Zai Lab Announces First Patient Dosed in Greater China in the Global Phase 2/3 MAHOGANY Study of Margetuximab in Gastric and Gastroesophageal Junction Cancer

October 6, 2020

SHANGHAI and SAN FRANCISCO, Oct. 06, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial stage biopharmaceutical company, announced dosing of the first patient in Greater China in the global MAHOGANY study evaluating margetuximab, an investigational, Fc-optimized monoclonal antibody targeting HER2, in combination with a checkpoint inhibitor, with or without chemotherapy, as a potential first-line treatment for patients with HER2-positive gastric cancer (GC) or gastroesophageal junction (GEJ) cancer.

“Gastroesophageal adenocarcinoma is the fifth and second most common tumor type worldwide and in China, respectively. The unmet need is significant considering it is often diagnosed at an advanced stage and patients with disease therefore have very poor prognosis,” said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. “Given margetuximab has shown promise in multiple combination regimens as a first-line treatment for patients whose tumors are positive for HER2, we look forward to working with our partner, MacroGenics, in the MAHOGANY study.”

MAHOGANY is a Phase 2/3 clinical trial in two modules designed to evaluate margetuximab in combination with a checkpoint inhibitor, with or without chemotherapy, as a potential first-line treatment for patients with advanced or metastatic HER2-positive GC/GEJ.

Module A is designed as a single arm study to evaluate margetuximab plus retifanlimab, an investigational anti PD-1 monoclonal antibody, in patients with HER2-positive and PD-L1-positive tumors. The primary outcome measure for efficacy is objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST).

Module B is designed as a randomized trial to evaluate margetuximab plus a checkpoint inhibitor in combination with chemotherapy compared to standard of care therapy of trastuzumab with chemotherapy in patients with HER2-positive tumors irrespective of PD-L1 expression. Patients randomized to one of two experimental arms containing a checkpoint inhibitor will receive either retifanlimab or tebotelimab, an investigational DART® molecule targeting PD-1 and LAG-3. The primary outcome measure for efficacy is overall survival (OS).

About Gastric and Gastroesophageal Junction Cancer

Cancer of the stomach (gastric cancer) or the gastroesophageal junction (where the esophagus joins the stomach) is collectively known as gastroesophageal adenocarcinoma. It is the second most common cancer type (679,100 new cases in 2015) and the second leading cause of death (498,000 deaths in 2015) in China. Both GC and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a 5-year survival of only 35.9%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for the approximately 20% of patients whose tumors are HER2-positive.

About Margetuximab

Margetuximab is an investigational monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Margetuximab was designed to provide HER2 blockade and has similar HER2 binding and antiproliferative effects as trastuzumab. In addition, margetuximab has been engineered with MacroGenics’ Fc Optimization technology to enhance the engagement of the immune system and affect killing of cancer cells through antibody dependent cellular cytotoxicity (ADCC). Beyond gastric and GEJ cancer, margetuximab is also being evaluated in combination with chemotherapy in the Phase 3 SOPHIA study for the treatment of patients with metastatic HER2-positive breast cancer who have previously been treated with anti-HER2-targeted therapies.

In 2018, MacroGenics and Zai Lab announced an exclusive collaboration and license agreement for the development and commercialization of margetuximab and tebotelimab in Greater China (mainland China, Hong Kong, Macau and Taiwan).

About Retifanlimab

Retifanlimab is an investigational, humanized, proprietary anti-PD-1 monoclonal antibody being developed for use as monotherapy as well as in combination with other potential cancer therapeutics. Retifanlimab was licensed to Incyte Corporation in 2017 under an exclusive global collaboration and license agreement. MacroGenics retains the right to develop its pipeline molecules with retifanlimab. Incyte is pursuing development of retifanlimab monotherapy in three potentially registration-directed trials 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.

In 2019, Incyte and Zai Lab announced a collaboration and license agreement for the development and commercialization of retifanlimab in Greater China.

About Tebotelimab

Tebotelimab is an investigational, first-in-class bispecific DART molecule designed to provide co-blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies.

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 margetuximab, retifanlimab and tebotelimab 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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Source: Zai Lab Limited