# Zai Lab Announces Approval of TIVDAK® for Patients with Recurrent or Metastatic Cervical Cancer in Hong Kong

September 2, 2025

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 1, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the Hong Kong Department of Health has approved TIVDAK (tisotumab vedotin-tftv) in Hong Kong for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

“Today’s approval of TIVDAK marks an important milestone for Zai Lab, further strengthening our Women’s franchise in Greater China,” said Andrew Zhu, Chief Commercial Officer, Greater China, Zai Lab. “Treatment options for patients with recurrent or metastatic cervical cancer after initial therapy are limited. TIVDAK, the first antibody-drug conjugate (ADC) therapy in cervical cancer, delivers a clinically meaningful survival benefit to patients. With our established commercial infrastructure for ZEJULA in Hong Kong, we are uniquely positioned to ensure TIVDAK reaches patients without delay.”

TIVDAK is currently under regulatory review for its Biologics License Application by China’s National Medical Products Administration (NMPA), which was accepted in March 2025.

**About TIVDAK® (tisotumab vedotin-tftv)**

TIVDAK® (tisotumab vedotin) is an ADC composed of Genmab’s human monoclonal antibody directed to tissue factor (TF) and Pfizer’s ADC technology that utilizes a protease-cleavable linker that covalently attaches the microtubule-disrupting agent monomethyl auristatin E (MMAE) to the antibody. Nonclinical data suggest that the anticancer activity of tisotumab vedotin is due to the binding of the ADC to TF-expressing cancer cells, followed by internalization of the ADC-TF complex, and release of MMAE via proteolytic cleavage. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death. In vitro, tisotumab vedotin also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity.

TIVDAK received full approval from U.S. Food and Drug Administration (FDA) in April 2024 for adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

Zai Lab has an exclusive license from Seagen Inc., acquired by Pfizer, to develop and commercialize TIVDAK in Greater China (mainland China, Hong Kong, Macau, and Taiwan, collectively).

**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, including, without limitation, statements relating to our prospects and plans for developing and commercializing TIVDAK in Hong Kong, the potential benefits of TIVDAK, and the potential treatment of cervical cancer. 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 decisions, (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. 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 the SEC's website at www.sec.gov.

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