



## Zai Lab Receives Orphan Drug Designation from the U.S. FDA for ZL-1310 (DLL3 ADC) for the Treatment of Small Cell Lung Cancer (SCLC)

January 23, 2025

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 22, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to ZL-1310, a potential highly active first-in-class DLL3 antibody-drug conjugate (ADC), for the treatment of small cell lung cancer (SCLC).

"Receiving an Orphan Drug Designation for ZL-1310 recognizes its potential to treat patients with SCLC. These patients have an urgent need for innovative treatment options with improved efficacy, safety and ready access in tertiary care and community settings," said Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab. "ZL-1310 has demonstrated promising objective response rates and a favorable safety profile from the ongoing Phase 1 trial in patients with recurrent SCLC recently disclosed. We look forward to continuing to advance the clinical development of this promising asset across lines of therapy in SCLC and other DLL3-expressing tumors."

ZL-1310 will be eligible for certain development incentives, including a waiver of the Prescription Drug User Fee Act registration application fee, tax credits for certain clinical trials and the potential to receive a seven-year U.S. market exclusivity period granted upon product approval.

This important regulatory designation follows promising data from the ongoing global Phase 1a/1b study in patients with previously treated extensive-stage SCLC (ES-SCLC) after at least one prior platinum-based chemotherapy regimen, which was presented at the EORTC-NCI-AACR (ENA) Symposium 2024 in October 2024.

### About ZL-1310

ZL-1310 is a novel ADC in Zai Lab's growing, global oncology pipeline that targets Delta-like ligand 3 (DLL3), an antigen that is overexpressed in many neuroendocrine tumors, is typically associated with poor clinical outcomes, and is a validated therapeutic target for SCLC. ZL-1310 comprises a humanized anti-DLL3 monoclonal antibody linked to a novel camptothecin derivative (a topoisomerase 1 inhibitor) as its payload. The compound was designed with a novel ADC technology platform called TMALIN<sup>®</sup>, which leverages the tumor microenvironment to overcome challenges associated with first-generation ADC therapies, including off-target payload toxicity.

The ongoing Phase 1a/1b clinical trial is evaluating ZL-1310 as monotherapy and in combination with atezolizumab, an immune checkpoint inhibitor, for the treatment of ES-SCLC.

### About Small Cell Lung Cancer (SCLC)

SCLC is one of the most aggressive and lethal solid tumors, accounting for ~15% of approximately 2.5 million patients diagnosed with lung cancer worldwide each year<sup>1,2</sup>. Two-thirds of all SCLC patients are diagnosed at extensive stage<sup>3</sup>, which is associated with high rates of relapse and poor prognosis. The outcomes of the patients with ES-SCLC are dismal, with median survival of approximately 12 months following initial therapy<sup>4</sup> and a 5-10% overall five-year survival rate<sup>5</sup>. Treatment options are limited when patients progress, with the current standard of care resulting in limited clinical benefit. Despite recent advancements, new readily available treatment options with improved efficacy and manageable safety are needed.

#### References:

<sup>1</sup> *J Thorac Oncol.* 2023 Jan;18(1):31-46; Lung Cancer Foundation of America.

<sup>2</sup> *WHO Globocan 2022.*

<sup>3</sup> Sabari JK, et al. *Nat Rev Clin Oncol.* 2017;14:549-561.

<sup>4</sup> *Phase 3 IMpower133 (atezolizumab) and CASPIAN study (durvalumab).*

<sup>5</sup> *National Cancer Institute.* [www.cancer.gov](http://www.cancer.gov). Accessed October 15, 2024.

### About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) 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](http://www.zailaboratory.com) or follow us at [www.X.com/ZaiLab\\_Global](http://www.X.com/ZaiLab_Global), [www.twitter.com/ZaiLab\\_Global](http://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](http://www.zailaboratory.com) and on the SEC's website at [www.sec.gov](http://www.sec.gov).

View source version on [businesswire.com](http://businesswire.com): <https://www.businesswire.com/news/home/20250123670143/en/>

**For more information, please contact:**

**Investor Relations:**

Christine Chiou / Lina Zhang

+1 (917) 886-6929 / +86 136 8257 6943

[christine.chiou1@zailaboratory.com](mailto:christine.chiou1@zailaboratory.com) / [lina.zhang@zailaboratory.com](mailto:lina.zhang@zailaboratory.com)

**Media:**

Shaun Maccoun / Xiaoyu Chen

+1 (857) 270-8854 / +86 185 0015 5011

[shaun.maccoun@zailaboratory.com](mailto:shaun.maccoun@zailaboratory.com) / [xiaoyu.chen@zailaboratory.com](mailto:xiaoyu.chen@zailaboratory.com)

Source: Zai Lab Limited