Priority Review Granted to Zai Lab's NDA Application for ZEJULA (Niraparib) in China

January 28, 2019

SHANGHAI, China, Jan. 28, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and US-based innovative commercial stage biopharmaceutical company, today announced that the Center for Drug Evaluation of China's National Medical Products Administration (NMPA, formally known as CFDA) has granted priority review status to the New Drug Application (NDA) for ZEJULA (niraparib, or ZL-2306) for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal ovarian cancer who are in a complete or partial response to platinum-based chemotherapy. ZEJULA is a potent and highly selective PARP1/2 inhibitor that does not require BRCA mutation or other biomarker testing prior to administration.

Zai Lab in-licensed rights to ZEJULA from Tesaro for China, Hong Kong and Macau as an important, new treatment option for more than 50,000 Chinese patients who suffer from ovarian cancer every year. ZEJULA is a potential best-in-class PARP inhibitor due to its differentiated efficacy, once-daily dosing and superior pharmacokinetic properties including its ability to cross the blood brain barrier. The NDA was accepted by the NMPA on December 12, 2018. Zai Lab obtained approval for marketing ZEJULA in Hong Kong in October 2018 and has been actively commercializing the product.

"The granting of priority review for ZEJULA by the NMPA highlights both urgency of the medical need and the potential importance of ZEJULA as an innovative therapeutic option for Chinese women suffering from this difficult to treat cancer," said Dr. Samantha Du, Chairman and Chief Executive officer of Zai Lab. "We will continue to work closely with the agency to bring this novel treatment to patients as soon as possible."

Priority review was established in China to facilitate drug registration and accelerate the development of new drugs with clinical value under the guidance of *Opinions on Encouraging Pharmaceutical Innovation via Priority Review & Approval* issued by CFDA in December 2017. According to these guidelines, the regulatory authority will prioritize the review process and evaluation resources for applications under priority review, which should expect reduced review and approval timelines.

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, which was recently acquired by GSK, Zai Lab obtained the approval for marketing ZEJULA in Hong Kong in October 2018.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and US-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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