Zai Lab Receives U.S. FDA Fast Track Designation for Zocilurtatug Pelitecan (Zoci), a DLL3-Targeting ADC, for Treatment of Extrapulmonary Neuroendocrine Carcinomas (epNECs)

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- epNECs are aggressive malignancies with poor prognosis and no approved therapies, representing significant unmet medical need
- Preliminary clinical data recently presented at the AACR Annual Meeting suggest zoci has potential to be a first-in-class therapy for epNECs
- Zoci NEC clinical program is advancing toward registration, with active engagement with Health Authorities underway

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 11, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to zocilurtatug pelitecan (zoci, formerly ZL-1310), the Company's potential first-in-class Delta-like ligand 3 (DLL3)-targeting antibody-drug conjugate (ADC), for the treatment of extrapulmonary neuroendocrine carcinomas (epNECs) following progression after standard first-line therapy. epNECs are an aggressive malignancy affecting approximately 100,000 people worldwide, with no targeted therapies and no approved standard of care in previously treated disease.

"This is the second FDA Fast Track Designation for zoci, underscoring the significant potential of this investigational medication to provide an important new treatment option for patients with difficult-to-treat cancers that have few available therapies," said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "This designation will support our efforts to advance this novel therapy through clinical development with both the speed and quality that define our approach. We are actively engaging with health authorities on a registrational plan for epNECs."

Zai Lab reported promising preliminary data from an ongoing registration-enabling multicenter, Phase 1b/2 clinical trial of zoci (NCT06885281) in patients with epNEC and other selected solid tumors at the American Association for Cancer Research (AACR) Annual Meeting 2026 last month. In heavily pretreated patients enrolled in the Phase 1b/2 study, zoci demonstrated encouraging antitumor activity, including an objective response rate (ORR) of 38.2%. Zoci also demonstrated a manageable safety profile—neutrophil count decrease was the only grade ≥3 treatment-related adverse event occurring in more than one patient.

Zai Lab received Fast Track designation for zoci for the treatment of extensive-stage small cell lung cancer (ES-SCLC) in May 2025. 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.

About Zocilurtatug Pelitecan (Zoci, ZL-1310)

Zoci targets Delta-like ligand 3 (DLL3), a validated therapeutic target for small cell lung cancer (SCLC) that is overexpressed in many neuroendocrine carcinomas 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 second-line SCLC, first-line SCLC, and extrapulmonary neuroendocrine carcinoma (epNEC) 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 (ADC) in first line combination regimens, including those that reduce the burdens of chemotherapy, such as check point inhibitors and T-cell engagers.

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 zoci, the potential benefits of zoci, and the potential treatment of small cell lung cancer and other 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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