Zai Lab Announces Updated Phase 1 Data for Zocilurtatug Pelitecan (formerly ZL-1310), Demonstrating Potential as a First-in-Class/Best-in-Class DLL3-Targeted ADC for Small Cell Lung Cancer, and Initiation of Global Phase 3 Registrational Study

October 24, 2025

- Robust responses observed in heavily pre-treated patients with a 68% ORR for 1.6 mg/kg in second-line setting

-Compelling activity in patients with baseline brain metastases (n=32), including an 80% ORR for patients without prior brain radiotherapy

- Duration of response of 6.1 months across all doses and all lines of therapy; enrollment continuing for 1.2 mg/kg and 1.6 mg/kg, with nearly half of responders ongoing at data cut-off

- Potential best-in-class safety profile with a low rate of Grade ≥3 TRAEs and no discontinuations in the 1.6mg/kg cohort

- Global Phase 3 trial, ZL-1310-003, has initiated in second-line plus small cell lung cancer (SCLC); first-line SCLC and neuroendocrine carcinoma programs advancing toward registrational phase in 2026

Zai Lab to host investor conference call and webcast to discuss data and clinical trial plans on October 24, 2025, at 11 a.m. ET / 11 p.m. HKT

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 24, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced updated data from the global Phase 1 clinical trial of zocilurtatug pelitecan (zoci), formerly known as ZL-1310, (NCT06179069) demonstrating robust and durable responses in heavily pre-treated patients with extensive-stage small cell lung cancer (ES-SCLC). This data will be presented as an oral presentation and was included as part of the press program at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, held October 22–26, 2025, in Boston, Massachusetts.

“The strong and durable antitumor activity we have observed with zoci, alongside a well-tolerated safety profile, highlights its potential to be a best-in-class, DLL3-targeted antibody-drug conjugate for small cell lung cancer,” said Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab. “Advancing this program from Phase 1 to a global, registrational study in less than two years reflects the speed, scientific rigor, and executional excellence of our team, and marks a major milestone for Zai Lab as we advance our global programs. Furthermore, we are rapidly expanding zoci’s development into other areas of high unmet need, including first-line small cell lung cancer and neuroendocrine carcinoma, both expected to enter the registrational phase next year.”

The presentation includes updated results from the Phase 1 monotherapy dose escalation and dose expansion portion of the study from 115 patients across six dose cohorts (0.8 mg/kg, 1.2 mg/kg, 1.6 mg/kg, 2.0 mg/kg, 2.4 mg/kg, and 2.8 mg/kg) as of the data cut-off date of September 15, 2025. 102 patients had the opportunity of at least one post-baseline tumor assessment per Response Evaluation Criteria in Solid Tumors version 1:1 (RECIST v1.1).

All patients in this multicenter study had progressed following platinum-based chemotherapy, and 90% of patients had progressed after immune checkpoint inhibitors. Of all patients, 44% had failed two prior lines of therapy, making this a highly pretreated population with limited therapeutic options. Eleven patients received a prior DLL3 bi-specific antibody. A total of 32% of patients had brain metastases at baseline. This study included patients in the United States, Spain, and China.

Key efficacy results include (n=102):

- Zoci demonstrated a high response rate across all dose levels in patients with ES-SCLC who progressed on or after platinum-based chemotherapy. Efficacy was consistent over time with additional patients and longer follow-up.
- In a subset of patients (n=53) receiving zoci as a second-line treatment, the best overall response rate (ORR) observed among patients in the 1.6 mg/kg arm (n=19) was 68%.
- A high response rate was also observed in patients (n=32) with brain metastasis at baseline, including an ORR of 80% for patients without prior brain radiotherapy.
- Three out of seven patients who progressed after prior tarlatamab, responded. Enrollment of tarlatamab pretreated patients continues.
- The estimated median duration of response (DoR) is 6.1 months, and median progression-free survival is 5.4 months across all doses and all lines of therapy. Responses were durable and clinically meaningful in this heavily pre-treated and difficult-to-treat population. In the dose finding cohort of the study, enrollment continues for 1.2 mg/kg and 1.6 mg/kg, with nearly half of responders still ongoing at data cut-off. Enrollment is expected to complete in Q4 2025.
- Responses occurred early in treatment with a median time to confirmed objective response of 6 weeks.

Key safety findings include (n=115):

- Zoci continues to demonstrate a well-tolerated safety profile with longer follow-up, particularly at the 1.2 or 1.6mg/kg dose level.
- In the 1.6 mg/kg dose cohort, Grade 3 or higher treatment-related adverse events (TRAE) occurred in 13% of patients and serious TRAEs occurred in 9%. No patients were discontinued due to toxicity.
- There were two cases of pneumonitis and interstitial lung disease, both Grade 1, in the 72 patients treated at 1.2 or 1.6 mg/kg dose.
- Across all dose cohorts, Grade 3 or higher TRAEs occurred in 20% of patients and serious TRAEs in 8%. The most common Grade 3 or higher TRAEs were anemia (10%) and neutropenia (11%). There were five patients who discontinued due to TRAEs, all in the higher dose levels.

“DLL3 represents a validated target in extensive-stage small cell lung cancer, where there is high need for new therapies given the disease’s aggressive nature and limited treatment options,” said Grace Dy, M.D., Roswell Park Comprehensive Cancer Center, Buffalo, NY, and study investigator. “These new Phase 1 results for zoci, including data that show rapid and sustained responses among the patient population, especially those with poor prognostic factors, are the latest clinical evidence that further demonstrate zoci’s potential as a differentiated, DLL3-targeted ADC.”

Global Phase 3 Registrational Study Opens for Patient Enrollment

The Phase 3 registrational clinical trial of zoci is a multicenter study that will enroll approximately 665 patients globally, including in North America, Asia, and Europe. The randomized, open-label study is designed to further evaluate the safety and efficacy of zoci compared to investigator’s choice single agent therapy (ICT) in patients with relapsed SCLC who have progressed on or after platinum-based first-line therapy as second-line therapy or one line of chemotherapy followed by tarlatamab. The primary endpoints are ORR assessed by Blinded Independent Central Review (BICR) per RECIST v1.1 for interim analysis and overall survival as the primary analysis. Secondary endpoints include duration of response, progression-free survival and safety.

To learn more about the Phase 3 clinical trial program and study locations, please visit ClinicalTrials.gov (identifier: NCT07218146).

Zai Lab will hold an investor conference call and webcast to highlight updated zoci data presented at the 2025 AACR-NCI-EORTC International Conference and outline next steps in clinical development.

Details regarding the webcast and conference call are as follows:

Date/Time: October 24, 2025, at 11 a.m. ET / 11 p.m. HKT, please register at:
Webcast presentation (preferred): https://edge.media-server.com/mmc/p/92agda72/
Dial-in: https://register-conf.media-server.com/register/BIcb9a4304d71946febe2796d440873654
Presenter: Rafael G. Amado, M.D., President and Head of Global Research and Development, Zai Lab

Details regarding the zoci oral presentation are as follows:

Title: Phase 1 trial of ZL-1310, a DLL3-targeted ADC, in patients with previously treated extensive-stage small cell lung cancer
Presenter: Grace K. Dy, M.D., Roswell Park Comprehensive Cancer Center, Buffalo, NY
Session Title: Plenary Session 3: Antibody Drug Conjugates
Date/Time: Friday, October 24, 2025, 9:17 a.m. – 9:27 a.m. ET (presentation), 9:27 a.m. – 9:45 a.m. ET (panel discussion)
Location: Hynes Convention Center, Level 3, Ballroom AB

About Small Cell Lung Cancer and Zocilurtatug Pelitecan (zoci)

Small cell lung cancer (SCLC) is one of the most aggressive and lethal solid tumors, accounting for ~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. Zocilurtatug pelitecan (zoci), formerly known as 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.

Zoci received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in January 2025, recognizing its potential to treat patients with SCLC.

About the Webcast and Conference Call

All participants must use the link provided above to complete the online registration process in advance of the conference call. Dial-in details will be in the confirmation email which the participant will receive upon registering.

A replay will be available shortly after the call and can be accessed by visiting the Company's website.

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.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at https://x.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 zocilurtatug pelitecan (formerly known as ZL-1310), the potential benefits of zocilurtatug pelitecan, 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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