Zai Lab to Present New PRIME Subgroup Analysis for Niraparib in Ovarian Cancer at 2022 ASCO Annual Conference

May 31, 2022

- *Presentation features a new subgroup analysis of the Phase 3 PRIME study exploring the efficacy of niraparib maintenance therapy for patients in China with advanced ovarian cancer based on their response to first-line platinum-based chemotherapy*
- *Results showed a significant extension of progression-free survival compared with placebo, regardless of the response status to prior platinum-based chemotherapy*

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., May 31, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced the presentation of a new subgroup data analysis from the Phase 3 PRIME study (NCT03709316) for niraparib in women in China with ovarian cancer at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 3-7, 2022. Since patient response to chemotherapy is associated with ovarian cancer prognosis, this subgroup analysis explores the treatment effect of niraparib maintenance therapy in patients with advanced ovarian cancer based on first-line platinum-based chemotherapy response.

This presentation highlights a new prespecified subgroup analysis examining 384 newly diagnosed stage III or IV ovarian cancer patients enrolled in the PRIME study, who also experienced a complete response (CR) or partial response (PR) to first-line platinum-based chemotherapy. The median progression-free survival was measured at 29.4 months for niraparib vs 8.3 months for placebo (HR=0.45; 95% CI, 0.32–0.61; P<0.001) in the complete response group. In the partial response group, the results showed median progression-free survival of 19.3 months for niraparib versus 8.3 months for placebo (HR=0.45; 95% CI, 0.23–0.86; P=0.014). The safety profile of niraparib was consistent with previous clinical trials, with no new safety issues identified in this subgroup analysis.

“Since response to chemotherapy is closely associated with the long-term outcome of advanced ovarian cancer, we are proud to present this data analysis showing the effect of niraparib on progression-free survival in patients who responded to first-line platinum-based chemotherapy,” said Alan Sandler, M.D., President and Head of Global Development, Oncology, Zai Lab. “This study helps us better understand advanced ovarian cancer regarding a potential treatment for women newly diagnosed with this serious disease.”

Details of this virtual poster presentation at ASCO 2022 are as follows:

Title: Efficacy of niraparib maintenance therapy in patients with newly diagnosed advanced ovarian cancer in phase 3 PRIME study: A subgroup analysis by response to first-line platinum-based chemotherapy.

Abstract number: 5551

Abstract link: https://meetings.asco.org/abstracts-presentations/207711

Session Title: Gynecologic Cancer

Session Date and Time: Saturday, June 4, 2022, 1:15 PM-4:15 PM CDT

Presenter: Dr. Rutie Yin, West China Second University Hospital, Key Laboratory of Birth Defects and Related Diseases of Women and Children, Ministry of Education, Sichuan University, Chengdu, China

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 an innovative, research-based, commercial stage biopharmaceutical company based in China and the U.S. focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases and neurological disorders to patients in China and around the world. Our longer-term goal is to leverage our competencies and resources to enable and impact human health worldwide.

For additional information about Zai Lab, including information on our products, business activities and partnerships, research, or 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 about clinical trials, data readouts and presentations, our clinical development programs, including our research and development program for the treatment of ovarian cancer in China; the potential of our commercial business and pipeline programs, 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 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 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.

More information about our SEC filings can be found 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

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