PMV Pharmaceuticals PYNNACLE Phase I Data of Rezatapopt in Advanced Ovarian Cancer Featured in Late-Breaking Oral Presentation at 2024 SGO Annual Meeting on Women's Cancer

March 18, 2024

- *Phase 1 analysis from the PYNNACLE Phase 1/2 study showed promising efficacy of rezatapopt (PC14586) in heavily pre-treated patients with advanced ovarian cancer harboring a TP53 Y220C mutation featured in a late-breaking oral presentation at 2024 SGO Annual Meeting*

- *Of the 15 patients in the efficacy evaluable population, seven patients achieved a confirmed partial response with a seven-month median duration of response and a favorable safety profile*

- *Rezatapopt is a first-in-class precision oncology investigational therapy in patients with advanced solid tumors with a TP53 Y220C mutation and KRAS wild-type which is being evaluated in a registrational Phase 2 study*

PRINCETON, N.J., March 18, 2024 (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 that a Phase 1 analysis reported promising anti-tumor activity of rezatapopt (PC14586) in heavily pre-treated patients with advanced ovarian cancer harboring a TP53 Y220C mutation. Rezatapopt is a first-in-class precision oncology small molecule investigational therapy that selectively targets the TP53 Y220C mutation in solid tumors.

These data were featured today in a late-breaking oral presentation at the 2024 Society for Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer being held March 16-18, 2024 in San Diego, CA. The presentation entitled, "Phase 1 Analysis from the PYNNACLE Phase 1/2 Study PC14586 in the Subgroup of Patients with Advanced Ovarian Cancer Harboring a TP53 Y220C Mutation," was delivered by Alison M. Schram, M.D., Medical Oncologist, Memorial Sloan Kettering Cancer Center.

"In this Phase 1 study, we observed promising efficacy of rezatapopt in heavily pre-treated patients with advanced ovarian cancer harboring a TP53 Y220C mutation. In addition, rezatapopt showed a favorable safety profile," said Dr. Schram. "These data are encouraging given the significant unmet medical need for patients with advanced solid tumors, particularly in patients with ovarian cancer who are platinum resistant. Further study of rezatapopt as monotherapy in ovarian cancer is warranted."

Deepika Jalota, Pharm.D., Chief Development Officer of PMV Pharma added, "These Phase 1 PYNNACLE data presented at the SGO meeting showed that rezatapopt, a first-in-class precision oncology investigational therapy, continues to demonstrate clinical benefit in a patient population of high unmet need. Our registrational, tumor-agnostic PYNNACLE Phase 2 trial, which includes an ovarian cancer cohort, remains on track to initiate in the first quarter of this year. The trial will assess rezatapopt as monotherapy at the recommended Phase 2 dose of 2000 mg daily in patients with TP53 Y220C and KRAS wild-type advanced solid tumors."

Results of Phase 1 Analysis of PYNNACLE in Advanced Ovarian Cancer

Phase 1 data from the PYNNACLE trial (NCT04585750) demonstrated that rezatapopt has a favorable safety profile and induced responses in heavily pre-treated patients across multiple tumor types. This subgroup analysis investigated the efficacy of rezatapopt in patients with advanced ovarian cancer treated across the efficacious dose range (1150 mg daily to 1500 mg twice daily).

Patient Characteristics

- As of September 5, 2023, the median age of patients with ovarian cancer (N=22) was 66 years (range 49 – 81 years)
- At baseline, 20 patients had high-grade serous ovarian cancer and two had endometrioid cancer
    - Nineteen patients were platinum resistant and one was platinum refractory
    - Two patients had a BRCA2 mutation
    - Six patients were homologous recombination deficiency positive
    - All patients were KRAS wild-type
    - Median number of prior lines of systemic therapy was four (range 1 – 9)

Efficacy

The efficacy evaluable population consisted of 15 patients with measurable disease at baseline and ≥1 post-baseline tumor assessment.

- Seven patients achieved a confirmed partial response (PR), seven had stable disease (SD), and one had progressive disease
- Median duration of response was seven months
- Of the 15 patients with measurable serum CA-125 at baseline, six had a CA-125 response. Among these, five patients achieved radiographic PR and one had SD

Safety

In the overall population of 67 patients assessed in the efficacious dose range (≥1150mg daily), including this subset of patients with ovarian cancer, treatment-related adverse events (TRAEs) were mostly grade 1 and 2.

- Most frequent TRAEs were nausea (51%), vomiting (43%), and increased blood creatinine (27%)
- Frequency and severity of TRAEs were similar in the ovarian cancer population compared with the overall population
- Rezatapopt administration with food led to an improvement in nausea and vomiting

About Rezatapopt

Rezatapopt (PC14586) is a first-in-class, small molecule, p53 reactivator designed to selectively bind to the pocket in the p53 Y220C mutant protein, 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 rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors with a p53 Y220C mutation.

About the PYNNACLE Clinical Trial

The ongoing Phase 1/2 PYNNACLE study is evaluating rezatapopt in patients with advanced solid tumors harboring a TP53 Y220C mutation. The primary objective of the Phase 1 portion of the trial was to determine the maximum tolerated dose and recommended Phase 2 dose (RP2D) of rezatapopt 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 rezatapopt 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 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. Our co-founder, Dr. Arnold Levine, established the field of p53 biology 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 a 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, statements regarding the Company’s future plans or expectations for rezatapopt, including our ability to obtain approval on a tumor-agnostic basis, ongoing safety and response rate of participants in our clinical trials and expectations regarding timing and success of the Phase 2 portion of its current clinical trial for rezatapopt, including rezatapopt’s potential efficacy and safety profile in ovarian cancer patients. 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 a clinical stage company, the potential for clinical trials of rezatapopt or any future clinical trials of other product candidates to differ from preclinical, preliminary, interim or expected results, the Company’s ability to fund operations, and the impact that any current or future global pandemic or geopolitical emergency 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 February 29, 2024, 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.

Investors Contact:
Tim Smith
Senior Vice President, Head of Corporate Development and Investor Relations
investors@pmvpharma.com

Media Contact:
Kathy Vincent
Greig Communications
kathy@greigcommunications.com