Cardiff Oncology Announces New Lead Program in First-Line Metastatic Colorectal Cancer and Expanded Pfizer Relationship

August 7, 2023

- Advance to first-line RAS-mutated mCRC follows the strong signal from new clinical and preclinical data, and agreement with FDA -

- First-line mCRC represents substantial increase in patient impact and market opportunity over second-line -

- Pfizer Ignite will be responsible for the clinical execution of new first-line mCRC trial with interim topline data expected in mid-2024 -

- Cash position on June 30, 2023 was $89.4 million; sufficient to fund operations into 2025 and through interim topline results from mCRC trial -

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

SAN DIEGO, Aug. 7, 2023 /PRNewswire/ -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers, today announced plans to advance the company's lead program to the first-line setting of metastatic colorectal cancer (mCRC) and conduct its new CRDF-004 trial with study execution support from Pfizer Ignite, a new end-to-end service for biotech companies.

"Our advance to the first-line mCRC setting is the result of a comprehensive data-driven review coupled with the agreement and support of the FDA. Ultimately, this decision moves Cardiff Oncology into a stronger position to realize the promise of onvansertib for the benefit of patients and all of our stakeholders," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "We are delighted to expand our relationship with Pfizer and conduct this new first-line trial beginning this fall through Pfizer Ignite, leveraging its clinical execution capabilities and expertise."

The company estimates that there are 48,000 new patients in the U.S. annually in the first-line RAS-mutated mCRC setting for whom there are no ongoing clinical trials and no new treatments approved in the past 20 years.

Dr. Erlander continued: "Key to today's decision has been our discovery of a novel mechanism of action by which onvansertib inhibits angiogenesis by turning off a 'survival switch' for tumorigenesis. This has helped us understand onvansertib's interaction with bevacizumab, and the compelling clinical results we observed in our Phase 1b/2 second-line KRAS-mutated mCRC trial."

The clinical activities of the company's new CRDF-004 trial in first-line RAS-mutated mCRC will be conducted with support from Pfizer Ignite. This expands the relationship established in November 2021 when Pfizer made an equity investment in Cardiff Oncology and nominated Adam Schayowitz, Ph.D., Vice President & Medicine Team Group Lead for Breast Cancer, Colorectal Cancer and Melanoma, Pfizer Global Product Development as a Scientific Advisory Board member.

Pfizer Ignite is a new end-to-end service for biotech companies with high potential science that leverages Pfizer Inc.'s significant R&D capabilities, scale and expertise to accelerate the development of breakthrough therapies.

Cardiff Oncology will maintain full economic ownership and control of onvansertib.

"We believe onvansertib, by inhibiting PLK1, has the potential to play a meaningful role in the treatment of several types of cancer, including the lead program in RAS-mutated mCRC," said Dr. Schayowitz. "We believe that by combining Pfizer's clinical development capabilities and expertise, with onvansertib's promising novel clinical findings, we have an opportunity to accelerate the advancement of this program for the benefit of the many patients in the RAS-mutated mCRC setting."

Cardiff Oncology's new lead program in first-line RAS-mutated mCRC will consist of two trials that will be conducted sequentially. The first trial will be CRDF-004, a Phase 2 randomized trial generating preliminary safety and efficacy data and evaluating two different doses of onvansertib to confirm an optimal dose. Onvansertib will be added to standard-of-care consisting of FOLFIRI plus bevacizumab, or FOLFOX plus bevacizumab. A total of 90 patients will be randomized in a 1:1:1 ratio to either 20mg of onvansertib plus standard-of-care, 30mg of onvansertib plus standard-of-care, or standard-of-care alone. Interim topline results from this trial are expected in mid-2024.

Contingent upon the results of CRDF-004, Cardiff Oncology will initiate a Phase 3, randomized trial with registrational intent. The FDA has agreed that a seamless trial with objective response rate (ORR) at an interim point is an acceptable endpoint to pursue accelerated approval, with progression-free survival (PFS) and trend in overall survival being the endpoints for full approval.

"The stand-out results from our Phase 1b/2 second-line mCRC trial of onvansertib were observed in a well-defined subset of patients, namely those who had not previously been treated with bevacizumab in the first-line setting," said Fairooz Kabbinavar, MD, Chief Medical Officer of Cardiff Oncology. "Bev naïve patients in our Phase 1b/2 trial who received FOLFIRI, bevacizumab and onvansertib had a remarkable 73% ORR and 15-month mPFS, comparing favorably against historical controls that report an ORR of approximately 25% with a 7 to 8-month mPFS. Such high levels of efficacy have not been previously observed in 2nd line mCRC. The clinical and preclinical data we are reporting today confirm our initial finding, and based on highly encouraging interactions with the FDA and Pfizer, we are moving into first-line RAS-mutated mCRC where we believe enrollment should occur more quickly given the significantly larger number of first-line patients versus second-line."

Consistent with the strategic decision to focus on first-line RAS-mutated mCRC, Cardiff Oncology will discontinue enrollment in its ONSEMBLE second-line trial to focus resources on its new lead first-line program. This decision is driven by the fact that both trials essentially test the same clinical hypothesis, the importance of deploying the Company's capital efficiently, and the FDA's suggestion that Cardiff Oncology consider focusing on the first-line RAS-mutated mCRC setting.

All other Cardiff Oncology programs remain unaffected by this decision.

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 August 7, 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 triple negative breast cancer (TNBC) and small cell lung cancer (SCLC). 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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