Zai Lab Partner Five Prime Therapeutics Announces Bemarituzumab Plus Chemotherapy Demonstrates Significant Progression-Free and Overall Survival Benefit Compared to Placebo Plus Chemotherapy in Front-Line Advanced Gastric or Gastroesophageal Junction Cancer

November 11, 2020

- All three efficacy endpoints in the global Phase 2 FIGHT trial met pre-specified statistical significance

  • Median progression-free survival (PFS) improved from 7.4 months in the placebo arm to 9.5 months in the bemarituzumab arm. Hazard ratio (HR) 0.68 (95% CI: 0.44-1.04) p=0.073

  • Median overall survival (OS) improved from 12.9 months to not reached. HR 0.58 (95% CI: 0.35-0.95) p=0.027

  • Overall response rate (ORR) improved by 13% (p=0.106)

- Bemarituzumab is a potential first-in-class therapeutic antibody targeting FGFR2b+ tumors found in approximately 30 percent of HER2- gastric cancers worldwide

- Trial results support FGFR2b as a novel target for the third most common cause of cancer mortality worldwide and highlight development opportunities in other tumors that overexpress FGFR2b

SHANGHAI and SAN FRANCISCO, Nov. 10, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited's (NASDAQ: ZLAB; HKEX: 9688) partner Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on developing immune modulators and precision therapies for solid tumor cancers, today announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 2 FIGHT trial. The trial compared bemarituzumab (FPA144), a potential first-in-class targeted therapy, in combination with mFOLFOX6 chemotherapy to placebo in combination with mFOLFOX6 in patients with fibroblast growth factor receptor 2b-positive (FGFR2b+), HER2-negative front-line advanced gastric or gastroesophageal junction (GEJ) cancer.

All three efficacy endpoints in the FIGHT trial – PFS, OS and ORR – achieved pre-specified statistical significance in the bemarituzumab arm compared to the placebo arm. The Phase 2 FIGHT trial results validate the importance of the novel target FGFR2b, which is overexpressed in approximately 30 percent of HER2- gastric cancers worldwide. The incidence of all-grade adverse events was comparable in the treatment and control arms of the study (100% vs. 98.7%, respectively), as were serious adverse events (31.6% vs. 36.4%) and deaths due to adverse events (6.6% vs. 5.2%). Adverse events ≥ Grade 3 were reported more frequently in the treatment arm (82.9% vs. 74.0%). Corneal and stomatitis adverse events were reported more frequently in the bemarituzumab arm. No adverse events of retinal detachment or hyperphosphatemia were reported in the bemarituzumab arm. More patients discontinued bemarituzumab (34.2%) compared to placebo (5.2%) due to an adverse event.

"These results bring us one step closer to the first potential targeted therapy for advanced gastric cancer in over a decade," said Helen Collins, M.D., Five Prime's Executive Vice President and Chief Medical Officer. "Benefit was observed in patients whose tumors overexpressed FGFR2b, even without evidence of amplification, and that may broaden the therapeutic potential of bemarituzumab in more cancer types. We are excited about the results of the FIGHT trial and the opportunity to advance bemarituzumab, the first and only investigational treatment for patients with FGFR2b+ tumors, to the next phase of development. Five Prime is grateful to the patients and investigators who participated in our clinical trials, and we look forward to discussing next steps with health authorities worldwide."

Five Prime will complete a full evaluation of the available FIGHT Phase 2 data and work with investigators to share the results at an upcoming medical conference.

"We have known for some time that FGFR is a viable target in gastric cancer and many other malignancies," said Zev A. Wainberg, M.D., Associate Professor of Medicine at UCLA, Co-director of the Gastrointestinal Oncology Program and Director of Early Phase Clinical Research Support at the Jonsson Comprehensive Cancer Center. "This is the first data to signal that a targeted therapy directed to FGFR2b may reduce the risk of disease progression and improve overall survival in gastric cancer. This study result showing bemarituzumab's potential benefit is an important and exciting development."

Five Prime and Roche Tissue Diagnostics (formerly Ventana Medical Systems) have also found that FGFR2b is overexpressed in numerous other cancers, including squamous non-small-cell lung cancer (NSCLC), triple negative breast cancer (TNBC), ovarian cancer, pancreatic cancer and intrahepatic cholangiocarcinoma. This finding points to additional potential areas for development of bemarituzumab beyond gastric and GEJ cancer.

About the FIGHT Trial

The **F**GFR2b **I**nhibition in **G**astric and Gastroesop**h**ageal Junction Cancer **T**reatment (FIGHT) trial (NCT03694522) was designed to evaluate the efficacy and safety of bemarituzumab in combination with modified FOLFOX6 (mFOLFOX6; leucovorin calcium, fluorouracil, and oxaliplatin) vs.

mFOLFOX6 plus placebo in the front-line setting of patients with newly diagnosed FGFR2b positive, locally advanced or metastatic gastric and GEJ cancer.

Patients' tumors were identified to be FGFR2b+ by immunohistochemistry and by *FGFR2* gene amplification using a blood-based circulating tumor DNA assay. Testing was performed at a central laboratory.

The trial enrolled 155 patients in 15 countries across Asia, the European Union, and the United States. Today's announcement contains the initial top-line results from the primary analysis based on a prespecified number of events.

About FGFR2b

The fibroblast growth factor (FGF) / fibroblast growth factor receptor (FGFR) pathway is implicated in the development and growth of cancer cells. FGFR2b is a form of FGFR found in epithelial cells, such as those in the stomach and skin. Data from the FIGHT trial suggests that approximately 30% of patients with HER2- gastroesophageal cancers overexpress FGFR2b.[1]

About Bemarituzumab

Bemarituzumab (anti-FGFR2b, FPA144) is a first-in-class targeted antibody that blocks fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pathways. Blocking FGFR2b activation is thought to slow cancer progression. Bemarituzumab is being developed in gastric and GEJ cancer as a targeted therapy for tumors that overexpress FGFR2b.

Five Prime granted an exclusive license to Zai Lab to develop and commercialize bemarituzumab in Greater China, and Zai Lab collaborated with Five Prime on the Phase 2 FIGHT trial in Greater China.

About Gastric Cancer and GEJ Cancer

Gastric cancer, also known as stomach cancer, is the third most common cause of cancer death and, excluding non-melanoma skin cancer, the fifth most common cancer worldwide, with over 1,000,000 new cases diagnosed each year.[2] In countries where routine screening is not readily available, up to 90 percent of patients are diagnosed with advanced disease that is inoperable.[3] For HER2- patients, front-line therapy available today is the same systemic chemotherapy available since the 1990s.[3,4]

Gastric cancer 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 gastric cancer and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a five-year survival of only 35.9%.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious diseases 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 global 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.

About Five Prime Therapeutics

Five Prime Therapeutics, Inc. discovers and develops innovative protein therapeutics to improve the lives of patients with serious diseases. Five Prime's product candidates have innovative mechanisms of action and address patient populations in need of better therapies. The company focuses on researching and developing immuno-oncology and targeted cancer therapies paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime's product candidates. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and preclinical development. For more information, please visit www.fiveprime.com.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding business strategy, plans and objectives for future operations. 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: Five Prime Therapeutics, Inc.

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Source: Zai Lab Limited