Zai Lab Announces Global Clinical Trial Collaboration and Supply Agreement to Evaluate Novel DLL3 ADC, Zocilurtatug Pelitecan, in Combination with a Bispecific T-cell Engager Therapy

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- Collaboration with Amgen to explore the clinical potential of Zai Lab's DLL3-targeting ADC, zocilurtatug pelitecan, in combination with Amgen's IMDELLTRA®

- Amgen to sponsor and lead global Phase 1b study; Zai Lab to retain full ownership of zocilurtatug pelitecan

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 1, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced a global clinical trial collaboration with Amgen Inc. (NASDAQ: AMGN) to evaluate Zai Lab's investigational delta-like ligand 3 (DLL3)-targeting antibody-drug conjugate (ADC), zocilurtatug pelitecan (zoci, formerly ZL-1310), in combination with Amgen's IMDELLTRA ® (tarlatamab-dlle), a DLL3-targeting Bispecific T-cell Engager (BiTE®) therapy in patients with extensive-stage small cell lung cancer (ES-SCLC).

As part of this collaboration agreement, Amgen will sponsor a global Phase 1b study to evaluate the safety and efficacy of zoci in combination with IMDELLTRA® in patients with ES-SCLC. Zai Lab will retain full ownership of zoci and will supply Amgen with the study drug.

"In combination, this dual-targeting strategy has the potential to increase the rate and deepen responses both systemically and, in the brain, address resistance pathways, and unlock new treatment paradigms for patients with small cell lung cancer," said Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab. "These two approaches leverage complementary mechanisms — our ADC delivers a potent cytotoxic payload directly to DLL3-expressing tumor cells, while the T-cell engager is designed to activate T-cells by binding the same antigen and eliciting an immune response against the tumor."

Zoci is a DLL3-targeting ADC for small cell lung cancer. Zai Lab has presented data from a Phase 1/2 clinical trial of zoci at the EORTC-NCI-AACR (ENA) Symposium 2025 and the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting, demonstrating a high response rate in heavily pretreated SCLC patients, including strong intracranial activity, and a tolerable safety profile. Amgen's IMDELLTRA ® received FDA approval and is currently marketed in the U.S. for the treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy. Please see full Prescribing Information, including Boxed Warnings, for IMDELLTRA®.

About Zocilurtatug Pelitecan (zoci, formerly ZL-1310)

Zoci is a novel ADC in Zai Lab's global oncology pipeline targeting 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. Zoci 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®, which leverages the tumor microenvironment to overcome challenges associated with first-generation ADC therapies, including off-target payload toxicity.

Zoci is being evaluated in a global development program, which includes DLLEVATE, a pivotal trial to further evaluate the safety and efficacy of zoci compared to investigator's choice single agent therapy in patients with relapsed ES-SCLC; a phase 1b/2 trial evaluating zoci in selected solid tumors including extrapulmonary neuroendocrine carcinoma; and a phase 1a/1b trial evaluating zoci as monotherapy and in combination with atezolizumab, an immune checkpoint inhibitor, for the treatment of ES-SCLC.

Zoci's safety profile, coupled with compelling systemic and intracranial efficacy, supports its potential as a backbone ADC in first-line combination regimens, including those that reduce the burdens of chemotherapy. Zoci received FDA Orphan Drug Designation and FDA Fast Track Designation for the treatment of 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[1,2]. Two-thirds of all SCLC patients are diagnosed at extensive stage[3], 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[4] and a ~5-10% overall five-year survival rate[5]. Treatment options have historically been limited once a patient progresses. IMDELLTRA® is the first DLL3-targeting bispecific T-cell engager therapy to demonstrate an overall survival benefit in this patient population. The combination of zocilurtatug pelitecan and IMDELLTRA® has the potential to build on these gains by further improving efficacy while maintaining manageable safety[6].

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.

[4] Phase 3 IMpower133 (atezolizumab) and CASPIAN study (durvalumab).

[5] National Cancer Institute. www.cancer.gov. Accessed October 15, 2024.

[6] Mountzios et al, NEJM 2025

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 www.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, the potential benefits of zocilurtatug pelitecan, and the potential treatment of SCLC and other 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.

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