SPERO THERAPEUTICS

Spero Therapeutics Announces Positive Top-Line Data for Two Product Candidates from its Potentiator Platform

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SPR741 Phase 1b Drug-Drug Interaction Study and SPR206 IND-enabling Studies Provide Support for Further Clinical Development

- Phase 1b data demonstrates pharmacokinetic compatibility and tolerability of SPR741 when co-administered with b-lactam antibiotics and continues to build on safety profile observed in prior clinical study
- SPR206 IND-enabling studies demonstrate potential for wide therapeutic margins and broad antimicrobial spectrum as a single agent, supporting progression to clinical studies
- Both compounds represent novel, differentiated potential approaches to treating MDR Gram-negative infections, for which no new classes of therapies have been approved for 30 years

CAMBRIDGE, Mass., May 23, 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 the Company's Phase 1b drug-drug interaction trial of SPR741, the first product candidate from its Potentiator Platform, demonstrating pharmacokinetic (PK) compatibility and tolerability when co-administered with b-lactam antibiotics. Spero also announced results today from the IND-enabling studies of SPR206, its second product candidate from the platform, that demonstrate the potential for this agent to achieve wide therapeutic margins in the treatment of serious Gram-negative infections and are supportive of advancement into clinical development.

"Phase 1b data highlighting tolerability and PK compatibility for SPR741 when dosed in combination with select b-lactams and pre-clinical data demonstrating potential for wide therapeutic margins for SPR206 as a single agent are encouraging and continue to support the potential of our Potentiator Platform to provide innovative drug candidates for multidrug-resistant Gram-negative infections in the hospital," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics.

SPR741:

In the Phase 1b trial, SPR741 was administered as a single dose of 400 mg alone and in combination with three commonly used b-lactam antibiotics, piperacillin/tazobactam, ceftazidime, and aztreonam. The trial enrolled 27 healthy volunteers in a cross over study design. The goal of the Phase 1b trial was to assess the impact, if any, on the PK or tolerability of SPR741 and the PK or tolerability of the b-lactam drug when the two are dosed together. The single dose data indicate that the administration of b-lactam antibiotics had no impact on PK or tolerability of SPR741, supporting further development of SPR741 as a combination agent for the treatment of MDR infections.

Results from the Phase 1b study build on the data from the Phase 1 SAD/MAD study announced in October, 2017 and presented at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) Conference in April 2018 that showed SPR741 to be generally well tolerated at doses up to and including 600 mg every 8 hours for 14 days. These data also complement results presented at ECCMID 2018 showing that combinations of SPR741 and b-lactams were active in vitro and in preclinical infection models.

SPR206:

SPR206 was assessed in a suite of non-clinical, IND-enabling studies, including 14-day, two species, GLP toxicology experiments, and in vitro and in vivo GLP safety pharmacology, and absorption, distribution, metabolism, and excretion (ADME) studies. The data provide support for an acceptable safety profile and combined with earlier microbiological and in vivo efficacy testing of SPR206, support its advancement as clinical candidate designed to treat MDR and extensively drug-resistant (XDR) bacterial strains, including carbapenem-resistant Pseudomonas aeruginosa, Acinetobacter baumannii, and Enterobacteriaceae. The composite data suggest SPR206 has the potential for wide therapeutic margins in the setting of serious hospital Gram-negative infections.

About the Spero Potentiator Platform

The Potentiator Platform molecules are designed to treat Gram-negative bacterial infections through the molecules’ interactions with the bacteria’s outer cell membrane as a monotherapy or by co-administering our Potentiator Platform molecules with existing antibiotics, potentially making the existing antibiotics more effective by clearing a path for them to enter and kill the bacteria. We have two Potentiator Platform product candidates – SPR741, our combination IV-administered agent that has been evaluated in vitro in which we observed expansion of the spectrum and increase in potency of a co-administered antibiotic; and SPR206, our direct acting IV-administered agent that has shown in vitro activity alone. Both have demonstrated potency in vitro against Gram-negative bacteria, including organisms identified by the Centers for Disease Control and Prevention, or the CDC, and the World Health Organization, or the WHO, as urgent and serious threats to human health. In preclinical studies, SPR741 was able to potentiate over two dozen existing antibiotics by expanding their activity against Gram-negative pathogens and has now been evaluated in two Phase 1 trials in healthy volunteers supporting its tolerability. SPR206 is designed to also have antibiotic activity as a single agent against MDR and extremely drug resistant, or XDR, bacterial strains, including variants isolated in Pseudomonas aeruginosa, Acinetobacter baumannii and carbapenem-resistant Enterobacteriaceae.
The work on these compounds was partially supported by non-dilutive funding from the Office of the Assistant Secretary of Defense for Health Affairs, through the Peer Reviewed Medical Research Program under Award No. W81XWH-16-2-0019. This work is also partially supported by the Cooperative Agreement Number IDSEP160030 from ASPR/BARDA and an award from the Wellcome Trust, as administrated by CARB-X. The contents of the press release are solely the responsibility of the authors and do not necessarily represent the official views of CARB-X, the HHS Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health or the Wellcome Trust.

About Spero

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

The Company’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.

The Company 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. The Company’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) infection, an orphan infectious disease.

For more information, visit [https://sperotherapeutics.com](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 the Company's preclinical studies and clinical trials and the Company's 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, the Company's cash forecast and anticipated expenses and the sufficiency of the Company’s cash resources. In some cases, forward-looking statements can be identified by terms such as “may,” “will,” “should,” “expect,” “plan,” “aim,” “anticipate,” “could,” “intend,” “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 the Company'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 the Company'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” section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 2, 2018 and the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2018, and risks described in other filings the Company may make with the Securities and Exchange Commission in the future. The forward-looking statements included in this press release represent the Company’s views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company’s views as of any date subsequent to the date of this press release.

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