Zai Lab Announces the First Listing of VYVGART® (efgartigimod alfa injection) and Other Updates in China's National Reimbursement Drug List

December 13, 2023

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 12, 2023-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the 2023 National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA) has been updated to include the following medicines and indications:

- **VYVGART**® (efgartigimod alfa injection) is included for the first time in the NRDL for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive;
- **NUZYRA**® (omadacycline) is included for its oral formulation for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI); and
- **ZEJULA**® (niraparib) is renewed for the maintenance treatment of adult patients with platinum-sensitive, first-line and recurrent ovarian cancer.

"The initial NRDL inclusion for VYVGART is an especially important milestone for gMG patients and underscores the clinical value Zai Lab is delivering to the medical community and to patients in China," said William Liang, Chief Commercial Officer of Zai Lab. "The addition of both VYVGART and NUZYRA (oral formulation) to the NRDL, as well as the renewal of previously included indications for ZEJULA, further supports patient access to these important medications throughout China at reduced prices, which significantly lower the cost of treatment 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 in China and around the world," said Josh Smiley, President and Chief Operating Officer of Zai Lab. "We are pleased that we now have four products included in the NRDL, and we will continue our efforts to expand patient access to our innovative treatments, including through NRDL coverage of different indications and formulations for our commercial products. We are grateful for this action by the NHSA, and we look forward to continuing to work with the NHSA to improve patient access and costs for high-quality treatments in China."

About Myasthenia Gravis in China

Myasthenia gravis (MG) is a chronic autoimmune disease, characterized by debilitating and potentially life-threatening muscle weakness. There are approximately 170,000 people in China living with gMG[1], and of those patients, 85% are estimated to have confirmed AChR antibodies; in this generalized form of the disease, skeletal muscles throughout the body may be affected, resulting in weakness and early fatigue. Difficulties with double vision, facial expression, speech, swallowing, and ambulation are frequent and difficult to manage for patients and treating physicians. In more life-threatening cases, gMG can affect the muscles responsible for breathing, which can be fatal. Acetylcholinesterase (AChE) inhibitors, steroids, immunosuppressants, and IVIg are the mainstay of treatment in China. These drugs often achieve only partial restoration of strength.

[1] *The growing burden of generalized myasthenia gravis: a population-based retrospective cohort study in Taiwan, 2023.*

About VYVGART

VYVGART is an antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation.

The National Medical Products Administration (NMPA) approved VYVGART as an add on to standard therapy for the treatment of adult patients with gMG who are anti-AChR antibody positive in June 2023. VYVGART is the first approved FcRn blocker in China. We commercially launched VYVGART in China in September 2023.

Zai Lab has an exclusive license from argenx to develop and commercialize efgartigimod in mainland China, Hong Kong, Macau, and Taiwan (Greater China).

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[2], and in 2015, the estimated incidence of ABSSSI was 2.8 million patients[3]. There are significant unmet needs for broad-spectrum antibiotics addressing multi-drug resistance (MDR) infections with a favorable

safety profile.

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

[3] 2015 estimates, Zai Lab analysis.

About NUZYRA

NUZYRA, 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.

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 in December 2021. It was included in the NRDL for the first time in January 2023 for the treatment of CABP and ABSSSI for IV formulation, and it will be added to the NRDL in January 2024 for the treatment of CABP and ABSSSI for oral formulation.

Zai Lab has an exclusive license from Paratek Pharmaceuticals, Inc. to develop, manufacture, and commercialize NUZYRA in Greater China.

About Ovarian Cancer in China

Ovarian cancer is one of the most common gynecologic cancers in China, with over 55,000 newly diagnosed cases and 37,000 deaths in China annually[4]. While platinum-based chemotherapy is effective at inducing an initial response in ovarian cancer, the disease will recur in the majority of women. Effective treatment options for patients with platinum-sensitive recurrent ovarian cancer remain limited. New agents that prolong the duration of response following first-line platinum-based treatment and delay the relapse of ovarian cancer will benefit patients with ovarian cancer in China.

[4] Globocan 2020.

About ZEJULA

ZEJULA (niraparib) is an oral, once-daily small-molecule poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor. A PARP inhibitor blocks the ability of cancer cells to repair themselves after they have been damaged by radiation and certain chemotherapies. This inhibition of DNA damage repair can result in the inability of cancer cells to replicate themselves and in programmed cell death. Tumors that are deficient in key DNA damage repair pathways, such as BRCA1 mutant tumors, are particularly sensitive to ZEJULA. As maintenance therapy, ZEJULA is for women who have had prior chemotherapy treatment but are at high risk of cancer recurrence. ZEJULA is intended to avoid or slow a recurrence of the cancer if it is in remission after prior treatment. In the maintenance setting, ZEJULA does not require the addition of radiation or chemotherapies to kill tumor cells.

As a first-line monotherapy maintenance treatment of patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively, ovarian cancer) following a response to platinum-based chemotherapy, ZEJULA was approved by the NMPA in September 2020 and included in the NRDL in December 2021.

As a maintenance treatment of patients with platinum sensitive recurrent ovarian cancer, ZEJULA was approved by the NMPA in December 2019 and included in the NRDL in December 2020.

Zai Lab has an exclusive license from GlaxoSmithKline to develop and commercialize ZEJULA in mainland China, Hong Kong, and Macau.

About Zai Lab

Zai Lab (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, autoimmune disorders, infectious diseases, and neuroscience. 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 of and increased patient access to VYVGART (efgartigimod alfa injection), NUZYRA (omadacycline), and ZEJULA (niraparib); the treatment of gMG, CAPB, and ovarian cancer in Greater China; and regulatory discussions, submissions, filings, and approvals and the timing thereof. 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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Source: Zai Lab Limited