Zai Lab Presents Interim Overall Survival Data for ZEJULA® (niraparib) from the NORA Phase 3 Study at the ESMO Virtual Plenary

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- *Median overall survival (mOS) was numerically longer for patients receiving ZEJULA regardless of biomarker status, at 46.3 months compared to 43.4 months in the placebo group*
- *No new safety issues were identified*

SHANGHAI, China and CAMBRIDGE, Mass., Dec. 15, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today presented new interim overall survival (OS) data in Chinese patients with platinum-sensitive recurrent ovarian cancer (PSROC) from the Phase 3 NORA study for ZEJULA® (niraparib) at the European Society for Medical Oncology (ESMO) Virtual Plenary.

The results showed that ZEJULA maintenance treatment using an individualized starting dose (ISD) regimen[1] provides a favorable OS trend irrespective of g*BRCA* mutation status compared with placebo, despite that 43% (38/88) of patients in placebo arm received subsequently at least one dose of a PARP inhibitor post progression.

- mOS in the ITT population: 46.3 months for patients receiving ZEJULA versus 43.4 months for placebo group [HR=0.82; 95% CI, 0.56-1.21].
- mOS in gBRCA mutation subgroup: Not reached for patients receiving ZEJULA versus 47.6 months for placebo group [HR=0.76; 95% CI, 0.40-1.46].
- mOS in non-gBRCA mutation subgroup: 43.1 months for patients receiving ZEJULA versus 38.4 months for placebo group [HR=0.86; 95% CI, 0.53-1.38].
- No new safety signals were identified based on long-term follow-up. Median follow-up time for OS in ZEJULA and placebo arm was 45.7 and 44.5 months, respectively.

Based on the OS analysis adjusted for subsequent PARP inhibitor therapy[2],

- mOS in the ITT population: 46.3 months for patients receiving ZEJULA versus 34.3 months for placebo group [HR=0.69; 95% CI, 0.45-1.07].
- mOS in gBRCA mutation subgroup: Not reached for patients receiving ZEJULA versus 42.1 months [HR=0.88; 95% CI 0.39-2.01].
- mOS in non-gBRCA mutation subgroup: 43.1 months for patients receiving ZEJULA versus 32.6 months [HR=0.62; 95% CI 0.37-1.05].

The final prespecified OS analysis of the NORA study is expected in 2023.

“We are proud to present this new interim OS data analysis from the NORA study for Chinese patients at ESMO, as it adds to the already existing body of evidence from the study to support the clinical profile of ZEJULA as a second-line maintenance therapy for ovarian cancer regardless of biomarker status,” said Josh Smiley, Chief Operating Officer, Zai Lab. “As one of the most commonly diagnosed gynecologic cancers in China, we are committed to address the urgent need for effective treatment options in ovarian cancer care for patients in China. ZEJULA is well positioned in China as the only PARP inhibitor approved as maintenance monotherapy for patients in both first-line and recurrent settings regardless of biomarker status.”

In September 2020, Zai Lab announced the detailed positive results from the NORA study, showing ZEJULA demonstrated significant progression-free survival (PFS) benefit for patients in China with platinum-sensitive, recurrent ovarian cancer, regardless of biomarker status. In NORA, niraparib treatment resulted in a 68% reduction in the risk of disease progression or death in the overall population (PFS HR 0.32; 95% CI, 0.23–0.45; p<0.0001). The median PFS was significantly longer for patients treated with niraparib compared to placebo: 18.3 months (95% CI, 10.9–not evaluable) versus 5.4 months (95% CI, 3.7–5.7).

About NORA

The NORA study was evaluated in 265 platinum-sensitive recurrent ovarian cancer patients 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 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 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[3]. 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] NORA was initially designed to evaluate the efficacy and safety profile of niraparib in Chinese patients with PSROC using a fixed starting dose (FSD) of 300mg orally daily. After the first 16 patients were treated with FSD, the NORA protocol was amended to use an ISD based on the NOVA retrospective analysis that the ISD may improve the safety profile of niraparib without compromising efficacy.

[2] In the adjusted OS analysis, patients in the placebo group who switched to PARP inhibitor were censored at time of switch-over.

[3] 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 other 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.
- 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 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.

For more information, please contact:

Investor Relations: Lina Zhang
+86 136 8257 6943
lina.zhang@zailaboratory.com

Media: Jennifer Chang / Xiaoyu Chen
+1 (917) 446-3140 / +86 185 0015 5011
jennifer.chang@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Zai Lab Limited

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