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Five Prime Therapeutics Initiates Patient Dosing in Phase 1 Lead-In to Phase 3, Global Registrational Trial of FPA144 in Front-Line Advanced Gastric Cancer

SOUTH SAN FRANCISCO, Calif., Jan. 02, 2018 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, today announced that on December 27, 2017, the company initiated dosing in the Phase 1 portion of the FIGHT Phase 1/3 clinical trial (NCT03343301) of FPA144, an isoform-selective anti-FGF receptor 2b antibody, in combination with chemotherapy in patients with previously untreated, advanced gastric or gastroesophageal cancer.

"Patients with advanced gastric cancer need new treatment options. Progression free survival with mFOLFOX6, a standard front-line therapy for gastric cancer, is typically less than seven months," said Charles Fuchs, M.D., Director of the Yale Cancer Center. "For patients whose tumors overexpress FGFR2b or have *FGFR2* gene amplification, prognosis has been found to be particularly poor, so we are hopeful that a targeted therapy like FPA144 may provide a clinical benefit in this setting."

The open label Phase 1 portion of the trial will evaluate ascending doses of FPA144 in combination with the modified FOLFOX6 regimen (mFOLFOX6) to identify a recommended dose for Phase 3. Endpoints include safety, tolerability, and pharmacokinetic and pharmacodynamics parameters. Approximately 21 patients with unresectable, locally advanced, or metastatic gastrointestinal cancer will be enrolled during the Phase 1 portion of the FIGHT trial. FGFR2 status will be tested retrospectively but is not a requirement for enrollment.

This safety lead-in portion of the study is designed to support the Phase 3 portion of the trial, which Five Prime expects to transition to in mid-2018. Five Prime designed the randomized, controlled Phase 3 portion of the trial to serve as a global registrational study. The FIGHT trial will evaluate FPA144 plus mFOLFOX6 versus placebo plus mFOLFOX6 in approximately 550 patients with advanced gastric or gastroesophageal cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification. Five Prime will use immunohistochemistry and circulating tumor DNA tests to identify patients who would be eligible for inclusion in the trial. The primary Phase 3 endpoint is overall survival with progression free survival, objective response rate, and safety as secondary endpoints. The Phase 3 portion of the trial is expected to include sites in the U.S., Europe and Asia, including China and Japan, where the incidence of gastric cancer is high.

"We are very pleased to have the initial run-in to the FIGHT trial underway and we anticipate transitioning to the global, registrational portion of the trial this year," 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, as has been seen with other targeted therapies. Similarly, our pre-clinical data suggest that FPA144 should be additive when combined with chemotherapy."

Data from the Phase 1 clinical trial of single-agent FPA144 were presented at the 2017 ASCO Annual Meeting. FPA144 demonstrated single-agent activity and an acceptable safety profile in heavily pretreated patients with metastatic gastric cancer whose tumors overexpress FGFR2b.

Efficacy Results:

- Objective Response Rate (ORR): 19.0%
- Disease control rate at 6 weeks: 57.1%
- Median duration of response of 15.4 weeks
- Median number of prior therapies: 3

About FPA144
FPA144 is an isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family. Clinical results to date suggest that the specificity of FPA144 avoids toxicities that have been seen with less selective FGFR2 small molecule therapeutics. FPA144 has also been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells.

FPA144 is being evaluated in clinical trials as a potential treatment for gastric cancer and bladder cancer. An estimated

10% of patients with gastric cancer have tumors that overexpress FGFR2b or have *FGFR2* gene amplification, which is associated with poor prognosis.

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 a growing 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.

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 for Five Prime's FPA144 product candidate; (ii) the potential use of FPA144 to treat cancer patients; (iii) the extent of *FGFR2* gene amplification and FGFR2b protein overexpression in gastric cancer patients; and (iv) the advancement of FPA144 into Phase 3 clinical development. 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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