Paratek Announces FDA Approval of NUZYRA™ (Omadacycline)

October 2, 2018



NUZYRA 100mg for injection & 150mg tablets

– Modernized Tetracycline for the Treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Skin and Skin Structure Infections (ABSSSI) specifically designed to overcome tetracycline resistance –

– First and only once-daily IV and oral antibiotic approved to treat both CABP and ABSSSI patients in nearly 20 Years –

– US launch expected first quarter 2019 –

BOSTON, Oct. 02, 2018 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (NASDAQ: PRTK) today announced that the U.S. Food and Drug Administration (FDA) has approved NUZYRA™ (omadacycline) for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute skin and skin structure infections (ABSSSI). NUZYRA, a modernized tetracycline, is a once-daily IV and oral antibiotic that exhibits activity across a spectrum of bacteria, including Gram-positive, Gram-negative, atypicals, and drug resistant strains. The Company plans on making NUZYRA available in the first quarter 2019.

"In the face of ever-increasing antibiotic resistance, the FDA approved NUZYRA with a label having full approval for both CABP and ABSSSI. We are excited to bring to physicians an effective, well-tolerated monotherapy option for patients," said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer, Paratek. "NUZYRA offers clinicians the ability to treat patients with the IV and transition them home to complete treatment with the oral formulation. This potentially helps reduce hospitalizations and the costs associated with hospital stays."

The Centers for Disease Control and Prevention (CDC) estimates that drug-resistant bacteria cause 2 million illnesses and approximately 23,000 deaths each year in the United States. The main bacteria causing CABP, *Streptococcus pneumoniae*, is responsible for 1.2 million infections and 7,000 deaths, whereas ABSSSI is responsible for more than 750,000 hospitalizations. The increase of antibiotic resistance continues to drive the need for new, effective therapies.

"Treating pneumonia and skin infections has become increasingly complex as existing antibiotic therapies sometimes have reduced efficacy as resistance continues to grow. This reality makes it increasingly challenging to provide safe and effective treatments to patients," said Keith Kaye, M.D., MPH, Director of Clinical Research, Division of Infectious Diseases, University of Michigan. "There continues to be a need for novel antibiotics with both IV and oral formulations, such as NUZYRA, to help physicians stay ahead of the evolving resistance landscape."

The approval of NUZYRA is supported by multiple clinical trials within the company's global development program. Nearly 2,000 adult patients received NUZYRA and it was found to be efficacious and generally safe and well tolerated. As part of the approval, Paratek has agreed to conduct post marketing studies in CABP and pediatrics.

"The approval of NUZYRA is an historic milestone for Paratek as it represents 20 years of research and development of this life-saving antibiotic for patients affected by community-acquired infections," said Michael F. Bigham, Chairman and CEO, Paratek. "There are countless champions of NUZYRA who have been tireless in their efforts to ensure its advancement to commercialization – from patients, clinicians and study investigators to our Paratek team. We are grateful to all who played a role in making NUZYRA available to patients in need. We are excited to launch NUZYRA early next year."

Conference Call and Webcast

Paratek's conference call for the NUZYRA approval will be broadcast tomorrow at 8:30 a.m. EDT on October 3, 2018. The webcast can be accessed under "Events and Presentations" in the Investor Relations section of Paratek's website at www.ParatekPharma.com.

Domestic investors wishing to participate in the call should dial: 877-407-0792 and international investors should dial: 201-689-8263. The conference ID is 13683728. Investors can also access the call at http://public.viavid.com/index.php?id=131551.

About NUZYRA

NUZYRA (omadacycline) is a novel antibiotic with both once-daily intravenous (IV) and oral 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 8 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 8 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.

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 commercial product, NUZYRA, is a once-daily intravenous and oral antibiotic for the treatment of adult patients with community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. Paratek is also studying NUZYRA for the treatment of urinary tract infections (UTI).

Paratek is also preparing a marketing authorization application for omadacycline in the European Union. Paratek has entered into a collaboration agreement with Zai Lab for the development and commercialization of omadacycline in 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 FDA approved product, SEYSARA™ (sarecycline), will be marketed by Almirall, SA in the U.S. as a new once-daily oral therapy for the treatment of acne. Paratek retains development and commercialization rights in the rest of the world.

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.

Forward Looking Statements

This press release contains forward-looking statements, including statements about the development, launch and commercialization of NUZYRA, the potential for NUZYRA to treat ABSSSI, CABP, UTI and other serious community-acquired bacterial infections, the prospect of NUZYRA providing broad-spectrum activity and commercialization activities. All statements, other than statements of historical facts, included in this press release are forward-looking statements, and are identified by words such as "potential," "prospective," "prepare" 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, 2017, 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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