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European Commission Grants Orphan Drug Designation to Cabiralizumab (FPA008) for Pigmented Villonodular Synovitis (PVNS)

Cabiralizumab (FPA008) is in a Phase 2 clinical trial for rare neoplastic joint disease for which there are no currently approved treatments

SOUTH SAN FRANCISCO, Calif., Jan. 24, 2017 (GLOBE NEWSWIRE) -- Five Prime Therapeutics, Inc. (Nasdaq:FPRX) today announced that the European Commission has granted orphan designation for cabiralizumab (FPA008) for the treatment of tenosynovial giant cell tumour, localised and diffuse type, also known as Pigmented Villonodular Synovitis (PVNS), a locally aggressive tumor of the synovium.

"PVNS is a rare neoplastic joint disease that is driven by CSF1R signaling and can be associated with significant pain and debilitation," said Helen Collins, M.D., vice president of clinical development, Five Prime. "Cabiralizumab is our investigational antibody that we believe could be a potential treatment for PVNS, a disease for which there are no currently approved medical treatments. This orphan drug designation in Europe highlights the need for new treatments to help patients."

Orphan designation is assigned to a medicine intended for use against a rare condition. The medicine must fulfill certain criteria for designation as an orphan medicine so that it can benefit from incentives such as protection from competition once on the market.

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 2 clinical trial studying cabiralizumab (FPA008) 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 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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