Zai Lab Announces Acceptance of NDA Submission of ZEJULA (Niraparib) in Mainland China by the NMPA

December 12, 2018

SHANGHAI, China, Dec. 12, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative commercial stage biopharmaceutical company, today announced that the China National Medical Products Administration (NMPA) has accepted its New Drug Application (NDA) for ZEJULA (niraparib, or ZL-2306) as a Category 1 drug for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal ovarian cancer who are in a complete or partial response to platinum-based chemotherapy. ZEJULA is a potent and highly selective PARP1/2 inhibitor that does not require BRCA mutation or other biomarker testing prior to administration.

“The NMPA’s acceptance of our NDA submission for ZEJULA represents a major milestone for Zai Lab as this is our first ever NDA submission in Mainland China,” said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. “ZEJULA will offer an important, new treatment option to more than 50,000 Chinese patients who suffer from ovarian cancer every year and we are grateful that NMPA recognizes this critical medical need and the promise of ZEJULA. Zai Lab is a leader in the field of innovative oncology treatments in China and we have a deep and highly-differentiated pipeline, including three U.S. FDA-approved products and four other assets in late stage clinical development. As a result, we expect additional regulatory submissions in the coming years as we continue to advance our pipeline.”

Dr. Yong-Jiang Hei, Chief Medical Officer for Oncology of Zai Lab said, “We believe ZEJULA is a best-in-class PARP inhibitor due to its compelling efficacy, once-daily dosing and superior pharmacokinetic properties including its ability to cross the blood brain barrier. The NDA submission based on the Category 1 designation of ZEJULA is a result of China-based clinical trials and manufacturing conducted by Zai Lab. We plan to expand our development efforts in collaboration with our partner Tesaro across several additional indications including, but not limited to, first-line maintenance treatment of ovarian cancer, lung cancer and gastric cancer.”

William Liang, Chief Commercial Officer noted, “The Zai Lab commercial team is very excited about the attractive profile of ZEJULA and plans to leverage ZEJULA’s recent Hong Kong approval and commercial launch to prepare for the launch in China. If approved, we believe ZEJULA will provide a differentiated treatment option to benefit more ovarian cancer patients. We also intend to closely collaborate with local authorities and NGOs to develop patient assistant programs to increase access to more women who could benefit from this treatment. Zai Lab is committed to making a meaningful impact on the way cancer is treated in China and will continue to develop and bring new innovative oncology treatment options to patients in need.”

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers in China with approximately 51,000 newly diagnosed cases and 23,000 deaths in China in 2014. The 5-year overall survival rate of ovarian cancer patients is 46% across all stages, but only 29% in patients are diagnosed with distant metastatic disease. While platinum-based chemotherapy is effective at inducing an initial response in ovarian cancer, the disease will recur in the majority of women. Effective treatment options for patients with platinum-sensitive recurrent ovarian cancer remain limited. New agents that prolong the duration of response following platinum-based treatment and delay the inevitable relapse of ovarian cancer will benefit patients with ovarian cancer in China.

About ZEJULA

ZEJULA (niraparib, ZL-2306) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2inhibitor. It was approved in March 2017 by the FDA in the United States and in November 2017 by the EMA in the European Union under the trade name ZEJULA® 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 United States and European Union by our partner, Tesaro, Zai Lab has obtained the approval for marketing ZEJULA in Hong Kong in October 2018.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a Shanghai-based innovative commercial stage 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", “plan” 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, CFO
+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
nsteinberg@burnsmc.com / rflamm@burnsmc.com

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

Source: Zai Lab Limited