PMV Pharmaceuticals Reports Third Quarter 2024 Financial Results

November 7, 2024

- *Enrollment on track in Phase 2 portion of PYNNACLE clinical trial evaluating rezatapopt as monotherapy in patients with TP53 Y220C and KRAS wild-type advanced solid tumors; more than 75% of sites activated across the U.S., Europe, and Asia-Pacific; interim analysis expected by mid-2025*

- *PMV Pharmaceuticals is collaborating with MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center to support an investigator-initiated Phase 1b study evaluating rezatapopt monotherapy and in combination with azacitidine in patients with relapsed or refractory AML/MDS harboring a TP53 Y220C mutation; enrollment planned to begin in the first quarter of 2025*

- *Cash, cash equivalents, and marketable securities of $197.9 million as of September 30, 2024, providing expected cash runway to end of 2026*

PRINCETON, N.J., Nov. 07, 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 reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

“The Phase 2 portion of the PYNNACLE trial continues to advance, with site activation and enrollment progressing well,” said David Mack, Ph.D., President and Chief Executive Officer of PMV Pharma. “We look forward to providing an update on the PYNNACLE clinical trial in the middle of next year.”

PYNNACLE Phase 2 Monotherapy Update

Enrollment is on track in the Phase 2 monotherapy portion of the PYNNACLE clinical trial. The multicenter, single-arm, registrational, tumor-agnostic Phase 2 trial is assessing rezatapopt as monotherapy at a dose of 2000 mg once-daily in patients with *TP53* Y220C and *KRAS* wild-type advanced solid tumors. The primary endpoint is overall response rate per blinded independent central review. The trial is designed to enroll 114 patients across five cohorts at approximately 60 sites.

Site activation is progressing well, with more than 75% of sites activated across the U.S., Europe, and Asia-Pacific. PMV Pharma plans to provide data from the interim analysis of the Phase 2 monotherapy portion of the PYNNACLE trial by mid-2025 and anticipates a New Drug Application filing by the end of 2026.

Third Quarter 2024 and Recent Corporate Highlights:

- PMV Pharma is collaborating with MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center to support an investigator-initiated Phase 1b study. The study is designed to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of rezatapopt monotherapy and in combination with azacitidine in approximately 25 patients with relapsed or refractory acute myeloid leukemia (AML)/myelodysplastic syndrome (MDS) harboring a *TP53 Y220C* mutation. Enrollment is planned to begin in the first quarter of 2025.
- Rezatapopt food effect data were presented on September 8, 2024 during a poster session at the American College of Clinical Pharmacology Annual Conference. Key data are summarized below:
    - In the Phase 1 portion of the PYNNACLE study, 13 patients received rezatapopt in a fasted state, while 12 patients received rezatapopt after eating. When taken with food, exposure levels at steady state as measured by $AUC_{0\text{-}24}$ and C_{max} increased by 42% and 40%, respectively. Additionally, variability in exposure decreased significantly with food.
    - Overall, rezatapopt was well-tolerated and associated with fewer gastrointestinal (GI) treatment-related adverse events (TRAEs) when administered with food. In addition, the frequency and severity of GI TRAEs were lowest in the 2000 mg once-daily (QD) fed cohort versus higher dose cohorts. These data supported the 2000 mg QD dose being recommended to be taken with food within the ongoing PYNNACLE Phase 2 study.
- Dose-limiting toxicities were observed in the combination arm of the Phase 1b PYNNACLE trial evaluating rezatapopt and Merck’s anti-PD-1 therapy KEYTRUDA ® (pembrolizumab). As a result, rezatapopt 500 mg once-daily in combination with pembrolizumab 200 mg every three weeks was established as the maximum tolerated dose. Due to limited clinical benefit at this dose, PMV Pharma discontinued enrollment in the Phase 1b combination arm.

Third Quarter 2024 Financial Results

PMV Pharma ended the third quarter with $197.9 million in cash, cash equivalents, and marketable securities, compared to $238.1 million as of September 30, 2023. Net cash used in operations was $34.6 million for the nine months ended September 30, 2024, compared to $43.6 million for the nine months ended September 30, 2023.

- Net loss for the quarter ended September 30, 2024, was $19.2 million compared to $16.6 million for the quarter ended September 30, 2023. The net loss increase was a result of increased research and development (R&D) spending associated with advancing our lead product candidate through the PYNNACLE Phase 1/2 clinical trial.
- R&D expenses were $16.9 million for the quarter ended September 30, 2024, compared to $13.6 million for the quarter ended September 30, 2023. The increase in R&D expenses was primarily related to increased contract research organization costs.
- General and administrative (G&A) expenses were $4.9 million for the quarter ended September 30, 2024, compared to $6.0 million for the quarter ended September 30, 2023. The decrease in G&A expenses was primarily due to reduced spend for facility and operational expenses.

KEYTRUDA® (pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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 (FDA) granted Fast Track designation to rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors with a TP53 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 were also assessed. In Phase 1, an overall response rate of 38% (6/16 evaluable patients) was achieved at the RP2D of 2000 mg daily reflective of the Phase 2 patient population (TP53 Y220C and KRAS wild-type). The median duration of response was seven months. The Phase 2 monotherapy portion is a registrational, single-arm, expansion basket clinical trial comprising five cohorts (ovarian, lung, breast, 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. 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 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 as a treatment option on a tumor-agnostic basis and as a monotherapy or in combination with other agents, including with azacytidine, expectations regarding timing for interim data readouts and success of the Phase 2 portion of the PYNNACLE trial, our expectation and timing of New Drug Application filing(s) with the U.S. Food and Drug Administration for the current clinical trial for rezatapopt, the current and future enrollment of patients in our clinical trials, the timing, progress and activation of sites for our clinical trials, collaboration with and plans for the MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center investigator-initiated study for the combination of rezatapopt and azacitidine, and the timing and expectations with respect to our projected cash runway. 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 or expected results; 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 February 29, 2024, our Quarterly Report on Form 10-Q for the three months ended March 31, 2024, filed with the SEC on May 9, 2024, and our 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. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

PMV Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 48,810	$ 37,706
Restricted cash	822	822
Marketable securities, current	134,031	165,351
Prepaid expenses and other current assets	5,957	3,530
Total current assets	189,620	207,409
Property and equipment, net	10,130	10,666
Marketable securities, noncurrent	15,096	25,505
Right-of-use assets	8,407	8,382
Other assets	242	190
Total assets	$ 223,495	$ 252,152
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,063	$ 3,237
Accrued expenses	10,257	9,940
Operating lease liabilities, current	1,243	852
Total current liabilities	13,563	14,029
Operating lease liabilities, noncurrent	12,024	12,434
Total liabilities	25,587	26,463
Stockholders' equity:		
Additional paid-in capital	543,210	535,468
Accumulated deficit	(345,712)	(310,003)
Accumulated other comprehensive income	410	224
Total stockholders' equity	197,908	225,689
Total liabilities and stockholders' equity	$ 223,495	$ 252,152

PMV Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 16,947	$ 13,586	$ 44,760	$ 42,503
General and administrative	4,941	6,042	15,520	18,727
Total operating expenses	21,888	19,628	60,280	61,230
Loss from operations	(21,888)	(19,628)	(60,280)	(61,230)
Other income (expense):				
Interest income, net	2,615	2,984	8,368	8,005
Other income, net	121	4	103	24
Total other income	2,736	2,988	8,471	8,029
Loss before provision for income taxes	(19,152)	(16,640)	(51,809)	(53,201)
Provision (benefit) from income taxes	74	-	(16,100)	3
Net loss	(19,226)	(16,640)	(35,709)	(53,204)
Unrealized gain (loss) on available for sale investments, net of tax	591	(27)	211	90
Foreign currency translation gain (loss)	4	-	(25)	-
Total other comprehensive income (loss)	595	(27)	186	90
Total comprehensive loss	$ (18,631)	$ (16,667)	$ (35,523)	$ (53,114)
Net loss per share -- basic and diluted	$ (0.37)	$ (0.34)	$ (0.69)	$ (1.13)

Weighted-average common shares outstanding	51,574,027	49,047,296	51,499,818	46,889,921

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