Spero Therapeutics to Present Data for All Pipeline Programs at the ASM Microbe 2019 Conference

June 17, 2019

Twenty-two presentations with data across all pipeline programs, including four oral presentations

CAMBRIDGE, Mass., June 17, 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 will present four oral presentations and eighteen poster presentations across all of Spero's pipeline programs at the American Society of Microbiology (ASM) Microbe 2019 Conference taking place June 20 - 24, 2019 in San Francisco, California.

Data to be presented at ASM Microbe 2019 for SPR994, Spero's oral carbapenem product candidate, will include data on its *in vitro* activity against clinical isolates from complicated urinary tract infections (cUTI), the first indication that Spero is pursuing for its lead asset and the indication in which SPR994 is being studied in an ongoing pivotal Phase 3 clinical trial. Presentations will also include pharmacokinetic, safety and tolerability data from the completed Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial of SPR994 that provided support for the dose selection for the Phase 3 clinical trial.

Data to be presented on SPR720, Spero's novel oral candidate being developed for the treatment of non-tuberculous mycobacterial (NTM) infections, will highlight its potent *in vitro* activity against various species of non-tuberculosis mycobacterium (NTM), and *in vivo* in combination regimens against *Mycobacterium tuberculosis* infection. Presentations will also include data from a GLP 28-day toxicology study of SPR720 in non-human primates.

Data to be presented on SPR206, Spero's IV-administered clinical candidate from its Potentiator Platform for MDR Gram-negative infections in the hospital setting, will characterize the profiling and optimization that led to the discovery of SPR206, mechanism of action and *in vitro* and *in vivo* data that highlight its differentiation from first generation polymyxins.

"The totality of the data to be presented at ASM Microbe speak to the robust pipeline we have built at Spero to address the unmet needs in infection and rare disease," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "The SPR994 pivotal Phase 3 trial continues to enroll cUTI patients and we look forward to providing Phase 1 data for SPR720 and SPR206 in the second half of 2019."

Presentations pertaining to SPR994, Spero's oral carbapenem antibiotic product candidate currently in Phase 3 development are below.

- **Oral Presentation - Tebipenem: Oral Carbapenem for the Treatment of Complicated Urinary Tract Infections – Pipeline Drugs to Treat Gram-negative Infections**
  Symposium S339, Sunday June 23, 2019, 3:00 PM - 3:30 PM, 306/307/308 South, Presenter: Akash Jain
- **Tebipenem is an Orally Available Carbapenem with Potent Activity against Biothreat Pathogens**
  Poster 776, Saturday June 22, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Sanae Lembirik
- **Monitoring the *In Vitro* Activity of Tebipenem, an Orally Available Carbapenem Agent, against a Current Collection of Surveillance *Enterobacteriaceae* Clinical Isolates (2018)**
  Poster 777, Saturday June 22, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Rodrigo E. Mendes
- **Evaluation of Tebipenem Activity Tested against a Collection of Isogenic *Escherichia coli* Strains Producing Various Clinically Relevant β-lactamases**
  Poster 778, Saturday June 22, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: L. M. Deshpande
- **Single-and Multiple-Ascending Dose (SAD/MAD) Study Demonstrates the Human Pharmacokinetics (PK) and Tolerability of SPR994 (Tebipenem Pivoxil hydrobromide), an Oral Carbapenem (CP), at the Predicted Therapeutic Dose**
  Poster 779, Saturday June 22, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Paul Eckburg
- **The burden of resistance among urinary tract isolates of *Escherichia coli* in the United States in 2017**
  Poster 602, Sunday June 23, 2019, 11:00 AM - 1:00 PM, Exhibit and Poster Hall, Presenter: Ian Critchley

Presentations pertaining to SPR720, Spero's novel investigational oral antibacterial agent that targets enzymes essential for bacterial DNA replication, are below. SPR720 was acquired from Vertex and is currently in a Phase 1 clinical trial in healthy subjects. SPR719 is the microbiologically active form of the oral prodrug SPR720.

- **Oral Presentation - SPR720: Novel Oral Mycobacterial Therapy – Pharma Pipeline Update**

S107, Friday June 21, 2019, 2:41 PM – 2:52 PM, AAR Track Hub (Booth 5053), Exhibit and Poster Hall, Presenter: Suzanne Stokes

- **Oral Presentation - *In Vitro* Activity of SPR719 against Non-Tuberculosis Mycobacterium Strains of *Mycobacterium ulcerans*, *Mycobacterium marinum*, and *Mycobacterium chimaera* - Pipeline Drugs to Treat Gram-positive, *C. Difficile* and Non-TB Mycobacterial Infections**
  Symposium S220, Saturday June 22, 2019, 3:30 PM - 3:45 PM, 203/204 South, Presenter: Troy Lister
- ***In Vitro* Activity of SPR719 against Non-Tuberculosis Mycobacterium Strains of *Mycobacterium ulcerans*, *Mycobacterium marinum*, and *Mycobacterium chimaera***
  Poster 750, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Troy Lister
- **Evaluating the Sterilizing Activity of SPR720 in Combination Therapy Against *Mycobacterium tuberculosis* Infection in Mice**
  Poster 749, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Carolyn Shoen
- **A GLP 28-Day Repeat Dose Toxicology Study of SPR720 in Monkeys**
  Poster LB-14, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Troy Lister

Presentations pertaining to SPR741 and SPR206, Spero's clinical candidates from its Potentiator Platform being developed to treat MDR Gram-negative infections in the hospital setting, are below.

- **Oral Presentation - Next-generation Polymyxin Analog SPR206 - New Agents Discovery Summary Session: Early New Antimicrobial Agents**
  Symposium S020, Friday June 21, 2019, 9:30 AM - 9:50 AM, 207/208 South, Presenter: Troy Lister
- **SPR741 in combination with minocycline increases antibacterial efficacy *in vitro* and *in vivo* against *XDR-Acinetobacter baumannii* in a pulmonary model of infection**
  Poster 791, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Daniel V. Zurawski
- **Bacterial Cytological Profiling of a Novel Polymyxin Analog, SPR741, that Allows Penetration of Antibiotics into Gram-Negative Bacteria**
  Poster 792, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Nicole Cotroneo
- **Optimisation of Next-Generation Polymyxins Leading to SPR206 as a Development Candidate**
  Poster 793, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Pamela Brown
- **Mechanism of Action of SPR206, a Next-Generation Polymyxin Active Against Gram-Negative Pathogens**
  Poster 794, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Dean Shinabarger
- **The Impact of Varied Test Conditions on the *In Vitro* Activity of SPR206, a Next-Generation Polymyxin B Analog, against Drug-susceptible and Multidrug-resistant Gram-negative Pathogens**
  Poster 795, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Dean Shinabarger
- **Activity of Investigational Polymyxin-B-Like Compound (SPR206) against Set of *Enterobacteriaceae* Organisms Responsible for Human Infections**
  Poster 796, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: S. J. Arends
- ***In Vitro* Bactericidal Activity of Next-Generation Polymyxin SPR206 against Susceptible and Multidrug-Resistant (MDR) *Acinetobacter baumannii, Pseudomonas aeruginosa, Escherichia coli*, and *Klebsiella pneumoniaeas* as compared to Levofloxacin and Meropenem**
  Poster 797, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Nicole Cotroneo
- ***In Vivo* Efficacy of Next-Generation Polymyxin SPR206 in an Immunocompetent Murine Ascending UTI Infection Model Caused by *Escherichia coli***
  Poster 798, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Troy Lister
- ***In Vivo* Efficacy of SPR206 in Murine Lung and Thigh Infection Models Caused by Multi-Drug Resistant Pathogens *Pseudomonas aeruginosa* and *Acinetobacter baumannii***
  Poster 799, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Troy Lister
- **A GLP 14-Day Repeat Dose Toxicology Study of SPR206 in Monkeys**

Poster 800, Friday June 21, 2019, 11:00 AM - 12:00 PM and 4:00 PM - 5:00 PM, Exhibit and Poster Hall, Presenter: Troy Lister

The complete abstracts for the presentations listed above can be accessed through the ***ASM Microbe website***.

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***.

SPR994 Research Support

These projects have 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.

Biodefense data generated with support from the Defense Threat Reduction Agency (CBCall18-CBM-01-2-0031).

SPR720 Research Support

Research reported in this publication was partially supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number R44AI131749. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

SPR206 Research Support

These projects have 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.

SPR741 Research Support

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. This work was supported by 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. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense. In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.

This work is supported by the Cooperative Agreement Number IDSEP160030 from ASPR/BARDA and by an award from Wellcome Trust, as administrated by CARB-X (subaward 4500002328). The contents 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 Wellcome Trust.

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 SPR206 and the Phase 1 clinical trial of SPR720; 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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