



Paratek Pharmaceuticals Announces FDA Approval of NUZYRA® (omadacycline) Oral Only Dosing Regimen for the Treatment of Community-Acquired Bacterial Pneumonia (CABP)

June 1, 2021

- Oral-only dosing for the Treatment of CABP Expands the Commercial Opportunity for Primary Care Promotion

- Primary Care Market Opportunity for CABP Estimated at Approximately \$1.5 Billion

BOSTON, June 01, 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 and for other public health threats for civilian, government and military use, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's supplemental New Drug Application (sNDA) for the oral-only dosing regimen of NUZYRA® for the treatment of adults with CABP.

"The approval of an oral-only dose regimen for NUZYRA in pneumonia represents a significant opportunity to offer clinicians the ability to treat patients in either the outpatient or primary care setting. Treating in this way potentially reduces or eliminates hospitalizations and the associated risk and costs from a hospital stay," said Adam Woodrow, President and Chief Commercial Officer of Paratek. "With the community expansion well under way we will broaden our promotional efforts to include this new dosing option and are particularly excited to bring primary care practitioners a new, safe and effective oral antibiotic in time for the upcoming pneumonia season."

Approved by the FDA on October 2, 2018, NUZYRA is a novel antibiotic with both once-daily oral and intravenous (IV) formulations for the treatment of CABP and acute bacterial skin and skin structure infections (ABSSSI). The recently approved oral-only dose for CABP has an initial dose of 300 mg twice on day one and 300 mg once daily thereafter for a total of 7 to 14 days. A modernized tetracycline, NUZYRA is specifically designed to overcome tetracycline resistance and exhibits activity across a broad spectrum of bacteria, including Gram-positive, Gram-negative, and atypicals including other drug-resistant strains.

"Treating serious community-acquired infections including pneumonia has become increasingly complex given significant bacterial resistance and major safety concerns seen with older generic antibiotics," said Christian Sandrock, M.D., M.P.H., FCCP, Professor of Pulmonary Medicine & Director of Critical Care, UC Davis Health. "Community-based physicians are in need of new effective and safe options given the lack of investment and innovation in the antibiotic ecosystem over the past two decades. The availability of an oral-only dosing regimen of NUZYRA in pneumonia helps address a significant gap for an effective, safe and well-tolerated oral antibiotic in the primary care setting."

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 an 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, 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). The oral-only dose for CABP has an initial dose of 300 mg twice on day one and 300 mg once daily thereafter for a total of seven to 14 days. 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, oral only dosing regimen for CABP, our plans to broaden the Company's sales efforts, the strategy, execution and progression of our commercial sales of NUZYRA, our ability to shape the future treatment paradigm for community-acquired pneumonia, and our potential to further drive long-term value for all of our shareholders. 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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