



U.S. FDA Grants Orphan Drug Designation to Zai Lab's DLL3-Targeting ADC Zocilurtatug Pelitecan (Zoci) for the Treatment of Neuroendocrine Carcinomas (NECs)

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- NECs are aggressive malignancies with poor prognoses and limited treatment options, representing significant unmet patient need

- U.S. FDA Orphan Drug Designation (ODD) follows receipt of ODD for zoci in pulmonary NECs from the European Medicines Agency, reinforcing zoci's first-in-class potential in a range of NECs

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 3, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to zocilurtatug pelitecan (zoci, formerly ZL-1310), the Company's potential first-in-class Delta-like ligand 3 (DLL3) antibody-drug conjugate (ADC), for the treatment of neuroendocrine carcinomas (NECs). NECs are aggressive malignancies that frequently express DLL3. There are no available targeted therapies and no approved standard of care for NECs in previously treated patients.

"Zoci has now received important regulatory designations around the world, signifying its potential to become an important new therapeutic option for patients with multiple types of cancer with DLL3 expressions," said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "Given the need among the NEC patient community, we are focused on efficiently advancing our clinical programs for this investigational DLL3-targeting ADC."

The U.S. FDA previously granted Fast Track designation (FTD) to zoci for extrapulmonary NECs (epNECs), as well as FTD and ODD to zoci for small cell lung cancer (SCLC), the most significant pulmonary NEC and one of the most aggressive and lethal solid tumors.^{1,2} The European Medicines Agency (EMA) has also granted ODD to zoci for pulmonary NECs.

Benefits of the ODD include eligibility for certain development incentives, including a waiver of the Prescription Drug User Fee Act registration application fee; tax credits for certain clinical trials; and the potential to receive a seven-year U.S. market exclusivity period granted upon product approval.

About Zocilurtatug Pelitecan (Zoci, ZL-1310)

Zoci targets Delta-like ligand 3 (DLL3), a validated therapeutic target that is overexpressed in many neuroendocrine carcinomas, such as small cell lung cancer (SCLC) and extrapulmonary neuroendocrine carcinomas (epNEC), 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- and third-line SCLC, first-line SCLC, and epNECs by the end of 2026. Its potential best-in-class safety profile, coupled with compelling systemic and intracranial efficacy, support its potential role as a new standard of care in previously treated extensive-stage SCLC as well as epNEC, and a backbone DLL3-targeting antibody-drug conjugate (ADC) in first-line combination regimens, including those that reduce the burdens of chemotherapy, such as checkpoint 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.

References:

1 J Thorac Oncol. 2023 Jan;18(1):31-46; Lung Cancer Foundation of America

2 WHO Globocan 2022

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