Zai Lab Doses First Patient in Phase III Trial of ZL-2306 (niraparib) in Patients with Small-Cell Lung Cancer in China

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First study of niraparib for this indication worldwide; a significant medical need in China

SHANGHAI, China, Aug. 28, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced dosing of the first patient in a Phase III trial of ZL-2306 (niraparib) in patients with small-cell lung cancer (SCLC).

The Phase III trial is a double-blind, placebo-controlled study randomizing 591 patients 2:1 for ZL-2306 (niraparib) vs. placebo as maintenance therapy with extensive-stage disease SCLC (ED-SCLC) who have responded to multiple cycles of first-line platinum-based chemotherapy. The primary endpoints are progression-free survival (PFS), adjudicated by blinded independent central review, and overall survival (OS). Secondary endpoints include investigator-assessed PFS, change in patient outcomes and safety. More information can be found at https://clinicaltrials.gov/ct2/show/NCT03516084?term=niraparib&draw=2&rank=42

“Maintenance therapy for SCLC patients who have responded to first-line therapy is urgently needed to extend survival but no such treatment has yet been approved anywhere in the world,” said Dr. Samantha Du, Chief Executive Officer of Zai Lab. “The large patient population with SCLC in China represents a high unmet need and we believe that ZL-2306 has the potential to be developed as an important therapeutic option for these patients. This study is an important part of our comprehensive clinical development program for ZL-2306 with the goal to establish ZL-2306 as the leading PARP inhibitor in China.”

Lung cancer is the most common cancer in China with annual incidence rate of over 730,000 patients as of 2015. Lung cancer is also the leading cause of cancer death in China with annual mortality rate of over 610,000 as of 2015. SCLC makes up approximately 15-20% of China’s lung cancer patients and SCLC is an area with high unmet clinical need. The standard of care is platinum-based chemotherapy; however, responders to this therapy typically relapse and there are no adequate alternative regimens to treat these patients.

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 (niraparib) 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 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.

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