Spero Therapeutics Announces FDA Acceptance and Priority Review of New Drug Application for Tebipenem HBr for the Treatment of Complicated Urinary Tract Infections including Pyelonephritis

January 3, 2022

The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2022

CAMBRIDGE, Mass., Jan. 03, 2022 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review designation and confirmed the acceptance for substantive review of the New Drug Application (NDA) seeking approval for tebipenem HBr oral tablets for treatment in adult patients with complicated urinary tract infections (cUTI), including acute pyelonephritis, caused by susceptible microorganisms. Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP), Fast Track, and Priority Review designations for these cUTI indications. The Agency is planning to hold an Advisory Committee meeting to discuss this application and has also set a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2022.

"The FDA acceptance of this NDA is a major step forward in our mission to provide patients the first and only oral carbapenem antibiotic to treat cUTI. If approved, tebipenem HBr may provide patients an oral treatment option, allowing them to potentially either recover at home from their infections or leave the hospital sooner," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. "This is an important accomplishment and an exciting moment for all of us at Spero, as we execute our plan on becoming a commercial organization. We are committed to working closely with the FDA throughout the NDA review process and look forward to tebipenem HBr's anticipated launch in the second half of 2022."

The NDA submission includes previously communicated positive data from the Phase 3 ADAPT-PO trial. These data showed that ADAPT-PO met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP).

David Melnick, M.D., Chief Medical Officer of Spero, added, "ADAPT-PO was rigorously designed both to support this NDA and to provide physicians with the confidence needed to prescribe oral tebipenem HBr to appropriate patients in place of IV therapy, if approved. We believe the positive results from the trial have allowed us to accomplish this first goal and indicate that use of tebipenem HBr may ultimately improve patient care and reduce healthcare resource utilization in cUTI."

About Spero Therapeutics

Spero Therapeutics, Inc. is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug-resistant (MDR) bacterial infections and rare diseases.

Spero's lead product candidate, tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994), is being developed as the first oral carbapenem antibiotic for use in cUTI, including pyelonephritis. Tebipenem HBr is an investigational drug in the United States and is currently not approved for the treatment of complicated urinary tract infection, including pyelonephritis.

Spero is also developing SPR720 as a novel oral therapy product candidate for the treatment of a rare, orphan pulmonary disease caused by non-tuberculous mycobacterial infections.

Spero also has an IV-administered next generation polymyxin product candidate, SPR206, developed from its potentiator platform, which is 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 the potential approval of tebipenem HBr by the FDA; the timing of launch of tebipenem HBr; the potential number of patients who could be treated by tebipenem HBr and market demand for tebipenem HBr generally; the effectiveness of tebipenem HBr and its potential impact on healthcare resource utilizations; the anticipated shift from IV to oral administration, and the length of time for which Spero's cash resources are expected to be sufficient. 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 any delays in review of the NDA submission by the FDA for any reason or that the PDUFA date for the NDA review may be revised; including the COVID-19 pandemic; the timing and content of advice given and decisions made by regulators, including the FDA; Spero's need for additional funding; the lengthy, expensive, and uncertain process of clinical drug development; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; Spero's reliance on third parties to manufacture, develop, and commercialize its product candidates, if approved; the ability to develop and commercialize Spero's product candidates, if approved; the potential impact of the COVID-19 pandemic; Spero's ability to retain key personnel and to manage its growth; 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 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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