Paratek Pharmaceuticals Broadens Clinical Profile of NUZYRA™ (Omadacycline) with New ECCMID 2019 Data Presentations

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- New microbiology data reinforce activity of NUZYRA against broad range of pathogens commonly associated with community-acquired infections

- Study supports no dose adjustments in patients based on BMI

AMSTERDAM, The Netherlands, April 15, 2019 (GLOBE NEWSWIRE) -- New data presented at the 29th European Congress of Clinical Microbiology & Infectious Diseases, ECCMID 2019, show that Paratek Pharmaceuticals, Inc.'s (Nasdaq:PRTK) NUZYRA™ (omadacycline) demonstrates highly potent *in vitro* activity against common bacterial pathogens in respiratory tract infections (RTI), acute bacterial skin and skin structure infections (ABSSSI), and urinary tract infections (UTI). Paratek is a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon tetracycline chemistry.

"NUZYRA continues to show significant clinical efficacy against resistant pathogens including MRSA and resistant strains of *Streptococcus pneumoniae*, which is important news for clinicians who treat these severe and sometimes life-threatening community-acquired infections," said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer, Paratek. "These data expand the understanding of NUZYRA's *in vitro* activity against pathogens responsible for urinary tract infections, where there is a significant unmet need for new oral, broad-spectrum antibiotic agents."

Available in the United States, NUZYRA is a once-daily oral and intravenous (IV), modernized tetracycline antibiotic approved by the FDA for the treatment of community-acquired bacterial pneumonia (CABP) and ABSSSI. Paratek is also studying NUZYRA for the treatment of uncomplicated UTI and acute pyelonephritis.

In a separate sub-group analysis presented today, NUZYRA showed similar efficacy and safety in obese, overweight and healthy-weight ABSSSI patients compared to linezolid, suggesting that a fixed-dosing strategy, regardless of adult body size, will not impact the safety profile and consistently high levels of efficacy of NUZYRA in patients with skin infections.

SENTRY Surveillance Program Results (Poster #1876)
This study, *In Vitro Activity of Omadacycline and Comparators against Gram-Positive and -Negative Clinical Isolates Collected in 2018 from Patients in European Medical Centres: SENTRY Surveillance Program Results*, evaluated the *in vitro* antibacterial activity of NUZYRA against Gram-positive and Gram-negative bacterial isolates collected from patients with multiple infection types in 38 European medical centers participating in the 2018 SENTRY Antimicrobial Surveillance Program.

In the study, bacterial isolates were initially identified by the submitting laboratories and confirmed using a matrix-assisted laser desorption, ionization-time of flight mass spectrometry. Susceptibility testing was performed according to the Clinical Laboratory Standards Institute (CLSI) reference broth microdilution methodology and results were interpreted using the CLSI and the European Committee of Antimicrobial Susceptibility Testing, and FDA breakpoint interpretive criteria.

Overall, NUZYRA was highly active against *Staphylococcus aureus*, including methicillin-susceptible *S. aureus* (MSSA) and methicillin-resistant *S. aureus* (MRSA) that included isolates from both ABSSSI and RTI ($MIC_{50/90}$ 0.12/0.25 mg/L), as well as strains displaying resistance to tetracyclines, levofloxacin, erythromycin, clindamycin and/or oxacillin.

NUZYRA was also highly active against other respiratory pathogens including *Streptococcus pneumoniae* including penicillin- and tetracycline-resistant strains ($MIC_{50/90}$ 0.06/0.12 mg/L). In addition, NUZYRA showed activity against *Haemophilus influenzae*, *Haemophilus parainfluenzae* and *Moraxella catarrhalis* strains ($MIC_{50/90}$ 0.5/1 mg/L, $MIC_{50/90}$ 1/4 mg/L and ≤0.12/0.25 mg/L, respectively).

UTI pathogens *Escherichia coli* (*E. coli*) and *ESBL-phenotype E. coli* were also shown to be susceptible to NUZYRA ($MIC_{50/90}$ 1/2 mg/L, and 1/4 mg/L respectively).

Safety and Efficacy of NUZYRA by Body Mass Index (ePoster #O0306)
OASIS-1 and OASIS-2 were randomized, double-blind, active comparator controlled, Phase 3 studies comparing NUZYRA to linezolid for the treatment of adults with ABSSSI. Patients from these studies were classified based on the World Health Organization body mass index (BMI) categories. Approximately two-thirds of patients were overweight (OMC: 221; LZD: 243) or obese (OMC: 210; LZD: 200) and baseline pathogens were similar across BMI categories with the most common being *S. aureus*.

Clinical success at early clinical response (ECR) in the modified intent-to-treat (mITT) population for NUZYRA and linezolid were similar in healthy-weight (OMC: 87.5%; LZD: 86.7%), overweight (OMC: 84.3%; LZD: 83.0%) and obese (OMC: 86.2%; LZD: 82.6%) patients. Similar clinical success was seen at post treatment evaluation (PTE) in the mITT population: healthy-weight (OMC: 82.7%; LZD: 81.8%), overweight (OMC: 84.3%; LZD: 82.2%) and obese (OMC: 88.2%; LZD: 83.2%).

The study showed no evidence of lower efficacy with increasing BMI. The observed treatment emergent adverse events (TEAEs) were consistent with the adverse event profile for the tetracycline class and there was no difference in rates of TEAEs and serious TEAEs across BMI categories or between treatment groups.

"We believe that the results of this sub-group analysis provide physicians with confidence that a fixed dosing strategy will not impact the safety and efficacy of NUZYRA in patients with skin infections and a high body mass index," Dr. Loh said.

About Paratek Pharmaceuticals, Inc.

Paratek Pharmaceuticals, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics. The company's lead commercial product, NUZYRA™ (omadacycline), which has launched and is available in the U.S., is a once-daily oral and intravenous antibiotic for the treatment of adults 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 has submitted a marketing authorization application of 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.

SEYSARA™ (sarecycline) is an FDA-approved product with respect to which we have exclusively licensed certain rights in the United States to Almirall, LLC, or Almirall. SEYSARA is currently being marketed by Almirall in the U.S. as a new once-daily oral therapy for the treatment of moderate to severe acne vulgaris. Paratek retains development and commercialization rights with respect to sarecycline 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.

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 antibiotic 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 or third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause irreversible 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, 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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