Revolution Medicines Doses First Patient in Phase 1/1b Clinical Trial of RMC-9805, an Oral, Covalent, Mutant-Selective KRASG12D(ON) Inhibitor

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$KRAS^{G12D}$(ON) Inhibitor with highly differentiated mechanism of action being evaluated in patients with cancers harboring the $KRAS^{G12D}$ mutation, the most common driver of RAS-addicted human cancers

REDWOOD CITY, Calif., Sept. 19, 2023 (GLOBE NEWSWIRE) -- Revolution Medicines, Inc. (Nasdaq: RVMD), a clinical-stage oncology company developing targeted therapies for RAS-addicted cancers, today announced the first patient was dosed in its Phase 1/1b monotherapy clinical trial of RMC-9805, an oral, covalent, mutant-selective $KRAS^{G12D}$(ON) Inhibitor designed to treat patients with cancers driven by the $KRAS^{G12D}$ mutation. $KRAS^{G12D}$ is the most common driver of RAS-addicted human cancers, accounting for nearly 55,000 newly diagnosed patients in the U.S. annually, predominantly among patients with pancreatic cancer, non-small cell lung cancer (NSCLC), and colorectal cancer.

The Phase 1/1b trial (NCT06040541) is a multicenter, open-label, dose-escalation and dose-expansion study of RMC-9805 in patients with advanced solid tumors harboring the $KRAS^{G12D}$ mutation. The primary objectives of the study are to evaluate safety and tolerability, and to inform the recommended Phase 2 dose and schedule for the compound.

“The initiation of patient dosing with RMC-9805 marks a major milestone for Revolution Medicines as its third oral RAS(ON) Inhibitor to begin clinical evaluation,” said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. “We are now studying in the clinic three highly innovative RAS(ON) Inhibitors derived from our pioneering tri-complex inhibitor platform that we believe have complementary profiles – RMC-6236 (RAS^{MULTI}) for patients with cancers caused by a wide range of RAS mutations, and the mutant-selective compounds RMC-6291 ($KRAS^{G12C}$) and RMC-9805 ($KRAS^{G12D}$) for patients with cancers harboring selected mutations. With this strong clinical portfolio, as well as a rich collection of additional mutant-selective drug candidates and research-stage assets, we believe our pipeline has the potential to change the standard of care for patients living with a wide range of RAS-addicted cancers including NSCLC, pancreatic cancers and colorectal cancers.”

About Revolution Medicines, Inc.
Revolution Medicines is a clinical-stage oncology company developing novel targeted therapies for RAS-addicted cancers. The company’s R&D pipeline comprises RAS(ON) Inhibitors designed to suppress diverse oncogenic variants of RAS proteins, and RAS Companion Inhibitors for use in combination treatment strategies. The company’s RAS(ON) Inhibitors RMC-6236 (RAS^{MULTI}), RMC-6291 ($KRAS^{G12C}$) and RMC-9805 ($KRAS^{G12D}$) are currently in clinical development. Additional RAS(ON) Inhibitors in the company’s pipeline include RMC-0708 ($KRAS^{Q61H}$) which is currently in IND-enabling development, RMC-8839 ($KRAS^{G13C}$), and additional compounds targeting other RAS variants. RAS Companion Inhibitors in clinical development include RMC-4630 (SHP2) and RMC-5552 (mTORC1/4EBP1).

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 dosing and enrollment in the company’s clinical trials and the tolerability, potential efficacy and utility of the company’s candidates being studied; and the ability of the company to change the standard of care for patients living with a wide range of RAS-addicted cancers. 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’ early stage of development, 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 worldwide COVID-19 pandemic. 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 8, 2023, and its future periodic reports to be filed with the Securities and Exchange Commission. 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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