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Five Prime Therapeutics Presents Updated Data From Phase 1 Trial of Single-Agent FPA144 at 2017 ASCO Annual Meeting

SOUTH SAN FRANCISCO, Calif., June 03, 2017 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX) announced that a poster featuring updated data from the ongoing Phase 1 trial of FPA144 was presented today at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The poster, titled "Updated Antitumor Activity and Safety of FPA144, an ADCC-enhanced, FGFR2b Isoform-specific Monoclonal Antibody, in Patients with FGFR2b+ Gastric Cancer" (Abstract #4067), is available at http://www.fiveprime.com/news-media/publications-presentations.

"We are pleased with the data from this ongoing Phase 1 trial, which demonstrate that FPA144 has single-agent activity and an acceptable safety profile in heavily pretreated patients with metastatic gastric cancer whose tumors overexpress FGFR2b," said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime. "While we have seen encouraging monotherapy activity as a late-line treatment, we believe front-line chemotherapy combination therapy will provide the greatest patient benefit. In addition, we recently opened a monotherapy bladder cancer cohort based on the one metastatic bladder cancer patient who enrolled in the dose escalation portion of the trial. That patient achieved complete response and continues on treatment more than two years later."

Part 2 of the ongoing Phase 1 trial is evaluating the safety, pharmacokinetics (PK) and efficacy (objective response rate and duration of response) of biweekly 15 mg/kg infusions of FPA144 in gastric cancer patients whose tumors overexpress FGFR2b.

Safety Results (as of the March 20, 2017 cut-off)

- FPA144 was well tolerated in doses tested up to 15 mg/kg in patients with advanced solid tumors, including patients with gastric cancer
  - -- No hyperphosphatemia reported
  - -- Ocular adverse events were all ≤ Grade 2; no retinal toxicity reported
- No dose-limiting toxicities (DLTs) during dose escalation; maximum tolerated dose (MTD) not reached
- No grade 4 or higher treatment-related adverse events (AEs)

Efficacy Results (as of the March 20, 2017 cut-off)

FPA144 monotherapy demonstrated early evidence of anti-tumor efficacy in heavily pretreated patients.

- Confirmed radiographic responses
  - -- 5 Partial Responses (4 confirmed, 1 unconfirmed) in 21 patients
  - -- Objective Response Rate (ORR): 19.0%
- Median number of prior therapies: approximately 3
- Median duration of response of 15.4 weeks
- Disease control rate at 6 weeks: 57.1%

While FPA144 demonstrated monotherapy activity in this late-line setting, Five Prime plans to initiate a chemotherapy combination gastric cancer trial to move into the front-line setting.

- FPA144 efficacy data compares favorably with approved targeted agents in gastric cancer
- Internal non-clinical data demonstrates additivity of FPA144 to platinum and 5-FU as well as paclitaxel chemotherapy
- Toxicities observed in this study (n = 64) suggest no overlapping toxicities with platinum and 5-FU or paclitaxel chemotherapy
- Data supports further evaluation of the combination of FPA144 with chemotherapy or immunotherapy in FGFR2b-selected gastric and bladder cancer patients

FPA144 in Bladder Cancer

- The prevalence of FGFR2b overexpression by an Immunohistochemistry (IHC) test in bladder cancer is approximately 11% in primary tumors and approximately 14% in metastases
- FGF7 (a ligand that binds to FGFR2b) overexpression in bladder cancer correlates with reduced survival

- Patient with bladder cancer (IHC 2+) in the dose-escalation phase of the ongoing Phase 1 trial (3 mg/kg) had a complete response and remains on study for more than two years
- Based on the prevalence of FGFR2b overexpression and encouraging response, Five Prime recently opened a FGFR2b-selected bladder cancer cohort in Part 2 of the ongoing Phase 1 trial
  -- 4 patients have been enrolled to date
  -- But it is too early to evaluate efficacy

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. FGFR2b overexpression and *FGFR2* gene amplification are 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. Internal non-clinical data demonstrates additivity of FPA144 to stand-of-care chemotherapy regimens. In addition, 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 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. 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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