Revolution Medicines' New Drug Application for Daraxonrasib Accepted for Review by U.S. FDA for Previously Treated Metastatic Pancreatic Cancer

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REDWOOD CITY, Calif., July 22, 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) accepted for review the company's New Drug Application (NDA) for daraxonrasib, an oral RAS(ON) multi-selective inhibitor, for previously treated metastatic pancreatic ductal adenocarcinoma (PDAC).

"The FDA's acceptance of the daraxonrasib NDA is an important step in the regulatory review process and brings us closer to the possibility of offering patients a new targeted medicine for previously treated metastatic pancreatic cancer," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "Daraxonrasib is an oral targeted medicine designed to inhibit RAS, the main cause of pancreatic cancer, and the application is supported by unprecedented results from the Phase 3 RASolute 302 trial. These findings underscore the potential for daraxonrasib to become a new standard of care and to help define a new class of RAS-targeted medicines for this disease. We look forward to continuing to work closely with the FDA as the agency reviews the application, and with other global regulatory authorities as we advance our efforts to bring daraxonrasib to patients as quickly as possible."

The NDA is based on results from the global, randomized Phase 3 RASolute 302 trial, evaluating daraxonrasib versus standard of care cytotoxic chemotherapy in patients with previously treated metastatic PDAC, with or without an identified tumor RAS mutation. The trial met all primary and key secondary endpoints, including unprecedented improvements in overall survival and progression-free survival. In addition, 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. Results from the RASolute 302 trial were presented at the 2026 American Society of Clinical Oncology Annual Meeting with simultaneous publication in *The New England Journal of Medicine*.

Daraxonrasib was selected for the FDA Commissioner's National Priority Voucher pilot program, which is designed to accelerate the review of medicines that address key national health priorities. The FDA previously granted daraxonrasib Breakthrough Therapy Designation and Orphan Drug Designation for the treatment of patients with previously treated metastatic PDAC.

The Company recently announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use has begun a phased review of daraxonrasib, allowing data to be evaluated as they become available before submission of a full marketing authorization application. Daraxonrasib has also received orphan medicine designation for the treatment of pancreatic cancer, and high-priority status under EMA's Cancer Medicines Pathfinder project based on its potential to address a significant unmet need.

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, most patients are diagnosed with pancreatic ductal adenocarcinoma (PDAC) at an advanced or metastatic stage. 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%.[2,3]

About Daraxonrasib

Daraxonrasib is an investigational, oral RAS(ON) multi-selective, noncovalent tri-complex inhibitor that works by suppressing RAS signaling through inhibition of the interaction between both wild-type and mutant RAS(ON) proteins and their downstream effectors. It is designed to target cancers driven by a broad range of common RAS genotypes, including pancreatic ductal adenocarcinoma (PDAC), non-small cell lung cancer (NSCLC), and colorectal cancer. Daraxonrasib is being advanced through a global Phase 3 registrational program comprising four trials, including the completed RASolute 302 trial and three additional trials in patients with PDAC and metastatic RAS mutant NSCLC.

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 Revolution Medicines, Inc.

Revolution Medicines is a 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 and the potential for a new class of RAS-targeted therapy to emerge; treatment practices for pancreatic cancer and the potential for daraxonrasib to become a standard of care; the company's regulatory interactions; the company's ability to bring daraxonrasib to patients; 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' Quarterly 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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