



Phase 2 FIGHT Trial Results Presented at ASCO GI Validate Importance of FGFR2b Overexpression and Reinforce Potential of Bemarituzumab Plus Chemotherapy as a Frontline Targeted Treatment for FGFR2b+ Gastric and GEJ Cancers

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- All three efficacy endpoints (PFS, OS and ORR) in the FIGHT Phase 2 trial met pre-specified statistical significance
- 2021 priorities for the bemarituzumab program include collaborating with regulatory agencies on next steps, initiating a global Phase 3 trial in gastric and GEJ cancers and evaluating bemarituzumab in other epithelial cancers that overexpress FGFR2b
- Results presented today in a late-breaking oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Virtual Annual Symposium
- Five Prime to host webcast and conference call today at 1:30pm PST / 4:30pm EST

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 15, 2021-- [Five Prime Therapeutics, Inc.](#) (NASDAQ: FPRX) today announced clinical results from the global, randomized, double-blind placebo-controlled Phase 2 FIGHT trial evaluating first-in-class targeted therapy bemarituzumab in advanced gastric or gastroesophageal junction (GEJ) cancer. Trial results were presented in a late-breaking oral presentation today by UCLA Health's Zev Wainberg, M.D., at the 2021 ASCO Gastrointestinal Cancers Virtual Annual Symposium (ASCO GI). The ASCO GI presentation slides are available on the company's [website](#).

The FIGHT trial evaluated bemarituzumab plus chemotherapy (mFOLFOX6) versus placebo plus chemotherapy in patients with fibroblast growth factor receptor 2b-positive (FGFR2b+), non HER2 positive frontline advanced gastric or GEJ cancer. The trial enrolled 155 patients in 15 countries across Asia, the European Union, and the United States, with 77 patients randomized to the bemarituzumab arm and 78 patients to the placebo arm.

The Phase 2 trial met all three efficacy endpoints and demonstrated statistically significant and clinically meaningful improvements in the primary endpoint of progression-free survival (PFS) and secondary endpoints of overall survival (OS) and overall response rate (ORR). Additional analysis showed a positive correlation between benefit and the percentage of FGFR2b+ tumor cells, confirming both the importance of the FGFR2b target and the activity of bemarituzumab against this target.

"Systemic chemotherapy is the standard of care for this deadly and aggressive form of gastric cancer. We are strongly encouraged by these data and the potential for a frontline targeted treatment that can improve overall survival," 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. "The FIGHT trial results demonstrate that treatment with bemarituzumab in combination with chemotherapy can deliver a significant reduction in the risk of disease progression and death in gastric cancer patients whose tumors overexpress FGFR2b."

"The Phase 2 FIGHT clinical trial results validate our pioneering work on the role of FGFR2b overexpression in gastric cancer, and we're excited about the implications of this new scientific understanding for other cancers," said Helen Collins, M.D., Five Prime's Executive Vice President and Chief Medical Officer. "With these data in hand, we plan to continue to collaborate with regulatory agencies on next steps, initiate a global Phase 3 trial in gastric cancer and begin studying bemarituzumab in other epithelial cancers that overexpress FGFR2b."

Phase 2 FIGHT Trial: Summary of Efficacy*

	Control Arm Placebo + mFOLFOX6	Investigational Arm Bema + mFOLFOX6	Statistical Measures
Median PFS, months			
All patients (n=155)	7.4	9.5	HR (95% CI): 0.68 (0.44, 1.04); p=0.073
IHC 2+/3+ ≥ 5% (n=118)	7.3	10.2	HR (95% CI): 0.54 (0.33, 0.87)
IHC 2+/3+ ≥ 10% (n=96)	7.3	14.1	HR (95% CI): 0.44 (0.25, 0.77)
Median OS, months			
All patients (n=155)	12.9	Not Reached	HR (95% CI): 0.58; (0.35, 0.95); p=0.027
IHC 2+/3+ ≥ 5% (n=118)	12.5	Not Reached	HR (95% CI): 0.52 (0.30, 0.91)
IHC 2+/3+ ≥ 10% (n=96)	11.1	Not Reached	HR (95% CI): 0.41 (0.22, 0.79)
ORR, %			
ORR (Intent to Treat)	33	47	Improved by 13.1% (p=0.106)
ORR (measurable disease at baseline)	40	53	Improved by 13%

* All three efficacy endpoints in the FIGHT Phase 2 trial met pre-specified statistical significance (2-sided alpha of 0.20)

The incidence of all grade adverse events was similar in the bemarituzumab and placebo arms of the study (100% vs 98.7%, respectively). Corneal events were reported more frequently in the bemarituzumab arm (67.1% vs 10.4%), with the most common corneal events in the bemarituzumab arm being dry eye (26.3%), keratitis (15.8%) and punctate keratitis (14.5%). Stomatitis (31.6% vs 13.0%) and elevated transaminases (34.2% vs 19.5%) were also more common in the bemarituzumab arm. Grade 3 and higher adverse events (82.9% vs 74.0%), serious adverse events (31.6% vs 36.4%) and deaths (6.6% vs 5.2%) were comparable across arms.

Ocular events are common in therapies targeting FGFR and were also reported in the FIGHT trial. More patients in the FIGHT trial discontinued bemarituzumab compared to placebo due to an adverse event (34.2% vs 5.2%) and the majority of these patients (21 of 26 patients) discontinued due to an ocular event.

The discontinuation of bemarituzumab due to an ocular event decreased the median duration of exposure to bemarituzumab by 3.2 weeks; from 25.3 weeks (n=55, range: 2.0 to 71.7 weeks) to 22.1 weeks (n=21, range: 12.0 to 46.7 weeks).

In designing the Phase 3 trial, the company plans to incorporate findings from the FIGHT trial including baseline eye exams, prophylactic lubricating eye drops and close monitoring for signs and symptoms of corneal toxicity, including dry eye.

Five Prime Webcast /Conference Call Information

Five Prime Therapeutics will host a KOL conference call and live audio webcast following ASCO GI on Friday, January 15, 2021 at 4:30pm (EST) / 1:30pm (PST) to review the Phase 2 FIGHT clinical trial results and provide an update on the bemarituzumab program. The presentation will feature members of the Five Prime management team and 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, and an investigator in the trial.

To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID: 2063209. 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 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 splice form of FGFR which can be found in tumors of epithelial origin. Data from the FIGHT trial suggests that approximately 30 percent of patients with non HER2 positive 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 cancer (TNBC), ovarian, pancreatic and intrahepatic cholangiocarcinoma.

About Bemarituzumab

[Bemarituzumab](#) (anti-FGFR2b) is a first-in-class targeted antibody that blocks fibroblast growth factors (FGFs) from binding and activating FGFR2b, inhibiting several downstream pro-tumor signaling pathways and potentially slowing cancer progression. Bemarituzumab is being developed in gastric and GEJ cancer as a targeted therapy for tumors that overexpress FGFR2b. The company is also evaluating the potential for bemarituzumab in other cancers 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 For HER2 negative patients, frontline therapy available today is the same systemic chemotherapy available since the 1990s.^{3,4}

About Five Prime Therapeutics

Five Prime is a clinical stage biotechnology company relentlessly focused on rewriting cancer. By tackling the tough scientific questions and untapped pathways, we aim to offer new hope by developing novel, breakthrough therapies that have potential to alter the course of disease in cancers with few treatment options. This vision is what defines us and guides our research, clinical development and partnerships. To build a better tomorrow for people with cancer, we are teaming up with patients, physicians, scientists, and industry partners to make a meaningful difference in patients' lives. Five Prime collaborates with leading global pharmaceutical companies and has therapies in pre-clinical and clinical 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

1. Data on file. Five Prime Therapeutics; 2020.
2. Bray F, Ferlay J, Soerjomataram I, et al: Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2018;68(6):394-424. doi:10.3322/caac.21492
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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