# Cardiff Oncology Presents Findings from its Expanded Access Program Highlighting the Clinical Benefit of Onvansertib in Heavily Pretreated Patients with Metastatic KRAS-Mutated mCRC

April 10, 2021

- Evaluable participants (n=20) are heavily pretreated (median of 3 prior lines of treatment); an increase in progression-free survival is a desired outcome

- Median progression free survival (mPFS) is 5.6 months as of AACR cutoff date, which is significantly greater than historical controls of 2-3 months1; 11 of 20 participants remain on treatment

- 62.5% of participants had a greater than 50% decrease in KRAS MAF after one cycle of treatment and continue to show a durable response and haven't reached the mPFS

- Participant featured in case report received 3 prior lines of treatment, including prior FOLFIRI/bevacizumab and had progressive disease at time of enrollment in the EAP

- 8-week CT scan showed decrease in size of numerous lung metastases; many appearing necrotic; further decrease in size of lung metastases observed on 16-week CT scan with many continuing to appear necrotic

- Decreases in tumor lesions were accompanied by a decrease in KRAS mutant allelic frequency (MAF) to undetectable

- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no serious adverse events (SAEs) reported as of the AACR cutoff date

SAN DIEGO, April 10, 2021 /PRNewswire/ -- **Cardiff Oncology, Inc.** (Nasdaq: CRDF), a clinical-stage biotechnology company developing onvansertib to treat cancers with the greatest medical need for new treatment options, including KRAS-mutated colorectal cancer, pancreatic cancer, and castrate-resistant prostate cancer, today announced observations from its Expanded Access Program (EAP) of onvansertib in KRAS-mutated metastatic colorectal cancer (mCRC), featured in a virtual oral poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2021.

Cardiff Oncology's EAP has enrolled participants who failed or progressed on multiple lines of standard-of-care treatment and uses the same combination regimen (onvansertib 15 mg/m$^2$ + FOLFIRI/bevacizumab) and dosing schedule as the Company's ongoing Phase 1b/2 mCRC clinical trial. The median progression free survival (mPFS) of evaluable participants in the EAP is 5.6 months to-date, which represents an increase over the 2-3 months mPFS of historical controls[1]. 62.5% of participants had a greater than 50% decrease in KRAS MAF after one cycle of treatment and continue to show a durable response, having not yet reached the mPFS. Onvansertib has been well tolerated with no serious adverse events (SAEs) reported as of the AACR cutoff date.

"The mPFS observed thus far is significantly better than what is expected and shows promise for improving overall prognosis in this patient population," said Dr. Manish R. Sharma, associate director of clinical research at START Midwest. "The Expanded Access Program has provided access to onvansertib for mCRC patients who are heavily pretreated and thus do not meet the stringent second line eligibility criteria for enrollment in Cardiff Oncology's ongoing Phase 2 clinical trial."

Dr. Mark Erlander, chief executive officer of Cardiff Oncology added, "We are very pleased to provide access to onvansertib for mCRC patients with the greatest need for a new treatment option. It's particularly gratifying to see many EAP participants benefit clinically from the addition of onvansertib to standard-of-care and improve from having progressive to stable disease or better."

**Highlights from the AACR presentation include:**

*Baseline Characteristics of Evaluable Patients (n = 20):*

- Evaluable participants received a median of 3 prior lines of therapy (range: 1-6)
- 15 of 20 (75%) evaluable participants received an irinotecan-based regimen as their last therapy prior to enrolling in the EAP
- 13 of 20 (65%) evaluable participants were progressing prior to enrolling in the EAP

*Clinical Benefit:*

- Evaluable participants had a mPFS of 5.6 months (95% confidence interval: 2.7 months – median PFS not reached)
- 11 of 20 of participants evaluable for clinical benefit remain on treatment as of the AACR cutoff date

*Biomarker:*

- 16 of 20 (80%) evaluable participants had a KRAS variant detected by droplet digital PCR (ddPCR) before beginning onvansertib treatment in the EAP
- Participants with a greater than 50% decrease in KRAS MAF (n=10) after one treatment cycle had a significant increase in PFS (mPFS not reached) compared to participants who had a decrease in KRAS MAF of less than 50% (n = 6; mPFS of 2.6 months)

*Tolerability:*

- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no SAEs reported in participants as of the AACR cutoff date

The virtual poster, "*Expanded access program of the PLK1 inhibitor onvansertib for treatment of patients with KRAS-mutant metastatic colorectal cancer"* is available for on-demand viewing on the AACR Annual Meeting 2021 e-poster website and is also posted on the "Scientific Presentations" section of the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

**References**


1. Bekaii-Saab et al., Clin. Colorectal Cancer, 2019


**About the EAP for Onvansertib in KRAS-mutated mCRC**

Sometimes called "compassionate use", expanded access is a potential pathway for a patient with a serious or life-threatening disease to gain access to an investigational drug for treatment outside of a clinical trial, particularly when no comparable or satisfactory alternative therapy options are available. The Cardiff Oncology EAP in KRAS-mutated mCRC is using the same combination treatment regimen (onvansertib 15 mg/m$^2$ + FOLFIRI and bevacizumab) and dosing schedule as the ongoing Phase 1b/2 clinical trial and is intended for patients that have progressed on prior therapy and do not meet the second line eligibility criteria for enrollment in the clinical trial. The program has reached capacity and is no longer open to enrollment.

**About Cardiff Oncology, Inc.**

Cardiff Oncology is a clinical-stage biotechnology company with the singular mission of developing new treatment options for cancer patients in indications with the greatest medical need. Our goal is to overcome resistance, improve response to treatment and 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 chemotherapy and targeted therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to enable assessment of patient response to treatment. We have three clinical programs currently in process: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castration-resistant prostate cancer (mCRPC); and a Phase 2 study of onvansertib in combination with decitabine in relapsed or refractory acute myeloid leukemia (AML). A new 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) is planned for initiation in the first half of 2021. 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 by the use of 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 a number of 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; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion 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.


**Cardiff Oncology Contact:**
Vicki Kelemen
Chief Operating Officer
858-952-7652
vkelemen@cardiffoncology.com

**Investor Contact:**
Joyce Allaire
LifeSci Advisors
212-915-2569
jallaire@lifesciadvisors.com

**Media Contact:**
Katelyn Caruso-Sharpe
LifeSci Communications
518-496-6302
kcaruso-sharpe@lifescicomms.com


SOURCE Cardiff Oncology, Inc.