Zai Lab and Turning Point Therapeutics Announce Topline Analysis in China Subpopulation for Repotrectinib in ROS1-Positive NSCLC Cohorts Within Global Phase 1/2 TRIDENT-1 Study

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- *91% confirmed objective response rate (cORR) (10/11) in China subpopulation by Blinded Independent Central Review (BICR) in TKI-naïve cohort (EXP-1)*
- *In the TKI-naïve China subpopulation by BICR, the duration of response (DOR) range was 3.6+-7.5+ months with median DOR follow-up of 3.7 months*
- *36-67% cORR by BICR in China subpopulation across three TKI-pretreated cohorts (EXP-2, EXP-3, and EXP-4)*
- *Zai Lab plans to discuss topline TKI-naïve data with Chinese health authority in the fourth quarter of 2022*

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass. and SAN DIEGO, April 28, 2022 (GLOBE NEWSWIRE) -- Zai Lab (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, and Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a clinical-stage precision oncology company developing next-generation therapies that target genetic drivers of cancer, today announced topline data for repotrectinib within the China region from the previously disclosed Phase 1/2 TRIDENT-1 study dataset.

“With over 800,000 newly diagnosed lung cancer patients every year in China, NSCLC accounts for approximately 85% of the cases, and ROS1 rearrangements occur in 2-3% of patients with advanced NSCLC. The majority of these patients are diagnosed at advanced stages, representing significant unmet medical need,” said Alan Sandler, M.D., President and Head of Global Development, Oncology, at Zai Lab. “It is encouraging to see the similar results of the efficacy analyses comparing data from sites in China and globally for repotrectinib, a potential best-in-class drug candidate for patients with ROS1-positive advanced NSCLC. We will continue to work closely with Turning Point to advance this program to help support NSCLC patients in China and around the world.”

“We are incredibly pleased with our collaboration with Zai Lab given their strong enrollment into the global TRIDENT-1 study and are happy to share these initial results,” said Mohammad Hirmand, M.D., Chief Medical Officer of Turning Point Therapeutics. “We look forward to discussing our global TRIDENT-1 data with the FDA prior to the end of this quarter and presenting detailed study results from the global dataset at a medical conference in the second half of the year.”

The primary objective of the TRIDENT-1 study is to determine the cORR based on BICR as assessed by RECIST 1.1. DOR is a key secondary objective of the study. The dataset utilizes a February 11, 2022 data cutoff date. The global safety analysis included 380 treated patients from the pooled Phase 1 and Phase 2 portions of TRIDENT-1 across all cohorts. The global efficacy analyses included pooled patients from Phase 1 across all dose levels with an identified ROS1 fusion by next generation sequencing at baseline and Phase 2 patients. All patients received at least one dose of repotrectinib with at least four months of follow-up, and the majority of responders had at least six months of DOR follow-up.

Topline Efficacy Analyses by BICR

- *In TKI-naïve patients (EXP-1), in 71 total patients, there was a cORR of 79% across the global trial. Ten of 11 patients responded within China for a cORR of 91% (95% CI: 59,100) and DOR ranged from 3.6+ to 7.5+ months with a median duration of follow-up of 3.7 months.*
- *In patients previously treated with 1 TKI and platinum-based chemotherapy (EXP-2), in 26 total patients, there was a cORR of 42% across the global trial. Two of 3 patients responded within China for a cORR of 67% (95% CI:9,99) and DOR ranged from 3.6+ to 3.7+ months with a median duration of follow-up of 3.7 months.*
- *In patients previously treated with two TKIs without prior chemotherapy (EXP-3), in 18 total patients, there was a cORR of 28% across the global trial. Two of 4 patients responded within China for a cORR of 50% (95% CI: 7,93) and DOR ranged from 1.9+ to 3.4+ months with a median duration of follow-up of 2.6 months.*
- *In patients previously treated with 1 TKI without prior chemotherapy (EXP-4), in 56 total patients, there was a cORR of 36% across the global trial. Four of 11 patients responded within China for a cORR of 36% (95% CI: 11,69) and DOR ranged from 2.0+ to 3.7+ months with a median duration of follow-up of 3.1 months.*

Global TRIDENT-1 Topline Safety Analyses

Repotrectinib was generally well tolerated in a total of 380 patients treated globally with a safety and tolerability profile that was consistent with previously reported findings. The most commonly reported treatment emergent adverse event remained dizziness (61% all grade), of which 76% of patients who reported dizziness had a maximum severity of grade 1. The safety profile was comparable among the 287 patients who were treated at the Phase 2 dose.

The TRIDENT-1 study continues to enroll patients globally across the study. As previously guided, Turning Point Therapeutics anticipates discussing the topline BICR data for the ROS1-positive advanced NSCLC cohorts with the U.S. Food and Drug Administration (FDA) at a pre-NDA meeting this quarter. Turning Point Therapeutics plans to present detailed study results, including intracranial activity, from the ROS1-positive advanced NSCLC cohorts of the TRIDENT-1 study, at a medical conference in the second half of 2022.

Zai Lab plans to complete enrollment in the phase 1/2 registrational TRIDENT-1 study and discuss the regulatory pathway with the National Medical Products Administration (NMPA) at a pre-NDA meeting in the fourth quarter of 2022.

About Zai Lab

Zai Lab (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 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 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 forward-looking statements about results from the global TRIDENT-1 study, the identification and treatment of lung cancer, the efficacy, safety and therapeutic potential of repotrectinib, including the belief that repotrectinib is a potentially best-in-class drug candidate across all ROS1-positive NSCLC indications, data readouts and presentations for repotrectinib, and risks and uncertainties regarding drug development, regulatory approval 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 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. More information about Zai Laboratory and its filings can be found on the SEC.gov website.

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 elzovantinib, 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. 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.

Turning Point Therapeutics Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “plans”, “will”, “believes,” “anticipates,” “expects,” “intends,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include statements regarding, among other things, the belief that repotrectinib is a potentially best-in-class drug candidate across all *ROS1*-positive NSCLC indications, anticipated timing for a pre-NDA meeting with the FDA regarding the topline BICR data for repotrectinib, the anticipated timing and plans for presenting detailed study results from the TRIDENT-1 trial at an upcoming medical conference, the efficacy, safety and therapeutic potential of repotrectinib, plans regarding future

regulatory submissions, and the regulatory approval path for repotrectinib. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Turning Point Therapeutics' current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Turning Point Therapeutics' business in general, risks and uncertainties related to the impact of the COVID-19 pandemic to Turning Point Therapeutics' business and the other risks described in Turning Point Therapeutics' filings with the Securities and Exchange Commission (SEC), including its annual report on Form 10-K filed with the SEC on February 28, 2022. All forward-looking statements contained in this press release speak only as of the date on which they were made. Turning Point Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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