Cardiff Oncology Announces New Data from Lead Clinical Program in KRAS-mutated Metastatic Colorectal Cancer Showing Robust Objective Response Rate and Progression Free Survival

January 18, 2022

- 12 of 35 (34%) patients treated per protocol at the recommended Phase 2 dose (RP2D) in combination with FOLFIRI and bevacizumab achieved a complete response or partial response (CR: 1 patient; PR: 11 patients)

- 17 of 48 (35%) patients across all dose levels achieved a CR or PR. Historically, objective response rates (ORR) of 5-13% have been reported in similar second line patient populations treated with various different drug combinations, including the standard of care chemotherapy of FOLFIRI with bevacizumab1-4

- 5 of 48 (10%) patients discontinued the trial to pursue potentially curative metastasis-directed therapy (surgical resection or microwave ablation)

- Median progression-free survival (mPFS) across all response-evaluable patients (n=48) 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 chemotherapy of FOLFIRI with bevacizumab1-4

- The combination regimen of onvansertib plus FOLFIRI/bevacizumab is well tolerated with no major or unexpected toxicities attributed to onvansertib

- Company management is hosting a webcast and conference call today at 5:00 PM ET

SAN DIEGO, Jan. 18, 2022 /PRNewswire/ -- 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). A subset of these data will be featured in a poster presented by Dr. Heinz-Josef Lenz, principal investigator, USC Norris Comprehensive Cancer Center, at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCOGI) on Saturday, January 22, 2022.

"As we have increased the number of patients evaluated and the duration of follow-up, our Phase 1b/2 trial has consistently generated data suggesting that onvansertib provides meaningful clinical benefits when added to SOC," said Katherine L. Ruffner, M.D., chief medical officer of Cardiff Oncology. "The objective response rate and median progression free survival observed substantially exceed what would be expected with SOC alone, and five patients receiving onvansertib have been able to pursue potentially curative metastasis-directed treatments. We also observed a confirmed complete response, which is exciting given the difficult-to-treat nature of second line mCRC patients."

The most current data for the trial are shown below and include patient follow up collected after the cutoff dates for both the ASCO-GI abstract and poster (one additional PR was recorded after December 3):

Efficacy data in evaluable patients (represents an update from ASCO-GI abstract/poster):

- Among patients treated per protocol at the recommended Phase 2 dose (RP2D; 15 mg/m^2) in combination with FOLFIRI-bev:
  - 12 of 35 (34%) achieved an initial complete response (CR) or partial response (PR)
  - 10 of 35 (29%) achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)
  - 33 of 35 (94%) had a best response of disease control (CR + PR + SD)
  - Objective response rates of 5-13% observed in historical control trials in similar patient populations treated with various different drug combinations, including the standard of care chemotherapy of FOLFIRI with bevacizumab[1-4]
- Patients evaluable for response treated at all dose levels (12 mg/m^2, 15 mg/m^2, 18 mg/m^2)
  - 17 of 48 (35%) achieved an initial CR or PR
  - 13 of 48 (27%) have achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)
  - 44 of 48 (92%) had a best response of disease control (CR + PR + SD)
- Status of 4 unconfirmed PRs:
  - 1 patient discontinued from the trial prior to confirmatory scan due to an adverse event that was unrelated to treatment (hepatitis B)
  - 1 patient went from PR to SD at the confirmatory scan and patient subsequently discontinued from the trial to pursue potentially curative metastasis-directed therapy
  - 1 patient went from PR to SD at the confirmatory scan (patient remains on treatment)
  - 1 patient has yet to have their confirmatory scan
- 5 of 48 (10%) evaluable patients discontinued therapy to pursue potentially curative metastasis-directed therapy (surgery or microwave ablation), including 2 patients with SD

Median progression free survival (mPFS; no update from ASCO-GI poster)

- mPFS has not yet been reached in patients treated per protocol at the RP2D
- mPFS across all response-evaluable patients (n = 48) is 9.4 months (95% confidence interval: 7.1 – not yet reached)
- mPFS of ~4.5-5.7 months has been reported in trials used as historical controls[1-4]

Biomarker data across all patients (no update from ASCO-GI poster):

- Responses (CRs or PRs) were observed across seven different KRAS mutation variants, including the 3 most commonly observed in colorectal cancer (G12D, G12V, G13D)
- Patients achieving a best response of a CR or PR showed the greatest decreases in plasma KRAS mutant allelic frequency (MAF) measured

by droplet digital PCR (ddPCR) after 1 cycle (28 days) of therapy

Safety data across all patients (no update from ASCO-GI poster):

- The combination of onvansertib and FOLFIRI/bevacizumab was shown to be well-tolerated with only 11% (84/788) of reported treatment-emergent adverse events (TEAEs) being G3/G4
  - The most commonly reported adverse event was neutropenia/neutrophil count decreased
  - Most reported TEAEs were manageable and reversible with supportive care

Baseline characteristics of patients at all dose levels (no update from ASCO-GI poster):

- The patients' median age was 61 years (range 35-83), and 56% were male
- 67% patients had previously received bevacizumab
- 16 of 48 (33%) evaluable patients remain on trial at the data cutoff date

Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology, commented, "These impressive results show radiographic responses across multiple KRAS mutation variants when onvansertib is combined with the standard of care regimen of FOLFIRI-bev and demonstrate a substantial increase in disease response relative to historical controls. We believe the data presented today further validate the potential of onvansertib to provide a meaningful improvement in the treatment outcome of a large patient population that has limited available treatment options. Looking forward, and with our strong cash position, we have the ability to explore the full potential of onvansertib."

Webcast and Conference Call

The newly announced data are being discussed today at 5:00 PM ET as part of a webcast and conference call with members of the Cardiff Oncology management team. To access the webcast, click here. To participate by phone, please dial 1-877-407-9208 (domestic) or 1-201-493-6784 (international) and refer to conference ID 13725845. Following the live event, an archived webcast will be available on the "Events" section of the Cardiff Oncology website.

About the Phase 1b/2 Trial of Onvansertib in the Second-Line Treatment of 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 experienced disease progression or treatment intolerance to first-line treatment with fluoropyrimidine and oxaliplatin (FOLFOX or CapeOx) 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 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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