Zai Lab Announces the Inclusion of AUGTYRO® (repotrectinib) for ROS1+ NSCLC and Other Updates in China's National Reimbursement Drug List

November 28, 2024

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 27, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the 2024 National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA) has been updated to include the following medicines and indications:

- **AUGTYRO®** (repotrectinib) is included in the NRDL for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC);
- **NUZYRA®** (omadacycline) is renewed for its intravenous (IV) formulation for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI); and
- **QINLOCK®** (ripretinib) is renewed for advanced gastrointestinal stromal tumor (GIST) patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.

"The NRDL inclusion of AUGTYRO significantly expands access to patients living with *ROS1*+ NSCLC in China to a new treatment option with promising durability. We look forward to launching AUGTYRO by the end of 2024," said Andrew Zhu, Chief Commercial Officer of Zai Lab. "The addition of AUGTYRO, as well as the renewals of NUZYRA and QINLOCK, further support patient access to these important medications throughout China at more affordable treatment costs for patients and their families."

"A key part of Zai Lab's mission is to bring innovative medicines to patients with significant unmet medical needs," said Josh Smiley, President and Chief Operating Officer of Zai Lab. "We are pleased that we now have six products included in the NRDL, and we will continue our efforts to broaden patient access to our innovative treatments across China. We look forward to continuing to work with the NHSA to improve affordability and accessibility for differentiated innovative treatments in China, with the goal of improving patient lives."

About *ROS1*+ NSCLC in China

Lung cancer is the most commonly diagnosed cancer type and the leading cause of cancer death in China. There were approximately 1,060,600 new cases and 733,300 cases of deaths from lung cancer in China in 2022.[1] NSCLC accounts for approximately 85% of lung cancer, and approximately 70% of NSCLC is locally advanced or metastatic at initial diagnosis. In China, *ROS1* rearrangements occur in approximately 2% of patients with advanced NSCLC.[2]

[1] *Bingfeng Han, et al. Cancer incidence and mortality in China, 2022.*

[2] *Zhang, et al. Prevalence of ROS1 fusion in Chinese patients with non-small cell lung cancer, Thoracic Cancer January 2019.*

About AUGTYRO

AUGTYRO (repotrectinib) is a next-generation tyrosine kinase inhibitor (TKI) that targets *ROS1* and *NTRK* oncogenic drivers. Patients with solid tumors, including NSCLC, harboring *ROS1* or *NTRK* gene fusions treated with approved targeted therapies often develop resistance mutations that limit binding of drugs to their target. Ultimately, this leads to shortened duration of response and tumor progression. AUGTYRO is the first next-generation TKI that targets *ROS1* oncogenic fusions in NSCLC and provides improved durability of benefit, including in metastases to the brain.

In November 2023, AUGTYRO was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC. In May 2024, AUGTYRO was approved by China's National Medical Products Administration (NMPA) for the same indications. Additionally, in August 2023, the NMPA granted AUGTYRO Breakthrough Therapy Designation for the treatment of patients with advanced solid tumors harboring a *NTRK* gene fusion.

Zai Lab has an exclusive license agreement with Turning Point Therapeutics, Inc. (a Bristol Myers Squibb company) to develop and commercialize AUGTYRO in Greater China (mainland China, Hong Kong, Taiwan, and Macau, collectively). Zai Lab expects to commercially launch AUGTYRO in mainland China by the end of 2024.

About CABP and ABSSSI in China

CABP is the most common type of pneumonia that is acquired outside of the hospital. It is one of the most common infectious diseases and is a significant 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 2020, the estimated incidence of CABP in mainland China was approximately 10 million patients[3], and in 2015, the estimated incidence of ABSSSI was 2.8

million patients[4]. There are significant unmet needs for broad-spectrum antibiotics addressing multi-drug resistance infections with a favorable safety profile.

[3] *Incidence of community-acquired pneumonia in urban China: A national population-based study, 2020.*

[4] *2015 estimates, Zai Lab analysis.*

About NUZYRA

NUZYRA (omadacycline), a novel tetracycline-class antibacterial with both oral and IV formulations, is active across a broad spectrum of bacterial infections, such as those caused by Gram-positive, Gram-negative, atypical, and many other pathogens.

The NMPA approved NUZYRA as a Category 1 innovative drug for both oral and IV formulations for the treatment of CABP and ABSSSI in adult patients, and Zai Lab launched NUZYRA in mainland China for these indications in December 2021. It was included in the NRDL for the treatment of adult patients with CABP and ABSSSI in January 2023 for its IV formulation and in January 2024 for its oral formulation.

Zai Lab has an exclusive license from Paratek Pharmaceuticals, Inc. (acquired by Novo Holdings A/S) to develop, manufacture, and commercialize NUZYRA in Greater China.

About GIST in China

It is estimated that approximately 30,000 GIST patients are newly diagnosed each year in China. Treatment of GIST remains an important unmet medical need in China as many GIST patients, who initially respond to traditional TKIs, ultimately develop tumor progression due to secondary mutations.

About QINLOCK

QINLOCK (ripretinib) is an orally administered switch-control TKI that inhibits KIT and PDGFRA kinases, including wild-type and forms with multiple primary and secondary mutations, by using a dual mechanism of action that regulates the kinase switch pocket and activation loop.

The NMPA approved QINLOCK in March 2021 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, and Zai Lab launched QINLOCK in mainland China for this indication in 2021. It was included in the NRDL in January 2023 for the treatment for GIST patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.

Zai Lab has an exclusive license agreement with Deciphera Pharmaceuticals, Inc. (a member of ONO Pharmaceutical) for the development and commercialization of QINLOCK in Greater China.

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide.

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

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements relating to the benefits and potential of AUGTYRO (repotrectinib), NUZYRA (omadacycline), and QINLOCK (ripretinib) and the treatment of *ROS1+* NSCLC, CAPB, ABSSSI and GIST in Greater China. 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 or 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 obtain funding for our operations and business initiatives, (3) the results of our 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) risks related to doing business in China, and (6) other factors identified in our most recent annual and quarterly reports 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.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC’s website at www.sec.gov.

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