Zai Lab Announces National Medical Products Administration (NMPA) Approval of AUGTYRO™ (repotrectinib) for Patients with NTRK-Positive Solid Tumors

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SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 6, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) has approved the supplemental New Drug Application (sNDA) for AUGTYRO™ (repotrectinib) for the treatment of adult patients with solid tumors that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. The approval is intended for patients whose disease is locally advanced or metastatic, or where surgical resection is likely to result in morbidity, and who have either progressed following prior therapies or have no satisfactory alternative treatment options.

"We are pleased with the NMPA's approval of AUGTYRO for patients with NTRK-positive solid tumors. This approval marks its second indication in China, addressing a critical treatment gap, as no prior therapy has been approved across both TKI-naïve and TKI-pretreated patients within this population," said Dr. Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "We believe this approval will help address the high unmet medical needs for patients across this treatment spectrum."

The NMPA's decision is based on the results from the pivotal Phase 1/2 TRIDENT-1 study, which demonstrated robust and durable efficacy and a manageable safety profile of repotrectinib in patients with NTRK fusion-positive solid tumors. Zai Lab contributed to the global pivotal TRIDENT-1 study and dosed the first patient in Greater China in May 2021.

In May 2024, the NMPA approved AUGTYRO (repotrectinib) for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).

Zai Lab has an exclusive license agreement with Bristol Myers Squibb Co., following their acquisition of Turning Point Therapeutics, Inc., to develop and commercialize AUGTYRO in Greater China (mainland China, Hong Kong, Taiwan, and Macau, collectively).

About AUGTYRO

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

In June 2024, AUGTYRO (repotrectinib) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a NTRK gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in morbidity, and have progressed following treatment or have no satisfactory alternative therapy.

In May 2024, AUGTYRO was approved by the NMPA for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC. It was approved by the FDA for this indication in November 2023.

About NTRK-Positive Solid Tumors

NTRK-positive advanced solid tumors are life-threatening with poor prognoses and represent an area of significant unmet medical need in adult and pediatric patients. Existing targeted therapies have demonstrated clinical benefits but are limited by the duration of response due to the emergence of acquired resistance mutations.[1] In China, the NMPA's approval is the first to span both TRK TKI-naïve and TRK TKI-pretreated patients across solid tumors.

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.

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 relating to our future expectations, plans, and prospects, including, without limitation, statements relating to our prospects and plans for developing and commercializing repotrectinib in Greater China, the potential benefits of repotrectinib, and the potential treatment of NTRK-positive solid tumors. 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 decisions, (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 the SEC's website at www.sec.gov.

[1] *Harada G, Santini FC, Wilhelm C, Drilon A, et al. NTRK fusions in lung cancer: From biology to therapy. Lung Cancer. 2021;161:108-113.*

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