Cardiff Oncology Announces Presentation of Positive Results from its Randomized, Controlled Phase 2 Trial of Onvansertib in First-Line RAS-Mutated mCRC at the 2026 ASCO Annual Meeting

June 2, 2026

- The trial achieved its primary goal of selecting the efficacious and safe dose of onvansertib + standard-of-care (SoC) regimen for the registrational program -

- 30 mg onvansertib + FOLFIRI/bevacizumab arm showed a dose-dependent improvement in efficacy, including confirmed ORR of 72.2% compared to 42.1% for SoC -

- Median PFS has not been reached in either 20 or 30 mg onvansertib + FOLFIRI/bevacizumab arm,with nine of the 14 patients remaining on treatment in these arms -

- Onvansertib continues to be safe and well-tolerated with no overlapping or new toxicities when added to SoC -

- Registrational trial planned in first-line RAS-mutated mCRC following successful End-of-Phase 2 meeting with FDA -

- Company to hold an investor webcast tomorrow, June 3, 2026 at 8:30 am ET/5:30 am PT to review the Phase 2 CRDF-004 data and registrational study plans for onvansertib -

SAN DIEGO, June 02, 2026 (GLOBE NEWSWIRE) -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel cancer therapies, today announced positive results from CRDF-004, a randomized, controlled, dose-finding Phase 2 clinical trial evaluating onvansertib in combination with SoC regimens (FOLFIRI/bevacizumab (bev) or FOLFOX/bev) in patients with first-line RAS-mutated metastatic colorectal cancer (mCRC). Results showed that the selected dose/regimen of the registrational program, onvansertib 30 mg + FOLFIRI/bev, demonstrated deep and durable tumor shrinkage, including clinically meaningful improvements in overall response rate (ORR) and progression-free survival (PFS) compared to SoC alone, with no additive adverse events. The data were presented today by Heinz-Josef Lenz, MD, associate director for clinical research and co-leader of the GI cancers program at the University of Southern California (USC) Norris Comprehensive Cancer Center, in a rapid oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Following the completion of the End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), the Company has aligned on the design of the registrational trial with onvansertib in mCRC. The randomized, controlled Phase 3 trial will evaluate the safety and efficacy of onvansertib 30 mg + FOLFIRI/bev as first-line therapy versus standard-of-care FOLFIRI/bev in patients with RAS-mutated mCRC.

“RAS-mutated metastatic colorectal cancer remains a significant clinical challenge, with limited therapeutic progress over the past two decades. Patients with RAS-mutated mCRC continue to face poor outcomes, and there are currently no treatment options specifically approved for patients with RAS-mutated mCRC—except for KRAS G12C mutations, which account for less than 4% of all colorectal cancers,” said Dr. Lenz. “With its novel mechanism of action, onvansertib, when combined with FOLFIRI/bev, demonstrated deep and durable tumor shrinkage over time. A positive confirmatory Phase 3 study that builds on the Phase 2 data presented today could potentially establish onvansertib + FOLFIRI/bev as a new standard-of-care for these patients.”

Data Highlights from the ongoing Phase 2 trial (Data cut: March 18, 2026):
In the intent-to-treat (ITT) population, the dose selected for the registrational program, 30 mg onvansertib arm in combination with FOLFIRI/ bev achieved:

- Primary endpoint of confirmed objective response rate of 72.2% (13/18), compared with 42.1% (8/19) for FOLFIRI/bev alone, a 30% improvement over standard-of-care (SoC). The responses were deeper and more durable in the onvansertib arm.
- Secondary endpoint of progression free survival (PFS) hazard ratio (HR) of 0.55 (95% CI: 0.15–2.09) and 0.57 (95% CI: 0.20–1.65) vs. FOLFIRI/bev by Blinded Independent Central Review (BICR) and investigator assessment (IA), respectively.
- Median PFS not reached in 30 mg onvansertib + FOLFIRI/bev arm, but has been reached in both SoC arms. Four patients remain on onvansertib treatment beyond 15 months, including 2 beyond 20 months.

Notably, fourteen patients remain on trial, with nine patients in the onvansertib (20 or 30 mg) plus FOLFIRI/bev arms and one patient remaining on SoC.

No meaningful differences in efficacy were observed between the onvansertib + FOLFOX/bev arms and FOLFOX/bev alone.

Safety/Tolerability:
Onvansertib in combination with both chemotherapy (FOLFIRI or FOLFOX)/bev regimens was well-tolerated. There were no major or unexpected toxicities observed and no additive adverse events reported. Grade 3 or higher adverse events were infrequent, with neutropenia being the most common treatment-emergent adverse event across both the onvansertib combination and SoC arms.

“We are excited to share these updated results and are highly encouraged by the consistent efficacy seen with onvansertib in combination with FOLFIRI/bev across two clinical trials in patients with RAS-mutated mCRC,” said Mani Mohindru, PhD, President and Chief Executive Officer. “The data generated to date continue to support the potential of onvansertib in combination with standard-of-care FOLFIRI/bev in RAS-mutated mCRC and reinforce our plans to advance the program into a global registrational study. We look forward to providing additional updates on those plans in the coming months.”

The ASCO presentation will be made available on the Scientific Publications page of the Company’s website following the rapid oral presentation.

Conference Call and Webcast

The investor webcast will take place on June 3, 2026 at 8:30 am ET/5:30 am PT. To register for and access the live webcast, please visit the “Events” page of the Cardiff Oncology website. The slides from the conference call will be posted after the call has concluded.

CRDF-004 Trial Design
The CRDF-004 Phase 2 trial was designed to evaluate the safety, efficacy, and pharmacokinetics of two different doses of onvansertib in combination with FOLFIRI/bevacizumab or FOLFOX/bevacizumab in first-line patients with KRAS- or NRAS-mutated metastatic colorectal cancer (mCRC). The randomized, controlled trial was designed to enroll 110 patients across 6 different arms, and 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 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 for advancement into a 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 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; ; uncertainty as to the outcome of pending litigation against Nerviano Medical Sciences S.r.l. with respect to our license agreement with Nerviano; 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, 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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