Zai Lab Announces Positive Topline Phase 3 Results for Bemarituzumab in Fibroblast Growth Factor Receptor 2b (FGFR2b) Positive First-Line Gastric Cancer

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At an Interim Analysis, Bemarituzumab Plus Chemotherapy Significantly Improved Overall Survival in People With FGFR2b Overexpression Compared to Chemotherapy Alone

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 30, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced the Phase 3 FORTITUDE-101 clinical trial evaluating first-line bemarituzumab plus chemotherapy (mFOLFOX6) met its primary endpoint of overall survival (OS) at a pre-specified interim analysis.

Bemarituzumab plus chemotherapy demonstrated a statistically significant and clinically meaningful improvement in OS as compared to placebo plus chemotherapy in people living with unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) cancer with FGFR2b overexpression and who are non-HER2 positive. FGFR2b overexpression was defined as 2+/3+ staining in ≥10% of tumor cells by centrally performed immunohistochemistry (IHC) testing.

Gastric cancer is the fifth leading cause of cancer-related death worldwide, with nearly one million new cases and over 650,000 deaths globally each year [1], highlighting a critical unmet medical need. In China, there are over 350,000 new cases each year[4]. The disease is associated with a poor prognosis, particularly in advanced stages where the five-year survival rate is less than 10%[6]. There are currently no approved therapies specifically targeting FGFR2b overexpression in gastric cancer in China.

“Bemarituzumab is the first FGFR2b inhibitor to demonstrate a statistically and clinically significant overall survival benefit in a randomized Phase 3 trial for the first-line treatment of FGFR2b-positive gastric cancer,” said Dr. Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. “The success of the global Phase 3 FORTITUDE-101 study highlights the potential of bemarituzumab to redefine the standard of care for a patient population that has faced poor outcomes with existing therapies. We are proud to have contributed meaningfully to this pivotal trial, including a substantial number of patients enrolled in China. Based on these results, and the regulatory Breakthrough Designation, we plan to move rapidly toward regulatory submission in China to bring this transformative therapy to patients as quickly as possible.”

The most common treatment-emergent adverse events (>25%) in patients treated with bemarituzumab plus chemotherapy were reduced visual acuity, punctate keratitis, anaemia, neutropenia, nausea, corneal epithelium defect and dry eye. While ocular events were consistent with the Phase 2 experience and observed in both arms, they occurred with greater frequency and severity in the Phase 3 bemarituzumab arm.

Detailed results from the trial will be shared at a future medical meeting.

Zai Lab holds the development and commercialization rights for bemarituzumab for mainland China, Hong Kong, Macau, and Taiwan. Bemarituzumab has been granted Breakthrough Therapy designation by the China Center for Drug Evaluation of the National Medical Products Administration for the treatment of FGFR2b-positive gastric and gastroesophageal junction adenocarcinoma.

A Phase 3 study of bemarituzumab plus chemotherapy and nivolumab is also ongoing in patients with first-line gastric cancer, with data readout anticipated in H2 2025.

About FGFR2b

The FGFR2b protein (also known as fibroblast growth factor receptor 2b) is an emerging biomarker which, when overexpressed, promotes aberrant signaling leading to tumor cell proliferation.[2]

The FGFR2b protein is overexpressed by G/GEJ tumor cells in approximately 38% of patients with advanced G/GEJ cancer. FGFR2b protein overexpression is defined as 2+/3+ staining intensity on tumor cell membrane, as detected by immunohistochemistry (IHC) testing. In approximately 16% of patients with advanced G/GEJ cancer, FGFR2b protein overexpression is observed on ≥10% of tumor cells by IHC.[3]

About FORTITUDE-101

FORTITUDE-101 is a randomized, multi-center, double-blind, placebo-controlled Phase 3 study of bemarituzumab plus mFOLFOX6 versus placebo plus mFOLFOX6 as first-line therapy in advanced G/GEJ cancer with FGFR2b overexpression. The FORTITUDE-101 trial spanned 300 sites across 37 countries, with 547 patients enrolled.

The primary outcome measure of the trial is overall survival in patients with FGFR2b ≥10% 2+/3+ tumor cell staining. Key secondary outcome measures include progression-free survival and overall response rate. Candidates were excluded from the trial if they were known to be human epidermal growth factor receptor 2 (HER2) positive. FORTITUDE-101 included more comprehensive ocular-related monitoring than previous studies of bemarituzumab.

About Gastric Cancer in China

Gastric cancer is the fifth most common cancer worldwide, while China bears one of the highest gastric cancer burdens in the world with an estimated

358,700 new cases and 260,400 deaths annually.[4] In China, approximately 80% of gastric cancer patients are diagnosed at an advanced or metastatic stage[5]. For those diagnosed with Stage IV gastric cancer, the overall 5-year survival rate is less than 10%[6]. Patients with advanced gastric and GEJ cancer that overexpress the FGFR2b protein may be associated with poor prognosis[7-10].

About Zai Lab

Zai Lab 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, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.X.com/ZaiLab_Global, www.twitter.com/ZaiLab_Global.

Zai Lab Forward Looking Statements

This press release contains forward-looking statements relating to our future expectations, plans, and prospects, including, without limitation, statements regarding the prospects and plans for developing and commercializing bemarituzumab, the potential benefits of bemarituzumab, and the potential treatment of gastric and gastroesophageal junction cancer. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by 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. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these 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 our 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) risks related to doing business in China, and (6) other factors identified 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 the SEC’s website at www.sec.gov.

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