Zai Lab Partner, GSK, Announces U.S. Food and Drug Administration Approval of Additional Indication for Zejula (niraparib) for Late-line Treatment for Women with Recurrent Ovarian Cancer

October 24, 2019

- *Expanded indication allows for treatment of women whose advanced ovarian cancer is associated with homologous recombination deficiency (HRD)*

- *Zejula is now the only, once-daily PARP inhibitor approved as monotherapy treatment for recurrent ovarian cancer beyond those with a BRCA mutation in both the recurrent maintenance and late-line treatment settings*

SHANGHAI, China, and SAN FRANCISCO, Oct. 24, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced that its partner GlaxoSmithKline plc (GSK) has received approval from the U.S. Food and Drug Administration (FDA) for an expanded indication for Zejula (niraparib), an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer patients, who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy. Patient selection is based on an FDA-approved companion diagnostic for Zejula.

This represents the first time a PARP inhibitor has been approved for use in patients beyond those with a BRCA-positive (BRCA+) mutation as monotherapy in the late-line treatment setting. Now women with late-line, HRD-positive (HRD+) disease are eligible to be treated with a PARP inhibitor.

This new indication in the U.S. is based on the QUADRA study, a Phase 2, multi-center, open-label, single-arm clinical study representing a real world, difficult-to-treat patient population with high unmet needs. QUADRA is the largest clinical trial of a PARP inhibitor in women who received three or more treatments for advanced ovarian cancer. The trial enrolled a broad patient population including women with BRCA+ platinum-sensitive, resistant and refractory disease as well as women with HRD+ platinum-sensitive disease.

Clinically meaningful and durable benefit was demonstrated in the FDA-indicated patient population with an objective response rate (ORR) of 24% (95% CI, 16–34). A median duration of response (mDOR) of 8.3 months (95% CI, 6.5–not estimable) was observed.

Additional analyses were conducted in various sub populations where efficacy of Zejula was also demonstrated for patients with tBRCA and GIS; defined as deleterious or suspected deleterious somatic or germline BRCA mutation and genomic instability score (GIS ≥42) as identified with FDA approved companion diagnostic test, respectively:

• tBRCA+ platinum-sensitive disease, ORR of 39% (95% CI, 17,64);
• tBRCA+ platinum-resistant disease, ORR of 29% (95% CI, 11,52);
• tBRCA+ platinum-refractory disease, ORR of 19% (95% CI, 4,46); or
• non-BRCA mut, GIS-positive, platinum-sensitive disease, ORR of 20% (95% CI, 8,37).

The safety profile was consistent with that seen in the Phase 3 NOVA trial in the recurrent maintenance population. Most common grade ≥3 adverse reactions reported in ≥10% of patients in the QUADRA study included thrombocytopenia (28%), anemia (27%), neutropenia (13%) and nausea (10%).

Zai Lab plans to leverage the QUADRA study to accelerate the approval pathway in China for this additional indication.

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 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.

For more information, please contact:

ZAI LAB CONTACTS:

Zai Lab
Billy Cho, CFO
+86 137 6151 2501
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 / rflamm@burnsmc.com

Investors: Pete Rahmer
Endurance Advisors, on behalf of Zai Lab
415-515-9763
prahmer@enduranceadvisors.com

Zai Lab Limited

Source: Zai Lab Limited