



Paratek Doses First Patient in Phase 3 Clinical Trial of Omadacycline in Acute Bacterial Skin and Skin Structure Infections

- First of Two Planned Phase 3 Clinical Trials of Paratek's Lead Antibiotic Candidate

- Studies Designed to Support Submission for Approval in Two Indications: Acute Bacterial Skin and Skin Structure Infections and Community Acquired Bacterial Pneumonia

BOSTON, June 23, 2015 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon tetracycline chemistry today announced the dosing of the first patient in its Phase 3 clinical trial of its lead drug candidate, omadacycline, for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI). This global Phase 3 study will assess the efficacy and safety of omadacycline compared with linezolid in ABSSSI.

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. It is being developed as a once-daily oral and intravenous antibiotic for use as empiric monotherapy when resistance is of concern. The ABSSSI study is the first of two planned Phase 3 clinical trials of omadacycline. The second trial, for the treatment of Community Acquired Bacterial Pneumonia (CABP), will begin enrolling patients later this year.

"The initiation of our registration trial for ABSSSI represents an important milestone for Paratek as a company," said Michael Bigam, Chairman and Chief Executive Officer at Paratek Pharmaceuticals. "We believe that omadacycline has the potential to become an important empiric monotherapy treatment option for patients suffering from ABSSSI, CABP, urinary tract infections, and other bacterial infections when resistance is of concern."

"Omadacycline is now one step closer to being available for patients with serious community-acquired bacterial infections," said Evan Loh, M.D., President and Chief Medical Officer at Paratek Pharmaceuticals. "This is an important development given the evolving bacterial resistance landscape worldwide."

About the 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 adult participants in approximately 100 centers worldwide. Outcome measures defined in the protocol include efficacy as assessed by at least a 20% reduction of ABSSSI lesion size compared to baseline measurements and investigator

assessment of clinical response, defined as 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 Omadacycline

Omadacycline is a new broad-spectrum antibiotic being developed in both once-daily oral tablet and intravenous formulations for potential use as empiric monotherapy for ABSSSI, CABP, UTI and other serious community-acquired bacterial infections, particularly when antibiotic resistance is of concern.

Omadacycline was designed to provide broad-spectrum activity, and possibly shorter hospital stays, by allowing for the completion of antibiotic therapy at home with an oral formulation, thereby potentially positioning omadacycline to become the primary antibiotic choice of physicians for the treatment of serious community-acquired bacterial infections.

Omadacycline has received Qualified Infectious Disease Product (QIDP) designation by the U.S. Food and Drug Administration (FDA) for both the oral and intravenous formulations in ABSSSI, CABP, and UTI. Paratek has Special Protocol Assessment (SPA) agreements with the FDA for the Phase 3 trials planned in ABSSSI and CABP.

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 an aminomethylcycline, derived from tetracyclines.

Paratek's second product candidate, sarecycline, also known as WC 3035, is a new once-daily oral tetracycline-derived compound, designed to provide both a narrow-spectrum of antibiotic activity and favorable tolerability profile, for the treatment of acne and rosacea in the community setting. Paratek has licensed rights to sarecycline for the treatment of acne in the United States to a subsidiary of Allergan, formerly Warner Chilcott, while retaining rights in the rest of the world. Allergan is responsible for the clinical development of sarecycline for the treatment of acne in the United States. A Phase 3 program was initiated by Allergan in December 2014 for sarecycline for the treatment of moderate to severe inflammatory acne.

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 into Phase 3 clinical trials for CABP 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 possibly shorter hospital stays, by allowing for the completion of therapy at home with an oral formulation, the possibility of omadacycline becoming the primary antibiotic choice of physicians for the treatment of serious community-

acquired bacterial infections, and our having the resources to execute on our clinical trials, expand operational capabilities and address unmet need for patients and society. 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, (v) the timing of the commencement of omadacycline Phase 3 trials for CABP, (vi) the potential for omadacycline to be successfully developed for use as a first-line empiric monotherapy for patients suffering from serious community-acquired bacterial infections, (vii) the potential of omadacycline to become the primary antibiotic choice of physicians for the treatment of serious community-acquired bacterial infections, (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 commencement of a 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 Quarterly Report on Form 10-Q for the quarter ended March 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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