# Zai Lab Receives U.S. FDA Fast Track Designation for ZL-1310, a DLL3-Targeted Antibody-Drug Conjugate, for Treatment of Extensive-Stage Small Cell Lung Cancer

May 19, 2025

*- The Company is on track to initiate a pivotal study for ZL-1310 in small cell lung cancer (SCLC) in 2025*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 19, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ZL-1310, the Company's potential first-in-class Delta-like ligand (DLL3) antibody-drug conjugate (ADC), for the treatment of extensive-stage small cell lung cancer (ES-SCLC). ZL-1310, which is being evaluated in an ongoing global Phase 1a/1b clinical trial (NCT06179069), previously received an Orphan Drug designation for SCLC from the FDA. The company will present updated data at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

"The FDA's decision to grant Fast Track designation to ZL-1310 highlights the significant need for expanded treatment options for patients with SCLC and represents an important step in our efforts to advance a novel therapeutic option as quickly as possible," said Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab. "This designation reinforces the clinical progress we have achieved for ZL-1310 to-date, and we remain on track to initiate a pivotal study in small cell lung cancer later this year, positioning us for a potential accelerated approval in 2027."

Fast Track designation facilitates the expedited development and review of new drugs to address an unmet medical need or treat serious or life-threatening diseases. Benefits of this designation include more frequent engagements with the FDA to discuss the drug's clinical development plan and eligibility for Accelerated Approval and Priority Review if relevant criteria are met. More information on the Fast Track process is available here.

Zai Lab will hold an investor conference call and webcast to highlight updated ZL-1310 data at ASCO and outline the next steps in clinical development.

**Details regarding upcoming ZL-1310 webcast and conference call are as follows:**

**Date/Time:** Monday, June 2, 2025, at 7:00 a.m. CT / 8:00 a.m. ET / 8:00 p.m. HKT., please register at:
**Webcast presentation (preferred):** https://edge.media-server.com/mmc/p/jnqqzjod;
**Dial-in:** https://register-conf.media-server.com/register/BIc7326906f3764306accd7708d21d2ecb.
**Presenter:** Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab

**About Small Cell Lung Cancer and ZL-1310**

SCLC is one of the most aggressive and lethal solid tumors, accounting for approximately ~15% of the approximately 2.5 million patients diagnosed with lung cancer worldwide each year. [1,2] Additionally, two-thirds of all SCLC patients are diagnosed at extensive stage. [3]

DLL3 is an antigen overexpressed in many neuroendocrine tumors, such as SCLC, and is often associated with poor clinical outcomes. ZL-1310 comprises a humanized anti-DLL3 monoclonal antibody connected via a cleavable linker to a novel camptothecin derivative (a topoisomerase 1 inhibitor) as its payload. The compound was designed with a novel ADC technology platform called TMALIN®, which leverages the tumor microenvironment to overcome challenges associated with first-generation ADC therapies.

**About Zai Lab**

Zai Lab is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.X.com/ZaiLab_Global, www.twitter.com/ZaiLab_Global.

**Zai Lab Forward-Looking Statements**

This press release contains forward-looking statements relating to our future expectations, plans, and prospects, for Zai Lab, including, without limitation, statements relating to our prospects and plans for developing and commercializing next generation ADCs, including ZL-1310, the potential benefits of ZL-1310, and the potential treatment of SCLC and neuroendocrine tumors. 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 or 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) risks related to doing business in China, and (6) 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 (SEC). 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.

**References:**

[1] J Thorac Oncol. 2023 Jan;18(1):31-46; Lung Cancer Foundation of America.

[2] WHO Globocan 2022.

[3] Sabari JK, et al. Nat Rev Clin Oncol. 2017;14:549-561.

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Source: Zai Lab Limited