Foundation Medicine and PMV Pharma Announce Collaboration to Develop Companion Diagnostic for Rezatapopt, a First-In-Class, Investigational, Selective p53 Y220C Reactivator

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BOSTON and PRINCETON, N.J., May 29, 2024 (GLOBE NEWSWIRE) -- Foundation Medicine, Inc. and PMV Pharmaceuticals, Inc. (NASDAQ: PMVP; "PMV Pharma") today announced a partnership to develop Foundation Medicine's tissue-based comprehensive genomic profiling test, FoundationOne®CDx, as a companion diagnostic for PMV Pharma's rezatapopt, a first-in-class, investigational therapy for patients with locally advanced or metastatic solid tumors that have a *TP53* Y220C mutation.

Across all human cancers, *TP53* is the most frequently altered gene, with mutations occurring in approximately 50% of cancer cases.[1] Historically, *TP53* mutations have been considered undruggable despite its prevalence across cancers. [2] *TP53* Y220C mutation is one of the most frequently observed *TP53* mutations, occurring in approximately 1% of all solid tumors.[3] PMV Pharma is developing rezatapopt, a small molecule, to reactivate the p53 function in an advanced cancer patient population harboring a *TP53* Y220C mutation.

"The innovative science driven by PMV Pharma's efforts specific to *TP53* Y220C has the potential to offer a new therapeutic option for patients in this area of high unmet medical need," said Troy Schurr, Chief Biopharma Business Officer at Foundation Medicine. "We're proud to provide our high-quality tissue-based genomic test, along with real-world data from our Flatiron Health-Foundation Medicine Clinico-Genomic Database, to support PMV Pharma as they develop this exciting new treatment option."

Rezatapopt (PC14586) is an investigational, first-in-class, selective p53 reactivator designed to stabilize p53 Y220C proteins. The *TP53* Y220C mutation creates a small pocket in the p53 protein, making it thermally unstable and unable to effectively interact with DNA. Rezatapopt is an orally available small molecule designed to selectively bind to a pocket in the p53 Y220C protein, leading to the restoration of the wild-type p53 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, and is the subject of the ongoing registrational, tumor-agnostic PYNNACLE Phase 2 clinical trial. For more information about the Phase 2 PYNNACLE clinical trial, refer to www.clinicaltrials.gov (NCT trial identifier NCT04585750).

Foundation Medicine's portfolio of FDA-approved comprehensive genomic profiling tests offers physicians both blood- and tissue-based testing options for detecting genomic alterations that help guide personalized treatment decisions. If the CDx and separately the therapy are approved, FoundationOne CDx would be the first companion diagnostic to identify patients with *TP53* Y220C mutations who may be eligible for rezatapopt.

About Foundation Medicine: Your Essential Partner in Cancer Care

Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and research. We collaborate with a broad range of partners across the cancer community and strive to set the standard for quality, scientific excellence, and regulatory leadership. Our deep understanding of cancer biology helps physicians make informed treatment decisions for their patients and empowers researchers to develop new medicines. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care. For more information, please visit us on www.FoundationMedicine.com and follow us on LinkedIn and X.

About FoundationOne®CDx

FoundationOne®CDx is a next-generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. FoundationOne CDx is for prescription use only and is intended as a companion diagnostic to identify patients who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For a full list of targeted therapies for which FoundationOne CDx is indicated as a companion diagnostic, please visit www.F1CDxLabel.com.

About Rezatapopt

Rezatapopt (PC14586) is an investigational, first-in-class, small molecule, p53 reactivator designed to selectively bind to a pocket in the p53 Y220C mutant protein leading to the restoration of the wild-type p53 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 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. 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.

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[1] Priestley P, Baber J, Lolkema MP, et al. Pan-cancer whole-genome analyses of metastatic solid tumours. *Nature.* 2019 *;* 575(7781) : 210–216. https://doi.org/10.1038/s41586-019-1689-y

[2] Hassin O, Oren M. Drugging p53 in cancer: one protein, many targets. *Nat Rev Drug Discov*. 2023; 22(2):127–144. https://doi.org/10.1038/s41573-022-00571-8

[3] *The prevalence of the TP53 Y220C and KRAS mutations across different diseases was analyzed by the FoundationInsights® web-based software platform to query a pan-solid tumor cohort of 367,651 US, consented for research patients in the FoundationCore® Database that received Foundation Medicine's Commercial Tissue or Heme assays between 1/1/2012 and 12/31/2020.*