Phase 3 NORA data of ZEJULA® (niraparib) demonstrate significant PFS benefit, 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

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- *The NORA study, presented as a late-breaker oral presentation at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress, demonstrates that niraparib maintenance treatment resulted in a 68% reduction in the risk of disease progression or death in the overall study population when compared to placebo.*

- *An individualized starting dose regimen based on patient's baseline weight and/or platelet count shown to be effective; lower rates of hematological adverse events were observed with the individualized dosing group.*

SHANGHAI and SAN FRANCISCO, Sept. 19, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial stage biopharmaceutical company, today announced detailed positive results from the NORA study, the Phase 3 randomized, double-blind, placebo-controlled study of ZEJULA (niraparib) as a maintenance therapy in Chinese patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) who are in a complete or partial response to platinum-based chemotherapy.

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 progression-free survival (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).

- PFS in g*BRCA* mutation subgroup: HR 0.22; 95%CI, 0.12-0.39; p<0.0001.
- PFS in non-g*BRCA* mutation subgroup: HR 0.40; 95%CI, 0.26-0.61; p<0.0001.

Implementation of an individualized dosing regimen based on body weight and/or platelet count reduced the incidence of hematological treatment-emergent adverse events. Grade≥3 hematological adverse events of neutrophil count decrease, anemia, and platelet count decrease in patients treated with niraparib versus placebo were 20.3% vs. 8.0%, 14.7% vs. 2.3%, and 11.3% vs. 1.1%, respectively.

"The NORA study is the first fully powered, randomized, placebo-controlled, phase III trial evaluating a PARP inhibitor in Chinese patients with platinum-sensitive recurrent ovarian cancer," said Dr. Xiaohua Wu, principal investigator of the NORA study, Professor and Chair of Gynecologic Oncology Department of Fudan University Shanghai Cancer Centre. "In addition to the fixed dosing regimen of niraparib, the individualized starting dose regimen is also effective and safe and should be considered the standard clinical practice for the maintenance therapy of patients with ovarian cancer."

In September 2020, the China National Medical Products Administration (NMPA) has approved ZEJULA's supplemental New Drug Application (sNDA) 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.

About NORA Study

The NORA study was evaluated in 265 platinum-sensitive recurrent ovarian cancer patients randomized 2:1 to receive ZEJULA or placebo until disease progression. The study evaluated the efficacy of ZEJULA as a maintenance treatment, with the primary endpoint of PFS as assessed by blinded independent central review. The starting dose was individualized at 200 mg except for those with a baseline body weight ≥77kg and a platelet count ≥150K/μL in which case the starting dose was 300 mg.

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. 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 relapse of ovarian cancer will benefit patients with ovarian cancer in China.

About ZEJULA (Niraparib)

ZEJULA (niraparib) is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor 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.

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.
- 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.

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.

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 / Mike Zanoni
Endurance Advisors, on behalf of Zai Lab
415-515-9763 / 610-442-8570
prahmer@enduranceadvisors.com / mzanoni@enduranceadvisors.com

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