Zai Lab Partner Turning Point Therapeutics Granted Breakthrough Therapy Designation for Repotrectinib Treatment in Patients With NTRK-Positive, TKI-Pretreated Advanced Solid Tumors

October 4, 2021

SHANGHAI, China and SAN FRANCISCO, Oct. 04, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) partner Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, today announced the U.S. Food and Drug Administration (FDA) granted a seventh regulatory designation to lead drug candidate, repotrectinib.

Breakthrough Therapy designation was granted 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. The company is planning to discuss next steps towards potential registration of repotrectinib in this patient population at a Type B meeting with the FDA anticipated in the first half of 2022.

Breakthrough Therapy designation is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. The criteria for Breakthrough Therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

Repotrectinib was previously granted Breakthrough Therapy designation in ROS1- positive metastatic non-small cell lung cancer (NSCLC) patients who have not been treated with a ROS1 tyrosine kinase inhibitor, as well as 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.

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.

Zai Lab Forward-Looking Statements
This press release contains forward-looking statements including but not limited to statements relating to our strategy and plans; potential of and expectations for our business and pipeline programs; capital allocation and investment strategy; clinical development programs and related clinical trial data; risks and uncertainties associated with drug development and commercialization; regulatory approvals for our pipeline programs and the timing thereof; the potential benefits, safety and efficacy of our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, collaborations and business development activities; and our future financial and operating results. 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. All of our filings with the U.S. Securities and Exchange Commission are available for free on the EDGAR system at www.SEC.gov.

Zai Lab Contacts:

Investors:
Ron Aldridge / Lina Zhang
+1 (781) 434-8465 / +86 136 8257 6943
ronald.aldridge@zailaboratory.com / lina.zhang@zailaboratory.com

Media:
Danielle Halstrom / Xiaoyu Chen
+1 (215) 280-3898 / +86 185 0015 5011
danielle.halstrom@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Zai Lab Limited

Source: Zai Lab Limited