

**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): **January 18, 2022**



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:
Common Stock

Trading Symbol(s)
CRDF

Name of each exchange on which registered:
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

On January 11, 2022, Cardiff Oncology, Inc. (the "Company") issued a press release announcing announced new data from its lead clinical program evaluating onvansertib in combination with standard-of-care (SOC) FOLFIRI/bevacizumab for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). The data will be presented as a poster by Dr. Heinz-Josef Lenz, principal investigator, USC Norris Comprehensive Cancer Center, at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI) on Saturday, January 22, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K. In addition, the Company plans to make a presentation to investors at 5:00 pm ET on January 18, 2022 with the Corporate Presentation furnished as Exhibit 99.2 to this Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release of Cardiff Oncology, Inc. dated January 18, 2022](#)
99.2 [Corporate Presentation dated January 18, 2022](#)

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: January 18, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces New Data from Lead Clinical Program in KRAS-mutated Metastatic Colorectal Cancer Showing Robust Objective Response Rate and Progression Free Survival

- 12 of 35 (34%) patients treated per protocol at the recommended Phase 2 dose (RP2D) in combination with FOLFIRI and bevacizumab achieved a complete response or partial response (CR: 1 patient; PR: 11 patients)
- 17 of 48 (35%) patients across all dose levels achieved a CR or PR. Historically, objective response rates (ORR) of 5-13% have been reported in similar second line patient populations treated with various different drug combinations, including the standard of care chemotherapy of FOLFIRI with bevacizumab¹⁻⁴
- 5 of 48 (10%) patients discontinued the trial to pursue potentially curative metastasis-directed therapy (surgical resection or microwave ablation)
- Median progression-free survival (mPFS) across all response-evaluable patients (n=48) is 9.4 months and has not yet been reached in those treated per protocol at the RP2D. Historically, mPFS of ~4.5-5.7 months has been reported in a similar patient population treated with standard of care chemotherapy of FOLFIRI with bevacizumab¹⁻⁴
- The combination regimen of onvansertib plus FOLFIRI/bevacizumab is well tolerated with no major or unexpected toxicities attributed to onvansertib
- Company management is hosting a webcast and conference call today at 5:00 PM ET

SAN DIEGO, January 18, 2022 -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need including KRAS-mutated colorectal cancer, pancreatic cancer, and castrate-resistant prostate cancer, today announced new data from its lead clinical program evaluating onvansertib in combination with standard-of-care (SOC) FOLFIRI/bevacizumab for second-line treatment of patients with KRAS-mutated metastatic colorectal cancer (mCRC). A subset of these data will be featured in a poster presented by Dr. Heinz-Josef Lenz, principal investigator, USC Norris Comprehensive Cancer Center, at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCOGI) on Saturday, January 22, 2022.

"As we have increased the number of patients evaluated and the duration of follow-up, our Phase 1b/2 trial has consistently generated data suggesting that onvansertib provides meaningful clinical benefits when added to SOC," said Katherine L. Ruffner, M.D., chief medical officer of Cardiff Oncology. "The objective response rate and median progression free survival observed substantially exceed what would be expected with SOC alone, and five patients receiving onvansertib have been able to pursue potentially curative metastasis-directed treatments. We also observed a confirmed complete response, which is exciting given the difficult-to-treat nature of second line mCRC patients."

The most current data for the trial are shown below and include patient follow up collected after the cutoff dates for both the ASCO-GI abstract and poster (one additional PR was recorded after December 3):

Efficacy data in evaluable patients (represents an update from ASCO-GI abstract/poster):

- Among patients treated per protocol at the recommended Phase 2 dose (RP2D; 15 mg/m²) in combination with FOLFIRI-bev:
 - 12 of 35 (34%) achieved an initial complete response (CR) or partial response (PR)
 - 10 of 35 (29%) achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)
 - 33 of 35 (94%) had a best response of disease control (CR + PR + SD)
 - Objective response rates of 5-13% observed in historical control trials in similar patient populations treated with various different drug combinations, including the standard of care chemotherapy of FOLFIRI with bevacizumab¹⁻⁴
- Patients evaluable for response treated at all dose levels (12 mg/m², 15 mg/m², 18 mg/m²)
 - 17 of 48 (35%) achieved an initial CR or PR
 - 13 of 48 (27%) have achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)
 - 44 of 48 (92%) had a best response of disease control (CR + PR + SD)
- Status of 4 unconfirmed PRs:
 - 1 patient discontinued from the trial prior to confirmatory scan due to an adverse event that was unrelated to treatment (hepatitis B)
 - 1 patient went from PR to SD at the confirmatory scan and patient subsequently discontinued from the trial to pursue potentially curative metastasis-directed therapy
 - 1 patient went from PR to SD at the confirmatory scan (patient remains on treatment)
 - 1 patient has yet to have their confirmatory scan
- 5 of 48 (10%) evaluable patients discontinued therapy to pursue potentially curative metastasis- directed therapy (surgery or microwave ablation), including 2 patients with SD

Median progression free survival (mPFS; no update from ASCO-GI poster)

- mPFS has not yet been reached in patients treated per protocol at the RP2D
- mPFS across all response-evaluable patients (n = 48) is 9.4 months (95% confidence interval: 7.1 – not yet reached)
- mPFS of ~4.5-5.7 months has been reported in trials used as historical controls¹⁻⁴

Biomarker data across all patients (no update from ASCO-GI poster):

- Responses (CRs or PRs) were observed across seven different KRAS mutation variants, including the 3 most commonly observed in colorectal cancer (G12D, G12V, G13D)
- Patients achieving a best response of a CR or PR showed the greatest decreases in plasma KRAS mutant allelic frequency (MAF) measured by droplet digital PCR (ddPCR) after 1 cycle (28 days) of therapy

Safety data across all patients (no update from ASCO-GI poster):

- The combination of onvansertib and FOLFIRI/bevacizumab was shown to be well-tolerated with only 11% (84/788) of reported treatment-emergent adverse events (TEAEs) being G3/G4
 - The most commonly reported adverse event was neutropenia/neutrophil count decreased
 - Most reported TEAEs were manageable and reversible with supportive care

Baseline characteristics of patients at all dose levels (no update from ASCO-GI poster):

- The patients' median age was 61 years (range 35-83), and 56% were male
- 67% patients had previously received bevacizumab
- 16 of 48 (33%) evaluable patients remain on trial at the data cutoff date

Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology, commented, "These impressive results show radiographic responses across multiple KRAS mutation variants when onvansertib is combined with the standard of care regimen of FOLFIRI-bev and demonstrate a substantial increase in disease response relative to historical controls. We believe the data presented today further validate the potential of onvansertib to provide a meaningful improvement in the treatment outcome of a large patient population that has limited available treatment options. Looking forward, and with our strong cash position, we have the ability to explore the full potential of onvansertib."

Webcast and Conference Call

The newly announced data are being discussed today at 5:00 PM ET as part of a webcast and conference call with members of the Cardiff Oncology management team. To access the webcast, click [here](#). To participate by phone, please dial 1-877-407-9208 (domestic) or 1-201-493-6784 (international) and refer to conference ID 13725845. Following the live event, an archived webcast will be available on the "[Events](#)" section of the Cardiff Oncology website.

About the Phase 1b/2 Trial of Onvansertib in the Second-Line Treatment of KRAS-mutated mCRC This is a multi-center, single-arm, Phase 1b/2 trial of onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab) to evaluate the safety and preliminary efficacy of the combination regimen in the second-line treatment of patients with KRAS-mutated mCRC. The trial, *A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation*, is enrolling patients with histologically confirmed metastatic and unresectable colorectal carcinoma harboring a KRAS mutation.

Patients must also have experienced disease progression or treatment intolerance to first-line treatment with fluoropyrimidine and oxaliplatin (FOLFOX or CapeOx) with or without bevacizumab to be eligible.

The trial is being conducted at the following cancer centers across the U.S.: USC Norris Comprehensive Cancer Center, The Mayo Clinic (Arizona, Rochester, and Jacksonville), Kansas University Medical Center (KUMC), CARTI Cancer Center and Inova Schar Cancer Institute. For more information on the trial, please visit [NCT03829410](#).

References

1. Giessen et al., *Acta Oncologica* 2015, 54: 187-193
2. Cremolini et al., *Lancet Oncol* 2020, 21: 497-507
3. Antoniotti et al., *Correspondence Lancet Oncol* June 2020
4. Bennouna et al., *Lancet Oncol* 2013; 14: 29-37

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need. Our goal is to target tumor vulnerabilities with treatment combinations that overcome disease resistance and improve disease response to standard treatment regimens and to 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 anti-cancer therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to refine assessment of patient response to treatment. We have three clinical programs currently ongoing: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan, leucovorin and fluorouracil for the second-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC); and a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castrate-resistant prostate cancer (mCRPC). 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 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; 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, 2020, 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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Onvansertib Ph 1b/2 mCRC Tria Data Update

TURNING THE TIDE ON CANCER
JANUARY 18, 2022

Forward-looking statements

CERTAIN STATEMENTS IN THIS PRESENTATION ARE

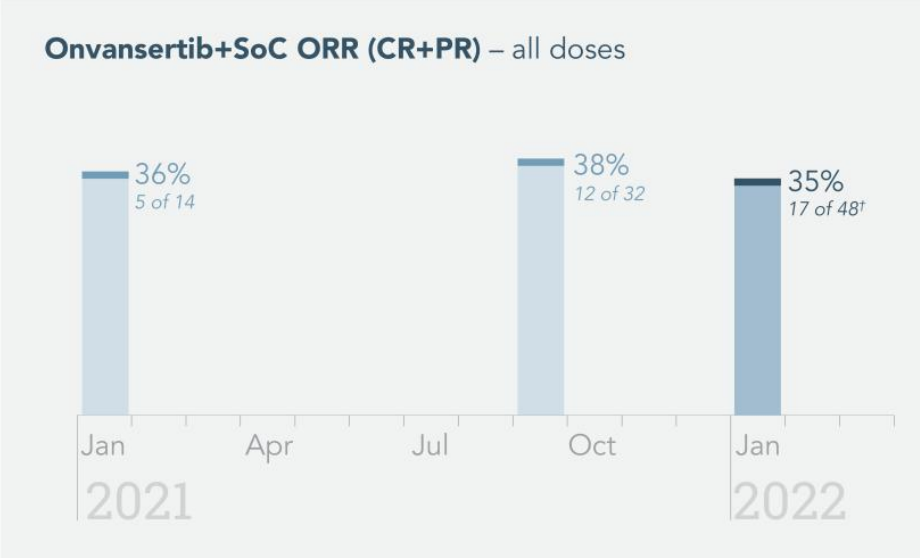
FORWARD-LOOKING within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern our expectations, strategy, plans 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; 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 on third parties; regulatory, and risks related to failure to obtain FDA clearances and approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove commercially successful. Additionally, there are no guarantees that future trials will be completed or successful or that any precision medicine therapies 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, 2020, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may represent significant additional obstacles to the realization of forward-looking statements included herein are made as of the date of this presentation and we do not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.



Mark Erlander, Ph.D.
Chief Executive Officer

Objective response rate for mCRC trial exceeds SoC over time



† Jan 2022 ORR are interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and includes one subsequent PR achieved on follow up through Jan 18, 2022 press release
 * 2008: Bennouna et al., Lancet Oncol 2013; 14: 29–37; 2013: Giessen et al., Acta Oncologica, 2015, 54: 187-193; 2017: Cremolini et al., Lancet Oncol 2020, 21: 497–507; and Antoniotti et al., Correspondence Lancet Oncol June 2020. SoC: Standard-of-care; ORR: objective response rate

Median progression free survival for mCRC trial exceeds SoC over time



† Jan 2022 PFS are interim data as of Dec 3, 2021 from an ongoing trial and unlocked database

* 2008: Bennouna et al., Lancet Oncol 2013; 14: 29-37; 2013: Giessen et al., Acta Oncologica, 2015, 54: 187-193; 2017: Cremolini et al., Lancet Oncol 2020, 21: 497-507; and Antoniotti et al., Correspondence Lancet Oncol June 2020. SoC: Standard-of-care. mPFS: median progression free survival

Onvansertib positions Cardiff Oncology to effectively target PLK1

SPECIFICITY

Exquisitely specific for PLK1

ENZYME	IC ₅₀ (μM)
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PLK1	0.002
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PLK2	>10
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PLK3	>10
------	-----

CK2	0.4
-----	-----

FLT3	0.4
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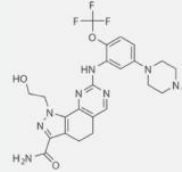
CDK1/CycB	>10
-----------	-----

42 other kinases	>10
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and >140 in the Millipore panel

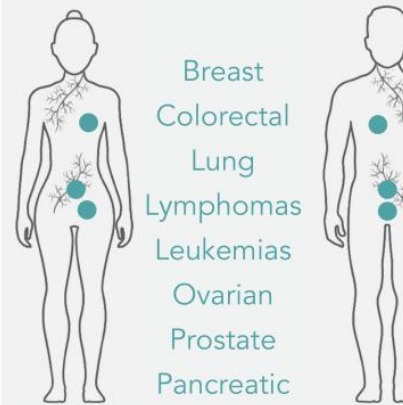
PROPERTIES

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



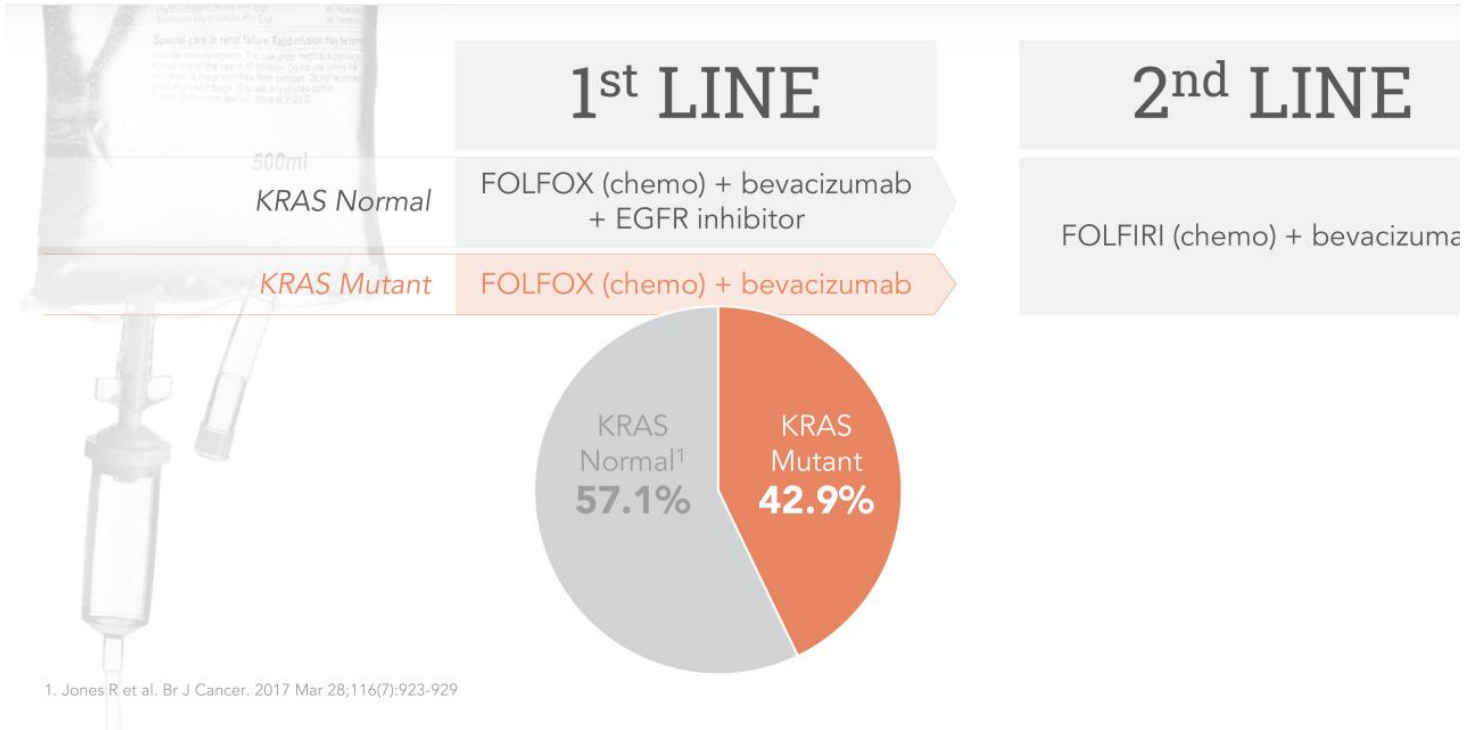
OPPORTUNITY

PLK1 is over-expressed in many cancer types¹



1. Renner Blood 2009; Mito Leukemia and Lymphoma 2005; 2005; Takai et al., Oncogene (2005) 24, 287-291

Gaps in current mCRC therapies leave a significant unmet need



The prognosis for second-line mCRC patients is poor



2nd LINE

FOLFIRI (chemo) + bevacizumab

5-year survival: 10%

Drugs in development do not address most prevalent KRAS mutations

HISTORICAL ORR

5%

2006 – 2008

ML18147 Phase 3 Registrational Trial: FOLFIRI + bev in second-line¹

11.4%

2000 – 2013

Systematic Literature-Based Analysis of 23 Randomized Trials (10,800 Patients) in Second-Line mCRC²

13%

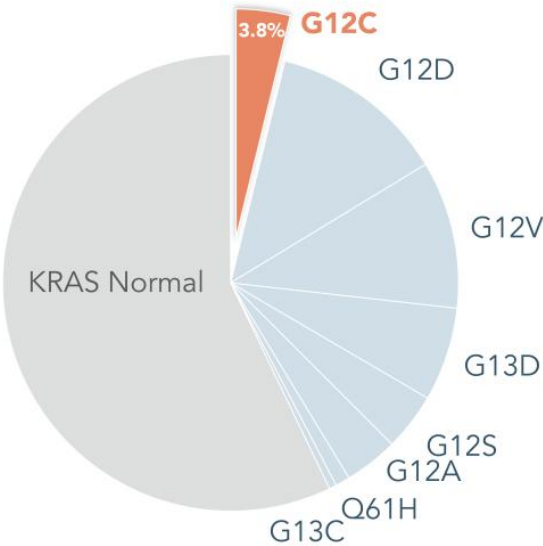
2015 – 2017

TRIBE2 Randomized Phase 3 Trial: 50% arm FOLFIRI + bev in Second-line following FOLFOX + bev First-line³

1. Bennouna et al., Lancet Oncol 2013; 14: 29–37; 2. Giessen et al., Acta Oncologica, 2015, 54: 187-193; 3. Cremolini et al., Lancet Oncol 2020, 21: 497–507; 4. Antoniotti et al., Correspondence Lancet Oncol June 2020. mCRC: metastatic colorectal cancer

Gaps in KRAS-mutated mCRC therapies leave a significant unmet need

KRAS Mutations in mCRC¹

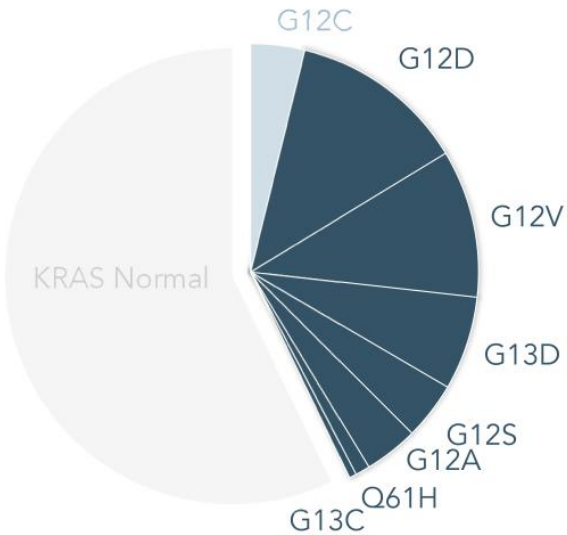


Investigational therapies (Amgen; Mirati) address the G12C KRAS mutation **only**

1. Jones R et al. Br J Cancer. 2017 Mar 28;116(7):923-929

Gaps in KRAS-mutated mCRC therapies leave a significant unmet need

KRAS Mutations in mCRC¹



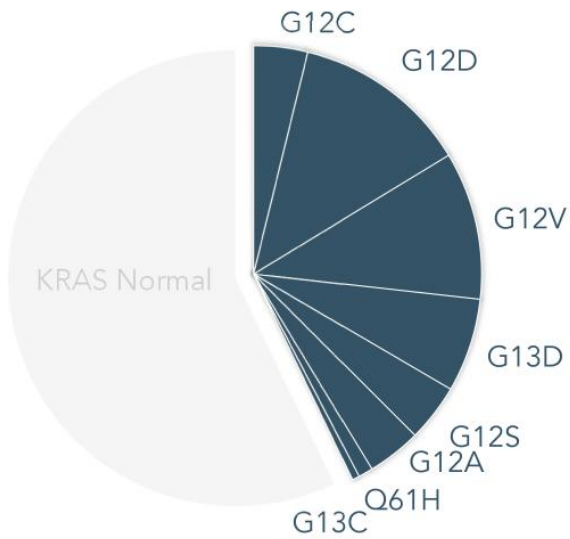
91.1%

of patients with KRAS mutations miss out on targeted therapy

1. Jones R et al. Br J Cancer. 2017 Mar 28;116(7):923-929

Gaps in KRAS-mutated mCRC therapies leave a significant unmet need

KRAS Mutations in mCRC¹

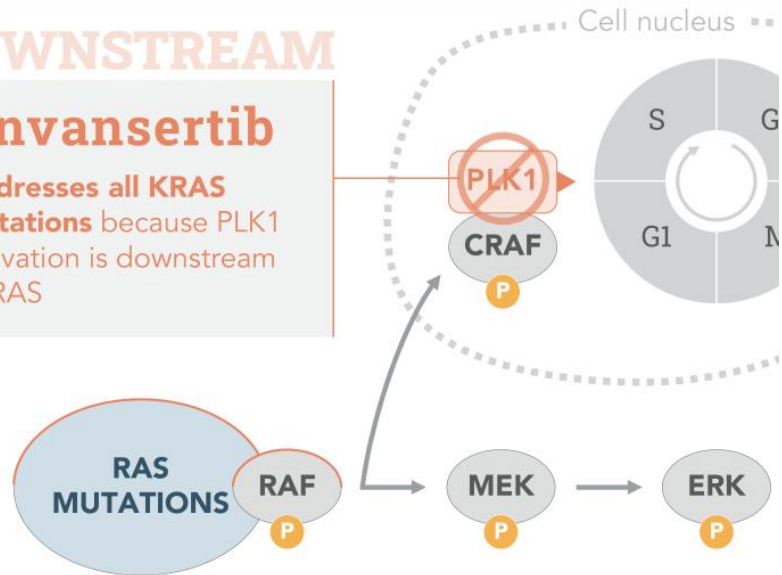


1. Jones R et al. Br J Cancer. 2017 Mar 28;116(7):923-929

DOWNSTREAM

Onvansertib

Addresses all KRAS mutations because PLK1 activation is downstream of RAS





Katherine Ruffner, MD
Chief Medical Officer



Ph 1b/2 trial of onvansertib in combination with FOLFIRI-bevacizumab in patients with KRAS-mutated mCRC

One Cycle = 28 Days

WEEKS 1-2



2nd-Line SoC: FOLFIRI
+ bevacizumab



6

7

8

9

10

11

12

13

— ONVANSERTIB —

WEEKS 3-4



2nd-Line SoC: FOLFIRI
+ bevacizumab



20

21

22

23

24

25

26

27

— ONVANSERTIB —



Trial endpoints: disease response and exploratory biomarkers

One Cycle = 28 Days

WEEKS 1-2



2nd-Line SoC: FOLFIRI
+ bevacizumab



— ONVANSERTIB —

WEEKS 3-4



2nd-Line SoC: FOLFIRI
+ bevacizumab



— ONVANSERTIB —

EFFICACY ENDPOINTS

- 1 Primary: Objective Response Rate (ORR) per RECIST v1.1 in patients who receive ≥ 1 cycle of treatment
- 2 Secondary: Progression-Free Survival (PFS) and Duration of Response (DoR)
- 3 Exploratory: decrease in KRAS mutational burden and response to treatment

Proof of concept criteria set to exceed historical ORR and mPFS

HISTORICAL ORR*

5%	2006 – 2008
11.4%	2000 – 2013
13%	2015 – 2017

HISTORICAL mPFS*

4.5–5.7 mo

SoC: FOLFIRI
mab

SERTIB-

SoC: FOLFIRI
mab

SERTIB-

PROOF OF CONCEPT CRITERIA

20% ORR

≥6 mo mPFS

* Bennouna et al., Lancet Oncol 2013; 14: 29-37; Giessen et al., Acta Oncologica, 2015, 54: 187-193; Cremolini et al., Lancet Oncol June 2020; ORR: Objective Response Rate; PFS: Progression-Free Survival

Enrollment and patient demographics

Enrollment*

Number of Patients (N)	Phase 1b, Dose Level 0 Onvansertib 12 mg/m ²	Phase 1b, Dose Level +1 Onvansertib 15 mg/m ²	Phase 1b, Dose Level +2 Onvansertib 18 mg/m ²	Phase 2 RP2D Onvansertib 15 mg/m ²	Total Patient All Doses
Treated	6	6	6	32	50
Currently on treatment	0	1	0	15	16

Total Patients N=50		Median [range] or n (%)	Total Patients N=50		Median n (%)
Age (years)		61 [35-83]	Liver metastasis ³		
Sex			None		11 (22%)
Male		28 (56%)	Liver and other		29 (59%)
Female		22 (44%)	Liver only		9 (18%)
ECOG ¹			Number of metastatic organs ⁴		
0		33 (69%)	1		17 (35%)
1		15 (31%)	≥2		32 (65%)
Primary tumor site ²			Prior bevacizumab treatment ⁵		
Colon		27 (55%)	Yes		33 (67%)
Rectum		17 (35%)	No		16 (33%)
Other		5 (10%)			

as of 03-Dec

* Jan 2022 data are interim as of Dec 3, 2021 from an ongoing trial and unlocked database. 1. ECOG not reported for two patients; 2. Primary tumor site not reported for one patient; 3. Liver metastasis presence not reported for one patient; 4. Number of metastatic organs not reported for one patient; 5. Prior bevacizumab treatment not reported for one patient

Safety: onvansertib in combination with FOLFIRI-bev is well-tolerated

N=50

No major/unexpected toxicities

- Of all TEAEs, only 11% (84/788) were G3/G4
- 7 patients had a total of 11 G4 adverse events:
 - Neutropenia (n=7); Decreased WBC (n=2); Neutropenic fever (n=1); Hyperphosphatemia (n=1)
- Discontinuation of the 5-FU bolus + use of growth factors ameliorated the severity of neutropenia observed

TEAEs*	GRADE					All	TEAEs*	GRADE					All
	1	2	3	4				1	2	3	4		
Neutropenia	1	13	15	6	35		Anemia	9	4	1	0	14	
Fatigue	15	15	3	0	33		Vomiting	9	3	1	0	13	
Nausea	24	7	2	0	33		Musculoskeletal Pain†	11	1	0	0	12	
Diarrhea	15	7	2	0	24		Infection†	3	4	4	0	11	
Abdominal Pain	13	7	1	0	21		Hemorrhage†	8	0	1	0	9	
Mucositis	11	6	2	0	19		Headache	7	0	0	0	7	
Alopecia	17	2	0	0	19		Neuropathy	5	2	0	0	7	
WBC Decrease	6	9	2	1	18		GERD	7	0	0	0	7	
Platelet Count Decrease	10	4	1	0	15		ALT Increase	4	0	1	0	5	
Hypertension	2	8	5	0	15								

* Jan 2022 data are interim as of Dec 3, 2021 from an ongoing trial and unlocked database. N: number of patients (total N=50); events shown occurred in ≥10% of patients; numbers indicate number of patients experiencing the event, (regardless of causality); each patient is only counted once and only for the highest grade of a given event. TEAEs: Treatment Emergent Adverse Events

† Musculoskeletal pain, infection and hemorrhage are pooled terms

as of 03-Dec

Rapid trial enrollment: increase in evaluable population over past year

Evaluable Patients

	ASCO-GI Jan 2021	KOL Event Sept 2021	ASCO-GI 2022		
			Abstract As of Sept 16	Poster As of Dec 3	Webcast As of Jan 1
All Doses	14	32	44	48	48
RP2D (15mg/m ²)		19	31	35	35

Today's webcast includes additional response data vs. ASCO-GI post

Evalu

COL Event
2021

ASCO-GI 2022

Webcast data release

- 16 patients remain on treatment at Dec 3, 2021 (ASCO-GI poster cutoff date)
- One additional initial PR after Dec 3, 2021
 - Patient 01-046: PR from scan on Dec 27

Abstract
As of Sept 16

Poster
As of Dec 3

Webcast
As of Jan 1

44

48

48

31

35

35

Efficacy events of interest

Evaluating

Clinical benefits observed

- 1 of 48 (2%) (with 41mm measurable disease) had a **confirmed Complete Response**
- 5 of 48 (10%) left trial for **potentially curative** metastasis-directed therapy
- 1 initial PR occurred at the **8-month scan**

ASCO GI Event
2021

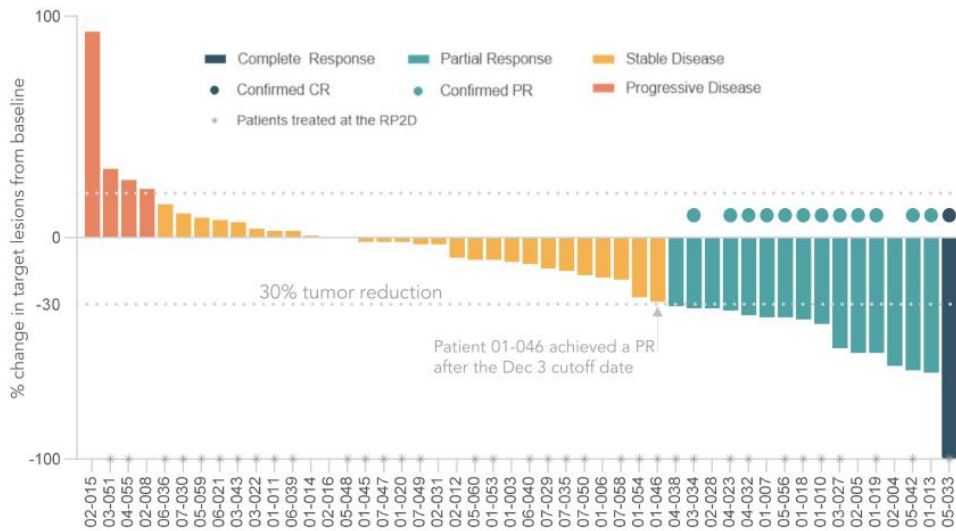
ASCO-GI 2022

	Abstract As of Sept 16	Poster As of Dec 3	Webcast As of Jan 1
	44	48	48
	31	35	35

Jan 2022 data are interim as of Dec 3, 2021 from an ongoing trial and unlocked database, and includes one subsequent PR achieved on follow up through Jan 18, 2022 press release

Efficacy: 92% disease control rate (DCR)

Best Radiographic Response* – all doses (as of Dec 3, 2021)

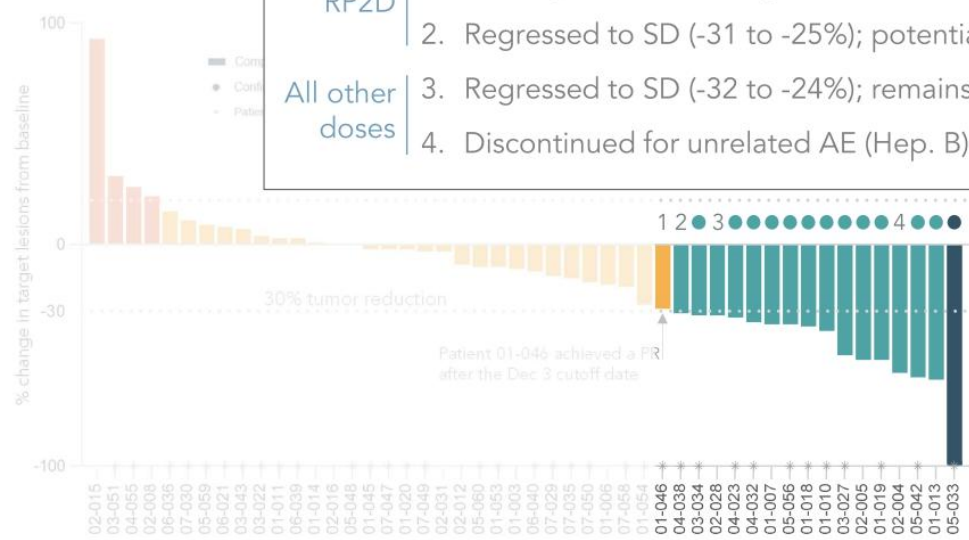


Objective Response* (CR + PR)	
- All doses	17 / 48
- RP2D	12 / 35
Tumor Reduction 33 / 48	
DCR (CR + PR + SD) 44 / 48	

* Waterfall plot and table reflect interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and indicates one subsequent PR achieved on follow up through Jan 18, 2022 press release

Efficacy: 92% disease control rate (DCR)

Best Radiographic



PR confirmation status

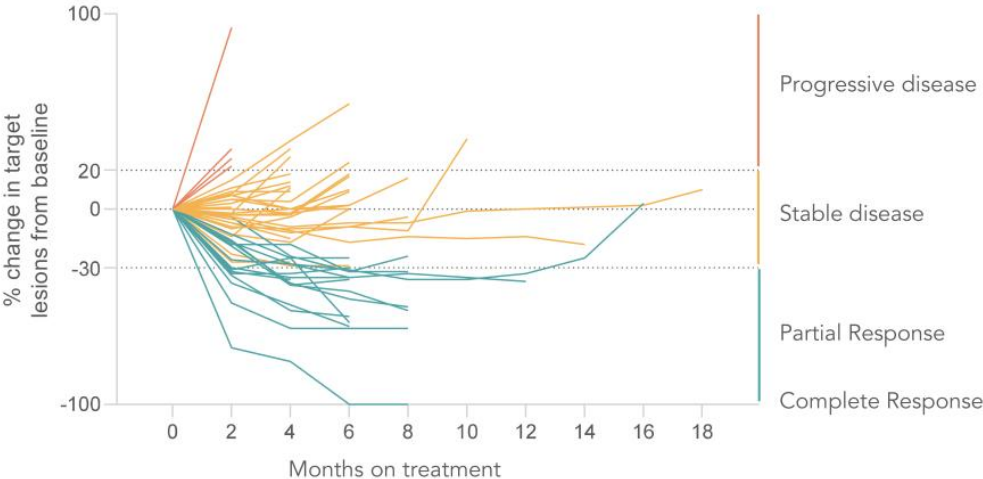
RP2D	1. Waiting for confirmatory scan; remains on trial
	2. Regressed to SD (-31 to -25%); potentially curative surgery
All other doses	3. Regressed to SD (-32 to -24%); remains on trial
	4. Discontinued for unrelated AE (Hep. B)

	17	48
- RP2D	12	35
Tumor Reduction	33	48
DCR (CR + PR + SD)	44	48

* Waterfall plot and table reflect interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and indicates one subsequent PR achieved on follow up through Jan 18, 2022 press release

Deepening of responses observed as patients remain on treatment

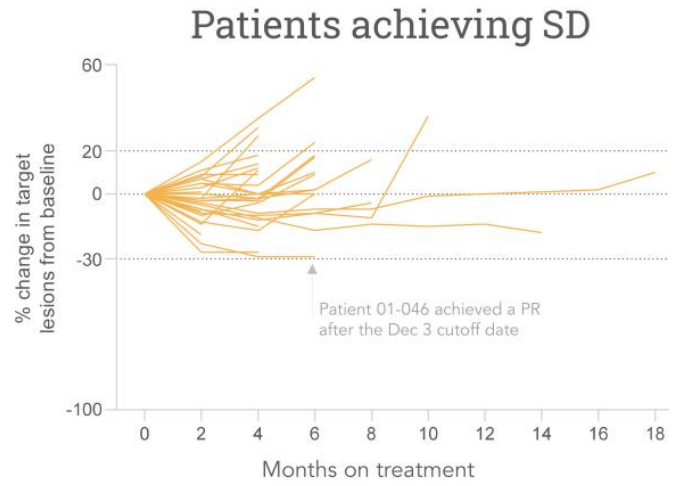
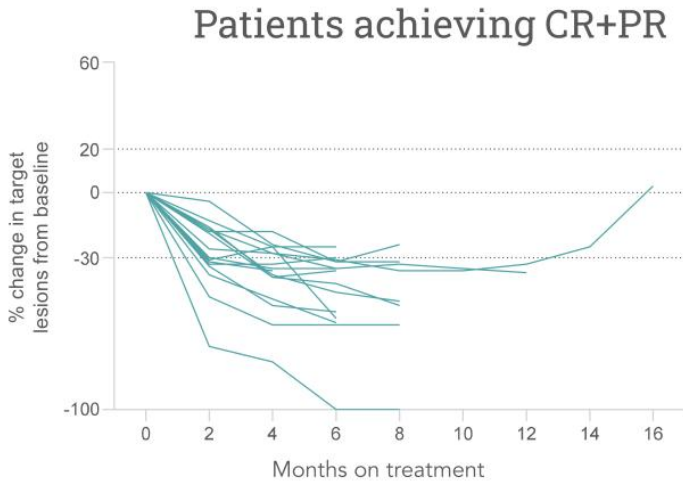
Change in tumor size from baseline* – all doses (as of Dec 3, 2021)



* Spider plot reflects interim data as of Dec 3, 2021 from an ongoing trial and unlocked database

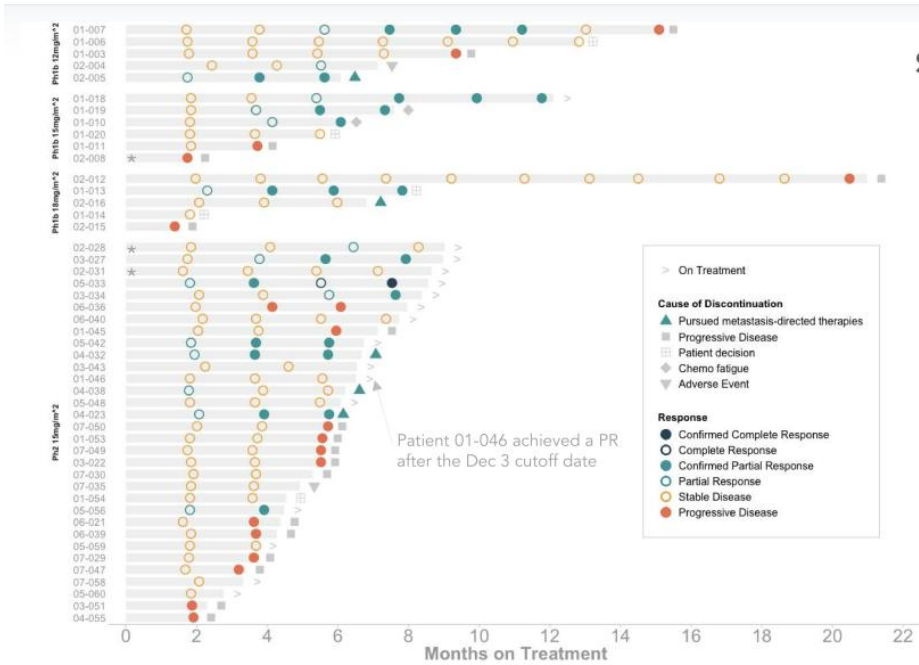
Deepening of responses observed as patients remain on treatment

Change in tumor size from baseline* – all doses (as of Dec 3, 2021)



* Spider plots reflect interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and indicates one subsequent PR achieved on follow up through Jan 18, 2022 press release

Initial disease responses may occur from week 8 to week 32



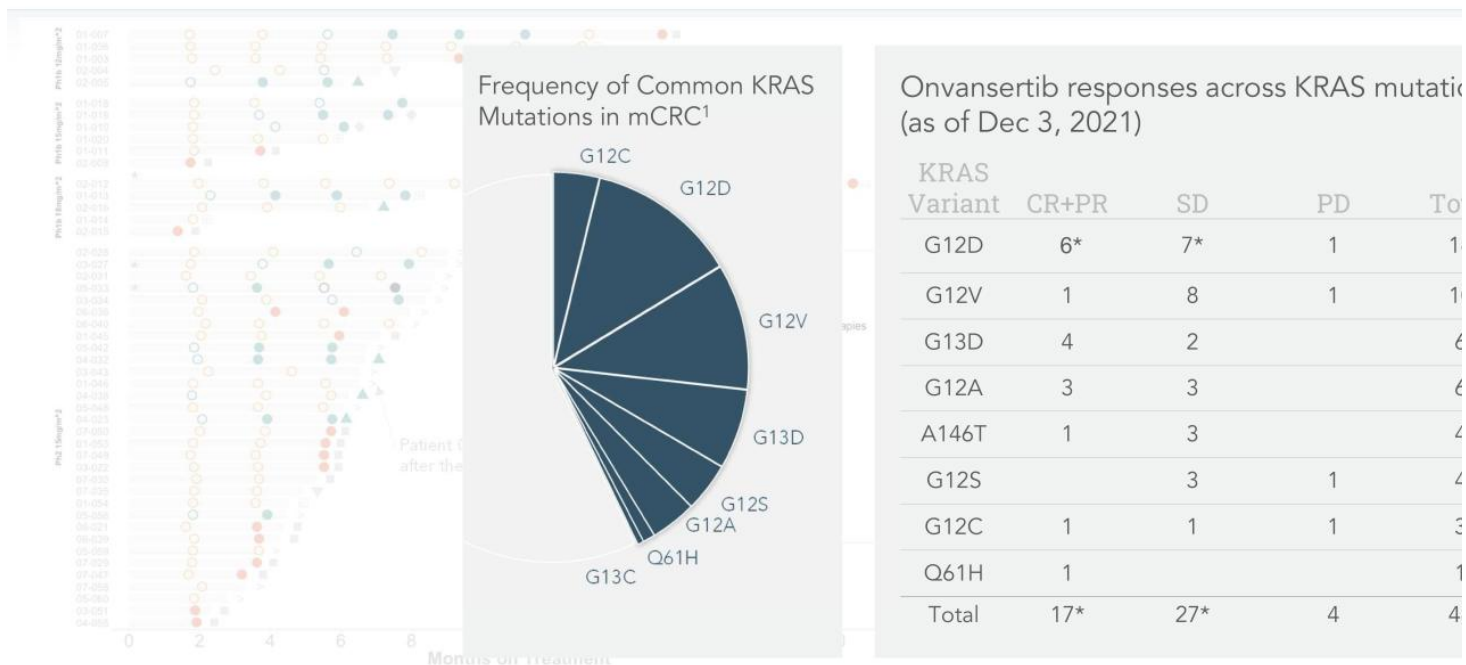
Swimmer plot† – all doses (as of Dec 3, 2021)

Evaluable Patients – all doses

Time of initial PR
8-week scan
16-week scan
24-week scan
32-week scan†

* Three patients were excluded from the RP2D efficacy evaluation because they received onvansertib 12 mg/m² instead of the assigned per protocol dose of 15 mg/m²
 † Swimmer plot and table reflect interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and indicates one subsequent PR achieved on follow up through Jan 18, 2022 press release

The all-dose cohort achieved responses across several KRAS mutations



1. Jones R et al, Br J Cancer. 2017 Mar 28;116(7):923-929

* Patient 01-046 (with a G12D mutation) achieved a PR after the Dec 3, 2021 data cutoff date and is included in the table above as a 6th PR in the G12D line and 17th PR in the total line

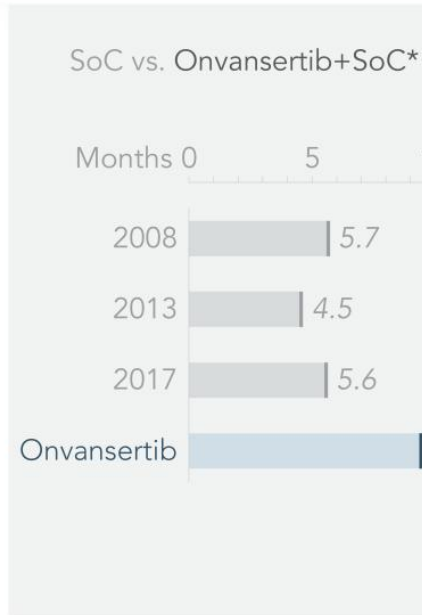
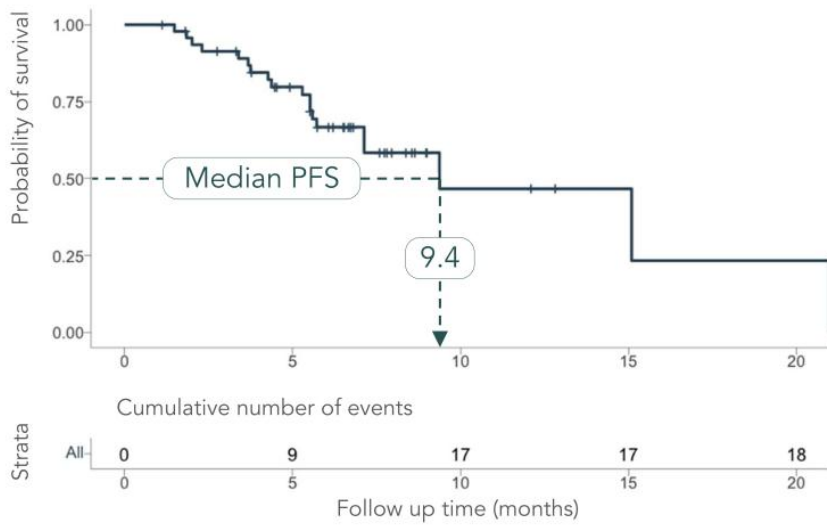
ORR continues to exceed the SoC and PoC threshold over time



† Jan 2022 ORR are interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and includes one subsequent PR achieved on follow up through Jan 18, 2022 press release
 * 2008: Bennouna et al., Lancet Oncol 2013; 14: 29-37; 2013: Giessen et al., Acta Oncologica, 2015, 54: 187-193; 2017: Cremonini et al., Lancet Oncol 2020, 21: 497-507; and Antoniotti et al., Correspondence Lancet Oncol June 2020. SoC: Standard-of-care; PoC: Proof-of-concept

Median PFS continues to exceed the SoC and PoC threshold over time

Progression free survival† – all doses (as of Dec 3, 2021)



† mPFS is interim data as of Dec 3, 2021 from an ongoing trial and unlocked database

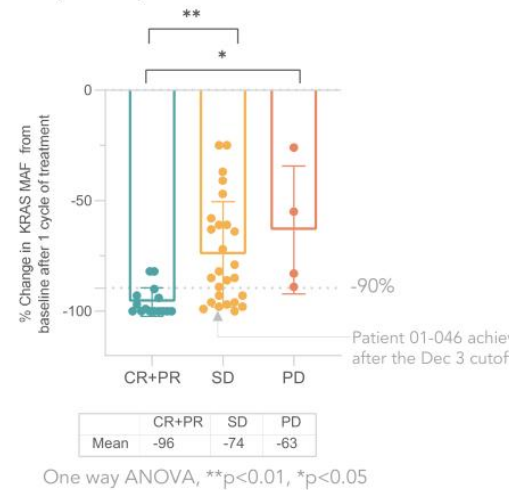
* 2008: Bennouna et al., Lancet Oncol 2013; 14: 29-37; 2013: Giessen et al., Acta Oncologica, 2015, 54: 187-193; 2017: Cremolini et al., Lancet Oncol 2020, 21: 497-507; and Antoniotti et al., Correspondence Lancet Oncol June 2020. SoC: Standard-of-care; PoC: Proof-of-concept

Early KRAS MAF ctDNA decrease correlates with radiographic response

Predictive response biomarker

- 87% (13/15) of PR patients had $\geq 90\%$ decrease in KRAS MAF after the 1st cycle
- 35% (9/26) of SD patients and none of the PD patients (n=4) had such a decrease

% KRAS Mutant Allelic Frequency (MAF)*
decrease after one 28-day treatment cycle
(as of Dec 3, 2021)



* KRAS MAF measured by droplet digital PCR (ddPCR) at baseline (day 1 of cycle 1, pre-dose) and on-treatment (day 1 of cycle 2). 1 PR and 2 SD patients had undetectable KRAS at baseline. KRAS MAF plot reflects interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and indicates one subsequent PR achieved on follow up through Jan 18, 2022 press release

KRAS-mutated mCRC: Cardiff Oncology's next steps

Cardiff Oncology management has decided to expand the activated Phase 2 trial and enroll ~40-50 additional patients as we prepare for initiation of the pivotal trial

- Obtain additional patient data:
 - Safety
 - Efficacy
 - Pharmacokinetic/pharmacodynamic (biomarkers)
 - Continue assessing the value of KRAS response biomarker
 - Keep current sites activated to lead into pivotal trial
-

Anticipated catalysts over the next twelve months

2022

CLINICAL PROGRAMS

Mid 2022

mCRC Phase 1b/2 data release

Launch pivotal trial

mPDAC Phase 2 data release

mCRPC Phase 2 data release

OTHER COMBINATIONS

- **Ovarian** cancer with PARP
- **Breast** cancer with paclitaxel
- **Medulloblastoma** with radiation (pediatric)

Our pipeline opens many attractive opportunities for onvansertib

		Preclinical	IND En.	Ph 0/1	Ph 2	Status	
mCRC	FOLFIRI/bev					Enrolled	
mPDAC	Onivyde/5-FU					Enrolling	
mCRPC	Abiraterone					Enrolling	Partner
mPDAC	Biomarker					Target Q1, '22	
TNBC	Combo w/ Paclitaxel					Development	
SCLC	Single agent					Development	
CMML	Single agent					Development	
Medullo- blastoma	Combo w/ radiation					Development	
Ovarian	PARP inhibitors					Preclinical	

Cardiff Oncology has many attractive options for onvansertib

	DNA DAMAGING AGENTS			MICROTUBULE TARGETING			EPIGENETIC LSD1 INHIBITORS
	CHEMOTHERAPY	PARP		DISRUPT	FREEZE	DISCONNECT	
		INHIBITORS	RADIATION				
mCRC	Phase 1b/2 Trial						
mPDAC	Phase 2 Trial	○●○			○●○		
mCRPC	○●○	○●○				Phase 2 Trial	○●○
Ovarian		○●○		○●○	○●○		
Breast		○●○			○●○		
SCLC	○●○	○●○			○●○		○●○
Medullo- blastoma			○●○				

○●○ = Cardiff Oncology potential

Our leadership is highly skilled in drug development



Mark Erlander, PhD
CEO



Kathrine Ruffner, MD
CMO



Charles Monahan, RPh
SVP, Regulatory



Vicki Kelemen
COO



Tod Smeal, PhD
CSO



Jamie Levine
CFO



Brigitte Lindsay
VP, Finance

Cardiff Oncology at a glance

Clinical-stage biotech company developing onvansertib, an oral, highly-selective **Polo-Like Kinase 1 (PLK1)** inhibitor, to treat cancers with the greatest medical needs for new treatment options

Exchange	Nasdaq: CRD
Cash, Cash Equivalents and Investments ¹	\$134.0M
Cash used in Operating Activities ¹ (9/30/21 YTD)	\$15.7M
Headquarters	San Diego, CA

1. As of 9/30/21. The above financial information is derived from our unaudited financials in Form 10Q filed on 11/04/21. Cash, cash equivalents and investments does not include the \$15M raised from the Pfizer investment in November 2021



Learn more at www.CardiffOncology.com

Appendix: Summary of onvansertib mCRC Ph1b/2 trial data over time

	ASCO GI Jan 2021	KOL Event Sept 2021		ASCO GI Jan 2022				Investor Webcast Jan 2022	
				Abstract		Poster			
				Sep 16, 2021		Dec 3, 2021			
Data Cutoff Date	Nov 1, 2020*	July 2, 2021*		Sep 16, 2021		Dec 3, 2021		Dec 3, 2021 - efficacy follow through Jan. 18, 2022	
	All Doses	All Doses	RP2D	All Doses	RP2D	All Doses	RP2D	All Doses	RP2D
						At data cutoff		After data cutoff	
Evaluable Patients	14	32	19	44	31	48	35	48	35
ORR (CR+PR)	36% (5)	38% (12)	42% (8)	36% (16)	35% (11)	33% (16)	31% (11)	35% (17)	34% (12)
Confirmed PRs	29% (4)	31% (10)	37% (7)	Data not disclosed in abstract		27% (13)	29% (10)	1 patient waiting for confirmatory scan	
mPFS	-	9.4 mo	NR			9.4 mo	NR	No change from poster	
Disease control rate (CR+PR+SD)	86% (12)	94% (30)	100% (19)			92% (44)	94% (33)		

* Data release include certain follow up data. "Investor Webcast Jan 2022" column reflects interim data as of Dec 3, 2021 from an ongoing trial and unlocked database, and indicates one subsequent PR achieved on follow up through Jan 18, 2022 press release. NR: Not reached

