



## **Zai Lab Announces NMPA Approval of ZEJULA® (Niraparib) in China as Maintenance Therapy for Patients with Recurrent Ovarian Cancer**

December 27, 2019

*ZEJULA is a potential best-in-class PARP inhibitor for ovarian cancer patients due to its compelling clinical data<sup>1</sup>, once-daily dosing and pharmacokinetic properties*

*ZEJULA is the first approval for Zai Lab in Mainland China*

SHANGHAI, China and SAN FRANCISCO, Dec. 27, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced the China National Medical Products Administration (NMPA) approved the New Drug Application (NDA) for ZEJULA (niraparib), an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor as maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal 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 approval of ZEJULA, our first product to be approved in Mainland China, is a testament to the hard work and dedication of the entire Zai Lab team," said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. "We are grateful to all of the patients and investigators who contributed to the success of the ZEJULA clinical development program. Additionally, we appreciate the NMPA for their partnership through this rapid and thorough assessment of the ZEJULA application, recognizing the high unmet medical need it serves. As the first PARP inhibitor with Category 1 designation and manufactured in Mainland China, we are very excited to bring ZEJULA to Chinese patients following the successful launch in Hong Kong. With enrollment completed with 265 patients, we remain committed to finish our pivotal trial for maintenance therapy for Chinese patients with recurrent ovarian cancer (the NORA study) by third quarter of next year."

"The approval of ZEJULA in Mainland China is welcoming news for the ovarian cancer community, where advances in treatment have been very limited despite the clinical need," said Dr. Xiaohua Wu, Professor and Chair of Gynecologic Oncology Department of Fudan University Shanghai Cancer Centre. "The NOVA study shows that ZEJULA is a potential best-in-class PARP inhibitor for ovarian cancer patients, regardless of BRCA mutation or biomarker status, due to its compelling clinical data, convenience of once-daily dosing and attractive pharmacokinetic properties, including its ability to cross the blood brain barrier."

The Committee of Gynecological Oncology, Chinese Anti-Cancer Association (CACA) has updated its clinical practice guidelines in *Consensus of Chinese Experts on Recurrent Epithelial Ovarian Cancer* to recommend ZEJULA (I/A category) as a maintenance treatment option for platinum sensitive recurrent ovarian cancer.

"Ovarian cancer is a devastating disease with a 5-year survival rate that hasn't improved in a decade," said Dr. Lingying Wu, Director of the Department of Gynecologic Oncology of the Cancer Hospital of China Academy of Medical Sciences. "In addition to helping patients with recurrent ovarian cancer, ZEJULA's recent PRIMA study demonstrated significant 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 anticipates filing a supplemental NDA for ZEJULA (niraparib) with the NMPA as a first-line monotherapy maintenance treatment of platinum-responsive ovarian cancer patients soon after GlaxoSmithKline plc (GSK) files with the relevant global health authorities.

### **Ovarian cancer in China**

Ovarian cancer is one of the most common gynecologic cancers in China with more than 52,000 newly diagnosed cases and 23,000 deaths in China each year. The 5-year overall survival rate of ovarian cancer patients is 46% across all stages, but only 29% in patients 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 (niraparib)**

ZEJULA (niraparib, ZL-2306) is a potential best-in-class PARP inhibitor for ovarian cancer patients due to its compelling clinical data<sup>1</sup>, once-daily dosing and pharmacokinetic properties, including its ability to cross the blood brain barrier. As maintenance therapy for recurrent ovarian cancer (the

NOVA study), ZEJULA treatment reduced the risk of disease progression or death by 73% in patients with germline BRCA mutations (HR 0.27) and by 55% in patients without germline BRCA mutations (HR 0.45).

Zai Lab also conducted a Phase 1 pharmacokinetic (PK) study of niraparib in Chinese patients with ovarian cancer. This study was published in August 2019 in *The Oncologist* and demonstrated that the PK profile of niraparib in Chinese patients were comparable to that of patients evaluated in ZEJULA's global PK study. Zai Lab in-licensed rights to ZEJULA from GSK for Mainland China, Hong Kong and Macau.

The NDA was accepted by the NMPA on December 12, 2018 and granted priority review status on January 29, 2019. Zai Lab has now obtained approvals for marketing ZEJULA in Mainland China, Hong Kong and Macau for maintenance therapy in patients with platinum-sensitive, recurrent ovarian cancer.

Since the Hong Kong launch of ZEJULA in October 2018, it has rapidly gained market share in the region despite being launched more than two years behind Lynparza<sup>®</sup>. Based on IQVIA (formerly IMS) data, ZEJULA is now the market leading PARP inhibitor with market share in Hong Kong of 77% by value in the third quarter of 2019.

ZEJULA is also being evaluated in China in pivotal studies as first-line maintenance therapy in small-cell lung cancer.

## **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 a China and U.S.-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 the potential for ZEJULA to be a best-in-class PARP inhibitor, the timing of ZEJULA entering the Mainland China market, the timing of filing of a supplemental NDA for ZEJULA as a first-line monotherapy maintenance treatment of platinum-responsive ovarian cancer patients 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, 2018 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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<sup>1</sup> Mirza MR, Monk BJ, Herrstedt J, et al; ENGOT-OV16/NOVA Investigators. Niraparib maintenance therapy in platinum-sensitive, recurrent ovarian cancer. *N Engl J Med.* 2016;375(22):2154-2164, and Supplementary Appendix.

## **ZAI LAB CONTACTS:**

Zai Lab  
Billy Cho, CFO  
+86 137 6151 2501  
[billy.cho@zailaboratory.com](mailto:billy.cho@zailaboratory.com)

Media: Ryo Imai / Robert Flamm, Ph.D.  
Burns McClellan, on behalf of Zai Lab  
212-213-0006 ext. 315 / 364

[rimai@burnsmc.com](mailto:rimai@burnsmc.com) / [rflamm@burnsmc.com](mailto:rflamm@burnsmc.com)

Investors: Pete Rahmer / Mike Zanoni  
Endurance Advisors, on behalf of Zai Lab  
415-515-9763 / 610-442-8570

[prahmer@enduranceadvisors.com](mailto:prahmer@enduranceadvisors.com) / [mzanoni@enduranceadvisors.com](mailto:mzanoni@enduranceadvisors.com)



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