Revolution Medicines Announces FDA Breakthrough Therapy Designation for Elironrasib

July 23, 2025

- Breakthrough Therapy Designation granted to elironrasib for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer who have received prior chemotherapy and immunotherapy but have not been previously treated with a KRAS G12C inhibitor
- Designation based on encouraging clinical data observed with elironrasib in patients with advanced KRAS G12C non-small cell lung cancer

REDWOOD CITY, Calif., July 23, 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 that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to elironrasib, the company's RAS(ON) G12C-selective inhibitor, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) who have received prior chemotherapy and immunotherapy but have not been previously treated with a KRAS G12C inhibitor.

The Breakthrough Therapy Designation is based on data from the Phase 1 RMC-6291-001 clinical trial evaluating elironrasib monotherapy in patients with advanced KRAS G12C solid tumors. Results from the trial have demonstrated highly competitive antitumor activity, including differentiated safety and tolerability along with a compelling objective response rate and progression-free survival.

"There continues to be a need for new targeted therapies for patients with RAS-addicted cancers, and this Breakthrough Therapy Designation from the FDA highlights the therapeutic potential of elironrasib, a differentiated inhibitor, for patients with KRAS G12C lung cancer," said Mark A. Goldsmith M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "Coming shortly after daraxonrasib was granted a designation for patients with advanced RAS mutant pancreatic cancer, this designation for elironrasib further validates our innovative product engine as a source for novel potential treatment approaches for patients with RAS mutant cancers."

Elironrasib is an innovative inhibitor that binds selectively and covalently to the oncogenic RAS(ON) form of the RAS G12C variant that drives approximately 12% of cases of NSCLC. Revolution Medicines is exploring elironrasib monotherapy and combinations in various treatment settings and continues work to prioritize multiple options for advancing its development.

NSCLC accounts for 80%-85% of all lung cancers, and most patients have advanced or metastatic disease at initial diagnosis.[1,2] KRAS mutations are found in nearly 30% of NSCLC cases, among which KRAS G12C is the most common. Currently there are no RAS-targeted inhibitors with full approval by the FDA to treat patients with KRAS G12C NSCLC.[3]

Breakthrough Therapy Designation is intended to expedite the development and review of potential new medicines designed to treat serious conditions and address significant unmet medical needs. Pursuant to FDA guidelines, the medicine needs to have shown encouraging preliminary clinical evidence that demonstrates substantial improvement on a clinically significant endpoint over available medicines.

About Non-Small Cell Lung Cancer

More than 197,000 people are diagnosed with non-small cell lung cancer (NSCLC) in the U.S. each year.[4] Despite treatment advancements, NSCLC remains a leading cause of cancer-related mortality worldwide, primarily due to its late-stage diagnosis and limited response to conventional therapies.

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; the therapeutic potential of elironrasib; the ability of the company's product engine to generate potential treatment approaches. 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on May 7, 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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[1] American Cancer Society. What is Lung Cancer. Available at: https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html. Accessed July 2025.

[2] National Cancer Institute. Non-Small Cell Lung Cancer Treatment. Available at: https://www.cancer.gov/types/lung/hp/non-small-cell-lung-treatment-pdq. Accessed July 2025.

[3] Reita D, Pabst L., Pencreach E, et al. Direct Targeting KRAS Mutation in Non-Small Cell Lung Cancer: Focus on Resistance. Cancers (Basel). 2022; 14(15):1321. doi: 10.3390/cancers14051321

[4] American Cancer Society. Key Statistics for Lung Cancer. Available at: https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html. Accessed July 2025.