U.S. FDA Approves Revolution Medicines' RASONQUE™ (daraxonrasib), the First Broad RAS-Targeted Medicine in Metastatic Pancreatic Cancer

August 26, 2026

- 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
- In the Phase 3 RASolute 302 trial, RASONQUE reduced the risk of death by 60% and demonstrated an unprecedented overall survival benefit compared with chemotherapy, with statistically significant and clinically meaningful improvements across all primary and key secondary endpoints
- In the RASolute 302 trial, RASONQUE demonstrated manageable safety and a favorable tolerability profile compared to chemotherapy, and improved maintenance of patient-reported quality of life measures
- Once-daily oral RASONQUE tablets now available by prescription in the U.S., with comprehensive patient support offered through the company's (ON) *Path* ™ program
- Company to host webcast today, August 26, at 1:30 p.m. Eastern Time

This release contains multimedia assets available for download here

REDWOOD CITY, Calif., Aug. 26, 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 U.S. Food and Drug Administration (FDA) has approved RASONQUE (daraxonrasib) once-daily oral tablets, for the treatment of adults with metastatic pancreatic adenocarcinoma (PDAC) who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy.[1] RASONQUE represents the first targeted cancer medicine to be approved from a groundbreaking new class of RAS(ON) multi-selective and mutant-selective inhibitors.

Pancreatic cancer is among the most challenging malignancies, frequently presenting with a late diagnosis, aggressive biology and limited responsiveness to conventional treatments. RAS, a key growth control switch in human cells, is the main cause of pancreatic cancer, which is characterized by excessive RAS signaling. The approval of RASONQUE is for adults with metastatic PDAC with or without an identified RAS tumor mutation and does not require use of a companion diagnostic test.

"The FDA approval of RASONQUE is a monumental step forward for patients with pancreatic cancer and for the oncology field. For the first time, patients have an approved targeted medicine designed to directly inhibit the main cause of pancreatic cancer, RAS, which has been one of the most intractable disease targets since its discovery decades ago. The unprecedented results of the global Phase 3 trial position RASONQUE to become the new standard of care for patients with metastatic pancreatic cancer under an approved label that supports real-world clinical decision-making. This approval further validates our bold RAS(ON) inhibitor strategy that includes multi-selective and mutant-selective approaches targeting a major driver of pancreatic cancer and multiple other cancers. We continue to engage with global regulatory authorities with the goal of expanding and accelerating the reach of RASONQUE," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines.

"Today's landmark approval is the most significant advance we have seen in the fight against pancreatic cancer, a devastating disease. I believe this drug will transform how pancreatic cancer is treated, giving people the opportunity for more time with loved ones, the possibility of a better quality of life and optimism that continued research may lead to even greater advances," said Anna Berkenblit, M.D., chief scientific and medical officer of the Pancreatic Cancer Action Network (PanCAN). "In addition, an oral pill can offer a less burdensome treatment experience than standard intravenous chemotherapy. PanCAN will continue to empower patients and caregivers with the resources and knowledge they need to advocate for the care they deserve now that RASONQUE is available for doctors to prescribe."

"I believe daraxonrasib is well positioned to become a new standard of care for adults with metastatic pancreatic cancer who have already received at least one systemic therapy or who are not candidates for multiagent systemic therapy. For decades, despite RAS being the main driver and potential drug target for pancreatic cancer, physicians have largely relied on intravenous cytotoxic chemotherapy to treat this aggressive disease. This approval gives physicians the confidence that directly inhibiting RAS can make a striking difference for patients and provides a critically needed new approach to treating patients with metastatic pancreatic cancer," added 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.

RASolute 302: Phase 3 Clinical Trial Results Supporting FDA Approval

The FDA approval of RASONQUE is based on data 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. 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*.

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 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.

RASONQUE demonstrated manageable safety and a favorable tolerability profile. The most common (≥ 20%) adverse reactions in patients treated with RASONQUE were rash, diarrhea, stomatitis, nausea, vomiting, abdominal pain, edema, decreased appetite, and hemorrhage. Please see the Important Safety Information for RASONQUE below.

The trial also evaluated patient-reported outcomes in the ITT population, given the high symptom burden that patients with metastatic PDAC experience. Patients who received RASONQUE demonstrated a statistically significant and clinically meaningful delay in time to deterioration (TTD) for global health status and pain when compared to chemotherapy. RASONQUE prolonged the maintenance of global health status and quality of life, with a median TTD of 5.7 months versus 2.6 months with chemotherapy (HR=0.60 [95% CI: 0.46–0.79]; p<0.001). Additionally, RASONQUE delayed the worsening of clinically relevant pain, demonstrating a median TTD of 9.2 months compared to 3.8 months with chemotherapy (HR=0.51 [95% CI: 0.37–0.71]; p<0.001).

RASONQUE U.S. Availability and Patient Support

RASONQUE, approved as a 300 mg once-daily oral medicine, is now available in the U.S. for physicians to prescribe. The company today also announced the launch of (ON)*Path*, a comprehensive program available to patients who have been prescribed RASONQUE. The program can help with navigating insurance, financial assistance, and treatment education to ensure that patients can start and stay on their medication. More information is available at RASONQUE.com.

Company Webcast

Revolution Medicines will host a webcast on August 26, 2026, at 1:30 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 Pancreatic Adenocarcinoma

Pancreatic adenocarcinoma, or PDAC, is the most common form of pancreatic cancer and among the most challenging malignancies. Approximately 55,000 people are diagnosed with PDAC in the U.S. each year, and more than 50,000 die from the disease with current standard of care.[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. For patients with metastatic PDAC, the five-year relative survival rate is approximately 3% in the U.S.[4,5]

About RASONQUE™ (daraxonrasib)

RASONQUE is an oral, RAS(ON) multi-selective, noncovalent, tri-complex inhibitor, designed to target cancers driven by a broad range of common RAS genotypes, including pancreatic adenocarcinoma (PDAC), non-small cell lung cancer (NSCLC), and colorectal cancer. RASONQUE works by suppressing RAS signaling through inhibition of the interaction between both wild-type and mutant RAS(ON) proteins and their downstream effectors.

RASONQUE was approved by the U.S. FDA for the treatment of adults with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy and is being advanced through a global Phase 3 registrational program in patients with PDAC and metastatic RAS mutant NSCLC.

RASONQUE 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 RASONQUE new drug application is included in the FDA's Project Orbis initiative, which provides a framework for concurrent review of oncology applications by participating international authorities. The FDA granted RASONQUE Breakthrough Therapy Designation and Orphan Drug Designation for the treatment of patients with previously treated metastatic PDAC, as well as Breakthrough Therapy Designation for the treatment of adult patients with previously treated, locally advanced or metastatic NSCLC with KRAS mutations other than G12C who have received prior platinum-based chemotherapy and anti-PD-(L)1 antibody therapy.

Outside the U.S., daraxonrasib is an investigational agent that has not been approved by any regulatory authority. 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 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.

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.

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.

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.

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 here for full Prescribing Information.

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; RASONQUE becoming a standard of care, including that daraxonrasib will transform how PDAC is treated; the results of continued research; treatment experience of daraxonrasib; treatment practices for pancreatic cancer; regulatory filings, including our ability to expand and accelerate the potential reach of RASONQUE; commercial launch, product availability, payer coverage and reimbursement, and patient uptake; the timing and outcome of the EMA phased review and other regulatory filings outside the U.S.; 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, risks associated with the commercial launch of RASONQUE, including product availability, supply, payer coverage and reimbursement, and patient uptake, the timing and outcome of regulatory reviews outside the U.S., 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.

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References

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