



## **Paratek's Omadacycline, Demonstrates Broad Spectrum Activity in Pathogens Relevant in Skin Infections, Community-Acquired Pneumonia and Urinary Tract Infections**

- *Phase 3 antibiotic demonstrates in vitro activity against Gram-positive bacteria, including community-acquired strains of MRSA, Gram-negatives and atypical pathogens such as Legionella*
- *Omadacycline offers promise against serious community-acquired bacterial infections when resistance is of concern*

**SAN DIEGO, September 17, 2015** (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), today provided updates on the potential broad-spectrum, in vitro activity for omadacycline. Across seven microbiology studies omadacycline demonstrated *in vitro* activity against Gram-positive, Gram-negative, and atypical bacteria, including those with resistance to currently available antibiotics. The data are being presented at the joint meeting of the International Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the International Congress of Chemotherapy and Infection (ICC) in San Diego, September 17 - 21. Paratek is a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon tetracycline chemistry. Omadacycline, Paratek's lead clinical candidate, is a once-daily oral and intravenous (IV), broad-spectrum antibiotic currently in Phase 3 development.

The breadth of data from microbiology testing of omadacycline demonstrated that the compound offers potential novel therapeutic value against *Staphylococcus aureus*, *Streptococcus pneumoniae*, [including resistant strains], and *Enterobacteriaceae* compared to commonly prescribed antibiotics. Additional *in vitro* data suggest that omadacycline may be useful in infections caused by *Legionella pneumophila* lending support to the compound's potential utility as an oral and IV monotherapy agent for the treatment of community-acquired bacterial pneumonia (CABP).

"Data from the microbiology studies presented this week reinforce omadacycline's *in vitro* activity against pathogens important in our target indications," said Evan Loh, M.D., Paratek's President and Chief Medical Officer. "Given the potential breadth of microbiologic *in vitro* coverage demonstrated in these studies by omadacycline, the favorable clinical tolerability profile we've seen to date, and the convenient and bioequivalent once-daily oral and IV formulations, we believe omadacycline has potential to be developed for clinical use as a monotherapy treatment option for serious community-acquired infections where resistance is of concern."

### Select Study Results: Activity Against *S. aureus*

- Omadacycline activity was tested against *S. aureus* strains that cause community-acquired (CA) and hospital (HA) infections in North America and Europe in comparison to data collected in the 2010 SENTRY Surveillance program. *S. aureus* is a major cause of acute bacterial skin and skin structure infections and bloodstream infections; methicillin-resistant strains (MRSA) account for approximately 50 percent of *S. aureus*.
- A total of 203 hospital-acquired MRSA (HA-MRSA), 199 community-acquired MRSA (CA-MRSA) and 100 MSSA (total n= 502) samples were selected from North America and Europe for testing using omadacycline and commonly-prescribed comparator agents.
- Overall, activity for omadacycline as evaluated by dry form microdilution and frozen form panels (2014) remained essentially unchanged between 2010 and 2014, with MIC<sub>50</sub> / MIC<sub>90</sub> of 0.12/0.12 µg/mL, respectively in 2014 and 0.12/0.25 for 2010. *S. aureus* susceptibility to other agents varied. These results demonstrate activity and indicate that omadacycline warrants further study, particularly where resistance is an issue.

### Select Study Results: Activity Against *S. pneumoniae*

- Omadacycline and comparator agents were tested against *Streptococcus pneumoniae* (SPN) samples selected from a 2014 global surveillance program and compared to the results of a 2010 surveillance program.
- Approximately 300 isolates from Europe and North America were selected for susceptibility testing using omadacycline and commonly-prescribed comparator agents.
- Activity for omadacycline MIC<sub>50</sub> / MIC<sub>90</sub> as evaluated by frozen form panels in 2014 was 0.06/0.06 µg/mL, respectively; results were similar to 2010, regardless of whether the pathogen was penicillin-susceptible, penicillin-resistant, or multidrug resistant. Resistance and co-resistance to other agents was common.
- In a separate *in vitro* study, results indicate that omadacycline activity against *Legionella pneumophila* remained unchanged between 1995 – 2005 and 2006 – 2014 isolates, suggesting potential use against these infections.

### Select Study Results: Activity Against *Enterobacteriaceae*

- Omadacycline and comparators were tested against *Enterobacteriaceae* (EB) from urinary tract infection (UTI) selected from a 2014 global surveillance program and compared to results of testing isolates causing UTI (urinary or bloodstream) from 2010 surveillance.
- Approximately 300 EB identified as causing UTI from Europe and North America (151 from Europe and 150 from North America) were selected for susceptibility testing against omadacycline and comparators.
- Omadacycline activity was similar between 2010 and 2014: Omadacycline MIC<sub>50</sub> / MIC<sub>90</sub> for EB collected in 2014 was 2 and ≥ 8 µg/mL, respectively and for *E. coli* was 1 and 2 µg/mL similar to 2010 (MIC<sub>50</sub> / MIC<sub>90</sub> , 0.5 and 2 µg/mL), warranting further study.

## Select Study Results for *In Vitro* Testing

- Guidance is provided for the quality control of *in vitro* susceptibility testing of omadacycline in accordance with the guidelines of CLSI by dilution MIC and disk diffusion.

## 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 a first-in-class aminomethylcycline, derived from tetracyclines. Paratek has initiated a Phase 3 registration trial in ABSSSI to determine the efficacy and safety of omadacycline compared to linezolid. A second Phase 3 registration trial in CABP to determine the efficacy and safety of omadacycline compared to moxifloxacin is planned to be initiated before the end of 2015.

Omadacycline is a first-in-class 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.

Paratek's second product candidate, sarecycline, also known as WC 3035, is a first-in-class once-daily oral tetracycline-derived compound, designed to provide both a narrow-spectrum of antibiotic activity and favorable tolerability profile, for the treatment of acne and rosacea in the community setting. Paratek has licensed rights to sarecycline for the treatment of acne in the United States to a subsidiary of Allergan, formerly Warner Chilcott, while retaining development and commercialization rights in the rest of the world. Allergan is responsible for the clinical development of sarecycline for the treatment of acne in the United States. A Phase 3 program was initiated by Allergan in December 2014 for sarecycline for the treatment of moderate to severe inflammatory acne.

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

## Forward Looking Statements

The statements in this press release regarding the potential utility of omadacycline as an oral and IV monotherapy agent for the treatment of CABP, Paratek's belief that omadacycline has potential to be developed for clinical use as a monotherapy treatment option for serious community-acquired infections where resistance is of concern, and the planned timing of a second Phase 3 registration trial in CABP with omadacycline, are forward-looking statements. These forward-looking statements are based upon Paratek's current expectations and involve substantial risks and uncertainties. Paratek may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in these forward-looking statements and investors should not place undue reliance on these forward-looking statements. 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, which include, without limitation, risks related to (i) Paratek's need for substantial additional funding to

complete the development and commercialization of omadacycline, (ii) Paratek's ability to raise the capital to do so, (iii) risks that data to date and trends may not be predictive of future results, (iv) risks related to the conduct of Paratek's clinical trials, and (v) risks that Paratek's clinical trials and product candidates do not receive regulatory approval. 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.

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