Paratek Completes Submission of New Drug Applications to U.S. Food and Drug Administration for Oral and Intravenous Omadacycline for Pneumonia and Skin Infections

February 5, 2018

BOSTON, Feb. 05, 2018 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK) announced today that on February 2, 2018, it completed the submission of two New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for the Company's once-daily oral and IV formulations of its broad-spectrum investigational antibiotic, omadacycline. Omadacycline is the first in a new class of tetracycline antibiotics known as aminomethylcyclines. Paratek is seeking FDA approval for omadacycline for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI), based on the results of three successful Phase 3 pivotal studies. The FDA has previously granted omadacycline both Qualified Infectious Disease Product and Fast Track designation for these indications, which provide for a Priority Review of the NDAs, once accepted.

"The completion of our NDA submissions marks a significant milestone for Paratek and we are deeply grateful to the patients, investigators, and entire Paratek team for their commitment to advancing omadacycline's development path to this major milestone," said Evan Loh, MD, President, COO & CMO of Paratek. "With antibiotic resistance on the rise, we look forward to working with the FDA during the regulatory review process with the goal of bringing a modernized tetracycline antibiotic, omadacycline, to clinicians and patients for the treatment of serious community-acquired bacterial infections."

The NDAs are supported by the Company's Phase 3 program for omadacycline, which includes three pivotal registration trials: two studies in ABSSSI and one study in CABP. Omadacycline met all FDA and European Medicines Agency (EMA) primary endpoints in each study and demonstrated a generally safe and well-tolerated profile.

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. The Company's lead product candidate, omadacycline, is a new, once-daily oral and intravenous broad-spectrum antibiotic being developed for the treatment of serious community-acquired bacterial infections, including community-acquired bacterial pneumonia (CABP), acute bacterial skin and skin structure infections (ABSSSI), and urinary tract infections. Omadacycline has been granted Qualified Infectious Disease Product designation and Fast Track status by the U.S. Food and Drug Administration (FDA) for the target indications of ABSSSI, CABP, uUTI and cUTI. Paratek has completed Phase 3 development activities for omadacycline in CABP and ABSSSI and has completed its New Drug Applications to the U.S. FDA and is preparing a marketing authorization in the European Union. Paratek has licensed rights for omadacycline to Zai Lab for the greater China region and retains all remaining global rights.

Under a research agreement with the U.S. Department of Defense, omadacycline also is being studied against pathogenic agents causing infectious diseases of public health and biodefense importance, including plague and anthrax.

Paratek's second Phase 3 product candidate, Seysara™ (sarecycline), is being developed by Allergan in the U.S. as a new once-daily oral therapy for the treatment of acne. Allergan has completed Phase 3 development activities for Seysara and its new drug application was accepted for review by the U.S. FDA in December 2017. Paratek retains all ex-U.S. rights to sarecycline.

Recognizing the serious threat of bacterial infections, Paratek is dedicated to providing solutions that enable positive outcomes and lead to better patient stories.

For more information, visit www.ParatekPharma.com or follow @ParatekPharma on Twitter.

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