



## **Paratek Pharmaceuticals and Zai Lab Announce Collaboration, Development and License Agreement for Omadacycline in China**

April 25, 2017

BOSTON, April 24, 2017 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK), a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon tetracycline chemistry, today announced that it has entered into a collaboration with Zai Lab (Shanghai) Co., Ltd., a biopharmaceutical company based in China, to support the development and commercialization of omadacycline for patients in China.

Under the agreement, Paratek has granted to Zai Lab an exclusive license to develop, manufacture and commercialize omadacycline for the greater China territory, specifically the People's Republic of China, Hong Kong, Macau, and Taiwan markets. The companies will establish a joint steering committee to review and oversee all development, manufacturing, and commercialization plans. Paratek will receive a \$7.5 million upfront payment in connection with the signing of the agreement and is eligible for additional milestone payments related to development, regulatory, and commercial milestones. In addition, Paratek will be eligible to receive royalty payments on sales of omadacycline in the territory.

"Our successful Phase 3 efficacy studies in both skin infections and pneumonia demonstrate the potential of omadacycline to be a promising new therapeutic option for the treatment of patients with serious bacterial infections," said Michael Bigham, Chairman and CEO of Paratek. "This agreement with Zai Lab further validates that potential, and represents an exciting step toward making omadacycline available to the many patients in the greater China territory where there is a proven need for a new, effective, well-tolerated, IV and once-daily oral, broad-spectrum antibiotic, particularly when resistance is of concern."

Samantha Du, Chairman and CEO of Zai Lab, added, "We are very pleased to partner with Paratek to potentially bring omadacycline to Chinese patients. It is estimated that per capita use of antibiotics in China is significantly higher than that in the United States. Consequently, antibiotic resistance is becoming an increasing and severe problem for China. Based on the data generated by Paratek to date, we believe omadacycline has the potential to be a valuable new tool for physicians in China as they try to combat the growing antibiotic resistance problem."

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.

### **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. 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 (ABSSSI) demonstrating the efficacy, 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 (CABP) demonstrating the efficacy, 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. Top-line data from this study are expected as early as the end of June. 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 urinary tract infections (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.

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](http://www.paratekpharma.com).

#### **About Zai Lab**

Zai Lab is a Shanghai-based innovative biopharmaceutical company. The company's globally-experienced drug development team is passionate about bringing transformative medicines to China and discovering and developing novel therapeutics for patients worldwide. The vision at Zai Lab is to create a premier drug discovery, development, manufacturing and commercialization organization built on a foundation of world-class expertise and insights into the existing and expanding needs of Chinese patients. Zai Lab has a team of leaders who have a collective track record in all aspects of our business, including pioneering success in the regulatory process in China. The company has assembled a pipeline of potential best-in-class and first-in-class in China biopharmaceuticals at different stages of development by securing partnerships with leading multinational pharmaceutical and highly innovative biotechnology companies.

For more information, please visit [www.zailaboratory.com](http://www.zailaboratory.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 development, manufacturing and commercialization of omadacycline for the greater China territory, 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, the timing of NDA and EMA submissions, 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," "anticipate," "continue," 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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