Spero Therapeutics Signs License Agreement with Everest Medicines to Develop, Manufacture and Commercialize SPR206 in Asia, with Option for SPR741 Rights, and Initiates SPR206 Phase 1 Clinical Trial

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CAMBRIDGE, Mass., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq:SPRO), a multi-asset clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multidrug-resistant (MDR) bacterial infections, and Everest Medicines announced today that they have entered into a collaboration to develop, manufacture and commercialize SPR206 in Greater China, South Korea and certain Southeast Asian countries (the "Territory"), along with an exclusive option to rights to SPR741 in the Territory.

SPR206 and SPR741, two intravenous (IV)-administered product candidates from Spero's Potentiator Platform, are being developed as innovative options to treat MDR Gram-negative bacterial infections. Based on microbiological and *in vivo* testing, Spero believes that SPR206 has the potential to offer a broad-spectrum of activity, including against extensively drug-resistant (XDR) bacterial strains, together with improved safety and tolerability compared with other molecules in its class. Spero initiated a Phase 1 clinical trial of SPR206 in December 2018, designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study in healthy subjects, and expects top-line data from this trial in the second half of 2019. Data from investigational new drug (IND)-enabling studies, together with data presented at the ESCMID/ASM Conference in September 2018, collectively demonstrate SPR206's favorable safety profile and *in vitro* activity against MDR Gram-negative pathogens, including carbapenem-resistant Enterobacteriaceae, *Acinetobacterbaumannii* and *Pseudomonas aeruginosa*. SPR741 is a novel compound designed to expand the spectrum and enhance the potency of existing antibiotics. SPR741 completed a Phase 1b drug-drug interaction clinical trial in July 2018, which demonstrated safety and pharmacokinetic compatibility of SPR741 when co-administered with beta-lactam antibiotics.

Spero, through certain of its wholly owned subsidiaries, has granted Everest an exclusive license to develop, manufacture, and commercialize SPR206 in the Territory. Everest also has a 12-month exclusive option to rights to SPR741 in the Territory. A Joint Development Committee will be established between the companies to coordinate and review the development, manufacturing and commercialization plans with respect to SPR206 in the Territory. Spero will receive an upfront payment of $2 million and is eligible to receive milestone payments of up to an additional $59.5 million upon achievement of specified clinical, regulatory and commercial milestones related to SPR206, of which Spero anticipates receiving at least $2 million in near-term milestones during 2019. Furthermore, Spero will be eligible to receive high single-digit to low double-digit royalties on any sales of SPR206 products in the Territory following regulatory approval. Everest will also pay Spero a $1 million upfront fee for its exclusive 12-month option to rights to SPR741.

"We look forward to working with Everest Medicines to further develop and bring SPR206 to market in Greater China, South Korea and Southeast Asia in an effort to address the growing, global problem of antibiotic resistance," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "Everest shares our passion and commitment to developing these important, novel medications. Having a local partner who understands the market dynamics and reimbursement landscape will significantly assist Spero's efforts to develop and commercialize these product candidates in Asia. Additionally, funding from this transaction will provide additional resources to advance our robust pipeline of products that address unmet medical needs."

"Bacterial drug resistance is a critical health issue and innovative new classes of antibiotics is an area of urgent unmet need," said Sean Cao, Interim CEO at Everest Medicines. "We partner with companies that develop innovative medicines and have large commercial potential in Asia. Development of safer polymyxins with a broad spectrum of antimicrobial activity including extensively resistant bacteria may provide a life-saving treatment to patients with limited or no alternative treatment options."

About the Spero Potentiator Platform – SPR206 and SPR741

The 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 SPR741 and SPR206 through 2038 and 2039, respectively.

About Everest Medicines

Everest Medicines is an emerging markets biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products that address critical unmet medical needs for patients across Greater China and other Asian territories. The Everest Medicines team has deep expertise and an extensive track record of high-quality clinical development, regulatory affairs, CMC, business development and operations with

leading global pharmaceutical companies, and in our territories of focus.

About Spero

Spero is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for 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 IV-administered agents, SPR206 and SPR741, that are 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**.

SPR206 Research Support

This project has been funded in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201500014C.

Forward-Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the future development or commercialization of SPR206 and SPR741 in Greater China, South Korea and certain Southeast Asian countries, the potential receipt of milestone payments, as well as royalties on potential future sales of SPR206, under the license with Everest Medicines, 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, including the availability of top-line data from the Phase 1 clinical trial of SPR206, 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 Spero's dependence on Everest Medicines to timely and successfully develop, manufacture and commercialize SPR206 in Greater China, South Korea and certain Southeast Asian countries; the fact that Spero may not receive any milestone or royalty payments from Everest Medicines; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Spero's product candidates, including SPR206, 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; Spero's ability to continue obtaining and maintaining intellectual property protection for its product candidates; 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.

Spero Investor and Media Contact:
Sharon Klahre
Director, Investor Relations
857-242-1547
IR@sperotherapeutics.com

Everest Medicines Media Contact:
James Heins
Senior Vice President
203-682-8251
James.Heins@icrinc.com

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