Decoding the Latest Developments in Locally Advanced and First-Line Recurrent Cervical Cancer

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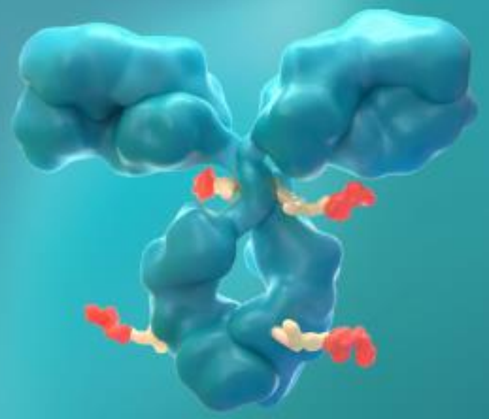
Seagen

Genmab



SEOUL IGCS 2023

CALLA: Overview of Study

A randomized, multi-center, double-blind, placebo-controlled, global, phase III study to determine the efficacy and safety of durvalumab + chemoradiotherapy versus chemoradiotherapy alone as treatment in women with locally advanced cervical cancer[1]

Eligible population[2]

- Women aged ≥18 years
- Histologically confirmed cervical adenocarcinoma, squamous carcinoma, or adenosquamous carcinoma
- High-risk LACC (FIGO 2009)
- Stages IB2 to IIB, node positive (N≥1)
- Stages IIIA to IVA with any node (N≥0)
- WHO ECOG performance status of 0 or 1

R 1:1

N=770

Durvalumab 1500 mg q4w × 24 doses

Platinum + EBRT + brachytherapy

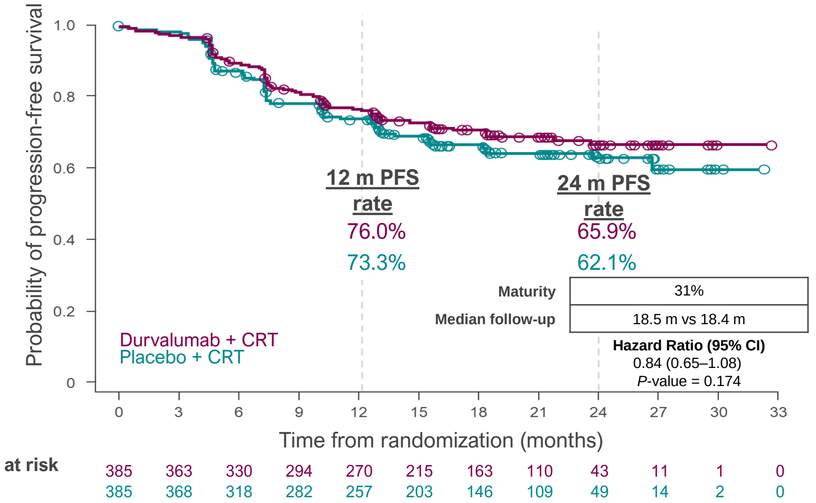
Placebo q4w × 24 doses

Platinum + EBRT + brachytherapy

Primary endpoint: PFS[a] (Investigator-assessed)

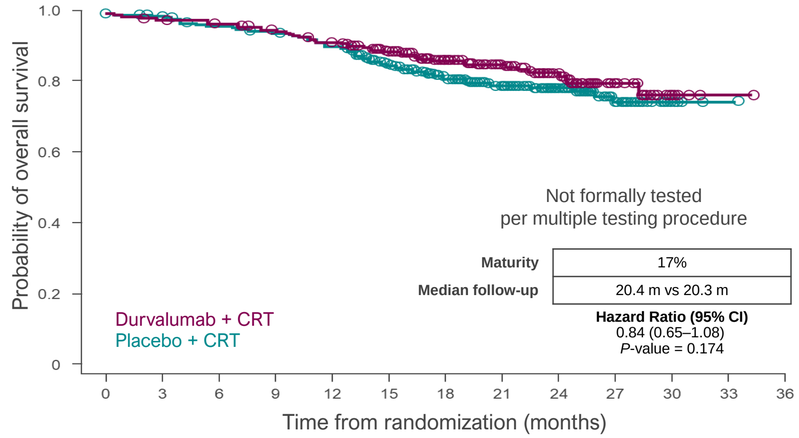
Secondary endpoints: OS, ORR, DOR, incidence of local or distant progression / secondary malignancy, safety and tolerability

Progression-Free Survival (primary endpoint)[2]



No. at risk												
Durvalumab + CRT	385	363	330	294	270	215	163	110	43	11	1	0
Placebo + CRT	385	368	318	282	257	203	146	109	49	14	2	0

Overall Survival (secondary endpoint)[2]



No. at risk												
Durvalumab + CRT	385	378	371	360	346	295	225	163	93	36	6	1
Placebo + CRT	385	379	366	357	342	282	206	151	94	40	5	1

[a]According to RECIST 1.1 or histopathologic confirmation of local tumor progression.

CI, confidence interval; CRT, chemoradiotherapy; DOR, duration of response; EBRT, external beam radiation therapy; ECOG, Eastern Cooperative Oncology Group; FIGO, International Federation of Gynecology and Obstetrics; HR, hazard ratio; LACC, locally advanced cervical cancer; m, months; ORR, objective response rate; OS, overall survival, PFS, progression-free survival; q4w, every 4 weeks; WHO, world health organization.

1. Monk B et al. Presentation #504. Presented at IGCS Annual Meeting 2022; 2. Clinicaltrials.gov. NCT03830866. Accessed October 17 2023

KEYNOTE-A18 (ENGOT-cx11/GOG-3047): Study Design

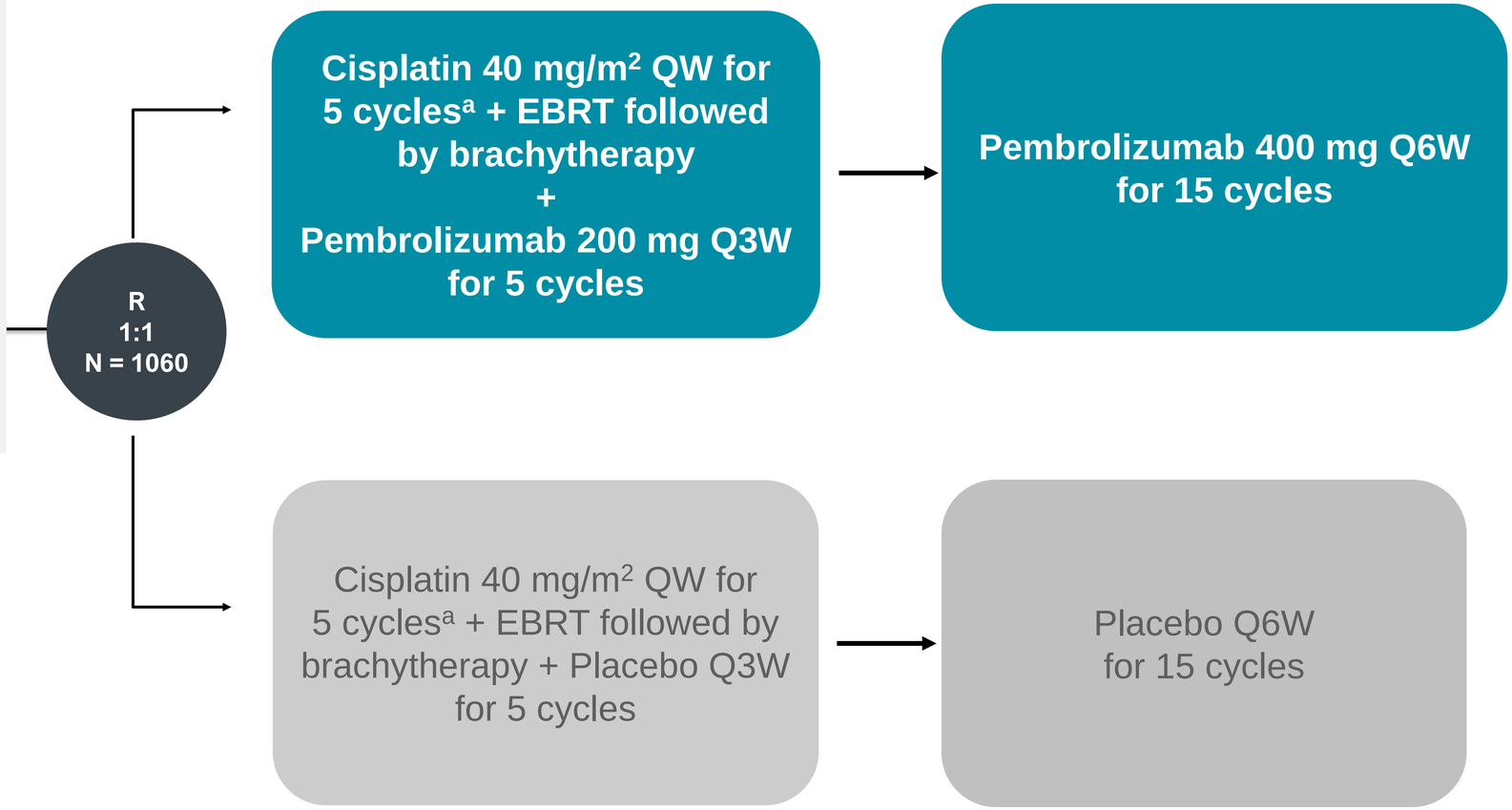
A randomized, phase 3, double-blind study of chemoradiotherapy with or without pembrolizumab for the treatment of high-risk, locally advanced cervical cancer (KEYNOTE-A18/ENGOT-cx11/GOG-3047)

Eligible Population[2]

- FIGO 2014 stage IB2-IIB (node-positive disease) or FIGO 2014 stage III-IVA (either node-positive or node-negative disease)
- RECIST 1.1 measurable or non-measurable disease
- Treatment naïve

Stratified by:

- Planned EBRT type (IMRT or VMAT vs non-IMRT or non-VMAT)
- Stage at screening (stage IB2-IIB vs III-IVA)
- Planned total radiotherapy dose (<70 Gy vs ≥70 Gy [EQ2D])



[a]A 6th cycle was allowed per investigator discretion.
EBRT, external beam radiotherapy; EQ2D, equivalent total doses in 2-Gy fractions; Gy, gray; FIGO, International Federation of Gynecology and Obstetrics; Gy, grays; IMRT, intensity-modulated radiotherapy; QW, weekly; Q3W, every 3 weeks; Q6W, every 6 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; R; randomized; VMAT, volumetric-modulated arc therapy.
Lorusso D, et al. Presented at ESMO 2023. Abstract LBA38

KEYNOTE-A18(ENGOT-cx11/GOG-3047): Baseline Characteristics

	Pembro Arm (N = 529)	Placebo Arm (N = 531)
Age, median (range)	49 y (22-87)	50 y (22-78)
Race[a]		
White	254 (48.0%)	264 (49.7%)
Asian	155 (29.3%)	148 (27.9%)
Multiple	78 (14.7%)	86 (16.2%)
American Indian or Alaska Native	24 (4.5%)	22 (4.1%)
Black or African American	14 (2.6%)	8 (1.5%)
Native Hawaiian or Other Pacific Islander	2 (0.4%)	1 (0.2%)
PD-L1 CPS		
<1	22 (4.2%)	28 (5.3%)
≥1	502 (94.9%)	498 (93.8%)
Missing	5 (0.9%)	5 (0.9%)
ECOG PS 1	149 (28.2%)	134 (25.2%)
Squamous cell carcinoma	433 (81.9%)	451 (84.9%)

	Pembro Arm (N = 529)	Placebo Arm (N = 531)
Stage at screening (FIGO 2014 criteria)		
IB2-IIB	235 (44.4%)	227 (42.7%)
III-IVA	294 (55.6%)	304 (57.3%)
Lymph node involvement[b]		
Positive pelvic only	326 (61.6%)	324 (61.0%)
Positive para-aortic only	14 (2.6%)	10 (1.9%)
Positive pelvic and para-aortic	105 (19.8%)	104 (19.6%)
No positive pelvic or para-aortic	84 (15.9%)	93 (17.5%)
Planned type of EBRT		
IMRT or VMAT	469 (88.7%)	470 (88.5%)
Non-IMRT and non-VMAT	60 (11.3%)	61 (11.5%)
Planned total radiotherapy dose (EQD2)		
<70 Gy	47 (8.9)	46 (8.7)
≥70 Gy	482 (91.1)	485 (91.3)

Data cutoff date: January 9, 2023.

[a]In each treatment arm, 2 patients (0.4%) had missing information for race. [b]Per protocol, a positive lymph node is defined as ≥1.5 cm shortest dimension by MRI or CT.

CPS, combined positive score; ECOG PS, Eastern Cooperative Oncology Group performance status; EQ2D, equivalent total doses in 2-Gy fractions; FIGO, The International Federation of Gynecology and Obstetrics; IMRT, intensity modulated radiotherapy; PD-L1, programmed death ligand 1; Pembro, pembrolizumab; VMAT, volumetric-modulated arc therapy.

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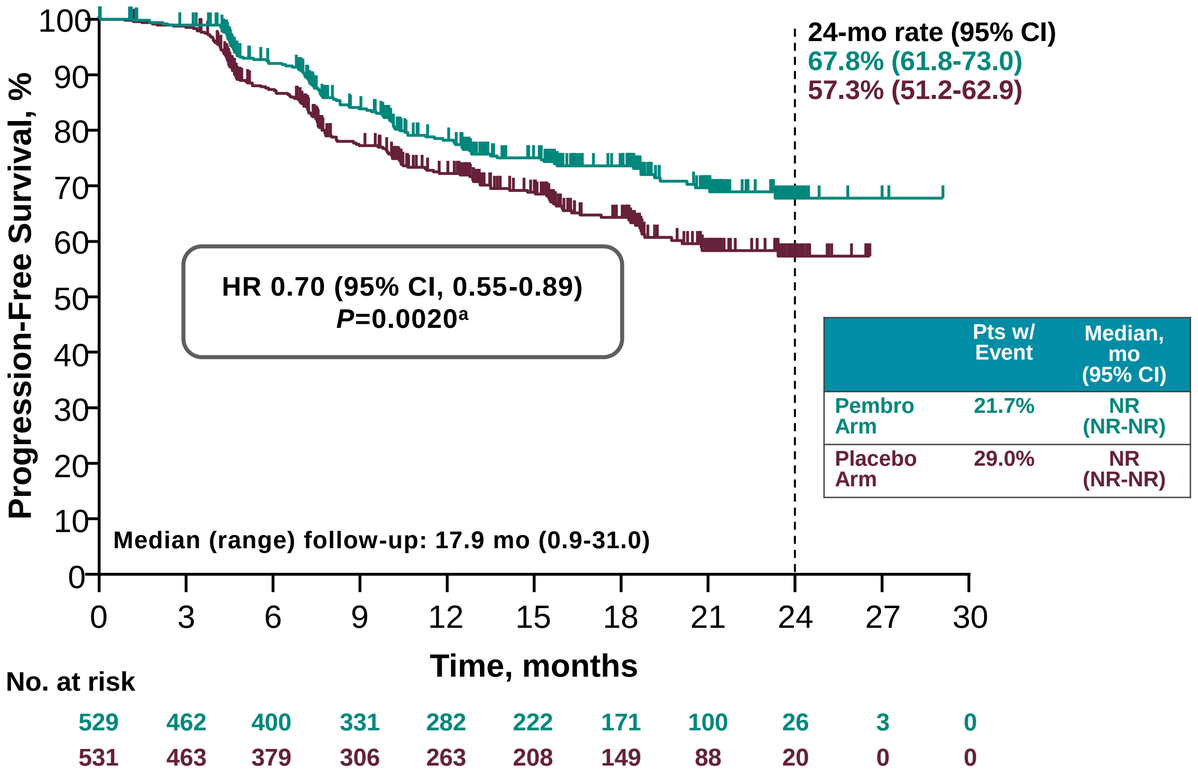
KEYNOTE-A18 (ENGOT-cx11/GOG-3047): Progression-Free Survival and Overall Survival

PFS

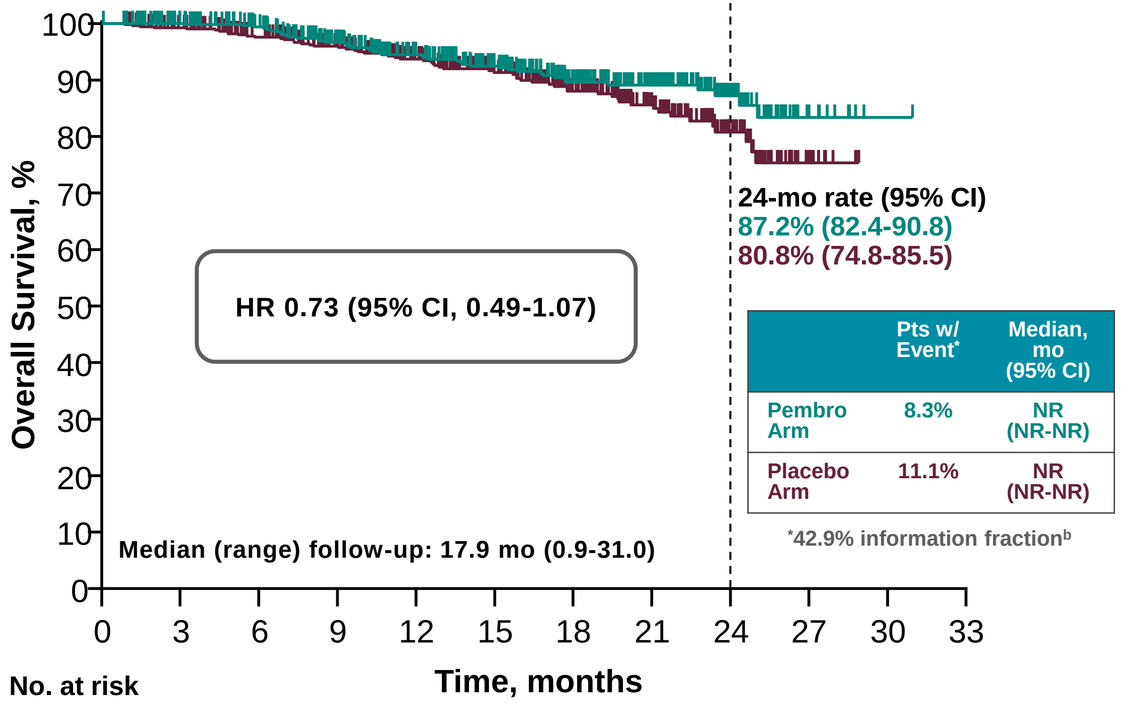


	Pts w/ Event	Median, mo (95% CI)
Pembro Arm	21.7%	NR (NR-NR)
Placebo Arm	29.0%	NR (NR-NR)

No. at risk

529	462	400	331	282	222	171	100	26	3	0
531	463	379	306	263	208	149	88	20	0	0

OS



	Pts w/ Event*	Median, mo (95% CI)
Pembro Arm	8.3%	NR (NR-NR)
Placebo Arm	11.1%	NR (NR-NR)

*42.9% information fraction[b]

No. at risk

529	496	456	405	351	294	223	151	67	10	1	0
531	498	449	402	339	278	214	139	62	12	0	0

Data cutoff date: January 9, 2023. Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation.
[a]With 269 events (88.5% information fraction), the observed *P* = 0.0020 (1-sided) crossed the prespecified nominal boundary of 0.0172 (1-sided) at this planned first interim analysis. The success criterion of the PFS hypothesis was met, and thus no formal testing of PFS will be performed at a later analysis. [b]At this analysis, 103 of the 240 deaths expected at the final analysis had occurred.
NR, not reached; OS, overall survival; pembro, pembrolizumab; PFS, progression-free survival; pts, patients; RECIST, Response Evaluation Criteria in Solid Tumors.
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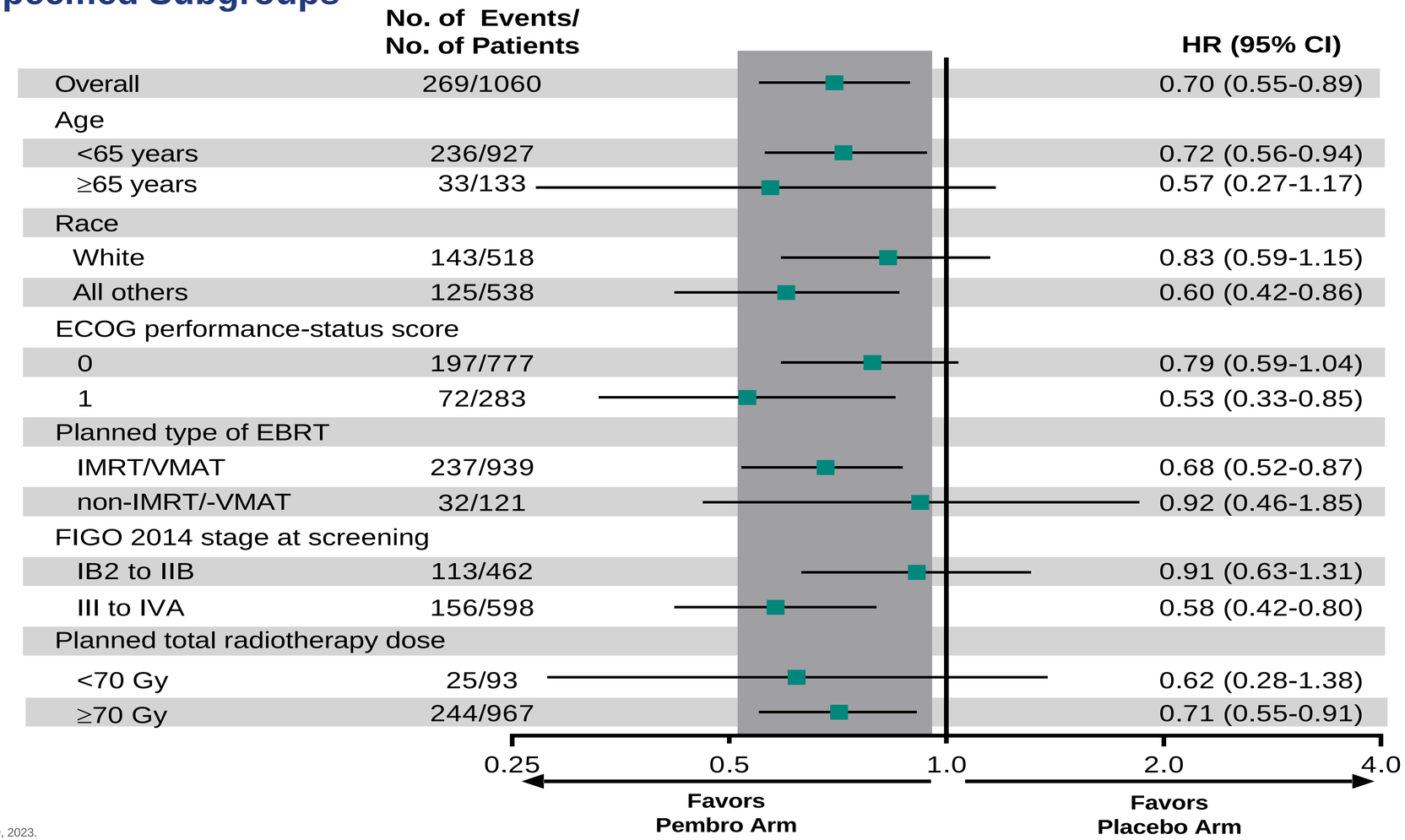
KEYNOTE-A18 (ENGOT-cx11/GOG-3047): Treatment Exposure and Protocol-Specified Subgroups

PFS[c]: Protocol-Specified Subgroups



Data cutoff date: January 9, 2023.

[a]Includes participants who completed concurrent chemoradiotherapy at this interim analysis and had final data review by the vendor (pembro arm N=518; placebo arm N=522). [b]Total radiation therapy (EBRT and brachytherapy) should not exceed 50 days, with extension to a maximum of 56 days for unforeseen delays, as per the study protocol. [c]Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation.

EBRT, external beam radiotherapy; ECOG, Eastern Cooperative Oncology Group; EQ2D, equivalent total doses in 2-Gy fractions; FIGO, The International Federation of Gynecology and Obstetrics; IMRT, intensity modulated radiotherapy; Pembro, pembrolizumab; PFS, progression-free survival; VMAT, volumetric-modulated arc therapy.

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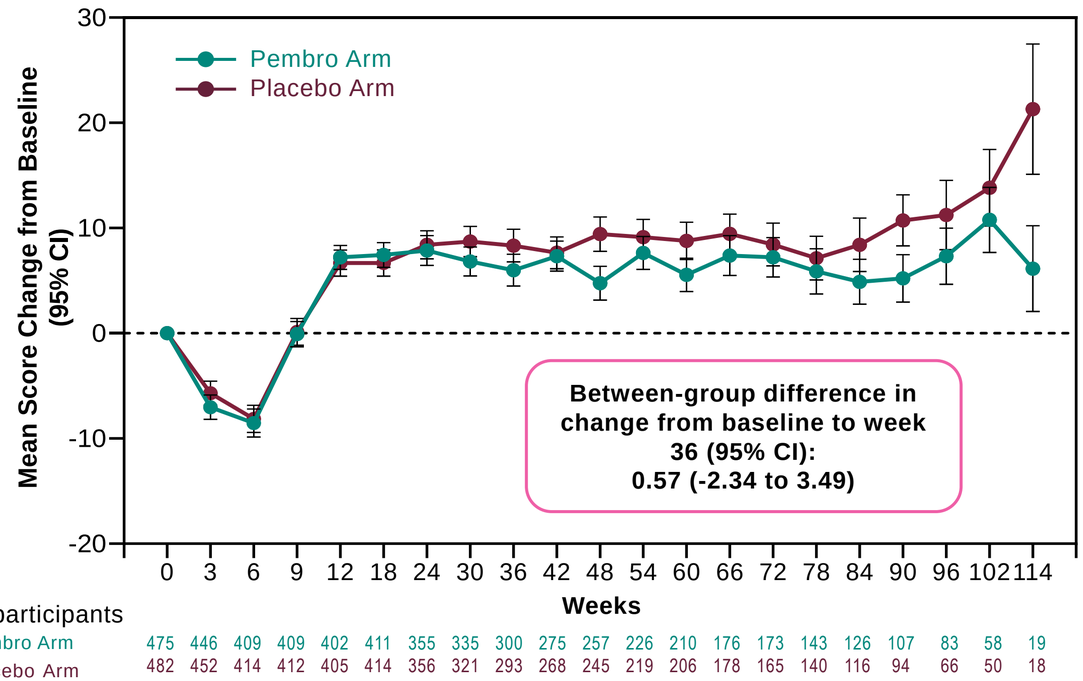
KEYNOTE-A18 (ENGOT-cx11/GOG-3047): Safety and Quality of Life

Adverse Events

	All-Cause AEs		Treatment-Related AEs[a]		Immune-Mediated AEs[b]	
	Pembro Arm (N = 528)	Placebo Arm (N = 530)	Pembro Arm (N = 528)	Placebo Arm (N = 530)	Pembro Arm (N = 528)	Placebo Arm (N = 530)
Any grade	525 (99.4%)	526 (99.2%)	507 (96.0%)	509 (96.0%)	172 (32.6%)	62 (11.7%)
Grade ≥3	394 (74.6%)	364 (68.7%)	354 (67.0%)	321 (60.6%)	22 (4.2%)	6 (1.1%)
Serious	150 (28.4%)	131 (24.7%)	91 (17.2%)	65 (12.3%)	15 (2.8%)	6 (1.1%)
Led to death	5 (0.9%)	6 (1.1%)	2 (0.4%)[c]	2 (0.4%)[d]	0	0
Led to discontinuation						
Any treatment	92 (17.4%)	75 (14.2%)	81 (15.3%)	67 (12.6%)	12 (2.3%)	2 (0.4%)
All treatment	1 (0.2%)	2 (0.4%)	0	1 (0.2%)	0	0

EORTC Quality-of-Life Core 30 (QLQ-C30)



No. of participants

Pembro Arm	475	446	409	409	402	411	355	335	300	275	257	226	210	176	173	143	126	107	83	58	19
Placebo Arm	482	452	414	412	405	414	356	321	293	268	245	219	206	178	165	140	116	94	66	50	18

- Compliance[e] at week 36: 96.0% for both pembrolizumab and placebo arms
- Analysis population: all treated participants with ≥1 available PRO assessment
- No clinically meaningful between-group differences in changes in score from baseline to week 36 were observed for QLQ-C30 global health status/QoL or QLQ-C30 physical functioning scores

Data cutoff date: January 9, 2023.
[a]Per investigator assessment. [b]Events were considered regardless of attribution to treatment by the investigator. [c]Immune-mediated gastritis and large intestine perforation. [d]Bone marrow failure and neutropenic colitis. [e]Compliance was defined as the proportion of participants who completed the questionnaire among those who were expected to complete the questionnaire at the time point, excluding those missing by design such as death, discontinuation, or translation not available.
AE, adverse event; EORTC , European Organisation for Research and Treatment; Pembro, pembrolizumab; PRO, patient-reported outcomes; QLQ-C30, Quality-of-Life Core 30.
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KEYNOTE-A18 (ENGOT-cx11/GOG-3047): Treatment Exposure and Protocol-Specified Subgroups

Summary of Treatment Exposure

	Pembro Arm (N = 528)	Placebo Arm (N = 530)
Total number of cycles, median (range)		
Pembro or placebo	11 (1-20)	11 (1-20)
Cisplatin[a]	5 (1-7)	5 (1-7)
Radiation therapy, median (range)[a]		
Overall treatment time (days)	52 (12-139)	52 (2-166)
Within 50 days[b], n (%)	184 (35.5%)	194 (37.2%)
Within 56 days, n (%)	386 (74.5%)	390 (74.7%)
Cervix total dose (Gy), median (range)[a]		
Total cervix physical dose	76 (14-94)	76 (3-125)
Total cervix EQD2 dose	87 (14-118)	87 (3-207)

Data cutoff date: January 9, 2023.
[a]Includes participants who completed concurrent chemoradiotherapy at this interim analysis and had final data review by the vendor (pembro arm N=518; placebo arm N=522). [b]Total radiation therapy (EBRT and brachytherapy) should not exceed 50 days, with extension to a maximum of 56 days for unforeseen delays, as per the study protocol. [c]Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation.
EBRT, external beam radiotherapy; ECOG, Eastern Cooperative Oncology Group; EQ2D, equivalent total doses in 2-Gy fractions; FIGO, The International Federation of Gynecology and Obstetrics; IMRT, intensity modulated radiotherapy; Pembro, pembrolizumab; PFS, progression-free survival; VMAT, volumetric-modulated arc therapy.
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GCIG INTERLACE: Study Design

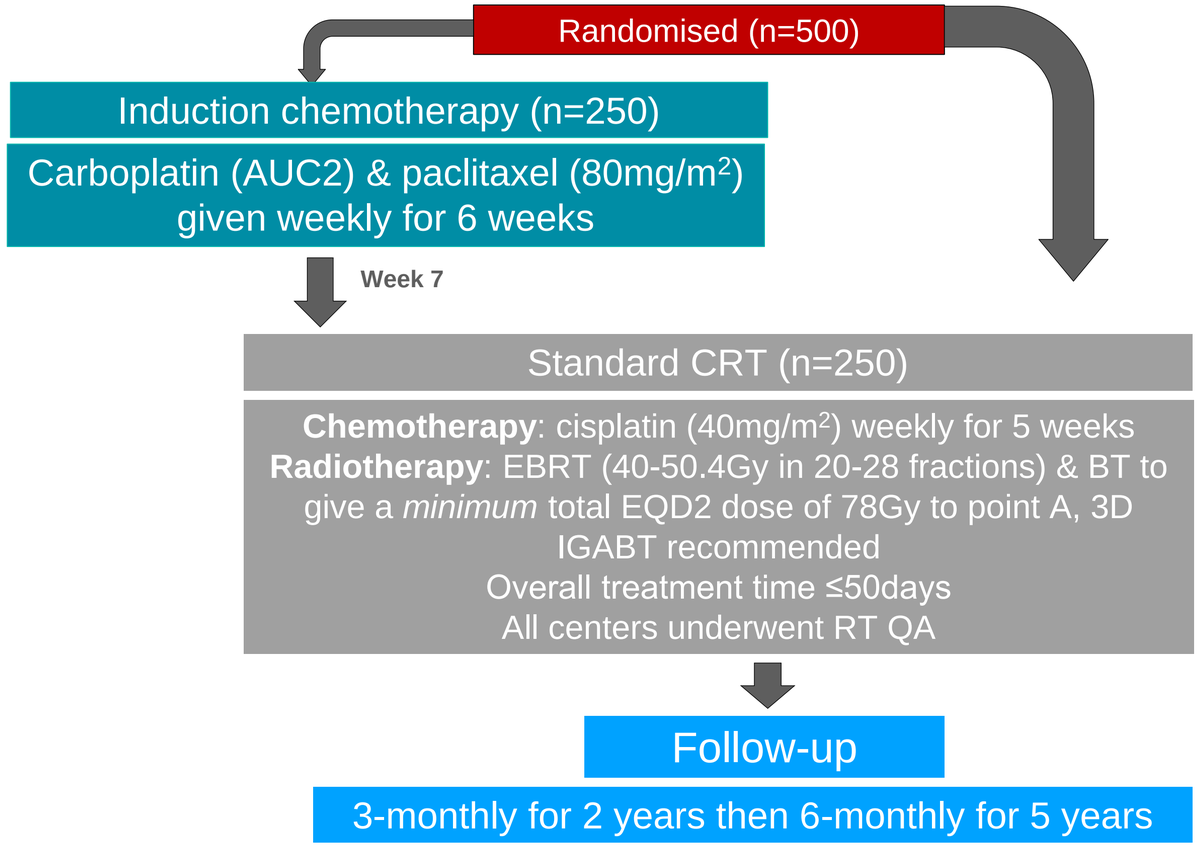
A randomised phase III trial of induction chemotherapy followed by chemoradiation compared with chemoradiation alone in locally advanced cervical cancer

Key Eligibility Criteria:[1,2]

- Newly diagnosed histologically confirmed FIGO (2008) stage IB1 node+, IB2, II, IIIB, IVA squamous, adeno, adenosquamous cervical cancer
- No nodes above aortic bifurcation
- Adequate renal/liver and bone marrow function
- Fit for chemotherapy & radical RT
- No prior pelvic RT

Stratified by:

Site, stage, nodal status, 3D-conformal vs IMRT EBRT, 2D v 3D BT, tumour size, SCC vs other



- **Primary endpoints:**
  - **PFS**
  - **OS**

Secondary endpoints:

- **Adverse events**
- **Pattern of relapse**
- **QOL**
- **Time to subsequent treatment**

Adeno, adenocarcinoma; CRT, chemoradiation therapy; EBRT, external beam radiotherapy; EQ2D, equivalent total doses in 2-Gy fractions; FIGO, The International Federation of Gynecology and Obstetrics; IC, induction chemotherapy; IGABT, image-guided adaptive brachytherapy; IMRT, intensity modulated radiotherapy; OS, overall survival; PFS, progression-free survival; RT, radiotherapy; QOL, quality of life; RT QA, radiotherapy quality assurance; SCC, squamous cell carcinoma; 3D-conformal, 3D conformal radiotherapy.

McCormack M, et al. Presented at ESMO 2023. LBA8

INTERLACE: Demographics and Disease Characteristics

Demographics at Baseline

	CRT alone (n=250)	Induction Chemo + CRT (n=250)
Age, years median (range)	46 (24-78)	46 (26-78)
ECOG status	No. of patients (%)	
0	221 (88)	214 (86)
1	29 (12)	36 (14)
Country		
UK	**190 (76)**	**190 (76)**
Mexico	**51 (20)**	**49 (20)**
Italy	3 (1)	5 (2)
India	5 (2)	5 (2)
Brazil	1 (<1)	1 (<1)

Disease Characteristics at Baseline

	CRT alone (n=250)	Induction Chemo + CRT (n=250)
FIGO stage (2008)	No. of patients (%)	
IB1	2 (<1)	2 (<1)
IB2	23 (9)	19 (8)
IIA	14 (6)	17 (7)
IIB	176 (70)	178 (71)
IIIB	30 (12)	26 (10)
IVA	5 (2)	8 (3)
Cell type		
Non-squamous	45 (18)	44 (18)
Squamous	205 (82)	206 (82)
Nodal status		
Negative	142 (57)	146 (58)
Positive	108 (43)	104 (42)
Longest tumour diameter, cm median (range)	4.9 (1.8-12.8)	4.8 (1.3-13.5)

Chemo, chemotherapy; CRT, chemoradiation therapy; ECOG, Eastern Cooperative Oncology Group; FIGO, The International Federation of Gynecology and Obstetrics.
McCormack M, et al. Presented at ESMO 2023. LBA8

INTERLACE: Adherence to Therapy

Adherence to Cisplatin

	CRT alone (n=250)	IC+ CRT (n=250)
	No. of patients (%)	
Completed 5 weekly cycles	197 (79)	169 (68)
Completed at least 4 cycles	224 (90)	212 (85)
Main reasons for <5 cycles:		
Adverse events leading to discontinuation:	33 (13)	68 (27)
Haematological	4	34
Non-haematological	25	20
Both	4	14
Other	20 (8)	13 (5)

Adherence to Radiation

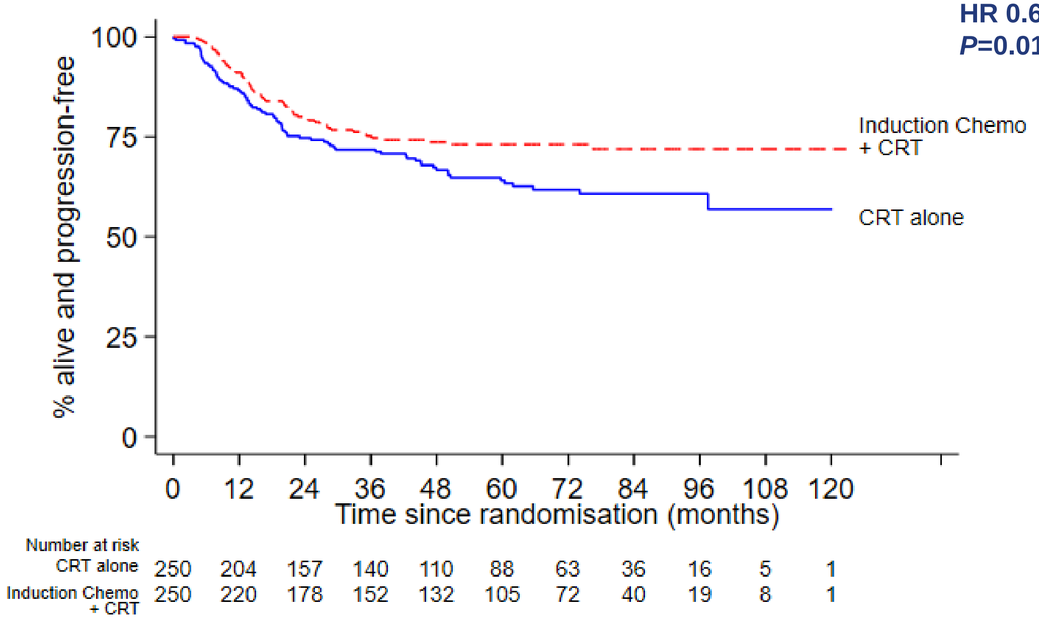
	CRT alone (n=250)	IC + CRT (n=250)
	No. of patients (%)	
Received external beam radiotherapy	**231 (92)**	**242 (97)**
IMRT	93 (40)	102 (42)
3D conformal	138 (60)	140 (58)
Received brachytherapy	**223 (97)**	**238 (98)**
2D point A	49(22)	46 (19)
3D point A	106 (48)	120 (51)
3D HRCTV D90	68 (30)	72 (30)
Median overall treatment time days(range)	**45 (37-88)**	**45 (36-70)**

CRT, chemoradiation therapy; HRCTV D90, minimum dose delivered to 90% of the high-risk clinical target volume; IC, induction chemotherapy; IMRT, intensity modulated radiotherapy; RT, radiotherapy; 3D-conformal, 3D conformal radiotherapy.
McCormack M, et al. Presented at ESMO 2023. LBA8

INTERLACE: Progression-Free Survival and Overall Survival

PFS (Median f/u: 64 months)

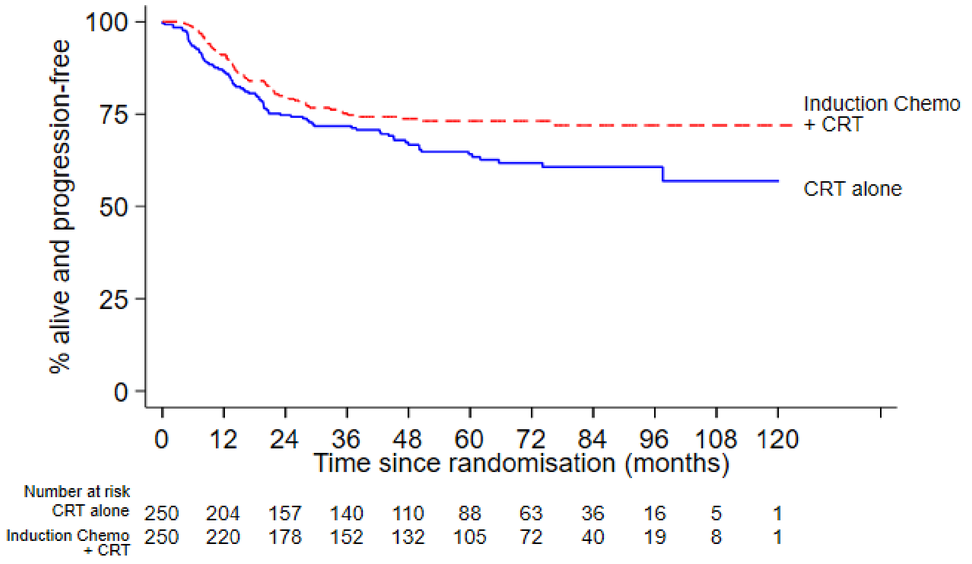
146 PFS events
HR 0.65;95% CI:0.46 -0.91
***P*=0.013**



	Induction Chemo+ CRT (n=250)	CRT alone (n=250)
3yr PFS	75%	72%
5yr PFS	73%	64%

OS (Median f/u: 64 months)

109 deaths
HR 0.61;95% CI: 0.40-0.91
***P*=0.04**



	Induction Chemo + CRT (n=250)	CRT alone (n=250)
3yr OS	86%	80%
5yr OS	80%	72%

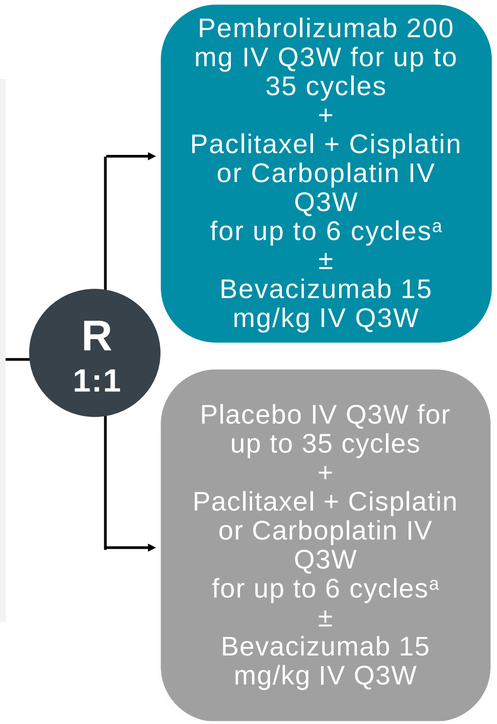
Chemo, chemotherapy; CRT, chemoradiation therapy; f/u, follow-up; OS, overall survival; PFS, progression-free survival.
McCormack M, et al. Presented at ESMO 2023. LBA8

KEYNOTE-826: Study Design

A phase 3 randomized, double-blind, placebo-controlled trial of pembrolizumab (MK-3475) plus chemotherapy vs chemotherapy plus placebo for the first-line treatment of persistent, recurrent, or metastatic cervical cancer[1,2]

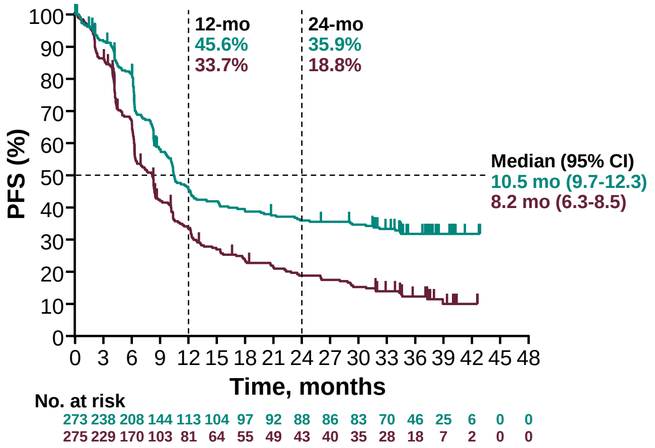
Key Eligibility Criteria:[1,2]

- Persistent, recurrent, or metastatic cervical cancer not amenable to curative treatment
- No prior systemic chemotherapy (prior radiotherapy and chemoradiotherapy permitted)
- ECOG PS 0 or 1



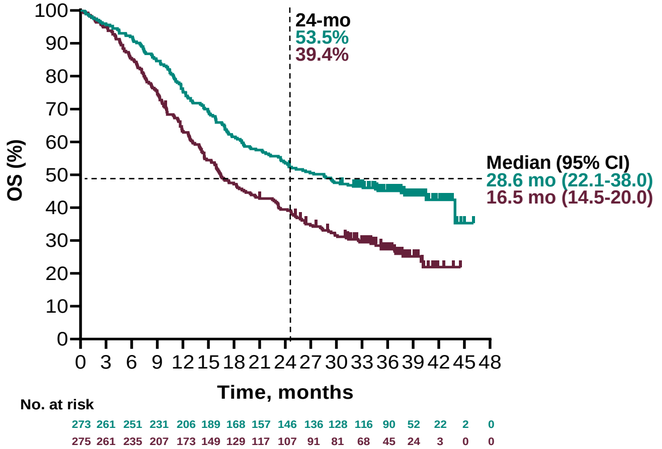
Primary Endpoints: PFS (per RECIST v1.1 by investigator), OS
Secondary Endpoints: ORR, DOR, 12-mo PFS, safety

PFS: PD-L1 CPS ≥1 Population[2,b]



	Pembro arm	Placebo arm
n/N	171/273	220/275
Events	62.6%	80.0%
HR (95% CI)	0.58 (0.47-0.71)	

OS: PD-L1 CPS ≥1 Population[2]



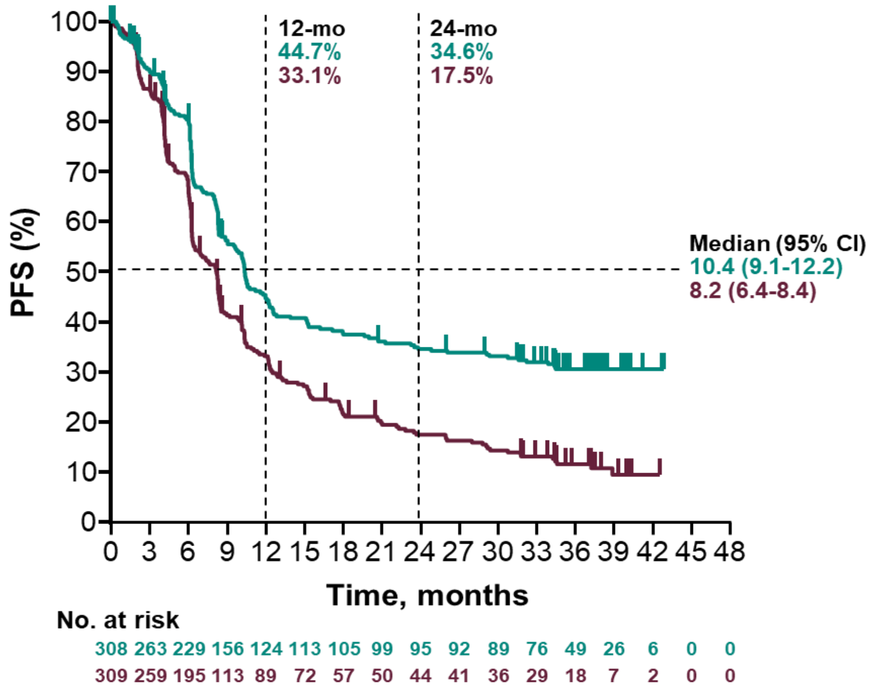
	Pembro arm	Placebo arm
n/N	153/273	201/275
Events	56.0%	73.1%
HR (95% CI)	0.60 (0.49-0.74)	

[a]Paclitaxel: 175 mg/m^2. Cisplatin: cisplatin 50 mg/m^2. Carboplatin: AUC 5 mg/mL/min. The 6-cycle limit was introduced with protocol amendment 2, although patients with ongoing clinical benefit who were tolerating chemotherapy could continue beyond 6 cycles after sponsor consultation. [b]Response assessed per RECIST v1.1 by investigator review.
Data cutoff date: October 3, 2022.
CPS, combined positive score (number of PD-L1–staining cells [tumor cells, lymphocytes, macrophages] divided by the total number of viable tumor cells, multiplied by 100.
CI, confidence inverval; CPS, combined positive score; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; IV, intravenous; HR, hazard ratio; mo, months; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand-1; Pembro, pembrolizumab; PFS, progression-free survival; PS, performance status; RECIST; Response Evaluation Criteria in Solid Tumours; Q3W, every 3 weeks.
1. ClinicalTrials.gov. Accessed September 20, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT03635567; 2. Lorusso et al. Poster # BO2-3. Presented at ESGO Annual Meeting 2023.

KEYNOTE-826: Protocol-Specified Final PFS and OS in All-Comer Population

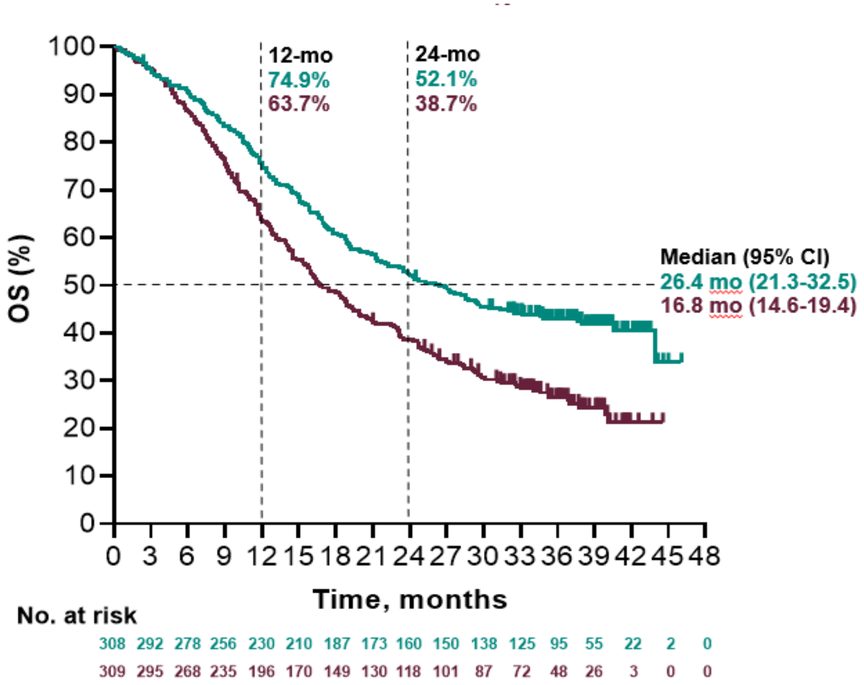
PFS: All-Comer Population[a]

	n/N	Events	HR (95% CI)
Pembro arm	195/308	63.3%	0.61 (0.50-0.74)
Placebo arm	248/309	80.3%	



OS: All-Comer Population

	n/N	Events	HR (95% CI)
Pembro	178/308	57.8%	0.63 (0.52-0.77)
Placebo	228/309	73.8%	



[a]Response assessed per RECIST v1.1 by investigator review. Data cutoff date: October 3, 2022.
CI, confidence interval; CPS, combined positive score; HR, hazard ratio; PD-L1, programmed death-ligand-1; Pembro, pembrolizumab; PFS, progression-free survival; OS, overall survival.
Lorusso et al. Poster # BO2-3. Presented at ESGO Annual Meeting 2023.

KEYNOTE-826: Summary of Treatment Duration and Adverse Events

Treatment Duration	Pembro Arm		Placebo Arm	
	Bev Yes	Bev No	Bev Yes	Bev No
Median, mos	13.9	6.3	9.7	5.4
Mean (SD)	16.8 (11.8)	10.3 (9.3)	13.1 (10.3)	7.1 (6.6)

Adverse Events	All-Cause AEs			
	Pembro Arm[b] (N=307)		Placebo Arm[b] (N=309)	
	Bev Yes (N=196)	Bev No (N=111)	Bev Yes (N=193)	Bev No (N=116)
Any grade	100%	98.2%	100%	98.3%
Grade ≥3	84.7%	78.4%	75.1%	75.9%
Serious	52.6%	48.6%	45.6%	37.9%
Led to death[c]	6.1%	3.6%	6.2%	2.6%
Led to discontinuation, any drug	50.0%	24.3%	36.3%	18.1%
Led to discontinuation, all drugs	6.6%	3.6%	3.6%	6.9%

Treatment-Related AEs[a]			
Pembro Arm[b] (N=307)		Placebo Arm[b] (N=309)	
Bev Yes (N=196)	Bev No (N=111)	Bev Yes (N=193)	Bev No (N=116)
97.4%	96.4%	98.4%	94.8%
74.0%	60.4%	66.8%	62.1%
33.7%	25.2%	25.9%	19.8%
0.5%	0.9%	1.6%	0.9%
40.8%	19.8%	32.6%	12.1%
3.6%	1.8%	1.0%	3.4%

Data cutoff date: October 3, 2022
[a]Per investigator assessment. [b]The treatment regimen in each arm included chemo ± bev. [c]Treatment-related AEs that led to death were encephalitis and pancreatitis in the pembro arm and embolism, female genital tract fistula, large intestine perforation, and pulmonary sepsis in the placebo arm
AE, adverse events; Bev, bevacizumab; Pembro, pembrolizumab.
Lorusso et al. Poster # BO2-3. Presented at ESGO Annual Meeting 2023.

BEATcc (ENGOT-Cx10/GEICO 68-C/JGOG1084/GOG-3030): Study Design and Efficacy

A randomised phase III trial of first-line atezolizumab combined with a platinum doublet and bevacizumab for metastatic (stage IVB), persistent or recurrent cervical cancer[1,2]

Key Eligibility Criteria:[1,2]

- Metastatic, persistent or recurrent cervical cancer not amenable to curative therapy
- GOG/ECOG PS
- No prior systemic anti-cancer therapy for R/M CC
- In patients with pelvic disease, no bladder or rectal mucosa involvement
- Available archival or fresh tumor sample for PD-L1 expression

Stratified by:

- Prior concurrent chemoradiation (Y/N)
- Histology (squamous cell carcinoma vs adenocarcinoma including Adenosquamous carcinoma)
- Chemotherapy backbone

R 1:1

N=410

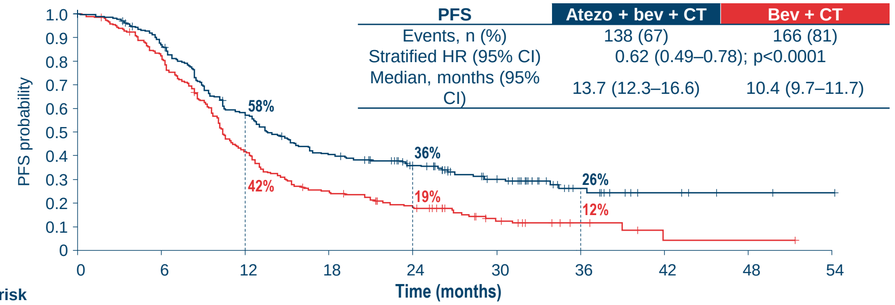
Atezolizumab 1200 mg + Bevacizumab 15 mg/kg + Paclitaxel+ cis/carboplatin[a] all IV Q3W

- Continued until disease progression/unacceptable toxicity

Bevacizumab 15 mg/kg + Paclitaxel + cis/carboplatin[a] all IV Q3W

Dual primary endpoint: PFS

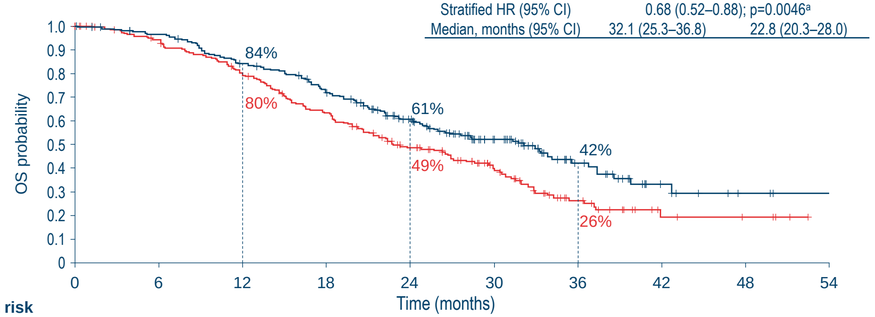
PFS	Atezo + bev + CT	Bev + CT
Events, n (%)	138 (67)	166 (81)
Stratified HR (95% CI)	0.62 (0.49–0.78); p<0.0001	
Median, months (95% CI)	13.7 (12.3–16.6)	10.4 (9.7–11.7)



No. at risk										
Atezo + bev + CT	206	174	114	79	58	37	13	5	2	1
Bev + CT	204	159	80	47	31	13	5	1	1	0

Dual primary endpoint: OS[c]

OS	Atezo + bev + CT	Bev + CT
Events, n (%)	105 (51)	129 (63)
Stratified HR (95% CI)	0.68 (0.52–0.88); p=0.0046[a]	
Median, months (95% CI)	32.1 (25.3–36.8)	22.8 (20.3–28.0)



No. at risk											
Atezo + bev + CT	206	194	167	140	103	64	27	9	3	1
Bev + CT	204	182	152	119	83	50	22	6	4	0

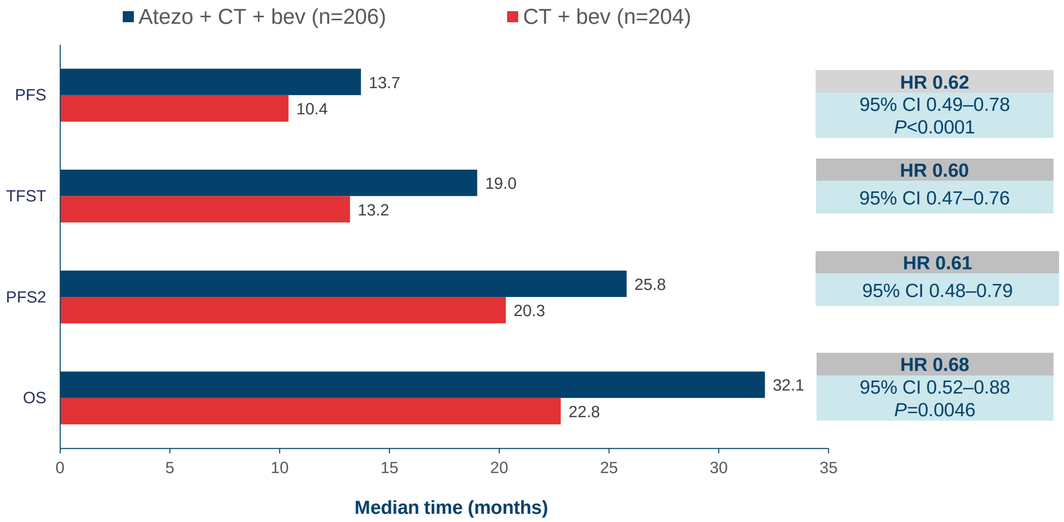
Data cutoff: 17 July 2023 (median follow-up: 32.9 months; 95% CI, 31.2 – 34.6 months).
[a]Paclitaxel 175 mg/m^2 day 1 + platinum (cisplatin 50 mg/m^2 or carboplatin AUC5) day 1; [b]capped at 20% of the overall population. [c]Interim OS was statistically significant, crossing the boundary of *P*=0.0238
Atezo, atezolizumab, bev, bevacizumab, CR, complete response; CT, chemotherapy; DOR, duration of response; ECOG, eastern cooperative oncology group; HR, hazard ratio; ORR, objective response rate; OS, overall survival; PFS, progression – free survival; PFS2, time from randomisation to second progression or death; PS, performance status; Q3W, every 3 weeks; RECIST, response evaluation criteria in solid tumors; TFST, time from randomisation to first subsequent therapy or death; Y/N, yes/no.

1. Oaknin et al. Presented at ESMO Virtual Meeting 2023. Abstract LBA 39; 2. ClinicalTrials.gov. Accessed November 03, 2023. https://clinicaltrials.gov/study/NCT03556839

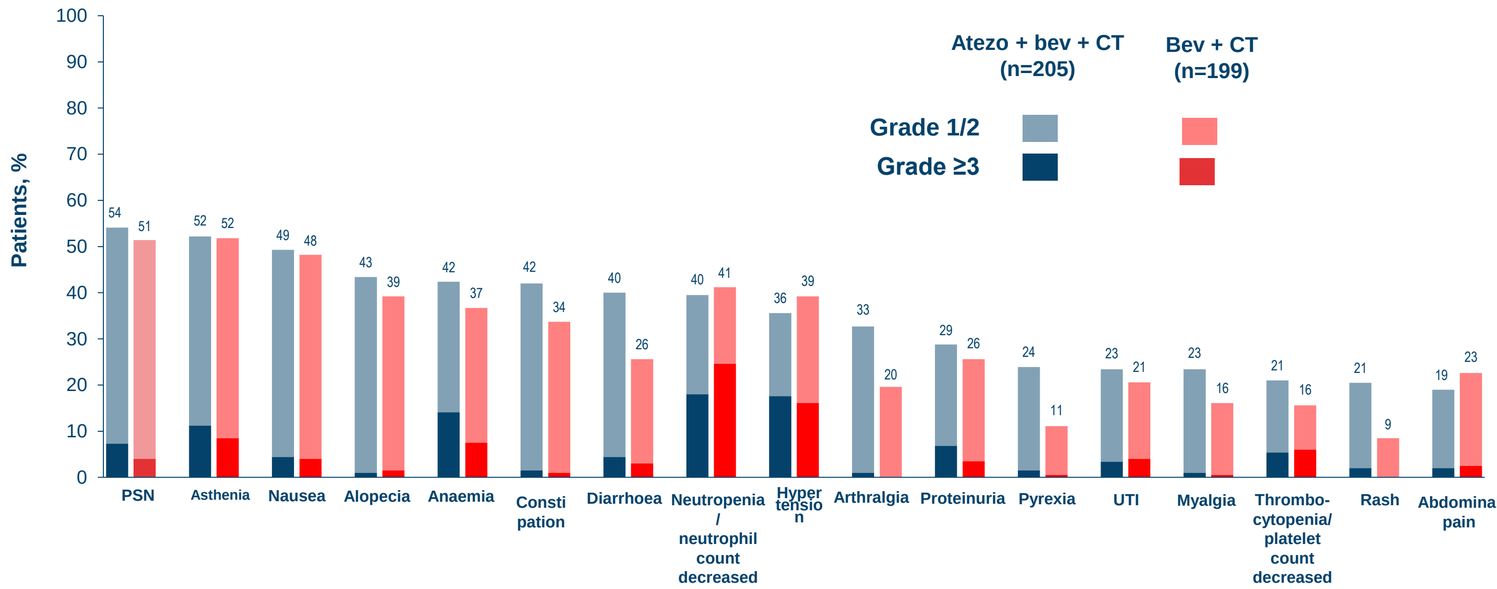
BEATcc (ENGOT-Cx10/GEICO 68-C/JGOG1084/GOG-3030): Efficacy and Safety

Summary of efficacy

Consistent results across primary and secondary efficacy endpoints



All cause AEs in ≥ 20% of patients in either arm



Data cutoff: 17 July 2023 (median follow-up: 32.9 months; 95% CI, 31.2–34.6 months).
AE, adverse event; atezo, atezolizumab; bev, bevacizumab; CT, chemotherapy; NA, not applicable; OS, overall survival; PFS, progression – free survival; PFS2, time from randomisation to second progression or death; PSN, peripheral /sensory neuropathy; TFST, time from randomisation to first subsequent therapy or death; UTI, urinary tract infection.
Oaknin et al. Presented at ESMO Virtual Meeting 2023. Abstract LBA 39.