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Five Prime Therapeutics Initiates Patient Dosing in Phase 1 Clinical Safety Trial Evaluating FPA144 in Gastric Cancer in Japan in Preparation for Future Global Late-Stage Development

SOUTH SAN FRANCISCO, Calif., July 17, 2017 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today announced the company has initiated dosing in its Phase 1 clinical trial of FPA144, an anti-FGF receptor 2b antibody, in patients with advanced gastric and gastroesophageal cancer in Japan.

"Gastric cancer is the sixth most common cancer by incidence globally and we estimate approximately 10% of gastric cancer patients have tumors that have *FGFR2* gene amplification or overexpress FGFR2b, which are associated with significantly lower survival rates than the gastric cancer patient population as a whole," said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime. "Moreover, the observed incidence of gastric cancer is higher in Asian populations than in other populations. We believe FPA144 represents a potentially promising treatment option for this targeted patient population with high unmet need."

The number of metastatic gastric and gastroesophageal junction cancer patients eligible for front-line treatment in Japan is approximately 73,000 patients per year. Five Prime estimates approximately 7,300 patients per year could be biomarker-positive and eligible for FPA144 treatment with front-line chemotherapy.

The Phase 1 open-label, dose-finding study will evaluate the safety, tolerability, pharmacokinetics (PK) and recommended dose of FPA144 in approximately 6 to 12 Japanese patients with advanced gastric or gastroesophageal cancer.

Completion of this Phase 1 trial is intended to enable the inclusion of Japanese patients in potential future Phase 3 trials of FPA144 in gastric cancer. Internal non-clinical data demonstrates additivity of FPA144 to standard-of-care chemotherapy regimens. Five Prime plans to initiate a global pivotal trial of FPA144 for front-line treatment of FGFR2b-overexpressing or FGFR2 gene-amplified metastatic gastric and gastroesophageal junction cancer in combination with chemotherapy in 2018.

About FPA144

FPA144 is an isoform-selective antibody in 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. FPA144 has been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells. FPA144 is an anti-FGF receptor 2b (FGFR2b) humanized monoclonal antibody in clinical development as a targeted immune therapy for tumors that over-express FGFR2b. FGFR2b overexpression and *FGFR2* gene amplification are associated with poor prognosis.

FPA144 is currently being studied in a Phase 1 monotherapy trial evaluating the safety, PK and efficacy of biweekly 15 mg/kg infusions of FPA144 in patients with advanced gastric cancer whose tumors overexpress FGFR2b. Five Prime plans to initiate a combination trial of FPA144 with chemotherapy to advance into front-line therapy in the U.S. Five Prime retains global development and commercialization rights to FPA144.

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 FivePrime'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; (iv) the incidence of gastric cancer in Japan; and (v) 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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