Paratek Announces Phase 3 Study of Oral-Only Dosing of Omadacycline Met All Primary and Secondary FDA and EMA Efficacy Endpoints in Acute Bacterial Skin Infections

BOSTON, July 17, 2017 (GLOBE NEWSWIRE) – Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK) announced today positive top-line results from a pivotal Phase 3 clinical study comparing its once-daily, oral investigational antibiotic, omadacycline, to twice-daily oral linezolid in the treatment of acute bacterial skin and skin structure infections (ABSSSI). The study met all of its primary and secondary endpoints required to support approval for this indication by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). This represents the third positive Phase 3 registration study of omadacycline.

"This successful study demonstrates the potential of an oral-only dosing regimen of omadacycline, which would enable treatment in the outpatient setting and potentially reduce the need for admission to the hospital," said Michael Bigham, Chairman and Chief Executive Officer of Paratek. "The utility of the oral only dosing regimen represents a significant potential benefit to patients and prescribers who are in need of new, effective oral agents to combat serious community-acquired infections."

The pivotal Phase 3 clinical study known as OASIS-2 (Omadacycline in Acute Skin Structure Infections Study) evaluated the efficacy and safety of once-daily, oral-only omadacycline compared to twice-daily, oral-only linezolid in 735 adults with ABSSSI. Omadacycline met the FDA-specified primary endpoint of statistical non-inferiority (NI) in the modified intent-to-treat (mITT) population (10% NI margin, 95% confidence interval) compared to linezolid at the early clinical response (ECR), 48 to 72 hours after the first dose of study drug. The ECR rate for omadacycline was 87.5% compared to 82.5% for linezolid.

Additionally, omadacycline met statistical NI compared to linezolid for the EMA-specified co-primary endpoints at the post therapy evaluation (PTE), 7 to 14 days after completion of therapy in the mITT and the Clinically Evaluable (CE) populations. Clinical success rates at PTE in the mITT population for the omadacycline and linezolid arms were 84.2% vs. 80.8%, respectively; and in the CE population were 97.9% vs. 95.5%, respectively.

Omadacycline demonstrated high clinical success rates for infections caused by the most common ABSSSI pathogens, including methicillin-resistant Staphylococcus aureus (MRSA).

In the OASIS-2 study, there was a low rate of study treatment discontinuation for both omadacycline and linezolid patients at 10.9% vs. 14.2%, respectively. Less than 2% of patients discontinued treatment due to adverse events in both treatment groups. No deaths occurred in the omadacycline treatment arm. The most common treatment emergent adverse events (TEAEs) in omadacycline and linezolid treated patients were nausea (30.2% vs. 7.6%, respectively) and vomiting (16.8% vs. 3.0%, respectively). Seventy-five percent of the nausea

was classified as mild with none reported as severe, and only one omadacycline patient discontinued treatment for gastrointestinal events. The vast majority of the onset of the nausea or vomiting in omadacycline patients occurred during the loading-dose phase on day 1 or day 2, and the median duration of these episodes was two days. Additional TEAEs, occurring in ≥ 3% of omadacycline patients were increased alanine aminotransferase (ALT; 5.2%), increased aspartate aminotransferase (AST; 4.6%), diarrhea (4.1%) and headache (3.5%), which were generally comparable between treatment arms. No subject in either treatment group developed *Clostridium difficile* infection.

“We are excited by the outstanding efficacy observed in our oral-only skin study, which is consistent with the efficacy we have observed in the OASIS-1 and OPTIC studies,” said Evan Loh, M.D., President, Chief Operating Officer and Chief Medical Officer of Paratek. “The gastrointestinal adverse event rates were higher in this study than in OASIS-1; however, these events were generally mild and transient. The completion and efficacy rates were very high in this study, confirming the utility of the oral-only omadacycline regimen and our confidence in the approvability of omadacycline for ABSSSI and CABP.”

The results of this study, including the results of the secondary endpoints, will be presented at an upcoming scientific congress.

Conference Call and Webcast

The Company will host a webcast and conference call for investors at 4:30 p.m. 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=125259. The webcast will be available for one year.

Domestic callers wishing to participate in the call should dial 877-407-0792 and international callers should dial 201-689-8263. Replays of the call will be available until July 31, 2017. 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 13665829.

About the OASIS-2 Study Design

The OASIS-2 study was a randomized, double-blind, multi-center study that enrolled 735 adult subjects with moderate to severe ABSSSI at 33 centers in the U.S. Patients received either once daily omadacycline or twice daily linezolid for 7-14 days. In addition to evaluating omadacycline against the FDA- and EMA-specified primary endpoints, the study comprised other efficacy outcome measurements including overall survival and resolution or improvement of signs and symptoms. In addition, safety and tolerability were assessed by treatment-emergent adverse events, vital sign measurements, ECGs and laboratory values.

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, if approved, will be the first in a new class of tetracyclines known as aminomethylcyclines, with broad-spectrum activity against Gram-positive, Gram-negative and atypical bacteria. Omadacycline is a new, once-daily oral and intravenous 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. 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.

In June 2016, Paratek announced positive efficacy data in a Phase 3 registration study in acute bacterial skin and skin structure infections (OASIS-1) demonstrating the efficacy and general safety and tolerability of intravenous (IV) to once-daily oral omadacycline compared to linezolid. In April 2017, Paratek announced positive efficacy data in a Phase 3 registration study in community-acquired bacterial pneumonia (OPTIC) demonstrating the efficacy and general safety and tolerability of IV to once-daily oral omadacycline compared to moxifloxacin. The Company plans to submit its NDAs in the U.S. as early as the first quarter of 2018 with an EMA submission later in 2018.

In addition to its Phase 3 program for omadacycline, in November 2016 Paratek reported positive top-line PK proof-of-principle in a Phase 1B study in uncomplicated urinary tract infections (UTI). The Company plans to begin enrolling patients in a proof-of-concept Phase 2 study of omadacycline in UTI as early as December 2017.

In October 2016, Paratek announced a research agreement with the U.S. Department of Defense to explore the utility of omadacycline against pathogenic agents causing infectious diseases of public health and biodefense importance including plague and anthrax.

In April 2017, Paratek Bermuda Ltd., a wholly-owned subsidiary of the Company, and Zai Lab (Shanghai) Co., Ltd., entered into a License and Collaboration Agreement. Under the terms of the Agreement, the Company granted Zai an exclusive license to develop, manufacture, and commercialize omadacycline in the People's Republic of China, Hong Kong, Macau and Taiwan, for all human therapeutic and preventative uses, other than biodefense.

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. Allergan has publicly announced plans to submit an NDA in the U.S. in the second half of 2017.

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, potential 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 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 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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