

**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 10, 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 8.01 Regulation FD Disclosure

On September 12, 2022, Cardiff Oncology, Inc. (the “Company”) issued a press release announcing plans to conduct a randomized Phase 2 trial of onvansertib in combination with standard-of-care (SoC) FOLFIRI/bevacizumab in second-line RAS-mutated mCRC, durability of responses from its ongoing Phase 1b/2 clinical trial in KRAS-mutated mCRC and additional business updates. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K. In addition, on September 12, 2022, the Company held a conference call and webcast providing a clinical and corporate update and presented the Investor Presentation attached hereto as Exhibit 99.3 and incorporated herein by reference.

The information under this Item 7.01, including Exhibits 99.1 and 99.3, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of such section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Item 8.01 Other Events.

On September 10, 2022, the Company issued a press release announcing new preclinical and clinical data from its program in KRAS-mutated mCRC. The data are featured in two posters being presented at the European Society for Medical Oncology (ESMO) Congress 2022, which is taking place at the Paris Expo Porte de Versailles in Paris, France, and virtually. A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release of Cardiff Oncology, Inc. dated September 10, 2022](#)
99.2 [Press Release of Cardiff Oncology, Inc. dated September 12, 2022](#)
99.3 [Investor Presentation](#)

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 12, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces New Preclinical and Clinical Data from Program in KRAS-mutated Metastatic Colorectal Cancer (mCRC) at the ESMO Congress 2022

Durable responses to treatment, with a median duration of response (mDoR) of 11.7 months, reported in Phase 1b/2 clinical trial of onvansertib plus FOLFIRI/bevacizumab in second-line KRAS-mutated mCRC

Observed mDoR is supported by preclinical findings that demonstrate onvansertib in combination with irinotecan can overcome intrinsic and refractory resistance to irinotecan in patient-derived xenograft models

Patients with a ≥90% decrease in KRAS mutant allele frequency (MAF), a response biomarker, in the first cycle of treatment had significantly higher ORR and longer PFS in Phase 1b/2 trial and an Expanded Access Program (EAP)

SAN DIEGO, September 10, 2022 – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced new preclinical and clinical data from its program in KRAS-mutated mCRC. The data are featured in two posters being presented at the European Society for Medical Oncology (ESMO) Congress 2022, which is taking place at the Paris Expo Porte de Versailles in Paris, France, and virtually.

Poster 397P: Early Decreases in KRAS Mutant Allele Frequency (MAF) Predict Clinical Benefit to the PLK1 Inhibitor Onvansertib in Combination with FOLFIRI/bev in 2L Treatment of Metastatic Colorectal Carcinoma (mCRC)

Poster 397P includes updated data (data cut-off date: July 25, 2022), as well as the results of correlative biomarker analyses from a Phase 1b/2 clinical trial of onvansertib plus FOLFIRI/bevacizumab in second-line KRAS-mutated mCRC. Measures of clinical response were compared between subsets of patients defined as KRAS responders or non-responders. KRAS responders were defined as patients with a ≥90% decrease in KRAS mutant allele frequency (MAF) in circulating tumor DNA (ctDNA) after one treatment cycle.

“The data from this trial show onvansertib plus FOLFIRI and bevacizumab outperforming historical controls on multiple key endpoints and are highly encouraging,” said Heinz-Josef Lenz, MD, FACP, professor of medicine at USC Norris Comprehensive Cancer Center and the trial’s principal investigator. “They suggest trial participants with various KRAS mutations experience durable clinical benefits and that the onvansertib-FOLFIRI combination is avoiding the mechanisms that typically drive rapid acquired resistance to the standard-of-care (SoC). This highlights onvansertib’s potential to fill a crucial gap in mCRC’s therapeutic paradigm, as there are currently limited options available for second line patients. In addition, the significant increases between response rates and progression-free survival in KRAS responders point to changes in MAF as a potential blood-based biomarker that could aid in treatment decisions.”

Key data and conclusions presented in the poster include:

Overall response rate (ORR) and median progression-free survival (mPFS) reported in Phase 1b/2 trial substantially exceed those reported in historical control trials

- ORR across all evaluable patients was 35%, with 17 of 48 evaluable patients achieving an objective response and responses have been observed across multiple KRAS variants
- Median duration of response (mDoR) across all evaluable patients was 11.7 months (95% confidence interval (CI): 8.9 – not reached)
- mPFS across all evaluable patients was 9.3 months (95% CI: 7.6 – 13.5)
- Historical control trials of different drug combinations, including the standard-of-care (SOC) of FOLFIRI with bevacizumab, in similar patient populations have shown ORR and mPFS of 5 – 13% and ~4.5 – 5.7 months, respectively¹⁻⁴

KRAS responders showed significantly greater ORR and mPFS compared to non-responders

- ORR in KRAS responders vs. KRAS non-responders: 63.6% (14/22) vs. 8.7% (2/23) (p = 0.00014)
- mPFS in KRAS responders vs. KRAS non-responders: 12.6 months vs. 6.0 months (p=0.019)

Poster 366P: The PLK1 Inhibitor Onvansertib Overcomes Irinotecan Resistance in RAS-mutated Metastatic Colorectal Cancer (mCRC) In Vivo and in Patients

Poster 366P includes findings (as of August 5, 2022) from Cardiff Oncology's EAP of onvansertib in KRAS-mutated mCRC, as well as data from murine studies evaluating onvansertib in combination with irinotecan in 6 PDX models of irinotecan-resistant, RAS-mutated CRC. Clinical findings reported in the Expanded Access Program (EAP) were compared between KRAS responders and non-responders. To enroll in the EAP, a patient must have been ineligible for the Phase 1b/2 clinical trial having received prior treatment with irinotecan or failed or progressed on multiple prior lines of standard-of-care therapy. EAP patients are treated with the same treatment regimen (onvansertib 15 mg/m² plus FOLFIRI and bevacizumab) and dosing schedule as patients in the Phase 1b/2 clinical trial.

Scott Kopetz, MD, PhD, FACP, professor, Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center commented, "Currently available third-line or later treatment options for patients are severely limited, due in large part to the high prevalence of tumors that show resistance to irinotecan. Based on the findings being presented at ESMO, combining onvansertib with the current SOC appears to be an innovative strategy that can overcome irinotecan resistance and address a broad and pressing unmet need. This hypothesis is further supported by onvansertib's mechanism of action, which targets DNA damage repair pathways underlying resistance to irinotecan and other chemotherapeutic agents."

Key findings and conclusions presented in the poster include:

EAP patients with prior irinotecan treatment (43 out of a total of 51 EAP patients) showed clinical benefit following treatment with onvansertib plus FOLFIRI/bevacizumab

- mPFS was 4.04 months (95% CI: 2.96 – 8.38); 6-month PFS rate was 37.3% (95% CI: 24.9 – 55.8)

Of EAP patients with prior irinotecan treatment, KRAS responders had significantly longer PFS compared to non-responders.

- mPFS in KRAS responders vs. KRAS non-responders: 11.18 months vs. 3.25 months (p=0.0014)

The combination of onvansertib and irinotecan showed significantly greater anti-tumor activity compared to onvansertib monotherapy in 5 of 6 tested PDX models of irinotecan-resistant, RAS-mutated CRC.

The ESMO posters are currently available for viewing on the congress's virtual platform and will also be presented by Drs. Lenz and Kopetz during Poster Sessions 8 and 7, respectively, on September 11, 2022. Following the congress, the posters will be available on the "Scientific Presentations" section of the Cardiff Oncology website at <https://cardiffoncology.com/scientific-presentations/>.

Clinical and Corporate Update Conference Call and Webcast

Cardiff Oncology will host a webcast and conference call to provide a clinical and corporate update to the investment community on Monday, September 12, 2022 at 4:30 PM ET. The event will feature discussions on the planned development pathway for onvansertib in KRAS-mutated metastatic colorectal cancer and updates on other development programs. In addition, company management will provide data updates from ongoing clinical trials. To access the call, please dial 1-877-407-9208 (domestic) or 1-201-493-6784 (international) and refer to conference ID 13731618. The conference call will also be webcast live and a link to the webcast can be accessed [here](#). A replay of the webcast will be available by visiting the "Events" section of the Cardiff Oncology website after its conclusion.

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](https://clinicaltrials.gov/ct2/show/study/NCT03829410).

About the EAP for Onvansertib in KRAS-mutated mCRC

Sometimes called "compassionate use", expanded access is a potential pathway for a patient with a serious or life-threatening disease to gain access to an investigational drug for treatment outside of a clinical trial, particularly when no comparable or satisfactory alternative therapy options are available. The Cardiff Oncology EAP in KRAS-

mutated mCRC is using the same combination treatment regimen (onvansertib 15 mg/m² + FOLFIRI and bevacizumab) and dosing schedule as the ongoing Phase 1b/2 clinical trial and is intended for patients that have progressed on prior therapy and do not meet the second line eligibility criteria for enrollment in the clinical trial. The program has reached capacity and is no longer open to enrollment.

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 biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers. Our lead asset is onvansertib, a PLK1 inhibitor we are evaluating in combination with standard-of-care (SOC) therapeutics in clinical programs targeting indications such as KRAS-mutated metastatic colorectal cancer, metastatic pancreatic ductal adenocarcinoma, and metastatic castrate-resistant prostate cancer. These programs and our broader development strategy are designed to target tumor vulnerabilities in order to overcome treatment resistance and deliver superior clinical benefit compared to the SOC. 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 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, 2021, 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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Cardiff Oncology Announces Plans for a Randomized Trial in Metastatic Colorectal Cancer (mCRC), Durability of Responses in Ongoing Phase 1b/2 Trial in mCRC and Additional Business Updates

Next trial in RAS-mutated mCRC (ONSEMBLE) is a randomized Phase 2 trial to demonstrate onvansertib's contribution to SoC and position for a possible accelerated approval opportunity; topline data expected in 2H 2024

Data from ongoing Phase 1b/2 trial in KRAS-mutated mCRC show durable responses to treatment, with a median duration of response (mDoR) of 11.7 months for all doses and 12.5 months for the recommended phase 2 dose

Initial data in Phase 2 trial in second-line pancreatic ductal adenocarcinoma (mPDAC) show 1 partial response (PR), 3 stable disease (SD) achieved in 5 evaluable patients treated with onvansertib plus SoC

Based on its current expectations and projections, the Company's current cash resources are sufficient to fund its operations into 2025

Company management is hosting a webcast and conference call today at 4:30 PM ET

SAN DIEGO, September 12, 2022 – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced plans to conduct a randomized Phase 2 trial of onvansertib in combination with standard-of-care (SoC) FOLFIRI/bevacizumab in second-line RAS-mutated mCRC, durability of responses from its ongoing Phase 1b/2 clinical trial in KRAS-mutated mCRC and additional business updates.

"We designed our next clinical program in mCRC, a randomized Phase 2 trial we have named ONSEMBLE, to accelerate and de-risk our lead indication," said Mark Erlander, PhD, chief executive officer of Cardiff Oncology. "Chief among ONSEMBLE's objectives is to generate a randomized dataset to demonstrate the contribution of onvansertib over standard-of-care alone, validating the Phase 1b/2 trial results. These results show patients with different KRAS mutations experiencing durable responses to treatment with onvansertib plus standard-of-care, with an objective response rate and median progression-free survival that are well above historical benchmarks. In line with the FDA's Project Optimus initiative, the ONSEMBLE trial will also seek to confirm the optimal dose of onvansertib in mCRC. We believe achieving these objectives could position onvansertib for a possible accelerated approval opportunity, though this would ultimately depend on the strength of the ONSEMBLE trial results."

Dr. Erlander continued, "With regards to our ongoing Phase 2 trial in pancreatic cancer, we are pleased to announce encouraging initial results that show 4 out of 5 evaluable patients achieving disease control and remaining on-treatment as of the data cutoff date. Based in part on the strength of our results in mCRC and PDAC, as well as the unmet need and market opportunity in these indications, we will be focusing our resources on these programs and will not independently fund future clinical activities in prostate cancer. We will also continue to explore onvansertib's potential in additional indications by leveraging investigator-initiated studies, which will allow us to operate with capital efficiency. Based on this approach and our current projections, we expect our current cash resources to fund company operations into 2025."

mCRC Program: Topline data from ONSEMBLE, an open-label, randomized Phase 2 trial, expected in 2H 2024

Cardiff Oncology's next trial in mCRC, ONSEMBLE, is designed to evaluate the safety and efficacy of onvansertib in combination with SoC FOLFIRI/bevacizumab in patients with second-line KRAS/NRAS-mutated mCRC. The trial is expected to enroll approximately 150 patients who will be randomized 1:1:1 to receive SoC alone, SoC plus 20 mg onvansertib, or SoC plus 30 mg onvansertib, with onvansertib administered on days 1-5 and 15-19 of 28-day treatment cycles. The primary endpoint of the trial is objective response rate (ORR). Progression-free survival (PFS) and duration of response (DoR) will be key secondary endpoints. Activation of the trial is expected in Q4 2022, with topline data expected in 2H 2024. If positive, Cardiff Oncology believes the trial results may position onvansertib for a possible accelerated approval opportunity in second-line KRAS/NRAS-mutated mCRC.

mCRC Program: Phase 1b/2 data presented at the ESMO Congress 2022 show durable responses to treatment

Data from the ongoing Phase 1b/2 trial of onvansertib plus FOLFIRI/bevacizumab in second-line KRAS-mutated mCRC show patients experiencing durable responses to treatment, with a median duration of response of 11.7 months (95% confidence interval (CI): 8.9 – not reached). The ORR across all evaluable patients in the trial (n=48) is 35%, with responses observed across multiple KRAS variants. Median PFS across all evaluable patients in the trial is 9.3 months (95% CI: 7.6 – 13.5). Historical control trials of different drug combinations, including the SoC of

FOLFIRI with bevacizumab, in similar patient populations have shown ORR and mPFS of 5 – 13% and approximately 4.5 – 5.7 months, respectively¹⁻⁴. These data were recently featured in a [poster presentation](#) at the European Society for Medical Oncology (ESMO) Congress 2022.

mCRC Program: Analysis from Phase 1b/2 trial shows improved ORR and mPFS in bevacizumab naïve patients

A new subgroup analysis from the ongoing Phase 1b/2 clinical trial of onvansertib plus FOLFIRI/bevacizumab in second-line KRAS-mutated mCRC show an ORR of 69% and median PFS of 13.5 months in bevacizumab naïve patients (n=13). The ORR and mPFS for bevacizumab naïve patients were greater than those for the subgroup of trial participants with prior bevacizumab exposure (ORR=23%, mPFS=7.8 months, n=35), and for the population of all evaluable trial participants (ORR=35%, mPFS=9.3 months, n=48). This is well above historical control trials in mCRC which show an ORR of approximately 25% and a mPFS of approximately 6.9 months in bevacizumab naïve patients⁴⁻⁹. The observed increase in ORR in bevacizumab naïve patients was seen consistently across all patient characteristics and demographics in the trial. Based on these findings, the Company plans to stratify for prior bevacizumab exposure within the randomization of the ONSEMBLE trial and conduct preclinical studies to explore the apparent synergy between onvansertib and bevacizumab.

Metastatic PDAC Program: 1 partial response, 3 stable disease achieved in 5 evaluable patients

Preliminary data from 5 evaluable patients in an ongoing open-label Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan and 5-FU in second-line metastatic PDAC show 1 patient achieving an initial partial response (PR) and 3 patients achieving stable disease (SD). The 4 patients achieving SD or a PR remain on study. The fifth evaluable patient discontinued the study due to progressive disease and an additional 3 patients are on-study and awaiting their first post-baseline scan as of the data cutoff date. Based on prior clinical studies, the historical ORR and median PFS for second-line PDAC patients are 7.7% and 3.1 months, respectively^{10,11}. Additional data from the ongoing Phase 2 trial are expected in Q2 or Q3 2023.

Prostate Cancer Program

Following a strategic review of its clinical data in metastatic castrate-resistant prostate cancer (mCRPC), as well as the current and projected therapeutic landscape in this indication, the Company has decided it will not independently fund any future clinical activities in mCRPC.

Investigator-initiated Trials in Triple Negative Breast Cancer (TNBC) and Small Cell Lung Cancer (SCLC)

A single-arm, Phase 1b/2 trial of onvansertib in combination with paclitaxel in patients with unresectable locally advanced or metastatic TNBC is open for enrollment at Dana Farber Cancer Institute (DFCI). In Phase 1b, approximately 14-16 patients will be treated with different doses of onvansertib in combination with a fixed dose of paclitaxel to determine the maximum tolerated dose and recommended phase 2 dose (RP2D) of onvansertib. In Phase 2, approximately 34 patients will be treated with the selected onvansertib RP2D in combination with paclitaxel. The primary endpoint of Phase 2 of the trial is ORR, with PFS included as a secondary endpoint. Preliminary data from the trial are expected in Q4 2023 or Q1 2024. For more information, please visit [NCT05383196](#).

A single-arm, two-stage, Phase 2 trial of onvansertib monotherapy in patients with relapsed SCLC is open for enrollment at the University of Pittsburgh Medical Center (UPMC). The trial is designed to enroll 15 patients in Stage 1, with the study proceeding to Stage 2 if 2 or more Stage 1 patients achieve an objective response. Stage 2 is designed to enroll an additional 20 patients. The primary endpoint of the trial is ORR, while key secondary endpoints include PFS and overall survival. Preliminary data from the trial are expected in Q2 or Q3 2023. For more information, please visit [NCT05450965](#).

Webcast and Conference Call

Cardiff Oncology will host a webcast and conference call to discuss its clinical data, business updates, and corporate strategy today at 4:30 PM ET. To access the call, please dial 1-877-407-9208 (domestic) or 1-201-493-6784 (international) and refer to conference ID 13731618. The conference call will also be webcast live and a link to the webcast can be accessed [here](#). A replay of the webcast will be available by visiting the "[Events](#)" section of the Cardiff Oncology website after its conclusion.

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
5. Hansen et al., Cancers 2021, 13, 1031
6. Tabernaro et al. Eur J Cancer, 2014, 50, 320-332

7. Van Cutsem et al., J. Clin. Oncol. 2012, 30,3499–3506
8. Tabenaro et al, Lancet Oncol 2015, 16, 499–508
9. Beretta et al., Med Oncol 2013, 30:486
10. Wang-Gillam A, Li C-P, Bodoky G, et al. Lancet 2016, 387:545-57
11. Waters AM, Der CJ. Cold Spring Harb Perspect Med 2018, 8(9)

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers. Our lead asset is onvansertib, a PLK1 inhibitor we are evaluating in combination with standard-of-care (SoC) therapeutics in clinical programs targeting indications such as KRAS/NRAS-mutated metastatic colorectal cancer (mCRC) and metastatic pancreatic ductal adenocarcinoma (mPDAC). These programs and our 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

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Clinical and Corporate Update

SEPTEMBER 12, 2022

Forward-looking statements

CERTAIN STATEMENTS IN THIS PRESENTATION ARE

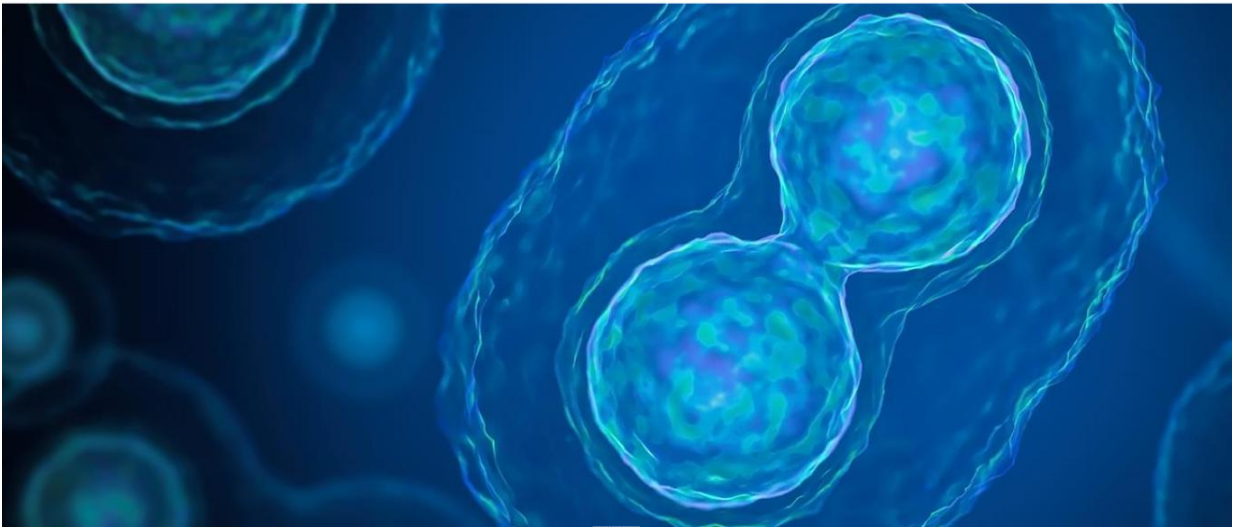
FORWARD-LOOKING within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern our expectations, strategy, plans 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; 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, 2021, 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.

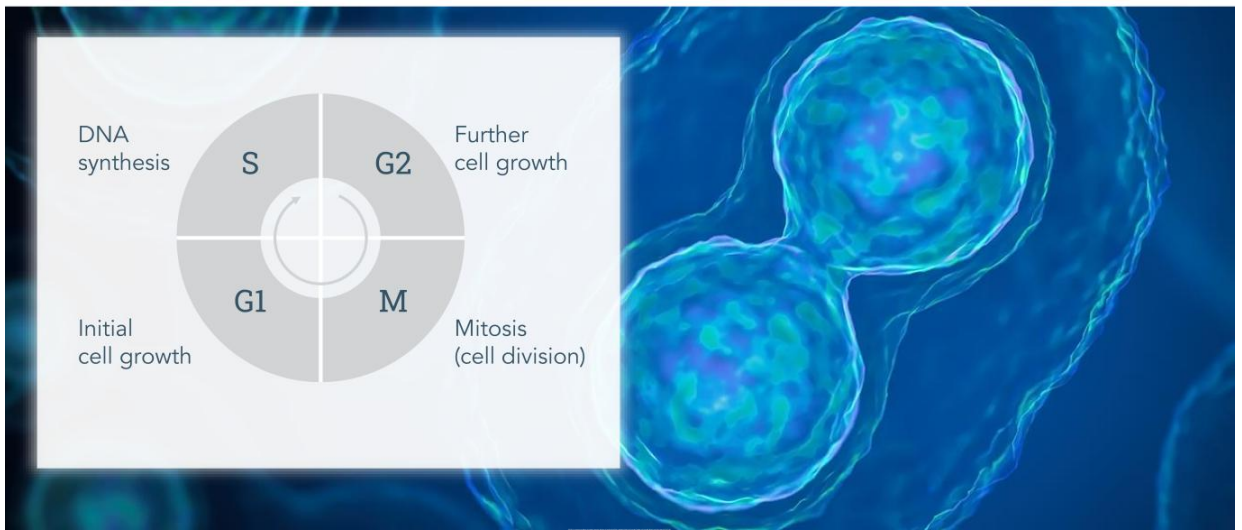
Many chemo agents damage a tumor cell's ability to replicate



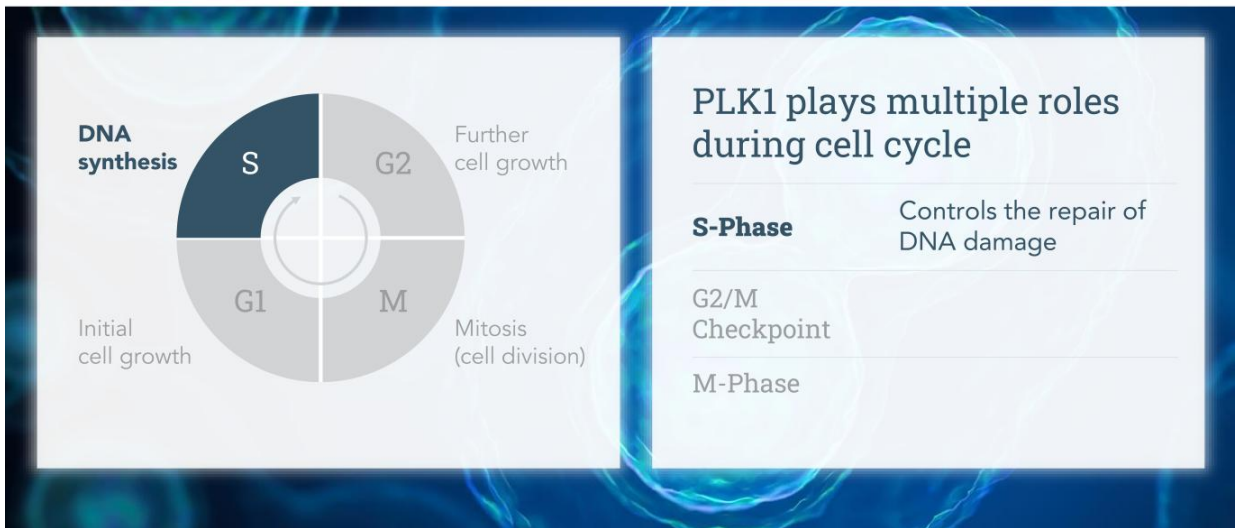
Cancers thrive because they prioritize DNA replication and cell division



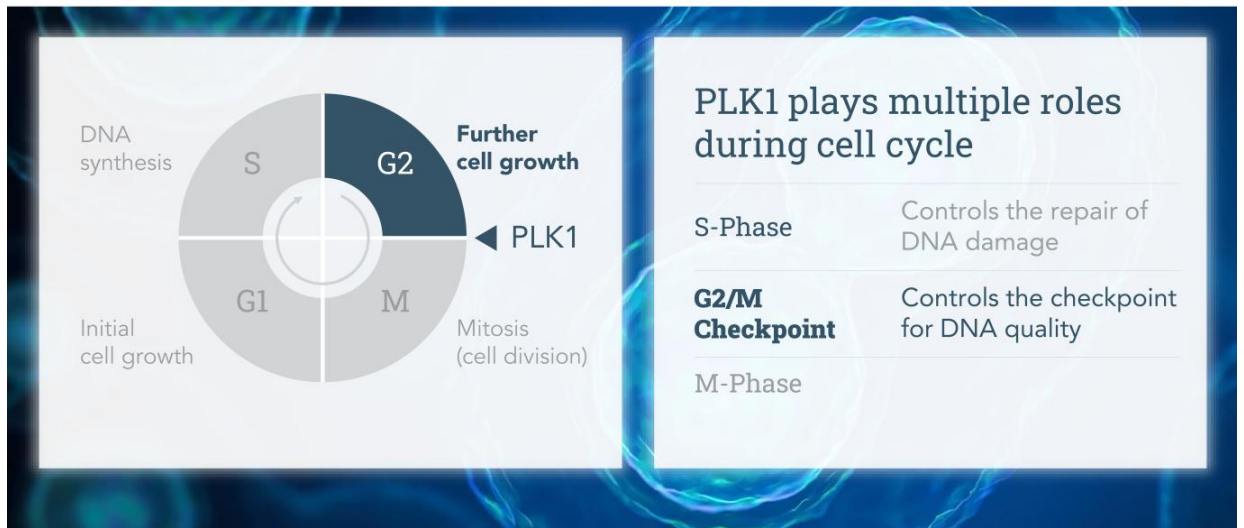
PLK1 is a master regulator of genome integrity during cell replication



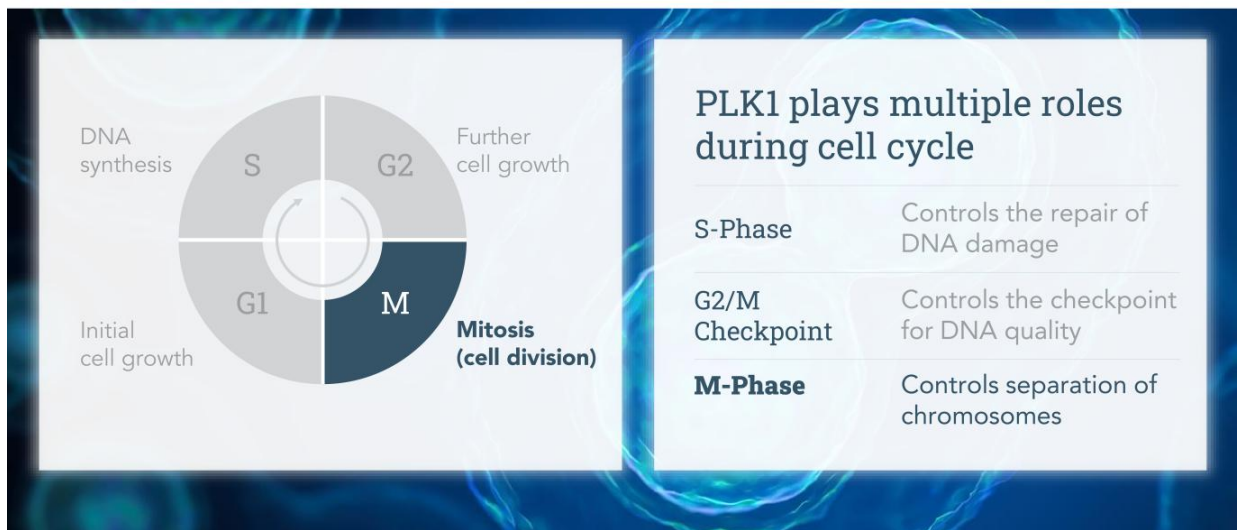
PLK1 is a master regulator of genome integrity during cell replication



PLK1 is a master regulator of genome integrity during cell replication

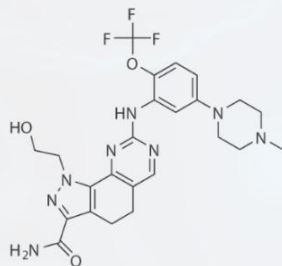


PLK1 is a master regulator of genome integrity during cell replication

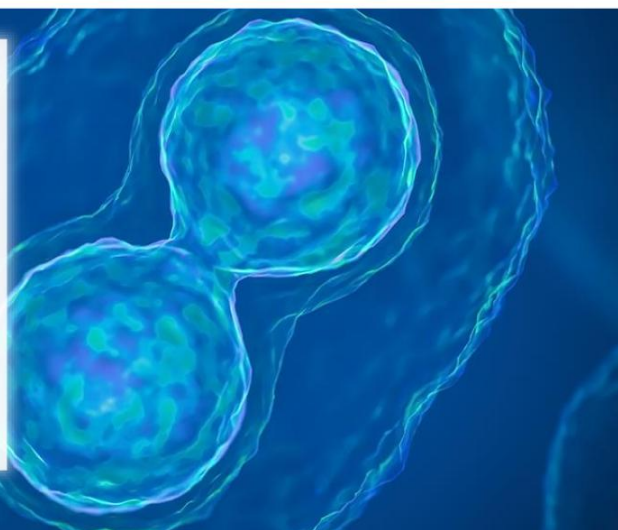


PLK1 is a master regulator of genome integrity during cell replication

ONVANSERTIB INHIBITS PLK1



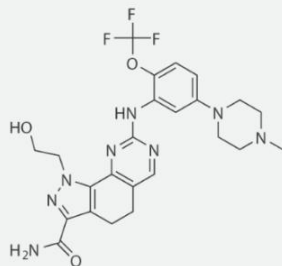
onvansertib shuts down PLK1's cell-preservation mechanisms, enhancing the efficacy of cell-damaging cancer therapies



Onvansertib positions Cardiff Oncology to effectively target PLK1

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



Two goals drive our near-term clinical development program

2022

Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
----	----	----	----	----	----	----	----	----	----	----	----

2023

2024

GOALS

- 1** Validate prior mCRC data with a randomized trial
- 2** Demonstrate clinical POC in additional indications



Today we'll see where we are, and where we're going

Accelerating our mCRC program

Additional onvansertib programs

Initial trial: phase 1b/2

Next trial

Today we'll see where we are, and where we're going

Accelerating our mCRC program

Additional onvansertib programs

Pancreatic cancer (mPDAC)

Prostate cancer (mCRPC)

Triple negative breast cancer (TNBC)

Small cell lung cancer (SCLC)

Accelerating our mCRC program

Additional onvansertib programs

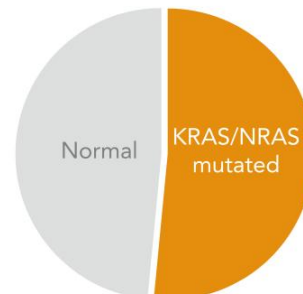
Initial trial: phase 1b/2

Next trial

There are no targeted therapies available for KRAS/NRAS mutations

	1 st LINE	2 nd LINE
Normal		
Standard	FOLFOX + bevacizumab	FOLFIRI + bevacizumab
Targeted	+ EGFR inhibitor	NONE
Mutated		
Standard	FOLFOX + bevacizumab	FOLFIRI + bevacizumab
Targeted	NONE	NONE

Mutated mCRC is approx. half the mCRC population¹



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

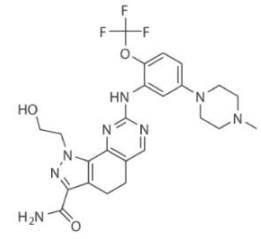
The prognosis for second-line mCRC patients is poor

	Normal	1 st LINE	2 nd LINE	HISTORICAL* ORR	
Normal	Standard	FOLFOX + bevacizumab	FOLFIRI + bevacizumab	5%	2006 – 2008
	Targeted	+ EGFR inhibitor	NONE		
Mutated	Standard	FOLFOX + bevacizumab	FOLFIRI + bevacizumab	11.4%	2000 – 2013
	Targeted	NONE	NONE		

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

Adding onvansertib to SoC could address the unmet need

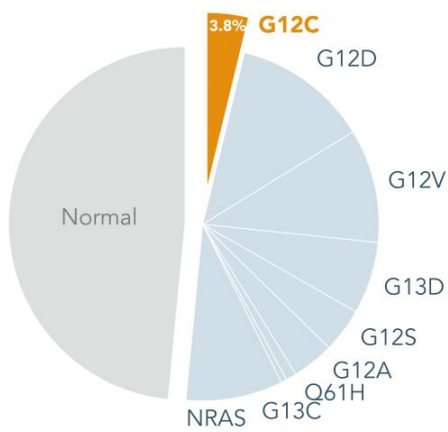
	1 st LINE	2 nd LINE
Normal		
Standard	FOLFOX + bevacizumab	FOLFIRI + bevacizumab
Targeted	+ EGFR inhibitor	NONE
Mutated		
Standard	FOLFOX + bevacizumab	FOLFIRI + bevacizumab
Targeted	NONE	ONVANSERTIB



◀ Onvansertib has the potential to fill this gap

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

KRAS/NRAS Mutations in mCRC¹

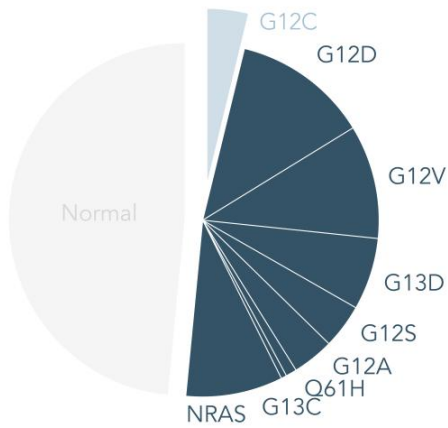


Investigational therapies (Amgen; Mirati) address the G12C KRAS mutation **only**

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/NRAS Mutations in mCRC¹



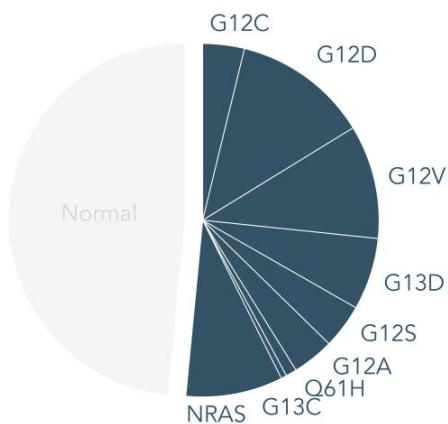
93%

of patients with
KRAS/NRAS mutations
miss targeted therapy

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

Onvansertib is positioned to address gaps in KRAS-mutated mCRC

KRAS/NRAS Mutations in mCRC¹



MOA

In KRAS-mutated mCRC, onvansertib has two mechanisms of action

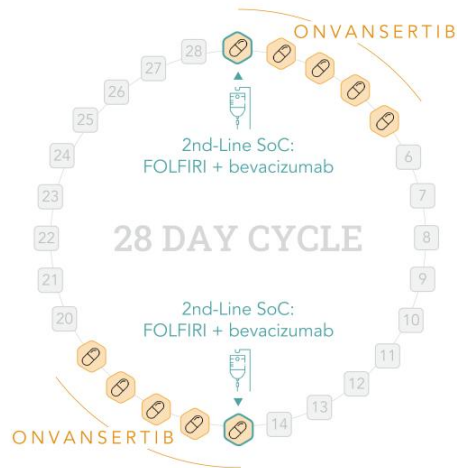
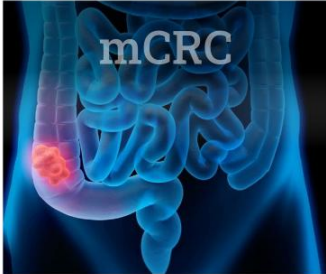
- 1 Synthetic lethality in KRAS mutants
- 2 Synergy with 2nd-line SoC

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

Our Ph1/2b trial combined onvansertib with the current SoC

ENROLLMENT CRITERIA

2nd line mCRC
KRAS+
Unresectable



SINGLE ARM TRIAL

N=50 (48 evaluable)

Can we get a signal that onvansertib complements and improves SoC?

Our Ph1/2b trial assessed safety, efficacy and response biomarker

ENROLLMENT CRITERIA

2nd line mCRC
KRAS+
Unresectable

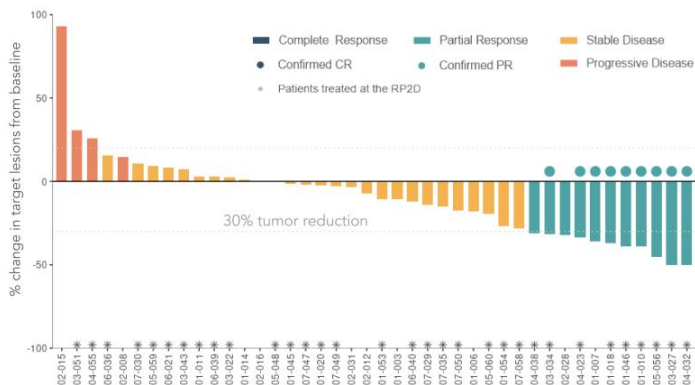


EFFICACY ENDPOINTS

- 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

Patients achieved a strong, durable response with onvansertib + SoC

Best Radiographic Response* – all doses (as of July 25, 2022)



	All Doses	RP2D
Objective Response Rate* (CR + PR)	35% (17/48)	34% (12/35)
Disease Control Rate (CR + PR + SD)	92% (44/48)	94% (33/35)
Durability		
Median Duration of Response	11.7 months	12.5 months

* Waterfall plot and table reflect interim data as of July 25, 2022 from an ongoing trial and unlocked database

We observe initial PRs up to eight months on treatment

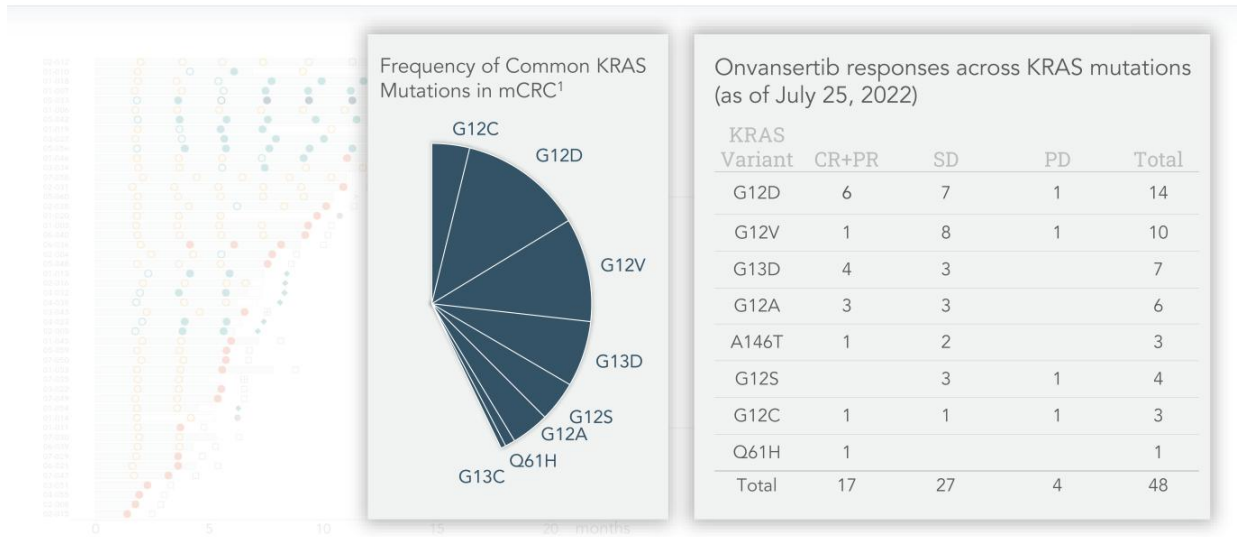


Swimmer plot* – all doses (as of July 25, 2022)

Evaluable Patients – all doses	
	48
Time of initial PR	
8-week scan	8
16-week scan	3
24-week scan	5
32-week scan	1

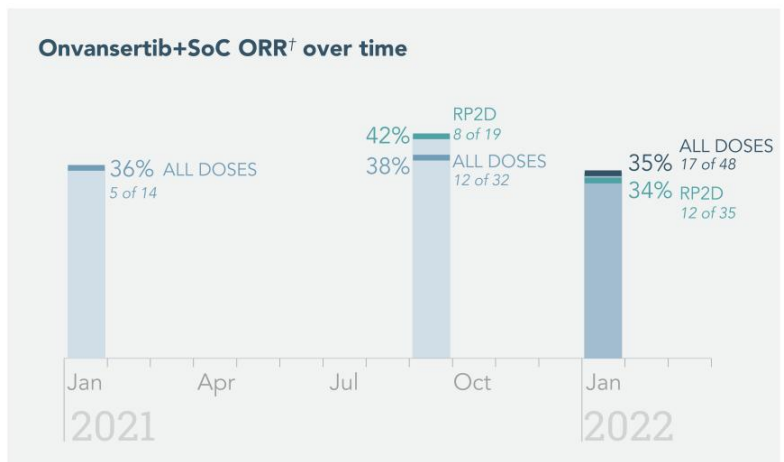
* Swimmer plot and table reflect interim data as of July 25, 2022 from an ongoing trial and unlocked database

Patients achieved responses across several KRAS mutations



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

Objective Response Rate for mCRC trial exceeds SoC over time



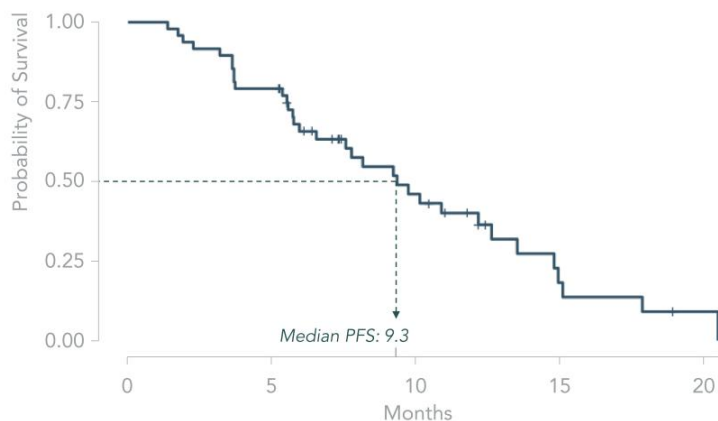
* 2008: Bennouna et al., Lancet Oncol 2013; 14: 29-37; 2013: Giessen et al., Acta Oncologica, 2015, 54: 187-193; 2017: Cremolini et al., Lancet Oncol 2020, 21: 497-507; and Antoniotti et al., Correspondence Lancet Oncol June 2020. SoC: Standard-of-care

† ORR data are interim data from an ongoing trial and unlocked database

Progression Free Survival for mCRC trial exceeds SoC over time



Progression free survival[†] – all doses (as of July 25, 2022)



* 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 is interim data from an ongoing trial and unlocked database.

Progression Free Survival for mCRC trial exceeds SoC over time



† Onvansertib mPFS are interim data 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 in combination with FOLFIRI-bev is well-tolerated

No major/unexpected toxicities	TEAEs*	GRADE					TEAEs*	GRADE				
		1	2	3	4	All		1	2	3	4	All
<ul style="list-style-type: none"> • Of all TEAEs, only 11% (84/788) were G3/G4 • 7 patients had a total of 11 G4 adverse events: <ul style="list-style-type: none"> – 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 	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						

* Data are interim as of July 25, 2022 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

The trial's patient demographics reflects 2nd line mCRC population

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 Patients All Doses
Treated	6	6	6	32	50
Currently on treatment	0	0	0	3	3

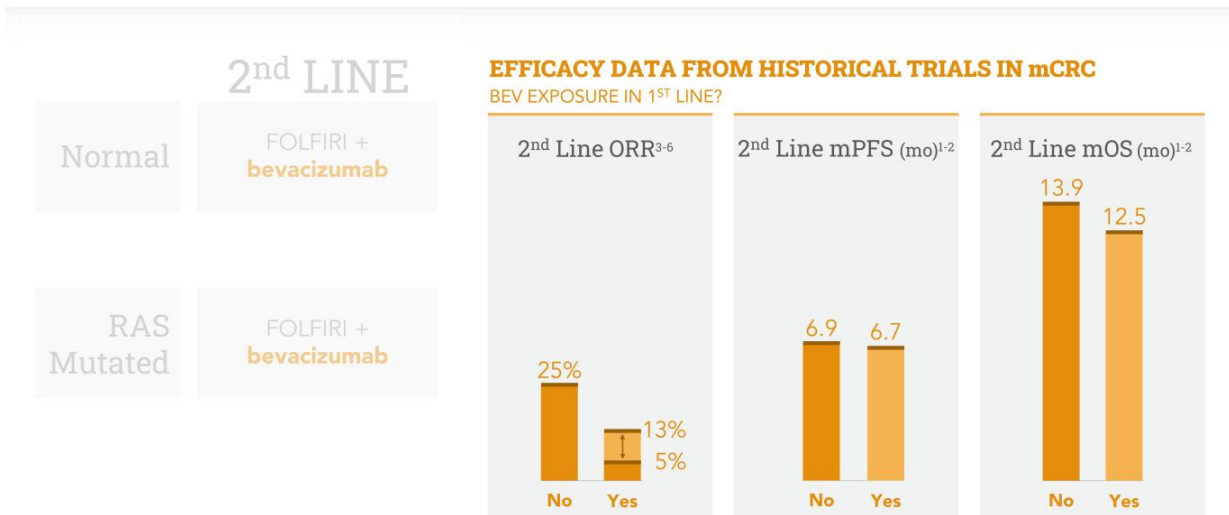
Total Patients N=50	Median [range] or n (%)	Total Patients N=50	Median n (%)
Age (years)	61 [35-83]	Liver metastasis	
Sex		None	13 (26%)
Male	28 (56%)	Liver and other	27 (54%)
Female	22 (44%)	Liver only	10 (20%)
ECOG		Number of metastatic organs	
0	33 (66%)	1	16 (32%)
1	17 (34%)	≥2	34 (68%)
Primary tumor site		Prior bevacizumab treatment⁵	
Colon	27 (54%)	Yes	35 (70%)
Rectum	18 (36%)	No	15 (30%)
Other	5 (10%)		

* Data are interim as of July 25, 2022 from an ongoing trial and unlocked database, for the first 50 subjects.

Anti-angiogenics, like bevacizumab, combine with 1st and 2nd line SoC

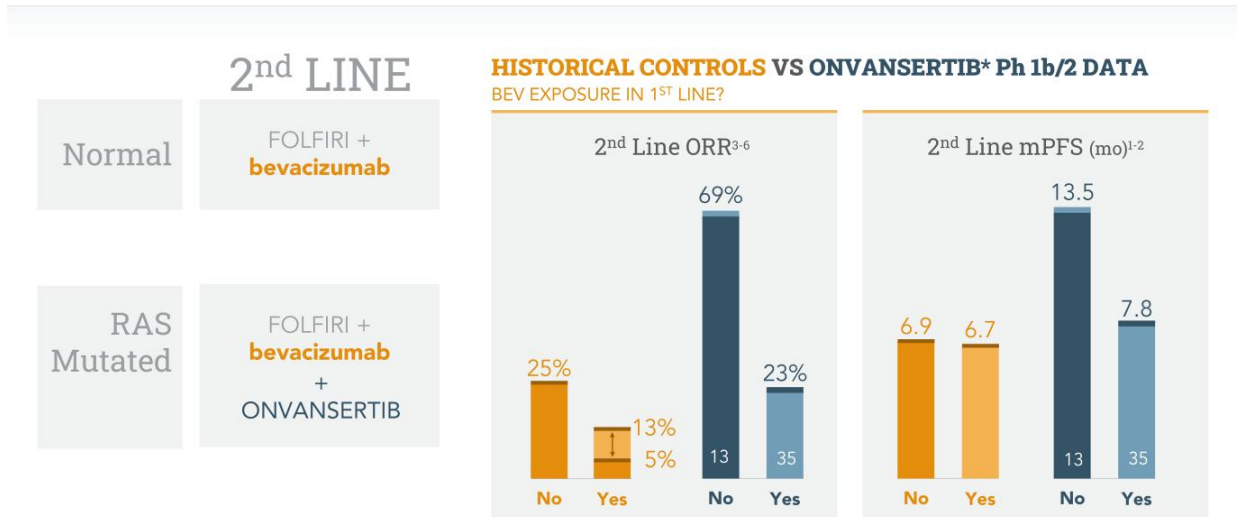
	1 st LINE	2 nd LINE	
Normal	FOLFOX + bevacizumab + EGFR inhibitor	FOLFIRI + bevacizumab	mCRC Ph1b/2 trial N=50 (48 evaluable)
RAS Mutated	FOLFOX + bevacizumab	FOLFIRI + bevacizumab	Do 2 nd line patients <i>naïve</i> to bev show better efficacy than 2 nd line patients with <i>prior</i> bev in 1 st line?

1st line use of bev in prior trials has minimal impact on 2nd line efficacy



1. Hansen et al., Cancers 2021, 13, 1031; 2. Tabernero et al. Eur J Cancer, 2014, 50, 320-332; 3. Bennouna et al., Lancet Oncol, 2013, 14, 29-37; 4. Van Cutsem et al., J. Clin. Oncol. 2012; 30,3499-3506; 5. Tabernero et al, Lancet Oncol 2015; 16: 499-508; 6. Beretta et al., Med Oncol (2013) 30:486; 7. Moriwakij et al, Med Oncol (2012) 29:2842-2848.

Ph 1b/2 trial bev naïve patients had unexpectedly high ORR and mPFS



1. Hansen et al., Cancers 2021, 13, 1031; 2. Tabernaro et al. Eur J Cancer, 2014, 50, 320-332; 3. Bennouna et al., Lancet Oncol. 2013, 14, 29-37; 4. Van Cutsem et al., J. Clin. Oncol. 2012, 30,3499-3506; 5. Tabernaro et al, Lancet Oncol 2015; 16: 499-508; 6. Beretta et al., Med Oncol (2013) 30:486.

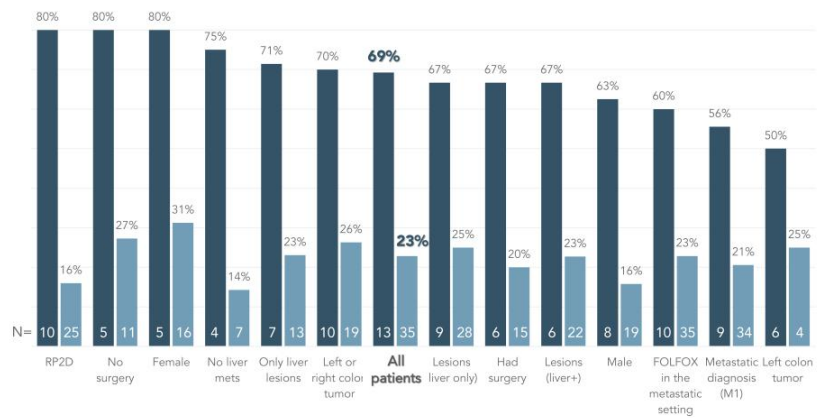
* Onvansertib ORR and mPFS are interim data as of July 25, 2022 from ongoing trial and unlocked database.

ORR is consistently greater for bev naïve patients across characteristics

No single patient characteristic explains observed ORR difference

BEV EXPOSURE IN 1 ST LINE?		
	No (naïve)	Yes (exposed)
Range of ORRs	50 – 80%	14 – 31%

ORR (%) for Bevacizumab Naïve vs. Exposed Patients*



* Onvansertib ORR and mPFS are interim data as of July 25, 2022 from an ongoing trial and unlocked database.

The potential onvansertib bevacizumab synergy is a new opportunity

How should we respond to this observation?

BEV EXPOSURE IN 1ST LINE?

	No (naïve)	Yes (exposed)
All Patients	69% ORR	23% ORR
RP2D	80% ORR	16% ORR

HYPOTHESES

- A. This is a statistical anomaly (small n)?
- B. This is due to onv / bev synergy?

ACTIONS

1. Stratify for prior bev exposure within randomization of next mCRC trial
2. Explore apparent onv / bev synergy in pre-clinical studies
3. Analyze baseline ctDNA in Ph 1b/2 patients for genomic alterations in bev naïve vs bev exposed

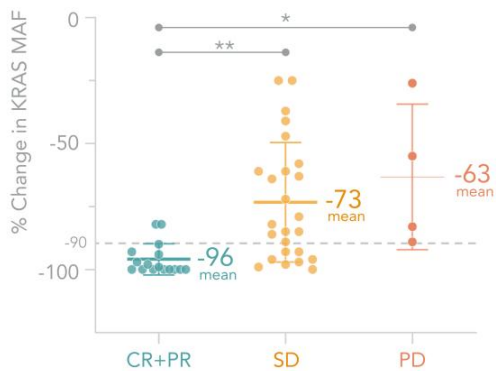
OPPORTUNITY

Conduct a 1st line exploratory mCRC trial of onvansertib + FOLFIRI + bev

* Onvansertib ORR and mPFS are interim data as of July 25, 2022 from an ongoing trial and unlocked database.

Early KRAS MAF ctDNA decrease correlates w/ radiographic response

% KRAS Mutant Allelic Frequency (MAF)*
decrease after one 28-day treatment cycle
(Mean \pm SD, as of July 25, 2022)



Onvansertib KRAS MAF are interim data as of July 25, 2022 from an ongoing trial and unlocked database.

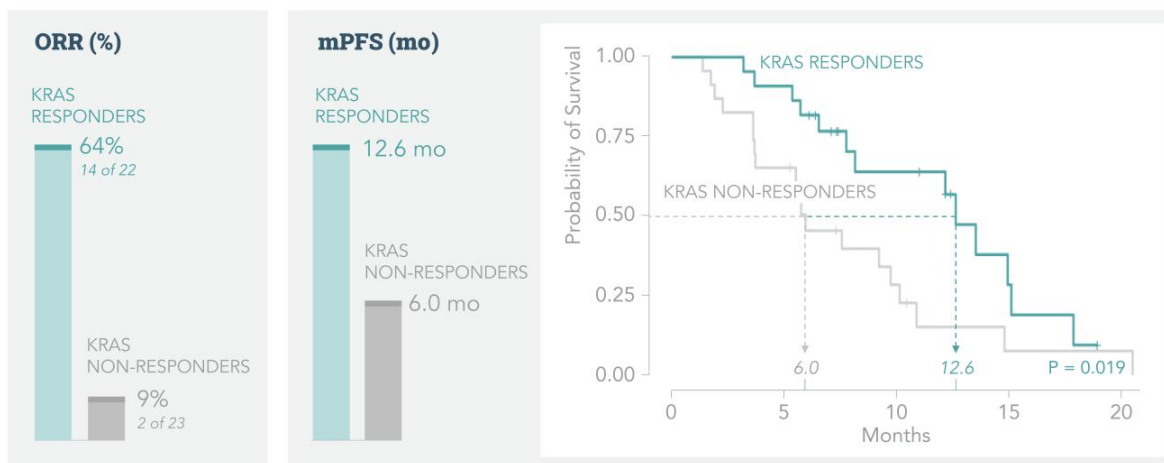
Predictive response biomarker

- 45 of the 48 evaluable patients were evaluated for KRAS MAF changes
- 87.5% (14/16) of CR/PR patients had \geq 90% decrease in KRAS MAF after the 1st cycle
- 32% (8/25) of SD patients and none of the PD patients (n=4) had such a decrease

* 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 pre-dose). 1 PR and 2 SD patients had undetectable KRAS MAF at baseline.

KRAS MAF plot reflects interim data as of July 25, 2022 from an ongoing trial and unlocked database.

Early Changes in KRAS MAF predicts clinical response



Onvansertib ORR and mPFS are interim data as of July 25, 2022 from an ongoing trial and unlocked database.

Accelerating our mCRC program

Additional onvansertib programs

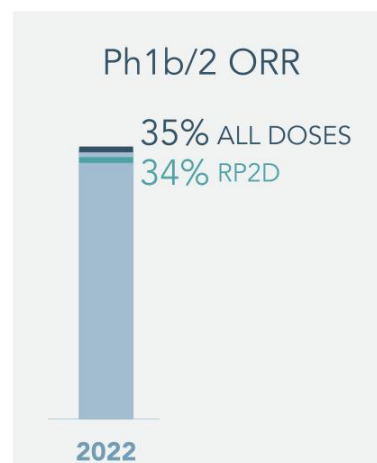
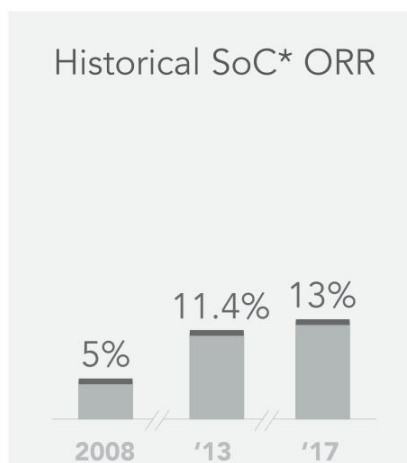
Initial trial: phase 1b/2

Next trial

We believe that onvansertib complements and improves SoC

Our Ph1b/2 Question:

Can we get a signal that onvansertib complements and improves SoC?



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

We approach our next trial with four clear objectives



DEMONSTRATE onvansertib's contribution to SoC

CONFIRM optimal dosing

POSITION for possible accelerated approval opportunity

OPERATE with capital efficiency

Our ONSEMBLE Ph2 trial is designed to demonstrate efficacy

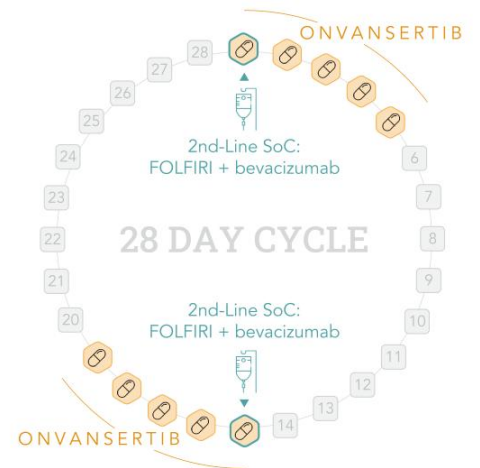
ENROLLMENT CRITERIA

2nd line mCRC
KRAS+/NRAS+
Unresectable

R
N=150
1:1:1



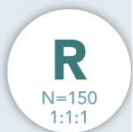
- SoC (FOLFIRI + Bev)
- SoC + onvansertib (20mg)
- SoC + onvansertib (30mg)



Our ONSEMBLE Ph2 trial is designed to demonstrate efficacy

ENROLLMENT CRITERIA

2nd line mCRC
KRAS+/NRAS+
Unresectable



ENDPOINTS

Primary Objective Response Rate: CR + PR

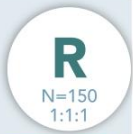
Key Secondary Progression-Free Survival

Other Secondary Disease Control Rate: CR + PR + SD
Duration of Response: DoR
Overall Survival: OS
Reduced MAF association with ORR,
PFS, DCR, DoR, OS

Our ONSEMBLE Ph2 trial will be statistically robust

ENROLLMENT CRITERIA

2nd line mCRC
KRAS+/NRAS+
Unresectable



DESIGN

- Randomized with control group exclusively the SoC
- Examine two doses of onvansertib for safety/efficacy
- Stratification within randomization for bev-naïve vs bev exposed
- Efficient and cost effective

STATS

- 80% minimum power to detect a meaningful difference in ORR
- Optimal use of the significance level (alpha 0.045 for each treatment arm vs. control)
- Ability to pool treatment arms for PFS

We are optimistic that randomized data will create substantial value



Opportunity to create value

- Rigorous demonstration of onvansertib's role in increasing efficacy in mCRC vs. SoC alone
- Position for possible accelerated approval opportunity in mCRC
- Early identification of likely responders (MAF)
- Strong indication that onvansertib has potential in other indications



Accelerating our mCRC program

Additional onvansertib programs

Pancreatic cancer (mPDAC)

Prostate cancer (mCRPC)

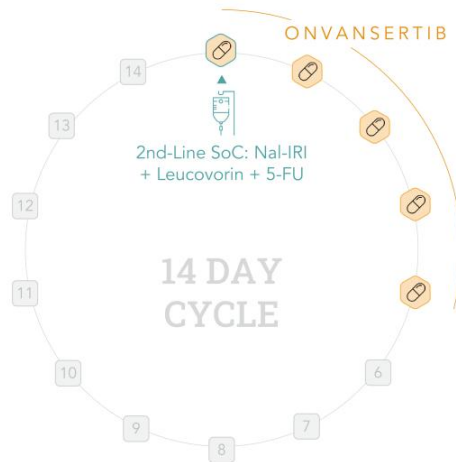
Triple negative breast cancer (TNBC)

Small cell lung cancer (SCLC)

Our mPDAC Ph2 trial combines onvansertib with standard-of-care

ENROLLMENT CRITERIA

Failed 1st Line
Gemcitabine / Abraxane



SINGLE ARM TRIAL

43 patients planned

Can we get a signal that
onvansertib complements
and improves SoC?

The endpoints measure tumor response and duration of response

ENROLLMENT CRITERIA

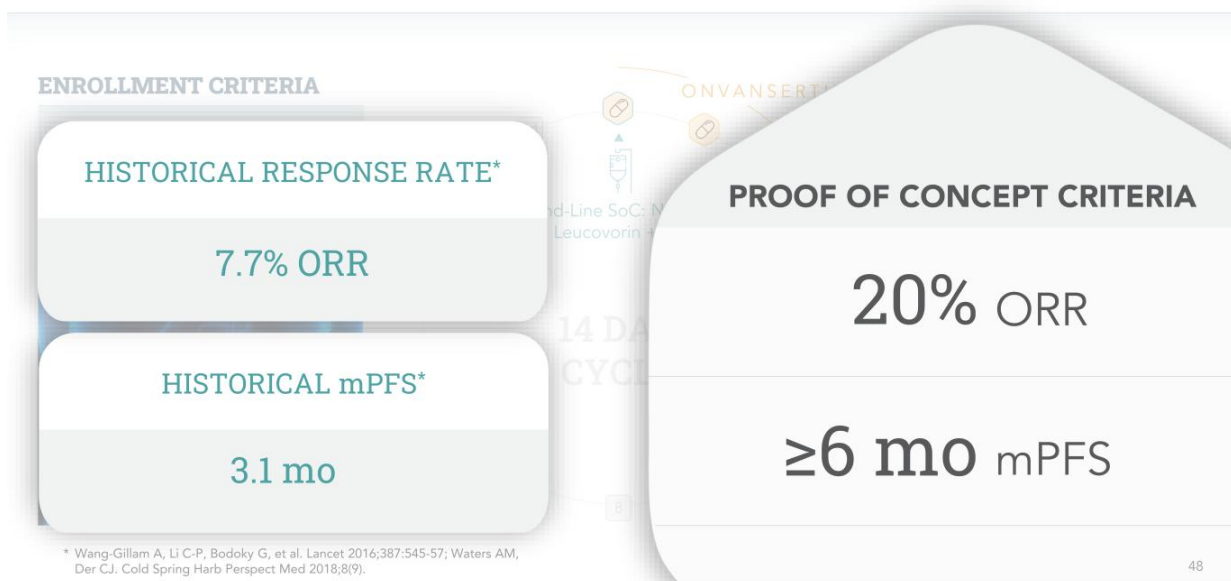
Failed 1st Line
Gemcitabine / Abraxane



EFFICACY ENDPOINTS

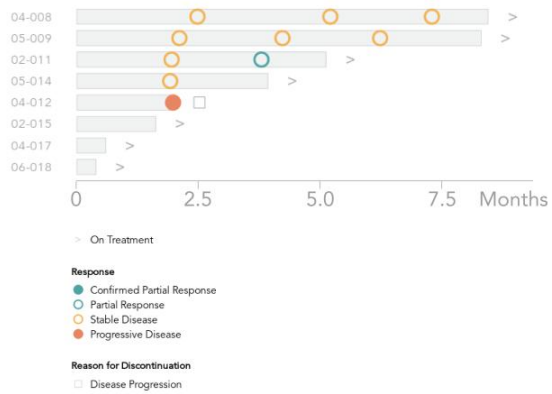
- 1 Primary: Objective Response Rate (ORR) in patients who receive ≥ 28 -days of treatment
- 2 Secondary: Duration of Response (DOR) and mPFS, Overall Survival (OS)
- 3 Exploratory: Identification of biomarkers related to sensitivity and resistance to treatment using patient-derived organoids, blood samples, and archival tissue biopsies

mPDAC trial is designed to demonstrate onvansertib's efficacy vs SoC

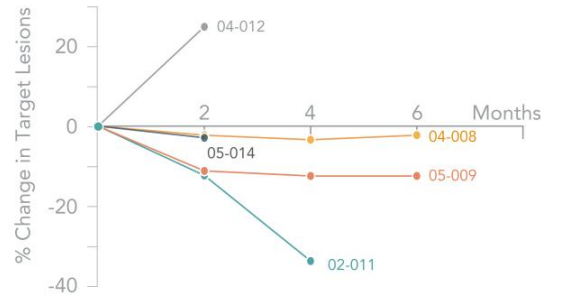


Early data from our mPDAC trial data is encouraging

Swimmer plot* – as of August 30, 2022



Change in tumor size from baseline*



* Swimmer and spider plots reflect interim data as of August 30, 2022 from an ongoing trial and unlocked database

Accelerating our mCRC program

Additional onvansertib programs

Pancreatic cancer (mPDAC)

Prostate cancer (mCRPC)

Triple negative breast cancer (TNBC)

Small cell lung cancer (SCLC)

AACR data showed disease control increased with dose density

The AACR logo features the letters 'AACR' in a bold, sans-serif font. The 'A', 'A', and 'C' are black, while the 'R' is green. A horizontal line is positioned below the letters.

American Association
for Cancer Research®

FINDING CURES TOGETHER®

APRIL 2022

Evaluated onvansertib + abiraterone / prednisone in mCRPC patients showing initial abiraterone resistance by rising PSA

Disease control increased with onvansertib dose density

- From 29% to 45% of patients achieving PSA stabilization, and
- From 53% to 75% of patients with radiographic stable disease

ctDNA analysis showed a correlation between the PI3K signaling pathway and sensitivity to onvansertib/abiraterone combination

We are not planning to fund any future mCRPC development activity

FINDINGS

The trial completed enrollment (n=72) and generated important clinical data:

- Negligible toxicities attributed to onvansertib
- Disease control increased with dose density

PATH FORWARD

Cardiff Oncology is not planning for any company-sponsored future steps in mCRPC

Accelerating our mCRC program

Additional onvansertib programs

Pancreatic cancer (mPDAC)

Prostate cancer (mCRPC)

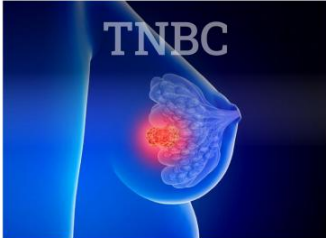
Triple negative breast cancer (TNBC)

Small cell lung cancer (SCLC)

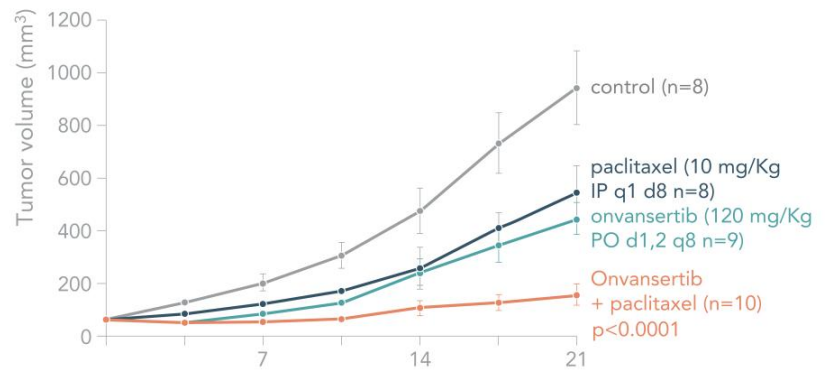
Onvansertib + paclitaxel is superior to single agent therapy

TRIAL RATIONALE

The combination of onvansertib + paclitaxel showed significant synergy



In vivo efficacy of onvansertib in combination with paclitaxel Tp53-Mutant SUM159 xenografts*



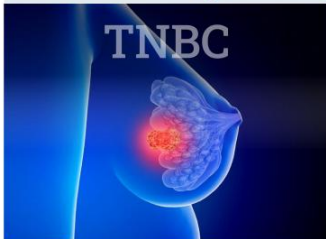
* SUM159 cells were implanted in the mammary fat pad of NOD-scid-IL2 receptor gamma null female mice, and treatments began as follows when tumor volume reached 40 mm³: vehicle, onvansertib oral (PO) twice per week (days 1-2), paclitaxel intraperitoneally (IP) weekly (day 1), or the combination.

This is the first trial to explore onvansertib + paclitaxel combination

ENROLLMENT CRITERIA

Metastatic TNBC relapsed or progressed

Single arm trial
Ph 1b: N=14-16
Ph 2: N=34



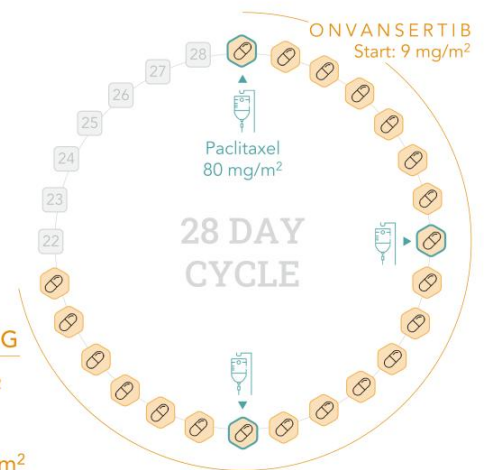
PRIMARY ENDPOINTS

Phase 1b
Safety, characterization of DLTs
Determination of RP2D

Phase 2
ORR (RECIST 1.1)

ONVANSERTIB DOSING

- Escalation: 12 mg/m²
- Starting: 9 mg/m²
- De-escalation: 6 mg/m²

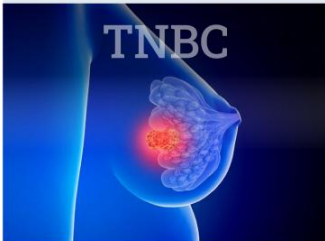


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Ph 1b: N=14-16
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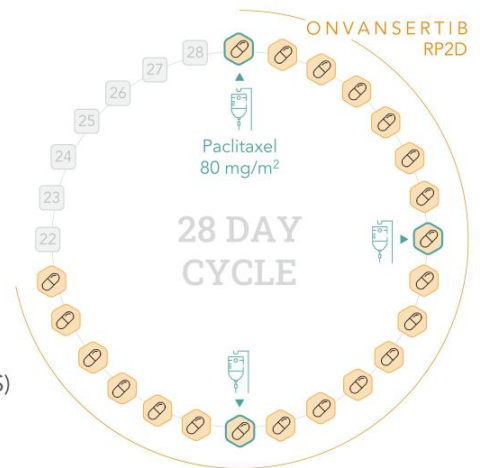
PRIMARY ENDPOINTS

Phase 1b
Safety, characterization of DLTs
Determination of RP2D

Phase 2
ORR (RECIST 1.1)

SECONDARY ENDPOINT

Phase 2
Progression-Free Survival (PFS)



Accelerating our mCRC program

Additional onvansertib programs

Pancreatic cancer (mPDAC)

Prostate cancer (mCRPC)

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Small cell lung cancer (SCLC)

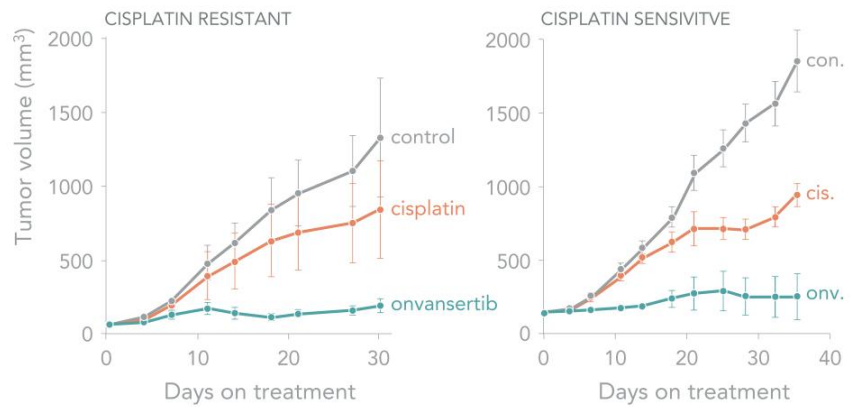
Onvansertib demonstrates single-agent activity in SCLC

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

This is the first trial to explore onvansertib monotherapy

ENROLLMENT CRITERIA

Relapsed who have received ≤ 2 prior therapies

Single-arm trial

Stage 1: N=15

Stage 2: N=20

UPMC LIFE CHANGING MEDICINE



PRIMARY ENDPOINT

Phase 2

ORR (RECIST 1.1)

SECONDARY ENDPOINTS

Phase 2

Progression-Free Survival (PFS)

Overall Survival (OS)



Our pipeline opens many attractive opportunities for onvansertib

	Combination with:	Preclinical	Ph1/2	Ph2/3	Status	
mCRC	FOLFIRI/bev				Activation	
mCRC	FOLFIRI/bev				Enrolling	
mPDAC	Onivyde/5-FU				Enrolling	
Ovarian	PARP inhibitors				Evaluating	

Investigator-initiated trials

					Investigator	
TNBC	Paclitaxel				Enrolling	
SCLC	None (monotherapy)				Enrolling	

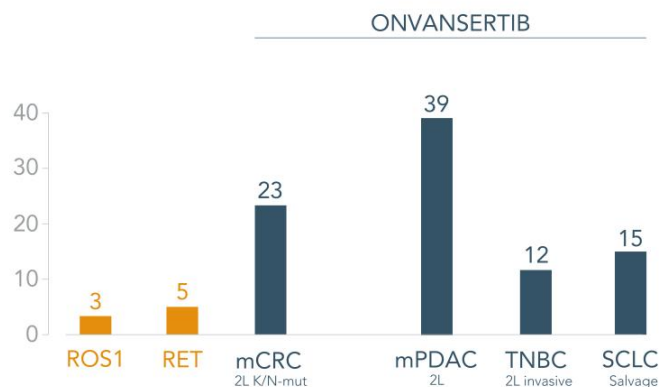
Targeting PLK1 opens doors to large patient populations

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>

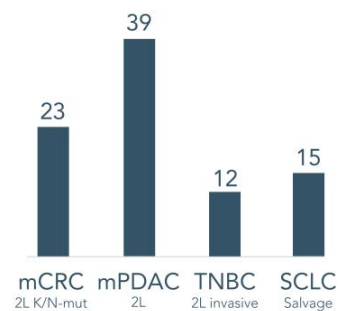
*ROS1 estimated eligible patients presented in Turning Point Therapeutics' corporate presentation May 2022 slide 6 (NSCLC disease incidence in the US of 140k of which 2% of patients harbor ROS1 translocation). RET estimated eligible patients presented in Loxo Oncology's corporate presentation January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

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

Annual eligible US patients ('000s)*



We have multiple important catalysts over the next two years



At June 30, 2022, our financial position is robust



June 30, 2022 cash and investments*	\$122.0M
Net cash used in Operating Activities* (Rolling two-quarter period ending June 30, 2022)	\$16.9M

* Financial information above is derived from our unaudited financials in Form 10Q filed on 8/4/22.

Our clinical development program supports our key goals



GOALS

- 1** Validate prior mCRC data with a randomized trial
- 2** Demonstrate clinical POC in additional indications



Our clinical development program supports our key goals



GOALS

- 1** Validate prior mCRC data with a randomized trial
- 2** Demonstrate clinical POC in additional indications

OUR STRATEGY

Phase 1b/2 single arm

Strong ORR + DoR + PFS
MAF biomarker opportunity

Phase 2 randomized

Efficient design
Confirm dose; stratify bev

Signal finding

APPENDIX

Summary of onvansertib mCRC Ph1b/2 trial data over time

	ASCO GI Jan 2021	KOL Event Sept 2021		Investor Webcast Jan 2022		Investor Webcast Sept 2022	
Data Cutoff Date	Nov 1, 2020*	July 2, 2021*		Dec 3, 2021*		July 25, 2022*	
	All Doses	All Doses	RP2D	All Doses	RP2D	All Doses	RP2D
Evaluable Patients	14	32	19	48	35	48	35
ORR (CR+PR)	36% (5)	38% (12)	42% (8)	35% (17)	34% (12)	35% (17)	34% (12)
Confirmed CR/PRs	29% (4)	31% (10)	37% (7)	27% (13)	29% (10)	29% (14)	31% (11)
Duration of Response						11.7 mos	12.5 mos
mPFS		9.4 mos		9.4 mos		9.3 mos	8.2 mos
Disease control rate (CR+PR+SD)	86% (12)	94% (30)	100% (19)	92% (44)	94% (33)	92% (44)	94% (33)

* Data releases include certain follow up data and reflect interim data from an ongoing trial and unlocked database.

