Paratek Announces Completion of Enrollment in Omadacycline Phase 3 Community-Acquired Bacterial Pneumonia Study

BOSTON, Jan. 18, 2017 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon tetracycline chemistry, announced today that it has completed enrollment in the pivotal Phase 3 clinical study evaluating omadacycline for the treatment of Community Acquired Bacterial Pneumonia (CABP). This study, which is designed to assess the efficacy and safety of intravenous (IV) to once-daily oral omadacycline compared with moxifloxacin in subjects with CABP, enrolled its first patient in November 2015. The company expects to report top-line data from this study in the second quarter of 2017.

“The completion of enrollment for our second Phase 3 study represents another significant milestone for Paratek. Achieving this milestone in our CABP study positions Paratek to submit a new drug application as early as the first half of 2018,” said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer, Paratek. “We are appreciative of the efforts of the clinical investigators, grateful to the patients who participated in this study, and very pleased with the performance of the Paratek Clinical Development organization that has enabled enrollment in this study to complete ahead of projections. We look forward to sharing the topline results from this study in the coming months.”

This Phase 3, randomized, double-blind, multi-center study is designed to compare the safety and efficacy of IV to once-daily oral (PO) omadacycline therapy to moxifloxacin IV/PO for treating adults with CABP. This study planned to enroll approximately 750 adult subjects at approximately 120 centers worldwide. The study was designed to satisfy both FDA and EMA requirements. The primary efficacy endpoint for FDA evaluation as defined in the protocol is the number of subjects with clinical success at the early clinical response assessment visit 72-120 hours after the first dose of study drug. The EMA Co-Primary Endpoints are the Investigator’s Assessment of Clinical Response 5-10 days after the completion of treatment for the Intent to Treat (ITT) and Clinically Evaluable (CE) populations. Other efficacy outcome measurements include overall survival and resolution or improvement of signs and symptoms at the post treatment evaluation visit. Safety and tolerability are being assessed by treatment-emergent adverse events, vital sign measurements, electrocardiograms, and laboratory values.

About Paratek Pharmaceuticals, Inc.
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 Phase 3 product candidate, omadacycline, is the first in a new class of tetracyclines known as aminomethylcyclines, with broad-spectrum activity against Gram-positive, Gram-negative, atypical and anaerobic bacteria. In addition to the Phase 3 study in CABP, the Phase 3 program for omadacycline includes two other studies: 1) in June 2016 Paratek announced positive efficacy data in a Phase 3 registration study in acute bacterial

skin and skin structure infections (ABSSSI) demonstrating the efficacy and safety of intravenous to once-daily oral omadacycline compared to IV/PO linezolid; 2) A second Phase 3 registration study in ABSSSI comparing once-daily oral-only dosing of omadacycline to twice-daily oral-only dosing of linezolid (enrollment initiated in August 2016). Top line data from this oral-only phase 3 registration ABSSSI study are expected as early as the second quarter of 2017. A Phase 1B study in uncomplicated urinary tract infections (UTI) reported positive top-line PK proof-of-principle data in November 2016. In October 2016, Paratek announced a research agreement with the U.S. Department of Defense to explore the utility of omadacycline against pathogenic agents including plague and anthrax. 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 Phase 3 data are expected in early 2017.

For more information, visit www.paratekpharma.com.

Forward Looking Statements

This press release contains forward-looking statements including statements related to our overall strategy, product candidates, clinical trials, cash resources, prospects and expected results, including statements about the timing of advancing omadacycline and otherwise preparing for clinical trials, the potential for omadacycline to serve as an empiric monotherapy treatment option for patients suffering from ABSSSI, CABP, UTI, and other bacterial infections when resistance is of concern, the prospect of omadacycline providing broad-spectrum activity, and our having the resources to execute on our clinical trials. All statements, other than statements of historical facts, included in this press release are forward-looking statements, and are identified by words such as "advancing," "believe," "expect," "well positioned," "look forward," "anticipated," "continued," and other words and terms of similar meaning. These forward-looking statements are based upon our current expectations and involve substantial risks and uncertainties. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Our actual results and the timing of events could differ materially from those included in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to (i) our need for substantial additional funding to complete the development and commercialization of our product candidates, (ii) our ability to raise the capital to do so, (iii) our ability to develop our drug candidates for potential commercialization, (iv) the advancement of omadacycline Phase 3

trials for ABSSSI and CABP, (v) the potential for omadacycline to be successfully developed as an empiric monotherapy for patients suffering from serious community-acquired bacterial infections, (vi) the potential of omadacycline to become a primary antibiotic choice of physicians for the treatment of serious community-acquired bacterial infections, (vii) the ability of our supply chain to provide adequate supply to satisfy our clinical and commercial demand (viii) the potential use and effectiveness of sarecycline for the treatment of acne and rosacea in the community setting, and (ix) the timing of the Phase 3 program in moderate-severe acne for sarecycline, risks that data to date and trends may not be predictive of future results, risks related to the conduct of our clinical trials, and risks that our clinical trials and product candidates do not receive regulatory approval. These and other risk factors are discussed under "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2015, and our other filings with the Securities and Exchange Commission. We expressly disclaim any obligation or undertaking to update or revise any forward-looking statements contained herein.

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