Spero Therapeutics Receives FDA Fast Track Designation for SPR994 for the treatment of Complicated Urinary Tract infections and Acute Pyelonephritis

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CAMBRIDGE, Mass., March 29, 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 the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for SPR994, Spero's lead product candidate designed to be the first oral carbapenem antibiotic, for the treatment of complicated urinary tract infections (cUTI) and acute pyelonephritis.

"We are pleased that the FDA has granted fast track status for SPR994," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "Receiving Fast Track status highlights the serious unmet need of multi-drug resistant infections and we look forward to working closely with the FDA as we conduct our planned pivotal Phase 3 clinical trial through the possible NDA submission with the goal of providing patients with the option of oral SPR994 as soon as possible, if approved."

The FDA's Fast Track program facilitates development and expedites review of drugs intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. Fast Track Designation provides opportunities for more frequent interaction with the FDA review team to expedite development and review as well as provides an opportunity for rolling review of the NDA upon request and agreement with the FDA. In addition, the Fast Track program allows for eligibility for Accelerated Approval and Priority Review, if relevant criteria are met. In addition to Fast Track Designation, SPR994 was previously granted QIDP designation. SPR994 will receive FDA priority review of the first marketing application or efficacy supplement for SPR994 and the indication for which QIDP designation was granted.

Spero's planned pivotal Phase 3 clinical trial of SPR994, ADAPT-PO, is designed as a double-blind, double-dummy trial to compare oral SPR994 with an existing standard of care intravenous (IV) antibiotic, ertapenem, in approximately 1,200 patients randomized 1:1 in each arm. The primary endpoint of the pivotal trial will be the combined clinical and microbiological response at the test of cure with a 10% non-inferiority margin versus IV ertapenem. Spero has begun start-up activities for the ADAPT-PO clinical trial and anticipates opening trial sites around the end of March 2019 to support study enrollment. The trial will incorporate a lead-in cohort of 70 patients with an intensive pharmacokinetics assessment to confirm the dose and exposure in the cUTI patient population. Spero expects to receive pharmacokinetic data from the lead-in cohort in the second half of 2019.

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/AP and Spero intends to open trial sites to support enrollment into the 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)] for the treatment of cUTI around the end of March 2019 in support of a new drug application (NDA). 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.

SPR994 Research Support:

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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 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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