



Paratek Pharmaceuticals Announces Initiation of Funding from BARDA for All FDA Required Post-marketing Studies for NUZYRA® (omadacycline)

April 2, 2020

-- BARDA award projected to total approximately \$77 million

BOSTON, April 02, 2020 (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 that the Biomedical Advanced Research and Development Authority (BARDA) has initiated funding to support all of the U.S. Food and Drug Administration (FDA) post-marketing requirements associated with the approval of NUZYRA including pneumonia and pediatric studies as well as the five-year post-marketing surveillance study. The reimbursement cost for these post-marketing commitments is projected to total approximately \$77 million.

In connection with the FDA approval of NUZYRA in October 2018, the FDA required that Paratek complete post-marketing pediatric studies examining the safety and efficacy of NUZYRA in children ages eight to 17 years. This includes a pharmacokinetic study as well as safety studies in children with acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP). The FDA also required Paratek conduct an additional safety and efficacy study in adults with CABP. Finally, the FDA required a five-year post-marketing bacterial surveillance study, which is mandatory for all newly approved antibiotics.

"We are eager and well-prepared to conduct these studies, which will now be funded entirely through the BARDA Project BioShield public-private partnership award. The clinical and microbiologic data from these studies will augment the wealth of existing data examining the safety and efficacy of once-daily, oral and intravenous NUZYRA in life-threatening community acquired infections," said Evan Loh, M.D., CEO, Paratek. "We are grateful for BARDA's significant investment and their shared commitment to fighting antimicrobial resistance and ensuring that life-saving antibiotics are available to the patients who need them."

In December 2019, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, awarded Paratek a five-year contract, valued at up to \$285 million, to support: 1) the development of NUZYRA for the treatment of pulmonary anthrax; 2) all of the U.S. Food and Drug Administration post-marketing requirements associated with the initial NUZYRA approval; 3) U.S. onshoring and manufacturing security requirements and 4) the procurement of up to 10,000 treatment courses of NUZYRA for the treatment of anthrax.

Under the terms of the contract that are now initiated, reimbursement has begun for all of the U.S. Food and Drug Administration post-marketing requirements associated with the initial NUZYRA approval.

Paratek Statement on COVID-19

We applaud the heroic efforts of medical professionals around the world who are working to protect public health and combat the COVID-19 pandemic. Whether directly treating patients impacted by the virus or implementing containment measures to constrain its transmission, you selflessly put the needs and journey of your patients first.

We at Paratek will strive to do our part during this crisis. The safety of our employees, the healthcare community and payers is paramount. We are taking appropriate steps to protect our employees, healthcare community and payers, following all local and federal requirements, and continually monitoring the situation to provide the appropriate guidance. Paratek has embraced the public health guidance regarding social distancing with all employees now working from home, utilizing a virtual model for meetings and interactions with the healthcare community and payers.

As the global COVID-19 pandemic continues to evolve, to date we have been able to provide an uninterrupted supply of our commercially available antibiotic, NUZYRA®. Based on current inventory levels and expected demand, we do not currently anticipate a shortage of NUZYRA.

Due to the demands on the healthcare system during this unprecedented crisis with COVID-19, the recruitment of our ongoing clinical studies has been paused. At the current time, the only study currently recruiting is our oral only pharmacokinetic study in patients with pneumonia. As the study has not yet completed recruitment, the study will take longer than anticipated. As the situation evolves, we intend to provide future updates on timing of the initiation of recruitment and completion of the study.

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 *Chlamydia 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 $\geq 2\%$) 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.

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. 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, or Almirall. Paratek retains the development and commercialization rights for sarecycline in the rest of the world.

In 2019, Paratek was awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA) to support the development of NUZYRA for the treatment of pulmonary anthrax.

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

Forward Looking Statements

This press release contains forward-looking statements including statements related to our overall strategy, products, prospects, funding status of post-marketing studies for NUZYRA, potential success for treating anthrax, timing and value of the BARDA award and contract, Covid-19 impact on the timing of our clinical trials, and potential of the business. 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, 2018 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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