Zai Lab Announces Positive Topline Results for TIVDAK in the China Subpopulation of the Global Phase 3 innovaTV 301 Trial in Patients with Recurrent or Metastatic Cervical Cancer

January 15, 2025

- *Improved overall survival (OS), progression-free survival (PFS) and confirmed objective response rate (ORR) were observed in the China subpopulation treated with TIVDAK compared to chemotherapy, consistent with those in the global population*
- *The safety profile of TIVDAK among the China subpopulation was manageable and consistent with that observed in the global population*
- *Zai Lab intends to submit a New Drug Application (NDA) to China's National Medical Products Administration (NMPA) in the first quarter of 2025*
- *Zai Lab will leverage its commercial footprint of ZEJULA in women's cancer to bring the medicine to patients in China if approved*

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 15, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced positive topline results from the China subpopulation of the global Phase 3 innovaTV 301 study, demonstrating a clinically meaningful improvement in overall survival with TIVDAK treatment for patients with previously treated recurrent or metastatic cervical cancer compared to chemotherapy.

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. Median OS for patients treated with TIVDAK was not reached versus chemotherapy 10.7 months [95% CI: 6.0-not reached] with a median follow-up of 11.5 months.
- Secondary endpoints of PFS and confirmed ORR also favored treatment with TIVDAK compared to chemotherapy.
- The safety profile of TIVDAK in the China subpopulation was manageable and consistent with the global profile.

"Recurrent or metastatic cervical cancer remains a significant challenge for patients, highlighting a critical unmet need for effective treatments that extend survival after relapse," said Dr. Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. "The consistent and positive results in the China subpopulation of the global Phase 3 study reinforce the potential for TIVDAK, the only ADC therapy in this disease setting, to increase options in this therapeutically unmet clinical setting. If approved, we expect TIVDAK to add to ZEJULA and augment our commercial franchise in women's tumors."

"There are approximately 150,000 new cases of cervical cancer annually in China[1], and patients face limited treatment options once their cancer recurs or spreads after initial treatment," said Dr. Lingying Wu, Professor of the Department of Gynecologic Oncology of National Cancer Center / Cancer Hospital Chinese Academy of Medical Sciences. "While the recent adoption of immunotherapy as a first-line treatment in China represents progress, there is a lack of effective options for patients following relapse. The promising results from TIVDAK, which demonstrated superior survival extension in patients whose disease progressed after initial treatments, including prior anti-PD(L)1 treatment, offer hope for addressing this critical unmet need."

In April 2024, the U.S. Food and Drug Administration (FDA) approved the supplemental Biologics License Application (sBLA) granting full approval for TIVDAK® (tisotumab vedotin-tftv) for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. The approval was based on results from the global, randomized, Phase 3 innovaTV 301 clinical trial (NCT04697628), 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.

- TIVDAK demonstrated a 30% reduction in the risk of death compared to chemotherapy (hazard ratio [HR]: 0.70 [95% CI: 0.54-0.89], two-sided p=0.0038)[2]. Median OS for patients treated with TIVDAK was 11.5 months [95% CI: 9.8-14.9] versus chemotherapy 9.5 months [95% CI: 7.9-10.7].
- PFS and confirmed ORR were also significantly improved compared to chemotherapy.
- The safety profile of TIVDAK was consistent with its known safety profile as presented in the U.S. prescribing information, and no new safety signals were observed.

Based on these encouraging results, Zai Lab intends to submit an NDA for TIVDAK to China's National Medical Products Administration (NMPA) in the first quarter of 2025. The full China subpopulation data will be presented at a future medical conference in 2025.

About innovaTV 301 Trial Design

The innovaTV 301 trial (NCT04697628) is a global, 1:1 randomized, open-label Phase 3 trial evaluating TIVDAK® (tisotumab vedotin) versus investigator's choice of single agent chemotherapy (topotecan, vinorelbine, gemcitabine, irinotecan, or pemetrexed) with recurrent or metastatic cervical cancer who received chemotherapy.

Patients with recurrent or metastatic cervical cancer with squamous cell, adenocarcinoma, or adenosquamous histology, and disease progression during or after treatment with chemotherapy doublet +/- bevacizumab and an anti-PD-(L)1 agent (if eligible) are included. The primary endpoint was overall survival. The main secondary outcomes were progression-free survival and objective response rate.

The study was conducted by Seagen, which was acquired by Pfizer in December 2023, in collaboration with Genmab, European Network of Gynaecological Oncological Trial Groups (ENGOT, study number ENGOT cx-12) and the Gynecologic Oncology Group (GOG) Foundation (study number GOG 3057), as well as other global gynecological oncology cooperative groups.

For more information about the Phase 3 innovaTV 301 clinical trial and other clinical trials with tisotumab vedotin, please visit www.clinicaltrials.gov.

About Cervical Cancer in China

Cervical cancer remains one of the leading causes of cancer death in women in China and globally. 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.

About TIVDAK® (tisotumab vedotin)

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 accelerated approval from the FDA in September 2021 and full approval in April 2024 for adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

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

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

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 worldwide.

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.

Notes:

[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.

[2] The threshold for statistical significance is 0.0226 (2-sided).

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Source: Zai Lab Limited