Paratek Pharmaceuticals Presenting New Data on NUZYRA® (Omadacycline) at IDWeek 2020

October 21, 2020

Key Highlights Include Data on NUZYRA as an Alternative to Standard of Care to Reduce Clostridioides Difficile Infections and Real-World Experience with NUZYRA for Nontuberculous Mycobacterial and MDR/XDR Gram Negative Infections

BOSTON, Oct. 21, 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, announced today that data from its NUZYRA (omadacycline) clinical and microbiology programs are being presented at the IDWeek 2020 virtual meeting.

NUZYRA 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.

Poster presentations are available beginning on Wednesday, October 21 in the IDWeek ePoster Gallery.

Presentation Title: Subinhibitory Concentrations of Omadacycline Inhibit Staphylococcus aureus Hemolytic Activity In Vitro
Poster #: 1202
Presenter: A. Serio

Presentation Title: In Vitro Activity of Omadacycline Against 7000 Bacterial Pathogens from the United States Stratified by Infection Type (2019)
Poster #: 1253
Presenter: M. Huband

Presentation Title: Comparative Activity of Omadacycline Against Extended-spectrum Beta-lactamase Positive and Negative Escherichia coli and Klebsiella pneumoniae Strains Recovered from Urine Specimens
Poster #: 1267
Presenter: T. Stone

Presentation Title: Real-World Experience with Omadacycline for Nontuberculous Mycobacterial and Gram-Negative Infections: A Multicenter Evaluation
Poster #: 1290
Presenter: T. Morrisette

Presentation Title: Targeted Substitution of Omadacycline in Place of Standard of Care for CABP Treatment is Associated with a Risk Reduction of Clostridioides difficile Infection and Financial Cost Savings in the Acute Care Setting
Poster #: 1492
Presenter: M. Rodriguez

Presentation Title: Omadacycline in Female Adults with Acute Pyelonephritis: Results from a Randomized, Double-Blind, Adaptive Phase 2 Study
Poster #: 1687
Presenter: K. Wright

Presentation Title: Omadacycline in Female Adults with Cystitis: Results from a Randomized, Double-Blinded, Adaptive Phase 2 Study
Poster #: 1688
Presenter: K. Wright

“These poster presentations continue our commitment to share new data about the clinical safety and efficacy of NUZYRA and ensure clinicians have comprehensive information available to them as they make treatment decisions for their patients with community-acquired infections,” said Randy Brenner, Chief Development & Regulatory Officer of Paratek. “To that end, Paratek supports analysis of real-world use of NUZYRA, including the potential utility of NUZYRA in nontuberculous mycobacterium abscessus lung infections, a rare, chronic and difficult-to-treat lung infection for which there are currently no FDA approved therapies.”

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 (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 to support the development 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 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 ≥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 and potential. 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, 2019 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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