Zai Lab Announces First Patient Treated in China in the Registrational Phase 2 TRIDENT-1 Study of Repotrectinib

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- *TRIDENT-1 study is enrolling patients with ROS1+ advanced NSCLC and NTRK+ advanced solid tumors.*

SHANGHAI and SAN FRANCISCO, May 28, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company today announced dosing of the first patient in China in the registrational Phase 2 portion of TRIDENT-1 study of repotrectinib being conducted by its partner Turning Point Therapeutics, Inc. and Zai Lab in patients with ROS1+ advanced non-small cell lung cancer (NSCLC) and NTRK+ advanced solid tumors. Zai Lab has an exclusive license agreement with Turning Point for the development and commercialization of repotrectinib in Greater China (mainland China, Hong Kong, Macau, and Taiwan).

“We believe repotrectinib has the potential to be the best-in-class treatment for patients with ROS1+ or NTRK+ tumors, including patients who are either TKI-naïve or TKI-pretreated,” said Alan Sandler, M.D., President, Head of Global Development, Oncology of Zai Lab. “Tumors with fusions in their ROS1 and NTRK genes have a high likelihood of developing resistance to existing targeted therapies. In many cases, these acquired resistance mutations prevent existing medicine from binding to the tumor as effectively as to tumors that don’t carry these resistance mutations. We are excited to announce the expansion of the TRIDENT-1 study into China and to support our partner Turning Point Therapeutics in bringing a potential best-in-class therapy to patients globally.”

The registrational Phase 2 portion of TRIDENT-1 study is a multi-center trial evaluating repotrectinib for the treatment of patients with ROS1+ advanced NSCLC as well as patients with NTRK+ advanced solid tumors. The primary endpoint of the Phase 2 portion of the trial is overall response rate (ORR) assessed by Blinded Independent Central Review (BICR). Secondary endpoints include duration of response (DOR), progression free survival (PFS), safety and tolerability. Zai Lab is enrolling patients in Greater China, while Turning Point is enrolling patients in other regions of the world.

The U.S. Food and Drug Administration (FDA) has granted repotrectinib breakthrough therapy designation for the treatment of patients with ROS1+ metastatic NSCLC who have not been treated with a ROS1 tyrosine kinase inhibitor (TKI). In addition, the FDA has granted orphan drug designation for the development of repotrectinib in patients with advanced NSCLC with adenocarcinoma histology. The FDA has also granted fast track designations for the treatment of NTRK+ advanced solid tumor patients who have been previously treated with one prior line of chemotherapy and one or two prior TRK TKIs, ROS1+ advanced NSCLC patients who have been previously treated with one prior line of platinum-based chemotherapy and one prior line of a ROS1 TKI, and ROS1+ advanced NSCLC patients who have not been previously treated with a ROS1 TKI.

Turning Point disclosed on May 5 that the FDA recently guided that a type B meeting should be requested to discuss topline BICR results of cohort 1 (EXP-1) of the registrational TRIDENT-1 study when responders have been followed for at least six months past onset of response. Turning Point believes it may be in a position to discuss the topline results from patients treated within EXP-1 with the FDA during the first quarter of 2022.

More information about the ongoing TRIDENT-1 study of repotrectinib can be found by searching clinical trial identifier NCT03093116 at https://clinicaltrials.gov.

About Non-Small Cell Lung Cancer in China

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

About Repotrectinib

Repotrectinib is a next-generation kinase inhibitor targeting the ROS1 and TRK oncogenic drivers of non-small cell lung cancer and advanced solid tumors. Turning Point Therapeutics is 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. ROS1 rearrangement is estimated to be an oncogenic driver in approximately 2-3% of patients with advanced NSCLC in China. NTRK is estimated to be an oncogenic driver in approximately 0.5% of patients with other advanced solid tumors in China.

Tumors with mutations to their ROS1, NTRK and ALK 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 don’t carry the mutations. Repotrectinib is designed to be smaller and less bulky than existing targeted therapies and may circumvent some the resistance mechanisms found in tumors with ROS1, NTRK and ALK mutations.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. 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.

About Turning Point Therapeutics Inc.

Turning Point Therapeutics is a clinical-stage precision oncology company with a pipeline of internally discovered investigational drugs designed to address key limitations of existing cancer therapies. The company's lead drug candidate, repotrectinib, is a next-generation kinase inhibitor targeting the ROS1 and TRK oncogenic drivers of non-small cell lung cancer and advanced solid tumors. Repotrectinib, which is being studied in a registrational Phase 2 study in adults and a Phase 1/2 study in pediatric patients, has shown antitumor activity and durable responses among kinase inhibitor treatment-naïve and pre-treated patients. The company's pipeline of drug candidates also includes TPX-0022, targeting MET, CSF1R and SRC, which is being studied in a Phase 1 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in MET; TPX-0046, targeting RET, which is being studied in a Phase 1/2 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in RET; and TPX-0131, a next-generation ALK inhibitor, which is being studied in a Phase 1/2 trial of previously treated patients with ALK-positive advanced or metastatic non-small cell lung cancer. Turning Point's next-generation kinase inhibitors are designed to bind to their targets with greater precision and affinity than existing therapies, with a novel, compact structure that has demonstrated an ability to potentially overcome treatment resistance common with other kinase inhibitors. The company is driven to develop therapies that mark a turning point for patients in their cancer treatment. For more information, visit www.tptherapeutics.com.

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 and plans for developing and commercializing repotrectinib in Greater China and other 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 Zai Lab's 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) Zai Lab's ability to successfully commercialize and generate revenue from its approved products; (2) Zai Lab's ability to finance its operations and business initiatives and obtain funding for such activities, (3) Zai Lab's results of clinical and pre-clinical development of its product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's 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 Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes 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 Zai Lab's views as of any date subsequent to the date of this press release.

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