



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

BOSTON, April 03, 2017 (GLOBE NEWSWIRE) -- Pharmaceuticals, Inc. (Nasdaq:PRTK), announced today positive top-line results from a global, pivotal Phase 3 clinical study comparing its once-daily oral and IV, broad spectrum investigational antibiotic, omadacycline, to moxifloxacin in the treatment of patients with community-acquired bacterial pneumonia (CABP). This study represents the second positive Phase 3 registration study of omadacycline, which will be used to support marketing applications to the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

“This successful study demonstrates the potential of omadacycline to treat community-acquired bacterial pneumonia, a significant and serious health issue,” said Michael Bigham, Chairman and Chief Executive Officer at Paratek. “This Phase 3 study in pneumonia along with our previously announced successful Phase 3 study in skin infections satisfy the regulatory filing requirements of our special protocol assessment with the FDA. We look forward to sharing these data with the FDA and EMA. Our plan is to submit our NDA in the U.S. as early as the first quarter of 2018 with an EMA submission later in 2018.”

Study Results

The global, pivotal Phase 3 clinical study known as OPTIC (Omadacycline for Pneumonia Treatment in the Community), compared the safety and efficacy of once-daily, IV-to-oral omadacycline to IV-to-oral moxifloxacin for treating adults with CABP. In the study, 774 patients were randomized. Omadacycline met the FDA-specified primary endpoint of statistical non-inferiority (NI) in the intent-to-treat (ITT) population (10% NI margin, 95% confidence interval) compared to moxifloxacin at the early clinical response (ECR) 72-120 hours after initiation of therapy. The ECR rates for the omadacycline and moxifloxacin treatment arms were 81.1 % and 82.7%, respectively.

Additionally, the FDA-specified secondary endpoints evaluated omadacycline at the post treatment evaluation (PTE) visit 5-10 days after the completion of therapy in both the ITT population (87.6% for omadacycline vs. 85.1% for moxifloxacin) and in the clinically evaluable (CE) population (92.9% for omadacycline vs. 90.4% for moxifloxacin) as determined by investigators. The secondary endpoints also achieved statistical non-inferiority.

The co-primary endpoints for the EMA were non-inferiority in the ITT and CE CABP populations in those patients with Pneumonia Severity Index (PORT) III and IV at the PTE time point. Omadacycline demonstrated a high response rate and met statistical non-inferiority to moxifloxacin for both populations using a prespecified 97.5% confidence interval. High success rates were observed with response rates of 88.4% (omadacycline) vs. 85.2% (moxifloxacin) and 92.5% (omadacycline) vs. 90.5% (moxifloxacin), respectively.

“We now have experience with omadacycline in more than 1,500 patients in our clinical program and we are very pleased with the safety, tolerability, and efficacy profile that we have seen to date,” said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer at Paratek. “We are deeply indebted to the patients, investigators, and entire Paratek team for their commitment to advancing omadacycline. We are delighted to have achieved this significant milestone for the program and the company as we work to bring omadacycline to patients.”

In the study, omadacycline was generally safe and well tolerated, consistent with prior studies of omadacycline. The most common treatment emergent adverse events (TEAEs) in omadacycline-treated patients (occurring in > 3% of patients) were ALT increase (3.7% with omadacycline vs. 4.6% with moxifloxacin) and hypertension (3.4% with omadacycline vs. 2.8% with moxifloxacin). Gastrointestinal adverse events of interest for omadacycline vs. moxifloxacin included: vomiting (2.6% vs. 1.5%), nausea (2.4% vs. 5.4%), and diarrhea (1.0% vs. 8.0%), respectively. There were no cases of clostridium difficile colitis or infection in patients treated with omadacycline, compared with seven cases (1.8%) in patients treated with moxifloxacin.

Rates of TEAEs were 41.1% for omadacycline vs. 48.5% for moxifloxacin. Drug-related TEAEs were 10.2% for omadacycline vs. 17.8% for moxifloxacin. Discontinuation for TEAEs was uncommon, 5.5% for omadacycline vs. 7.0% for moxifloxacin. Serious TEAEs occurred in 6.0% of omadacycline patients and 6.7% of moxifloxacin patients; four of these were considered related to study drug, two for omadacycline and two for moxifloxacin. The mortality rate was 2.1% with omadacycline and 1.0% with moxifloxacin. Drug-related serious TEAEs leading to premature discontinuation of test article were 2.6% with omadacycline and 2.8% with moxifloxacin.

“Community-acquired bacterial pneumonia results in approximately 3.3 million hospitalizations in the United States each year with a significant mortality risk of more than 5 percent seen in observational studies, putting a significant burden on the healthcare system,” said Dr. Thomas M. File Jr., M.D., MS, Chair of the Infectious Disease Section, Northeast Ohio Medical University, and Chair of the Infectious Disease Division, Summa Health. “Antibiotic resistance is a national issue as susceptibility rates have decreased across most antibiotics since 2010, underscoring the need for new, effective therapies. The positive top-line results of omadacycline in community-acquired bacterial pneumonia is welcome news.”

Results of this study will be submitted for presentation at an upcoming scientific congress.

Conference Call and Web Cast

The company will host a webcast and conference call for investors at 4:30 pm ET today. The live webcast can be accessed under “Events and Presentations” in the Investor Relations section of Paratek’s website at www.paratekpharma.com. The webcast can also be accessed at this link <http://public.viavid.com/index.php?id=123672>. The webcast will be available for one year.

Domestic callers wishing to participate in the call should dial 877-407-9039 and international callers should dial 201-689-8470. Replays of the call will be available until April 17. Using the same conference ID, replays can be accessed by domestic callers by dialing 844-512-2921. International callers should dial 412-317-6671. The replay PIN is 13659016.

About the OPTIC Study Design

The OPTIC study was a double-blind, active-controlled, global, multi-center study that enrolled 774 adult subjects with moderate to moderately severe CABP and included approximately 14% PORT Class II, 57% PORT Class III, and 28% PORT Class IV. Patients initially received IV administration of either 100 mg of omadacycline or 400 mg of moxifloxacin. Study investigators were permitted to switch patients to oral dosing of their assigned drug (300 mg once daily omadacycline or 400 mg once daily moxifloxacin) for a total of 7 to 14 days based on assessment of clinical stability.

About Omadacycline

Omadacycline is a once-daily oral and IV, well-tolerated broad spectrum investigational 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. Omadacycline has been granted Qualified Infectious Disease Product designation and Fast Track status by the U.S. Food and Drug Administration for the target indications.

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 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 acute bacterial skin and skin structure infections (ABSSSI) demonstrating the efficacy, general safety, and tolerability of intravenous (IV) to once-daily oral omadacycline compared to linezolid. 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 from this study are expected as early as the end of June. A Phase 1B study in uncomplicated urinary tract infections (UTI) was initiated in May 2016 and positive top-line PK proof-of-principle data was reported in November 2016. The company plans to begin enrolling patients in a proof-of-concept Phase 2 study in complicated UTI as early as December of 2017.

In October 2016, Paratek announced a new cooperative research effort with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to study omadacycline against pathogenic agents causing infectious diseases of public health and biodefense importance. These studies are designed to confirm dosing regimens and assess efficacy of omadacycline against biodefense pathogens, including *Yersinia pestis* (plague) and *Bacillus anthracis* (anthrax).

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 and Paratek reported positive results from two identical Phase 3 registration studies of sarecycline for the treatment of moderate to severe acne vulgaris in March 2017 and

Allergan plans to submit a New Drug Application with the U.S. Food and Drug Administration in the second half of this year.

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 studies, prospects and expected results, including statements about the timing of advancing omadacycline and otherwise preparing for clinical studies, the timing of enrollment in our clinical studies and of our reporting of the results of such studies, 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 ability to obtain regulatory approval of omadacycline for the treatment of CABP. 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. 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, 2016, 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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