

Evolving the Treatment Landscape of Platinum-Resistant Ovarian Cancer (PROC) : The Impact of KEYNOTE-B96

MSD

KEYTRUDA® (pembrolizumab) Injection 100 mg

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Background on Platinum-Resistant Ovarian Cancer (PROC)

난소암의 미충족 수요

2003

Chemotherapy

No further improvement in survival with chemotherapy alone since the introduction of platinum–taxane chemotherapy[1,2]

2011-2018

Paradigm shift 1

Bevacizumab

Bevacizumab improved PFS versus chemotherapy alone[3,4]

Bevacizumab	**GOG-0218** (1L) NCT00262847
	ICON-7 (1L) NCT00483782
	GOG-0213 (PSOC) NCT00565851
	AURELIA (PROC) NCT00976911

2018–2023

Paradigm shift 2

PARP inhibitors

PARPi significantly improved PFS in Mtx with clinically meaningful OS for pts with BRCAm and HRD+ tumors

Olaparib	SOLO-1[5] NCT01844986
Olaparib + bevacizumab	PAOLA-1[6] NCT02477644
Niraparib	PRIMA[7] NCT02655016
Rucaparib	ATHENA-MONO[8,9] NCT03522246

2024+

Paradigm shift 3

Immune therapies

Explored, although many failed to show clinically meaningful benefit

~~Olaparib + bevacizumab + durvalumab~~	DUO-O[10] NCT03737643
~~Niraparib + dostarlimab ± bevacizumab~~	FIRST[11] NCT03602859
Olaparib + pembrolizumab ± bevacizumab	KEYLYNK-001[12] NCT03740165
Pembrolizumab + chemo +/- bevacizumab	KEYNOTE-B96 NCT05116189
~~Atezolizumab + chemo + bevacizumab~~	Ago-OVAR 2.29

2024+

Paradigm shift 4

ADCs

First two are approved and many more expected to enter the market in 2027+

Mirvetuximab soravtansine	MIRASOL[13] NCT04209855
T-DXd	DESTINY-PanTumor02[14] NCT04482309
Rina-S	RAINFOL-01 - ph2 RAINFOL-02 – ph3 NCT06619236
R-DXd	REJOICE-Ovarian01[17] NCT06161025
Sac-TMT	TroFuse-022[18] NCT06824467
Others	40+ in development

Background of KEYNOTE-B96

- In the phase 3 AURELIA study, bevacizumab plus weekly paclitaxel showed the greatest efficacy among evaluated chemotherapy regimens in platinum-resistant recurrent ovarian cancer (PRROC).[1,2]
- Paclitaxel boosts immunity by increasing tumor immunogenicity and reducing immunosuppressive factors within the tumor microenvironment, particularly when administered at a lower dose on a weekly schedule.[3–5]
- Consistent with this rationale, previous phase 2 studies of pembrolizumab plus chemotherapy showed improved outcomes in recurrent ovarian cancer.[6,7]
- In ENGOT-ov65/KEYNOTE-B96, pembrolizumab (vs placebo) plus weekly paclitaxel, with or without bevacizumab, showed statistically significant and clinically meaningful improvements in PFS regardless of PD-L1 status and in OS in PD-L1-expressing tumors in participants with PRROC.

1.Pujade-Lauraine E, et al. J Clin Oncol. 2014;32:1302-1308. 2.Poveda AM, et al. J Clin Oncol. 2015;33:3836-3838. 3.Muraro E, et al. Cancers. 2023;15:2471. 4.Pfirschke C, et al. Immunity. 2016;44:343-354. 5.Vafaei S, et al. Cancer Cell Int. 2022;22:2. 6.Zsiros E, et al. JAMA Oncol. 2021;7:78-85. 7.Wenham RM, et al. Int J Gynecol Cancer. 2025;102856.

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KEYNOTE-B96는 왜 'weekly paclitaxel'만을 Backbone으로 설계했나? (Protocol § 2.1–2.2)

1 AURELIA 백본별 분석 = wPAC + bev

Pujade-Lauraine E, et al. J Clin Oncol. 2014;32:1302-8
AURELIA 본편 · 화학요법에 bev 추가 시 PFS 6.7 vs 3.4개월, ORR 27.3% vs 11.8%

Poveda AM, et al. J Clin Oncol. 2015;33:3836-8
백본별 코호트 분석 · PAC: ORR 53.3 vs 30.2%, PFS HR 0.46 (10.4 vs 3.9개월) / TOP: 17.0 vs 0%, HR 0.32 (5.8 vs 2.1개월) / PLD: 13.7 vs 7.8%, HR 0.57 (5.4 vs 3.5개월)

▶ 프로토콜 원문: wPAC + bev가 AURELIA에서 가장 활성 높은 조합이며 ideal option으로 간주된다

PROC = platinum-resistant ovarian cancer; wPAC = weekly paclitaxel; PLD = pegylated liposomal doxorubicin; TOP = topotecan; DCR = disease control rate; EOC = epithelial ovarian cancer.
출처: MK-3475-B96-00 / ENGOT-ov65 Protocol (27-JUL-2021) Section 2.1 Study Rationale, 2.2.2 Therapeutic Strategies in PRROC, 2.2.3 Immunotherapy Plus Chemotherapy in PRROC, 2.2.4 Pembrolizumab and Paclitaxel in PRROC — Lancet 2026 논문 부록(Supplementary appendix) 수록 프로토콜 전문 기준.

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AURELIA Trial : Efficacy by regimen

	Paclitaxel	Bevacizumab + Paclitaxel	PLD	Bevacizumab + PLD	Topotecan	Bevacizumab + Topotecan
n	55	60	64	62	63	57
ORR	30.2%	**53.3%**	7.8%	13.7%	0%	17%
PFS months	3.9	**10.4**	3.5	5.4	2.21	5.8
PFS HR	0.46 (0.30-0.71)		0.57 (0.39-0.83)		0.32 (0.21-0.49)	
OS months	13.2	**22.4**	14.1	13.7	13.8	13.3
OS HR	0.65 (0.42-1.02)		0.91 (0.62-1.36)		1.09 (0.72-1.67)	

Pujade-Lauraine, JCO 2014

KEYNOTE-B96는 왜 'weekly paclitaxel'만을 Backbone으로 설계했나? (Protocol § 2.1–2.2)

2 Chemotherapy + Immunotherapy synergistic effect

Tartour E, et al. Cancer Metastasis Rev. 2011;30:83-95

Zsiros E, et al. JAMA Oncol. 2021;7:78-85

Pembrolizumab + bevacizumab + metronomic cyclophosphamide

PROC 30명 → ORR 43.3%, DCR 93.3%, mPFS 7.6개월

PROC = platinum-resistant ovarian cancer; wPAC = weekly paclitaxel; PLD = pegylated liposomal doxorubicin; TOP = topotecan; DCR = disease control rate; EOC = epithelial ovarian cancer.
출처: MK-3475-B96-00 / ENGOT-ov65 Protocol (27-JUL-2021) Section 2.1 Study Rationale, 2.2.2 Therapeutic Strategies in PRROC, 2.2.3 Immunotherapy Plus Chemotherapy in PRROC, 2.2.4 Pembrolizumab and Paclitaxel in PRROC — Lancet 2026 논문 부록(Supplementary appendix) 수록 프로토콜 전문 기준.

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Pembrolizumab과 Chemotherapy 병용의 근거[1-5]

Chemotherapeutic agents activate molecular pathways eliciting upregulation and/or the release of stress molecules that promote tumor cell recognition.[1,2]

Chemotherapy primes anti-tumor immunity[1-3]

- DNA damage and cellular stress trigger DAMP exposure with APC activation and antigen cross-presentation
- Upregulation of NK and T-cell activating ligands on stressed tumor cells improves immune recognition
- Death receptor pathways are enhanced on chemotherapy-treated tumor cells supporting immune-mediated killing

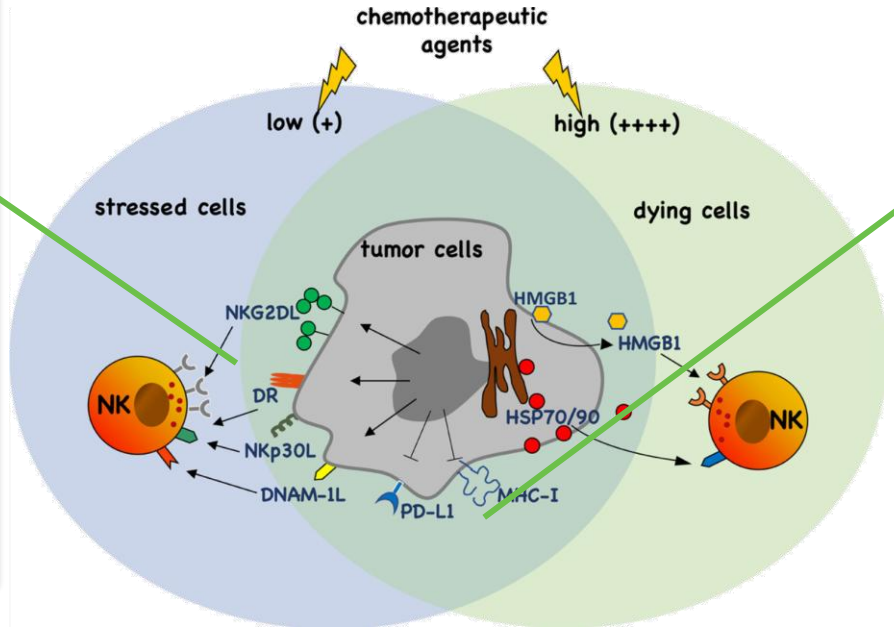


Image used with permission from Zingoni A et al. 2017. CC BY-4.0

Why add a checkpoint inhibitor?

Blocking PD-1 can convert chemotherapy-primed immune engagement into durable tumor control in responsive patients[1,5]

Metronomic dosing of chemotherapy (mCT) modulates the immune environment[3]

- Metronomic regimens reduce immunosuppressive cells, enhances dendritic cell maturation and antigen presentation, and recruits NK and cytotoxic T cells

Recurrent tumors can be more immunogenic[4]

- Recurrent OC has immune-suppressive VEGF signaling that impairs T-cell trafficking
- Anti-VEGF plus mCT can normalize vessels and lift suppression, setting up PD-1 activity

APC, antigen-presenting cell; DNA, deoxyribonucleic acid; NK, natural killer (cell); OC, ovarian cancer; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PRROC, platinum-resistant recurrent ovarian cancer; TME, tumor microenvironment; VEGF, vascular endothelial growth factor

1. Zingoni A et al. *Front Immunol*. 2017;8:1194. 2. Jiménez-Sánchez A et al. *Nat Genet*. 2020;52(6):582-593. 3. Muraro E et al. *Cancers (Basel)*. 2023;15(9):2471. 4. Zsiros E et al. *JAMA Oncol*. 2021;7(1):78-85. 5. Vafaei Set al. *Cancer Cell Int*. 2022;22(1):2.

Phase 2 study of pembrolizumab and weekly paclitaxel for platinum-resistant epithelial ovarian cancer

- Multi-center open-label, single-arm study was conducted and participants received weekly intravenous paclitaxel 80 mg/m^2 and every 3-week intravenous pembrolizumab 200 mg until progression or toxicity
- The primary objectives were to determine the progression-free survival at 6 months and safety
- Secondary analyses included objective response rate, disease control rate, duration of response, median progression-free survival, and overall survival
- All patients receiving any drug were included in the toxicity evaluation.
- Exploratory analysis of programmed cell death ligand-1 in archival tissue was performed

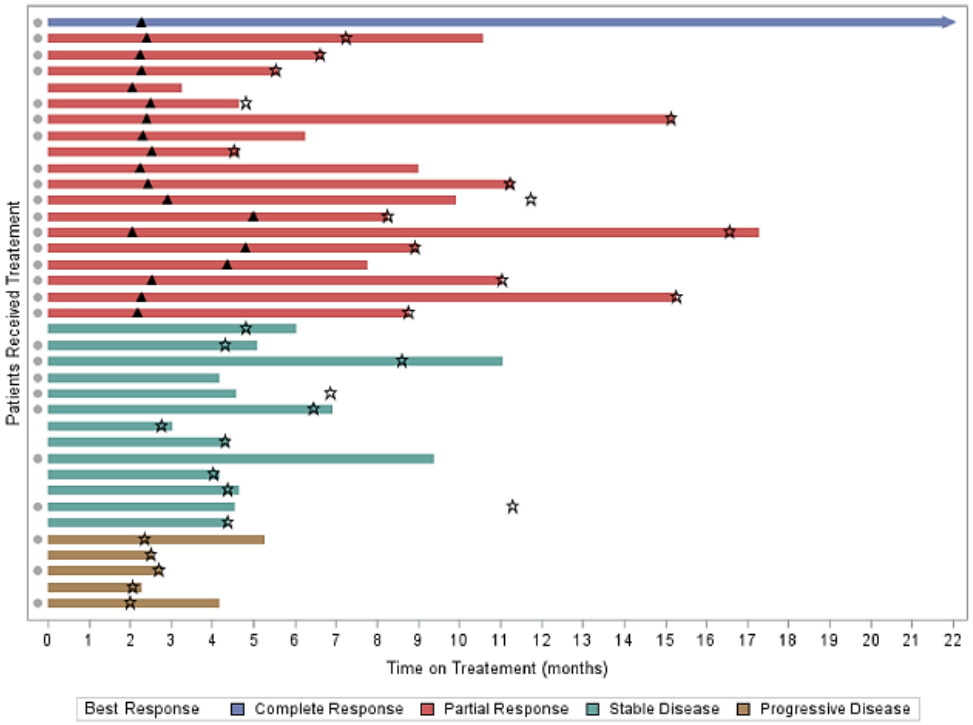


Table 1 Patient and Cancer Characteristics

Variable	Intention-to-treat group (*N* = 41)	RECIST-evaluable group (*N* = 37)
Race, *n* (%)		
White	34 (82.9)	31 (83.8)
Black	4 (9.8)	4 (10.8)
Native American	1 (2.4)	
Unknown	2 (4.9)	2 (5.4)
Age, y		
Mean	62.6	62.7
Range	39-78	39-77
Performance status, *n* (%)		
0	32 (78.0)	30 (81.1)
1	9 (22.5)	7 (28.6)
Previous lines of therapy, *n* (%)		
1	14 (34.1)	12 (32.4)
2	16 (39.0)	15 (40.5)
3	11 (26.8)	10 (27.0)
Recurrence interval from platinum therapy[a], *n* (%), mo		
<3	15 (36.6)	13 (35.1)
3-6	26 (63.4)	24 (64.9)
Time from last platinum therapy[b], *n* (%), mo		
<6	21 (51.2)	19 (51.4)
6-12	13 (31.7)	11 (29.7)
>12	7 (17.1)	7 (18.9)
Primary histology and site, *n* (%)		
HGSC-O[c]	28 (68.3)	26 (70.3)
HGSC-F	7 (17.1)	6 (16.2)
HGSC-P	2 (4.9)	2 (5.4)
HGC-O	2 (4.9)	2 (5.4)
HGC-F[d]	1 (2.4)	0
HGEC-O	1 (2.4)	1 (2.7)
Original stage, *n* (%)		
1A	1 (2.4)	1 (2.7)
2[e]	2 (4.9)	1 (2.7)
2C	1 (2.4)	1 (2.7)
3[e]	1 (2.4)	1 (2.7)
3A	1 (2.4)	1 (2.7)
3B	1 (2.4)	1 (2.7)
3C	23 (56.1)	21 (56.8)
4	11 (26.8)	10 (27.0)

Table 2 Response Rates

Best response	Patients (*N*)	RECIST-evaluable Cohort (*n* = 37) (%)	Intention-to-treat cohort (*n* = 41) (%)
Complete response	1	2.7	2.4
Partial response	18	48.6	43.9
Stable disease	13	35.1	31.7
Progressive disease	5	13.5	12.2[a]
Unassessed	4	N/A	9.8[a]
Disease control rate	32	86.5	78.0

Table 3 TEAEs That Occurred in 20% or More of All Treated Patients (*N* = 42)[a]

Adverse event	Patients with TEAEs, *n* (%)
Anemia	29 (69.1)
Fatigue	22 (52.4)
Investigations - other[b]	21 (50.0)
Edema[c]	20 (47.6)
Dyspnea	18 (42.9)
Nausea	16 (38.1)
Lymphocyte count decreased	15 (35.7)
Hypoalbuminemia	15 (35.7)
Alkaline phosphatase increased	14 (33.3)
Hypomagnesemia	14 (33.3)
Vomiting	13 (31.0)
Activated partial thromboplastin time prolonged	13 (31.0)
Diarrhea	12 (28.6)
Aspartate aminotransferase increased	12 (28.6)
Hyponatremia	12 (28.6)
Bloating	11 (26.2)
Alanine aminotransferase increased	11 (26.2)
Anorexia	11 (26.2)
Cough	11 (26.2)
Constipation	10 (23.8)
Pain	10 (23.8)
Neutrophil count decreased	10 (23.8)
Back pain	10 (23.8)
Leukocytosis	9 (21.4)
Fever	9 (21.4)
Hypocalcemia	9 (21.4)
Headache	9 (21.4)
Peripheral motor neuropathy[d]	9 (21.4)
Peripheral sensory neuropathy[d]	9 (21.4)

E, endometrioid; F, fallopian tube; HGC, high-grade (2-3) carcinoma; HGSC, high-grade serous carcinoma; O, ovary; P, peritoneal; RECIST, Response Evaluation Criteria in Solid Tumors; S, serous.

Wenham RM et al. *Int J Gynecol Cancer.* Published online 13 December 2025. doi:10.1016/j.ijgc.2025.102856.

Images used with permission from: Wenham et al. 2025.

KEYNOTE-B96 Study Key Results

Study Design, Clinical Data, and Safety Profile

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KEYNOTE-B96: Eligibility Criteria

A multicenter, randomized, double-blind, placebo-controlled trial of KEYTRUDA in combination with paclitaxel, with or without bevacizumab for the treatment of platinum-resistant ovarian cancer.

Key Inclusion Criteria

- Histologically-confirmed epithelial ovarian, fallopian tube, or primary peritoneal carcinoma.
- **1** or **2** prior lines of systemic therapy for ovarian carcinoma.
  - Patients must have received at least 1 line of platinum-based chemotherapy for ovarian cancer with radiographic **evidence of disease progression within 6 months after the last dose**.
- Prior therapy with an anti–PD-1/PD-L1 inhibitor, PARP inhibitor, or **bevacizumab was permitted**.

Key Exclusion Criteria

- Patients were ineligible if they had an autoimmune disease that required systemic therapy within 2 years of treatment or a medical condition that required immunosuppression.

Stratification Factors

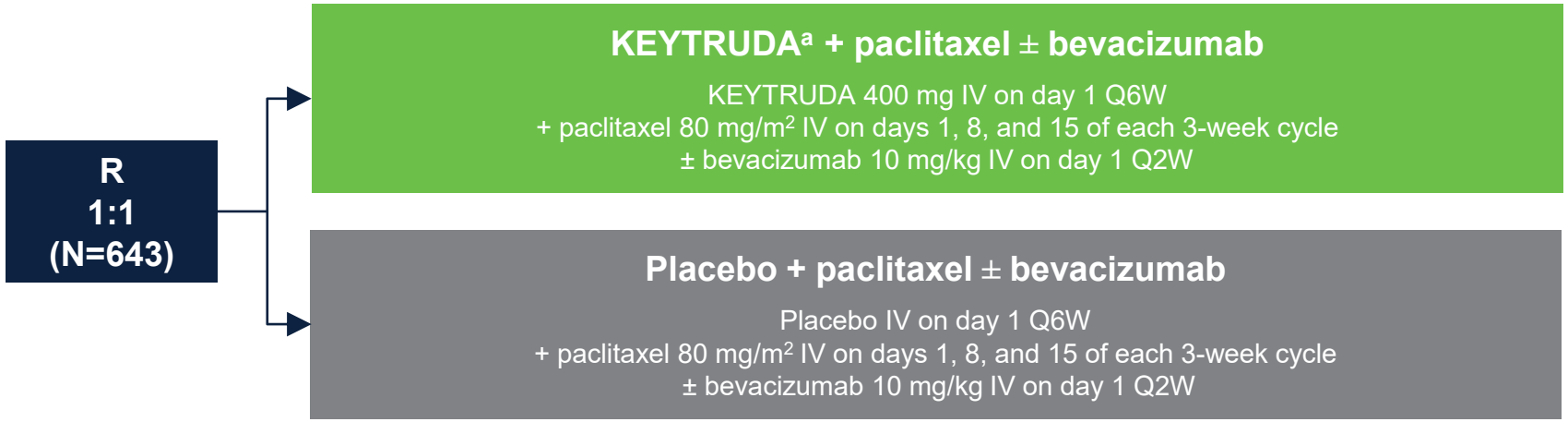
- Investigator decision to use bevacizumab
- Geographic region
- PD-L1 status (CPS <1 vs CPS 1 to <10 vs CPS ≥10)

CPS = combined positive score; PARP = poly (ADP ribose) polymerase; PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1.

1. 식품의약품안전처. 키트루다 허가사항. 2. Colombo N, et al. Pembrolizumab plus weekly paclitaxel in platinum-resistant recurrent ovarian cancer (ENGOT-ov65/KEYNOTE-B96): a multicentre, randomised, double-blind, phase 3 study. Lancet. 2026 Apr 18;407(10538):1525-1537. 3. Colombo N, et al. Pembrolizumab plus weekly paclitaxel in platinum-resistant recurrent ovarian cancer (ENGOT-ov65/KEYNOTE-B96): a multicentre, randomised, double-blind, phase 3 study. Lancet . 2026 Apr 18;407(10538):1525-1537. (Supplementary appendix)

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KEYNOTE-B96: Study Design



Assessment of tumor status was performed at week 9 and then every 9 weeks for the first year, followed by every 12 weeks thereafter

Primary efficacy outcome measure: PFS as assessed by investigator according to RECIST v1.1

Secondary outcome measure: OS

KEYNOTE-B96 evaluated KEYTRUDA in combination with paclitaxel and included the option to add bevacizumab.

[a]Treatment with KEYTRUDA continued until RECIST v1.1-defined progression of disease, unacceptable toxicity, or a maximum of 24 months. Administration of KEYTRUDA was permitted beyond RECIST-defined disease progression if the patient was clinically stable and considered to be deriving clinical benefit by the investigator.

IV = intravenous; OS = overall survival; PFS = progression-free survival; Q2W = every 2 weeks; Q6W = every 6 weeks; R = randomization; RECIST = Response Evaluation Criteria in Solid Tumors.

1. 식품의약품안전처. 키트루다 허가사항. 2. Colombo N, et al. Pembrolizumab plus weekly paclitaxel in platinum-resistant recurrent ovarian cancer (ENGOT-ov65/KEYNOTE-B96): a multicentre, randomised, double-blind, phase 3 study. Lancet. 2026 Apr 18;407(10538):1525-1537. 3. Colombo N, et al . Pembrolizumab plus weekly paclitaxel in platinum-resistant recurrent ovarian cancer (ENGOT-ov65/KEYNOTE-B96): a multicentre, randomised, double-blind, phase 3 study. Lancet . 2026 Apr 18;407(10538):1525-1537. (Supplementary appendix)

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KEYNOTE-B96: Baseline Patient Characteristics in the ITT Population

Baseline Characteristics[a]	KEYTRUDA + Chemo[b] (n=322)	Placebo + Chemo[b] (n=321)
Median age, years (range)	62 (37–85)	61 (37–82)
Race, n (%)[c]		
White	207 (64.3)	217 (67.6)
Asian	72 (22.4)	58 (18.1)
Multiple	12 (3.7)	17 (5.3)
Black or African American	8 (2.5)	6 (1.9)
Hawaiian/Pacific Islander	1 (0.3)	1 (0.3)
PD-L1 CPS, n (%)		
<1	88 (27.3)	89 (27.7)
1 to <10	133 (41.3)	132 (41.1)
≥10	101 (31.4)	100 (31.2)
Stage at diagnosis (FIGO 2014 criteria), n (%)		
IA–IIB	25 (7.8)	26 (8.1)
IIIA–IIIC	183 (56.8)	189 (58.9)
IVA–IVB	114 (35.4)	106 (33.0)

Baseline Characteristics[a] *(continued)*	KEYTRUDA + Chemo[b] (n=322)	Placebo + Chemo[b] (n=321)
ECOG PS 1, n (%)	142 (44.1)	144 (44.9)
High-grade serous histology, n (%)[d]	278 (86.3)	275 (85.7)
Bevacizumab use as study treatment, n (%)	235 (73.0)	236 (73.5)
Prior lines of therapy,[e] n (%)		
1 line	121 (37.6)	113 (35.2)
2 lines	200 (62.1)	207 (64.5)
Prior anticancer therapy, n (%)		
Anti–PD-1/PD-L1 inhibitor	7 (2.2)	7 (2.2)
Bevacizumab	149 (46.3)	146 (45.5)
PARP inhibitor	112 (34.8)	123 (38.3)
Platinum-free interval, n (%)[f]		
<3 months	137 (42.5)	162 (50.5)
≥3 to ≤6 months	183 (56.8)	154 (48.0)
>6 months	2 (0.6)	4 (1.2)

[a]Data cutoff date: March 5, 2025. [b]Chemo (paclitaxel) with or without bevacizumab. [c]44 participants had missing information for race, 22 (6.8%) in the KEYTRUDA arm and 22 (6.9%) in the placebo arm. [d]Other histology subtypes in the KEYTRUDA and placebo arms, respectively, were clear cell in 24 (7.5%) and 26 (8.1%), endometrioid in 9 (2.8%) and 4 (1.2%), low-grade serous in 6 (1.9%) and 10 (3.1%), carcinosarcoma in 3 (0.9%) and 5 (1.6%), and other carcinoma in 2 (0.6%) and 1 (0.3%). [e]Two participants had 3 prior lines of therapy, 1 (0.3%) in each treatment arm. [f]One participant in the placebo arm had missing information for platinum-free interval.

Chemo = chemotherapy; CPS = combined positive score; ECOG PS = Eastern Cooperative Oncology Group performance status; FIGO = International Federation of Gynecology and Obstetrics; ITT = intention-to-treat; PARP = poly (ADP ribose) polymerase; PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1.

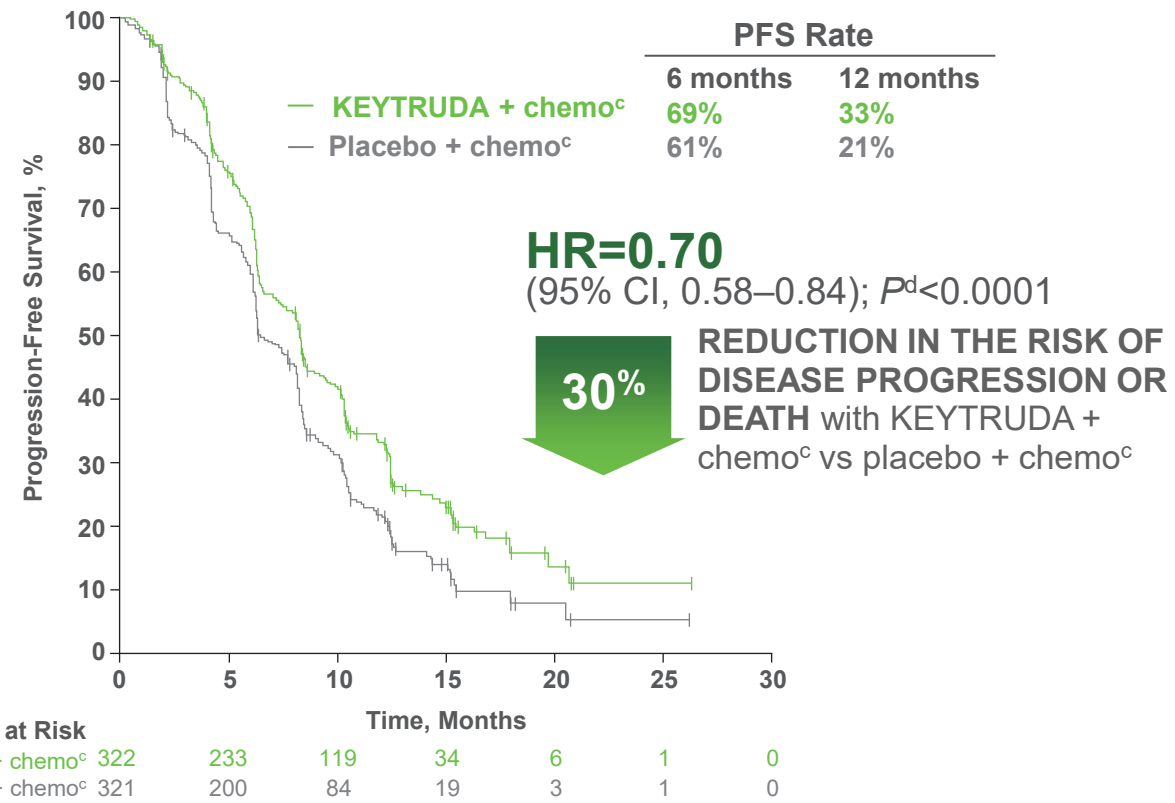
Colombo N et al. Presented at: European Society for Medical Oncology (ESMO) Congress; October 17–21, 2025; Berlin, Germany.

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KEYNOTE-B96: Statistically Significant PFS in the ITT Population at IA1[1,2,a]

KEYTRUDA + paclitaxel ± bevacizumab demonstrated a statistically significant PFS benefit relative to placebo + paclitaxel ± bevacizumab.[1] Paclitaxel ± bevacizumab is an active, guideline-recommended[b] treatment option for patients with PROC.[3]

Kaplan-Meier Curve for PFS in the ITT Population[1]



	KEYTRUDA + Chemoc (n=322)	Placebo + Chemoc (n=321)
Number of patients with an event	231 (72%)	253 (79%)
Median PFS, months	8.3 (95% CI, 7.2–8.6)	6.4 (95% CI, 6.2–8.1)

A longer median PFS of 8.3 months was observed with KEYTRUDA + paclitaxel ± bevacizumab vs 6.4 months with placebo + paclitaxel ± bevacizumab in patients with PROC.

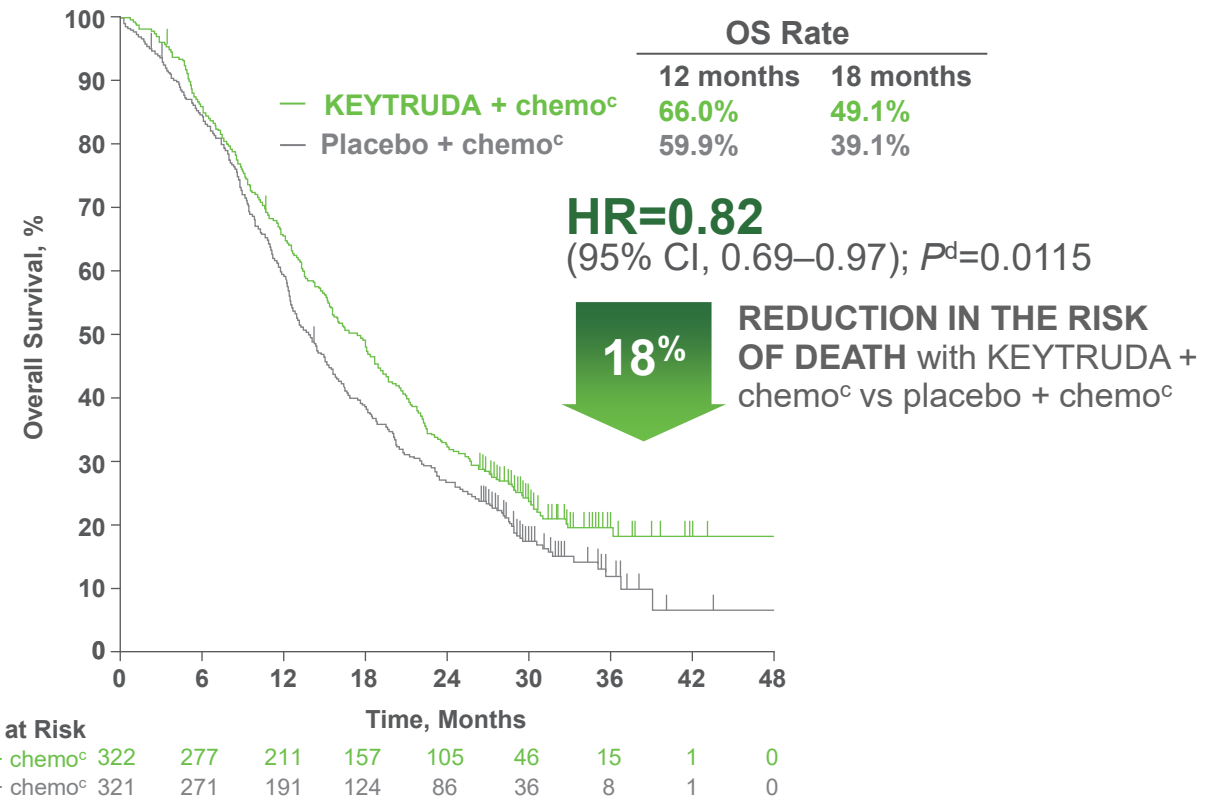
[a]Data cutoff date: April 3, 2024; median follow-up time: 15.6 months.[2] [b]Category 2A (based upon lower-level evidence, there is uniform National Comprehensive Cancer Network® [NCCN®] consensus [≥85% support of the Panel] that the intervention is appropriate), preferred (interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability) recurrence therapy option for PROC.[3] [c]Chemo (paclitaxel) with or without bevacizumab.[1] [d]Based on stratified log-rank test (*P* value is compared to an alpha boundary of 0.0023).[1]
Chemo = chemotherapy; CI = confidence interval; HR = hazard ratio; IA = interim analysis; ITT = intention-to-treat; PFS = progression-free survival; PROC = platinum-resistant ovarian cancer.
1. [Insert local label.] **2.** Colombo N et al. Presented at: European Society for Medical Oncology (ESMO) Congress; October 17–21, 2025; Berlin, Germany. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.4.2026.
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KEYNOTE-B96: Statistically Significant OS in the ITT Population at FA[1,a]

KEYTRUDA + paclitaxel ± bevacizumab demonstrated a statistically significant and clinically meaningful OS benefit relative to placebo + paclitaxel ± bevacizumab.[1] Paclitaxel ± bevacizumab is an active, guideline-recommended[b] treatment option for patients with PROC.[2]

Kaplan-Meier Curve for OS in the ITT Population[1]



	KEYTRUDA + Chemoc (n=322)	Placebo + Chemoc (n=321)
Percent of patients with an event	76.7%	82.9%
Median OS, months	17.7 (95% CI, 15.2–19.2)	14.0 (95% CI, 12.5–15.6)

A longer median OS of 17.7 months was observed with KEYTRUDA + paclitaxel ± bevacizumab vs 14.0 months with placebo + paclitaxel ± bevacizumab in patients with PROC.

[a]Data cutoff date: September 5, 2025; median follow-up time: 32.7 months.[1] [b]Category 2A (based upon lower-level evidence, there is uniform NCCN consensus [≥85% support of the Panel] that the intervention is appropriate), preferred (interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability) recurrence therapy option for PROC.[2] [c]Chemo (paclitaxel) with or without bevacizumab.[1] [d]HR (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. The observed *P* value crossed the prespecified nominal boundary of 0.0242 at this planned FA.[1]
Chemo = chemotherapy; CI = confidence interval; FA = final analysis; HR = hazard ratio; ITT = intention-to-treat; OS = overall survival; PROC = platinum-resistant ovarian cancer.

1. Colombo N et al. Presented at: European Society of Gynaecological Oncology (ESGO) Congress; February 26-28, 2026; Copenhagen, Denmark. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed April 13, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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KEYNOTE-B96: Baseline Characteristics in the PD-L1 (CPS ≥1) Population

- **72%** (466/643) of the patients enrolled in KEYNOTE-B96 **had tumors expressing PD-L1 (CPS ≥1)**.

Baseline Characteristics of Study Participants	PD-L1 (CPS ≥1) Population (n=466)
Median age, years (range)	62 (37–85)
Aged ≥65 years	38%
Race/ethnicity	
White	67%
Asian	20%
Black	2%
Hispanic or Latino	13%

Baseline Characteristics of Study Participants *(continued)*	PD-L1 (CPS ≥1) Population (n=466)
ECOG PS	
0	55%
1	44%
Bevacizumab use as study treatment	73%
Type of prior therapy	
Bevacizumab	46%
PARP inhibitor	39%
Anti–PD-1/PD-L1 inhibitor	3%

- 234 patients were randomized to KEYTRUDA + paclitaxel ± bevacizumab and 232 patients were randomized to placebo + paclitaxel ± bevacizumab.

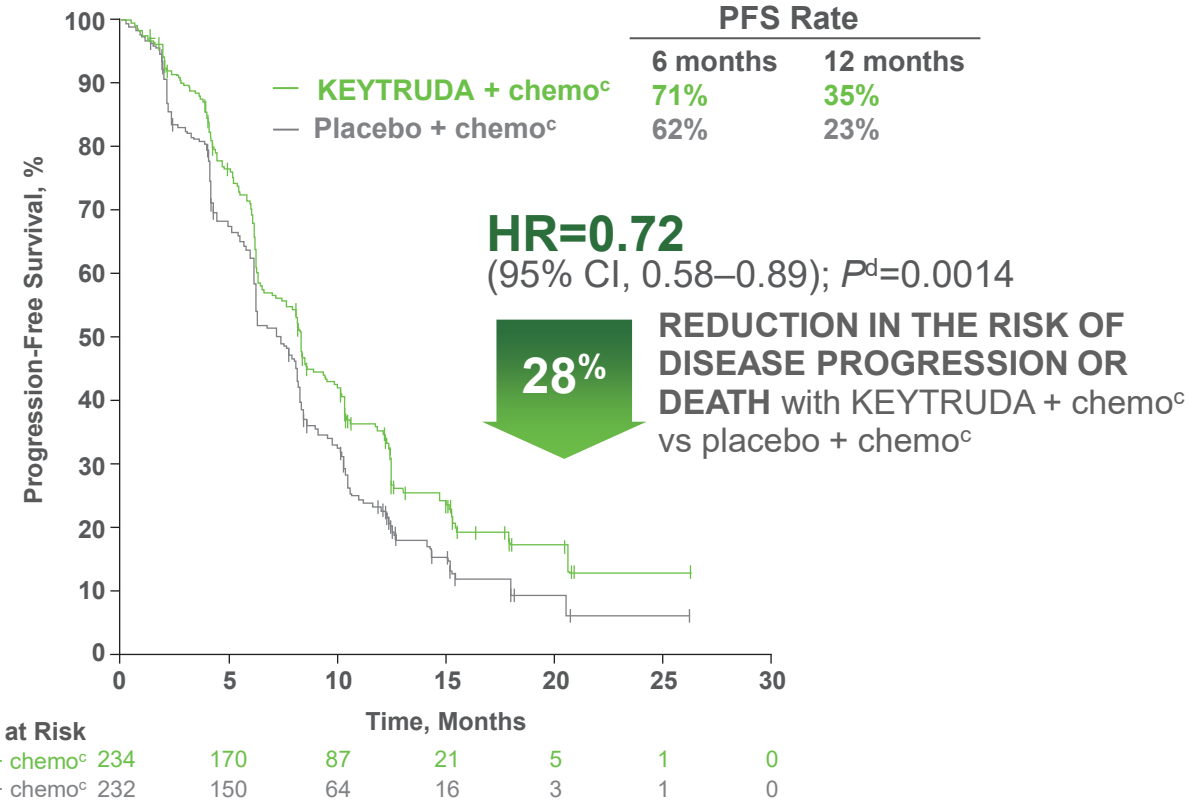
CPS = combined positive score; ECOG PS = Eastern Cooperative Oncology Group performance status; PARP = poly (ADP ribose) polymerase; PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1.

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KEYNOTE-B96: Statistically Significant PFS in the PD-L1 (CPS ≥1) Population at IA1[1,2,a]

KEYTRUDA + paclitaxel ± bevacizumab demonstrated a statistically significant PFS benefit relative to placebo + paclitaxel ± bevacizumab.[1] Paclitaxel ± bevacizumab is an active, guideline-recommended[b] treatment option for patients with PROC.[3]

Kaplan-Meier Curve for PFS in the PD-L1 (CPS ≥1) Population[1]



	KEYTRUDA + Chemoc (n=234)	Placebo + Chemoc (n=232)
Number of patients with an event	162 (69%)	180 (78%)
Median PFS, months	8.3 (95% CI, 7.0–9.4)	7.2 (95% CI, 6.2–8.1)

A longer median PFS of 8.3 months was observed with KEYTRUDA + paclitaxel ± bevacizumab vs 7.2 months with placebo + paclitaxel ± bevacizumab in patients with PROC.

[a]Data cutoff date: April 3, 2024; median follow-up time: 15.6 months.[2] [b]Category 2A (based upon lower-level evidence, there is uniform National Comprehensive Cancer Network® [NCCN®] consensus [≥85% support of the Panel] that the intervention is appropriate), preferred (interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability) recurrence therapy option for PROC.[3] [c]Chemo (paclitaxel) with or without bevacizumab.[1] [d]Based on stratified log-rank test (*P* value [one-sided] is compared to an alpha boundary of 0.0116).[1] Chemo = chemotherapy; CI = confidence interval; CPS = combined positive score; HR = hazard ratio; IA = interim analysis; PD-L1 = programmed death ligand 1; PFS = progression-free survival; PROC = platinum-resistant ovarian cancer.

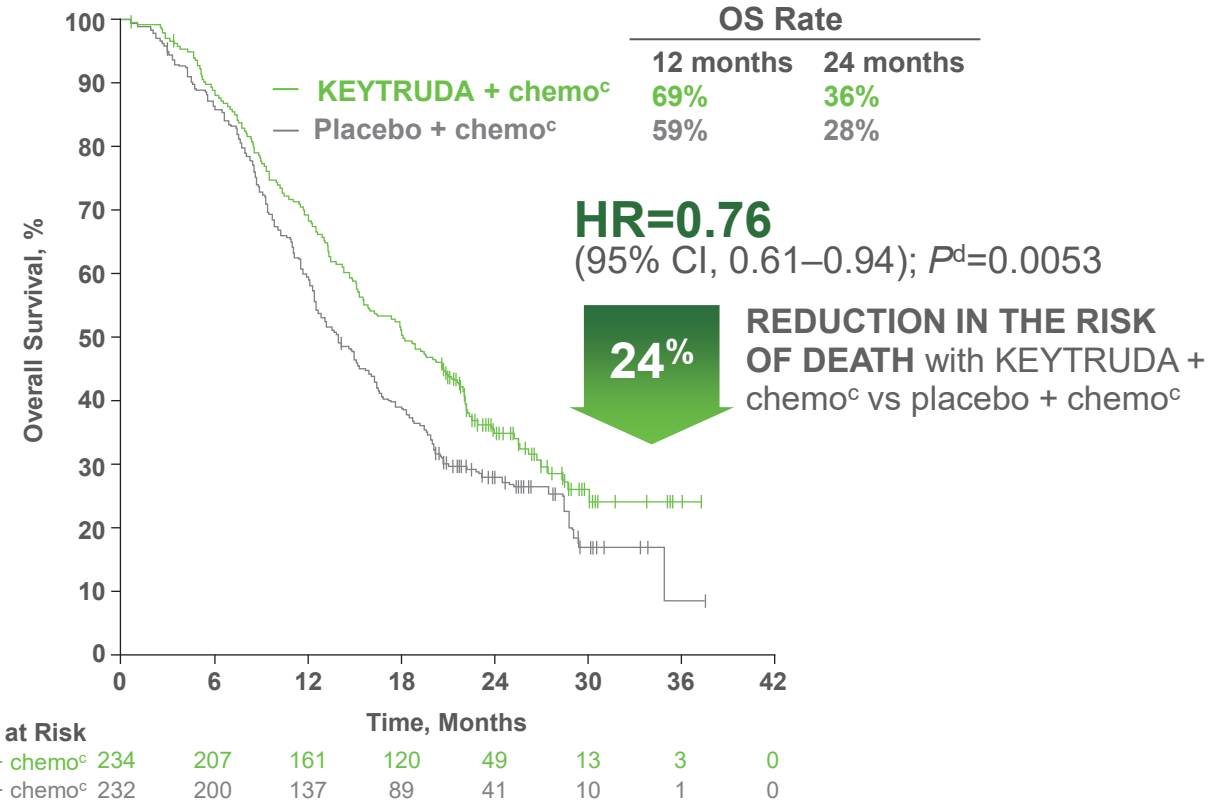
1. 식품의약품안전처. 키트루다 허가사항 **2.** Colombo N et al. Presented at: European Society for Medical Oncology (ESMO) Congress; October 17–21, 2025; Berlin, Germany. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed April 13, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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KEYNOTE-B96: Statistically Significant OS in the PD-L1 (CPS ≥1) Population at IA2[1,2,a]

KEYTRUDA + paclitaxel ± bevacizumab demonstrated a statistically significant and clinically meaningful OS benefit relative to placebo + paclitaxel ± bevacizumab.[1] Paclitaxel ± bevacizumab is an active, guideline-recommended[b] treatment option for patients with PROC.[3]

Kaplan-Meier Curve for OS in the PD-L1 (CPS ≥1) Population[1]



	KEYTRUDA + Chemoc (n=234)	Placebo + Chemoc (n=232)
Number of patients with an event	157 (67%)	175 (75%)
Median OS, months	18.2 (95% CI, 15.3–21.0)	14.0 (95% CI, 12.5–16.1)

A longer median OS of 18.2 months was observed with KEYTRUDA + paclitaxel ± bevacizumab vs 14.0 months with placebo + paclitaxel ± bevacizumab in patients with PROC.

[a]Data cutoff date: March 5, 2025; median follow-up time: 26.6 months.[2] [b]Category 2A (based upon lower-level evidence, there is uniform NCCN consensus [≥85% support of the Panel] that the intervention is appropriate), preferred (interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability) recurrence therapy option for PROC.[3] [c]Chemo (paclitaxel) with or without bevacizumab.[1] [d]Based on stratified log-rank test (*P* value [one sided] is compared to an alpha boundary of 0.0083).[1] Chemo = chemotherapy; CI = confidence interval; CPS = combined positive score; HR = hazard ratio; IA = interim analysis; OS = overall survival; PD-L1 = programmed death ligand 1; PROC = platinum-resistant ovarian cancer.

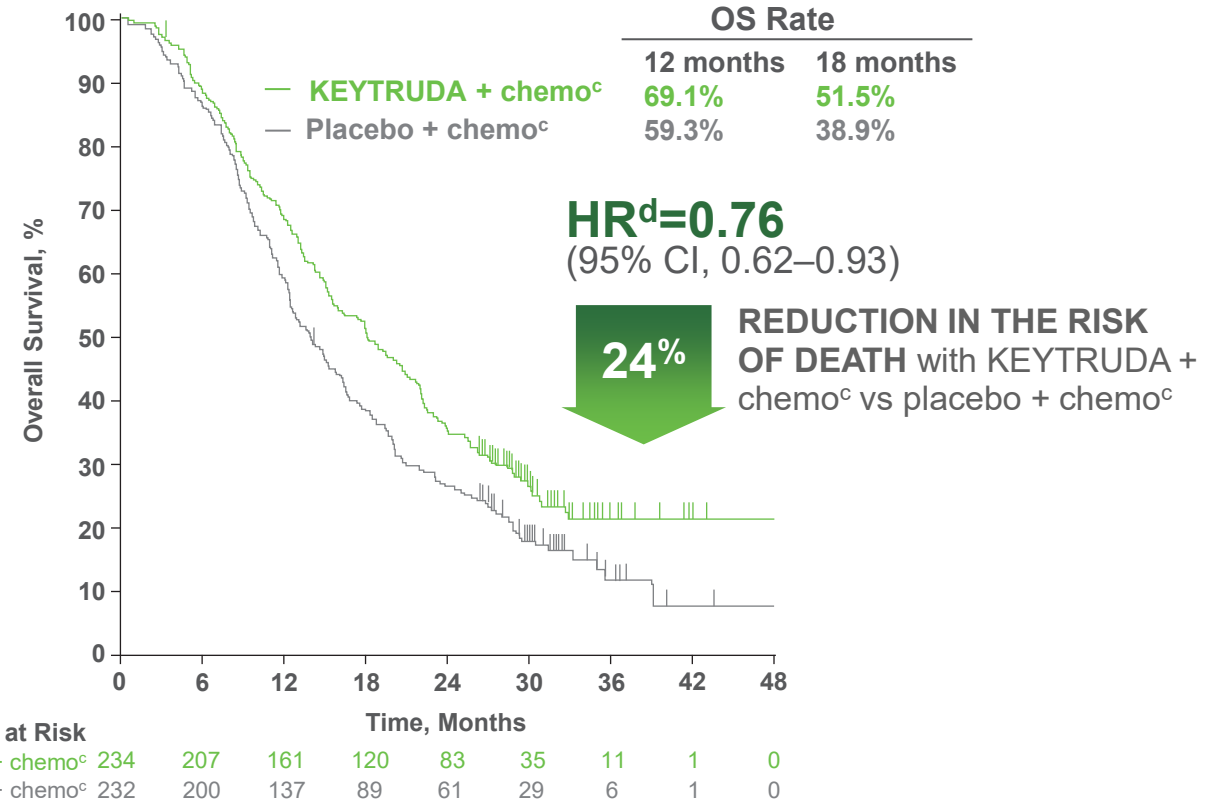
1. [Insert local label.] **2.** Colombo N et al. Presented at: European Society for Medical Oncology (ESMO) Congress; October 17–21, 2025; Berlin, Germany. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed April 13, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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KEYNOTE-B96: Clinically Meaningful OS in the PD-L1 (CPS ≥1) Population at FA[1,a]

KEYTRUDA + paclitaxel ± bevacizumab demonstrated a clinically meaningful OS benefit relative to placebo + paclitaxel ± bevacizumab.[1] Paclitaxel ± bevacizumab is an active, guideline-recommended[b] treatment option for patients with PROC.[2]

Kaplan-Meier Curve for OS in the PD-L1 (CPS ≥1) Population[1]



	KEYTRUDA + Chemoc (n=234)	Placebo + Chemoc (n=232)
Percent of patients with an event	74.4%	82.8%
Median OS, months	18.2 (95% CI, 15.3–21.3)	14.0 (95% CI, 12.5–16.1)

A longer median OS of 18.2 months was observed with KEYTRUDA + paclitaxel ± bevacizumab vs 14.0 months with placebo + paclitaxel ± bevacizumab in patients with PROC.

[a]Data cutoff date: September 5, 2025; median follow-up time: 32.7 months.[1] [b]Category 2A (based upon lower-level evidence, there is uniform NCCN consensus [≥85% support of the Panel] that the intervention is appropriate), preferred (interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability) recurrence therapy option for PROC.[2] [c]Chemo (paclitaxel) with or without bevacizumab.[1] [d]HR (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors.[1] Chemo = chemotherapy; CI = confidence interval; CPS = combined positive score; FA = final analysis; HR = hazard ratio; OS = overall survival; PD-L1 = programmed death ligand 1; PROC = platinum-resistant ovarian cancer.

1. Colombo N et al. Presented at: European Society of Gynaecological Oncology (ESGO) Congress; February 26-28, 2026; Copenhagen, Denmark. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed April 13, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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Dr Nicoletta Colombo
Gynecologic Oncology Program, European Institute of Oncology, IRCCS, Milan, Italy

3 October 2026

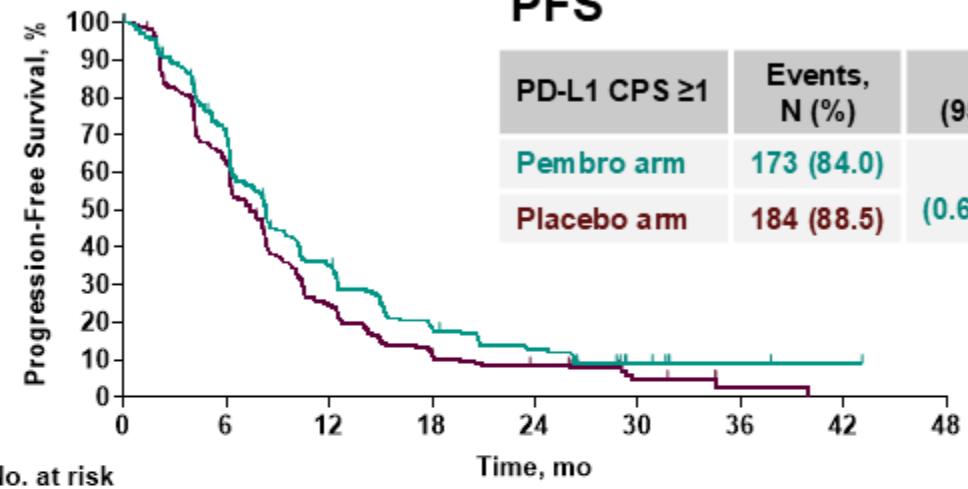
Pembrolizumab vs Placebo Plus Paclitaxel With or Without Bevacizumab for Platinum-Resistant Recurrent Ovarian Cancer: Results by Histologic Subtype From the Phase 3 ENGOT-ov65/KEYNOTE-B96 Study

Nicoletta Colombo,[1] Emese Zsiros,[2] Allan Covens,[3] Radoslaw Madry,[4] Pamela Salman,[5] Mihai Meirovitz,[6] Kazuki Sudo,[7] Fatih Köse,[8] Roberto Iván Romero Díaz,[9] Iain McNeish,[10] Bo Gao,[11] Judith R Kroep,[12] Lilian Arruda do Rêgo Barros,[13] Hannelore G. Denys,[14] Jae Hoon Kim,[15] Karin Yamada,[16] Agata M. Bogusz,[16] Thomas Jemielita,[16] Diana Bello-Roufai,[17] Xiaohua Wu[18]

[1]MaNGO and Gynecologic Oncology Program, European Institute of Oncology, IRCCS, Milan, Italy; [2]Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA; [3]University of Toronto, Sunnybrook Health Sciences, Toronto, ON, Canada; [4]PGOG, Szpital Kliniczny Przemienienia Pańskiego, and Uniwersytet Medyczny im K. Marcinkowskiego w Poznaniu, Poznań, Poland; [5]Fundación Arturo López Pérez, Santiago, Chile; [6]ISGO and Soroka University Medical Center, Ben-Gurion University of the Negev, Beer-Sheva, Israel; [7]National Cancer Center Hospital, Tokyo, Japan; [8]TRSGO, Baskent University Adana Dr. Turgut Noyan Application and Research Center, Adana, Türkiye; [9]Centro de Investigación Clínica de Oaxaca, Oaxaca, Mexico; [10]GTG-UK and Imperial College London, London, UK; [11]Blacktown and Westmead Hospitals, Sydney, NSW, Australia; [12]DGOG and Leiden University Medical Center, Leiden, Netherlands; [13]Instituto Brasileiro de Controle do Câncer, São Paulo, Brazil; [14]BGOG, Ghent University Hospital, and Cancer Research Institute Ghent (CRIG), Ghent, Belgium; [15]Gangnam Severance Hospital, Yonsei University College of Medicine, Seoul, Republic of Korea; [16]Merck & Co., Inc., Rahway, NJ, USA; [17]GINECO and Institut Curie - Hôpital René Huguenin, Saint-Cloud, France; [18]Fudan University Shanghai Cancer Center, Shanghai, China

Efficacy in High-Grade Serous Participants

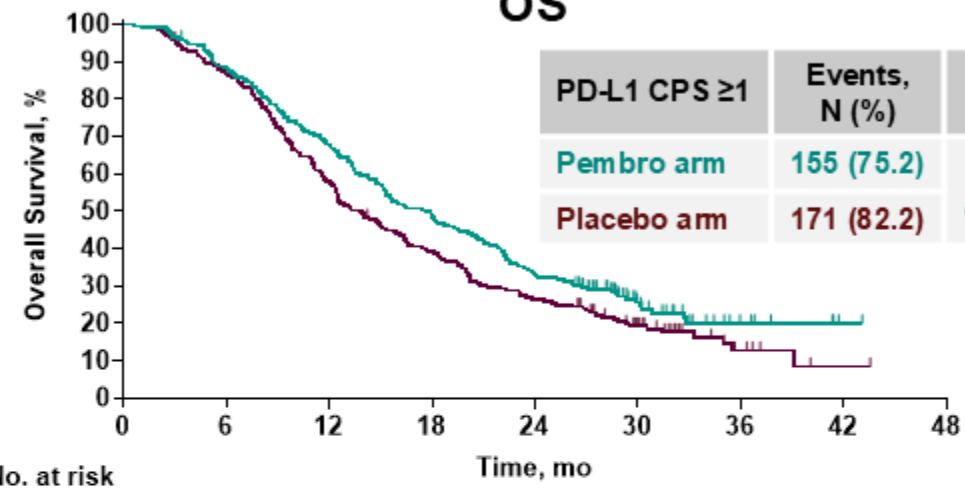
PFS



PD-L1 CPS ≥1	Events, N (%)	HR (95% CI)
Pembro arm	173 (84.0)	0.79 (0.64–0.98)
Placebo arm	184 (88.5)	

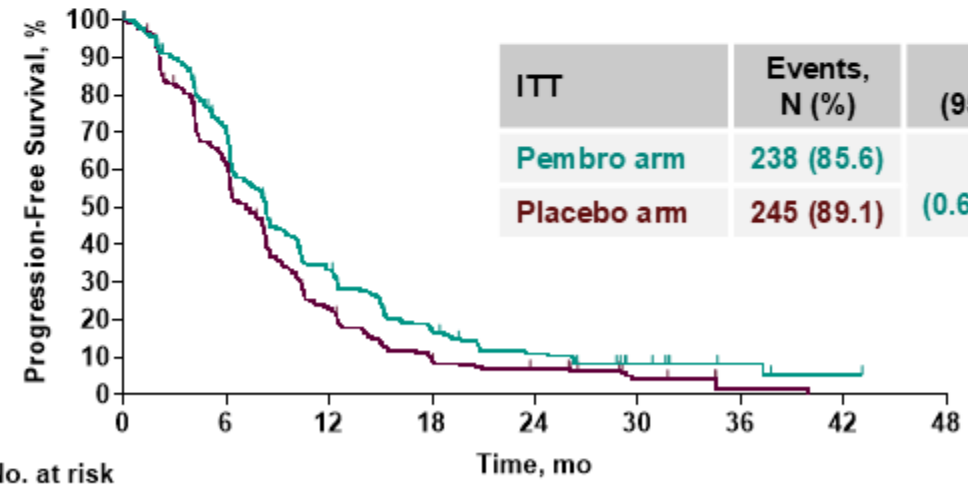
No. at risk									
Pembro	206	138	66	33	22	6	2	1	0
Placebo	208	124	46	21	14	5	1	0	0

OS



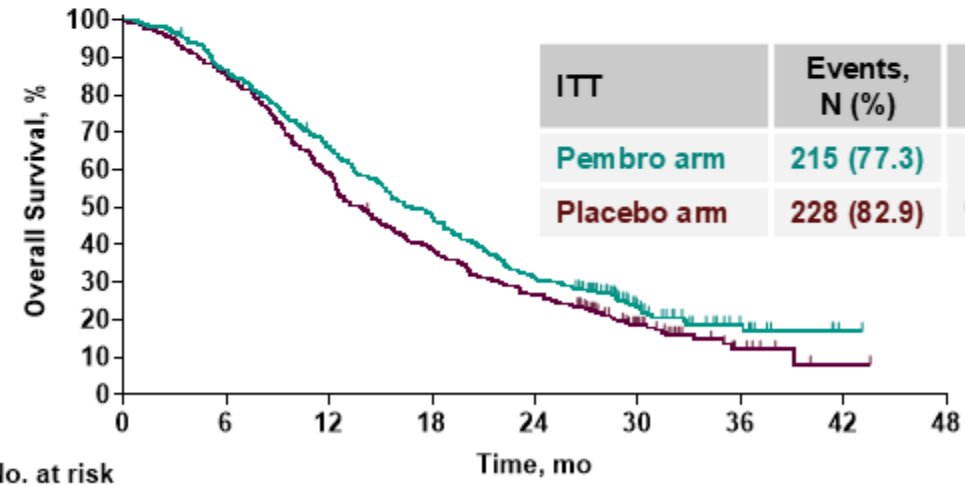
PD-L1 CPS ≥1	Events, N (%)	HR (95% CI)
Pembro arm	155 (75.2)	0.79 (0.64–0.99)
Placebo arm	171 (82.2)	

No. at risk									
Pembro	206	181	139	100	68	28	8	1	0
Placebo	208	180	120	80	54	28	6	1	0



ITT	Events, N (%)	HR (95% CI)
Pembro arm	238 (85.6)	0.77 (0.64–0.92)
Placebo arm	245 (89.1)	

No. at risk									
Pembro	278	186	85	41	25	9	3	1	0
Placebo	275	161	56	22	15	6	1	0	0



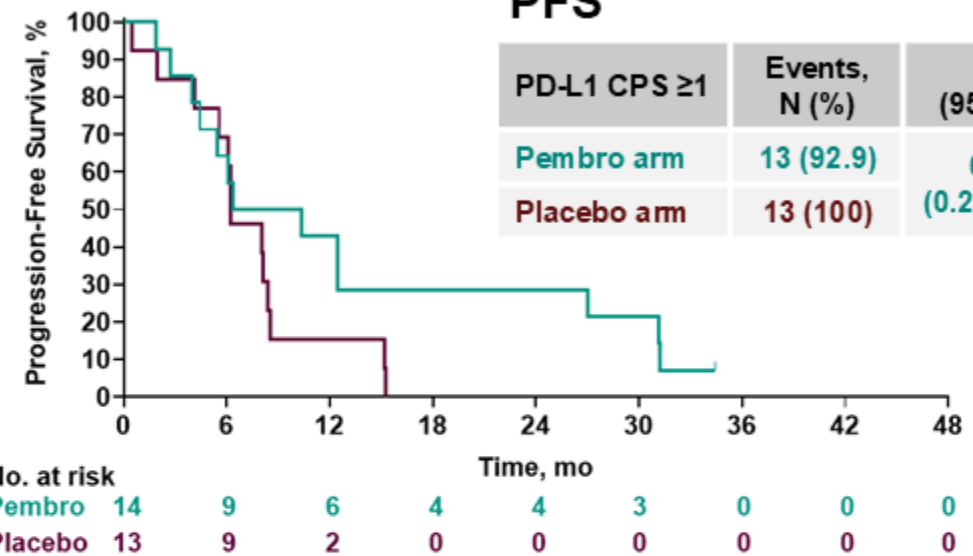
ITT	Events, N (%)	HR (95% CI)
Pembro arm	215 (77.3)	0.83 (0.69–1.00)
Placebo arm	228 (82.9)	

No. at risk									
Pembro	278	240	182	132	86	36	11	1	0
Placebo	275	234	162	106	72	32	7	1	0

Subgroup analyses were based on an unstratified Cox regression model. Data cutoff date: September 5, 2025.

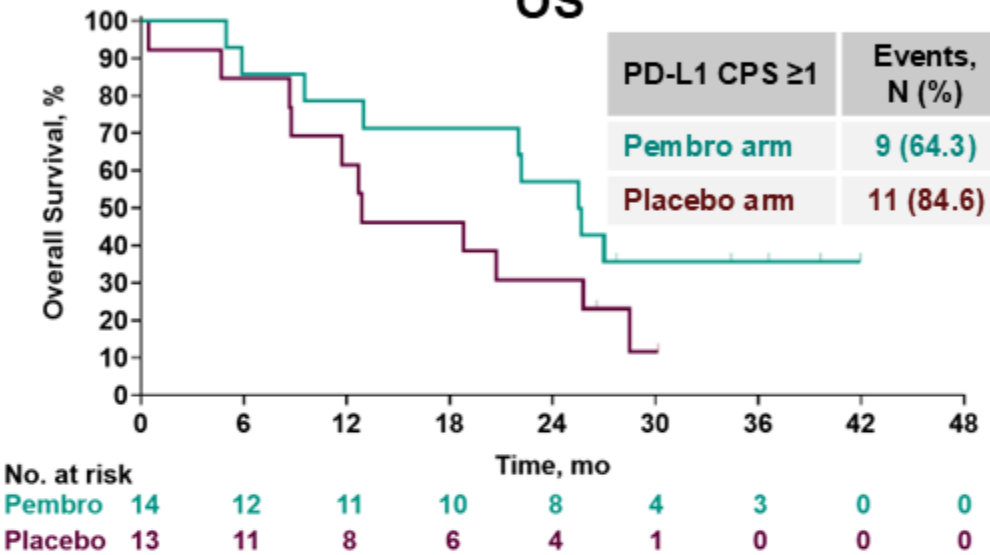
Efficacy in Clear Cell Carcinoma Participants

PFS

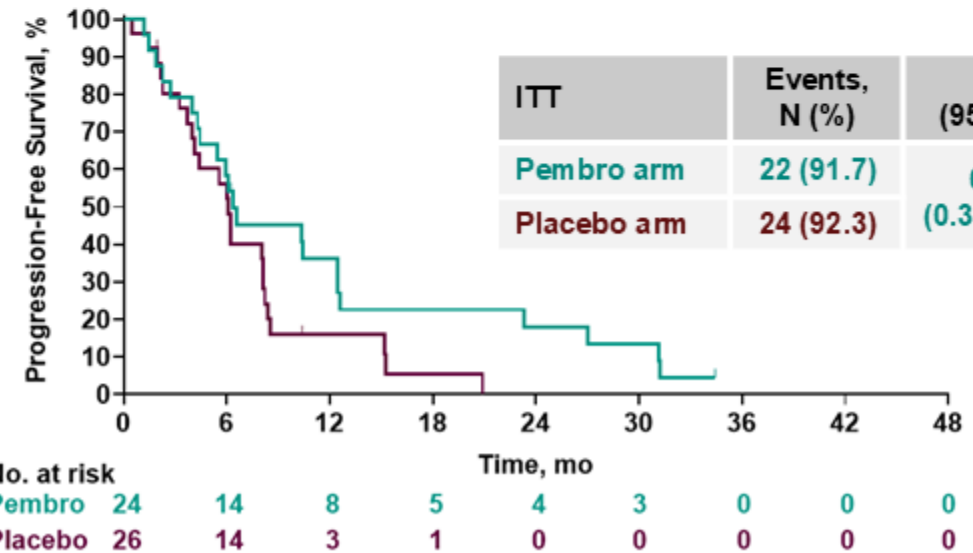


PD-L1 CPS ≥1	Events, N (%)	HR (95% CI)
Pembro arm	13 (92.9)	0.53 (0.23–1.24)
Placebo arm	13 (100)	

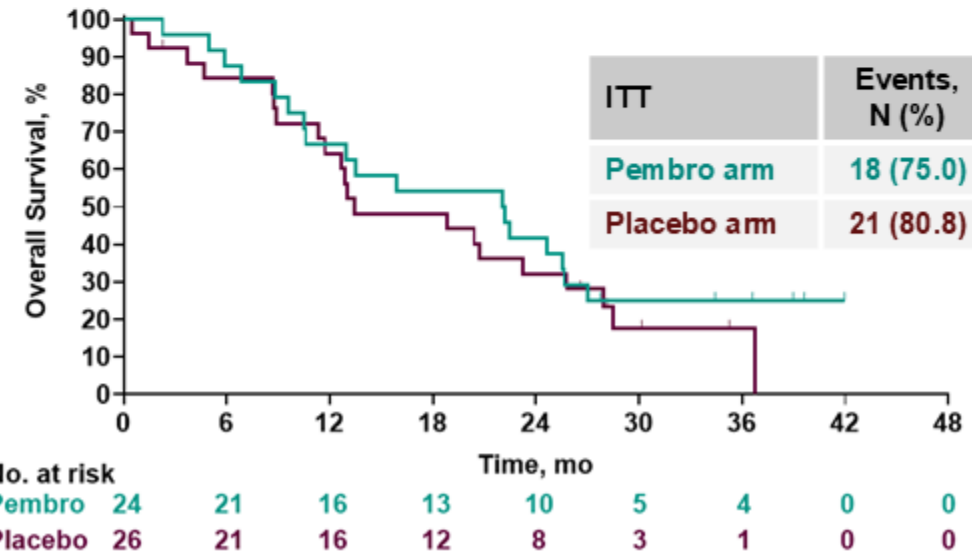
OS



PD-L1 CPS ≥1	Events, N (%)	HR (95% CI)
Pembro arm	9 (64.3)	0.52 (0.21–1.26)
Placebo arm	11 (84.6)	



ITT	Events, N (%)	HR (95% CI)
Pembro arm	22 (91.7)	0.59 (0.31–1.09)
Placebo arm	24 (92.3)	

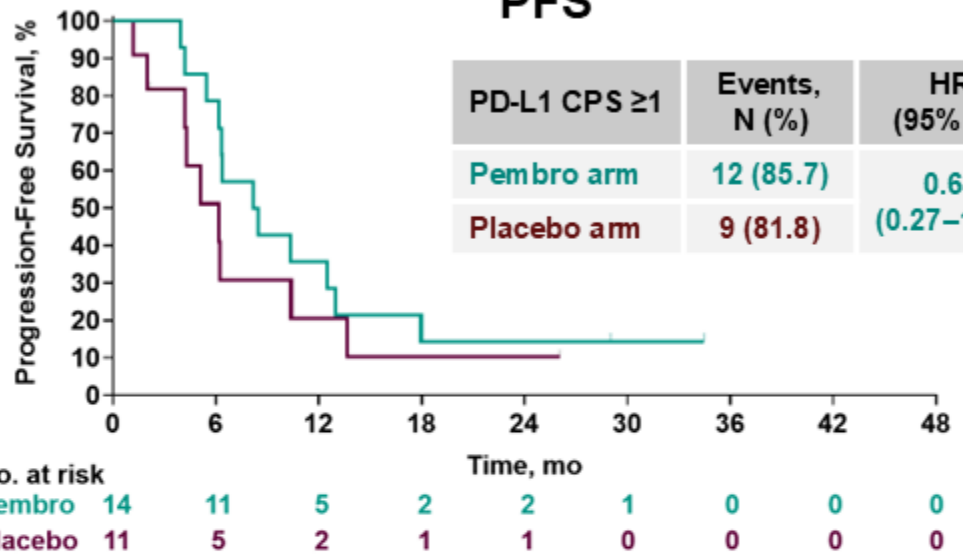


ITT	Events, N (%)	HR (95% CI)
Pembro arm	18 (75.0)	0.78 (0.41–1.47)
Placebo arm	21 (80.8)	

Subgroup analyses were based on an unstratified Cox regression model. Data cutoff date: September 5, 2025.

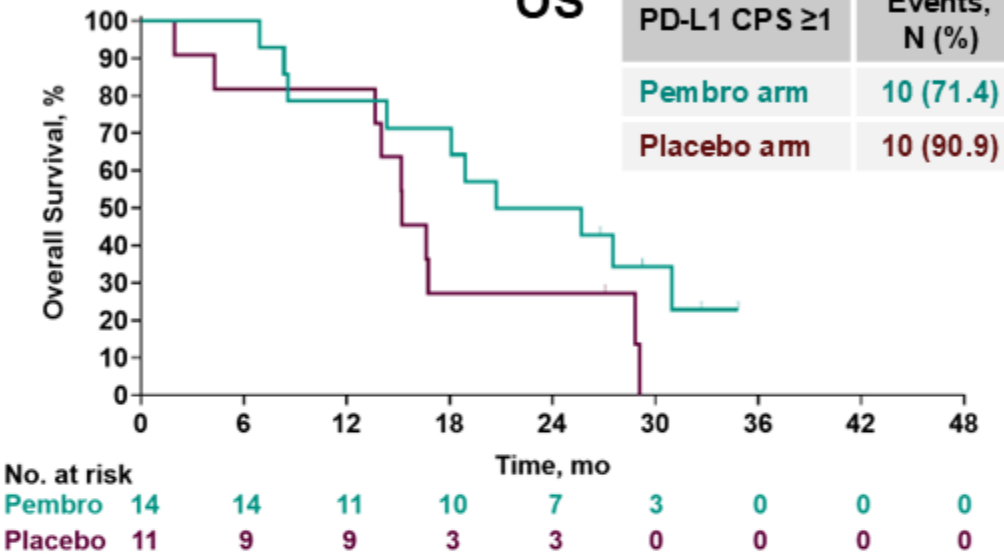
Efficacy in Other Histologic Subtypes

PFS

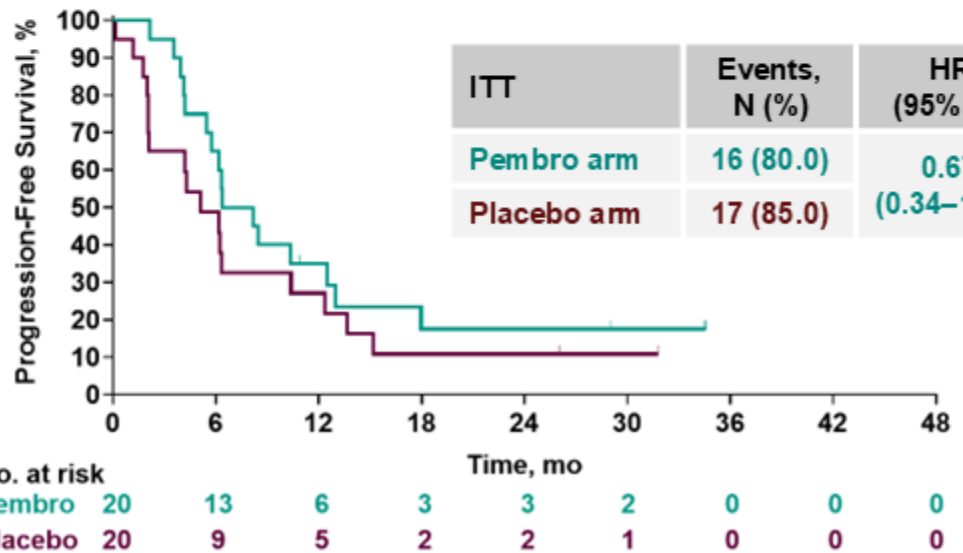


PD-L1 CPS ≥1	Events, N (%)	HR (95% CI)
Pembro arm	12 (85.7)	0.64 (0.27–1.54)
Placebo arm	9 (81.8)	

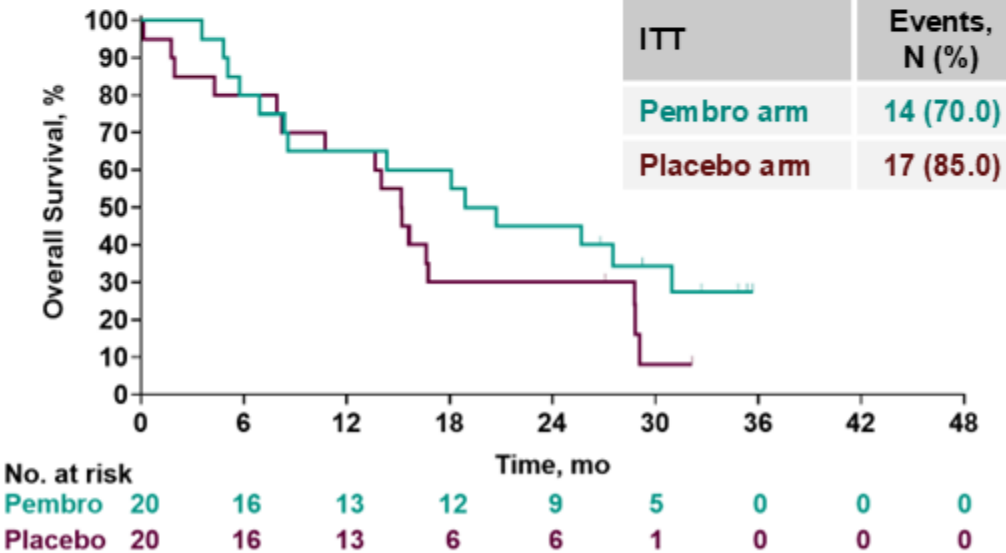
OS



PD-L1 CPS ≥1	Events, N (%)	HR (95% CI)
Pembro arm	10 (71.4)	0.47 (0.19–1.18)
Placebo arm	10 (90.9)	



ITT	Events, N (%)	HR (95% CI)
Pembro arm	16 (80.0)	0.67 (0.34–1.33)
Placebo arm	17 (85.0)	



ITT	Events, N (%)	HR (95% CI)
Pembro arm	14 (70.0)	0.62 (0.30–1.28)
Placebo arm	17 (85.0)	

Other histology categories included low-grade serous, any-grade endometrioid, and carcinosarcoma. Subgroup analyses were based on an unstratified Cox regression model. Data cutoff date: September 5, 2025.

KEYNOTE-B96: Selected Safety Profile

Adverse Events Occurring at a Higher Incidence (≥2% Difference) of Grades 3–4 Severity Among Patients Receiving KEYTRUDA + Paclitaxel ± Bevacizumab Compared to Placebo + Paclitaxel ± Bevacizumab

Adverse Event, %	KEYTRUDA + Paclitaxel ± Bevacizumab	Placebo + Paclitaxel ± Bevacizumab
Anemia	13.4	10.4
Urinary tract infection	6.3	2.8
Diarrhea	5.0	1.3
Hyponatremia	4.7	1.9
Pneumonia	3.8	1.6
Adrenal insufficiency	2.2	0

KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYNOTE-B96: Selected Safety Profile *(continued)*

The safety profile of KEYTRUDA + paclitaxel ± bevacizumab was consistent with the known profiles of the individual therapies.

- At FA, the median duration of therapy was **33 weeks** for KEYTRUDA + paclitaxel ± bevacizumab and **28 weeks** for placebo + paclitaxel ± bevacizumab.[a]

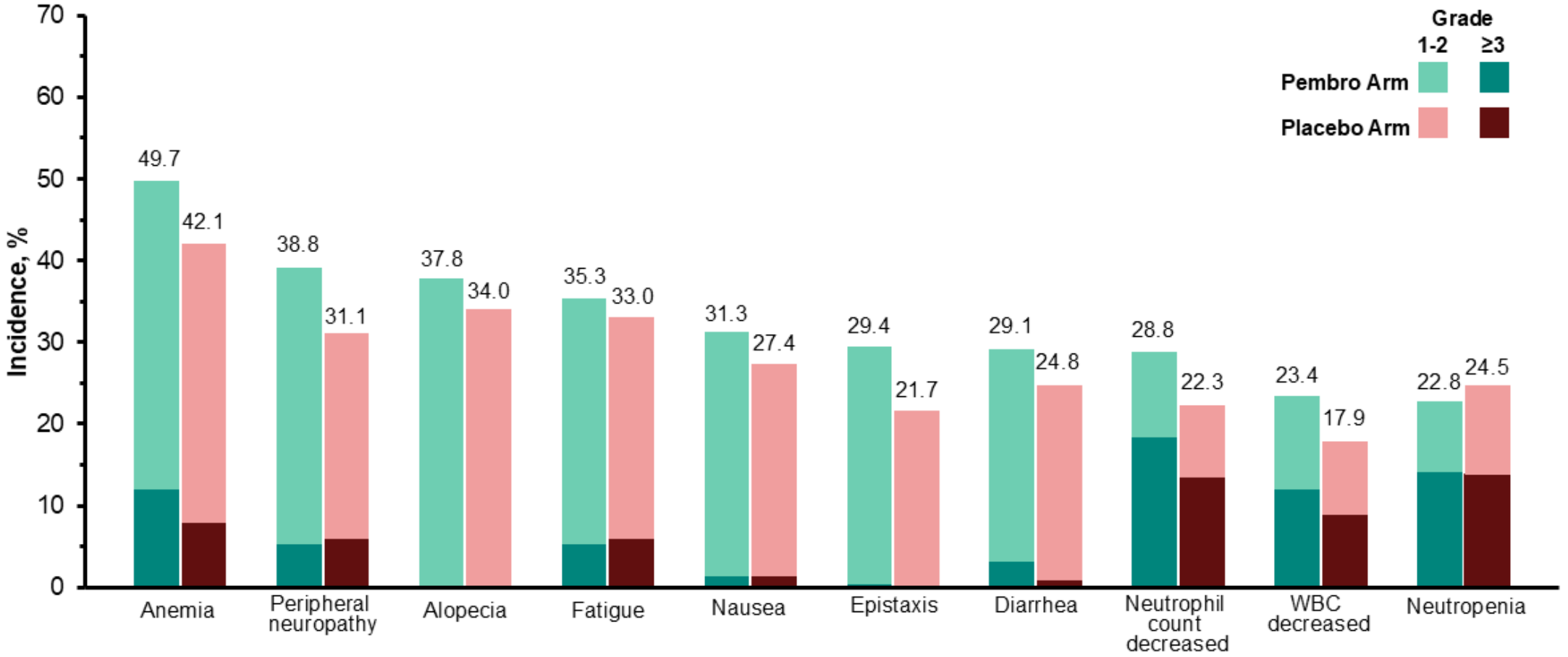
Summary of Adverse Events at FA[a]

	All-Cause AEs		Treatment-Related AEs[b]		Immune-Mediated AEs and Infusion Reactions[c]	
Incidence, n (%)	**KEYTRUDA Arm (n=320)**	**Placebo Arm (n=318)**	**KEYTRUDA Arm (n=320)**	**Placebo Arm (n=318)**	**KEYTRUDA Arm (n=320)**	**Placebo Arm (n=318)**
Any grade	319 (99.7)	316 (99.4)	313 (97.8)	303 (95.3)	126 (39.4)	60 (18.9)
Grade ≥3	**265 (82.8)**	**225 (70.8)**	217 (67.8)	176 (55.3)	38 (11.9)	11 (3.5)
Serious	180 (56.3)	123 (38.7)	107 (33.4)	63 (19.8)	36 (11.3)	7 (2.2)
Led to death	16 (5.0)	14 (4.4)	4 (1.3)[d]	5 (1.6)[e]	2 (0.6)[f]	0
Led to discontinuation of:						
Any treatment	136 (42.5)	109 (34.3)	120 (37.5)	90 (28.3)	23 (7.2)	8 (2.5)
KEYTRUDA or placebo	**50 (15.6)**	**32 (10.1)**	37 (11.6)	20 (6.3)	16 (5.0)	5 (1.6)
Paclitaxel	**101 (31.6)**	**90 (28.3)**	91 (28.4)	78 (24.5)	13 (4.1)	7 (2.2)
Bevacizumab	63 (19.7)	47 (14.8)	46 (14.4)	33 (10.4)	8 (2.5)	1 (0.3)

[a]Data cutoff date: September 5, 2025. [b]Per investigator assessment. [c]Events were based on a list of preferred terms intended to capture the known risks of KEYTRUDA and considered regardless of attribution to treatment by the investigator. [d]Colitis, interstitial lung disease, acute myeloid leukemia, and intestinal perforation. [e]Cardiac failure, intestinal perforation (n=2), and large intestine perforation (n=2). [f]Colitis and pneumonitis (reported by the investigator as treatment-related interstitial lung disease).
AE = adverse event; FA = final analysis.
Colombo N et al. Presented at: European Society of Gynaecological Oncology (ESGO) Congress; February 26–28, 2026; Copenhagen, Denmark.

KEYTRUDA® (pembrolizumab) Injection 100 mg

Treatment-Related AEs at FA, Incidence ≥20% in Either Arm

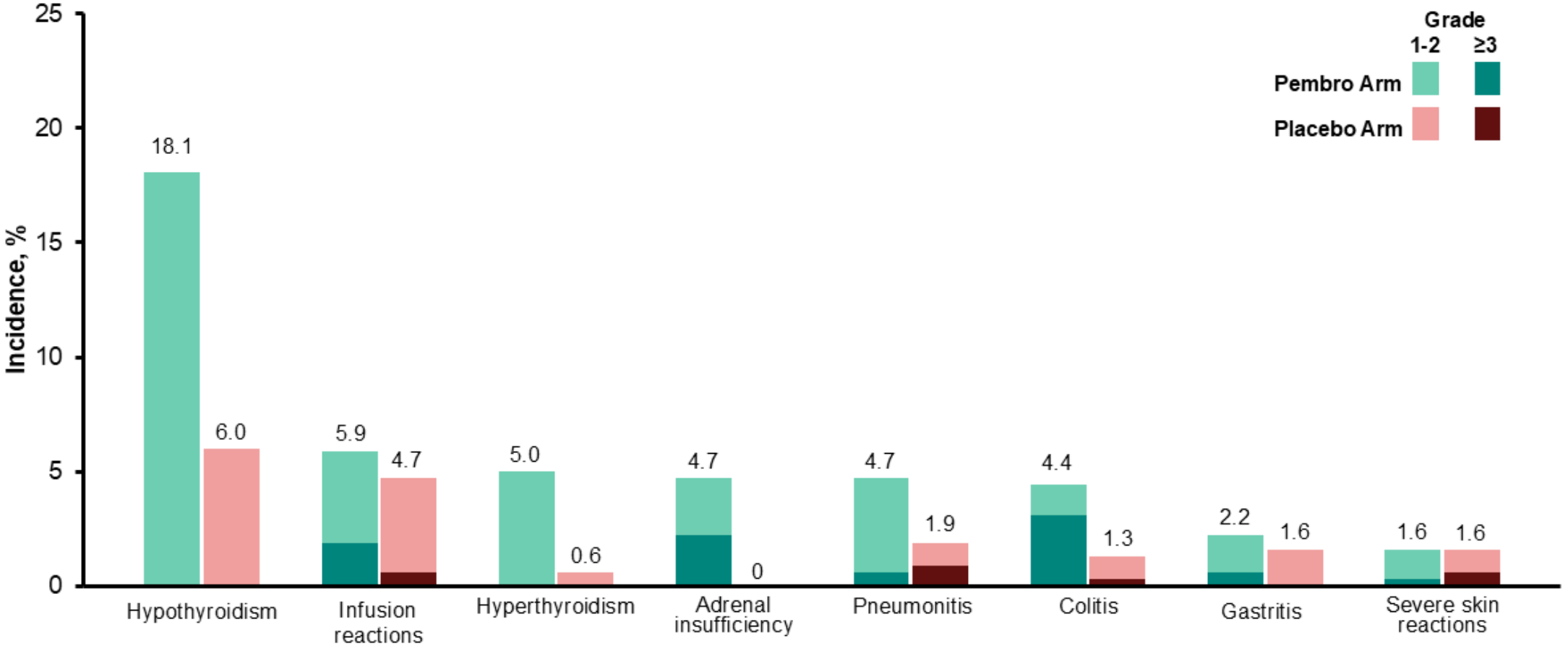


Data cutoff date: September 5, 2025

Colombo N et al. Presented at: ESGO Congress; February 26–28, 2026; Copenhagen, Denmark

KEYTRUDA® (pembrolizumab) Injection 100 mg

Immune-Mediated AEs and Infusion Reaction at FA, Incidence ≥5 Participants in Either Arm



Events were based on a list of preferred terms intended to capture the known risks of pembrolizumab and considered regardless of attribution to treatment by the investigator

Data cutoff date: September 5, 2025

Colombo N et al. Presented at: ESGO Congress; February 26–28, 2026; Copenhagen, Denmark

KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYTRUDA® (pembrolizumab) Ovarian Cancer Indication and Key Findings From KEYNOTE-B96 in the PD-L1 (CPS ≥1) Population

Indication

KEYTRUDA, in combination with paclitaxel, with or without bevacizumab, is indicated for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥1) as determined by a validated test, and who have received one or two prior systemic treatment regimens.

Efficacy Data From KEYNOTE-B96 in the PD-L1 (CPS ≥1) Population

Among the 72% of enrolled patients with tumors expressing PD-L1 (CPS ≥1), there was a statistically significant improvement in PFS with KEYTRUDA + paclitaxel ± bevacizumab vs placebo + paclitaxel ± bevacizumab.

- **28% reduction in the risk of disease progression or death** with KEYTRUDA + paclitaxel ± bevacizumab vs placebo + paclitaxel ± bevacizumab (HR=0.72 [95% CI, 0.58–0.89]; *P*[a]=0.0014)

There was a statistically significant improvement in OS with KEYTRUDA + paclitaxel ± bevacizumab vs placebo + paclitaxel ± bevacizumab.

- **24% reduction in the risk of death** with KEYTRUDA + paclitaxel ± bevacizumab vs placebo + paclitaxel ± bevacizumab (HR=0.76 [95% CI, 0.61–0.94]; *P*[b]=0.0053)

Safety Data From KEYNOTE-B96

Adverse events that occurred at a higher incidence (≥2% difference) of Grades 3–4 severity among patients receiving KEYTRUDA + paclitaxel ± bevacizumab compared to placebo + paclitaxel ± bevacizumab included anemia, urinary tract infection, diarrhea, hyponatremia, pneumonia, and adrenal insufficiency.

[a]Based on stratified log-rank test (*P* value [one-sided] is compared to an alpha boundary of 0.0116). [b]Based on stratified log-rank test (*P* value [one-sided] is compared to an alpha boundary of 0.0083).
CI = confidence interval; CPS = combined positive score; HR = hazard ratio; OS = overall survival; PD-L1 = programmed death ligand 1; PFS = progression-free survival.
키트루다® 허가사항. 식품의약품안전처

KEYTRUDA® (pembrolizumab) Injection 100 mg

키트루다® 난소암 식품의약품안전처 허가사항



KEYNOTE-B96 NOW APPROVED

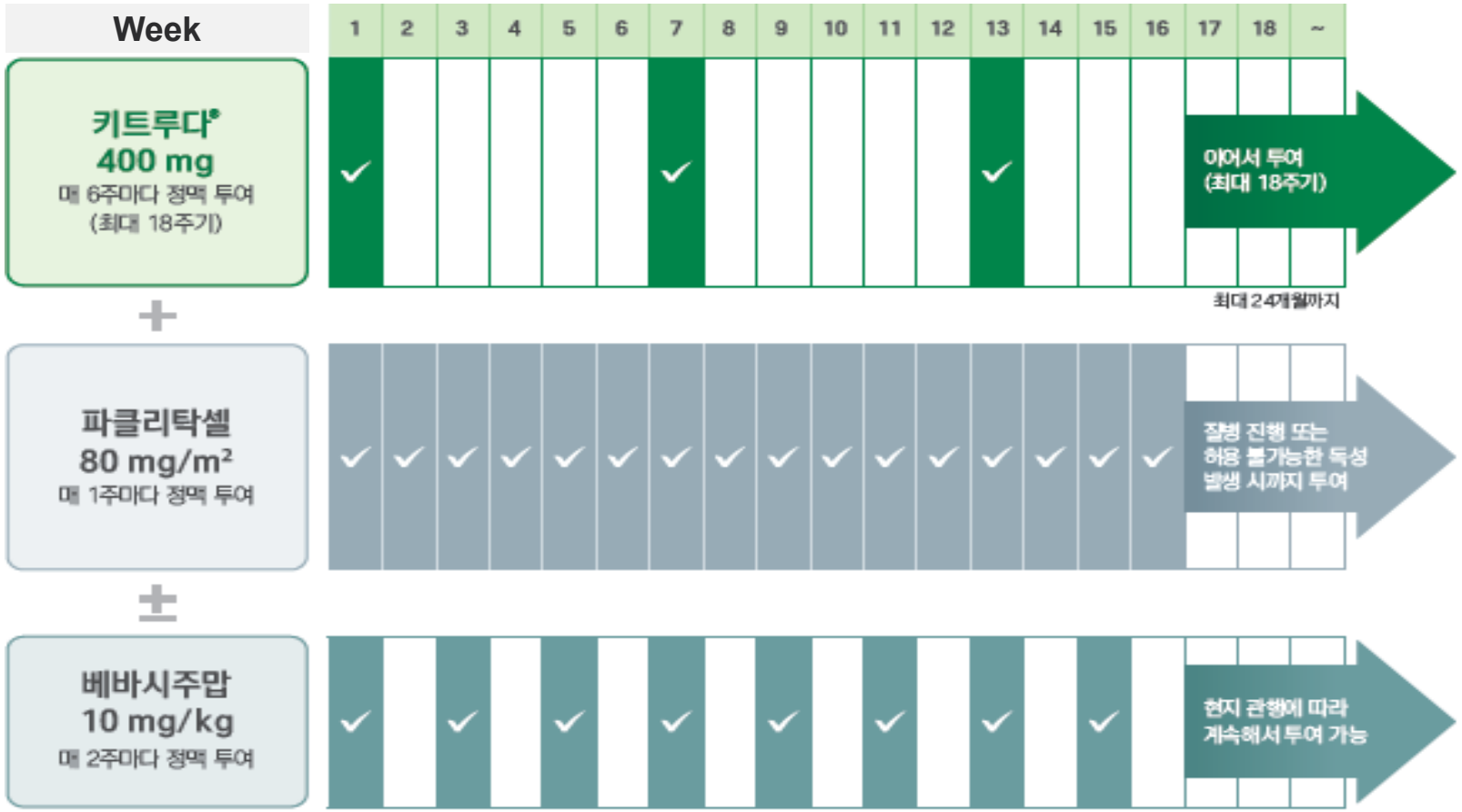
키트루다® 난소암 적응증 (2026년 7월 8일 기준)

PD-L1 발현 양성(CPS ≥1) 이며,
이전에 1회 또는 2회의 전신 치료 요법을 받은
백금-저항성 상피성 난소암, 난관암 또는 원발성 복막암 환자의 치료로서
베바시주맙을 포함하거나 포함하지 않는 파클리탁셀과의 병용요법

Reference. 키트루다® 허가사항. 식품의약품안전처.

KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYNOTE-B96 투여 정보



- 용법용량: 키트루다®는 200 mg을 매 3주마다 또는 400 mg을 매 6주마다 30분에 걸쳐 정맥 점적주입합니다.[1]
- 키트루다®의 치료는 RECIST 1.1에 따른 질병의 진행이 확인되기 전, 허용 불가능한 독성 발생 전, 또는 최대 24개월까지 계속되었습니다.[1,2]
- 키트루다®의 투여는 환자가 임상적으로 안정적이고 연구자가 임상적 이익이 있다고 판단되는 경우 RECIST가 정의한 질병 진행 후에도 허용되었습니다.[1,2]

1. 식품의약품안전처. 키트루다 허가사항. **2.** Colombo N, et al. Pembrolizumab plus weekly paclitaxel in platinum-resistant recurrent ovarian cancer (ENGOT-ov65/KEYNOTE-B96): a multicentre, randomised, double-blind, phase 3 study. Lancet. 2026 Apr 18;407(10538):1525-1537

KEYTRUDA® (pembrolizumab) Injection 100 mg

키트루다® 난소암 KEYNOTE-B96 부분급여

wPAC+Bev+Pembro(d) 항암요법							
	용량	C1D1	C1D8	C1D15	C2D1	C2D8	C2D15
weekly Paclitaxel	80mg/m2	●	●	●	●	●	●
Bevacizumab	10mg/kg	●		●		●	
Pembrolizumab(D)	400mg	●					

KEYTRUDA® (pembrolizumab) Injection 100 mg

키트루다® 난소암 KEYNOTE-B96 부분급여

요양급여로 인정되고 있는 항암요법(기존 항암요법)에 타 항암제를 병용 시 아래의 조건 가), 나)를 모두 만족하는 경우
기존 항암요법의 본인부담률은 기존의 본인부담률을 적용하고, 이 경우, 요양급여비용 청구방법은 다)와 같이 기재해야 함.

- 아 래 -

가) 기존 항암요법과 타 항암제의 병용요법은 식품의약품안전처의 허가사항 범위 이내
나) 투여대상은 기존 항암요법의 급여범위(항암요법, 투여대상, 투여단계, 투여요법) 이내
다) 약값 전액본인부담의 투여 내역은 '명세서 진료내역 U항(건강보험 100분의 100 본인부담)', 비급여 약제의 투여 내역은 '요양급여비용 명세서(참조란 등)'에 명기

연번	주요 암종	항암제 병용요법	허가사항	급여 요법	급여기준
35	난소암	pembrolizumab + paclitaxel ± bevacizumab	Pembrolizumab PD-L1 발현 양성(CPS≥1)이며, 이전에 1회 또는 2회의 전신 치료 요법을 받은 백금-저항성 상피성 난소암, 난관암, 또는 원발성 복막암 환자의 치료로서 베바시주맙을 포함하거나 포함하지 않는 파클릭탁셀과의 병용 요법	paclitaxel	재발성(1차 이상, 고식적요법)
				bevacizumab + paclitaxel	다음의 조건을 모두 만족하는 경우 ① 'platinum'에 실패한 재발성 난소암, 난관암 또는 원발성 복막암 ② 이전에 2가지 이하의 화학요법을 투여 ③ 이전에 이 약을 포함하여 VEGF 저해제 또는 VEGF 수용체-표적 치료제를 투여한 적이 없음 (2차 또는 3차, 고식적요법)

가) 식품의약품안전처의 허가사항 범위 이내

나) 기존 항암요법의 급여범위 이내

Reference 1. 식품의약품안전처. 키트루다 허가사항. 2. 건강보험심사평가원 공고 제2026-210호, 2026.9.29

KEYTRUDA® (pembrolizumab) Injection 100 mg

Real-World Case Sharing

KEYTRUDA®
(pembrolizumab) Injection 100 mg

Case 1

F/53 ECOG 0

25. 11. 14　dx laparoscopy (R: Metastatic carcinoma, gynecologic origin, G2)
24. 11. 17 - 26. 01. 05　TC(NAC) #1-3
26. 01. 27　MRH, BSO, PLND, PaLND, SCOM, appe, peritonectomy (Rt diaph 100%, Lt diaph 80%, Rt para 50%, Lt para 50%, bladder 100%, PCDS), SB mesentery cauterization, CPLND, Rt chest drain, anal drain(3-way foley cath), HIPEC
　* endometrioid carcinoma, FIGO grade 3, bilateral ovary.ypT3cN1a(Ⅲc)
26. 02. 24 - 26. 04. 08　TC #3
26. 05. 21 - 26. 06. 17　Zejula

gNGS :POLE Variant of Uncertain Significance (VUS)
sNGS :CSMD3 mutation (c.3358_3359insT, p.Y1120Lfs*49)
MAP2K4 mutation (c.143_165delTTGCAAATCCACCTTTCAAATCT, p.F48Yfs*27)TP53 mutation (c.375G>A, p.T125=)
Copy number variant (AURKA)

PD-L1 CPS 25
HRD positive

FOLR1(RxDx) | Negative (20%)
pan TRK | Negative
HER2(c-erb B2) | Negative (1+)

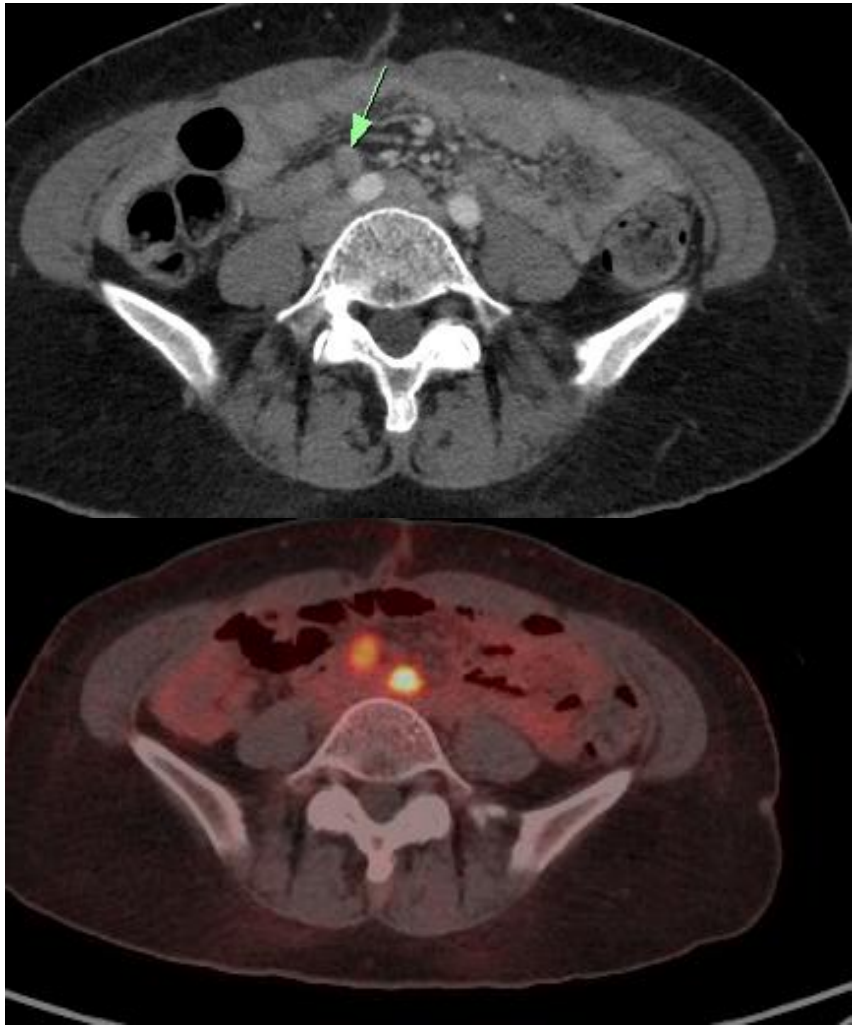
KEYTRUDA®
(pembrolizumab) Injection 100 mg

Case 1

F/53 ECOG 0

25. 11. 14　dx laparoscopy (R: Metastatic carcinoma, gynecologic origin, G2)
24. 11. 17 - 26. 01. 05　TC(NAC) #1-3
26. 01. 27 1st CRS * endometrioid carcinoma, FIGO grade 3, bilateral ovary.ypT3cN1a(Ⅲc)
26. 02. 24 - 26. 04. 08　TC #3
26. 05. 21 - 26. 06. 17　Zejula

26.06.19 CT: increased enhancing masses or L/Ns in rt common iliac area
　: R/O metastasis
　cystic lesion appeared in anterior pelvic cavity
　: R/O seeding/metastasis vs benign loculated fluid collection

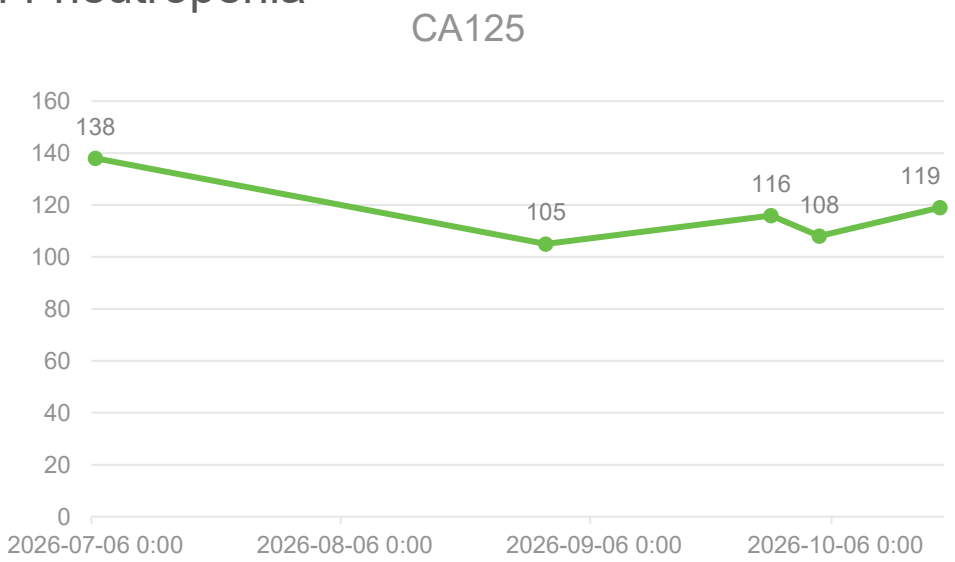


KEYTRUDA®
(pembrolizumab) Injection 100 mg

Case 1

F/53 ECOG 0
26. 07. 14 wPAC+Bevacizumab+Pembrolizumab 400mg #1 D1 & g-csf 2days
26. 08. 06 wPAC(D) #2 D1 & g-csf 2days
26. 09. 02 wPAC+Bevacizumab+Pembrolizumab 400mg #3 D1 & g-csf 2days
26. 09. 23Compared with 26-6-19 CT,
paraaortic LN 10.4mm -> 6.2mm

Gr1 neutropenia





KEYTRUDA® (pembrolizumab) Injection 100 mg

Case 2

F/58 ECOG 0

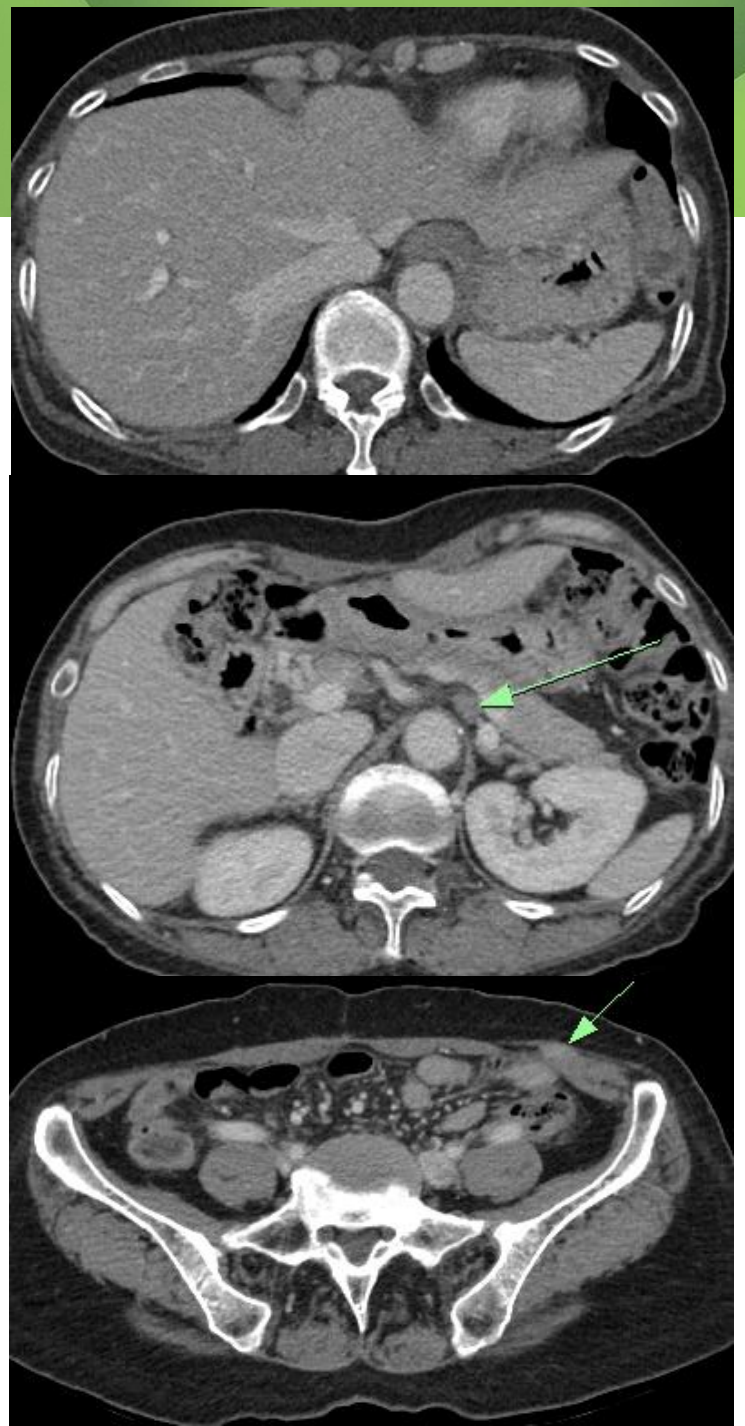
24. 10. 29 D-lapa
  *HG carcinoma
24. 11. 11 - 24. 12. 26 TC #3(NAC)
25. 01. 24 BSO, LAR (E-E, IMA saved), ileocecetomy, cholecystectomy, SCOM, peritonectomy (rt daip 100%, repair 5cm, lf daip 30%, rt para 30%, lf para 30%, bladder 100%,lesser sac 100%), multiple mass excision (SB & LB mesentery, umbilical mass), lf inguinal LND
    *Residual high grade serous carcinoma, bilateral ovary . ypT3cN0 (IIIC)
25. 02. 13 - 25. 06. 10 TC #6 + Bevacizumab (7.5mg) #4
25 .07. 03 - 25. 11. 27 Bevacizumab (7.5mg) #5-12
26. 02. 03 - 26. 04. 20 Mirvetuximab+Carboplatin #4

FOLR1 | Positive (80%)
HRD (GC Genmome) GIS 30 negative

Case 2

24. 10. 29 D-lapa
  *HG carcinoma
24. 11. 11 - 24. 12. 26 TC #3(NAC)
25. 01. 24 BSO, LAR (E-E, IMA saved), ileocecetomy, cholecystectomy, SCOM, peritonectomy (rt daip 100%, repair 5cm, lf daip 30%, rt para 30%, lf para 30%, bladder 100%,lesser sac 100%), multiple mass excision (SB & LB mesentery, umbilical mass), lf inguinal LND
  *Residual **high grade serous carcinoma**, bilateral ovary . ypT3cN0 (IIIC)
25. 02. 13 - 25. 06. 10 TC #6 + Bevacizumab (7.5mg) #4
25 .07. 03 - 25. 11. 27 Bevacizumab (7.5mg) #5-12
26. 02. 03 - 26. 04. 20 Mirvetuximab+Carboplatin #4

P-CT:more increased lt inguinal L/N
  increased L/N or nodule in peripancreatic area
  : R/O metastasis
  increased enhancing lesions in lt lower abdominal wall
  : R/O metastasis



Case 2

26. 02. 03 - 26. 04. 20 Mirvetuximab+Carboplatin #4
P-CT:more increased lt inguinal L/N
increased L/N or nodule in peripancreatic area
: R/O metastasis
increased enhancing lesions in lt lower abdominal wall
: R/O metastasis

(24.11.04)
gNGS : CHEK1 VUS
(25.02.04)
sNGS :ATM mutation (c.72+1G>A, c.3662G>A, p.W1221*)
ATR mutation (c.4503+1G>A, c.7192+2T>C)
ATRX mutation (c.7072-1G>A)
CTNNB1 mutation (c.1081+1G>A)
FANCI mutation (c.475C>T, p.Q159*)
KRAS mutation (c.35G>A, p.G12D)
NBN mutation (c.1845+1G>A)
NF1 mutation (c.2875C>T, p.Q959*)
PTEN mutation (c.361G>A, p.A121T)
TP53 mutation (c.584T>C, p.I195T)
CHEK1 mutation (c.964C>T, p.R342P)
Copy number variant (MYCL)

MSS (microsatellite stable)
PDL1:CPS (Combined positive score): 5
pan TRK | Negative
c-erb B2 | Equivocal (2+)

Genomic Alteration	ATR c.4503+1G>A, ATR c.7192+2T>C
Gene Name	ATR serine/threonine kinase
Tier	IIC
Allele Frequency	4.49%, 4.00% (2 variants)
Locus	chr3:142234236, chr3:142180780 (2 variants)
Transcript	NM_001184.4
Relevant Therapies In this cancer type	None
Relevant Therapies In other cancer type	talazoparib + hormone therapy [1]
Clinical Trials	1
Prognostic significance	None
Diagnostic significance	None

Genomic Alteration	NBN c.1845+1G>A
Gene Name	nibrin
Tier	IIC
Allele Frequency	5.84%
Locus	chr8:90965471
Transcript	NM_002485.5
Relevant Therapies In this cancer type	None
Relevant Therapies In other cancer type	talazoparib + hormone therapy [1]
Clinical Trials	1
Prognostic significance	None
Diagnostic significance	None

Genomic Alteration	KRAS p.(G12D) c.35G>A
Gene Name	KRAS proto-oncogene, GTPase
Tier	IIC
Allele Frequency	2.53%
Locus	chr12:25398284
Transcript	NM_033360.4
Relevant Therapies In this cancer type	None
Relevant Therapies In other cancer type	bevacizumab + chemotherapy
Clinical Trials	1
Prognostic significance	None
Diagnostic significance	None

Genomic Alteration	NF1 p.(Q959*) c.2875C>T
Gene Name	neurofibromin 1
Tier	IIC
Allele Frequency	5.62%
Locus	chr17:29556877
Transcript	NM_001042492.3
Relevant Therapies In this cancer type	None
Relevant Therapies In other cancer type	selumetinib
Clinical Trials	0
Prognostic significance	None
Diagnostic significance	None

Case 2

26. 02. 03 - 26. 04. 20 Mirvetuximab+Carboplatin #4
P-CT:more increased lt inguinal L/N
increased L/N or nodule in peripancreatic area
: R/O metastasis
increased enhancing lesions in lt lower abdominal wall
: R/O metastasis

(24.11.04)
gNGS : CHEK1 VUS
(25.02.04)
sNGS :ATM mutation (c.72+1G>A, c.3662G>A, p.W1221*)
ATR mutation (c.4503+1G>A, c.7192+2T>C)
ATRX mutation (c.7072-1G>A)
CTNNB1 mutation (c.1081+1G>A)
FANCI mutation (c.475C>T, p.Q159*)
KRAS mutation (c.35G>A, p.G12D)
NBN mutation (c.1845+1G>A)
NF1 mutation (c.2875C>T, p.Q959*)
PTEN mutation (c.361G>A, p.A121T)
TP53 mutation (c.584T>C, p.I195T)
CHEK1 mutation (c.964C>T, p.R342P)
Copy number variant (MYCL)

MSS (microsatellite stable)
PDL1:CPS (Combined positive score): 5
pan TRK | Negative
HER-2 | Equivocal (2+)

1. Private insurance
Yes

2. T-Dxd? wPAC?
T-Dxd: Mirvetuximab – Microtubule inhibitor and wPAC also microtubule target agent
wPAC: ADC resistance (ex efflux pump)
HER-2 2+ equivocal

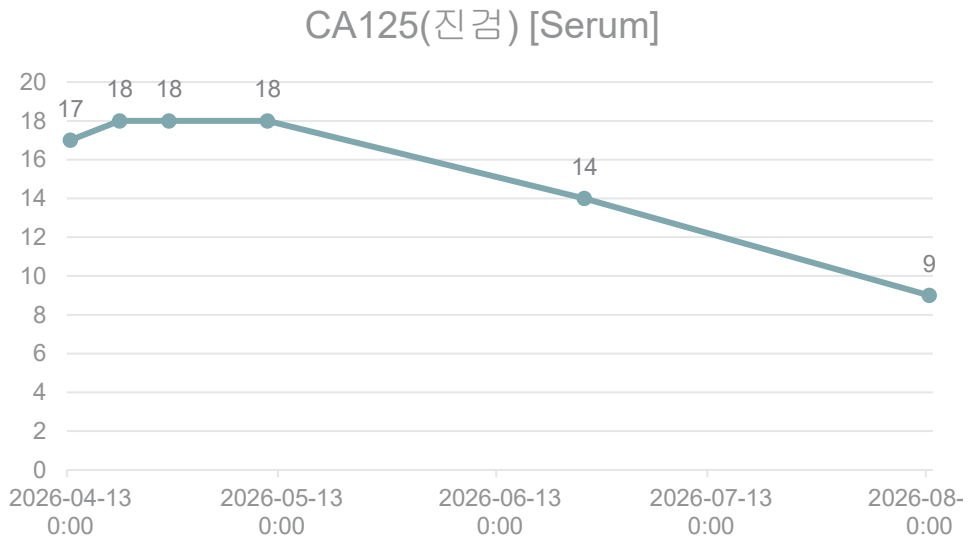
Case 2

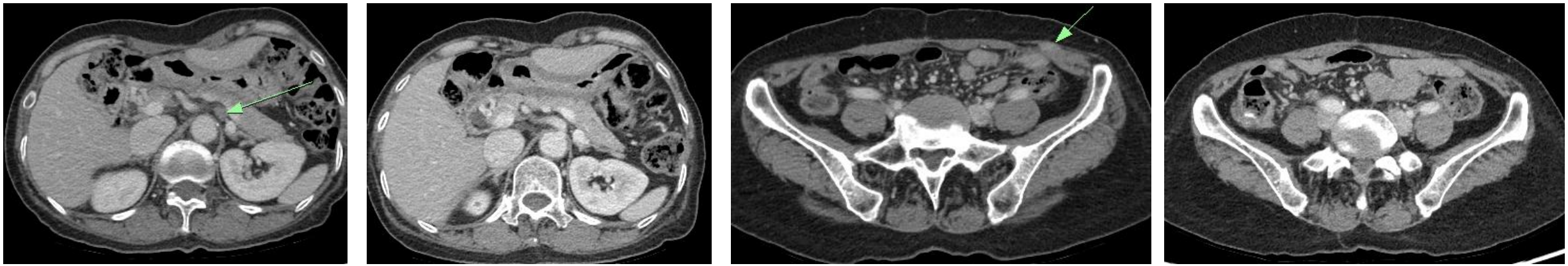
26. 02. 03 - 26. 04. 20 Mirvetuximab+Carboplatin #4
P-CT:more increased lt inguinal L/N
increased L/N or nodule in peripancreatic area
: R/O metastasis
increased enhancing lesions in lt lower abdominal wall
: R/O metastasis

26. 05. 18 wPAC+Bevacizumab+Pembrolizumab (D) 400mg #1~

26. 06. 04 Gr2 Leukocytopenia

CR





Thank you

Selected Safety Information

[제품명] 키트루다®주 (펨브롤리주맙, 유전자재조합) 100 mg [금기] 다음 환자에는 투여하지 말 것 이 약 및 그 구성 성분에 과민증인 환자 **[신중투여] 다음 환자에는 신중히 투여할 것** 자가면역질환이 있거나 만성적 혹은 재발성 자가면역질환의 기왕력이 있는 환자

[이상사례] *임상시험에서 보고된 이상사례: 대조 및 비대조 임상시험에서 총 2,799명을 대상으로 이 약의 안전성을 분석하였다. 치료 기간의 중앙값은 4.2개월(범위: 1일 ~ 30.4개월)이었고, 6개월 이상 치료받은 환자는 1,153명, 1년 이상 치료받은 환자는 600명이었다. 환자의 5%가 치료 관련 약물이상반응으로 이 약 투여를 중단하였다. 최종 투여 후 90일째까지 보고된 치료 관련 중대한 이상사례(SAE)는 이 약을 투여 받은 환자의 10%에서 발생하였다. 발생한 치료 관련 중대한 이상사례 중 가장 흔하게 발생한 이상사례는 다음과 같다; 폐염증, 결장염, 설사, 발열. 치료 관련 중대한 이상사례로 자가면역성 간염과 부신기능저하증도 보고되었다. ***면역-매개 약물이상반응:** 흑색종 및 비소세포폐암 환자 2,799 명에 대한 면역-매개 약물이상반응은 다음과 같다. 갑상선 저하증. 갑상선기능항진증. 폐염증. 결장염. 부신부전. 간염. 뇌하수체염. 신장염. 제1형 당뇨병.

[일반적 주의] 1) 면역-매개 약물이상반응: 면역-매개 폐염증, 면역-매개 결장염, 면역-매개 간염 (이 약) 및 간독성 (이 약과 엑시티닙 병용 요법), 면역-매개 신장염, 면역-매개 내분비병증, 중증의 피부반응, 기타 면역-매개 약물이상반응, 이식 관련 약물이상반응. 이 약 투여 환자에서 중증인 사례와 치명적인 사례를 포함한 면역-매개 약물이상반응이 발생한 바 있다. 면역-매개 약물이상반응은 치료를 중단한 이후에도 발생할 수 있다. 의심되는 면역-매개 약물이상반응에 대해서는 적절한 평가를 통해 병인을 확인하고 약물이상반응의 중증도를 토대로 이 약 투여를 보류하고 코르티코스테로이드 투여를 고려한다. 1등급 이하로 개선되면 코르티코스테로이드를 최소 1개월 이상의 기간을 두고 점감 절차를 시작해야 한다. 면역 관련 약물이상반응이 코르티코스테로이드 사용으로 조절이 되지 않는 환자의 경우 다른 전신 면역억제제의 투여를 고려할 수 있다. 코르티코스테로이드 점감 절차를 실시한 이후에 약물이상반응이 1 등급 이하에 머무르면 이 약 투여를 재개한다. 중증 약물이상반응 사례가 다시 발생하면, 이 약 투여를 영구 중단한다. 2) 다발성 골수종 환자에게 펨브롤리주맙을 탈리도마이드 유사체와 덱사메타손 병용 요법에 추가 시 사망률 증가. 3) 주입 관련 반응: 과민증과 아나필락시스를 포함하는 중증의 주입 관련 반응이 보고되었다.

작성일자: 2026년 07월 08일

[제품명] 키트루다 피하주사™(펨브롤리주맙, 유전자재조합) 395 mg,790 mg [금기] 다음 환자에는 투여하지 말 것 이 약 및 그 구성 성분에 과민증인 환자 **[신중투여] 다음 환자에는 신중히 투여할 것** 자가면역질환이 있거나 만성적 혹은 재발성 자가면역질환의 기왕력이 있는 환자

[이상사례] *임상시험에서 보고된 이상사례: 이 약과 백금 화학요법 병용 연구(MK-3475A-D77)에서 백금기반 화학요법과 병용한 이 약의 안전성 프로파일은 이미 알려진 백금기반 화학요법과 병용하여 투여한 키트루다 정맥주사의 안전성 프로파일과 전반적으로 일관되었으며, 이 약을 투여 받은 환자군에서만 추가로 주사 부위 반응이 2.4%(6/251) 추가로 발생하였으나 모두 1등급이었다. MK-3475A-D77 연구에서 이 약과 백금 기반 화학요법을 병용한 251명의 환자에게 가장 흔하게 발생한 ***면역-매개 약물이상반응**은 갑상선 저하증(14%), 갑상선 항진증(8%), 폐염증(5%), 주입반응(3.2%), 부신 부전(2%), 중증 피부 반응(1.6%), 대장염(1.2%), 간염(0.4%), 갑상선염(0.4%), 그리고 1형 당뇨병(0.4%)였다.

[일반적 주의] 1) 면역-매개 약물이상반응: 면역-매개 폐염증, 면역-매개 결장염, 면역-매개 간염 (이 약) 및 간독성 (이 약과 엑시티닙 병용 요법), 면역-매개 신장염, 면역-매개 내분비병증, 중증의 피부반응, 기타 면역-매개 약물이상반응, 이식 관련 약물이상반응. 펨브롤리주맙의 작용기전에 따라 중증인 사례와 치명적인 사례를 포함한 면역-매개 약물이상반응이 이 약 투여 환자에서 발생할 수 있고, 키트루다 정맥주사를 단독으로 투여한 환자에서 발생한 바 있다(n=2,799). 면역-매개 약물이상반응은 치료를 중단한 이후에도 발생할 수 있다. 의심되는 면역-매개 약물이상반응에 대해서는 적절한 평가를 통해 병인을 확인하고 약물이상반응의 중증도를 토대로 이 약 투여를 보류하고 코르티코스테로이드 투여를 고려한다. 1등급 이하로 개선되면 코르티코스테로이드를 최소 1개월 이상의 기간을 두고 점감 절차를 시작해야 한다. 면역 관련 약물이상반응이 코르티코스테로이드 사용으로 조절이 되지 않는 환자의 경우 다른 전신 면역억제제의 투여를 고려할 수 있다. 코르티코스테로이드 점감 절차를 실시한 이후에 약물이상반응이 1 등급 이하에 머무르면 이 약 투여를 재개한다. 중증 약물이상반응 사례가 다시 발생하면, 이 약 투여를 영구 중단한다. 2) 다발성 골수종 환자에게 펨브롤리주맙을 탈리도마이드 유사체와 덱사메타손 병용 요법에 추가 시 사망률 증가. 3) 주입 관련 반응: 이 약의 투여로 과민증과 아나필락시스를 포함하는 중증의 주입 관련 반응이 발생할 수 있다.

작성일자: 2026년 05월 19일

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