JAMA Oncology Publishes Data from Zai Lab Study Demonstrating Significant Reduction in Disease Progression or Death with ZEJULA (Niraparib) Maintenance Therapy in Broad Population of Advanced Ovarian Cancer Patients

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The Phase 3 PRIME study demonstrates that treatment with ZEJULA significantly extends progression-free survival versus placebo and reduces the risk of disease progression or death by 55%

Findings confirm the benefit of ZEJULA monotherapy as first-line maintenance treatment, regardless of residual disease or biomarker status, in patients with newly diagnosed advanced ovarian cancer

SHANGHAI, China and CAMBRIDGE, Mass., July 19, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that *JAMA Oncology* published data from the pivotal Phase 3 PRIME study evaluating ZEJULA® (niraparib) as a first-line maintenance therapy in Chinese patients with newly diagnosed advanced ovarian cancer. These data demonstrate that maintenance treatment with ZEJULA significantly prolongs progression-free survival (PFS) versus placebo and reduces the risk of disease progression or death by 55%. These findings are consistent with prior studies that indicate that front-line maintenance therapy with ZEJULA can provide statistically and clinically meaningful benefit in a broad population of patients, regardless of postoperative residual disease or biomarker status.

“Women with advanced ovarian cancer have a poor prognosis, with a global 5-year survival rate of less than 50 percent and a recurrence rate of approximately 75 percent,” said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development at Zai Lab. “The positive results from the PRIME study, which show a substantial reduction in risk of disease progression or death with ZEJULA maintenance, offer insights into the potential to delay the progression of this devastating disease in a broad group of patients. We look forward to continuing to work with our partners to improve outcomes for women living with ovarian cancer.”

The PRIME study is a Phase 3, randomized, double-blind, placebo-controlled clinical trial conducted at 29 hospitals in mainland China. The study evaluated the use of ZEJULA, a potent, highly selective PARP 1 and PARP 2 inhibitor, as first-line maintenance therapy among 384 patients with newly diagnosed advanced ovarian cancer who had received first-line platinum-based chemotherapy and had a complete response or partial response, including patients who underwent debulking surgery to remove all tumor (R0 resection). The primary endpoint was blinded independent central review (BICR)-assessed PFS in the intention-to-treat population (ITT). Patients in the study were randomized 2:1 to receive ZEJULA or placebo. Patients receiving ZEJULA received an individual starting dose (ISD) of 200 or 300 mg based on baseline bodyweight and platelet count.

The *JAMA Oncology* PRIME publication includes the following key efficacy and safety findings:

- ZEJULA significantly extended PFS versus placebo and reduced the risk of disease progression or death by 55%, regardless of postoperative residual disease or biomarker status.
- Median PFS (mPFS) with ZEJULA versus placebo in the ITT population was 24.8 versus 8.3 months (hazard ratio [HR], 0.45; 95% CI, 0.34–0.60; p<.001).
- At the time of data cut-off, overall survival (OS) data were not yet mature in the ITT population.
- Utilization of an ISD demonstrated a tolerable safety profile in the maintenance setting.
- Grade ≥3 treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) were reported in 54.5% versus 17.8% and 18.8% vs 8.5% in ZEJULA-treated and placebo-treated patient respectively.
- Similar proportions of ZEJULA-treated and placebo-treated patients (6.7% vs 5.4%) discontinued therapy due to TEAEs.

Additional sub-analyses consistently demonstrated that ZEJULA improved PFS versus placebo in a broad range of patients:

- PFS not reached versus 10.8 months in patients with the gBRCA mutation (HR, 0.40; 95% CI, 0.23-0.68)
- 19.3 versus 8.3 months in patients without the gBRCA mutation (HR, 0.48; 95% CI, 0.34-0.67)
- 24.8 versus 8.3 months in patients with optimal debulking (HR, 0.44; 95% CI, 0.32-0.61)
- 16.5 versus 8.3 months in patients with suboptimal debulking (HR, 0.27; 95% CI, 0.10–-0.72)

“The complexity of ovarian cancer demands multiple, innovative treatment options,” said Lead Author Dr. Lingying Wu. “These data from the PRIME study prospectively demonstrate that an ISD of 200 or 300 mg of ZEJULA based on baseline bodyweight and platelet count can bring significant benefit to patients with an improved safety and tolerability profile of ZEJULA compared to a fixed 300 mg starting dose in previous studies, and further support the use of an ISD to improve patient outcomes in clinical practice.” Dr. Wu is Director of the Department of Gynecologic Oncology, National

Cancer Center / National Clinical Research Center for Cancer / Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College.

Zai Lab has a license and collaboration agreement with Tesaro, Inc. (a company later acquired by GSK) for the development and commercialization of ZEJULA (independently manufactured by Zai Lab) in mainland China, Hong Kong, and Macau.

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers in China, with over 55,000 newly diagnosed cases and 37,000 deaths in China annually.[i] 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 relapse of ovarian cancer will benefit patients with ovarian cancer in China.

About ZEJULA (niraparib)

ZEJULA (niraparib) is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the maintenance treatment of adult patients with advanced and platinum sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first- and second-and further line platinum-based chemotherapy.

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, including our products, business activities and partnerships, research, and other events or developments, 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 about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements regarding the prospects and plans for ZEJULA in mainland China, Hong Kong, and Macau and related clinical trials, the safety and efficacy of ZEJULA, and the potential treatment of patients with ovarian 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 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 product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and results of operations, (6) risks related to doing business in China, and (7) 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 (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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[i] Globocan 2020

Source: Zai Lab Limited