PMV Pharmaceuticals Announces First Patient Dosed in Global Tumor-Agnostic Phase 2 PYNNACLE Trial for Rezatapopt in TP53 Y220C-Positive Solid Tumors

March 27, 2024

- *Rezatapopt is a first-in-class precision oncology investigational therapy for patients with advanced solid tumors with a TP53 Y220C mutation and KRAS wild-type (WT)*
- *First patient dosed in Phase 2 portion of the PYNNACLE trial which will assess rezatapopt as monotherapy in patients with TP53 Y220C and KRAS WT advanced solid tumors*

PRINCETON, N.J., March 27, 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 the first patient has been dosed in the registrational, tumor-agnostic PYNNACLE Phase 2 trial of rezatapopt (PC14586) in patients with advanced solid tumors harboring a TP53 Y220C mutation and KRAS wild-type (WT). Rezatapopt is a first-in-class precision oncology small molecule investigational therapy that selectively targets mutated p53 Y220C proteins in solid tumors.

“Building upon our promising Phase 1 data, we are pleased to announce the dosing of our first patient in the global Phase 2 PYNNACLE trial of rezatapopt as a monotherapy in patients with advanced solid tumors harboring a TP53 Y220C mutation and KRAS wild-type,” said Deepika Jalota, Pharm.D., Chief Development Officer of PMV Pharma. “This pivotal trial is a testament to PMV’s commitment to developing new treatment options for patients with advanced solid tumors with a significant unmet medical need.”

The multi-center, single-arm, registrational, tumor-agnostic Phase 2 trial will assess rezatapopt as monotherapy at a dose of 2000 mg once-daily in patients with TP53 Y220C and KRAS WT advanced solid tumors. The primary endpoint of the trial is overall response rate per blinded independent central review. The trial is designed to enroll 114 patients across five cohorts at approximately 60 sites across the U.S., Europe, and Asia-Pacific.

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 clinical trial 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. The Phase 2 portion is a registrational, expansion basket clinical trial comprising five cohorts (ovarian, lung, breast, and endometrial cancers, and other solid tumors) with the primary objective of evaluating the efficacy of rezatapopt at the RP2D in patients with TP53 Y220C and KRAS wild-type advanced solid tumors. For more information about the Phase 1/2 PYNNACLE clinical trial, refer to www.clinicaltrials.gov (NCT trial 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, expectations regarding timing, expected trial design and success of the Phase 2 portion of its current clinical trial for rezatapopt, and potential market opportunity of rezatapopt. 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.

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