Zai Lab Announces Positive Topline Results from Phase 3 PRIME Study of ZEJULA® (Niraparib) as First-Line Monotherapy Maintenance Treatment in Chinese Women with Platinum-Responsive Advanced Ovarian Cancer

November 30, 2021

- *PRIME study demonstrates that niraparib treatment had a clinically meaningful and statistically significant benefit in improving progression-free survival in the overall study population regardless of biomarker status when compared to placebo*
- *Treatment was tolerable in the population studied and showed a safety profile consistent with previous trials*
- *Zai Lab plans to present the PRIME study data at an upcoming medical conference*

SHANGHAI, SAN FRANCISCO, and CAMBRIDGE, Mass., Nov. 30, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the Phase 3 PRIME study of ZEJULA (niraparib) as maintenance therapy met its primary endpoint. ZEJULA demonstrated a statistically significant and clinically meaningful progression-free survival (PFS) benefit 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.

“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 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 monotherapy maintenance therapy in all Chinese patients with newly diagnosed ovarian cancer, regardless of biomarker status.”

“The PRIME clinical data in Chinese patients confirmed the clinical profile of ZEJULA and were consistent with the results seen in the global PRIMA study,” said Alan Sandler, M.D., President and Head of Global Development, Oncology, Zai Lab. “Importantly, the PRIME study further underscores the status of ZEJULA as the first and only PARP inhibitor approved globally, including in China, as monotherapy for all-comer patients in the first-line maintenance treatment settings.”

In September 2020, the China National Medical Products Administration (NMPA) approved ZEJULA’s supplemental New Drug Application (sNDA) as a maintenance treatment of adult patients with advanced ovarian cancer who are in a complete or partial response to first-line 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 first-line platinum-based chemotherapy.

ZEJULA is seeking National Reimbursement Drug List (NRDL) inclusion for a first-line ovarian cancer indication.

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 first-line platinum-based chemotherapy and who were randomized 2:1 to receive ZEJULA 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 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 first-line 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.

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 (PK) study of ZEJULA was conducted in Chinese patients with ovarian cancer.

ZEJULA is also being evaluated in China in a Phase 1b/2 study in combination with tebotelimab (PD-1 x LAG-3 DART molecule) for advanced gastric cancer, triple negative breast cancer, biliary tract cancer, and endometrial cancer.

Zai Lab has a collaboration and license agreement with GlaxoSmithKline for the development and commercialization of ZEJULA 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 Laboratory and its filings can be found on the SEC.gov website.

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