



December 1, 2016

Five Prime Presents Data from FPA144 in Urothelial Cancer at 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapies

SOUTH SAN FRANCISCO, Calif., Dec. 01, 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 a poster featuring data related to FPA144 in urothelial cancer (UC), also known as bladder cancer, was presented today at 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Munich, Germany. The Poster titled "FGFR2b Represents a Novel Target for Treatment of Urothelial Cancer," is available at <http://www.fiveprime.com/news-media/publications-presentations>.

"This translational data suggest that FGFR2b protein is expressed in a subset of bladder cancers," said Robert Sikorski, M.D., Ph.D., senior vice president and chief medical officer of Five Prime. "In our Phase 1 clinical trial, a patient with bladder cancer that expressed FGFR2b achieved a complete response after treatment with FPA144. We are actively investigating FPA144 as a treatment for gastric cancer and are now exploring its clinical potential in bladder cancer."

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.

As reported at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting, in the dose escalation phase of the Phase 1 clinical trial, a 76-year-old patient diagnosed with stage 4 bladder cancer received FPA144 at the 3 mg/kg dose level. That patient achieved a durable complete response, suggesting potential efficacy for FPA144 in bladder cancer. As of the November 4, 2016 cutoff, the patient has remained on treatment with FPA144 for 571 days.

The poster presented today includes data showing positive FGFR2b immunohistochemistry (IHC) staining in 11.6% of 387 archival primary bladder cancer tumor samples tested. Five Prime believes bladder cancer patients could be selected for treatment with FPA144 using an IHC molecular diagnostic test, similar to what is being used to identify gastric cancer patients for treatment with FPA144.

FivePrime has completed dose escalation testing in the ongoing Phase 1 study of single-agent FPA144 in patients with solid tumors including gastric cancer, and the drug was well tolerated with no dose limiting toxicities, and no maximum tolerated dose was reached. Enrollment continues in the expansion portion of the trial evaluating the safety, pharmacokinetics (PK) and efficacy of biweekly 15 mg/kg infusions of FPA144 in patients with gastric cancer whose tumors overexpress FGFR2b as well as in a new cohort to evaluate FPA144 in patients with bladder cancer whose tumors overexpress FGFR2b.

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 over-expression 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 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 regarding Five Prime's potential receipt of upfront and milestone payments and royalties. 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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