Zai Lab Receives EMA Orphan Drug Designation for Zocilurtatug Pelitecan (Zoci) in Pulmonary Neuroendocrine Carcinomas

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- European Medicines Agency's Committee for Orphan Medicinal Products recognized zoci's preliminary clinical data as suggestive of a clinically relevant advantage over currently authorized therapies in relapsed or refractory extensive-stage small cell lung cancer (SCLC)
- SCLC is the most significant pulmonary neuroendocrine carcinoma (NEC), affecting an estimated 375,000 patients annually worldwide, with limited treatment options
- EMA designation for zoci in pulmonary NECs closely follows receipt of Fast Track designation from the U.S. Food and Drug Administration for zoci in extrapulmonary neuroendocrine carcinomas (epNECs) and promising data presented at the AACR Annual Meeting in April 2026

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 16, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the European Medicines Agency (EMA) 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)-targeting antibody-drug conjugate (ADC), for the treatment of pulmonary neuroendocrine carcinomas (NECs).

The designation follows a positive opinion from the EMA's Committee for Orphan Medicinal Products (COMP), recognizing both the seriousness of neuroendocrine carcinomas and the need for new treatment options. Small cell lung cancer (SCLC) is the most significant pulmonary NEC, accounting for around 15% of the approximately 2.5 million patients diagnosed with lung cancer worldwide each year (an estimated 375,000 new cases annually), and is one of the most aggressive and lethal solid tumors. [1,2]

In granting the designation, the COMP noted that preliminary clinical data in patients with relapsed or refractory extensive-stage SCLC suggest zoci may offer a more favorable effect than currently authorized therapies, including durable responses, a finding the Committee characterized as a clinically relevant advantage.

The U.S. FDA previously granted Fast Track designation (FTD) and ODD to zoci for SCLC. The FDA also recently granted FTD to zoci for extrapulmonary NECs (epNECs).

"This important designation from the EMA supports zoci's potential to become a first-in-class therapy for pulmonary neuroendocrine carcinomas," said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "This milestone is another demonstration of Zai Lab's commitment to address critical unmet needs for patients with limited treatment options."

The EMA's ODD provides important regulatory and development incentives, including potential market exclusivity following approval, reduced development fees, and enhanced development efficiency, which may help streamline clinical development.

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 (epNECs), 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, supports its potential role as a new standard of care in previously treated extensive stage SCLC, 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.

References:

1 J Thorac Oncol. 2023 Jan:18(1):31-46; Lung Cancer Foundation of America
2 WHO Globocan 2022

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