Paratek Pharmaceuticals Announces Initiation of Phase 2b Study in Nontuberculous Mycobacterial (NTM) Pulmonary Disease Caused by Mycobacterium abscessus Complex (MABc) with NUZYRA® (omadacycline)

June 16, 2021

-- U.S.-Based Sites Ready to Begin Enrolling Patients, Placebo-Controlled Study Evaluating NUZYRA Efficacy at 12 Weeks of Treatment

-- Potential $1.0 Billion Addressable Market Opportunity in the U.S. Based on Company Estimates

-- Paratek Hosting Investor Webinar with Corporate Updates and Key Opinion Leader and Patient Advocate Presentations on NTM abscessus today, June 16, 2021 at 10:00am ET

-- Company Providing Update on the Expected Timing of the Second Procurement under the BARDA Project BioShield Agreement

BOSTON, June 16, 2021 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq: PRTK), 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, today announced the initiation of clinical trial sites for the Company's Phase 2b study exploring the potential utility of NUZYRA® (omadacycline) as a treatment for Nontuberculous Mycobacterial (NTM) Pulmonary Disease caused by *Mycobacterium abscessus* complex (MABc).

Pulmonary infections caused by MABc, an orphan disease with no FDA-approved antibiotic therapies, affects approximately 11,500 patients in the U.S. Patients with pulmonary disease caused by *M. abscessus* have a myriad of symptoms including severe fatigue, fever, cough and shortness of breath. The standard of care typically involves a combination of multiple antibiotics, which can often be life-long in duration and complicated by long-term tolerability challenges and multiple adverse events.

"Physicians have continued to highlight the clinical unmet need for an efficacious and well-tolerated oral antibiotic to treat infections caused by *M. abscessus*. With its once-daily, oral, broad-spectrum profile, NUZYRA has significant potential to address important unmet medical needs in the treatment of *M. abscessus* pulmonary disease, which represents an important life-cycle opportunity for NUZYRA," said Randy Brenner, Chief Development and Regulatory Officer of Paratek. "We are excited to begin this Phase 2b study, which we believe will build upon the expanding and compelling real-world data seen to date examining the potential efficacy of NUZYRA in *M. abscessus* pulmonary disease."

About the Study
The Phase 2b study is a placebo-controlled, randomized monotherapy study of *M. abscessus* pulmonary disease in patients in the early treatment phase who are not receiving other treatments. The U.S.-based study will enroll approximately 75 subjects, 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. Due to the small numbers of patients with this rare disease, Paratek expects the study will take about two years to complete enrollment.

More information can be found at clinicaltrials.gov under the study ID number (NCT04922554).

Paratek Pharmaceuticals Hosting Investor Webinar Today
Paratek will host a conference call that will include a corporate update, key opinion leader (KOL) update on NTM, specifically *M. abscessus*, and future development opportunities today, Wednesday, June 16, 2021 at 10:00am Eastern Time.

The webinar will feature a presentation by Kevin L. Winthrop, M.D., M.P.H., Professor of Infectious Disease at Oregon Health & Science University, and Amy Leitman, President of NTM Info & Research, a nonprofit advocacy group for patients with nontuberculous mycobacterial disease, who will discuss NTM, the current treatment landscape, the unmet medical need and the disease's impact on patients and their families.

NUZYRA is a novel antibiotic FDA approved 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.

To register for the event, please click here. The live audio webcast and replay can be accessed under "Events and Presentations" in the Investor Relations section of Paratek's website at www.ParatekPharma.com.

BARDA Project BioShield Procurement Update
The Company recently announced that the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), initiated the first procurement of NUZYRA valued at ~$38 million. This procurement has been delivered and we are in the final stages of completing the activities required for BARDA to take title of the product.

Paratek and BARDA are engaged in ongoing discussions regarding the timing of the second and future procurements under the Project BioShield Agreement. As a result of these discussions, the timing of future procurements and the definition of progress of the program will be linked to specific development milestones. Paratek now anticipates securing the second procurement in the second half of 2022. Accordingly, the Company has removed approximately $38 million associated with the second procurement from its 2021 revenue expectations.

The revised timing of the second procurement is not expected to impact the Company's previously stated cash runway guidance. Based upon the Company's current operating plan, Paratek anticipates its existing cash and cash equivalents will provide for a cash runway through the end of 2023

with a pathway to cash flow break even.

This Project BioShield project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00001.

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 U.S. for the treatment of adults with community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. 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.

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.

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 (Almirall). Paratek retains the development and commercialization rights for sarecycline in the rest of the world.

In 2019, Paratek was awarded a contract from BARDA, valued at ~$285 million, to support the development and U.S.-based manufacturing of NUZYRA for the treatment of pulmonary anthrax.

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

Indications and Usage
NUZYRA is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

Community-Acquired Bacterial Pneumonia (CABP) caused by the following: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by the following: Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae.

Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Important Safety Information

Contraindications
NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline class antibacterial drugs, or to any of the excipients.

Warnings and Precautions
Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients > 65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

The use of NUZYRA during tooth development (last half of pregnancy, infancy and childhood to the age of eight years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of eight years may cause reversible inhibition of bone growth.

Hypersensitivity reactions have been reported with NUZYRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue

NUZYRA if any of these adverse reactions are suspected.

Prescribing NUZYRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions
The most common adverse reactions (incidence =2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

Drug Interactions
Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA.
Absorption of tetracyclines, including NUZYRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

Use in Specific Populations
Lactation: Breastfeeding is not recommended during treatment with NUZYRA.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for NUZYRA at www.NUZYRA.com.

Forward Looking Statements
This press release contains forward-looking statements including statements related to our overall strategy, products, prospects, NTM disease, our clinical studies for NTM, real world data of NUZYRA for NTM patients, the potential for NUZYRA to fill an unmet medical need for NTM patients, the status and timing of delivery of the first procurement, and the trigger and expected timing for the second procurement, each under our Agreement with BARDA. 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, 2020 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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