European Commission Approves Revolution Medicines' RASONQUE® (daraxonrasib), the First Broad RAS-Targeted Medicine in Metastatic Pancreatic Cancer

November 16, 2026

- RASONQUE once-daily oral tablets indicated as a monotherapy for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy
- Approval includes patients with or without an identified RAS tumor mutation
- Revolution Medicines is working to enable patient access in European Union, with timing dependent on country-specific pricing and reimbursement processes

REDWOOD CITY, Calif., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Revolution Medicines, Inc. (Nasdaq: RVMD), a global, commercial-stage oncology company dedicated to discovering, developing and delivering innovative medicines for patients with RAS-addicted cancers, today announced that the European Commission (EC) has approved RASONQUE (daraxonrasib) for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy.[1] RASONQUE, given once daily as oral tablets, is approved for adults with metastatic pancreatic adenocarcinoma with or without an identified RAS tumor mutation.

"For decades, physicians treating metastatic pancreatic cancer have had limited options beyond cytotoxic chemotherapy, underscoring the urgent need for new therapeutic approaches," said Dr. Thomas Seufferlein, medical director, Clinic for Internal Medicine I, Ulm University Hospital. "The European Commission's approval of daraxonrasib represents an important advance for patients with this aggressive and difficult-to-treat disease. The unprecedented survival benefit demonstrated in the RASolute 302 clinical trial underscores the potential of daraxonrasib to establish a new standard of care for eligible patients with metastatic pancreatic cancer across the European Union."

"Today's European Commission approval of RASONQUE represents a pivotal moment for people in the European Union living with metastatic pancreatic cancer, as well as their families," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "With RASONQUE now approved, we are actively working with healthcare systems and stakeholders across the region to support timely access for eligible patients. We also continue to engage with regulatory authorities around the world with the goal of expanding and accelerating the reach of RASONQUE to patients who may benefit from it."

The approval by the EC follows the positive opinion of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), which was part of an expedited phased review under the EMA's Cancer Medicines Pathfinder project based on its potential to address a high unmet medical need.

The EC approval is based on results from the Phase 3 RASolute 302 clinical trial, presented at the 2026 American Society of Clinical Oncology Annual Meeting and simultaneously published in *The New England Journal of Medicine*. RASolute 302 was a global, randomized Phase 3 trial evaluating RASONQUE versus investigator's choice of cytotoxic chemotherapy in patients with previously treated metastatic PDAC. The trial met all primary and key secondary endpoints in both the RAS G12 mutant population and the overall intent-to-treat (ITT) population, which included patients with or without an identified tumor RAS mutation.

The EC has granted marketing authorization for RASONQUE in all European Union member states as well as the European Economic Area (EEA) countries Iceland, Norway, and Liechtenstein. This marketing authorization does not apply in the United Kingdom or Switzerland, which have separate regulatory approval processes.

Revolution Medicines is working closely with reimbursement and assessment bodies in European Union countries to enable broad and rapid access to patients in need. Timing of patient access will vary by country and depends on completion of national pricing, health-technology assessment and reimbursement processes.

About Pancreatic Adenocarcinoma

Pancreatic adenocarcinoma, or PDAC, is the most common form of pancreatic cancer and among the most lethal malignancies, frequently with a late diagnosis, aggressive biology, and limited responsiveness to conventional treatments. RAS, a key growth control switch in human cells, is the main driver of pancreatic cancer, which is characterized by excessive RAS signaling. Approximately 147,000 people are diagnosed with pancreatic cancer in Europe each year, and the five-year survival rate remains below 10%.[2,3] Because early-stage pancreatic cancer often causes few or no symptoms, approximately 80% of patients are diagnosed after the disease has spread, when treatment options are more limited.[4]

About RASONQUE™ (daraxonrasib)

RASONQUE (daraxonrasib) is an oral, RAS(ON) multi-selective, noncovalent, tri-complex inhibitor (TCI), approved by the U.S. FDA for the treatment of adult patients with metastatic pancreatic adenocarcinoma (PDAC) who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy, and granted marketing authorization by the EC for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy.[1,5] RASONQUE is being investigated through global Phase 3 registrational trials in patients with PDAC and metastatic RAS mutant non-small cell lung cancer (NSCLC).

About the RASolute 302 Clinical Trial

RASolute 302 (NCT06625320) was a global, randomized Phase 3 registrational clinical trial designed to evaluate the efficacy and safety of RASONQUE as a monotherapy in patients with previously treated metastatic pancreatic adenocarcinoma (PDAC). In the trial, patients were randomized to receive either an oral dose of 300 mg RASONQUE once daily or investigator's choice of four different cytotoxic chemotherapy regimens, which represented 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.

EU Indication

RASONQUE as monotherapy is indicated for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy.

U.S. INDICATION

RASONQUE is indicated for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy.

U.S. IMPORTANT SAFETY INFORMATION

RASONQUE is associated with the following **Warnings and Precautions**: Dermatologic and Soft Tissue Toxicity, Stomatitis and Oral Disorders, Diarrhea, Gastrointestinal Perforation, Interstitial Lung Disease (ILD)/Pneumonitis, and Embryo-Fetal Toxicity.

U.S. WARNINGS AND PRECAUTIONS

Dermatologic and Soft Tissue Toxicity

RASONQUE can cause dermatologic toxicity, which may be severe. Clinical manifestations included, but were not limited to, rash, pruritus, paronychia, dry skin, and skin fissures. In clinical trials of patients with pancreatic adenocarcinoma, dermatologic toxicity occurred in 86% of patients treated with RASONQUE, of which 10% were Grade 3.

Monitor patients who develop dermatologic or soft tissue toxicities while receiving RASONQUE. Initiate prophylactic measures (e.g., topical corticosteroids, emollient creams, sunscreen, oral antibiotics) prior to the first dose of RASONQUE to reduce the risk of moderate to severe dermatologic reactions. Advise patients to limit sun exposure while taking RASONQUE. Initiate supportive measures (e.g., oral corticosteroids) as clinically indicated, and consider dermatologic consultation. Withhold, reduce the dose, or permanently discontinue RASONQUE based on severity.

Stomatitis and Oral Disorders

RASONQUE can cause stomatitis, including mouth ulcers and oral mucositis. In clinical trials of patients with pancreatic adenocarcinoma, stomatitis occurred in 57% of patients, of which 9% were Grade 3.

Monitor patients for signs and symptoms of stomatitis while receiving RASONQUE. Initiate a steroid-containing mouthwash for treatment of stomatitis and administer other topical treatments (e.g., chlorhexidine mouthwash, 2% lidocaine viscous) as clinically indicated. Withhold, reduce the dose, or permanently discontinue RASONQUE based on severity.

Diarrhea

RASONQUE can cause diarrhea. In clinical trials of patients with pancreatic adenocarcinoma, diarrhea occurred in 63% of patients, of which 6% were Grade 3.

If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Withhold, reduce the dose, or permanently discontinue RASONQUE based on severity.

Gastrointestinal Perforation

RASONQUE can cause gastrointestinal perforation. In clinical trials of patients with pancreatic adenocarcinoma, gastrointestinal perforation occurred in 0.9% of patients treated with RASONQUE, of which 0.5% were Grade 3, one event was Grade 4, and one event was fatal.

Monitor patients for gastrointestinal perforation. Withhold RASONQUE if gastrointestinal perforation is suspected. Reduce the dose or permanently discontinue RASONQUE if no other potential causes of gastrointestinal perforation are identified.

Interstitial Lung Disease (ILD)/Pneumonitis

RASONQUE can cause interstitial lung disease or pneumonitis. In clinical trials of patients with pancreatic adenocarcinoma, ILD/pneumonitis occurred in 2.4% of patients treated with RASONQUE, of which 0.9% were Grade 3, and one event was fatal.

Monitor patients for new or worsening pulmonary symptoms. Withhold RASONQUE if ILD/pneumonitis is suspected. Reduce the dose or permanently discontinue RASONQUE if no other potential causes of ILD/pneumonitis are identified.

Embryo-Fetal Toxicity

Based on findings in animals, RASONQUE can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with RASONQUE and for 1 week after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 30% of patients treated with RASONQUE. Serious adverse reactions occurring in ≥ 2% of patients treated with RASONQUE were diarrhea (3.7%), pyrexia (3.3%), sepsis (2.9%), fatigue (2.1%), and hemorrhage (2.1%).

Adverse reactions leading to permanent discontinuation of RASONQUE occurred in 2.9% of patients, including two patients who discontinued due to rash (0.8%).

The most common (≥ 20%) adverse reactions in patients treated with RASONQUE were rash, diarrhea, stomatitis, nausea, fatigue, vomiting, abdominal pain, edema, decreased appetite, and hemorrhage.

DRUG INTERACTIONS

- Strong CYP3A Inhibitors with P-gp Inhibition: Avoid concomitant use.
- Strong CYP3A Inhibitors without P-gp Inhibition: Reduce RASONQUE dosage.
- Moderate CYP3A Inhibitors with or without P-gp Inhibition: Reduce RASONQUE dosage.
- P-gp Inhibitors: Reduce RASONQUE dosage.
- Cyclosporine A: Avoid concomitant use.
- Strong CYP3A Inducers: Avoid concomitant use. Increase RASONQUE dosage if concomitant use cannot be avoided.
- Moderate CYP3A Inducers: Increase RASONQUE dosage.
- P-gp Substrates: Take at least 4 hours apart from RASONQUE.

PROPHYLACTIC MEASURES

When initiating RASONQUE and throughout treatment, prophylactic and concomitant medications are recommended to reduce the risk of dermatologic reactions:

- administer a topical corticosteroid (applied to the face and chest) and emollient creams
- advise patients to limit sun exposure and use broad-spectrum sunscreen (SPF 30 or higher)
- consider prophylactic oral antibiotics (e.g., doxycycline or minocycline)

Please see U.S. Full Prescribing Information for RASONQUE.

About Revolution Medicines, Inc.

Revolution Medicines is a global, commercial-stage oncology company dedicated to discovering, developing and delivering innovative medicines for patients with RAS-addicted cancers. Leveraging its differentiated RAS(ON) tri-complex inhibitor platform, the company is advancing a broad, integrated portfolio of oral RAS(ON) inhibitors designed to directly target the active, cancer-driving state of RAS. Founded on rigorous scientific inquiry and a willingness to challenge long-held assumptions, Revolution Medicines is committed to changing the trajectory of disease for patients with RAS-addicted cancers worldwide. For more information, visit www.revmed.com and follow Revolution Medicines on LinkedIn, X (Twitter) and Instagram.

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; treatment practices, including the potential of RASONQUE to establish a new standard of care; the availability of RASONQUE in Europe and beyond, including the timing patients will have access to the product; the company's regulatory interactions; and reactions to RASONQUE.

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 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 4, 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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[4] Rahib L, Coffin T, Kenner B. Factors driving pancreatic cancer survival rates. *Pancreas*. 2025;54(6):e530-e536. doi:10.1097/MPA.0000000000002489

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