Paratek Announces FDA Approval of NUZYRA™ (Omadacycline)

NUZYRA 100mg for injection & 150mg tablets

– Modernized Tetracycline for the Treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Skin and Skin Structi

– First and only once-daily IV and oral antibiotic approved to treat both CABP and A

– 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 D adults with community-acquired bacterial pneumonia (CABP) and acute skin and skin structure infections (ABSSSI). NUZYRA, a moderniz spectrum of bacteria, including Gram-positive, Gram-negative, atypicals, and drug resistant strains. The Company plans on making NUZY

"In the face of ever-increasing antibiotic resistance, the FDA approved NUZYRA with a label having full approval for both CABP and ABSS for patients," said Evan Loh, M.D., President, Chief Operating Officer, and Chief Medical Officer, Paratek. "NUZYRA offers clinicians the ab 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 *Streptococcus pneumoniae*, is responsible for 1.2 million infections and 7,000 deaths, whereas ABSSSI is responsible for more than 750,(new, effective therapies.

"Treating pneumonia and skin infections has become increasingly complex as existing antibiotic therapies sometimes have reduced effica provide safe and effective treatments to patients," said Keith Kaye, M.D., MPH, Director of Clinical Research, Division of Infectious Disease 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 pa 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 an Chairman and CEO, Paratek. "There are countless champions of NUZYRA who have been tireless in their efforts to ensure its advancemei 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 ne

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 Paratek's website at www.ParatekPharma.com (https://www.globenewswire.com/Tracker?data=sZPM22OVQ7DLSWRsb5rS4E2rlcCVlv QCHwNbkpBA6SH6Ak=).

Domestic investors wishing to participate in the call should dial: 877-407-0792 and international investors should dial: 201-689-8263. Th at http://public.viavid.com/index.php?id=131551 (https://www.globenewswire.com/Tracker? data=5LoF0V6gnaVGylr6DsX14j9ymmoHCGu_iFlSSp2yq6FAgSvj80PWJlgWgsaVroRr1p171EE4fcGLlTEGTx8bK0fkd5djtuPnGaFslGyKts GR_vYTqjDfzfEsC_LU1BEEinTvsTUHpFCo2-q_EJxmDEurUbR6gi1c-b2Y3G9dTXKwn7M17AjpC-G48DBh3lN_N45LwsmyHiRBc1HVtXeVy sniA3lKYXTobPMUYGClUrBlc5tQ1pUFOjHelk3Z_E5AplrSQDloDDjhQbCtJkwQWJv2sCAG9uhRsC0UgqBxl9S1u7wBPd3yLM-2CWq8h9RC

About NUZYRA

NUZYRA (omadacycline) is a novel antibiotic with both once-daily intravenous (IV) and oral formulations for the treatment of community-a infections (ABSSSI). A modernized tetracycline, NUZYRA is specifically designed to overcome tetracycline resistance and exhibits activity 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 suscep

Community-Acquired Bacterial Pneumonia (CABP) caused by the following: Streptococcus pneumoniae, Staphylococcus aureus (n Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by the following: Staphylococcus aureus (methicillin-suscepti Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, a

Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA s 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

Warnings and Precautions
Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared t imbalance has not been established. All deaths, in both treatment arms, occurred in patients > 65 years of age; most patients had multipl complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those a

The use of NUZYRA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent

The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversi

Hypersensitivity reactions have been reported with NUZYRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reporte other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacter

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity fr

NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions inc increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetr 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 ir

Adverse Reactions

The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, a 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 subsalicyl

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-1 data=asR6mERztPSP8JFbra0WoX0qXRRa20uTmtr5jhk-ypLIQb-RFkvoE87dqB_XhI8zRTtfcXjFGF1-JFwqW4GGjWlqjTYMEzgwZ3poFBMy

Please see full Prescribing Information for NUZYRA at www.NUZYRA.com (https://www.globenewswire.com/Tracker?data=2RdlcxzMvy bKKpmGdGyEAPBXrtpXDTjWj7hCoMKsHsWCQRZQBxI8QhkCDus7WMgg==).

About Paratek Pharmaceuticals, Inc.

Paratek Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapie commercial product, NUZYRA, is a once-daily intravenous and oral antibiotic for the treatment of adult patients with community-acquirec 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 collat 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 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 t 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 t

For more information, visit www.ParatekPharma.com (https://www.globenewswire.com/Tracker?data=sZPM22OVQ7DLSWRsb5rS4E2rlcCVIvxurUfnmYpEZwQQJ8MT7JOv8m19DU5MsnlwIeE47tR3gszl7eG7rCPKMoMo8GzmrktT3EWw

Forward Looking Statements

This press release contains forward-looking statements, including statements about the development, launch and commercialization of N community-acquired bacterial infections, the prospect of NUZYRA providing broad-spectrum activity and commercialization activities. All forward-looking statements, and are identified by words such as "potential," "prospective," "prepare" and other words and terms of simila and involve substantial risks and uncertainties. We may not actually achieve the plans, carry out the intentions or meet the expectations c undue reliance on these forward-looking statements. Our actual results and the timing of events could differ materially from those includ These and other risk factors are discussed under "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended De expressly disclaim any obligation or undertaking to update or revise any forward-looking statements contained herein.

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A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/a4a64298-98c2-4(data=5LoF0V6gnaVGylr6DsX14k2kXviCj_7jgOCYK8TuCQdZw4NEN8CUKbcChyjikretn00cvKCkVv0CY1JdEUkLxy8G2PrzKyIZDRe9WImBY86Emc80srD3r4PGSa8lUcsKpU7ZCyo-bwx7tDVe6gFlMJ6MkZnnFBMVyASFfVB8B4SW3fJY-J616x0FFazxaQEK1CUDgrOdOFPbbncZD

PARATEK (https://www.globenewswire.com/NewsRoom/AttachmentNg/004d3d9f-8cdc-44bc-82de-0acba4447377)

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