Revolution Medicines Reports First Quarter 2025 Financial Results and Update on Corporate Progress

May 7, 2025

- Strong execution of two ongoing Phase 3 trials of daraxonrasib; company expects to substantially complete enrollment of RASolute 302 in patients with pancreatic cancer this year
- New non-small cell lung cancer clinical data from RAS(ON) inhibitor portfolio support strategies for first-line metastatic and earlier lines of treatment
- Anthony Mancini joins as chief global commercialization officer
- Revolution Medicines to hold webcast today at 4:30 p.m. Eastern Time

REDWOOD CITY, Calif., May 07, 2025 (GLOBE NEWSWIRE) -- Revolution Medicines, Inc. (Nasdaq: RVMD), a late-stage clinical oncology company developing targeted therapies for patients with RAS-addicted cancers, today announced its financial results for the quarter ended March 31, 2025, and provided an update on corporate progress.

The company continues to make meaningful progress on its 2025 strategic priorities:

Execute pivotal trials with daraxonrasib monotherapy in patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC) and non-small cell lung cancer (NSCLC)

In RASolute 302, a global Phase 3 trial in patients with previously treated PDAC, the company continues its strong pace of enrollment in the U.S. and has begun enrolling patients in the EU and Japan. The company expects to substantially complete enrollment this year to enable an expected data readout in 2026.

For RASolve 301, a global Phase 3 trial in patients with previously treated NSCLC, the company is currently activating study sites.

Advance daraxonrasib into first-line metastatic and earlier-line randomized pivotal trials in patients with PDAC

Planning continues for registrational trials for daraxonrasib as first-line (1L) treatment for patients with metastatic PDAC and as adjuvant treatment for patients with resectable disease, and the company expects to initiate both studies in the second half of this year.

Generate sufficient data to inform development priorities for the mutant-selective inhibitors elironrasib and zoldonrasib and prepare to initiate one or more pivotal trials either as monotherapy or in a drug combination

The company expects to initiate one or more pivotal combination trials in 2026 that incorporate either zoldonrasib or elironrasib. The company believes the updated data shared today support this approach.

Last month, zoldonrasib monotherapy data in patients with previously treated KRAS G12D mutant NSCLC were featured in a late-breaking oral presentation and included in the press program at the American Association for Cancer Research (AACR) Annual Meeting.

The company today announced updated elironrasib monotherapy data in patients with previously treated KRAS G12C mutant NSCLC.

The company today also announced several clinical combination updates in NSCLC, including daraxonrasib with pembrolizumab, elironrasib with pembrolizumab, and first data for the RAS(ON) inhibitor doublet combination of daraxonrasib with elironrasib in NSCLC.

Progress earlier-stage pipeline, including advancing next-generation innovations from the company's highly productive discovery organization

Last month at AACR, RMC-5127, a RAS(ON) G12V-selective inhibitor, was highlighted in a New Drugs on the Horizon presentation. This program is on track to reach a clinic-ready stage later this year to enable expected Phase 1 initiation in 2026.

Grow commercial and operational capabilities and increase pre-commercial activities in support of a potential launch

The company continues building its commercialization capabilities in the U.S. and welcomed Anthony Mancini as chief global commercialization officer and member of its senior management team. Mr. Mancini, who brings substantial experience from a decades-long career in the biotech and biopharmaceutical industry, will oversee commercialization strategy and operations and will contribute additional strength both to the company's commercialization approach in the U.S. and its evaluation of options for reaching patients outside of the U.S.

"We are executing well in our ongoing registrational studies of daraxonrasib in patients with previously treated PDAC and NSCLC, and continuing preparations to start the earlier-line PDAC trials this year. Today we've shared important data from all three of our clinical-stage investigational RAS(ON) inhibitors that reinforce exciting opportunities in NSCLC," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "As we continue growing our commercial and operational capabilities and advancing launch readiness activities, I'm pleased to welcome Anthony Mancini to our executive team."

Clinical Data Highlights

Data presented today, including items first shared at last month's AACR meeting, create exciting opportunities for the company in both previously treated and 1L metastatic NSCLC, including development approaches with mutant-selective inhibitors and drug combinations.

Zoldonrasib monotherapy in previously treated G12D NSCLC patients

Zoldonrasib, the company's RAS(ON) G12D-selective inhibitor, demonstrated acceptable tolerability and encouraging initial antitumor activity in patients with previously treated KRAS G12D mutant NSCLC. The company believes these results support further evaluation of zoldonrasib as

monotherapy and in combinations.

On April 27, 2025, the company presented initial clinical results from the zoldonrasib monotherapy trial. In 90 solid tumor patients treated at the candidate recommended Phase 2 dose of 1200 mg once daily (QD), as of a December 2, 2024 data cutoff, zoldonrasib was well tolerated with predominantly low-grade treatment-related adverse events (TRAEs). Grade 3 TRAEs were reported in 2% of patients and there were no Grade 4 or 5 TRAEs. The mean dose intensity (MDI) was favorable at 98%.

Preliminary antitumor activity was assessed in 18 efficacy-evaluable patients with previously treated NSCLC. The objective response rate (ORR) (confirmed or pending confirmation) was 61% and the disease control rate (DCR) was 89%.

Elironrasib monotherapy in previously treated G12C NSCLC patients

Elironrasib, the company's RAS(ON) G12C-selective inhibitor, demonstrated acceptable tolerability and encouraging initial antitumor activity in patients with KRAS G12C NCSLC who were previously treated with immunotherapy and chemotherapy.

Today, the company shared data for 36 patients who were treated with elironrasib monotherapy at the candidate monotherapy recommended dose of 200 mg twice daily (BID) as of an April 7, 2025 data cutoff. Elironrasib was generally well tolerated with predominantly low-grade TRAEs. Grade 3 TRAEs were reported in 19% of patients and there were no Grade 4 or 5 TRAEs. The MDI was favorable at 94%.

At the 200 mg BID dose, the ORR in NSCLC patients was 56%, and the DCR was 94%. The estimated median progression-free survival (PFS) in these patients was 9.9 months.

Combinations in NSCLC

The company presented several datasets that support combination strategies to enable its goal of improving treatment outcomes for patients with RAS mutant NSCLC in the 1L metastatic setting.

Daraxonrasib and pembrolizumab with or without chemotherapy

Daraxonrasib, a RAS(ON) multi-selective inhibitor, demonstrated acceptable tolerability and encouraging preliminary antitumor activity in combination with pembrolizumab with or without chemotherapy.

Today, the company shared data for ten patients in the 1L NSCLC setting treated with daraxonrasib and pembrolizumab, as of a February 10, 2025 data cutoff. No new safety signals were seen, and the overall safety profile was consistent with those of daraxonrasib alone and the standard of care agents.

Hepatotoxicity did not appear as a safety signal (no Grade 3 or higher events) in the combination of daraxonrasib and pembrolizumab with or without chemotherapy. No Grade 3 or higher AST or ALT elevations were reported and there was also no evidence of increased immune-related adverse events, such as colitis or pneumonitis, with the addition of daraxonrasib to pembrolizumab.

Daraxonrasib achieved a favorable MDI of 93% in combination with pembrolizumab and 90% with the addition of chemotherapy.

Of the seven 1L patients who had sufficient follow up to have had a tumor assessment, preliminary antitumor activity was encouraging.

Patients selected for treatment with daraxonrasib and pembrolizumab had tumors with a tumor proportion score (TPS) greater than or equal to 50%, consistent with a population where pembrolizumab is the preferred standard of care. Among seven efficacy-evaluable patients treated with the combination, the ORR was 86% and the DCR was 100%.

Patients selected for treatment with daraxonrasib with pembrolizumab and chemotherapy had tumors with TPS scores of less than 50%, where pembrolizumab and chemotherapy is the preferred standard of care. Among ten efficacy-evaluable patients treated with the combination, the ORR was 60% and the DCR was 90%. The company believes these data collectively support continued development of daraxonrasib with standard of care in RAS mutant NSCLC in the 1L metastatic setting.

Elironrasib with pembrolizumab in 1L RAS G12C mutant NSCLC

Today, the company shared data for eight patients with 1L KRAS G12C NSCLC from the combination of elironrasib with pembrolizumab, which showed acceptable tolerability and encouraging preliminary antitumor activity. As of a February 10, 2025 data cutoff, Grade 3 or higher TRAEs were reported in 25% of patients, and no new safety signals were observed. The MDI was favorable at 85%.

Among five efficacy-evaluable patients with 1L NSCLC with a TPS score of greater than or equal to 50% (where pembrolizumab monotherapy is the preferred standard of care), the ORR and DCR were both 100%.

RAS(ON) inhibitor doublet of elironrasib with daraxonrasib in NSCLC

Today, the company presented data that demonstrate acceptable tolerability and encouraging antitumor activity of the RAS(ON) inhibitor doublet of elironrasib with daraxonrasib in NSCLC patients previously treated with a KRAS G12C(OFF) inhibitor.

As of a February 10, 2025 data cutoff, in 33 patients treated with elironrasib at 200 mg BID and daraxonrasib at doses ranging from 100 mg to 200 mg daily, Grade 3 TRAEs were reported in 46% of patients. There were no Grade 4 or 5 TRAEs. Hepatotoxicity was not observed as a safety signal (no Grade 3 or higher events) and QT prolongation was limited with one asymptomatic Grade 3 event (3%).

The MDIs were favorable at 95% for elironrasib and 85% for daraxonrasib.

The combination of elironrasib with daraxonrasib showed encouraging preliminary antitumor activity in patients with NSCLC who have been previously treated with a KRAS G12C(OFF) inhibitor. The ORR was 62% and the DCR was 92%.

The company believes the preliminary results described for the above pairwise combinations support its goal of developing a chemotherapy-sparing triplet combination including elironrasib, daraxonrasib and pembrolizumab in patients with first-line metastatic RAS G12C NSCLC.

Financial Highlights

First Quarter Results

Cash Position: Cash, cash equivalents and marketable securities were $2.1 billion as of March 31, 2025.

R&D Expenses: Research and development expenses were $205.7 million for the quarter ended March 31, 2025, compared to $118.0 million for the quarter ended March 31, 2024. The increase in expenses was primarily due to increases in clinical trial expenses and manufacturing expenses for daraxonrasib, zoldonrasib and elironrasib, and personnel-related expenses and stock-based compensation expense related to additional headcount.

G&A Expenses: General and administrative expenses were $35.0 million for the quarter ended March 31, 2025, compared to $22.8 million for the quarter ended March 31, 2024. The increase was primarily due to increases in personnel-related expenses and stock-based compensation expense associated with additional headcount, and an increase in commercial preparation activities.

Net Loss: Net loss was $213.4 million for the quarter ended March 31, 2025, compared to net loss of $116.0 million for the quarter ended March 31, 2024.

Financial Guidance
Revolution Medicines is reiterating projected full year 2025 GAAP net loss guidance of between $840 million and $900 million, which includes estimated non-cash stock-based compensation expense of between $115 million and $130 million. Based on the company's current operating plan, the company projects current cash, cash equivalents and marketable securities can fund planned operations into the second half of 2027.

Webcast
Revolution Medicines will host a webcast this afternoon, May 7, 2025, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific 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 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; and zoldonrasib (RMC-9805), a RAS(ON) G12D-selective inhibitor, are currently in clinical development. The company anticipates that RMC-5127, a RAS(ON) G12V-selective inhibitor, will be its next RAS(ON) inhibitor to enter 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 the company's financial projections; the company's development plans and timelines and its ability to advance its portfolio and R&D pipeline; 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 expectations regarding timing of clinical trial initiation, enrollment and data readouts or disclosures; the company's plans to initiate registrational trials for daraxonrasib as first-line treatment for patients with metastatic PDAC and as adjuvant treatment for patients with resectable disease; the company's plans to initiate one or more pivotal trials that incorporate either zoldonrasib or elironrasib; the company's expectation that RMC-5127 will be its next RAS(ON) inhibitor to enter clinical development and that a Phase 1 study for this compound will be initiated; potential additional development opportunities in the company's pipeline, including RMC-0708 (Q61H) and RMC-8839 (G13C); and commercial strategy and priorities, including its commercialization approach in the U.S. and its evaluation of options for reaching patients outside of the U.S. Forward-looking statements are typically, but not always, identified by the use of words such as "may," "will," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," 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 the 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 7, 2025, 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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REVOLUTION MEDICINES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	205,749	118,021
General and administrative	35,011	22,838
Total operating expenses	240,760	140,859
Loss from operations	(240,760)	(140,859)
Other income (expense), net:		

Interest income	24,915	23,760
Other expense, net	(10)	(2,809)
Change in fair value of warrant liability and contingent earn-out shares	2,439	3,905
Total other income, net	27,344	24,856
Net loss	$ (213,416)	$ (116,003)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.13)	$ (0.70)
Weighted-average common shares used to compute net loss per share, basic and diluted	188,145,904	164,729,200

REVOLUTION MEDICINES, INC.
SELECTED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, unaudited)

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 2,102,675	$ 2,289,299
Working capital (1)	1,975,983	2,163,718
Total assets	2,365,353	2,558,301
Total liabilities	287,203	293,097
Total stockholders' equity	2,078,150	2,265,204

(1) Working capital is defined as current assets less current liabilities.