

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 26, 2023**



Cardiff Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-35558
(Commission File Number)

27-2004382
IRS Employer
Identification No.)

11055 Flintkote Avenue
San Diego, CA 92121
(Address of principal executive offices)

Registrant's telephone number, including area code: **(858) 952-7570**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	CRDF	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

Cardiff Oncology, Inc. (the "Company") intends to conduct meetings with third parties in which its corporate slide presentation will be presented. A copy of the presentation materials is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and the document attached as Exhibit 99.1 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 26, 2023, the Company issued a press release announcing 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). A copy of the press release is attached as Exhibit 99.2 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Cardiff Oncology, Inc. Corporate Presentation](#)
99.2 [Press Release of Cardiff Oncology, Inc. dated September 26, 2023](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 26, 2023

CARDIFF ONCOLOGY, INC.

By: /s/ Mark Erlander
Mark Erlander
Chief Executive Officer



Pancreatic Cancer and Small Cell Lung Cancer Program Updates

SEPTEMBER 26, 2023

Forward-looking statements

CERTAIN STATEMENTS IN THIS PRESENTATION 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 our expectations, strategy, plans or intentions. These forward-looking statements are based on our 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; our clinical trials may encounter delays in initiation or enrollment that impact the cost and timing of the trial readout; 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; regulatory, 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 our 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 we do not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Highlights of today's mPDAC and SCLC program update

Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)

1. CRDF-001 trial

- Onvansertib, in combination with 2nd line standard-of-care, generated an efficacy signal and was well-tolerated

2. Biomarker discovery investigator-initiated trial

- Onvansertib monotherapy generated an efficacy biomarker response
- Onvansertib inhibited hypoxia-response pathway in treatment-responsive patient

3. First-line investigator-initiated trial planned

Small Cell Lung Cancer (SCLC)

Monotherapy investigator-initiated trial

- Confirmed PR in first seven patients in onvansertib monotherapy trial
-

Onvansertib specifically targets PLK1, a well-established cancer target

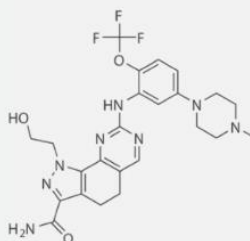
Onvansertib

First oral, well-tolerated
PLK1-selective inhibitor



PROPERTIES

- Small molecule
- Oral dosing
- 24-hour half-life



SPECIFICITY

Exquisitely specific for PLK1

ENZYME	IC ₅₀ (μM)
PLK1	0.002
PLK2	>10
PLK3	>10
CK2	0.4
FLT3	0.4
CDK1/CycB	>10
42 other kinases and >140 in the Millipore panel	>10

Our pipeline opens many attractive opportunities for onvansertib

	Line of Therapy	Trial	IIT*	Ph2	Ph3	Combination w
mCRC (RAS-mut)	1 st line	Ph 2 (w/Pfizer)				FOLFIRI/ and FOLFOX/
	2 nd line	Ph 1b/2				FOLFIRI/
mPDAC	2 nd line	Ph 2				Nal-IRI/leucovorin 5
	1 st line	Ph 2				Gemzar®/Abraxane
SCLC	2 nd line	Ph 2				None (monotherapy)
TNBC	2 nd line	Ph 2				Paclitaxel

* For investigator-initiated trials (IITs) only, the investigator's institution is provided.

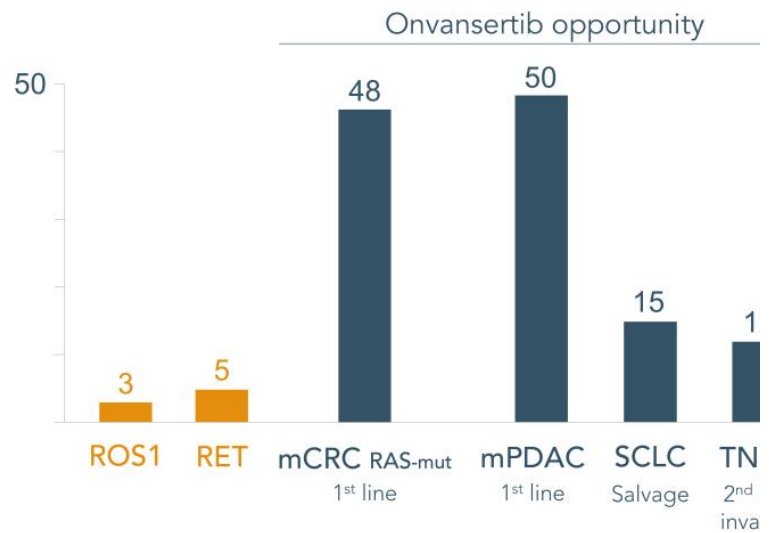
Onvansertib's MOA targets large patient populations with unmet need

Targets with oncogenic alterations	Targets without oncogenic alterations
<p>ROS1</p> <p>RET</p> <p>KRAS G12C</p> <p>EGFR</p> <p>TRK</p>	<p>PLK1</p> <p>PARP</p> <p>CDK4/6</p> <p>PD1/PDL1</p> <p>VEGF</p>

*ROS1 estimated eligible patients presented in Turning Point Therapeutics' corporate presentation May 2022 slide 6 (NSCLC disease incidence in the US of 140k of which 2% of patients harbor ROS1 translocation). RET estimated eligible patients presented in Loxo Oncology's corporate presentation January 2018 disclosed on Form 8-K (Jan 8, 2018).

mCRC estimated population includes 1st line, KRAS- and NRAS-mutated cancers. mPDAC estimated population includes 1st line PDAC patients. SCLC estimated population includes SCLC salvage patients. TNBC estimated population includes invasive, 2nd line TNBC patients.

Annual eligible U.S. patients ('000s)*





Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)

Small Cell Lung Cancer (SCLC)

Data from two mPDAC trials provides a path forward in 1st line setting

mPDAC
CRDF-001 Ph 2 Second-Line Trial

- Combination with Nal-irinotecan/leucovorin/5-FU

mPDAC
Biomarker Discovery Trial (IIT)

- Patients have 10 days of onvansertib monotherapy with pre- and post-therapy biopsies and bloodwork



Path forward: Move to 1st line mPDAC

- New IIT combining onvansertib with SoC (Gemzar/Abraxane)
-

Data from two mPDAC trials provides a path forward in 1st line setting

mPDAC
CRDF-001 Ph 2 Second-Line Trial

- Combination with Nal-irinotecan/leucovorin/5-FU

mPDAC
Biomarker Discovery Trial (IIT)

- Patients have 10 days of onvansertib monotherapy with pre- and post-therapy biopsies and bloodwork



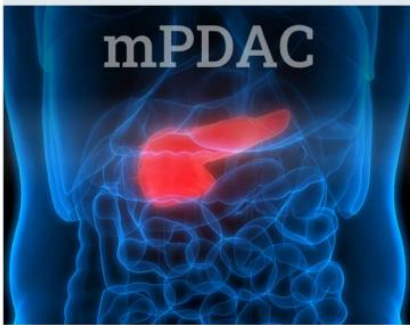
Path forward: Move to 1st line mPDAC

- New IIT combining onvansertib with SoC (Gemzar/Abiraxane)
-

CRDF-001 mPDAC 2nd line Ph2 trial combines onvansertib with SoC

ENROLLMENT CRITERIA

2nd line refractory patients
Measurable tumor by
RECIST 1.1



OBJECTIVE

To determine the efficacy and safety of onvansertib when added to standard of care

PRIMARY ENDPOINT

ORR (RECIST 1.1)

SECONDARY ENDPOINT

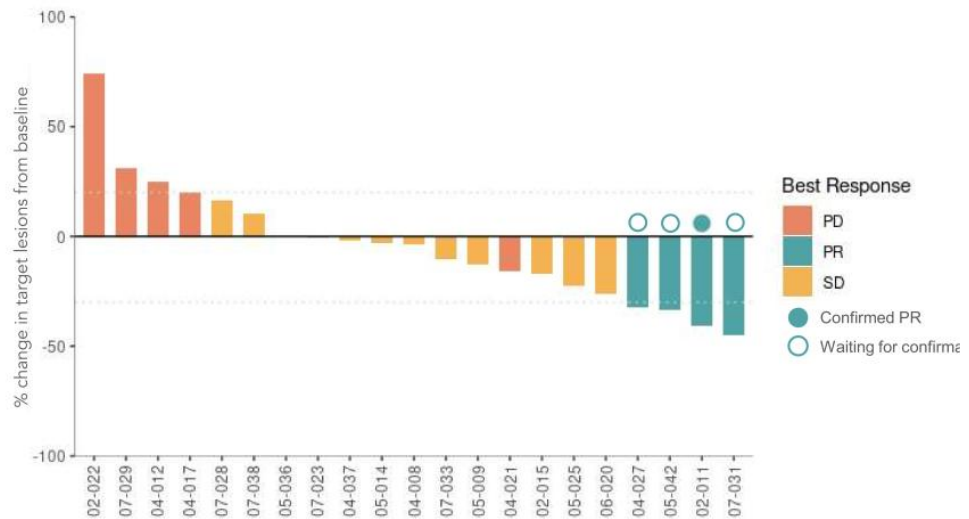
Disease Control Rate (DCR)



Onvansertib+SoC has higher efficacy than 2nd line historical controls

Best Radiographic Response – 21 evaluable patients (as of September 13, 2023)*

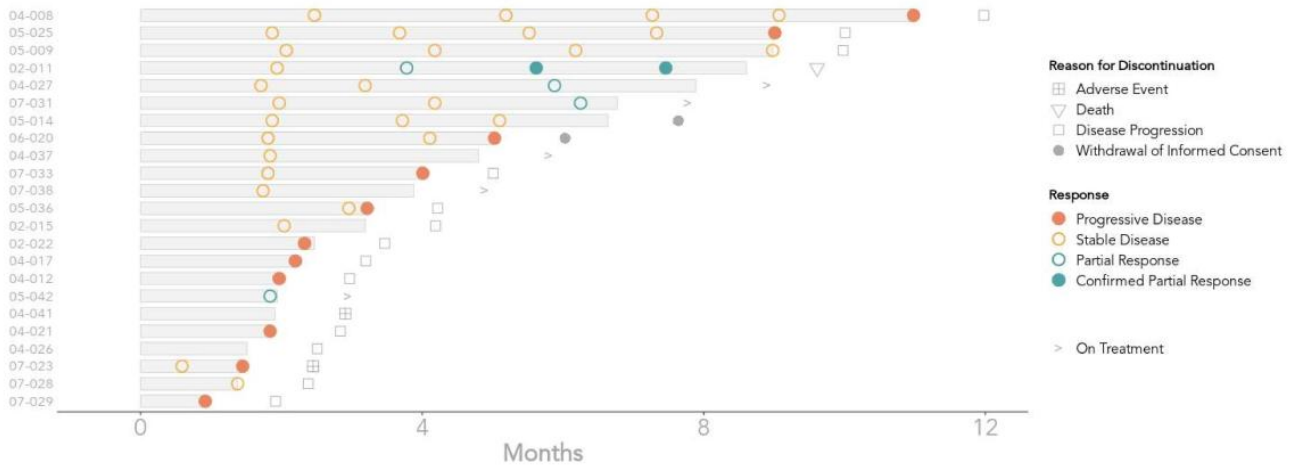
	CRDF-001	Historical controls ¹	
		2 nd line mPDAC	1 st line mPDAC
ORR	19% (4/21)	7.7%	23%



* Radiographic response determined per RECIST 1.1. Waterfall plot and table reflect interim data as of September 13, 2023 from an ongoing trial and unlocked database. For ORR analysis, there are two patients excluded (04-026 and 04-041) that had two cycles of treatment but left the trial before their first post-baseline scan.
 1. FDA insert for Onivyde (Nal-IRI): https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207793lbl.pdf; 387: 545–57. Von Hoff et al., N Engl J Med 2013; 369:1691-703.

Stable disease patients have converted to partial responses over time

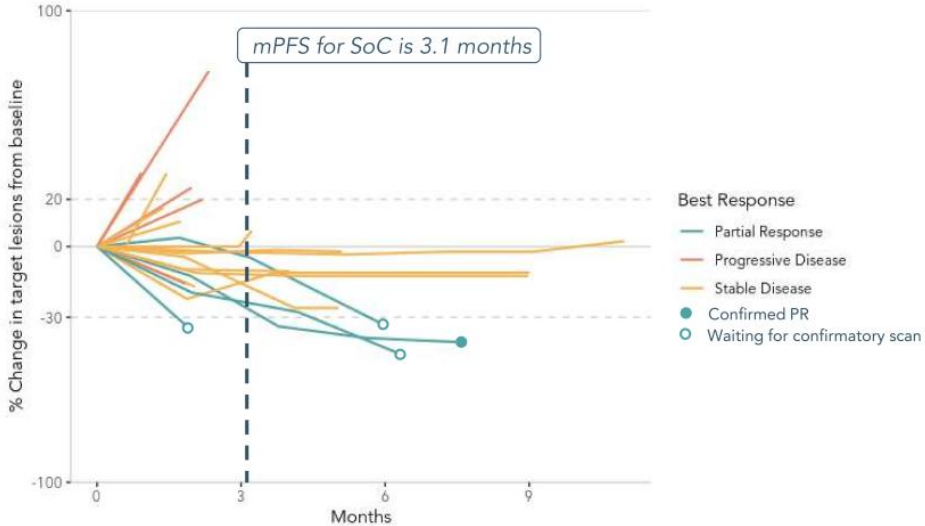
Swimmer plot – 23 evaluable patients (as of September 13, 2023)*



* Swimmer plot reflects interim data as of September 13, 2023 from an ongoing trial and unlocked database. For the swimmer plot, there are two patients included (04-026 and 04-041) that had two cycles of treatment but left the trial before their first post-baseline scan.

Patient responses to onvansertib+SoC can deepen over time

Spider plot – 21 evaluable patients (as of September 13, 2023)*

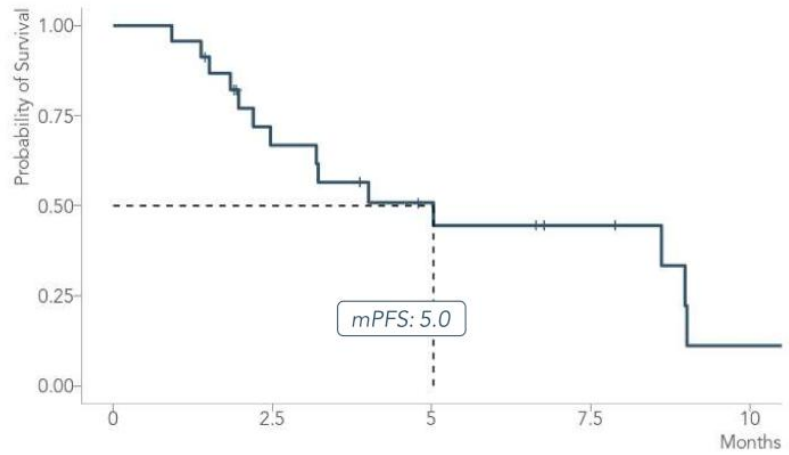


* Spider plot reflect interim data as of September 13, 2023 from an ongoing trial and unlocked database. For ORR analysis, there are two patients excluded (04-026 and 04-041) that had two cycles of treatment but left the trial before their first post-baseline scan.

Onvansertib+SoC has longer median PFS than 2nd line historical control

Progression-free survival – 23 evaluable patients (as of September 13, 2023)*

	CRDF-001	Historical controls ¹	
		2 nd line mPDAC	1 st line mPDAC
mPFS	5.0 mos	3.1 mos	5.5 mos
16 week progression-free ²	56%	Not available	48%



* Onvansertib mPFS are interim data as of September 13, 2023 from an ongoing trial and unlocked database. For PFS analysis, there are two patients included (04-026 and 04-041) that had two cycles of treatment but left the trial before their first post-baseline scan.

1. FDA insert for Onivyde (Nal-IRI): https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207793lbl.pdf; 387: 545-57, Von Hoff et al., N Engl J Med 2013; 369:1691-703.

2. Probability of being progression-free at 16 weeks using KM survival analysis. Data not available for 2nd line

Data from two mPDAC trials provides a path forward in 1st line setting

mPDAC
CRDF-001 Ph 2 Second-Line Trial

- Combination with Nal-irinotecan/leucovorin/5-FU

mPDAC
Biomarker Discovery Trial (IIT)

- Patients have 10 days of onvansertib monotherapy with pre- and post-therapy biopsies and bloodwork



Path forward: Move to 1st line mPDAC

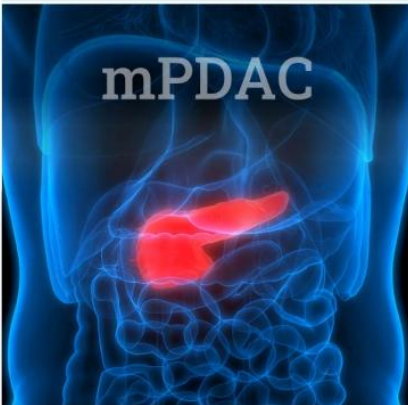
- New IIT combining onvansertib with SoC (Gemzar/Abraxane)
-

mPDAC Biomarker Discovery trial evaluates onvansertib monotherapy

Investigator-initiated trial at OHSU Knight Cancer Center

ENROLLMENT CRITERIA

Patients with metastatic pancreatic cancer (any line)



OBJECTIVES

Responsive biomarkers

- To demonstrate pancreatic tumor response to onvansertib monotherapy by measuring Ki67 and CA 19-9

Predictive biomarkers

- Use multi-omic analyses to identify predictive biomarkers of pancreatic tumor response to onvansertib

ONVANSERTIB MONOTHERAPY

(12mg/m² QD, 10 days)



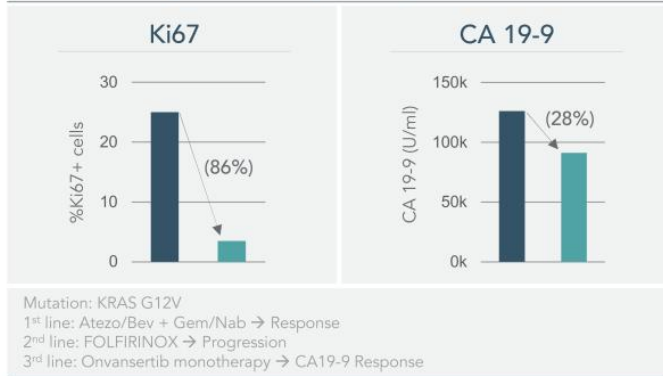
Obtain biopsies / bloodwork before and after 10 days of onvansertib monotherapy to conduct extensive multi-omic analysis

Onvansertib monotherapy decreased tumor proliferation and CA19-9

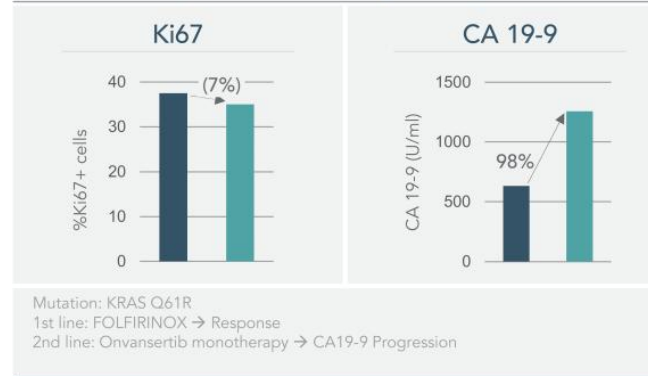
Biomarker Discovery Trial: Biomarker Response* – 2 patients (as of September 13, 2023)

- Ki67 is a well-established marker of tumor proliferation
- CA 19-9 is a clinically-used biomarker to monitor treatment response

Patient 28 (tumor responder)



Patient 33 (tumor non-responder)



■ Pre-treatment ■ Post-treatment

* Patient 28 and patient 33 had liver metastases and biopsies were taken pre- and post-onvansertib monotherapy treatment for ten days.

Data from two mPDAC trials provides a path forward in 1st line setting

mPDAC
CRDF-001 Ph 2 Second-Line Trial

- Combination with Nal-irinotecan/leucovorin/5-FU

mPDAC
Biomarker Discovery Trial (IIT)

- Patients have 10 days of onvansertib monotherapy with pre- and post-therapy biopsies and bloodwork



Path forward: Move to 1st line mPDAC

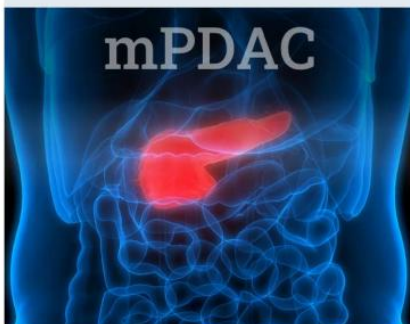
- New IIT combining onvansertib with SoC (Gemzar/Abraxane)
-

Proposed mPDAC 1st line Ph2 trial combines onvansertib with SoC

Proposed investigator-initiated trial with the OHSU Knight Cancer Institute

ENROLLMENT CRITERIA

First-line patients
 Unresectable
 Locally advanced or metastatic



TWO LEAD-IN COHORTS

Cohort 1

- 10-day lead-in with onvansertib monotherapy (30mg po daily)

Cohort 2

- No lead-in therapy



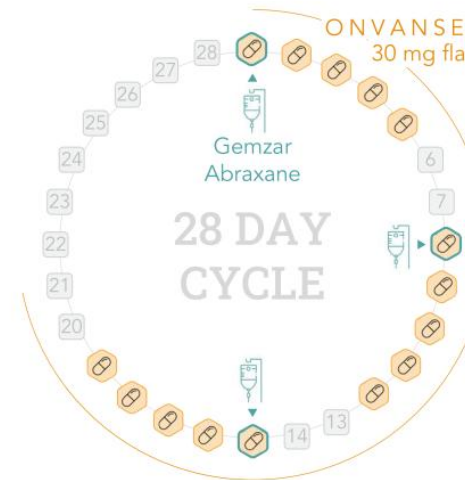
SUBSEQUENT CHEMO + ONVANSERTIB TREATMENT

PRIMARY ENDPOINT

ORR, DCR at 16 weeks

SECONDARY ENDPOINTS

DoR, PFS, Safety



* If a DLT occurs at dose level 1; then omit day 8 chemo only, and continue with onvansertib 30mg dose; but if toxicity persists at day 15, then decrease onvansertib dose to 20mg daily



Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)

Small Cell Lung Cancer (SCLC)

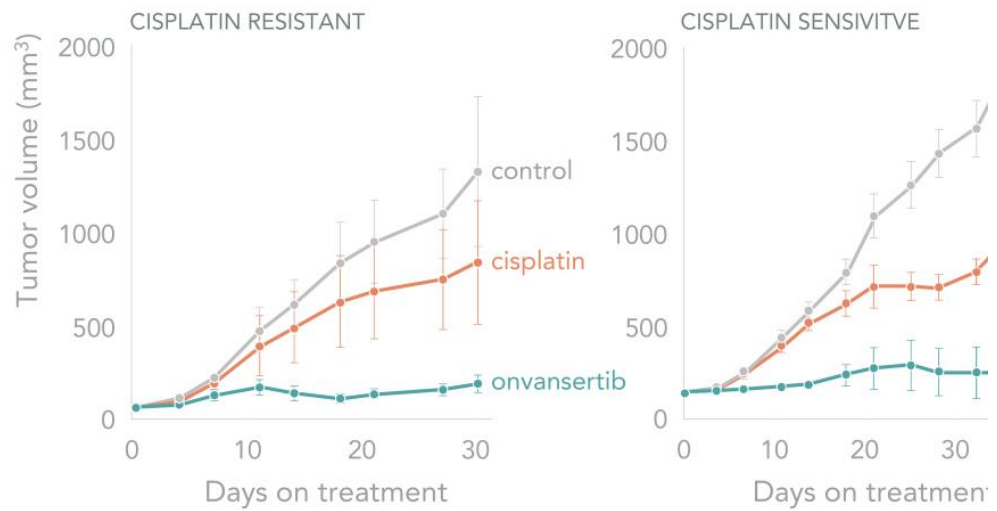
Onvansertib demonstrates single-agent activity in preclinical SCLC mod

TRIAL RATIONALE

Onvansertib monotherapy showed significant tumor growth inhibition against platinum-sensitive and -resistant models



In vivo efficacy of onvansertib monotherapy (SCLC xenografts)*



* Mice were implanted with SCLC PDX and treated with vehicle, cisplatin 3mg/kg IP weekly, or onvansertib oral 60mg/kg 10 ON / 4 OFF

Trial design for onvansertib monotherapy in extensive stage SCLC

ENROLLMENT CRITERIA

Relapsed who have received ≤ 2 prior therapies

Single-arm trial

Stage 1: N=15

Stage 2: N=20



OBJECTIVE

To determine the efficacy and safety of onvansertib monotherapy

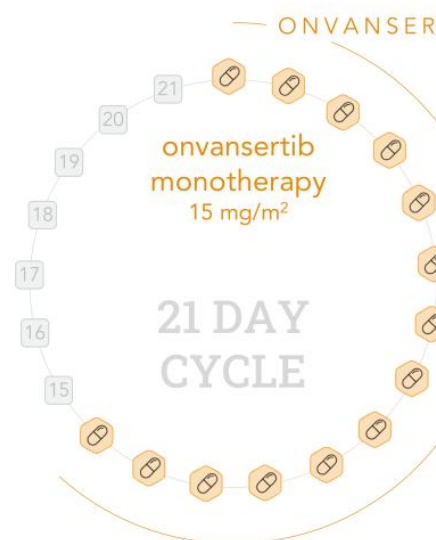
PRIMARY ENDPOINT

ORR (RECIST 1.1)

SECONDARY ENDPOINTS

Progression-Free Survival (PFS)

Overall Survival (OS)



Preliminary safety and efficacy for onvansertib monotherapy in SCLC

ENROLLMENT CRITERIA

Relapsed who have received ≤ 2 prior therapies

Single-arm trial
Stage 1: N=15
Stage 2: N=20



PRELIMINARY SAFETY (N=6)

IRB reviewed safety data for the first 6 patients. Post IRB review, the trial continues to enroll with no conditions.

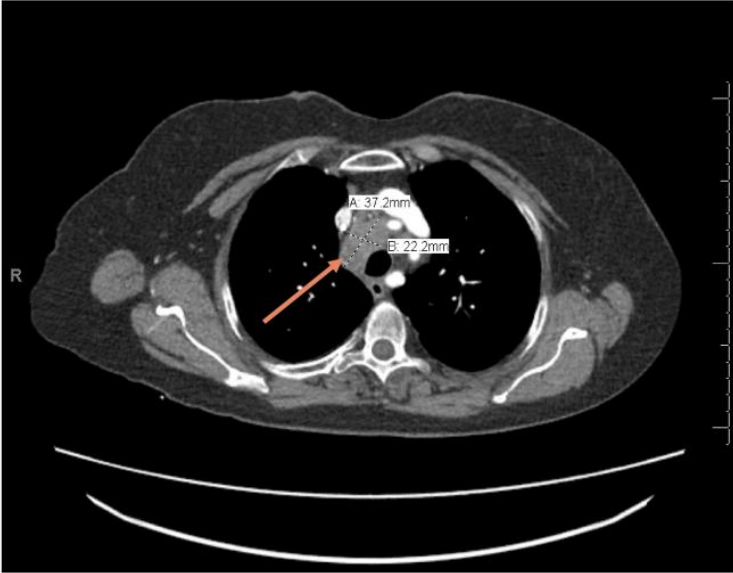
PRELIMINARY EFFICACY (N=7)

Best response	PR	SD	PD
# of patients	1 (confirmed)	3	3

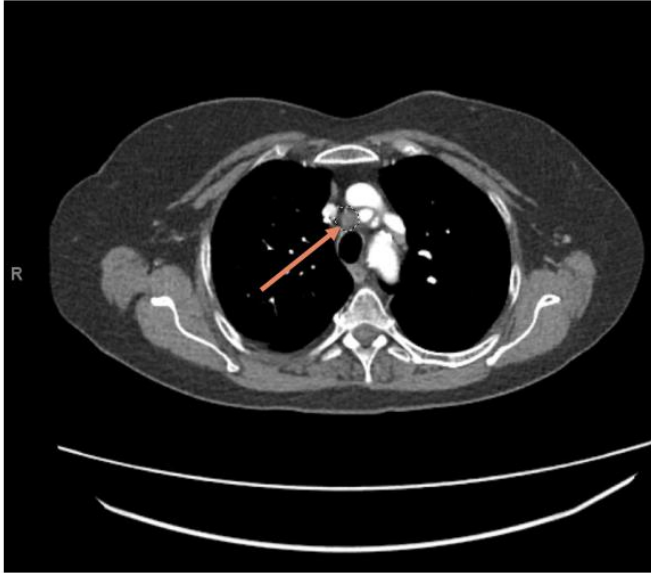
Disease control rate = 57% (4/7)

Radiographic scans for patient with a confirmed PR in SCLC IIT

Baseline Scan



Restaging after Cycle 2



We have multiple near-term clinical data read outs



June 30, 2023 cash and investments*	\$89.4M
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Net cash used in Operating Activities* (Rolling two-quarter period ending June 30, 2023)	\$15.8M
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Based on our current projections we expect that our capital resources are sufficient to fund our operations into 2025

* Financial information above is derived from our unaudited financials in Form 10Q filed on 8/9/23.

Highlights of today's mPDAC and SCLC program update

Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)

1. CRDF-001 trial

- Onvansertib, in combination with 2nd line standard-of-care, generated an efficacy signal and was well-tolerated

2. Biomarker discovery investigator-initiated trial

- Onvansertib monotherapy generated an efficacy biomarker response
- Onvansertib inhibited hypoxia-response pathway in treatment-responsive patient

3. First-line investigator-initiated trial planned

Small Cell Lung Cancer (SCLC)

Monotherapy investigator-initiated trial

- Confirmed PR in first seven patients in onvansertib monotherapy trial
-



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

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, September 26, 2023 -- 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 Fairouz Kabbinar, 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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