Zai Lab Presents Positive Results from Phase 3 PRIME Study of ZEJULA® (Niraparib) at Society of Gynecologic Oncology Meeting

March 21, 2022

- *PRIME study demonstrates that niraparib treatment had a statistically significant and clinically meaningful improvement in progression-free survival in the overall study population regardless of biomarker status when compared to placebo*
- *The primary endpoint of the trial was met, with median progression-free survival of 24.8 months for niraparib patients versus 8.3 months for patients taking placebo*
- *Treatment was tolerable in the population studied and showed a safety profile consistent with previous trials*

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., March 20, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today presented data from the Phase 3 PRIME study of ZEJULA (niraparib) as maintenance therapy at the Society of Gynecologic Oncology annual meeting. ZEJULA demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) with a tolerable safety profile in Chinese patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) following a response to platinum-based chemotherapy, regardless of biomarker status.

In the PRIME study, median PFS was significantly longer for patients treated with niraparib compared to placebo: 24.8 months versus 8.3 months, hazard ratio (HR), 0.45; $p<0.001$. Other pre-specified efficacy results included:

- g*BRCA*mut patients: mPFS, not reached vs. 10.8 months; HR and 95% CI: 0.40 (0.23, 0.68);
- Non-g*BRCA*mut patients: mPFS, 19.3 months vs. 8.3 months; HR and 95% CI: 0.48 (0.34, 0.67);
- Overall survival data are still immature (percentage of death in niraparib and placebo groups are 14.5% vs. 21.7%); there is a trend in favor of niraparib at the data cut-off.

The PRIMA study previously conducted by Zai Lab's partner GlaxoSmithKline plc (GSK) demonstrated that niraparib conferred a PFS benefit to patients with advanced ovarian cancer after a response to first-line platinum-based chemotherapy compared with placebo, regardless of biomarker status. An individualized starting dosing (ISD) based on baseline bodyweight and platelet count to personalize treatment of niraparib was used in approximately 35% of patients in PRIMA. 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.

The current PRIME study was designed to prospectively assess the efficacy and safety of niraparib with this ISD as maintenance therapy in patients with newly diagnosed advanced ovarian cancer after a response to first-line platinum-based chemotherapy, regardless of biomarker status and postoperative residual disease status.

In PRIME, the safety profile of niraparib was improved with the ISD prospectively applied to all patients. Based on the prospective ISD with niraparib, less than 7% of patients discontinued treatment due to adverse events, the lowest rate of any PARPi Phase 3 first-line maintenance ovarian cancer trial. Compared with previous fixed starting dose, the ISD reduced the incidence of hematological treatment-emergent adverse events (TEAEs). Grade ≥3 hematological TEAEs of neutrophil count decrease, anemia, and platelet count decrease in patients treated with niraparib versus placebo were 17.3% vs. 1.6%, 18.0% vs. 1.6%, and 14.1% vs. 0.8%, respectively.

"The PRIME data continue to support niraparib monotherapy as the standard of care after first-line platinum-based chemotherapy regardless of biomarker status," said Alan Sandler, M.D., President and Head of Global Development, Oncology, Zai Lab. "More specifically, ZEJULA is the first and only PARP inhibitor approved globally, including in China, as monotherapy for all-comer patients in the first-line maintenance treatment settings."

"I believe the data of the PRIME study will have a significant impact on the clinical practice in the first-line treatment of ovarian cancer in China and beyond, as the individualized starting dose regimen has demonstrated an improved efficacy and safety profile," said Dr. Lingying Wu, 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. "In addition, the PRIME study is the only study conducted in China that has demonstrated that a PARP inhibitor significantly improved PFS when given as first-line monotherapy maintenance treatment in all Chinese patients with newly diagnosed advanced ovarian cancer, regardless of biomarker status and postoperative residual disease status."

In September 2020, the China National Medical Products Administration (NMPA) approved ZEJULA's supplemental New Drug Application as a maintenance treatment of adult patients with advanced ovarian cancer who are in a complete or partial response to platinum-based chemotherapy. ZEJULA was also approved by the Hong Kong Department of Health as a maintenance treatment for adult patients with high-grade serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy.

In December 2021, Zai Lab announced that the National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA) was updated to include ZEJULA (niraparib) as a first-line maintenance treatment of adult patients with advanced ovarian cancer following a response to platinum-based chemotherapy, regardless of biomarker status.

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 advanced and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first- and second-line 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 (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio in order to impact human health worldwide.

For additional information about the Company, 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 the results from our Phase 3 PRIME Study of ZEJULA ® (niraparib); statements relating to our strategy and plans for niraparib in China; clinical trial data for niraparib; the potential clinical effects of niraparib; the potential benefits, safety and efficacy of niraparib; the clinical development program for niraparib in China; our research and development program for the treatment of ovarian cancer in China; the potential of our commercial business and pipeline programs, including niraparib; and the risk and uncertainties associated with drug development and commercialization. These forward-looking statements include, without limitation, statements containing 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 nor are they 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 finance our operations and business initiatives and obtain funding for such activities, (3) our results of 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 general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report 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.

More information about Zai Lab and its filings can be found on the SEC.gov website.
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