Pfizer Logo

Spero Therapeutics Announces $40 Million Equity Investment from Pfizer Inc. and Licensing Agreement for SPR206

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Spero grants Pfizer rights to develop, manufacture, and commercialize SPR206 in ex-U.S. and ex-Asia territories in exchange for potential development and commercial milestone payments and royalties.

CAMBRIDGE, Mass., June 30, 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 Pfizer Inc. (NYSE: PFE) has made a $40 million equity investment in Spero as part of the Pfizer Breakthrough Growth Initiative, a program focused on funding innovative science to meet patient needs. The two parties have also entered into a licensing agreement for SPR206, Spero's intravenously (IV)-administered next-generation polymyxin product candidate being developed to treat serious multi-drug resistant (MDR) Gram-negative infections in the hospital setting.

Spero intends to use the proceeds from the equity investment to prepare for the potential approval and launch of tebipenem HBr, as well as to support the continued clinical development of SPR720 and SPR206. Pfizer purchased 2,362,348 shares of Spero's common stock at a price of $16.93 per share, pursuant to a securities purchase agreement between the parties. Pursuant to a licensing agreement between the parties, Spero has granted Pfizer the rights to develop, manufacture, and commercialize SPR206 in ex-U.S. and ex-Asia territories. In exchange for these rights, Spero is eligible to receive up to $80 million in development and sales milestones, and high single digit to low double-digit royalties on net sales of SPR206 in these territories.

"We are thrilled to reach these agreements with Pfizer, which serve as further external validation for our pipeline and corporate strategy," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "The newly announced equity investment will provide us with valuable capital and financial flexibility as we advance our SPR206 and SPR720 clinical programs and work towards an NDA filing for tebipenem HBr. We also expect the licensing agreement for SPR206 will be key to expanding global access to this important candidate, as Pfizer is uniquely positioned to successfully commercialize this asset in the Pfizer territories (ex-U.S. and ex-Asia). We look forward to collaborating with Pfizer on the continued advancement of this asset."

"There is a pressing unmet need for effective medicines to address antimicrobial resistant infections, and Pfizer is dedicated to meeting this global health challenge through scientific research, collaboration, and strategic investment," added Annaliesa Anderson, Chief Scientific Officer of Bacterial Vaccines and Hospital, Pfizer. "Our latest agreements with Spero further establish Pfizer as a leader in this area, building on our $100 million commitment to the Antimicrobial Resistance Action Fund and recent acquisitions of both Amplyx Pharmaceuticals and Arixa Pharmaceuticals. In addition, we believe the strong characteristics of SPR206

position this potential medicine to complement our pipeline and portfolio of antimicrobial products, and we look forward to its continued clinical development."

Based on its current projections, Spero believes that the net proceeds from the newly announced $40 million equity investment will extend its cash runway into the second half of 2022.

About SPR206

SPR206 is an IV-administered next generation polymyxin product candidate designed to act directly on Gram-negative bacterial infections through the molecule's interactions with the bacterial outer membrane. SPR206 has demonstrated potent broadspectrum activity against Gram-negative bacteria, including organisms identified by the Centers for Disease Control and Prevention and the World Health Organization as urgent and serious threats to human health. Spero has completed a firstin-human Phase 1 assessment of SPR206 in which the product candidate was generally well tolerated and demonstrated no evidence of nephrotoxicity at anticipated therapeutic doses. Spero recently announced the initiation of a Phase 1 bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment and a Phase 1 renal impairment clinical trial of SPR206 in the second quarter of 2021. For more information on these trials and their design, see **ClinicalTrials.gov** identifiers **NCT04868292** (BAL trial) and **NCT04865393** (renal impairment trial). SPR206 has been granted Qualified Infectious Disease Product (QIDP) designation by the United States Food and Drug Administration for the treatment of complicated urinary tract infections and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).

About Spero

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). 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 is also developing SPR720 as a novel oral therapy product candidate 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, 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 future development and commercialization of SPR206 and the potential receipt of milestone payments, as well as royalties on potential future sales of SPR206; the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs; management's assessment of the results of such preclinical studies and clinical trials; and Spero's cash forecast and anticipated expenses, 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 Spero's

ability to timely complete the NDA submission to the FDA for tebipenem HBr; 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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