Cardiff Oncology Announces Positive Clinical Data in Pancreatic Cancer and Small Cell Lung Cancer, including Single-Agent Activity from Onvansertib Monotherapy

September 26, 2023

Pancreatic Cancer Program

- Pancreatic cancer Phase 2 trial of onvansertib + SoC in the second-line setting demonstrated greater efficacy vs. historical controls with ORR of 19% (vs. 7.7%) and mPFS of 5.0 months (vs. 3.1 months) -

- Pancreatic cancer biomarker discovery trial in refractory patients demonstrated tumor biomarker response to onvansertib treatment as a single-agent -

- Based on positive data from both pancreatic trials and supportive preclinical data, a first-line pancreatic investigator-initiated trial is planned to evaluate the efficacy of onvansertib + SoC -

Small Cell Lung Cancer Program

- Preliminary data from small cell lung cancer Phase 2 trial in refractory patients with extensive stage disease demonstrate single-agent activity from onvansertib monotherapy -

- Company will hold a conference call today at 5:00 p.m. ET/2:00 p.m. PT -

SAN DIEGO, Sept. 26, 2023 /PRNewswire/ -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced positive clinical data with onvansertib monotherapy and combination therapy in our ongoing trials in metastatic pancreatic ductal adenocarcinoma (mPDAC) and small cell lung cancer (SCLC), as well as plans for a mPDAC first-line investigator-initiated trial (IIT) of the combination of onvansertib plus standard-of-care (SoC).

"We are excited that the data released from these trials, in two challenging cancers with low survival rates, expands the opportunity for onvansertib beyond our lead program in RAS-mutated mCRC," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "In pancreatic cancer, the strength of the data provides a clear rationale for a first-line trial using onvansertib in combination with standard of care, which we believe provides the greatest opportunity for a positive impact on patients. In small cell lung cancer, we are encouraged to observe single-agent activity with onvansertib monotherapy in this difficult-to-treat extensive stage refractory setting."

mPDAC Phase 2 CRDF-001 trial: 19% ORR and 5.0-month mPFS

Data from the ongoing Phase 2 open-label trial of onvansertib combined with nanoliposomal irinotecan, leucovorin, and 5-FU in patients with second-line mPDAC demonstrated an objective response rate (ORR) of 19% (4 of 21 evaluable patients; 1 confirmed PR, 3 waiting for confirmatory scan) and median progression-free survival (mPFS) of 5.0 months as of the data cutoff of September 13, 2023. Historical control trials in similar patient populations have shown an ORR of 7.7% and mPFS of 3.1 months with SoC.

mPDAC biomarker discovery trial: decrease in clinically-validated tumor biomarkers from onvansertib monotherapy

The investigator-initiated biomarker discovery trial is exploring the impact of onvansertib 10-day monotherapy on tumors in mPDAC patients, and is currently enrolling at the Oregon Health & Science University (OHSU) Knight Cancer Institute. Two patients have been enrolled to date. One patient demonstrated an 86% decrease in Ki67, a well-established biomarker of tumor proliferation, and a 28% decrease in CA 19-9, a clinically-used biomarker to monitor treatment response.

"Serum carbohydrate antigen 19-9 is the most extensively studied and validated serum biomarker in PDAC, which provides a clinically meaningful surrogate for response to treatment. We are encouraged by the ability of onvansertib to provide an approximately 30% reduction in this biomarker with only 10 days of monotherapy in a refractory setting," said Fairooz Kabbinavar, MD, Chief Medical Officer of Cardiff Oncology. "We will continue to explore onvansertib in the first-line mPDAC investigator-initiated trial at the OHSU Knight Cancer Institute."

Update in Clinical Development Plan for mPDAC

The next trial in mPDAC will be a new Phase 2 investigator-initiated trial at OHSU Knight Cancer Institute in mPDAC in the first-line setting. There are two cohorts in this trial. In cohort 1, patients will receive the combination of onvansertib with SoC (Gemzar + Abraxane). In cohort 2, patients will receive 10 days of onvansertib monotherapy followed by onvansertib + SoC to identify biomarkers that predict response to onvansertib.

SCLC Phase 2 Investigator-Initiated Trial

The ongoing Phase 2 trial of onvansertib monotherapy in patients with relapsed extensive stage SCLC who have received up to two prior therapies is currently enrolling patients at the University of Pittsburgh Medical Center. An examination of the safety data from the first six patients by the institutional review board confirmed the trial can continue to enroll as planned. Preliminary efficacy data in evaluable patients will be discussed on the company conference call.

Conference Call and Webcast

Cardiff Oncology will host a corresponding conference call and live webcast at 5:00 p.m. ET/2:00 p.m. PT on September 26, 2023. Individuals interested in listening to the live conference call may do so by using the webcast link in the "Investors" section of the company's website at www.cardiffoncology.com. A webcast replay will be available in the investor relations section on the company's website for 30 days following the completion of the call.

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers. The Company's lead asset is onvansertib, a PLK1 inhibitor being evaluated in combination with standard-of-care (SoC) therapeutics in clinical programs targeting indications such as RAS-mutated metastatic colorectal cancer (mCRC) and metastatic pancreatic ductal adenocarcinoma (mPDAC), as well as in investigator-initiated trials in small cell lung cancer (SCLC) and triple negative breast cancer (TNBC). These programs and the Company's broader development strategy are designed to target tumor vulnerabilities in order to overcome treatment resistance and deliver superior clinical benefit compared to the SoC alone. 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; 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 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 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, 2022, 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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