Zai Lab Limited Announces Dosing of First Patient in Phase 3 Registration Trial of ZL-2306 (niraparib) for Treatment of Ovarian Cancer

2017年 9月 29日

SHANGHAI, China, Sept. 29, 2017 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, announced today that it has dosed the first patient in a Phase 3 registration trial to evaluate the safety and efficacy of ZL-2306 (niraparib) for the maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube and primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

"We are pleased to report dosing of the first patient in this Phase 3 trial," stated Samantha Du, Chairman and CEO of Zai Lab. "We believe ZL-2306 is uniquely suited for the China marketplace as it does not require BRCA or other biomarker diagnostic tests. Going forward, we would look to expand ZL-2306 to be available as a potential treatment across a number of other indications."

The Phase 3 trial is designed to evaluate ZL-2306 as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. Patients with recurrent platinum sensitive ovarian cancer who have responded to a second line platinum-containing treatment will be enrolled in the study. A separate Phase 3 study is expected to evaluate ZL-2306 as a first-line maintenance therapy in patients with platinum-responsive ovarian cancer. The details of the clinical trial designs are being discussed with the CFDA, and, pending authorization, Zai Lab plans to initiate this trial in the first half of 2018. Tesaro, Inc. is also evaluating niraparib in the PRIMA trial, a Phase 3 clinical trial in the first-line maintenance setting in platinum-responsive ovarian cancer patients.

About ZL-2306 (niraparib)

ZL-2306 is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) polymerase 1/2 inhibitor with the potential to be a first-in-class category 1 drug for treatment across multiple solid tumor types in China. Zai Lab obtained an exclusive license for the development and commercialization of ZL-2306 in China, Hong Kong and Macau in 2016. In March 2017, niraparib was approved by the FDA as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer.

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.

Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the anticipated timing of clinical trials. You can identify forward-looking statements because they contain words such as "believes" and "expects." 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 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.

Contact:

Zai Lab
Jonathan Wang
+86 21 6163 2588
jwang@zailaboratory.com

The Trout Group
John Graziano
+1 646 378 2942
jgraziano@troutgroup.com

Zai Lab Limited