Spero Therapeutics Completes Patient Enrollment in Pivotal Phase 3 Clinical Trial (ADAPT-PO) of Oral Tebipenem HBr versus Intravenous Ertapenem for the Treatment of Complicated Urinary Tract Infection

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ADAPT-PO topline results expected in the third quarter of 2020

CAMBRIDGE, Mass., May 05, 2020 (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 bacterial infections and rare diseases, today announced the completion of patient enrollment in its Phase 3 clinical trial, ADAPT-PO, of tebipenem HBr for the treatment of complicated urinary tract infection (cUTI) and acute pyelonephritis (AP).

"Completing enrollment of ADAPT-PO is a significant milestone in the development of tebipenem HBr," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "Resistance to current orally available antibiotic therapies impacts millions of people in the United States each year and leads to more than two million avoidable hospitalizations for complicated urinary tract infections. The need for new oral therapies to keep patients out of the hospital has never been greater. We are committed to providing patients with cUTI or AP, who otherwise do not require hospitalization, with an alternative and allowing them to once again use an oral agent and remain at home. With enrollment now complete, we are on track to report topline data in the third quarter of 2020, consistent with our prior guidance."

ADAPT-PO enrolled over 1,370 eligible subjects in a global study designed as a double-blind, double-dummy clinical trial to compare an all-oral regimen of tebipenem HBr dosed as 600 mg TID with a standard-of-care intravenous (IV) antibiotic, ertapenem, in patients with cUTI and AP, randomized 1:1 in each arm. With enrollment complete, the final group of patients in the trial will complete their treatment course and final safety follow-up visit. Spero anticipates reporting topline results from the ADAPT-PO clinical trial in the third quarter of 2020.

About Tebipenem HBr

Tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994) is Spero's novel investigational oral formulation of tebipenem pivoxil, 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 observed to be safe and effective against drug-resistant Gram-negative bacterial infections. The ADAPT-PO Phase 3 clinical trial of tebipenem HBr for the treatment of complicated urinary tract infection and acute pyelonephritis has completed patient enrollment and topline results are expected in the third quarter of 2020. Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of cUTI.

Tebipenem HBr Research Support

This project has 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.

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, tebipenem HBr (tebipenem pivoxil hydrobromide; formerly 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 an IV-administered next generation polymyxin product candidate, SPR206, being developed 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 tebipenem HBr and ancillary supportive studies to be conducted in parallel with the Phase 3 trial will support the approval of tebipenem HBr; the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including the timing of Spero's regulatory meeting with the FDA regarding SPR720, the timing of Spero's IND submission with the FDA regarding SPR720, the commencement of Spero's planned Phase 2a clinical trial of SPR720 and the commencement of Spero's planned Phase 1 bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment; management's assessment of the results of such preclinical studies and clinical trials; the timing of clinical data, including the availability of topline data from the Phase 3 clinical trial of tebipenem HBr, final data from the Phase 1 clinical trial of SPR720 and final data from the Phase 1 clinical trial of SPR206; and Spero's cash forecast and anticipated expenses, anticipated payments under Spero's agreement with Everest Medicines, potential payments under Spero's agreement with BARDA, 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 tebipenem HBr; 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 will satisfy all of the pre-conditions to receipt of the development milestone payment under its agreement with Everest Medicines; whether BARDA elects to exercise its second option under Spero’s agreement with BARDA; whether Spero’s cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether Spero’s clinical and preclinical development programs are delayed or disrupted due to the coronavirus; and other factors discussed in the “Risk Factors” set forth in filings that Spero periodically makes with the U.S. Securities and 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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