PMV Pharmaceuticals Reports Second Quarter 2024 Financial Results and Provides a Progress Update on PYNNACLE Clinical Trial

August 8, 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 60% of sites activated across the U.S., Europe, and Asia-Pacific; interim analysis from Phase 2 monotherapy expected by mid-2025*
- *Eligibility criteria in ongoing Phase 1b rezatapopt and pembrolizumab combination arm of PYNNACLE trial adjusted to align with Phase 2 TP53 Y220C and KRAS wild-type patient population*
- *Cash, cash equivalents, and marketable securities of $212.9 million as of June 30, 2024, providing expected cash runway to end of 2026*

PRINCETON, N.J., Aug. 08, 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 second quarter ended June 30, 2024, and provided an update on the Phase 2 monotherapy and Phase 1b combination portions of the PYNNACLE clinical trial.

“We are encouraged by the pace of site activation and patient enrollment in the Phase 2 PYNNACLE trial,” said David Mack, Ph.D., President and Chief Executive Officer of PMV Pharma. “I would like to thank our team for their continued execution, and we look forward to providing an update on the PYNNACLE clinical trial 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 will assess 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 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.

Site activation is progressing well, with more than 60% of sites activated across the U.S., Europe, and Asia-Pacific. PMV 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 (NDA) filing by the end of 2026.

PYNNACLE Phase 1b Rezatapopt/Pembrolizumab Combination Update

Enrollment continues in the Phase 1b combination arm of the PYNNACLE trial evaluating rezatapopt in combination with pembrolizumab (200 mg every three weeks) in patients with advanced solid tumors harboring a *TP53* Y220C mutation.

- Eight patients were initially enrolled at a dose of 1000 mg once-daily of rezatapopt and pembrolizumab. Three patients experienced a dose-limiting toxicity (DLT). Subsequently, per protocol, eight patients were enrolled at 500 mg once-daily rezatapopt and pembrolizumab. As no DLTs were observed at this dose level, the Safety Review Committee escalated the rezatapopt dose to 1000 mg once-daily. Enrollment is currently ongoing at this dose level for rezatapopt. The pembrolizumab dose has remained at 200 mg every three weeks throughout the course of the Phase 1b combination clinical trial. Further characterization to identify the optimal combination dose is in progress.
- The safety profile of the rezatapopt and pembrolizumab combination has been consistent with either agent as monotherapy.
- Based on a preliminary review of the Phase 1b combination data, *KRAS* wild-type patients experienced more of a clinical benefit compared to patients with a *KRAS* single-nucleotide variant (SNV). As a result, PMV has decided to exclude patients with a *KRAS* SNV from the Phase 1b combination arm in order to maximize the opportunity for patients to benefit from rezatapopt in combination with pembrolizumab. This exclusion criterion is aligned with the Phase 2 monotherapy portion of the PYNNACLE clinical trial.

Second Quarter 2024 Financial Results

PMV Pharma ended the second quarter with $212.9 million in cash, cash equivalents, and marketable securities, compared to $213.1 million as of March 31, 2024. Net cash used in operations was $17.8 million for the six months ended June 30, 2024, compared to $27.9 million for the six months ended June 30, 2023.

- Net loss for the quarter ended June 30, 2024, was $1.2 million compared to $17.4 million for the quarter ended June 30, 2023. The net loss reduction was a result of the company’s sale of its New Jersey accumulated net operating losses, with a corresponding $16.2 million income tax benefit.

- Research and development (R&D) expenses were $14.6 million for the quarter ended June 30, 2024, compared to $13.8 million for the quarter ended June 30, 2023. The increase in R&D expenses was primarily related to increased contractual research organization costs.
- General and administrative (G&A) expenses were $5.5 million for the quarter ended June 30, 2024, compared to $6.3 million for the quarter ended June 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, 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.

In addition, rezatapopt in combination with pembrolizumab is being evaluated in the Phase 1b portion of the Phase 1/2 PYNNACLE trial. The primary objective of the Phase 1b portion of the trial is to determine the maximum tolerated dose and RP2D of rezatapopt when administered with pembrolizumab.

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 and in combination with pembrolizumab, expectations regarding timing for interim data readouts and success of the Phase 1b and Phase 2 portions of the PYNNACLE trial, our expectation and timing of NDA filing(s) with the FDA for the current clinical trial for rezatapopt, expectations regarding eligibility criteria of our clinical trials, the current and future enrollment of patients in our clinical trials, the timing, progress and activation of sites for our clinical trials, the results and preliminary data of our clinical trials 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, and the Company’s Quarterly Report on Form 10-Q for the three months ended March 31, 2024, filed with the SEC on May 9, 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.

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

	June 30, 2024	December 31, 2023
Assets		

Current assets:		
Cash and cash equivalents	$ 48,526	$ 37,706
Restricted cash	822	822
Marketable securities, current	164,393	165,351
Prepaid expenses and other current assets	5,048	3,530
Total current assets	218,789	207,409
Property and equipment, net	10,530	10,666
Marketable securities, noncurrent	—	25,505
Right-of-use assets	8,038	8,382
Other assets	182	190
Total assets	$ 237,539	$ 252,152
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,533	$ 3,237
Accrued expenses	5,701	9,940
Operating lease liabilities, current	1,151	852
Total current liabilities	11,385	14,029
Operating lease liabilities, noncurrent	11,839	12,434
Total liabilities	23,224	26,463
Stockholders' equity:		
Additional paid-in capital	540,986	535,468
Accumulated deficit	(326,486)	(310,003)
Accumulated other comprehensive (loss) income	(185)	224
Total stockholders' equity	214,315	225,689
Total liabilities and stockholders' equity	$ 237,539	$ 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 14,628	$ 13,843	$ 27,813	$ 28,916
General and administrative	5,542	6,279	10,578	12,686
Total operating expenses	20,170	20,122	38,391	41,602
Loss from operations	(20,170)	(20,122)	(38,391)	(41,602)
Other income (expense):				
Interest income, net	2,801	2,696	5,753	5,022
Other income (expense), net	(17)	(6)	(18)	20
Total other income	2,784	2,690	5,735	5,042
Loss before provision for income taxes	(17,386)	(17,432)	(32,656)	(36,560)
Benefit from income taxes	(16,173)	4	(16,173)	4
Net loss	(1,213)	(17,436)	(16,483)	(36,564)
Unrealized (loss) gain on available for sale investments, net of tax	(61)	(212)	(380)	117
Foreign currency translation gain (loss)	5		(28)	
Total other comprehensive (loss) income	(56)	(212)	(408)	117
Total comprehensive loss	$ (1,269)	$ (17,648)	$ (16,891)	$ (36,447)
Net loss per share -- basic and diluted	$ (0.02)	$ (0.38)	$ (0.32)	$ (0.80)
Weighted-average common shares outstanding	51,478,751	45,813,132	51,462,307	45,793,355

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