Zai Lab Announces Breakthrough Therapy Designations Granted for Repotrectinib in China

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-- Breakthrough Therapy Designations granted for ROS1-positive non-small cell lung cancer (NSCLC) patients pretreated with one prior line of ROS1 tyrosine kinase inhibitor (TKI) with or without prior chemotherapy

-- Potential best-in-class therapy for ROS1-positive metastatic NSCLC and NTRK-positive advanced solid tumors

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., June 10, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted two Breakthrough Therapy Designations for investigational repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and one prior line of platinum-based chemotherapy (EXP-2) and for those with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and no chemotherapy or immunotherapy (EXP-4). The Breakthrough Therapy Designations for repotrectinib were supported by the data from both global and Chinese TKI-pretreated ROS1-positive NSCLC patients enrolled in the Phase 1/2 TRIDENT-1 study.

“Since repotrectinib received Breakthrough Therapy Designation by the CDE earlier this year for ROS1-positive TKI-naïve patients, today’s recognition further supports repotrectinib as a potential best-in-class treatment for ROS1-positive NSCLC in both TKI-naïve and pretreated patients in China,” said Alan Sandler, M.D., President and Head of Global Development, Oncology at Zai Lab. “There remain significant unmet needs for ROS1-positive NSCLC patients, 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.”

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.

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 Repotrectinib

Repotrectinib is a next-generation kinase inhibitor targeting the ROS1 and NTRK oncogenic drivers of NSCLC and advanced solid tumors. Tumors with mutations to their ROS1 and NTRK genes have a higher likelihood of developing resistance to existing targeted therapies. In many cases, these mutations prevent existing medicine from targeting and binding to the tumor as effectively as tumors that do not carry the mutations. Repotrectinib is designed to be smaller and less bulky than existing targeted therapies and may circumvent some of the resistance mechanisms found in tumors with ROS1 and NTRK mutations. Zai Lab and Turning Point Therapeutics, Inc. are studying repotrectinib in TRIDENT-1, a registrational Phase 1/2 study in adults, and CARE, a Phase 1/2 study in pediatric patients. The compound has shown antitumor activity and durable responses among kinase inhibitor treatment-naïve and pre-treated patients. Zai Lab is enrolling patients in the registrational Phase 2 portion of TRIDENT-1 in Greater China, 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; 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 no satisfactory alternative treatments; and ROS1-positive metastatic NSCLC patients who have previously been treated with a ROS1 TKI and who have not received prior platinum-based chemotherapy. 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 no satisfactory alternative treatments. Repotrectinib was also granted an Orphan Drug designation in 2017.

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

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the U.S. focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including information on our products, business activities and partnerships, research, or 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 forward-looking statements about clinical trials, data readouts and presentations, our clinical development programs, including our research and development program for the treatment of non-small cell lung cancer in China; the potential of our commercial business and pipeline programs, and the risk and uncertainties associated with drug development and commercialization. These forward-looking statements include, without limitation, statements containing 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 general economic, regulatory and political conditions (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. 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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