PMV Pharmaceuticals Updated PC14586 Phase 1 Data Demonstrated Anti-Tumor Activity Across Multiple Solid Tumor Types With a TP53 Y220C Mutation

October 12, 2023

- *Updated PC14586 Phase 1 data presented today as a late-breaking poster at 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics*
- *Confirmed responses observed in multiple tumor types including ovarian, breast, prostate, lung, and endometrial cancer with median duration of response of seven months*
- *Confirmed overall response rate of 38% at Recommended Phase 2 Dose of 2000 mg daily (6/16 evaluable patients) reflective of the planned Phase 2 patient population (TP53 Y220C and KRAS wild-type)*
- *Company to host KOL webinar at 4:00 PM ET today to review updated PC14586 Phase 1 clinical data*

PRINCETON, N.J., Oct. 12, 2023 (GLOBE NEWSWIRE) -- PMV Pharmaceuticals, Inc. (Nasdaq: PMVP), a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53, today announced updated Phase 1 results from its ongoing Phase 1/2 PYNNACLE clinical trial that showed PC14586 achieved efficacy in heavily pretreated patients across multiple tumor types and was well tolerated with a favorable safety profile. Results are being presented in a late-breaking poster session today by Alison M. Schram, M.D., Medical Oncologist at Memorial Sloan Kettering Cancer Center and PYNNACLE Study Investigator, at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics taking place in Boston, Massachusetts.

Dr. Schram commented, “Patients with a solid tumor harboring a TP53 Y220C mutation are in need of new treatment options, as currently there are no approved therapies targeting p53. The safety and efficacy data presented today demonstrate the potential of PC14586 to address a high unmet need in patients with TP53 Y220C-positive advanced solid tumors.”

Study highlights include:

Patient Characteristics

- As of the September 5, 2023 data cutoff, 67 safety evaluable patients were treated in the efficacious dose range (1150 mg daily and above).
- Median age was 63 years (32-84); 61% of patients were female.
- Median number of prior lines of systemic therapy was three (range: 1-9).

Efficacy

- Confirmed responses were observed in patients whose tumors were TP53 Y220C and KRAS wild-type in the efficacious dose range, in multiple tumor types including ovarian, breast, prostate, small-cell lung, and endometrial cancer.
- Median duration of response was seven months.
- Overall response rate (ORR) per RECIST version 1.1 was 38% (6/16 evaluable patients) at the Recommended Phase 2 Dose (RP2D) of 2000 mg daily and 34% (13/38) in the efficacious dose range.

Safety

- Treatment-related adverse events (TRAEs) were mostly Grade 1-2 with the most frequent TRAEs observed (>20%) being nausea, vomiting and blood creatinine increased, with a low rate of discontinuations due to a TRAE (3%).
- Gastrointestinal toxicity improved when PC14586 was administered with food.

Phase 2 Plans

- A RP2D of 2000 mg once daily was selected based on overall safety, pharmacokinetics (PK), and efficacy in alignment with the U.S. Food and Drug Administration at an End of Phase 1 meeting held in Q3 2023.
- The planned Phase 2 patient population includes TP53 Y220C and KRAS wild-type patients.
- PMV plans to initiate a registrational Phase 2 trial in early 2024.

“These updated data from our ongoing Phase 1/2 PYNNACLE clinical trial showed that PC14586, a first-in-class precision oncology investigational therapy, continues to demonstrate clinical benefit in a patient population of high unmet need. The emerging Phase 1 data have guided us in designing our Phase 2 registrational trial to enroll a TP53 Y220C and KRAS wild-type patient population. This represents approximately 90% of patients with TP53 Y220C-positive tumors and the patient population most likely to derive benefit from PC14586,” said Leila Alland, M.D., Chief Medical Officer of PMV Pharma. “We are excited to initiate our registrational Phase 2 trial in early 2024.”

KOL Webinar
PMV will host a KOL webinar via webcast today at 4:00 PM ET to review the data and provide a regulatory update. The event will feature presentations by Aparna Parikh, M.D., M.S., Director of the Global Cancer Care Program at Mass General Hospital Cancer Center, and PYNNACLE Study Investigator, and PMV management.

To register for the event please click here.

Additional PMV Presentations at AACR-NCI-EORTC Conference
The updated PYNNACLE clinical trial data will also be discussed by Dr. Alland during the Chemistry in Cancer Research Town Hall at 6:00 PM ET on Friday, October 13, 2023, and by Dr. Parikh at 10:00 AM ET on Saturday, October 14, 2023.

About the PYNNACLE Clinical Trial
The ongoing Phase 1/2 PYNNACLE study is evaluating PC14586 in patients with advanced solid tumors harboring a TP53 Y220C mutation. The primary objective of the Phase 1 portion of the trial is to determine the maximum tolerated dose (MTD), and Recommended Phase 2 dose (RP2D) of PC14586 when administered orally to patients. Safety, tolerability, pharmacokinetics and effects on biomarkers will also be assessed. Phase 2 will be an expansion study with the primary objective of evaluating the efficacy of PC14586 at the RP2D in patients with TP53 Y220C advanced solid tumors. For more information about the Phase 1/2 PYNNACLE clinical trial, 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 pocket present in the p53 Y220C mutant protein, hence, restoring the wild-type, or normal, p53 protein structure and tumor-suppressing function. The U.S. Food and Drug Administration (FDA) granted Fast Track designation to 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 Arnold Levine, Ph.D., when he discovered the p53 protein in 1979. Bringing together leaders in the field to utilize more than four decades of p53 biology, PMV Pharma combines unique biological understanding with pharmaceutical development focus. PMV Pharma is headquartered in Princeton, 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, expectations regarding timing of the Phase 2 portion of its current clinical trial for PC14586, expected therapeutic benefits of PC14586 including potential efficacy and tolerability, statements regarding the Company’s future plans or expectations for PC14586, including expectations regarding ongoing safety and response rate of participants in our clinical trials, as well as the overall success of the current and future clinical trials for PC14586, and the adequacy of the data to support its regulatory approval, 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 will 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, 2023 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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