Daraxonrasib Demonstrates Unprecedented Overall Survival Benefit in Pivotal Phase 3 RASolute 302 Clinical Trial in Patients with Metastatic Pancreatic Cancer

April 13, 2026

- *Trial met all primary and key secondary endpoints, including progression-free survival and overall survival*
- *Company intends to include these data in a future New Drug Application submission to the U.S. Food and Drug Administration and to other global regulatory authorities*

REDWOOD CITY, Calif., April 13, 2026 (GLOBE NEWSWIRE) -- Revolution Medicines, a late-stage clinical oncology company developing targeted therapies for patients with RAS-addicted cancers, today announced positive topline results from its global, randomized, controlled Phase 3 RASolute 302 clinical trial evaluating daraxonrasib in patients with metastatic pancreatic ductal adenocarcinoma (PDAC) who had been previously treated. Daraxonrasib taken orally once daily demonstrated statistically significant and clinically meaningful improvements in progression-free survival (PFS) and overall survival (OS) compared with standard of care cytotoxic chemotherapy delivered intravenously. In the overall (intent-to-treat) study population, daraxonrasib demonstrated a median OS of 13.2 months versus 6.7 months for chemotherapy, with a hazard ratio of 0.40 ($p < 0.0001$). Daraxonrasib was generally well tolerated, with a manageable safety profile and with no new safety signals.

Based on the results from this first interim analysis, all PFS and OS endpoint results are considered final. Revolution Medicines intends to submit these data to global regulatory authorities, including to the U.S. Food and Drug Administration as part of a future New Drug Application under a Commissioner's National Priority Voucher, and for presentation at the 2026 American Society of Clinical Oncology Annual Meeting.

"For patients with metastatic pancreatic cancer, new treatment options are urgently needed to increase survival time and improve quality of life," said Brian M. Wolpin, M.D., M.P.H., professor of medicine at Harvard Medical School, director of the Hale Family Center for Pancreatic Cancer Research at Dana-Farber Cancer Institute, and principal investigator for the RASolute 302 trial. "The widely anticipated results of this study indicate that daraxonrasib provides a clear and highly meaningful step forward for patients with pancreatic cancer who have experienced progression on prior treatment, typically chemotherapy. I believe that this new approach is a very important advance for the field that I expect will be practice-changing for physicians and improve the care for patients with previously treated metastatic pancreatic cancer."

Pancreatic cancer is the most RAS-addicted of all major cancers, with more than 90% of patients harboring tumors driven by mutations in RAS proteins. These mutations span a range of RAS variants that fuel aggressive tumor behavior. Daraxonrasib, a multi-selective inhibitor of RAS(ON) proteins, is the first investigational agent in a novel class of RAS inhibitors designed to address a diverse and broad spectrum of oncogenic RAS drivers.

The RASolute 302 trial enrolled patients with pancreatic tumors harboring a wide range of RAS variants, as well as those without an identified RAS mutation. The primary endpoints of the trial were PFS and OS in patients with tumors harboring RAS G12 mutations. Secondary endpoints assessed PFS and OS in all enrolled patients (the intent-to-treat population), including those with tumors with and without (wild type) an identified RAS mutation.

"In this pivotal trial, daraxonrasib as a targeted medicine delivered a dramatic improvement in overall survival in patients with previously treated metastatic pancreatic cancer compared to standard of care chemotherapy, consistent with earlier findings. These results represent a potentially transformative advance for patients and underscore daraxonrasib's potential to redefine the treatment landscape. We are moving with urgency toward global regulatory submissions and remain committed to rapidly advancing this therapy for patients with a broad range of RAS-addicted cancers. We are deeply grateful to the patients, families, investigators, and study teams whose participation made the RASolute 302 trial possible, and we look forward to sharing detailed results with the scientific and clinical communities," commented Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines.

Dr. Goldsmith added, "We believe these results firmly validate our pioneering approach to targeting common RAS-addicted cancers through RAS(ON) inhibition, exemplified today by four clinical-stage, investigational drugs with differentiated profiles. This class of inhibitors reflects more than 15 years of investment in groundbreaking scientific research, including creative work from Warp Drive Bio, acquired by Revolution Medicines in 2018, which established the initial technology foundation we have developed into a robust innovation engine for delivering and sustaining our compelling pipeline."

About the RASolute 302 Clinical Trial

RASolute 302 (NCT06625320) is an ongoing, global, randomized Phase 3 registrational clinical trial designed to evaluate the efficacy and safety of daraxonrasib as a monotherapy in patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC). In the trial, patients were randomized to receive either an oral dose of 300 mg daraxonrasib once daily or investigator's choice of standard of care cytotoxic chemotherapy. The trial enrolled patients with metastatic PDAC harboring a wide range of RAS variants, including those with RAS G12 mutations (such as G12D, G12V, and G12R), as well as patients without an identified tumor RAS mutation (wild type).

The primary endpoints of RASolute 302 are progression-free survival (PFS), as assessed by a Blinded Independent Central Review, and overall survival (OS) in patients with tumors harboring RAS G12 mutations. Secondary endpoints include PFS and OS in all enrolled patients (the intent-to-treat population) encompassing patients with and without identified tumor RAS mutations, as well as objective response rate, duration of response, and patient-reported quality of life.

About Daraxonrasib

Daraxonrasib is an investigational, oral RAS(ON) multi-selective, non-covalent inhibitor that is not approved by any regulatory authority, including in the United States or Europe. The U.S. Food and Drug Administration (FDA) granted daraxonrasib Breakthrough Therapy Designation and Orphan Drug Designation for the treatment of patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC) harboring G12 mutations. In addition, daraxonrasib was selected for the FDA Commissioner's National Priority Voucher pilot program, which is intended to accelerate the development and review of therapies aligned with U.S. national health priorities.

Daraxonrasib is designed to target cancers driven by a broad range of common RAS mutations, including PDAC, non-small cell lung cancer (NSCLC), and colorectal cancer. It is currently being evaluated in four global Phase 3 registrational trials, including three in PDAC and one in NSCLC.

Daraxonrasib works by suppressing RAS signaling through inhibition of the interaction between both wild-type and mutant RAS(ON) proteins and their downstream effectors.

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 annually approximately 60,000 people will be diagnosed with pancreatic cancer, and about 50,000 people will die from this aggressive disease.[1]

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 commonly RAS-addicted of all major cancers, and more than 90% of patients have tumors that harbor RAS mutations.[2] 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%.[3,4]

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 company's development strategy and its ability to build or advance its portfolio and R&D pipeline, including plans to submit data to global regulatory authorities and the anticipated regulatory review pathway and timeline, including with respect to the Commissioner's National Priority Voucher program; progression of clinical studies and findings from these studies, including the tolerability, safety, and potential efficacy of the company's candidates being studied; and daraxonrasib's potential as a therapeutic option across multiple tumor types, including the ability of daraxonrasib to redefine the treatment landscape and be practice-changing.

Forward-looking statements are typically, but not always, identified by the use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "potential," "will" 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' development stages, 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 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 25, 2026, 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.

Revolution Medicines Media & Investor Contact:
media@revmed.com
investors@revmed.com

[1]Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. *CA Cancer J Clin.* 2024;74(1):12-49. doi:10.3322/caac.21820

[2]Lee JK, Sivakumar S, Schrock AB, et al. Comprehensive pan-cancer genomic landscape of KRAS altered cancers and real-world outcomes in solid tumors. *NPJ Precis Oncol.* 2022;6(1);91. doi:10.1038/s41698-022-00334-z.

[3]Halbrook CJ, Lyssiotis CA, Pasca di Magliano M, Maitra A. Pancreatic cancer: Advances and challenges. *Cell.* 2023;186(8):1729-1754. doi:10.1016/j.cell.2023.02.014

[4]American Cancer Society. Survival Rates for Pancreatic Cancer. Available at: https://www.cancer.org/cancer/types/pancreatic-cancer/detection-diagnosis-staging/survival-rates.html. Accessed March 2026.