



Cardiff Oncology Receives FDA Orphan Drug Designation for Onvansertib in Chronic Myelomonocytic Leukemia

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SAN DIEGO, Oct. 21, 2026 (GLOBE NEWSWIRE) -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel cancer therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to onvansertib for the treatment of patients with chronic myelomonocytic leukemia (CMML).

"CMML remains a difficult-to-treat hematologic malignancy with limited treatment options for patients, and 40-50% of myeloproliferative CMML¹ patients harbor RAS-pathway mutations, which are associated with more aggressive disease," said Mani Mohindru, PhD, President and Chief Executive Officer of Cardiff Oncology. "Receiving Orphan Drug Designation for onvansertib in CMML further validates the therapeutic potential of PLK1 inhibition in cancers with significant unmet need and adds to the growing body of evidence supporting this mechanism across both solid tumors and hematologic malignancies. We believe this designation highlights the broader clinical opportunity for onvansertib as a monotherapy as we continue advancing therapies for patients across cancers where new therapeutic approaches are urgently needed."

Onvansertib is being evaluated in both company-sponsored and investigator-initiated clinical studies, including a Phase 1 investigator-initiated study in relapsed/refractory CMML. As presented at the 2025 American Society of Hematology (ASH) Annual Meeting, onvansertib was relatively well-tolerated as a monotherapy and demonstrated preliminary efficacy in approximately 40% of myeloproliferative CMML patients in the dose ranging trial. The responses included three patients experiencing clinical benefits (38%), with one each of the following: a 100% platelet response, normalization of White Blood Cells, WBC (baseline WBC count > 50 x 10⁹/L), and spleen response. Additionally, one patient (12.5%) had optimal marrow response with bone marrow blast reduction from 8% to 2% facilitating for allogeneic hematopoietic stem transplant and 3 patients experienced stable disease (38%).

Orphan Drug Designation is granted by the FDA to support the development of therapies intended to treat rare diseases or conditions affecting fewer than 200,000 people in the United States. Benefits of the designation may include tax credits for qualified clinical trials, exemption from certain FDA user fees, and up to seven years of market exclusivity upon regulatory approval. Orphan Drug Designation does not alter the standard regulatory requirements or approval process.

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 2 trial in second-line RAS-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), small cell lung cancer (SCLC), triple-negative breast cancer (TNBC), and chronic myelomonocytic leukemia (CMML).

About Chronic Myelomonocytic Leukemia

Chronic myelomonocytic leukemia (CMML) is a rare and aggressive hematologic malignancy characterized by features of both myelodysplastic syndromes and myeloproliferative neoplasms. CMML primarily affects older adults and is associated with poor clinical outcomes, including progressive bone marrow failure and risk of transformation to acute myeloid leukemia (AML). Current treatment options remain limited, highlighting the need for novel targeted therapies that can improve outcomes for patients with this disease.

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; 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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¹. Carr RM, Vorobyev D, Lasho T, et al. RAS mutations drive proliferative chronic myelomonocytic leukemia via a KMT2A-PLK1 axis. *Nat Commun*. 2021;12(1):2901. Published 2021 May 18. doi:10.1038/s41467-021-23186-w