



Paratek Accelerates Timing for Projected Reporting of Top-Line Data for Omadacycline Phase 3 Skin Trial

BOSTON, Jan. 06, 2016 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), announced today that it projects its ongoing pivotal Phase 3 clinical trial evaluating omadacycline for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) to report top-line data in mid-2016. The company had previously estimated that this trial would report top-line data in the second half of 2016. The revised estimate reflects to date better-than-anticipated enrollment performance in the trial. This trial, which is designed to assess the efficacy and safety of once-daily oral and intravenous formulations of omadacycline compared to linezolid in ABSSSI, enrolled its first patient in June 2015. In November 2015, Paratek initiated enrollment of a Phase 3 trial of oral and IV omadacycline for community acquired bacterial pneumonia (CABP).

“We have seen significant interest by the medical community in our ongoing skin trial, which has confirmed the need for new skin agents, specifically an agent that is broad spectrum and well-tolerated with a bioequivalent once-daily oral and IV formulation,” said Evan Loh, M.D., President and Chief Medical Officer, Paratek. “The potential of omadacycline, particularly the value of a well-tolerated, once-daily oral formulation, should not be underestimated, as it appears from research to be a particularly attractive proposition to physicians treating serious community acquired skin infections where bacterial resistance is of concern. We thank every patient for their participation and we look forward to reporting the top-line efficacy and safety results mid-year.”

The Phase 3, randomized, double-blind, multi-center study will compare the safety and efficacy of IV step-down to oral treatment of both omadacycline and linezolid in 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.

Financial Position

As of December 31, 2015, Paratek had unaudited cash and cash equivalents of approximately \$131.3 million, which is expected to fund operations through the top line data of the Phase 3 IV/Oral study in CABP, which are expected in the second half of 2017. This cash estimate is based on information currently available, and may differ from the actual cash balance set forth in the company’s audited financial statements.

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. Paratek initiated a Phase 3 registration study in ABSSSI in June to determine the efficacy and safety of omadacycline compared to linezolid. A Phase 3 registration study for CABP with omadacycline was initiated in November 2015.

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, 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, expectations as to the conduct of, and measurements to be made in, the Phase 3 clinical trials of omadacycline, Paratek's belief that omadacycline has the potential to become an attractive therapeutic option for serious community acquired skin infections, particularly when antibiotic resistance is of concern, and Paratek's approximate cash and cash equivalents 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 Phase 3 clinical trial, (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 and (vi) year-end financial accounting procedures. 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 September 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.

CONTACT: Media Relations:

Michael Lampe

(484) 575-5040

michael@michaellampeconsulting.com

Investor Relations:

Hans Vitzthum

LifeSci Advisors, LLC.

212-915-2568



Paratek Pharmaceuticals