Five Prime Therapeutics Completes Phase 1 Safety Lead-In and Initiates Phase 3, Global Registrational Trial of Bemarituzumab in Front-Line Advanced Gastric and Gastroesophageal Junction Cancers

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- *Five Prime plans to submit Phase 1 lead-in data for presentation at medical conference in the first half of 2019*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 10, 2018-- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, today announced that the company completed the Phase 1 safety lead-in portion and has initiated the Phase 3 portion of the FIGHT Phase 1/3 clinical trial of bemarituzumab (FPA144), an isoform-selective anti-FGF receptor 2b antibody, in combination with chemotherapy in patients with previously untreated, advanced gastric cancer (GC) or gastroesophageal junction (GEJ) cancer.

“We are very pleased to have completed the safety lead-in and move into the Phase 3 registrational portion of the bemarituzumab trial in patients with gastric cancer,” said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime. “Patients with advanced gastric cancer are in dire need of new treatment options. Bemarituzumab is a targeted therapy and we are using state-of-the-art diagnostic tools to help us identify patients with FGFR2b overexpression, which is associated with a worse prognosis. Bemarituzumab has demonstrated encouraging monotherapy activity as a late-line treatment for gastric cancer and we believe that combining with chemotherapy in the front-line setting should provide the greatest patient benefit.”

In December 2017, Five Prime initiated the Phase 1 portion (NCT03343301) of the Phase 1/3 FIGHT (FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment) global registrational trial. The Phase 1 portion tested bemarituzumab doses of 6 mg/kg and 15 mg/kg in combination with modified FOLFOX6 (mFOLFOX6) with no overlapping toxicities identified.

The randomized, controlled, double-blinded Phase 3 portion of the FIGHT trial will evaluate bemarituzumab plus mFOLFOX6 versus placebo plus mFOLFOX6 in approximately 550 patients with gastric cancer (GC) or gastroesophageal junction (GEJ) cancer whose tumors overexpress FGFR2b. The Phase 3 trial will include approximately 250 sites in the U.S., Europe and Asia, including China, South Korea and Japan, where the incidence of gastric cancer is high. Zai Lab will manage the Phase 3 portion of the FIGHT trial in China.

The primary endpoint of the FIGHT trial is overall survival (OS) with secondary endpoints of 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.

Current first-line chemotherapy treatment delays progression by approximately 6 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 6 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.

Five Prime is developing companion diagnostics to identify FGFR2b overexpression using an IHC test and *FGFR2* gene amplification using 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. 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.

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 clinical trials for Five Prime's bemarituzumab product candidate; (ii) the potential use of bemarituzumab to treat cancer patients; (iii) the extent of FGFR2b overexpression in gastric cancer patients; and (iv) the advancement of bemarituzumab into 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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