Five Prime Therapeutics Presents Data from Safety Lead-in to Phase 3 FIGHT Trial of Bemarituzumab at 2019 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--January 17, 2019-- Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, announced today that a poster entitled “Phase 1 Results from the Phase 1/3 FIGHT Study Evaluating Bemarituzumab and mFOLFOX6 in Advanced Gastric/GEJ Cancer” was presented today at the ASCO Gastrointestinal Cancer Symposium in San Francisco. The poster (Board J1, Abstract #91) can be found online at Five Prime Therapeutics Scientific Publications.

“Gastric cancer with FGFR2b overexpression or FGFR2 gene amplification is associated with a poor prognosis for patients with advanced disease,” said Helen Collins, M.D., senior vice president and chief medical officer of Five Prime. “We completed the Phase 1 safety lead-in and saw no dose-limiting toxicities with the combination of bemarituzumab and mFOLFOX6. Additionally, we are encouraged to see evidence of clinical activity with the combination. The FIGHT Phase 3 study is currently enrolling patients worldwide with newly diagnosed advanced gastric and gastroesophageal junction cancer whose tumors overexpress FGFR2b with the goal of providing a better first-line treatment option for these patients.”

The Phase 1 portion of the study achieved the primary objective of determining a recommended dose of bemarituzumab in combination with mFOLFOX6 to initiate the Phase 3 portion of the FIGHT trial. Key inclusion criteria for the Phase 1 patient population included: adults with incurable GI cancer for whom mFOLFOX6 was an appropriate therapy, an ECOG score of 0-1, and evaluable disease by RECIST v1.1. The patient population was not selected for FGFR2b status or limited to patients without prior chemotherapy treatment for advanced or metastatic disease. At the time of publication, 2 patients with gastric/esophageal cancer were confirmed to be FGFR2 positive with 1 achieving a PR and the other demonstrating a complete metabolic response.

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 was 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 began in September 2018 and will include more than 250 sites in the U.S., Europe and Asia.

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 at 6 weeks: 57.1%
  - Median duration of response was 15.4 weeks

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

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.

Companion Diagnostic Development for FGFR2b

Five Prime is using 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.

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. 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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