Five Prime Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

- Significant Pipeline Expansion and Strong Clinical Execution in 2018
    - Phase 3 FIGHT Registrational Trial in Gastric and GEJ Cancer Enrolling
    - Phase 2 Cabiralizumab/*Opdivo*® (nivolumab) Trial in Pancreatic Cancer Enrolling
    - Phase 1 Starts for FPA150, FPT155 and BMS-986258
- Multiple Data Readouts in 2019

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--February 26, 2019-- Five Prime Therapeutics, Inc. (NASDAQ: FPRX), a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, today announced its financial results for the fourth quarter and year ended December 31, 2018, in addition to providing an update on the company's recent activities.

"2018 was a year of significant expansion of our clinical pipeline," said Aron Knickerbocker, Chief Executive Officer of Five Prime Therapeutics. "Thanks to strong execution across our research, preclinical and clinical organizations along with the contributions of the entire Five Prime team, we are positioned for a year of multiple data readouts. "Thanks to strong execution across our research, preclinical and clinical organizations, along with the contributions of the entire Five Prime team, we are positioned for a year of multiple data readouts. We began 2019 in a strong position with five assets in clinical development as well as the capital and support from our collaborators required to achieve our goals. By the end of 2019, we expect the bema FIGHT Phase 3 to be enrolling across nearly 200 sites globally and to disclose data from FPA150 and FPT155 that will inform the clinical path forward for these first-in-class programs. In addition, we are pleased with the continued progress of our BMS-partnered cabira and TIM-3 programs."

Review of 2018 Business Highlights and 2019 Milestones

Clinical Pipeline:

Bemarituzumab (FPA144) is a first-in-class isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immuno-therapy for tumors that overexpress FGFR2b.

2018

- Completed the Phase 1 safety lead-in and dosed the first patient in the randomized Phase 3 FIGHT global registration trial.

2019

- Presented safety lead-in data from the Phase 3 FIGHT trial at the 2019 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium. Trial results showed no dose-limiting toxicities and no impact to the pharmacokinetics of bemarituzumab from the combination of mFOLFOX6 plus bemarituzumab. Signs of clinical activity from the combination were observed in each of the two patients with advanced gastric or gastroesophageal junction (GEJ) cancer who were biomarker-positive.

- Expect to open approximately 200 clinical sites in 18 countries in the Phase 3 FIGHT trial by year end. The Phase 3 FIGHT trial is a pivotal global registration trial evaluating bemarituzumab in combination with mFOLFOX6 chemotherapy as front-line treatment of patients with gastric or GEJ cancer that overexpresses FGFR2b.

FPA150 (anti-B7-H4) is a first-in-class anti-B7-H4 antibody designed to target tumor cells by blocking B7-H4 from sending an inhibitory signal to CD8 T cells and by enhancing killing of B7-H4 overexpressing tumors through ADCC. B7-H4 is frequently overexpressed in breast, ovarian and endometrial cancers.

2018

- Initiated the Phase 1a monotherapy dose escalation portion of a Phase 1a/1b clinical trial of FPA150 in solid tumors.
- Initiated patient dosing in the exploratory cohort of the ongoing Phase 1a portion of the trial to enroll patients with tumors that overexpress B7-H4, as assessed by an immunohistochemistry (IHC) assay.

2019

- Completed the Phase 1a monotherapy dose escalation portion of the Phase 1a/1b trial.
- Initiated the Phase 1b monotherapy expansion cohorts at the selected 20 mg/kg dose given every three weeks, enrolling patients with breast, ovarian, and endometrial tumors with B7-H4 overexpression.
- Plan to present data from the Phase 1a/1b trial at the ASCO Annual Meeting in June and the European Society for Medical Oncology's (ESMO) 2019 Annual Congress in September.

FPT155 (CD80-Fc) is a first-in-class CD80-Fc fusion protein that uses the binding interactions of soluble CD80 to directly engage CD28 to enhance its co-stimulatory T cell activity without inducing super agonism and to block CTLA-4 from competing for endogenous CD80, allowing CD28 signaling to prevail in T cell activation in the tumor microenvironment.

2018

- Initiated patient dosing in a Phase 1a/1b clinical trial of FPT155. The Phase 1a dose escalation portion of the trial will characterize the safety and pharmacokinetic (PK)/pharmacodynamic (PD) profile of FPT155 to identify a recommended dose for the Phase 1b portion of the trial.

2019

- Plan to present data from the Phase 1a dose escalation at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November.

Cabiralizumab (FPA008) is an antibody that inhibits CSF1R and has been shown to block the activation and survival of tumor-associated macrophages.

2018

- Bristol-Myers Squibb Company (BMS) initiated a multi-arm, Phase 2 clinical trial (NCT03336216) evaluating cabiralizumab in combination with *Opdivo*, triggering a $25 million milestone payment to Five Prime.

2019

- The Phase 2 trial is currently enrolling patients across sites in the U.S., Canada, Europe, Japan, Korea and Taiwan, and is expected to enroll approximately 160 patients with locally advanced or metastatic pancreatic cancer that has progressed during or after one line of chemotherapy.

BMS-986258 (anti-TIM-3) is a fully-human monoclonal antibody targeting TIM-3 (T cell immunoglobulin and mucin domain-3), an immune checkpoint receptor that may limit the duration and magnitude of T cell responses. This is the first clinical candidate from the discovery collaboration between Five Prime and BMS that includes targets in three immune checkpoint pathways.

2018

- BMS initiated the Phase 1 portion of the Phase 1/2 clinical trial of BMS-986258 as a single agent as well as in combination with *Opdivo* or hyaluronidase, with the objective of evaluating the safety and tolerability of the combination with *Opdivo*.

2019

- Continued progress in the Phase 1/2 clinical trial.

Corporate Highlights

2018

- Raised net proceeds of $107.6 million from a public offering of 5,897,435 shares of common stock, including 769,230 shares sold upon the underwriters' full exercise of their option to purchase additional shares.

2019

- Announced a corporate restructuring to focus resources on clinical development and late-stage research programs, primarily eliminating positions in research, pathology, and manufacturing.

Summary of Financial Results and Guidance:

Cash Position: Cash, cash equivalents and marketable securities totaled $270.1 million as of December 31, 2018, compared to $292.7 million as of December 31, 2017. The decrease was primarily attributable to cash used in operating activities more than fully offsetting $107.6 million in net proceeds from the public offering of Five Prime’s common stock in January 2018.

Revenue: Collaboration and license revenue for the fourth quarter of 2018 decreased by $9.2 million, or 70%, to $4.0 million from $13.2 million for the fourth quarter of 2017. The decrease was primarily due to Five Prime’s recognition in the fourth quarter of 2017 of a $5.0 million milestone payment received from BMS under the immuno-oncology research collaboration, lower revenue under the cabiralizumab collaboration agreement with BMS, and lower research and development funding from several older collaboration agreements, partially offset by an increase from Five Prime’s collaboration with Zai Lab.

Collaboration and license revenue for the year ended December 31, 2018 increased by $10.4 million, or 26%, to $49.9 million from $39.5 million for the year ended December 31, 2017. This increase was primarily due to $25.0 million of revenue recognized under Five Prime's cabiralizumab collaboration agreement with BMS for BMS's achievement of the developmental milestone for the dosing of the first patient in the Phase 2 clinical trial of cabiralizumab in combination with *Opdivo,* and an increase from Five Prime's collaboration with Zai Lab that was partially offset by lower research and development funding from several older collaboration agreements.

R&D Expenses: Research and development expenses for the fourth quarter of 2018 increased by $2.0 million, or 6%, to $34.7 million from $32.7 million primarily due to increased clinical expenses associated with the FIGHT trial and FPA150 program, partially offset by lower companion diagnostic development costs.

Research and development expenses for the year ended December 31, 2018 increased by $5.4 million, or 4%, to $156.3 million from $150.9 million for the year ended December 31, 2017. This increase was primarily related to milestone payments associated with the first patient dosed in Five Prime's Phase 3 FIGHT trial and companion diagnostic development costs that were partially offset by lower manufacturing and preclinical expenses.

G&A Expenses: General and administrative expenses for the fourth quarter of 2018 decreased by $0.9 million, or 9%, to $9.6 million from $10.5 million, primarily due to lower compensation expenses. General and administrative expenses for the year ended December 31, 2018 were $39.7 million, which were essentially flat with the prior year.

Net Loss: Net loss for the fourth quarter of 2018 was $38.8 million, or $1.12 per basic and diluted share, compared to a net loss of $29.2 million, or $1.04 per basic and diluted share for the fourth quarter of 2017.

Net loss for the full year 2018 was $140.4 million, or $4.13 per basic and diluted share, compared to a net loss of $150.2 million, or $5.38 per basic and diluted share, for the full year 2017.

Shares Outstanding: Total shares outstanding were 34,745,721 million as of December 31, 2018.

Cash Guidance: Five Prime expects full-year 2019 net cash used in operating activities to be between $117 and $122 million and estimates ending 2019 with cash, cash equivalents and marketable securities between $148 and $153 million.

Conference Call Information

Five Prime will host a conference call and live audio webcast today at 4:30 p.m. (ET) / 1:30 p.m. (PT) to discuss its financial results and provide a corporate update. To participate in the conference call, please dial (877) 878-2269 (domestic) or (253) 237-1188 (international) and refer to conference ID 9689855. To access the live webcast please visit the "Events & Presentations" page under the "Investors" tab on Five Prime's website at www.fiveprime.com. An archived copy of the webcast will be available on Five Prime's website beginning approximately two hours after the conference call. Five Prime will maintain an archived replay of the webcast on its website for at least 30 days after the conference call.

About Five Prime Therapeutics

Five Prime Therapeutics, Inc. discovers and develops innovative protein therapeutics to improve the lives of patients with serious diseases. Five Prime's product candidates have innovative mechanisms

of action and address patient populations in need of better therapies. The company focuses on researching and developing immuno-oncology and targeted cancer therapies paired with companion diagnostics to identify patients who are most likely to benefit from treatment with Five Prime's product candidates. 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 or follow us on LinkedIn, Twitter and Facebook.

Cautionary Note on Forward-looking Statements

Forward-looking statements contained in this press release include statements regarding (i) the timing of initiation, progress and scope of clinical trials for Five Prime's product candidates; (ii) the potential use of Five Prime's product candidates, including in combination with other products, to treat certain patients; (iii) the timing of the presentation of data for Five Prime's product candidates; (iv) Five Prime's full-year 2019 net cash used in operating activities; and (v) the amount of Five Prime's cash, cash equivalents and marketable securities at the end of 2019. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during research, 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.

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