Zai Lab Announces First Patient Dosed in China in a Global Phase 3 Study of Retifanlimab in Patients with NSCLC

October 5, 2020

SHANGHAI and SAN FRANCISCO, Oct. 05, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial stage biopharmaceutical company, announced dosing of the first patient in China in the global Phase 3 POD1UM-304 study evaluating retifanlimab, an investigational anti-PD-1 antibody, in combination with platinum-based chemotherapy in patients with first-line metastatic non-small-cell lung cancer (NSCLC).

“Non-small cell lung cancer is the most common tumor type and represents a significant unmet medical need in China,” said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. “Anti-PD-1 therapies are the backbone to many current and future immuno-oncology therapy combinations and we are excited to contribute patients to the POD1UM-304 Phase 3 registrational study and join Incyte in its endeavor to bring this potential new therapy to patients globally.”

POD1UM-304 is a Phase 3, randomized, multicenter, double-blind study evaluating retifanlimab in combination with platinum-based chemotherapy in patients with first-line metastatic squamous and non-squamous non-small cell lung cancer. The study is expected to enroll approximately 530 adult patients randomized to receive retifanlimab or placebo in combination with standard therapy of platinum-based chemotherapy. Zai Lab and its partner, Incyte, will cooperate in conducting the study in Greater China with Zai Lab taking the operational lead by conducting the screening, enrollment and treatment of patients in Greater China. The primary endpoints of the study are overall survival (OS) and progression-free survival (PFS) as determined by blinded independent central review using RECIST v1.1. Key secondary endpoints include objective response rate (ORR), duration of response (DOR), safety and pharmacokinetics.

About NSCLC

Lung cancer is the most commonly diagnosed cancer type and the leading cause of cancer death in China. There were approximately 774,000 new cases and 690,500 deaths of lung cancer in China in 2018, respectively. NSCLC accounts for approximately 85 percent of lung cancer, and approximately 70 percent of NSCLC is locally advanced or metastatic at initial diagnosis.

About Retifanlimab (INCMGA0012)

Retifanlimab (formerly INCMGA0012), an investigational anti-PD-1 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 commercialization of retifanlimab in Greater China.

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.

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

Zai Lab Limited

Source: Zai Lab Limited