Zai Lab to Present Analysis of the Impact of Timing for ZEJULA® (niraparib) Maintenance Treatment in Newly Diagnosed Advanced Ovarian Cancer at the 2022 International Gynecologic Cancer Society Meeting

September 20, 2022

New subgroup analysis of the Phase 3 PRIME study reveals improvement in efficacy outcomes for ZEJULA® (niraparib) maintenance treatment when started within 12 weeks after first-line platinum-based chemotherapy (1LCT)

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Sept. 20, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, will present a poster featuring initiation timing analysis from the Phase 3 PRIME study of ZEJULA® (niraparib) as maintenance therapy at the upcoming 2022 International Gynecologic Cancer Society (IGCS) Annual Meeting.

This post-hoc analysis of the PRIME Phase 3 study evaluated adults with newly diagnosed advanced ovarian cancer who responded to first-line platinum-based chemotherapy, and they were randomized to receive niraparib maintenance treatment or placebo within 12 weeks after chemotherapy completion. The results are as follows:

- For patients who received niraparib treatment less than 9 weeks after chemotherapy completion, the median progression-free survival (PFS) (95% CI) was measured at 29.4 months with niraparib versus 8.3 months with placebo (HR =0.31; 95% CI, 0.20–0.48).
- For patients who received niraparib at 9 – 12 weeks after chemotherapy completion, the median PFS was 24.7 months with niraparib versus 10.8 months with placebo (HR=0.60; 95% CI, 0.41–0.89).
- The initiation timing of niraparib maintenance treatment had no significant impact on its safety profile.

This subgroup analysis provides evidence to support the initiation of niraparib maintenance treatment in patients with newly diagnosed advanced ovarian cancer within 12 weeks after chemotherapy completion.

“We are excited to be presenting at the 2022 International Gynecologic Cancer Society Annual Meeting showing these results improved clinical efficacy when niraparib maintenance treatment is initiated within 12 weeks after chemotherapy in patients with advanced ovarian cancer,” said Alan Sandler, M.D., President and Head of Global Development, Oncology, Zai Lab. “This study further supports ZEJULA as an important maintenance treatment therapy after platinum-based chemotherapy in people with advanced ovarian cancer.”

“This PRIME study analysis will help support clinical practice in treating advanced ovarian cancer in China, showing niraparib extended progression-free survival when maintenance treatment begins within 12 weeks after chemotherapy,” said Jing Wang, M.D., Director of the Early Clinical Research Center, Hunan Cancer Hospital. “Since a majority of women face recurrence of advanced ovarian cancer after chemotherapy, this study supports niraparib maintenance treatment having a significant clinical benefit in extending progression-free survival compared to placebo.”

Details regarding the e-poster presentation at IGCS 2022 are as follows:

Abstract number: 876
Title: Impact of initiation timing of niraparib maintenance treatment in newly diagnosed advanced ovarian cancer
Speaker: Jing Wang, M.D., Hunan Cancer Hospital
Date: September 29-October 1, 2022

About PRIME Study

The fully powered Phase 3 PRIME study was evaluated in 384 advanced ovarian cancer patients who were in a complete or partial response to platinum-based chemotherapy and who were randomized 2:1 to receive ZEJULA or placebo as maintenance therapy. The study evaluated the efficacy of ZEJULA as a maintenance treatment, with the primary endpoint of PFS as assessed by blinded independent central review. The starting dose was individualized at 200 mg except for those patients with a baseline body weight ≥ 77kg and a platelet count ≥ 150K/μL, in which case the starting dose was 300 mg.

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[1]. 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.

[1] *Globocan 2020.*

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 newly diagnosis and platinum-sensitive relapsed advanced and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

In addition to the PRIME study, Zai Lab has completed several studies in Chinese patients with ovarian cancer:

- In September 2020, Zai Lab announced that ZEJULA demonstrated a significant PFS benefit with an improved safety profile in the company's Phase 3 NORA study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer, regardless of biomarker status.
- A Phase 1 pharmacokinetic study of ZEJULA was conducted in Chinese patients with ovarian cancer.

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

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 focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health 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 relating to our Phase 3 PRIME study of ZEJULA® (niraparib); clinical development programs; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; and the potential benefits, safety, and efficacy of our collaboration partners' products and of our pipeline therapies. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by 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 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. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these 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, including any government actions or lockdown measures taken in response, on our business and general economic, regulatory, and political conditions, (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. 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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Source: Zai Lab Limited