PMV Pharma Doses First Patient in Phase 1/2 Study of PC14586, a First-in-Class Precision Oncology Therapy That Targets Mutant p53

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- PC14586 targets p53 Y220C mutants to selectively reactivate p53, restoring the protein’s tumor-suppressing function
- Phase 1/2 study is enrolling patients with advanced solid tumors that have a p53 Y220C mutation

CRANBURY, N.J., Nov. 23, 2020 (GLOBE NEWSWIRE) -- PMV Pharmaceuticals, Inc. (Nasdaq: PMVP), a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53 mutants, today announced dosing of the first patient in its Phase 1/2 clinical trial evaluating PC14586, the company’s investigational lead compound that targets the Y220C mutant of p53. The trial will enroll up to 130 patients with advanced solid tumors that have the specific p53 Y220C variant.

“This is an important step forward in the battle against the many cancers that are driven by a p53 mutation,” said David Mack, Ph.D., President and Chief Executive Officer of PMV Pharma. “Initiating our Phase 1/2 study represents a significant milestone for PMV, as PC14586 is our first tumor-agnostic therapy to enter the clinic. By selectively binding to the p53 Y220C mutant, PC14586 is designed to reactivate the tumor suppressing function of p53. We look forward to the opportunity to address the significant unmet need for patients whose cancers have a p53 Y220C mutation as we advance PC14586 in the clinic.”

The multi-center, single-arm Phase 1/2 study will evaluate PC14586 in patients with advanced solid tumors with a p53 Y220C mutation. Phase 1 will assess the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity of PC14586. Phase 2 will determine the overall response rate and duration of response of PC14586 at a dose identified in Phase 1.

About p53

p53 plays a pivotal role in preventing abnormal cells from becoming a tumor by inducing programmed cell death. Mutant p53 takes on oncogenic properties that endow cancer cells with a growth advantage and resistance to anti-cancer therapy. The p53 Y220C mutation is associated with many cancers, including but not limited to breast, non-small cell lung cancer, colorectal, pancreatic, and ovarian cancers.

About PC14586

PC14586 is a first-in-class, small molecule, p53 reactivator designed to selectively bind to the crevice created by 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 advanced solid tumors that have a p53 Y220C mutation identified by next generation sequencing. PC14586 was granted Fast Track Designation by the U.S. Food and Drug Administration in October 2020.

For information on the Phase 1/2 trial, please visit www.clinicaltrials.gov (NCT study 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 mutants. p53 is mutated in approximately half of all cancer. 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 expectations regarding the timing for patient enrollment and success of its current clinical trial for PC14586. 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on November 13, 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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