Cardiff Oncology Receives FDA Fast Track Designation for Onvansertib in First-Line RAS-Mutated Metastatic Colorectal Cancer

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Designation covers onvansertib in combination with FOLFIRI/bevacizumab for adult patients with KRAS- or NRAS-mutated mCRC

The designation is supported by clinical data from the ongoing randomized, controlled CRDF-004 clinical trial

SAN DIEGO, Nov. 16, 2026 (GLOBE NEWSWIRE) -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company targeting RAS-mutated cancer by leveraging PLK1 inhibition, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to onvansertib in combination with FOLFIRI/bevacizumab (bev) for the first-line treatment of adult patients with KRAS- or NRAS-mutated metastatic colorectal cancer (mCRC).

“Patients with RAS-mutated mCRC have no first-line therapies specifically approved for their disease, and Fast Track designation reflects the potential of onvansertib to address this serious unmet need,” said Mani Mohindru, PhD, President and Chief Executive Officer of Cardiff Oncology. “Our randomized Phase 2 data give us confidence that onvansertib may provide an additive benefit to the current standard-of-care, as reflected in the maturing data from the ongoing trial. We look forward to working closely with the FDA as we advance onvansertib into our planned registrational trial and bringing this potential new treatment option to patients as quickly as possible.”

The Fast Track designation is supported by data from the Company’s ongoing randomized Phase 2 CRDF-004 trial in first-line RAS-mutated mCRC. The proposed Phase 3 regimen, 30 mg onvansertib + FOLFIRI/bev, achieved a 72.2% confirmed objective response rate, a 30-point improvement over FOLFIRI/bev alone (42.1%) in the intent-to-treat population. As of September 28, 2026, median progression-free survival had not been reached in the 30 mg arm, compared with approximately 11 months in the combined standard-of-care arms, and all patients remaining in the 30 mg arm have now been on treatment for at least 21 months. These results build on a prior Phase 1b/2 trial in second-line KRAS-mutated mCRC.

This designation also follows the FDA’s recent grant of Orphan Drug Designation to onvansertib for the treatment of chronic myelomonocytic leukemia and small cell lung cancer in October and November 2026, respectively.

About Fast Track Designation

Fast Track is an FDA program designed to facilitate the development and expedite the review of drugs intended to treat serious conditions and address an unmet medical need. A drug that receives Fast Track designation may be eligible for more frequent meetings and written communication with the FDA regarding its development plan, and, if relevant criteria are met, for Accelerated Approval and Priority Review. Fast Track designation also allows for Rolling Review, under which a company may submit completed sections of its marketing application for FDA review rather than waiting until every section is complete. Fast Track designation does not alter the standards for approval.

About Onvansertib

Onvansertib is a highly specific, oral PLK1 inhibitor advancing toward a registrational trial in first-line RAS-mutated metastatic colorectal cancer (mCRC). In a randomized Phase 2 trial, onvansertib in combination with FOLFIRI/bevacizumab (first-line standard-of-care) demonstrated dose-dependent improvements in overall response rate and progression-free survival compared to standard-of-care alone, building on findings from a prior Phase 1b/2 trial in second-line KRAS-mutated mCRC. Based on these results, the Company has selected the 30 mg dose of onvansertib in combination with FOLFIRI/bevacizumab as the regimen to advance into the planned registrational trial in first-line patients with RAS-mutated mCRC.

Onvansertib is also being evaluated in multiple other cancers through investigator-initiated studies, including metastatic pancreatic ductal adenocarcinoma (mPDAC) and triple-negative breast cancer (TNBC), as well as chronic myelomonocytic leukemia (CMML) and small cell lung cancer (SCLC), both of which have received FDA Orphan Drug Designation.

About RAS-Mutated Metastatic Colorectal Cancer (mCRC)

Colorectal cancer is among the most commonly diagnosed cancers and the second-leading cause of cancer deaths in the United States, with approximately 150,000 new cases each year[1]. About 23% of patients have metastatic disease at diagnosis, and the five-year relative survival rate for mCRC is approximately 15%[2]. Mutations in the KRAS or NRAS genes occur in approximately 52% of patients with mCRC and are associated with poorer outcomes. Patients with RAS-mutated mCRC are not candidates for anti-EGFR therapies, and first-line treatment has remained largely unchanged for two decades: chemotherapy combined with bevacizumab. There are currently no therapies specifically approved for first-line pan-RAS-mutated mCRC, highlighting the need for new treatments that can improve outcomes for this population.

1. American Cancer Society. Colorectal Cancer Statistics, 2026 (Siegel RL, et al. CA Cancer J Clin. 2026).
2. National Cancer Institute SEER Cancer Statistics

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage biotechnology company advancing innovative cancer treatments focused on PLK1 inhibition, a validated oncology target with practice-changing potential. Our lead asset, onvansertib, is a highly specific, oral PLK1 inhibitor currently being evaluated for first-line treatment of RAS-mutated metastatic colorectal cancer (mCRC), addressing a large, underserved patient population with high unmet need. Onvansertib is also under investigation in other PLK1-driven cancers through ongoing investigator-initiated trials and has shown robust single agent clinical activity in hard-to-treat tumors. By targeting tumor vulnerabilities, we aim to overcome treatment resistance and deliver improved clinical outcomes for patients.

For more information, please visit https://www.cardiffoncology.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified using words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Cardiff Oncology's expectations, strategy, plans or intentions. These forward-looking statements are based on Cardiff Oncology's current expectations and actual results could differ materially. There are several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; Fast Track designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that onvansertib will receive marketing approval; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidate; results of preclinical studies or clinical trials for our product candidate could be unfavorable or delayed; our need for additional financing; risks related to business interruptions, including cyber-attacks on our information technology infrastructure, which could seriously harm our financial condition and increase our costs and expenses; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that our product candidate will be utilized or prove to be commercially successful. Additionally, there are no guarantees that future clinical trials will be completed or successful or that our product candidate will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Cardiff Oncology's Form 10-K for the year ended December 31, 2025, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Cardiff Oncology does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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