Zai Lab Announces Breakthrough Therapy Designation Granted for Repotrectinib for Treatment of Patients with NTRK-positive TKI-pretreated advanced solid tumors in China

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Candidate precision medicine has shown encouraging clinical activity for both ROS1-positive NSCLC and NTRK fusion-positive advanced solid tumors

SHANGHAI, China and CAMBRIDGE, Mass., Aug. 30, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted Breakthrough Therapy Designation for investigational repotrectinib for the treatment of patients with advanced solid tumors that have an *NTRK* gene fusion who have progressed following treatment with TRK tyrosine kinase inhibitors (TKIs). The Breakthrough Therapy Designation for repotrectinib was supported by data from both global and Chinese *NTRK*-positive TKI-pretreated patients enrolled in the Phase 1/2 TRIDENT-1 study.

"We are excited to receive our fourth Breakthrough Therapy Designation for repotrectinib in China. Today's recognition further supports repotrectinib as a potential first-in-class treatment for patients with *NTRK*-positive, TKI-pretreated solid tumors in China," said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development at Zai Lab. "*NTRK* is estimated to be an oncogenic driver in approximately 0.5 percent of patients with a variety of advanced solid tumors.[1] There remains an unmet medical need for *NTRK*-positive, TKI-pretreated advanced solid tumor patients where there are no targeted therapies currently approved. We look forward to working with regulatory authorities in China to bring this important medicine to patients in need as soon as possible."

The Breakthrough Therapy Designation review policy is designed to facilitate the development and expeditious review of novel medicines that are intended for the prevention or treatment of serious, life-threatening diseases or diseases that severely impact the quality of life for which there is no existing treatment, or where sufficient evidence indicates advantages of the novel drug over currently available treatment options. Drugs granted Breakthrough Therapy Designations receive priority communications and guidance from the CDE to promote and expedite the drug development process.

In June 2023, Zai Lab announced that the NMPA in China has accepted its New Drug Application (NDA) for repotrectinib for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC, after granting priority review in May 2023.

[1] *NTRK fusion detection across multiple assays and 33,997 cases: diagnostic implications and pitfalls, 2020.*

About Repotrectinib

Repotrectinib is a next-generation tyrosine kinase inhibitor targeting the *ROS1* and *NTRK* oncogenic drivers of advanced solid tumors, including NSCLC. Patients with tumor harboring *ROS1* and *NTRK* gene fusions treated with approved targeted therapies often develop resistance mutations, eventually leading to tumor progression. Repotrectinib is the first next-generation TKI for *ROS1*- positive metastatic NSCLC and tumors with NTRK fusions, uniquely designed to address key drivers of disease progression. Zai Lab and Turning Point Therapeutics, Inc. (Turning Point, acquired by Bristol Myers Squibb) are studying repotrectinib in TRIDENT-1, a registrational Phase 1/2 study in adults, and CARE, a Phase 1/2 study in pediatric patients. Repotrectinib has shown robust antitumor activity and durable responses among TKI-naïve and pre-treated patients. Zai Lab participated in the registrational TRIDENT-1 study in Greater China (mainland China, Hong Kong, Taiwan, and Macau), while Turning Point Therapeutics is enrolling patients in other regions of the world.

In the United States, repotrectinib has been granted three Breakthrough Therapy Designations from the U.S. Food and Drug Administration (FDA) in: *ROS1*-positive metastatic NSCLC patients who have not been treated with a *ROS1* TKI; *ROS1*-positive metastatic NSCLC patients who have previously been treated with a *ROS1* TKI and who have not received prior platinum-based chemotherapy; and patients with advanced solid tumors that have an *NTRK* gene fusion who have progressed following treatment with one or two prior *TRK* TKIs, with or without prior chemotherapy, and have not had satisfactory alternative treatments. Additionally, repotrectinib was previously granted four Fast-Track Designations by the FDA in *ROS1*-positive advanced NSCLC patients who are *ROS1* TKI naïve; *ROS1*-positive advanced NSCLC patients who have been previously treated with one prior line of platinum-based chemotherapy and one prior *ROS1* TKI; *ROS1*-positive advanced NSCLC patients pretreated with one prior *ROS1* TKI without prior platinum-based chemotherapy; and *NTRK*-positive patients with advanced solid tumors who have progressed following treatment with at least one prior line of chemotherapy and one or two prior *TRK* TKIs and have not had satisfactory alternative treatments. Repotrectinib was also granted an Orphan Drug Designation by the FDA in 2017.

In China, repotrectinib has been granted three Breakthrough Therapy Designations from the CDE of the NMPA in *ROS1*-positive metastatic NSCLC patients who have not been treated with a *ROS1* TKI; *ROS1*-positive metastatic NSCLC patients who have previously been treated with a *ROS1* TKI and who have not received prior platinum-based chemotherapy; and *ROS1*-positive metastatic NSCLC patients who have previously been treated with a *ROS1* TKI and one prior line of platinum-based chemotherapy.

Zai Lab has an exclusive license agreement with Turning Point to develop and commercialize repotrectinib in Greater China.

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 regarding the prospects of repotrectinib and the potential treatment of NTRK-positive solid tumors in 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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