Spero Therapeutics Announces $5.9 Million Award from U.S. Department of Defense to Further Clinical Development of SPR206

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CAMBRIDGE, Mass., July 16, 2019 (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, today announced that it has received a $5.9 million award from the U.S. Department of Defense (DoD) Congressionally Directed Medical Research Programs (CDMRP) Joint Warfighter Medical Research Program (Award number W81XWH-19-1-0295). The U.S. Army Medical Research Acquisition Activity, 839 Chandler Street, Fort Detrick MD 21702- 5014 is the awarding and administering acquisition office.

The funding will support the further clinical development of SPR206, Spero's intravenous (IV)-administered product candidate from its Potentiator Platform that is being developed as an innovative alternative option to treat MDR Gram-negative bacterial infections. The award commits non-dilutive funding of $5.9 million over a four-year period to cover the costs of select Phase 1 pharmacology studies, a 28-day GLP non-human primate toxicology study, and microbiological surveillance studies that would be required for a potential New Drug Application (NDA) submission with the U.S. Food and Drug Administration for SPR206.

In preclinical studies, SPR206 has demonstrated activity as a single agent against MDR and extensively drug resistant (XDR) bacterial strains, including isolates of *Pseudomonas aeruginosa*, *Acinetobacter baumannii* and carbapenem-resistant *Enterobacteriaceae*, in both *in vitro* and *in vivo* models of infection. SPR206 is currently being evaluated in a first-in-human Phase 1 clinical trial, designed as a double-blind, placebo-controlled, single and multiple ascending dose, multi-cohort study in healthy subjects. Spero expects to report top-line data from this trial in the second half of 2019.

"Spero is dedicated to fighting emerging drug-resistant infections and tackling this critical problem that faces our civilian and military populations alike," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. "We are honored to be selected for this award, which will enable us to advance the clinical development of SPR206 using non-dilutive funding, and we look forward to strengthening our existing relationship with the Department of Defense."

The DoD recognizes the need for safe, novel antibiotics effective against MDR organisms that can cause hospital or community-associated infections in veterans or combat wound infections in active duty military personnel.

About the Spero Potentiator Platform – SPR206 and SPR741

Spero's Potentiator Platform molecules are designed to treat Gram-negative bacterial infections through the molecule's interactions with the bacterium's outer membrane. The Potentiator Platform molecules exhibit this effect as a monotherapy or by co-administration with existing antibiotics. Spero currently has two Potentiator Platform drug candidates – SPR206, a direct acting IV-administered agent that has demonstrated broad Gram-negative antibacterial activity; and SPR741, an IV-administered agent that has demonstrated Gram-negative antibacterial activity when co-administered with existing antibiotics. Both have demonstrated activity against Gram-negative bacteria, including organisms identified by the Centers for Disease Control and Prevention and the World Health Organization as urgent and serious threats to human health. SPR206 is designed to have antibiotic activity as a single agent against MDR and XDR bacterial strains, including carbapenem-resistant *Pseudomonas aeruginosa, Acinetobacter baumannii* and Enterobacteriaceae. Spero initiated a Phase 1 trial of SPR206 in December 2018 and anticipates top-line data from the trial in the second half of 2019. In preclinical studies, SPR741 was able to potentiate over two-dozen existing antibiotics by expanding their activity against Gram-negative pathogens. SPR741 has been evaluated in two Phase 1 clinical trials in healthy volunteers supporting its safety and tolerability. Spero believes that its current intellectual property portfolio and pending patent applications will provide global protection, including China, the United States and Europe for SPR206 and SPR741 through 2039 and 2038, respectively.

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, 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 lead product candidates generated from its Potentiator Platform are two IV-administered agents, SPR206 and SPR741, designed to treat MDR Gram-negative infections in the hospital setting.

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

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 SPR994 and ancillary supportive studies to be conducted in parallel with the Phase 3 trial will support the approval of SPR994; the initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs; statements regarding 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 SPR994 and top-line data from the Phase 1 clinical trial of SPR720 and the Phase 1 clinical trial of SPR206; and 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 the FDA will accept a single pivotal study for approval of SPR994; 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'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 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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