PMV Pharmaceuticals Announces Promising Updated Data From the PYNNACLE Phase 2 Pivotal Trial of Rezatapopt Monotherapy in Patients With TP53 Y220C-Mutated Advanced Solid Tumors

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- *48% confirmed overall response rate (ORR) with a 10.4-month median duration of response in the primary analysis population of 65 patients with platinum-resistant/refractory ovarian cancer*
- *36% ORR with an 8.1-month median duration of response across all cohorts in the overall population of 168 evaluable patients*
- *Data presented today as a late-breaking oral presentation at ENA 2026*
- *Rezatapopt NDA submission for platinum-resistant/refractory ovarian cancer planned in first quarter of 2027*

PRINCETON, N.J., Nov. 20, 2026 (GLOBE NEWSWIRE) -- PMV Pharmaceuticals, Inc. ("PMV Pharma" or the "Company"; Nasdaq: PMVP), a precision oncology company pioneering the discovery and development of small molecule therapies targeting p53, today reported updated results from the pivotal Phase 2 portion of the PYNNACLE clinical trial of rezatapopt monotherapy in patients with *TP53* Y220C-mutated advanced solid tumors.

The data presented include investigator-assessed efficacy across all tumor types, including the primary analysis population of 65 platinum-resistant/refractory ovarian cancer patients who received prior standard of care. In this group, the overall response rate (ORR) was 48%, with a median duration of response of 10.4 months. In the overall population across all cohorts among 168 evaluable patients, the ORR was 36% and the median duration of response was 8.1 months.

Results were presented today in a late breaking oral presentation by Alison M. Schram, M.D., Medical Oncologist at Memorial Sloan Kettering Cancer Center and PYNNACLE Study Investigator at the 38th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2026) in Barcelona, Spain.

"Patients with platinum-resistant ovarian cancer who have progressed on standard therapies have few treatment options," said Dr. Schram. "In this heavily pretreated population, nearly half of patients with platinum-resistant/refractory ovarian cancer responded to rezatapopt, and those responses lasted a median of more than 10 months. These results support rezatapopt as a potential new targeted option for patients whose tumors harbor a *TP53* Y220C mutation."

"The primary analysis reinforces the consistent, durable activity of rezatapopt in patients with platinum-resistant ovarian cancer that has been observed throughout the study," said Deepika Jalota, Pharm.D., Chief Development Officer of PMV Pharma. "For patients who have endured multiple rounds of chemotherapy, rezatapopt has the potential to be a single-agent, chemotherapy-free, once-daily oral option they can take at home. We expect to submit our NDA for accelerated approval in the first quarter of 2027."

The Phase 2 clinical trial data as of a September 4, 2026 data cutoff date are summarized below:

Patient Population

- The safety population consisted of 180 patients across tumor types, including 113 ovarian cancer patients, treated with at least one dose of rezatapopt 2000 mg once daily as monotherapy.
- The efficacy population consisted of 168 patients, including 101 ovarian cancer patients, treated with at least one dose of rezatapopt as of the data cutoff date and either had ≥1 post-baseline tumor assessment or discontinued early.
- In the overall population, patients received a median of 3 prior lines of systemic therapy (range: 0-9) and median age was 65 years (range: 33-91).
- In the ovarian cancer cohort, 93% of patients had high-grade serous ovarian cancer and 97% had platinum-resistant/refractory disease, with a median of 4 prior lines of systemic therapy (range: 1-9).

Efficacy Results

- Confirmed responses were observed in patients whose tumors were *TP53* Y220C mutated and KRAS wild-type in eight tumor types including ovarian, lung, breast, endometrial, head and neck, colorectal, gallbladder cancers, and ampullary carcinoma.
    - In the primary analysis population of platinum-resistant/refractory ovarian cancer patients who had received prior

standard of care, the investigator-assessed confirmed overall response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 was 48% (31/65 patients, including one CR and 30 PRs), with a 10.4-month median duration of response and an 83% disease control rate.

- A biomarker analysis revealed that, among 50 patients with available ctDNA data, 90% (45/50) achieved a ≥50% reduction in ctDNA levels of the *TP53* Y220C VAF within 3-6 weeks of starting rezatapopt which supports the on-target activity of rezatapopt.

- In the ovarian cancer population, responses were observed regardless of additional TP53 alterations or other oncogenic alterations at baseline.

- In the overall population across all cohorts, a 36% ORR (61/168 patients, including four complete responses [CR], 53 partial responses [PR], and four unconfirmed partial responses [uPR]), with a median time to response of 1.3 months and a median duration of response of 8.1 months was observed.
- The cohort-specific ORRs were as follows:
  - Ovarian cancer: 45% ORR (45/101 patients, including four confirmed CRs, 37 confirmed PRs, and four uPRs)
  - Lung cancer: 21% confirmed ORR (4/19 patients)
  - Breast cancer: 17% confirmed ORR (3/18 patients)
  - Endometrial cancer: 45% confirmed ORR (5/11 patients)
  - Other solid tumors: 21% confirmed ORR (4/19 patients)

Safety Results

- Treatment-related adverse events (TRAEs) were mostly Grade 1 or 2 with the most frequent TRAEs observed (>15%) being nausea, fatigue, blood creatinine increase, vomiting, AST increase, ALT increase and anemia. The rates of individual Grade 3 TRAEs were ≤7.2%.
- Lab abnormalities were manageable and monitorable, with most cases being transient and reversible.
- Eleven patients (6%), including seven ovarian cancer patients, discontinued treatment due to TRAEs.
- Rezatapopt continued to demonstrate a manageable safety profile.

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 tumor-suppressor function. The U.S. Food and Drug Administration granted Fast Track designation to rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors with a p53 Y220C mutation and Orphan Drug Designation for the treatment of *TP53* Y220C positive ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

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 clinical 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 were also assessed. The Phase 2 portion is a registrational, single arm, 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 advanced solid tumors, conducted across approximately 70 sites.

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 therapies targeting p53. *TP53* 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 more than 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 the Company’s ability to obtain approval as a treatment option as a monotherapy, expectations regarding timing, enrollment status and success of the Phase 2 portion of the current clinical trial for rezatapopt and the timing of a filing

of a New Drug Application (NDA) for platinum-resistant/refractory ovarian cancer, expected therapeutic benefits of rezatapopt including safety profile and potential efficacy and tolerability, the expectations and timing regarding receipt and disclosures of data results from clinical trials, and the adequacy of the efficacy and safety data from clinical trials to support the Company's pursuit of regulatory approval of a NDA for platinum-resistant/refractory ovarian cancer. 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, including the successful filing of NDAs, 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 or expected results, maintenance by the Company of ODD status and related benefits for rezatapopt, the Company's ability to fund operations, and the impact that a global pandemic, other public health emergencies or geopolitical tensions or conflicts 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 6, 2026, the company's Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2026, 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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