Zai Lab Presents Updated Clinical Data Demonstrating Zocilurtatug Pelitecan (Zoci) Induces Clinically Meaningful Responses and a Manageable Safety Profile in Previously Treated Extrapulmonary Neuroendocrine Carcinomas

November 5, 2026

- *In the Phase 1b/2 trial, zoci, a potential first-in-class DLL3-targeting antibody drug conjugate, demonstrated clinically meaningful responses in patients with previously treated advanced extrapulmonary neuroendocrine carcinomas (epNECs), with a confirmed objective response rate (ORR) of 40.0% and a median duration of response (mDOR) of 5.6 months*
- *Results indicate responses to zoci monotherapy treatment among multiple epNEC subtypes, including gastroenteropancreatic NEC (GEP-NEC) and other epNEC subgroups, with confirmed ORRs of 35.9% and 47.6%, respectively; deepening anti-tumor activity was observed over time*
- *Zoci demonstrated a manageable safety profile, with a treatment-related discontinuation rate of less than 1%, no treatment-related deaths, and a low rate of interstitial lung disease (ILD)/pneumonitis (1.5%, 2 cases, both Grade 2)*
- *Zai will pursue a potential accelerated approval pathway for zoci in previously treated advanced epNECs based on results from Phase 1/2 trial, with topline data of the full epNEC population expected in 2027*
- *Global Phase 3 first-line maintenance trial of zoci monotherapy in epNECs expected to initiate in 2027*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 5, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovation-driven, global biopharma company, today announced that updated data from a Phase 1b/2 trial of zocilurtatug pelitecan (zoci, formerly ZL-1310), a DLL3-targeting antibody-drug conjugate (ADC), will be shared tomorrow at the North American Neuroendocrine Tumor Society (NANETS) 2026 Multidisciplinary NET Medical Symposium in Las Vegas. The data indicate that zoci demonstrated clinically meaningful, durable anti-tumor responses in patients with previously treated advanced extrapulmonary neuroendocrine carcinomas (epNECs), aggressive cancers that arise outside the lung and share biological characteristics with small cell lung cancer.

There is currently no established standard of care for patients with epNECs who progress on or after first-line platinum-based chemotherapy. Chemotherapy regimens commonly used in clinical practice have limited efficacy, particularly in gastroenteropancreatic NEC (GEP-NEC), and outcomes remain poor.[1]

“Given the aggressiveness of epNECs and the relatively limited treatment options following platinum-based chemotherapy, patients who have advanced or metastatic disease need additional options,” said Amr Mohamed, M.D., study investigator and Director of the Neuroendocrine Tumor Program at UH Seidman Cancer Center, University Hospitals and Case Western Reserve University. “The efficacy and safety data from this trial are encouraging and underscore the possibility that zoci could play a key role in a new standard of care for patients with epNEC.”

Updated data from the Phase 1b/2 clinical trial of zoci (NCT06885281) showed clinically meaningful responses in patients with advanced or metastatic epNECs that had progressed on or after platinum-based chemotherapy. The study evaluated zoci administered intravenously as monotherapy at 1.6 mg/kg every three weeks. Tumor response was evaluated by investigator-assessed RECIST v1.1 with additional assessments for some NECs.

- In the study’s primary efficacy population of 60 patients by the data cutoff, investigator-assessed confirmed ORR was 40.0% (24/60; 95% CI: 27.6%-53.5%), and disease control rate was 55.0% (33/60, 95% CI: 41.6%-67.9%).
- Treatment with zoci decreased tumor sizes in multiple epNEC subtypes: Confirmed ORR was 35.9% (14/39, 95% CI: 21.2%-52.8%) in GEP-NEC and 47.6% (10/21, 95% CI: 25.7%-70.2%) in other epNECs.
- Overall median duration of response (mDOR) was 5.6 months (95% CI: 3.0-9.3).
- Among 18 responders with at least 6 months of opportunity for follow-up from initial response, 6 (33.3%) remain in response or had a response lasting 6 months or longer.
- Zoci demonstrated a manageable safety profile: Among all 133 patients in the study, 12.8% (17/133) experienced Grade ≥3 treatment-related adverse events (TRAEs) and 29.3% (39/133) experienced Grade ≥3 treatment-emergent adverse events (TEAEs), with anemia (7/133, 5.3%) and neutropenia (5/133, 3.8%) as the highest Grade ≥3 TEAEs. Grade 2 interstitial lung disease (ILD)/pneumonitis was reported in 2 patients (1.5%), with no Grade ≥3 ILD events observed. Treatment related discontinuation occurred in 1/133 (0.8%) patients; only one Phase 2 participant experienced a fatal TEAE, determined by the investigator to be unrelated to the study drug.

Efficacy results from this larger dataset are consistent with those previously reported at AACR 2026. Data from patients recently enrolled in Phase 2 is not yet sufficiently mature for analysis, and follow-up is ongoing. Additional data is expected in 2027.

DLL3 expression was assessed by immunohistochemistry. Antitumor activity was observed across the spectrum of DLL3 expression levels, including in patients with low or absent DLL3 expression.

“We are increasingly excited about the potential of zoci to provide an important new targeted therapeutic option for patients with multiple cancer types that commonly express DLL3, including epNECs,” said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. “We are pleased that results from this larger dataset, with longer follow-up, are consistent with the earlier data we shared at AACR. A confirmed objective response rate of 40 percent, including response in multiple epNEC subtypes, with anti-tumor activity observed over time and a treatment related discontinuation rate of less than one percent, are encouraging signals for patients who have few treatment options following platinum-based chemotherapy. We are pursuing an accelerated approval pathway for zoci in previously treated epNECs and will continue to advance our clinical programs for this disease with urgency.”

Zai Lab has completed enrollment in the Phase 2 second-line expansion cohort of the Phase 1b/2 zoci monotherapy trial. Based on feedback from the U.S. Food and Drug Administration (FDA), the company will pursue a potential accelerated approval pathway based on this single-arm expansion study with topline data expected in 2027. Zai Lab also intends to initiate a global Phase 3 first-line maintenance trial of zoci monotherapy in epNECs next year.

In August, the U.S. FDA granted Orphan Drug Designation (ODD) to zoci for the treatment of NECs, following receipt of ODD for zoci in pulmonary NECs from the European Medicines Agency. The U.S. FDA previously granted Fast Track designation (FTD) to zoci for EP-NECs, as well as FTD and ODD to zoci for SCLC.

NANETS 2026 zoci presentation details:

Abstract title: Phase 1b/2 Study of Zocilurtatug Pelitecan in Patients with Advanced Extrapulmonary Neuroendocrine Carcinomas (epNEC)

Abstract ID: 36547

Presenter: Amr Mohamed, M.D.

Date/time: Friday, November 6, 2026, 9:34–9:46 AM PT

Session/location: Featured Abstracts 2: Emerging Strategies in High-Grade and Advanced NENs

Notes:

[1] Sorbye H, Hjortland GO, Vestermark LW, et al. Characteristics and treatment outcome in a prospective cohort of 639 advanced high-grade digestive neuroendocrine neoplasms (NET G3 and NEC). The NORDIC NEC 2 study. *British Journal of Cancer*. 2025;133:316-324. doi:10.1038/s41416-025-03054-w

About Zocilurtatug Pelitecan (zoci, formerly ZL-1310)

Zoci is a novel, potential first-in-class antibody-drug conjugate (ADC), that targets Delta-like ligand 3 (DLL3), a validated therapeutic target that is overexpressed in small cell lung cancer (SCLC) and other neuroendocrine carcinomas (NECs), including extrapulmonary NECs, making it a promising target for the treatment of these aggressive, lethal and difficult-to-treat malignancies. The DLL3 antigen is generally associated with poor clinical outcomes.

Zoci remains on track to become Zai Lab’s first global oncology launch. In addition to the Phase 3 combination trial in first-line extensive stage SCLC that Zai Lab is advancing toward initiation, the Company is also conducting the Phase 3 DLLEVATE study evaluating zoci in previously treated extensive stage SCLC (ES-SCLC) vs. physician’s choice of chemotherapy, and a Phase 1/2 trial in neuroendocrine carcinomas and other DLL3-positive solid tumors. Data presented at ESMO 2026 from an ongoing global Phase 1b trial in first-line ES-SCLC showed that zoci 1.6 mg/kg plus atezolizumab achieved a confirmed ORR of 81.8% (27/33), 6 months PFS 81.9% and was well tolerated, with Grade ≥ 3 adverse events related to zoci in 9.1% (3/33) of patients. Earlier data presented at AACR 2026 from the monotherapy part of the same Phase 1 trial in previously-treated ES-SCLC demonstrated that zoci achieved meaningful intracranial efficacy, including in patients who have not received radiotherapy to the brain.

Earlier this year, Zai Lab entered into a global clinical trial collaboration with Amgen to evaluate zoci in combination with Amgen’s IMDELLTRA® (tarlatamab-dlle), a DLL3/CD3 bispecific T-cell engager (TCE), for ES-SCLC, and a clinical collaboration with Boehringer Ingelheim to evaluate zoci in combination with obrixtamig, a DLL3/CD3 bispecific TCE, for ES-SCLC and other NECs.

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 www.linkedin.com/company/zai-lab or 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 zoci, and the potential treatment of extrapulmonary

neuroendocrine carcinomas (epNECs). 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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Source: Zai Lab Limited