Revolution Medicines Announces ASCO Plenary Presentation Highlighting Unprecedented Results from Pivotal Phase 3 RASolute 302 Clinical Trial of Daraxonrasib in Previously Treated Metastatic Pancreatic Cancer

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Results simultaneously published in The New England Journal of Medicine

REDWOOD CITY, Calif., May 31, 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 detailed results from the global, randomized Phase 3 RASolute 302 clinical trial evaluating daraxonrasib, an oral RAS(ON) multi-selective inhibitor, in patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC). The results will be presented during a late-breaking Plenary Session (LBA5) at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting at 3:21 p.m. CDT today and were published today in *The New England Journal of Medicine*.

RAS, a key growth control switch in human cells, is the primary oncogenic driver of PDAC, a disease that is typically characterized by excessive RAS(ON) signaling in tumors with or without a mutant allele of RAS. Daraxonrasib is the first investigational agent in a novel class of RAS(ON) multi-selective inhibitors designed to address a diverse and broad spectrum of RAS variants. In the randomized Phase 3 RASolute 302 trial, once-daily oral daraxonrasib demonstrated unprecedented improvements in overall survival (OS) and progression-free survival (PFS) compared to standard of care cytotoxic chemotherapy in patients with previously treated metastatic PDAC, with or without an identified tumor RAS mutation. All primary and key secondary endpoints of the trial were met. Daraxonrasib exhibited a manageable safety profile and patients treated with daraxonrasib reported significantly delayed deterioration in cancer-related pain, overall global health status and quality of life, compared to those treated with chemotherapy.

“Revolution Medicines has been singularly focused on developing bold new targeted medicines for treating patients with RAS-driven cancers, which are some of the most aggressive and difficult-to-treat diseases in oncology. The data from the Phase 3 RASolute 302 trial clearly validate our pioneering, science-driven approach and add to the growing body of evidence underscoring the broad potential of RAS(ON) inhibition that we are testing across pancreatic cancer and other RAS-driven cancers,” said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines.

“Daraxonrasib significantly elevates the survival bar in the treatment of one of the deadliest human cancers, while better preserving quality of life compared to chemotherapy. In this trial, daraxonrasib redefined treatment expectations in previously treated metastatic pancreatic cancer by reducing the risk of death by 60% and increasing median overall survival to more than one year, a result not previously reported in any Phase 3 clinical trial in any line of therapy for this disease. These striking results firmly support daraxonrasib as the new standard of care for patients with previously treated metastatic pancreatic cancer, and usher in a new era of RAS-targeted therapy for patients living with this disease,” added Dr. Goldsmith.

"These results from the Phase 3 RASolute 302 trial of daraxonrasib represent a major milestone for patients facing metastatic pancreatic cancer,” said Brian M. Wolpin, M.D., M.P.H., director of the Hale Family Center for Pancreatic Cancer Research at Dana-Farber Cancer Institute, professor of medicine at Harvard Medical School, and principal investigator for the RASolute 302 trial. “For many patients, second line chemotherapy provides modest benefits, and new treatments delivering more durable tumor control have been urgently needed. In this global randomized trial, daraxonrasib, an oral RAS(ON) inhibitor, doubled median overall survival compared to standard of care chemotherapy for patients with previously treated metastatic pancreatic cancer. Importantly, this survival benefit was achieved with a generally manageable safety profile, highlighted by the low rate of treatment discontinuation due to treatment-related side effects. These results will change how scientists, clinicians, and patients think about treatment for pancreatic cancer, and support a new paradigm where RAS(ON) inhibition enters standard of care for patients with previously treated metastatic pancreatic adenocarcinoma."

Summary of Phase 3 RASolute 302 Clinical Trial Results

The trial enrolled 500 patients with previously treated metastatic PDAC, randomized to receive once-daily oral daraxonrasib (n=248) or investigator’s choice of four different cytotoxic chemotherapy regimens (n=252), which represent standard of care across the globe. At the February 10, 2026 data cutoff, median follow-up was 8.5 months (range, 3.2–15.9). The trial met all primary and key secondary endpoints, demonstrating statistically significant and clinically meaningful improvements versus chemotherapy in both the RAS G12 mutant population (daraxonrasib n=228; chemotherapy n=231) and the overall, or intent-to-treat (ITT), population, which included patients with or without an identified tumor RAS mutation.

Daraxonrasib resulted in a 60% reduction in the risk of death in both the RAS G12 and ITT populations. In the RAS G12 population, daraxonrasib demonstrated a hazard ratio (HR) of 0.40 (95% confidence interval [CI]: 0.30–0.54; p<0.0001), with a median OS of 13.2 months (95% CI: 10.0–not estimable [NE]) compared to 6.6 months (95% CI: 5.4–8.2) for chemotherapy. Consistent results were observed in the ITT population, which showed an HR of 0.40 (95% CI: 0.30–0.53; p<0.0001), with a median OS of 13.2 months (95% CI: 10.0–NE) for daraxonrasib compared to 6.7 months (95% CI: 5.8–8.0) for chemotherapy. Patients on daraxonrasib also showed significant improvements in PFS as assessed by a blinded independent central review. In the RAS G12 population, the HR for PFS was 0.45 (95% CI: 0.34–0.59; p<0.0001), with a median PFS of 7.3 months (95% CI: 6.3–8.1) for daraxonrasib compared to 3.5 months (95% CI: 2.9–3.8) for chemotherapy. Similarly, in the ITT population, the HR for PFS was 0.49 (95% CI: 0.38–0.64; p<0.0001), with a median PFS of 7.2 months (95% CI: 5.7–7.5) for daraxonrasib versus 3.6 months (95% CI: 2.9–4.2) for chemotherapy. Objective response rates were 33.2% with daraxonrasib compared to 11.8% with chemotherapy in the RAS G12 population, and 31.6% with daraxonrasib compared to 11.2% with chemotherapy in the ITT population.

Daraxonrasib was generally well tolerated with a manageable safety profile and no unexpected safety findings. Grade 3 or higher treatment-related adverse events (TRAEs) occurred in 43.6% of patients receiving daraxonrasib versus 57.5% of patients receiving chemotherapy. The most frequent Grade 3 or higher TRAEs occurring in at least 10% of patients who received daraxonrasib were rash (14%) and stomatitis (12%). In patients who received chemotherapy, the most common Grade 3 or higher TRAEs were neutropenia (28%), anemia (16%), and thrombocytopenia (10%). Treatment-related serious adverse events occurred in 10.8% of patients receiving daraxonrasib versus 18.7% receiving chemotherapy. One Grade 5 TRAE of pneumonitis was reported in the daraxonrasib arm (0.4%), and no Grade 5 TRAEs were reported in the chemotherapy arm. Discontinuation of therapy due to TRAEs occurred in 1.2% of patients receiving daraxonrasib, compared with 11.2% on chemotherapy. The median dose intensity for daraxonrasib was 93.1% and across chemotherapy regimens it was 65.3-95.0%.

The RASolute 302 trial also evaluated patient-reported outcomes as an important secondary outcome, given the high symptom burden that patients

with metastatic PDAC experience. Daraxonrasib demonstrated a statistically significant and clinically meaningful delay in the time to deterioration in pain, global health status and quality of life when compared to standard of care chemotherapy. In the ITT population, the HR for time to deterioration in pain was 0.51 (95% CI: 0.37–0.71; p<0.0001), and the HR for global health status and quality of life was 0.60 (95% CI: 0.46–0.79; p=0.0002).

Revolution Medicines intends to submit these data to global regulatory authorities, including to the U.S. Food and Drug Administration (FDA) as part of a New Drug Application under a Commissioner's National Priority Voucher. In addition, the U.S. FDA recently authorized the company to initiate an expanded access treatment protocol (EAP) for daraxonrasib for eligible patients. Additional details on the daraxonrasib EAP are available here.

Company Webcast

Revolution Medicines will host a webcast on May 31, 2026, at 6:00 p.m. Central Time (7:00 p.m. Eastern Time). To listen to the live webcast, or access the archived webcast, please visit: https://ir.revmed.com/events-and-presentations. Following the live webcast, a replay will be available on the company's website for at least 14 days.

About the RASolute 302 Clinical Trial

RASolute 302 (NCT06625320) is a 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 four different cytotoxic chemotherapy regimens, which represent standard of care across the globe. 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 the RASolute 302 trial were progression-free survival (PFS), as assessed by a Blinded Independent Central Review according to RECIST 1.1, and overall survival (OS) in patients with tumors harboring RAS G12 mutations. Secondary endpoints included 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 genotypes, including PDAC, non-small cell lung cancer (NSCLC), and colorectal cancer. In addition to the RASolute 302 trial, daraxonrasib is being evaluated in three other global Phase 3 registrational trials, including in patients with PDAC and metastatic RAS mutant 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]

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.

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 broad potential of RAS(ON) inhibition; daraxonrasib becoming a standard of care; treatment practices for pancreatic cancer; and progression of clinical studies and findings from these studies, including the tolerability, safety, and potential efficacy of the company's candidates being studied.

Forward-looking statements are typically, but not always, identified by the use of words such as "aims," "anticipate," "believe," "estimate," "expect," "plan," "potential," "project," "up to," "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 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-Q filed with the Securities and Exchange Commission (the "SEC") on May 6, 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.

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