



Paratek, U.S. Department of Defense Enter Research Agreement to Study Omadacycline Against Biodefense Pathogens - Initiating studies to explore omadacycline activity against plague and anthrax

BOSTON, Oct. 11, 2016 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), announced today it has entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to study omadacycline against pathogenic agents causing infectious diseases of public health and biodefense importance. These studies are designed to confirm humanized dosing regimens of omadacycline in order to study the efficacy of omadacycline against biodefense pathogens, including *Yersinia pestis* (plague) and *Bacillus anthracis* (anthrax). Funding support for the trial has been made available through the Defense Threat Reduction Agency (DTRA)/Joint Science and Technology Office (JSTO) and Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD)/Joint Project Manager Medical Countermeasure Systems (JPM-MCS)/BioDefense Therapeutics (BDTX).

“Scientists at USAMRIID recognize the unique potential of omadacycline as a novel once-daily oral antimicrobial agent and we are extremely pleased to have the opportunity to work with USAMRIID on these projects,” said Evan Loh, President and Chief Medical Officer, Paratek. “Earlier research suggests the potential efficacy of omadacycline against anthrax, plague, and other diseases of public health and biodefense concern, which underscores the importance of this partnership and the potential outcomes of these studies. Considering omadacycline’s broad spectrum of activity, oral bioavailability and robust safety and tolerability profile, we believe it is an excellent candidate for study in these infections.”

“We welcome the partnership with Paratek, DTRA-JSTO and JPEO-CBD/JPM-MCS/BDTX to evaluate a new therapeutic that may provide unique advantage in the important area of biodefense,” said Colonel Bret Purcell, Ph.D., M.D. (Director of Translational Sciences and Chief, Therapeutics Division, USAMRIID). “This agreement with Paratek seeks to improve our understanding about the potential utility of omadacycline against these pathogens.”

Under the terms of the CRADA, Paratek will provide omadacycline and technical expertise to support USAMRIID’s conduct of the pre-clinical pharmacokinetic studies and efficacy studies of omadacycline against a variety of biodefense pathogens. Data generated from these studies may support further development, which could ultimately lead to the approval of omadacycline in the treatment of these important biodefense pathogens.

About Paratek

Paratek Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon its expertise in novel tetracycline chemistry. Paratek's lead product candidate, omadacycline, is the first in a new class of tetracyclines known as aminomethylcyclines, with broad-spectrum activity against Gram-positive, Gram-negative and atypical bacteria. In June 2016 Paratek announced positive efficacy data in a Phase 3 registration study in ABSSSI demonstrating the efficacy and safety of omadacycline compared to linezolid. A Phase 3 registration study for community acquired bacterial pneumonia (CABP) comparing IV-to-oral omadacycline to IV-to-oral moxifloxacin was initiated in November 2015. Enrollment continues on track to report top line data as early as the third quarter of 2017. A Phase 3 registration study in ABSSSI comparing once-daily oral-only dosing of omadacycline to twice-daily oral-only dosing of linezolid was initiated in August 2016. Top line data are expected as early as the second quarter of 2017. A Phase 1B study in uncomplicated urinary tract infections (UTI) was initiated in May 2016. Enrollment is nearly complete with top line data expected as early as the fourth quarter of 2016. Omadacycline has been granted Qualified Infectious Disease Product designation and Fast Track status by the U.S. Food and Drug Administration.

Omadacycline is a new once-daily oral and IV, well-tolerated broad spectrum antibiotic being developed for use as empiric monotherapy for patients suffering from serious community-acquired bacterial infections, such as acute bacterial skin and skin structure infections, community acquired bacterial pneumonia, urinary tract infections and other community-acquired bacterial infections, particularly when antibiotic resistance is of concern to prescribing physicians.

Paratek's second Phase 3 product candidate, sarecycline, is a well-tolerated, once-daily, oral, narrow spectrum tetracycline-derived antibiotic with potent anti-inflammatory properties for the potential treatment of acne and rosacea in the community setting. Allergan owns the U.S. rights for the development and commercialization of sarecycline. Paratek retains all ex-U.S. rights. Allergan initiated two identical Phase 3 registration studies in December 2014 for sarecycline for the treatment of moderate to severe acne vulgaris. Top line data are expected in the first half of 2017.

For more information, visit www.paratekpharma.com.

About United States Army Medical Research Institute of Infectious Diseases

USAMRIID's mission is to provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents. Research conducted at USAMRIID leads to medical solutions—vaccines, drugs, diagnostics, and information—that benefit both military personnel and civilians. The Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit www.usamriid.army.mil

[The information contained in this press release does not necessarily reflect the position or the policy of the Government and no official endorsement should be inferred.]

Forward Looking Statement

Certain statements in this press release are forward-looking statements. These forward-looking statements are based upon Paratek's current expectations and involve substantial risks and uncertainties. These risks and uncertainties include, but are not limited to: (i) unexpected results may cause the designs of the clinical trials to change, or the projected timelines of the trials to be extended, (ii) unexpected decline in the rates of patient enrollment in the clinical trials, (iii) unforeseen adverse effects experienced by patients resulting in a clinical hold, (iv) failure of patients to complete clinical trials, (v) risks related to regulatory oversight of the trials, (vi) the need for substantial additional funding to complete the development and commercialization of product candidates and (vii) risks that data to date and trends may not be predictive of future results. These and other risk factors are discussed under "Risk Factors" and elsewhere in Paratek's Annual Report on Form 10-K for the year ended December 31, 2015 and Paratek's other filings with the Securities and Exchange Commission. Paratek expressly disclaims any obligation or undertaking to update or revise any forward-looking statements contained herein.

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