

# Zai Lab Announces Publication of Pharmacokinetic Study of Niraparib in Chinese Ovarian Cancer Patients

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Study demonstrated comparable profile to non-Chinese patients Clinical study published in The Oncologist

SHANGHAI, China, and SAN FRANCISCO, Aug. 27, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced publication of the open-label study evaluating the pharmacokinetic (PK) profile of niraparib in Chinese ovarian cancer patients. Results from the study show a PK profile of niraparib in Chinese patients comparable to that of patients evaluated in GSK's global PK study. The study was published online in *The Oncologist* (DOI: 10.1634/theoncologist.2019-0565).

The open-label PK study enrolled 36 Chinese patients with stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer. Patients received no more than two lines of platinum-based therapy and were responsive to the most recent platinum-based treatment. Subjects were randomly assigned to dose levels of 100mg, 200mg and 300mg of niraparib. The primary objective of the study was to assess the PK profile of niraparib in Chinese patients following both single and multiple doses. The secondary objective was a safety assessment.

Niraparib showed that PK parameters and safety profiles observed in Chinese patients were comparable to those in the U.S. and Europe patient populations enrolled in the GSK's global studies. The study results and population PK data did not identify ethnicity differences between Chinese and non-Chinese patients.

Zai Lab in-licensed rights to niraparib (ZEJULA<sup>®</sup>) from GSK (formerly Tesaro) for China, Hong Kong and Macau as an important, new treatment option for more than 52,000 Chinese patients who suffer from ovarian cancer every year. Niraparib is a PARP inhibitor with compelling efficacy, once-daily dosing and superior PK properties including its ability to cross the blood brain barrier. Zai Lab's new drug application for niraparib in China was accepted by the China National Medical Product Administration in December 2018 and is currently under priority review. Zai Lab obtained approval for marketing niraparib in Hong Kong in October 2018 and Macau in June 2019. 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.

# **About Niraparib**

Niraparib, ZEJULA<sup>®</sup> is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. 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, GSK, Zai Lab obtained the approval for marketing ZEJULA in Hong Kong in October 2018 and Macau in June 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, 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 plans for commercializing niraparib in China. All statements, other than statements of historical fact, included in this press release are forward-looking statements and are identified by 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 fillings 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 dat

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