European Medicines Agency Expedites Assessment of Revolution Medicines' Daraxonrasib Under Phased Review Process

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- Phased review by EMA aims to accelerate assessment of company's investigational drug daraxonrasib in pancreatic cancer based on unprecedented clinical results from pivotal Phase 3 RASolute 302 trial
- Rolling submission of NDA for daraxonrasib to U.S. FDA under Commissioner's National Priority Voucher pilot program nearing completion

REDWOOD CITY, Calif., July 07, 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 European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has started a phased review of data on daraxonrasib, the company's investigational RAS(ON) multi-selective inhibitor. A phased review aims to accelerate the assessment of a medicine by evaluating the data in phases as they become available, ahead of the submission of a full marketing authorization application. Daraxonrasib was designated by the EMA as an orphan medicinal product for the treatment of pancreatic cancer and has been recognized as a high priority under EMA's Cancer Medicines Pathfinder project based on its potential to address a high unmet medical need.

In addition, the company continues to make significant progress on its rolling submission of a New Drug Application (NDA) for daraxonrasib to the U.S. Food and Drug Administration (FDA) under the 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.

"As our rolling submission of an NDA to the FDA nears completion, we are encouraged by the strong engagement we've received from health authorities around the world," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "The EMA's decision to include daraxonrasib in its new phased review process is an important step toward making this medicine available to patients globally as quickly as possible. We believe this milestone underscores both the significant unmet medical need in pancreatic cancer and the potential of daraxonrasib to address that need."

The company continues to engage in discussions with regulatory authorities around the world as it prepares for submissions in additional territories. The ongoing FDA review and planned regulatory submissions in other territories are supported by the positive results from the pivotal Phase 3 RASolute 302 trial, which demonstrated unprecedented improvements in overall survival and progression-free survival compared to standard of care cytotoxic chemotherapy in patients with previously treated metastatic PDAC, with or without an identified tumor RAS mutation. In the trial, 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.

About Daraxonrasib

Daraxonrasib is an investigational, oral RAS(ON) multi-selective, non-covalent tri-complex inhibitor. 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. 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.

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. Pancreatic ductal adenocarcinoma, or PDAC, is the most common form of pancreatic cancer.[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. PDAC is the most commonly RAS-driven malignancy of all major cancers, with more than 90% of patients having 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 progression of clinical studies and findings from these studies, including the tolerability, safety, and potential efficacy of the company's

candidates being studied; the company's regulatory strategy and the timing, status and progress of any regulatory submissions; discussions with regulatory agencies including the EMA and FDA; and the potential for daraxonrasib to address unmet medical needs.

Forward-looking statements are typically, but not always, identified by the use of words such as "aims," "anticipate," "believe," "continues," "intend," "nears," "plan," "potential," 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' 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.

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

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