New Microbiology Data Reinforce Activity of Paratek's Omadacycline Against Pathogens of Importance in Respiratory, Skin and Urinary Tract Infections

NEW ORLEANS, June 03, 2017 (GLOBE NEWSWIRE) -- New data presented today at ASM Microbe 2017 showed that Paratek Pharmaceuticals, Inc.'s (Nasdaq:PRTK) Phase 3 antibiotic omadacycline is highly active against common bacterial pathogens in acute skin and skin structure infections (ABSSSI), respiratory tract infections (RTI), and the key bacterial pathogens responsible for urinary tract infections (UTI). The study evaluated the *in vitro* antibacterial activity of omadacycline against Gram-positive and Gram-negative bacterial isolates collected from patients with multiple infection types in the United States, Europe, and Israel medical centers participating in the 2016 SENTRY Antimicrobial Surveillance Program. Paratek is a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon tetracycline chemistry.

"These data reinforce the results of clinical and microbiologic data presented earlier this year at ECCMID. Omadacycline continues to show significant clinical promise against resistant pathogens such as MRSA and resistant strains of *Streptococcus pneumoniae*, and these findings are consistent with the clinical success we have seen with omadacycline to date in ABSSSI and community-acquired bacterial pneumonia," said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer, Paratek. "Importantly, this study also contributes to our growing body of knowledge of omadacycline's *in vitro* activity against pathogens responsible for UTI, including *E. coli*. We believe there is a significant clinical unmet need for new oral, broad-spectrum antibiotic agents for the treatment of UTI and we are committed to advancing our clinical development program in this population."

In the study, bacterial isolates were initially identified by the submitting laboratories and confirmed using a matrix-assisted laser desorption/ionization-time of flight mass spectrometry. Susceptibility testing was performed according to the Clinical Laboratory Standards Institute (CLSI) reference broth microdilution methodology and results were interpreted using the CLSI and the European Committee of Antimicrobial Susceptibility Testing breakpoint interpretive criteria.

Overall, omadacycline was highly active against *Staphylococcus aureus*, including methicillin-resistant Staphylococcus aureus (MRSA) that included isolates from both ABSSSI and RTI (MIC50/90 0.12/0.25 µg/mL), as well as strains displaying resistance to tetracyclines, fluoroquinolones, macrolides, and lincosamides.

Omadacycline was also highly active against other respiratory pathogens including *Streptococcus pneumoniae* including penicillin-, tetracycline- and macrolide-resistant strains (MIC50/90 0.06/0.12 µg/mL). In addition, omadacycline showed activity against *Haemophilus influenza* and *Moraxella catarrhalis* strains (MIC50/90 1/1 µg/mL and 0.25/0.25 µg/mL, respectively).

UTI pathogens *Escherichia coli* (*E. coli*) and *ESBL-phenotype E. coli* were also shown to be susceptible to omadacycline (MIC50/90 0.5/2 µg/mL, and 1/2 µg/mL respectively).

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, when 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 (ABSSSI), community-acquired bacterial pneumonia (CABP), urinary tract infections (UTI), 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 ABSSSI 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 CABP demonstrating the efficacy and general safety and tolerability of IV to once-daily oral omadacycline compared to moxifloxacin. 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. This study completed enrollment in May 2017 and top-line data are expected in mid-July. The Company plans to submit its new drug application (NDA) 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, a Phase 1B study in uncomplicated 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 of omadacycline in acute pyelonephritis, the most common subset of complicated urinary tract infections, 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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