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Five Prime to Present Preclinical Data at 2016 SITC Annual Meeting Demonstrating Potent Anti-Tumor Activity with Novel Tetravalent Anti-GITR Antibody

SOUTH SAN FRANCISCO, Calif., Nov. 11, 2016 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today announced that a poster featuring preclinical data related to its tetravalent anti-GITR agonist antibody, FPA154, was presented today at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, Maryland. Poster #175 titled, "Novel tetravalent anti-GITR antibody is a potent anti-tumor agent in vivo," is available at http://www.fiveprime.com/news-media/publications-presentations.

"With our lead anti-GITR candidate, FPA154, now in pre-IND enabling studies, we are pleased to highlight our first preclinical data supporting the development and differentiation of this novel, tetravalent antibody," said Luis Borges, Ph.D., Senior Vice President of Research, at Five Prime. "In vitro data demonstrates that our tetravalent antibody has agonistic activity in the absence of Fc-mediated crosslinking. In vivo, the antibody has potent anti-tumor activity in various murine tumor models and it confers long-term anti-tumor immunity. It alters the ratio of Tregs to effector T cells, creating a favorable environment for an effective anti-tumor immune response. These findings suggest the potential for FPA154 to activate T cell immunity against various tumors and we are working to move this program rapidly toward clinical development."

FPA154 has been designed using single-domain antibodies in a tetravalent format, inducing effector T cell stimulation in vitro that is superior to a conventional bivalent antibody format and conferring agonistic activity even in the absence of Fc-mediated crosslinking. The poster features preclinical data provided by a mouse-reactive surrogate molecule that demonstrate potent inhibition of tumor growth in mouse tumor models:

- **Potent anti-tumor activity following a single dose:** A single dose of tetravalent anti-GITR significantly inhibited tumor growth in multiple models including CT26 and MC38. Treatment was capable of inducing complete tumor rejection, and activity was observed at doses as low as 0.08 mg/kg in both models.
- **Fc-independent activity:** Tetravalent anti-GITR antibody retained partial tumor growth inhibition activity even in the absence of Fc-mediated crosslinking or effector function, whereas a conventional bivalent antibody (DTA-1) required Fc function.
- **Pharmacodynamic responses:** Tetravalent anti-GITR antibody treatment reduced the number of T cells in the peripheral blood 3 days post-treatment. In the tumor, Treg and conventional CD4 T cells decreased, but CD8 T cell numbers were maintained. This resulted in a ratio of CD4 and CD8 effector T cells to Treg that created a favorable environment for an effective anti-tumor immune response.
- **Induction of long-term immunity:** Mice that eliminated CT26 tumors in response to tetravalent anti-GITR were resistant to tumor regrowth upon re-challenge with the same tumor, but not to an antigenically-unrelated tumor.

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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