Zai Lab Announces Breakthrough Therapy Designation Granted for Repotrectinib in China

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

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Feb. 17, 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 Breakthrough Therapy Designation for investigational repotrectinib for the treatment of patients with ROS1-positive metastatic non-small-cell lung cancer (NSCLC) who have not been treated with a ROS1 tyrosine kinase inhibitor (TKI). The breakthrough therapy designation for repotrectinib was supported by the initial data from both global and Chinese TKI-naïve ROS1-positive NSCLC patients enrolled in the Phase 1/2 TRIDENT-1 study.

“In granting Breakthrough Therapy Designation, we are pleased to see that the CDE recognizes the promise of repotrectinib,” said Alan Sandler, M.D., President and Head of Global Development, Oncology, at Zai Lab. “We believe repotrectinib has the potential to be the best-in-class treatment for patients with ROS1-positive NSCLC, including patients who are either TKI-naïve or TKI-pretreated. 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 the Breakthrough Therapy Designation receive priority communications and guidance from the CDE to promote and expedite the drug development progress.

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 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.

The U.S. Food and Drug Administration has granted repotrectinib breakthrough therapy designation both for the indication described above as well as for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with one or two prior TRK tyrosine kinase inhibitors, with or without prior chemotherapy, and have no 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 no satisfactory alternative treatments. Repotrectinib was also granted an Orphan Drug designation in 2017.

Zai Lab has an exclusive license to develop and commercialize repotrectinib in Greater China.

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, 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 Breakthrough Therapy Designation. It should be noted that Breakthrough Therapy Designation does not change the standards for approval, nor is it 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 finance our operations and business initiatives and obtain funding for such activities, (3) our results of 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, and (6) the risk factors identified in our most recent annual or quarterly report 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.

For more investor-related information about Zai Lab, please go to www.SEC.gov or visit www.zailaboratory.com.

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