Zai Lab Announces First Patient Dosed in China in a Potentially Registrational Study of Retifanlimab in Patients with Endometrial Cancer

October 29, 2020

SHANGHAI and SAN FRANCISCO, Oct. 29, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial stage biopharmaceutical company, today announced dosing of the first patient in China in the global POD1UM-101 study evaluating retifanlimab in patients with previously treated, microsatellite instability-high endometrial cancer.

“Endometrial cancer is one of the most common gynecological cancers in China and represents a significant unmet need,” said Dr. Beihua Kong, Professor of Department of Obstetrics and Gynecology, Qilu Hospital of Shandong University. “More specifically, high levels of microsatellite instability (MSI-H) have been reported in up to 30% of all endometrial cancers in the recurrent setting. PD-1 inhibition with a therapeutic such as retifanlimab represents a promising clinical approach for these patients.”

This is a potentially registrational, Phase 1b, open-label study evaluating retifanlimab as monotherapy in patients with previously treated, MSI-H endometrial cancer. The study is expected to enroll approximately 100 patients in the US and China. The primary endpoint of the study is overall response rate (ORR). Key secondary endpoints include duration of response (DOR), progression free survival (PFS), overall survival (OS), safety and pharmacokinetics.

About Endometrial Cancer

Endometrial cancer is one of the most common gynecological cancers in China, and its incidence is increasing. Surgery is the main treatment for most women with this cancer, with 5-year overall survival (OS) rate of 81.2%. However, the 5-year OS rate is only 17.3% for patients with metastasis or recurrence, and effective treatment options are limited.

About Retifanlimab

Retifanlimab (formerly INCMGA0012), an investigational anti-PD1 antibody, is currently under evaluation in registration-directed studies as a monotherapy for patients with microsatellite instability-high endometrial cancer, Merkel cell carcinoma and squamous cell carcinoma of the anal canal (SCAC); and in combination with platinum-based chemotherapy for patients with non-small cell lung cancer and SCAC.

Retifanlimab has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of anal cancer.

In 2019, Incyte and Zai Lab announced a collaboration and license agreement for the development and exclusive commercialization of retifanlimab in China, Hong Kong, Macau and Taiwan.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) 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 retifanlimab in China. 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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