



Five Prime Announces Bemarituzumab Plus Chemotherapy Demonstrates Significant Progression-Free and Overall Survival Benefit Compared to Placebo Plus Chemotherapy in Front-Line Advanced Gastric and Gastroesophageal Junction Cancer

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- All 3 efficacy endpoints in the Global Phase 2 FIGHT trial met pre-specified statistical significance
 - Median progression-free survival (PFS) improved from 7.4 months to 9.5 months. Hazard ratio (HR) 0.68 (95% CI: 0.44-1.04) $p=0.073$
 - Median overall survival (OS) improved from 12.9 months to not reached. HR 0.58 (95% CI: 0.35-0.95) $p=0.027$
 - Overall response rate (ORR) improved by 13.1% ($p=0.106$)
- Bemarituzumab is a first-in-class therapeutic antibody targeting FGFR2b+ tumors found in approximately 30 percent of HER2- gastric cancers worldwide
- Trial results validate FGFR2b as a novel target for the third most common cause of cancer mortality worldwide and highlight development opportunities for other tumors that overexpress FGFR2b
- Webcast and conference call today at 1:30pm PST / 4:30pm EST

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 10, 2020-- [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 positive topline results from the global, randomized, double-blind placebo-controlled Phase 2 FIGHT trial. The trial compared mFOLFOX6 chemotherapy in combination with bemarituzumab (bema, FPA144), a first-in-class targeted therapy, in patients with fibroblast growth factor receptor 2b-positive (FGFR2b+), non HER2 positive (non HER2+) front-line advanced gastric or gastroesophageal junction (GEJ) cancer.

"These results bring us one step closer to the first potential targeted therapy for advanced gastric cancer in over a decade," said Helen Collins, M.D., Five Prime's Executive Vice President and Chief Medical Officer. "Benefit was observed in patients whose tumors overexpressed FGFR2b, even without evidence of amplification, and that may broaden the therapeutic potential of bemarituzumab in more cancer types. We are excited about the results of the FIGHT trial and the opportunity to advance the development of bemarituzumab, the first and only investigational treatment targeting FGFR2b+. Five Prime is grateful to the patients and investigators who participated in our clinical trials, and we look forward to discussing next steps with health authorities worldwide."

All three efficacy endpoints in the FIGHT trial – PFS, OS and ORR – achieved pre-specified statistical significance at a 2-sided alpha of 0.20. The incidence of all grade adverse events was comparable in the treatment and control arms of the study (100% vs 98.7%, respectively) as were serious adverse events (31.6% vs 36.4%) and deaths due to adverse events (6.6% vs 5.2%). Adverse events \geq Grade 3 were reported more frequently in the treatment arm than in the placebo arm (82.9% vs 74.0%). Corneal and stomatitis adverse events were reported more frequently in the bemarituzumab arm, and more patients discontinued bemarituzumab (34.2%) compared to placebo (5.2%) due to an adverse event. Importantly, no adverse events of retinal detachment or hyperphosphatemia were reported in the bemarituzumab arm. Despite the higher frequency of discontinuation of bemarituzumab compared to placebo, all efficacy endpoints favored bemarituzumab. Overall, the Phase 2 FIGHT trial results validate the importance of the novel target, FGFR2b, which is overexpressed in approximately 30 percent of HER2- gastric cancers worldwide.

The company will complete a full evaluation of the available FIGHT Phase 2 data and work with investigators to share the results at an upcoming medical conference.

"We have known for some time that FGFR is a viable target in gastric cancer and many other malignancies," said Zev A. Wainberg, M.D., Associate Professor of Medicine at UCLA, Co-director of the Gastrointestinal Oncology Program and Director of Early Phase Clinical Research at the Jonsson Comprehensive Cancer Center. "This is the first data to signal that a targeted therapy directed to FGFR2b may reduce the risk of disease progression and improve overall survival in gastric cancer. This study result showing bemarituzumab's potential benefit is an important and exciting development."

Five Prime and Roche Tissue Diagnostics (formerly Ventana Medical Systems) have also found that FGFR2b is overexpressed in numerous other cancers, including squamous non-small cell lung cancer, triple negative breast cancer, ovarian cancer, pancreatic cancer and intrahepatic cholangiocarcinoma. This represents additional potential areas for development of bemarituzumab beyond gastric and GEJ cancer.

Conference Call Information

Five Prime will host a conference call and live audio webcast today at 4:30pm (EST) / 1:30 (PST) to discuss topline results from the Phase 2 FIGHT trial. To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID 9977806. To access the live webcast please visit <https://investor.fiveprime.com/events-presentations>.

An archived copy of the webcast will be available on Five Prime's website beginning approximately two hours after the conference call. Five Prime will maintain an archived replay of the webcast on its website for at least 30 days after the conference call.

About the FIGHT Trial

The FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment (FIGHT) trial ([NCT03694522](#)) was designed to evaluate the efficacy and safety of bemarituzumab in combination with modified FOLFOX6 (mFOLFOX6; leucovorin calcium, fluorouracil, and oxaliplatin) vs. mFOLFOX6 plus placebo in the front-line setting of patients with newly diagnosed FGFR2b positive, locally advanced or metastatic gastric and GEJ cancer.

Patients' tumors were identified to be FGFR2b+ by immunohistochemistry and by *FGFR2* gene amplification using a blood-based circulating tumor DNA assay. Testing was performed at a central laboratory.

The trial enrolled 155 patients in 15 countries across Asia, the European Union, and the United States. Today's announcement contains the initial top-line results from the primary analysis based on a prespecified number of events.

About FGFR2b

The fibroblast growth factor (FGF)/fibroblast growth factor receptor (FGFR) pathway is implicated in the development and growth of cancer cells. FGFR2b is a form of FGFR found in epithelial cells, such as those in the stomach and skin. Data from the FIGHT trial suggests that approximately 30% of patients with non HER2+ gastroesophageal cancers overexpress FGFR2b.¹ Five Prime and Roche Tissue Diagnostics have also found that FGFR2b is overexpressed in numerous other cancers, including squamous non-small cell lung cancer (NSCLC), triple negative breast (TNBC), ovarian, pancreatic and intrahepatic cholangiocarcinoma.

About Bemarituzumab

[Bemarituzumab](#) (anti-FGFR2b, FPA144) is a first-in-class targeted antibody that blocks fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pathways. Blocking FGFR2b activation is thought to slow cancer progression. [Bemarituzumab](#) is being developed in gastric and GEJ cancer as a targeted therapy for tumors that overexpress FGFR2b.

Five Prime granted an exclusive license to Zai Lab to develop and commercialize bemarituzumab in Greater China, and Zai Lab collaborated with Five Prime on the Phase 2 FIGHT trial in Greater China.

About Gastric Cancer and GEJ Cancer

Gastric cancer, also known as stomach cancer, is the third most common cause of cancer death worldwide and, excluding non-melanoma skin cancer, the fifth most common cancer worldwide, with over 1,000,000 new cases diagnosed each year.² In countries where routine screening is not readily available, up to 90 percent of patients are diagnosed with advanced disease that is inoperable.³ For HER2- patients, frontline therapy available today is the same systemic chemotherapy available since the 1990s.^{3,4}

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.

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. Forward-looking statements contained in this press release include statements regarding (i) the potential advancement of the development of bemarituzumab; (ii) the potential use of bemarituzumab, including in combination with other products, to treat patients; (iii) the potential development of bemarituzumab in indications in addition to gastric and GEJ cancer; (iv) the timing of the presentation of data for bemarituzumab; and (v) the extent of FGFR2b protein overexpression in certain patient populations. Actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during research, preclinical or clinical studies, changes in expected or existing competition, changes in the regulatory, pricing or reimbursement environment, and unexpected litigation or other disputes. In addition, while the company expects the COVID-19 pandemic to adversely affect its business operations and financial results, the extent of the impact on the company's ability to advance its preclinical development and business and corporate development and other objectives will depend on future developments that are highly uncertain, and the company cannot predict with confidence the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries and the effectiveness of actions taken globally to contain and treat COVID-19. 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.

References

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3. Wagner AD, Syn NL, Moehler M, et al. Chemotherapy for advanced gastric cancer. *Cochrane Database Syst Rev.* 2017;8(8):CD004064. doi:10.1002/14651858.CD004064.pub4
4. Drugs approved for stomach (gastric) cancer. Food and Drug Administration. Updated April 21, 2020. Accessed October 14, 2020. <https://www.cancer.gov/about-cancer/treatment/drugs/stomach#1>

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Media and Investor Contact

Martin Forrest

VP, Investor Relations & Corporate Communications

Five Prime Therapeutics, Inc.

415-365-5625

martin.forrest@fiveprime.com

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