Paratek Initiates Omadacycline Phase 3 Clinical Study in Community Acquired Bacterial Pneumonia (CABP)

- *Dosing initiated in second of two Phase 3 registration studies for Paratek's omadacycline*
- *Phase 3 program designed to support approval in two indications: acute bacterial skin and skin structure infections and community acquired bacterial pneumonia*

BOSTON, Nov. 9, 2015 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), today announced the dosing of the first patient in its Phase 3 clinical study of its lead drug candidate, omadacycline, for the treatment of Community Acquired Bacterial Pneumonia (CABP). This global Phase 3 study will assess the efficacy and safety of omadacycline compared with moxifloxacin in subjects with CABP.

Omadacycline is the first in a new class of tetracyclines known as aminomethylcyclines. It is being developed as a once-daily oral and IV therapy to treat serious community-acquired bacterial infections, particularly when antibiotic resistance is of concern. Omadacycline is designed with mechanisms to circumvent the two clinically important mechanisms of bacterial resistance seen with prior generations of tetracycline derivatives. Data from omadacycline microbiology and clinical studies to date show that it has the potential to offer broad-spectrum coverage against Gram-positive, Gram-negative and atypical bacteria, and it has demonstrated activity against a variety of resistant bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), penicillin-resistant *Streptococcus pneumoniae* (PRSP), macrolide-resistant *Streptococcus pneumoniae*, vancomycin-resistant *enterococcus* (VRE) and other bacteria that are resistant to older generation tetracycline antibiotics and other classes of antibiotics.

The CABP study is the second of two planned Phase 3 registration studies of omadacycline. Top-line data from this pivotal study is projected to be available in the second half of 2017. A Phase 3 trial in Acute Bacterial Skin and Skin Structure Infections (ABSSSI) began enrolling patients in June of this year with top-line data projected to be available in the second half of 2016.

"The initiation of our second Phase 3 registration study this year is a significant milestone for Paratek," said Michael Bigham, Chairman and Chief Executive Officer. "Antibiotic resistance is a significant healthcare challenge that requires novel treatment options. We believe omadacycline has the potential to become an important therapeutic option for serious community acquired bacterial infections, particularly when antibiotic resistance is a concern."

"Dosing of this first patient in our pivotal Phase 3 study for Community Acquired Bacterial Pneumonia Infections is another important step forward in Paratek's commitment to bring omadacycline to patients with serious respiratory and skin infections," said Evan Loh, M.D., President and Chief Medical Officer.

About the Phase 3 Study of Omadacycline in CABP

This Phase 3, randomized, double-blind, multi-center study will compare the safety and efficacy of intravenous (IV) to oral (PO) omadacycline therapy to moxifloxacin IV/PO for treating adults with CABP. The study is designed to enroll approximately 750 adult subjects in approximately 150 centers worldwide. The primary efficacy endpoint for FDA evaluation as established in the protocol is defined as the number of subjects with clinical success at the early clinical response assessment visit 72-120 hours after the first dose of study drug. Other efficacy outcome measurements will include investigator assessment of clinical response, overall survival and resolution or improvement of signs and symptoms at the post treatment evaluation visit (5-10 days after the last day of therapy). In addition, safety and tolerability as assessed by treatment-emergent adverse events, vital sign measurements, ECGs, and laboratory values will be measured.

About the Ongoing Phase 3 Study of Omadacycline in ABSSSI

This Phase 3, randomized, double-blind, multi-center study will compare the safety and efficacy of omadacycline IV/PO to linezolid IV/PO for treating adults with ABSSSI. The study is designed to enroll approximately 650 patients at approximately 100 centers worldwide. The primary efficacy endpoint as established in the protocol is defined as the number of subjects with clinical success at the early clinical response assessment 48-72 hours after the first dose of study drug. Other efficacy outcome measurements will include investigator assessment of clinical response, overall survival and resolution or improvement of signs and symptoms at the post treatment evaluation visit (7-14 days after the last day of therapy). In addition, safety and tolerability as assessed by treatment-emergent adverse events, vital sign measurements, ECGs, and laboratory values will be measured.

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.

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 (ABSSSI), community acquired bacterial pneumonia (CABP), complicated urinary tract infections (cUTI), 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 new once-daily oral tetracycline-derived compound for the potential treatment of acne and rosacea in the community setting. Sarecycline is designed to be a well-tolerated, once-daily, oral, narrow spectrum antibiotic with anti-inflammatory properties. Allergan owns the U.S. rights for the development and commercialization of sarecycline. Paratek retains all ex-U.S. rights. Two identical Phase 3 registration studies were initiated by Allergan in December 2014 for sarecycline for the treatment of moderate to severe acne vulgaris.

For more information, visit www.paratekpharma.com.

Forward Looking Statements

The statements in this press release regarding the projected availability of top-line data from Paratek's Phase 3 clinical trials of omadacycline, as well as expectations as to the conduct of, and measurements to be made in, the Phase 3 clinical trials of omadacycline, and Paratek's belief that omadacycline has the potential to become an important therapeutic option for serious community acquired bacterial infections, particularly when antibiotic resistance is a concern, 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; and (ii) risks related to regulatory oversight of the trials. These and other risk factors are discussed under "Risk Factors" and elsewhere in Paratek's Quarterly Report on Form 10-Q for the quarter ended June 30, 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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