



Revolution Medicines Announces FDA Breakthrough Therapy Designation for Zoldonrasib

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- Breakthrough Therapy Designation granted to zoldonrasib for the treatment of adult patients with KRAS G12D-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) who have been previously treated with anti-PD-1/PD-L1 therapy and platinum-based chemotherapy
- First Breakthrough Therapy Designation for an investigational drug specifically targeting KRAS G12D mutation in NSCLC
- Revolution Medicines' third RAS(ON) inhibitor to receive this designation

REDWOOD CITY, Calif., Jan. 08, 2026 (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 zoldonrasib, a RAS(ON) G12D-selective inhibitor, for the treatment of adult patients with KRAS G12D-mutated locally advanced or metastatic NSCLC who have been previously treated with anti-PD-1/PD-L1 therapy and platinum-based chemotherapy.

The Breakthrough Therapy Designation is based on data from the monotherapy cohort of the Phase 1 RMC-9805-001 clinical trial evaluating zoldonrasib in patients with advanced KRAS G12D solid tumors. Results from the monotherapy cohort of the trial have demonstrated a robust clinical profile, including encouraging antitumor activity and acceptable safety and tolerability.

"The Breakthrough Therapy Designation for zoldonrasib, our RAS(ON) G12D-selective covalent inhibitor – the first ever granted for an investigational drug specifically targeting the RAS G12D mutation – underscores the significant unmet need for patients with KRAS G12D cancers, which currently lack any approved targeted therapies," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "This recognition expands upon prior designations for the RAS(ON) multi-selective inhibitor daraxonrasib and G12C-selective inhibitor elironrasib, further recognizing the promise of our first three clinical-stage RAS(ON) inhibitors as potentially transformative therapies for people living with RAS-addicted cancers."

Zoldonrasib is an innovative tri-complex inhibitor that binds to cyclophilin A, creating a complex that selectively recognizes and inhibits the active, oncogenic RAS G12D(ON) mutant. Revolution Medicines is evaluating zoldonrasib as a monotherapy and combination treatment across multiple tumor types and lines of therapy.

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

Non-small cell lung cancer (NSCLC) accounts for 80%-85% of all lung cancers, with more than 197,000 people diagnosed in the U.S. each year.^{1,2,3} 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. G12D is the most common oncogenic driver of human cancers and represents 4% of NSCLC cases.⁴

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; zoldonrasib (RMC-9805), a RAS(ON) G12D-selective inhibitor; and RMC-5127, a RAS(ON) G12V-selective inhibitor, are currently in 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](https://www.linkedin.com/company/revolution-medicines).

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 the therapeutic potential of zoldonrasib and 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 "potentially," "anticipate," 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 November 5, 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

December 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 December 2025.

³ American Cancer Society. Key Statistics for Lung Cancer. Available at: <https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html>. Accessed December 2025.

⁴ Ricciuti B, Alessi JV, Elkrief A, et al. Dissecting the clinicopathologic, genomic, and immunophenotypic correlates of KRAS^{G12D}-mutated non-small-cell lung cancer. *Ann Oncol*. 2022;33(10): 1029-1040. doi:10.1016/j.annonc.2022.07.005