Five Prime Therapeutics Announces Publication of the Phase 1 Bemarituzumab Study in the Journal of Clinical Oncology

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Phase 1 data illustrates the therapeutic potential of bemarituzumab as a novel approach to treating patients with FGFR2b-overexpressing gastric and gastroesophageal junction adenocarcinoma (GEA)

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- 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 the publication of results from the phase 1 escalation and expansion study of bemarituzumab in patients with advanced solid tumors and FGFR2b-selected gastroesophageal adenocarcinoma in the digital edition of the Journal of Clinical Oncology.

The purpose of the phase 1 trial was to evaluate the safety, pharmacokinetics, and preliminary activity of single-agent bemarituzumab in patients with FGFR2b-overexpressing GEA. Seventy-nine patients were enrolled in the trial and no dose-limiting toxicities were reported. Bemarituzumab was well tolerated and the most frequent treatment-related adverse events (TRAEs) were fatigue, nausea, and dry eye. The overall response rate observed in this study of advanced-stage patients with high FGFR2b-overexpressing GEA was 17.9% (95% CI 6.1% to 36.9%) with five of 28 patients achieving a confirmed partial response.

“Gastroesophageal adenocarcinoma is the third most common cause of cancer death worldwide and the median overall survival of patients who present with advanced disease remains dismal at only 11 months,” said Helen Collins, M.D., Executive Vice President and Chief Medical Officer of Five Prime Therapeutics. “The results of this study underscore the potential of bemarituzumab evaluation as a novel treatment option for patients with advanced gastric and gastroesophageal junction cancer.”

“Monotherapy activity of bemarituzumab and its lack of significant overlapping toxicities with standard chemotherapeutic agents suggest that combining bemarituzumab with chemotherapy may potentially benefit patients in the front-line setting whose GEA tumors overexpress FGFR2b,” said Daniel Catenacci, M.D. and Associate Professor, the University of Chicago Medical Center and Biological Sciences.

Bemarituzumab is being evaluated in combination with mFOLFOX6 in the Phase 3 FIGHT (**F**GFR2b **I**nhibition in **G**astric and Gastroesop**h**ageal Junction Cancer **T**reatment) trial in the front-line treatment setting.

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 or follow us on LinkedIn, Twitter and Facebook.

About Bemarituzumab and the FIGHT Trial

Bemarituzumab (anti-FGFR2b) is a first-in-class isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immunotherapy for tumors that overexpress FGFR2b. Bemarituzumab is being evaluated in combination with mFOLFOX6 in the **Phase 3 FIGHT** (**F**GFR2b **I**nhibition in **G**astric and Gastroesop**h**ageal Junction Cancer **T**reatment) 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 is evaluating bemarituzumab in combination with mFOLFOX6 versus placebo plus mFOLFOX6 in approximately 550 patients with gastric cancer or gastroesophageal junction cancer whose tumors overexpress FGFR2b. The Phase 3 portion of the trial began in September 2018 and 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.

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. 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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