

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

Omadacycline met all FDA primary and secondary endpoints and EMA co-primary endpoints
Omadacycline was generally safe and well tolerated
U.S. New Drug Application planned as early as Q1 2018
Company to host a webcast and conference call for investors at 4:30 PM ET to review top-line results

BOSTON, April 03, 2017 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK) announced today positive top-line results for 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 U.S. 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 leading cause of death in the United States," said Evan Loh, President and Chief Executive Officer at Paratek. "This Phase 3 study in pneumonia along with our previously announced successful Phase 3 study in acute bacterial sinusitis met the regulatory 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 a New Drug Application to the FDA in the second 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 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 in the intent-to-treat (ITT) population (10% NI margin, 95% confidence interval) compared to moxifloxacin at the early clinical response (ECR) endpoint. The percentages of patients achieving ECR 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 treatment (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). 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 (PSI) Class II, III, and IV. Omadacycline demonstrated a high response rate and met statistical non-inferiority to moxifloxacin for both populations using a prespecified primary endpoint. The percentages of patients achieving ECR 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, efficacy, and tolerability," said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer at Paratek. "We are deeply indebted to the patients and healthcare providers who participated in this study. We are delighted to have achieved this significant milestone for the program and the company as we move forward with the development of omadacycline."

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 $\geq 3\%$ of patients) were ALT increase (3.7% with omadacycline vs. 4.6% with moxifloxacin) and nausea (2.6% with omadacycline vs. 1.5% with moxifloxacin). Gastrointestinal adverse events of interest for omadacycline vs. moxifloxacin included: vomiting (2.6% vs. 1.5%), nausea (2.6% vs. 1.5%), and diarrhea (1.8% vs. 1.5%). 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. 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. The mortality rate was 2.1% with omadacycline and 1.0% with moxifloxacin. The discontinuation of study drug due to TEAEs was 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 burden on the healthcare system," said Dr. Thomas M. File Jr., M.D., MS, Chair of the Infectious Disease Division, Summa Health. "Antibiotic resistance is a national issue as susceptibility rates have decreased over time, increasing the need for new, effective therapies. The positive top-line results of omadacycline in community-acquired bacterial pneumonia is welcome news for patients and healthcare providers."

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" on Paratek's website at www.paratekpharma.com (https://www.globenewswire.com/Tracker?data=uUXZxLkc8bKdU-RLc5ww5YohV_SAv_yxLaGOffejiGV7aquAU8mAUJW9JgXRzrFV7QNnkQP-riKKWv1QI=). The webcast can also be accessed at this link <http://public.viaid.com> (https://www.globenewswire.com/Tracker?data=g4CZQRFYURi6FZ98q30kXOSRLeuM-qQPCXwfnPlyvQG9Uuo53XSoBke6titXBQQItVvJ0aeMilRvokzsnTYbVKQooOp0pH2oZxoBmriW_BL9E1zX8zvig0gMk76l8f842cNBXBoXNfh) 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 same conference ID, replays can be accessed by domestic callers by dialing 844-512-2921. International callers should dial 412-317-6677.

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 moderate-severe community-acquired bacterial pneumonia (CABP). Patients initially received IV administration of either 100 mg of omadacycline or 400 mg of moxifloxacin. Patients were permitted to switch patients to oral dosing of their assigned drug (300 mg once daily omadacycline or 400 mg once daily moxifloxacin) if they were unable to tolerate IV administration or if they achieved clinical stability.

