Zai Lab Announces NMPA Approval of ZEJULA® (Niraparib) for First-Line Maintenance Treatment of Ovarian Cancer in China

September 10, 2020

- ZEJULA is the only PARP inhibitor approved as monotherapy for all-comer patients in the first-line and recurrent maintenance treatment settings regardless of biomarker status

- ZEJULA was recommended as a monotherapy first-line maintenance treatment for women with platinum-responsive advanced ovarian cancer in the Ovarian Cancer PARP Inhibitor Clinical Guidelines published by Gynecological Oncology, Chinese Medical Association

SHANGHAI and SAN FRANCISCO, Sept. 10, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial stage biopharmaceutical company, today announced that the China National Medical Products Administration (NMPA) has approved its supplemental New Drug Application (sNDA) for ZEJULA® (niraparib), an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

"We believe ZEJULA is a potential best-in-class PARP inhibitor. It is the first and only PARP inhibitor approved anywhere globally, including in China as monotherapy for all-comer patients in the first-line and recurrent maintenance treatment settings," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "The NMPA's rapid approval of our sNDA for ZEJULA underscores the unmet medical needs it serves and further enables Zai Lab to make a meaningful impact on the way ovarian cancer is treated in China."

"The approval of ZEJULA for the first-line maintenance treatment setting represents an opportunity to fundamentally change how women with ovarian cancer will be treated in China and a new standard of care for these patients," said Dr. Lingying Wu, Director of the Department of Gynecologic Oncology of the Cancer Hospital of China Academy of Medical Sciences. "In addition to its compelling efficacy data as monotherapy for all-comer patients, ZEJULA also has the convenience of once-daily dosing, excellent safety profile and attractive pharmacokinetic properties, including its ability to cross the blood brain barrier."

ZEJULA's sNDA for the first-line maintenance treatment setting was accepted by the NMPA in March 2020, and was granted priority review status in April 2020.

About Ovarian Cancer

Ovarian cancer is one of the most common gynecologic cancers in China with approximately 52,000 newly diagnosed cases and 23,000 deaths in China per year. 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 (Niraparib)

ZEJULA (niraparib) is indicated as monotherapy for the maintenance treatment of adult patients with advanced and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first and second-line platinum-based chemotherapy.

The PRIMA study conducted by Zai Lab's partner GlaxoSmithKline plc (GSK) demonstrated significant progression-free survival (PFS) improvement when given as monotherapy in women with first-line platinum responsive ovarian cancer, resulting in a 38% reduction in the risk of disease progression or death in the overall study population. Clinically meaningful reduction in risk of disease progression or death was further demonstrated with hazard ratios (HRs) of 0.40, 0.43 and 0.68 for BRCA mutant, HRD positive and HRD negative tumors, respectively. This study showed ZEJULA as the first PARP inhibitor to significantly improve PFS in this setting, regardless of biomarker status.

Zai Lab has several studies ongoing or completed in Chinese patients with ovarian cancer:

- In November 2019, Zai Lab completed patient enrollment of its self-sponsored Phase III PRIME study evaluating ZEJULA as a first-line maintenance therapy in ovarian cancer patients who are in a complete or partial response to first-line platinum-based chemotherapy.
- In May 2020, Zai Lab announced positive top-line results from its self-sponsored Phase III NORA study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer. The full results from the NORA study will be presented at European Society for Medical Oncology (ESMO) 2020 Virtual Congress on September 19, 2020.
- In August 2020, the first patient was dosed in the registrational bridging trial for late-line ovarian cancer treatment.

- Zai Lab also conducted a Phase I pharmacokinetic (PK) study of ZEJULA in Chinese patients with ovarian cancer.

ZEJULA is also being evaluated in China in a Phase Ib dose escalation and expansion clinical study, in combination with tebotelimab (PD-1 x LAG-3 DART molecule) for the treatment of patients with advanced or metastatic gastric cancer who failed prior treatment.

Zai Lab has a collaboration, development and license agreement with GSK for the development and commercialization of ZEJULA in Mainland China, Hong Kong and Macau.

Important Safety Information

The most common side effects for patients taking ZEJULA include heart not beating regularly, nausea, constipation, vomiting, pain in the stomach area, mouth sores, diarrhea, indigestion or heartburn, dry mouth, tiredness, loss of appetite, urinary tract infection, shortness of breath, cough, rash, changes in liver function or other blood tests, pain in your joints, muscles, and back, headache, dizziness, change in the way food tastes, trouble sleeping, anxiety, sore throat and changes in the amount or color of your urine. Other potential serious side effects include bone marrow problems called Myelodysplastic Syndrome (MDS) or a type of blood cancer called Acute Myeloid Leukemia (AML), symptoms of low blood cell counts (which can be a sign of serious bone marrow problems) and high blood pressures. Patients should take a few medical tests before they are treated with ZEJULA. Healthcare providers should periodically monitor their patients' blood cell counts and blood pressures.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its portfolio in order to impact human health worldwide.

For additional information about the Company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing ZEJULA in China 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, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, 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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