Five Prime Therapeutics and Zai Lab Dosed First Patient in Phase 3, Global Registrational Trial of Bemarituzumab in Front-Line Advanced Gastric and Gastroesophageal Junction Cancers

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- *Phase 3 trial evaluating bemarituzumab plus mFOLFOX6 versus placebo plus mFOLFOX6*

SOUTH SAN FRANCISCO, Calif. & SHANGHAI--(BUSINESS WIRE)--Oct. 1, 2018-- Five Prime Therapeutics, Inc. (Nasdaq: FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, and Zai Lab Limited (Nasdaq: ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced dosing of the first patient in the Phase 3 FIGHT pivotal trial of bemarituzumab (FPA144), an isoform-selective FGF receptor 2b (FGFR2b) antibody, in combination with chemotherapy in patients with previously untreated, advanced gastric cancer (GC) or gastroesophageal junction (GEJ) cancer. The first patient was dosed at a participating investigative site in China on Sept. 28.

"We are very pleased to have dosed the first patient in our FIGHT gastric cancer trial in China, where Zai Lab is responsible for the regulatory and development timeline for this global study," said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime. "Tumors overexpressing FGFR2b are associated with a poor prognosis, and a targeted therapy that provides improved efficacy when added to standard therapy could transform treatment options for these patients. Bemarituzumab has demonstrated encouraging monotherapy activity in the late-line setting, and we hope to provide greater benefit by combining with chemotherapy in the front-line setting."

"This is the first time that the first patient dosed in a global registrational trial came from China as a result of the collaboration between a U.S. biotechnology company and a Chinese biotechnology company," said Dr. Yongjiang Hei, CMO of Zai Lab. "Gastric cancer is the fifth most common cancer in the world and the second most common in China. There is an urgent need globally, and particularly in China, where we are responsible for both development and commercialization, for more effective and well-tolerated targeted therapies for gastric cancer patients. We are pleased that the clinical trial application (CTA) was approved three months ahead of schedule, which will help accelerate the global FIGHT trial in our collaboration with Five Prime."

About the FIGHT Trial

The double-blind randomized and controlled Phase 3 FIGHT (**F**GFR2b **I**nhibition in **G**astric and Gastroesop**h**ageal Junction Cancer **T**reatment)trial will evaluate 15 mg/kg of bemarituzumab or placebo given every two weeks combined with modified FOLFOX6 (mFOLFOX6) chemotherapy in approximately 550 patients with GC or GEJ cancer whose tumors overexpress FGFR2b. The Phase 3 global registration trial is the first prospective FGFR2b-specific front-line gastric study and will include approximately 250 sites in the U.S., Europe and Asia, including China, South Korea, Taiwan and Japan, where the incidence of gastric cancer is among the highest worldwide. Zai Lab and Five Prime have a strategic development collaboration under which Zai Lab will manage the Phase 3 portion of the FIGHT trial in China, where approximately half of the patients in the trial are expected to be enrolled.

The primary endpoint of the FIGHT trial is overall survival (OS), with key secondary endpoints being progression-free survival (PFS), objective response rate (ORR), safety and pharmacokinetic (PK) parameters.

Unmet Need in GC and GEJ

GC, including GEJ cancer, is the fifth most common cancer worldwide and third leading cause of cancer death. Gastric cancer is the second most common cancer in China.

Current first-line chemotherapy treatment delays progression by approximately six months compared to best supportive care, but median OS remains poor with literature-reported ranges of approximately 10 to 11 months and PFS of approximately six months. The presence of FGFR2b overexpression is present in approximately 10% of patients with GC/GEJ and is associated with a worse prognosis. Few treatment options following progression are available after first-line chemotherapy, and a significant unmet need remains in the treatment of GC/GEJ worldwide.

Five Prime is developing companion diagnostics to identify FGFR2b overexpression using an immunohistochemistry (IHC) test and *FGFR2* gene amplification using circulating tumor DNA (ctDNA) analysis. Five Prime will use both assays to select patients for the FIGHT trial.

About Bemarituzumab

Bemarituzumab is a first-in-class, isoform-selective, humanized monoclonal antibody in clinical development as a targeted immunotherapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family. Bemarituzumab blocks FGFs 7, 10 and 22 from binding to FGFR2b, and has been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells. Clinical results to date suggest that the specificity of bemarituzumab avoids the dose-limiting toxicities that have been seen with less selective pan-FGFR tyrosine kinase inhibitors that act on multiple FGFRs, including FGFR2.

In December 2017, Five Prime and Zai Lab announced a strategic collaboration for the development and commercialization of bemarituzumab in Greater China.

About Five Prime

Five Prime Therapeutics, Inc. (NASDAQ:FPRX) discovers and develops innovative therapeutics to improve the lives of patients with serious diseases. Five Prime's comprehensive discovery platform, which encompasses virtually every medically relevant extracellular protein, positions it to explore pathways in cancer, inflammation and their intersection in immuno-oncology, an area with significant therapeutic potential and the focus of the company's R&D activities. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and late preclinical development. For more information, please visit www.fiveprime.com or follow us on LinkedIn, Twitter and Facebook.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The Company'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 global 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.

Cautionary Note on Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Five Prime's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements about (i) the timing of initiation, progress and scope of the Phase 3 FIGHT trial for Five Prime's bemarituzumab product candidate; (ii) the potential use of bemarituzumab to treat cancer patients; (iii) the extent of FGFR2b overexpression and *FGFR2* gene amplification in gastric cancer patients; and (iv) the advancement of bemarituzumab in Phase 3 clinical development. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Five Prime's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as required by law, Five Prime assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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