Zai Lab Announces First Patient Treated in Mainland China for the Global Phase 3 FORTITUDE-101 Study of Bemarituzumab in First-Line Gastric Cancer

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SHANGHAI, China and CAMBRIDGE, Mass., July 14, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the first patient has been treated in the mainland China portion of the global registrational, Phase 3 FORTITUDE-101 study for bemarituzumab, a potential first-in-class Fc-optimized monoclonal antibody that is designed to block fibroblast growth factors from binding and activating Fibroblast Growth Factor Receptor 2b (FGFR2b), inhibiting several downstream pro-tumor signaling pathways and potentially slowing tumor proliferation. FORTITUDE-101 is a global trial of bemarituzumab in first-line gastric cancer sponsored by Amgen.

The FORTITUDE-101 study is a double-blind, placebo-controlled Phase 3 trial in patients with untreated, unresectable locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma not amenable to curative therapy. Adult patients with FGFR2b overexpression will be randomized to bemarituzumab plus chemotherapy (mFOLFOX6), versus placebo plus chemotherapy (mFOLFOX6).

“Approximately 30 percent of advanced HER2-negative gastric cancer patients are estimated to have FGFR2b overexpression, and currently, there are no approved treatments targeting FGFR2b in gastric cancer,” said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development at Zai Lab. “We are focused on expanding treatment options to patients with advanced cancer, and we look forward to our continued partnership with Amgen to advance this global Phase 3 study and gain a greater understanding of the potential of bemarituzumab to impact gastric cancer treatment.”

Previously, Zai Lab collaborated with Five Prime Therapeutics, a company later acquired by Amgen, to evaluate bemarituzumab plus chemotherapy (modified FOLFOX6) as a frontline targeted treatment for FGFR2b+ gastric and GEJ cancers in the Phase 2 FIGHT study.

In early 2024, Zai Lab will join the Amgen-sponsored global Phase 3 FORTITUDE-102 study in first-line gastric cancer. This study is evaluating bemarituzumab plus chemotherapy and nivolumab, versus placebo plus chemotherapy and nivolumab for untreated advanced gastric and GEJ cancer with FGFR2b overexpression.

About Bemarituzumab

Bemarituzumab (anti-FGFR2b) is a potential first-in-class targeted antibody that is designed to block fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pro-tumor signaling pathways and potentially slowing cancer progression. Bemarituzumab is not currently approved for marketing; it is being developed in gastric and GEJ cancers as a targeted therapy for tumors that overexpress FGFR2b. It is also being developed in other solid tumors with FGFR2b overexpression, including squamous non-small cell lung cancer.

Bemarituzumab has been granted Breakthrough Therapy Designations by both the U.S. Food and Drug Administration and China Center for Drug Evaluation of the National Medical Products Administration.

Zai Lab has an exclusive license to develop and commercialize bemarituzumab in Greater China (mainland China, Hong Kong, Taiwan, and Macau).

About Gastric Cancer in China

Gastric cancer is the second most common cancer in China (478,508 newly diagnosed cases in 2020, which was 18 times higher than newly diagnosed cases in the United States), and is the third leading cause of cancer deaths in China (373,789 deaths in 2020).[1] The 5-year overall survival rate of metastatic gastric cancer is only 5.5%.[2] Current therapies include surgery, radiotherapy, chemotherapy, immuno-oncology, and targeted therapy. Nearly 88% of patients with advanced gastric and GEJ cancers are HER2-negative, and approximately 30% of these patients present with FGFR2b overexpression.[3]

[1] *Globocan 2020.*

[2] *Rui-Hua Xu, et al. Lancet Gastroenterol Hepatol 2021, Published Online October 6, 2021.*

[3] *Data on file. Five Prime Therapeutics; 2020; Cancer assessed by local and central laboratories: Chinese results of the HER EAGLE Study; HER2 status in gastric cancers: a retrospective analysis from four Chinese representative clinical centers and assessment of its prognostic significance, 2013.*

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide.

For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for developing bemarituzumab in Greater China and related clinical trials and the potential treatment of patients with gastric and GEJ cancers. These forward-looking statements may contain words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would,” 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 or guarantees or assurances of future performance. Forward-looking statements are based on our 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) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and results of operations, (6) risks related to doing business in China, and (7) other factors discussed in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to 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 our views as of any date subsequent to the date of this press release.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC’s website at www.SEC.gov.

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