



Zai Lab Announces Inclusion of ZEJULA® (Niraparib) in China's National Reimbursement Drug List

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SHANGHAI and SAN FRANCISCO, Dec. 28, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced that ZEJULA® has been included in the updated National Reimbursement Drug List (NRDL) released by China's National Healthcare Security Administration (NHSA). ZEJULA (niraparib) is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor with national Category 1 designation. It has been included in the NRDL 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.

"A key part of Zai Lab's mission is to bring transformative medicines to patients in China," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "The inclusion of our first NMPA-approved medicine, ZEJULA, in the NRDL is an important step in achieving that mission. We are grateful for this action by the NHSA to make ZEJULA more accessible to Chinese patients with ovarian cancer. We look forward to working tirelessly to make sure that ZEJULA is available to all patients who can benefit from it."

"NHSA reimbursement will help make ZEJULA affordable to many patients in need across China," said William Liang, Chief Commercial Offer. "It is the only PARP inhibitor approved as monotherapy for first-line and recurrent maintenance therapy for ovarian cancer patients regardless of biomarker status in China. This action underscores ZEJULA's significant clinical value for a broad range of ovarian cancer patients."

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.

The NORA study self-sponsored by Zai Lab demonstrated significant PFS improvement, regardless of biomarker status, with an improved safety profile when given with individualized starting dose regimen in Chinese women with platinum-sensitive recurrent ovarian cancer. Niraparib treatment resulted in a 68% reduction in the risk of disease progression or death in the overall population (PFS HR 0.32; 95% CI, 0.23–0.45; $p < 0.0001$). The median PFS was significantly longer for patients treated with niraparib compared to placebo: 18.3 months (95% CI, 10.9–not evaluable) versus 5.4 months (95% CI, 3.7–5.7). Lower rates of hematological adverse events were observed with the individualized dosing group.

Zai Lab has several other 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 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.

ZEJULA is marketed by GlaxoSmithKline (GSK) in the United States, the European Union, and other global markets. In 2016, Zai reached a collaboration, development, and license agreement for ZEJULA for Mainland China, Hong Kong and Macau with Tesaro, later acquired by GSK. Zai launched ZEJULA in Hong Kong in 2018, in Macau in 2019, and in Mainland China in January 2020.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and drug candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our 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 Greater 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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