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Five Prime Therapeutics Submits Investigational New Drug Application for Novel B7-H4 Antibody FPA150

Dual mechanism of action blocks a T cell checkpoint pathway and delivers enhanced ADCC against B7-H4-expressing tumor cells

SOUTH SAN FRANCISCO, Calif., Jan. 03, 2018 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, today announced the December 2017 submission of an Investigational New Drug (IND) application for FPA150, a first-in-class immuno-oncology antibody that targets B7-H4. Five Prime discovered FPA150 using the company's protein therapeutics platform and anticipates initiating a Phase 1 trial of FPA150 during the first half of 2018.

FPA150 is a high affinity, afucosylated monoclonal antibody designed with a dual mechanism of action: blocking a T cell checkpoint pathway and delivering enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) against tumor cells expressing B7-H4. B7-H4 expression is seen in tumor types such as breast, ovarian and endometrial cancer, and has been correlated with poor prognosis in some studies. Non-clinical data of FPA150 featured in an oral poster presentation at the European Society for Medical Oncology (ESMO) 2017 Congress described potent ADCC and T cell checkpoint blockade activity *in vitro* and significant dose-dependent anti-tumor efficacy *in vivo.*

"We are excited to expand our clinical pipeline with the addition of FPA150, which offers a differentiated approach to existing immunotherapies," said Bryan Irving, Ph.D., Senior Vice President of Research at Five Prime. "B7-H4 represents a T cell checkpoint ligand that is not currently targeted by other immuno-oncology agents and is also expressed in several solid tumor types not typically associated with elevated PD-L1 expression."

Five Prime designed the planned Phase 1 trial with a standard 3+3 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 urothelial carcinomas. Phase 1a dose escalation endpoints include identification of a maximum tolerated dose (MTD), safety, and pharmacokinetics (PK) of FPA150. Phase 1b dose expansion endpoints include objective response rate, as well as safety and PK.

About FPA150
FPA150 is a novel, high affinity, afucosylated monoclonal antibody discovered by Five Prime with its protein therapeutics platform. FPA150 is designed with a dual mechanism of action: blocking a T cell checkpoint pathway and delivering enhanced antibody-dependent cell-mediated cytotoxicity against tumor cells expressing B7-H4. B7-H4 expression is seen in tumor types such as breast, ovarian and endometrial cancer, and has been correlated with poor prognosis in some studies. Five Prime anticipates initiating Phase 1 development of FPA150 during the first half of 2018.

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.

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 about (i) the timing of initiation, progress and scope of the planned Phase 1 clinical trial of FPA150; (ii) the potential use of FPA150 to treat patients with cancer; and (iii) the extent of B7-H4 protein expression in patients with cancer. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates

that are lower than expected and changes in expected or existing competition. 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.

CONTACT:
Heather Rowe
Senior Director, Investor Relations and Corporate Communications
415-365-5737
heather.rowe@fiveprime.com


Primary Logo

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