Spero Therapeutics Highlights SPR994 Data at the 29th European Congress of Clinical Microbiology and Infectious Diseases

April 8, 2019

Five presentations on SPR994 and cUTI resistance trends at ECCMID provide support for Phase 3 program and unmet need

CAMBRIDGE, Mass., April 08, 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 bacterial infections, announced today one oral poster presentation and four paper poster presentations on SPR994 at the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) being held April 13-16, 2019 in Amsterdam, Netherlands. Presentations will include data from Spero's Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial of SPR994, Spero's lead product candidate designed to be the first oral carbapenem antibiotic, as well as other posters supporting the SPR994 dose and comparator agent selected for the pivotal Phase 3 clinical trial, ADAPT-PO, for the treatment of complicated urinary tract infections (cUTI).

"The data to be presented at ECCMID highlight the utility of SPR994 in treating the serious unmet need of multi-drug resistant infections and provide additional supporting data for the design of the pivotal Phase 3 trial of SPR994 for the treatment of cUTI," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics.

Presentations pertaining to SPR994 at the ECCMID conference are as follows:

Mini-oral ePoster Presentation – O0305; Presenter: Paul Eckburg
Saturday, April 13, 2019, 2:45 p.m. – 3:45 p.m. CET
Single- and multiple-ascending dose study demonstrates the human pharmacokinetics and tolerability of SPR994 (tebipenem pivoxil hydrobromide), an oral carbapenem, at the predicted therapeutic dose

Poster Presentation – P1627; Presenter: Ian Critchley
Monday, April 15, 2019, 1:30 p.m. – 2:30 p.m. CET
Escherichia coli from urinary tract infections in Europe in 2017 are increasingly multidrug-resistant to oral antibiotics in an era of co-resistance to extended-spectrum beta-lactamases

Poster Presentation – P1862; Presenter: Nicole Cotroneo
Monday, April 15, 2019, 1:30 p.m. – 2:30 p.m. CET
Activity of tebipenem, an oral carbapenem, against multidrug-resistant urinary tract infection-causing pathogens with characterized resistance mechanisms collected in Europe and the United States in 2016

Poster Presentation – P1950; Presenter: Shampa Das
Monday, April 15, 2019, 1:30 p.m. – 2:30 p.m. CET
Phase III dose selection for tebipenem

Poster Presentation – P2133; Presenter: Laura McEntee
Monday, April 15, 2019, 1:30 p.m. – 2:30 p.m. CET
Pharmacodynamics of ertapenem

Complete abstracts for the presentations listed above can be accessed through the ***ECCMID website***.

SPR994 Research Support:

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About SPR994
SPR994 is Spero's novel investigational oral formulation of tebipenem, a carbapenem-class antibiotic marketed by Meiji Seika Pharma Co. Ltd. (Meiji) in Japan as Orapenem® since 2009 for pediatric infections limited to pneumonia, otitis media and sinusitis. Carbapenems are an important class of antibiotics because they have been demonstrated to be safe and effective against drug-resistant Gram-negative bacterial infections. Spero completed a Phase 1 clinical trial of SPR994 in Australia, designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study to enable dose selection for Spero's planned pivotal Phase 3 clinical trial. The FDA has accepted Spero's IND for SPR994 in cUTI and Spero expects site initiation to commence imminently to support enrollment into its pivotal Phase 3 clinical trial of SPR994 entitled ADAPT-PO [A Phase 3, Randomized, Double-blind, Double-dummy, Multicenter, Prospective Study to Assess the Efficacy, Safety and Pharmacokinetics of Orally Administered Tebipenem Pivoxil Hydrobromide (SPR994) Compared to Intravenous Ertapenem in Patients with Complicated Urinary Tract Infection (cUTI) or Acute Pyelonephritis (AP)]. SPR994 has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA. In preclinical studies, SPR994 has shown potent antibiotic activity against Gram-negative bacteria, including E. coli-producing extended-spectrum beta-lactamases (ESBLs) and ESBL-producing Klebsiella pneumoniae, similar to IV-administered ertapenem. Approximately 1,200 subjects have been dosed with tebipenem in

clinical and pharmacologic studies conducted by Meiji during its development of tebipenem in Japan. In addition, available post-marketing outcomes data report of tebipenem in 3,540 pediatric patients with pneumonia, otitis media or sinusitis, and these data are consistent with the safety profile of tebipenem as observed in the clinical trial conducted by Meiji.

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 planned 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, including the anticipated timing of the opening of sites to support enrollment into the planned pivotal Phase 3 clinical trial of SPR994; 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 planned 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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