PMV Pharmaceuticals Announces a Clinical Trial Collaboration with Merck to Evaluate PC14586 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Advanced Solid Tumors

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Combination trial to be initiated in Q4 2022

CRANBURY, N.J., July 18, 2022 (GLOBE NEWSWIRE) -- PMV Pharmaceuticals, Inc. (Nasdaq: PMVP; "PMV Pharma"), a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53, today announced that it has entered into a clinical trial collaboration and supply agreement with Merck (known as MSD outside the US and Canada) to evaluate PC14586, a first-in-class precision oncology small molecule investigational therapy that selectively targets the p53 Y220C mutation, in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors.

PMV Pharma will evaluate PC14586 in combination with KEYTRUDA as a separate arm of the company's ongoing Phase 1/2 PYNNACLE trial in patients with advanced solid tumors. Approximately 36 patients are expected to be enrolled in the combination arm of the trial. This combination arm will assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of PC14586 in combination with KEYTRUDA in patients with advanced solid tumors harboring a p53 Y220C mutation. Under the terms of the agreement, PMV Pharma will sponsor the trial and Merck will supply KEYTRUDA.

"Building upon the preliminary efficacy observed with PC14586 as monotherapy that was presented at ASCO in June of 2022, we look forward to evaluating the potential of combining PC14586 with KEYTRUDA in a clinical study in collaboration with Merck," said Leila Alland, M.D., Chief Medical Officer of PMV Pharma. "Our tumor-agnostic study provides compelling scientific rationale for exploring PC14586 in combination with KEYTRUDA in an effort to improve outcomes for more patients. We are excited to be collaborating with Merck on this study."

The emerging scientific literature has established a strong link between p53 and the immune system. PMV Pharma has conducted a series of experiments to evaluate the combination of p53 Y220C reactivators with checkpoint inhibitors, the results of which were presented in a poster at the American Association of Cancer Research (AACR) Annual Meeting 2022. The combination resulted in increases in anti-tumor activity and mean survival time in mouse tumor models, an improvement compared to either agent as monotherapy. The data suggest that p53 reactivation leads to changes in the tumor immune cell microenvironment, specifically increases in T-cell numbers resulting in a potentially additive anti-tumor effect when combining the two agents.

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

About PC14586
PC14586 is a first-in-class, small-molecule p53 reactivator designed to selectively bind to the crevice present in the p53 Y220C mutant protein, hence, restoring the wild-type, or normal, p53 protein structure and tumor-suppressing function. PC14586 is being developed for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. Fast Track designation has been granted by the Food and Drug Administration (FDA) for evaluating PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation.

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 Cranbury, 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 PC14586, including the planned combination trial with KEYTRUDA ® (pembrolizumab). 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 or expected results, the Company's ability to fund operations, and the impact that the current COVID-19 pandemic 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 1, 2022, the Company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2022 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.

Contacts

Investor Contact:

Winston Kung
PMV Pharmaceuticals, Inc.
investors@pmvpharma.com

Media Contact:

Kathy Vincent
Greig Communications
kathy@greigcommunications.com

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