



Zai Lab Announces Dosing of First Patient in Phase 3 China Registration Trial of ZL-2306 (niraparib) for First-Line Maintenance Therapy in Platinum Responsive Ovarian Cancer

June 29, 2018

SHANGHAI, June 29, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced dosing of the first patient in the Company's Phase 3 China registration trial of ZL-2306 (niraparib) for first-line maintenance therapy of patients with platinum-responsive ovarian cancer. ZL-2306 is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) polymerase 1/2, or PARP 1/2, inhibitor with the potential to be a first-in-class Category 1 drug in China for treatment across multiple solid tumor types. In September 2017, Zai Lab commenced its Phase 3 China registration trial of ZL-2306 as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. The Company is also currently preparing for its Phase 3 registration trial of ZL-2306 for small cell lung cancer, which it anticipates to commence by mid-2018.

"Zai Lab is making significant progress in its ZL-2306 clinical program, with the initiation of our second Phase 3 study in China as announced today, as well as the recent early completion of enrollment in our PK trial for Chinese patients with platinum-sensitive ovarian cancer," said Samantha Du, Zai Lab's Chief Executive Officer. "PARP inhibitor has recently shown to prolong PFS for first-line maintenance therapy in gBRCA+ platinum responsive ovarian patients, and we believe ZL-2306 offers substantial advantages over other treatment options for the Chinese market given its broad applicability across all patient population, regardless of gBRCA mutation status. We look forward to continued momentum in our program, including potential commercial launch in Hong Kong later this year and potential expansion in additional cancer indications with substantial unmet needs."

Zai Lab's Phase 3 China registration study announced today is a 2:1 randomized, double-blind, placebo-controlled, multi-center trial to evaluate the efficacy and safety of ZL-2306 as maintenance therapy following first-line platinum-based chemotherapy in patients with ovarian cancer.

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 US 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 US and EU, Zai Lab submitted a market registration application for ZL-2306 in Hong Kong and plans to launch and commercialize ZL-2306 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 global 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 includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the commencement of Zai Lab's Phase 3 registration trial of ZL-2306 and the timing of commercialization of ZL-2306. You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth 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 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.

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