China NMPA Approves NUZYRA® as a Category 1 Innovative Drug for the Treatment of Patients with Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

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NUZYRA demonstrated efficacy against common pathogens in three Phase 3 studies, including pathogens resistant to other antibiotic classes as a potential best-in-class tetracycline

NUZYRA is Zai Lab's fourth new product approval and the first outside oncology

SHANGHAI, SAN FRANCISCO, and CAMBRIDGE, Mass., Dec. 16, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the China National Medical Products Administration (NMPA) has approved its New Drug Application (NDA) for NUZYRA® (omadacycline), a novel antibiotic with both oral and intravenous (IV) formulations, for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). NUZYRA was approved as a Category 1 innovative drug by the NMPA and is locally manufactured in China. It is the fourth Zai Lab product approved over the last 24 months.

"In the face of ever-increasing antibiotic resistance, the NMPA's approval of NUZYRA brings an important new treatment option for CABP and ABSSSI to millions of patients in China," said Dr. Harald Reinhart, Chief Medical Officer for Autoimmune and Infectious Diseases at Zai Lab. "We believe NUZYRA is particularly well positioned due to its broad activity against a wide spectrum of pathogens, including multi-drug-resistant (MDR) bacteria, associated with these serious infections. In addition, NUZYRA offers clinicians the ability to treat patients in the hospital with the intravenous formulation and transition them to complete treatment at home with the oral formulation. This flexible treatment regimen potentially helps reduce exposure to hospital pathogens and the costs associated with hospital stays."

"CABP is a common secondary infection associated with respiratory viruses like influenza," said Professor Haihui Huang, Chief Physician, Fudan University Affiliated Huashan Hospital, Deputy Director of Antibiotic Research Institute. "We believe omadacycline is a potential best-in-class tetracycline, with demonstrated efficacy comparable to moxifloxacin in CABP and to linezolid in ABSSSI."

"Omadacycline is one of the most potent antibiotics with intravenous and oral formulations in these indications," said Professor Jing Zhang, Chief of Pharmacy, Fudan University Affiliated Huashan Hospital, Deputy Director of Drug Clinical Trial Center. "Importantly, it also has a favorable safety and tolerability profile, particularly regarding GI side effects, which can be a serious liability with other tetracyclines."

NUZYRA was approved by the U.S. Food and Drug Administration (FDA) for both CABP and ABSSSI based on comprehensive clinical trial programs involving more than 2,000 patients and, since 2019, it has been marketed in the United States by Paratek Pharmaceuticals, Inc. In 2017, while NUZYRA was still in its clinical stage, Zai Lab in-licensed the rights to NUZYRA for the Greater China region (mainland China, Hong Kong, Macau, and Taiwan). Since then, Zai Lab conducted three clinical trials involving Chinese patients in support of NUZYRA's registration in mainland China.

About CABP and ABSSSI

CABP is the most common type of pneumonia that is acquired outside the hospital. It is one of the most common infectious diseases and is an important cause of mortality and morbidity worldwide. ABSSSI are bacterial infections of skin and associated soft tissues, such as loose connective tissue and mucous membranes. ABSSSI are common and encompass a variety of disease presentations and degrees of severity. In 2015, the estimated incidences of ABSSSI and CABP were 2.8 million patients and 16.5 million patients, respectively, in China alone. Linezolid and moxifloxacin are the current standards of care for ABSSSI and CABP, respectively. There are significant unmet needs for broad-spectrum antibiotics addressing MDR infections with a favorable safety profile.

About NUZYRA

NUZYRA® (omadacycline), a novel tetracycline-class antibacterial with both once-daily oral and IV formulations, is specifically designed to overcome tetracycline resistance and to improve activity across a broad spectrum of bacterial infections, such as those caused by Gram-positive, Gram-negative, atypical, and many other pathogens. NUZYRA was launched in the United States in February 2019 as a once-daily oral and intravenous antibiotic for the treatment of adults with CABP and ABSSSI. It was approved in June 2021 by the FDA as an oral-only dosing regimen for the treatment of adults with CABP.

Important Safety Information

NUZYRA is structurally similar to other drugs of the tetracycline class and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action that has led to increased blood urea nitrogen, azotemia, acidosis, hyperphosphatemia, pancreatitis, and elevated liver enzymes have been reported for other tetracycline-class antibacterial drugs and may occur with NUZYRA. Physicians and patients should discontinue use of 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%) seen with NUZYRA include nausea, vomiting, infusion-site reactions, increased alanine aminotransferase, increased aspartate aminotransferase, increased gamma-glutamyl transferase, hypertension, headache, diarrhea, insomnia, and constipation.

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the prospects and plans for developing and commercializing NUZYRA® (omadacycline) in the Greater China region. These forward-looking statements may contain words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, nor are they guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to finance our operations and business initiatives and obtain funding for such activities, (3) our results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory, and political conditions, and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

For more investor-related information about Zai Lab, please go to www.SEC.gov or visit www.zailaboratory.com.

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