Zai Lab Announces That Repotrectinib Granted Priority Review by China's NMPA

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SHANGHAI, China and CAMBRIDGE, Mass., May 18, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has granted priority review to repotrectinib for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small-cell lung cancer (NSCLC).

"The CDE's decision to grant priority review to repotrectinib underscores repotrectinib as a potential next-generation best-in-class treatment for *ROS1*-positive NSCLC in both TKI-naïve and pretreated patients in China," said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development at Zai Lab. "We thank the agency for their commitment and continued support to patients in need, and we look forward to our continued partnership with regulatory authorities in China to bring this important medicine to patients in need as soon as possible."

Priority review was established in China to encourage innovative drug development with significant clinical value and urgent clinical need. It is implemented under the Drug Registration Regulation (Bureau Order 27) and the Working Procedure for Priority Review and Approval of Drug Marketing Authorization (Interim, NMPA 2020 No. 82) effective on July 1, 2020, and July 7, 2020, respectively. According to the regulation and guidance, the regulatory authority will prioritize the evaluation resources for applications under priority review to expedite the review and approval timelines.

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, limiting binding of these drugs to their target, eventually leading to tumor progression. Repotrectinib is the first next-generation TKI for *ROS1*-positive metastatic NSCLC, uniquely designed to address key drivers of disease progression. Zai Lab and Turning Point Therapeutics, Inc. (Turning Point Therapeutics, 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 is enrolling patients 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.

Repotrectinib has been granted three Breakthrough Therapy Designations from the U.S. Food and Drug Administration 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 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 in 2017.

Repotrectinib has been granted three Breakthrough Therapy Designations from the CDE of China's 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 Therapeutics to develop and commercialize repotrectinib in Greater China.

About Non-Small Cell Lung Cancer in China

Lung cancer is both the most commonly diagnosed cancer type and the leading cause of cancer death in China. The incidence of lung cancer in China in 2020 was 815,563 cases, with 714,699 deaths.[1] NSCLC accounts for approximately 85% of lung cancer, and about 70% of NSCLC is locally advanced or metastatic at initial diagnosis. In China, *ROS1* rearrangements occur in 2-3% of patients with advanced NSCLC.

[1]*Globocan 2020.*

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, including our products, business activities and partnerships, research, and other events or developments, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing repotrectinib in the Greater China region, the potential efficacy and safety of repotrectinib, and the regulatory pathway afforded by the Priority Review. It should be noted that Priority Review is not a guarantee of approval. 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, nor are they 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) the effects of the novel coronavirus (COVID-19) pandemic on our business and results of operations, and (6) risks related to doing business in China, and (7) 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 (SEC). 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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