Spero Therapeutics Announces FDA Acceptance of IND Application for SPR994

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CAMBRIDGE, Mass., Feb. 04, 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, today announced the acceptance by the U.S. Food and Drug Administration (FDA) of its Investigational New Drug (IND) application for SPR994, Spero's lead product candidate designed to be the first oral carbapenem antibiotic, for the treatment of complicated urinary tract infections (cUTI). This IND acceptance will enable Spero to initiate U.S. enrollment in its planned global, single pivotal Phase 3 clinical trial of SPR994 in cUTI.

"With the FDA's acceptance of our IND application for SPR994, we are excited to continue our Phase 3 initiation efforts, including opening clinical trial sites for enrollment in the U.S.," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "We look forward to enrolling patients in our single pivotal Phase 3 clinical trial with the hope, following approval, of providing patients with the option for an oral carbapenem to address the serious unmet need of multi-drug resistant infections."

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. The trial will incorporate a lead-in cohort of 70 patients with intensive pharmacokinetics assessment to confirm the dose and exposure in the cUTI patient population. Spero anticipates receiving interim pharmacokinetic data from the trial's lead-in cohort in the second half of 2019. In addition, Spero will conduct routine ancillary clinical pharmacology studies in parallel with the ADAPT-PO clinical trial, including a renal insufficiency study, a thorough QT prolongation study and a drug-drug interaction study. Spero has begun start-up activities for the ADAPT-PO clinical trial and anticipates opening trial sites to support study enrollment in the first quarter 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 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 in the first quarter of 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 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 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 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 interim data from the Phase 3 trial's lead-in cohort; 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, including SPR994, 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, clinical outcomes and findings of ancillary supportive studies to be conducted in parallel with the planned Phase 3 trial; 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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