

Cardiff Oncology Announces Upcoming Presentations at the AACR Annual Meeting 2024

March 6, 2024

SAN DIEGO, March 06, 2024 (GLOBE NEWSWIRE) -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced publications of five abstracts that will be presented in a poster session at the American Association for Cancer Research (AACR) Annual Meeting, taking place from April 5-10, 2024, in San Diego, California.

"The posters we will be presenting at this year's AACR meeting represent a broad view of the potential of onvansertib in several different cancer indications, including RAS-mutant mCRC, RAS-wild type mCRC, small cell lung cancer and ovarian cancer," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "In RAS-mutated mCRC, we are showing the underlying mechanism through which the combination of onvansertib and bevacizumab targets the hypoxia response pathway. We believe this mechanism explains the strong clinical results we have seen in both our Phase 1b/2 and ONSEMBLE second-line RAS-mutated mCRC clinical trials. The additional posters provide new insights and rationale for future clinical trials in other cancer indications."

Details on the posters and corresponding abstracts are shown below.

Poster Title: A phase 1b/2 clinical study of onvansertib in combination with FOLFIRI/bevacizumab revealed a new role of PLK1 in regulating the hypoxia pathway in KRAS-mutant colorectal cancer Session Title: Microenvironment, Immunity, and DNA Repair in Therapeutic Response Session Date and Time: Monday Apr 8, 2024: 9:00 AM - 12:30 PM PT Location: Poster Section 27, Poster Board #14, Abstract Number #2031

This abstract presents updated clinical data and biomarker analysis from the Phase 1b/2 study evaluating onvansertib in combination with FOLFIRI/bevacizumab for second-line treatment of KRAS-mutant metastatic colorectal cancer (mCRC) patients. Analysis of patient baseline characteristics revealed superior clinical benefit in patients not exposed to bevacizumab in first-line treatment (Bev-naïve) compared to Bev-exposed patients. Bev-naïve patients exhibited higher objective response rates (73.3% versus 15.7%) and longer median progression-free survival (14.9 versus 7.8 months) compared to Bev-exposed patients. Preclinical studies, using KRAS-mutant colorectal cancer mouse models revealed robust antitumor activity of onvansertib in combination with bevacizumab and a novel role of onvansertib in regulating tumor vascularization. Further preclinical investigations showed that PLK1 regulates the hypoxia pathway in KRAS-mutant CRC cells through the modulation of the hypoxia-inducible factor 1 alpha, HIF1α, emphasizing the potential crosstalk between PLK1 and angiogenesis. These findings reinforce the rationale for exploring onvansertib in combination with FOLFIRI/bevacizumab for Bev-naïve mCRC patients with KRAS mutation.

Poster Title: The PLK1 inhibitor, onvansertib, is active as monotherapy and in combination with cetuximab in RAS wild-type colorectal cancer patientderived xenografts

Session Title: Drug Resistance 2: Ras GTPase

Session Date and Time: Monday Apr 8, 2024: 9:00 AM - 12:30 PM PT Location: Poster Section 24, Poster Board #12, Abstract Number #1934

This abstract focuses on the preclinical assessment of onvansertib's antitumor activity in RAS wild-type colorectal cancer, as both a monotherapy and in combination with cetuximab, a monoclonal antibody targeting the epidermal growth factor receptor (EGFR). Employing patient-derived xenograft (PDX) models, the study highlights the robust antitumor efficacy of onvansertib monotherapy, in cetuximab-sensitive and -resistant RAS wild-type colorectal cancer models. Furthermore, the combination of onvansertib and cetuximab was highly effective, resulting in tumor regression in 90% of the PDXs. These compelling data strongly support the clinical development of onvansertib as a potential treatment for RAS wild-type colorectal cancer.

Poster Title: A phase 2, randomized, open-label study of onvansertib in combination with standard-of-care (SoC) versus SoC alone for first-line treatment of RAS-mutant metastatic colorectal cancer(mCRC) Session Title: Phase II and Phase III Clinical Trials in Progress Session Date and Time: Tuesday, Apr 9, 2024: 1:30 PM - 5:00 PM PT Location: Poster Section 50, Poster Board #5, Abstract Number #CT275

This abstract describes a clinical trial in progress.

Poster Title: The PLK1 inhibitor, onvansertib, synergizes with paclitaxel in small cell lung cancer Session Title: Kinase and Phosphatase Inhibitors 1 Session Date and Time: Sunday Apr 7, 2024: 1:30 PM - 5:00 PM PT Location: Poster Section 25, Poster Board #16, Abstract Number #606

This abstract outlines preclinical studies showing the promising potential of combining onvansertib with paclitaxel for small cell lung cancer (SCLC). The research reveals significant synergy of the combination in SCLC cell lines and demonstrates its robust antitumor activity in patient-derived xenograft models, including models resistant to the standard therapy cisplatin. Further insights into the combination's mechanism of action will be presented. These findings support that combining onvansertib with paclitaxel could emerge as a highly promising treatment strategy for SCLC.

Poster Title: In vivo anti-tumor activity of onvansertib, a PLK1 inhibitor, combined with gemcitabine or carboplatin in platinum-resistant ovarian carcinoma patient-derived xenograft models

Session Title: Application of Precision Medicine for Cancer Care Session Date and Time: Sunday Apr 7, 2024: 1:30 PM - 5:00 PM PT Location: Poster Section 39, Poster Board #13, Abstract Number #945

This abstract explores preclinically the potential of combining onvansertib with the chemotherapeutic agents carboplatin or gemcitabine for platinumresistant high-grade ovarian carcinoma. Using patient-derived xenografts, we demonstrated robust efficacy for both combinations, coupled with favorable tolerability. These data underscore the potential of onvansertib to improve the efficacy of the standard-of-care carboplatin and gemcitabine for patients with platinum-resistant high-grade ovarian carcinoma. The abstracts are available on the AACR Online Program and will be published in the online *Proceedings of the AACR*. Following presentation, the posters will be posted to the "Scientific Presentations" section of the Cardiff Oncology website.

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.

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