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Five Prime Therapeutics Presents Initial Clinical Trial Data from Phase 1/2 trial of Cabiralizumab in Pigmented Villonodular Synovitis (PVNS) at 2017 ASCO Annual Meeting

SOUTH SAN FRANCISCO, Calif., June 04, 2017 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX) announced that a poster featuring initial clinical data from the ongoing Phase 1/2 clinical trial of cabiralizumab in patients with PVNS was presented today at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The poster, titled "A Phase 1/2 Dose Escalation and Expansion Study of Cabiralizumab (FPA008), an anti-CSF1R antibody, in Tenosynovial Giant Cell Tumor (TGCT, Diffuse Pigmented Villonodular Synovitis, D-PVNS)" (Abstract #11078), is available at http://www.fiveprime.com/news-media/publications-presentations.

"Cabiralizumab clearly demonstrates clinical benefit in patients with PVNS, including reduction in tumor size and improvements in pain and functional status," said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime. "Our recent market research indicates that patients with PVNS have significant unmet needs, especially in alleviating the pain and functional impairment caused by this chronic joint disease. The encouraging safety and efficacy results support continued development of cabiralizumab for this condition for which there are no currently approved medical treatments. We plan to have discussions with regulatory authorities about a potential pivotal trial in this orphan indication."

This Phase 1/2 clinical trial is an open-label, dose escalation and dose expansion study designed to evaluate the pharmacokinetics (PK), pharmacodynamics (PD), safety, and efficacy of cabiralizumab in patients with PVNS. The protocol was amended to allow for continued treatment with cabiralizumab with asymptomatic creatine kinase (CK) elevations. After the amendment, 21 additional patients were enrolled between November 2016 and March 2017. The efficacy results included in the poster and summarized below include only the 11 patients treated prior to the protocol amendment.

Safety Results

- PK and PD of cabiralizumab support dosing at 4 mg/kg every two weeks or less frequently
- No dose-limiting toxicities (DLTs) were observed at doses up to 4mg/kg
- Most frequently reported adverse events (AEs) of periorbital and eyelid edema, rash and pruritus are similar to AEs reported in other agents in this drug class
  -- 3 out of 11 patients enrolled prior to the protocol amendment discontinued drug due to asymptomatic laboratory elevations of CK

Efficacy Results

- Cabiralizumab demonstrates clinical benefit in patients with PVNS at 4mg/kg every two weeks
  -- Most patients enrolled at the 4 mg/kg dose prior to the amendment experienced tumor reduction
  -- 5 out of 11 patients had a radiographic response (4 confirmed)
  -- Improvement in median Ogilvie-Harris composite score of pain and function was reported in both responders and non-responders (per RECIST v1.1 on MRI)
  -- 12 additional patients enrolled after the amendment were considered efficacy evaluable with evidence of early shrinkage in tumor, but it was too early to assess overall response as of the data cut-off date

About PVNS
PVNS is a rare, locally aggressive tumor of the synovium. It is characterized by local over-expression of CSF-1, which recruits macrophages into the joints, forming the non-malignant tumor mass. It is associated with high morbidity, and there are no approved therapies for the condition. Five Prime is conducting a Phase 1/2 clinical trial studying cabiralizumab as a treatment for PVNS.

About Cabiralizumab (FPA008)
Cabiralizumab is an investigational antibody that inhibits the CSF-1 receptor and has been shown in preclinical models to block the activation and survival of monocytes and macrophages. Inhibition of CSF1R in preclinical models of several cancers reduces the number of immunosuppressive tumor-associated macrophages (TAMs) in the tumor microenvironment, thereby facilitating an immune response against tumors. Cabiralizumab is currently in a Phase 1/2 clinical trial in pigmented villonodular synovitis (PVNS) and a Phase 1 clinical trial in oncology indications. Cabiralizumab is being developed under an exclusive worldwide license and collaboration agreement entered into with Bristol-Myers Squibb (BMS) in October 2015.

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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