# Zai Lab Announces Acceptance of Supplemental New Drug Application for Repotrectinib for Patients with NTRK-Positive Solid Tumors

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SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 21, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) has accepted the supplemental New Drug Application (sNDA) for repotrectinib for the treatment of adult patients with solid tumors that harbor a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion. The application is intended for patients whose disease is locally advanced or metastatic, or where surgical resection is likely to result in severe morbidity, and who have either progressed following prior therapies or have no satisfactory alternative treatment options.

"*NTRK* fusion-positive tumors represent a significant therapeutic challenge, particularly in the setting of acquired resistance to existing TRK tyrosine kinase inhibitors (TKIs)," said Dr. Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. "There are no approved treatments for *NTRK*-positive cancers for both TKI-naïve and TKI-pretreated patients in China. Repotrectinib has the potential to become a next-generation TKI that can be used across a broad range of *NTRK* fusion-positive solid tumors in both settings."

In February 2025, China's NMPA granted priority review to repotrectinib for the treatment of adult patients with advanced solid tumors that have an *NTRK* gene fusion.

**About Repotrectinib**

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 shortened duration of response and tumor progression. Repotrectinib is the first next-generation ROS1 and TRK 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 severe 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 non-small-cell lung cancer (NSCLC). It was approved by the FDA for this indication in November 2023.

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).

**About *NTRK*-Positive Solid Tumors**

*NTRK*-positive advanced malignancies 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, there was no approved treatment option for *NTRK*-positive cancers that was studied in both TKI-naïve and TKI-pretreated patients across solid tumors.

[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.*

**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 https://x.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.

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