Zai Lab Announces China's NMPA Grants Priority Review to the sNDA for ZEJULA (Niraparib) for First-Line Ovarian Cancer Maintenance Treatment

April 16, 2020

SHANGHAI, China, and SAN FRANCISCO, April 16, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced that the Center for Drug Evaluation of China's National Medical Products Administration (NMPA) has granted priority review status to the supplemental New Drug Application (sNDA) for ZEJULA (niraparib) as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

"China NMPA's decision to grant priority review to our sNDA for ZEJULA underscores both the urgency of the medical need and the potential of ZEJULA as an innovative therapeutic option in the first-line setting for ovarian cancer patients," said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. "Ovarian cancer remains a devasting disease in China and we are excited that many more patients may soon have access to ZEJULA earlier in the course of their treatment. We thank the agency for their commitment and continued support to patients in need and look forward to working closely with them to move this important indication for ZEJULA toward approval."

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 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 a monotherapy maintenance treatment in adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

Zai Lab has ongoing pivotal studies in Chinese patients for first-line and second-line maintenance therapies in ovarian cancer. Zai Lab also 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 approvals 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.

Since the Hong Kong launch of ZEJULA in October 2018, it has rapidly gained market share in the region despite being launched more than two years behind Lynparza®. Based on IQVIA (formerly IMS) data, ZEJULA is now the market leading PARP inhibitor with market share in Hong Kong of 71% for the full year ended December 31, 2019.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a China and U.S.-based 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.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding plans for approval and commercializing niraparib in China 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, 2018 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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Source: Zai Lab Limited