Spero Therapeutics Announces Positive Results from SPR720 IND-Enabling Studies and Plans to Initiate a Phase 1 Trial

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CAMBRIDGE, Mass., Nov. 05, 2018 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq:SPRO), a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug resistant (MDR) bacterial infections, today announced results from preclinical IND-enabling studies of SPR720, an oral antimicrobial agent being developed for the treatment of pulmonary non-tuberculous mycobacterial (NTM) infections. The preclinical *in vitro* and *in vivo* toxicology studies demonstrate that SPR720 achieved wide therapeutic margins and activity versus multiple clinically important species of non-tuberculous mycobacteria, which Spero believes supports its advancement into human clinical trials.

"With these encouraging results, we look forward to advancing SPR720 into the clinic in early 2019," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "SPR720 offers the potential to address an important unmet need as the first oral agent for the treatment of pulmonary NTM, a chronic debilitating disease with limited treatment options."

SPR720 was assessed in a series of non-clinical studies, including IND-enabling 28- and 31-day GLP toxicology studies in non-human primates and rats, respectively, and safety pharmacology studies. *In vitro* MIC studies demonstrated potent activity for SPR720 against prevalent NTM pathogens, including *Mycobacterium avium* complex and *Mycobacterium abscessus.* Furthermore, *in vivo* studies in murine models of pneumonia demonstrated favorable efficacy relative to standard-of-care comparator agents. The data suggest that SPR720 has an acceptable safety profile, encouraging target pathogen efficacy, and a wide therapeutic margin. These results, in conjunction with the recent regulatory interactions Spero has had, support the further development of SPR720. Spero plans to initiate a First-in-Human Phase 1 clinical trial of SPR720 in early 2019.

SPR720 Research Support

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About SPR720

SPR720 represents a novel class of antibacterial agents that target enzymes essential for bacterial DNA replication. SPR720 was in-licensed from Vertex and is being developed as an oral therapy for the treatment of pulmonary non-tuberculous mycobacterial (NTM) infections. NTM are ubiquitous environmental pathogens that can cause progressive lung damage and respiratory failure, particularly in patients with compromised immune systems or underlying pulmonary disorders. Although rare, the incidence of pulmonary NTM infections is increasing worldwide. Treatment of pulmonary NTM infections requires prolonged therapy (continuing for approximately 12 to 24 months) with a combination regimen and is frequently complicated by tolerability and/or toxicity issues. Additionally, there are currently no oral antibiotics specifically approved for use to treat pulmonary NTM infections. Thus, if successfully developed, SPR720 has the potential to address an important unmet need as the first oral antibiotic approved for the treatment of this debilitating disease. Pre-clinical *in vitro* and *in vivo* studies have demonstrated potency for SPR720 against a range of bacteria that cause pulmonary NTM infections, including *Mycobacterium avium* complex and *Mycobacterium abscessus*, a highly resistant strain responsible for high mortality. Spero believes that its intellectual property portfolio for SPR720 will provide protection globally, including in the United States and Europe, through 2033.

About Spero Therapeutics

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.

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 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 (NTM) infections.

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 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 the SPR720 preclinical studies and management's belief that SPR720 may demonstrate favorable clinical results and may be able to address an unmet medical need, 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 the SPR720 preclinical studies will be indicative of results obtained in future clinical trials; whether SPR720 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 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 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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