Interim Results from the Randomized, Controlled Phase 2 CRDF-004 Trial

Onvansertib + SoC Chemo/Bevacizumab in First-Line RAS-Mutated mCRC

JUNE 3, 2026

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AGENDA

CARDIFF LEADERSHIP:

Mani Mohindru, PhD
President and CEO

GI ONCOLOGY KOLS:

Heinz-Josef Lenz, MD

Josep Tabernero, MD, PhD

Program Overview

Mani Mohindru, PhD, *President and CEO*

CRDF-004 Clinical Update & Path Forward

Mani Mohindru, PhD, *President and CEO*

KOL Perspectives

Heinz-Josef Lenz, MD, *University Professor of Medicine, Population and Public Health Sciences and Cancer Biology; Professor of Medicine and Preventive Medicine of USC. He serves as Co-Leader of the Gastrointestinal Cancers Program and Co-Director of the USC Center for Cancer Drug Development*

Josep Tabernero, MD, PhD, *Head of the Medical Oncology Department at Vall d'Hebron University Hospital, Professor of Medicine at the Universitat de Vic and Director of the Vall d'Hebron Institute of Oncology*

Q&A

ONVANSERTIB

FIRST-LINE RAS-MUTATED mCRC

Program Overview

CRDF-004 Clinical Update

Path Forward

Highly selective PLK1 inhibitor with practice-changing potential in first-line RAS-mutated metastatic colorectal cancer

Strong Efficacy in RAS-mutated mCRC

- 72% ORR in randomized Phase 2 trial, +30% over SoC; median PFS not reached vs 12.2 months in SoC*
- Synergy with FOLFIRI/bev in first-line RAS-mut mCRC with a favorable safety profile
- Confirms earlier efficacy shown in Ph 1b/2 trial in second-line KRAS-mut mCRC in bev-naïve patients

Large Commercial Opportunity

- First-line RAS-mutated mCRC, is an area of high unmet need and limited innovation
- Practice-changing potential in large, underserved populations
- Opportunity for market expansion, including in rare RAS-driven cancers such as CMML

Clear Registrational Path

- Successful End-of-Phase 2 meeting: aligned on the registrational trial in first-line RAS-mutated mCRC
- Dose and chemo regimen selected: 30 mg onvansertib + FOLFIRI/bev
- Ph 3 designed to allow for Accelerated Approval (ORR) and full approval (PFS)

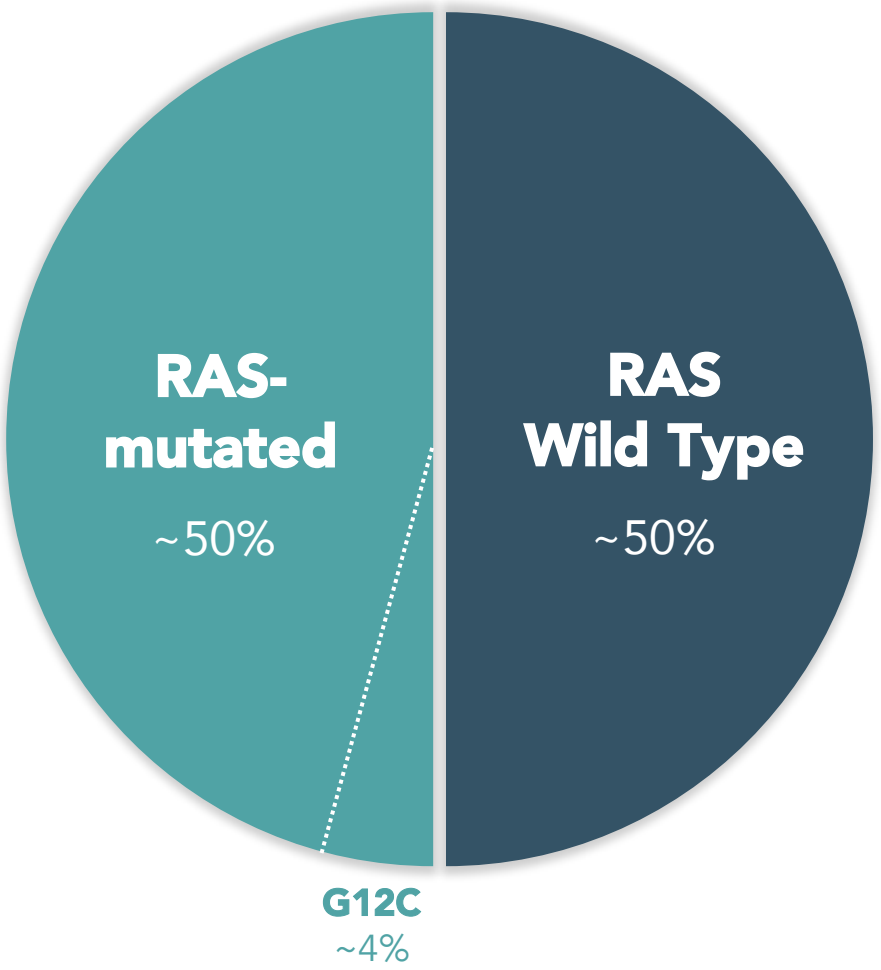
ORR reflects BICR. PFS reflects Investigator Assessment
ORR: Objective Response Rate; PFS: Progression Free Survival; BICR: Blinded Independent Central Review

Positioned to address the first-line RAS-mutated mCRC market

~150,000 newly diagnosed CRC patients in U.S.; 20% present metastatic disease*

Blockbuster potential:

Onvansertib targets **All RAS-mut mCRC**



1st Line Standard-of-Care Remains Unchanged for Two Decades

Chemotherapy (FOLFOX/FOLFIRI/FOLFOXIRI) + Bevacizumab (Avastin®)

No approvals specific to panRAS-mut mCRC

For patients with mCRC

15%
5-year relative OS

Less than **12** months
median PFS

*American Cancer Society; NCI SEER database
CRC, colorectal cancer; mCRC, metastatic colorectal cancer

Large unmet need in first-line mCRC: efficacy data from existing therapies

Data from positive first-line mCRC chemo/bev Phase 3 clinical trials by RAS-mutated status*

Targeted agent	Trial	Mechanism of action	Trial population		Sample size	ORR Exp. vs Ctrl.	PFS (months) Exp. vs Ctrl.	Hazard ratio
bevacizumab	IFL/bev vs IFL	Antiangiogenic	KRAS WT or mutant	All ITT patients	813	45% vs 35%	10.6 vs 6.2	0.54 p<0.0001
				Mutant only[1]	**78**	**43% vs 41%**	**9.3 vs 5.5**	**0.41**
FOLFOXIRI/bev (TRIBE trial)	FOLFOXIRI/bev vs FOLFIRI/bev	Chemo	RAS WT or mutant	All ITT patients	508	65% vs 54%	12.3 vs 9.7	0.77 p=0.006
				Mutant only[1]	**236**	**66% vs 55%**	**12.0 vs 9.5**	**0.78**

* Source: bevacizumab: USPI from accessdata.fda.gov, Hurwitz H, et al. The Oncologist 2009. FOLFOXIRI: Cremolini C, et al. Lancet Oncol 2015.
1. RAS mutation was evaluated retrospectively and tumor samples for RAS analysis were not available for all patients.

ONVANSERTIB

FIRST-LINE RAS-MUTATED mCRC

Program Overview

CRDF-004 Clinical Update *(Data cut-off Mar 18, 2026)*

Path Forward

CRDF-004: dose-finding, randomized, controlled Phase 2 trial in first-line patients with RAS-mutated mCRC

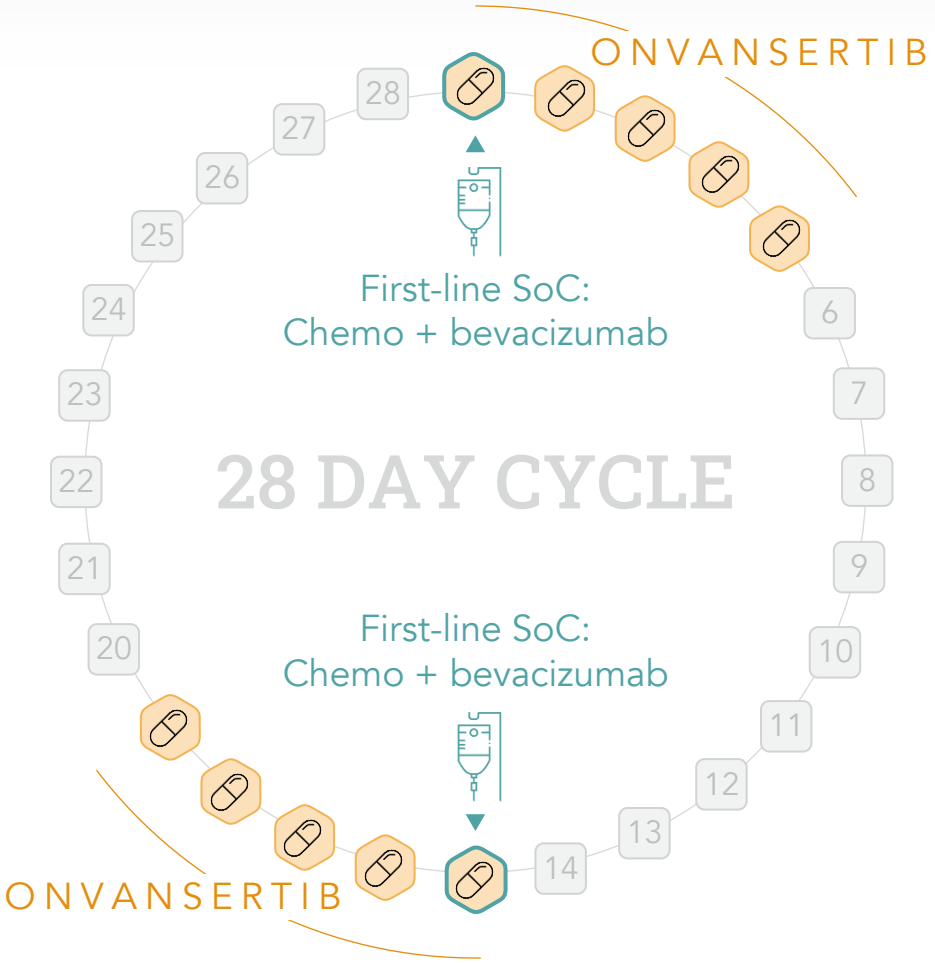
ENROLLMENT CRITERIA

- First-line mCRC
- KRAS+/NRAS+
- No BRAF-V600 or MSI-H/dMMR
- Unresectable
- No prior bev

R
ITT=110

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



Patient's tumors are scanned every 8 weeks

ENDPOINTS*

Primary:	ORR
Secondary:	DoR and PFS

* Assessed by blinded independent central review (BICR)

mCRC: metastatic colorectal cancer; ORR: objective response rate; DoR: duration of response; PFS: progression free survival; SoC: standard of care; onv: onvansertib; bev: bevacizumab

Demographics and baseline characteristics

	FOLFIRI/bev (N=19)	Onv 20 mg + FOLFIR/bev (N=18)	Onv 30 mg + FOLFIRI/bev (N=18)	FOLFOX/bev (N=18)	Onv 20 mg + FOLFOX/bev (N=18)	Onv 30 mg + FOLFOX/bev (N=19)
Age (years)						
Mean (SD)	55.41 (14.34)	52.41 (13.13)	59.67 (12)	56.24 (12.04)	59.41 (14.5)	60.11 (14.1)
Median (Min, Max)	53 (32, 81)	52 (30, 78)	60 (34, 81)	57 (34, 82)	66 (34, 79)	59.5 (39, 86)
ECOG						
0	6 (31.6%)	13 (72.2%)	11 (61.1%)	7 (38.9%)	10 (55.6%)	11 (57.9%)
1	11 (57.9%)	4 (22.2%)	7 (38.9%)	10 (55.6%)	7 (38.9%)	7 (36.8%)
Stage at initial diagnosis*						
STAGE IV	9 (47.4%)	10 (55.6%)	14 (77.8%)	9 (50.0%)	11 (61.1%)	13 (68.4%)
STAGE III	4 (21.1%)	4 (22.2%)	2 (11.1%)	6 (33.3%)	2 (11.1%)	3 (15.8%)
STAGE II	3 (15.8%)	2 (11.1%)	2 (11.1%)	2 (11.1%)	3 (16.7%)	1 (5.3%)
STAGE I	0	1 (5.6%)	0	0	1 (5.6%)	1 (5.3%)
Side of tumor						
RIGHT	5 (26.3%)	8 (44.4%)	6 (33.3%)	8 (44.4%)	7 (38.9%)	7 (36.8%)
LEFT	6 (31.6%)	7 (38.9%)	6 (33.3%)	5 (27.8%)	8 (44.4%)	4 (21.1%)
BILATERAL	6 (31.6%)	2 (11.1%)	6 (33.3%)	4 (22.2%)	2 (11.1%)	7 (36.8%)
Liver metastasis at study entry						
Yes	10 (52.6%)	10 (55.6%)	14 (77.8%)	10 (55.6%)	12 (66.7%)	14 (73.7%)
No	7 (36.8%)	7 (38.9%)	4 (22.2%)	7 (38.9%)	5 (27.8%)	4 (21.1%)
Liver only disease						
No	15 (78.9%)	15 (83.3%)	11 (61.1%)	14 (77.8%)	16 (88.9%)	15 (78.9%)
Yes	2 (10.5%)	2 (11.1%)	7 (38.9%)	3 (16.7%)	1 (5.6%)	3 (15.8%)
Number of metastatic organs						
Multiple	11 (57.9%)	9 (50.0%)	9 (50%)	9 (50.0%)	13 (72.2%)	15 (78.9%)
Single	6 (31.6%)	8 (44.4%)	9 (50%)	8 (44.4%)	4 (22.2%)	3 (15.8%)
Prior adjuvant or neo-adjuvant chemo						
No	13 (68.4%)	12 (66.7%)	14 (77.8%)	12 (66.7%)	12 (66.7%)	16 (84.2%)
Yes	4 (21.1%)	5 (27.8%)	4 (22.2%)	5 (27.8%)	5 (27.8%)	2 (10.5%)

*Missing in one patient

Trial is ongoing as of March 18, 2026 cut-off: 13 of 14 remaining patients are on onvansertib + SOC chemo/bev

Population, n	FOLFIRI/bev	Onv 20mg + FOLFIRI/bev	Onv 30mg + FOLFIRI/bev	FOLFOX/bev	Onv 20mg + FOLFOX/bev	Onv 30mg + FOLFOX/bev	Total
Intent-to-treat (ITT)	19	18	18	18	18	19	110
Safety population (dosed)	17	17	18	17	17	18	104
Patients still on study treatment	**1**	**5**	**4**	**0**	**3**	**1**	**14**

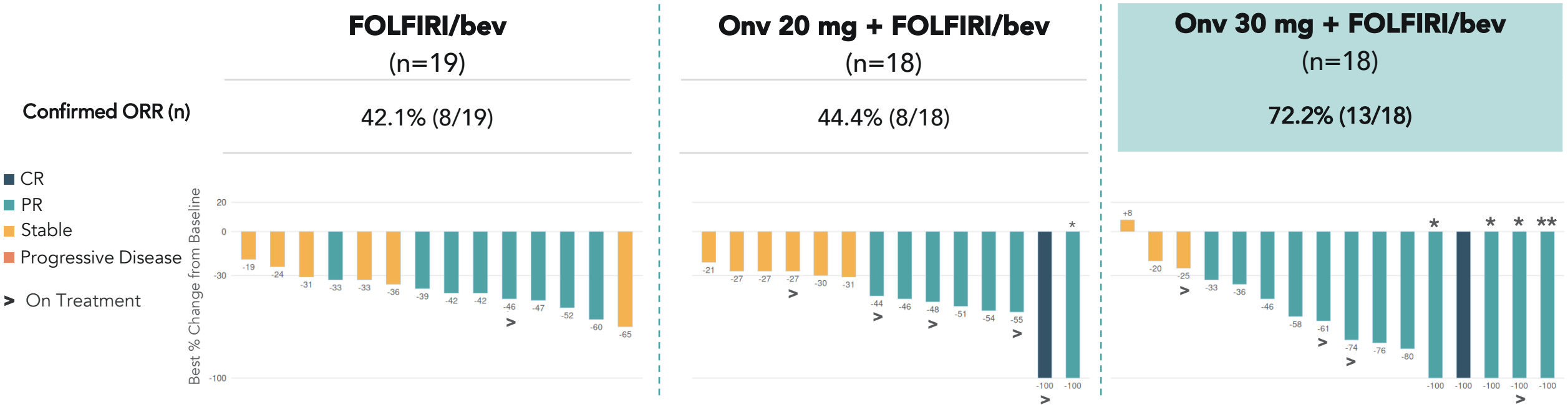
Onv 30 mg + FOLFIRI/bev delivers superior ORR & depth of response: 30% improvement in ORR over FOLFIRI/bev

Objective Response Rate (per BICR) - ITT Analysis

Onv 20 mg/Onv 30 mg + FOLFIRI/bev
(n=36)

Combined ORR: 58.3% (21)

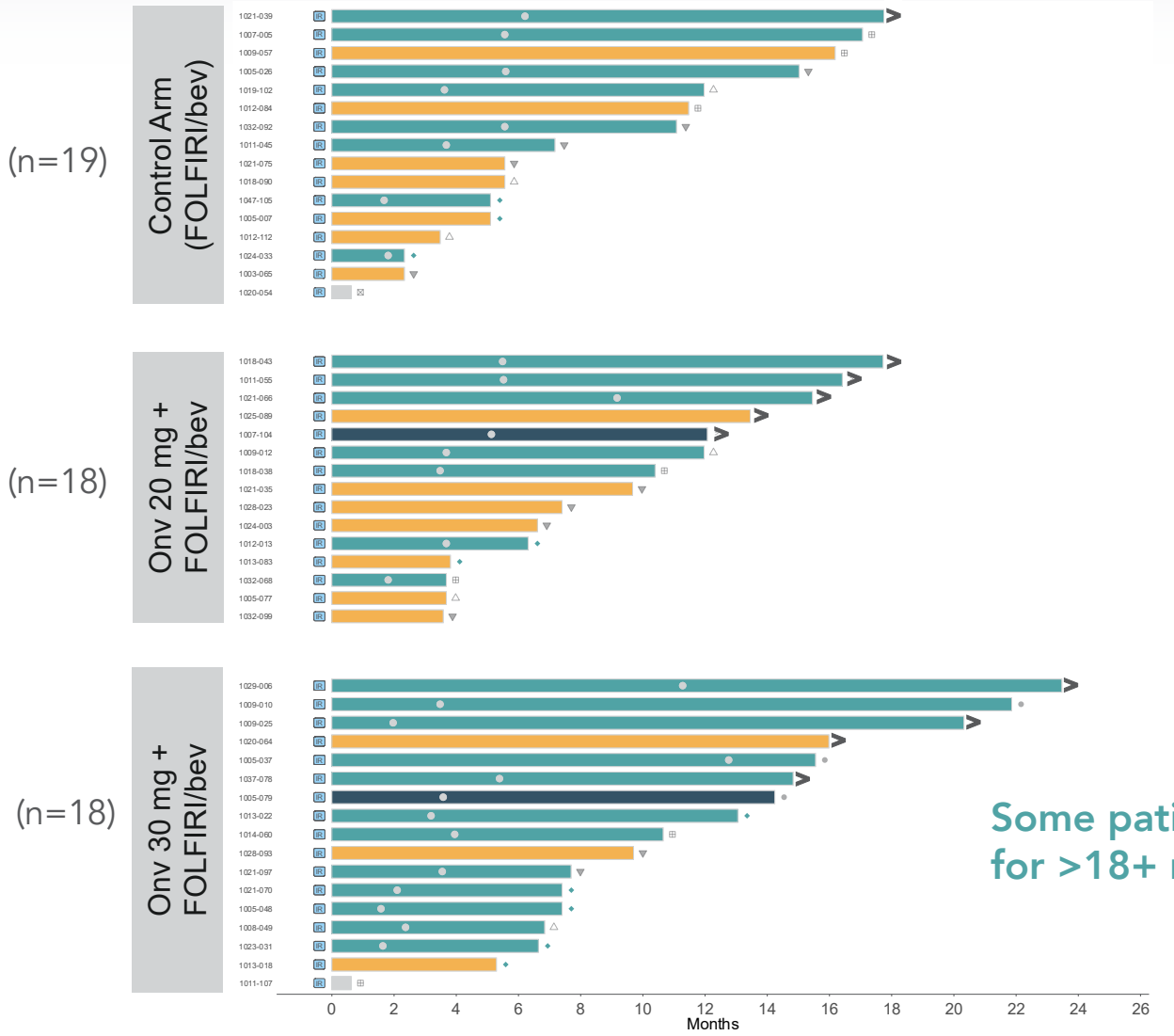
	FOLFIRI/bev (n=19)	**Onv 20 mg + FOLFIRI/bev** (n=18)	**Onv 30 mg + FOLFIRI/bev** (n=18)
Confirmed ORR (n)	42.1% (8/19)	44.4% (8/18)	**72.2% (13/18)**



** CR at last assessment; unconfirmed due to discontinuation for curative surgery
* Residual non-target disease (Non-CR/Non-PD)
Patients that are not-evaluable or do not have target lesions are not shown in the plots

Onv 30 mg + FOLFIRI/bev demonstrates longer duration of treatment

9 of 10 remaining patients on onv + FOLFIRI/bev



Time on Trial by Best Confirmed Response

- Complete Response
- Partial Response
- Stable Disease

- > On Treatment
- First Response Scan

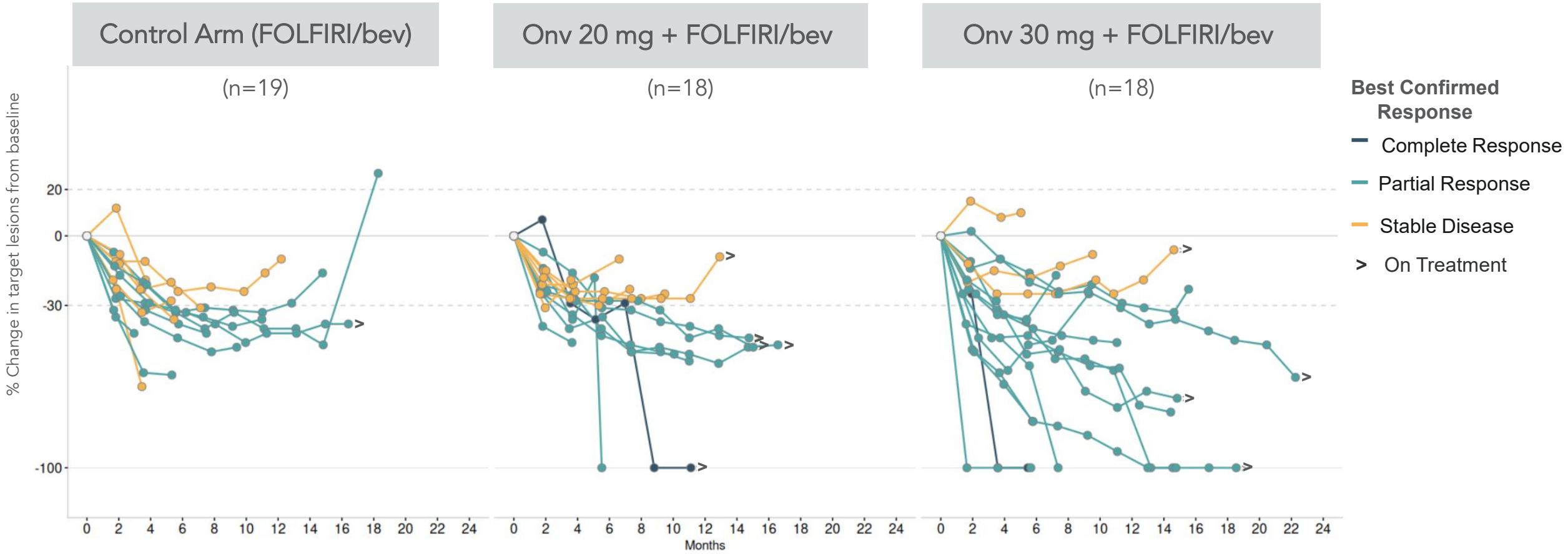
Reason For Discontinuation

- Death
- Adverse Event
- To Pursue Surgery
- Progressive Disease (Investigator)
- Patient Decision
- Other

Some patients on treatment for >18+ months

Patients that are not evaluable are not shown in the plots

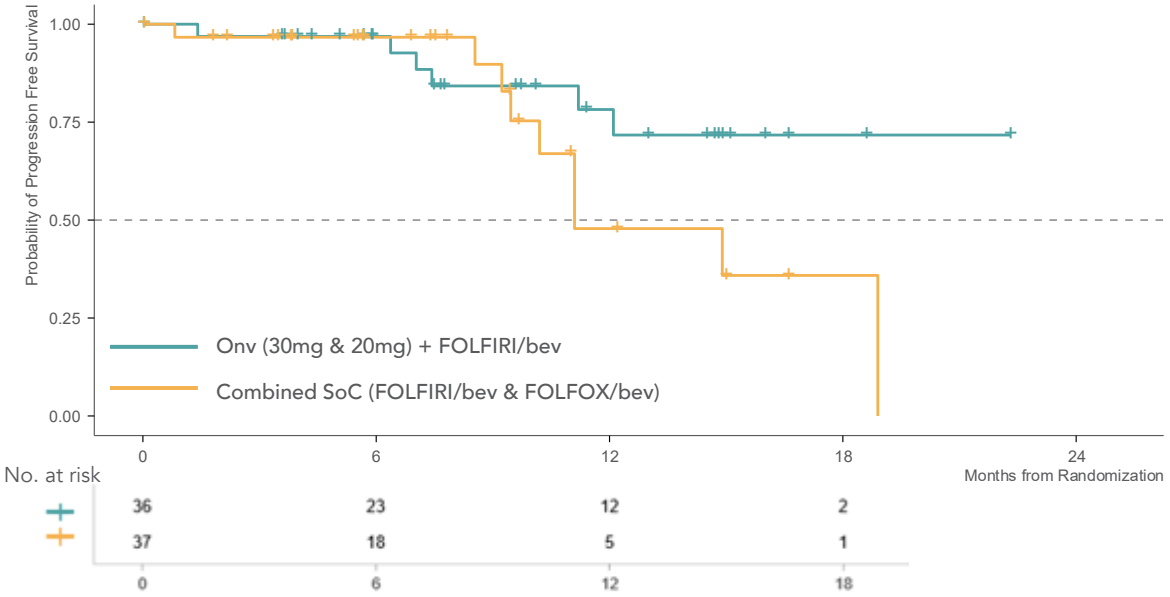
Onv 30 mg + FOLFIRI/bev demonstrates deep and durable tumor shrinkage over time



Patients that are not-evaluable or do not have target lesions are not shown in the plots.

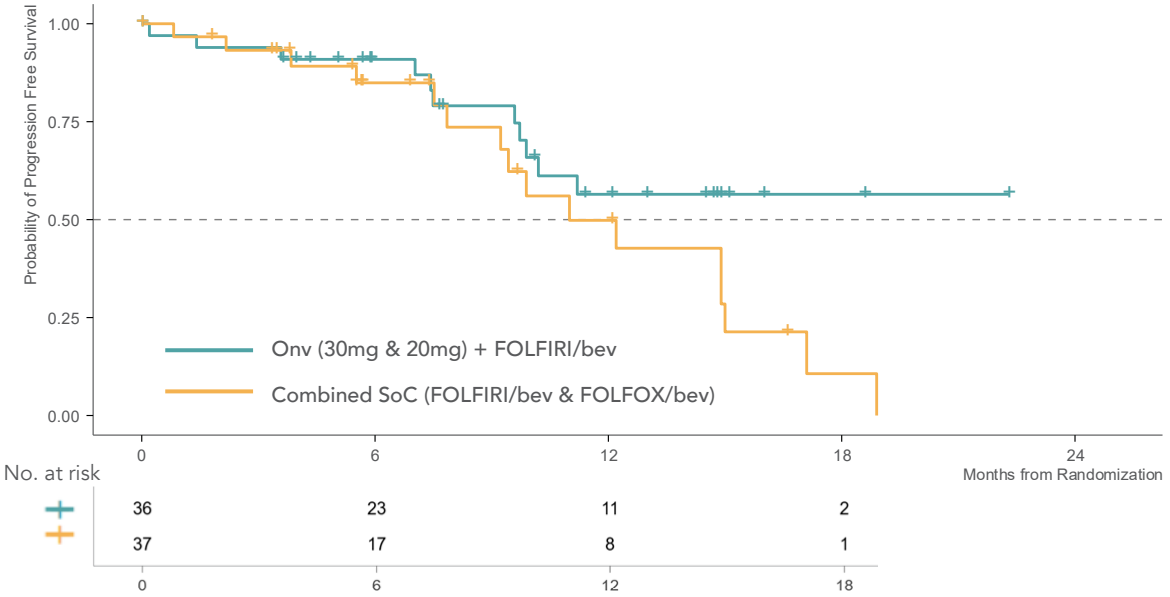
Onv (20 & 30 mg) + FOLFIRI/bev shows improved PFS vs SoC (FOLFIRI/bev & FOLFOX/bev)

BICR Assessment



	FOLFIRI/bev + FOLFOX/bev	Onv (20 & 30mg) + FOLFIRI/bev
N	37	36
Median PFS	11.07	NR*
HR (95% CI)	0.44 (0.15, 1.25)	

Investigator Assessment

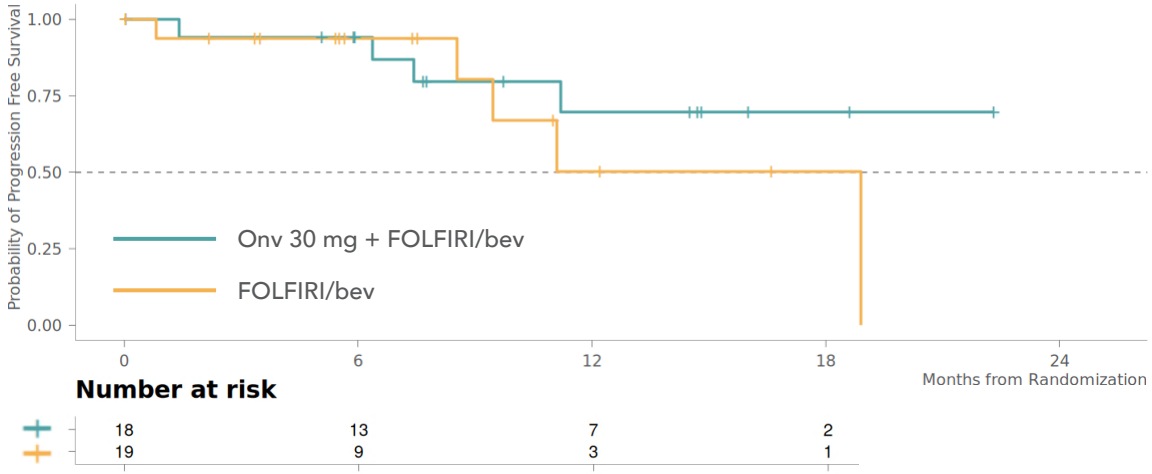


	FOLFIRIbev + FOLFOX/bev	Onv (20 & 30mg) + FOLFIRI/bev
N	37	36
Median PFS	10.97	NR*
HR (95% CI)	0.53 (0.25, 1.15)	

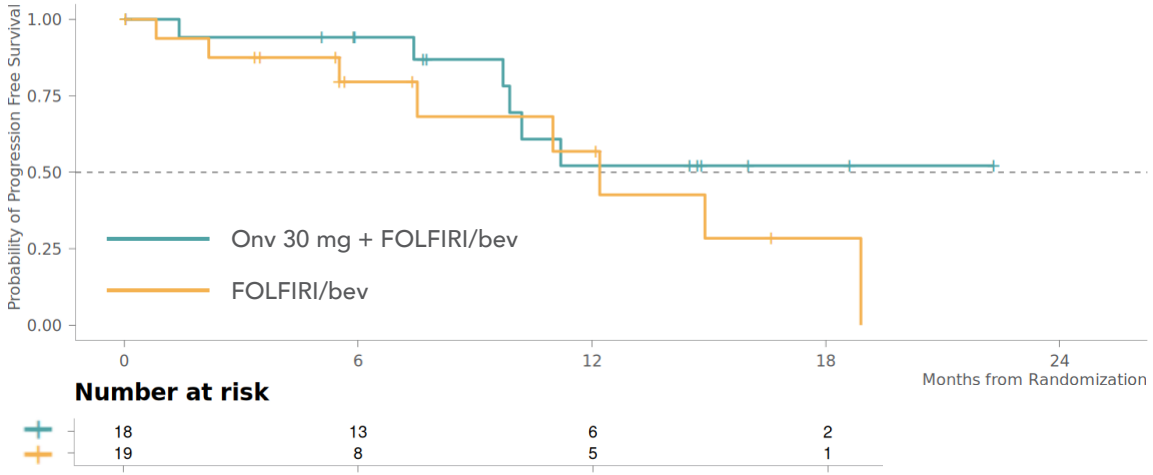
HR: hazard ratio; PFS: Progression Free Survival; BICR: Blinded Independent Central Review; * Nine patients still on study

Onv 30 mg + FOLFIRI/bev shows improved PFS vs FOLFIRI/bev

BICR Assessment



Investigator Assessment

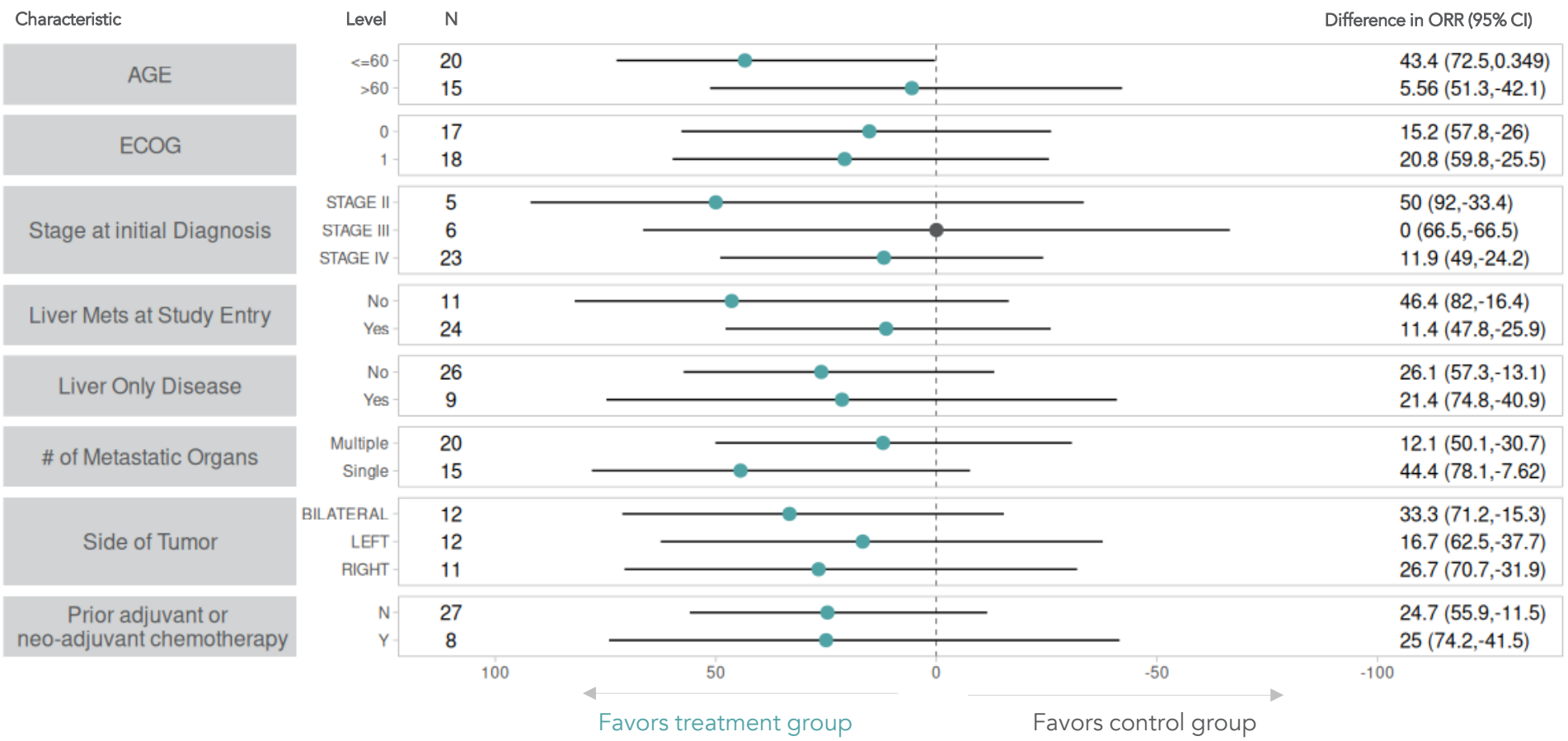


	FOLFIRI/bev	Onv 30 mg + FOLFIR/bev
N	19	18
Median PFS	18.89*	NR**
HR (95% CI)	0.55 (0.15, 2.09)	

	FOLFIRI/bev	Onv 30 mg + FOLFIR/bev
N	19	18
Median PFS	12.22*	NR**
HR (95% CI)	0.57 (0.2, 1.65)	

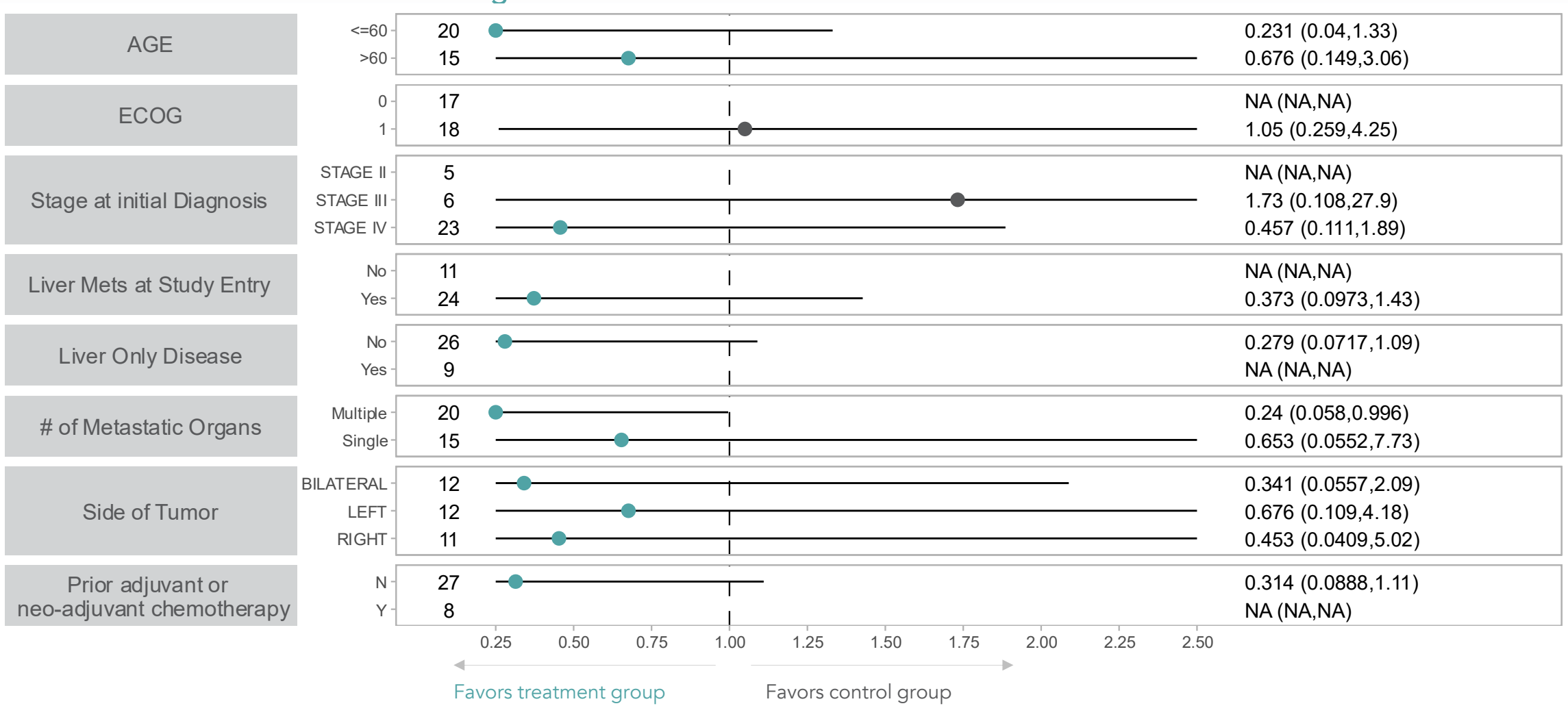
*Discordance in median PFS in FOLFIRI/ bev arm due to investigator-assessed progressive disease (PD) and discontinuation prior to BICR confirmation of progression
**Four patients still on study

Forest plot of ORR (BICR) by baseline characteristics demonstrates consistent benefit across subgroups with Onv 30 mg + FOLFIRI/bev



STAGE I at initial diagnosis excluded due to too few patients to meaningfully analyze.

Forest plot of PFS* by baseline characteristics demonstrates trends in benefit across subgroups with Onv 30 mg + FOLFIRI/bev



* Progressive disease events were based on events of BICR and Investigator assessments. The earliest reported date was used for a conservative estimate
STAGE I at initial diagnosis excluded due to too few patients to meaningfully analyze.

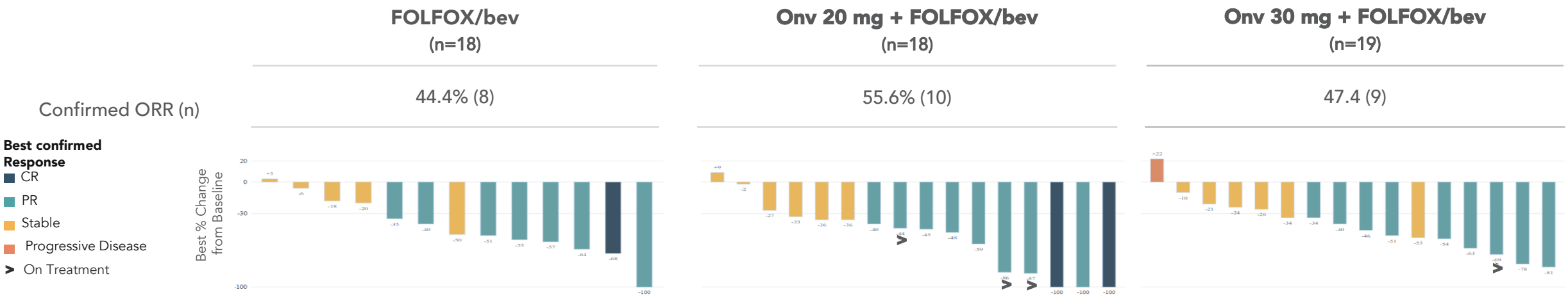
Onvansertib shows no unexpected, overlapping, or new toxicities when added to FOLFIRI/bev or FOLFOX/bev

	FOLFIRI/bev (N=17)		Onv 20 mg + FOLFIRI/bev (N=17)		Onv 30 mg + FOLFIRI/bev (N=18)		FOLFOX/bev (N=17)		Onv 20 mg + FOLFOX/bev (N=17)		Onv 30 mg + FOLFOX/bev (N=18)	
Number (%) of Participants: by Preferred Term	Any Grade n (%)	Gr ≥ 3 n (%)	Any Grade n (%)	Gr ≥ 3 n (%)	Any Grade n (%)	Gr ≥ 3 n (%)	Any Grade n (%)	Gr ≥ 3 n (%)	Any Grade n (%)	Gr ≥ 3 n (%)	Any Grade n (%)	Gr ≥ 3 n (%)
Participants with events	17 (100.0)	15 (88.2)	17 (100.0)	13 (76.5)	18 (100.0)	15 (83.3)	16 (94.1)	11 (64.7)	17 (100.0)	12 (70.6)	18 (100.0)	16 (88.9)
Nausea	9 (52.9)	1 (5.9)	13 (76.5)	1 (5.9)	12 (66.7)	0	11 (64.7)	1 (5.9)	12 (70.6)	0	11 (61.1)	0
Fatigue	9 (52.9)	0	12 (70.6)	0	11 (61.1)	0	10 (58.8)	2 (11.8)	12 (70.6)	1 (5.9)	10 (55.6)	0
Diarrhea	11 (64.7)	1 (5.9)	13 (76.5)	2 (11.8)	9 (50.0)	0	8 (47.1)	1 (5.9)	7 (41.2)	1 (5.9)	7 (38.9)	0
Neutrophil count decreased	9 (52.9)	5 (29.4)	5 (29.4)	2 (11.8)	7 (38.9)	3 (16.7)	5 (29.4)	5 (29.4)	7 (41.2)	4 (23.5)	7 (38.9)	4 (22.2)
Peripheral sensory neuropathy	5 (29.4)	0	2 (11.8)	0	3 (16.7)	0	6 (35.3)	0	10 (58.8)	2 (11.8)	11 (61.1)	1 (5.6)
Vomiting	6 (35.3)	1 (5.9)	8 (47.1)	0	7 (38.9)	0	5 (29.4)	1 (5.9)	7 (41.2)	1 (5.9)	4 (22.2)	0
Hypertension	6 (35.3)	2 (11.8)	8 (47.1)	3 (17.6)	7 (38.9)	3 (16.7)	3 (17.6)	0	5 (29.4)	1 (5.9)	7 (38.9)	5 (27.8)
Constipation	3 (17.6)	1 (5.9)	6 (35.3)	0	5 (27.8)	0	2 (11.8)	0	10 (58.8)	0	8 (44.4)	0
Abdominal pain	5 (29.4)	2 (11.8)	4 (23.5)	1 (5.9)	7 (38.9)	1 (5.6)	4 (23.5)	0	6 (35.3)	1 (5.9)	7 (38.9)	1 (5.6)
Decreased appetite	7 (41.2)	1 (5.9)	5 (29.4)	0	7 (38.9)	1 (5.6)	4 (23.5)	0	7 (41.2)	0	3 (16.7)	0
Epistaxis	4 (23.5)	0	9 (52.9)	0	7 (38.9)	0	4 (23.5)	0	5 (29.4)	0	4 (22.2)	0
Anemia	4 (23.5)	1 (5.9)	7 (41.2)	1 (5.9)	5 (27.8)	1 (5.6)	3 (17.6)	0	4 (23.5)	1 (5.9)	8 (44.4)	4 (22.2)
Platelet count decreased	2 (11.8)	1 (5.9)	4 (23.5)	0	3 (16.7)	1 (5.6)	7 (41.2)	1 (5.9)	7 (41.2)	0	8 (44.4)	2 (11.1)
Weight decreased	7 (41.2)	2 (11.8)	2 (11.8)	1 (5.9)	6 (33.3)	0	2 (11.8)	0	3 (17.6)	0	5 (27.8)	1 (5.6)
Alopecia	5 (29.4)	0	4 (23.5)	0	6 (33.3)	0	2 (11.8)	0	5 (29.4)	0	2 (11.1)	0
Dizziness	3 (17.6)	0	4 (23.5)	0	2 (11.1)	0	3 (17.6)	0	5 (29.4)	0	7 (38.9)	0
Headache	4 (23.5)	0	7 (41.2)	0	2 (11.1)	0	4 (23.5)	0	6 (35.3)	0	1 (5.6)	0
Hypokalemia	4 (23.5)	1 (5.9)	3 (17.6)	2 (11.8)	5 (27.8)	2 (11.1)	5 (29.4)	1 (5.9)	3 (17.6)	0	4 (22.2)	1 (5.6)
Insomnia	0	0	5 (29.4)	0	4 (22.2)	0	3 (17.6)	0	6 (35.3)	0	6 (33.3)	0
Stomatitis	3 (17.6)	1 (5.9)	7 (41.2)	0	3 (16.7)	0	6 (35.3)	0	3 (17.6)	0	1 (5.6)	0
White blood cell count decreased	5 (29.4)	1 (5.9)	5 (29.4)	0	5 (27.8)	0	6 (35.3)	2 (11.8)	0	0	2 (11.1)	1 (5.6)
Dysgeusia	2 (11.8)	0	1 (5.9)	0	4 (22.2)	0	5 (29.4)	0	5 (29.4)	0	5 (27.8)	0

*Data cut-off March 18, 2026, from an ongoing trial and unlocked EDC database. events shown occurred in ≥20% of total patients; Subjects reporting more than one adverse event (AE) within a preferred term are counted only once in that preferred term. For subjects reporting more than one AE within a preferred term, the AE with maximum grade is included in the table.

Onvansertib adds no consistent meaningful benefit to FOLFOX/bev

Objective Response Rate (per BICR)[a] - ITT Analysis



Progression Free Survival	FOLFOX/bev (n=18)	Onv 20 mg + FOLFOX/bev (n=18)		Onv 30 mg + FOLFOX/bev (n=19)	
	Median (95% CI)	Median (95% CI)	Hazard Ratio (95% CI)	Median (95% CI)	Hazard Ratio (95% CI)
BICR only	11.07 (10.18-NR)	14.13 (10.94-NR)	1.14 (0.32, 4.04)	11.37 (9.4-NR)	2.2 (0.67, 7.28)
Investigator only	9.89 (9.23-NR)	12.78 (7.39-NR)	1.02 (0.39, 2.64)	11.37 (8.15-NR)	1.81 (0.64, 5.08)

Patients that are not evaluable are not shown in the plots

Mechanistic rationale for onvansertib's synergy with FOLFIRI but not FOLFOX

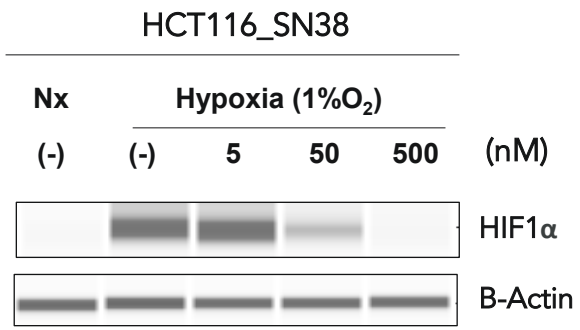
- **Onvansertib & irinotecan both cause HIF1α suppression (anti-angiogenic effects)**
- **Onvansertib may inhibit DNA-repair pathway activated upon irinotecan-induced DNA damage**

Topoisomerase I inhibitors (Irinotecan/SN38) + Onvansertib

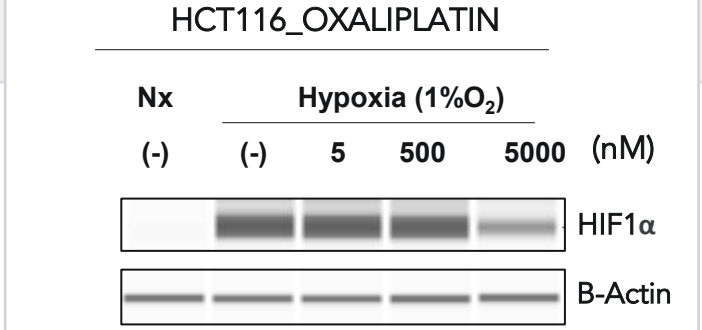
- Both suppress HIF1α → dual anti-angiogenic effect
- Irinotecan-induced double stranded breaks (DSBs) rely on PLK1-dependent Homologous Recombination repair

Oxaliplatin + Onvansertib

- Oxaliplatin has low impact on HIF1a suppression — no shared antiangiogenic effect
- Oxaliplatin induced DNA damage uses Nucleotide Excision Repair mechanism — limited/no role of PLK1



SN38 decreases HIF1α in a dose-dependent manner; HIF1α less sensitive to oxaliplatin



HCT116 is a human colorectal cell line; Irinotecan, a component of FOLFIRI, is a prodrug of SN38

CRDF-004 Phase 2 trial: key goals/endpoints achieved

Primary Goal:
DOSE + CHEMO SELECTION

30 mg onvansertib + FOLFIRI/bev

Selected the efficacious and safe dose of onvansertib + SoC for the registrational program

Primary Endpoint:
ORR

30% improvement in ORR

30 mg onvansertib + FOLFIRI/bev demonstrated improvement in ORR compared to SoC

Secondary Endpoint:
PFS

Median PFS not yet reached vs SoC

9 of 14 patients remain on onvansertib + FOLFIRI/bev treatment; median PFS not reached but reached in SoC

ONVANSERTIB

FIRST-LINE RAS-MUTATED mCRC

Program Overview

CRDF-004 Clinical Update

Path Forward

Proposed pivotal trial design in first-line RAS-mutated mCRC

FDA End-of-Phase 2 meeting completed in 2Q 2026

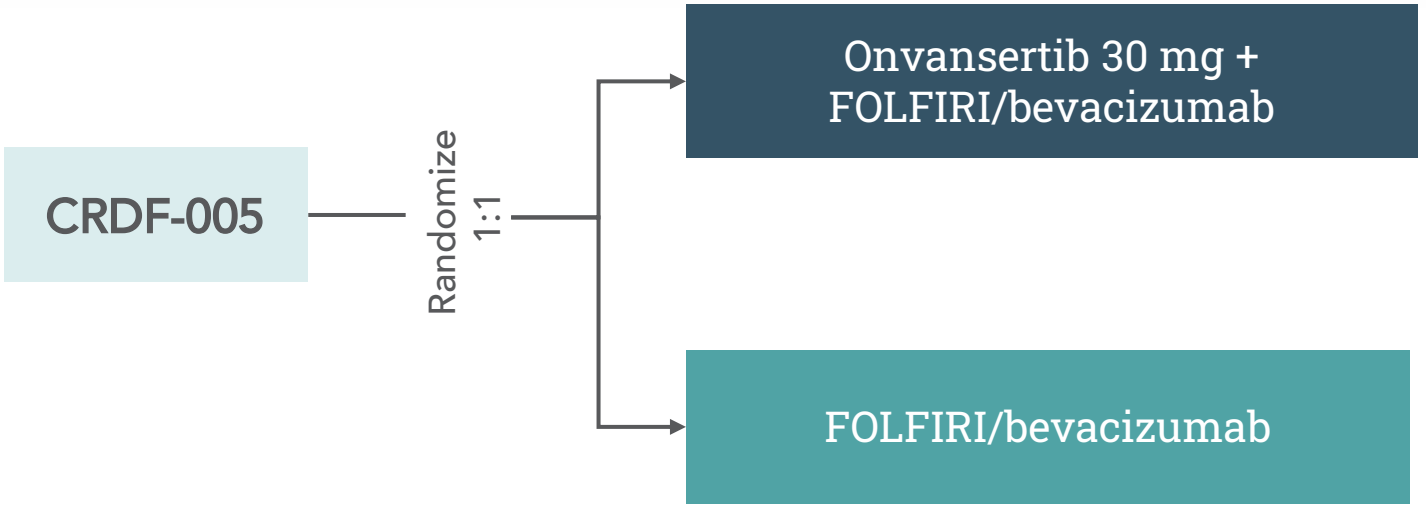
ENROLLMENT CRITERIA

- First-line mCRC
- KRAS+/NRAS+
- No BRAF-V600 or MSI-H/dMMR
- Unresectable
- No prior bev

ENDPOINTS

Dual Primary Endpoints: ORR and PFS

Secondary: DoR and OS



Design details:

- Proposed sample size ~ 640 patients
- >90% power to detect PFS and ORR difference in the two arms
- Potential for accelerated approval based on ORR and durability of responses
- FDA feedback received, EMA feedback pending

Key takeaways for onvansertib

Onvansertib:
highly selective, oral, small molecule inhibitor of PLK1

Proven Synergy with FOLFIRI/bev	Two clinical studies demonstrate improved outcomes in bev-naïve patients, validating combination synergy
Improved Efficacy in 1L RAS-mut mCRC	Phase 2 CRDF-004 data show 72% ORR at 30mg, +30% over SoC; median PFS not reached with some patients on treatment > 18 months
Clean Safety Profile	No added safety signals — side effects consistent with background therapy
Advancement to Registrational Trial	30 mg dose selected; Phase 3 designed for accelerated approval via ORR and full approval via PFS
Large Unmet Need	No meaningful treatment advances in first-line RAS-mutated mCRC in over 20 years

mCRC, metastatic colorectal cancer; bev, bevacizumab; ORR, objective response rate; PFS, progression-free survival; PLK1, polo-like kinase 1; SoC, standard of care

KOL perspectives: mCRC market and therapeutic landscape

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