Paratek Pharmaceuticals Announces Positive Top-line Efficacy and Safety Data from Post-Marketing Study of NUZYRA® (omadacycline) for Patients with Moderate to Severe Community-Acquired Bacterial Pneumonia

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- *Met all Primary and Secondary Efficacy Endpoints and Was Generally Safe and Well-Tolerated*
- *Largest Clinical Data Set in Pneumonia for Any Antibiotic Approved in the Last Decade*
- ***Label Update Discussions with FDA to Begin as Early as 4Q2024***

BOSTON, July 18, 2024 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc., a biopharmaceutical company focused on providing innovative medical therapies that create positive patient stories in the hospital, community and public health settings, today released positive top-line results from a global, Phase 3 post-marketing commitment study comparing its once-daily oral and IV, broad-spectrum antibiotic NUZYRA® (omadacycline) to moxifloxacin in the treatment of patients with moderate to severe community-acquired bacterial pneumonia (CABP).

Results from this double-blind study of moderate to severe CABP patients (n = 670 patients; PORT Risk Class III or IV) are consistent with findings from the pivotal Phase 3 study “Omadacycline for Pneumonia Treatment in the Community” (OPTIC; n = 774 adults; PORT Risk II, III, IV), which supported approval of NUZYRA for CABP by the U.S. Food and Drug Administration (FDA) and which was published in *The New England Journal of Medicine* in 2019.

“This study provides additional data confirming NUZYRA as an effective and well-tolerated treatment option for community-acquired bacterial pneumonia, a serious respiratory illness with significant impact to morbidity and mortality in the United States,” said Randy Brenner, chief development and regulatory officer of Paratek. “With the completion of this post-marketing study, our clinical study database now includes data from 1,438 pneumonia patients and is the largest clinical trial dataset in pneumonia across all antibiotics approved by the FDA in the last decade. We believe these data support a near-term opportunity to update the current American Thoracic Society/Infectious Diseases Society of America CAP guidelines. We are extremely grateful to the patients, investigators, Paratek team, and our partners for their commitment to this study. We intend to submit the study report to the FDA and engage in label update negotiations later this year.”

Study Design and Top-Line Findings
The global, Phase 3 clinical study known as OPTIC-2 (Omadacycline for Pneumonia Treatment in the Community-2), compared the efficacy and safety of once-daily, IV-to-oral omadacycline to IV-to-oral moxifloxacin for treating adults with moderate to severe CABP. In the study, 670 patients were randomized. Omadacycline met the FDA-specified primary endpoint of statistical non-inferiority (NI) in the intent-to-treat (ITT) population (10% NI margin, 95% confidence interval) compared to moxifloxacin at the early clinical response (ECR) timepoint (72-120 hours after initiation of therapy). High rates of clinical success were observed with ECR rates of 89.6 % and 87.7%, for the omadacycline and moxifloxacin treatment arms, respectively. Omadacycline also met all FDA-specified secondary endpoints, achieving non-inferiority vs moxifloxacin at the post-treatment evaluation (PTE) visit 5-10 days after the completion of therapy in both the ITT population (86.0% for omadacycline vs. 87.7% for moxifloxacin) and in the clinically evaluable (CE) population (94.1% for omadacycline vs. 95.9% for moxifloxacin) as determined by investigators. Efficacy results were consistent across study populations, PORT Risk Class and causative pathogen.

In the study, omadacycline was generally safe and well-tolerated, consistent with prior studies of omadacycline and the current FDA prescribing information for NUZYRA. The most common treatment emergent adverse events (TEAEs) in omadacycline-treated patients (occurring in > 2% of patients) were headache (3.6% with omadacycline vs. 4.5% with moxifloxacin), COVID-19 (3.3% with omadacycline vs. 1.2% with moxifloxacin) and AST increase (2.1% with omadacycline vs. 0.0% with moxifloxacin). Gastrointestinal adverse events of interest were rare and infrequent for omadacycline vs. moxifloxacin and included: vomiting (0.0% vs. 0.3%), nausea (0.6% vs. 1.5%), and diarrhea (0.0% vs. 3.0%). There were no cases of clostridium difficile colitis or infection in either treatment group. Rates of TEAEs were 27.7% for omadacycline vs. 23.5% for moxifloxacin. Drug-related TEAEs were 2.7% for omadacycline vs. 6.9% for moxifloxacin. Discontinuation due to TEAEs was uncommon, 2.7% for both omadacycline and moxifloxacin. The overall mortality rate was 1.8 % and balanced with six deaths in each treatment arm.

Results of this study will be submitted for publication and for presentation at an upcoming scientific congress.

The study has been supported in whole or part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under contract number 75A50120C00001.

About Paratek Pharmaceuticals, Inc.
Paratek Pharmaceuticals, Inc. is a commercial-stage biopharmaceutical company focused on providing innovative medical therapies that create positive patient stories in the hospital, community and public health settings.

The company's lead commercial product, NUZYRA® (omadacycline), is a once-daily oral and intravenous antibiotic available in the United States for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). Paratek has a collaboration agreement with Zai Lab Limited for the development and commercialization of omadacycline in the greater China region and retains all remaining global rights. Zai Lab received approval of both IV and oral NUZYRA as a Category 1 innovative drug by the National Medical Products Administration of China for the treatment of CABP and ABSSSI in December 2021. Paratek is also conducting a Phase 2b study with

NUZYRA in a rare disease, non-tuberculous mycobacterial (NTM) pulmonary disease, caused by *Mycobacterium abscessus* complex.

In December 2019, BARDA awarded Paratek a contract that is now valued at up to approximately $304 million. In addition to supporting the development of NUZYRA for both the treatment and prophylaxis of pulmonary anthrax, this contract supports the U.S. onshoring of NUZYRA and manufacturing security requirements; FDA post-marketing requirements associated with the initial NUZYRA approval; and the procurement of up to 10,000 treatment courses of NUZYRA for the treatment of anthrax.

For more information, visit www.ParatekPharma.com or follow us on LinkedIn and X.

About NUZYRA®

NUZYRA® (omadacycline) is a novel antibiotic with both once-daily oral and intravenous (IV) formulations for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). A modernized tetracycline, NUZYRA is specifically designed to overcome tetracycline resistance and exhibits activity across a spectrum of bacteria, including Gram-positive, Gram-negative, atypicals and other drug-resistant strains.

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