Five Prime Therapeutics Presents Updated Data from Phase 1 trial of Single-Agent FPA144 at 2016 ASCO Annual Meeting

- Initial data show a 33% confirmed objective response rate, 77% disease control rate, and 12-week progression free survival of 67% in 9 FGFR2b+ gastric cancer patients available for analysis
- Complete response seen in bladder cancer patient with moderate overexpression of the FGFR2b protein, suggesting potential in other indications outside of gastric cancer

SOUTH SAN FRANCISCO, Calif., June 06, 2016 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, announced that updated data from the ongoing Phase 1 trial of FPA144 was featured today in an oral presentation during the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. Dr. Jeeyun Lee from the Division of Hematology-Oncology, Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea, gave the presentation, titled Antitumor Activity and Safety of FPA144, an ADCC-enhanced, FGFR2b Isoform-Selective Monoclonal Antibody, in Patients with FGFR2b+ Gastric Cancer and Advanced Solid Tumors (Abstract 2502). The presentation is available on the Five Prime website: http://www.fiveprime.com/publications.

Part 1 of the trial evaluated escalating doses of FPA144 as a single agent in 27 patients, 19 with advanced solid tumors in Part 1a and 8 with advanced gastric cancer in Part 1b, including 6 with FGFR2b-overexpressing tumors. Enrollment is underway in Part 2 of the trial, evaluating the safety, pharmacokinetics (PK) and efficacy (objective response rate and duration of response) of biweekly 15 mg/kg infusions of FPA144 across multiple cohorts: gastric cancer patients whose tumors have high, moderate and low levels of FGFR2b protein overexpression and gastric cancer patients whose tumors do not have FGFR2b protein overexpression. Five Prime plans to expand the scope of this trial further by the end of 2016 to include a cohort of patients with a tumor type (other than gastric) that overexpresses FGFR2b.

Safety findings presented in this update are consistent with initial data presented during the ASCO Gastrointestinal Symposium in January 2016. Data across 40 patients in the full safety population of this trial (all gastric and solid tumor patients receiving any portion of at least one dose of FPA144) suggest that FPA144 has an acceptable safety profile in doses up to 15 mg/kg:

- No dose-limiting toxicities (DLTs); maximum-tolerated dose (MTD) was not reached
- No treatment-related serious adverse events (SAEs); 17 reported SAEs across 9 patients
- No treatment-related adverse events (AEs) resulting in treatment discontinuation
- No treatment-related hyperphosphatemia or retinal toxicity (differentiated from small molecule kinase inhibitors targeting FGFR receptor tyrosine kinases)
- The most common treatment-related AEs ( > 5%) were all grades 1 or 2: fatigue (22.5%), nausea (20%) and vomiting (12.5%)
- One transient treatment-related Grade 3 AE of decreased neutrophil count
- Comparable safety between gastric cancer patients and full safety population

FPA144 monotherapy demonstrated early evidence of anti-tumor efficacy in the 9 gastric cancer patients with FGFR2b protein overexpression (6 from Part 1b of the trial; 3 from Part 2) that were available for analysis as of the April 1, 2016 data cutoff. These patients were heavily pre-treated, having received between 1 and 6 prior therapies with a median of 2 prior therapies. The activity observed includes:

- 3 confirmed partial responses (PRs) out of 9 gastric cancer patients treated (33%) (one of these three PRs confirmed after the April 1, 2016 data cutoff)
- 7 of 9 gastric cancer patients with disease control (3 PRs + 4 stable disease), disease control rate (DCR) = 77%
- 12-week progression-free survival (PFS) in 6 of 9 gastric cancer patients (67%)
- Median duration of treatment of 112 days (range 42-182 days), with 2 of 9 gastric cancer patients still on study
- 1 complete response (CR) in a patient with metastatic bladder cancer

In addition to the 3 PRs noted above, there was an additional unconfirmed PR in the 10th gastric cancer patient with FGFR2b protein overexpression (the 4th patient in the 15 mg/kg cohort). This 10th patient's scan became available after the data cutoff of April 1, 2016, and the patient remains on treatment.
"The data suggest that FPA144 is an active drug that warrants further clinical development. The initial single-agent efficacy and safety data seen during the dose escalation portion of the study is encouraging," said Dr. Charles Fuchs, Director of the Center for Gastrointestinal Cancer, Dana Farber Cancer Institute. “Patients with advanced gastric cancer have a significant unmet medical need, and the literature suggests that those with tumors that overexpress FGFR2b have an even worse prognosis. New treatments options are needed for these patients."

"We are pleased with the data from this ongoing trial," said Lewis T. "Rusty" Williams, M.D., Ph.D., president and chief executive officer of Five Prime. "The data we have observed in this trial suggest that FPA144 has an acceptable safety profile and can be dosed biweekly. FPA144 monotherapy also showed evidence of clinical activity in the first nine FGFR2b+ gastric cancer patients that were available for analysis, with a disease control rate of 77% and a 12-week progression free survival of 67%. We were also pleased to see an unexpected complete response in a patient with bladder cancer in part 1a of the trial. We look forward to continuing the study and to further exploring FPA144 in gastric cancer with varying levels of FGFR2b protein overexpression as well as additional FGFR2b+ tumors."

About the FPA144 Phase 1 Trial
Parts 1a and 1b of the Phase 1 study evaluated the safety and pharmacokinetics (PK) of escalating doses of FPA144 in 27 patients with solid tumors, including gastric cancer patients. Enrollment is underway in Part 2 of the trial, evaluating the safety, PK and efficacy (response rate and duration of response) of biweekly 15 mg/kg infusions of FPA144 across multiple cohorts: gastric cancer patients with high, moderate and low levels of FGFR2b protein overexpression, FGFR2b+ gastric cancer patients, and FGFR2b+ patients with other tumor types. Up to 30 patients may be enrolled in each tumor setting. Tumors will be biopsied pre- and post-treatment in order to determine levels of FGFR2b protein overexpression and FGFR2 gene amplification, and to detect PD-L1 and immune infiltrate changes within the tumor. Testing for FGFR2b protein overexpression is being conducted centrally, using a proprietary immunohistochemistry assay.

About FPA144
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, as determined by a proprietary immunohistochemistry (IHC) diagnostic assay. FGFR2 gene amplification (as identified by FISH) is found in a number of tumors, including in approximately 5% of gastric cancer patients, and is associated with poor prognosis.

FPA144 is designed to block tumor growth through two distinct mechanisms. First, it has been engineered to drive immune-based killing of tumor cells by antibody-dependent cell-mediated cytotoxicity (ADCC) and the recruitment of natural killer (NK) cells and T cells. Second, it binds specifically to FGFR2b and prevents the binding of certain fibroblast growth factors that promote tumor growth. When combined with PD-1 blockade, FPA144 has shown an additive effect in tumor growth inhibition in preclinical models. 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 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. 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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Source: Five Prime Therapeutics, Inc.
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