PMV Pharmaceuticals Reports Third Quarter 2023 Financial Results and Corporate Highlights

November 9, 2023

- *Updated data from Phase 1 PYNNACLE clinical trial of PC14586 presented at 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics demonstrated responses across multiple tumor types with median duration of response of seven months*
- *An overall response rate of 38% observed at the recommended Phase 2 dose of 2000 mg daily for the intended Phase 2 population of TP53 Y220C and KRAS wild-type patients*
- *Registrational Phase 2 clinical trial expected to initiate in Q1 2024*
- *Ongoing enrollment in the combination arm of the PYNNACLE study with PC14586 and KEYTRUDA® (pembrolizumab)*

PRINCETON, N.J., Nov. 09, 2023 (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, 2023, and provided a corporate update.

“We were very pleased to recently share updated Phase 1 data from our PYNNACLE clinical trial with the oncology community, demonstrating clinical efficacy and safety of PC14586 in heavily pretreated patients across multiple solid tumor types,” said David Mack, Ph.D., President and Chief Executive Officer. “On the strength of the positive findings and guidance from the FDA, we selected the recommended Phase 2 dose and are aligned on the clinical and regulatory pathway for further development of PC14586. We look forward to initiating a registrational Phase 2 study in the first quarter of 2024.”

Third Quarter 2023 and Recent Corporate Highlights:

- Updated clinical results from the Phase 1 PYNNACLE study evaluating PC14586 were featured in a late-breaking poster at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on October 12, 2023. Confirmed responses were observed in patients whose tumors were TP53 Y220C and KRAS wild-type in the efficacious dose range, in multiple tumor types including ovarian, breast, prostate, small-cell lung, and endometrial cancer. An overall response rate of 38% was achieved at the Recommended Phase 2 Dose (RP2D) of 2000 mg daily (6/16 evaluable patients) reflective of the planned Phase 2 patient population (TP53 Y220C and KRAS wild-type). The median duration of response was seven months. A copy of the poster can be found on the PMV corporate website here.
- The RP2D of 2000 mg once daily was selected based on overall safety, pharmacokinetics (PK), and efficacy in alignment with the U.S. Food and Drug Administration (FDA) at an End of Phase 1 meeting held in Q3 2023. PMV plans to initiate a registrational tumor-agnostic Phase 2 clinical trial in early 2024.
- The PYNNACLE clinical trial results were also highlighted in a KOL webinar which included a presentation by Aparna Parikh, M.D, M.S., Director of the Global Cancer Care Program at Mass General Hospital Cancer Center. A copy of the webinar presentation can be accessed here.
- Ongoing enrollment in the combination arm of PYNNACLE evaluating PC14586 with KEYTRUDA® (pembrolizumab). PMV and Merck entered into a collaboration in 2022 under the terms of which Merck is supplying KEYTRUDA for this study.

Third Quarter 2023 Financial Results

- During the nine months ended September 30, 2023, the Company raised $35.1 million in net proceeds through an At-the-Market facility (ATM).
- PMV Pharma ended the third quarter with $238.1 million in cash, cash equivalents, and marketable securities.
- Net loss for the nine months ended September 30, 2023, was $53.2 million compared to $54.0 million for the nine months ended September 30, 2022.
- Research and development (R&D) expenses were $42.5 million for the nine months ended September 30, 2023, compared to $37.0 million for the nine months ended September 30, 2022. The increase in R&D expenses was primarily related to increased headcount and clinical expenses to advance research on PC14586, the Company’s lead drug candidate.
- General and administrative (G&A) expenses were $18.7 million for the nine months ended September 30, 2023, compared to $18.9 million for the nine months ended September 30, 2022. The decrease in G&A expenses was primarily due to facility-related costs now allocated to research as our new laboratory building in Princeton, New Jersey began operations.

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. The field of p53 biology was established by our co-founder Dr. Arnold Levine 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 pharmaceutical development focus. PMV Pharma is headquartered in Princeton, New Jersey. For more information, please visit www.pmvpharma.com.

About PC14586

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

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 PC14586, including our ability to obtain approval on a tumor agnostic basis, expectations regarding timing of the Phase 2 portion of its current clinical trial for PC14586, expected therapeutic benefits of PC14586 including potential efficacy and tolerability, statements regarding the Company’s future plans or expectations for PC14586, including expectations regarding ongoing safety and response rate of participants in our clinical trials, timing for submission of a New Drug Application, as well as the overall success of current and future clinical trials for PC14586, and the adequacy of the data to support its regulatory approval, and any future commercialization plans for the product candidate. 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 an early clinical stage company, the potential for clinical trials of PC14586 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 the current COVID-19 pandemic will 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 1, 2023, the Company’s Quarterly Report on Form 10-Q for the three months ended June 30, 2023, filed with the SEC on August 9, 2023, 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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PMV Pharmaceuticals, Inc.
Condensed Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 52,057	$ 108,297
Restricted cash	822	822
Marketable securities, current	149,861	132,757
Prepaid expenses and other current assets	2,556	5,130
Total current assets	205,296	247,006
Property and equipment, net	10,822	10,955
Marketable securities, noncurrent	36,184	2,495
Right-of-use assets	8,545	9,539
Other assets	180	313
Total assets	$ 261,027	$ 270,308
Liabilities and Stockholders’ Equity		

Current liabilities:		
Accounts payable	$ 1,678	$ 2,996
Accrued expenses	9,038	7,308
Operating lease liabilities, current	—	528
Total current liabilities	10,716	10,832
Operating lease liabilities, noncurrent	12,699	13,448
Total liabilities	23,415	24,280
Stockholders' equity:		
Additional paid-in capital	532,214	487,516
Accumulated deficit	(294,247)	(241,043)
Accumulated other comprehensive loss	(355)	(445)
Total stockholders' equity	237,612	246,028
Total liabilities and stockholders' equity	$ 261,027	$ 270,308

PMV Pharmaceuticals, Inc.
Condensed 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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 13,586	$ 13,666	$ 42,503	$ 36,963
General and administrative	6,042	5,709	18,727	18,915
Total operating expenses	19,628	19,375	61,230	55,878
Loss from operations	(19,628)	(19,375)	(61,230)	(55,878)
Other income (expense):				
Interest income, net	2,984	1,124	8,005	1,830
Other income (expense), net	4	13	24	67
Total other income (expense)	2,988	1,137	8,029	1,897
Loss before (benefit) provision for income taxes	(16,640)	(18,238)	(53,201)	(53,981)
(Benefit) provision for income taxes	—	(9)	3	(9)
Net loss	(16,640)	(18,229)	(53,204)	(53,972)
Unrealized (loss) gain on available for sale investments, net of tax	(27)	(2)	90	(947)
Comprehensive loss	$ (16,667)	$ (18,231)	$ (53,114)	$ (54,919)
Net loss per share -- basic and diluted	$ (0.34)	$ (0.40)	$ (1.13)	$ (1.18)
Weighted-average common shares outstanding	49,047,296	45,622,957	46,889,921	45,556,635