



## **Paratek Pharmaceuticals Announces FDA Grant of Qualified Infectious Disease Product (QIDP) Designation for Its Lead Product Candidate, Omadacycline**

### **- QIDP Status Designated for Both Intravenous and Oral Formulations -**

**BOSTON, January 3, 2013 --** Paratek Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has designated the Company's lead antibiotic candidate, omadacycline (formerly known as PTK 0796), as a Qualified Infectious Disease Product (QIDP) for both intravenous (IV) and oral formulations in the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP). The QIDP designation provides Paratek access to certain incentives, including priority review associated with a New Drug Application (NDA) submission, eligibility for fast-track status for smaller population studies targeting certain resistant organisms, and a five-year extension of exclusivity under the Hatch-Waxman Act upon FDA approval of omadacycline.

The QIDP designation is provided under the Generating Antibiotic Incentives Now Act (GAIN Act), which was enacted in July 2012 under the Food and Drug Administration Safety and Innovation Act (FDASIA), formerly known as Prescription Drug User Fee Act V (PDUFA V).

Paratek has completed clinical studies necessary to advance oral and IV formulations of omadacycline into Phase 3 development. These studies will be conducted under two Special Protocol Assessment, or SPA, agreements, one in ABSSSI and one in CABP. Paratek is currently planning additional studies of omadacycline for the urinary tract infection (UTI) indication.

### **About Paratek Pharmaceuticals**

Paratek is a pharmaceutical company focused on the discovery, development, and commercialization of innovative medicines. The Company's lead product candidate, omadacycline, is a new tetracycline-derived, broad-spectrum antibiotic being developed for use as a first-line monotherapy for acute bacterial skin and skin structure infections (ABSSSI), community-acquired bacterial pneumonia (CABP), urinary tract infections (UTI) and other serious community-acquired bacterial infections.

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