Paratek Pharmaceuticals' NUZYRA® Receives FDA Fast Track Designation for the Treatment of Pulmonary Nontuberculous Mycobacterial (NTM) Disease Caused by Mycobacterium Avium Complex (MAC) and Mycobacterium Abscessus (MAB)

-- Phase 2b Study in MAB Pulmonary Infections Ongoing and Enrolling as Planned

-- Nonclinical Studies in MAC Initiating

BOSTON, June 21, 2022 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq: PRTK) today announced the U.S. Food and Drug Administration has granted Fast Track designation for the oral and IV formulations of the company's novel, broad-spectrum antibiotic NUZYRA® (omadacycline) for the treatment of pulmonary Nontuberculous Mycobacterial (NTM) disease caused by both *Mycobacterium avium* complex (MAC) and *Mycobacterium abscessus* (MAB). These NTM indications are rare diseases for which new therapies are desperately needed. FDA granted NUZYRA orphan drug designation for these infections in August 2021.

Fast Track is a process designed to facilitate the development and expedite the review of new medicines intended to treat or prevent serious conditions and address significant unmet medical needs.

"Fast Track designation opens the door to more frequent dialogue with the FDA and the opportunity to expedite development of NUZYRA as an option to help patients with NTM pulmonary disease and health providers who struggle to manage these devastating lung infections because of significant antimicrobial resistance or considerable tolerability challenges associated with many of the treatments used for NTM," said Randy Brenner, chief development and regulatory officer of Paratek. "We look forward to growing the body of scientific evidence in NTM with the continued enrollment in our Phase 2b MAB study and the initiation of nonclinical studies in MAC and continue to believe NUZYRA has the potential to address important unmet medical needs for patients with infections caused by these species of NTM."

In the United States alone, currently NTM pulmonary infections caused by MAB affect approximately 11,500 patients while an estimated 100,000 cases are caused by MAC. Patients exhibit a myriad of symptoms including severe fatigue, fever, cough and shortness of breath. The standard of care typically involves a combination of multiple antibiotics, many of which are intravenous only, and are not approved for this disease. Treatment can often be life-long in duration and complicated by long-term tolerability challenges and multiple adverse events.

Clinical study of NUZYRA in NTM
Paratek initiated patient enrollment last October for a U.S.-based Phase 2b randomized, placebo-controlled monotherapy study to evaluate the safety and efficacy of NUZYRA in patients with NTM pulmonary disease caused by MAB.

The study will enroll approximately 75 patients who are not receiving other antibiotic treatments for their NTM pulmonary disease, randomized in a 1.5 to 1 ratio. The primary study endpoints are improvement in symptoms and safety and tolerability following 12 weeks of treatment. Enrollment has progressed as planned and Paratek continues to expect that the study will take approximately two years to complete due to the small numbers of patients with this rare disease. More information can be found at clinicaltrials.gov under the study ID number NCT04922554.

About Paratek Pharmaceuticals, Inc.
Paratek Pharmaceuticals, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel life-saving therapies for life-threatening diseases or other public health threats for civilian, government and military use.

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 for the development and commercialization of omadacycline in the greater China region and retains all remaining global rights.

As noted above, Paratek is conducting a Phase 2b study with NUZYRA in a rare disease, non-tuberculous mycobacterial (NTM) pulmonary disease caused by MAB. Paratek estimates this opportunity represents a potential $1 billion addressable market in the United States.

Paratek exclusively licensed U.S. rights and rights to the greater China territory for SEYSARA® (sarecycline), a once-daily oral therapy for the treatment of moderate to severe acne vulgaris, to Almirall, LLC. Paratek retains the development and commercialization rights for sarecycline in the rest of the world.

In 2019, Paratek was awarded a contract from the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA), now valued at up to $304 million, to support the development and U.S.-based manufacturing of NUZYRA for pulmonary anthrax.

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

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.

Forward Looking Statements

This press release contains forward-looking statements, including statements about our expectations regarding NUZYRA's potential utility to meet the unmet need in NTM, the status of our Phase 2b NTM MAB study and the potential market opportunity of NTM.

All statements, other than statements of historical facts, included in this press release are forward-looking statements, and are identified by words such as "advancing," "expect," "look forward," "anticipate," "continue," and other words and terms of similar meaning. These forward-looking statements are based upon our current expectations and involve substantial risks and uncertainties. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Our actual results and the timing of events could differ materially from those included in such forward-looking statements as a result of these risks and uncertainties. These and other risk factors are discussed under "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2021 and our other filings with the Securities and Exchange Commission. We expressly disclaim any obligation or undertaking to update or revise any forward-looking statements contained herein.

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