Zai Lab Announces Positive Topline Results from the NORA Phase 3 Study of ZEJULA® as Maintenance Therapy for Chinese Patients with Platinum-sensitive, Recurrent Ovarian Cancer

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- The NORA study meets all primary and secondary endpoints

- Largest randomized clinical trial (RCT) in ovarian cancer ever conducted in China

- Individualized starting dose regimen shown to be effective with improved safety profile in Chinese patients

SHANGHAI and SAN FRANCISCO, May 28, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited ("Zai Lab") (NASDAQ: ZLAB), an innovative commercial-stage biopharmaceutical company, today announced positive topline results from the NORA study, the Phase 3 randomized, double-blind, placebo-controlled, study of ZEJULA (niraparib) as a maintenance therapy in Chinese patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) who are in a complete or partial response to platinum-based chemotherapy.

The NORA study randomized 265 patients at 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 progression-free survival (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 is 300 mg. The study met its primary endpoint of a statistically significant improvement in progression free survival for patients with ovarian cancer regardless of their biomarker status. The safety profile was consistent with what was observed from the global NOVA study with lower rates of anemia and thrombocytopenia.

"The NORA clinical data in Chinese patients confirmed the compelling clinical profile of ZEJULA and were consistent with the results seen in the global NOVA study," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer. "Importantly, the NORA study demonstrated an individualized starting dose regimen at 200 mg preserved the efficacy while improving safety profile in Chinese patients, particularly with regard to the hematological toxicities. Building on both the promising results of NOVA and Zai Lab's PK study that demonstrated no ethnicity difference between Chinese and global subjects, the NORA study further underscores the promise of ZEJULA as a maintenance therapy for Chinese patients with platinum-sensitive recurrent ovarian cancer."

"The data of the NORA study will have a significant impact on the clinical practice in the treatment of ovarian cancer in China and beyond, as the individualized starting dose regimen has demonstrated clear clinical benefit with improved safety profile," said Dr. Xiaohua Wu, Professor and Chair of Gynecologic Oncology Department of Fudan University Shanghai Cancer Centre. "In addition, the NORA study is the first fully powered, randomized, controlled (RCT) Phase 3 trial ever done in ovarian cancer in China."

The full results from the NORA study will be presented at an upcoming scientific meeting.

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers in China with more than 52,000 newly diagnosed cases and 23,000 deaths each year. 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 inevitable relapse of ovarian cancer will benefit patients with ovarian cancer in China.

About ZEJULA (niraparib)

ZEJULA (niraparib) is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. The NMPA is currently reviewing Zai Lab's sNDA under priority review for niraparib as maintenance treatment in patients with first-line ovarian cancer following platinum-based chemotherapy.

Additional development program for niraparib in ovarian cancer by Zai Lab includes an ongoing pivotal study of niraparib as first-line maintenance therapy for Chinese patients with ovarian cancer following platinum-based chemotherapy. Previously, Zai Lab conducted a Phase 1 pharmacokinetic (PK) study of niraparib in Chinese patients with ovarian cancer. This study was published in August 2019 in The Oncologist and demonstrated that the PK profile of niraparib in Chinese patients were comparable to that of patients evaluated in ZEJULA's global PK study.

Zai Lab in-licensed rights to ZEJULA from GSK for Mainland China, Hong Kong and Macau. The NDA for recurrent ovarian cancer was accepted by the NMPA in December 2018, granted priority review status in January 2019 and approved in December 2019. Zai Lab has obtained approval to market ZEJULA in Mainland China, Hong Kong and Macau for maintenance therapy in patients with platinum-sensitive, recurrent ovarian cancer. In March 2020, China NMPA accepted our sNDA for ZEJULA for first-line maintenance treatment of patients with ovarian cancer.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is an innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its 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 statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing ZEJULA in China. 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 Zai Lab's 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) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to publicly 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 Zai Lab's views as of any date subsequent to the date of this press release.

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