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CLINICAL TOPIC NEWSLETTER

THE LATEST DEVELOPMENTS IN *BRAF*-MUTATED AND MSI-H mCRC

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mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high

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CLINICAL TAKEAWAYS

- **Dual immunotherapy is now 1st line for dMMR mCRC patients:** CheckMate 8HW demonstrated significant benefit from adding ipilimumab to nivolumab in dMMR patients regardless of *BRAF* status
- **FOLFOX + encorafenib/cetuximab is a new 1st line standard for *BRAF*-mutant/pMMR mCRC:** BREAKWATER showed the combination of encorafenib/cetuximab with FOLFOX chemotherapy significantly improves outcomes, doubling survival in *BRAF*V600E-mutant patients
- **Encorafenib + cetuximab remains effective post-immunotherapy:** for dMMR and *BRAF*-mutant patients progressing after immunotherapy, 2nd line treatment with encorafenib + cetuximab is effective, showing comparable benefit regardless of MMR status, supported by real-world evidence
- **Clear treatment sequencing is emerging:**
  - **dMMR/*BRAF*-mutant mCRC:** 1) immunotherapy (ipi-nivo), 2) targeted therapy (encorafenib + cetuximab), and 3) chemotherapy as a third-line option
  - **pMMR/*BRAF*-mutant mCRC:** 1) FOLFOX +EC, 2) chemotherapy/anti-angiogenesis), and 3) FTD-TPI/bevacizumab as a third-line option

d/pMMR, deficient/proficient mismatch repair; ipi, ipilimumab; mCRC, metastatic colorectal cancer; FOLFOX, fluorouracil / leucovorin / oxaliplatin; FTD-TPI, trifluridine-tipiracil; nivo, nivolumab

EDUCATIONAL OBJECTIVES

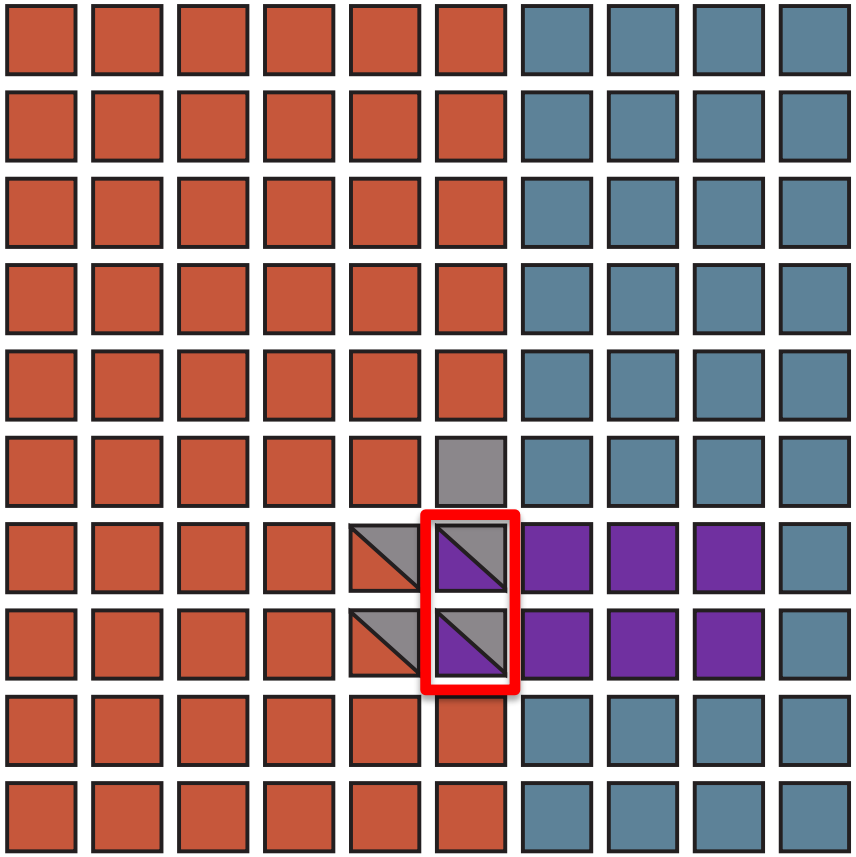
1. Understand **clinical trial data and real-world evidence** of therapies for the **treatment of *BRAF*V600E-mutant and MSI-H mCRC** and relevant patient subgroups

2. Recognise the appropriate **sequencing of therapies** for the treatment of ***BRAF*V600E-mutant and MSI-H mCRC** across the patient journey to ensure **optimal outcomes**

mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high

MOLECULAR SUBGROUPS OF mCRC

ACCORDING TO INTERNATIONAL GUIDELINES

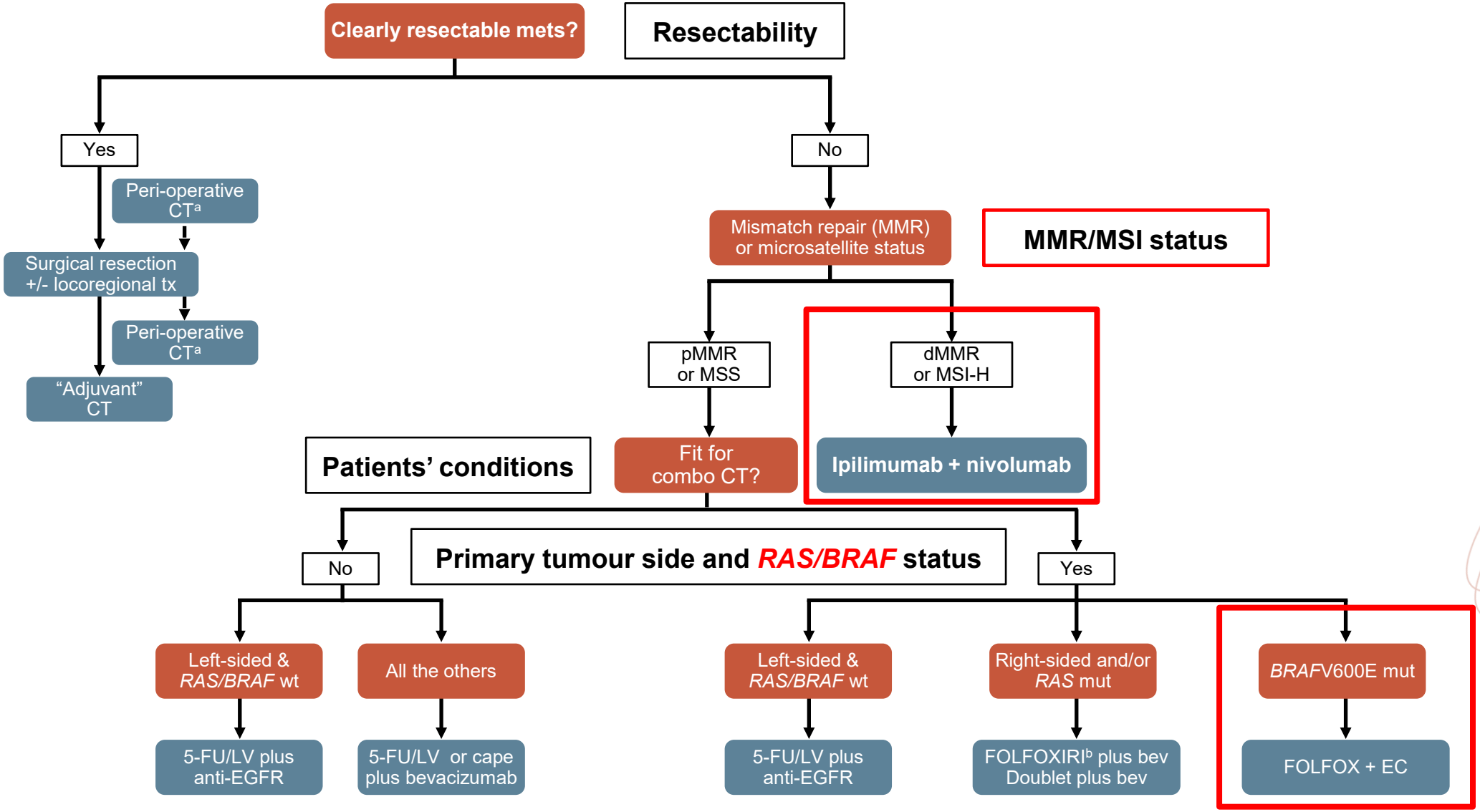


- dMMR/MSI-high
- *RAS*-mutant
- *BRAF*V600E-mutant
- No genomic alterations

dMMR, deficient mismatch repair; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high

Cervantes A, et al. Ann Oncol 2023;34(1):10-32; Cervantes A, et al. Ann Oncol. 2024;35(2):241-243

CHOICE OF THE FIRST-LINE



[a] Not in dMMR/MSI-H?; [b] Only if <75 years old (71-75 years old with ECOG performance status 0)

bev, bevacizumab; cape, capecitabine; CT, chemotherapy; (d/p)MMR, (deficient/proficient) mismatch repair; EC, encorafenib-cetuximab; FOLFOX(IRI), fluorouracil / leucovorin / oxaliplatin (/ irinotecan); mets, metastases; MSI-H, microsatellite instability-high; MSS, microsatellite stable; mut, mutant; tx, treatment; wt, wild-type

Adapted from Cremolini C, ESMO 2022, Educational Session

CHECKMATE 8HW – STUDY DESIGN

- CheckMate 8HW is a randomised, multicentre, open-label phase 3 study[a]

Key eligibility criteria:
- Histologically confirmed unresectable or metastatic CRC
- MSI-H/dMMR status by local testing
- Immunotherapy-naïve
- ECOG PS 0 or 1

Stratification factors:
- Prior lines of treatment (0 vs 1 vs ≥2)
- Primary tumour location (right vs left)

R 2:2:1

N=353 → **NIVO 240 mg Q2W for 6 doses, followed by NIVO 480 mg Q4W[b]**

N=354 → **NIVO 240 mg + IPI 1 mg/kg Q3W for 4 doses,[c] followed by NIVO 480 mg Q4W[b]**

N=132 → **Investigator's choice chemo[d] (mFOLFOX6 or FOLFIRI ± bevacizumab or cetuximab)**

Treatment until disease progression, unacceptable toxicity, withdrawal of consent (all arms), or a maximum treatment duration of 2 years (NIVO and NIVO + IPI arms only)

Dual primary endpoints in patients with centrally confirmed MSI-H/dMMR status[e]:
- PFS by BICR[f] (NIVO + IPI vs chemo in the 1L setting)
- PFS by BICR[f] (NIVO + IPI vs NIVO across all lines)

Other select endpoints:
- Safety
- ORR by BICR[f] (NIVO + IPI vs NIVO across all lines)
- HRQoL
- OS

- At data cutoff (August 28, 2024), the median follow-up[g] was 47.0 months (range, 16.7-60.5)

[a] ClinicalTrials.gov. NCT04008030; [b] Patients with ≥2 prior lines are randomised only to the NIVO or NIVO + IPI arms; [c] Patients can continue NIVO treatment upon early IPI discontinuation; [d] Patients receiving investigator's choice of chemo are eligible to receive NIVO + IPI upon progression (crossover treatment); [e] Confirmed using either IHC and/or polymerase chain reaction-based tests; [f] Evaluated using RECIST v1.1; [g] Time between randomisation and data cutoff among all randomised patients across all 3 treatment arms

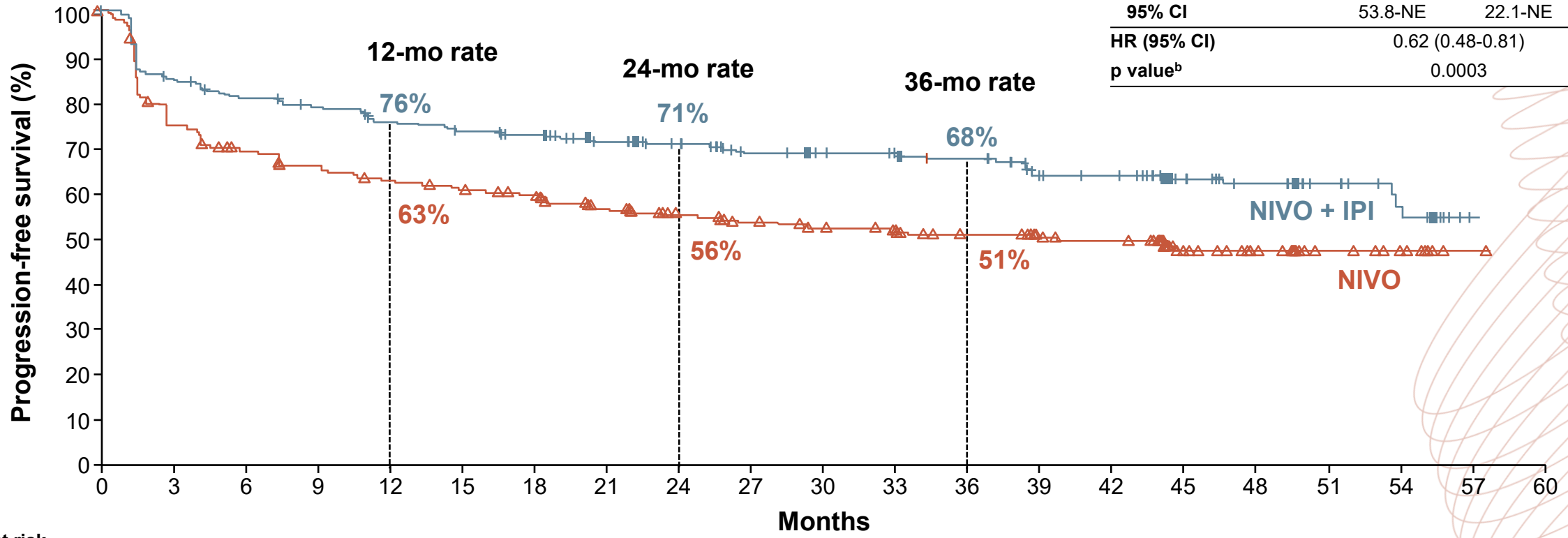
1L, first-line; BICR, blinded independent central review; chemo, chemotherapy; CRC, colorectal cancer; dMMR, deficient mismatch repair; ECOG PS, Eastern Cooperative Oncology Group performance status; FOLFIRI, fluorouracil / leucovorin / irinotecan; HRQoL, health related quality of life; IPI, ipilimumab; IHC, immunohistochemistry; mFOLFOX6, modified fluorouracil / leucovorin / oxaliplatin; MSI-H, microsatellite instability-high; NIVO, nivolumab; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q2/3/4W, every 2/3/4 weeks; R, randomisation; RECIST, Response Evaluation Criteria in Solid Tumours

André T, et al. J Clin Oncol. 43(Number 4_suppl; abstract LBA143) [ASCO GI 2025; oral presentation]; André T, et al. Lancet. 2025;405:383-395

CHECKMATE 8HW: NIVO +/- IPI ACROSS ALL LINES OF THERAPY IN dMMR/MSI-H mCRC

PROGRESSION-FREE SURVIVAL

Centrally confirmed MSI-H/dMMR	NIVO + IPI (N=296)	NIVO (N=286)
Median PFS, mo[a]	NR	39.3
95% CI	53.8-NE	22.1-NE
HR (95% CI)	0.62 (0.48-0.81)	
p value[b]	0.0003	



No. at risk

NIVO + IPI	296	248	234	225	214	207	200	180	164	146	136	134	121	102	100	61	54	29	23	0	0
NIVO	286	210	191	179	169	164	158	141	124	109	98	95	81	72	69	39	31	15	12	1	0

[a] Per BICR; [b] Boundary for statistical significance: p<0.0095

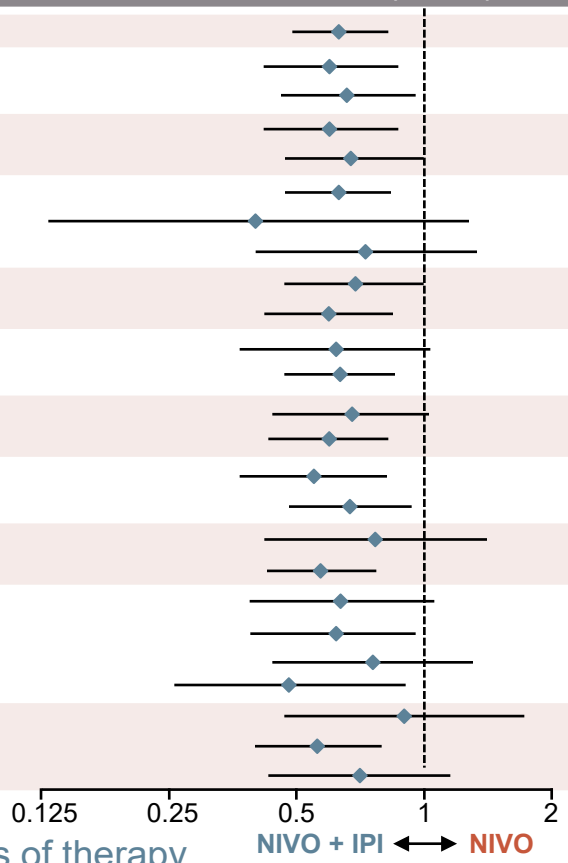
BICR, blinded independent central review; CI, confidence interval; dMMR, deficient mismatch repair; HR, hazard ratio; IPI, ipilimumab; mCRC, metastatic colorectal cancer; mo, months; MSI-H, microsatellite instability-high; NE, not evaluable; NIVO, nivolumab; NR, not reached; PFS, progression-free survival

André T, et al. J Clin Oncol. 43(4_suppl; abstract LBA143) [ASCO GI 2025; oral presentation]; André T, et al. Lancet. 2025;405:383-395

CHECKMATE 8HW – NIVO +/- IPI ACROSS ALL LINES OF THERAPY IN dMMR/MSI-HIGH mCRC

PROGRESSION-FREE SURVIVAL SUBGROUP ANALYSIS

Category (centrally confirmed MSI-H/dMMR)	Subgroup	Median PFS,[a] mo		Unstratified HR
		NIVO + IPI	NIVO	
Overall (N=582)		NR	39.3	0.63
Age, years	<65 (n=321)	NR	NR	0.60
	≥65 (n=261)	NR	29.4	0.66
Sex	Male (n=284)	NR	28.2	0.60
	Female (n=298)	NR	NR	0.67
Region	US/Canada/Europe (n=415)	NR	29.4	0.63
	Asia (n=52)	NR	NR	0.40
	Rest of world (n=115)	NR	NR	0.73
EGOG PS	0 (n=313)	54.1	NR	0.69
	1 (n=269)	NR	18.2	0.60
Tumour sidedness	Left (n=152)	NR	NR	0.62
	Right (n=430)	NR	33.2	0.64
Liver metastases[a,b]	Yes (n=210)	NR	NR	0.68
	No (n=368)	NR	33.2	0.60
Peritoneal metastases[a,b]	Yes (n=226)	54.1	24.8	0.55
	No (n=352)	NR	NR	0.67
Tumour cell PD-L1 expression	≥1% (n=133)	NR	NR	0.77
	<1% (n=427)	NR	24.8	0.57
***BRAF/KRAS/NRAS* mutation status**	*BRAF/KRAS/NRAS* all wild type (n=156)	NR	44.3	0.64
	BRAF mutant (n=179)	NR	25.9	0.62
	KRAS or *NRAS* mutant (n=125)	NR	NR	0.76
	Unknown (n=114)	54.1	38.1	0.48
Clinical history of Lynch syndrome	Yes (n=83)	53.8	38.1	0.90
	No (n=334)	NR	44.3	0.56
	Unknown (n=156)	NR	33.2	0.71



- PFS consistently favoured NIVO + IPI vs NIVO in prespecified subgroups across all lines of therapy

[a] Per BICR; [b] Patients may have had more than one site of metastasis

BICR, blinded independent centra review; CI, confidence interval; dMMR, deficient mismatch repair; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IPI, ipilimumab; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high; NIVO, nivolumab; NR, not reached; PFS, progression-free survival; US, United States

André T, et al. J Clin Oncol. 43(4_suppl; abstract LBA143) [ASCO GI 2025; oral presentation]; André T, et al. Lancet. 2025;405:383-395

BREAKWATER: FOLFOX/ENCO/CET VS SOC IN FIRST-LINE *BRAF*-MUTANT mCRC

Inclusion criteria

- Age ≥16 years (or ≥18 years based on country)
- No prior systemic treatment for metastatic disease
- Measurable disease (RECIST 1.1)
- *BRAF*V600E-mutant mCRC by local or central laboratory testing
- ECOG PS 0 or 1
- Adequate bone marrow, hepatic, and renal function

Exclusion criteria

- Prior BRAF or EGFR inhibitors
- Symptomatic brain metastases
- MSI-H/dMMR tumours (unless patients were ineligible to receive immune checkpoint inhibitors due to a pre-existing medical condition)
- Presence of a *RAS* mutation

N=637

R
1:1:1

The EC arm was dropped following interim analysis

- EC (n=158)
- EC + mFOLFOX6 (n=236)
- SOC (n=243)

SOC = chemotherapy with or without bevacizumab
Stratified by regions (US/Canada vs Europe vs Rest of World) and ECOG PS (0 vs 1)

Dual primary endpoints:
PFS and ORR by BICR
(EC + mFOLFOX6 vs SOC)

Key secondary endpoint:
OS (EC + mFOLFOX6 vs SOC)

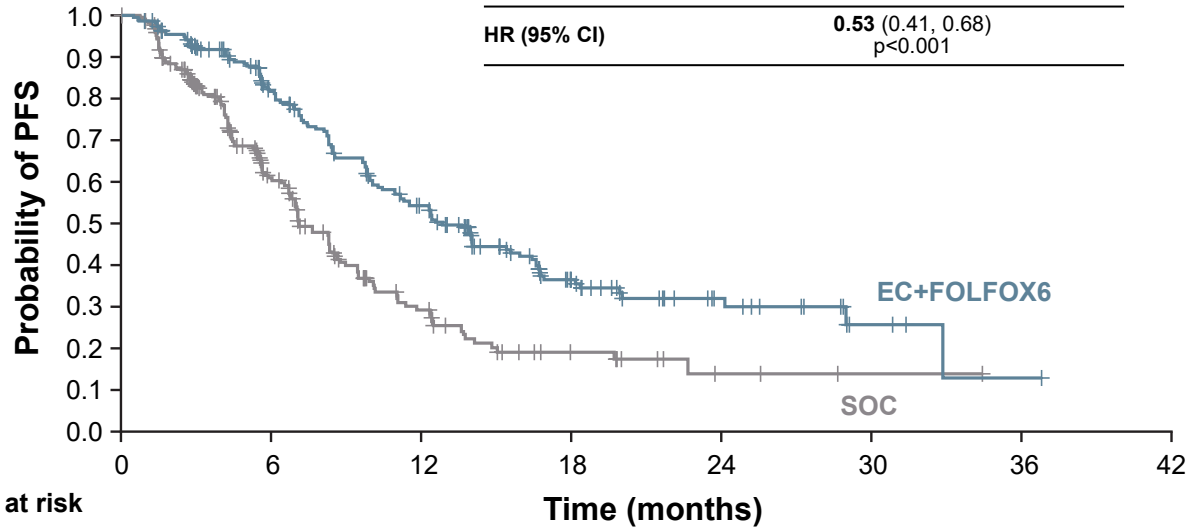
BICR, blinded independent central review; CET, cetuximab; dMMR, deficient mismatch repair; EC, encorafenib plus cetuximab; ECOG PS, Eastern Cooperative Oncology Group performance status; ENCO, encorafenib; mCRC, metastatic colorectal cancer; (m)FOLFOX(6), (modified) fluorouracil / leucovorin / oxaliplatin; MSI-H, microsatellite instability-high; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R, randomisation; RECIST, Response Evaluation Criteria in Solid Tumours; SOC, standard of care

Elez E, et al. N Eng J Med. 2025; 392:2425-37; Kopetz S, et al. J Clin Oncol. 43(4_suppl; abstract 16) [ASCO GI 2025; oral presentation]

BREAKWATER: FOLFOX/ENCO/CET VS SOC IN FIRST-LINE *BRAF*-MUTANT mCRC

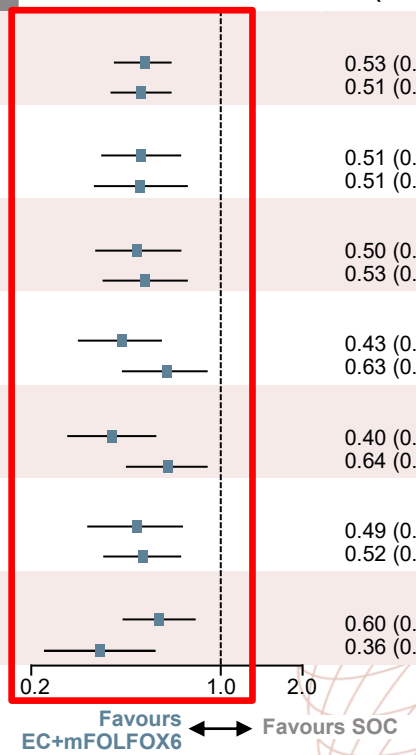
PROGRESSION-FREE SURVIVAL

	EC + mFOLFOX6 N=236	SOC N=243
No. of events, n (%)	122 (51.7)	132 (54.3)
Median PFS, mo (95% CI)	**12.8** (11.2, 15.9)	**7.1** (6.8, 8.5)
HR (95% CI)	**0.53** (0.41, 0.68) p<0.001	



No. at risk							
EC+ FOLFOX6	236	156	96	39	16	4	1
SOC	243	100	34	11	3	1	0

Subgroup	No. of events/no. of patients: EC + mFOLFOX6	No. of events/no. of patients: SOC	Hazard ratio (95% CI)
All patients			
Stratified	122/236	132/243	0.53 (0.41-0.68)
Unstratified	122/236	132/243	0.51 (0.40-0.65)
Age			
<65 years	78/150	71/139	0.51 (0.37-0.71)
≥65 years	44/86	61/104	0.51 (0.34-0.75)
Sex			
Male	59/123	63/119	0.50 (0.35-0.72)
Female	63/113	69/124	0.53 (0.37-0.75)
ECOG performance-status score			
0	60/131	74/136	0.43 (0.30-0.61)
1	62/105	58/107	0.63 (0.44-0.90)
No. of organs involved			
≤2	52/119	66/127	0.40 (0.28-0.58)
≥3	70/117	66/116	0.64 (0.45-0.90)
Location of tumour			
Left side of colon	51/90	53/98	0.49 (0.33-0.73)
Right side of colon	71/146	79/145	0.52 (0.37-0.72)
Liver metastases			
Yes	87/147	86/160	0.60 (0.44-0.81)
No	35/89	46/83	0.36 (0.23-0.57)



Data cutoff: January 6, 2025.

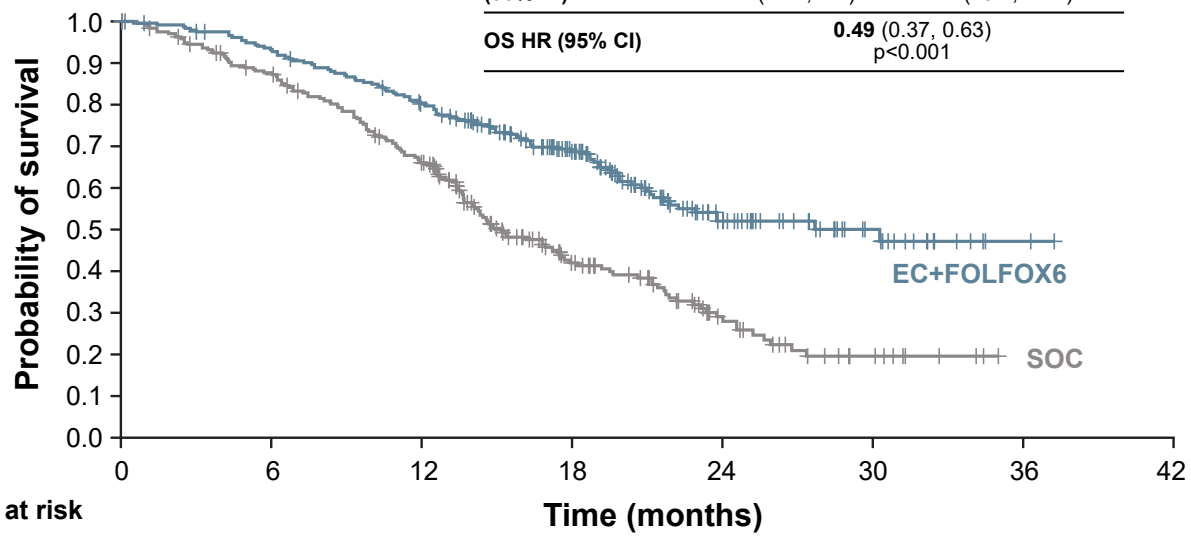
CET, cetuximab; CI, confidence interval; EC, encorafenib plus cetuximab; ECOG PS, Eastern Cooperative Oncology Group; ENCO, encorafenib; HR, hazard ratio; mCRC, metastatic colorectal cancer; (m)FOLFOX(6), (modified) fluorouracil / leucovorin / oxaliplatin; mo, months; PFS, progression-free survival; SOC, standard of care

Elez E, et al. N Eng J Med. 2025; 392: 2425-37

BREAKWATER: FOLFOX/ENCO/CET VS SOC IN FIRST-LINE *BRAF*-MUTANT mCRC

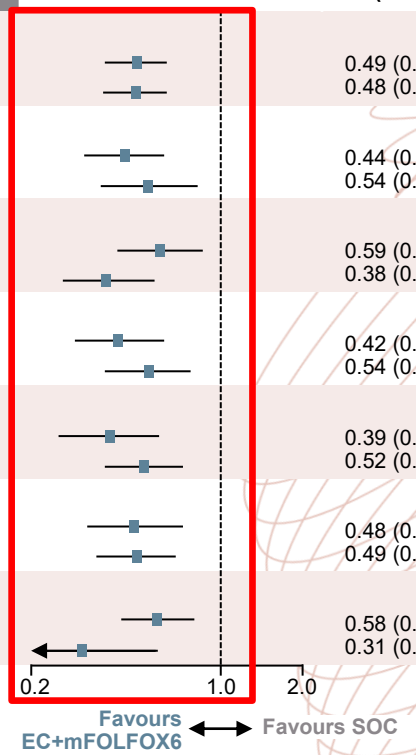
OVERALL SURVIVAL

	EC + mFOLFOX6 N=236	SOC N=243
No. of events, n (%)	94 (39.8)	148 (60.9)
Median OS, mo (95% CI)	**30.3** (21.7, NE)	**15.1** (13.7, 17.7)
OS HR (95% CI)	**0.49** (0.37, 0.63) p<0.001	



No. at risk								
EC+ FOLFOX6	236	216	182	121	48	17	2	0
SOC	243	202	147	64	27	9	0	0

Subgroup	No. of events/no. of patients: EC + mFOLFOX6	No. of events/no. of patients: SOC	Hazard ratio (95% CI)
All patients			
Stratified	94/236	148/243	0.49 (0.38-0.63)
Unstratified	94/236	148/243	0.48 (0.37-0.62)
Age			
<65 years	56/150	85/139	0.44 (0.31-0.62)
≥65 years	38/86	63/104	0.54 (0.36-0.82)
Sex			
Male	54/123	71/119	0.59 (0.42-0.85)
Female	40/113	77/124	0.38 (0.26-0.56)
ECOG performance-status			
0	42/131	76/136	0.42 (0.29-0.62)
1	52/105	72/107	0.54 (0.38-0.77)
No. of organs involved			
≤2	32/119	66/127	0.39 (0.25-0.59)
≥3	62/117	82/116	0.52 (0.38-0.73)
Side of tumour			
Left	38/90	62/98	0.48 (0.32-0.72)
Right	56/146	86/145	0.49 (0.35-0.68)
Liver metastases			
Yes	73/147	104/160	0.58 (0.43-0.78)
No	21/89	44/83	0.31 (0.18-0.52)

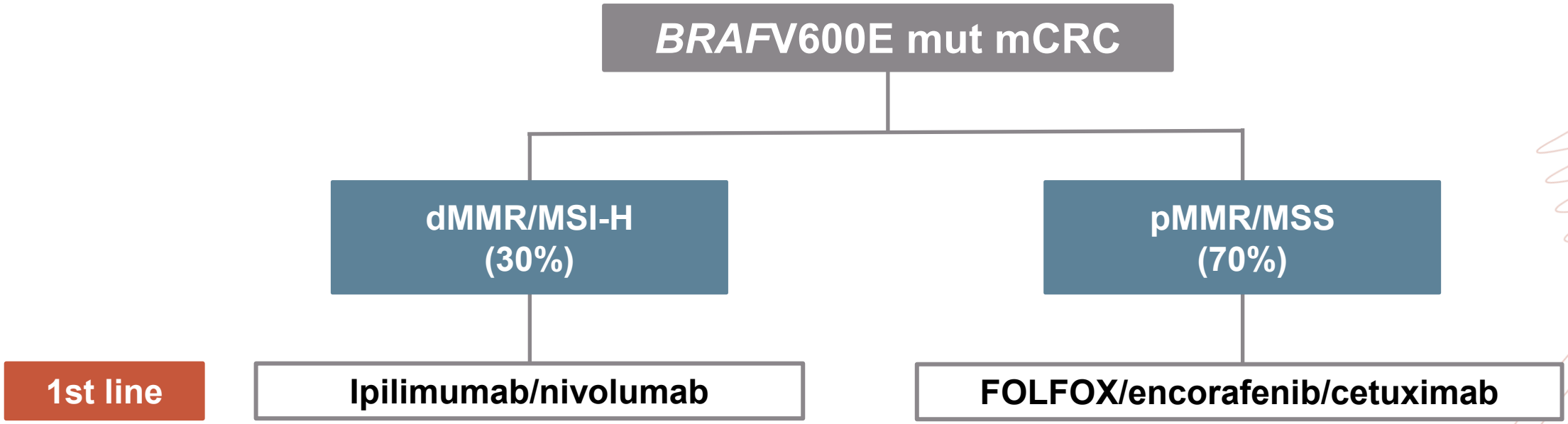


Data cutoff: January 6, 2025.

CET, cetuximab; CI, confidence interval; EC, encorafenib plus cetuximab; ECOG PS, Eastern Cooperative Oncology Group; ENCO, encorafenib; HR, hazard ratio; mCRC, metastatic colorectal cancer; (m)FOLFOX(6), (modified) fluorouracil / leucovorin / oxaliplatin; mo, months; OS, overall survival; SOC, standard of care

Elez E, et al. N Eng J Med. 2025;392: 2425-37

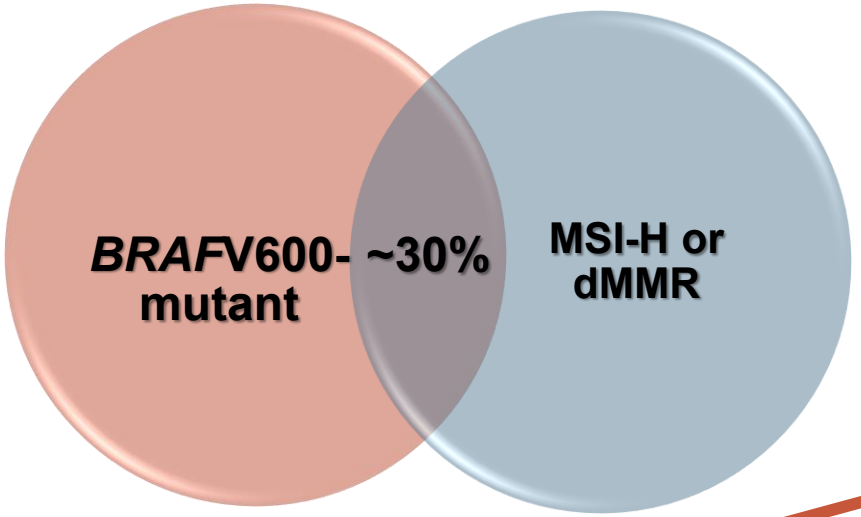
CONTINUUM OF CARE FOR *BRAF*V600E-MUTANT mCRC PATIENTS



Cremolini C. Personal communication

d/pMMR, deficient/proficient mismatch repair; FOLFOX, fluorouracil / leucovorin / oxaliplatin; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high; MSS, microsatellite stable; mut, mutant

ON THE HORIZON FOR UNTREATED dMMR/MSI-H AND *BRAF*-MUTANT mCRC



SEAMARK

Patient Population	Open-Label, Multicenter, Randomized, Phase 2 (N=104)

- Previously untreated stage IV mCRC
- Locally confirmed MSI-H/dMMR
- Locally confirmed *BRAF* V600E mutation in tumor tissue or blood
- Measurable disease per RECIST 1.1
- ECOG PS ≤1
- Adequate organ function

Randomization 1:1 (stratified by ECOG PS: 0 vs 1)

- Triplet arm (arm A): Encorafenib + cetuximab + pembrolizumab (n=52)
- Control arm (arm B): Pembrolizumab (n=52)

Primary Endpoint	PFS per investigator according to RECIST 1.1
Secondary Endpoints	Safety and tolerability, OS, OR, DOR, and QOL

Accrual completed

NCT05217446

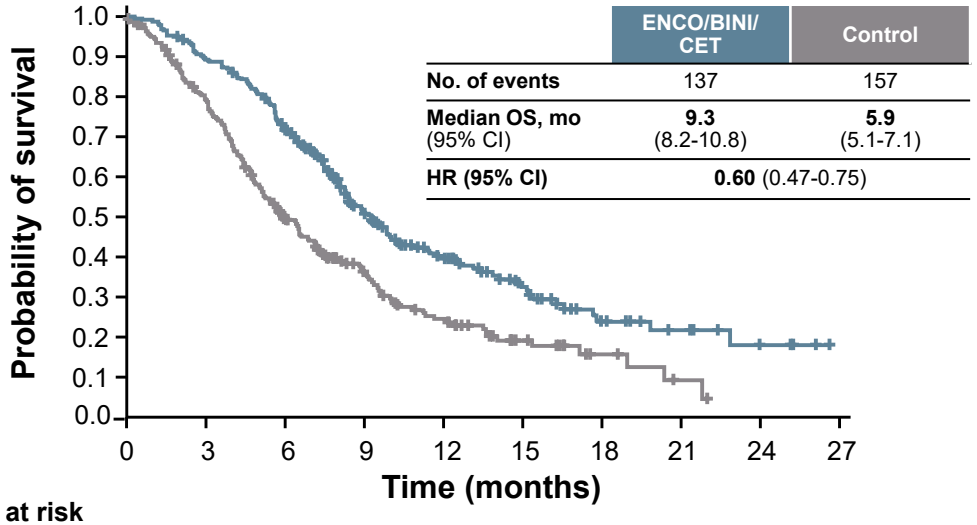
dMMR, deficient mismatch repair; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high; OR, objective response; OS, overall survival; PFS, progression-free survival; QOL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumours

Kopetz S, et al. J Clin Oncol. 2022;40(16_suppl; abstract TPS3634) [ASCO 2022; oral presentation]

BEACON: ENCO/CET VS SOC IN PRE-TREATED *BRAF*-MUTANT mCRC

OVERALL SURVIVAL RESULTS[a]

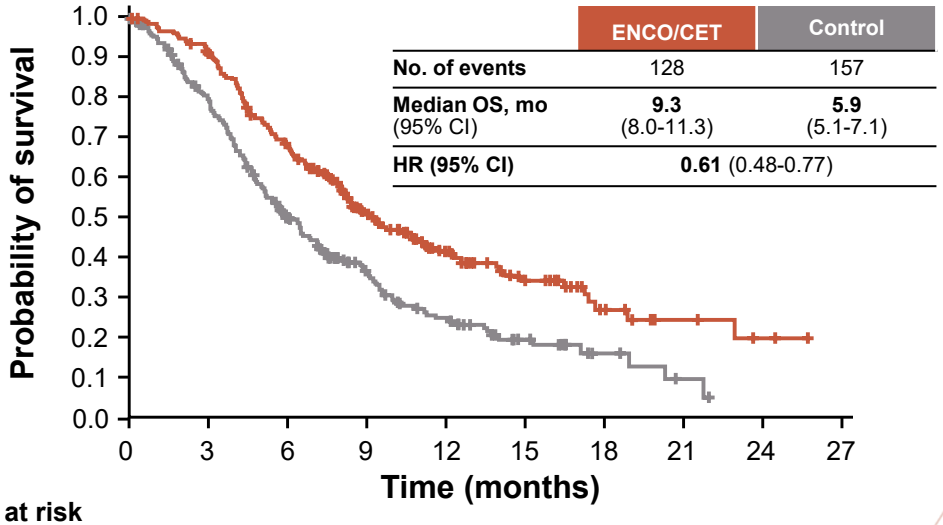
ENCO/BINI/CET vs control



	ENCO/BINI/CET	Control
No. of events	137	157
Median OS, mo (95% CI)	**9.3** (8.2-10.8)	**5.9** (5.1-7.1)
HR (95% CI)	**0.60** (0.47-0.75)	

No. at risk										
ENCO/BINI/CET	224	198	157	89	56	33	15	9	4	0
Control	221	166	98	54	33	15	6	2	0	0

ENCO/CET vs control



	ENCO/CET	Control
No. of events	128	157
Median OS, mo (95% CI)	**9.3** (8.0-11.3)	**5.9** (5.1-7.1)
HR (95% CI)	**0.61** (0.48-0.77)	

No. at risk										
ENCO/CET	220	197	143	83	47	28	13	7	2	0
Control	221	166	98	54	33	15	6	2	0	0

OBJECTIVE RESPONSE RATE

Confirmed response by blinded central review	ENCO/BINI/CET (triplet) N=224	ENCO/CET (doublet) N=220	Control N=221
Objective response rate, %	**27%**	**20%**	**2%**
95% CI	21%, 33%	15%, 25%	<1%, 5%
p value vs control	<0.0001	<0.0001	NA

[a] Median follow-up: 12.8 months

BINI, binimetinib; CET, cetuximab; CI, confidence interval; ENCO, encorafenib; HR, hazard ratio; mCRC, metastatic colorectal cancer; mo, months; NA, not applicable; OS, overall survival; SOC, standard of care

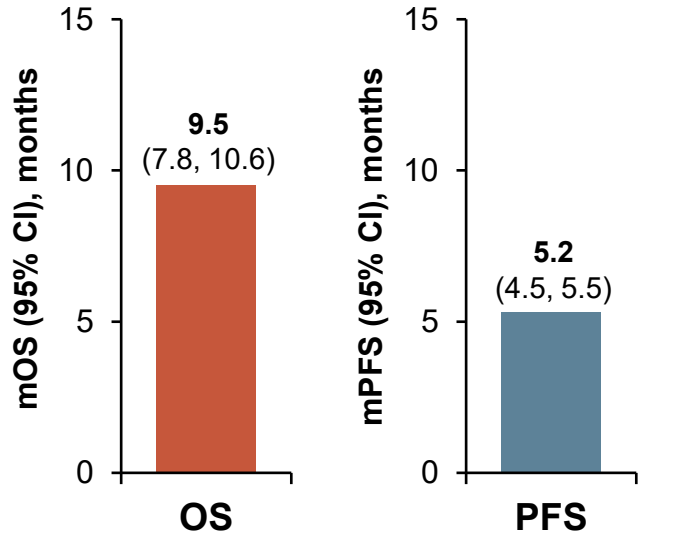
Tabernero J, et al. J Clin Oncol. 2021;39:273-284

CONFIRMATORY REAL-WORLD EVIDENCE: FINDINGS CONSISTENT WITH THE BEACON TRIAL, FOR EC TREATMENT IN *BRAF*-MUTATED CRC

BEACON EFFICACY FINDINGS (DOUBLET THERAPY)
Median PFS: 4.3 months; median OS: 9.3 months

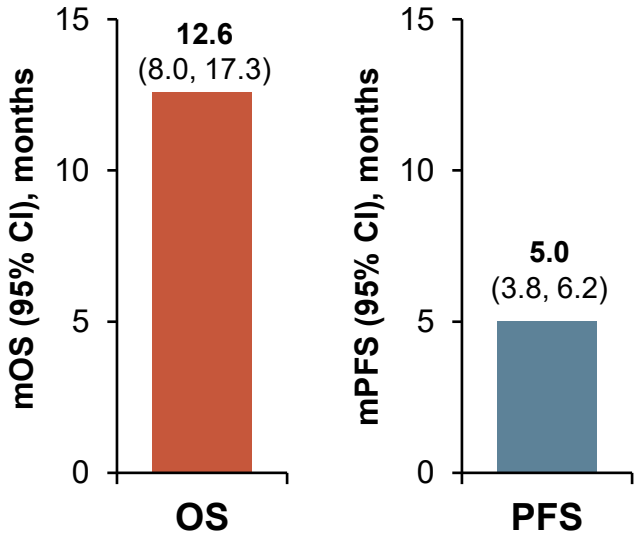
BERING CRC (N=150)
(3 Sep 2020 to 26 Apr 2024; ongoing)[1]

Encorafenib + cetuximab (n=141; FAS)



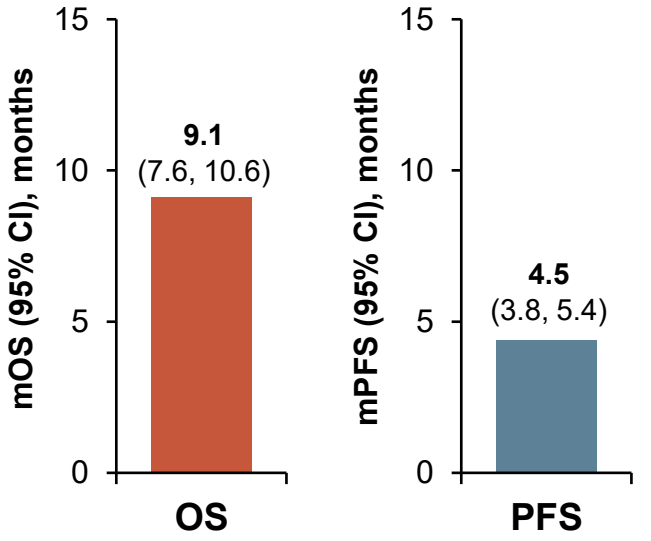
CONFIDENCE (N=81)
(Mar to Jul 2022)[2]

Encorafenib + cetuximab (N=81)



B-REAL, an AGEO study (N=201)
(Jan 2020 to Jun 2022)[3]

Encorafenib + cetuximab (n=176)



AGEO, Association des Gastro-Entérologues Oncologues; CI, confidence interval; FAS, full analysis set; (m)OS, (median) overall survival; (m)PFS, (median) progression-free survival

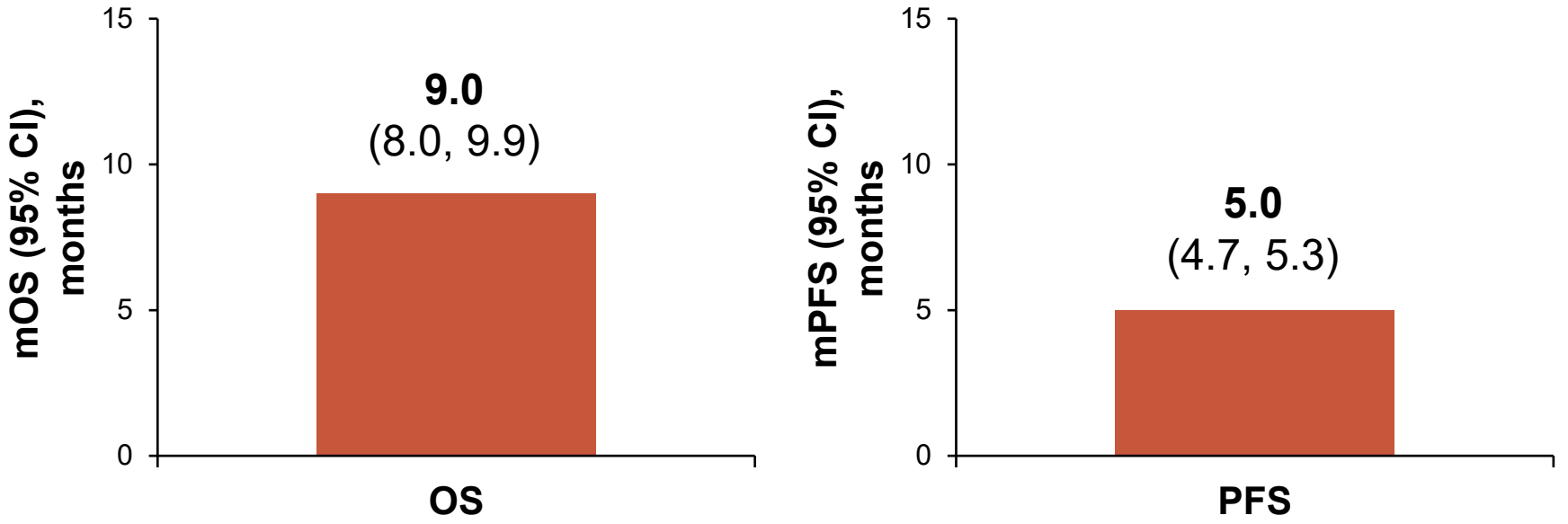
1. Stintzing S, et al. Annals of Oncology (2025) 36 (suppl_1): S1-S65. 10.1016/annonc/annonc1820 (ESMO GI 2025; poster presentation); 2; Fernandez Montes A, et al. ESMO Real World Data and Digital Oncology 2024; 5:100055; 3. Gallois C, et al. ESMO Open 2024; 9: doi.org/10.1016/j.esmoop.2024.103696

CONFIRMATORY REAL-WORLD EVIDENCE: FINDINGS CONSISTENT WITH THE BEACON TRIAL, FOR EC TREATMENT IN *BRAF*-MUTATED CRC

RETROSPECTIVE, LONGITUDINAL, POOLED ANALYSIS

Results from pooled dataset (N=709)
(BERING CRC, B-REAL, CATAMARAN, CONFIDENCE, GONO Cohort)

Encorafenib + cetuximab (n=709)



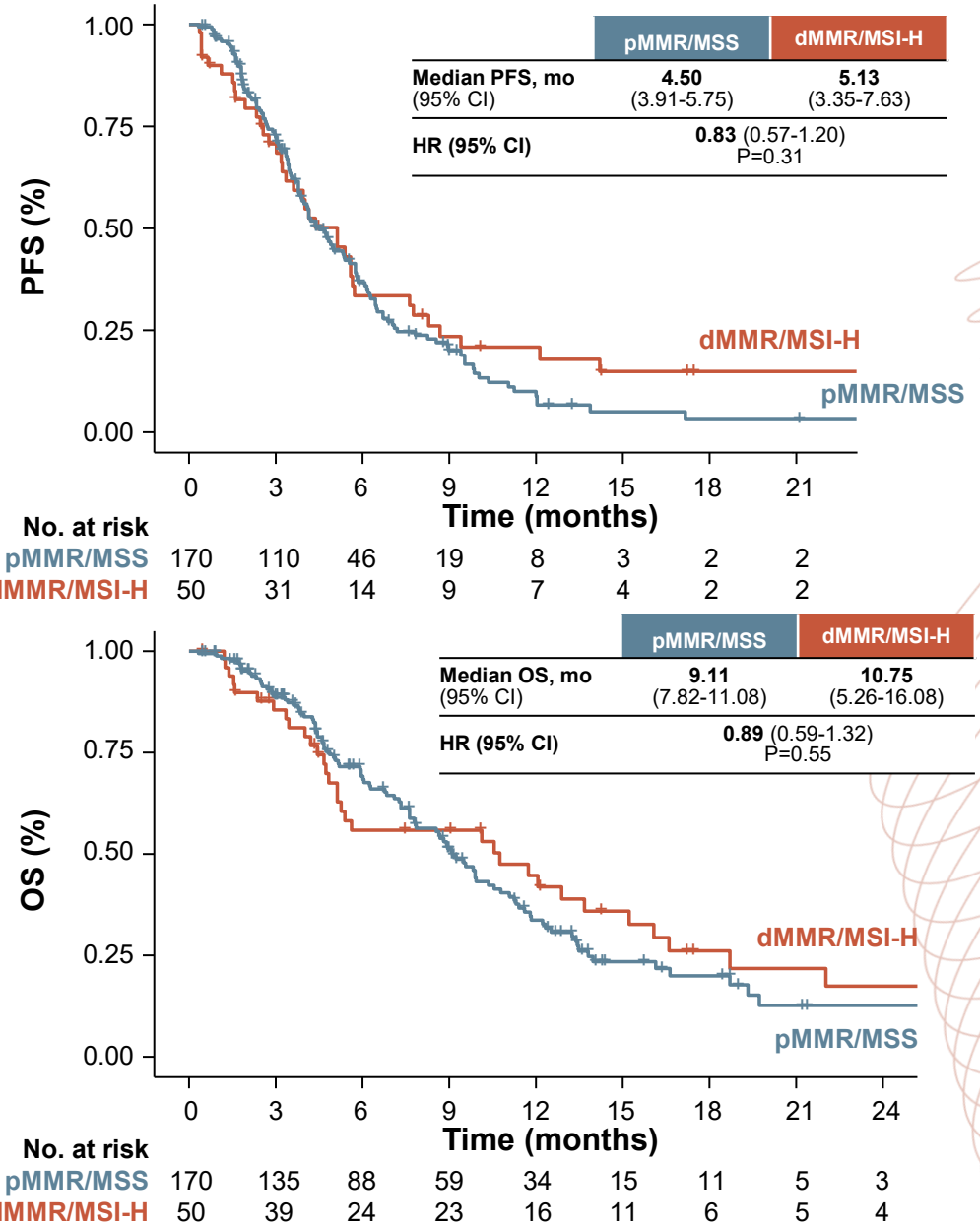
CI, confidence interval; EC, encorafenib +cetuximab; (m)OS, (median) overall survival; (m)PFS, (median) progression-free survival

Cremolini C, et al. Ann Oncol. 2025;36(supplement 1: S23-S24) [ESMO GI 2025; poster presentation]

BRAFi + EGFRi ± MEKi FOLLOWING ICIs IN *BRAF*-MUTANT AND dMMR/MSI-H mCRC[1,2]

B-REAL and AGEO-IMMUNODIG MSI, AGEO studies (N=220) (Jan 2017 to Jan 2024)

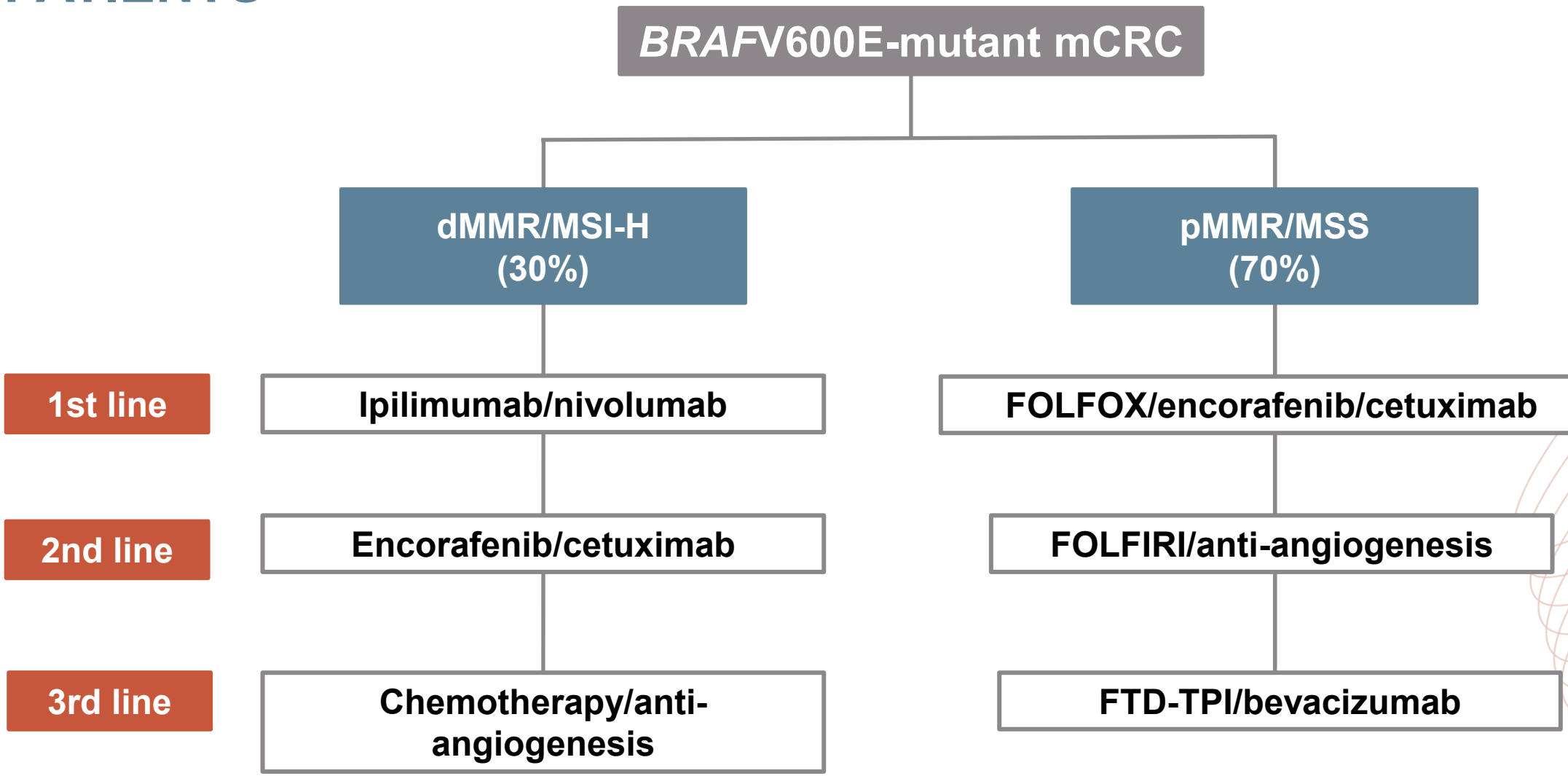
	BRAFV600E-mut pMMR/MSS (n=170)	BRAFV600E-mut dMMR/MSI-H (n=50)	HR (95% CI)	p value
ORR, %	32	18		0.09
DCR, %	73	60		0.11
mPFS, months	4.50	5.13	0.83	0.31
mOS, months	9.11	10.75	0.89	0.55



AGEO, Association des Gastro-Entérologues Oncologues; BRAFi, BRAF inhibitor; CI, confidence interval;
BRAFi, BRAF inhibitor; DCR, disease control rate; d/pMMR, deficient/proficient mismatch repair; EGFRi, EGFR inhibitor; HR, hazard ratio; ICI, immune checkpoint inhibitor; mCRC, metastatic colorectal cancer; MEKi, MEK inhibitor; MSI-H, microsatellite instability-high;
(m)OS, (median) overall survival; (m)PFS, (median) progression-free survival; MSS, microsatellite stability; mut, mutant; ORR, overall response rate

1. Ambrosini M, et al. Ann Oncol. 2024;35(Supplement 1; S32) [ESMO GI Congress 2024; poster presentation]; 2. Ambrosini M, et al. Eur J Cancer. 2024;210:114290

CONTINUUM OF CARE FOR *BRAF*V600E-MUTANT mCRC PATIENTS



d/pMMR, deficient/proficient mismatch repair; FOLFIRI, fluorouracil / leucovorin / irinotecan; FOLFOX, fluorouracil / leucovorin / oxaliplatin; FTD-TPI, trifluridine-tipiracil; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high; MSS, microsatellite stable

Cremolini C. Personal communication.

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