Five Prime Therapeutics Announces Collaboration with Roche to Develop Companion Diagnostics for Targeted Immuno-Oncology Investigational Drug Candidates

May 30, 2018

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 30, 2018-- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today announced it has entered into a collaboration with Roche to develop immunohistochemistry (IHC) companion diagnostic assays for use with Five Prime's first-in-class investigational drug candidates, bemarituzumab, an anti-FGFR2b antibody (also known as FPA144), and FPA150, a B7-H4 antibody.

"We are pleased to collaborate with Roche, a world leader and innovator of tissue-based diagnostic solutions, to identify patients with advanced cancers who might be eligible for treatment with our targeted immuno-oncology agents," said Aron Knickerbocker, chief executive officer of Five Prime Therapeutics, Inc. "We believe targeted therapies, such as bemarituzumab and FPA150, could provide clinical benefit to patients. Roche's tissue-based assays will be important tools to help us identify the patients who might benefit most from these treatments."

Five Prime and Roche are collaborating to develop, validate and commercialize a tissue-based IHC companion diagnostic (CDx) assay to help identify patients whose tumors overexpress FGFR2b and are eligible for treatment with bemarituzumab. The CDx assay will be used in Five Prime's global registrational study of bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, a regimen known as mFOLFOX6, as front-line treatment in patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification (the FIGHT trial) that Five Prime expects to start in the second half of 2018. Five Prime plans to use the Roche IHC assay along with a circulating tumor DNA (ctDNA) test in the FIGHT trial to identify the estimated 10 percent of patients with gastric and gastroesophageal junction cancer who would be eligible for treatment with bemarituzumab.

Five Prime and Roche will also collaborate to develop and validate a tissue-based IHC diagnostic assay for use as a laboratory developed test (LDT) to help identify patients whose tumors overexpress B7-H4. Five Prime plans to use this IHC assay in the expansion portion of the ongoing Phase 1 clinical trial of FPA150 to identify patients with advanced or metastatic breast, ovarian, endometrial and bladder cancers whose tumors overexpress B7-H4.

Financial terms of the agreement were not disclosed.

About Bemarituzumab

Bemarituzumab is a first-in-class, isoform-selective, humanized monoclonal antibody in clinical development as a targeted immunotherapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family, or amplify the *FGFR2* gene. Bemarituzumab has been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells. Clinical results to date suggest that the specificity of bemarituzumab avoids the dose-limiting toxicities that have been seen with less selective pan-FGFR tyrosine kinase inhibitors that act on multiple FGFRs, including FGFR2.

Bemarituzumab is being evaluated in the FGF2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment (FIGHT) Phase 1/3 clinical trial, a global registrational study in patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification. The Phase 3 portion of the trial is expected to begin in the second half of 2018. In December 2017, Five Prime and Zai Lab announced a collaboration for the development and commercialization of bemarituzumab in Greater China. Zai Lab will manage the Phase 3 portion of the FIGHT trial in China.

About FPA150

FPA150 is a first-in-class, fully human, afucosylated monoclonal antibody targeting B7-H4. B7-H4 expression is observed in multiple solid tumors, including breast, bladder and gynecologic cancers, and has been documented to correlate with poor prognosis. FPA150 is designed with a dual mechanism of action: blocking the T cell checkpoint activity of B7-H4 as well as delivering potent ADCC against tumor cells expressing B7-H4. B7-H4 is being studied in a Phase 1 trial of monotherapy FPA150 with a dose-escalation phase in patients with solid tumors, followed by dose expansion in pre-specified cohorts in tumor types based on B7-H4 expression levels. The initial targeted tumors are advanced or metastatic breast, ovarian, endometrial and bladder cancers.

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 the 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 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. Forward-looking statements contained in this press release include statements regarding (i) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates; and (ii) the extent of gene amplification

and protein overexpression in certain patient populations. Many factors may cause differences between current expectations and actual results including unexpected safety, efficacy or other data observed during research, preclinical or clinical studies, changes in expected or existing competition, changes in the regulatory environment, and unexpected litigation or other disputes. Other 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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