Zai Lab to Present Two New Phase 3 Analyses for Niraparib in Ovarian Cancer at the 2023 ESMO Gynaecological Cancers Congress

February 22, 2023

SHANGHAI, China and CAMBRIDGE, Mass., Feb. 22, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) will present two oral presentations highlighting the ad hoc interim overall survival (OS) study results of ZEJULA® (niraparib) from the NORA Phase 3 study and a post hoc analysis from the Phase 3 PRIME trial of niraparib maintenance therapy at the upcoming European Society for Medical Oncology (ESMO) Gynaecological Cancers Congress on February 23-24, 2023.

One presentation will feature an ad hoc interim OS data analysis of the Phase 3 NORA trial, showing how niraparib maintenance therapy with an individualized starting dose (ISD) provided a favorable OS (OS; secondary endpoint) trend versus placebo in Chinese patients with platinum-sensitive recurrent ovarian cancer (PSROC) regardless of biomarker status. The median overall survival (mOS) in the niraparib-treated group was numerically higher (46.3 months) compared to 43.4 months in placebo [HR=0.82; 95% CI, 0.56-1.21]. The mOS in the g*BRCA* mutation subgroup was not reached for patients receiving niraparib versus 47.6 months for placebo group [HR=0.76; 95% CI, 0.40-1.46], and in the non-g*BRCA* mutation subgroup, the mOS was 43.1 months for the niraparib-treated group versus 38.4 months for placebo [HR=0.86; 95% CI, 0.53-1.38]. This new data analysis explores the treatment effect of niraparib versus placebo on OS adjusted for subsequent poly (ADP-ribose) polymerase inhibitor (PARPi) use in the placebo group.

Another presentation will feature a post hoc analysis from the randomized, double-blind, placebo-controlled Phase 3 PRIME trial, with results showing niraparib associated with improved progression-free survival (PFS) regardless of surgical timing and residual disease status compared with placebo in patients with newly diagnosed advanced ovarian cancer in China. A summary of the results is as follows:

- Median PFS for the primary debulking surgery (PDS) group: Not reached in patients receiving niraparib versus 12 months PFS for placebo group [HR 0.63; 95% CI 0.42–0.94]
- Median PFS in the interval debulking surgery (IDS) group: 22.3 months for patients receiving niraparib versus 5.6 months for placebo [HR = 0.32; 95% CI 0.21-0.48]
- Adverse events were experienced at a similar rate in the niraparib-treated patients who underwent PDS and IDS compared to placebo (50.7% experiencing grade ≥3 adverse events versus 58.7% in placebo) and treatment discontinuation due to adverse events was also similar (6.7% in the niraparib-treated group versus 6.6% for placebo).

"Our data presentations at this ESMO Gynaecological Cancers Congress continue to support the clinical profile of ZEJULA ® as a maintenance monotherapy for patients in China for both first-line and recurrent ovarian cancer regardless of biomarker status," said Rafael Amado, MD, President, Head of Global Oncology Research and Development, Zai Lab. "We remain committed to addressing the urgent need for ovarian cancer treatment options globally."

The details of the presentations are as follows:

Abstract Number: #189
Presentation Number: #35O
Title: Overall Survival of Niraparib with Individualized Starting Dose as Maintenance Therapy in Patients with Platinum-Sensitive Recurrent Ovarian Cancer Adjusted for Subsequent PARPi Use in Placebo Group: Results from an Ad Hoc Interim Analysis for the Phase 3 NORA Study
Presentation Date and Time: Thursday, February 23, 2023, 12:24-12:32pm Central European Time
Presenting Author: Dr. Xiaohua Wu, Fudan University Shanghai Cancer Center, Shanghai, China

Abstract Number: #180
Presentation Number: #37MO
Title: Niraparib maintenance therapy in patients with newly diagnosed advanced ovarian cancer: a post hoc analysis on efficacy by surgical timing and residual disease status in the phase III PRIME trial
Presentation Date and Time: Friday, February 24, 2023, 4:20- 4:25pm Central European Time
Presenting Author: Dr. Lingya Pan, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

About NORA

The NORA study evaluated 265 platinum-sensitive recurrent ovarian cancer patients in China randomized 2:1 to receive niraparib or placebo until disease progression. 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 once daily except for those with a baseline body weight ≥77kg and a platelet count ≥150K/μL in which case the starting dose was 300 mg.

About PRIME

The fully powered Phase 3 PRIME study was evaluated in 384 newly diagnosed advanced ovarian cancer patients in China who were in a complete or partial response to first-line platinum-based chemotherapy and who were randomized 2:1 to receive ZEJULA or placebo as maintenance monotherapy. 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 once daily 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 PARPi indicated as monotherapy for the maintenance treatment of adult patients with newly diagnosed 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.

Zai Lab has completed several studies in patients with ovarian cancer in China:

- In March 2022, Zai Lab announced that, in the company's Phase 3 PRIME study, ZEJULA demonstrated a statistically significant and clinically meaningful improvement in PFS with a tolerable safety profile when given with an individualized starting dose regimen in Chinese patients with newly diagnosed advanced ovarian cancer, regardless of biomarker status.
- In September 2020, Zai Lab announced that, in the company's Phase 3 NORA study, ZEJULA demonstrated a significant PFS benefit with an improved safety profile with individualized starting dose in 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 in mainland China, Hong Kong, and Macau. (ZEJULA supply for China is independently manufactured by Zai Lab.)

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 future expectations, plans, and prospects, including, without limitation, statements relating to the benefits, safety, and efficacy of ZEJULA (niraparib); the treatment of ovarian cancer in mainland China, Hong Kong, and Macau; and clinical trial data, data readouts, and presentations. 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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