Zai Lab Receives China NMPA Approval of TIVDAK® (tisotumab vedotin for injection) for the Treatment of Adult Patients with Recurrent or Metastatic Cervical Cancer

June 9, 2026

- TIVDAK is the first antibody-drug conjugate (ADC) approved for the treatment of previously treated recurrent or metastatic cervical cancer in China

- TIVDAK demonstrated a statistically significant overall survival benefit in the global Phase 3 innovaTV 301 clinical trial, including in the trial's China subpopulation

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 8, 2026-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) has approved the Biologics License Application (BLA) for TIVDAK® (tisotumab vedotin for injection) for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. This approval is based on results from the global, randomized, Phase 3 innovaTV 301 clinical trial, which met its primary endpoint, demonstrating overall survival (OS) benefit in adult patients with previously treated recurrent or metastatic cervical cancer treated with TIVDAK compared to chemotherapy, including in an exploratory subpopulation of patients in China.

The NMPA approval follows regulatory approvals in the United States, Japan, European Union, United Kingdom, Macau (China), and Hong Kong (China), underscoring the broad global clinical evidence supporting TIVDAK availability in China. The indication statement for TIVDAK differs slightly by region.

"Cervical cancer remains one of the leading causes of cancer death in women in China. Antibody-drug conjugates have proven to be novel and effective treatments for many types of cancer, and we are pleased to bring this innovative therapeutic class to patients in China with cervical cancer," said Rafael G. Amado, M.D., President and Head of Global Research and Development at Zai Lab. "Coupled with the previous global approvals of TIVDAK for this disease, the China BLA approval further validates the robust global evidence of clinical benefit for this population of advanced patients with limited therapeutic options."

Results from the Phase 3 innovaTV 301 clinical trial, including data from the China subpopulation of this study that Zai Lab conducted, supported global approval of TIVDAK:

- In the global study, the trial met its primary endpoint of OS in the intention-to-treat (ITT) population of the global study (HR=0.70; 95% CI: 0.54–0.89; two-sided p=0.0038). The China subpopulation showed consistent results, with a clinically meaningful improvement in OS (HR: 0.55, 95% CI: 0.27- 1.15), corresponding to a 45% reduction in the risk of death compared to chemotherapy.[1]
- 54.1% of the China subpopulation received prior anti-PD(L)1 therapy, the current standard of care for second-line treatment of cervical cancer. TIVDAK showed consistent OS benefit trends irrespective of prior immunotherapy exposure.[2]
- There were no new safety signals identified among patients in the China subpopulation who received TIVDAK. The most common Grade ≥3 treatment-emergent adverse events (TEAEs) in the global study were anemia (8.4%), urinary tract infection (4.4%), and abdominal pain (4.0%).[1] The most common Grade ≥3 TEAEs in the China subpopulation were anemia (11.4%), cough (5.7%), and malaise (5.7%).[2]

"Treatment options are very limited for cervical cancer patients once recurrence or metastasis occurs," said Dr. Lingying Wu, Ph.D., China Leading Principal Investigator of the innovaTV 301 Study and Professor of the Department of Gynecologic Oncology of National Cancer Center / Cancer Hospital Chinese Academy of Medical Sciences. "Consistent with findings from the global innovaTV 301 trial, the China subpopulation data demonstrate that TIVDAK offers significant clinical benefits to these patients, irrespective of prior PD-(L)1 inhibitor therapy."

Zai Lab will leverage the company's extensive experience and expanding presence in the Chinese gynecologic oncology community, as well as commercial synergies with its ZEJULA® team, to bring TIVDAK to patients in China.

About Cervical Cancer in China

An estimated 150,000 new cases of cervical cancer occur annually in China[3]. Current treatment options are limited for patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy. TIVDAK is well positioned to provide a new option for previously treated advanced cervical cancer patients.

About Tisotumab Vedotin

Tisotumab vedotin (approved under the brand name TIVDAK® in the EU, U.K., U.S. and Japan) is an antibody-drug conjugate (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 the U.S. Food and Drug Administration in April 2024, and U.S. approval was first secured in September 2021 under the accelerated approval pathway for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Approval has also been received in Japan, European Union, Macau (China), and Hong Kong (China) for the same indication.

Zai Lab has an exclusive license from Seagen Inc., a company later acquired by Pfizer, for TIVDAK in Greater China (mainland China, Hong Kong, Macau, and Taiwan, collectively). Zai Lab is solely responsible for the development, supply, and commercialization of TIVDAK in Greater China.

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.twitter.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 Greater China, 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.

References:

1. Vergote I, et al. N Engl J Med. 2024 Jul 4;391(1):44-55.

2. 2025 Chinese Society of Clinical Oncology (CSCO) Meeting, Tisotumab Vedotin versus Chemotherapy in Recurrent or Metastatic Cervical Cancer with Disease Progression on or after Systemic Therapy: Prespecified China Subpopulation Analysis of Phase 3 innovaTV.

3. Bingfeng Han et al., "Cancer incidence and mortality in China, 2022" Journal of the National Cancer Center, 2024. DOI: 10.1016/j.jncc.2024.01.006.

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Source: Zai Lab Limited