Five Prime Therapeutics Provides Update on Phase 2 Trial of Cabiralizumab Combined with Opdivo® in Pancreatic Cancer

February 18, 2020

Phase 2 Trial of Cabiralizumab plus Opdivo (nivolumab) with and without Chemotherapy in Advanced Pancreatic Cancer Did not Meet Primary Endpoint

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 18, 2020-- Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on developing immune modulators and precision therapies for solid tumor cancers, today announced that Bristol-Myers Squibb informed the company that the randomized Phase 2 trial testing the combination of cabiralizumab with Opdivo® (nivolumab) with and without chemotherapy in patients with advanced pancreatic cancer did not meet its primary endpoint. While Bristol-Myers Squibb has no near term plans for additional sponsored development of cabiralizumab, Bristol-Myers Squibb will continue to support the evaluation of cabiralizumab in select, ongoing investigator-sponsored trials and may continue to assess future development opportunities for the investigational asset. Bristol-Myers Squibb also informed the company that no new safety signals were observed in the Phase 2 trial.

“Pancreatic cancer is a difficult disease to treat, and unfortunately the combination of cabiralizumab and Opdivo with and without chemotherapy did not show any meaningful benefit over standard of care chemotherapy in this randomized, controlled Phase 2 trial,” said Helen Collins, M.D., Executive Vice President and Chief Medical Officer of Five Prime Therapeutics. “We are disappointed by this outcome and appreciate the participation of the investigators, staff, patients, caregivers, and our development partner who all contributed to the conduct and completion of this Phase 2 clinical trial.”

The multi-arm, randomized, controlled Phase 2 clinical trial (NCT03336216) enrolled approximately 160 patients with locally advanced or metastatic pancreatic cancer that has progressed during or after one line of chemotherapy.

About Five Prime Therapeutics

Five Prime Therapeutics, Inc. develops innovative protein therapeutics to improve the lives of patients with cancer. The company focuses on developing immune modulators and precision therapies for solid tumor cancers paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime’s product candidates. The company’s product candidates have innovative mechanisms of action and address patient populations in need of better therapies. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and preclinical development. For more information, please visit www.fiveprime.com.

About Cabiralizumab (FPA008)

Cabiralizumab is an investigational antibody that inhibits the CSF-1 receptor and has been shown in preclinical models and clinical studies 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. Bristol-Myers Squibb acquired rights in October 2015 to cabiralizumab under an exclusive worldwide license and collaboration agreement.

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. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, changes in expected or existing competition, changes in the regulatory, pricing or reimbursement 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.

Source: Five Prime Therapeutics, Inc.

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