Zai Lab Announces Approval of ZEJULA® (Niraparib) for Patients with Relapsed Ovarian Cancer in Hong Kong

October 22, 2018

ZEJULA is the first and only PARP inhibitor approved in Hong Kong for the maintenance treatment of platinum-sensitive relapsed ovarian cancer irrespective of BRCA mutation status

Zai Lab expects to launch ZEJULA in Hong Kong in 4Q18

SHANGHAI, China, Oct. 22, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced that the Hong Kong Department of Health has approved ZEJULA® (niraparib), an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor in Hong Kong for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response (CR or PR) to platinum-based chemotherapy. Unlike other PARP inhibitors approved in Hong Kong, ZEJULA does not require *BRCA* mutation or other biomarker testing prior to administration.

“We are now in final preparations to launch ZEJULA in Hong Kong this quarter to offer an important treatment option to ovarian cancer patients,” said William Liang, Chief Commercial Officer of Zai Lab. “With the compelling clinical data, ZEJULA has the potential to save lives and have a major impact on public health. We have developed commercial and medical infrastructure in Hong Kong to educate physicians about the differentiated benefits of ZEJULA to drive its adoption. In addition, our upcoming launch is an excellent opportunity for Zai Lab to optimize best practices, as we prepare for the future launch of ZEJULA in Mainland China.”

The approval of ZEJULA in Hong Kong was based upon the international Phase 3 ENGOT-OV16/NOVA trial sponsored by TESARO, Inc., a double-blind, placebo-controlled study that enrolled 553 patients with relapsed predominantly high grade serous ovarian, fallopian tube, or primary peritoneal cancer who were platinum sensitive, defined by a CR or PR for more than six months to their penultimate (next to last) platinum-based therapy. The primary endpoint of the trial was progression free survival (PFS). Approximately two-thirds of study participants did not have germline *BRCA* mutations. Progression in the NOVA study was determined by a robust, unbiased, blinded central review to be the earlier of radiographic or clinical progression. ZEJULA significantly increased PFS in patients both with and without germline *BRCA* mutations as compared to the control arm. Treatment with ZEJULA reduced the risk of disease progression or death by 73% in patients with germline *BRCA* mutations (hazard ratio (HR) 0.27) and by 55% in patients without germline *BRCA* mutations (HR 0.45). The magnitude of benefit was similar for patients entering the trial with a CR or PR.

“Today’s approval of ZEJULA in Hong Kong represents a significant milestone for Zai Lab as it signifies our transition into a commercial stage company,” said Dr. Samantha Du, Chief Executive Officer of Zai Lab. “We are grateful to the patients who participated in the clinical trials in the U.S. and Europe, the clinical investigators, our partner TESARO and our dedicated employees who collectively made this approval possible. While we are focused on making ZEJULA a commercial success in Hong Kong, we continue to drive development of ZEJULA in China, along with the rest of our broad and late-stage pipeline.”

About ZL-2306

ZL-2306 (niraparib) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2inhibitor. 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 expects to launch and commercialize niraparib in Hong Kong in the fourth quarter 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. 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", “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: Nancie Steinberg / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006, exts. 318 / 364, nsteinberg@burnsmc.com / rflamm@burnsmc.com

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

Zai Lab Limited

Zai Lab Limited