Revolution Medicines

RASONQUE™ (daraxonrasib) U.S. FDA Approval

August 26, 2026

Legal Disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, product candidates, availability of funding, ability to manage existing collaborations and establish new strategic collaborations, licensing or other arrangements, the scope, progress, results and costs of developing our product candidates or any other future product candidates, conducting clinical trials, the broad potential of RAS(ON) inhibition, the potential market size and size of the potential patient populations for our product candidates, commercialization plans and capabilities, our launch readiness and the timing and success of our U.S. launch and our launch readiness and plans outside the United States, RASONQUE becoming, or being positioned or poised to become, a new or practice-changing standard of care, expected treatment practices for pancreatic cancer and the treatment experience associated with RASONQUE, the potential tolerability, safety and efficacy of our product candidates and of RASONQUE in settings outside its FDA-approved indication, the timing and likelihood of success of obtaining product approvals, plans and objectives of management for future operations, future results of anticipated products and the impact of global events and other macroeconomic conditions on our business are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. The information included in these materials is provided as of August 26, 2026, unless specified elsewhere herein, and is qualified as such. Except as required by applicable law, we undertake no obligation to update any forward-looking statements or other information contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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 on August 5, 2026. Except for RASONQUE in its FDA-approved indication, all other Revolution Medicines product candidates and uses discussed in this presentation are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

This presentation includes certain information regarding publicly available results from clinical trials by third parties evaluating other products and product candidates. Such trials were not head-to-head trials with any of Revolution Medicines' product candidates and include differences in study protocols, patient populations and reporting standards, and caution should be exercised when comparing data across trials.

The summaries of RASONQUE's indication, dosage, warnings and precautions and adverse reactions included herein are not complete and do not include all of the information needed to use RASONQUE safely and effectively. Please see the Important Safety Information included in this presentation and the full Prescribing Information for RASONQUE at RASONQUE.com.

Outside the United States, daraxonrasib is investigational and has not been approved by any regulatory authority.

Participants

Mark A. Goldsmith, M.D., Ph.D.

Chief Executive Officer and Chairman

Alan Sandler, M.D.

Chief Development Officer

Anthony Mancini

Chief Global Commercialization Officer

Wei Lin, M.D.

Chief Medical Officer

Jack Anders

Chief Financial Officer

Opening Remarks

Now Approved

RASONQUE™

(daraxonrasib) tablets 100 mg 150 mg

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RASONQUE | Key Takeaways

Unprecedented overall survival in registrational Phase 3 trial

Poised to become new **practice-changing standard of care** in eligible patients with metastatic PDAC

Fully **launch ready and operational** in the U.S.

First approval proof point for RevMed's **bold RAS(ON) inhibitor strategy**

PDAC, pancreatic adenocarcinoma

RASolute 302 was a Phase 3 trial evaluating the efficacy and safety of RASONQUE monotherapy vs SOC combination chemotherapy in adults with previously treated metastatic pancreatic adenocarcinoma.
mPDAC=metastatic pancreatic adenocarcinoma; RAS=rat sarcoma; SOC=standard of care.

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.

SELECT 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.

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%).

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.

Please see full Important Safety Information and Prescribing Information.

Historical PDAC Treatment Landscape and RASONQUE Clinical Evidence

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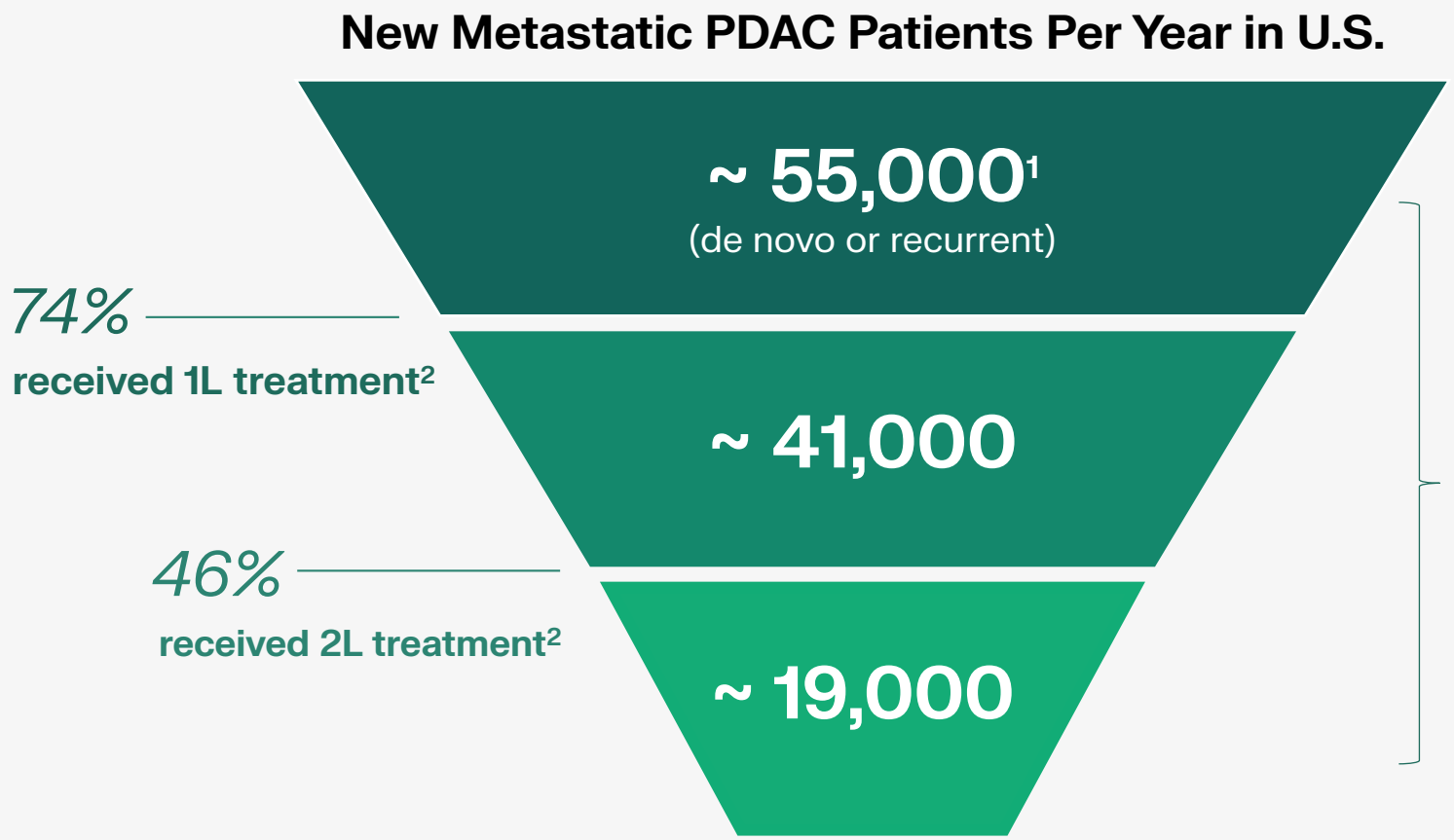
Historical U.S. Metastatic Pancreatic Cancer Management



Typical cytotoxic chemotherapy regimens for all treatment lines based on 5-FU or gemcitabine/paclitaxel

1L, first line; 2L, second line; 5-FU, 5-fluorouracil; PDAC, pancreatic adenocarcinoma.

References:
1. Oracle CancerMPact Patient Metrics, Stage IV newly incident + recurrent from earlier stages; accessed July 2026
2. King G, Ittershagen S, He L, Shen Y, Li F, Villacorta R. Treatment patterns in US patients receiving first-line and second-line therapy for metastatic pancreatic adenocarcinoma in the real world. Adv Ther. 2022;39(12):5433-5452. doi:10.1007/s12325-022-02317-9

RASONQUE Monotherapy Showed Encouraging Antitumor Activity and Manageable Safety Profile in Phase 1 Studies Across Tumor Types and Treatment Settings

Previously Treated Metastatic PDAC[1]

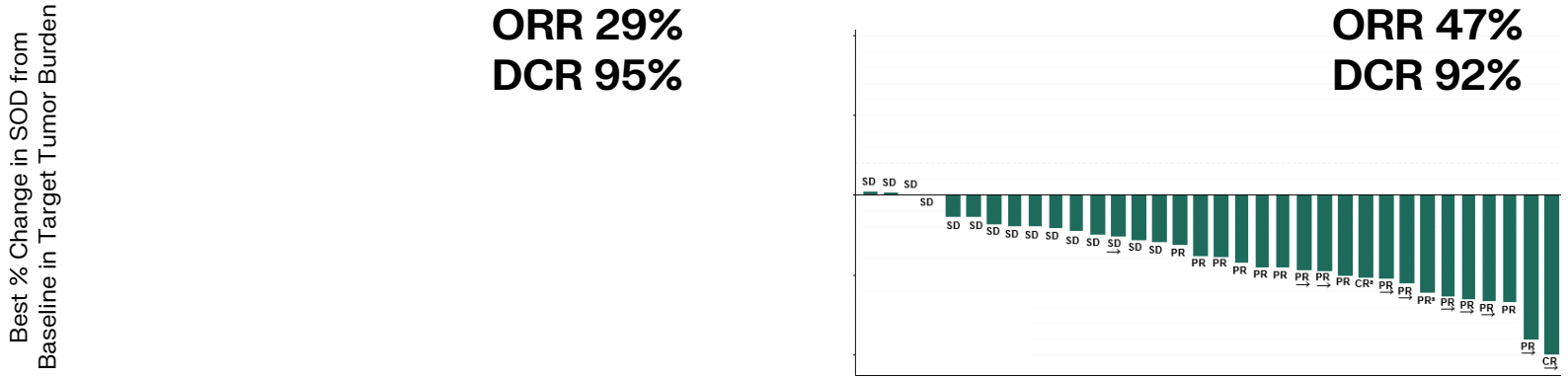
ORR 29%
DCR 95%

First-line Metastatic PDAC[2]

ORR 47%
DCR 92%

Previously Treated NSCLC[3]

ORR 38%
DCR 85%



Compelling Phase 1 results drove initiation of broad Phase 3 program

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Patient populations, doses, and duration of follow-up differ; cross-population comparisons are not intended. [1]Wolpin BM, et al. N Engl J Med. 2026;394:1790-1802. Previously treated PDAC: RAS mutant, n=38. [2]O'Reilly EM, et al. Cancer Res. 2026;86(8 Suppl):LB337. AACR Annual Meeting 2026. First-line PDAC: RAS mutant, n=38. [3]Punekar SR, et al. J Thorac Oncol. 2025;20(3):S10-S11. ELCC 2025. Previously treated NSCLC: RAS G12X, n=40. Data cutoffs: [1]30 Jun 2025; [2]1 Dec 2025; [3]30 Sep 2024. ORR, objective response rate; DCR, disease control rate; PDAC, pancreatic adenocarcinoma; NSCLC, non-small cell lung cancer; SOD, sum of diameters. Ongoing studies and uses outside the approved indication remain investigational.

RASONQUE in Five Global, Randomized Phase 3 Trials to Date

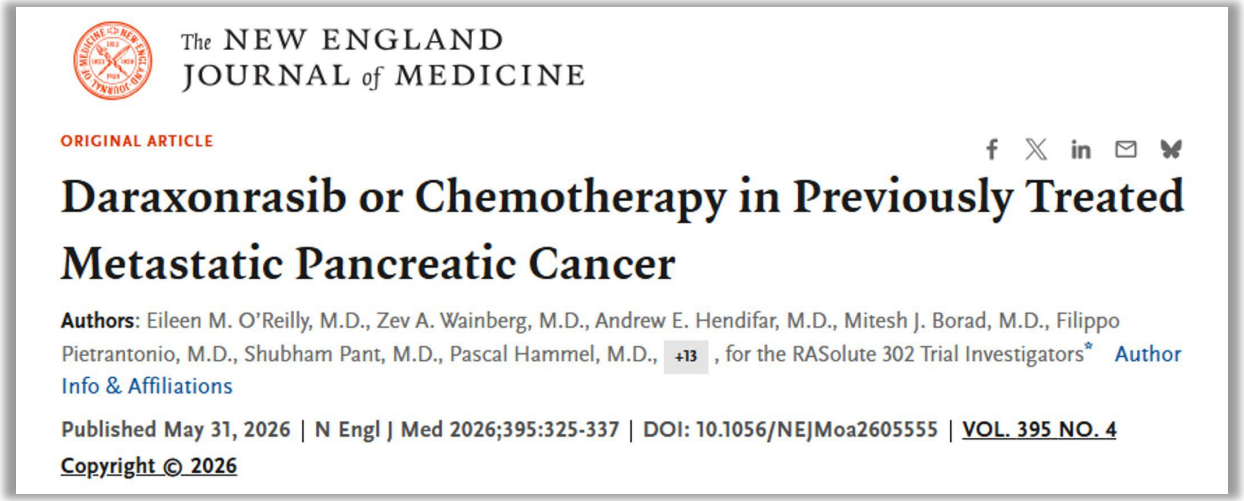
>2,000 patients treated with RASONQUE across clinical studies in multiple tumor types and treatment settings

Tumor	Phase 3 Trial	Treatment Setting	Status
PDAC	RASolute 302	Previously treated metastatic PDAC	Completed
PDAC	RASolute 303	First-line metastatic PDAC	Ongoing
PDAC	RASolute 304	Adjuvant for resectable PDAC	Ongoing
PDAC	RASolute 309	First-line RAS G12D metastatic PDAC	Initiated
NSCLC	RASolve 301	Previously treated RAS mutant NSCLC	Ongoing

Ongoing studies and uses remain investigational. PDAC, pancreatic adenocarcinoma; NSCLC, non-small cell lung cancer.

Supporting Data and Approved Label

RASolute 302: Unprecedented Overall Survival Benefit in Patients with Previously Treated Metastatic Pancreatic Cancer



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Daraxonrasib or Chemotherapy in Previously Treated Metastatic Pancreatic Cancer

Authors: Eileen M. O'Reilly, M.D., Zev A. Wainberg, M.D., Andrew E. Hendifar, M.D., Mitesh J. Borad, M.D., Filippo Pietrantonio, M.D., Shubham Pant, M.D., Pascal Hammel, M.D., +13, for the RASolute 302 Trial Investigators* Author Info & Affiliations

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Oral, once-daily RASONQUE demonstrated **statistically significant and clinically meaningful** improvements in overall survival, progression-free survival, and patient reported outcomes compared with SOC IV chemotherapy

RASONQUE outcomes in the overall, intent-to-treat population:

60% reduction
in the risk of death
OS hazard ratio: **0.40**

Near doubling median OS
to **13.2 months**

Generally well tolerated[1]
Manageable safety profile

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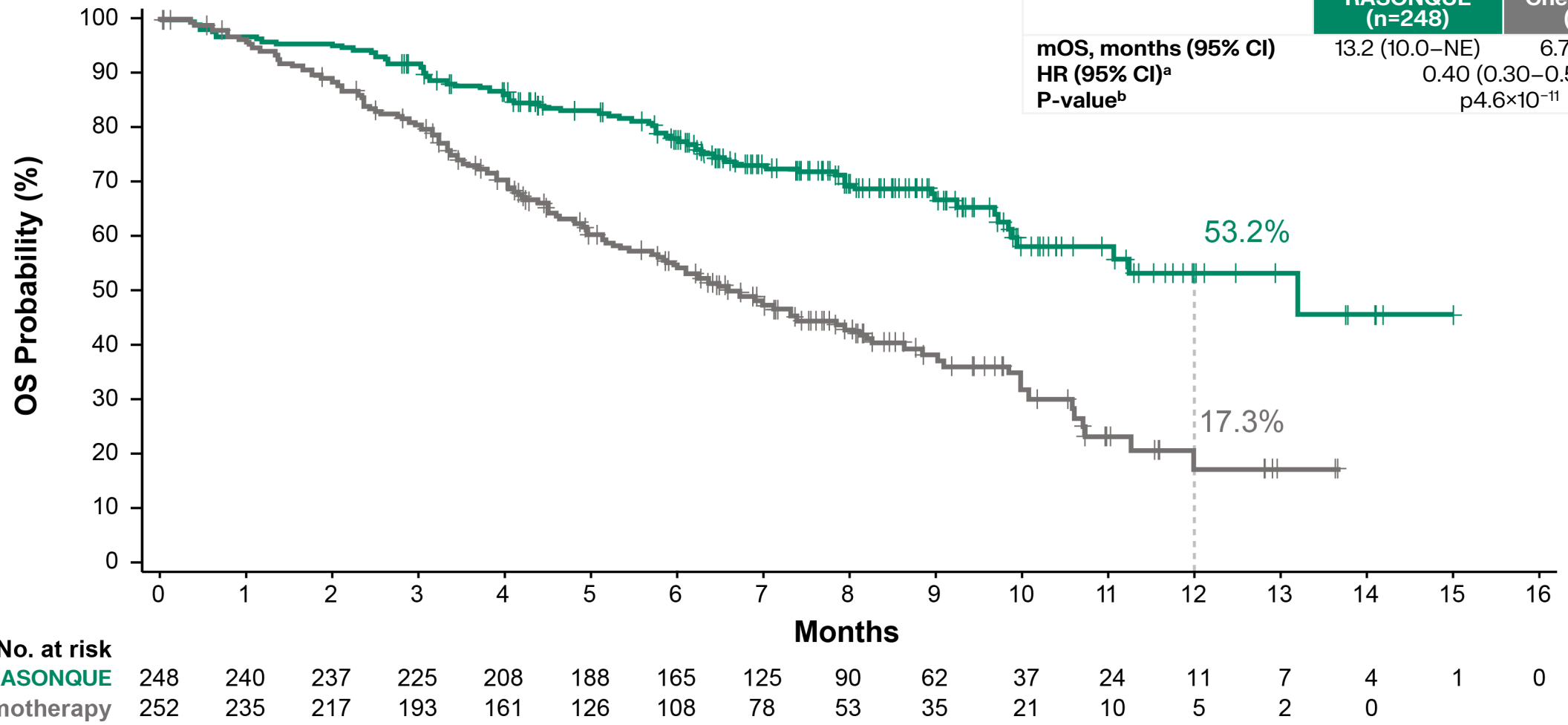
[1]Please see Important Safety Information on slides 32 and 33 and Full Prescribing Information at rasonque.com
Data cutoff: 10 Feb 2026; data from overall intent-to-treat population. Intent-to-treat population includes patients with and without identified tumor RAS mutations. OS, overall survival; PFS, progression-free survival; SOC, standard of care.

Overall Survival in the Overall Study Population

	RASONQUE (n=248)	Chemotherapy (n=252)
mOS, months (95% CI)	13.2 (10.0–NE)	6.7 (5.8–8.0)
HR (95% CI)[a]	0.40 (0.30–0.53)	
P-value[b]	p4.6×10^{-11}	



No. at risk																
RASONQUE	248	240	237	225	208	188	165	125	90	62	37	24	11	7	4	1	0
Chemotherapy	252	235	217	193	161	126	108	78	53	35	21	10	5	2	0		

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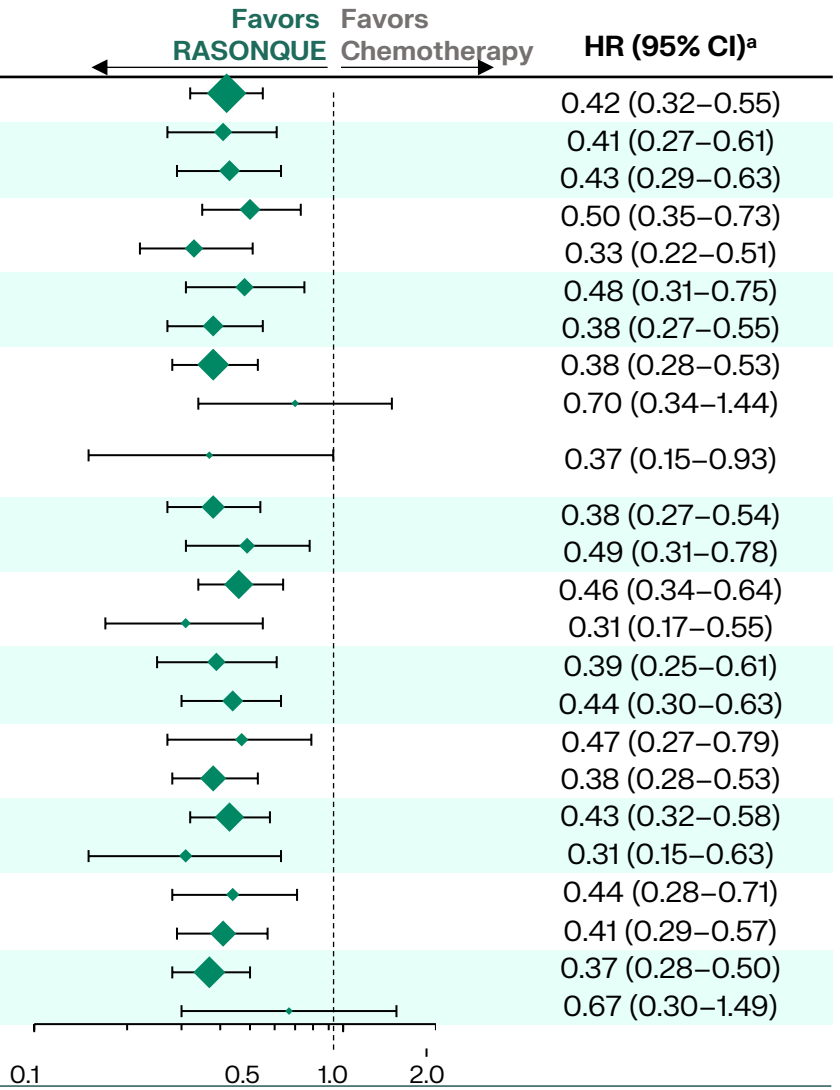
Presented at ASCO Annual meeting 2026. Data from O'Reilly EM, et al. N Engl J Med. 2026. DOI: 10.1056/NEJMoa2605555.
Data cutoff: 10 Feb 2026. Median (range) follow-up time was 8.5 (3.2–15.9) months; number of events: RASONQUE: 79 (32%); chemotherapy: 141 (56%).
[A] HRs and 95% CIs were based on the stratified Cox model with Efron's method of tie handling. [b] P-values were calculated using the stratified log-rank test.
m, median; NE, not estimable; OS, overall survival.

Overall Survival Benefit was Consistent Across All Subgroups

Population		Events/N RASONQUE	Events/N Chemotherapy	HR (95% CI)[a]
Overall		79/248	141/252	0.42 (0.32–0.55)
Age, years	<65	37/114	68/121	0.41 (0.27–0.61)
	≥65	42/134	73/131	0.43 (0.29–0.63)
Sex	Male	45/131	77/144	0.50 (0.35–0.73)
	Female	34/117	64/108	0.33 (0.22–0.51)
ECOG PS	0	33/129	51/118	0.48 (0.31–0.75)
	1[b]	46/119	90/134	0.38 (0.27–0.55)
Tumor RAS mutational status	RAS G12D/V	59/197	110/197	0.38 (0.28–0.53)
	Other RAS G12	13/31	17/34	0.70 (0.34–1.44)
	RAS G13 or Q61, or no RAS mutation identified	7/20	14/21	0.37 (0.15–0.93)
Metastatic disease at diagnosis	Yes	51/154	94/154	0.38 (0.27–0.54)
	No	28/94	47/98	0.49 (0.31–0.78)
Prior 5-FU-based regimen	Yes	62/181	103/186	0.46 (0.34–0.64)
	No	17/67	38/66	0.31 (0.17–0.55)
Prior gemcitabine-based regimen	Yes	31/110	61/114	0.39 (0.25–0.61)
	No	48/138	80/138	0.44 (0.30–0.63)
Prior pancreatectomy	Yes	21/83	40/92	0.47 (0.27–0.79)
	No	58/165	101/160	0.38 (0.28–0.53)
Liver metastases at baseline	Yes	68/174	113/176	0.43 (0.32–0.58)
	No	11/74	28/76	0.31 (0.15–0.63)
Peritoneal metastases at baseline	Yes	28/76	48/83	0.44 (0.28–0.71)
	No	51/172	93/169	0.41 (0.29–0.57)
CA19-9 level at baseline	≥40 U/mL	70/211	121/195	0.37 (0.28–0.50)
	<40 U/mL	9/36	19/56	0.67 (0.30–1.49)

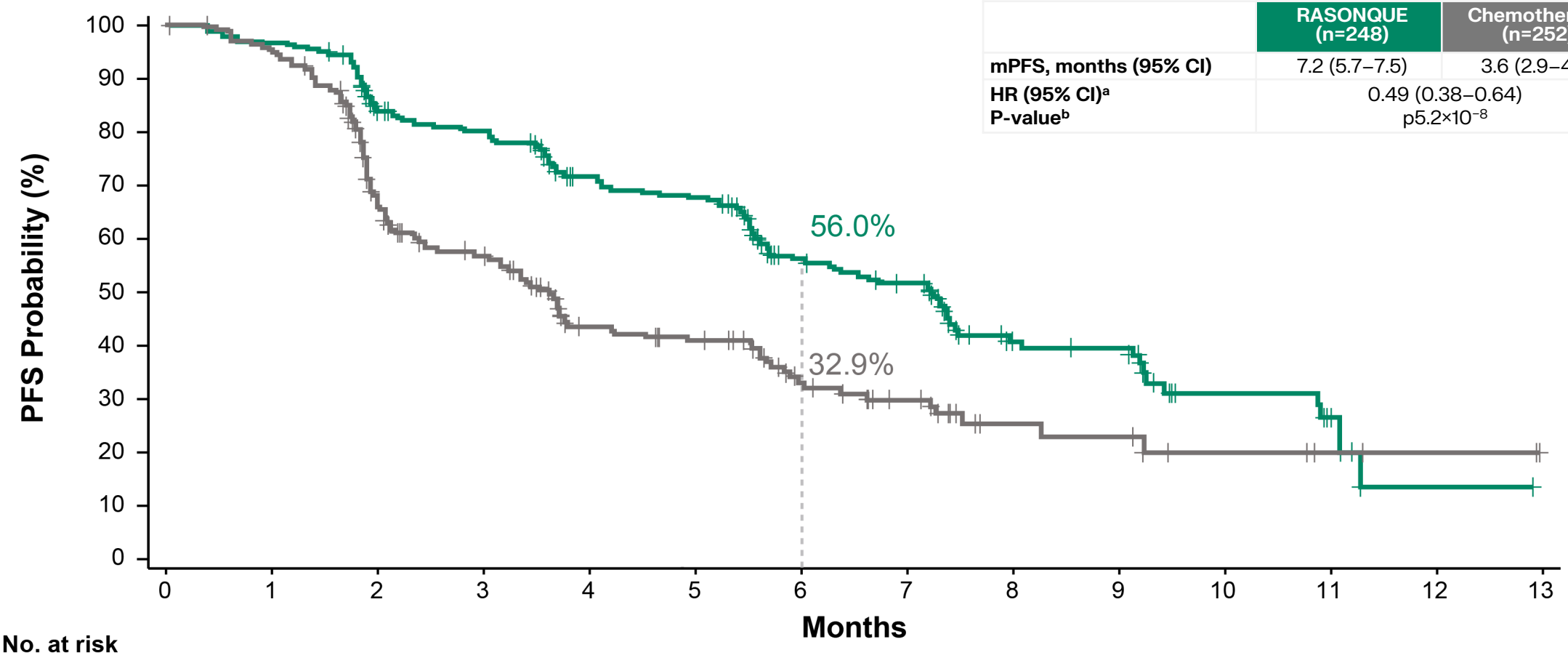


Revolution Medicines

Presented at ASCO Annual meeting 2026. Data from O'Reilly EM, et al. N Engl J Med. 2026. DOI: 10.1056/NEJMoa2605555.
Data cutoff: 10 Feb 2026. 5-FU, 5-fluorouracil; ECOG, Eastern Cooperative Oncology Group; PS, performance status.
aThe size of diamonds is relative to the size of the population in each subgroup. HRs and 95% CIs were based on the unstratified Cox model with Efron's method of tie handling. bThree patients (including 2 patients randomized to the RASONQUE arm and 1 patient randomized to the chemotherapy arm) had ECOG PS >1 at baseline. These patients were not dosed due to no longer meeting trial eligibility criteria.

Progression-Free Survival in the Overall Study Population

	RASONQUE (n=248)	Chemotherapy (n=252)
mPFS, months (95% CI)	7.2 (5.7–7.5)	3.6 (2.9–4.2)
HR (95% CI)[a]	0.49 (0.38–0.64)	
P-value[b]	p5.2×10^{-8}	



No. at risk													
RASONQUE	248	238	198	184	147	139	86	76	32	30	14	10	1	0
Chemotherapy	252	203	129	102	64	58	32	24	10	9	5	3	2	0

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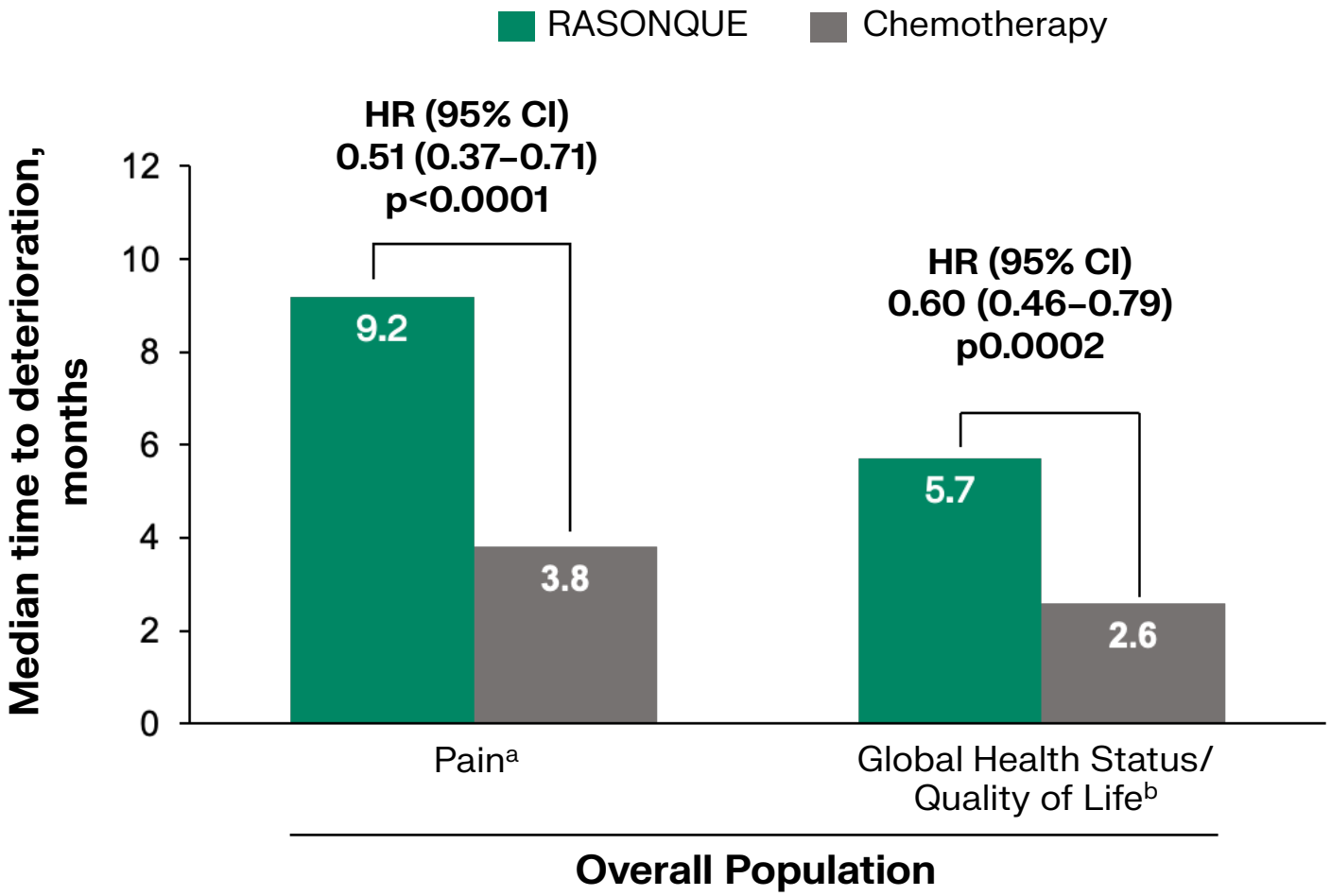
Presented at ASCO Annual meeting 2026. Data from O'Reilly EM, et al. N Engl J Med. 2026. DOI: 10.1056/NEJMoa2605555.
Progression-free survival was assessed by blinded independent central review (BICR). Data cutoff: 10 Feb 2026. Median (range) follow-up time was 8.5 (3.2–15.9) months; number of events: RASONQUE: 127 (51%); chemotherapy: 130 (52%). [a] HRs and 95% CIs were based on the stratified Cox model with Efron's method of tie handling. [b] P-values were calculated using the stratified log-rank test.
m, median; PFS, progression-free survival.

Patient-Reported Outcomes in the Overall Study Population



- EORTC QLQ-PAN26 and EORTC QLQ-C30 questionnaires were administered on day 1 of each cycle and at end of treatment visit
- RASONQUE significantly delayed time to deterioration in both symptom of pain and global health status/quality of life compared with chemotherapy

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Presented at ASCO Annual meeting 2026. Data from O'Reilly EM, et al. N Engl J Med. 2026. DOI: 10.1056/NEJMoa2605555.
Data cutoff: 10 Feb 2026. EORTC QLQ-C30, European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire; EORTC QLQ-PAN26, European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire – Pancreatic Cancer Module. [a] Time to deterioration in clinically relevant symptom of pain was defined as the time from randomization to an increase of at least 10 points from baseline in pain, or death, whichever occurs first, in the EORTC QLQ-PAN26 pain scale. [b] Time to deterioration in global health status/quality of life was defined as the time from randomization to a decrease of at least 10 points from baseline in global health status/quality of life, or death, whichever occurs first, in EORTC QLQ-C30.

Safety Overview

	RASONQUE (N=241)	Chemotherapy (N=214)
Median time on treatment, months (range)	6.2 (0.03-14.1)	1.5-3.2[a] (0.03-12.9)
Any TEAEs, n (%)	241 (100)	209 (98)
TEAEs leading to dose interruption	167 (69)	135 (63)
TEAEs leading to dose reduction	90 (37)	126 (59)
TEAEs leading to discontinuation	7 (3)	31 (15)
Grade ≥3 TEAEs	149 (62)	149 (70)
Serious TEAEs	73 (30)	71 (33)
Grade 5 TEAEs	5 (2)	4 (2)

- Median dose intensity:
  - 93% with daraxonrasib
  - 65-95%[a] across chemotherapy regimens
- RASONQUE exposure
  - 52% of patients exposed to RASONQUE for 6 months or longer
  - 2% exposed for greater than 1 year
- Most common (≥5%) TEAEs leading to dose reduction:
  - RASONQUE: rash (18%), stomatitis (8%) and diarrhea (5%)

Source: RASONQUE U.S. Prescribing Information.
Data cutoff: 10 Feb 2026. TEAE, treatment-emergent adverse event.
[a] Medians across each component of the chemotherapy regimens.

RASONQUE U.S. Label: Highlights of Prescribing Information

Indications and Usage	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.
Dosage and Administration	Recommended dosage: 300 mg orally once daily with or without food.
Dosage Form and Strengths	Tablets: 100 mg and 150 mg.
Warnings and Precautions	Dermatologic and soft tissue toxicity, stomatitis and oral disorders, diarrhea, gastrointestinal perforation, interstitial lung disease/pneumonitis, and embryo-fetal toxicity.
Adverse Reactions	Most common adverse reactions (≥ 20%) were rash, diarrhea, stomatitis,nausea, fatigue, vomiting, abdominal pain, edema, decreased appetite, andhemorrhage

Not to scale.

RASONQUE U.S. Prescribing Information. This summary does not include all information needed to use RASONQUE safely and effectively. Please see full Prescribing Information at rasonque.com.

Commercialization Strategy

Launch is Focused on Three Strategic Priorities

RASONQUE™ (daraxonrasib) tablets 100 mg 150 mg

Enable

patients and HCPs to achieve optimal treatment experience

Establish

RASONQUE as the new standard of care for eligible patients with metastatic PDAC

Ensure

broad coverage and seamless patient access

HCP, healthcare professional; PDAC, pancreatic adenocarcinoma

Ready to Reach All Key U.S. PDAC Stakeholders

U.S. PDAC Patients Treated by Site of Care

ACADEMIC HCPs

40% Scientific leadership, KOL activation & early adoption

COMMUNITY ONCOLOGY HCPs

60% Large treatment volume; focus on broad education & account reach

Key Access Stakeholders

PAYERS | IDNs | GPOs

Payers

Top 15 Payers ~80% of U.S. Covered Lives

Community & IDN/AMC

GPOs

Top 25 Stakeholders ~50% of Volume

Fit-for-purpose Field Teams in Place

Medical Affairs / MSLs

Academic HCPs / Opinion Leaders

Sales

Academic & Community HCPs

Fit-for-purpose Access Teams

National Account Teams

Primary: Payers, Integrated Delivery Networks & Group Purchasing Organizations

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HCP: Healthcare Professionals; IDN: Integrated Delivery Networks; GPO: Group Purchasing Organizations; AMC: Academic Medical Center; MSL: Medical Science Liaison; KOL, key opinion leader; PDAC, pancreatic adenocarcinoma

Comprehensive Patient Support at Launch to Enable Broad Access

U.S. Launch Access Strategy

- Broad coverage and seamless patient access
- Integrated access, affordability and adherence support designed to help eligible patients initiate and remain on therapy

Patient Services Program

- As little as $0 co-pay for eligible commercially insured patients*
- Support available from prescription through treatment journey

ON Path™

Integrated services at launch

1. Coverage navigation
2. Financial support
3. Adherence support
4. Education & resources

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* Program eligibility, terms and conditions apply.

Launching in the U.S. and Accelerating Global Launch Readiness

UNITED STATES

Full U.S. launch now underway

Commercial supply, distribution, patient services and field teams operational

EUROPE + JAPAN

Launch readiness advancing

Core teams established and rapidly expanding capabilities

GLOBAL ACCESS

International opportunity prioritized in phases

Broader international opportunity to be addressed market-by-market over time

GLOBAL NAMED PATIENT ACCESS[1]: Please visit revmed.com/pre-approval-access-to-investigational-medicines/

(1) Ability to access the drug will vary from country to country depending on local and regional requirements for the supply of unapproved medicinal products.

Closing Messages

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Pancreatic Cancer | Our Broad Strategy Aimed at Changing Standard of Care Across Early- to Late-Stage Disease Settings

Approved in Metastatic PDAC

RASONQUE

First Line Trials

RASolute 303 | RASolute 305 | RASolute 309

Adjuvant Trial

RASolute 304

Objectives:

- Establish RASONQUE as the new standard of care
  - First approved targeted medicine designed to broadly address metastatic PDAC by inhibiting RAS, its main driver
  - Foundation for commercial leadership in pancreatic cancer
- Expand across the treatment continuum
  - Four global Phase 3 registrational programs underway across first-line metastatic and adjuvant PDAC
  - Complementary monotherapy and combination strategies designed to address diverse patient needs

Strategy designed to transform treatment with a comprehensive franchise spanning **every major stage of disease**

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PDAC, pancreatic adenocarcinoma

Momentum with Broad and Differentiated Pipeline of RAS(ON) Inhibitors

Phase 3 Registrational Trials

	Molecule	Target	Trial	Treatment Setting	Regimen	Status
PDAC	RASONQUE	MULTI	RASolute 302	2L metastatic	Mono	Approved*
PDAC	RASONQUE	MULTI	RASolute 303	1L metastatic	Mono & Combo	Ongoing
PDAC	RASONQUE	MULTI	RASolute 304	Adjuvant in resectable	Mono	Ongoing
PDAC	Zoldonrasib	G12D	RASolute 305	1L metastatic	Combo	Ongoing
PDAC	Zoldonrasib + RASONQUE	G12D	RASolute 309	1L metastatic	Combo	Initiated
NSCLC	RASONQUE	MULTI	RASolve 301	2L/3L metastatic	Mono	Ongoing
NSCLC	Zoldonrasib	G12D	RASolve 308	1L metastatic	Combo	Initiated
NSCLC	Elironrasib	G12C	RASolve 307	1L metastatic	Combo	Pending

Phase 1/2 Clinical Development

RASONQUE™ (daraxonrasib) is approved in the U.S. and is also being evaluated in other settings, where it remains investigational.
Zoldonrasib (G12D), elironrasib (G12C), and RMC-5127 (G12V) are being evaluated in solid tumors across a range of monotherapy and combination treatment strategies.
RM-055 is currently advancing through IND-enabling studies. For more information, visit ClinicalTrials.gov.

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1L, first line; 2L, second line; 3L, third line; NSCLC, non-small cell lung cancer; PDAC, pancreatic adenocarcinoma
*RASONQUE is approved for adult patients with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy.

Our Vision | Creating an Industry-Leading Global Targeted Medicines Franchise for Patients with RAS-Addicted Cancers

DISCOVER

Continuous innovation through unique platform and insights to sustain leadership position and impact

DEVELOP

Broad clinical development of multiple investigational medicines across tumor types and treatment settings

DELIVER

Bringing transformative targeted medicines to patients through commercial excellence and global expansion

Insights from all three pillars drive a virtuous cycle that fuels **innovation** and **impact**

Thank you

Patients and their families who participated in RASolute 302 and other Revolution Medicines clinical studies

Investigators, nurses, support staff and KOLs in the US and internationally

Patient advocacy organizations

Revolution Medicines employees who have worked tirelessly to bring **RASONQUE** to patients

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Q&A

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On Target to Outsmart Cancer®

The information included in these materials is provided as part of an oral presentation on August 26, 2026 and is qualified as such. Revolution Medicines disclaims any duty to update the information contained in this presentation.

This presentation concerns RASONQUE™ (daraxonrasib), which has been approved for marketing by the U.S. Food and Drug Administration (FDA), as well as other product candidates and other uses of RASONQUE that are under clinical or pre-clinical investigation. Except for RASONQUE in its FDA-approved indication, the products and uses discussed in this presentation have not been approved for marketing by the FDA, are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated. Outside the United States, daraxonrasib is investigational and has not been approved by any regulatory authority. Please see the full Prescribing Information for RASONQUE at rasonque.com.

IMPORTANT SAFETY INFORMATION (1 of 2)

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.

IMPORTANT SAFETY INFORMATION (2 of 2)

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.

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)