Zai Lab Partner, MacroGenics, Announces Initiation of Phase 2/3 MAHOGANY Study of Margetuximab in Gastric or Gastroesophageal Junction Cancer

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SHANGHAI, China and SAN FRANCISCO, Oct. 25, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced that its partner MacroGenics, Inc. (NASDAQ: MGNX) has dosed the first patient in the Phase 2/3 MAHOGANY clinical trial of 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.

The Phase 2/3 clinical trial is planned to be conducted at clinical sites globally, in collaboration with Zai Lab, the regional partner in Greater China. Zai Lab will lead clinical development in its territory by leveraging its regulatory and clinical development expertise and broad regional network of investigators to maximize potential clinical benefit in gastric cancer, the fifth most common cancer in the world and the second most common cancer in China. Based on Cancer Statistics in China 2015, the annual incidence for gastric cancer is approximately 680,000 in China.

The MAHOGANY Study Design

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 GEJ/GC.

Module A is designed as a single arm study to test margetuximab plus MGA012 (also known as INCMGA00012), 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 test 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 MGA012 or MGD013, an investigational DART® molecule targeting PD-1 and LAG-3. The primary outcome measure for efficacy is overall survival (OS).

The MAHOGANY study is based on results from an ongoing Phase 2 study of margetuximab plus pembrolizumab, an anti-PD-1 monoclonal antibody, for patients with advanced HER2-positive GC or GEJ cancer who have previously been treated with chemotherapy and trastuzumab in the metastatic setting. Data were presented at the European Society for Medical Oncology (ESMO) Annual Congress in September 2019.

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 and is the fifth most common tumor type worldwide and the second most common tumor type 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 5-20%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for patients whose tumors are HER2-positive in China.

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.

About MGA012

MGA012 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. MGA012 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 MGA012. Incyte is pursuing development of MGA012 monotherapy in three potentially registration-directed trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer. Incyte and MacroGenics are each conducting multiple studies of MGA012 in combination with other agents. Zai Lab in-licensed the rights to develop and exclusively commercialize MGA012 (also known as INCMGA00012) in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan.

About MGD013

MGD013 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. Zai Lab has exclusive collaboration and license agreement to develop and commercialize MGD013 in mainland China, Hong Kong, Macau and Taiwan.

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies.

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 margetuximab 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.

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