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Paratek Pharmaceuticals Signs Worldwide License and Commercialization Agreement for PTK 0796, Broad-Spectrum Oral and IV Antibiotic in Phase 3

BOSTON, Oct. 8 /PRNewswire-FirstCall/ -- Paratek Pharmaceuticals, Inc. announced today that it has entered into an exclusive worldwide collaborative development, manufacturing and commercialization license agreement with Novartis for Paratek's lead broad-spectrum antibiotic, PTK 0796, a first-in-class aminomethylcycline (AMC) in Phase 3 clinical trials. PTK 0796 is the most advanced once-daily, oral and IV antibiotic with a spectrum that is broad enough for single-agent treatment of life threatening infections such as complicated skin and skin structure infections (cSSSI) and moderate to severe community acquired bacterial pneumonia (CABP), with activity against resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA), multi-drug resistant *Streptococcus pneumoniae* (MDRSP) and vancomycin-resistant *enterococci* (VRE).

Under the terms of the agreement, Novartis and Paratek will share responsibility and costs for worldwide development of PTK 0796, while Novartis will have the exclusive right to commercialize PTK 0796 on a worldwide basis. Paratek will be eligible to receive up to \$485 million in payments, which include up-front and future milestone payments, and will also receive a royalty on net sales of PTK 0796 around the world.

"We are pleased to announce our collaboration with Novartis, which will allow us to develop and commercialize a significant advance in the treatment of resistant infections that are found in community and hospital in an expeditious manner," said Thomas J. Bigger, President and CEO of Paratek Pharmaceuticals. "PTK 0796 is the only once-daily, oral and IV MRSA-active compound in clinical development with a spectrum broad enough for single-agent treatment of cSSSI and CAP. This deal will also help us to bring PTK 0796 to the market without the need for additional financing in this currently challenging and unpredictable economic environment."

Wedbush PacGrow Life Sciences acted as an advisor to Paratek Pharmaceuticals in this transaction.

More on PTK 0796 and Bacterial Resistance

PTK 0796 was developed to address the growing problem of bacterial resistance to currently available antibiotics. In a study published in the Journal of the American Medical Association (JAMA), Dr. Monina Klevins and her colleagues found that invasive MRSA infections, an unfortunate complication of serious infections such as cSSSI, led to a projected 18,650 deaths in the U.S. in 2005; this is more than HIV/AIDS and tuberculosis combined. MRSA is just one example among several where bacteria have developed resistance during decades of antibiotic use, so that many of the standard antibiotic regimens relied upon until very recently are no longer effective, while the pipeline of replacement products that target antibiotic resistance is remarkably thin.

PTK 0796 represents a new class of antibiotics that has shown potent, broad-spectrum activity against multi-drug resistant and susceptible Gram-positive bacteria, Gram-negative, anaerobic and atypical bacteria. PTK 0796 has shown favorable safety and tolerability in more than a dozen clinical studies and more than 500 subjects and offers the convenience of a once-daily 30 minute IV infusion or pill treatment. Paratek and Novartis are developing PTK 0796 as a single-agent antibiotic therapy with IV/oral step-down option for the leading infections requiring hospitalization, such as cSSSIs and moderate to severe community-acquired bacterial pneumonia (CABP).

Prior to Phase 3 studies, Paratek conducted a Phase 2 study in cSSSI of a similar design with more than 200 patients. Positive results of this study were presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) last Fall. The Phase 2 study met its primary safety and tolerability endpoint, demonstrating no relevant differences between PTK 0796 and Zyvox® in incidence or pattern of adverse events (AEs). In the clinically evaluable population of patients (N=188), the clinical success rates were 98.0% and 93.2% for PTK 0796 and Zyvox®, respectively.

About Paratek Pharmaceuticals

Paratek Pharmaceuticals, Inc. is engaged in the discovery and commercialization of new therapeutics that treat serious and life-threatening diseases, with a particular focus on the growing worldwide problem of antibiotic resistance. Paratek is advancing novel compounds that can circumvent or block bacterial resistance involving technology initially developed by Paratek co-founder Dr. Stuart Levy's laboratory at Tufts University School of Medicine, and licensed to Paratek. Paratek's lead compound, PTK 0796, is a broad-spectrum antibiotic derived from the tetracycline class with oral and IV formulations that are being developed for the treatment of the most common and serious hospital and community bacterial infections. PTK 0796 was previously

licensed to Merck & Co., Inc. until this arrangement ended in 2007. Oral and IV formulations of PTK 0796 are being compared to Zyvox® in Phase 3 clinical studies to treat cSSSIs. Phase 3 studies in additional indications such as CABP are planned.

Outside of its tetracycline antibacterial program, Paratek has also identified small molecules that inhibit bacteria-specific transcription factors for Multiple Adaptational Response (MAR) genes which control bacterial virulence and resistance development.

Paratek is privately held and headquartered in Boston, Massachusetts, U.S. For more information about Paratek and its research and development initiatives, visit Paratek's website at <http://www.paratekpharm.com>.

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