Phase 3 PRIMA trial of Zejula® (niraparib) is the first study to show a PARP inhibitor significantly improves PFS, regardless of biomarker status, when given as monotherapy in women with first-line platinum responsive advanced ovarian cancer

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- The PRIMA study, presented in a Presidential Symposium at the 2019 European Society for Medical Oncology congress and simultaneously published in The New England Journal of Medicine, demonstrates that niraparib treatment resulted in a 38% reduction in the risk of disease progression or death in the overall study population when compared to placebo

- Importantly women in both the HR-deficient ('HRD positive') and HR-proficient ('HRD negative') subgroups experienced a clinically meaningful and statistically significant benefit

SHANGHAI, China, and SAN FRANCISCO, Sept. 29, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced its partner GlaxoSmithKline plc results from PRIMA (ENGOT-OV26/GOG-3012). PRIMA is a double-blind, randomized, placebo-controlled Phase 3 study of Zejula (niraparib) as a maintenance therapy in women with first-line ovarian cancer following a response to platinum-based chemotherapy. Niraparib treatment resulted in a 38% reduction in the risk of disease progression or death in the overall population (PFS, HR 0.62; 95% CI, 0.50–0.75; p<0.001).

These results were driven by a clinically meaningful reduction in risk of progression in women with:

- BRCA mutation tumors (risk reduction of 60%, HR 0.40 (95% CI, 0.27–0.62) p<0.001).

- HR-deficient BRCA wild type tumors (risk reduction of 50%, HR 0.50 (95% CI, 0.30–0.83), p=0.006).

- HR-proficient tumors (risk reduction of 32%, HR 0.68 (95% CI, 0.49–0.94), p=0.020).

The PRIMA study enrolled patients with a response to their first-line treatment with platinum-based chemotherapy including those with high risk of disease progression, a population with high unmet need and previously under-represented in first-line ovarian cancer studies.

In an interim analysis of overall survival (OS), niraparib also demonstrated an encouraging trend toward improvement in OS relative to placebo. A pre-planned interim analysis of OS numerically favored niraparib in the overall population (HR 0.70; 95% CI 0.44-1.11). In the HR-deficient subgroup, 91% of women on niraparib were alive at 24 months vs. 85% for placebo (HR=0.61; 95% CI, 0.27-1.40). These data are not yet mature, and the significance is not fully known. The OS interim analysis also showed 81% of women receiving niraparib in the HR-proficient subgroup were alive at 24 months vs. 59% of women receiving placebo (HR=0.51; 95% CI, 0.27-0.97).

Niraparib is not currently approved in the first-line ovarian cancer maintenance setting.

The safety profile demonstrated in PRIMA did not differ from the established safety profile. The most common grade 3 or higher adverse events with niraparib included anemia (31%), thrombocytopenia (29%), and neutropenia (13%). Implementation of an individualized dosing regimen based on body weight and/or platelet count reduced the incidence of hematological treatment-emergent adverse events. No new safety signals were identified. Validated patient reported outcomes indicate quality of life was similar between the niraparib and placebo treatment arms.

Zai Lab in-licensed rights to Zejula® (niraparib) from GSK for China, Hong Kong and Macau as an important, new treatment option for more than 52,000 Chinese patients who suffer from ovarian cancer every year. Zai Lab's new drug application for niraparib in China was accepted by the China National Medical Product Administration in December 2018 and is currently under priority review. Zai Lab obtained approval for marketing niraparib in Hong Kong in October 2018 and Macau in June 2019. Niraparib is also being evaluated in China in pivotal studies as first-line maintenance therapy in platinum-sensitive ovarian cancer and in small-cell lung cancer.

In August 2019, Zai Lab announced publication of "Phase I Pharmacokinetic Study of Niraparib in Chinese Patients with Epithelial Ovarian Cancer" in *The Oncologist*, demonstrating that the pharmacokinetic (PK) profile of niraparib in Chinese patients were comparable to that of patients evaluated in GSK's global PK study.

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. Based on IQVIA* (formerly IMS) data, Zejula is now the market leading PARP inhibitor with market share in Hong Kong of 66% in the second quarter of 2019.

* *IQVIA Hong Kong Pharmaceutical Audit QTR 2Q2019 data*

About PRIMA

PRIMA is a double-blind, randomized Phase 3 study designed to evaluate niraparib versus placebo in first-line Stage III or IV ovarian cancer patients. The study assessed the efficacy of niraparib as maintenance treatment, as measured by progression free survival. Patients with a response to first-line platinum chemotherapy were randomized 2:1 to niraparib or placebo. The trial was amended to include an individualized niraparib starting dose of 200 mg once-daily in patients with baseline weight <77kg and/or platelet count <150K/μL and 300 mg in all other patients.

About Zejula (niraparib)

Niraparib is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. 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, GSK, Zai Lab obtained the approval for marketing ZEJULA in Hong Kong in October 2018 and Macau in June 2019.

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 plans for commercializing niraparib in China. All statements, other than statements of historical fact, included in this press release are forward-looking statements and are identified by 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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