Zai Lab to Present Final Overall Survival (OS) Data from Phase 3 NORA Study of ZEJULA (niraparib) in Platinum-Sensitive Recurrent Ovarian Cancer (PSROC)

March 6, 2024

- Findings will be shared in oral presentations at the 2024 Congress of the European Society of Gynaecological Oncology (ESGO) and the 2024 Society for Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer -

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 6, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the final overall survival (OS) data from the Phase 3 randomized, double-blind, placebo-controlled NORA study evaluating ZEJULA® (niraparib) in Chinese patients with platinum-sensitive recurrent ovarian cancer (PSROC) will be shared in oral presentations at the 2024 Congress of the European Society of Gynaecological Oncology (ESGO), March 7-10, 2024, in Barcelona, Spain, and the 2024 Society for Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer, taking place March 16-18, 2024, in San Diego, CA.

"Previous progression-free survival and interim OS data from the NORA study demonstrated the benefit of niraparib maintenance therapy with an individualized starting dose among Chinese patients with PSROC," said Dr. Rafael Amado, President, Head of Global Oncology Research and Development, Zai Lab. "We look forward to sharing the final OS findings from this study at both the 2024 ESGO and SGO conferences. Based on these results, ZEJULA remains the only PARP inhibitor approved as maintenance monotherapy for ovarian cancer patients in both first-line and recurrent settings regardless of biomarker status."

In the NORA study, 265 patients with PSROC were randomized (2:1) to receive niraparib or placebo. The final OS analysis was conducted after ≥ 50% of OS events occurred in the intent-to-treat population. The ESGO presentation will feature data analyses showing that niraparib maintenance therapy with an individualised starting dose (ISD) based on patient weight and platelet count demonstrated a favorable OS trend versus placebo in this disease setting, regardless of BRCA-gene mutation status. No new safety signals were identified during the long-term follow up period subsequent to the primary analysis.

Details regarding the oral presentation at the 2024 ESGO Congress are as follows:

Title: Niraparib maintenance therapy using an individualised starting dose in patients with platinum-sensitive recurrent ovarian cancer (NORA): Final overall survival analysis of a randomised, double-blind, placebo-controlled phase 3 trial
Presenter: Xiaohua Wu, M.D., PhD., Fudan University Shanghai Cancer Center, Shanghai, China
Date/Time: Saturday, March 9, 2024, 4:13 p.m. – 4:19 p.m. CET/Spain
Location: Session Hall III (112)

Details regarding the late-breaking oral presentation at the 2024 SGO Annual Meeting are as follows:

Title: Niraparib maintenance therapy using an individualized starting dose in patients with platinum-sensitive recurrent ovarian cancer (NORA): Final overall survival analysis of a randomized, double-blind, placebo-controlled phase 3 trial
Presenter: Xiaohua Wu, M.D., PhD., Fudan University Shanghai Cancer Center, Shanghai, China
Date/Time: Monday, March 18, 2024, 3:24 p.m. to 3:30 p.m. Pacific Time
Location: San Diego Convention Center, Hall F

About Ovarian Cancer
Ovarian cancer is one of the most common gynecologic cancers in China with more than 55,000 newly diagnosed cases and 37,000 deaths each year. While platinum-based chemotherapy is effective at inducing an initial response in ovarian cancer, the disease will recur in the majority of women. New agents that prolong the duration of response following platinum-based treatment and delay the inevitable relapse of ovarian cancer will benefit patients with ovarian cancer in China.

About ZEJULA (niraparib)
ZEJULA (niraparib) is an oral, once-daily small-molecule poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor. A PARP inhibitor blocks the ability of cancer cells to repair themselves after they have been damaged by radiation and certain chemotherapies. This inhibition of DNA damage repair can result in the inability of cancer cells to replicate themselves and in programmed cell death. Tumors that are deficient in key DNA damage repair pathways, such as BRCA1 mutant tumors, are particularly sensitive to ZEJULA. As maintenance therapy, ZEJULA is for women who have had prior chemotherapy treatment but are at high risk of cancer recurrence. ZEJULA is intended to avoid or slow a recurrence of the cancer if it is in remission after prior treatment. In the maintenance setting, ZEJULA does not require the addition of radiation or chemotherapies to kill tumor cells.

As a first-line monotherapy maintenance treatment of patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively, ovarian cancer) following a response to platinum-based chemotherapy, ZEJULA was approved by the NMPA in September 2020 and included in the NRDL in December 2021.

As a maintenance treatment of patients with platinum sensitive recurrent ovarian cancer, ZEJULA was approved by the NMPA in December 2019 and included in the NRDL in December 2020.

Zai Lab has an exclusive license from GSK to develop and commercialize ZEJULA in mainland China, Hong Kong, and Macau.

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, autoimmune disorders, infectious diseases and neuroscience. 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 www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements relating to the benefits of ZEJULA and the treatment of ovarian cancer in China. 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 initiatives; (3) the results of our clinical and pre-clinical development of our drug candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our drug candidates, (5) risks related to doing business in China; and (6) other factors discussed 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.

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