Zai Lab Announces Acceptance of Biologics License Application for TIVDAK for the Treatment of Patients with Recurrent or Metastatic Cervical Cancer

March 12, 2025

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 12, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that China's National Medical Products Administration (NMPA) has accepted the Biologics License Application (BLA) for TIVDAK (tisotumab vedotin-tftv) for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy.

"In China, cervical cancer is a serious health concern with approximately 150,000 new cases diagnosed annually [1]," said Dr. Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. "Treatment options for patients experiencing recurrence or metastasis after initial treatment are limited. TIVDAK, the only antibody-drug conjugate (ADC) therapy in cervical cancer, demonstrated promising benefits including a clinically meaningful improvement in overall survival (OS) in the pivotal global innovaTV 301 trial. If approved, TIVDAK will leverage our existing commercial infrastructure for ZEJULA, expanding our ability to offer treatment for women's cancer."

The BLA submission is supported by the results from the global, randomized, Phase 3 innovaTV 301 clinical trial (NCT04697628) and the results from the China subpopulation of this study. As reported in January 2025, the China subpopulation results were consistent with those in the global population:

- TIVDAK demonstrated a 45% reduction in the risk of death compared to chemotherapy (HR: 0.55 [95% CI: 0.27-1.15] in the China subpopulation who had received prior standard systemic therapies, with more than half of this Chinese population having received prior anti-PD(L)1 therapy. After a median follow-up of 11.5 months, the median OS was not reached in the TIVDAK arm versus 10.7 months in the chemotherapy arm.
- Secondary endpoints of progression-free survival (PFS) and confirmed objective response rate (ORR) also favored treatment with TIVDAK.
- The safety of TIVDAK in the China subpopulation was manageable and consistent with the global profile.

About TIVDAK® (tisotumab vedotin-tftv)

TIVDAK® (tisotumab vedotin) 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 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.

Please see full U.S. prescribing information, including BOXED WARNING for TIVDAK here.

Zai Lab has an exclusive license from Seagen Inc., acquired by Pfizer in 2023, to develop and commercialize TIVDAK in Greater China (mainland China, Hong Kong, Macau, and Taiwan, collectively).

About Cervical Cancer in China

Cervical cancer remains one of the leading causes of cancer death in women in China. An estimated 150,000 new cases of cervical cancer occur annually in China[1]. 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 who currently have limited treatment options and poor outcomes.

Note:

[1] *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.*

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 in China and worldwide.

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 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.

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