



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

- QIDP Status Designated for complicated Urinary Tract Infections (cUTI)

BOSTON, May 1, 2013 --Paratek Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has designated the Company's lead antibiotic candidate, omadacycline, as a Qualified Infectious Disease Product (QIDP) for the treatment of complicated Urinary Tract Infections (cUTI). This QIDP designation is applicable for both intravenous (IV) and oral formulations of omadacycline.

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. This designation is in addition to that announced by Paratek on January 3, 2013 granting QIDP status for IV and oral formulations of omadacycline for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP).

The QIDP designation, which the Company believes is a first for an orally available antibiotic for the treatment of cUTI, 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). Experts have noted that there is a serious unmet need for new oral antibiotics to treat multi-drug resistant (MDR) bacteria such as *E. coli* that occur in cUTI and other infections. In studies conducted to date, omadacycline achieves high concentrations in the urinary tract following oral dosing and retains activity against MDR *E. coli* and other bacteria common to community-acquired cUTI. Paratek plans to conduct a cUTI Phase 2 clinical study with omadacycline.

Paratek has completed clinical studies necessary to advance its commercial-ready oral and IV formulations of omadacycline into Phase 3 development. As previously announced, Paratek has obtained two Special Protocol Assessment, or SPA, agreements, one in ABSSSI and one in CABP for omadacycline.

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.

CONTACT: Kathryn M. Boxmeyer, Vice President & CFO, Paratek Pharmaceuticals, Inc., +1-617-275-0040 ext. 238, kboxmeyer@paratekpharm.com; <http://www.pاراتekpharm.com>