Revolution Medicines Presents Initial Data from Zoldonrasib (RMC-9805) Study in Patients with KRAS G12D Mutant Non-Small Cell Lung Cancer at the 2025 AACR Annual Meeting

April 27, 2025

Zoldonrasib, a RAS(ON) G12D-selective inhibitor, demonstrated acceptable tolerability and encouraging initial antitumor activity in patients with previously treated KRAS G12D mutant non-small cell lung cancer

REDWOOD CITY, Calif., April 27, 2025 (GLOBE NEWSWIRE) -- Revolution Medicines, Inc. (Nasdaq: RVMD), a late-stage clinical oncology company developing targeted therapies for patients with RAS-addicted cancers, today announced new clinical data for zoldonrasib (RMC-9805), a RAS(ON) G12D-selective inhibitor, as monotherapy in patients with KRAS G12D mutant non-small cell lung cancer (NSCLC). Results were highlighted in the official press program at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois, and will be featured in a late-breaking oral presentation on April 27, 2025, at 5:00 p.m. Central Time.

“We are pleased to share new clinical data for zoldonrasib, our innovative, oral RAS(ON) G12D-selective inhibitor, which demonstrates acceptable safety and tolerability and encouraging initial antitumor activity in patients with non-small cell lung cancer. These data reinforce the clinical potential of zoldonrasib following the initial tolerability and antitumor activity reported late last year in patients with pancreatic ductal adenocarcinoma,” said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. “Together these results support further evaluation of zoldonrasib as monotherapy and in combination as we continue efforts to advance innovative targeted medicines for patients living with these hard-to-treat cancers.”

RMC-9805-001 is a multicenter, open-label, dose escalation and dose-expansion Phase 1 study designed to evaluate zoldonrasib in patients with advanced solid tumors harboring a KRAS G12D mutation.

As of a December 2, 2024 data cutoff date, 90 solid tumor patients were treated with 1200 mg once daily (QD), the candidate recommended Phase 2 dose. In these patients, zoldonrasib demonstrated an acceptable safety profile, that was generally consistent with previously reported data for this compound in pancreatic cancer, and was generally well tolerated. The most common treatment-related adverse events (TRAEs) occurring in at least 10% of patients were nausea (39%), diarrhea (24%), vomiting (18%), and rash (12%). TRAEs were primarily Grade 1 or 2 in severity, with two patients (2%) experiencing Grade 3 events that resolved following dose interruption. Zoldonrasib had a favorable mean dose intensity of 98% and no dose limiting toxicities were observed.

Preliminary antitumor activity was assessed in 18 efficacy-evaluable patients with NSCLC at the 1200 mg QD dose. The objective response rate (confirmed or pending confirmation) was 61% (n=11) and the disease control rate was 89% (n=16).

“There is a high unmet need for new treatments within this patient population as there are currently no targeted therapies approved for any RAS G12D mutant cancer,” said Kathryn Arbour, M.D., thoracic medical oncologist at Memorial Sloan Kettering Cancer Center and principal investigator and lead author for the RMC-9805-001 presentation. “While the data are from an early, small subset of patients, it is encouraging to see this level of tolerability and antitumor activity in patients with NSCLC carrying this RAS mutation.”

About Revolution Medicines, Inc.
Revolution Medicines is a late-stage clinical oncology company developing novel targeted therapies for patients with 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 daraxonrasib (RMC-6236), a RAS(ON) multi-selective inhibitor; elironrasib (RMC-6291), a RAS(ON) G12C-selective inhibitor; and zoldonrasib (RMC-9805), a RAS(ON) G12D-selective inhibitor, are currently in clinical development. The company anticipates that RMC-5127, a RAS(ON) G12V-selective inhibitor, will be its next RAS(ON) inhibitor to enter clinical development. Additional development opportunities in the company’s pipeline focus on RAS(ON) mutant-selective inhibitors, including RMC-0708 (Q61H) and RMC-8839 (G13C). For more information, please visit www.revmed.com and follow us on LinkedIn.

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 and antitumor activity of the company’s candidates being studied and the durability of these results; dosing and enrollment in the company’s clinical trials; and the potential of zoldonrasib as a therapeutic option for pancreatic ductal adenocarcinoma or non small cell lung cancer. 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’ current stage of development, the process of designing and conducting preclinical and clinical trials, risks that the results of prior clinical trials may not be predictive of future clinical trials, clinical efficacy, or other future results, 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’ Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on February 26, 2025, 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.

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