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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 f its once-daily oral and IV, broad spectrum investigational antibiotic, omadacycline, to moxifloxacin in the treatment of patients with comm represents the second positive Phase 3 registration study of omadacycline, which will be used to support marketing applications to the UI the European Medicines Agency (EMA).

"This successful study demonstrates the potential of omadacycline to treat community-acquired bacterial pneumonia, a significant and si and Chief Executive Officer at Paratek. "This Phase 3 study in pneumonia along with our previously announced successful Phase 3 study i requirements of our special protocol assessment with the FDA. We look forward to sharing these data with the FDA and EMA. Our plan is quarter of 2018 with an EMA submission later in 2018."

# **Study Results**

The global, pivotal Phase 3 clinical study known as OPTIC (<u>O</u>madacycline for <u>P</u>neumonia <u>T</u>reatment <u>in</u> the <u>C</u>ommunity), compared the saf to IV-to-oral moxifloxacin for treating adults with CABP. In the study, 774 patients were randomized. Omadacycline met the FDA-specific the intent-to-treat (ITT) population (10% NI margin, 95% confidence interval) compared to moxifloxacin at the early clinical response (ECF 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 (87.6% for omadacycline vs. 85.1% for moxifloxacin) and in the clinically evaluable (CE) population (92.9% for omadacycline vs. 90.4% for 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 Omadacycline demonstrated a high response rate and met statistical non-inferiority to moxifloxacin for both populations using a prespeci observed with response rates of 88.4% (omadacycline) vs. 85.2% (moxifloxacin) and 92.5% (omadacycline) vs. 90.5% (moxifloxacin), respe

"We now have experience with omadacycline in more than 1,500 patients in our clinical program and we are very pleased with the safety, date," said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer at Paratek. "We are deeply indebted to the patien commitment to advancing omadacycline. We are delighted to have achieved this significant milestone for the program and the company a

In the study, omadacycline was generally safe and well tolerated, consistent with prior studies of omadacycline. The most common treation omadacycline-treated patients (occurring in  $\geq$  3% of patients) were ALT increase (3.7% with omadacycline vs. 4.6% with moxifloxacin) and moxifloxacin). Gastrointestinal adverse events of interest for omadacycline vs. moxifloxacin included: vomiting (2.6% vs. 1.5%), nausea (2). There were no cases of clostridium difficile colitis or infection in patients treated with omadacycline, compared with seven cases (1.8%) ir

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 uncommon, 5.5% for omadacycline vs. 7.0% for moxifloxacin. Serious TEAEs occurred in 6.0% of omadacycline patients and 6.7% of moxi to study drug, two for omadacycline and two for moxifloxacin. The mortality rate was 2.1% with omadacycline and 1.0% with moxifloxacin 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 sign observational studies, putting a significant burden on the healthcare system," said Dr. Thomas M. File Jr., M.D., MS, Chair of the Infectious and Chair of the Infectious Disease Division, Summa Health. "Antibiotic resistance is a national issue as susceptibility rates have decrease need for new, effective therapies. The positive top-line results of omadacycline in community-acquired bacterial pneumonia is welcome n

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 Paratek's website at <u>www.paratekpharma.com (https://www.globenewswire.com/Tracker?data=uUXZxLkc8bKdU-RLc5ww5YohV\_SAv\_yxLaGOffeejiGV7aquAU8mAUJW9JgXRzrFV7QNnkQP-rIKKWv1QI=)</u>. The webcast can also be accessed at this link <u>http://public.viavid.com</u> (<u>https://www.globenewswire.com/Tracker?data=g4CZQRFRYURi6FZ98q30kXOSRLeuM-</u>

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Domestic callers wishing to participate in the call should dial 877-407-9039 and international callers should dial 201-689-8470. Replays same conference ID, replays can be accessed by domestic callers by dialing 844-512-2921. International callers should dial 412-317-667

## 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 mode PORT Class II, 57% PORT Class III, and 28% PORT Class IV. Patients initially received IV administration of either 100 mg of omadacycline permitted to switch patients to oral dosing of their assigned drug (300 mg once daily omadacycline or 400 mg once daily moxifloxacin) fo stability.

# About Omadacycline

Omadacycline is a once-daily oral and IV, well-tolerated broad spectrum investigational antibiotic being developed for use as empiric mor community-acquired bacterial infections, such as acute bacterial skin and skin structure infections, community-acquired bacterial pneum acquired bacterial infections, particularly when antibiotic resistance is of concern to prescribing physicians. Omadacycline has been grar 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 therapie chemistry. Paratek's lead product candidate, omadacycline, is the first in a new class of tetracyclines known as aminomethylcyclines, wit negative and atypical bacteria. In June 2016, Paratek announced positive efficacy data in a Phase 3 registration study in acute bacterial s demonstrating the efficacy, general safety, and tolerability of intravenous (IV) to once-daily oral omadacycline compared to linezolid. A Pt daily oral-only dosing of omadacycline to twice-daily oral-only dosing of linezolid was initiated in August 2016. Top line data from this stu study in uncomplicated urinary tract infections (UTI) was initiated in May 2016 and positive top-line PK proof-of-principle data was reporte 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 Diseas pathogenic agents causing infectious diseases of public health and biodefense importance. These studies are designed to confirm dosing 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 antib potential treatment of acne and rosacea in the community setting. Allergan owns the U.S. rights for the development and commercializat Allergan and Paratek reported positive results from two identical Phase 3 registration studies of sarecycline for the treatment of moderat 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 (https://www.globenewswire.com/Tracker?data=uUXZxLkc8bKdU-

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#### **Forward Looking Statements**

This press release contains forward-looking statements including statements related to our overall strategy, product candidates, clinical statements about the timing of advancing omadacycline and otherwise preparing for clinical studies, the timing of enrollment in our clinic studies, the potential for omadacycline to serve as an empiric monotherapy treatment option for patients suffering from ABSSSI, CABP, U concern, the prospect of omadacycline providing broad-spectrum activity, and our ability to obtain regulatory approval of omadacycline fc statements of historical facts, included in this press release are forward-looking statements, and are identified by words such as "advanc forward," "anticipated," "continued," and other words and terms of similar meaning. These forward-looking statements are based upon ou uncertainties. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our for undue reliance on these forward-looking statements. Our actual results and the timing of events could differ materially from those includ these risks and uncertainties. These and other risk factors are discussed under "Risk Factors" and elsewhere in our Annual Report on For other filings with the Securities and Exchange Commission. We expressly disclaim any obligation or undertaking to update or revise any f

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