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Five Prime Announces Updated Data in Mesothelioma Patients from Ongoing Phase 1b Trial of FP-1039 at ESMO 2017 Congress

- Objective response rate of 48% and six-month disease control rate of 81% in patients at or below the maximum tolerated dose level; progression free survival of 7.4 months
- Progression-free survival correlated positively with increasing expression levels of tumoral FGF2

SOUTH SAN FRANCISCO, Calif., Sept. 10, 2017 (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 1b trial of FP-1039/GSK3052230 (hereafter FP-1039) in mesothelioma patients were reported today in an oral presentation at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain. The presentation titled "Multicenter, Nonrandomized, Open-Label Phase 1b Study of FP-1039/GSK3052230 with Chemotherapy: Results in Malignant Pleural Mesothelioma (MPM)" by Dr. Jose Trigo et al., is available at http://www.fiveprime.com/news-media/publications-presentations.

"We are encouraged by the results of FP-1039 in the front-line treatment of malignant pleural mesothelioma, a rare aggressive cancer with a poor prognosis," said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime. "The majority of patients across all dose levels experienced tumor reduction. While this is single-arm data, we believe the findings compare favorably to historical data for chemotherapy alone. In addition to the safety and efficacy results, duration of progression-free survival correlated positively with increasing expression levels of tumoral FGF2."

The mesothelioma arm of the open-label Phase 1b trial evaluated weekly infusions of FP-1039, an FGF ligand trap, in combination with first-line pemetrexed and cisplatin chemotherapy in patients with untreated, unresectable MPM. Following the dose escalation portion of the trial, 15 mg/kg weekly was identified as the maximum tolerated dose (MTD) for FP-1039 and established as the dose for expansion in patients with MPM. The primary study endpoints are safety and overall response rate (ORR), disease control rate (DCR) at 6 months, progression free survival (PFS) and exploratory translational objectives. The poster includes data from MPM patients who had received FP-1039 as of the March 17, 2017 cut-off.

Safety Data

- The most common adverse events across all dose levels (AEs; all grades) observed were: nausea (56%), decreased appetite (36%), fatigue (33%) and infusion reaction (36%)
- The vast majority of events were Grades 1-2
- Three dose-limiting toxicities (DLTs) were observed at the 20 mg/kg dose (Grade 5 bowel perforation/ischemia; Grade 3 elevated creatinine level and Grade 3 infusion reaction)
- No DLTs were observed at the 15 mg/kg dose level and so MTD was established at 15 mg/kg
- Toxicities associated with small-molecule FGFR inhibitors, such as hyperphosphatemia, retinal detachment and nailbed changes, have not been observed

Efficacy Data

In the 27 patients evaluable as of March 17, 2017, who had received FP-1039 at or below the 15 mg/kg MTD dose level:

- Preliminary ORR was 48%, with six-month DCR of 81%, evaluated per mRECIST 1.1

  - 13 confirmed Partial Responses (PRs) and 9 durable Stable Disease (SD) (lasting at least six months)

  - Evaluable patients are defined as patients who enrolled at least 42 days (2 cycles) prior to the cutoff date

- Median PFS at or below the 15 mg/kg MTD dose level was 7.4 months. Historical median time to progression for cisplatin/pemetrexed is 5.7 months.

FGF2 IHC Exploratory Biomarker Data

- FGF2 overexpression is associated with worse prognosis in MPM
- Statistically significant correlation between PFS and cytoplasmic FGF2 H-score was observed for the 15 mg/kg expansion group

About FP-1039

FP-1039 is a protein drug designed to intervene in FGF signaling. As a ligand trap, FP-1039 binds to FGF ligands circulating in the extracellular space (such as FGF2), preventing these signaling proteins from reaching FGFR1 on the surface of tumor cells. Treatment with FP-1039 treatment has not been shown to cause hyperphosphatemia, a side effect seen with small molecule inhibitors of FGF receptors, which block the activity of both cancer-associated FGFs and FGF-23. GlaxoSmithKline (GSK) was the sponsor of the trial.

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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