Spero Therapeutics Announces Collaboration with Bill & Melinda Gates Medical Research Institute to Develop SPR720 for Tuberculosis

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CAMBRIDGE, Mass., June 20, 2019 (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 (MDR) bacterial infections and rare diseases, today announced that it entered into a collaboration with the Bill & Melinda Gates Medical Research Institute (Gates MRI) to develop SPR720 for the treatment of lung infections caused by *Mycobacterium tuberculosis* (Mtb), an indication that is designated as a critical concern by the World Health Organization (WHO).

SPR720 is an orally administered antimicrobial agent currently being developed by Spero Therapeutics for the treatment of rare non-tuberculous mycobacterial (NTM) infections. Spero has granted Gates MRI an exclusive license to develop, manufacture and commercialize SPR720 for the treatment of tuberculosis (TB) in low- and middle- income countries (LMIC). Gates MRI will conduct and fund preclinical and clinical studies for the development of SPR720 against TB, and also fund certain collaborative activities in furtherance of Gates MRI's charitable purposes. SPR720 was discovered by Vertex Pharmaceuticals and was acquired by Spero Therapeutics in 2016. Vertex and Spero have reached an agreement to enable the collaboration between Spero and the Bill & Melinda Gates Medical Research Institute for the further development of this compound in low- and middle-income countries.

"We are excited about the prospects of SPR720 for treatment of NTM, and also see an important unmet need in the treatment of TB around the world. We look forward to working with Gates MRI to advance the development of SPR720 to help address the current public health crisis in TB within LMIC," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "Spero will benefit from the significant development and industry experience that the Gates MRI team can offer as well as synergies between the TB and NTM development paths as SPR720 progresses through clinical trials."

"Our translational medicine focus is on advancing novel product candidates from the lab to human studies against diseases that disproportionately affect the poor," remarked Bill & Melinda Gates Medical Research Institute Chief Executive Officer Penny Heaton, MD. "We are very pleased to work with Spero on SPR720, a potential new tool to meaningfully address tuberculosis, the leading causing of death from infectious disease in the world."

SPR720 is currently being evaluated in a double-blind, placebo-controlled Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of SPR720 in healthy volunteers. Spero expects to report top-line data from the Phase 1 clinical trial in the second half of 2019. Preclinical *in vitro* and *in vivo* studies have demonstrated the potency of SPR720 against clinically important mycobacteria, including NTM species *Mycobacterium avium* complex and *Mycobacterium abscessus,* as well as *Mycobacterium tuberculosis*. The collective data to date suggest that SPR720 has an acceptable safety profile, encouraging target pathogen efficacy, drug distribution to key sites of infection, such as the lung, and a wide therapeutic margin.

About SPR720

SPR720 represents a novel class of antibacterial agents that target enzymes essential for bacterial DNA replication. SPR720 was acquired from Vertex and is currently under development as an oral therapy for the treatment of non-tuberculous mycobacterial (NTM) infections, a rare orphan disease. NTM 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 infections is increasing worldwide. Treatment of pulmonary NTM infections 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 infections. Thus, if successfully developed, SPR720 has the potential to address an important unmet need as the first oral antibiotic approved for the treatment of this debilitating disease. Under Spero's collaboration with Gates MRI, SPR720 will also be developed for the treatment of *Mycobacterium tuberculosis* (Mtb) infections. Tuberculosis is a priority pathogen as defined by the World Health Organization with it being one of the top ten causes of death worldwide, and a situation where resistance is increasing and current treatments approaches are not optimal. Spero believes that its intellectual property portfolio for SPR720 will provide protection globally, including in the United States and Europe, through 2033. SPR720 has been granted Qualified Infectious Disease Product (QIDP) designation by the U.S. Food and Drug Administration for the treatment of lung infections caused by non-tuberculous mycobacteria and lung infections caused by *Mycobacterium tuberculosis* (Mtb).

About Spero

Spero Therapeutics, Inc. is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multidrug-resistant (MDR) bacterial infections and rare diseases.

Spero's lead product candidate, SPR994, is designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.

Spero is also advancing SPR720, its novel oral therapy product candidate designed for the treatment of rare, orphan disease caused by pulmonary non-tuberculous mycobacterial (NTM) infections.

Spero also has a platform technology known as its Potentiator Platform that it believes will enable it to develop drugs that will expand the spectrum and potency of existing antibiotics, including formerly inactive antibiotics, against Gram-negative bacteria. Spero's lead product candidates generated from its Potentiator Platform are two IV-administered agents, SPR206 and SPR741, designed to treat MDR Gram-negative infections in the hospital setting.

For more information, visit ***https://sperotherapeutics.com***.

About Gates MRI

The Bill & Melinda Gates Medical Research Institute (Gates MRI) is a non-profit biotechnology development organization focused on reducing or eliminating vexing diseases in global health. The Gates MRI's mission is to develop products to prevent and/or treat tuberculosis, malaria, enteric infections and maternal, neonatal and childhood diseases, all of which are major causes of mortality and inequality in Low-Middle Income Countries (LMIC). Gates MRI takes an integrated approach to product development: multi-disciplinary teams are at the heart of the organization, populated by functional area members with deep translational medicine expertise. The institute is different than a large pharma organization with a focus on diseases that have little commercial potential but create a huge burden of morbidity and mortality in LMIC. Unlike biotechs, Gates MRI has secured long-term funding to accomplish a clear mission. Further, building on the partner network of the Bill & Melinda Gates Foundation, the organization is uniquely positioned to rally both private- and public-sector partners and help bring their vast array of expertise and resources to bear against Gates MRI's diseases of interest. Gates MRI was founded to serve the global health community by accelerating the availability of efficacious drugs, vaccines, and biologics with an acceptable safety profile for low income countries.

For more information, visit: https://www.gatesmri.org/

Forward-Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about Spero's expectation that positive results from a single pivotal Phase 3 clinical trial of SPR994 and ancillary supportive studies to be conducted in parallel with the Phase 3 trial will support the approval of SPR994; the initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs; statements regarding management's assessment of the results of such preclinical studies and clinical trials; the timing of clinical data, including the availability of pharmacokinetic data from the lead-in cohort in the Phase 3 clinical trial of SPR994 and top-line data from the Phase 1 clinical trial of SPR720 and the Phase 1 clinical trial of SPR206; Spero's ability to leverage data from Gates MRI's studies in TB, the Gates MRI's development and industry experience and synergies expected to result from the collaboration with Gates MRI in the development of SPR720 for the treatment of NTM infections; 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 whether the FDA will accept a single pivotal study for approval of SPR994; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Spero's product candidates will advance through the preclinical development and 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 U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether the anticipated benefits and potential of Spero's collaboration with the Gates MRI can be achieved; 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 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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