medicine for biodefense applications."

Tebipenem HBr Research Support
This project has been funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800015C.

About Tebipenem HBr
Tebipenem HBr (tebipenem pivoxil hydrobromide; formerly 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 pediatric infections limited to pneumonia, otitis media and sinusitis. Carbapenems are an important class of antibiotics because they have been observed to be safe and effective against drug-resistant Gram-negative bacterial infections. Spero is conducting a pivotal Phase 3 clinical trial of tebipenem HBr entitled ADAPT-PO (a Phase 3, randomized, double-blind, double-dummy, multicenter, prospective study to assess the efficacy, safety and pharmacokinetics of orally administered tebipenem pivoxil hydrobromide compared to intravenous ertapenem in patients with complicated urinary tract infection (cUTI) or acute pyelonephritis (AP)). Spero expects to report top-line data from the Phase 3 clinical trial in the third quarter of 2020. Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of cUTI.

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

Spero's lead product candidate, tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994), is designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.

Spero is also advancing SPR720, its novel oral therapy product candidate designed for the treatment of rare, orphan disease caused by pulmonary non-tuberculous mycobacterial (NTM) 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 potentiator product candidate, SPR206, is designed to treat MDR Gram-negative infections in the hospital setting.

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/***.

Forward Looking Statements
This press release may contain forward-looking statements. These statements include, but are not limited to, statements about Spero's expectation that positive results from a single pivotal Phase 3 clinical trial of tebipenem HBr and ancillary supportive studies to be conducted in parallel with the Phase 3 trial will support the approval of tebipenem HBr; the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including the timing of Spero's regulatory meeting with the FDA regarding SPR720, the timing of Spero's IND submission with the FDA regarding SPR720, the commencement of Spero's planned Phase 2a clinical trial of SPR720 and the commencement of Spero's planned Phase 1 bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment; management's assessment of the results of such preclinical studies and clinical trials; the timing of clinical data, including the availability of pharmacokinetic data from the lead-in cohort in the Phase 3 clinical trial of tebipenem HBr, final data from the Phase 1 clinical trial of SPR720 and final data from the Phase 1 clinical trial of SPR206; and Spero's cash forecast and anticipated expenses, anticipated payments under Spero's agreement with Everest Medicines, potential payments under Spero's agreement with BARDA, 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 the FDA will accept a single pivotal study for approval of tebipenem HBr; 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, taking into account the effects of possible regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, clinical trial design and clinical outcomes; whether the results of such trials will warrant submission for approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether Spero will satisfy all of the pre-conditions to receipt of the development milestone payment under its agreement with Everest Medicines; whether BARDA elects to exercise its second option under Spero's agreement with BARDA; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; and other factors discussed in the "Risk Factors" set forth in filings that Spero periodically makes with the U.S. Securities and 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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