Cardiff Oncology Presents Data at ESMO Confirming Efficacy of Onvansertib and Durability of Response in KRAS-Mutated Metastatic Colorectal Cancer (mCRC)

September 17, 2020

-10 of 11 (91%) patients achieved disease control (SD - stable disease plus PR - partial response) with only 1 patient progressing in <6 months while on treatment

- 5 (45%) patients achieved a partial response (PR); 4 patients had a confirmed PR (≥ 30% tumor shrinkage) with 1 patient going on to curative surgery; 1 patient with an initial PR went off study prior to confirmatory scan due to non-treatment related event

- All 5 PRs were associated with different KRAS mutation variants, including the most common that comprise nearly 80% of mutations in CRC

- 8 of 11 (73%) patients demonstrated durable response ranging from 6 to >12 months, and 4 patients remain on treatment

- Onvansertib in combination with FOLFIRI/bevacizumab is safe and well tolerated with only 9% of adverse events being grade 3 or 4; none being attributed to onvansertib and all being resolved within 2.5 weeks

SAN DIEGO, Sept. 17, 2020 /PRNewswire/ -- **Cardiff Oncology, Inc. (Nasdaq: CRDF)**, a clinical-stage oncology therapeutics company developing drugs to treat cancers with the greatest medical need for new treatment options, including KRAS-mutated colorectal cancer, castration-resistant prostate cancer and leukemia, today announced an electronic poster presentation of clinical data further demonstrating the safety, efficacy and durability of response of onvansertib in KRAS-mutated metastatic colorectal cancer (mCRC) patients at the European Society of Medical Oncology (ESMO) Virtual Congress 2020.

"We are pleased to observe the clinical benefit and durability of response to treatment, with confirmed PRs and patients exceeding one year on treatment without disease progression," said Daniel H. Ahn, D.O., lead investigator and medical oncologist, Mayo Clinic Cancer Center, Arizona. "The addition of onvansertib to standard-of-care shows promise as a novel second-line option for patients with difficult-to-treat KRAS-mutated mCRC. A critical unmet need exists for these patients, as second line treatment has a relatively low response rate and generally confers a poor prognosis."

Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology added, "As we continue to advance our lead clinical program in KRAS-mutated mCRC, we are highly encouraged by the efficacy signal in our ongoing trial. Our analysis of changes in plasma KRAS mutation levels, from baseline to the end of cycle 1 of treatment, appears to be predictive of subsequent tumor shrinkage and may prove to be a useful clinical tool to quickly assess patient response to treatment with onvansertib."

Highlights of the ESMO Poster Presentation:

Efficacy:

- 10 of 11 (91%) patients achieved disease control (SD – stable disease plus PR – partial response) with only 1 patient progressing in <6 months while on treatment
- 5 (45%) patients achieved a partial response (PR); 4 patients had a confirmed PR with 1 patient going on to curative surgery; 1 patient with an initial PR went off study prior to confirmatory scan due to non-treatment related event
- 8 of 11 (73%) patients demonstrated durable response ranging from 6 to >12 months, and 4 patients remain on treatment

Biomarker Analyses:

- All 5 PRs were associated with different KRAS mutation variants, including the 3 most common that comprise nearly 80% of mutations in CRC
- Patients achieving a PR showed the greatest decreases in plasma KRAS mutation levels (ranging from -78% to -100%) after one cycle of therapy

Safety:

- The first two onvansertib dose levels (12 and 15 mg/m^2) have been cleared for safety; four patients have been treated at the third dose level (18 mg/m^2) and two more will be enrolled
- Onvansertib in combination with FOLFIRI/bevacizumab is safe and well tolerated with only 9% of AEs being grade 3 or 4; none being attributed to onvansertib and all being resolved within 2.5 weeks
- No major or unexpected toxicities have been attributed to onvansertib

The poster presented as part of the ESMO Virtual Congress 2020 is available on the "Scientific Presentations" section of the Cardiff Oncology website at https://cardiffoncology.com/scientific-presentations/.

About the Phase 1b/2 Trial of Onvansertib in Metastatic KRAS-mutated Colorectal Cancer
Cardiff Oncology's ongoing KRAS-mutated metastatic colorectal cancer clinical trial is a single-arm Phase 1b/2 study assessing the safety and preliminary efficacy of onvansertib in combination with FOLFIRI and bevacizumab in second line KRAS-mutated metastatic colorectal cancer. Trial participants are treated with onvansertib on Days 1-5, and FOLFIRI and bevacizumab on Day 1, of 14-day treatment courses. Primary outcome measures include safety and tolerability assessments. Secondary outcome measures include preliminary efficacy determined by radiographic scans every 8 weeks and reduction in KRAS mutant allelic burden evaluated by liquid biopsy. The trial is being conducted at the USC Norris Comprehensive Cancer Center and the Mayo Clinic Cancer Centers. For more information on the trial, please visit https://clinicaltrials.gov/ct2/show/NCT03829410.

About Cardiff Oncology, Inc.
Cardiff Oncology (formerly Trovagene, Inc.) 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 ongoing clinical programs that are demonstrating the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® 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). 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, our need for additional financing; our ability to continue as a going concern; 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, 2019, 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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