PMV Pharma Granted FDA Fast Track Designation of PC14586 for the Treatment of Advanced Cancer Patients that have Tumors with a p53 Y220C Mutation

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CRANBURY, N.J., Oct. 13, 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 mutations, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its lead product candidate PC14586, for the treatment of cancer patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. There are currently no FDA-approved medicines that target the p53 Y220C mutation.

p53 plays a pivotal role in cellular function by preserving the integrity of DNA and preventing abnormal cells from entering or progressing through the cell cycle. Mutant p53 takes on oncogenic properties that endow cancer cells with a growth advantage and resistance to anti-cancer therapy. Mutant p53 proteins are very common and are found in approximately half of all human cancers. 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. PC14586 is a first-in-class small molecule designed to structurally correct the p53 Y220C mutant protein.

“Fast Track designation reflects the recognition by the FDA that PC14586 has the potential to address a significant unmet medical need for advanced cancer patients with a p53 Y220C mutation,” said David Mack, Ph.D., President and Chief Executive Officer of PMV Pharma. “While targeted therapies have improved outcomes for many patients with advanced cancers, those with tumors carrying a p53 mutation do not yet have precision treatment options for these mutations and often have poor outcomes. We look forward to working closely with the FDA as we advance PC14586 through the clinic as part of our mission to discover and develop novel, tumor-agnostic, precision oncology therapies.”

PMV Pharma plans to conduct a Phase 1/2 open-label, multicenter study to assess the safety, tolerability, pharmacokinetics, and anti-tumor activity of PC14586 in adult patients with a p53 Y220C mutation in locally advanced or metastatic solid tumors. Phase 1 is a first-in-human, open-label, dose-escalation study designed to up to 30 patients with solid tumors that have a p53 Y220C mutation using next-generation sequencing. Phase 2 is an open-label study designed to assess anti-tumor efficacy and safety in patients with solid tumors that have a p53 Y220C mutation. Phase 2 is expected to enroll up to 100 patients.

About FDA Fast Track

Fast Track designation is intended to facilitate the development and expedite the review of products to treat serious conditions while fulfilling an unmet medical need, enabling products to reach patients more rapidly. A product that receives Fast Track designation may be eligible for more frequent interactions with the FDA on matters pertaining to the drug’s clinical development plan as well as eligibility for priority review.

About PC14586

PC14586 is a first-in-class, orally available structural corrector of the p53 Y220C mutant protein, designed to selectively bind to the crevice created by the p53 Y220C mutation, 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.

About PMV Pharma

PMV Pharma is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53 mutations. 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 potential of Fast Track designation to accelerate development and approval of PC14586, the Company’s future plans or expectations for PC14586, including expectations regarding the success of its current clinical trial for PC14586 and future plans or expectations for the company’s discovery platform. 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, regulatory developments in the United States 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 its S1 filed with the United States Securities and Exchange Commission and its other filings filed with the United States Securities and Exchange Commission. 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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