Zai Lab’s ZL-2306 (niraparib) Completes Pharmacokinetics (PK) Study in Chinese Ovarian Cancer Patients Showing Comparable Profile to non-Chinese Patients

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Niraparib made in China shows comparable PK profile to Tesaro’s product

SHANGHAI, China, Aug. 20, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced the early completion of an open-label study to evaluate the pharmacokinetic (PK) profile of ZL-2306 (niraparib) made in China in Chinese ovarian cancer patients. The study demonstrated comparable PK profile of Chinese patients who were administered ZL-2306 to the PK profile of patients evaluated in Tesaro’s clinical trials using product manufactured outside of China. These results are important in supporting the regulatory review of ZL-2306, a potent and highly selective PARP1/2 inhibitor, in ovarian cancer patients in mainland China.

The open-label PK Study enrolled 36 subjects with dose levels ranging from 100mg, 200mg and 300mg, and assessed the PK profile of ZL-2306 made in China. The objective was to evaluate ZL-2306’s PK profile and tolerability in Chinese patients, and to compare the key PK parameters with global data. The results showed that the drug exposure increased proportionally from 100mg to 300mg, with no unexpected safety issues noted. All key PK parameters were comparable to those in global studies. The population PK data and analysis showed no ethnicity differences between Chinese and non-Chinese patients.

“Demonstrating comparability of key PK parameters of niraparib with that used by our partner, Tesaro, is an important milestone for us,” said Dr. Samantha Du, Zai Lab’s Chief Executive Officer. “These data further de-risk our ovarian cancer program and increase our confidence on the regulatory approval in China for ZL-2306 (niraparib).”

About ZL-2306

ZL-2306 (niraparib) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. Niraparib was approved in March 2017 by the FDA in the U.S. and by the EMA in the EU under the trade name ZEJULA® in November 2017 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 U.S. and EU, Zai Lab submitted a market registration application for niraparib in Hong Kong and plans to launch and commercialize niraparib in Hong Kong in the second half of 2018. Zai Lab believes ZL-2306 has the potential to be a first-in-class Category 1 drug for treatment across multiple solid tumor types in China.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company’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", “plans” 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.

For more information, please contact:

ZAI LAB CONTACTS:

Zai Lab
Billy Cho
+86 137 6151 2501
billy.cho@zailaboratory.com

Media: Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 364, rflamm@burnsmc.com

Investors: Jill Steier
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 367, jsteier@burnsmc.com

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