Zai Lab Presents New Data Demonstrating Zocilurtatug Pelitecan (Zoci) Induces Rapid and Robust Intracranial Responses in Small Cell Lung Cancer with Brain Metastases and Promising Activity in Other Neuroendocrine Carcinomas

April 17, 2026

- *Zoci, a potential first-in-class DLL3-targeting antibody drug conjugate, showed a 53.7% confirmed intracranial objective response rate (iORR) for small cell lung cancer (SCLC) with brain metastases; at 1.6 mg/kg dose, the confirmed iORR was 62.5% (10/16), including complete responses*
- *Encouraging activity was observed in extrapulmonary neuroendocrine carcinomas (NECs), with a 38.2% confirmed objective response rate*
- *Global Phase 3 trial ongoing in second-line-plus SCLC; first-line SCLC and neuroendocrine carcinoma programs advancing toward registrational phase in 2026*
- *Investor conference call and webcast to discuss data being presented at AACR Annual Meeting 2026 and clinical trial plans scheduled for Monday, April 20, at 5:30 a.m. PT / 8:30 a.m. ET / 8:30 p.m. HKT*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 17, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced clinical data indicating zocilurtatug pelitecan (zoci, formerly ZL-1310), a DLL3-targeting antibody-drug conjugate (ADC), provides rapid and robust intracranial responses in patients with previously treated extensive stage small cell lung cancer (ES-SCLC) and brain metastases as measured by independent assessment using modified Response Assessment in Neuro-Oncology for Brain Metastases (mRANO-BM) criteria, as well as promising data in patients with other neuroendocrine carcinomas (NECs). These findings, as well as preclinical data evaluating ZL-6201 (LRRC15 ADC) and ZL-1222 (PD-1/IL-12), will be presented at the American Association for Cancer Research (AACR) Annual Meeting 2026 in San Diego.

Results from an ongoing, global Phase 1 trial (NCT06179069) demonstrate that treatment with zoci results in significant intracranial lesion regression and reduced tumor size among patients with ES-SCLC whose cancer metastasized to the brain, a population with poor survival and limited effective treatment options.

“For patients with extensive stage small cell lung cancer who develop brain metastases, a frequent and clinically significant driver of disease progression, the prognosis is poor and existing therapeutic options delays systemic therapy and offer limited efficacy,” said Luis Paz-Ares, M.D. Ph.D., senior investigator and Chair of the Medical Oncology Department at the Hospital Universitario 12 de Octubre and Head of the Lung Cancer Unit at the CNIO (Spanish National Cancer Research Center) in Madrid, Spain. “The data from these ongoing zoci clinical trials are encouraging, demonstrating not only rapid and robust responses across multiple dose cohorts, but also notable activity in patients regardless of prior intracranial radiotherapy. These findings suggest the potential for zoci to provide a novel treatment option for difficult-to-treat cancers with limited therapies, addressing significant unmet needs in this patient population."

Additionally, researchers will share preliminary data from a Phase 1b/2 clinical trial of zoci (NCT06885281) in patients with extrapulmonary neuroendocrine carcinomas (epNECs) and other selected solid tumors. These data indicate that zoci has antitumor activity, with an objective response rate (ORR) of 38.2% in an additional patient population with aggressive malignancies, poor prognosis, and limited treatment options. Notably, there are no approved standard therapies in previously treated epNEC and no targeted therapies in this disease.

Abstract title: Intracranial activity of ZL-1310, a DLL3-targeted ADC, in patients with previously treated extensive-stage small cell lung cancer and baseline brain metastasis: Analysis of a Phase 1 trial

Patients with ES-SCLC and baseline brain metastasis were enrolled in a clinical trial with zoci monotherapy administered intravenously every three weeks at varying doses (0.8, 1.2, 1.6, 2, 2.4, or 2.8 mg/kg). The data presented had a median follow-up of 7.9 months. Systemic efficacy was measured with RECIST v1.1 by investigator assessment and intracranial efficacy was assessed with mRANO-BM by blinded independent radiologic committee review.

- Among 136 treated patients, 36% had baseline brain metastases.
- In all patients with brain metastases and the opportunity to finish at least two post-baseline scans, intracranial objective response rate (iORR) among patients who received zoci was 53.7% (22/41), including seven complete responses. At the 1.6 mg/kg dose, confirmed iORR was 62.5% (10/16), including four complete responses. Fourteen patients were censored after a median follow-up of 9.2 months.
- Intracranial tumor reductions occurred across multiple dose levels and responses were observed in both patients with (50%, 13/26) and without (60%, 9/15) prior radiotherapy.
- Zoci demonstrated a manageable safety profile, with most treatment emergent adverse events (TEAEs) reported as low grade with minimal discontinuation. Grade ≥3 treatment-related adverse events (TRAEs) occurred in 19.9% (27/136) of the overall population and in 16.4% (9/55) of patients who received 1.6mg/kg. The most common grade ≥3 TRAEs included:

neutropenia (9.6%, 13/136), anemia (8.8%, 12/136), thrombocytopenia (3.7%, 5/136), lymphopenia (2.9%, 4/136), and leukopenia (2.9%, 4/136). No intracranial metastasis complications or treatment-related neurologic serious adverse events were reported.

Abstract title: Preliminary results from the Phase 1b/2, open-label, multi-center study of ZL-1310, a DLL3-targeted ADC, in patients with neuroendocrine carcinomas and other selected solid tumors

In another important analysis for patients with high unmet need due to aggressive malignancies with limited treatment options, preliminary results from the multicenter Phase 1b/2 study of zoci in patients with NECs demonstrated clinically meaningful responses. Researchers administered zoci intravenously at 1.6 mg/kg every three weeks until disease progression or unacceptable toxicity, with a data cutoff date of February 18, 2026, representing a median follow up of 3.7 months in the Phase 1b portion of the study. Tumor response was evaluated by investigator-assessed RECIST v1.1 with additional assessments for some NECs.

- Of the 46 patients who were pretreated with prior platinum-based chemotherapy and other prior systemic therapies, treatment with zoci decreased tumor sizes within multiple epNEC subtypes with confirmed responses in pretreated patients.
- Among response evaluable patients, the overall response rate was 38.2% (13/34) across study cohorts and the overall disease control rate was 55.9% (19/34).
- Zoci demonstrated a manageable safety profile; neutrophil count decrease (5.2%, 3/58) was the only Grade ≥3 TRAE occurring in more than one patient.

These findings highlight the potential for zoci across a broad range of DLL3-expressing NECs.

“The zoci data that we will present at AACR, alongside our ZL-6201 and ZL-1222 preclinical data, highlight the breadth, diversity and potential of our global oncology pipeline,” said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. “The rapid progression of zoci into pivotal development, with three registration-enabling studies planned by the end of this year, is a prime example of our strategy to deliver our first global oncology launch. This accelerated progress is made possible by our unique integrated U.S.-China infrastructure, which allows us to evolve drug discovery into life-changing medicines with a focus on speed and quality."

Data from two additional Zai Lab internally developed investigational oncology therapies will also be presented at AACR. Researchers will share promising findings from preclinical studies of ZL-6201, a leucine-rich repeat-containing protein 15 (LRRC15) targeting ADC for the treatment of sarcoma and epithelial tumors with LRRC15 expressing cancer-associated fibroblasts; and, ZL-1222, a potential next generation anti-PD-1 and interleukin-12 (IL-12) signaling attenuated mutein agonist immunocytokine for cancer immunotherapy.

Details regarding the webcast and conference call are as follows:

Date/Time: Monday, April 20, 2026, at 5:30 a.m. PT / 8:30 a.m. ET / 8:30 p.m. HKT
Registration available at:
Webcast presentation (preferred): https://edge.media-server.com/mmc/p/8v9n78fj/
Dial-in: https://register-conf.media-server.com/register/BId10f18579c7947b29fda2857a99f26b9
Presenters: Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab; Luis Paz-Ares, M.D. Ph.D., Chair of the Medical Oncology Department at the Hospital Universitario 12 de Octubre and Head of the Lung Cancer Unit at the CNIO (Spanish National Cancer Research Center), Madrid, Spain; Rohit Thummalapalli, M.D., gastrointestinal medical oncologist, Memorial Sloan Kettering Cancer Center

About Zocilurtatug Pelitecan (Zoci, ZL-1310)

Zoci targets DLL3, a validated therapeutic target for small cell lung cancer that is overexpressed in many neuroendocrine tumors and is generally associated with poor clinical outcomes. Zoci is on track to potentially become Zai Lab’s first global oncology launch, with plans for three registration-enabling studies across 2L+ SCLC, 1L SCLC and extrapulmonary neuroendocrine carcinomas by the end of 2026. Its potential best-in-class safety profile, coupled with compelling systemic and intracranial efficacy, supports its potential role as a new standard of care in previously treated extensive stage small cell lung cancer, as well as a backbone DLL3-targeting antibody drug conjugate in first line combination regimens, including those that reduce the burdens of chemotherapy, such as check point inhibitors and T-cell engagers.

About ZL-6201

Zai Lab is evaluating ZL-6201 as a potential first-in-class LRRC15-targeting antibody drug conjugate for the treatment of multiple solid tumors. LRRC15 is a type I transmembrane protein and an attractive target for cancer therapy because it is overexpressed in various mesenchymal tumors, such as sarcoma, glioblastoma and melanoma, as well as in cancer associated fibroblasts across many other tumor types.

About ZL-1222

Zai Lab is evaluating ZL-1222 as a potential next-generation bispecific immunocytokine comprising anti-PD-1 and attenuated IL-12 for cancer immunotherapy across multiple indications, with potential to combine potent antitumor activity with improved systemic safety. Previously, interleukin-12 therapies have shown potential benefit across a range of cancer types; however, narrow therapeutic windows and toxicity concerns have limited the utility of this therapeutic class.

About Zai Lab

Zai Lab Limited (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 zocilurtatug pelitecan (zoci), ZL-6201 and ZL-1222, the potential benefits of zoci, ZL-6201 and ZL-1222, and the potential treatment of small cell lung cancer, neuroendocrine carcinomas, and solid tumors. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by 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 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. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by 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.

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