



Paratek Reports Positive Phase 2 Clinical Data on its New Antibiotic PTK 0796 in Late Breaker Presentation at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy

BOSTON, Oct. 26 /PRNewswire/ -- Paratek Pharmaceuticals, Inc. today announced positive Phase 2 data for the Company's lead antibiotic, PTK 0796, a first-in-class aminomethylcycline (AMC). The Phase 2 study compared safety and efficacy of oral and intravenous (IV) forms of PTK 0796 to Zyvox(R) in the treatment of patients with complicated skin and skin structure infections (cSSSIs). Paratek's trial met its primary safety and tolerability endpoint, demonstrating no differences between PTK 0796 and Zyvox in incidence or pattern of adverse events (AEs). Of note, no patients discontinued therapy with PTK 0796 because of AEs, and no drug-related serious adverse events (SAEs) were seen for either drug. 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. The Phase 2 data are being reported and discussed today at a press briefing at 10:00 a.m. and in a Late Breaker poster presentation at 12:15 p.m. at the 48th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), taking place in Washington, D.C.

Paratek's U.S.-based Phase 2 multi-center, randomized (1:1), investigator-blinded, comparative trial enrolled 234 patients with cSSSI who required initial IV therapy. Patients were randomized to receive up to 14-days of therapy of either PTK 0796 (100mg once-daily IV with 200mg once-daily oral step-down) or Zyvox (600mg twice-daily IV with 600mg twice-daily oral step-down).

Dr. Stuart Levy, Co-founder and Chief Scientific Officer of Paratek Pharmaceuticals, stated, "New antibiotics are critically needed as multi-drug resistance grows at alarming rates in both the hospital and community settings. The Phase 2 results for Paratek's PTK 0796 are highly encouraging, particularly in context with previous findings showing activity of PTK 0796 against a broad spectrum of drug resistant bacteria, including MRSA. Overall, the Phase 2 data indicate a convincing safety profile and promising clinical outcomes comparable to other antibiotics either on the market or in development. What is most encouraging about PTK 0796 is that it is the first broad-spectrum antibiotic with activity against MRSA that will have the oral and IV formulations needed for seamless transition of treatment from the hospital out into the community. I look forward to continued progress of this program."

PTK 0796 represents a new class of antibiotics that has shown potent, broad-spectrum activity against multi-drug resistant and susceptible Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), as well as Gram-negative, anaerobic and atypical bacteria. Paratek is developing PTK 0796 as a firstline agent for empiric therapy for the leading infections requiring hospitalization, such as cSSSIs and moderate to severe community-acquired pneumonia (CAP).

Thomas J. Bigger, Paratek's President and CEO, stated, "PTK 0796 is the only once-a-day, oral and IV MRSA-active compound in development with a spectrum broad enough

for single agent treatment of cSSSI and CAP. These attributes have generated great enthusiasm and interest among investigators planning to participate in our Phase 3 program. We expect to initiate our pivotal Phase 3 trials in the U.S. and overseas for the treatment of cSSSI patients, including those with diabetic foot infections, in the first quarter of 2009. We are thrilled by the rapid advancement of these efforts and by the ability to present our Phase 2 results at the leading infectious diseases conference.”

Background on Aminomethylcyclines (AMCs)

Using Paratek's novel medicinal chemistry techniques, AMCs were evolved from tetracycline antibiotics as potential agents to combat multiple antibiotic-resistant bacteria, including MRSA, penicillin-resistant *Streptococcus pneumoniae* (PRSP), vancomycin-resistant *Enterococcus* (VRE), multidrug resistant *Escherichia coli* and other difficult-to-treat pathogens. Introduced more than 50 years ago, tetracyclines remain among the most commonly used anti-infective agents to combat bacterial infections. However, the emergence of resistance has curtailed their effectiveness in certain infections. Paratek has utilized its expertise to create AMC compounds, such as PTK 0796, that retain the appealing safety and spectrum of activity of the tetracyclines while overcoming tetracycline and multi-drug resistance.

Representing one of the top therapeutic categories, the antibiotics market generates worldwide sales of over \$26 billion, despite the availability of low-priced generic products for many infections. In recent years, eight antibiotics have attained annual sales of more than \$1 billion each. The growing medical problem of drug-resistant bacteria presents a new and expanding market opportunity. Bacterial resistance is causing many of the current antibiotics to lose efficacy, while the pipeline of replacement products that target antibiotic resistance is remarkably thin.

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. Paratek's lead compound, PTK 0796, is a broad-spectrum antibiotic derived from the tetracycline class with oral and IV formulations that is being developed for the treatment of the most common and serious hospital bacterial infections, including those caused by resistant strains such as MRSA (methicillin-resistant *Staphylococcus aureus*) and MDRSP (multi-drug resistant *Streptococcus pneumoniae*). Oral and IV formulations of PTK 0796 were compared to Zyvox® in a recently completed Phase 2 clinical study in complicated skin and skin structure infections (cSSSIs). In addition to PTK 0796, Paratek is also developing other broad- and narrow-spectrum tetracycline antibiotics to treat hospital and community infections based on its novel tetracycline chemistry expertise.

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.

Based upon a growing body of clinical research and as part of its effort to exploit its novel tetracycline derivatives and their unique mechanism of action in selected inflammatory and neurodegenerative conditions, Paratek has an active chemical synthesis effort to produce novel and diverse small molecules, with the goal of developing nonantibacterial compounds with improved activity in serious inflammatory

and neurodegenerative diseases. In addition, Paratek is encouraged by early evidence of the ability of tetracycline derivatives to affect mRNA splicing, as in spinal muscular atrophy (SMA), which may also have activity in related orphan genetic disorders, such as cystic fibrosis and Duchenne Muscular Dystrophy.

Paratek has active collaborations with Merck & Co., MerckSerono, Warner Chilcott and FSMA to develop tetracycline-derived small molecule drugs for a range of uses, including community-acquired bacterial infections, multiple sclerosis (MS), acne & rosacea, and SMA. 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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