Revolution Medicines Announces First Patient Dosed in Phase 3 Study Evaluating RMC-6236 in Previously Treated Patients with Metastatic Pancreatic Ductal Adenocarcinoma

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REDWOOD CITY, Calif., Oct. 21, 2024 (GLOBE NEWSWIRE) -- Revolution Medicines, Inc. (Nasdaq: RVMD), a clinical-stage oncology company developing targeted therapies for patients with RAS-addicted cancers, today announced that the first patient has been dosed in RASolute 302, a Phase 3 registrational study of RMC-6236, a RAS(ON) multi-selective inhibitor, in patients with previously treated, metastatic pancreatic ductal adenocarcinoma (PDAC).

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RASolute 302 is a global, randomized, open-label Phase 3 study designed to evaluate the safety and efficacy of RMC-6236 monotherapy for patients with metastatic pancreatic cancer compared with standard of care chemotherapy. The trial is anticipated to enroll approximately 460 patients worldwide who had received one prior line of therapy with a 5-fluorouracil (5-FU)-based or gemcitabine-based regimen. The study design focuses on a core population of patients with PDAC harboring RAS mutations at position 12 (RAS G12X) and an expanded population that includes patients with tumors harboring RAS mutations at position G12 (RAS G12X), G13 (RAS G13X) or Q61 (RAS Q61X), or those without any identified targetable mutation. The dual primary endpoints for the study are progression-free survival (PFS) and overall survival (OS) in the core patient population. Key secondary endpoints include PFS and OS in the expanded population of patients. Additional information about RASolute 302 (NCT06625320) is available at clinicaltrials.gov.

“Treating the first patient in RASolute 302 is a significant milestone for Revolution Medicines as we seek to revolutionize treatment for patients with RAS-addicted cancers,” said Mark A. Goldsmith M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. “RMC-6236 is designed to directly inhibit RAS(ON) signaling, which is the primary oncogenic driver of pancreatic cancer. Supported by the encouraging initial PFS and OS observations and safety profile reported from the Phase 1 RMC-6236 monotherapy trial, the randomized RASolute 302 trial will formally assess the potential for this bold investigational drug to make a meaningful difference for people living with metastatic PDAC, one of the most difficult-to-treat cancers.”

About Pancreatic Cancer and Pancreatic Ductal Adenocarcinoma

Pancreatic cancer is one of the most lethal malignancies, characterized by its typically late stage diagnosis, resistance to standard chemotherapy, and high mortality rate. In the U.S., recent estimates indicate that in 2024, approximately 60,000 people will be diagnosed with pancreatic cancer, and about 50,000 people will die from this aggressive disease.

The most common form of pancreatic cancer, pancreatic ductal adenocarcinoma (PDAC) and its variants, accounts for approximately 92% of all pancreatic cancer cases. Due to the lack of early symptoms and detection methods, approximately 80% of patients are diagnosed with PDAC at an advanced or metastatic stage. It is the most RAS-addicted of all major cancers, and more than 90% of patients have tumors that harbor RAS mutations. Metastatic PDAC remains one of the most common causes of cancer-related deaths in the U.S., with a five-year survival rate of approximately 3%.

About RMC-6236

RMC-6236 is an oral, direct RAS(ON) multi-selective inhibitor with the potential to help address a wide range of cancers driven by oncogenic RAS mutations. RMC-6236 suppresses RAS signaling by blocking the interaction of RAS(ON) with its downstream effectors. It does so across oncogenic RAS mutations G12X, G13X and Q61X, in major cancers including pancreatic ductal adenocarcinoma (PDAC), non-small cell lung cancer (NSCLC) and colorectal cancer (CRC).

About Revolution Medicines, Inc.

Revolution Medicines is a clinical-stage oncology company developing novel targeted therapies for RAS-addicted cancers. The company’s R&D pipeline comprises RAS(ON) inhibitors designed to suppress diverse oncogenic variants of RAS proteins. The company’s RAS(ON) inhibitors RMC-6236, a RAS(ON) multi-selective inhibitor, RMC-6291, a RAS(ON) G12C-selective inhibitor, and RMC-9805, a RAS(ON) G12D-selective inhibitor, are currently in clinical development. Additional development opportunities in the company’s pipeline focus on RAS(ON) mutant-selective inhibitors, including RMC-5127 (G12V), RMC-0708 (Q61H) and RMC-8839 (G13C), in addition to RAS companion inhibitors RMC-4630 and RMC-5552.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this press release that are not historical facts may be considered "forward-looking statements," including without limitation statements regarding progression of clinical studies and findings from these studies, including the safety, tolerability, potential efficacy and durability of the company’s candidates being studied; dosing and enrollment in the company’s clinical trials; and the company’s goals to impact treatment of RAS-addicted cancers. Forward-looking statements are typically, but not always, identified by the use of words such as "may," "will," "would," "believe,"

"intend," "plan," "anticipate," "estimate," "expect," and other similar terminology indicating future results. Such forward-looking statements are subject to substantial risks and uncertainties that could cause the company's development programs, future results, performance or achievements to differ materially from those anticipated in the forward-looking statements. Such risks and uncertainties include without limitation risks and uncertainties inherent in the drug development process, including the company's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, the company's ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of the company's capital resources to fund operations, reliance on third parties for manufacturing and development efforts, changes in the competitive landscape, and the effects on the company's business of the global events, such as international conflicts or global pandemics. For a further description of the risks and uncertainties that could cause actual results to differ from those anticipated in these forward-looking statements, as well as risks relating to the business of Revolution Medicines in general, see Revolution Medicines' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 7, 2024, and its future periodic reports to be filed with the SEC. Except as required by law, Revolution Medicines undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/acdbaed2-d2de-4f6a-a00c-141b3d49a029

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