Cardiff Oncology Investor Relations

Cardiff Oncology Announces Onvansertib Phase 1b/2 Data that Continues to Demonstrate Robust Response to Treatment and Progression-Free Survival in KRAS-Mutated mCRC

- 7 of 18 (39%) evaluable patients in the Phase 1b/2 trial have achieved a partial response to-date
- Evaluable patients have a median progression free survival (mPFS) of 9.4 months, more than double the historical 4.5-month mPFS from analysis of 23 randomized trials in second-line metastatic colorectal cancer (data from ~10,800 patients)[1]
- Decreases in KRAS mutant allelic frequency after the first cycle of treatment continues to be predictive of subsequent tumor shrinkage
- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no major or unexpected toxicities attributed to onvansertib

SAN DIEGO, April 12, 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 data from its ongoing Phase 1b/2 trial that demonstrate the continued robust patient response to treatment with onvansertib and progression-free survival when combined with standard-of-care therapy in second line KRAS-mutated metastatic colorectal cancer (mCRC).

Patients enrolled in the ongoing Phase 1b/2 trial receive onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab). The overall response rate (ORR) in the trial is 39% to-date, and onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no major or unexpected toxicities attributed to onvansertib. The median progression free survival (mPFS) of evaluable patients is 9.4 months. This represents an increase over the mPFS observed in a systematic literature-based analysis of second line mCRC clinical trial data from 23 randomized trials including a total of ~10,800 patients (mPFS of 4.5 months)[1] and the 5.7-month mPFS observed in the pivotal trial that supported the regulatory approval of FOLFIRI plus bevacizumab in second line mCRC[2].

"As we have continued to collect data from this ongoing trial, we have consistently seen an impressive and durable response to treatment, and a favorable safety and tolerability profile," said Daniel H. Ahn, D.O., lead investigator and medical oncologist, Mayo Clinic Cancer Center, Arizona. "Notably, the ORR and mPFS observed in the trial compare very favorably to what has been seen historically in second line mCRC patients. These promising results highlight the potential of onvansertib to address the unmet needs in mCRC, and I look forward to discussing them in detail during Cardiff Oncology's upcoming key opinion leader webinar."

Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology added, "We are very pleased with the results to-date from our Phase 1b/2 mCRC trial. In addition to continuing to show a consistent and robust response rate, we have also reported intriguing biomarker analyses highlighting the potential of plasma KRAS mutant allelic frequency as a tool to predict patient response to onvansertib. We look forward to providing results from the Phase 2 trial later this year."

Highlights from the updated data announcement include:

Efficacy:

- 7 of 18 (39%) evaluable patients achieved a partial response (PR); 4 patients had a confirmed PR with 1 patient going on to curative surgery; 1 patient with a non-confirmed PR went off study following PR prior to confirmatory scan due to a treatment-unrelated adverse event; 2 patients with non-confirmed

PRs await results from confirmatory scans
- Evaluable patients have a mPFS of 9.4 months (95% confidence interval: 7.85 months – not reached)
- 7 patients remain on treatment to-date

Biomarker:

- Clinical responses were observed across different KRAS mutations, including the 3 most common in colorectal cancer (G12D, G12V, G13D)
- The greatest decreases in plasma KRAS mutant allelic frequency (MAF) after 1 cycle of treatment were observed in patients achieving a PR
- All 7 patients with a PR had a >75% decrease in KRAS MAF after one cycle of treatment

Safety/Tolerability

- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no major or unexpected toxicities attributed to onvansertib

Key Opinion Leader Webinar

The updated Phase 1b/2 mCRC trial data will be presented during a key opinion leader (KOL) webinar taking place today, April 12, 2021 at 11:00 a.m. ET. The webinar will feature KOLs Dr. Ahn (Mayo Clinic Arizona), and Dr. Sharma (START Midwest), who will also discuss the current treatment landscape and unmet medical need in KRAS-mutated mCRC and observations from the EAP evaluating onvansertib in combination with FOLFIRI/Avastin® in KRAS-mutated mCRC.

During the webinar, Dr. Erlander will also present a corporate update and outlook for the year. Dr. Erlander and Drs. Sharma and Ahn will be available to answer questions following the conclusion of the formal presentations.

To register for the webinar, please click here.

References

1. Giessen et al, Acta Oncologica, 2015; 54:187-193
2. Bennouna et al., Lancet Oncol. 2013; 14(1):29-37

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

This is a multi-center, open-label 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,* will enroll up to 44 patients with a KRAS mutation and histologically confirmed metastatic and unresectable disease. In addition, eligible patients must have failed treatment with, or be intolerant to, FOLFOX (fluoropyrimidine and oxaliplatin) with or without bevacizumab. The trial is being conducted at six 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.

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.

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