



## Paratek Receives FDA Fast Track Designation for Omadacycline

**BOSTON, Nov. 4, 2015** (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), announced today that the U.S. Food and Drug Administration (FDA) has granted omadacycline Fast Track Designation for the development of omadacycline in Acute Bacterial Skin and Skin Structure Infections (ABSSSI), Community Acquired Bacterial Pneumonia (CABP), and Complicated Urinary Tract Infections (cUTI). Fast track designation facilitates the development, and expedites the review of drugs which treat serious or life-threatening conditions and fill an unmet medical need. Omadacycline, the first in a new class of tetracyclines known as aminomethylcyclines, is being developed as a once-daily oral and IV therapy to treat serious community-acquired bacterial infections, particularly when antibiotic resistance is of concern.

The FDA has previously designated omadacycline as a Qualified Infectious Disease Product (QIDP) for the treatment of ABSSSI, CABP, cUTI. With this QIDP designation, omadacycline is eligible to benefit from certain incentives as provided under the Generating Antibiotic Incentives Now (GAIN) Act. These incentives include FDA priority review, eligibility for fast-track status and, if ultimately approved by the FDA, omadacycline would be eligible for an additional five-year extension of Hatch-Waxman new chemical entity exclusivity.

"This is a significant development for Paratek as we implement our Phase 3 registration program for omadacycline," said Michael Bigham, Chairman and Chief Executive Officer, Paratek. "Antibiotic resistance remains a significant public health challenge, and as a result, there is an increasing need for effective, well-tolerated antibiotics that can be used in both inpatient and community settings. We believe that the FDA's Fast Track designation for omadacycline underscores its potential as an important treatment option for patients suffering from serious community-acquired bacterial infections, particularly when resistance is of concern."

Each year in the United States, at least 2 million people are infected with bacteria that are resistant to existing antibiotics; at least 23,000 people die each year as a direct result of these infections.<sup>1</sup> Omadacycline is designed with mechanisms to circumvent the two clinically important mechanisms of bacterial resistance seen with prior generations of tetracycline derivatives. Data from omadacycline microbiology and clinical studies to date show that it has the potential to offer broad-spectrum coverage against Gram-positive, Gram-negative and atypical bacteria, and it has potential activity against a variety of resistant bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), penicillin-resistant *S. pneumoniae* (PRSP), vancomycin-resistant *enterococcus* (VRE) and other bacteria that are resistant to tetracyclines and other classes of antibiotics.

Once daily oral and IV formulations of omadacycline are being evaluated in two Phase 3 registration studies. Earlier this year, Paratek began enrolling patients into a pivotal Phase 3 clinical study to assess efficacy and safety of omadacycline compared with linezolid in the treatment of ABSSSI. This study will recruit approximately 650 patients at approximately 100 sites, with top-line data from that study projected to be available in the second half of 2016. Before the end of 2015, the company plans to have initiated its second pivotal Phase 3 clinical study to assess the safety and efficacy of omadacycline in the treatment of CABP. This study will recruit approximately 750 patients being treated with IV and once daily oral formulations of omadacycline at approximately 150 centers worldwide. Top-line data from this study is projected to be available in the second half of 2017.

### **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, is the first in a new class of tetracyclines known as aminomethylcyclines, with broad-spectrum activity against Gram-positive, Gram-negative and atypical bacteria. Paratek initiated a Phase 3 registration study in ABSSSI in June 2015 to determine the efficacy and safety of omadacycline compared to linezolid. A second Phase 3 registration study for CABP with omadacycline is planned to be initiated before the end of 2015.

Omadacycline is a new once-daily oral and IV, well-tolerated broad-spectrum antibiotic being developed for use as empiric monotherapy for patients suffering from serious community-acquired bacterial infections, such as ABSSSI, CABP, cUTI, and other community-acquired bacterial infections, particularly when antibiotic resistance is of concern to prescribing physicians.

Paratek's second Phase 3 product candidate, sarecycline, is a new once-daily oral tetracycline-derived compound for the potential treatment of acne and rosacea in the community setting. Sarecycline is designed to be a well-tolerated, once-daily, oral, narrow spectrum antibiotic with anti-inflammatory properties. Allergan owns the U.S. rights for the development and commercialization of sarecycline. Paratek retains all ex-U.S. rights. Two identical Phase 3 registration studies were initiated by Allergan in December 2014 for sarecycline for the treatment of moderate to severe acne vulgaris.

For more information, visit [www.paratekpharm.com](http://www.paratekpharm.com).

## Forward Looking Statements

The statements in this press release regarding the projected availability of top-line data from Paratek's Phase 3 clinical trials of omadacycline, as well as expectations as to the conduct of the Phase 3 clinical trials of omadacycline, are forward-looking statements. These forward-looking statements are based upon Paratek's current expectations and involve substantial risks and uncertainties. These risks and uncertainties include, but are not limited to: (i) unexpected results may cause the designs of the clinical trials to change, or the projected timelines of the trials to be extended; and (ii) risks related to regulatory oversight of the trials. These and other risk factors are discussed under "Risk Factors" and elsewhere in Paratek's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, and Paratek's other filings with the Securities and Exchange Commission. Paratek expressly disclaims any obligation or undertaking to update or revise any forward-looking statements contained herein.

<sup>1</sup> <http://www.cdc.gov/drugresistance/>

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