Spero Announces NDA Resubmission of Tebipenem HBr by GSK to the FDA for the Treatment of Complicated Urinary Tract Infections, Including Pyelonephritis

CAMBRIDGE, Mass., Dec. 19, 2025 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), a clinical-stage biopharmaceutical company focused on identifying and developing novel treatments for rare diseases and multi-drug resistant (MDR) bacterial infections, today announced that its development partner, GSK, filed a New Drug Application (NDA) resubmission to the U.S. Food and Drug Administration (FDA) for tebipenem HBr, an investigational oral carbapenem antibiotic being developed for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis. The NDA submission triggers a $25 million milestone payment to Spero, expected to be received in Q1 2026.

The NDA resubmission is supported by results from the successful Phase 3 PIVOT-PO trial (NCT number - NCT06059846). The trial was stopped early for efficacy in May, 2025 following a planned interim analysis. Trial results were presented as a late breaker at the IDWeek conference in October 2025.

Spero has granted GSK an exclusive license to commercialize tebipenem HBr in all territories except for certain Asian territories, where Meiji retains development and commercialization rights.

Tebipenem HBr Research Support

Select tebipenem HBr studies have been funded in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; and Biomedical Advanced Research and Development Authority, under contract number HHSO100201800015C.

About Spero Therapeutics

Spero Therapeutics, headquartered in Cambridge, Massachusetts, is a clinical-stage biopharmaceutical company focused on identifying and developing novel treatments for rare diseases and MDR bacterial infections with high unmet need. For more information, visit www.sperotherapeutics.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the timing of a $25 million milestone payment expected to be received by Spero in Q1 2026. In some cases, forward-looking statements may be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intent," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue," the negative of these terms or other similar expressions; however, the absence of these words does not mean that statement is not forward looking . Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of important risks, uncertainties and other factors that may cause actual results to differ materially from those indicated by such forward looking statements, including whether the results of any of Spero's clinical 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, taking into account the effects of possible regulatory delays; 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; Spero's reliance on third parties to manufacture, develop, and commercialize its product candidates, if approved; Spero's reliance on GSK pursuant to the exclusive GSK License Agreement to develop tebipenem HBr and GSK's right thereunder to determine, in its sole discretion, whether to further develop tebipenem HBr; Spero's need for additional funding; Spero's ability to

retain key personnel; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods anticipated; and other factors discussed in the "Risk Factors" set forth in filings that Spero periodically makes with the Securities Exchange Commission. The forward-looking statements included in this press release represent Spero's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Spero explicitly disclaims any obligation to update any forward-looking statements.

Investor Relations Contact:
Shai Biran, PhD
Spero Therapeutics
IR@Sperotherapeutics.com

Media Inquiries:
media@sperotherapeutics.com

12/19/2025 8:00:00 AM