



Paratek Initiates Phase 3 Study of Oral-only Omadacycline in ABSSSI

BOSTON, Aug. 15, 2016 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), announced today the dosing of the first patient in its second pivotal Phase 3 study of omadacycline in patients with acute bacterial skin and skin structure infections (ABSSSI). This Phase 3 study will assess the efficacy and safety of once-daily oral-only omadacycline compared with twice-daily oral-only linezolid in subjects with ABSSSI.

“Oral antibiotic therapies for community-acquired skin infection, when effective, are advantageous, because they can eliminate the need for a hospital stay, thereby substantially reducing the overall cost of treatment and limiting a patient’s exposure to secondary infection in the hospital setting. Unfortunately, resistance to the existing, older oral agents has led to increasing hospital visits, so there is a need for a new, effective, broad spectrum oral agent with MRSA coverage for community-acquired skin infections,” said Evan Loh, President and Chief Medical Officer, Paratek. “Omadacycline is an excellent candidate for study in these infections as it is broad spectrum, well-tolerated, and available in a once-daily oral formulation. We look forward to building on the strength of our clinical program, having already demonstrated robust efficacy and safety in our Phase 3 study of IV to oral omadacycline in ABSSSI, reported earlier this year.”

The Phase 3, randomized, double-blind, multi-center study in adults with moderate to severe ABSSSI will compare the safety and efficacy of once-daily oral omadacycline to twice-daily oral linezolid. The study is designed to enroll approximately 700 patients at approximately 60 centers. For the purposes of regulatory filings in the United States, the primary efficacy endpoint defined in the protocol is the number of subjects with clinical success at the early clinical response assessment 48-72 hours after the first dose of study drug. For regulatory filings in the European Union, the primary endpoint will be clinical response at the post therapy evaluation, also known as ‘test of cure’. Other efficacy outcome measurements 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 assessed.

About Acute Bacterial Skin and Skin Structure Infections (ABSSSIs)

Acute Bacterial Skin and Skin Structure Infections are responsible for more than 750,000 hospitalizations per yearⁱ, representing a 17.3% increase in hospitalized ABSSSI patients from 2005 to 2011.ⁱⁱ

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.

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.

I LaPensee KT, Fan W, Wang Y. PIN22 Economic Burden of Hospitalization With Antibiotic Treatment for ABSSSI in the United States: An Analysis Of the Premier Hospital Database. *Value in Health*. 2012;15(4):A240–A241.

ii Kaye, Keith S., et al. "Rising United States hospital admissions for acute bacterial skin and skin structure infections: recent trends and economic impact." *PloS one* 10.11 (2015): e0143276.

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