Spero Therapeutics Announces Closing of Exclusive License Agreement with GSK for Tebipenem HBr

Pursuant to the agreement, Spero will be receiving a $66 million upfront payment, received a $9 million direct equity investment in shares of Spero common stock, and is eligible for potential future milestone payments and tiered royalties

CAMBRIDGE, Mass., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO) (Spero), a multi-asset clinical-stage biopharmaceutical company, focused on identifying, developing and commercializing treatments in high unmet need areas involving rare diseases and multi-drug resistant (MDR) bacterial infections, today announced the closing of its previously announced exclusive license agreement with GlaxoSmithKline Intellectual Property (No. 3) Limited (LSE/NYSE: GSK) (GSK) for tebipenem HBr, an investigational drug being developed as the potentially first oral carbapenem antibiotic for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by certain bacteria.

Pursuant to the license agreement, Spero will be receiving a $66 million upfront payment from GSK and is eligible to receive up to $525 million in development, sales, and commercial milestones payments, as well as low-single digit to low-double digit tiered royalties on net product sales. In exchange, GSK has been granted an exclusive license to develop and commercialize tebipenem pivoxil and tebipenem pivoxil HBr in all territories, except Japan, and certain other Asian countries, territories which will be retained by Spero partner, Meiji Seika. In connection with closing, pursuant to the license agreement and a previously announced stock purchase agreement between the parties, an affiliate of GSK has purchased 7,450,000 shares of Spero's common stock at a purchase price of $1.20805 per share, resulting in gross proceeds to Spero of approximately $9 million.

Under the terms of the license agreement, Spero is responsible for the execution and costs of a follow-up Phase 3 clinical trial of tebipenem HBr. GSK is responsible for the execution and costs of additional development, including Phase 3 regulatory filing and commercialization activities for tebipenem HBr outside of the Meiji Seika territory.

About Spero Therapeutics

Spero Therapeutics, headquartered in Cambridge, Massachusetts, is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing novel treatments for serious bacterial infections, including MDR bacterial infections and rare diseases.

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

- Tebipenem HBr is an investigational oral carbapenem candidate antimicrobial in development for the treatment of cUTI, including pyelonephritis, including infections caused by MDR pathogens in adult patients who have limited oral treatment options; tebipenem HBr is not FDA-approved.

- Spero Therapeutics is developing SPR206 as an investigational intravenous-administered next-generation polymyxin product candidate developed from its potentiator platform, which is in development 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 regulatory path forward for tebipenem HBr and potential FDA approval; the potential commercialization of tebipenem HBr and its future value; the potential receipt of milestone payments and royalties on future sales under the license agreement; and the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs. 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 tebipenem HBr will advance through the 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 FDA or equivalent foreign regulatory agencies; whether the FDA will ultimately approve tebipenem HBr and, if so, the timing of any such approval; whether the FDA will require any additional clinical data or place labeling restrictions on the use of tebipenem HBr that would delay approval and/or reduce the commercial prospects of tebipenem HBr; whether a successful commercial launch can be achieved and market acceptance of tebipenem HBr can be established; 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 commercialize Spero's product candidates, if approved; Spero's ability to retain key personnel; 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.

Investor Relations Contact:
Ted Jenkins
Vice President, Investor Relations and Strategic Finance
IR@sperotherapeutics.com
(617) 798-4039

Media Inquiries:
Lora Grassilli, Health Media Relations
Zeno Group
lora.grassilli@zenogroup.com
646-932-3735

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