



Cardiff Oncology Announces New Data from Phase 1b/2 Trial in KRAS-mutated Metastatic Colorectal Cancer Showing Robust Objective Response Rate and Progression Free Survival

September 8, 2021

- 8 of 19 (42%) patients treated per protocol at the recommended Phase 2 dose (RP2D) of onvansertib 15 mg/m² who were evaluable for disease response as of the data cut-off achieved a partial response (PR). Historically, objective response rates (ORR) of 5-13% have been reported in a similar patient population treated with standard of care chemotherapy¹⁻⁴
- 12 of 32 (38%) patients evaluable for response as of data cutoff date across all dose levels achieved a PR
- Median progression-free survival (mPFS) across all response-evaluable patients is 9.4 months and has not yet been reached in those treated per protocol at the RP2D. Historically, mPFS of ~4.5-5.7 months has been reported in a similar patient population treated with standard of care chemotherapy¹⁻⁴
- The combination regimen of onvansertib plus FOLFIRI/bevacizumab is well tolerated
- Management is hosting key opinion leader webinar to discuss data today at 4:00 PM ET; a replay of the webinar will be available on the events section of the Cardiff Oncology website for 90 days

Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need including KRAS-mutated colorectal cancer, pancreatic cancer, and castrate-resistant prostate cancer, today announced new data from its lead clinical program evaluating onvansertib in combination with standard-of-care (SOC) FOLFIRI/bevacizumab for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC).

"Our Phase 1b/2 trial continues to generate data suggesting that the addition of onvansertib to SOC results in an objective response rate and median progression-free survival that substantially exceed those previously achieved with SOC alone," said Katherine L. Ruffner, M.D., chief medical officer of Cardiff Oncology. "Radiographic responses have been observed across multiple KRAS mutation variants, which speaks to a key advantage of onvansertib over competing agents targeting individual mutations. These impressive results, which have remained consistent across both academic and community trial sites, highlight the potential for onvansertib to address the unmet need for new second-line therapeutic options to treat patients with KRAS-mutated mCRC. I look forward to the trial's continued advancement and future data readouts."

Highlights from today's data announcement include:

Efficacy data in patients evaluable for disease response as of data cutoff date (July 2, 2021):

- *Patients treated per protocol at the recommended Phase 2 dose (RP2D; 15 mg/m²) across both Phase 1b and Phase 2:*
 - 8 of 19 (42%) achieved an initial partial response (PR) as of the data cutoff date
 - 7 of 19 (37%) have achieved a confirmed PR (based on further follow-up of patients with an initial PR as of data cutoff date)
 - Objective response rates observed in historical control trials in similar patient populations treated with standard of care are 5-13%¹⁻⁴
- *Patients evaluable for response treated at all dose levels (12 mg/m², 15 mg/m², 18 mg/m²) across both phases of the study*
 - 12 of 32 (38%) achieved an initial PR as of the data cutoff date
 - 10 of 32 (31%) have achieved a confirmed PR (based on further follow-up of patients with an initial PR as of data cutoff date)

Median progression free survival (mPFS)

- mPFS has not yet been reached in patients treated per protocol at the RP2D
- mPFS across all response-evaluable patients (n = 32) is 9.4 months (95% confidence interval: 7.8 – not yet reached)
- mPFS of ~4.5-5.7 months has been reported in trials used as historical controls¹⁻⁴

Biomarker data as of data cutoff date across all patients:

- Partial responses (PRs) were observed across different KRAS mutation variants, including the 3 most common observed in colorectal cancer (G12D, G12V, G13D)
- Patients achieving a best response of PR showed the greatest decreases in plasma KRAS mutant allelic frequency (MAF) after 1 cycle (28 days) of therapy

Safety data as of data cutoff date across all patients:

- The combination of onvansertib and FOLFIRI/bevacizumab was shown to be well-tolerated with only 10% (49/490) of reported treatment-emergent adverse events (TEAEs) being G3/G4
- Most reported treatment-related adverse events (TRAEs) were manageable and reversible with supportive care

Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology, commented, "The strong signal of efficacy and favorable tolerability profile observed in this trial bodes well not only for our lead mCRC program, but for each of our KRAS-focused clinical programs. The meaningful improvements we are seeing in treatment response relative to historical controls demonstrate the value of combination therapy and support the synergistic effect observed preclinically when onvansertib is added to standard-of-care irinotecan and 5-FU (FOLFIRI). We are also seeing compelling biomarker results that highlight the potential utility of plasma KRAS MAF as a predictive tool that could aid in the design of subsequent trials. Looking forward, we anticipate the ongoing Phase 2 portion of the trial to provide additional data catalysts that will advance the clinical development of onvansertib, generate value for shareholders and, most importantly, provide new treatment options for patients."

Key Opinion Leader Webinar

The newly announced data are being discussed today at 4:00 PM ET as part of a key opinion leader (KOL) webinar being hosted by Cardiff Oncology. The webinar is featuring the clinical trial principal investigator, Heinz-Josef Lenz, M.D., FACP, USC Norris Comprehensive Cancer Center, key clinical

advisor Afsaneh Barzi, M.D., Ph.D., City of Hope Comprehensive Cancer Center, and members of the Cardiff Oncology management team.

To attend the webinar, click [here](#). A replay of the webinar will be available by visiting the "[Events](#)" section of the Cardiff Oncology website shortly after its conclusion.

About the Phase 1b/2 Trial of Onvansertib in KRAS-mutated mCRC

This is a multi-center, single-arm, Phase 1b/2 trial of onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab) to evaluate the safety and preliminary efficacy of the combination regimen in the second-line treatment of patients with KRAS-mutated mCRC. The trial, *A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation*, is enrolling patients with histologically confirmed metastatic and unresectable colorectal carcinoma harboring a KRAS mutation. Patients must also have failed treatment with, or be intolerant to, FOLFOX (fluoropyrimidine and oxaliplatin) with or without bevacizumab to be eligible. The trial is being conducted at the following cancer centers across the U.S.: USC Norris Comprehensive Cancer Center, The Mayo Clinic (Arizona, Rochester, and Jacksonville), Kansas University Medical Center (KUMC), CARTI Cancer Center and Inova Schar Cancer Institute. For more information on the trial, please visit <https://clinicaltrials.gov/ct2/show/NCT03829410>.

References

1. Giessen et al., *Acta Oncologica* 2015, 54: 187-193
2. Cremolini et al., *Lancet Oncol* 2020, 21: 497-507
3. Antoniotti et al., *Correspondence Lancet Oncol* June 2020
4. Bennouna et al., *Lancet Oncol* 2013; 14: 29-37

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need. Our goal is to target tumor vulnerabilities with treatment combinations that overcome disease resistance and improve disease response to standard treatment regimens and to increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 ("PLK1") inhibitor, in combination with standard-of-care anti-cancer therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to refine assessment of patient response to treatment. We have three clinical programs currently ongoing: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan, leucovorin and fluorouracil for the second-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC); and a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castrate-resistant prostate cancer (mCRPC). 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 candidates; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, 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 any of our technology or products 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 any precision medicine therapeutics 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, 2020, 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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