Company Overview
The Onvansertib Opportunity

FEBRUARY 2025

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 several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidate; results of preclinical studies or clinical trials for our product candidate could be unfavorable or delayed; our need for additional financing; risks related to business interruptions, including the outbreak of COVID-19 coronavirus and cyber-attacks on our information technology infrastructure, 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 our product candidate 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, 2023, 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.

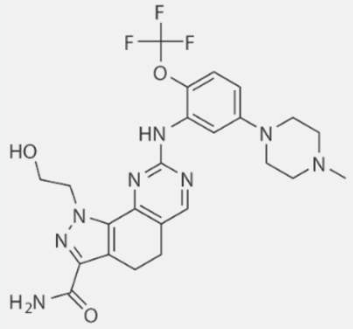
Cardiff Oncology's lead development asset is onvansertib

Onvansertib

First oral, well-tolerated PLK1-selective inhibitor

PROPERTIES

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

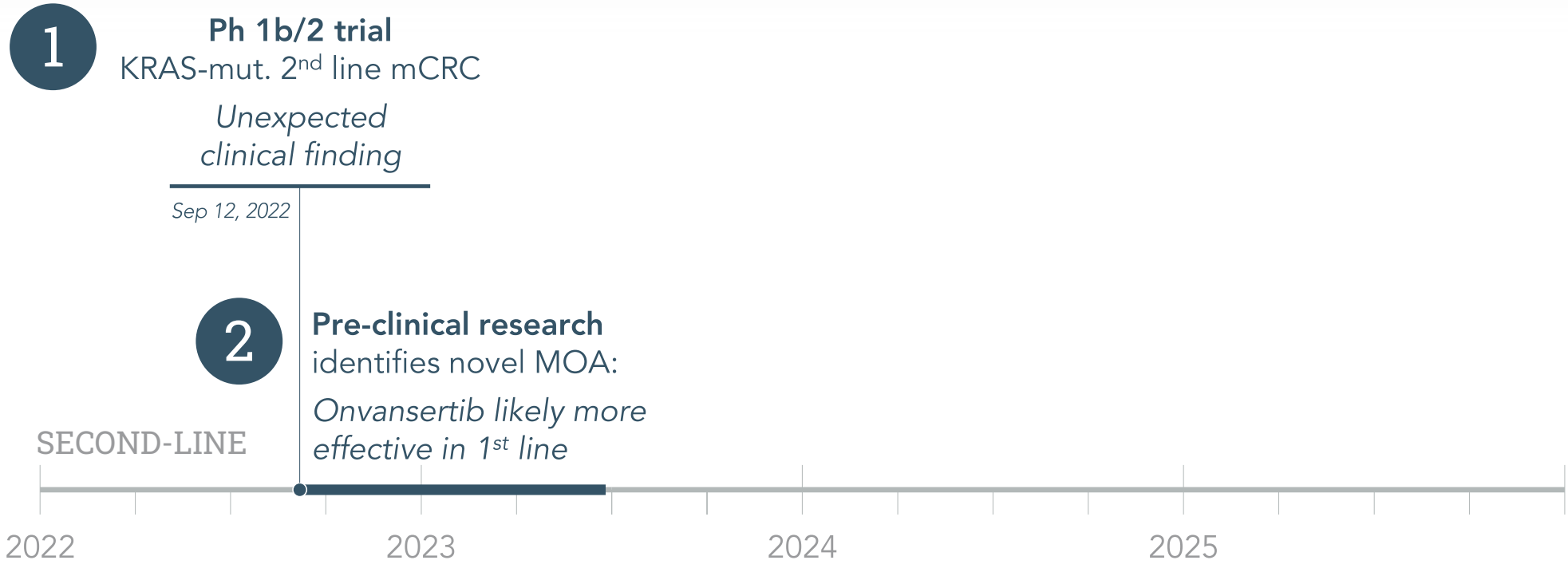


SPECIFICITY

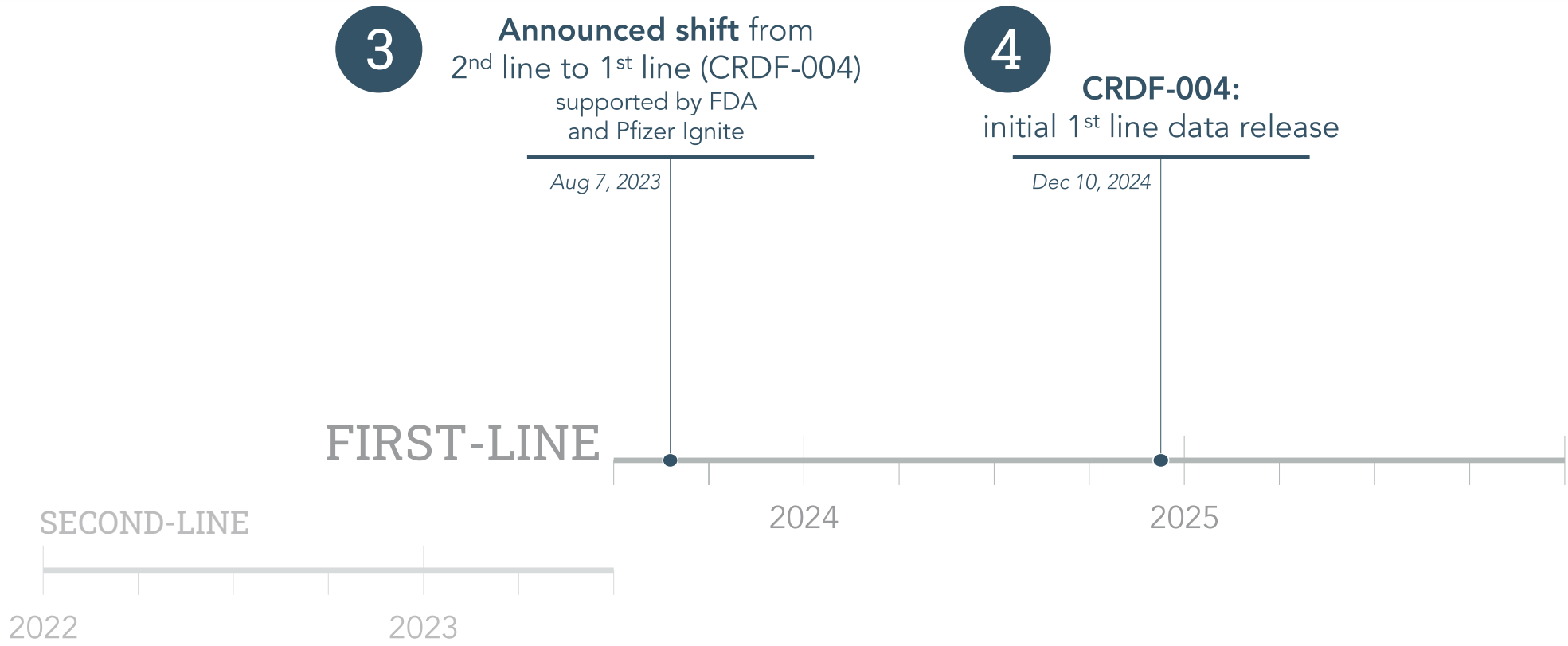
Exquisitely specific for PLK1

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

We shifted our RAS-mutated mCRC program to the first-line



We are encouraged by the initial clinical data from CRDF-004



OUR SHIFT

TO FIRST-LINE RAS-MUTATED mCRC

The strength of our 1st-line program

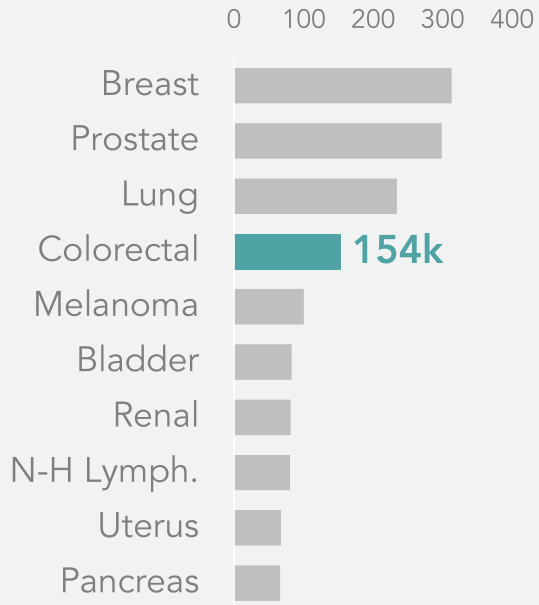
The rationale for our shift from 2nd-line

The coming catalysts in 2025

Our lead program targets RAS-mutated metastatic colorectal cancer

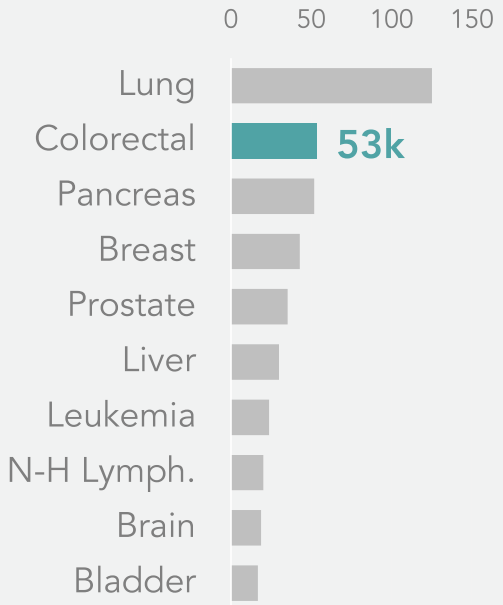
mCRC is BOTH common…

2024 new US cases ('000s)*



…and challenging to treat

2024 US deaths ('000s)*



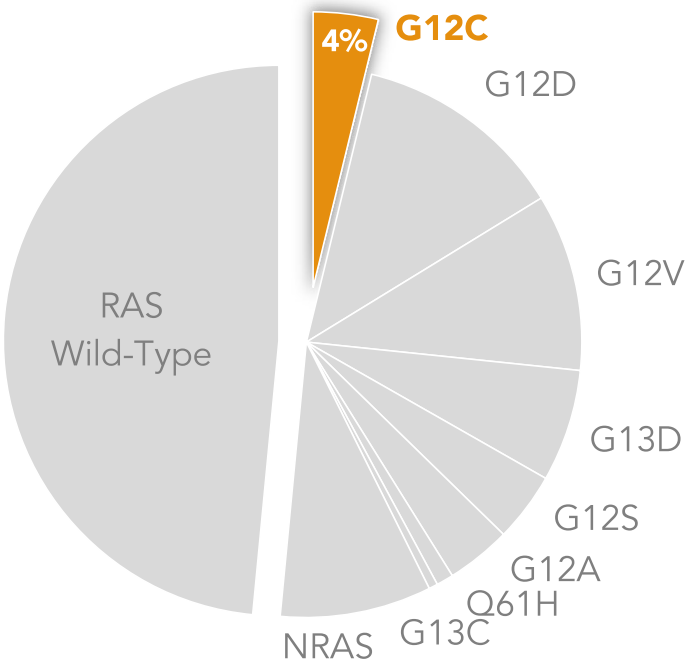
* American Cancer Society Cancer Facts and Figures 2025.

No new drugs approved in 1st line RAS-mut. mCRC in over 20 years

FIRST-LINE STANDARD OF CARE
for RAS-mutated mCRC

Drug Approved	
1996	**Chemotherapy, either:** FOLFOX
2002	FOLFIRI
2004	**Antiangiogenic** Bevacizumab ("bev", Avastin®)

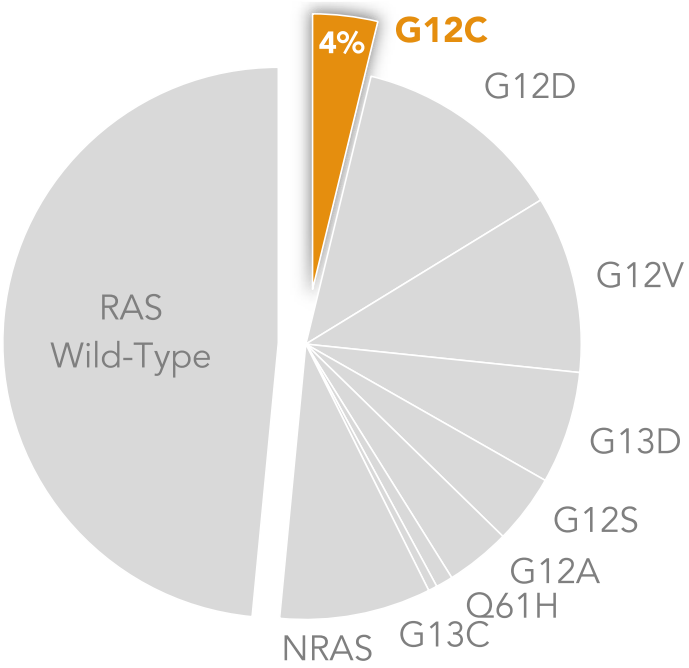
KRAS G12C therapies would address a small part of the need[1]



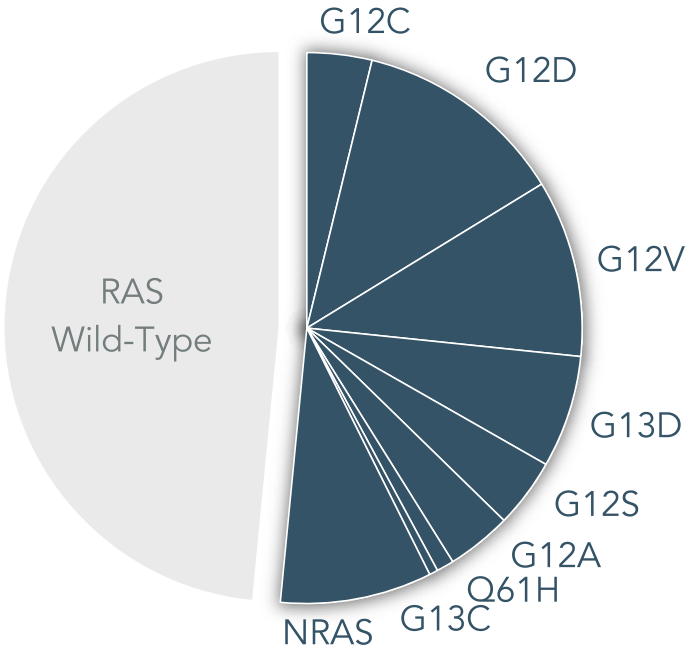
1. Jones R et al. Br J Cancer. 2017 Mar 28;116(7):923-929.

Onvansertib's MOA allows us to target ALL RAS-mutated mCRC

KRAS G12C therapies would address a small part of the need[1]



ONVANSERTIB addresses 52% of mCRC cases are RAS-mutated[1]



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

Trial design of CRDF-004: first-line RAS-mutated mCRC Phase 2 trial

ENROLLMENT CRITERIA

First-line mCRC

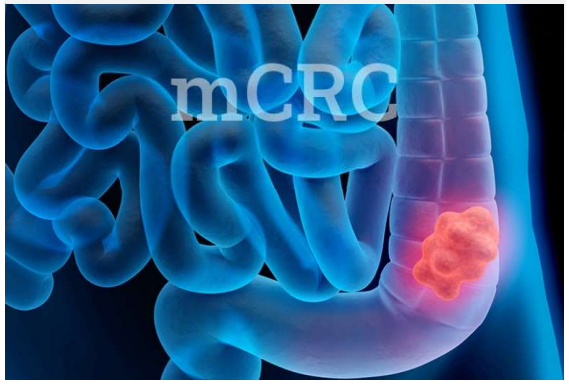
KRAS+/NRAS+

Unresectable

No prior bev

R

N=90



6 RANDOMIZATION ARMS

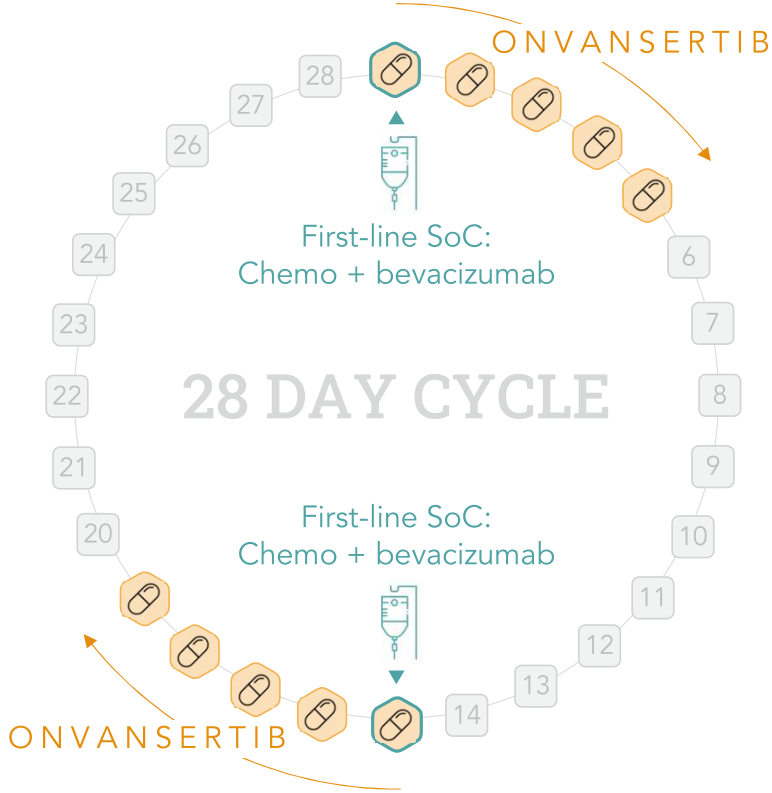
SoC alone	1. FOLFIRI/bev 2. FOLFOX/bev
Onv 20mg +	3. FOLFIRI/bev 4. FOLFOX/bev
Onv 30mg +	5. FOLFIRI/bev 6. FOLFOX/bev

ENDPOINTS *

Primary: ORR

Secondary: DoR and PFS

* Assessed by blinded independent central review (BICR)



Patients' tumors are scanned every 8 weeks

Trial design of CRDF-004: first-line RAS-mutated mCRC Phase 2 trial

ENROLLMENT CRITERIA

First-line mCRC

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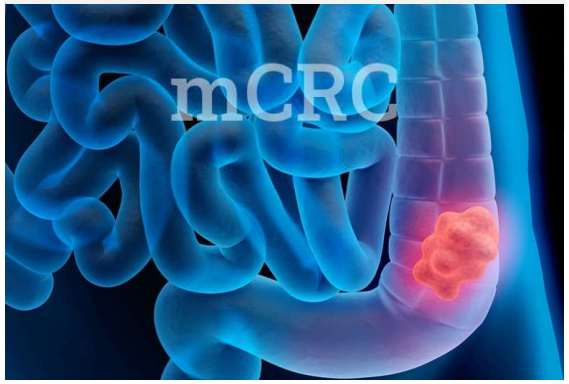

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ENDPOINTS *

Primary: ORR

Secondary: DoR and PFS

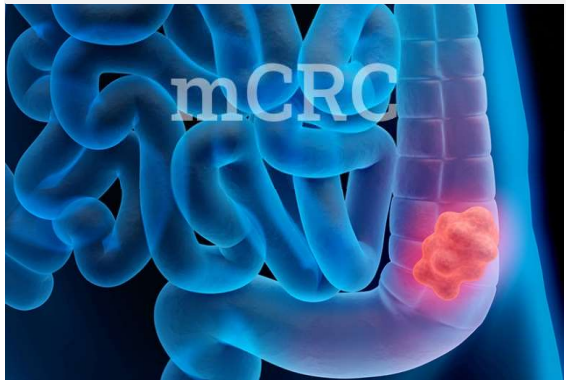
* Assessed by blinded independent central review (BICR)

OBJECTIVES OF THE TRIAL

1. Demonstrate onvansertib's efficacy in first-line RAS-mut mCRC
2. Evaluate two doses of onvansertib per FDA's Project Optimus
3. Demonstrate the safety and tolerability of onvansertib when combined with FOLFIRI/bev and FOLFOX/bev

Patient maturity across arms are balanced in the current data set

R
N=90



6 RANDOMIZATION ARMS

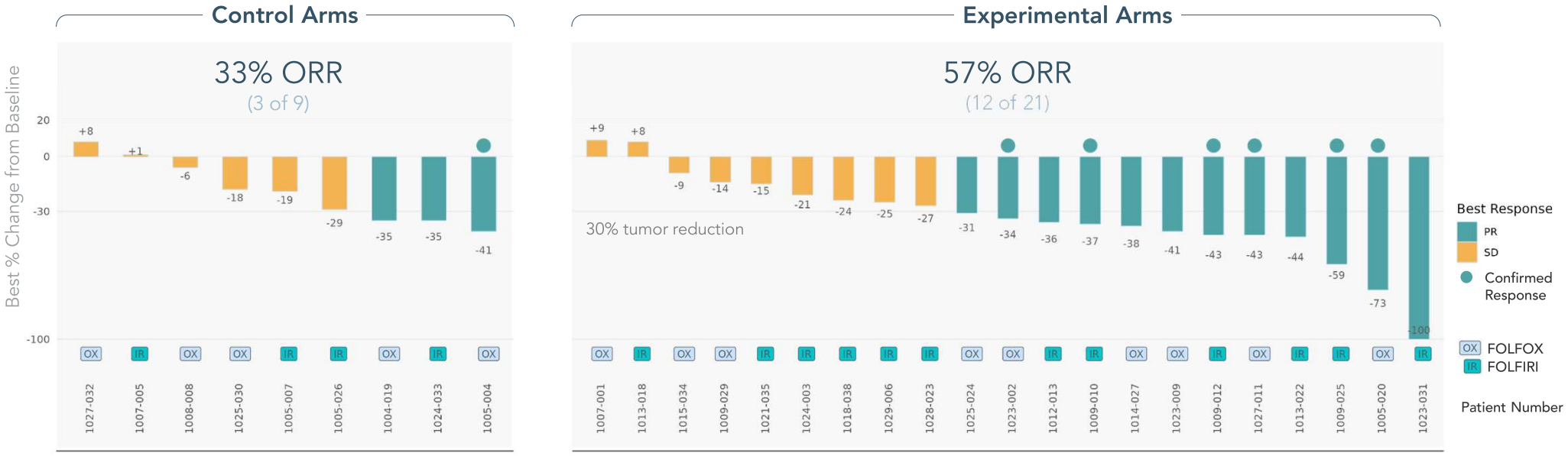
NUMBER OF EVALUABLE* PATIENTS TIME ON TRIAL – as of Nov 26, 2024

		2 mos	4 mos	6+mos	Total patients
SoC alone	1. FOLFIRI/bev 2. FOLFOX/bev	3	2	4	9
Onv 20mg +	3. FOLFIRI/bev 4. FOLFOX/bev	4	4	2	10
Onv 30mg +	5. FOLFIRI/bev 6. FOLFOX/bev	3	5	3	11
	Total patients	10	11	9	30

* Evaluable patients defined as those with at least their first post-baseline scan (2 months after beginning treatment). mos: months.

ORR for the experimental arms is higher than for the control arms

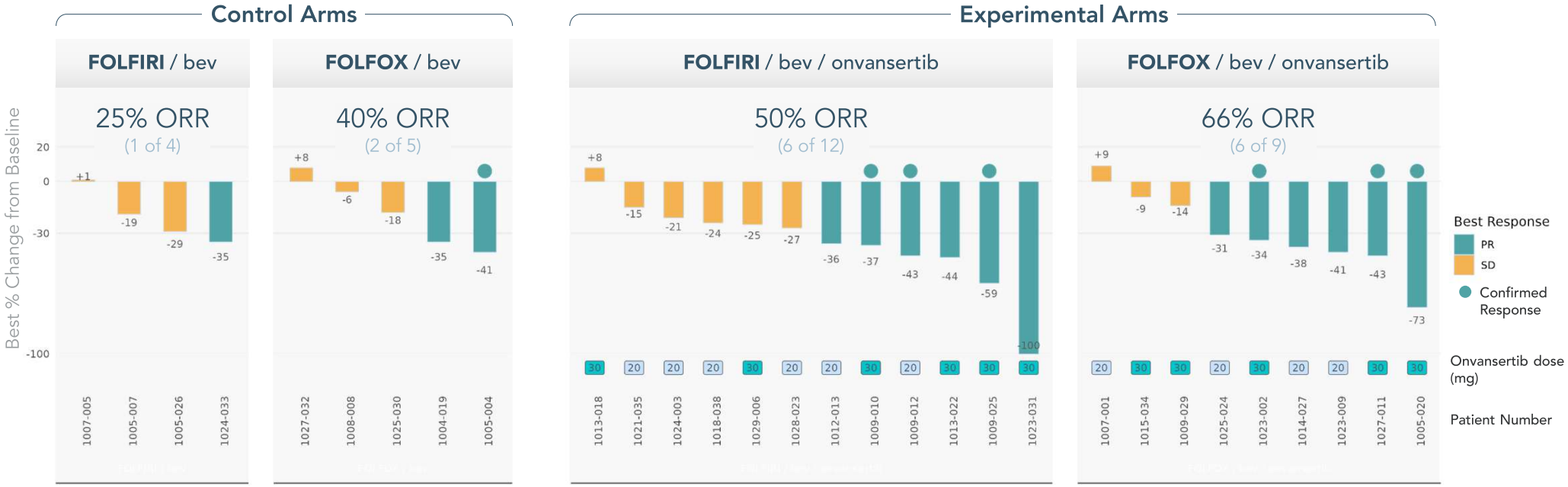
Best Radiographic Response OVERALL* – CRDF-004 as of November 26, 2024



* Radiographic response determined per RECIST 1.1 by blinded independent central review. Waterfall plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

ORR for the experimental arms is higher with both chemo backbones

Best Radiographic Response BY CHEMO BACKBONE* – CRDF-004 as of November 26, 2024



* Radiographic response determined per RECIST 1.1 by blinded independent central review. Waterfall plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

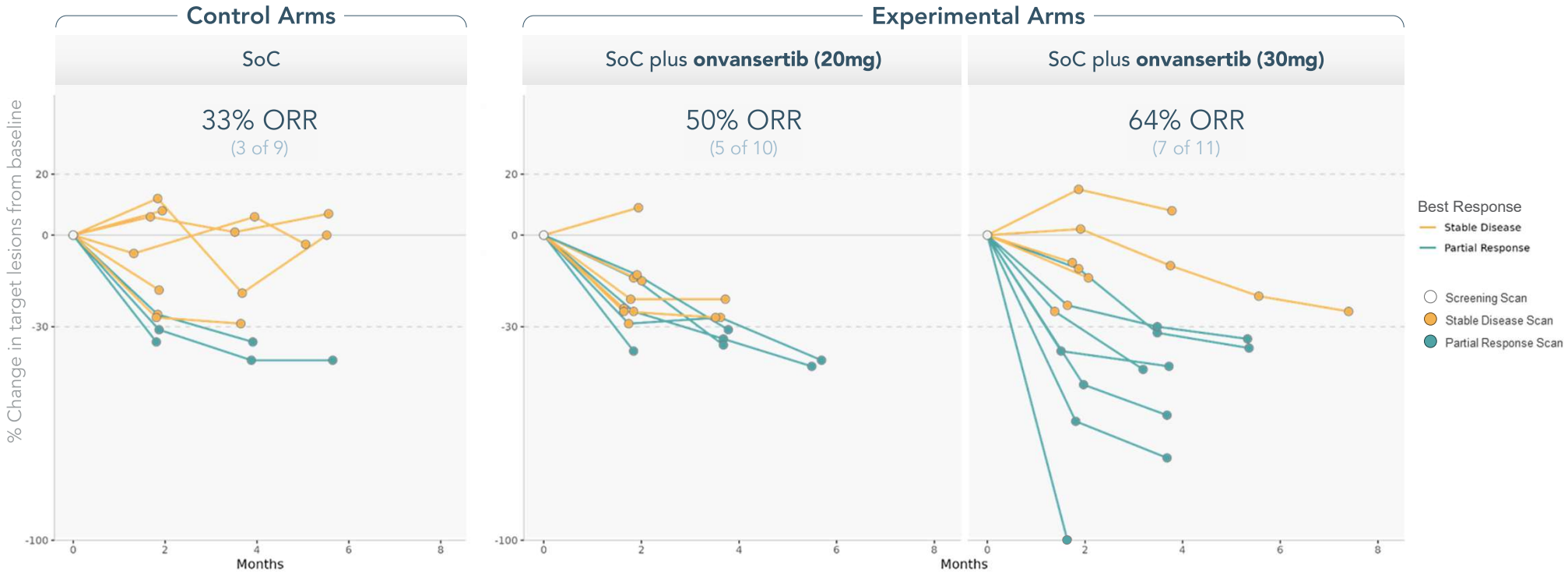
Dose response: Higher onvansertib dose shows increased ORR with deeper responses

Best Radiographic Response BY ONVANSERTIB DOSE* – CRDF-004 as of November 26, 2024

* Radiographic response determined per RECIST 1.1 by blinded independent central review. Waterfall plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

Spider plots show deepening responses for onvansertib 30mg dose

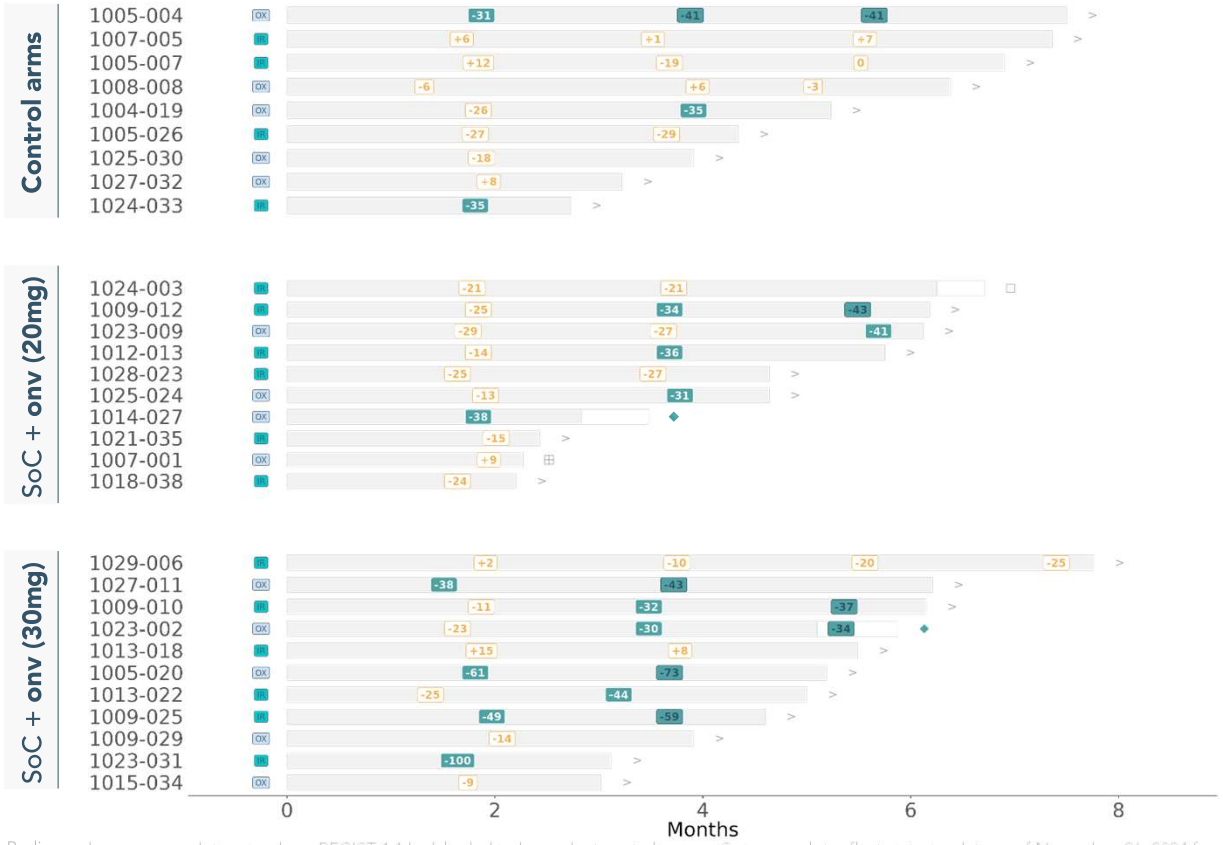
Radiographic Response over Time* – CRDF-004 as of November 26, 2024



* Radiographic response determined per RECIST 1.1 by blinded independent central review. Spider plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

Swimmer plot shows most patients remain on trial

Radiographic Response over Time* – CRDF-004 as of November 26, 2024



> On Treatment

Best Response

- # Confirmed Partial Response
- # Partial Response
- # Stable Disease
- # Progressive Disease

# indicates % change from baseline

Reason For Discontinuation

- To Pursue Surgery
- Adverse Event
- Progressive Disease

Chemotherapy Backbone

- IR FOLFIRI
- OX FOLFOX

* Radiographic response determined per RECIST 1.1 by blinded independent central review. Swimmer plot reflects interim data as of November 26, 2024 from an ongoing trial and unlocked database.

ORR is consistently higher for patients receiving onvansertib + SoC

Summary of Objective Response Rates by Cohort* – CRDF-004 as of November 26, 2024

	CRDF-004 Evaluable Population (N = 30)				Historical Controls at End of Trial (Hecht, et al)**
		Onvansertib Arms			
	Control Arms	All	20mgs onv	30mgs onv	
FOLFIRI + bev	25% (1 of 4)	50% (6 of 12)	33% (2 of 6)	66% (4 of 6)	38%
FOLFOX + bev	40% (2 of 5)	66% (6 of 9)	75% (3 of 4)	60% (3 of 5)	44%
Total	33% (3 of 9)	57% (12 of 21)	50% (5 of 10)	64% (7 of 11)	

* Radiographic response determined per RECIST 1.1 by blinded independent central review. Interim data as of November 26, 2024 from an ongoing trial and unlocked database. Blue boxes indicate the 6 trial arms.
** Hecht et al., J Clin Oncol 2009 10 Feb; 27: 672-680.

CRDF-004 demographics and baseline characteristics*

	Control Arms (SoC) N=9	SoC + Onvansertib 20mg N=10	SoC + Onvansertib 30mg N=11	Total N=30
Age (years)				
Median (range)	56.0 (32, 82)	47.0 (38, 69)	62.0 (39, 75)	55.5 (32, 82)
Gender, n (%)				
Male	6 (66.7)	4 (40.0)	6 (54.5)	16 (53.3)
Female	3 (33.3)	6 (60.0)	5 (45.5)	14 (46.7)
Race, n (%)				
White	8 (88.9)	9 (90.0)	11 (100)	28 (93.3)
Asian	1 (11.1)	0	0	1 (3.3)
Native Hawaiian or Other Pacific Islander	0	1 (10.0)	0	1 (3.3)
ECOG, n (%)				
0	4 (44.4)	6 (60.0)	8 (72.7)	18 (60.0)
1	5 (55.6)	4 (40.0)	3 (27.3)	12 (40.0)
Time to metastases, n (%)				
Metachronous	3 (33.3)	3 (30.0)	3 (27.3)	9 (30.0)
Synchronous	6 (66.7)	7 (70.0)	8 (72.7)	21 (70.0)
Side of Tumor, n (%)				
Bilateral	4 (44.4)	1 (10.0)	2 (18.2)	7 (23.3)
Left	2 (22.2)	4 (40.0)	3 (27.3)	9 (30.0)
Right	3 (33.3)	4 (40.0)	6 (54.5)	13 (43.3)
Liver metastasis at study entry, n (%)				
No	2 (22.2)	3 (30.0)	1 (9.1)	6 (20.0)
Yes	7 (77.8)	7 (70.0)	10 (90.9)	24 (80.0)
Liver only disease, n (%)				
No	7 (77.8)	10 (100)	8 (72.7)	25 (83.3)
Yes	2 (22.2)	0	3 (27.3)	5 (16.7)
Number of metastatic organs, n (%)				
Multiple	6 (66.7)	9 (90.0)	8 (72.7)	23 (76.7)
Single	3 (33.3)	1 (10.0)	3 (27.3)	7 (23.3)
Prior adjuvant or neo-adjuvant chemotherapy, n (%)				
No	7 (77.8)	7 (70.0)	10 (90.9)	24 (80.0)
Yes	2 (22.2)	3 (30.0)	1 (9.1)	6 (20.0)
Surgery on Primary tumor, n (%)				
No	4 (44.4)	5 (50.0)	7 (63.6)	16 (53.3)
Yes	5 (55.6)	5 (50.0)	4 (36.4)	14 (46.7)

* Demographics and baseline characteristics are as of November 26, 2024 from an ongoing trial and unlocked database. Side of tumor data for one patient is currently not available.

CRDF-004 treatment emergent adverse events (TEAE) data*

	FOLFIRI/Bev (N=4)		FOLFIRI/Bev/Onv 20mg (N=6)		FOLFIRI/Bev/Onv 30mg (N=6)		FOLFOX/Bev (N=5)		FOLFOX/Bev/Onv 20mg (N=4)		FOLFOX/Bev/Onv 30mg (N=5)		All Control Arms (N=9)		All Experimental Arms (N=21)	
N (% of total)	All Grades	Gr ≥3	All Grades	Gr ≥3	All Grades	Gr ≥3	All Grades	Gr ≥3	All Grades	Gr ≥3	All Grades	Gr ≥3	All Grades	Gr ≥3	All Grades	Gr ≥3
Any Adverse Events	4 (100.0)	2 (50.0)	6 (100.0)	4 (66.7)	6 (100.0)	5 (83.3)	5 (100.0)	3 (60.0)	4 (100.0)	3 (75.0)	5 (100.0)	3 (60.0)	9 (100.0)	5 (55.6)	21 (100.0)	15 (71.4)
Fatigue	2 (50.0)	0	3 (50.0)	0	3 (50.0)	0	4 (80.0)	1 (20.0)	3 (75.0)	0	3 (60.0)	0	6 (66.7)	1 (11.1)	12 (57.1)	0
Nausea	2 (50.0)	0	5 (83.3)	0	2 (33.3)	0	3 (60.0)	0	4 (100.0)	0	2 (40.0)	0	5 (55.6)	0	13 (61.9)	0
Neutrophil count decreased	4 (100.0)	1 (25.0)	2 (33.3)	1 (16.7)	2 (33.3)	1 (16.7)	2 (40.0)	2 (40.0)	3 (75.0)	1 (25.0)	1 (20.0)	0	6 (66.7)	3 (33.3)	8 (38.1)	3 (14.3)
Neutropenia	0 (0.0)	0	0	0	3 (50.0)	3 (50.0)	0	0	0	0	0	0	0	0	3 (14.3)	3 (14.3)
Thrombocytopenia	0 (0.0)	0	0	0	1 (16.7)	0	0	0	1 (25.0)	0	2 (40.0)	0	0	0	4 (19.0)	0
White blood cell count decreased	1 (25.0)	0	2 (33.3)	0	0	0	2 (40.0)	0	0	0	0	0	3 (33.3)	0	2 (9.5)	0
Lymphocyte count decreased	1 (25.0)	0	1 (16.7)	0	0	0	0	0	0	0	1 (20.0)	1 (20.0)	1 (11.1)	0	2 (9.5)	1 (4.8)
Diarrhoea	0 (0.0)	0	3 (50.0)	1 (16.7)	6 (100.0)	0	2 (40.0)	0	0	0	2 (40.0)	0	2 (22.2)	0	11 (52.4)	1 (4.8)
Abdominal pain	2 (50.0)	1 (25.0)	1 (16.7)	0	2 (33.3)	0	1 (20.0)	0	1 (25.0)	0	2 (40.0)	0	3 (33.3)	1 (11.1)	6 (28.6)	0
Vomiting	1 (25.0)	0	3 (50.0)	0	1 (16.7)	0	0	0	2 (50.0)	0	1 (20.0)	0	1 (11.1)	0	7 (33.3)	0
Alopecia	1 (25.0)	0	1 (16.7)	0	3 (50.0)	0	1 (20.0)	0	1 (25.0)	0	0	0	2 (22.2)	0	5 (23.8)	0
Anaemia	2 (50.0)	0	1 (16.7)	0	0	0	1 (20.0)	0	2 (50.0)	0	1 (20.0)	1 (20.0)	3 (33.3)	0	4 (19.0)	1 (4.8)
Peripheral sensory neuropathy	1 (25.0)	0	0	0	1 (16.7)	0	1 (20.0)	0	0	0	4 (80.0)	0	2 (22.2)	0	5 (23.8)	0
Constipation	0 (0.0)	0	1 (16.7)	0	3 (50.0)	0	0	0	1 (25.0)	0	1 (20.0)	0	0	0	6 (28.6)	0
Decreased appetite	0 (0.0)	0	1 (16.7)	0	2 (33.3)	0	0	0	2 (50.0)	0	1 (20.0)	0	0	0	6 (28.6)	0
Dizziness	0 (0.0)	0	1 (16.7)	0	2 (33.3)	0	1 (20.0)	0	0	0	2 (40.0)	0	1 (11.1)	0	5 (23.8)	0
Dysgeusia	0 (0.0)	0	0	0	2 (33.3)	0	1 (20.0)	0	2 (50.0)	0	1 (20.0)	0	1 (11.1)	0	5 (23.8)	0
Arthralgia	1 (25.0)	1 (25.0)	1 (16.7)	0	0	0	0	0	1 (25.0)	0	2 (40.0)	0	1 (11.1)	1 (11.1)	4 (19.0)	0
Dyspepsia	0 (0.0)	0	1 (16.7)	0	1 (16.7)	0	1 (20.0)	0	0	0	2 (40.0)	0	1 (11.1)	0	4 (19.0)	0
Headache	1 (25.0)	0	1 (16.7)	0	1 (16.7)	0	2 (40.0)	0	0	0	0	0	3 (33.3)	0	2 (9.5)	0
Insomnia	0 (0.0)	0	1 (16.7)	0	1 (16.7)	0	1 (20.0)	0	0	0	2 (40.0)	0	1 (11.1)	0	4 (19.0)	0
Weight decreased	0 (0.0)	0	1 (16.7)	0	2 (33.3)	0	0	0	1 (25.0)	0	1 (20.0)	0	0	0	5 (23.8)	0
Epistaxis	0 (0.0)	0	1 (16.7)	0	1 (16.7)	0	0	0	1 (25.0)	0	1 (20.0)	0	0	0	4 (19.0)	0
Hypertension	0 (0.0)	0	2 (33.3)	0	1 (16.7)	0	0	0	1 (25.0)	0	0	0	0	0	4 (19.0)	0
Hypokalaemia	0 (0.0)	0	0	0	1 (16.7)	0	1 (20.0)	0	0	0	2 (40.0)	0	1 (11.1)	0	3 (14.3)	0
Paraesthesia	0 (0.0)	0	0	0	0	0	1 (20.0)	0	0	0	3 (60.0)	0	1 (11.1)	0	3 (14.3)	0
Asthenia	0 (0.0)	0	0	0	2 (33.3)	1 (16.7)	1 (20.0)	0	0	0	0	0	1 (11.1)	0	2 (9.5)	1 (4.8)
Cough	1 (25.0)	0	2 (33.3)	0	0	0	0	0	0	0	0	0	1 (11.1)	0	2 (9.5)	0
Flushing	0 (0.0)	0	2 (33.3)	0	0	0	1 (20.0)	0	0	0	0	0	1 (11.1)	0	2 (9.5)	0
Haematochezia	1 (25.0)	0	0	0	2 (33.3)	0	0	0	0	0	0	0	1 (11.1)	0	2 (9.5)	0
Influenza like illness	1 (25.0)	0	2 (33.3)	0	0	0	0	0	0	0	0	0	1 (11.1)	0	2 (9.5)	0
Infusion related reaction	0 (0.0)	0	2 (33.3)	0	0	0	0	0	1 (25.0)	0	0	0	0	0	3 (14.3)	0
Neuropathy peripheral	0 (0.0)	0	0	0	0	0	2 (40.0)	0	1 (25.0)	0	0	0	2 (22.2)	0	1 (4.8)	0
Oedema peripheral	1 (25.0)	0	1 (16.7)	0	0	0	1 (20.0)	0	0	0	0	0	2 (22.2)	0	1 (4.8)	0
Proteinuria	1 (25.0)	0	0	0	0	0	0	0	1 (25.0)	0	1 (20.0)	0	1 (11.1)	0	2 (9.5)	0
Stomatitis	0 (0.0)	0	2 (33.3)	0	0	0	1 (20.0)	0	0	0	0	0	1 (11.1)	0	2 (9.5)	0

* Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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. Columns show the absolute # of patients and (%) of the population.

mCRC program positions onvansertib for accelerated and full-approval

First-line RAS-mutated mCRC clinical development program

Agreed with FDA June 2023 Type C meeting

CRDF-004

PHASE 2 DOSE-CONFIRMATION TRIAL

90 patients

Randomized

2 onvansertib doses

Provide randomized clinical safety / efficacy data

Confirm optimal 1st line dose

Pfizer Ignite provides clinical execution

CRDF-005

PHASE 3 REGISTRATIONAL TRIAL

320 patients

Randomized

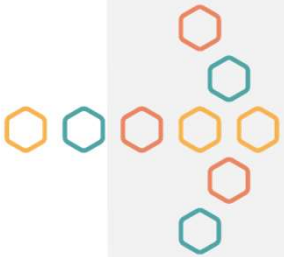
Designed for accelerated and full-approval (agreed with FDA)

ORR endpoint:
For accelerated approval

PFS / OS trend endpoint:
For full-approval

OUR SHIFT

TO FIRST-LINE RAS-MUTATED mCRC

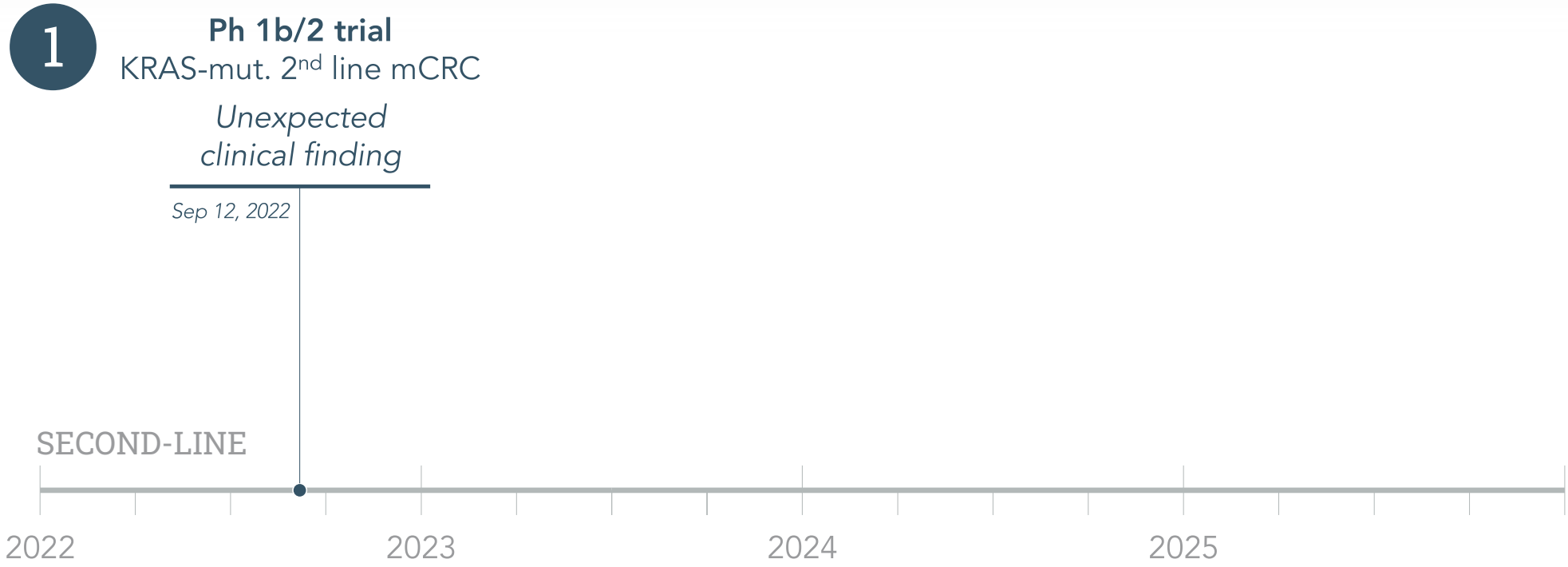


The strength of our 1st-line program

The rationale for our shift from 2nd-line

The coming catalysts in 2025

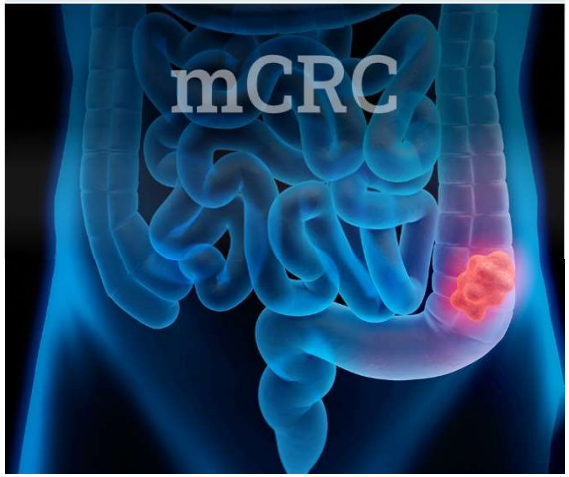
Our second-line phase 1b/2 trial generated a novel finding

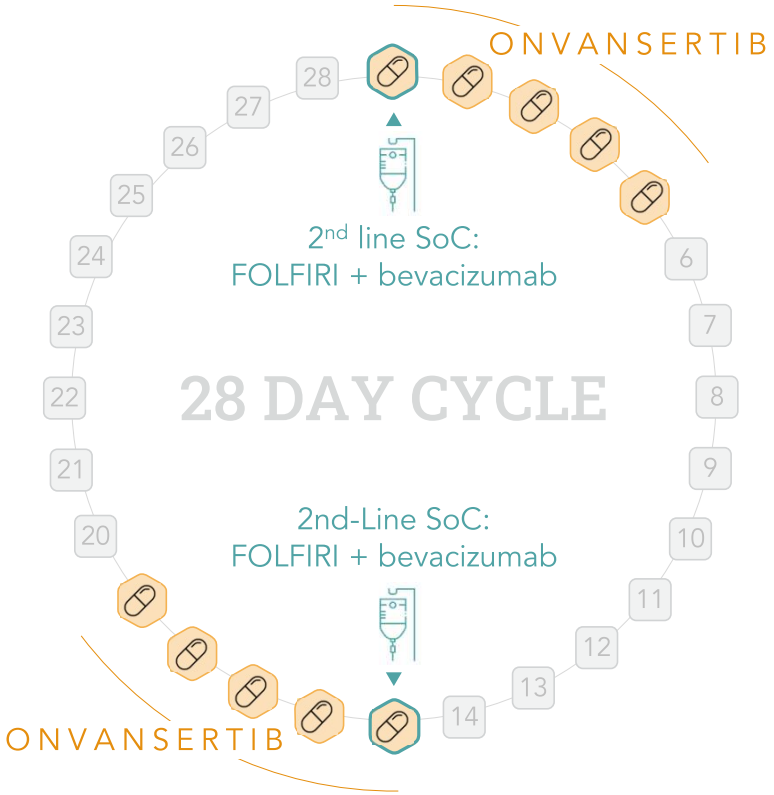


Our Ph1b/2 trial combined onvansertib with the current SoC in 2nd line

ENROLLMENT CRITERIA

- 2nd line mCRC
- KRAS-mut
- Unresectable
- N=68 (66 evaluable)





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

Our Ph1b/2 trial added onvansertib to SoC in the 2nd line setting

Patients who came to our second-line trial not having received bev in first-line are called, “bev naïve”

1st LINE

Standard of Care

FOLFOX	*chemotherapy*	
Bev (optional)	Yes	No

“bev naïve"

2nd LINE

Cardiff Oncology Phase 1b/2 trial

FOLFIRI	*chemotherapy*
Bev	*antiangiogenic*
Onvansertib	*PLK1 inhibitor*

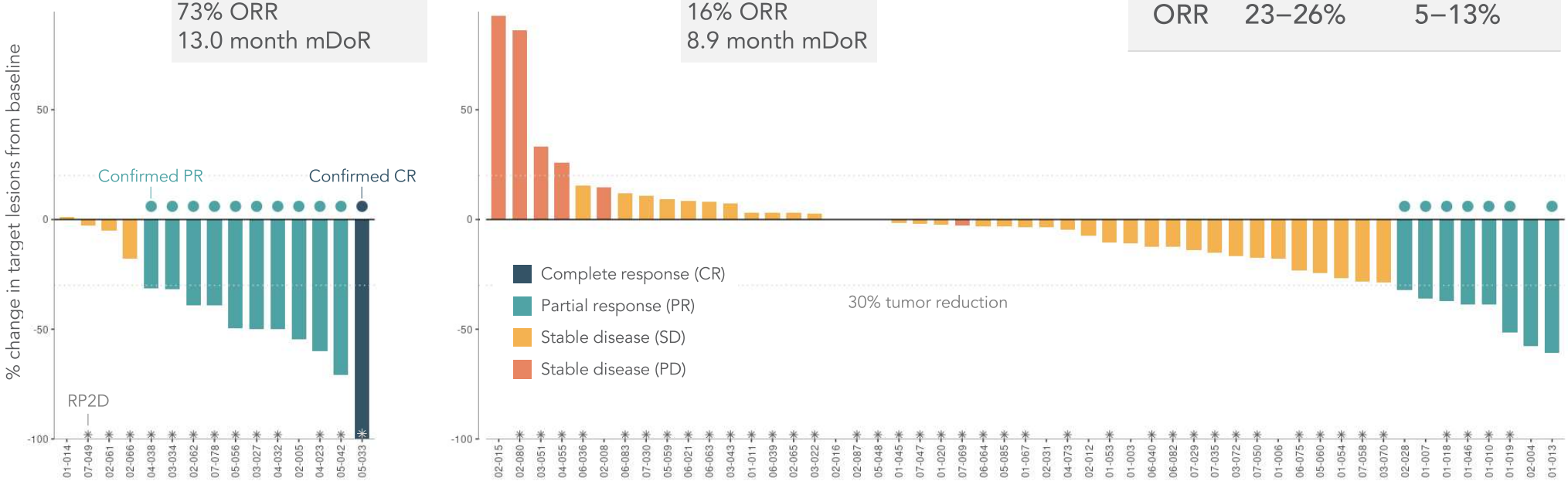
Ph 1b/2 trial bev naïve patients achieved higher response rates

Best Radiographic Response and Duration of Response*

66 evaluable patients (as of June 16, 2023)

Bev naïve: 15 of 66 patients (23%)
73% ORR
13.0 month mDoR

Bev exposed: 51 of 66 (77%)
16% ORR
8.9 month mDoR



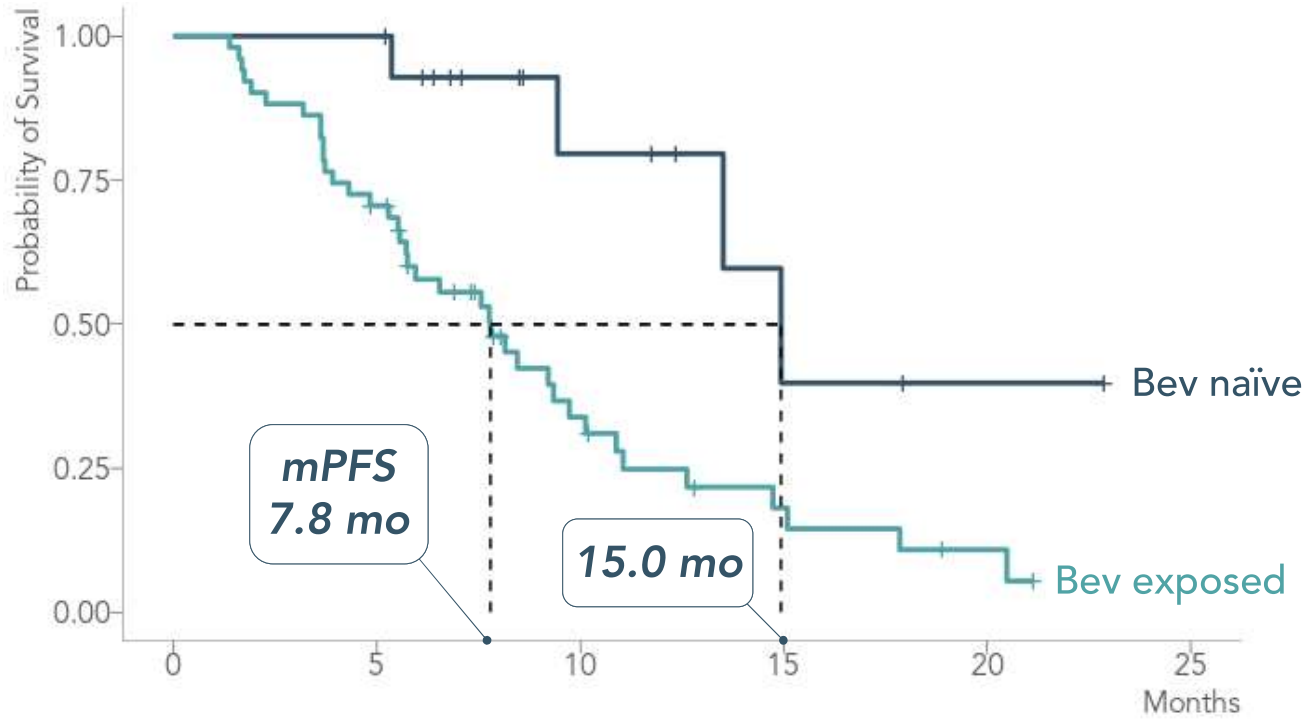
	Historical controls**	
	Bev naïve	Bev exposed
ORR	23–26%	5–13%

* Radiographic response determined per RECIST 1.1. Waterfall plot and table reflect interim data as of June 16, 2023 from an ongoing trial and unlocked EDC database.

** 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. Giantonio et al., 2007, J Clin Oncol 25:1539-1544; Moriwaki et al., Med Oncol, 2012, 29:2842–2848; Beretta et al, Med Oncol 2013, 30:486.

Ph 1b/2 trial mPFS exceeds historical controls for SoC

Progression-free survival*
66 evaluable patients (as of June 16, 2023)



	Historical controls**	
	Bev naïve	Bev exposed
mPFS (mo)	6.9–8.5	4.5–6.7

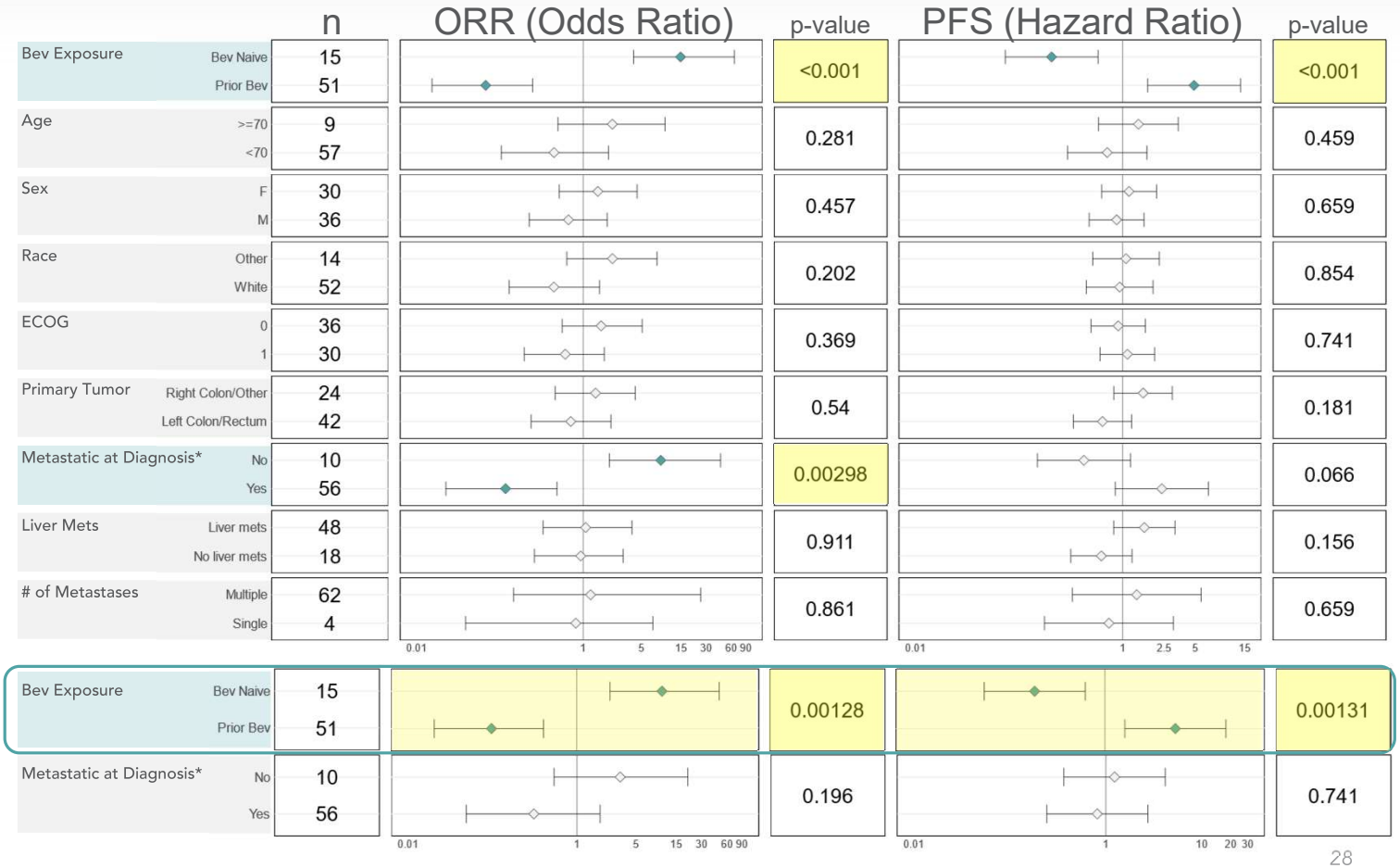
* Onvansertib mPFS are interim data as of June 16, 2023 from an ongoing trial and unlocked EDC database.

** 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. Giantonio et al., 2007, J Clin Oncol 25:1539-1544; Moriwaki et al., Med Oncol, 2012, 29:2842–2848; Beretta et al, Med Oncol 2013, 30:486.

Phase 1b/2 multivariable analysis shows prior exposure to bev is the only patient characteristic associated with greater ORR and PFS

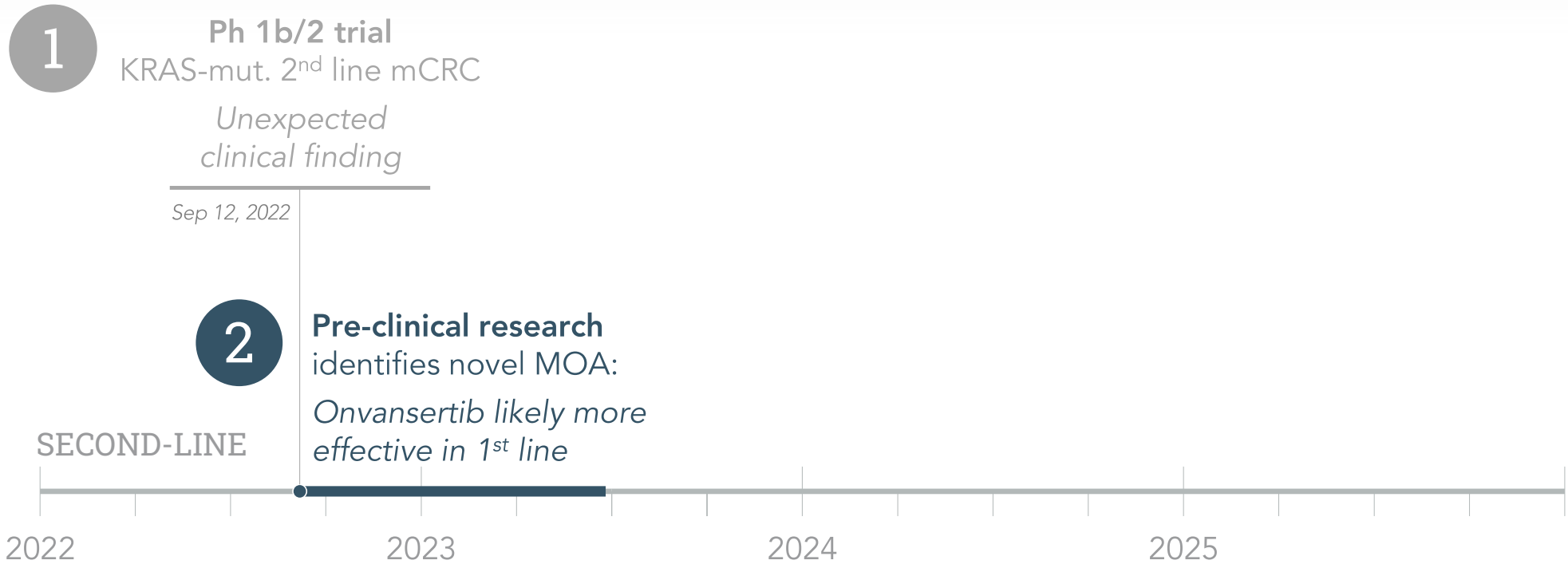
Univariable analysis of baseline characteristics for ORR and PFS indicate superior clinical benefit for bev naïve patients and for patients without metastatic disease at time of diagnosis

Multivariable Analysis was performed with these two characteristics, resulting in only prior bev exposure remaining independently associated with clinical benefit

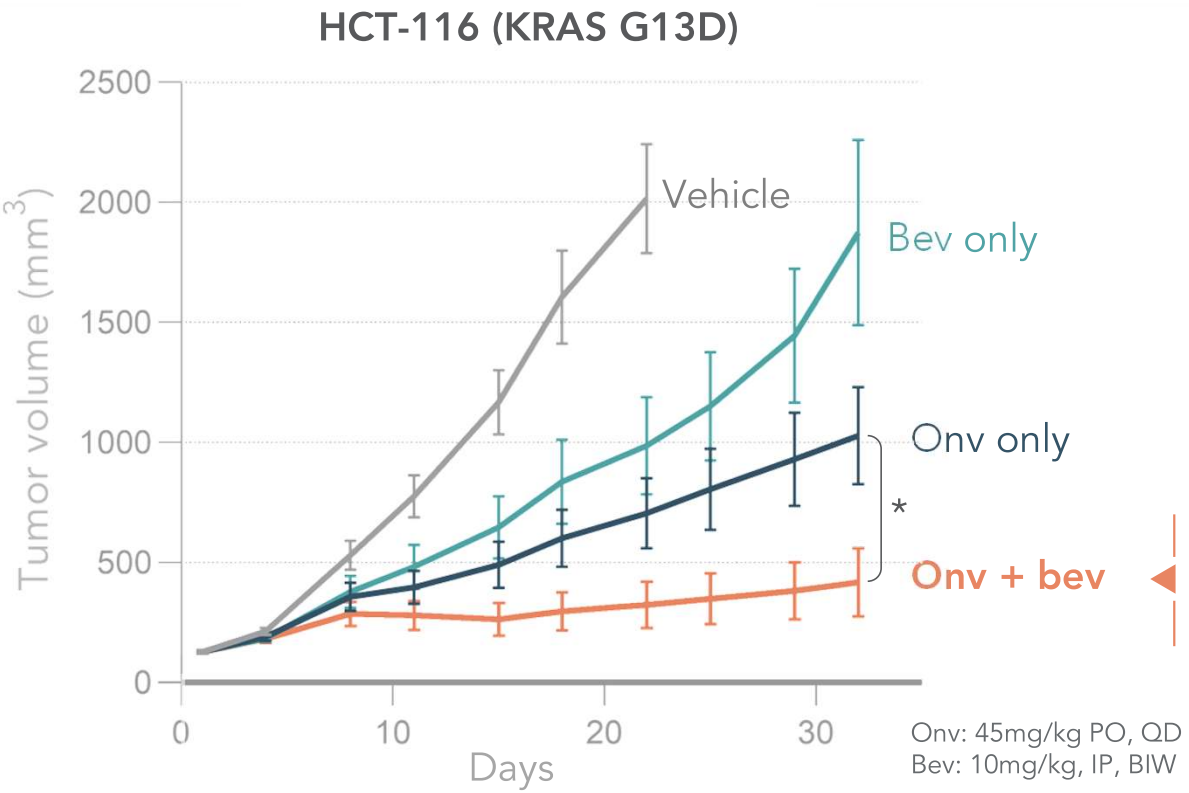


* Metastatic at Diagnosis: "Yes" means the patient's cancer had already metastasized when first diagnosed. "No" means the patient's initial diagnosis was non-metastatic CRC, but subsequently developed metastatic disease prior to enrolling in our Ph 1b/2 trial.

Unexpected clinical findings prompted new pre-clinical research



Onvansertib + bev inhibits tumor growth greater than either agent alone

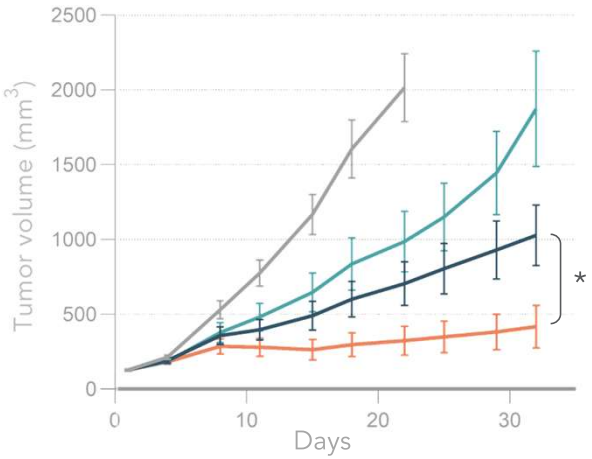


The combination had significant superior anti-tumor activity compared to the single agents

Three KRAS-mutant mCRC xenograft models were treated with vehicle (control), onvansertib, bevacizumab or the combination of onvansertib and bev 8-9mice/ group. Mean ± SEM are represented on graphs. An unpaired t-test was used to test the difference in tumor volume change on the last day of treatment between the combination treatment and the most effective control arm. *p<0.05, ***p<0.001, ****p<0.0001.

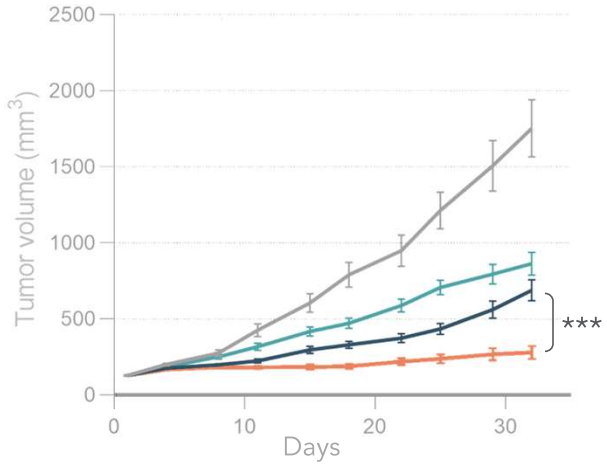
Onvansertib + bev inhibits tumor growth greater than either agent alone

HCT-116 (KRAS G13D)



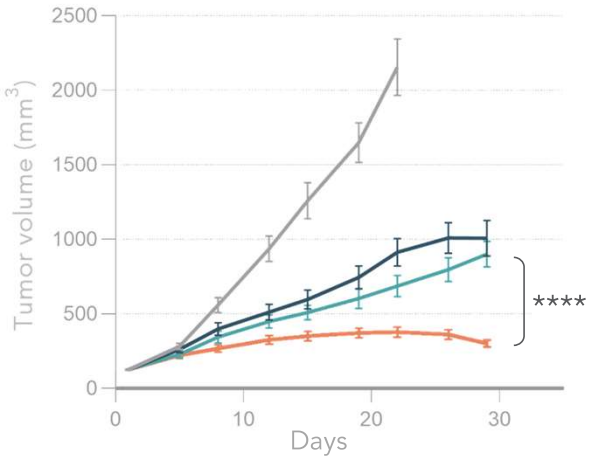
Onv: 45mg/kg PO, QD
Bev: 10mg/kg, IP, BIW

LoVo (KRAS G13D)



Onvansertib 45mg/kg PO, QD
Bev 5mg/kg, IP, BIW

SW620 (KRAS G12V)

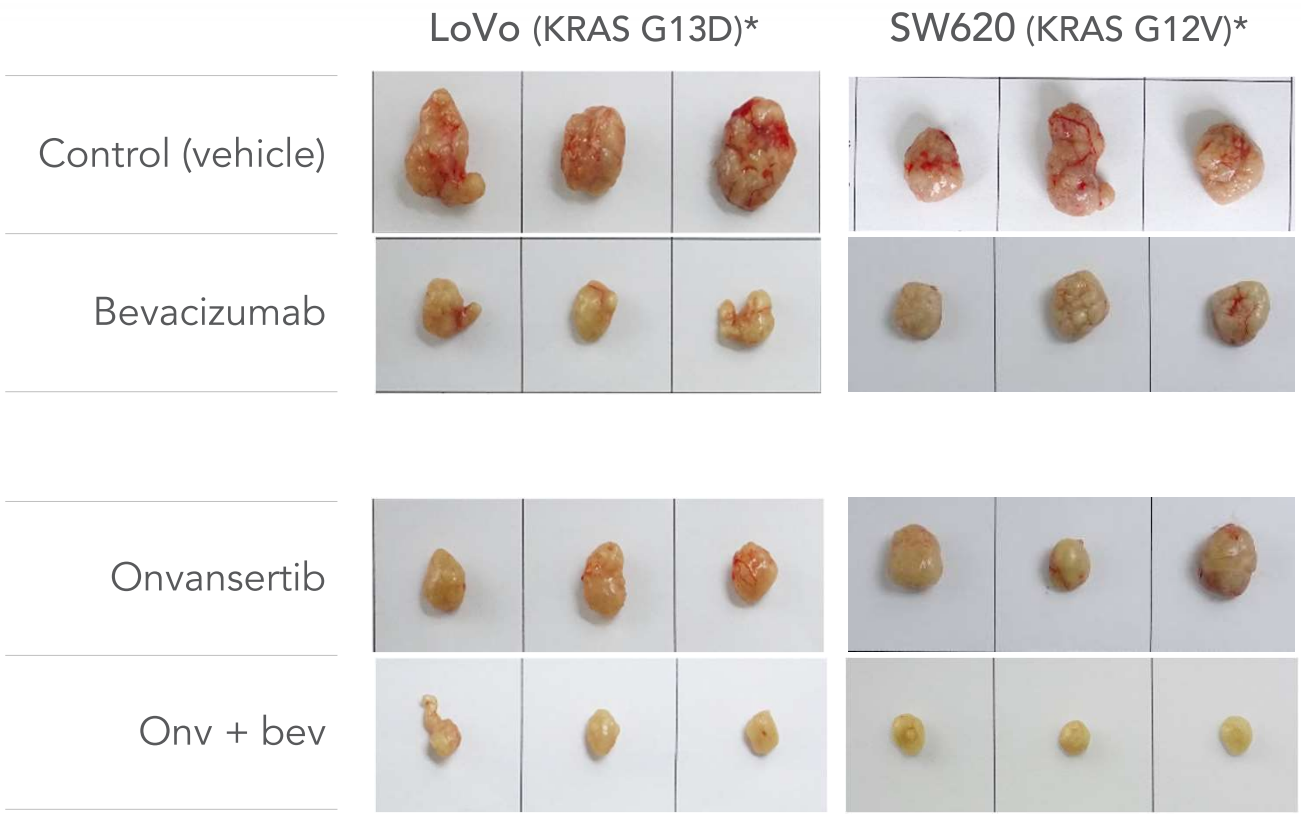


Onvansertib 45mg/kg PO, QD
Bev 1mg/kg, IP, BIW

Vehicle
Bev only
Onv only
Onv + bev

Three KRAS-mutant mCRC xenograft models were treated with vehicle (control), onvansertib, bevacizumab or the combination of onvansertib and bev 8-9mice/ group. Mean ± SEM are represented on graphs. An unpaired t-test was used to test the difference in tumor volume change on the last day of treatment between the combination treatment and the most effective control arm. *p<0.05, ***p<0.001, ****p<0.0001.

Onvansertib's independent role in antiangiogenesis complements bev



- Roche drug Avastin®
  8th largest global drug in 2019
  ($7.1B sales)

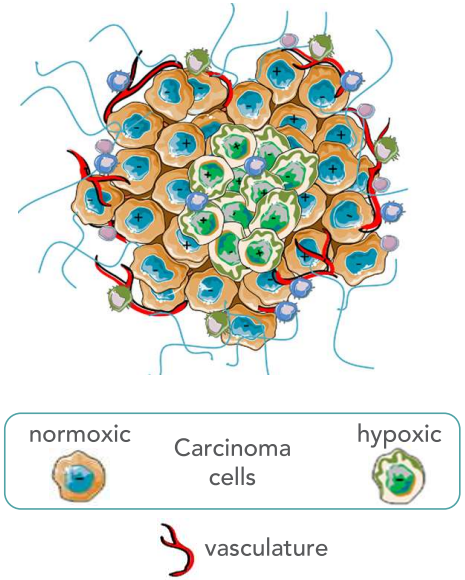
- KRAS-mut mCRC tumors from mice treated with onv + bev appear smaller and pale (less vascularized)

* Two KRAS-mutant mCRC xenograft models were treated with control (vehicle), onvansertib, bevacizumab or the combination of onvansertib and bev 8-9mice / group. Tumors were removed and photographed at the end of the study. Representative photographs from three mice from each group are shown.

HIF1α plays a critical role in a tumor's response to hypoxia

Tumor growth

The tumor cells outgrow the blood supply and become starved of oxygen and nutrients…



Hypoxia

… low oxygen levels lead to elevated HIF1α protein expression

HIF1α

… turns on VEGF-A expression and secretion to recruit new vasculature as well as turning on a multitude of downstream survival genes

VEGF-A

- Angiogenesis: Vascularization of the tumor
- Tumor cell survival
- Proliferation

https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2017.01625/full

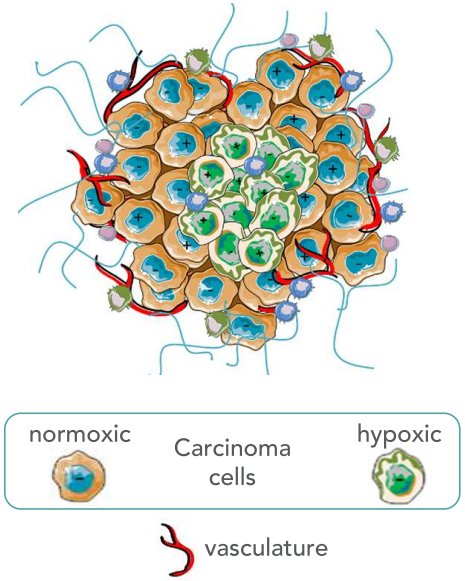
Bev inhibits tumor angiogenesis by neutralizing VEGF-A

Tumor growth → **Hypoxia** → **HIF1α**

The tumor cells outgrow the blood supply and become starved of oxygen and nutrients…

… low oxygen levels lead to elevated HIF1α protein expression

… turns on VEGF-A expression and secretion to recruit new vasculature as well as turning on a multitude of downstream survival genes



bevacizumab ⊣ VEGF-A

neutralizes VEGF-A

- Angiogenesis: Vascularization of the tumor
- Tumor cell survival
- Proliferation

https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2017.01625/full

Onvansertib restricts tumor's broader ability to adapt to hypoxia

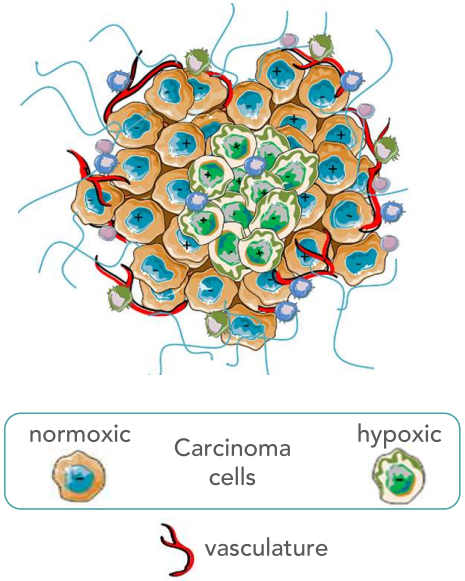
Tumor growth → **Hypoxia** → **HIF1α** ⊣ **onvansertib**

The tumor cells outgrow the blood supply and become starved of oxygen and nutrients…

… low oxygen levels lead to elevated HIF1α protein expression

… turns on VEGF-A expression and secretion to recruit new vasculature as well as turning on a multitude of downstream survival genes

onvansertib: inhibits HIF1α expression



bevacizumab ⊣ VEGF-A

neutralizes VEGF-A

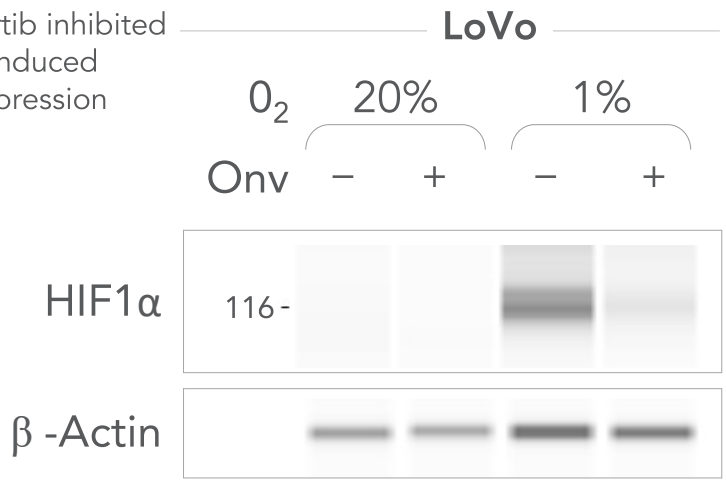
- Angiogenesis: Vascularization of the tumor
- Tumor cell survival
- Proliferation

https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2017.01625/full

Onvansertib inhibits the hypoxia signaling pathway by downregulating HIF1α expression

PLK1 inhibition in LoVo RAS-mutant CRC cell lines[1]

Onvansertib inhibited hypoxia-induced HIF1α expression

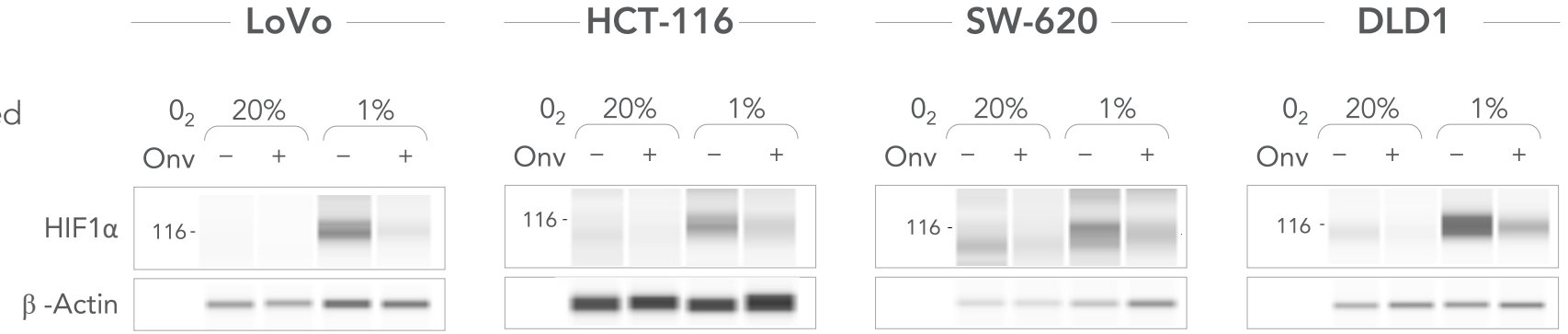


PLK1 inhibition using siRNA against PLK1 (siPLK1)[2] prevented hypoxia-induced HIF1α expression

1. KRAS-mutant CRC cell lines were cultured under normoxia (20%O_2) or hypoxia (1%O_2), in the presence (+) or absence (-) of onvansertib. HIF1α expression was induced under hypoxia.
2. LoVo and HCT116 cells were transfected with siRNA control (-) or siRNA targeting PLK1 (siPLK1) and then exposed to 20% or 1%O_2. Cells were collected 24h after transfection.

Onvansertib inhibits the hypoxia signaling pathway by downregulating HIF1α expression

In 4 RAS-mutant CRC cell lines[1], onvansertib inhibited hypoxia-induced HIF1α expression



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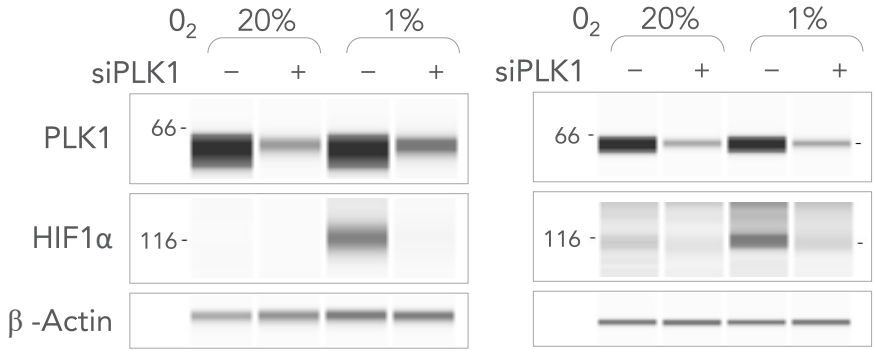

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2. LoVo and HCT116 cells were transfected with siRNA control (-) or siRNA targeting PLK1 (siPLK1) and then exposed to 20% or 1%O_2. Cells were collected 24h after transfection.

ASCO's flagship publication, JCO, published our clinical data and MOA

Journal of Clinical Oncology®

Ph 1b/2 trial	Bev naïve 2nd line KRAS-mutated mCRC
MOA	Onvansertib's inhibition of the hypoxia response pathway

Onvansertib in Combination With Chemotherapy and Bevacizumab in Second-Line Treatment of *KRAS*-Mutant Metastatic Colorectal Cancer: A Single-Arm, Phase II Trial

Daniel H. Ahn, DO[1]; Maya Ridinger, PhD[2]; Timothy L. Cannon, MD[3]; Lawrence Mendelsohn, MD[4]; Jason S. Starr, DO[5]; Joleen M. Hubbard, MD[6]; Anup Kasi, MD[7]; Afsaneh Barzi, MD, PhD[8]; Errin Samuëlsz, BA[2], Anju Karki, PhD[2], Ramanand A. Subramanian, PhD[2]; Divora Yemane, BA[2]; Roy Kim, BA[2]; Chu-Chiao Wu, PhD[2]; Peter J.P. Croucher, DPhil[2]; Tod Smeal, PhD[2]; Fairooz F. Kabbinavar, MD[2]; and Heinz-Josef Lenz, MD[9]

DOI https://doi.org/10.1200/JCO-24-01266

ABSTRACT

PURPOSE This phase II study evaluated the efficacy and tolerability of onvansertib, a polo-like kinase 1 (PLK1) inhibitor, in combination with fluorouracil, leucovorin, and irinotecan (FOLFIRI) + bevacizumab for the second-line treatment of *KRAS*-mutant metastatic colorectal cancer (mCRC).

PATIENTS AND METHODS This multicenter, open-label, single-arm study enrolled patients with *KRAS*-mutated mCRC previously treated with oxaliplatin and fluorouracil with or without bevacizumab. Patients received onvansertib (15 mg/m² once daily on days 1-5 and 15-19 of a 28-day cycle) and FOLFIRI + bevacizumab (days 1 and 15). The primary end point was the objective response rate (ORR), and secondary endpoints included progression-free survival (PFS), duration of response (DOR), and tolerability. Translational and preclinical studies were conducted in *KRAS*-mutant CRC.

RESULTS Among the 53 patients treated, the confirmed ORR was 26.4% (95% CI, 15.3 to 40.3). The median DOR was 11.7 months (95% CI, 9.4 to not reached). Grade 3/4 adverse events were reported in 62% of patients. A post hoc analysis revealed that patients with no prior bevacizumab treatment had a significantly higher ORR and longer PFS compared with patients with prior bevacizumab treatment:

ACCOMPANYING CONTENT

Appendix

Data Sharing Statement

Protocol

Accepted September 19, 2024
Published October 30, 2024

J Clin Oncol 00:1-12

View Online Article

Proposed MOA of onv+bev therapy in bev naïve / bev exposed tumors

Journal of Clinical Oncology®

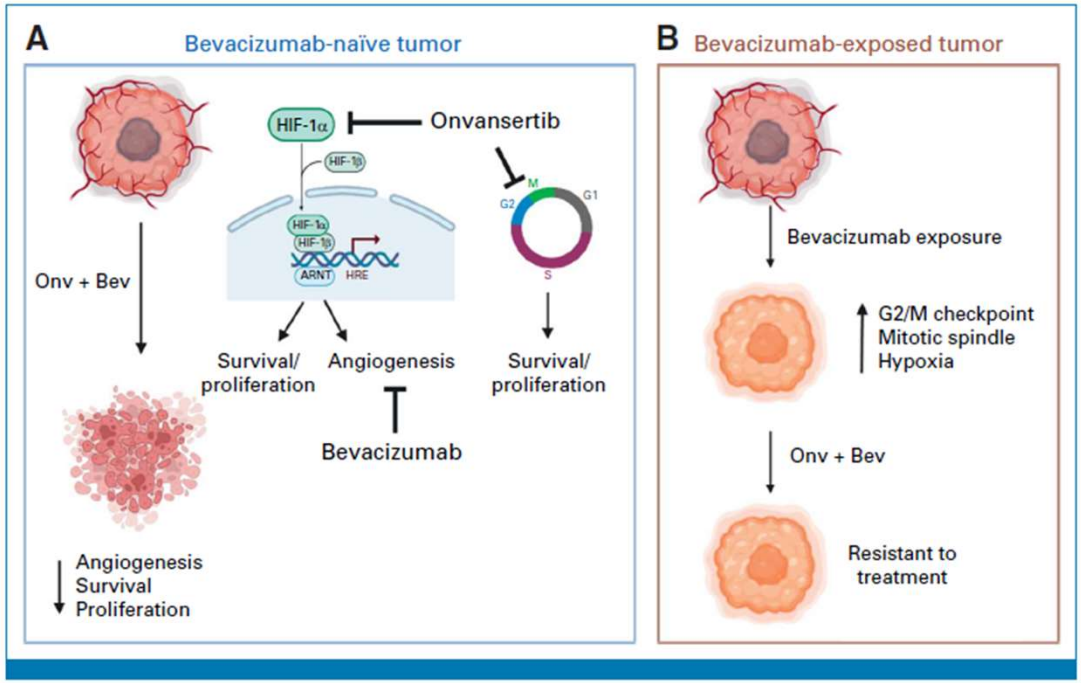
MOA

Onvansertib's inhibition of the hypoxia response pathway

(A) In bev naïve tumors, the combination of onvansertib and bev effectively inhibits cell survival, proliferation, and angiogenesis

(B) In bev exposed tumors, bev exposure leads to upregulation of mitotic and hypoxia pathways resulting in resistance to both onvansertib and bev

Proposed mechanisms of onvansertib and bev combination therapy in bev naïve and bev exposed tumors



Prior bev therapy in 1st line can confer resistance to bev, and onvansertib

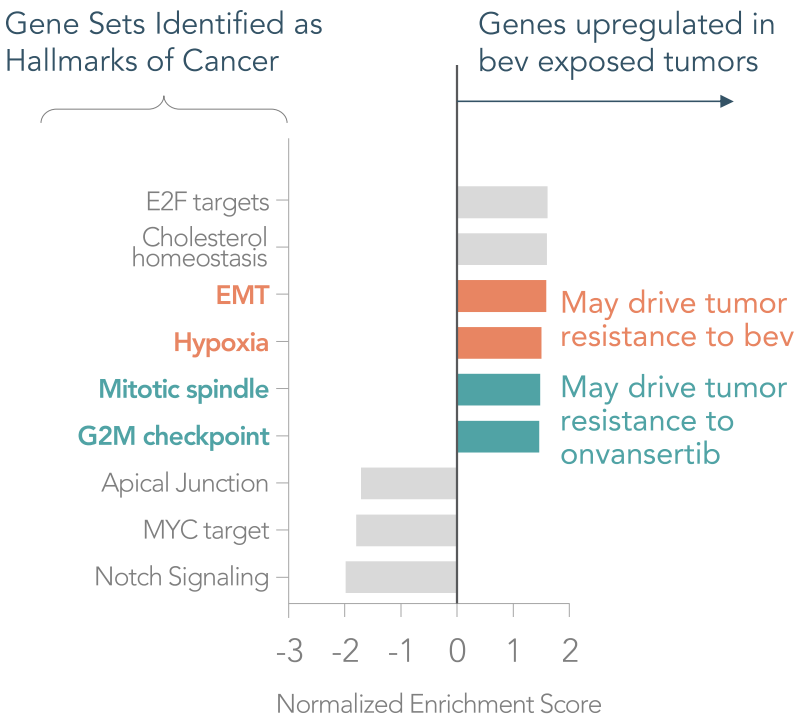
TEMPUS
Tumor Biopsy Library

135 biopsies:

All from KRAS-mut mCRC patients after completing first-line therapy (prior to second-line)

Bev naïve	vs.	Bev exposed
1st line: FOLFOX n=71		1st line: FOLFOX+bev n=64

Performed RNA sequencing to see changes in tumor biology after 1st line treatment +/- bev



OUR SHIFT

TO FIRST-LINE RAS-MUTATED mCRC

The strength of our 1st-line program

The rationale for our shift from 2nd-line

The coming catalysts in 2025

Cardiff Oncology: Positioned to improve 1st line RAS-mut mCRC treatment

First-in-Class PLK1 inhibitor

Onvansertib

First well-tolerated PLK1-selective inhibitor

2nd line KRAS-mut. mCRC program

Ph 1b/2 data

High efficacy in bev naïve patients

Shift to 1st line

Strong support

- 2nd line data
- FDA agreed path to 1st line accelerated approval
- Pfizer: clinical execution in 1st line

Clinical signal from CRDF-004 1st trial

Encouraging initial data

- 64% response rate for 30 mg onv + SoC
- 33% response rate for SoC alone

Additional clinical data

from our 1st line RAS-mutated mCRC trial is expected in H1 2025

September 30, 2024 cash and investments (pro forma for capital raised after September 30, 2024)*	$102.1M
6-month net cash used in Operating Activities* (Two-quarter period ending September 30, 2024)	$19.7M

* Financial information above is derived from our unaudited financials in Form 10Q filed on 11/7/24. Pro forma cash includes reported cash and short-term investments as of 9/30/24 of $57.7M; net proceeds of $6.8M from ATM sales from 10/1/24 through 11/4/2024 disclosed as subsequent event in Form 10Q filed on 11/7/24; and $37.6M net proceeds from a common stock offering disclosed in our prospectus supplement filed 12/11/24.

Our pipeline opens many attractive opportunities for onvansertib

	Line of Therapy	Trial	IIT*	Ph2	Ph3	Combination with:
mCRC (RAS-mut)	1st line	CRDF-004 (w/Pfizer)		randomized		FOLFIRI/bev and FOLFOX/bev
	2nd line	Ph 1b/2		completed		FOLFIRI/bev
	2nd line	CRDF-003 (ONSEMBLE)		completed		FOLFIRI/bev
mPDAC	1st line	Ph 2	KU MEDICAL CENTER The University of Kansas	planned		NALIRIFOX
	2nd line	Ph 2		completed		Nal-IRI/leucovorin/ 5-FU
SCLC	2nd line	Ph 2	UNIVERSITY of MARYLAND MARLENE AND STEWART GREENEBAUM COMPREHENSIVE CANCER CENTER			None (monotherapy)
TNBC	2nd line	Ph 2	Dana-Farber Cancer Institute			Paclitaxel

* For investigator-initiated trials (IITs) only, the investigator's institution is provided. The planned first-line mPDAC trial will be conducted by an investigator to be named.
mPDAC = metastatic pancreatic ductal adenocarcinoma; SCLC = small-cell lung cancer; TNBC = triple-negative breast cancer; bev= bevacizumab.

Pfizer supports clinical execution of CRDF-004, our first-line mCRC trial

PFIZER BREAKTHROUGH GROWTH INITIATIVE

November 2021

- $15M investment
- Nicholas Choong, MD (Vice President of Clinical Development and Therapeutic Area Head for GI cancers, Gynecologic cancers and Melanoma at Pfizer) serves on Scientific Advisory Board
- Right of first access to data

PFIZER Ignite

August 2023

- Pfizer Ignite is responsible for the clinical execution of 1st line mCRC trial (CRDF-004), including development capabilities, scale and expertise
- Cardiff Oncology retains full economic ownership and control of onvansertib

Cardiff Oncology™

Appendix

Additional mCRC Data

CRDF-004 FOLFIRI/Bev Treatment Emergent Adverse Effects (TEAEs)

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	4 (100.0)	2 (50.0)	2 (50.0)	0 (0.0)	4 (100.0)
Fatigue	1 (25.0)	1 (25.0)	0 (0.0)	0 (0.0)	2 (50.0)
Nausea	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (50.0)
Neutrophil count decreased	1 (25.0)	2 (50.0)	1 (25.0)	0 (0.0)	4 (100.0)
Neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thrombocytopenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
White blood cell count decreased	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Lymphocyte count decreased	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	1 (25.0)	0 (0.0)	1 (25.0)	0 (0.0)	2 (50.0)
Vomiting	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Alopecia	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Anaemia	1 (25.0)	1 (25.0)	0 (0.0)	0 (0.0)	2 (50.0)
Peripheral sensory neuropathy	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	1 (25.0)
Dyspepsia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Headache	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Insomnia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Weight decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypokalaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haematochezia	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Influenza like illness	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Infusion related reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuropathy peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Proteinuria	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Control arm

FOLFIRI/Bev (N=4)

- Patients received FOLFIRI+Bev

Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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; Columns show the absolute # of patients and (%) of the population

CRDF-004 FOLFIRI/Bev/Onvansertib 20mg Treatment Emergent Adverse Effects (TEAEs)

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	6 (100.0)	6 (100.0)	4 (66.7)	0 (0.0)	6 (100.0)
Fatigue	2 (33.3)	1 (16.7)	0 (0.0)	0 (0.0)	3 (50.0)
Nausea	2 (33.3)	3 (50.0)	0 (0.0)	0 (0.0)	5 (83.3)
Neutrophil count decreased	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	2 (33.3)
Neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thrombocytopenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
White blood cell count decreased	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)
Lymphocyte count decreased	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	1 (16.7)
Diarrhoea	1 (16.7)	1 (16.7)	1 (16.7)	0 (0.0)	3 (50.0)
Abdominal pain	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Vomiting	1 (16.7)	2 (33.3)	0 (0.0)	0 (0.0)	3 (50.0)
Alopecia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Anaemia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Peripheral sensory neuropathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Decreased appetite	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	1 (16.7)
Dizziness	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Arthralgia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Dyspepsia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Headache	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Insomnia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Weight decreased	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Epistaxis	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Hypertension	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	2 (33.3)
Hypokalaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)
Flushing	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)
Haematochezia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza like illness	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)
Infusion related reaction	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	2 (33.3)
Neuropathy peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Proteinuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)

Experimental arm

FOLFIRI/Bev/Onv 20mg (N=6)

- Patients received FOLFIRI + Bev +20 mg dose of onvansertib

Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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; Columns show the absolute # of patients and (%) of the population

CRDF-004 FOLFIRI/Bev/Onvansertib 30mg Treatment Emergent Adverse Effects (TEAEs)

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	6 (100.0)	5 (83.3)	5 (83.3)	2 (33.3)	6 (100.0)
Fatigue	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (50.0)
Nausea	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)
Neutrophil count decreased	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	2 (33.3)
Neutropenia	0 (0.0)	0 (0.0)	1 (16.7)	2 (33.3)	3 (50.0)
Thrombocytopenia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
White blood cell count decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymphocyte count decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	5 (83.3)	1 (16.7)	0 (0.0)	0 (0.0)	6 (100.0)
Abdominal pain	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)
Vomiting	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Alopecia	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (50.0)
Anaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral sensory neuropathy	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Constipation	1 (16.7)	2 (33.3)	0 (0.0)	0 (0.0)	3 (50.0)
Decreased appetite	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	2 (33.3)
Dizziness	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	2 (33.3)
Dysgeusia	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspepsia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Headache	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Insomnia	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Weight decreased	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	2 (33.3)
Epistaxis	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)
Hypertension	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	1 (16.7)
Hypokalaemia	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	1 (16.7)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	2 (33.3)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haematochezia	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)
Influenza like illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infusion related reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuropathy peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Proteinuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Experimental arm

FOLFIRI/Bev/Onv 30mg (N=6)

- Patients received FOLFIRI + Bev + 30 mg dose of onvansertib
- Grade 4 neutropenia in both patients resolved in 9 and 16 days. Treatment was delayed by 7 and 15 days, respectively until the AE resolved.
- Both patients are still on study treatment.

Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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; Columns show the absolute # of patients and (%) of the population

CRDF-004 FOLFOX/Bev Treatment Emergent Adverse Effects (TEAEs)

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	4 (80.0)	5 (100.0)	2 (40.0)	1 (20.0)	5 (100.0)
Fatigue	3 (60.0)	0 (0.0)	1 (20.0)	0 (0.0)	4 (80.0)
Nausea	1 (20.0)	2 (40.0)	0 (0.0)	0 (0.0)	3 (60.0)
Neutrophil count decreased	0 (0.0)	0 (0.0)	1 (20.0)	1 (20.0)	2 (40.0)
Neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thrombocytopenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
White blood cell count decreased	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	2 (40.0)
Lymphocyte count decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	1 (20.0)	1 (20.0)	0 (0.0)	0 (0.0)	2 (40.0)
Abdominal pain	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alopecia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Anaemia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Peripheral sensory neuropathy	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Dysgeusia	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspepsia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Headache	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)
Insomnia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Weight decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypokalaemia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Paraesthesia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Asthenia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)
Haematochezia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza like illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infusion related reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuropathy peripheral	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	2 (40.0)
Oedema peripheral	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Proteinuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)

Control arm

FOLFOX/Bev (N=5)

- Patients received FOLFOX+ Bev
- Grade 4 neutropenia resolved in 8 days. Treatment was delayed for 8 days until the AE resolved.
- Patient is still on study treatment.

Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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; Columns show the absolute # of patients and (%) of the population

CRDF-004 FOLFOX/Bev/Onvansertib 20mg Treatment Emergent Adverse Effects (TEAEs)

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	4 (100.0)	4 (100.0)	3 (75.0)	0 (0.0)	4 (100.0)
Fatigue	2 (50.0)	1 (25.0)	0 (0.0)	0 (0.0)	3 (75.0)
Nausea	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	4 (100.0)
Neutrophil count decreased	2 (50.0)	0 (0.0)	1 (25.0)	0 (0.0)	3 (75.0)
Neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thrombocytopenia	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
White blood cell count decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymphocyte count decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Vomiting	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (50.0)
Alopecia	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Anaemia	0 (0.0)	2 (50.0)	0 (0.0)	0 (0.0)	2 (50.0)
Peripheral sensory neuropathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Decreased appetite	1 (25.0)	1 (25.0)	0 (0.0)	0 (0.0)	2 (50.0)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (50.0)
Arthralgia	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Dyspepsia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Insomnia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Weight decreased	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
Epistaxis	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Hypertension	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Hypokalaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haematochezia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza like illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infusion related reaction	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Neuropathy peripheral	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Proteinuria	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Experimental arm

FOLFOX/Bev/Onv 20mg (N=4)

- Patients received FOLFOX+ Bev +20 mg dose of onvansertib

Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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; Columns show the absolute # of patients and (%) of the population

CRDF-004 FOLFOX/Bev/Onvansertib 30mg Treatment Emergent Adverse Effects (TEAEs)

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	5 (100.0)	4 (80.0)	3 (60.0)	0 (0.0)	5 (100.0)
Fatigue	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (60.0)
Nausea	1 (20.0)	1 (20.0)	0 (0.0)	0 (0.0)	2 (40.0)
Neutrophil count decreased	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thrombocytopenia	1 (20.0)	1 (20.0)	0 (0.0)	0 (0.0)	2 (40.0)
White blood cell count decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymphocyte count decreased	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	1 (20.0)
Diarrhoea	1 (20.0)	1 (20.0)	0 (0.0)	0 (0.0)	2 (40.0)
Abdominal pain	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)	2 (40.0)
Vomiting	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)
Alopecia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anaemia	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	1 (20.0)
Peripheral sensory neuropathy	3 (60.0)	1 (20.0)	0 (0.0)	0 (0.0)	4 (80.0)
Constipation	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)
Decreased appetite	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Dizziness	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)
Dysgeusia	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Arthralgia	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)
Dyspepsia	1 (20.0)	1 (20.0)	0 (0.0)	0 (0.0)	2 (40.0)
Headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Insomnia	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)
Weight decreased	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Epistaxis	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypokalaemia	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)
Paraesthesia	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (60.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haematochezia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza like illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infusion related reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuropathy peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Proteinuria	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Experimental arm

FOLFOX/Bev/Onv 30mg (N=5)

- Patients received FOLFOX+ Bev + 30 mg dose of onvansertib

Data consists of all adverse events entered into the EDC as of Nov 26, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; events shown occurred in ≥10% of total 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; Columns show the absolute # of patients and (%) of the population

Ph 1b/2 trial's patient demographics reflect 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	50	68

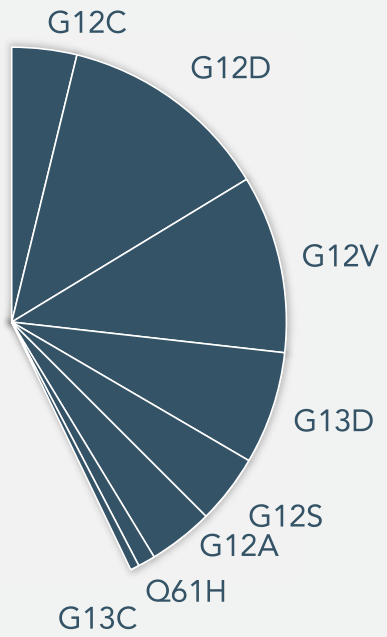
Total Patients N=68	Median [range] or n (%)
Age (years)	56 [34-83]
Sex	
Male	37 (54%)
Female	31 (46%)
ECOG	
0	36 (53%)
1	32 (47%)
Primary tumor site	
Colon	44 (65%)
Rectum	22 (32%)
Other	2 (3%)

Total Patients N=68	Median n (%)
Liver metastasis	
None	20 (29%)
Liver and other	36 (53%)
Liver only	12 (18%)
Number of metastatic organs	
None	1 (1.5%)
1	4 (6%)
≥2	63 (92.5%)
Prior bevacizumab treatment	
Yes	51 (75%)
No	17 (25%)

* Data are interim as of June 16, 2023 from an ongoing trial and unlocked EDC database.

Ph 1b/2 trial patients achieved responses across KRAS mutations

Frequency of Common KRAS Mutations in mCRC[1]



Onvansertib responses across KRAS mutations (as of June 16, 2023)[2]

KRAS Variant	Bev naïve			Bev exposed			
	CR+PR	SD	PD	PR	SD	PD	Total
G12D	3	1		4	12	1	21
G12V	1				10	2	13
G13D	2			2	4		8
G12A	3	1		1	2		7
G12C	1				2	1	4
G12S		1			2	1	4
A146T				1	2		3
Q61H	1	1			1		3
K117N					1	1	2
G12R					1		1
Total	11	4	0	8	37	6	66

1. Jones R et al. Br J Cancer. 2017 Mar 28;116(7):923-929.
2. One patient that was categorized as G12A in the August 2023 data release has now been updated as G12R.

Ph 1b/2 trial bev naïve patients experienced more durable responses

Swimmer plot* – 66 evaluable patients (as of June 16, 2023)

	All patients	Bev naïve	Bev exposed
Pursued surgery / ablation	18% (12/66)	53% (8/15)	8% (4/51)
Initial PR at 8 week scan	9	8	1
Initial PR at 16+ week scan	10	3	7

* Swimmer plot / table reflect interim data as of June 16, 2023 from an ongoing trial and unlocked EDC database. After external review of the tumor measurements completed May 12, 2023, it was determined that patients 02-028 and 04-038 were confirmed PRs.

Ph 1b/2 trial: onvansertib in combination with FOLFIRI-bev is well-tolerated*

- All treated patients (N=68)
  - All dose levels (12mg/m^2, 15mg/m^2, 18mg/m^2)
- No major / unexpected toxicities are seen as compared to FOLFIRI / bev
- 8 G4 hematologic AEs occurred
  - All resolved without issue through dose holds, including the removal of the 5-FU bolus (as per NCCN Guidelines), and/or growth factor support
  - None of the 8 patients discontinued treatment due to these AEs

TEAE	GR1	GR2	GR3	GR4	TOTAL		TEAE	GR1	GR2	GR3	GR4	TOTAL	
Fatigue	24	22	7	0	53	78%	Cough	11	0	0	0	11	16%
Neutropenia	1	18	23	7	49	72%	Pyrexia	8	1	1	0	10	15%
Nausea	29	13	4	0	46	68%	Dyspnea	7	3	0	0	10	15%
Diarrhea	21	13	4	0	38	56%	AST Increase	7	2	1	0	10	15%
Leukopenia	9	14	5	1	29	43%	Lymphocytopenia	2	7	0	0	9	13%
Anemia	22	5	2	0	29	43%	Dyspepsia	9	0	0	0	9	13%
Alopecia	20	5	0	0	25	37%	ALT Increase	8	0	1	0	9	13%
Abdominal Pain	14	8	3	0	25	37%	Hypocalcemia	9	0	0	0	9	13%
Stomatitis	15	6	3	0	24	35%	Insomnia	9	0	0	0	9	13%
Hypertension	4	10	9	0	23	34%	Dehydration	1	5	2	0	8	12%
Thrombocytopenia	17	5	1	0	23	34%	Hypokalemia	6	2	0	0	8	12%
Constipation	17	2	1	0	20	29%	Arthralgia	6	2	0	0	8	12%
Vomiting	11	6	3	0	20	29%	Hand / Foot Syndrome	5	2	0	0	7	10%
Epistaxis	15	0	0	0	15	22%	Hemorrhoids	5	2	0	0	7	10%
Headache	13	0	0	0	13	19%	Non-Cardiac Chest Pain	6	1	0	0	7	10%
Decreased Appetite	4	6	2	0	12	18%	ALP Increase	5	1	1	0	7	10%
Back Pain	10	2	0	0	12	18%							

* Data consists of all adverse events entered into the EDC as of June 13, 2023, from an ongoing trial and unlocked EDC database. N: number of patients (total N=68); 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; TOTAL shows the absolute # of patients and (%) of the population. COVID, as an AE, is not included as that data is still under review and being tabulated.

ONSEMBLE Ph 2 trial was designed to generate randomized data

ENROLLMENT CRITERIA

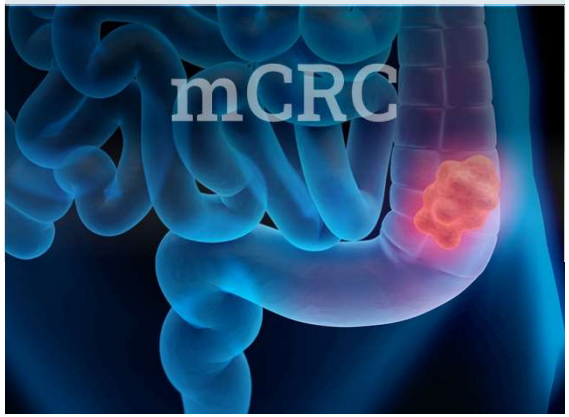
2nd line mCRC

KRAS+/NRAS+

Unresectable

R

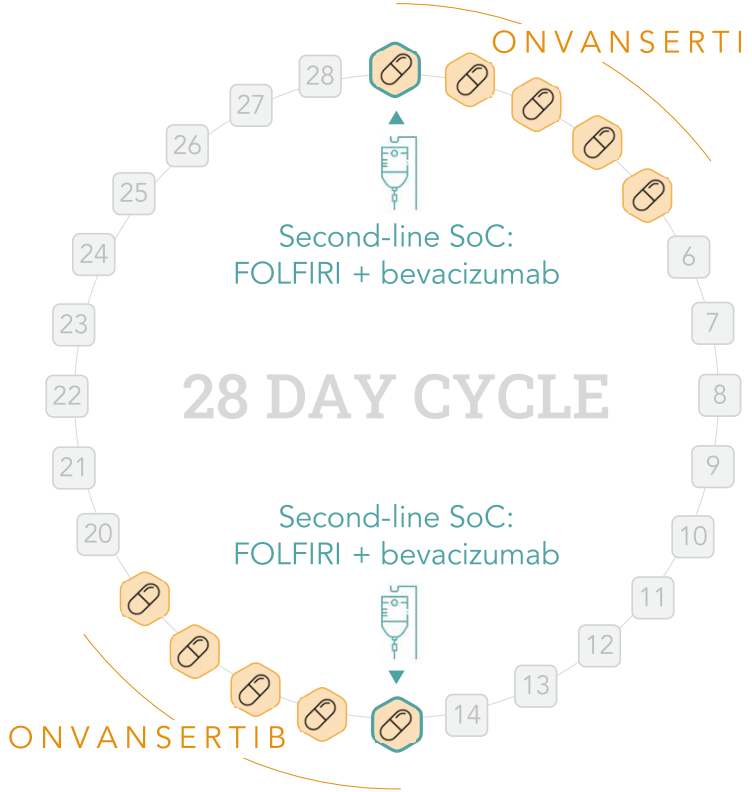
N=23
1:1:1



- SoC: FOLFIRI/bev
- Onv 20mg + FOLFIRI/bev
- Onv 30mg + FOLFIRI/bev

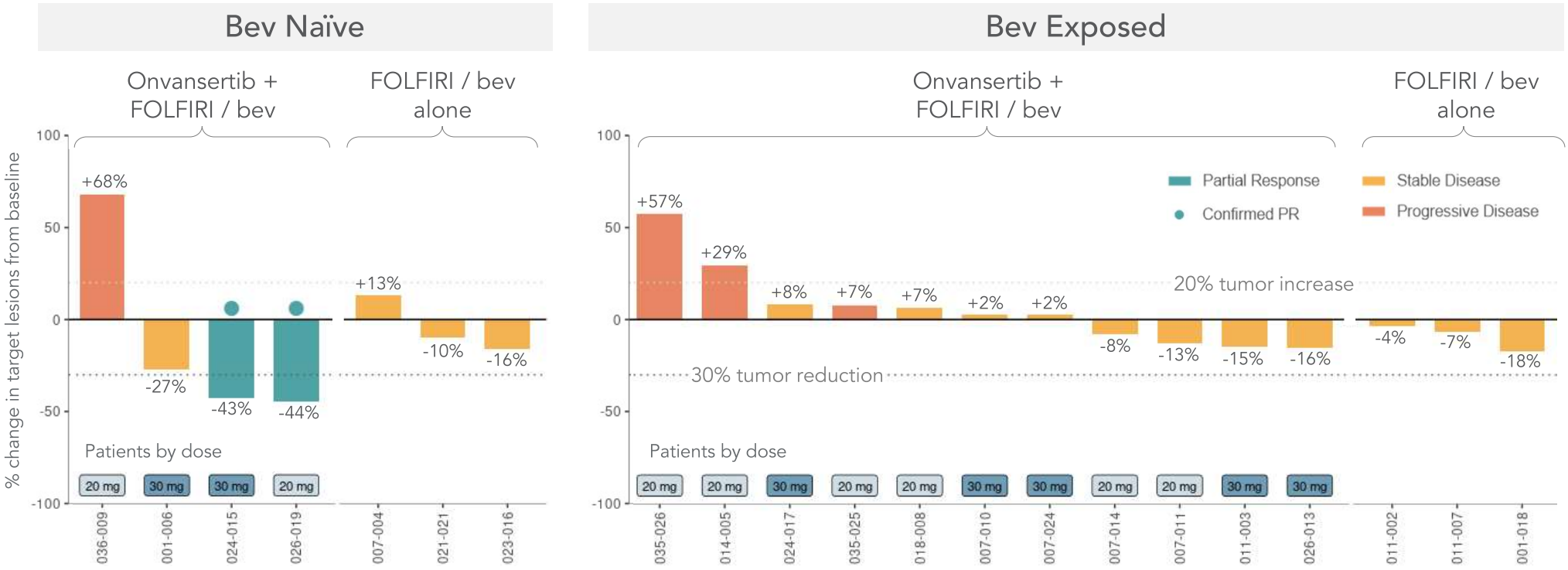
PRIMARY ENDPOINT

Objective Response Rate



ONSEMBLE bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

Best Radiographic Response* – ONSEMBLE mCRC Clinical Trial patients (as of February 26, 2024)

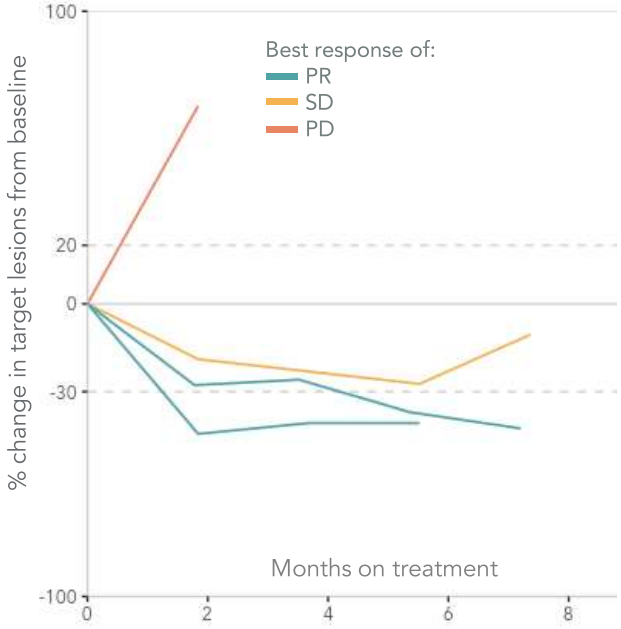


* Radiographic response determined per RECIST 1.1. Waterfall plot reflects interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked EDC database.

ONSEMBLE bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

Change in tumor size from baseline* – ONSEMBLE mCRC Clinical Trial bev naïve patients (as of February 26, 2024)

Bev naïve: onvansertib + FOLFIRI/bev arm



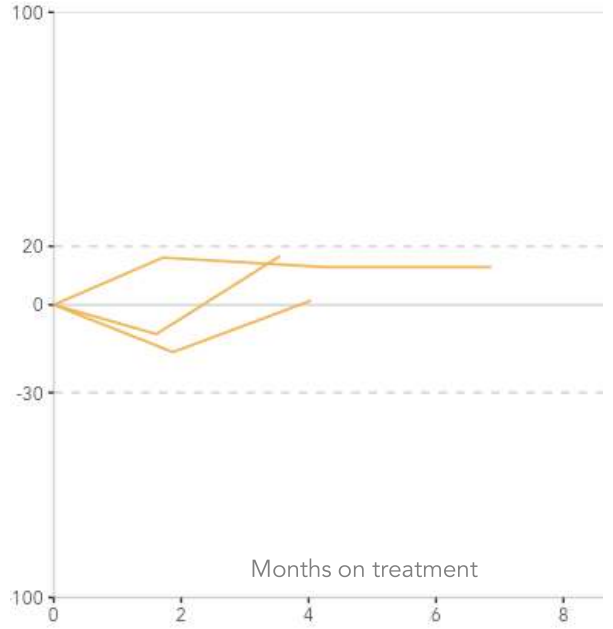
Progressive disease

Stable disease

30% tumor reduction

Partial response

Bev naïve: FOLFIRI/bev (control) arm

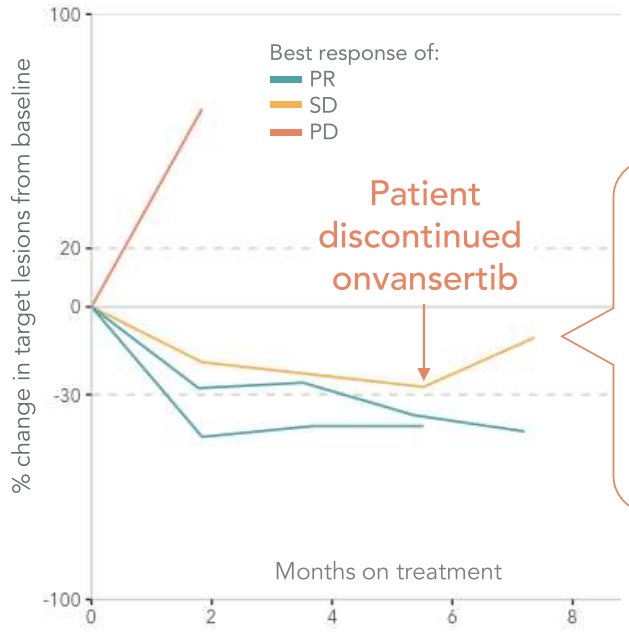


* Spider plots reflect interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked EDC database.

ONSEMBLE bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

Change in tumor size from baseline* – ONSEMBLE mCRC Clinical Trial bev naïve patients (as of February 26, 2024)

Bev naïve: onvansertib + FOLFIRI/bev arm

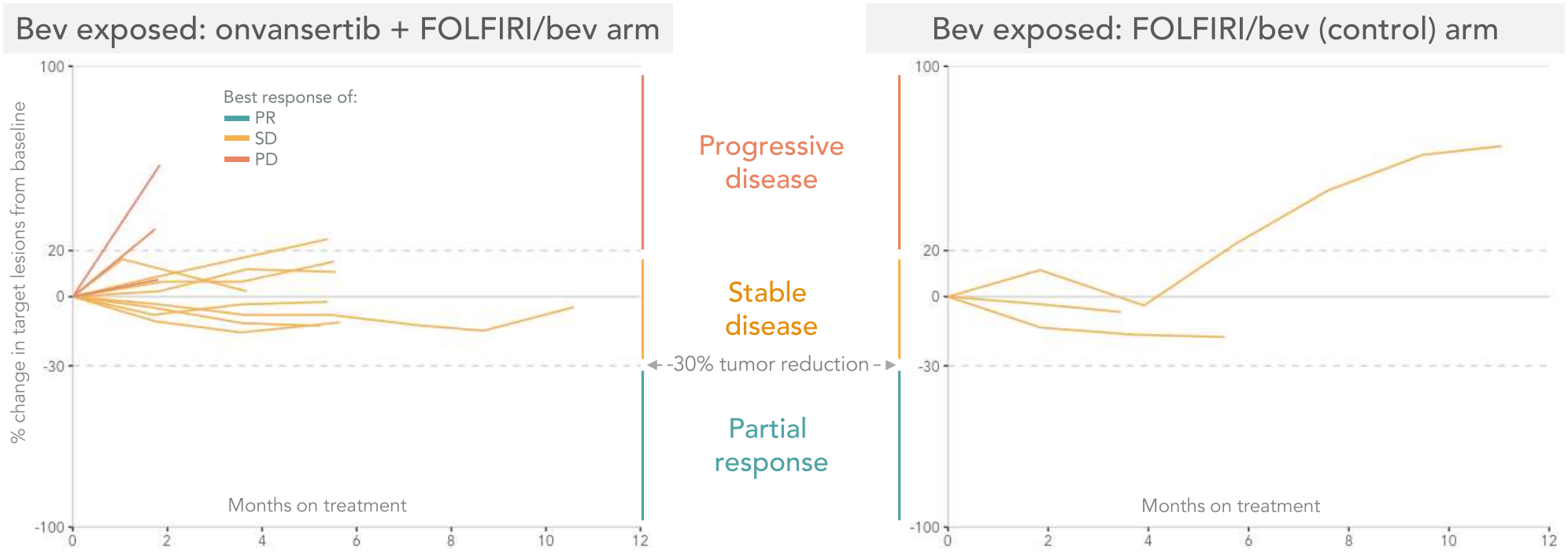


Patient 006 discontinued onvansertib but remained on FOLFIRI/bev at their 6-month scan due to a suspicious new lung lesion.
Lesion was later biopsy-confirmed as a Valley fever (fungal) infection, not a new tumor lesion

* Spider plots reflect interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked EDC database.

ONSEMBLE bev exposed patients, with or without onvansertib, showed no responses

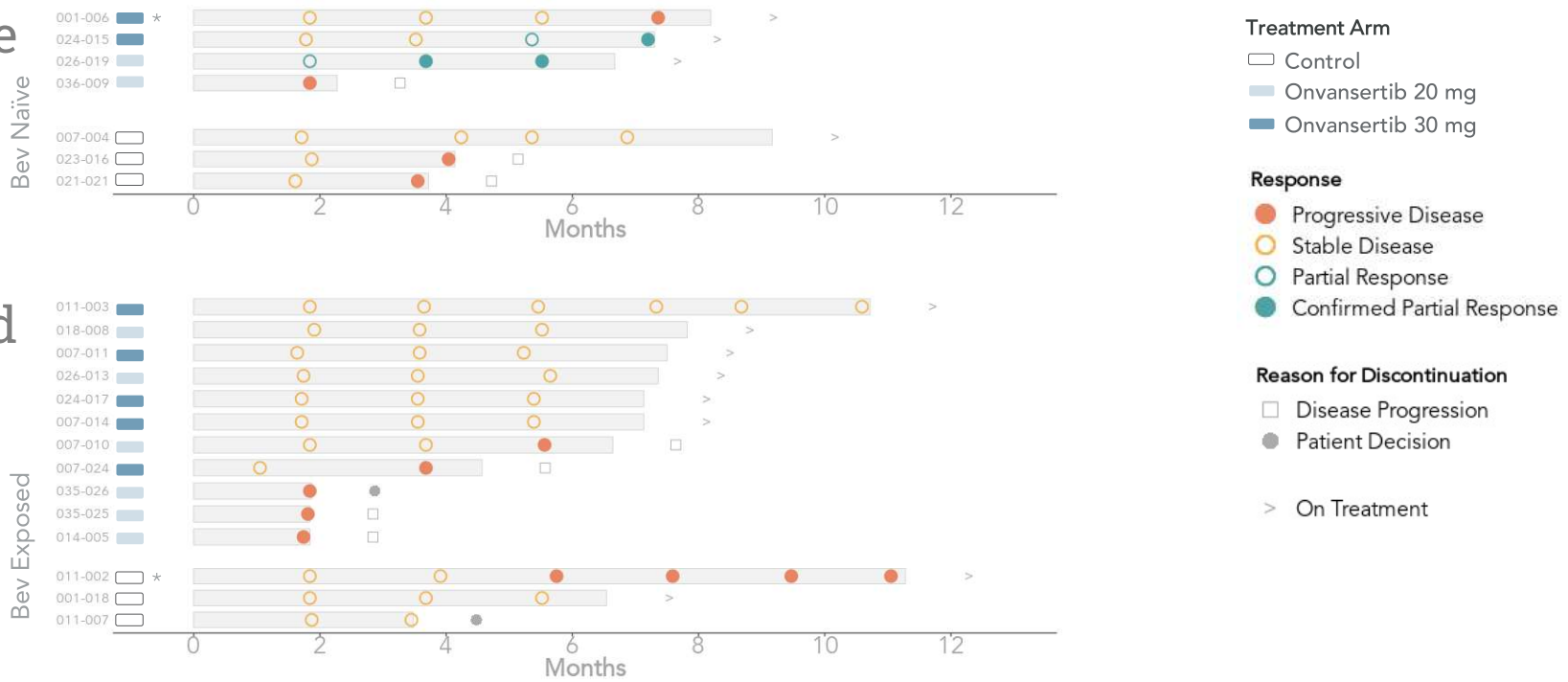
Change in tumor size from baseline* – ONSEMBLE mCRC Clinical Trial bev exposed patients (as of February 26, 2024)



* Spider plots reflect interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked EDC database.

ONSEMBLE swimmer plot

Swimmer plot* – ONSEMBLE mCRC Clinical Trial patients (as of February 26, 2024)



* Swimmer plot reflects interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked EDC database. Patient 001-006 discontinued onvansertib at their 6-month scan due to a suspicious new lung lesion, which was later biopsy-confirmed as a Valley fever (fungal) infection. Patient 011-002 continues on trial in the control arm despite progressive disease, as the treating physician believes the patient continues to have clinical benefit from second-line standard of care treatment..

ONSEMBLE's patient demographics reflect second-line mCRC population

Enrollment*

Number of Patients (N)	FOLFIRI and bev	FOLFIRI-bev and Onvansertib - 20mg	FOLFIRI-bev and Onvansertib - 30mg	Total Patients All Doses
Intent to Treat	8	8	7	23
Treated (included in safety evaluable patients)	7	8	7	22
Evaluable for efficacy	6	8	7	21

Total Patients N=22	Median [range] or n (%)
Age (years)	53 [35-81]
Sex	
Male	12 (54%)
Female	10 (46%)
ECOG[1]	
0	9 (41%)
1	12 (55%)

Total Patients N=22	Median n (%)
Liver metastasis	
None	5 (23%)
Liver and other	13 (59%)
Liver only	4 (18%)
Number of metastatic organs	
1	7 (32%)
≥2	15 (68%)
Prior bevacizumab treatment	
Yes	15 (68%)
No	7 (32%)

* Data are interim as of January 3, 2024 from an ongoing trial and unlocked EDC database. ONSEMBLE enrolled 23 patients, and 2 patients were not evaluable because one withdrew consent prior to their first dose and one withdrew consent before their first post-baseline scan. Both patients were "bev exposed" and randomized to the control arm.

[1] ECOG was not recorded for one patient.

ONSEMBLE Control Arm: Treatment Emergent Adverse Effects (TEAEs)

Control arm
(N=7)

Patients received FOLFIRI+bev

No major/unexpected toxicity seen

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	6 (85.7)	6 (85.7)	3 (42.9)	0 (0.0)	6 (85.7)
Diarrhea	3 (42.9)	1 (14.3)	0 (0.0)	0 (0.0)	4 (57.1)
Nausea	2 (28.6)	1 (14.3)	1 (14.3)	0 (0.0)	4 (57.1)
Fatigue	3 (42.9)	0 (0.0)	1 (14.3)	0 (0.0)	4 (57.1)
Neutropenia	0 (0.0)	3 (42.9)	0 (0.0)	0 (0.0)	3 (42.9)
Stomatitis	1 (14.3)	1 (14.3)	1 (14.3)	0 (0.0)	3 (42.9)
Vomiting	1 (14.3)	0 (0.0)	1 (14.3)	0 (0.0)	2 (28.6)
Alopecia	1 (14.3)	2 (28.6)	0 (0.0)	0 (0.0)	3 (42.9)
Constipation	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42.9)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Insomnia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Hypokalaemia	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28.6)
Anaemia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Cough	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspepsia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Hypertension	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	1 (14.3)
Lymphopenia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Pyrexia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)

* Data consists of all adverse events entered into the EDC as of January 3, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; 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; Columns show the absolute # of patients and (%) of the population.

ONSEMBLE onvansertib 30mg Arm TEAEs: Onvansertib in combination with FOLFIRI+bev is well-tolerated

Experimental arm

Onv 30mg (N=7)

Patients received FOLFIRI+bev +30 mg dose of onvansertib

No major/unexpected toxicity seen

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	7 (100.0)	7 (100.0)	4 (57.1)	0 (0.0)	7 (100.0)
Diarrhea	1 (14.3)	1 (14.3)	2 (28.6)	0 (0.0)	4 (57.1)
Nausea	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42.9)
Fatigue	3 (42.9)	1 (14.3)	0 (0.0)	0 (0.0)	4 (57.1)
Neutropenia	0 (0.0)	1 (14.3)	2 (28.6)	0 (0.0)	3 (42.9)
Stomatitis	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42.9)
Vomiting	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28.6)
Alopecia	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28.6)
Constipation	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28.6)
Decreased appetite	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	2 (28.6)
Insomnia	3 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 (42.9)
Hypokalaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anaemia	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)
Cough	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28.6)
Dysgeusia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Dyspepsia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Hypertension	0 (0.0)	1 (14.3)	1 (14.3)	0 (0.0)	2 (28.6)
Lymphopenia	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28.6)
Pyrexia	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	1 (14.3)
Thrombocytopenia	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	2 (28.6)

* Data consists of all adverse events entered into the EDC as of January 3, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; 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; Columns show the absolute # of patients and (%) of the population.

ONSEMBLE onvansertib 20mg Arm TEAEs: Onvansertib in combination with FOLFIRI+bev is well-tolerated

Experimental arm

Onv 20mg (N=8)

Patients received FOLFIRI+bev +20 mg dose of onvansertib

No major/unexpected toxicity seen

2 Grade 4 TEAEs of neutropenia seen in patients (008 and 019) receiving 20mg onvansertib+SoC

- Both patients recovered after delaying their next cycle of treatment for 7 and 10 days, respectively
- Both patients are still on-trial

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	8 (100.0)	7 (87.5)	2 (25.0)	2 (25.0)	8 (100.0)
Diarrhea	4 (50.0)	3 (37.5)	0 (0.0)	0 (0.0)	7 (87.5)
Nausea	3 (37.5)	3 (37.5)	0 (0.0)	0 (0.0)	6 (75.0)
Fatigue	2 (25.0)	0 (0.0)	1 (12.5)	0 (0.0)	3 (37.5)
Neutropenia	1 (12.5)	0 (0.0)	1 (12.5)	2 (25.0)	3 (37.5)
Stomatitis	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	2 (25.0)
Vomiting	2 (25.0)	2 (25.0)	0 (0.0)	0 (0.0)	4 (50.0)
Alopecia	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (25.0)
Constipation	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)
Decreased appetite	2 (25.0)	2 (25.0)	0 (0.0)	0 (0.0)	4 (50.0)
Insomnia	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)
Hypokalaemia	1 (12.5)	0 (0.0)	1 (12.5)	0 (0.0)	2 (25.0)
Anaemia	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (25.0)
Dyspepsia	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	1 (12.5)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymphopenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pyrexia	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)
Thrombocytopenia	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	1 (12.5)

* Data consists of all adverse events entered into the EDC as of January 3, 2024, from an ongoing trial and unlocked EDC database. N: number of patients; 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; Columns show the absolute # of patients and (%) of the population.

Onvansertib and bev independently inhibit tumor response to hypoxia in bev naïve tumors

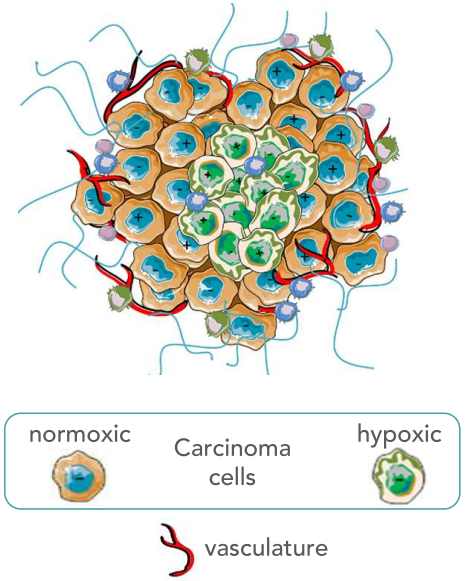
Tumor growth → **Hypoxia** → **HIF1α** ⊣ **onvansertib**

The tumor cells outgrow the blood supply and become starved of oxygen and nutrients…

… low oxygen levels lead to elevated HIF1α protein expression

… turns on VEGF-A expression and secretion to recruit new vasculature as well as turning on a multitude of downstream survival genes

onvansertib: inhibits HIF1α expression



bevacizumab ⊣ VEGF-A

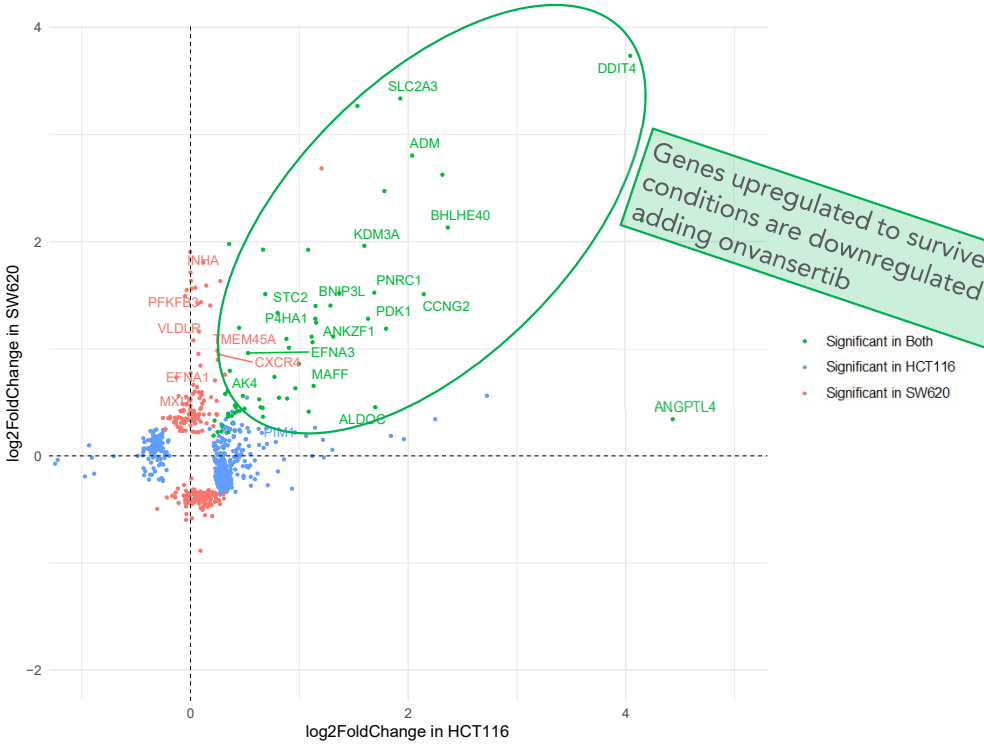
neutralizes VEGF-A

- Angiogenesis: Vascularization of the tumor
- Tumor cell survival
- Proliferation

https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2017.01625/full

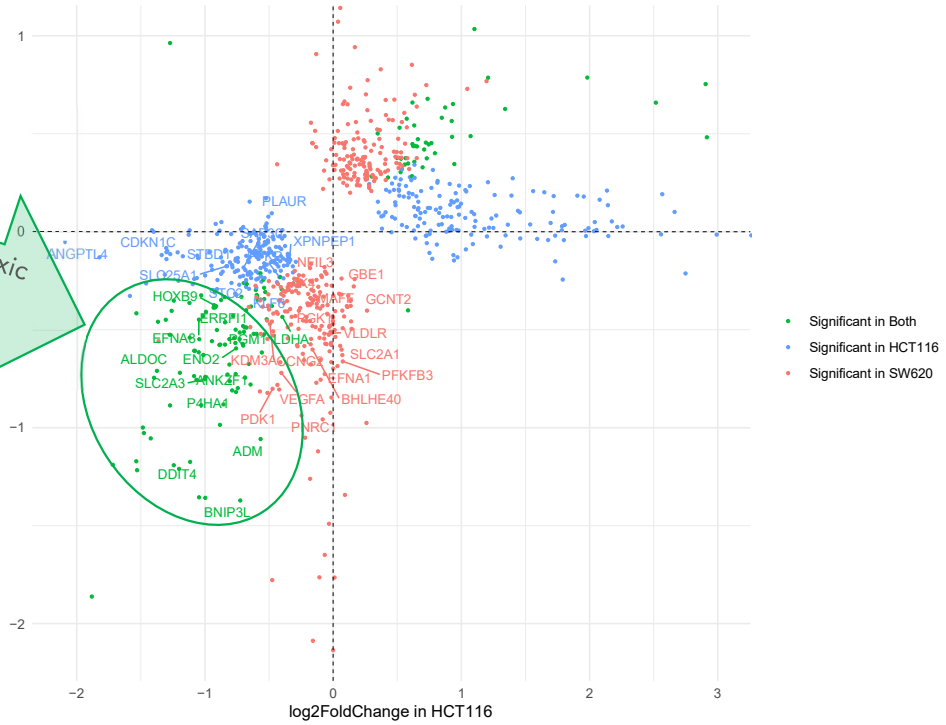
Onvansertib down-regulates genes induced by tumors in hypoxic conditions

Genes induced by hypoxia in two mCRC cell lines



Hypoxia vs normoxia gene expression in HCT116 and SW620 cells

Adding onvansertib inhibits adaptation to hypoxia



With vs without onvansertib gene expression in hypoxic HCT116 and SW620 cells

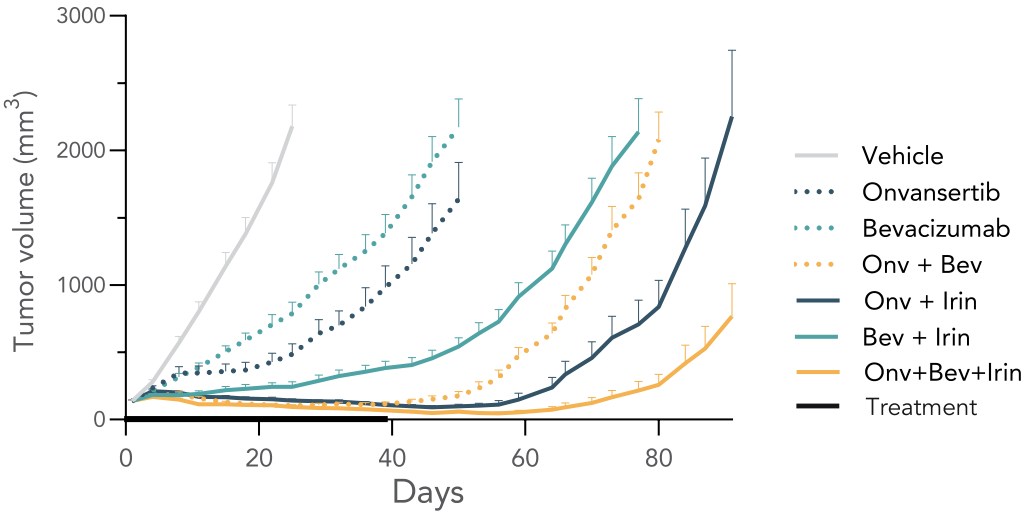
* Genes in the Hallmarks Hypoxia gene set are labeled. Top 250 genes with P-adjusted < 0.05 shown.

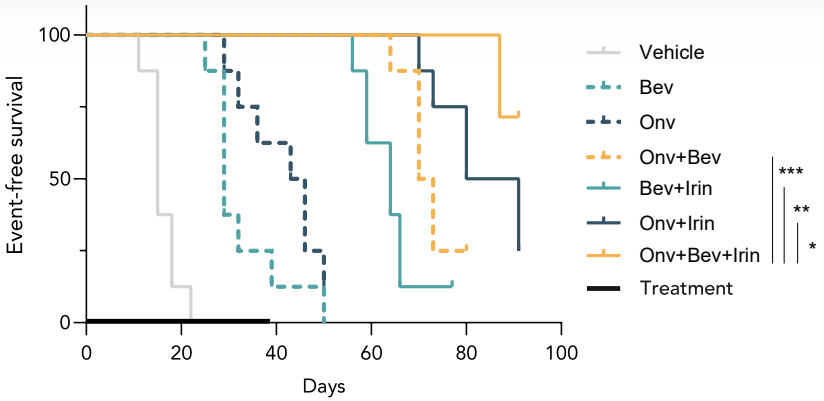
The combination of onvansertib, bevacizumab and irinotecan showed greater potency than each individual or doublet therapy

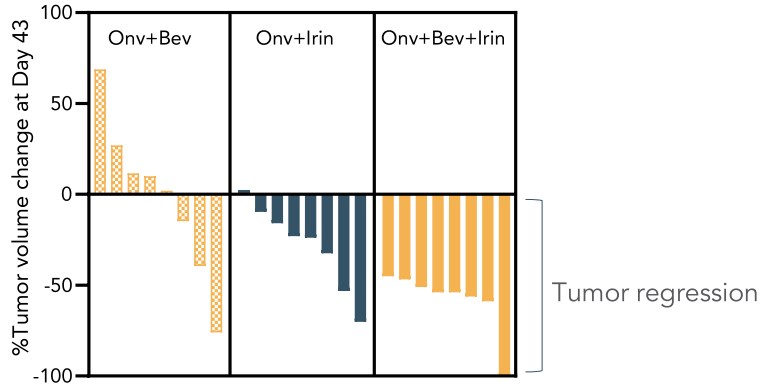
The combination of onvansertib, bevacizumab and irinotecan was potent in the HCT116 xenograft model, resulting in:

- tumor regression in all treated mice (8/8), including 1 CR
- prolonged event-free survival

At the end of the study (Day 91), 6 of the 8 mice treated with the triplet combination had tumors<1000mm^3



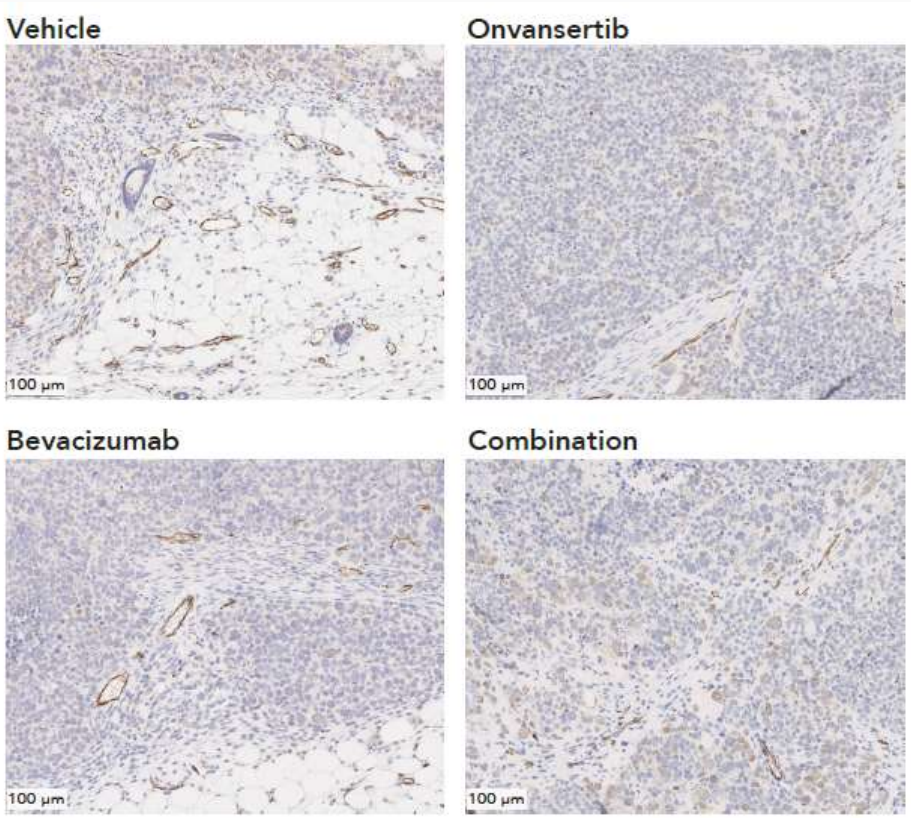




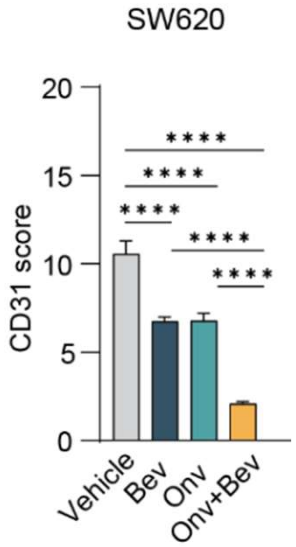
HCT116 xenografts were treated with the indicated drugs for 39 days and tumor volumes were measured (8mice/group, mean + SEM are represented on graph).
Kaplan-Meier survival curve for event-free survival (time to reach tumor volume 1000mm^3) was calculated. Log-rank Mantel Cox test was used for survival analyses, *p<0.05, **p<0.01, ***p<0.001.

The combination of onvansertib and bev reduces tumor vascularization

CD31



- Vascularization was quantified using the endothelial marker CD31
- Onvansertib and bev monotherapies reduced tumor vascularization
- The combination treatment of onvansertib and bev resulted in further decrease in vascularization



SW620 xenograft model is shown. CD31 scoring: for each sample 5 fields of view at 100 µm magnification were randomly selected in the tumor area. CD31 positive vessels were manually counted in these fields. Mean score ± SEM for each treatment group (n=6/group) are plotted. One-way ANOVA was used to test differences between treatment arms. *p<0.05, **p<0.01, ***p<0.001, ****p<0.0001.

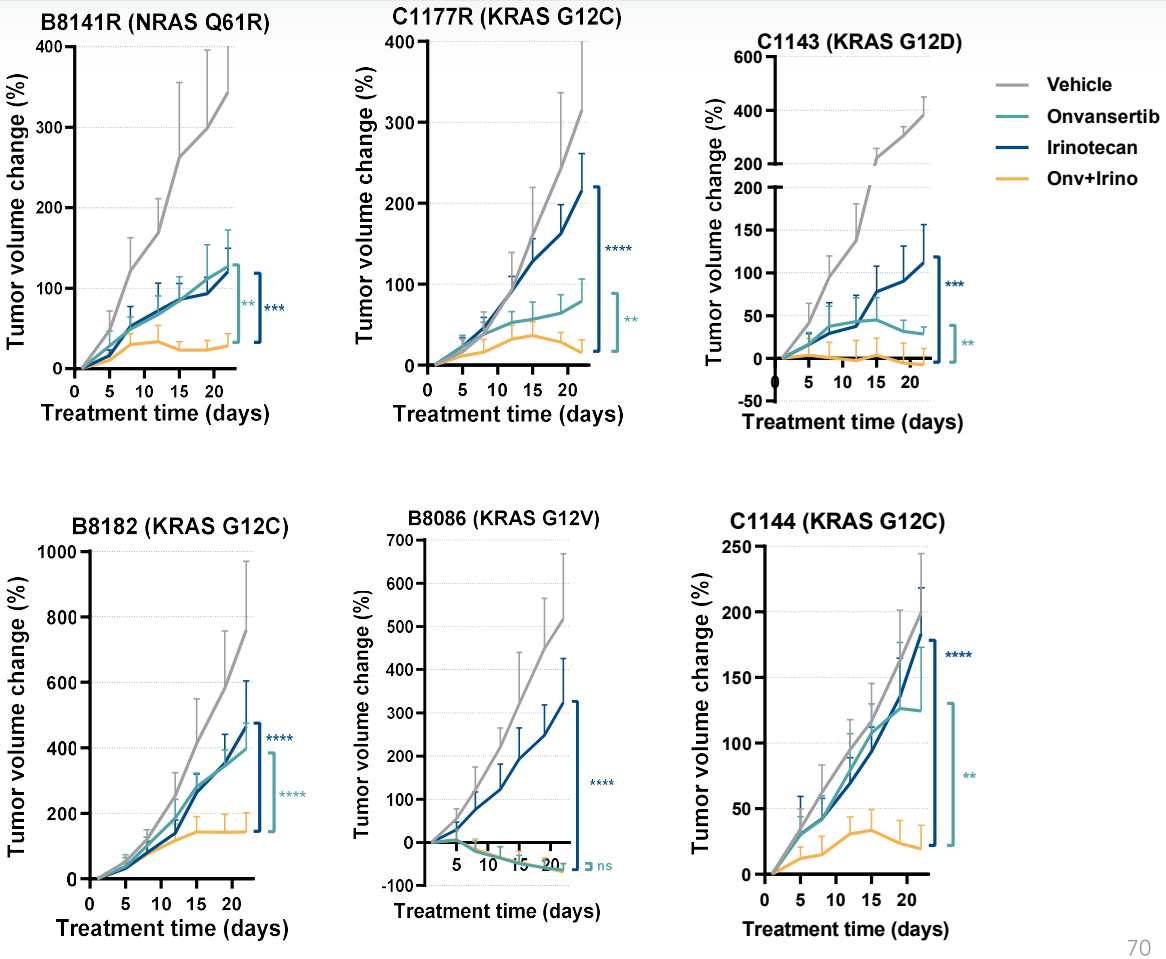
Onvansertib in combination with irinotecan in RAS-mutant CRC PDXs

The combination of onvansertib and irinotecan showed anti-tumor activity in 6 RAS-mutated PDX models with either acquired or intrinsic resistance to irinotecan.

The combination showed significant increased anti-tumor activity compared to onvansertib single agent in 5 of the 6 models.

These data support that onvansertib + irinotecan is an active combination in RAS-mutated PDX models and that Onvansertib can sensitize tumors to irinotecan.

In collaboration with Dr. Kopetz (MD Anderson)



Dosing schedule: onvansertib 60 mg/kg daily; irinotecan 40mg/kg weekly, for up to 21days. Mean + SD are represented. Unpaired t-test, **p<0.01, ***p<0.001, ****p<0.0001.

Onvansertib in combination with FOLFOX in RAS-mutant CRC PDXs

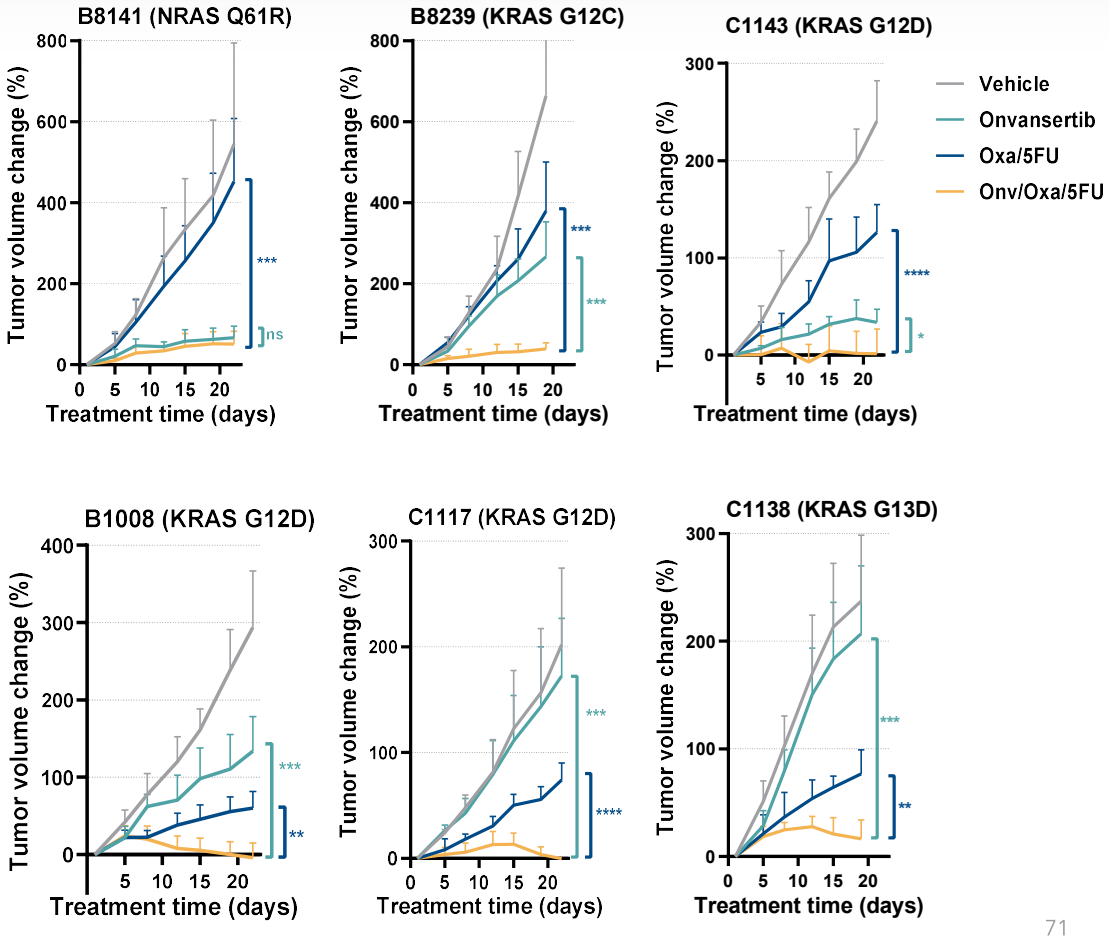
The chemotherapeutics oxaliplatin+5FU had no or modest activity in the 6 RAS-mutant PDX models tested.

Conversely, the combination of onvansertib with oxaliplatin+5FU was efficacious in all 6 models, resulting in tumor statis or tumor regression.

In 5 of the 6 models, the combination had significantly superior activity than the single agent treatments.

These data support the efficacy of onvansertib in combination with oxaliplatin+5FU in RAS-mutant CRC PDXs resistant or partially sensitive to oxaliplatin+5FU.

In collaboration with Dr. Kopetz (MD Anderson)



Dosing schedule: onvansertib 45 mg/kg daily; oxaliplatin 10mg/kg weekly; 5-FU 25mg/kg 5times/week for up to 21days. Mean + SD are represented. Unpaired t-test, *p<0.05, **p<0.01, ***p<0.001, ****p<0.0001.

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Appendix:

Metastatic Pancreatic Adenocarcinoma (mPDAC)

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

mPDAC
CRDF-001 Ph 2 Second-Line Trial

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

mPDAC
Biomarker Discovery Trial (IIT)

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

Path forward: Move to 1st line mPDAC

- New IIT combining onvansertib with SoC (NALIRIFOX)

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

mPDAC
CRDF-001 Ph 2 Second-Line Trial

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

mPDAC
Biomarker Discovery Trial (IIT)

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

Path forward: Move to 1st line mPDAC

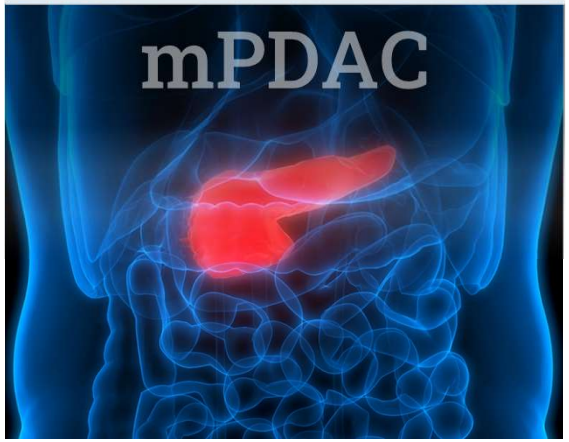
- New IIT combining onvansertib with SoC (NALIRIFOX)

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

ENROLLMENT CRITERIA

2nd line refractory patients

Measurable tumor by RECIST 1.1



OBJECTIVE

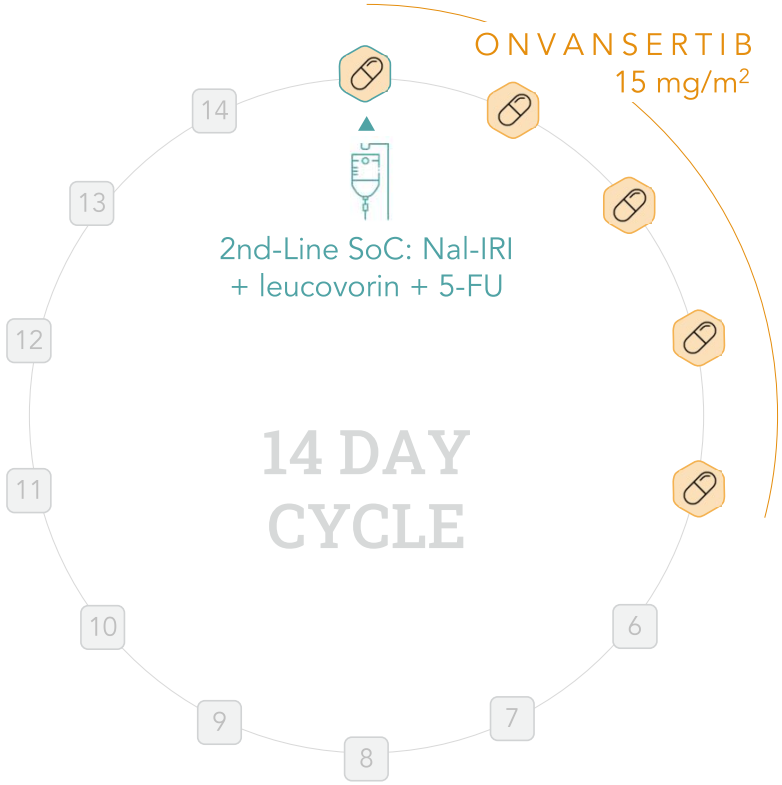
To determine the efficacy and safety of onvansertib when added to standard of care

PRIMARY ENDPOINT

ORR (RECIST 1.1)

SECONDARY ENDPOINT

Disease Control Rate (DCR)

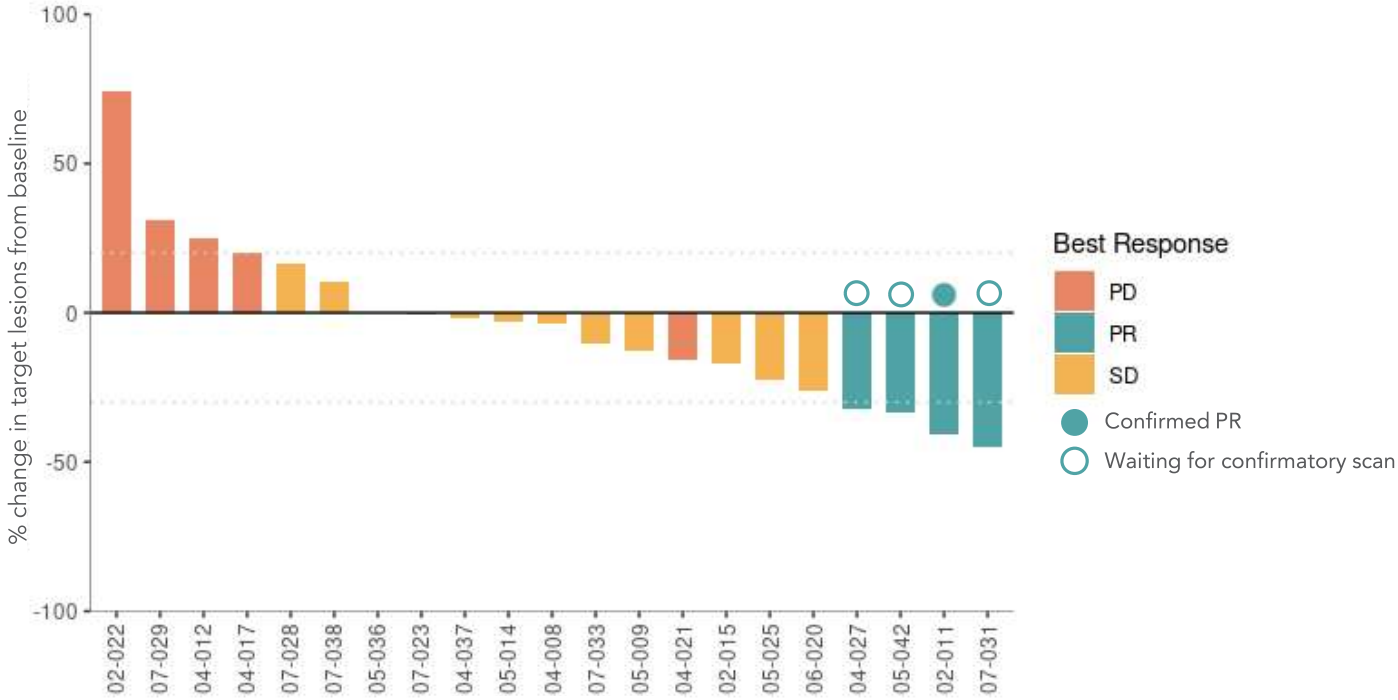


Onvansertib+SoC has higher efficacy than 2nd line historical controls

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

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

Subsequent disclosure on Feb 29, 2024: Three of the four initial partial responses confirmed on their subsequent scan, and one initial partial response did not confirm

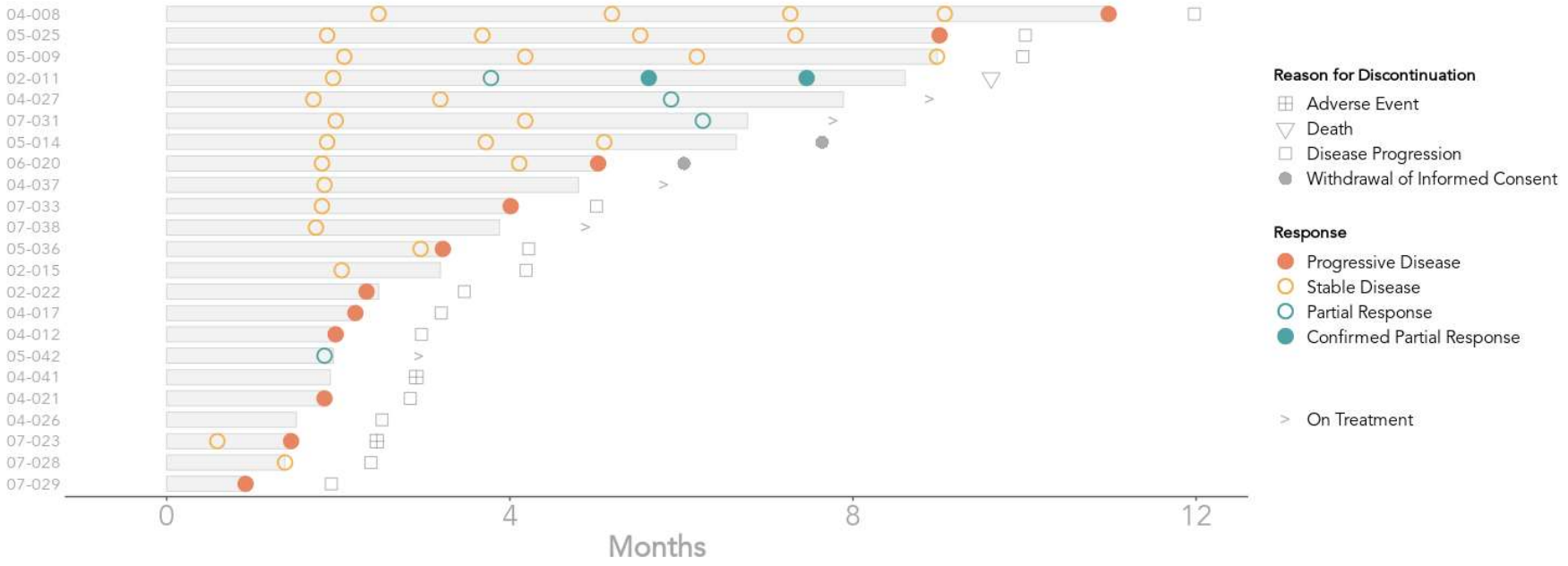


* Radiographic response determined per RECIST 1.1. Waterfall plot and table reflect interim data as of September 13, 2023 from an ongoing trial and unlocked EDC database. For ORR analysis, there are two patients excluded (04-026 and 04-041) that had two cycles of treatment but left the trial before their first post-baseline scan.

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

Stable disease patients have converted to partial responses over time

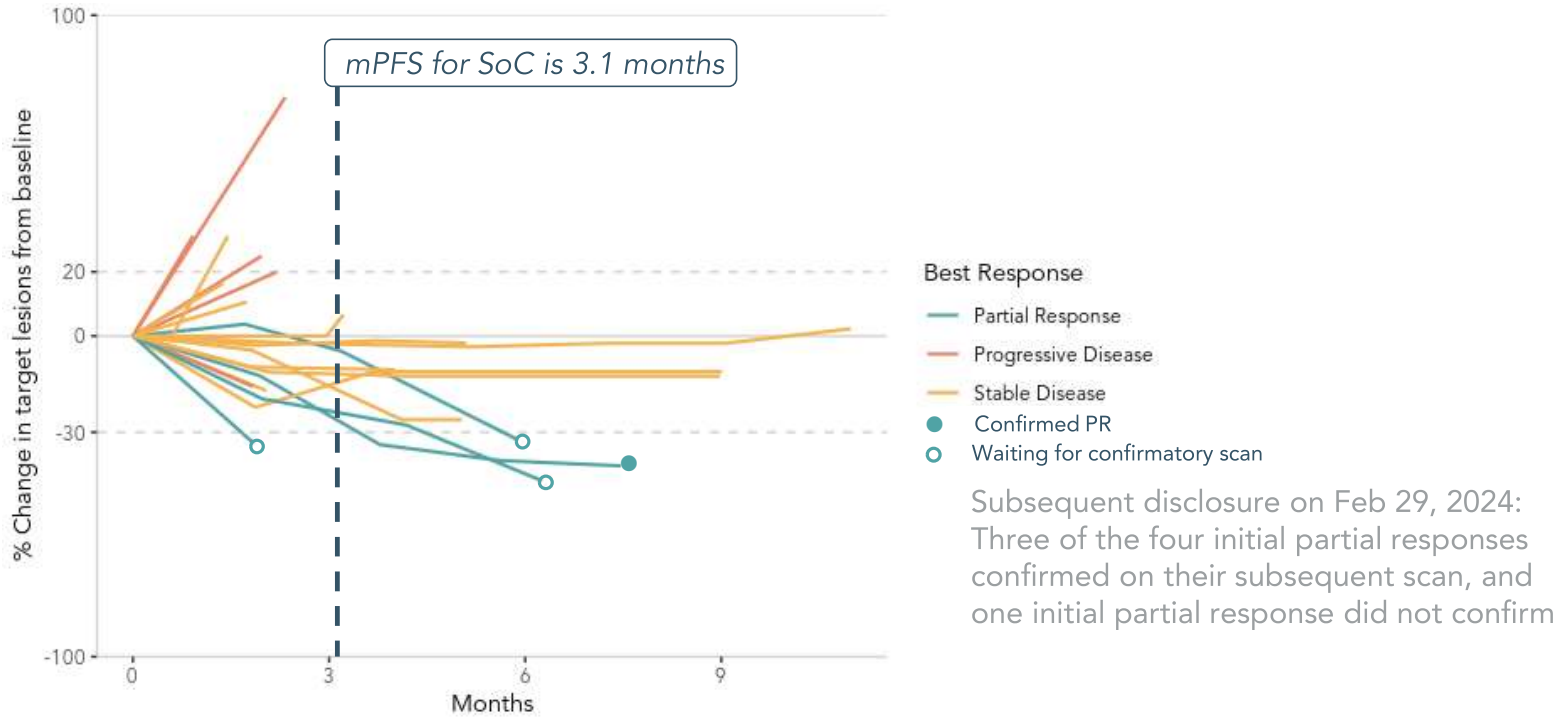
Swimmer plot – 23 evaluable patients (as of September 13, 2023)*



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

Patient responses to onvansertib+SoC can deepen over time

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



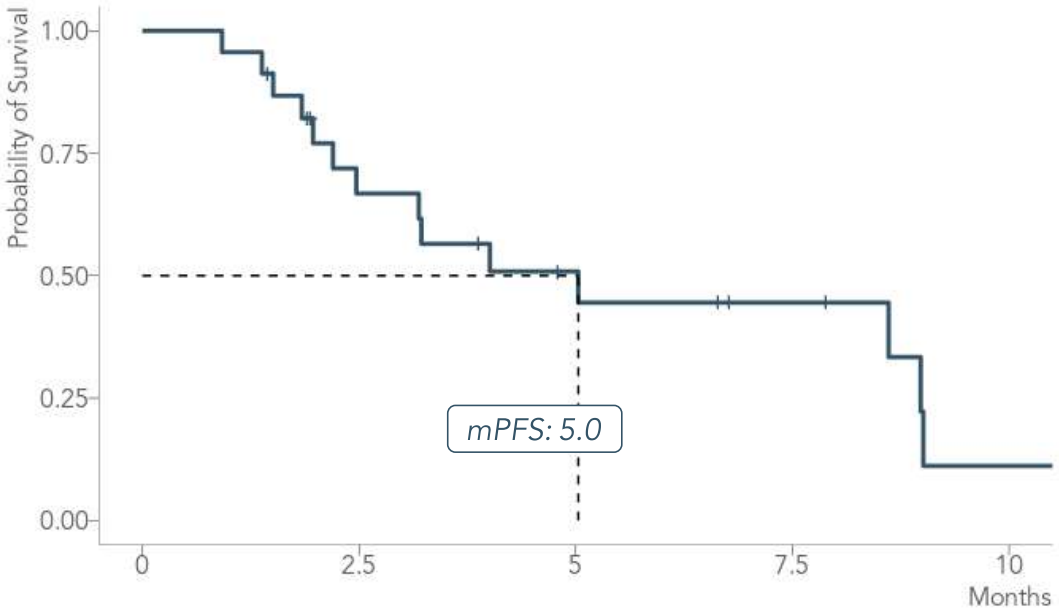
Subsequent disclosure on Feb 29, 2024: Three of the four initial partial responses confirmed on their subsequent scan, and one initial partial response did not confirm

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

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

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

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



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

1. FDA insert for Onivyde (Nal-IRI): https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207793lbl.pdf ; 387: 545–57. Von Hoff et al., N Engl J Med 2013; 369:1691-703.
2. Probability of being progression-free at 16 weeks using KM survival analysis. Data not available for 2nd line.

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

mPDAC
CRDF-001 Ph 2 Second-Line Trial

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

mPDAC
Biomarker Discovery Trial (IIT)

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

Path forward: Move to 1st line mPDAC

- New IIT combining onvansertib with SoC (NALIRIFOX)

mPDAC Biomarker Discovery trial evaluates onvansertib monotherapy

Investigator-initiated trial at OHSU Knight Cancer Institute

ENROLLMENT CRITERIA

Patients with metastatic pancreatic cancer (any line)

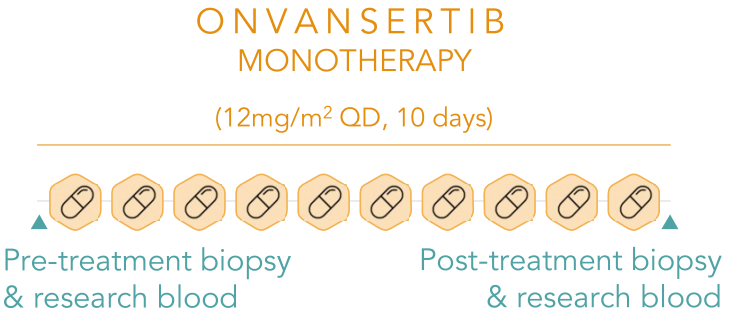
OBJECTIVES

Responsive biomarkers

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

Predictive biomarkers

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



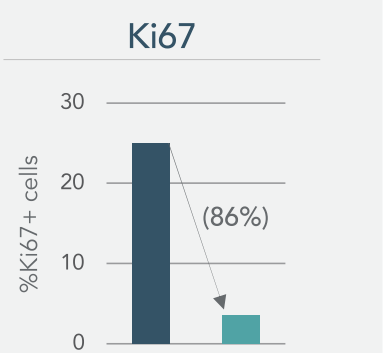
Obtain biopsies / bloodwork before and after 10 days of onvansertib monotherapy to conduct extensive multi-omic analyses

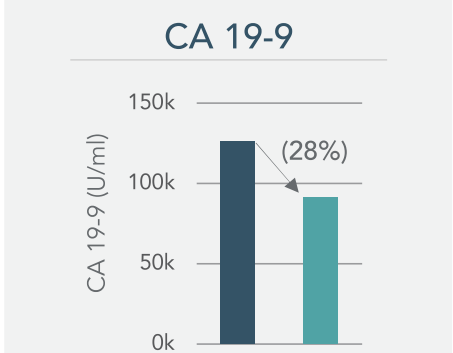
Onvansertib monotherapy decreased tumor proliferation and CA19-9

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

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

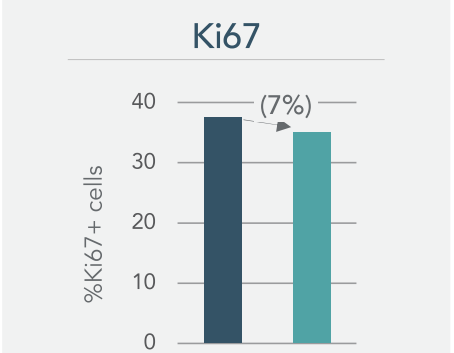
Patient 28 (tumor responder)

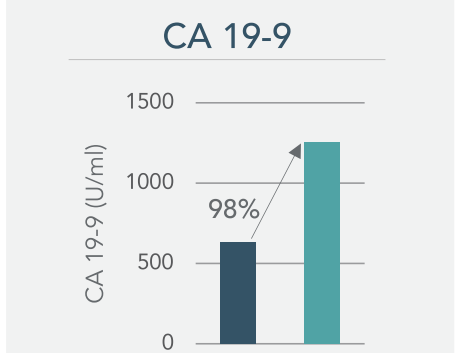




Mutation: KRAS G12V
1st line: Atezo/Bev + Gem/Nab → Response
2nd line: FOLFIRINOX → Progression
3rd line: Onvansertib monotherapy → CA19-9 Response

Patient 33 (tumor non-responder)





Mutation: KRAS Q61R
1st line: FOLFIRINOX → Response
2nd line: Onvansertib monotherapy → CA19-9 Progression

Pre-treatment Post-treatment

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

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

mPDAC
CRDF-001 Ph 2 Second-Line Trial

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

mPDAC
Biomarker Discovery Trial (IIT)

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

Path forward: Move to 1st line mPDAC

- New IIT combining onvansertib with SoC (NALIRIFOX)

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Appendix:
Investigator-Initiated Trial
Small Cell Lung Cancer (SCLC)

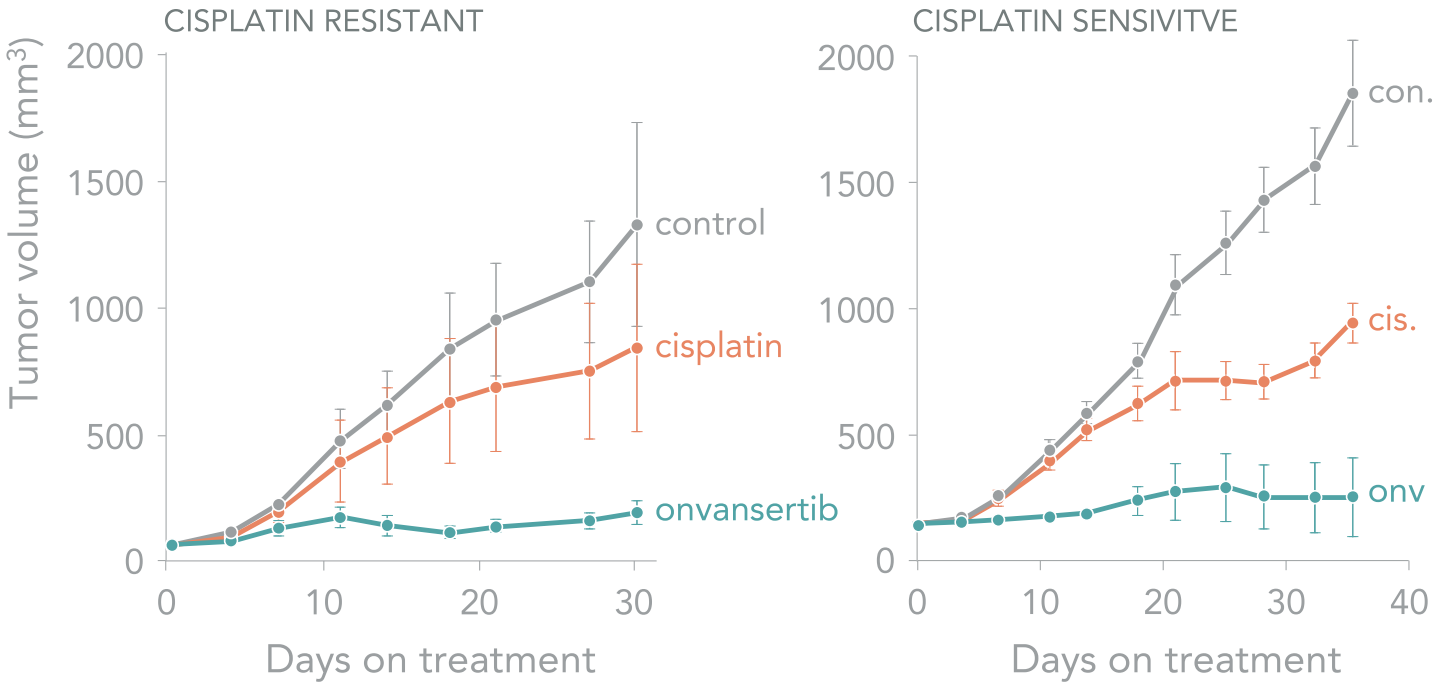
Onvansertib demonstrates single-agent activity in SCLC

TRIAL RATIONALE

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

SCLC

In vivo efficacy of onvansertib monotherapy (SCLC xenografts)*



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

Trial design for onvansertib monotherapy in extensive stage SCLC

ENROLLMENT CRITERIA

Relapsed who have received ≤2 prior therapies

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

UPMC LIFE CHANGING MEDICINE

SCLC

OBJECTIVE

To determine the efficacy and safety of onvansertib monotherapy

PRIMARY ENDPOINT

ORR (RECIST 1.1)

SECONDARY ENDPOINTS

Progression-Free Survival (PFS)
Overall Survival (OS)

Additional preliminary data for the small cell lung cancer investigator-initiated trial are available in our investor presentation filed on Form 8-K on September 26, 2023 (page 22 – 26).

Preliminary safety and efficacy for onvansertib monotherapy in SCLC

ENROLLMENT CRITERIA

Relapsed who have received ≤2 prior therapies

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

UPMC LIFE CHANGING MEDICINE

SCLC

PRELIMINARY SAFETY (N=6)

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

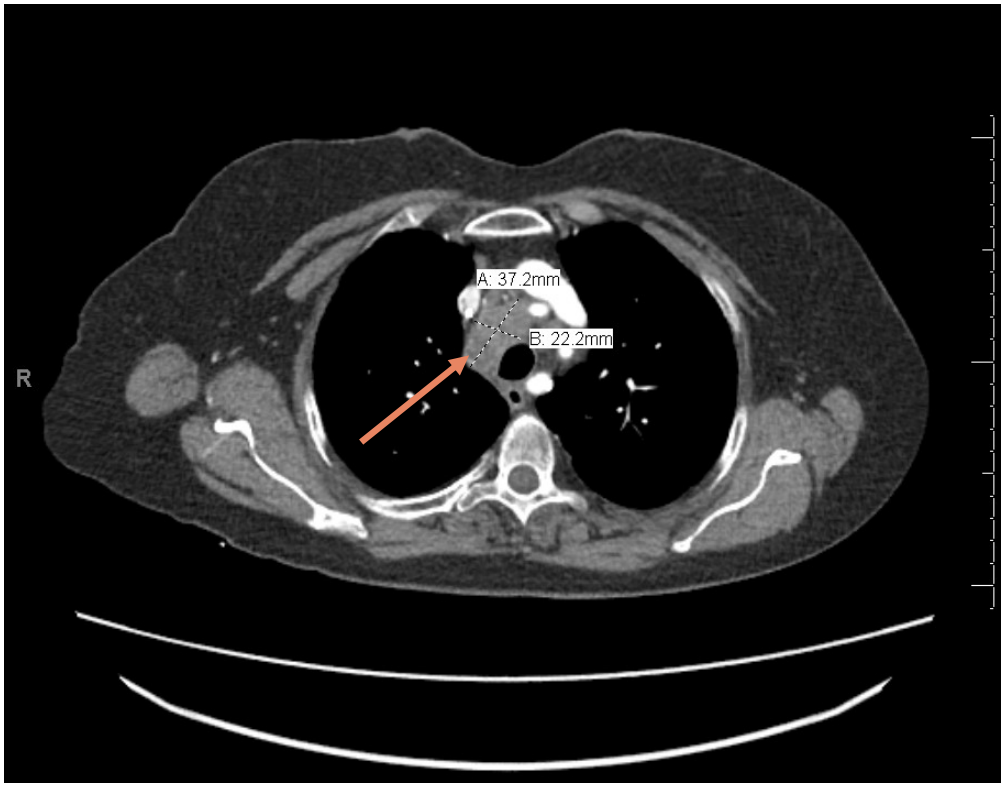
PRELIMINARY EFFICACY (N=7)

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

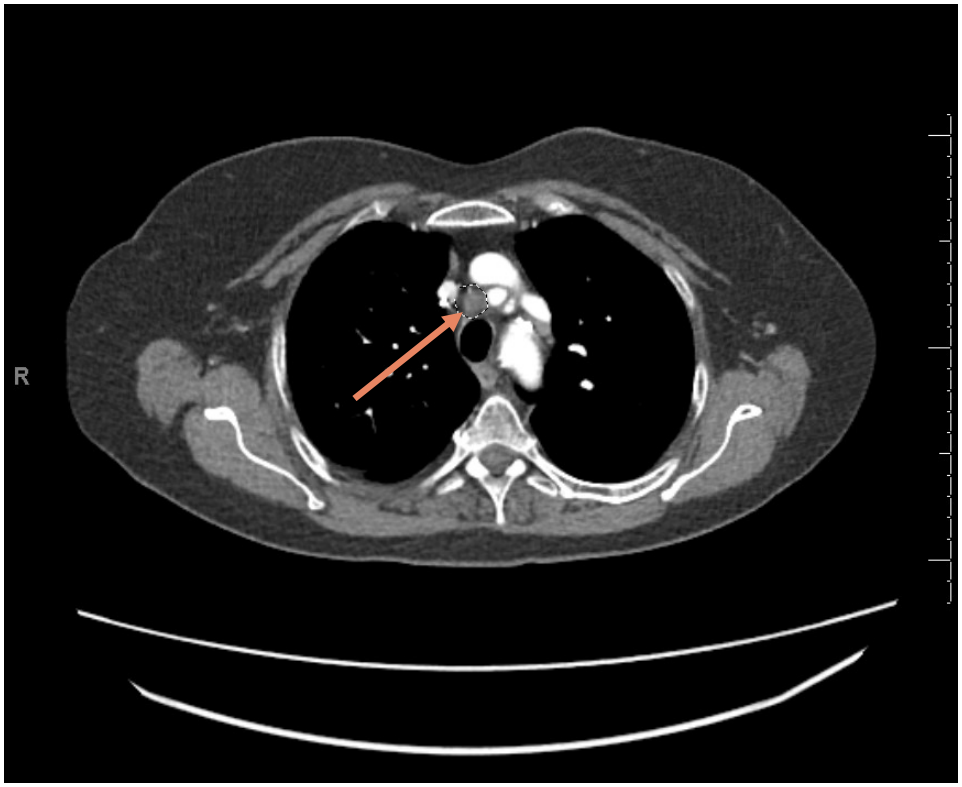
Disease control rate = 57% (4/7)

Radiographic scans for patient with a confirmed PR in SCLC

Baseline Scan



Restaging after Cycle 2



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Appendix:

Investigator-Initiated Trial

Triple Negative Breast Cancer (TNBC)

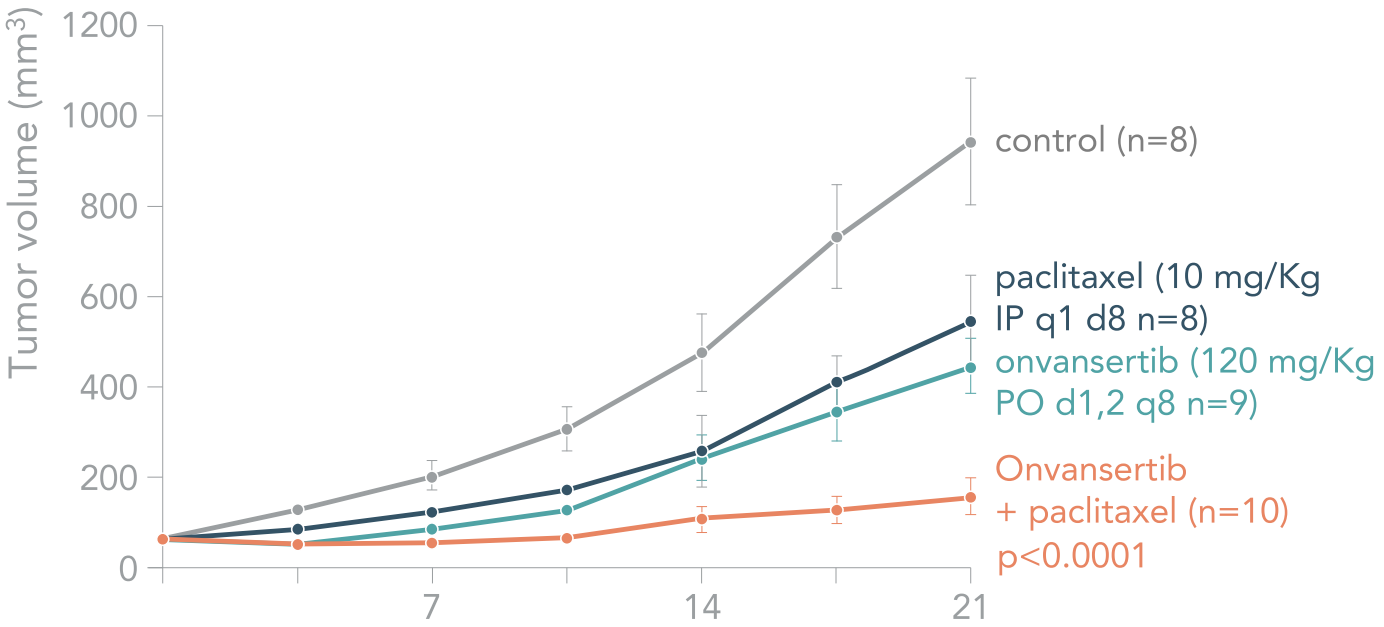
Preclinical: Onvansertib + paclitaxel is superior to single agent therapy

TRIAL RATIONALE

The combination of onvansertib + paclitaxel showed significant synergy

TNBC

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 mm^3: 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

Dana-Farber Cancer Institute

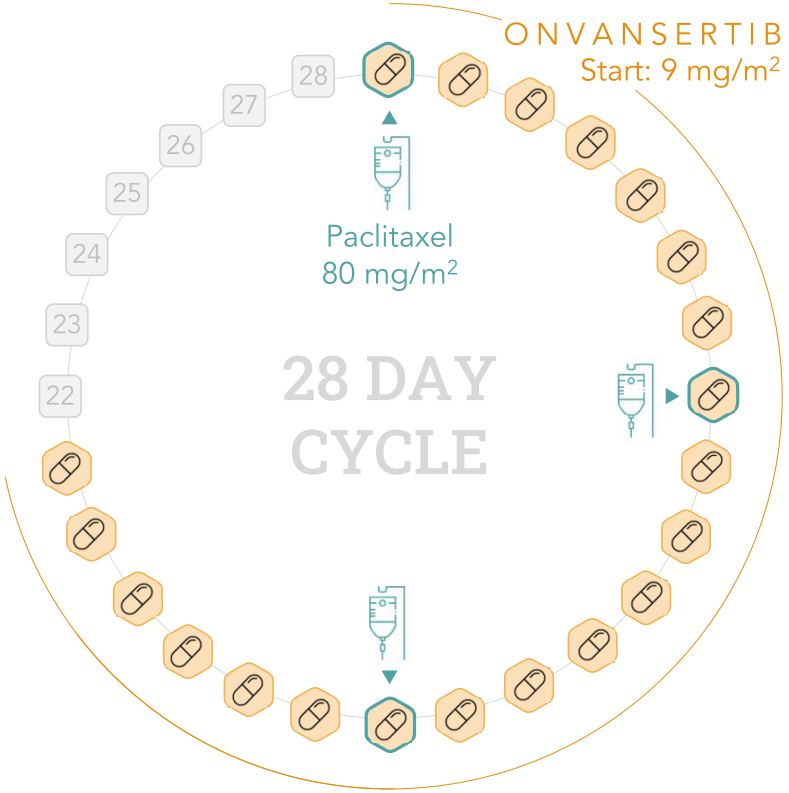
PRIMARY ENDPOINTS

Phase 1b
Safety, characterization of DLTs
Determination of RP2D

Phase 2
ORR (RECIST 1.1)

ONVANSERTIB DOSING

Starting: 9 mg/m^2
- Escalation: 12 mg/m^2, 18 mg/m^2
- De-escalation: 6 mg/m^2



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

TNBC

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)