



Revolution Medicines' RASONQUE™ (daraxonrasib) Receives Positive CHMP Opinion Recommending Marketing Authorization in European Union for Metastatic Pancreatic Cancer

October 15, 2026

- Recommendation based on results from Phase 3 RASolute 302 trial, which demonstrated a 60% reduction in risk of death compared with chemotherapy in the overall study population with statistically significant and clinically meaningful improvements across all primary and key secondary endpoints, regardless of tumor RAS mutation status
- Positive CHMP opinion follows an expedited phased review of RASONQUE under the EMA's Cancer Medicines Pathfinder project based on its potential to address a high unmet medical need

REDWOOD CITY, Calif., Oct. 15, 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 Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion of RASONQUE (daraxonrasib) once-daily oral tablets as a monotherapy indicated for the treatment of adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy. If approved by the European Commission (EC), RASONQUE would provide the first broad RAS-targeted treatment option in the European Union for adults with metastatic pancreatic adenocarcinoma.

"Today's positive CHMP opinion marks a major step toward making RASONQUE available to eligible adults with metastatic pancreatic cancer in the European Union," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "RASONQUE is an oral medicine designed to address RAS, the key driver of pancreatic cancer, and unprecedented results from the Phase 3 RASolute 302 trial demonstrated its potential to benefit patients with this devastating disease. Its expedited review under the EMA's Cancer Medicines Pathfinder project highlights how innovative regulatory pathways may help bring promising medicines to patients sooner. We look forward to the EC's consideration of this CHMP positive opinion as we continue to work with regulatory authorities around the world to pursue additional approvals and broaden access to RASONQUE."

RASolute 302: Phase 3 Clinical Trial Results Supporting Positive CHMP Opinion

The positive CHMP opinion is based on results from RASolute 302, 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 primary analysis from RASolute 302 was [presented](#) at the 2026 American Society of Clinical Oncology Annual Meeting with simultaneous publication in [The New England Journal of Medicine](#). In the ITT population, RASONQUE reduced the risk of death by 60% compared with chemotherapy, with a hazard ratio (HR) of 0.40 (95% confidence interval [CI]: 0.30–0.53; $p < 0.0001$). The median overall survival (OS) was 13.2 months (95% CI: 10.0–NE) with RASONQUE compared to 6.7 months (95% CI: 5.8–8.0) for chemotherapy. RASONQUE also showed significant improvements in progression-free survival (PFS) with an HR of 0.49 (95% CI: 0.38–0.64; $p < 0.0001$). The median PFS was 7.2 months (95% CI: 5.7–7.5) with RASONQUE compared to 3.6 months (95% CI: 2.9–4.2) with chemotherapy. Results were generally consistent in the RAS G12 population. A subsequent ad hoc OS analysis showed the median OS was 12.4 months with RASONQUE compared to 6.7 months for chemotherapy [HR: 0.49 (95% CI 0.39, 0.62)], which was generally consistent with the prespecified primary analysis.

The most common adverse reactions in patients treated with RASONQUE were diarrhea (63.1%), dermatitis acneiform (62.4%), stomatitis (55.5%), nausea (50.8%), vomiting (41.6%) and fatigue (33.2%).

Once granted by the EC, the centralized marketing authorization will be valid in all EU member states, as well as in the European Economic Area (EEA) countries Iceland, Norway and Liechtenstein; marketing authorization by the EC is not applicable in the United Kingdom or Switzerland, which have separate processes for considering new drug applications.

This CHMP Positive Opinion follows the approval of RASONQUE by U.S. Food and Drug Administration (FDA) on August 26, 2026.

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 available 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%.^{1,2} 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.³

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 PDAC who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy.⁴ RASONQUE is being investigated through a global Phase 3 registrational program in patients with PDAC and metastatic RAS mutant non-small cell lung cancer (NSCLC).

Outside the U.S., RASONQUE is an investigational agent that has not been approved by any regulatory authority. RASONQUE received orphan medicinal product designation for pancreatic cancer and high-priority status under EMA's Cancer Medicines Pathfinder project based on its potential to address a significant unmet need.

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 $\geq 2\%$ 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 ($\geq 20\%$) 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)

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; the review of the CHMP Opinion by the EC; the availability of RASONQUE in Europe and other jurisdictions; treatment practices; the company's regulatory interactions; and reactions to RASONQUE; 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 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 August 5, 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 Contacts

Media

media@revmed.com

Investors

investors@revmed.com

References

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³ Rahib L, Coffin T, Kenner B. Factors driving pancreatic cancer survival rates. *Pancreas.* 2025;54(6):e530-e536. doi:10.1097/MPA.0000000000002489

⁴ RASONQUE (daraxonrasib) Prescribing Information. Redwood City, CA: Revolution Medicines, Inc.; August 2026.