Cardiff Oncology Announces Positive Update from its Randomized Phase 2 Trial of Onvansertib in First-line RAS-mutated mCRC

January 27, 2026

- Onvansertib added to FOLFIRI/bev first-line standard of care regimen showed dose-dependent improvement in overall response rates and durability trends as measured by progression-free survival in patients with RAS-mutated mCRC –

- Data support selection of 30 mg onvansertib dose for registrational program in first-line RAS-mutated mCRC –

- Data validate previously reported positive results from Phase 2 trial of onvansertib with FOLFIRI/bev in second-line mCRC bev-naïve patients, as published in the Journal of Clinical Oncology –

- Onvansertib continues to be safe and well-tolerated –

- Company expects to provide final data and registrational plans in first half of 2026 –

- Company to hold conference call today at 8:30 a.m. ET/5:30 a.m. PT -

SAN DIEGO, Jan. 27, 2026 (GLOBE NEWSWIRE) -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced a positive update from CRDF-004, a randomized dose-finding Phase 2 clinical trial evaluating onvansertib in combination with standard of care (SoC) regimens (FOLFIRI/bevacizumab (bev) or FOLFOX/bev) in patients with first-line (1L) RAS-mutated metastatic colorectal cancer (mCRC). In an intent-to-treat analysis, the clinical data show dose-dependent benefits across multiple efficacy measures in patients receiving onvansertib with FOLFIRI/bev compared to patients receiving either SoC regimen. In this trial, onvansertib with FOLFIRI/bev also performed better than onvansertib with FOLFOX/bev.

Based on these results, the Company has selected the 30 mg dose of onvansertib with FOLFIRI/bev to bring forward in a registrational trial in 1L patients with RAS-mutated mCRC. Cardiff Oncology plans to initiate a registrational program later this year pending finalization of the trial design in consultation with the FDA, in which the Company expects to compare onvansertib with FOLFIRI/bev to SoC regimens, FOLFIRI/bev or FOLFOX/bev.

“These data demonstrate promising enhanced benefits of onvansertib when combined with FOLFIRI/bev in RAS-mutated mCRC patients,” said Mani Mohindru, PhD, interim Chief Executive Officer. “We observed a consistent, dose-dependent treatment benefit across multiple measures of efficacy, including achieving statistical significance for PFS compared to SoC even with relatively small patient numbers. The 30 mg onvansertib–FOLFIRI/bev arm outperformed both SoC arms with no significant additive toxicity, supporting findings from our previous Phase 2 trial in second-line RAS-mutated mCRC. While we continue to review data from the ongoing trial, our plan is to rapidly move forward with the onvansertib 30 mg dose in combination with FOLFIRI/bev and we believe confirmatory data from a registrational trial has the potential to make this regimen a new SoC for 1L treatment of RAS-mutated mCRC.”

Topline Results in intent-to-treat (ITT) population, data cut-off as of January 22, 2026

Parameter	SoC[c] (FOLFIRI/bev+FOLFOX/bev) (n=37)	FOLFIRI/bev (n=19)	Onv 20 mg +FOLFIRI/bev (n=18)	Onv 30 mg +FOLFIRI/bev (n=18)
Objective Response Rate (per BICR)[a]				
Confirmed Responders	16	8	8	13
Confirmed ORR (%)	43.2	42.1	44.4	72.2 p-value = 0.051[f] (vs SoC)
Progression Free Survival[b]				
Median PFS (months, 95% CI)	10.97 (9.43-15.44)	10.97 (7.52-NR)	NR (7.49-NR)	NR (9.72-NR)
PFS HR (vs FOLFIRI/bev)			0.56 (0.18-1.73)[d]	0.38 (0.12-1.17)[d]
PFS HR (vs SoC)			0.57 (0.21-1.58)[e]	0.37 (0.13-1.02)[e] p-value = 0.048[g] (vs SoC)
PFS Rate at 6 months (95% CI)	88.8 (77.4-100)	79.5 (61.1-100)	88.1 (73.9-100)	94.1 (83.6-100)

Bev=bevacizumab; BICR=Blinded Independent Central Review; CI=confidence interval; HR=hazard ratio; NR=not reached; Onv=onvansertib; ORR=objective response rate; PFS=progression-free survival; SoC=standard of care.

[a]ORR is confirmed responses

[b]Progressive disease events were based on combined BICR and Investigator assessments due to very small number of events in BICR assessment. The earliest reported date was used for a conservative estimate.

[c]SoC is the combination of the FOLFIRI/bev and FOLFOX/bev arms

[d]PFS HR is the comparison of the onvansertib arm to FOLFIRI/bev

[e]PFS HR is the comparison of the onvansertib arm to SoC

[f]Fisher’s exact test

[g]Log-rank test

“There is a clear need for improved first-line treatment options for patients with mCRC, especially the half of those with RAS-mutated disease,” said Dr.

J Randolph Hecht, MD, Professor of Clinical Medicine at the David Geffen School of Medicine at UCLA. “Unfortunately, first-line treatment for these patients hasn’t improved significantly for more than two decades. Onvansertib has a novel mechanism of action and these preliminary responses and PFS results in combination with FOLFIRI/bevacizumab are encouraging enough to test in a large Phase 3 trial. If such a trial were positive, it could become a new standard of care for these patients.”

Onvansertib in combination with both chemo/bev regimens was well-tolerated. There were no major or unexpected toxicities observed and no additive adverse events. Grade 3 or higher adverse events were infrequent, with neutropenia being the most common treatment-emergent adverse event across both the onvansertib combination and standard of care arms.

Conference Call and Webcast
Cardiff Oncology will host a conference call and live webcast today, January 27, 2026 at 8:30 a.m. ET / 5:30 a.m. PT. Individuals interested in listening may do so by using the link in the "Events" section of the Company's website. A replay will be available in the investor relations section on the Company's website following the completion of the call.

CRDF-004 Trial Design
The CRDF-004 Phase 2 trial was designed to evaluate two doses of onvansertib to identify the lowest maximally effective dose and to assess the safety, efficacy, and pharmacokinetics of onvansertib in combination with FOLFIRI/bevacizumab or FOLFOX/bevacizumab in first-line patients with KRAS- or NRAS-mutated metastatic colorectal cancer (mCRC). The trial’s endpoints include objective response rate (ORR), progression-free survival (PFS), duration of response, and safety.

For additional information about the trial, please visit www.clinicaltrials.gov (Trial ID: NCT06106308).

About Onvansertib
Onvansertib is a highly specific, oral PLK1 inhibitor currently in mid-stage clinical development for RAS-mutated metastatic colorectal cancer. It 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). Promising monotherapy clinical results from an ongoing CMML trial were recently presented at the American Society of Hematology annual meeting in December 2025. CMML represents a rare disease with significant unmet need.

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 in a Phase 2 trial 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 the outbreak of COVID-19 coronavirus and 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, 2024, 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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