Zai Lab Completes Enrollment of China Pivotal Trial of Niraparib as Second-Line Maintenance Therapy for Ovarian Cancer in China

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SHANGHAI, China, Jan. 09, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative commercial stage biopharmaceutical company, today announced completion of patient enrollment of its pivotal trial of niraparib (ZL-2306; ZEJULA®) in development for second-line maintenance therapy in patients with recurrent, platinum-sensitive ovarian cancer.

“Completion of patient enrollment of this pivotal trial is an important milestone for Zai as it further demonstrates our clinical development capabilities and commitment to our clinical investigators and ovarian patients in China,” said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. “We are encouraged by the early acceptance of our NDA submission for niraparib by the NMPA based on the comprehensive data package.”

The Phase 3 trial is evaluating niraparib as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. Recurrent ovarian cancer patients who have responded to a platinum-containing regimen were enrolled in the study and randomized 2:1 to receive either niraparib or placebo once daily. Patients were stratified by gBRCA status. The primary endpoint is progression-free survival. The study enrolled its first patient in September 2017.

Zai Lab in-licensed rights to ZEJULA from Tesaro for China, Hong Kong and Macau as an important, new treatment option to more than 50,000 Chinese patients who suffer from ovarian cancer every year. ZEJULA is positioned as a best-in-class PARP inhibitor due to its compelling efficacy, once-daily dosing and superior pharmacokinetic properties including its ability to cross the blood brain barrier. The NDA was accepted by the NMPA in December 2018. Zai Lab obtained approval for marketing ZEJULA in Hong Kong in October and launched the product in December 2018. Niraparib is also being evaluated in China in pivotal studies as first-line maintenance therapy in platinum-sensitive ovarian cancer and in small-cell lung cancer.

“Treating ovarian cancer is quite challenging because the tumor typically recurs despite responses to chemotherapy,” said Dr. Yong-Jiang Hei, Chief Medical Officer for Oncology at Zai Lab. “We conducted this study with this very promising agent with the objective of improving patient care and prolonging the lives of our patients. We look forward to the results of this study which will further demonstrate the clinical benefit of niraparib in Chinese patients with ovarian cancer.”

About ZEJULA

ZEJULA (niraparib, ZL-2306) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2inhibitor. It was approved in March 2017 by the FDA in the United States and in November 2017 by the EMA in the European Union under the trade name ZEJULA® as a maintenance treatment for women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Based on the approval status in the United States and European Union by our partner, Tesaro, Zai Lab has obtained the approval for marketing ZEJULA in Hong Kong in October 2018.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a Shanghai-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab’s experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding business strategy, plans and objectives for future operations and other statements containing words such as "anticipates", “believes”, "expects", “plan” 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 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, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2017 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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