

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

Omadacycline generally safe and well tolerated

Company on track to file NDAs with FDA as early as 1Q 2018

Webcast and conference call for investors at 4:30 p.m. today EDT to review top-line results

BOSTON, July 17, 2017 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK) announced today the results of a pivotal Phase 3 clinical study comparing its once-daily, oral investigational antibiotic, omadacycline, to twice-daily, oral-only linezolid in 735 adults with acute bacterial skin and skin structure infections (ABSSSI). The study met all of its primary and secondary endpoints for approval for this indication by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in a positive Phase 3 registration study of omadacycline.

"This successful study demonstrates the potential of an oral-only dosing regimen of omadacycline, which will be used in an outpatient setting and potentially reduce the need for admission to the hospital," said Michael Bigham, Chairman of Paratek. "The utility of the oral only dosing regimen represents a significant potential benefit to patients and 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) compared once-daily, oral-only omadacycline to twice-daily, oral-only linezolid in 735 adults with ABSSSI. The primary endpoint of statistical non-inferiority (NI) in the modified intent-to-treat (mITT) population (10% NI margin) was met, with omadacycline compared to linezolid at the early clinical response (ECR), 48 to 72 hours after the first dose of study drug. The ECR rates were 87.5% compared to 82.5% for linezolid.

Additionally, omadacycline met statistical NI compared to linezolid for the EMA-specified co-primary endpoint (PTE), 7 to 14 days after completion of therapy in the mITT and the Clinically Evaluable (CE) populations. The clinical response rates for the omadacycline and linezolid arms were 84.2% vs. 80.8%, respectively; and in the CE population, the response rates were 84.2% vs. 80.8%, respectively.

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

In the OASIS-2 study, there was a low rate of study treatment discontinuation for both omadacycline and linezolid, respectively. Less than 2% of patients discontinued treatment due to adverse events in both treatment groups. The most common treatment emergent adverse events (TEAEs) in omadacycline patients were nausea (30.2% vs. 7.6%, respectively) and vomiting (16.8% vs. 3.0%, respectively). Seventy-five percent of the patients who reported nausea or vomiting in omadacycline patients discontinued treatment for gastrointestinal events. The nausea or vomiting in omadacycline patients occurred during the loading-dose phase on day 1 or day 2, and the duration of the episodes was two days. Additional TEAEs, occurring in ≥ 3% of omadacycline patients were increased alanine aminotransferase (AST; 4.6%), diarrhea (4.1%) and headache (3.5%), which were generally mild to moderate in severity. 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 OASIS-1 and OPTIC studies," said Evan Loh, M.D., President, Chief Operating Officer and Chief Medical Officer of Paratek. "The adverse event rates were higher in this study than in OASIS-1; however, these events were generally mild and the efficacy rates were very high in this study, confirming the utility of the oral-only omadacycline regimen and the utility of omadacycline for ABSSSI and CABP."

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

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 will be titled "Paratek Pharmaceuticals Q2 2017 Financial and Operational Presentations" in the Investor Relations section of Paratek's website at www.paratekpharma.com (https://www.paratekpharma.com/data=CgivLk070bQR9wPErBOEDd1UIWQ38TrZDR9R_UOXGCsoXRAp6T5FMv5F1MYJ3RijYk_jsm_F-pTWnC).

The webcast can also be accessed at this link <http://public.viavid.com/index.php?id=125259> (https://www.globenewswire.com/Track?data=Mq9W4fubh2EM1aj1X7CYZ3ERlrkf9DuWecV7kDR6JMTtfZC1MhVgLRwY-kkZlaDb8rFTErLuljmmZ--jPre6u9C_d-wdF2thnpAlc_g9DiUMXS3Mitx6PcW7UBdqqDlL7AlJwaL_IrGyQ7Q00Z_AYA==). The webcast will be available until July 31, 2017. Using the same conference ID, replays can be accessed by domestic callers should dial 412-317-6671. The replay PIN is 13665829.

Domestic callers wishing to participate in the call should dial 877-407-0792 and 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 centers in the U.S. Patients received either once daily omadacycline or twice daily linezolid for 7-14 days. In addition to the FDA- and EMA-specified primary endpoints, the study comprised other efficacy outcome measures such as resolution or improvement of signs and symptoms. In addition, safety and tolerability were assessed by treatment sign measurements, ECGs and laboratory values.

About Paratek Pharmaceuticals, Inc.

Paratek Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of novel tetracycline chemistry. Paratek's lead product candidate, omadacycline, is a novel tetracycline known as aminomethylcyclines, with broad-spectrum activity against Gram-positive, Gram-negative bacteria. Omadacycline is a new, once-daily oral and intravenous broad-spectrum antibiotic being developed for use in patients suffering from serious community-acquired bacterial infections, such as acute bacterial skin and skin structure infections, bacterial pneumonia, urinary tract infections, and other community-acquired bacterial infections, particularly those of concern to prescribing physicians. Omadacycline has been granted Qualified Infectious Disease Product designation 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 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. 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/PD study in uncomplicated urinary tract infections (UTI). The Company plans to begin enrolling patients in a Phase 3 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 use 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 Collaboration Agreement. Under the terms of the Agreement, the Company granted Zai an exclusive license to commercialize omadacycline in the People's Republic of China, Hong Kong, Macau and Taiwan, for all human and veterinary uses other than biodefense.

Paratek's second Phase 3 product candidate, sarecycline, is a well-tolerated, once-daily oral, narrow-spectrum tetracycline with potent anti-inflammatory properties for the potential treatment of acne and rosacea in the community setting. Paratek retains all ex-U.S. rights. Allergan and Paratek are conducting identical Phase 3 registration studies of sarecycline for the treatment of moderate to severe acne vulgaris in patients. Paratek announced plans to submit an NDA in the U.S. in the second half of 2017.

For more information, visit www.paratekpharma.com (https://www.globenewswire.com/Track?data=CgivLk070bQR9wPErBOEDd1UIWQ38TrZDR9R_UOXGCuU_2nu4RV23OCHwn_IdcGc-Qph_m02gd2mJd3R0yEM8j3JLfzkZzrkJZXpvXt47NAIwryRHK9NGZ_JDMf6gYhZyOUwWWMn8vVa3g-cECNwTMXyquK05T0vgoU1G9BNnXJA9x0k8E_ClOMGV3EoBekRmVwLJUXVIMIQQusJVj2ej8QJmck0mwY).

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Forward Looking Statements

This press release contains forward-looking statements including statements related to our overall strategy prospects, potential and expected results, including statements about the timing of advancing omadacycline studies, the timing of enrollment in our clinical studies and our reporting of the results of such studies, the potential as an empiric monotherapy treatment option for patients suffering from ABSSSI, CABP, UTI, and other bacterial infections, the prospect of omadacycline providing broad-spectrum activity, and our ability to obtain regulatory approvals. Statements, other than statements of historical facts, included in this press release are forward-looking statements such as "advancing," "believe," "expect," "well positioned," "look forward," "anticipated," "continued," and "other" having no certain meaning. These forward-looking statements are based upon our current expectations and involve substantial risks that we may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our financial statements. You should not place undue reliance on these forward-looking statements. Our actual results and the timing of our operations may differ materially from those included in such forward-looking statements as a result of these risks and uncertainties. These and other risks are discussed in "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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