PMV Pharmaceuticals Initial PC14586 Phase 1 Data Presented at ASCO Demonstrated Anti-Tumor Activity Across Multiple Solid Tumor Types With a p53 Y220C Mutation

June 7, 2022

- *Overall response rate (ORR) of 32% (8/25) achieved in higher dose cohorts per RECIST v1.1*
- *Partial responses observed across six distinct tumor types*
- *Data featured as an oral presentation at ASCO; Company to host investor event via webcast today at 6:30 pm CDT to review data presented*

CRANBURY, N.J., June 07, 2022 (GLOBE NEWSWIRE) -- PMV Pharmaceuticals, Inc. (Nasdaq: PMVP; "PMV Pharma"), a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53, today announced that preliminary results from the ongoing Phase 1/2 PYNNACLE study of PC14586 in patients with advanced solid tumors harboring a p53 Y220C mutation demonstrated anti-tumor efficacy across multiple tumor types with an acceptable safety profile. PC14586 is a first-in-class precision oncology small molecule investigational therapy that selectively targets the p53 Y220C mutation in solid tumors.

The data were featured in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) annual meeting. The presentation entitled, "First-in-human study of PC14586, a small molecule structural corrector of Y220C mutant p53, in patients with advanced solid tumors harboring a TP53 Y220C mutation," was delivered by Ecaterina Ileana Dumbrava, M.D., Assistant Professor of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center.

Dr. Dumbrava commented, "p53 is a target that until now was widely believed to be undruggable. The favorable safety and tolerability of PC14586, along with the clinical activity across six distinct tumor types, supports the potential of PC14586 to become a new treatment modality that can address the unmet need of patients with advanced solid tumors harboring a TP53 Y220C mutation."

Safety

- The most common treatment-emergent adverse events (>15%) included nausea, vomiting, AST increase, ALT increase, anemia, blood creatinine increase, and fatigue.
- The maximum tolerated dose (MTD) was reached at 1500 mg twice daily.
- Enrollment at doses below the MTD is ongoing to support the determination of a recommended Phase 2 dose.

Efficacy

- ORR assessed by investigators according to RECIST v1.1 was 32% (8/25) in patients receiving an initial total daily dose of 1150 mg and above. Of the 8 responding patients, 6 have confirmed partial responses and 2 have unconfirmed partial responses, pending confirmation.
- ORR was 24% (8/33) across all dose cohorts.
- Responses were observed across six distinct tumor types including breast, endometrial, prostate, pancreatic, ovarian, and small cell lung cancer.
- Best Response of stable disease or partial response was observed in 19/25 patients at doses ≥1150 mg (76%).

"These encouraging Phase 1 safety and preliminary efficacy data provide proof of concept for PC14586 as monotherapy to selectively reactivate p53 across multiple tumor types," said Leila Alland, M.D., Chief Medical Officer of PMV Pharma. "We look forward to completing the Phase 1 portion of the PYNNACLE study in the second half of this year and initiating the potentially pivotal Phase 2 portion of the study early in 2023."

Investor Event
Management will host an investor event via webcast on June 7, 2022, at 6:30 pm CDT to discuss the PC14586 Phase 1 data. The event will feature a presentation by Dr. Dumbrava who will review the data presented at ASCO.

To listen to the webcast and view the accompanying slide presentation, please refer to the Events and Presentations section of the PMV Pharma website.

About the PYNNACLE Study
PYNNACLE is an open-label, multicenter Phase 1/2 clinical study assessing safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of PC14586 in patients with advanced solid tumors harboring a p53 Y220C mutation. A total of 41 patients were enrolled as of May 10, 2022; 36 patients with measurable disease at baseline including 33 patients determined to be eligible for response evaluation. During the Phase 1 dose-escalation portion of the study, multiple dose levels of PC14586 were evaluated (150 mg QD, 300 mg QD, 600 mg QD, 1150 mg QD, 1500 mg QD, 2000 mg QD, 2500 mg QD, and 1500 mg BID). Preliminary efficacy was assessed by RECIST v1.1. A recommended Phase 2 dose will be selected at the end of Phase 1. For more information on the Phase 1/2 PYNNACLE study (PMV-586-101), refer to www.clinicaltrials.gov (NCT study identifier NCT04585750).

About PC14586

PC14586 is a first-in-class, small molecule p53 reactivator designed to selectively bind to the crevice present in the p53 Y220C mutant protein, hence, restoring the wild-type, or normal, p53 protein structure and tumor-suppressing function. PC14586 is being developed for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. Fast Track designation has been granted by the Food and Drug Administration (FDA) for evaluating PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation.

About PMV Pharma

PMV Pharma is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Dr. Arnold Levine when he discovered the p53 protein in 1979. Bringing together leaders in the field to utilize over four decades of p53 biology, PMV Pharma combines unique biological understanding with pharmaceutical development focus. PMV Pharma is headquartered in Cranbury, New Jersey. For more information, please visit www.pmvpharma.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the Company’s future plans or expectations for PC14586, including expectations regarding success of its current clinical trial for PC14586 and any future commercialization plans for the product candidate; and the future plans or expectations for the Company’s discovery platform for its other early-stage and clinical candidates. Any forward-looking statements in this statement are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company’s product candidate development activities and planned clinical trials, the Company’s ability to execute on its strategy and operate as an early clinical stage company, the potential for clinical trials of PC14586 or any future clinical trials of other product candidates to differ from preclinical, preliminary or expected results, the Company’s ability to fund operations, and the impact that the current COVID-19 pandemic may have on the Company’s clinical trials, supply chain, and operations, as well as those risks and uncertainties set forth in the section entitled “Risk Factors” in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 1, 2022, the Company’s Quarterly Report on Form 10-Q filed with the SEC on May 10, 2022 and its other filings filed with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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