

**CME**



**CAST**

**EPISODE 2**

# **Confusion on the Horizon: Novel Therapies Emerging for the Treatment of Endometrial Cancer**

*Supported by an independent educational grants from AstraZeneca Pharmaceuticals and Merck & Co., Inc., Rahway, NJ, USA*



**Richard T. Penson, MD, MRCP**  
Physician at Mass General Brigham  
Associate Professor Harvard Medical School  
Institutional Review Board (IRB) Chair  
Dana Farber Harvard Cancer Center  
Boston, MA



**Matthew A. Powell, MD, FACOG**  
Ira C. and Judith Gall Distinguished Professor  
Division of Gynecologic Oncology  
Washington University School of Medicine  
St. Louis, MO  
Chair, Uterine Corpus Cancer Committee  
National Cancer Institute sponsored NRG Oncology  
Cooperative Group  
Philadelphia, PA



# Learning Objective

Identify the role of agents with novel MOAs in the treatment of endometrial cancer



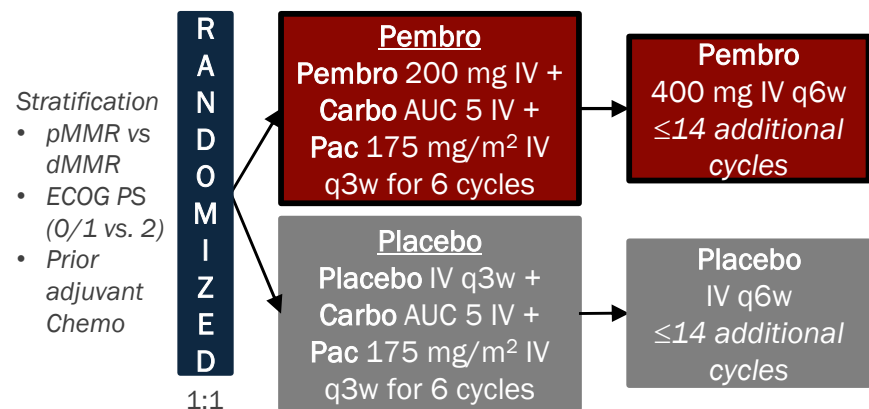
# Endometrial Cancer: Three Cancers in One

- Endometrial cancer has features of
  - Colon – mismatch repair features
  - Breast – estrogen receptor features
  - Ovarian – DNA damage features
- Lynch-associated endometrial cancer
  - Promoter methylation of *MLH1*
  - Older patients, more clinical heterogeneity

# Phase 3 NRG GY018 Trial of Pembrolizumab + Chemo vs. Chemo in Patients With Advanced/Recurrent EC: Study Design and Patients

## Key Eligibility Criteria

- Measurable stage III/IVA or measurable/nonmeasurable stage IVB or recurrent EC, with institutional MMR IHC testing results
- ECOG PS 0-2
- No prior Chemo except adjuvant Chemo if completed  $\geq 12$  months before study



**Primary endpoints:** PFS by INV in pMMR and dMMR

**Secondary endpoints:** Safety, ORR/DOR by BICR or INV by treatment and MMR IHC status, OS in pMMR and dMMR, PRO/QOL in pMMR, concordance of MMR testing

Patient Characteristics, n (%)	dMMR (n=225)		pMMR (n=588)	
	Pembro (n=112)	Placebo (n=113)	Pembro (n=293)	Placebo (n=295)
Median age (range), years	67 (38-81)	66 (37-85)	66 (31-93)	65 (29-90)
ECOG PS, n (%)	0	72 (64.3)	73 (64.6)	196 (66.9)
	1	39 (34.8)	35 (31.0)	88 (30.0)
	2	1 (0.9)	5 (4.4)	9 (3.1)
Histology, n (%)	Clear cell	1 (0.9)	0	17 (5.8)
	Endometrioid, G1	21 (18.8)	35 (31.0)	54 (18.4)
	Endometrioid, G2	52 (46.4)	41 (36.3)	51 (17.4)
	Endometrioid, G3	15 (13.4)	16 (14.2)	53 (18.1)
Serous, n (%)	4 (3.6)	1 (0.9)	78 (26.6)	72 (24.4)
No prior Chemo, n (%)	107 (95.5)	105 (92.9)	221 (75.4)	218 (73.9)

Eskander R, et al. SGO 2023. Abstract 264.

## Local vs Central MMR IHC: dMMR and pMMR Populations

- Strong concordance between local and central MMR IHC assessment
- Agreement: Kappa = 0.88 (95% CI: 0.84-0.91)
- Central MMR was used for all subsequent analyses

AUC = area under the curve; BICR = blinded independent central review; DOR = duration of response; ECOG-PS = Eastern Cooperative Oncology Group Performance Status; INV = investigators; ORR = objective response rate; OS = overall survival; Pembro = pembrolizumab; PFS = progression-free survival; q3w = every 3 weeks; QOL = quality of life.  
Eskander R, et al. ESMO 2023. Abstract LBA43. Eskander R, et al. SGO 2023. Abstract 264.

# NRG GY018 Trial of Pembrolizumab + Chemo vs Chemo in Patients With Advanced/Recurrent EC

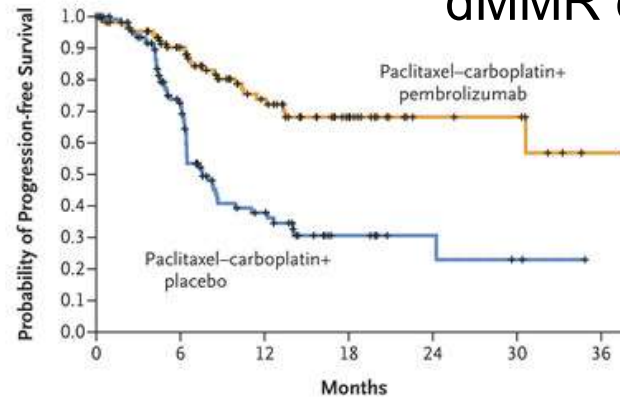
**PFS: Pembrolizumab + chemo was superior to chemo alone**

dMMR cohort:  
NR vs. 7.6 months

pMMR cohort:  
13.1 months vs. 8.7 months

NR = not reached.  
Eskander RN, et al. *N Engl J Med.* 2023;388(23):2159-2170.

## dMMR cohort

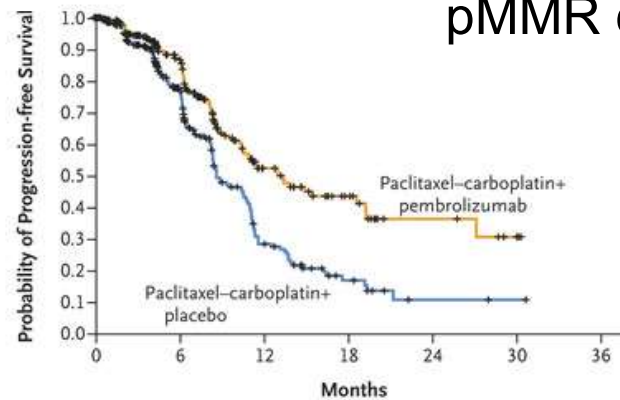


No. of Events	No. of Patients	Median Progression-free Survival (95% CI) mo
26	112	NR (30.6–NR)
59	113	7.6 (6.4–9.9)

Hazard ratio for disease progression or death, 0.30 (95% CI, 0.19–0.48)

No. at Risk	0	6	12	18	24	30	36
Paclitaxel-carboplatin+ pembrolizumab	112	80	44	22	9	8	2
Paclitaxel-carboplatin+ placebo	113	62	24	8	4	2	0

## pMMR cohort

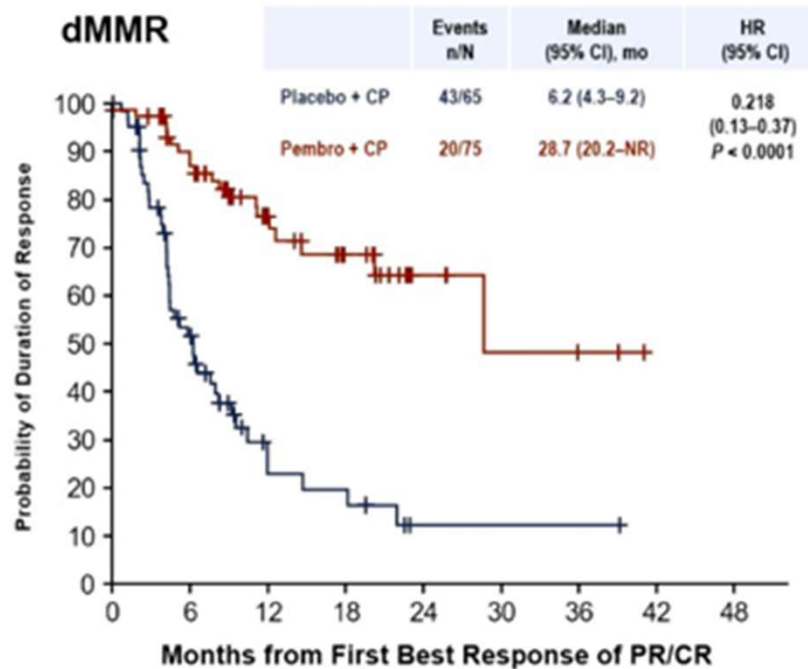


No. of Events	No. of Patients	Median Progression-free Survival (95% CI) mo
89	290	13.1 (10.5–18.8)
133	292	8.7 (8.4–10.7)

Stratified hazard ratio for disease progression or death, 0.54 (95% CI, 0.41–0.71)

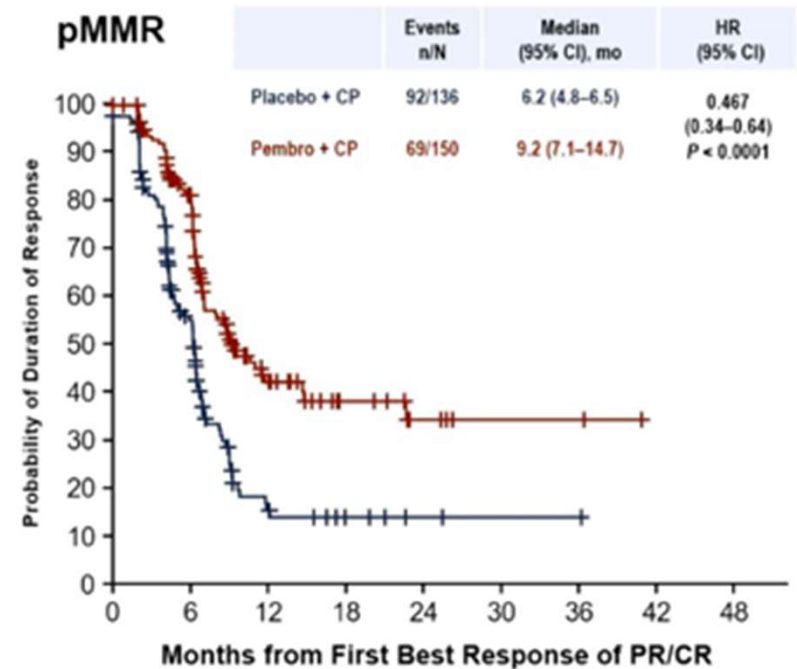
No. at Risk	0	6	12	18	24	30	36
Paclitaxel-carboplatin+ pembrolizumab	290	150	45	20	7	3	0
Paclitaxel-carboplatin+ placebo	292	129	33	10	2	1	0

# NRG GYO18 Trial: DOR by MMR Status in Patients With CR or PR



Number at risk (Cumulative number censored)  
 Placebo + CP 65 (2) 28 (9) 7 (18) 6 (18) 1 (21) 1 (21) 1 (21) 0 (22)  
 Pembro + CP 75 (2) 58 (8) 31 (29) 20 (37) 6 (50) 3 (52) 2 (53) 0 (55)

HR 0.218 (95% CI: 0.13-0.37)  
 $p < .0001$



Number at risk (Cumulative number censored)  
 Placebo + CP 136 (5) 59 (21) 11 (34) 5 (39) 2 (42) 1 (43) 1 (43) 0 (44)  
 Pembro + CP 150 (6) 98 (26) 30 (54) 13 (69) 5 (76) 2 (79) 2 (79) 0 (81)

HR 0.467 (95% CI: 0.34-0.64)  
 $p < .0001$

Data cutoff: August 18, 2023.

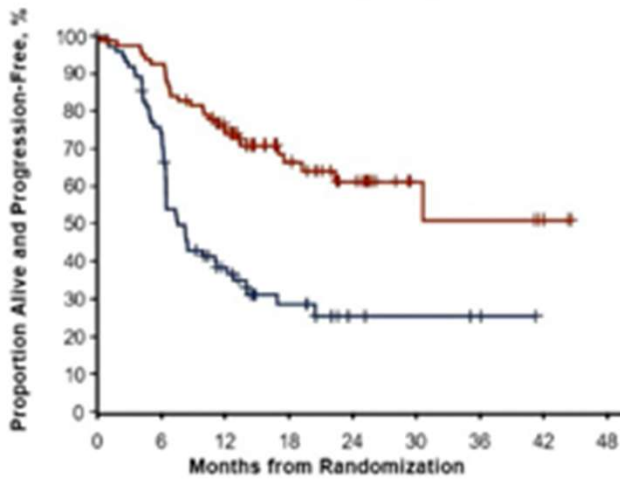
Eskander R, et al. ESMO 2023. Abstract LBA43.



# NRG GYO18 Trial: PFS and Summary by Methylation Status in dMMR Population

## Methylation Pembro + CP vs Placebo + CP

	Events n/N	Median (95% CI), mo	HR (95% CI)
Placebo + CP	51/77	7.5 (6.4-11.3)	0.307 (0.15-0.45) P < 0.0001
Pembro + CP	28/83	NR (22.3-NR)	

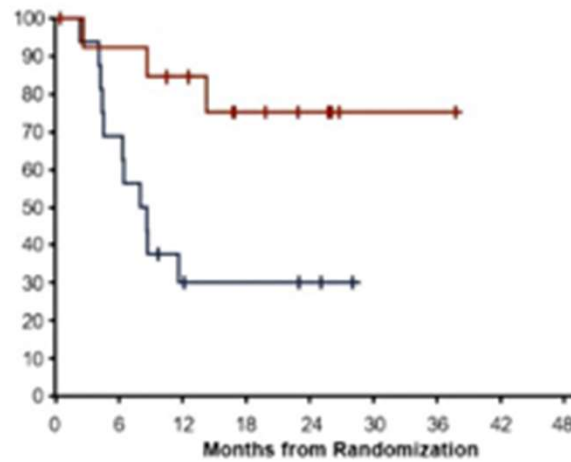


Number at risk (Cumulative number censored)

Time (mo)	0	6	12	18	24	30	36	42	48
Placebo + CP	77 (2)	55 (3)	23 (9)	11 (16)	4 (22)	3 (23)	2 (24)	0 (26)	
Pembro + CP	83 (8)	76 (1)	56 (7)	38 (28)	18 (38)	6 (50)	5 (50)	3 (52)	0 (55)

## No Methylation Pembro + CP vs Placebo + CP

	Events n/N	Median (95% CI), mo	HR (95% CI)
Placebo + CP	11/17	8.3 (4.4-NR)	0.263 (0.07-0.99) P = 0.0172
Pembro + CP	3/13	NR (14.2-NR)	

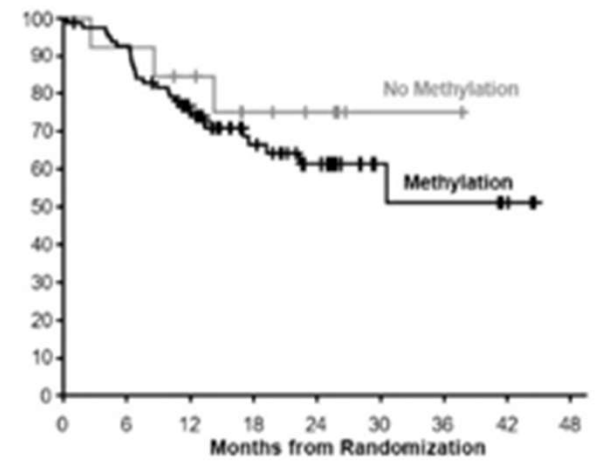


Number at risk (Cumulative number censored)

Time (mo)	0	6	12	18	24	30	36	42	48
Placebo + CP	17 (0)	11 (1)	4 (2)	3 (3)	2 (4)	0 (6)			
Pembro + CP	13 (0)	12 (0)	10 (1)	6 (4)	4 (6)	1 (9)	1 (9)	0 (10)	

## Methylation Status Pembro + CP Arm

	Events n/N	Median (95% CI), mo
No Methylation	3/13	NR (14.2-NR)
Methylation	28/83	NR (22.3-NR)



Number at risk (Cumulative number censored)

Time (mo)	0	6	12	18	24	30	36	42	48
No Methylation	13 (0)	12 (0)	10 (1)	6 (4)	4 (6)	1 (9)	1 (9)	0 (10)	
Methylation	83 (0)	76 (1)	56 (7)	30 (28)	18 (38)	6 (50)	5 (50)	3 (52)	0 (55)

Data cutoff: August 18, 2023.

Eskander R, et al. ESMO 2023. Abstract LBA43.



# NRG GY018 Trial: PFS and Summary by Histology in pMMR Population

Histology	No. of patients	Hazard ratio (95% CI)
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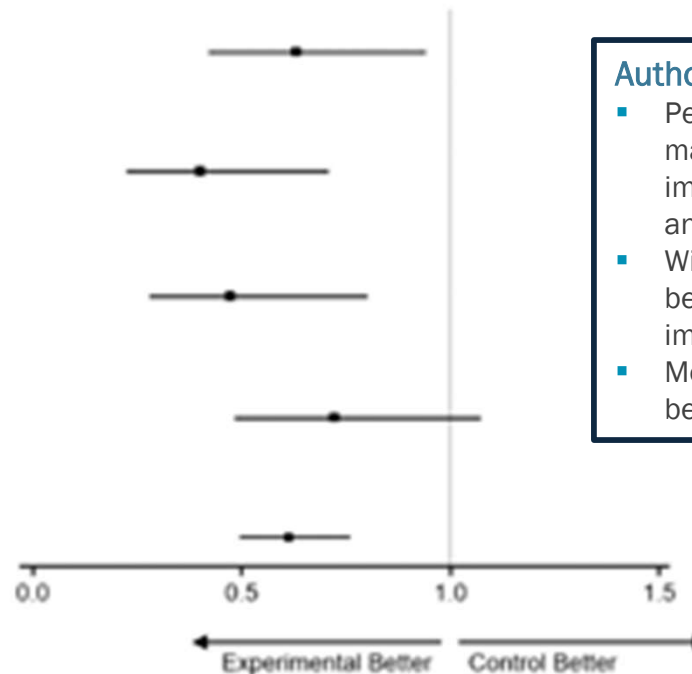
**Endometrioid, G1 or G2**      **207**

**Endometrioid, G3**      **96**

**Other Types**      **128**

**Serous**      **155**

**Overall**      **591**



### Authors' Conclusions

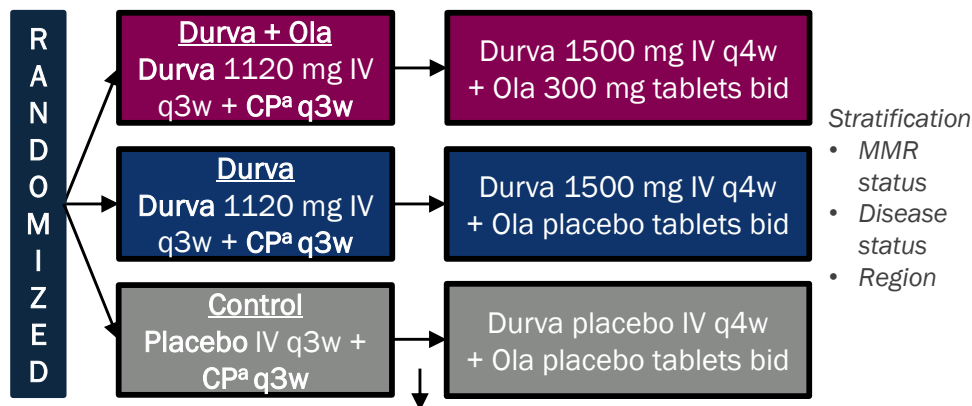
- Pembro + CP followed by Pembro maintenance led to a statistically significant improvement in PFS for patients with dMMR and pMMR EC
- With additional follow-up, the magnitude of benefit was maintained, with significant improvement in ORR and DOR
- Mechanism of MMR loss did not appear to be prognostic of response

EC = endometrial cancer.  
 Data cutoff: August 18, 2023.  
 Eskander R, et al. ESMO 2023. Abstract LBA43.

# DUO-E/GOG-3041/ENGOT-EN10 Trial of Durvalumab + Chemo Followed by Durvalumab ± Olaparib Maintenance in Patients With Advanced/Recurrent EC: Study Design and Patients

## Key Eligibility Criteria

- Newly diagnosed FIGO 2009 stage III/IV or recurrent EC
- Known MMR status
- No prior PARPi, IO, or 1L systemic therapy for advanced disease
- Adjuvant Chemo allowed if ≥12 months to relapse



1:1:1 Patients without PD went on to maintenance

Primary endpoint: PFS by INV (Durva or Durva + Ola vs control)

Secondary endpoints: OS, safety

Exploratory endpoints: PFS (Durva + Ola vs Durva), subgroup analyses

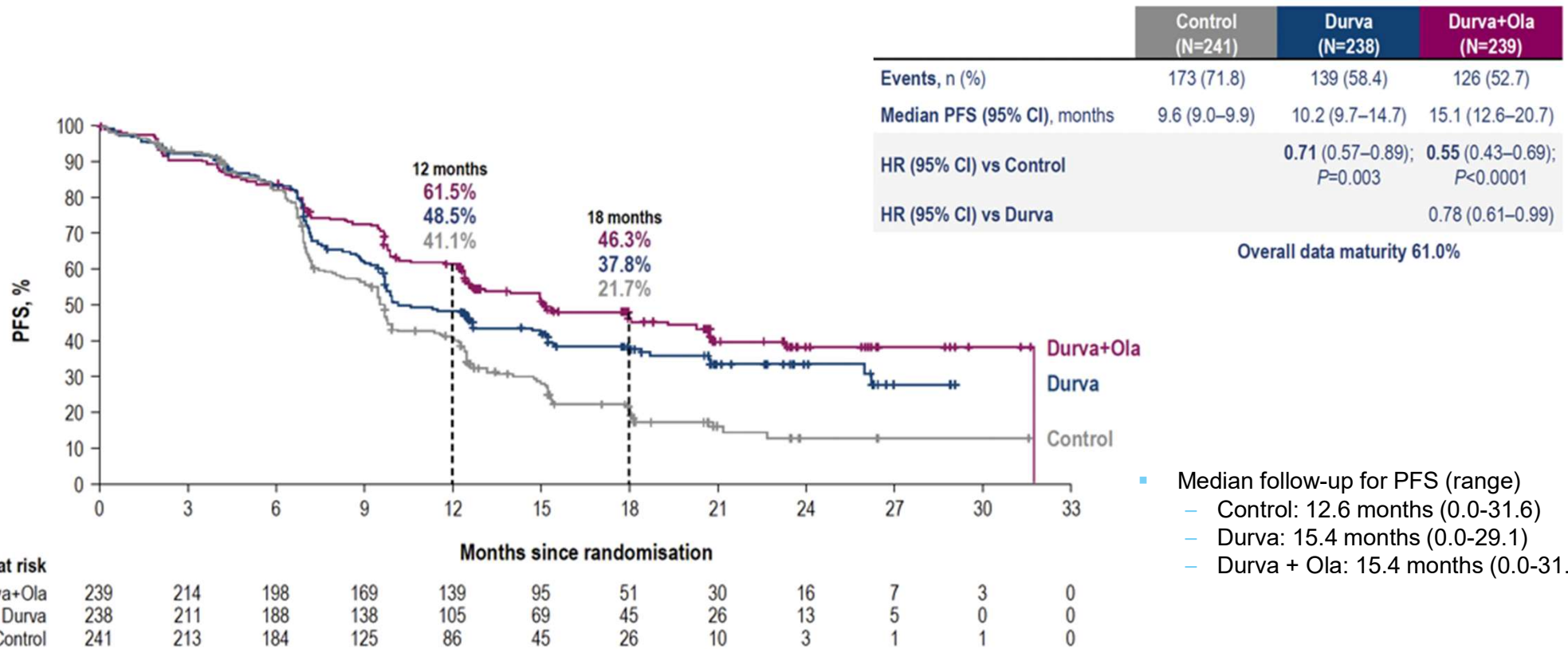
1L = first line; IO = immuno-oncology; PARP = poly (ADP-ribose) polymerase; PD-L1 = programmed death-ligand 1.

<sup>a</sup>CP: Carbo AUC 5 or 6 mg/mL/min and Pac 175 mg/m<sup>2</sup> for 6 cycles.

Westin SN, et al. ESMO 2023. Abstract LBA41.

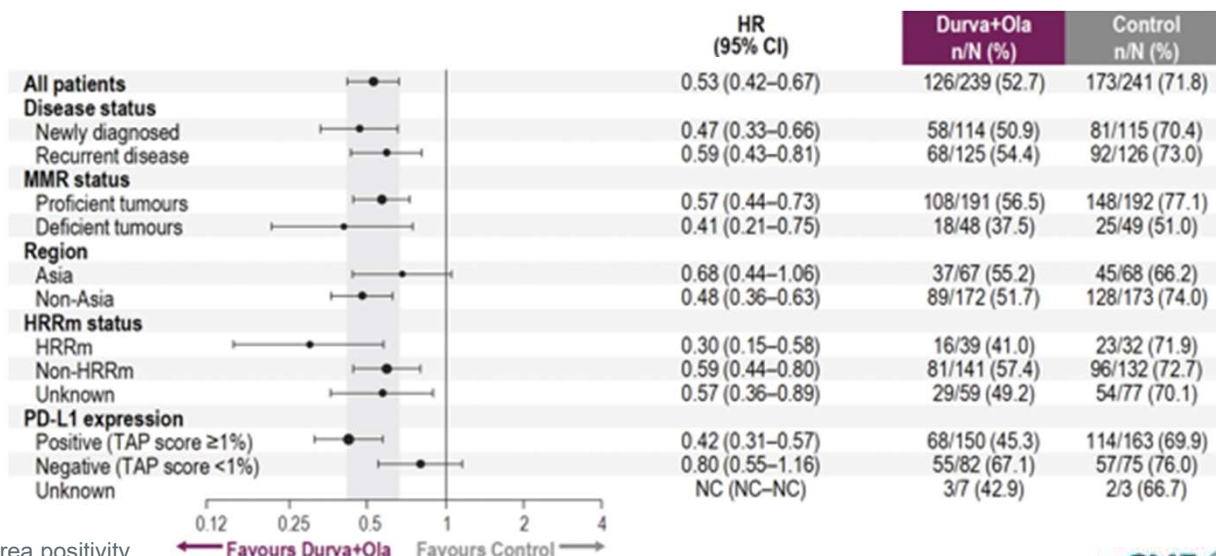
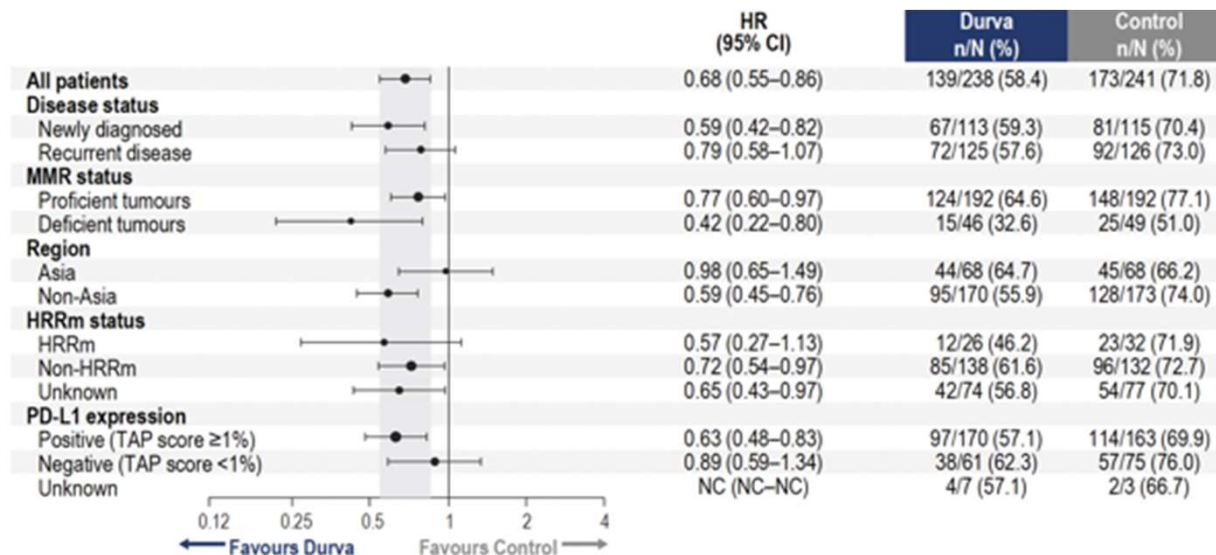
Patient Characteristics	Control (n=241)	Durva (n=238)	Durva + Ola (n=239)	
Median age (range), years	64 (31-85)	64 (22-84)	63 (27-86)	
Region, Asia/Non-Asia, %	28/72	29/71	28/72	
White race, %	59	57	56	
Not Hispanic or Latino ethnicity, %	90	87	86	
Newly diagnosed/recurrent, %	48/52	47/53	48/52	
ECOG PS 0/1, %	65/35	66/34	69/31	
PD-L1 positive, % <sup>b</sup>		71	63	
pMMR/dMMR, %	80/20	81/1689	80/20	
Histology type at diagnosis, %	Endometrioid	58	59	64
	Serous	22	24	18
	Carcinosarcoma	9	5	8
	Other	11	12	11
Previous chemo, %	21	21	23	
Previous radiotherapy, %	26	31	36	
Prior surgery, %	84	86	87	

# DUO-E/GOG-3041/ENGOT-EN10 Trial: PFS



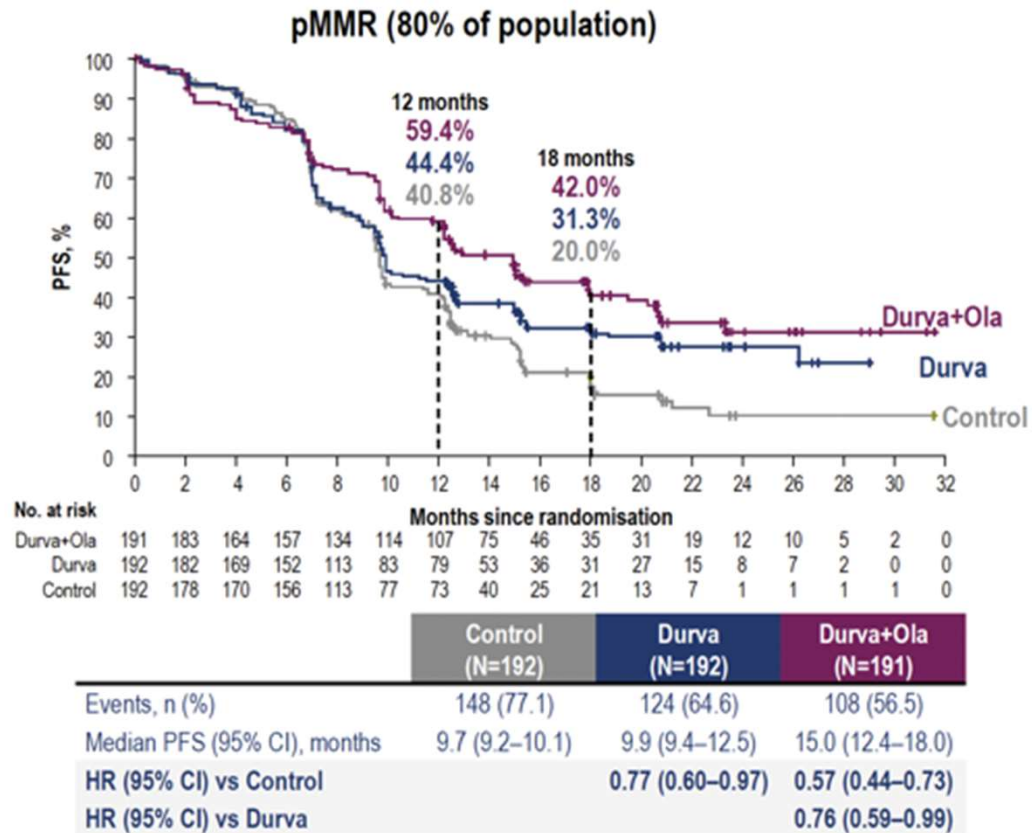
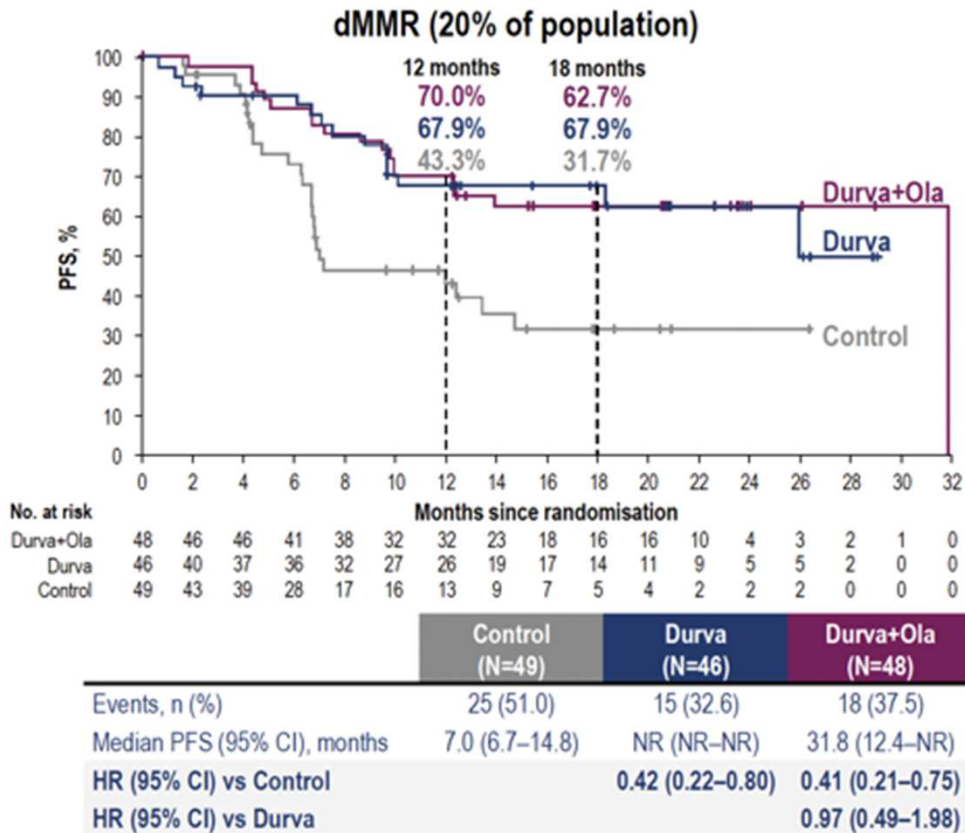
- Median follow-up for PFS (range)
  - Control: 12.6 months (0.0-31.6)
  - Durva: 15.4 months (0.0-29.1)
  - Durva + Ola: 15.4 months (0.0-31.7)

# DUO-E/GOG-3041/ENGOT-EN10 Trial: PFS Subgroup Analyses



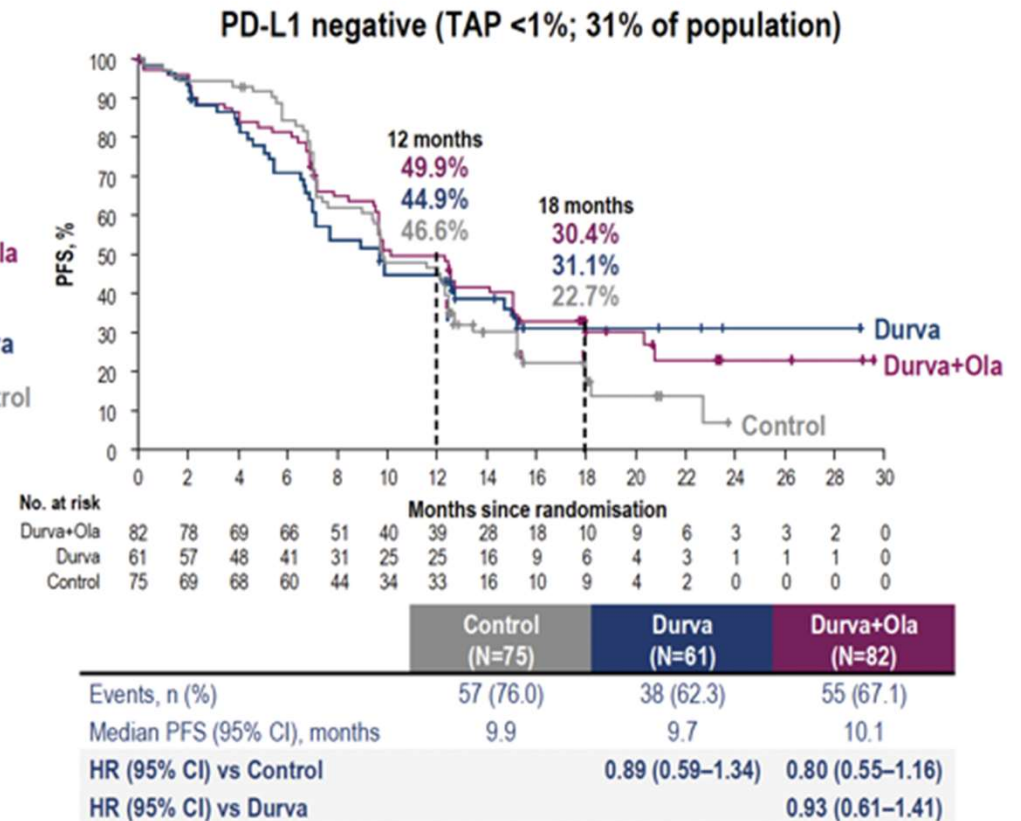
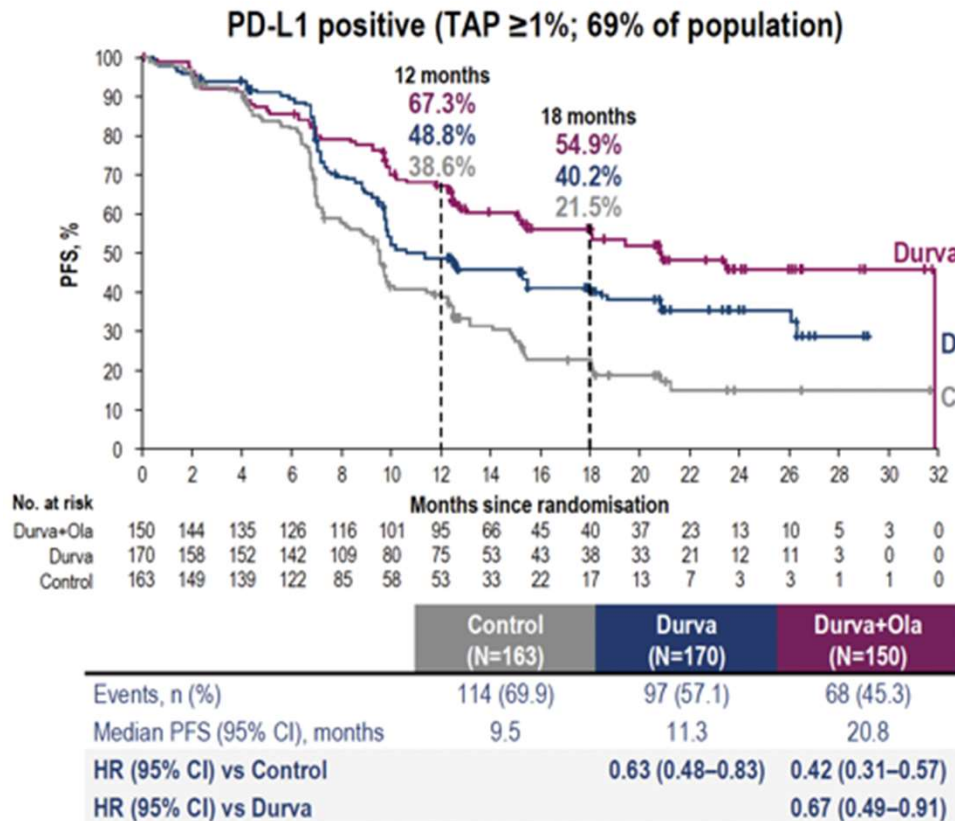
HRRm = homologous recombination repair gene mutation; TAP = tumor area positivity. Westin SN, et al. ESMO 2023. Abstract LBA41.

# DUO-E/GOG-3041/ENGOT-EN10 Trial: PFS by MMR Status

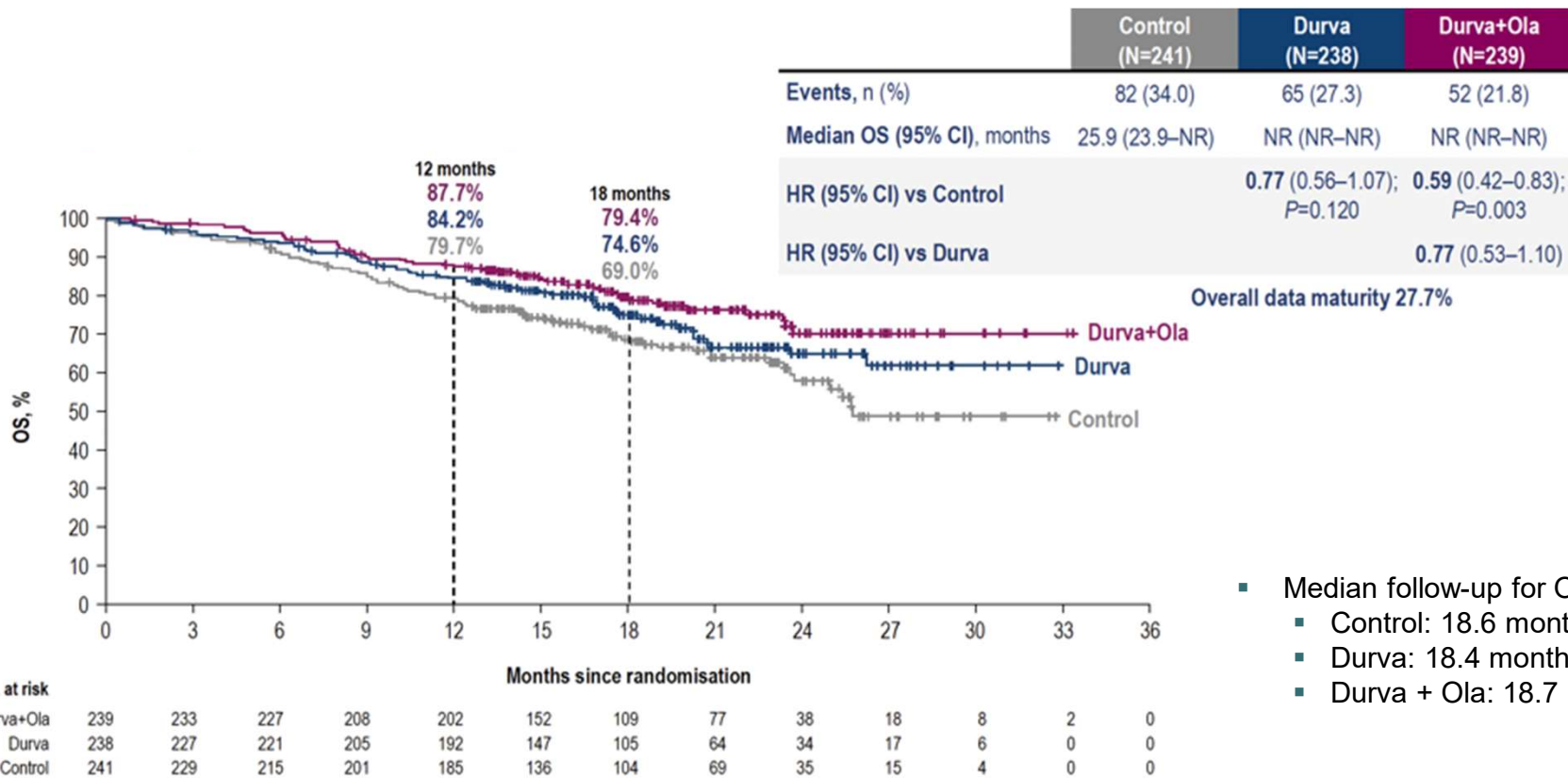




# DUO-E/GOG-3041/ENGOT-EN10 Trial: PFS by PD-L1 Status



# DUO-E/GOG-3041/ENGOT-EN10 Trial: OS



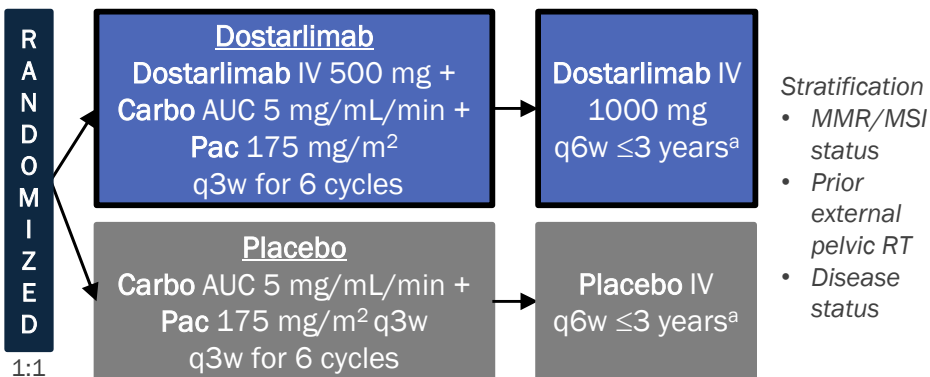
- Median follow-up for OS (range)
  - Control: 18.6 months (0.5-32.9)
  - Durva: 18.4 months (2.1-33.0)
  - Durva + Ola: 18.7 months (1.1-33.4)



# ENGOT-EN3-NSGO/GOG-3031/RUBY Trial of Dostarlimab + Chemo vs Chemo in Patients With Advanced/Recurrent EC: Study Design and Patients

## Key Eligibility Criteria

- Histologically/cytologically proven stage III/IV or first recurrent EC
- Naive to systemic anticancer therapy or had a recurrence or PD  $\geq 6$  months after completing systemic anticancer therapy
- ECOG PS 0-1



**Primary endpoints:** PFS by INV, OS

**Secondary endpoints:** PFS by BICR, PFS2, ORR, DOR, DCR, HRQOL/PRO, safety

Patient Characteristics	dMMR/MSI-H		Overall	
	Dostarlimab (n=53)	Placebo (n=65)	Dostarlimab (n=245)	Placebo (n=249)
Median age (range), years	61 (45-81)	66 (39-85)	64 (41-81)	65 (28-85)
ECOG PS, n (%)	0	28 (53.8)	145 (60.2)	160 (65.0)
	1	24 (46.2)	26 (40.0)	86 (35.0)
Histology, n (%)	Clear cell	0	8 (3.3)	9 (3.6)
	Carcinosarcoma	4 (7.5)	1 (1.5)	25 (10.2)
	Endometrioid	44 (83.0)	56 (86.2)	134 (54.7)
Prior systemic therapy, n (%)				
	Carbo/Pac	4 (7.5)	6 (9.2)	36 (14.7)
Measurable disease at baseline, n (%)	49 (92.5)	58 (89.2)	212 (86.5)	219 (88.0)

Mirza MR, et al. SGO 2023. Abstract 265.

## Analyses

- PFS and OS by molecular classification<sup>1</sup>
- PFS2<sup>b</sup> and adjustment of OS for subsequent anticancer therapy<sup>2</sup>
- PROs in patients with dMMR/MSI-H disease<sup>3</sup>

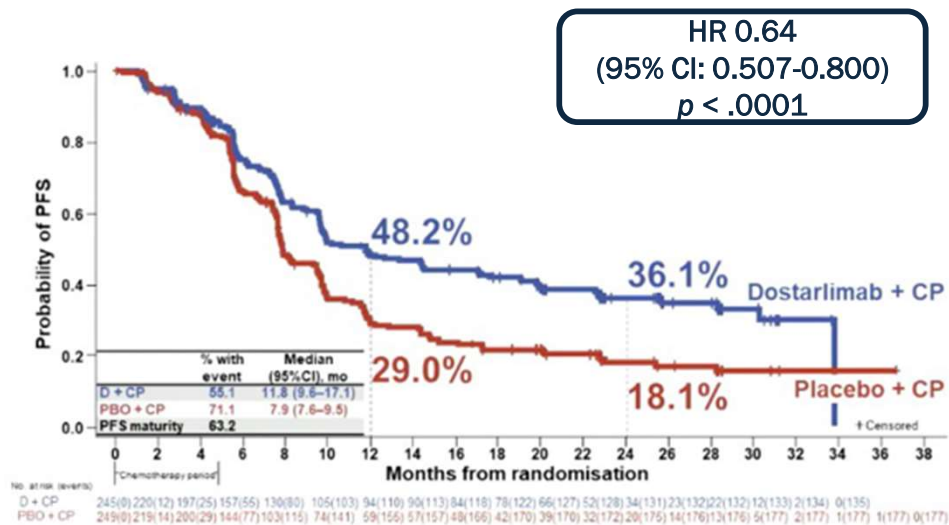
DCR = disease control rate; MSI-H = microsatellite instability-high.

<sup>a</sup>Treatment ends after 3 years. <sup>b</sup>PFS2 was defined as the time from treatment randomization to the date of assessment of progression on the first subsequent anticancer therapy following study treatment, or death by any cause, whichever was earlier.

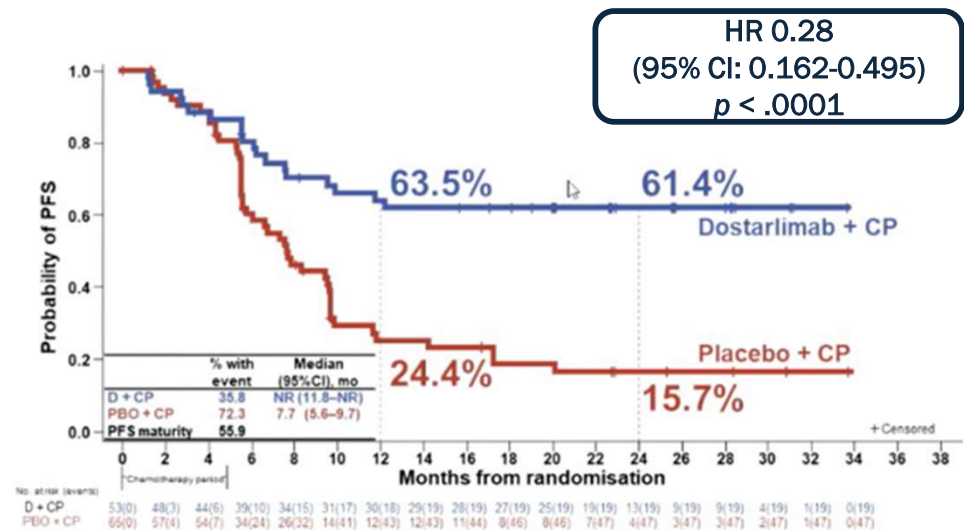
1. Mirza MR, et al. ESMO 2023. Abstract 740MO. 2. Slomovitz BM, et al. ESMO 2023. Abstract 750P. 3. Valabrega G, et al. ESMO 2023. Abstract 749P. Mirza MR, et al. SGO 2023. Abstract 265.

# ENGOT-EN3-NSGO/GOG-3031/ RUBY Trial: PFS

## Overall population



## dMMR/MSI-H

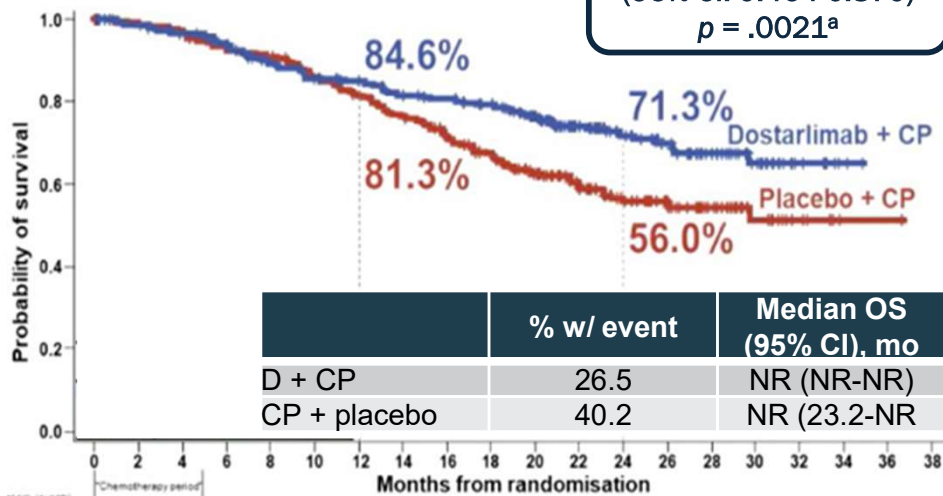


- Median duration of follow-up
  - dMMR/MSI-H population: 24.8 months
  - Overall population: 25.4 months

# ENGOT-EN3-NSGO/GOG-031/RUBY Trial: OS

## Overall population

HR 0.64  
(95% CI: 0.464-0.870)  
 $p = .0021^a$



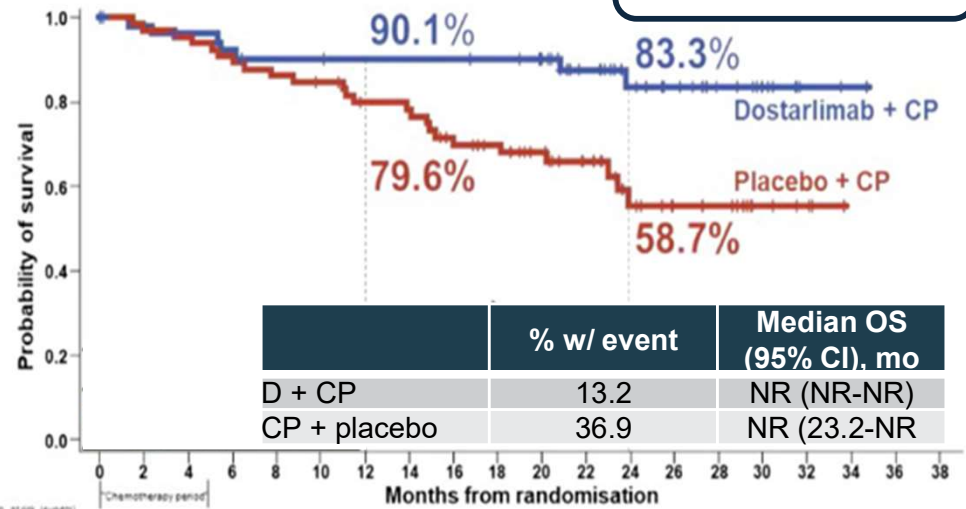
No. at risk (events)  
 D + CP 245(0) 235(3) 224(8) 214(15) 199(25) 190(33) 183(35) 174(42) 169(44) 162(47) 145(53) 110(57)(83(60) 64(62) 45(64) 25(65) 7(65) 2(65) 0(65)  
 PBO + CP 249(0) 242(3) 237(7) 226(17) 219(22) 203(35) 189(45) 177(57) 162(68) 147(78) 125(88) 88(93) 65(97) 48(98) 33(99) 15(100) 6(100) 1(100) 1(100) 0(100)

25.4 mo median duration of follow-up  
 Received subsequent immunotherapy:

- 34.5% of patients on placebo arm
- 15.5% of patients on dostarlimab arm

## dMMR/MSI-H

HR 0.30  
(95% CI: 0.127-0.699)



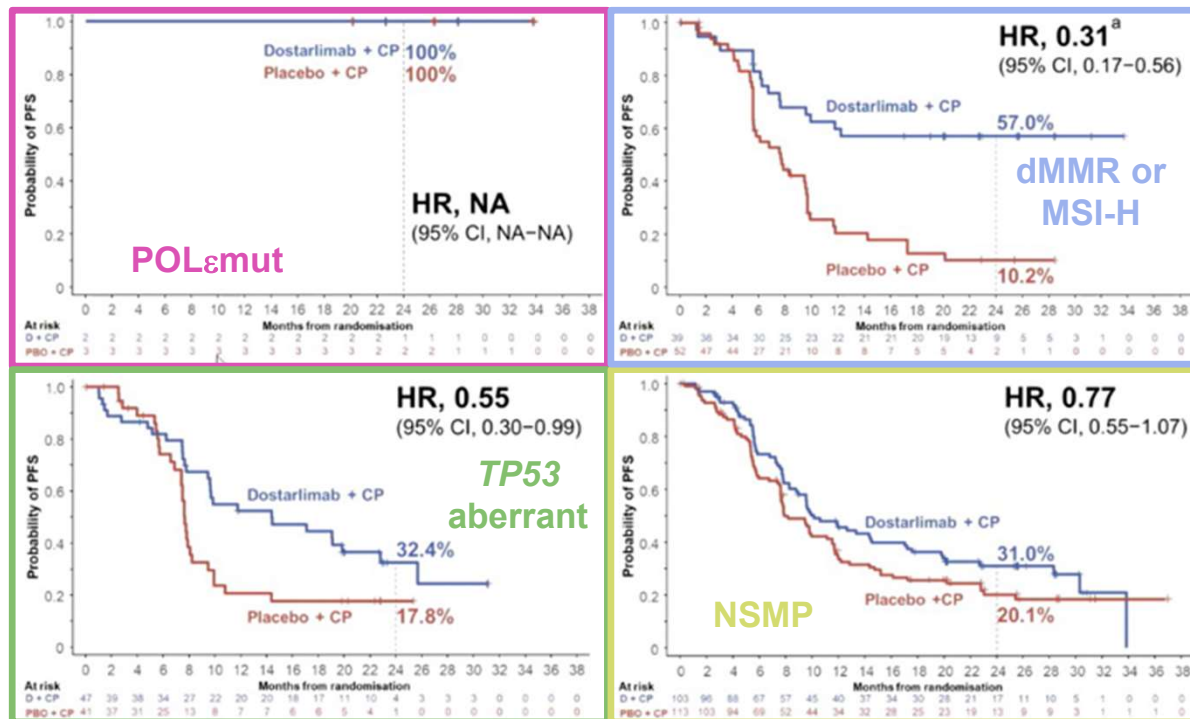
No. at risk (events)  
 D + CP 53(0) 50(1) 48(2) 46(4) 44(5) 44(5) 43(5) 43(5) 43(5) 42(5) 41(5) 29(6) 20(7) 16(7) 12(7) 9(7) 2(7) 1(7) 0(7)  
 PBO + CP 65(0) 63(2) 62(3) 59(6) 55(9) 53(10) 48(13) 47(14) 41(18) 37(19) 32(20) 25(21) 16(23) 12(24) 10(24) 5(24) 3(24) 0(24)

24.8 mo median duration of follow-up  
 Received subsequent immunotherapy:

- 38.5% of patients on placebo arm
- 15.1% of patients on dostarlimab arm

<sup>a</sup> $p \leq .00177$  required to declare statistical significance at first interim analysis.  
 Mirza MR, et al. ESMO 2023. Abstract 740MO. Mirza, MR et al. *New Engl J Med.* 2023;388:2145-2158.

# ENGOT-EN3-NSGO/GOG-3031/ RUBY Trial: PFS by Molecular Subgroups



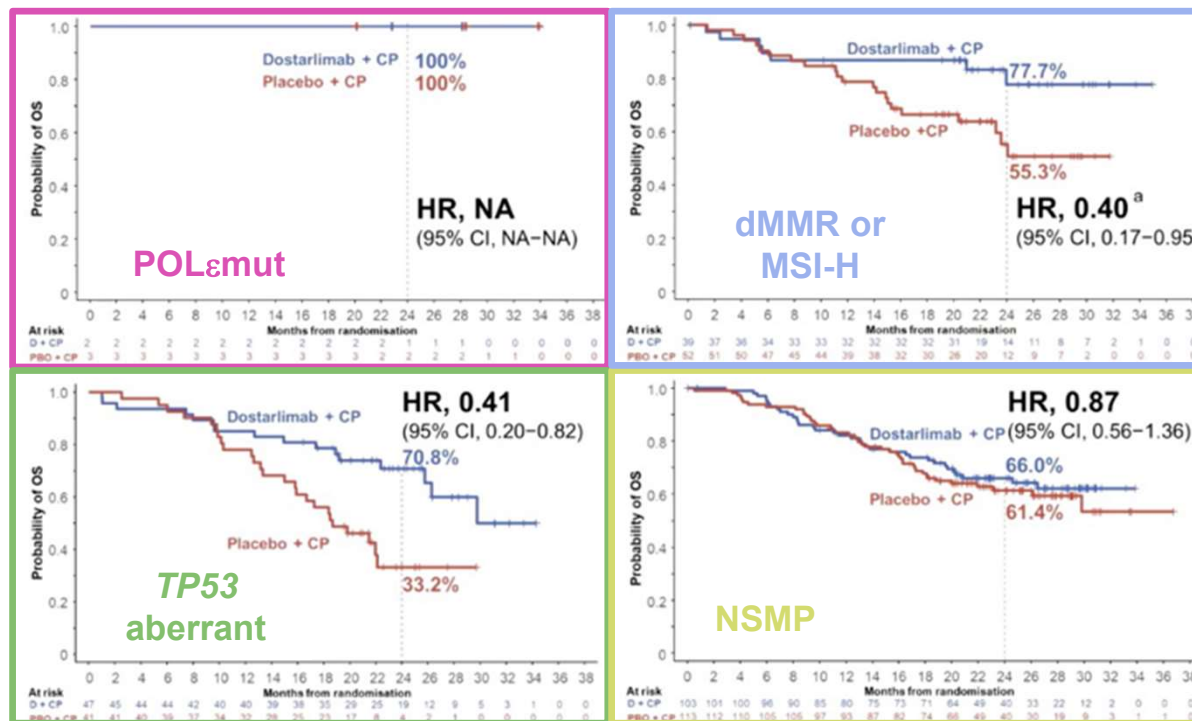
- This PFS analysis is based on 400/494 patients with known molecular classification per whole exome sequencing

<sup>a</sup>Primary endpoint of PFS in dMMR/MSI-H patients (n=118) showed HR 0.28, p < .0001.

NSMP, no specific molecular profile.

Mirza MR, et al. ESMO 2023. Abstract 740MO.

# ENGOT-EN3-NSGO/GOG-3031/ RUBY Trial: OS by Molecular Subgroup

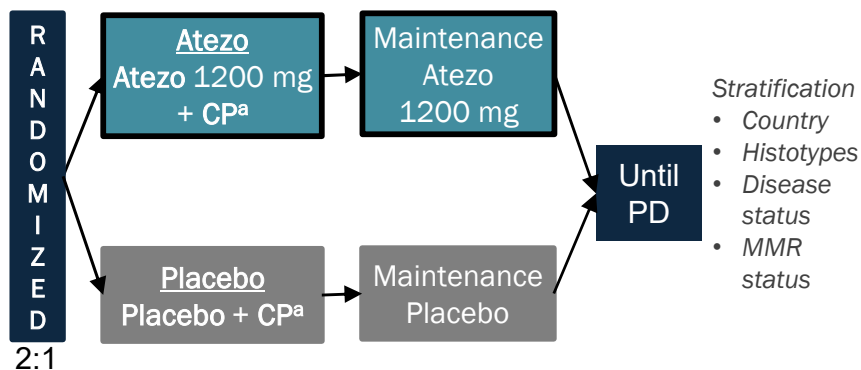


NA = not available; NSMP = no specific molecular profile; POL<sub>3</sub>mut = DNA polymerase..  
Mirza MR, et al. ESMO 2023. Abstract 740MO.

# AtTend/MaNGO/ENGOT-en7 Trial of Atezolizumab + Chemo vs Chemo in Patients With Advanced/Recurrent EC: Study Design and Patients

## Key Eligibility Criteria

- Advanced (stage III/IV) newly diagnosed or recurrent EC with no prior systemic chemotherapy for recurrence
- In recurrent patients, 1 prior line of systemic platinum-based regimen was permitted with a PFI  $\geq$  6 months
- ECOG PS 0-2



## Hierarchical endpoints:

PFS for dMMR  $\rightarrow$  PFS all-comers  $\rightarrow$  OS all-comers

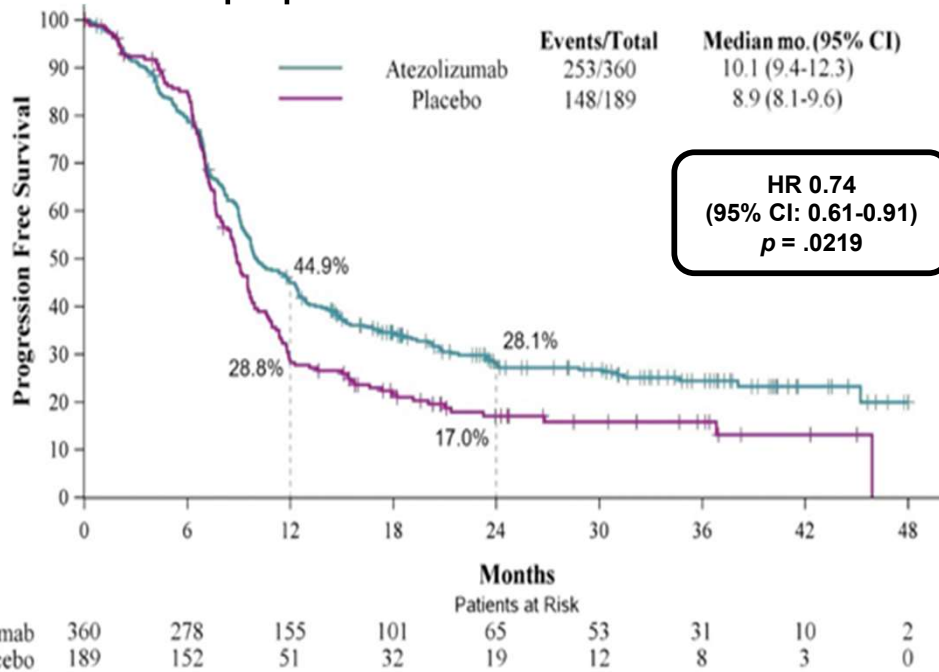
<sup>a</sup> CP: Carbo AUC 5 or 6 mg/mL/min and Pac 175 mg/m<sup>2</sup> for 6 cycles.  
Colombo N, et al. ESMO 2023. Abstract LBA40.

Patient Characteristics	dMMR		All-Comers	
	Atezo (n=81)	Placebo (n=44)	Atezo (n=360)	Placebo (n=189)
Median age (range), years	64 (30-85)	64 (39-81)	67 (30-89)	65 (30-89)
Race, n (%)				
Caucasian	70 (86.4)	33 (75.0)	289 (80.3)	143 (75.7)
Asian	11 (13.6)	11 (25.0)	69 (19.2)	43 (22.7)
Positive PD-L1 exp, n (%)	38 (46.9)	17 (38.6)	86 (23.9)	44 (23.3)
Histology at diagnosis, n (%)				
Endometrioid	74 (91.4)	38 (86.4)	227 (63.1)	125 (66.1)
Carcinosarcoma	3 (3.7)	1 (2.3)	35 (9.7)	15 (7.9)
Papillary serous	0	0	59 (16.4)	29 (15.3)
MMR status, n (%)				
dMMR	81 (100)	44 (100)	81 (22.5)	44 (23.3)
pMMR	–	–	269 (74.7)	140 (74.1)
Disease stage, n (%)				
ND stage II/III	0/6 (7.4)	0/1 (2.3)	0/21 (5.8)	1 (0.5)/10 (5.3)
ND stage IV	23 (28.4)	15 (34.1)	96 (26.7)	52 (27.5)
Recurrent	52 (64.2)	28 (63.6)	243 (67.5)	126 (66.7)
Previous chemo, n (%)	14 (17.3)	11 (25.0)	107 (29.7)	60 (31.7)



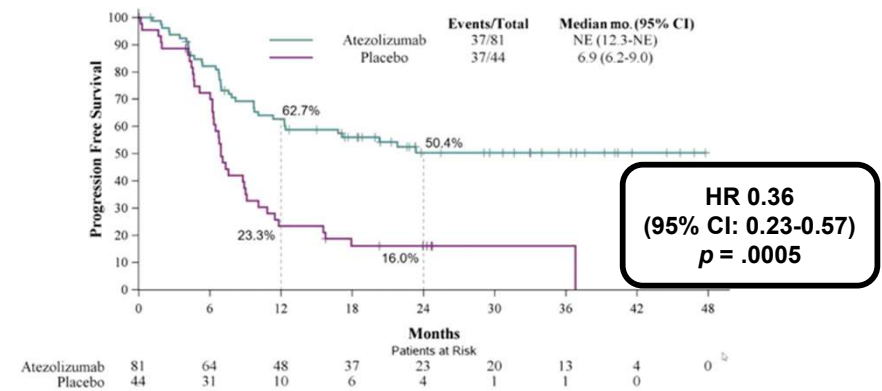
# AtTEnd/MaNGO/ENGOT-en7 Trial: PFS

## Overall population

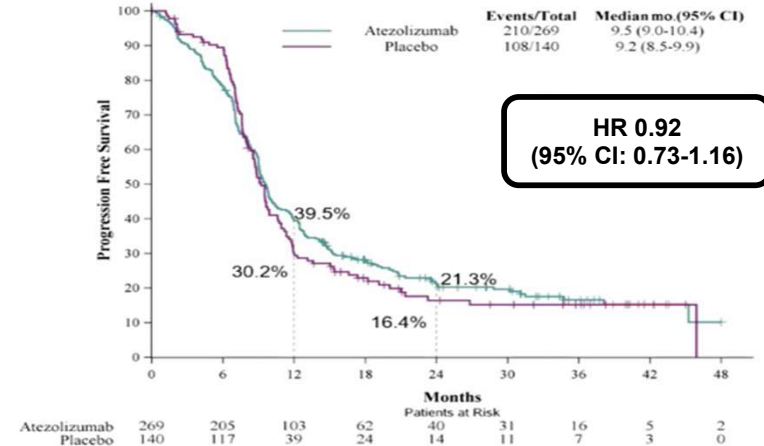


- Median follow-up for PFS
  - dMMR: 26.2 months
  - All-comers: 28.3 months

## dMMR/MSI-H



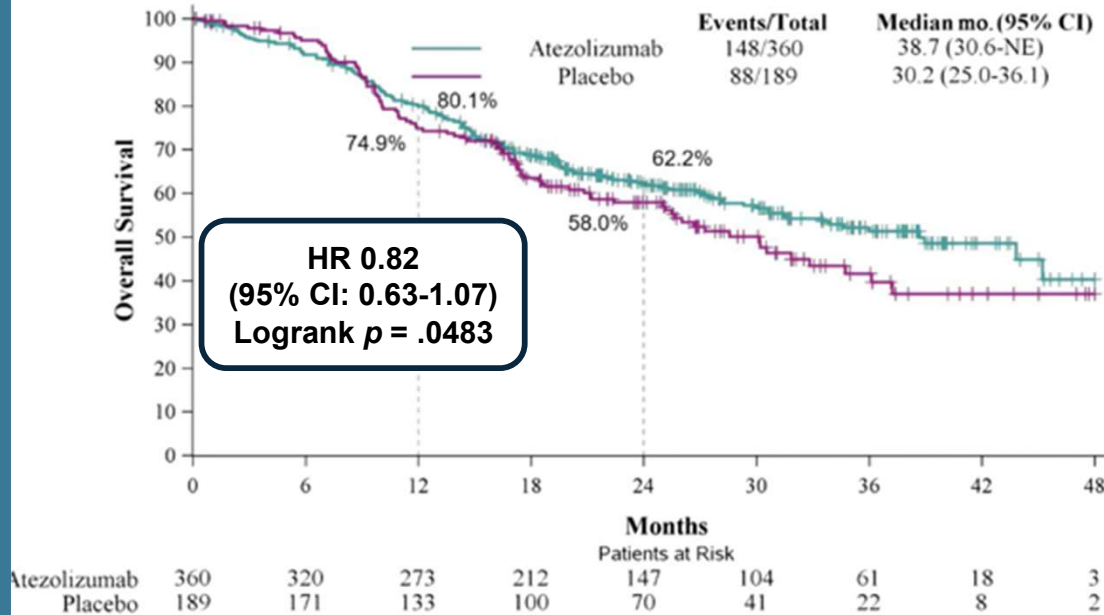
## pMMR





# AtTEnd/MaNGO/ENGOT-en7 Trial: OS

## OS in All-Comers



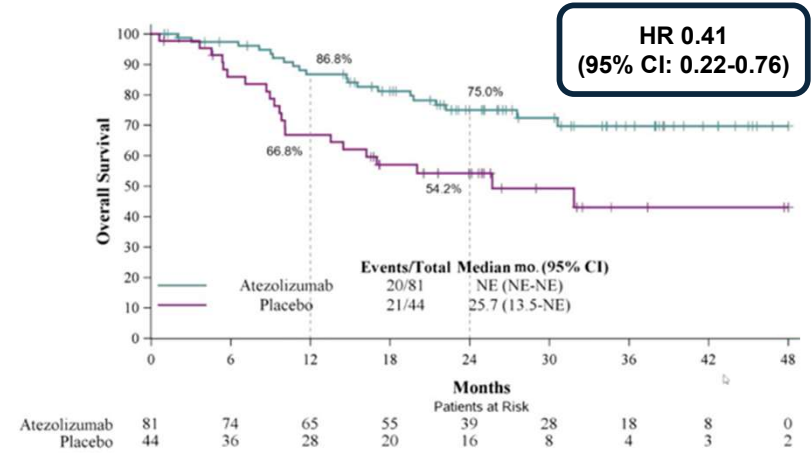
## Interim Analysis

Data maturity: 43%  
236 deaths/549 patients

Colombo N, et al. ESMO 2023. Abstract LBA40.

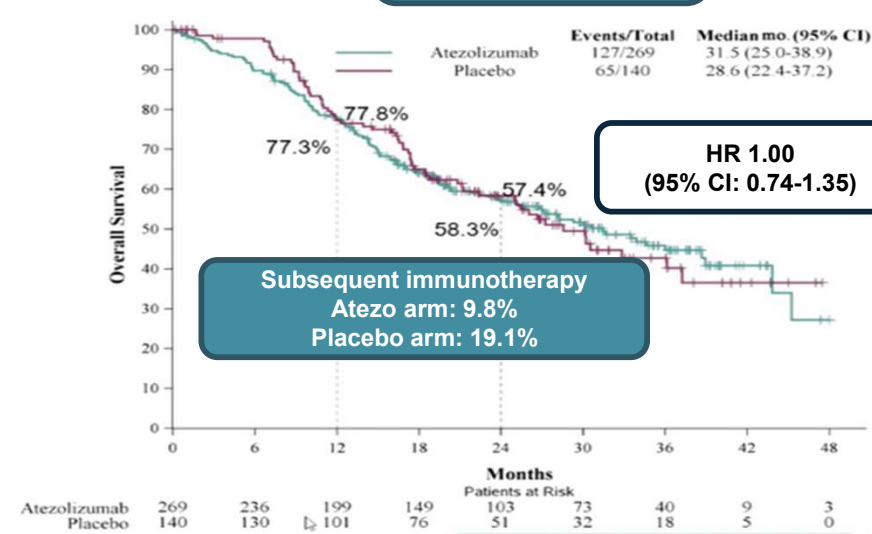
**Subsequent immunotherapy**  
Atezo arm: 9.0%  
Placebo arm: 24.3%

## OS in dMMR



**Subsequent immunotherapy**  
Atezo arm: 6.2%  
Placebo arm: 40.9%

## OS in pMMR



**Subsequent immunotherapy**  
Atezo arm: 9.8%  
Placebo arm: 19.1%

# Emerging Antibody-drug Conjugates for EC

- HER2-directed ADC: trastuzumab deruxtecan, trastuzumab duocarmazine
- Folate receptor  $\alpha$  (FR $\alpha$ )-directed ADC: mirvetuximab soravtansine, luveltamab tazide, farletuzumab ecteribulinm
- TROP2-directed ADC: sacituzumab govitecan
- B7-H4-directed ADC: puxitatug samrotecan (AZD8205)
- Claudin 6-directed ADC: TORL-1-23

# DESTINY-PanTumor02: Single-arm T-DXd Study

## Key Eligibility Criteria

- Locally advanced, unresectable, or metastatic disease with  $\geq 1$  prior systemic therapy
- HER2 IHC 3+

Colorectal cancer

Urothelial bladder cancer

Biliary tract cancer

Non-small cell lung cancer

Endometrial cancer

Ovarian cancer

Cervical cancer

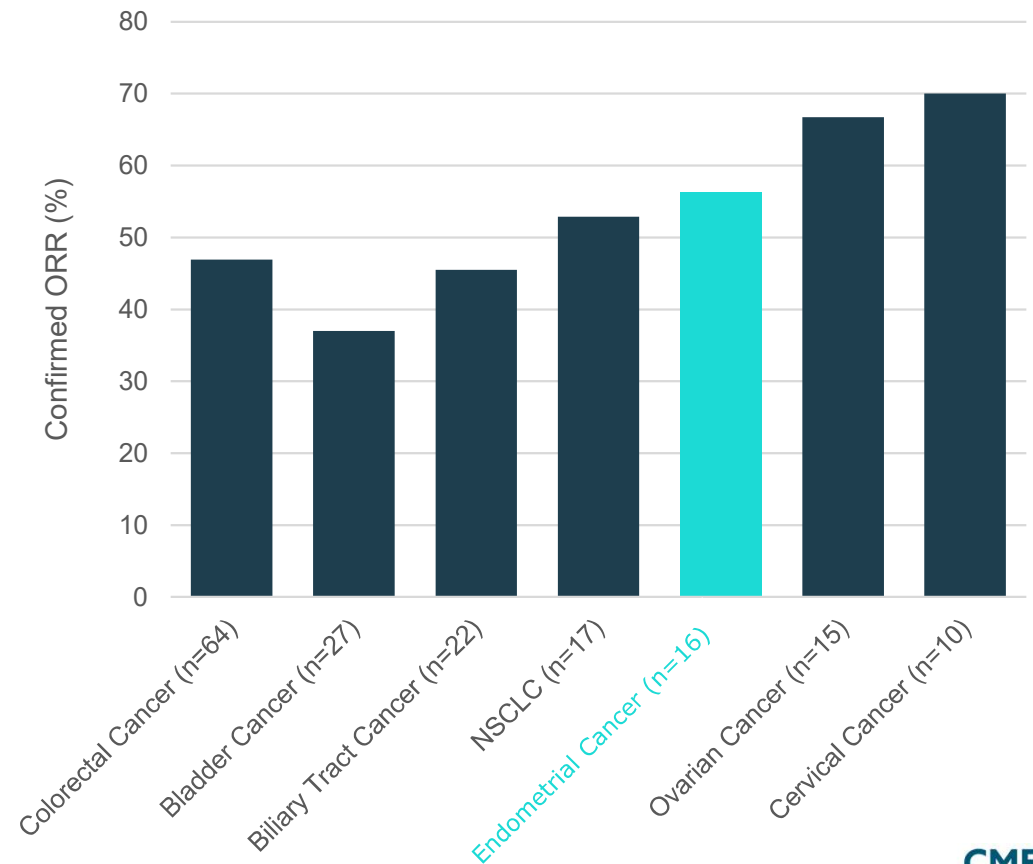
Other and rare tumors

Trastuzumab deruxtecan  
5.4 mg/kg  
q3w for 6 cycles

Primary endpoints: ORR, confirmed ORR

Secondary endpoints: DOR, DCR, PFS and OS (median, and 6- and 12-month), safety, pharmacokinetics, T-DXd immunogenicity

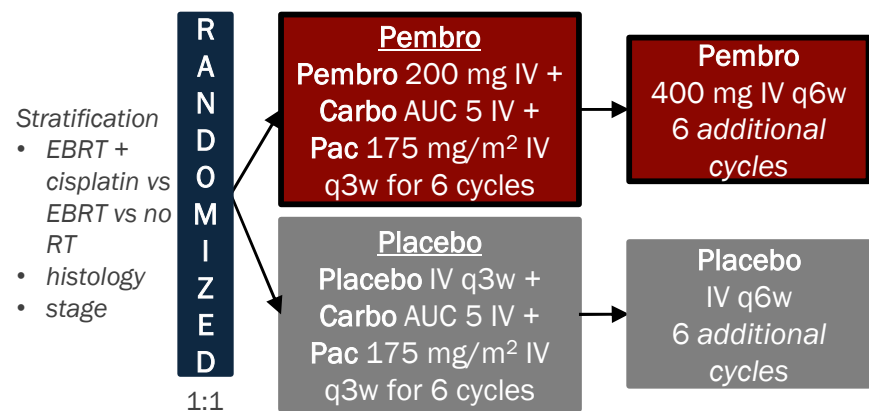
Li BT, et al. *Lancet Oncol.* 2024;25(6):707-719.



# Phase 3 ENGOT-en11/GOG-3053/KEYNOTE-B21 Trial of Pembrolizumab or Placebo Plus Adjuvant Chemotherapy With or Without Radiotherapy in Patients With Newly Diagnosed, High-Risk Endometrial Cancer: Study Design and Patients

## Key Eligibility Criteria

- Histologically confirmed high-risk (FIGO stage I/II of non-endometrioid histology or endometrioid histology with p53/TP53 abnormality, or stage III/IVA of any histology)
- No evidence of disease postoperatively
- No prior radiotherapy or systemic therapy



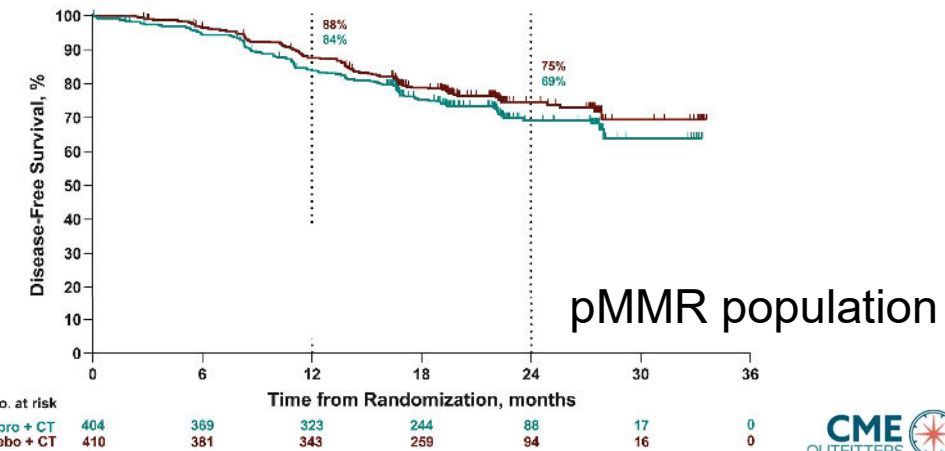
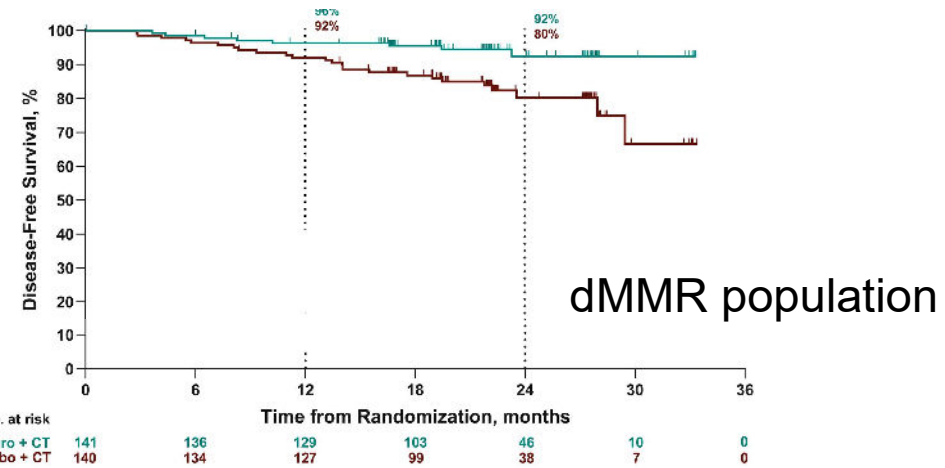
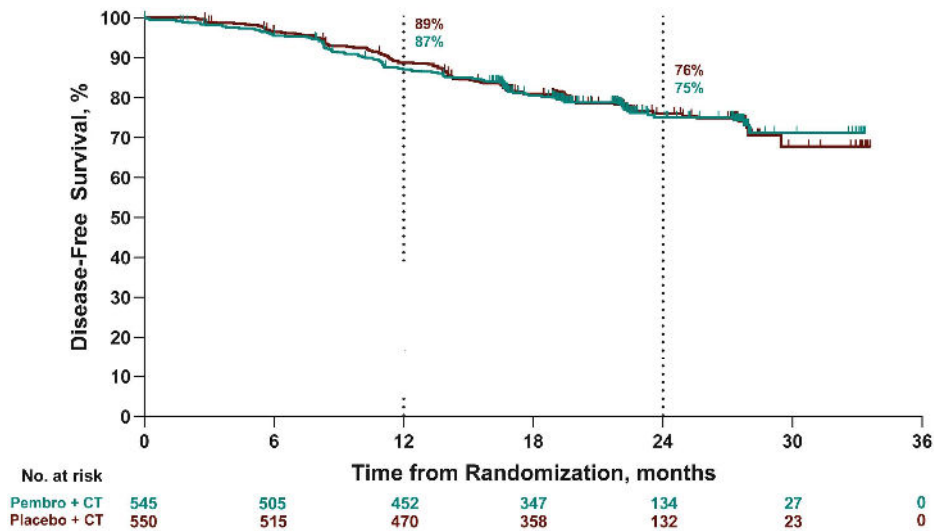
**Primary endpoints: DFS, OS**

**Secondary endpoints: DFS (independent review), safety, patient-reported outcomes**

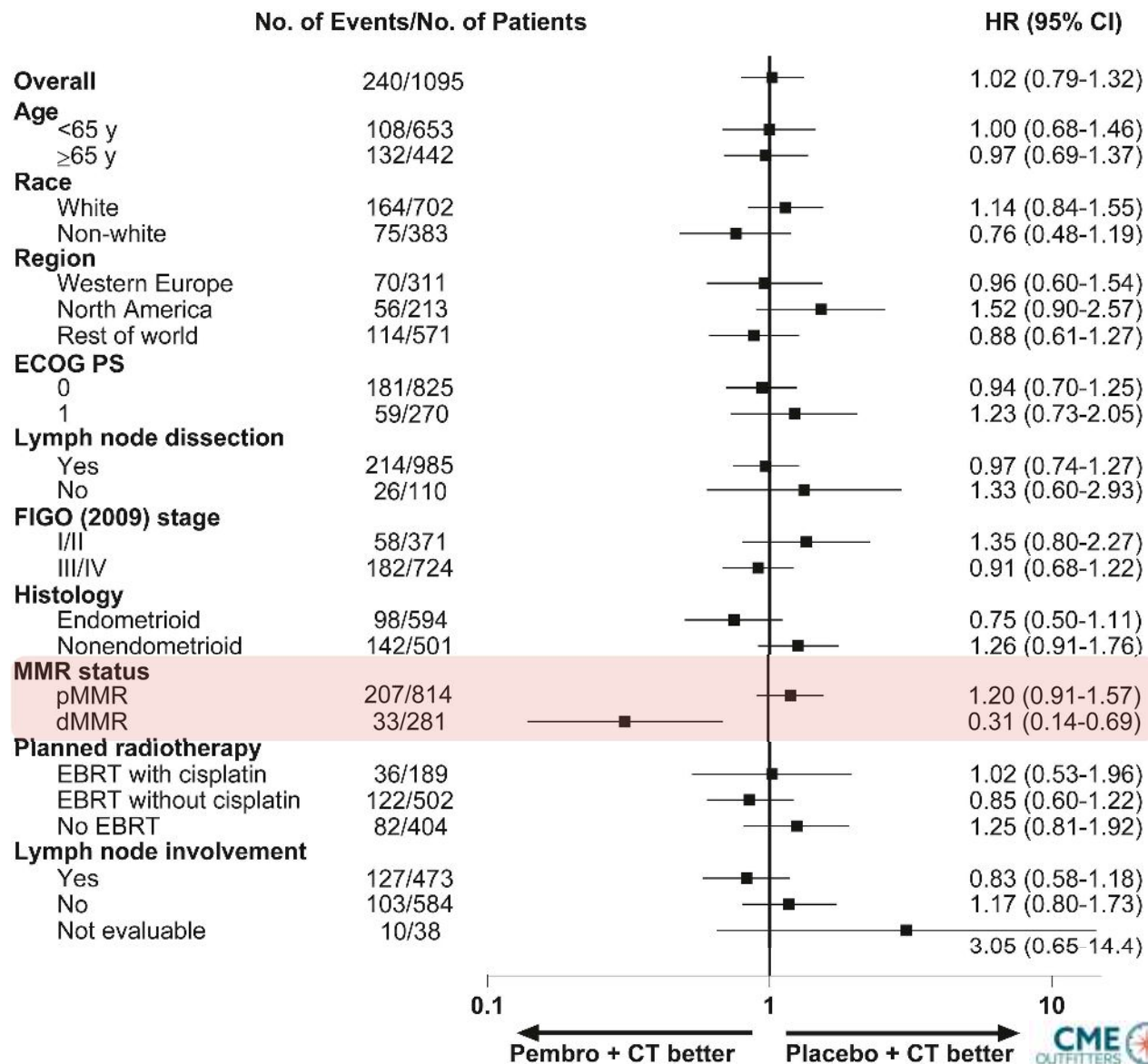
Patient Characteristics, n (%)		Pembrolizumab + Chemotherapy (n = 545)	Placebo + Chemotherapy (n = 550)
Age, median (range), y		62.0 (29.0–95.0)	62.0 (27.0–89.0)
ECOG performance status	0	409 (75)	416 (76)
	1	136 (25)	134 (24)
Histology	Endometrioid	297 (54)	297 (54)
	Non-endometrioid	248 (46)	253 (46)
MMR status	pMMR	404 (74)	410 (75)
	dMMR	141 (26)	140 (25)
Planned radiotherapy	EBRT with cisplatin	94 (17)	95 (17)
	EBRT without cisplatin	256 (47)	246 (45)
	Brachytherapy only	49 (9)	52 (9)
	No EBRT or brachytherapy	146 (27)	157 (29)

# ENGOT-en11/GOG-3053/KEYNOTE-B21: DFS

ITT population



# ENGOT-en11/GOG-3053/KEYNOTE-B21: DFS in ITT Subgroups



# SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

- Discuss first-line checkpoint inhibitor therapy in patients with dMMR endometrial tumors, as documented by inclusion of discussion notes in EHR records.
- Recommend patients with endometrial tumors consider clinical trial participation as a method to access emerging therapies.



# CME CAST

## EPISODE 1

The When and How of Maintenance Therapy in  
Endometrial Cancer

## EPISODE 2

Confusion on the Horizon: Novel Therapies  
Emerging for the Treatment of Endometrial  
Cancer

Go to [www.cmeoutfitters.com/practice/oncology-hub/](http://www.cmeoutfitters.com/practice/oncology-hub/) for additional educational podcasts and activities in gynecologic cancers and free resources and education for health care professionals and patients



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