Spero Therapeutics Announces Publication of SPR720 Phase 1 Lung Exposure Data in Antimicrobial Agents and Chemotherapy

Phase 1 study showed significant lung uptake and enhanced epithelial lining fluid (ELF) and alveolar macrophage (AM) concentrations of SPR719 (active moiety of SPR720)

CAMBRIDGE, Mass., Oct. 02, 2024 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), a multi-asset clinical-stage biopharmaceutical company, focused on identifying and developing novel treatments for rare diseases and multi-drug resistant (MDR) bacterial infections, today announced the publication of data from its Phase 1 clinical trial, which assessed the intrapulmonary pharmacokinetics (PK) of SPR719. The full manuscript, titled "*Intrapulmonary pharmacokinetics of SPR719 following oral administration of SPR720 to healthy volunteers*" was published ahead of print in *Antimicrobial Agents and Chemotherapy*. A copy of the paper can be accessed here.

SPR720 is an oral, chemically stable phosphate ester prodrug that is converted rapidly *in vivo* to SPR719, the active moiety. SPR719 targets the ATPase site of DNA gyrase B in mycobacteria, a mechanism that is distinct from that of other antibiotics in use for Non Tuberculous Mycobacterial- Pulmonary Disease (NTM-PD).

"The Phase 1 study is part of a series of studies Spero is conducting in order to explore the potential of SPR720 as a treatment for NTM-PD," said Sath Shukla, President and CEO of Spero. "Effective oral therapy for NTM lung disease requires adequate uptake into the pulmonary epithelial lining fluid and alveolar macrophages, where mycobacteria reside and proliferate. The results of this Phase 1 study suggest that SPR719 (the active moiety of SPR720) had significant lung uptake and enhanced concentrations in these compartments."

Background

- This study was designed to determine safety and intrapulmonary PK of SPR719, including concentrations in pulmonary epithelial lining fluid (ELF) and alveolar macrophages (AM) in the lung to provide essential dose selection information for the development of SPR720 for the treatment of NTM-PD.

Study Highlights

- This was a Phase 1, single-center, open-label study in healthy adult male and female subjects. Subjects received a 1,000 mg dose of SPR720 administered once daily for 7 days. Blood samples were collected for plasma pharmacokinetic assessments. Each subject also underwent a standardized bronchoscopy and Bronchoalveolar Lavage (BAL) on Day 7. The safety population comprised 33 healthy adult subjects, and the PK population included 30 subjects.
- There were no meaningful concentrations of SPR720 detected in the plasma. Mean plasma concentrations of SPR719 reached a peak at approximately 4 hours and then declined over the remaining 24 hours.
- The concentrations of SPR719 in ELF and AM were found to be greater than total plasma concentrations.
- These results suggested that SPR719 had significant lung uptake and enhanced ELF and AM concentrations because unbound plasma concentrations predominantly influence penetration into lung compartments.
- No unexpected safety findings were observed.
- Results from this study of the intrapulmonary disposition of SPR719 support further investigation of SPR720 as a potential oral agent for treatment of NTM-PD.

Upcoming Presentation at IDWeek

Data from *in vitro* evaluation of the development of microbial resistance against SPR719 have been accepted for presentation at IDWeek, taking place October 16 to 19, 2024 in Los Angeles, CA.

About Nontuberculous Mycobacterium Pulmonary Disease (NTM-PD)

NTM-PD, also known as NTM lung disease, is caused by bacteria naturally found in soil, dust, and water. These bacteria belong to the Mycobacterium family, excluding those that cause tuberculosis and leprosy. The most common cause of NTM infections is the *Mycobacterium avium* complex (MAC). NTM is a growing global health concern with significant unmet medical need. Although rare, the incidence of NTM pulmonary disease is increasing worldwide. It is estimated that approximately 130,000 patients suffer from NTM in the U.S. and Europe, a figure that is growing at a rate of 8% annually. Patients with NTM lung disease experience progressive symptoms, lung damage, and reduced quality of life due to chronic symptoms and impaired lung function. NTM infections can occur after surgery, trauma, injections, or exposure to contaminated water. Prevention involves effective water management programs in healthcare facilities, and treatment typically requires consultation with infectious disease or pulmonary specialists. Patients currently have limited treatment options for NTM lung disease.

About Spero Therapeutics

Spero Therapeutics, headquartered in Cambridge, Massachusetts, is a multi-asset 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, progress and results of Spero's preclinical studies, clinical trials and research and development programs; and the potential benefits of any of Spero's current or future product candidates in treating patients. 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. 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 tebipenem HBr, SPR720 and SPR206 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; Spero's need for additional funding; the ability to commercialize Spero's product candidates, if approved; Spero's ability to retain key personnel; Spero's leadership transitions; 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 SEC. 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

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