Spero Therapeutics Announces Lifting of FDA Clinical Trial Hold on SPR720

January 4, 2022

CAMBRIDGE, Mass., Jan. 04, 2022 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Phase 2 trial of SPR720, Spero's investigational oral product candidate being developed for nontuberculous mycobacterial (NTM) disease.

"We are very pleased with the FDA's decision and eager to bring SPR720 back into the clinic," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. "Extensive analyses, together with prior clinical and non-clinical data, support our belief that SPR720 has the potential to offer a new, well-tolerated, oral treatment option for patients suffering from NTM-PD. We would like to thank the FDA for its guidance and look forward to SPR720's continued clinical development."

David Melnick, M.D., Chief Medical Officer of Spero, added, "Current treatments for nontuberculous mycobacteria are often ineffective and involve lengthy and complex combination regimens that include injectable and/or inhalable antibiotics. Through SPR720's clinical development and potential future marketing approval, we aim to provide appropriate NTM-PD patients with a once-daily oral therapy, in conjunction with existing therapeutic regimens. This has the potential to address a pressing unmet need for an indication that represents a global health concern with increasing incidence."

The SPR720 program was placed on a clinical hold by the FDA following a review of data from a non-human primate (NHP) toxicology study in which mortalities with inconclusive causality to treatment were observed. The FDA's decision to lift the hold follows Spero's submission of a comprehensive study report with detailed analyses from the NHP toxicology study. Spero plans on engaging with the FDA in Q1 of 2022 to discuss the re-initiation of the SPR720 Phase 2 trial for NTM-pulmonary disease (NTM-PD) patients, with an expected study start date commencing in the second half of 2022.

About SPR720
SPR720 represents a novel class of antibacterial agents that target enzymes essential for bacterial DNA replication. It is currently under development as an oral therapy for the treatment of non-tuberculous mycobacterial (NTM) disease, a rare orphan disease. Non-tuberculous mycobacteria are ubiquitous environmental pathogens that can cause progressive lung damage and respiratory failure, particularly in patients with compromised immune systems or underlying pulmonary disorders. Although rare, the incidence of pulmonary NTM disease is increasing worldwide. Treatment of pulmonary NTM disease requires prolonged therapy (continuing for approximately 12 to 24 months) with a combination of mostly unapproved drugs and is frequently complicated by tolerability and/or toxicity issues. Additionally, there are currently no oral antibiotics specifically approved for use to treat pulmonary NTM disease. Thus, if approved, SPR720 has the potential to address an important unmet need as the first oral antibiotic approved for the treatment of this debilitating disease.

SPR720 has been granted Qualified Infectious Disease Product (QIDP) designation by the FDA for the treatment of lung infections caused by non-tuberculous mycobacteria and lung infections caused by *Mycobacterium tuberculosis* (Mtb). It has also received an orphan drug designation from the FDA for the treatment of NTM infection. The FDA has also designated the investigation of SPR720 capsules for treatment of adult patients with NTM-PD a Fast Track development program.

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 acute pyelonephritis. On January 3, 2022, Spero announced that FDA has accepted its NDA for tebipenem HBr tablets.

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 plans for Spero's ongoing development of SPR720 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 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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