Five Prime Therapeutics Presents Monotherapy Data from the Phase 1a/1b Trial of FPA150 in Patients with Advanced Solid Tumors at the 2019 ASCO Annual Meeting

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)—June 1, , 2019--Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today presented monotherapy data from the dose escalation portion of the Phase 1a/1b clinical trial of FPA150 in patients with advanced solid tumors. These data were presented at the Developmental Immunotherapy and Tumor Immunobiology Poster Session during the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. The poster can be found on the Scientific Publications page of the Five Prime Therapeutics website.

The data are the first presentation of FPA150 results and include safety and pharmacokinetics results from the Phase 1a monotherapy dose escalation portion of the study. The Phase 1a monotherapy portion of the study is being conducted in patients with advanced solid tumors, and the Phase 1b monotherapy expansion is enrolling patients with breast, ovarian and endometrial tumors that overexpress B7-H4.

“FPA150 is a first-in-class B7-H4 antibody that blocks inhibitory signaling to CD8 T cells and promotes the killing of B7-H4 overexpressing tumors through enhanced ADCC,” said Jasgit Sachdev, M.D. and Director of Breast and Gynecologic Early Phase Trials at the HonorHealth Research Institute. “It is promising to see in this study that FPA150 was well tolerated at doses as high as 20mg/kg with no dose-limiting toxicities.”

The open-label, multi-dose, multi-center Phase 1a dose escalation study was conducted in patients with advanced-stage solid tumors regardless of B7-H4 overexpression at monotherapy doses ranging from 0.01 to 20 mg/kg every three weeks in an accelerated titration followed by 3+3 design and in a separate dose exploration cohort in which patients with tumors that overexpress B7-H4 were treated at doses of 3 or 10 mg/kg every three weeks with mandatory pre- and on-treatment biopsies.

FPA150 monotherapy demonstrated a favorable safety profile with no dose-limiting toxicities or treatment-related serious adverse events. Evaluation of anti-tumor activity is ongoing. A recommended dose of 20 mg/kg every three weeks was selected based on safety and pharmacokinetics.

“Rapid enrollment of this first-in-human study of a novel targeted agent with checkpoint blockade and ADCC activity highlights the significant unmet need in patients with advanced breast and gynecologic cancers,” said Helen Collins, Chief Medical Officer of Five Prime Therapeutics. “The preliminary data from the Phase 1a portion of this study, in patients with tumors overexpressing B7-H4, support continued evaluation of FPA150 in the monotherapy and in the anti-PD1 combination therapy setting.”

Of the 29 patients in the Phase 1a portion of the study,18 had B7-H4 positive tumors based on medium or high immunohistochemistry (IHC) scores, including 11 patients with advanced ovarian cancer. Of these, one patient with ovarian cancer, who had been treated with seven prior lines of therapy including anti-PD1 therapy, achieved a confirmed partial response with a duration of 6.2 months.

Monotherapy Phase 1b expansion began in February 2019 and is enrolling cohorts of patients with B7-H4 positive breast, ovarian and endometrial cancers at a dose of 20 mg/kg every three weeks. A safety lead-in of the combination of Keytruda® (pembrolizumab), a PD1 antibody, and FPA150 has also begun enrolling patients with B7-H4 positive ovarian cancer. The company expects to present preliminary efficacy results from the monotherapy expansion cohorts and early safety results from the FPA150-Keytruda combination at the European Society of Medical Oncology in September 2019.

About FPA150

FPA150 is a novel, fully human, afucosylated monoclonal antibody targeting B7-H4. B7-H4 overexpression is observed in multiple solid tumors, including breast and gynecologic cancers. FPA150 is designed with a dual mechanism of action: blocking the T cell checkpoint activity of B7-H4 as well as promoting enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) against tumor cells expressing B7-H4.

About Five Prime Therapeutics

Five Prime Therapeutics, Inc. discovers and develops innovative protein therapeutics to improve the lives of patients with serious diseases. Five Prime’s product candidates have innovative mechanisms of action and address patient populations in need of better therapies. The company focuses

on researching and developing immuno-oncology and targeted cancer therapies paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime's product candidates. 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 or follow us on LinkedIn, Twitter and Facebook.

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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