Spero Therapeutics Announces Issuance of Allowance for a U.S. Patent Covering Lead Candidate Tebipenem HBr

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CAMBRIDGE, Mass., Jan. 21, 2021 (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 that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 10,889,587, which is directed to a crystalline formulation of tebipenem HBr, Spero's oral carbapenem in development for the treatment of complicated urinary tract infection (cUTI) and acute pyelonephritis (AP). In September 2020, Spero announced positive top-line results from its Phase 3 ADAPT-PO clinical trial of tebipenem HBr in cUTI and AP.

The U.S. Patent No. 10,889,587 covers a crystalline form and pharmaceutical compositions of tebipenem HBr, including the methods of manufacturing and methods of use. The patent expires in February 2038.

"This patent issuance by the USPTO is an important milestone in protecting the commercial potential of tebipenem HBr and is a sign of Spero's innovation while developing the drug as the first oral carbapenem, if approved," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "We remain focused on advancing oral tebipenem HBr towards a potential approval and look forward to submitting the New Drug Application for tebipenem HBr to the FDA in the second half of 2021."

Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP) status by the U.S. Food and Drug Administration (FDA), which provides for an additional five-year extension of Hatch-Waxman Act exclusivity. Tebipenem HBr has also been granted fast track status by the FDA.

About Tebipenem HBr
Tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994) is Spero's novel investigational oral formulation of tebipenem pivoxil, a carbapenem antibiotic of the β-lactam class marketed by Meiji Seika Pharma Co. Ltd. (Meiji) in Japan as Orapenem® since 2009 for pediatric infections limited to pneumonia, otitis media and sinusitis. Orapenem® is not approved in the U.S. Carbapenems are an important subclass of antibiotics because they have been observed to be safe and effective in the treatment of drug-resistant Gram-negative bacterial infections. Tebipenem HBr is being developed for the treatment of cUTI and AP. In September 2020, Spero announced positive top-line results from its Phase 3 ADAPT-PO clinical trial of tebipenem HBr in cUTI and AP. Spero expects to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) for tebipenem HBr in the second half of 2021. If approved, tebipenem HBr would be the first oral carbapenem to receive marketing approval in the United States.

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 complicated urinary tract infections (cUTI) and acute pyelonephritis (AP).

Spero is also advancing SPR720, its novel oral therapy product candidate being developed for the treatment of rare, orphan pulmonary disease caused by non-tuberculous mycobacterial (NTM) infections.

Spero also has an IV-administered next generation polymyxin product candidate, SPR206, developed from its potentiator platform that 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 initiation, timing and submission to the FDA of a NDA for tebipenem HBr, the potential approval of tebipenem HBr by the FDA and

commercialization of tebipenem HBr and the potential therapeutic and other benefits of Spero's product candidates. 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 Spero's ability to timely complete related Phase 1 trials for its planned NDA submission for tebipenem HBr, taking into account the possible effects of the COVID-19 pandemic; 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; Spero's ability to maintain and enforce its intellectual property; 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.

Spero Investor and Media Contact:
Sharon Klahre
Vice President, Investor Relations
857-242-1547
IR@sperotherapeutics.com

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