# Zai Lab to Present Interim Overall Survival Results for ZEJULA® (niraparib) from the Phase 3 NORA Study at the ESMO Virtual Plenary

December 1, 2022

SHANGHAI and CAMBRIDGE, Mass., Dec. 1, 2022 -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, will present the interim overall survival (OS) results of ZEJULA® (niraparib) as maintenance therapy in Chinese patients with platinum-sensitive recurrent ovarian cancer from the NORA Phase 3 study at the European Society for Medical Oncology (ESMO) Virtual Plenary on December 15-16, 2022.

The NORA study is the first fully powered, randomized, placebo-controlled, double-blind, multi-center phase 3 trial evaluating niraparib in Chinese patients with platinum-sensitive recurrent ovarian cancer. The presentation at the ESMO Virtual Plenary will highlight the long-term survival results of niraparib maintenance treatment in Chinese patients with platinum-sensitive recurrent ovarian cancer.

The details about the oral presentation are as follows:

- **Submission i/d:** 453
- **Final Publication Number:** VP7-2022
- **Title:** An ad hoc interim overall survival results of niraparib with individualized starting dose as maintenance therapy in patients with platinum-sensitive recurrent ovarian cancer (NORA): A double-blind, randomized, placebo-controlled, phase III trial
- **Speaker:** Mansoor Raza Mirza, Copenhagen University Hospital, Denmark
- **Leading PI:** Xiaohua Wu, Fudan University Shanghai Cancer Center
- **ESMO Virtual Plenary Presentation Date:** 18:30-19:30 Central European Time (CET), December 15, 2022
- **Virtual Plenary Expert Insights Q&A session:** 13:00-14:10 Central European Time (CET), December 16, 2022

**About NORA Study**
The NORA study was evaluated in 265 platinum-sensitive recurrent ovarian cancer patients 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 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. Effective treatment options for patients with platinum-sensitive recurrent ovarian cancer remain limited. 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.

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 (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.

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