Five Prime Therapeutics Presents Bemarituzumab Trial-in-Progress Poster at the 2018 ASCO Annual Meeting

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 3, 2018-- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, announced that a poster titled “FIGHT: A Phase 3 Randomized, Double-Blind, Placebo Controlled Study Evaluating Bemarituzumab (FPA144) and Modified FOLFOX6 (mFOLFOX6) in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Cancer with a Dose Finding Phase 1 Lead-In” was presented today at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The poster (Abstract #TPS4135), is available at http://www.fiveprime.com/publications.

“Patients with advanced gastric or gastroesophageal junction cancer need new treatment options, particularly those whose tumors overexpress FGFR2b and whose prognosis is especially poor,” said Helen Collins, M.D., senior vice president and chief medical officer of Five Prime. “We have seen encouraging monotherapy activity with FPA144 as a late-line treatment for gastric cancer and we believe that combining with chemotherapy in the front-line setting will provide the greatest patient benefit. Our global Phase 1/3 FIGHT trial is studying bemarituzumab in combination with mFOLFOX6 in patients with newly diagnosed gastric and gastroesophageal junction cancer whose tumors overexpress FGFR2b with the goal of providing a new treatment option for patients.”

FIGHT Trial

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 safety lead-in portion of the trial is designed to identify a recommended dose of bemarituzumab in combination with the modified FOLFOX6 standard-of-care chemotherapy regimen (mFOLFOX6) to support the initiation of the Phase 3 portion of the trial.

The Phase 3 portion of the FIGHT trial will evaluate bemarituzumab in combination with 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 portion of the trial is expected to begin in the second half of 2018 and will include more than 250 sites in the U.S., Europe and Asia, including China, South Korea and Japan, where the incidence of gastric cancer is high.

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.

Previous Bemarituzumab Trial Results

Data from a Phase 1 clinical trial of single-agent bemarituzumab were presented at the 2017 ASCO Annual Meeting. Bemarituzumab demonstrated single-agent activity and an acceptable safety profile in heavily pretreated patients with metastatic gastric cancer whose tumors overexpress FGFR2b.

Efficacy:

- In 21 treated patients with late-line GC/GEJ and high FGFR2b overexpression:
  - ORR was 19.0% with 4 confirmed PRs
  - Disease control rate was 54.9%
  - Median duration of response was 15.4 weeks

Overall safety:

- Bemarituzumab was well tolerated
- There were no dose-limiting toxicities
- Maximum tolerated dose was not reached during dose escalation

Unmet Need in GC and GEJ

GC, including GEJ cancer, is the fifth most common cancer worldwide and third leading cause of cancer death. More than 50 percent of GC cases occur in eastern Asia.

Current first-line chemotherapy treatments prolong survival 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 from 5 to 5.6 months. An unmet medical need exists in the treatment for GC/GEJ since few treatment options following progression are available after first-line chemotherapy.

The presence of *FGFR2* amplification or FGFR2b overexpression is associated with a worse prognosis and is present in approximately 10% of patients with GC/GEJ.

FGFs can stimulate transformation and proliferation of tumor cells through signaling mediated by FGF receptors (FGFR 1-4). FGFR2 has 2 splice variants (b and c).

FGFR2b is expressed in tissues of epithelial origin and alterations in FGF/FGFR2 pathway are associated with gastric, breast and other cancers. As a

result, targeting this pathway appears to be important in GC/GEJ cancer treatment.

Rationale for Combination with Chemotherapy and Companion Diagnostics

Five Prime made a strategic decision to pursue a front-line bemarituzumab plus chemotherapy combination trial based on preclinical data that showed additive efficacy of bemarituzumab plus chemotherapy. Mutational heterogeneity of GC/GEJ suggests that combining bemarituzumab plus chemotherapy will result in improved activity by acting on non-FGFR2b overexpressing tumor cells and by improving the activity of bemarituzumab in FGFR2b overexpressing tumor cells.

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 to identify the estimated 10% of patients with gastric and GEJ tumors that would qualify for the 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 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.

Bemarituzumab is being evaluated in the FGF2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment (FIGHT) Phase 1/3 clinical trial, a global registrational study in patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification. The Phase 3 portion of the trial is expected to begin in the second half of 2018. In December 2017, Five Prime and Zai Lab announced a collaboration for the development and commercialization of bemarituzumab in Greater China. Zai Lab will manage the Phase 3 portion of the FIGHT trial in 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 of bemarituzumab; (ii) the extent of FGFR2b protein overexpression and *FGFR2* gene amplification in certain patient populations; and (iii) the prevalence and incidence of GC and GEJ cancers. 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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