The Systemic Treatment of Rcurrent Ovarian Cancer

유 헌 종
충남 의대
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DECLATATION OF INTERESTS

I have something to disclose

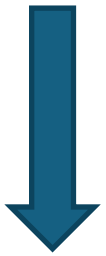
- Research Funding :한미헬쓰케어, AZ

목차

Introduction: The Evolving Paradigm

- **Epidemiology:** OC remains a leading cause of gynecologic cancer death, with >80% of advanced cases recurring

- **The Continuum of Sensitivity:** Move beyond the binary 6-month cutoff; PFI is now viewed as a continuum of probability for platinum response.



- **Key Drivers of Treatment Selection:**
  - Prior therapies (especially PARP inhibitors and bevacizumab).
  - Molecular profile (gBRCA/sBRCA, HRD status, FRα expression).
  - Patient factors: Residual toxicity (neuropathy/renal), performance status, and goals of care

Q. Rec Ova Ca_ Diagnosis_

Rec Ova Ca_ Diagnosis_ NCCN guideline

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NCCN Guidelines Version 3.2025
Epithelial Ovarian Cancer/Fallopian Tube Cancer/ Primary Peritoneal Cancer

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MONITORING/FOLLOW-UP FOR PATIENTS NOT RECEIVING TREATMENT

RECURRENT DISEASE[bb]

Stage I, II, III, and IV after primary treatment →

- Visits every 2–4 mo for 2 y, then 3–6 mo for 3 y, then annually after 5 y
- Physical exam including pelvis exam as clinically indicated
- Imaging as clinically indicated[a] (eg, C/A/P CT, chest CT, A/P MRI, PET/MRI, PET/CT) (skull base to mid-thigh)
- CBC and chemistry profile as indicated
- CA-125[aa] or other tumor markers if initially elevated
- Refer for genetic risk evaluation, if not previously done[f]
- Long-term wellness care (See NCCN Guidelines for Survivorship)

→ **Rising CA-125, no previous chemotherapy or Clinical relapse, no previous chemotherapy** →
- Imaging studies as clinically indicated[a,cc]: C/A/P CT, MRI, PET/CT, or PET
- Tumor molecular testing[dd] if not previously done

→ Primary Treatment (OV-1)

→ **Clinical relapse, previous chemotherapy** →
- Imaging studies as clinically indicated[a,cc]: C/A/P CT, MRI, PET/CT, or PET
- Tumor molecular testing[dd] if not previously done

→ Therapy for Persistent Disease or Recurrence (OV-7)

→ **Serially rising CA-125, previous chemotherapy** →
- Imaging studies as clinically indicated[a,cc]: C/A/P CT, MRI, PET/CT, or PET
- Tumor molecular testing[dd] if not previously done

→ Delay treatment until clinical relapse or Immediate treatment for recurrent disease (category 2B)[n] → Therapy for Persistent Disease or Recurrence (OV-7)

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CLINICAL PRESENTATION

Suspicious/ palpable pelvic mass on abdomen/ pelvis exam and/or ascites, abdominal distention

and/or

Symptoms without source of malignancy (ie, bloating, pelvis/ abdomen pain, difficulty eating or feeling full quickly, urinary symptoms [urgency or frequency])

WORKUP

- Abdominal/pelvic exam
- Pelvis ultrasound, abdomen/ pelvis CT/MRI as clinically indicated[a,b]
- Chest CT as clinically indicated[a,c]
- Complete blood count (CBC), chemistry profile with liver function test (LFT)
- CA-125 or other tumor markers as clinically indicated[d]
- Evaluate performance status and nutritional status
- Gastrointestinal (GI) evaluation as clinically indicated
- Reproductive endocrinology and infertility (REI) evaluation as clinically indicated[e]
- Obtain family history[f,g,h]
- Refer to gynecologic oncologist for clinically suspicious lesions[l]

CLINICAL STAGE[i]

PRIMARY TREATMENT[i,j,k]

IA (fertility desired) → Unilateral salpingo-oophorectomy (USO) + comprehensive surgical staging[j,k,l,m]

IB (fertility desired) → Bilateral salpingo-oophorectomy (BSO) + comprehensive surgical staging[j,k,l,m]

IA–IV, surgical candidate, optimal cytoreduction likely (fertility not desired) → Hysterectomy/BSO + comprehensive staging[j,k] and debulking as needed

Poor surgical candidate or Low likelihood of optimal cytoreduction[j] → Neoadjuvant Therapy (OV-2)[n]

Patients with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer should have genetic risk evaluation and germline and somatic testing (if not previously done)[f,g,h,k]

- Pathologic Staging (OV-4)
- For less common ovarian cancers (LCOC),[o] see LCOC-1

Diagnosis by previous surgery or tissue biopsy (cytopathology) → Workup, Findings, and Primary Treatment (OV-3)

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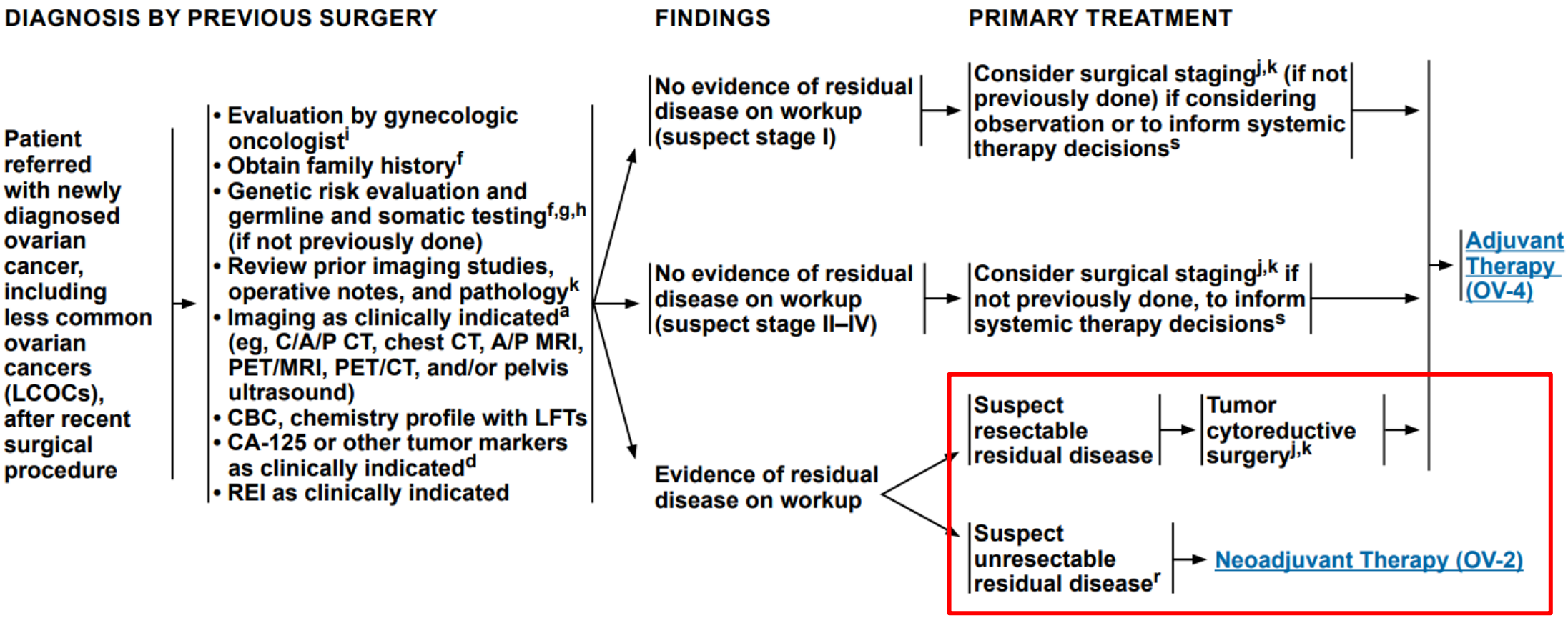

Rec Ova Ca_ Diagnosis_ NCCN guideline

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or
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Serially rising CA-125, previous chemotherapy

- Imaging studies as clinically indicated[a,cc]: C/A/P CT, MRI, PET/CT, or PET
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→ Delay treatment until clinical relapse
or
Immediate treatment for recurrent disease (category 2B)[n]

Rec Ova Ca_ Diagnosis

- CA 125 - Gynecologic Cancer Intergroup(GCIG)

Scenario	Pre Treatment	Post Treatment	Failure definition
1	increased	Normal	>2 times upper limit of normal on 2 occasions at least 1 week apart
2	increased	Increased from normal	>2 times of Nadir on 2 occasions at least 1 week apart

- CT Scan – Basic investigation but sensitivity – 40-95%, specificity 45-90%, FNR – 45%
- MRI Abdomen – better sensitivity & specificity than CT
- PETCT - sensitivity ≈ 90%, specificity – 85%
- PET CT + CA 125 sensitivity ≈ 98% in recurrence

Zouwei et al. Cancer innov 2025 Jun

Q. Although asymptomatic, Rec Ova Ca was found

Can you treat later?

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→ Therapy for Persistent Disease or Recurrence (OV-7)

Early versus delayed treatment of relapsed ovarian cancer (MRC OV05/EORTC 55955): a randomised trial

*Gordon J S Rustin, Maria E L van der Burg, Clare L Griffin, David Guthrie, Alan Lamont, Gordon C Jayson, Gunnar Kristensen, César Mediola, Corneel Coens, Wendi Qian, Mahesh K B Parmar, Ann Marie Swart, for the MRC OV05 and EORTC 55955 investigators**

Summary

Background Serum CA125 concentration often rises several months before clinical or symptomatic relapse in women with ovarian cancer. In the MRC OV05/EORTC 55955 collaborative trial, we aimed to establish the benefits of early treatment on the basis of increased CA125 concentrations compared with delayed treatment on the basis of clinical recurrence.

Methods Women with ovarian cancer in complete remission after first-line platinum-based chemotherapy and a normal CA125 concentration were registered for this randomised controlled trial. Clinical examination and CA125 measurement were done every 3 months. Patients and investigators were masked to CA125 results, which were monitored by coordinating centres. If CA125 concentration exceeded twice the upper limit of normal, patients were randomly assigned (1:1) by minimisation to early or delayed chemotherapy. Patients and clinical sites were informed of allocation to early treatment, and treatment was started as soon as possible within 28 days of the increased CA125 measurement. Patients assigned to delayed treatment continued masked CA125 measurements, with treatment commencing at clinical or symptomatic relapse. All patients were treated according to standard local practice. The primary outcome was overall survival. Analysis was by intention to treat. This study is registered, ISRCTN87786644.

Findings 1442 patients were registered for the trial, of whom 529 were randomly assigned to treatment groups and were included in our analysis (265 early, 264 delayed). With a median follow-up of 56·9 months (IQR 37·4–81·8) from randomisation and 370 deaths (186 early, 184 delayed), there was no evidence of a difference in overall survival between early and delayed treatment (HR 0·98, 95% CI 0·80–1·20, p=0·85). Median survival from randomisation was 25·7 months (95% CI 23·0–27·9) for patients on early treatment and 27·1 months (22·8–30·9) for those on delayed treatment.

Interpretation Our findings showed no evidence of a survival benefit with early treatment of relapse on the basis of a raised CA125 concentration alone, and therefore the value of routine measurement of CA125 in the follow-up of patients with ovarian cancer who attain a complete response after first-line treatment is not proven.

Lancet 2010; 376: 1155–1163

See Editorial page 1117

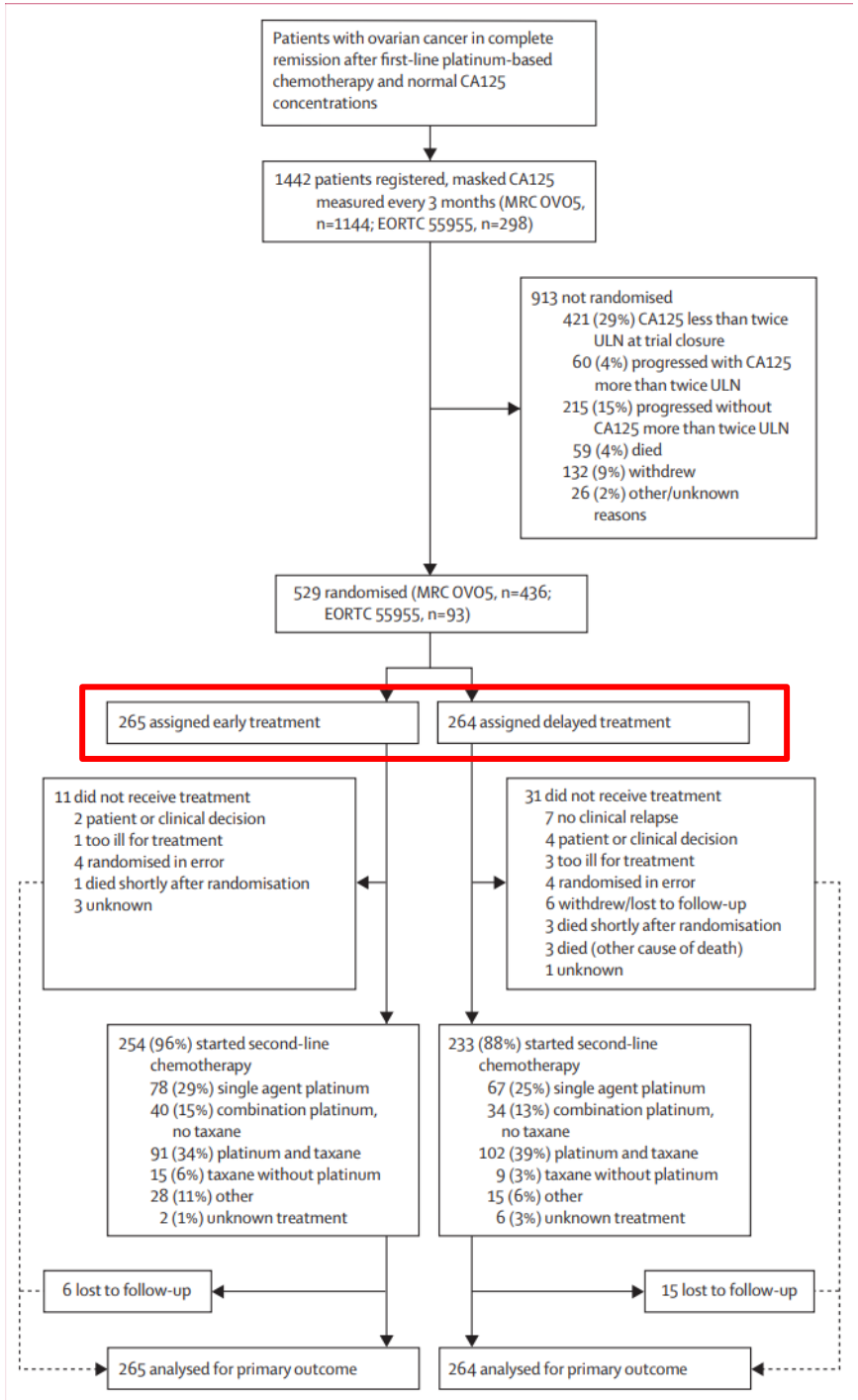
See Comment page 1120

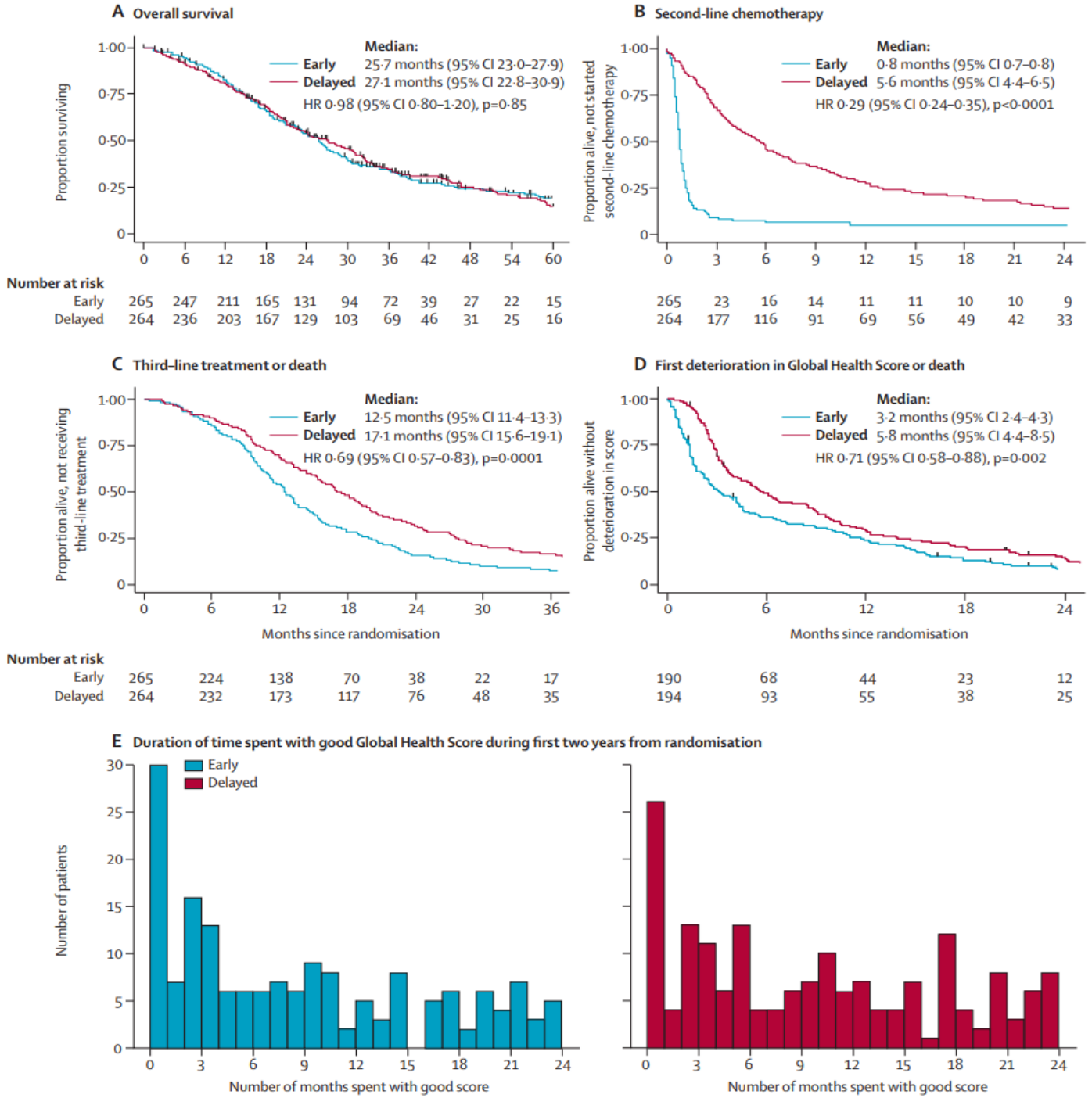
*Investigators are listed at the end of the paper

†Dr Guthrie is now retired

Mount Vernon Cancer Centre, Northwood, UK (Prof G J S Rustin MD); **Erasmus MC University Medical Centre Rotterdam, Rotterdam, Netherlands** (M E L van der Burg MD); **Medical Research Council Clinical Trials Unit, London, UK** (C L Griffin MSc, W Qian PhD, Prof M K B Parmar DPhil, A M Swart MD); **Derbyshire Royal Infirmary, Derby, UK** (D Guthrie FRCR†); **Colchester Hospital University NHS Foundation Trust, Colchester, UK** (A Lamont FRCR); **Christie Hospital and the University of Manchester, Manchester, UK** (Prof G C Jayson FRCP); **Oslo University Hospital, The Norwegian Radium Hospital, Oslo, Norway** (G Kristensen MD);

Trial profile





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EORTC 5595: Early versus Delayed Treatment of Recurrence

- The primary end point was OS.
- After 370 events of death
- No evidence of a difference in OS between early and delayed treatment

  (25.7 versus 27.1 months,HR, 0.98; 95% CI, 0.8 to 1.2; *P* = 0.85)

Criticism-

- Old trial starting in 1997
- Targeted therapy and other chemotherapy were not there
- Treatment to start early t achieve at least good PFS & QOL.
- No secondary CRS

Q. Rec Ova Ca_ platinum sensitivity 6months???

History of platinum re-treatment_ platinum sensitivity

- **Platinum-based chemotherapy** re-challenge was introduced in the late 1980s for recurrent ovarian cancer

- Studies **(Blackledge, Gore, Markman et al.)** observed the highest response rates with combinations including **cisplatin** or **carboplatin**

- The **treatment-free interval** was consistently identified as the most critical variable predicting response to subsequent platinum therapy
  - Definitions rely on **treatment-free interval (TFI)** "cut-offs" of 4-12 months

- A **6-month TFI** has been the standard for defining platinum sensitivity for the last 30 years

- A 4-category system for **platinum resistance/sensitivity** was proposed by Markman and Hoskins

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Definitions by Markman and Hoskins

- **Platinum Refractory-** Progression during primary chemo

- **Platinum Resistance** – Progression within 6 months of Last CT
  - Options - single agents such as pegylated liposomal doxorubicin (PLD) or topotecan and other agents.

- **Partial Platinum sensitive** – Progression with in 6-12 months of last CT
  - can benefit from platinum-based re-induction chemotherapy

- **Platinum sensitive** – if DFI is more than 12 months
  - reinduction of platinum-based chemotherapy. Doublet with Pacli, PLD, Gemcitabine can be considered.

Journal of Clinical Oncology
The Official Journal of the American Society of Clinical Oncology
Vol 10, No 4 **April 1992**

EDITORIAL

Responses to Salvage Chemotherapy in Ovarian Cancer: A Critical Need for Precise Definitions of the Treated Population

Maurie Markman
William Hoskins
Memorial Sloan-Kettering Cancer Center
New York, NY

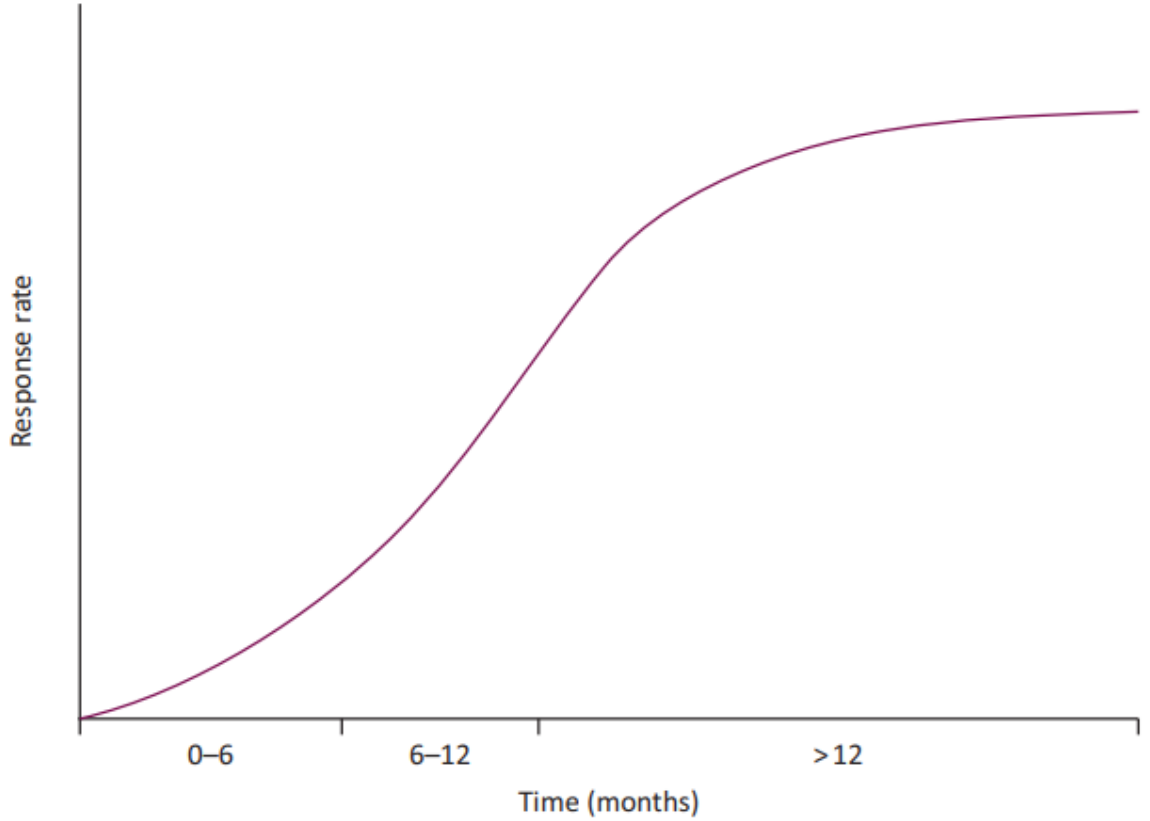
Journal of Clinical Oncology, Vol 10, No 4 (April), 1992: pp 513-514

History of platinum re-treatment

The **GCIG** has moved away from rigid "platinum-sensitive/resistant" definitions based on fixed time cut-offs

- **2010:** Acknowledged tumor response is a **continuous** function of the treatment-free interval (TFIp)

- **2015: Abandoned** the terminology in clinical trials; now stratify patients using **TFIp as a continuous variable**.



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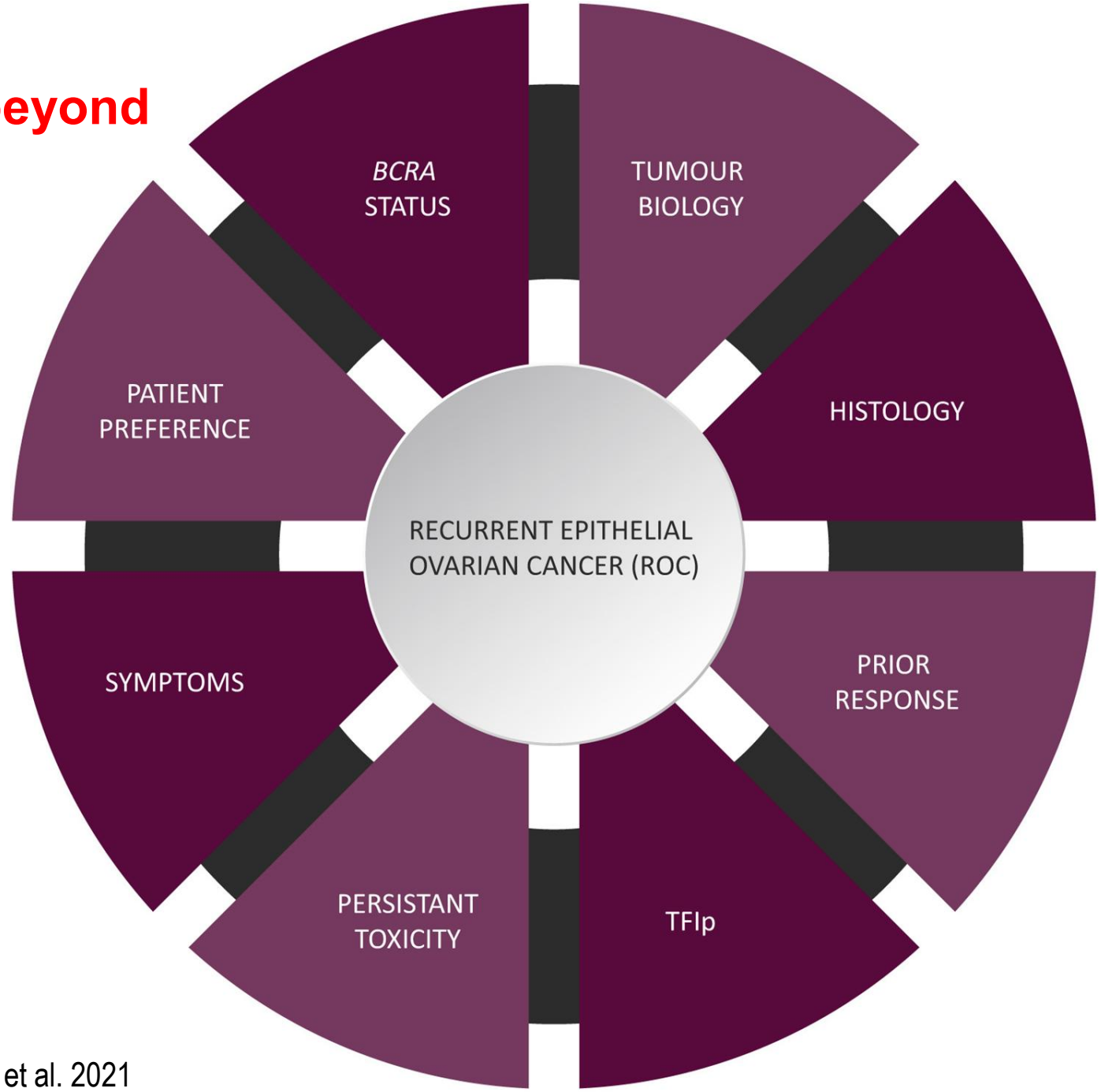
Overview of studies on anti-angiogenic drugs in relapsed ovarian cancer

Inhibition of the VEGF-R tyrosine kinase	Multi-target	Sorafenib	TRIAS	174	Recurrence <6 months after last platinum Tx (max. three prior lines)	Topotecan followed by either oral sorafenib and continue allocated study therapy (sorafenib or placebo) for up to 1 year or until PD	HR 0.60 (95% CI, 0.43-0.83) *P* = 0.0018–6.7 versus 4.4 Mo	HR 0.65 (95% CI, 0.45-0.93) *P* = 0.017–17.1 versus 10.1 Mo
			MITO-11	74	Recurrence <6 months after last platinum Tx (max. two prior lines)	Weekly Paclitaxel plus pazopanib /placebo until PD	HR 0.42 (95% CI, 0.25-0.69) *P* = 0.0002–6.35 versus 3.49 Mo	HR 0.60 (95% CI, 0.32-1.13) *P* = 0.056–19.1 versus 13.7 Mo
		Pazopanib	Richardson. *JAMA Oncol* 2018	106	Recurrence <6 months after last platinum Tx (max. three prior lines (one non-platinum)	Paclitaxel plus pazopanib/placebo given daily until PD	HR 0.84 (90% CI, 0.57-1.22) *P* = 0.20–7.5 versus 6.2 months	HR 1.04 (90% CI, 0.60-1.79) *P* = 0.90–20.7 versus 23.3 Mo
	VEGF-R, FGF-R and PDGF-R	Nintedanib	Ledermann et al. *JCO* 2011	83	PR or CR after last line of CTx for Rec serous Ova Ca, with a TFI of ≤12 Mo	BIBF 1120 250 mg/placebo twice daily maintenance starting 4-8 weeks after completion of chemotherapy	HR 0.65 (95% CI, 0.42-1.02) *P* = 0.06–36-week PFS rate 16.3% versus 5.0%	HR 0.84 (95% CI, 0.51-1.39) *P* = 0.51
		BIBF 1120						
	VEGF-R	Cediranib	ICON6	456	Recurrence ≥6 Mo after front-line platinum Tx	In arm A: platinum Tx plus daily oral placebo tablets and then placebo during the maintenance In arm B: platinum Tx plus once-daily oral cediranib 20 mg, and then placebo during the maintenance phase In arm C: received once-daily oral cediranib 20 mg during both phases	HR 0.56 (95% CI, 0.44-0.72) *P* < 0.0001–11.0 versus 8.7 months (arm C versus arm A). Arm B PFS 9.9 Mo (95% CI, 9.4-10.5)	Immature HR 0.77 (95% CI, 0.55-1.07) *P* = 0.11–26.3 versus 21 Mo (arm C versus arm A)
Inhibition of the interaction of ANG-1 and ANG-2 to the TIE2-receptor		Trebananib	Karlan et al. *JCO* 2012	161	ROC with maximum three prior lines of CTx, including at least one platinum Tx	Weekly Paclitaxel and were randomly assigned 1 : 1 : 1 to also receive intravenous AMG 386 10 mg/kg (arm A), AMG 386 3 mg/kg (arm B) QW or placebo QW (arm C) until PD	HR 0.76 (95% CI, 0.52-1.12) *P* = 0.165 (arm A + B versus arm C) 7.2 (arm A) versus 5.7 (arm B) versus 4.6 Mo (arm C)	HR 0.60 (95% CI, 0.34-1.06) *P* = 0.081–22.5 versus 20.9 Mo (arm A versus arm C)
		AMG 386	TRINOVA-1	919	Recurrence ≤12 months after last platinum Tx (max. three prior lines)	Paclitaxel 80 mg/m2 once weekly (3 weeks on/1 week off) plus either intravenous trebananib 15 mg/kg or placebo once weekly	HR 0.70 (95% CI, 0.61-0.80) *P* < 0.001–7.4 versus 5.4 Mo	HR 0.95 (95% CI, 0.81-1.11) *P* = 0.52–19.3 versus 18.3 Mo

Considerations beyond TFIp



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Guidelines

- NCCN
- 부인종양학회_ 난소암 진료 권고안
- ESMO

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DISEASE STATUS[f,dd,ee]

RECURRENCE THERAPY FOR PLATINUM-SENSITIVE DISEASE[n,gg,hh,ii]

Platinum-sensitive disease[ff]**: Complete remission and relapse ≥6 mo after completing prior chemotherapy**

- **Radiographic and/or clinical relapse** → **Consider secondary cytoreductive surgery**[j,k] → **Combination platinum-based chemotherapy,**[n] **preferred for first recurrence (category 1) or Recurrence therapy**[n,kk] **and/or Best supportive care (See NCCN Guidelines for Palliative Care)**
- **Biochemical relapse (rising CA-125 and no radiographic evidence of disease)**
  - **Delay treatment until radiographic and/or clinical relapse** (→ Radiographic and/or clinical relapse)
  - **Immediate platinum-based recurrence therapy**[n] **(category 2B) and/or Best supportive care (See NCCN Guidelines for Palliative Care)**

→ **Maintenance therapy (if PR or CR)**

- **Useful in certain circumstances:**
  - **Continue bevacizumab if previously treated with chemotherapy + bevacizumab;**

  or

  - **PARPi therapy (for those with *BRCA 1/2* mutation)**[ll]**:**
    - **If not previously used (category 1)**
    - **If disease has not progressed during prior PARPi treatment**

or

Observe

→ **Monitoring/ Follow-up (OV-6)**

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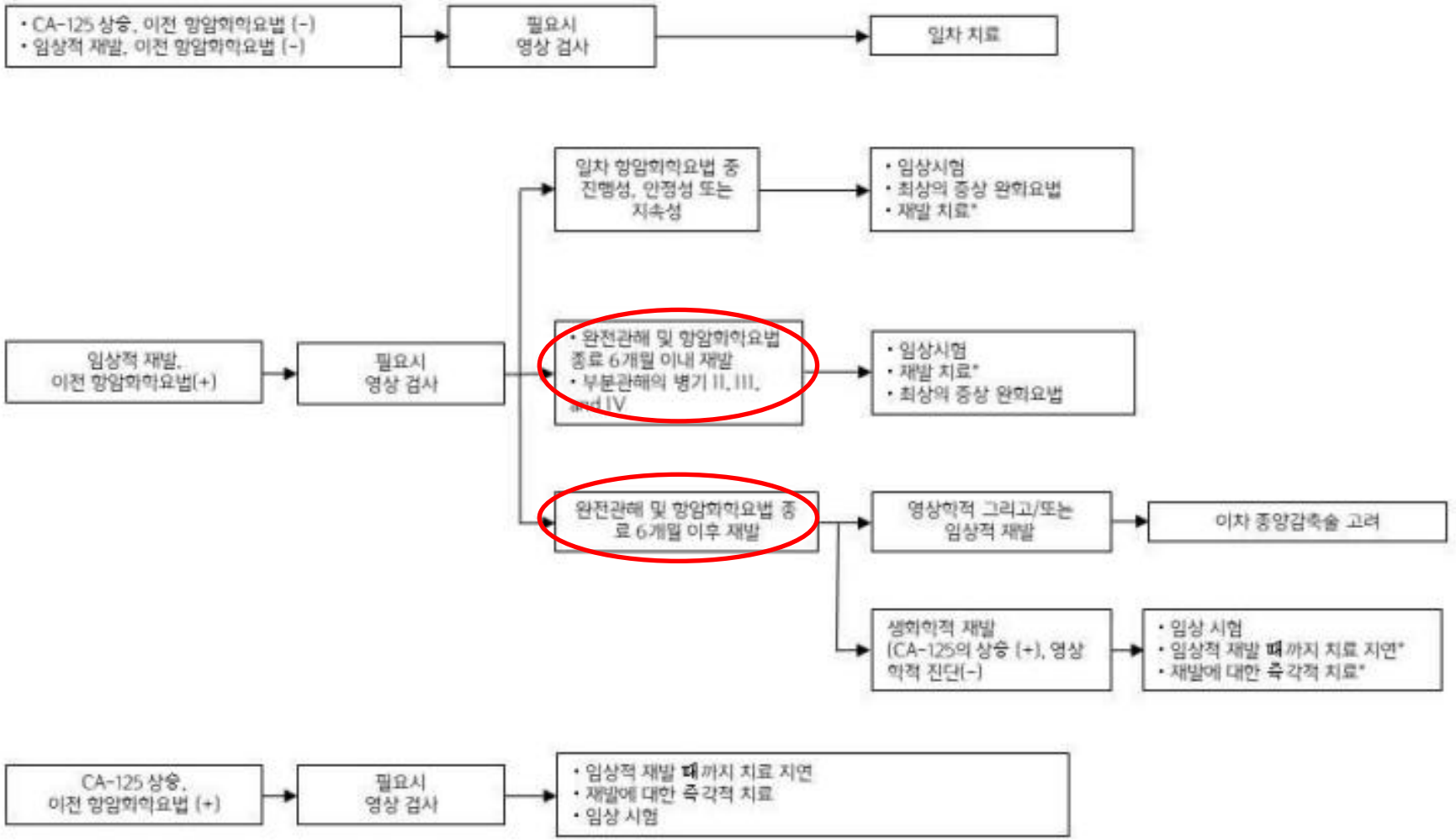
DISEASE STATUS[f,dd,ee]	THERAPY FOR PERSISTENT DISEASE OR RECURRENCE[n,gg,hh,ii]
Platinum-resistant disease[ff]: Progression on primary, maintenance or recurrence therapy or Stable or persistent disease (if not on maintenance therapy) or Complete remission and relapse <6 mo after completing chemotherapy	→ Best supportive care (See NCCN Guidelines for Palliative Care) and/or Recurrence therapy (OV-C, 9 of 12)[n,jj,kk]
Platinum-sensitive disease[ff]: Complete remission and relapse ≥6 mo after completing prior chemotherapy	→ OV-8

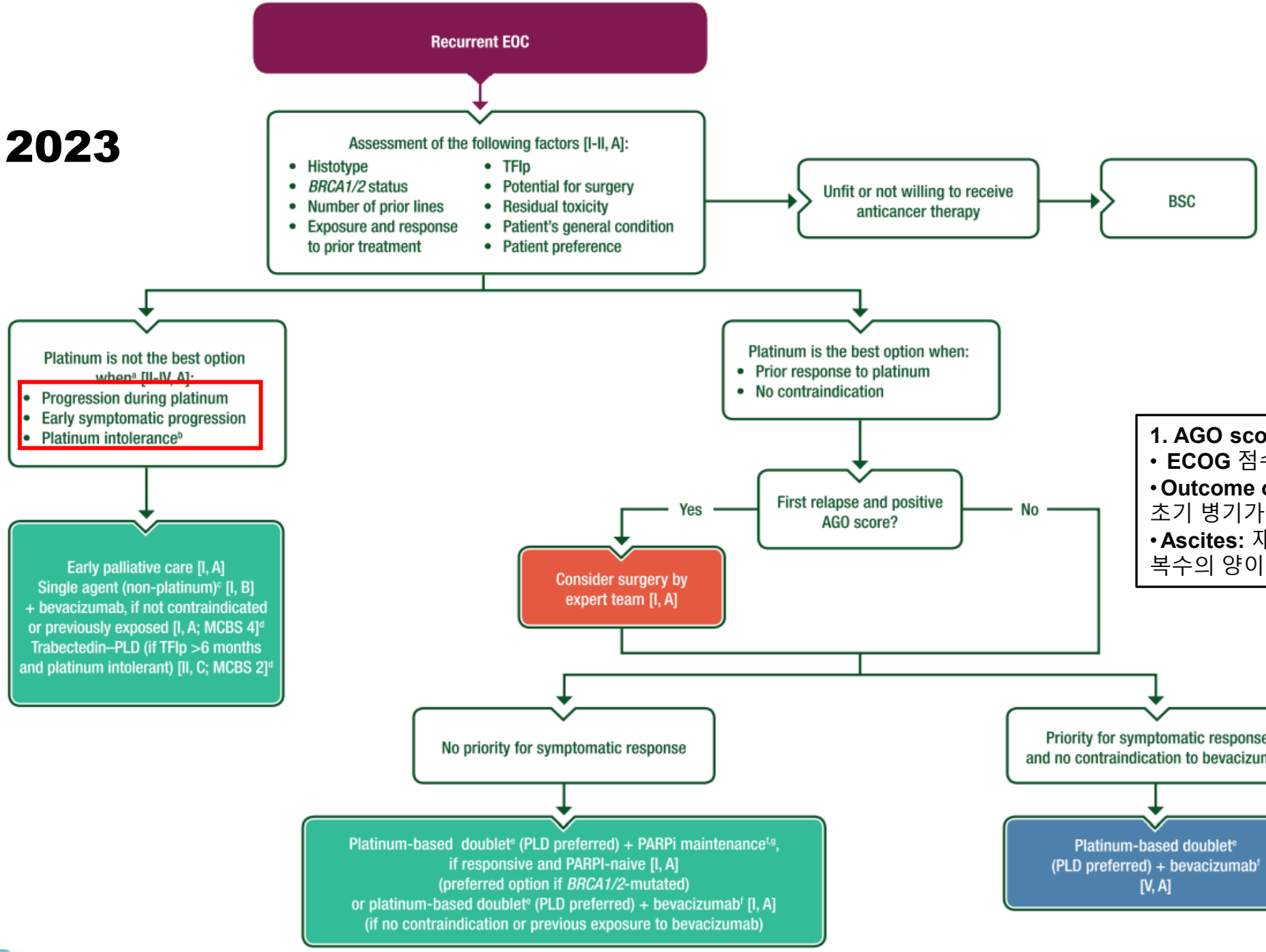
대한부인종양학회 진료 권고안
(5판, 2024)

상피성 난소암 진료권고안 요약(2)

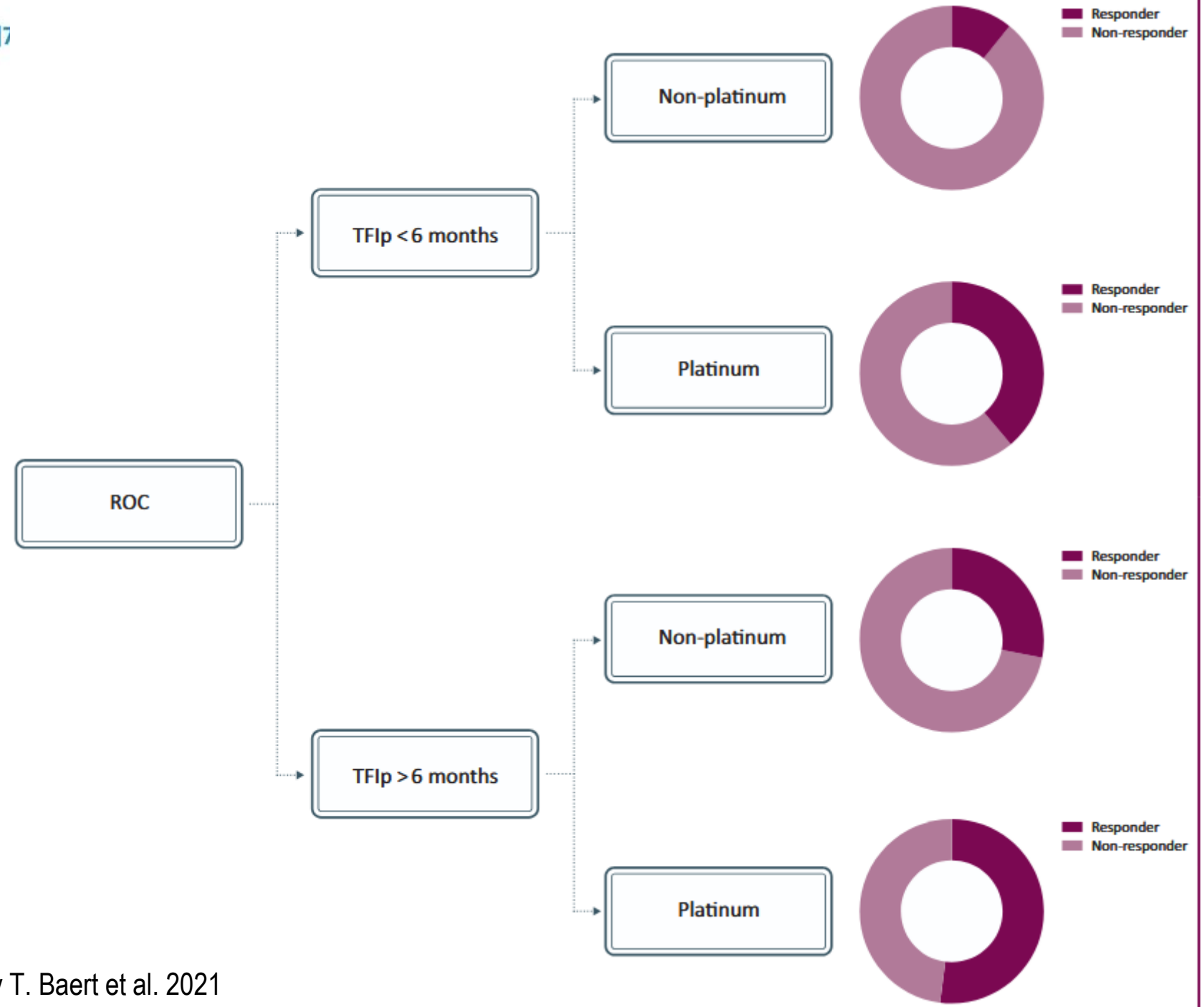
재발 치료



ESMO 2023



1. AGO score_ 모두 충족시
- **ECOG** 점수가 **0점**
- **Outcome of Primary Surgery: R0**, 초기 병기가 **FIGO I/II기**
- **Ascites:** 재발 시점에 확인되는 복수의 양이 **500mL 미만**



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The systemic treatment of recurrent ovarian cancer

2. Platinum-Sensitive Recurrence

Platinum-Sensitive Recurrence (PFI > 6 Months)

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PRINCIPLES OF SYSTEMIC THERAPY

Acceptable Recurrence Therapies for Epithelial Ovarian (including LCOC)[o]/Fallopian Tube/Primary Peritoneal Cancer

Recurrence Therapy for Platinum-Sensitive Disease[p] (alphabetical order)

Preferred Regimens	Other Recommended Regimens[s]	Useful in Certain Circumstances
Carboplatin/gemcitabine[14] ± bevacizumab[q,r,15] Carboplatin/liposomal doxorubicin[16] ± bevacizumab[q,17] Carboplatin/paclitaxel[g,18] ± bevacizumab[q,r,19] Cisplatin/gemcitabine[20] Targeted Therapy (single agents) Bevacizumab[q,21,22]	Capecitabine Carboplatin[14] Carboplatin/docetaxel[23,24] Carboplatin/paclitaxel (weekly)[g,25] Cisplatin[18] Cyclophosphamide Doxorubicin Ifosfamide Irinotecan Melphalan Oxaliplatin Paclitaxel Paclitaxel, albumin bound Pemetrexed Vinorelbine Targeted Therapy Niraparib/bevacizumab (category 2B)[q,26] Niraparib (category 3)[t,27] Olaparib (category 3)[u,28] Pazopanib (category 2B)[29] Rucaparib (category 3)[v,30] Hormone Therapy Aromatase inhibitors (anastrozole, exemestane, letrozole) Goserelin acetate Leuprolide acetate Megestrol acetate Tamoxifen[j]	For mucinous carcinoma: • 5-FU/leucovorin/oxaliplatin ± bevacizumab (category 2B for bevacizumab)[q] • Capecitabine/oxaliplatin ± bevacizumab (category 2B for bevacizumab)[q] Carboplatin/paclitaxel (for age >70)[g,w] Carboplatin/paclitaxel, albumin bound (for confirmed taxane hypersensitivity) Irinotecan/cisplatin (for clear cell carcinoma)[31] Targeted Therapy[x] Dabrafenib + trametinib (for *BRAF* V600E-positive tumors)[32] Entrectinib[33] or larotrectinib[34] or repotrectinib[35] (for *NTRK* gene fusion-positive tumors) Fam-trastuzumab deruxtecan-nxki (for HER2-positive tumors [IHC 3+ or 2+])(category 2B)[36] Mirvetuximab soravtansine-gynx[y] (for FRα-expressing tumors [≥75% positive tumor cells])[37] Mirvetuximab soravtansine-gynx/bevacizumab[q] (for FRα-expressing tumors [≥50% positive tumor cells]) (category 2B)[38] Selpercatinib (for *RET* gene fusion-positive tumors)[39] For low-grade serous carcinoma: • Avutometinib/defactinib (for *KRAS*-mutated tumors)[40] • Trametinib[41] • Binimetinib (category 2B)[42,43] Hormone Therapy Fulvestrant (for low-grade serous carcinoma) Immunotherapy[x] Dostarlimab-gxly (for dMMR/MSI-H recurrent or advanced tumors)[44] Pembrolizumab (for MSI-H or dMMR solid tumors, or patients with TMB-H tumors ≥10 mutations/megabase)[45]

Principle of Platinum Sensitive Recurrence Treatment

PRINCIPLES OF SYSTEMIC THERAPY

Acceptable Recurrence Therapies for Epithelial Ovarian (including LCOC)[p]/Fallopian Tube/Primary Peritoneal Cancer[q]

Recurrence Therapy for Platinum-Sensitive Disease[r] (alphabetical order)

Preferred Regimens	Other Recommended Regimens[u]		Useful in Certain Circumstances
Carboplatin/ gemcitabine[14] ± bevacizumab[k,s,t,15] (2006 AGO-OVAR/2012 OCEANS)	Capecitabine	Ifosfamide	For mucinous carcinoma:
Carboplatin/liposomal doxorubicin[16] ± bevacizumab[k,s,17] (2010)	Carboplatin[14]	Irinotecan	• 5-FU/leucovorin/oxaliplatin ± bevacizumab (category 2B for bevacizumab)[k,s]
Carboplatin/paclitaxel[g,18] ± bevacizumab[k,s,t,19] (2003 ICON4/2017 GOG213)	Carboplatin/docetaxel[23, 24]	Melphalan	• Capecitabine/oxaliplatin ± bevacizumab (category 2B for bevacizumab)[k,s]
Cisplatin/gemcitabine[20] (2005)	Carboplatin/paclitaxel (weekly)[g,25]	Oxaliplatin	Carboplatin/paclitaxel (for age >70)[g,y]
Targeted Therapy (single agents)	Cisplatin[18]	Paclitaxel	Carboplatin/paclitaxel, albumin bound (for confirmed taxane hypersensitivity)
Bevacizumab[k,s,21,22] (2007)	Cyclophosphamide	Paclitaxel, albumin bound	Irinotecan/cisplatin (for clear cell carcinoma)[31]
	Doxorubicin	Pemetrexed	Targeted Therapy
		Vinorelbine	Dabrafenib + trametinib (for *BRAF* V600E-positive tumors)[z,32]
	Targeted Therapy		Entrectinib or larotrectinib or repotrectinib[33] (for *NTRK* gene fusion-positive tumors)[z]
	Niraparib/bevacizumab (category 2B)[k,26]		Mirvetuximab soravtansine-gynx/bevacizumab (for FRα-expressing tumors) (category 2B)[k,34]
	Niraparib (category 3)[v,27]		Selpercatinib (for *RET* gene fusion-positive tumors)[z,35]
	Olaparib (category 3)[w,28]		For low-grade serous carcinoma:
	Pazopanib (category 2B)[29]		• Trametinib[36]
	Rucaparib (category 3)[x,30]		• Binimetinib (category 2B)[37,38]
	Hormone Therapy		Hormone Therapy
	Aromatase inhibitors (anastrozole, exemestane, letrozole)		Fulvestrant (for low-grade serous carcinoma)
	Goserelin acetate		Immunotherapy
	Leuprolide acetate		Dostarlimab-gxly (for dMMR/MSI-H recurrent or advanced tumors)[z,39]
	Megestrol acetate		Pembrolizumab (for MSI-H or dMMR solid tumors, or patients with TMB-H tumors ≥10 mutations/megabase)[z,40]
	Tamoxifen[j]		

Described by prof Choi, 2025

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2025
Epithelial Ovarian Cancer/Fallopian Tube Cancer/ Primary Peritoneal Cancer

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DISEASE STATUS[f,dd,ee]

RECURRENCE THERAPY FOR PLATINUM-SENSITIVE DISEASE[n,gg,hh,ii]

Platinum-sensitive disease[ff]: Complete remission and relapse ≥6 mo after completing prior chemotherapy

Radiographic and/or clinical relapse → **Consider secondary cytoreductive surgery[j,k]** → **Combination platinum-based chemotherapy,[n] preferred for first recurrence (category 1) or Recurrence therapy[n,kk] and/or Best supportive care (See NCCN Guidelines for Palliative Care)**

Biochemical relapse (rising CA-125 and no radiographic evidence of disease)

- **Delay treatment until radiographic and/or clinical relapse**
- **Immediate platinum-based recurrence therapy[n] (category 2B) and/or Best supportive care (See NCCN Guidelines for Palliative Care)**

Maintenance therapy (if PR or CR)

- **Useful in certain circumstances:**
  - **Continue bevacizumab if previously treated with chemotherapy + bevacizumab;**

or

- **PARPi therapy (for those with *BRCA 1/2* mutation)[ll]:**
  - **◊ If not previously used (category 1)**
  - **◊ If disease has not progressed during prior PARPi treatment**

or

Observe

→ **Monitoring/ Follow-up (OV-6)**

Principle of Platinum Sensitive Recurrence Treatment

(2) 일차 보조항암화학요법으로 완전 관해에 도달하였으나 치료 종료 후 6개월 이후에 재발한 경우에 백금 민감성이 있는 것으로 간주하여 백금 복합 항암화학요법으로 carboplatin/paclitaxel[36], carboplatin/liposomal doxorubicin (6개월–1년사이 재발한 부분적 백금 민감성의 경우 특히 우선 사용 고려)[37], carboplatin/gemcitabine/bevacizumab[38], carboplatin/weekly paclitaxel[21], carboplatin/docetaxel[39], carboplatin/gemcitabine[40], cisplatin/gemcitabine[40]을 치료법으로 고려할 수 있으며, 임상 시험을 적극적으로 고려할 수 있다. 백금 민감성이 있으나 복합요법 치료를 받을 수 없는 경우는 carboplatin 또는 cisplatin 단독 요법을 시행할 수 있으며, oxaliplatin도 사용할 수 있다.[41] 백금 민감성 재발성 상피성 난소암에서 항암화학요법 후 반응을 보인 경우 PARP 억제제 (Olaparib, niraparib, rucaparib) 유지요법의 효과는 무진행생존율의 증가가 있다는 것이 밝혀졌으므로, 사용을 권고한다.[42–45] Study 19, SOLO2, NOVA study결과를 살펴보면, PARP억제제 사용군에서 비사용군에 비해 구역, 호중구 감소, 빈혈, 설사, 탈모, 말초 신경병증과 같은 부작용 발생이 증가하여 이에 대한 충분한 설명과 관리가 필요하다. GOG213연구를 기반으로, 백금 민감성 재발성 상피성 난소암 환자에서 이차 치료로 bevacizumab 병합 백금항암화학요법 및 유지요법은 환자의 무진행생존율을 향상시키므로, 사용을 권고한다.[46–48] 개정된 본 진료 권고안에서, 백금민감성 bevacizumab의 재투약에 따른 의미 있는 차이가 없었다. 따라서, 백금민감성 재발성 난소암 환자에서 bevacizumab을 일차항암화학치료에 포함한 경우 bevacizumab을 재투약 할 수 있는 것으로 권고한다 (권고수준: 약하게/조건부 권고(Weak/Conditional for)).

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ASCO recommendations for PARPi use

PARPi	First remission: maintenance	Second or greater remission: maintenance[b]
Olaparib	g/s*BRCA*	g/s*BRCA*
Olaparib combined with bevacizumab	g/s*BRCA*[a]	No
Niraparib	g/s*BRCA*; HRD; wt	g/s*BRCA*; HRD; wt
Rucaparib	g/s*BRCA*; HRD; wt	g/s*BRCA*; HRD; wt

Abbreviations. g/s*BRCA*, germline or somatic *BRCA*1/2 mutation; HRD, homologous recombination deficiency; wt, *BRCA*1/2 wild-type.

should (blue), may (red), caution (green).
Of note: (1) PARPis are not recommended for use in combination with chemotherapy, nor is it recommended for monotherapy treatment.
(2) HRD score companion diagnostic (Myriad MyChoice for niraparib; FoundationOne CDx for rucaparib).
(3) Olaparib has not been studied in the HRD population. Olaparib may be considered an option in the HRD population in settings where
any PARPi is recommended.
[a]After completion of up-front chemotherapy, continue bevacizumab (1 year) and olaparib (2 years). [b]PARPi-naive.
g/sBRCA, germline or somatic BRCA1/2; HRD, homologous recombination deficiency; PARPi, poly(ADP-ribose) polymerase inhibitor; wt, BRCA1/2 wildtype.

1. Panagiotis A. Konstantinopoulos et al. Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. 2022

Platinum-Sensitive Recurrence (PFI > 6 Months) _ Summary

- **Standard of Care:** Platinum-based doublets remain the backbone.
  - *Preferred Regimens:* Carboplatin/Paclitaxel, Carboplatin/Gemcitabine, or Carboplatin/Liposomal Doxorubicin

- **The Surgical Question:** Secondary cytoreductive surgery should be offered to selected patients (positive iMODEL score or DESKTOP criteria) where complete gross resection (R0) is achievable

- **Maintenance Strategies (2025 Update):**
  - **PARP Inhibitors (PARPi):** Primarily reserved for BRCA-mutated or HRD-positive patients if they have not received a PARPi in the frontline setting. Note the 2024-2025 shift: withdrawal of some PARPi indications for BRCA-wildtype patients in later lines due to OS concerns.

  - **Bevacizumab:** Integration with chemotherapy followed by maintenance, particularly in patients who did not receive it first-line

The systemic treatment of recurrent ovarian cancer

3. Platinum-Resistant Recurrence

Platinum-Resistant Recurrence (PFI < 6 Months)

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2025
Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

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Recurrence Therapy for Platinum-Resistant Disease (alphabetical order)

Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
Cytotoxic Therapy Cyclophosphamide (oral)/ bevacizumab[q,46] Docetaxel[47] Etoposide (oral)[48] Gemcitabine[49,50] Liposomal doxorubicin[49,50] Liposomal doxorubicin/ bevacizumab[q,51] Paclitaxel (weekly)[g,52] Paclitaxel (weekly)/ bevacizumab[g,q,51] Topotecan[53,54] Topotecan/bevacizumab[q,51] Targeted Therapy (single agents) Bevacizumab[q,21,22] Mirvetuximab soravtansine-gynx (for FRα-expressing tumors [≥75% positive tumor cells])(category 1)[x,55,56]	Cytotoxic Therapy[s] Capecitabine Carboplatin[*] Carboplatin/docetaxel[*] Carboplatin/paclitaxel (weekly)[g,*] Carboplatin/gemcitabine[14] ± bevacizumab[q,r,15,*] Carboplatin/liposomal doxorubicin[16] ± bevacizumab[q,17,*] Carboplatin/paclitaxel[g,18] ± bevacizumab[q,r,19,*] Cyclophosphamide Cyclophosphamide (oral)/pembrolizumab/bevacizumab[58,59] Doxorubicin Gemcitabine/bevacizumab[60] Gemcitabine/cisplatin[20,*] Ifosfamide Irinotecan Ixabepilone/bevacizumab (category 2B)[z,61] Melphalan Oxaliplatin Paclitaxel Paclitaxel, albumin bound Pemetrexed Sorafenib/topotecan[57] Vinorelbine Targeted Therapy (single agents) Niraparib (category 3)[t,27] Olaparib (category 3)[u,28] Pazopanib (category 2B)[29] Rucaparib (category 3)[v,30] Hormone Therapy Aromatase inhibitors (anastrozole, exemestane, letrozole) Goserelin acetate Leuprolide acetate Megestrol acetate Tamoxifen[j]	Carboplatin/paclitaxel (for age >70)[g,w,*] Carboplatin/paclitaxel, albumin bound (for confirmed taxane hypersensitivity)[*] Immunotherapy[x] Dostarlimab-gxly (for dMMR/MSI-H recurrent or advanced tumors)[43] Pembrolizumab (for patients with MSI-H or dMMR solid tumors, or TMB-H tumors ≥10 mutations/megabase)[44] Hormone Therapy Fulvestrant (for low-grade serous carcinoma) Targeted Therapy[x] Dabrafenib + trametinib (for *BRAF* V600E-positive tumors)[32] Entrectinib[33] or larotrectinib[34] or repotrectinib[35] (for *NTRK* gene fusion-positive tumors) Fam-trastuzumab deruxtecan-nxki (for HER2-positive tumors [IHC 3+ or 2+])[36] Mirvetuximab soravtansine-gynx/bevacizumab (for FRα-expressing tumors [≥25% positive tumor cells])[q,38,62,63] Selpercatinib (for *RET* gene fusion-positive tumors)[39] For low-grade serous carcinoma: • Avutometinib/defactinib (for KRAS-mutated tumors)[40] • Trametinib[41] • Binimetinib (category 2B)[42,43] For mucinous carcinoma: • FOLFIRI ± bevacizumab (category 2B)[64-67]

대한부인종양학회 Korean Society of Gynecologic Oncology

Principle of Platinum Resistant Recurrence Treatment

PRINCIPLES OF SYSTEMIC THERAPY

Acceptable Recurrence Therapies for Epithelial Ovarian (including LCOC)[p]/Fallopian Tube/Primary Peritoneal Cancer[q]

Recurrence Therapy for Platinum-Resistant Disease (alphabetical order)

Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
Cytotoxic Therapy Cyclophosphamide (oral)/ bevacizumab[k,41] — 2013 Docetaxel[42] — 2003 Etoposide (oral)[43] — 1998 Gemcitabine[44,45] — 2007/ 2008 Liposomal doxorubicin[44,45] Liposomal doxorubicin/ bevacizumab[k,s,46] — 2014 AURELIA Paclitaxel (weekly)[g,47] — 2006 Paclitaxel (weekly)/ bevacizumab[g,k,s,46] — 2014 AURELIA Topotecan[48,49] — 2004/ 2011 Topotecan/bevacizumab[k,s,46] Targeted Therapy (single agents) Bevacizumab[k,s,21,22] — 2007 Mirvetuximab soravtansine-gynx (for FRα-expressing tumors [≥75% positive tumor cells])(category 1)[z,50,51] — 2022 SORAYA/2023 MIRASOL	Cytotoxic Therapy[u] Capecitabine Carboplatin[*] Carboplatin/docetaxel[*] Carboplatin/paclitaxel (weekly)[g,*] Carboplatin/gemcitabine[14] ± bevacizumab[k,s,t,15,*] Carboplatin/liposomal doxorubicin[16] ± bevacizumab[k,s,17,*] Carboplatin/paclitaxel[g,18] ± bevacizumab[k,s,t,19,*] Cyclophosphamide Cyclophosphamide (oral)/pembrolizumab/bevacizumab[k,53,54] Doxorubicin Gemcitabine/bevacizumab[k,55] Gemcitabine/cisplatin[20,*] Ifosfamide Irinotecan Ixabepilone/bevacizumab (category 2B)[k,aa,56] Melphalan Oxaliplatin Paclitaxel Paclitaxel, albumin bound Pemetrexed Sorafenib/topotecan[51] Vinorelbine Targeted Therapy (single agents) Niraparib (category 3)[v,27] Olaparib (category 3)[w,28] Pazopanib (category 2B)[29] Rucaparib (category 3)[x,30] Hormone Therapy Aromatase inhibitors (anastrozole, exemestane, letrozole) Goserelin acetate Leuprolide acetate Megestrol acetate Tamoxifen[j]	Carboplatin/paclitaxel (for age >70)[g,y,*] Carboplatin/paclitaxel, albumin bound (for confirmed taxane hypersensitivity)[*] Immunotherapy Dostarlimab-gxly (for dMMR/MSI-H recurrent or advanced tumors)[z,39] Pembrolizumab (for patients with MSI-H or dMMR solid tumors, or TMB-H tumors ≥10 mutations/megabase)[z,40] Hormone Therapy Fulvestrant (for low-grade serous carcinoma) Targeted Therapy Dabrafenib + trametinib (for *BRAF* V600E-positive tumors)[z,32] Entrectinib or larotrectinib or repotrectinib[33] (for *NTRK* gene fusion-positive tumors)[z] Fam-trastuzumab deruxtecan-nxki (for HER2-positive tumors [IHC 3+ or 2+])[57] Mirvetuximab soravtansine-gynx/bevacizumab (for FRα-expressing tumors)[k,z,34,58,59] Selpercatinib (for *RET* gene fusion-positive tumors)[z,35] For low-grade serous carcinoma: • Trametinib[36] • Binimetinib (category 2B)[37,38]

* Platinum agents have limited activity when the disease has demonstrated growth through a platinum-based regimen, and platinum rechallenge is generally not recommended in this setting.

Footnotes

Described by prof Choi, 2025

Principle of Platinum Resistant Recurrence Treatment

(1) 일차 보조항암화학요법으로 완전 관해에 도달하였으나 항암화학요법 종료 후 6개월 이내에 재발된 경우, 혹은 병기 II-IV이면서 일차 항암화학요법 시행 후 부분 관해(이차 추시술에서 암이 확인된 경우 포함)에 도달한 환자는 임상 시험 또는 재발용 항암치료(single non-platinum-based agent)를 고려한다. 백금 저항성이 있는 환자에 대해서 non-platinum계 단독 약제가 권고된다. 재발성 난소암에 대한 여러 약제에 대한 반응률은 topotecan 20%[27], gemcitabine 19%[28], liposomal doxorubicin 26%[28,29], oral etoposide 27%[30], belotecan (CKD-602) 20%[31], docetaxel 22%[32], irinotecan 29%[33], weekly paclitaxel 21%[34]로 나타나고 있다. 다른 약제들로 vinorelbine, cyclophosphamide, melphalan 등이 있다. 재발성 또는 지속성 난소암 환자에서 bevacizumab은 21% 반응율을 보이고 있다.[35] bevacizumab과 paclitaxel/topotecan/liposomal doxorubicin 중 한 가지를 함께 사용하는 병합표적치료가 단독항암화학요법에 비해서 무진행 생존율을 유의하게 향상시킬 수 있어, 고혈압, 장천공, 단백뇨와 같은 부작용이 증가함에도 불구하고, 사용할 수 있다.

Described by prof Choi, 2025

Platinum-Resistant Recurrence (PFI < 6 Months)

OS improvement

Mirasol vs KNB96

2023 ASCO ANNUAL MEETING

Phase III MIRASOL (GOG 3045/ENGOT-ov55) Study: Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers with High Folate Receptor-Alpha (FRα) Expression

Kathleen N. Moore[1], Antoine Angelergues[2], Gottfried E. Konecny[3], Susana Banerjee[4], Sandro Pignata[5], Nicoletta Colombo[6], John Moroney[7], Casey Cosgrove[8], Jung-Yun Lee[9], Andrzej Roszak[10], Shani Breuer[11], Jacqueline Tromp[12], Diana Bello Roufai[13], Lucy Gilbert[14], Rowan Miller[15], Tashanna Myers[16], Yuemei Wang[17], Anna Berkenblit[17], Domenica Lorusso[18], Toon Van Gorp[19]

[1]Stephenson Cancer Center University of Oklahoma College of Medicine, Oklahoma City, OK, USA; [2]Groupe Hospitalier Diaconesses Croix Saint Simon, Paris, France; [3]UCLA Jonsson Comprehensive Cancer Center, Los Angeles, CA, USA; [4]The Royal Marsden NHS Foundation Trust - Royal Marsden Hospital, London, UK; [5]Istituto Nazionale Tumori- G. Pascale, Naples, Italy; [6]European Institute of Oncology IRCCS, Milan, Italy and University of Milan-Bicocca, Milan, Italy; [7]The University of Chicago, Chicago, IL, USA; [8]The Ohio State University, Columbus, OH, USA; [9]Severance Hospital, Seoul, South Korea; [10]Wielkopolskie Centrum Onkologii, Poznan, Poland; [11]Hadassah Ein Kerem – Sharett, Jerusalem, Israel; [12]Amsterdam UMC, Amsterdam, The Netherlands; [13]Hopital Rene Huguenin, Institut Curie, Saint-Cloud, France; [14]McGill University Health Centre, Montreal, Canada; [15]University College London Hospital, London, UK; [16]Baystate Medical Center, Springfield, MA, USA; [17] ImmunoGen, Inc., Waltham, MA, USA; [18]Fondazione Policlinico Universitario A. Gemelli, IRCCS and Catholic University of Sacred Heart, Rome, Italy; [19]University Hospital Leuven Leuven Cancer Institute, Leuven, Belgium

ENGOT European Network of Gynaecological Oncological Trial groups

GOG FOUNDATION® Transforming the standard of care™

PRESENTED BY: Kathleen Moore, Associate Director of Clinical Research, Stephenson Cancer Center University of Oklahoma College of Medicine

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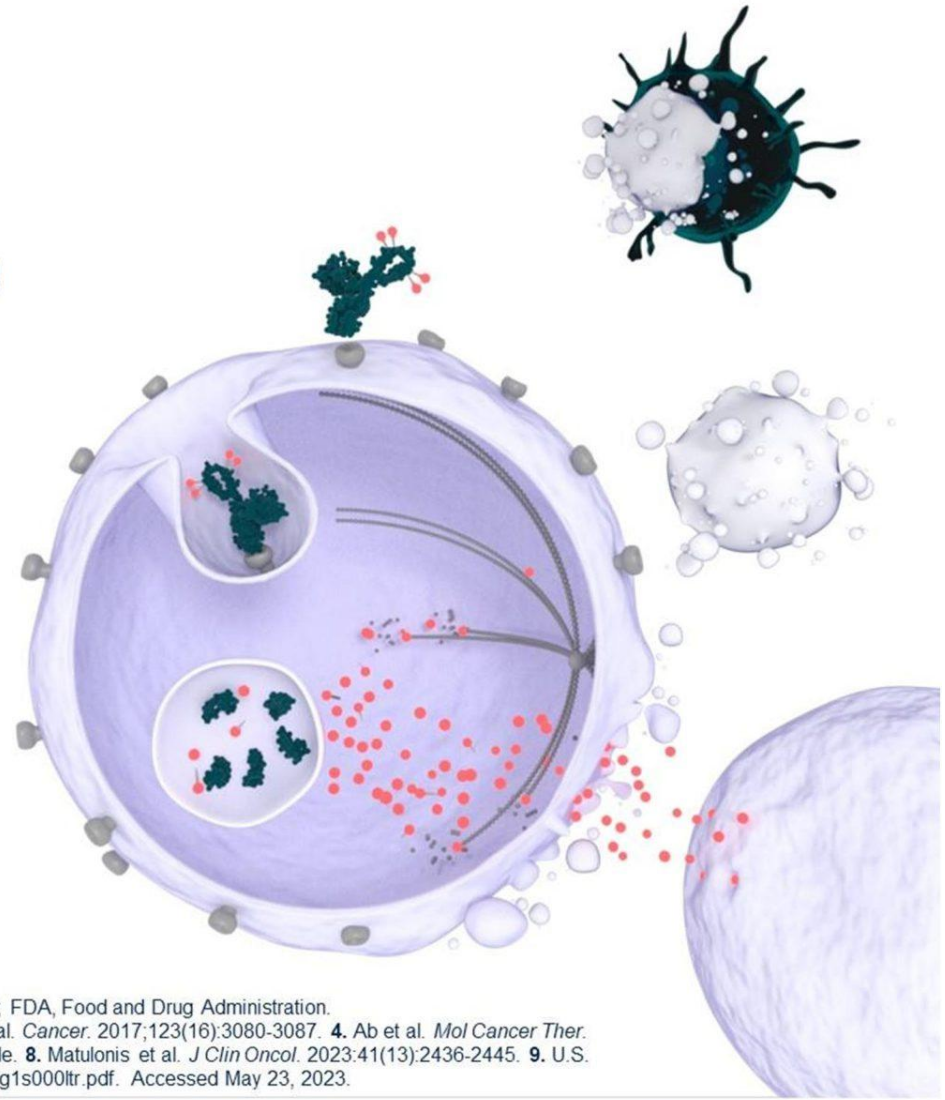
Background

- No trial has shown an overall survival (OS) benefit in platinum-resistant ovarian cancer (PROC)[1, 2]
- Mirvetuximab soravtansine (MIRV) is an ADC comprising a FRα-binding antibody, cleavable linker, and maytansinoid DM4, a potent tubulin-targeting agent[3,4]
- FRα is expressed in ~90% of ovarian carcinomas,[5,6] with 35-40%[7] of PROC tumors exhibiting high FRα expression (≥75% of tumor cells positive with ≥2+ intensity)[8]
- MIRV demonstrated an ORR of 32% and mDOR 6.9 months in the single-arm study, SORAYA[8], of BEV pre-treated PROC to support accelerated approval by the FDA[9]
- MIRASOL is the confirmatory, randomized, global phase 3 trial designed to support full approval in the US and EU



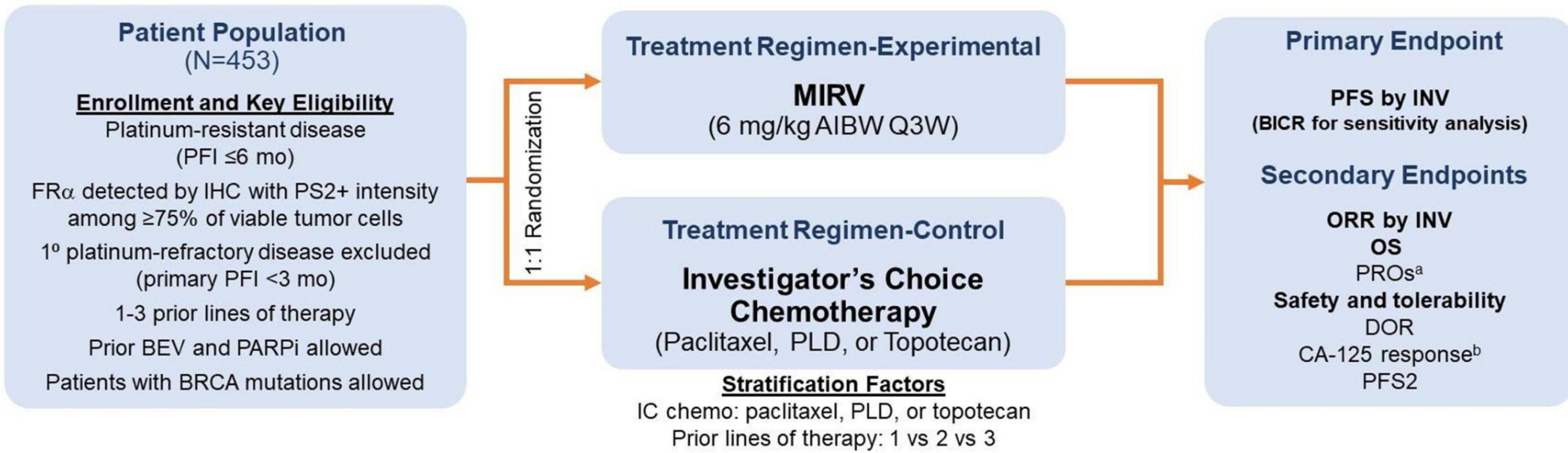
PFS, progression-free survival; OS, overall survival; FRα, folate receptor alpha; ORR, objective response rate; mDOR, median duration of response; FDA, Food and Drug Administration.

1. Pujade-Lauraine et al. *J Clin Oncol*. 2014;32(13):1302-1308. **2.** Richardson et al. *JAMA Oncol*. 2023;10.1001/jamaoncol.2023.0197. **3.** Moore et al. *Cancer*. 2017;123(16):3080-3087. **4.** Ab et al. *Mol Cancer Ther*. 2015;14(7):1605-1613. **5.** Markert et al. *Anticancer Res*. 2008;28(6A):3567-3572. **6.** Martin et al. *Gynecol Oncol*. 2017;147(2):402-407. 7. Data on file. **8.** Matulonis et al. *J Clin Oncol*. 2023:41(13):2436-2445. **9.** U.S. FOOD & DRUG ADMINISTRATION. BLA ACCELERATED APPROVAL. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/761310Orig1s000ltr.pdf. Accessed May 23, 2023.

PRESENTED BY: Kathleen Moore, Associate Director of Clinical Research, Stephenson Cancer Center University of Oklahoma College of Medicine

MIRASOL (NCT04209855) – Study Design[1,2]

An open-label, phase 3 randomized trial of MIRV vs investigator's choice chemotherapy in patients with FRα-high platinum-resistant ovarian cancer



AIBW, adjusted ideal body weight; BEV; bevacizumab; BICR, blinded independent central review; BRCA, BReast CAncer gene; CA-125, cancer antigen 125; chemo, chemotherapy; DOR, duration of response; FRα, folate receptor alpha; IC, investigator's choice; IHC, immunohistochemistry; INV, investigator; MIRV, mirvetuximab soravtansine; ORR, objective response rate; OS, overall survival; PARPi, poly (ADP-ribose) polymerase inhibitors; PFI, platinum-free interval; PFS, progression-free survival; PFS2, time from randomization until second disease progression; PLD, pegylated liposomal doxorubicin; PROs, patient-reported outcomes; PS2+, positive staining intensity ≥2; Q3W, every 3 weeks.
[a]PROs will be measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire, 28-item Ovarian Cancer Module (OV28) study instrument.
[b]Gynecological Cancer InterGroup (GCIG) criteria.

1. ClinicalTrials.gov identifier: NCT04209855. Updated June 16, 2022. Accessed October 5, 2022. https://clinicaltrials.gov/ct2/show/NCT04209855
2. Moore K, et al. Presented at: 2020 American Society of Clinical Oncology Annual Meeting; May 29-31, 2020; Virtual. Abstract TPS6103.

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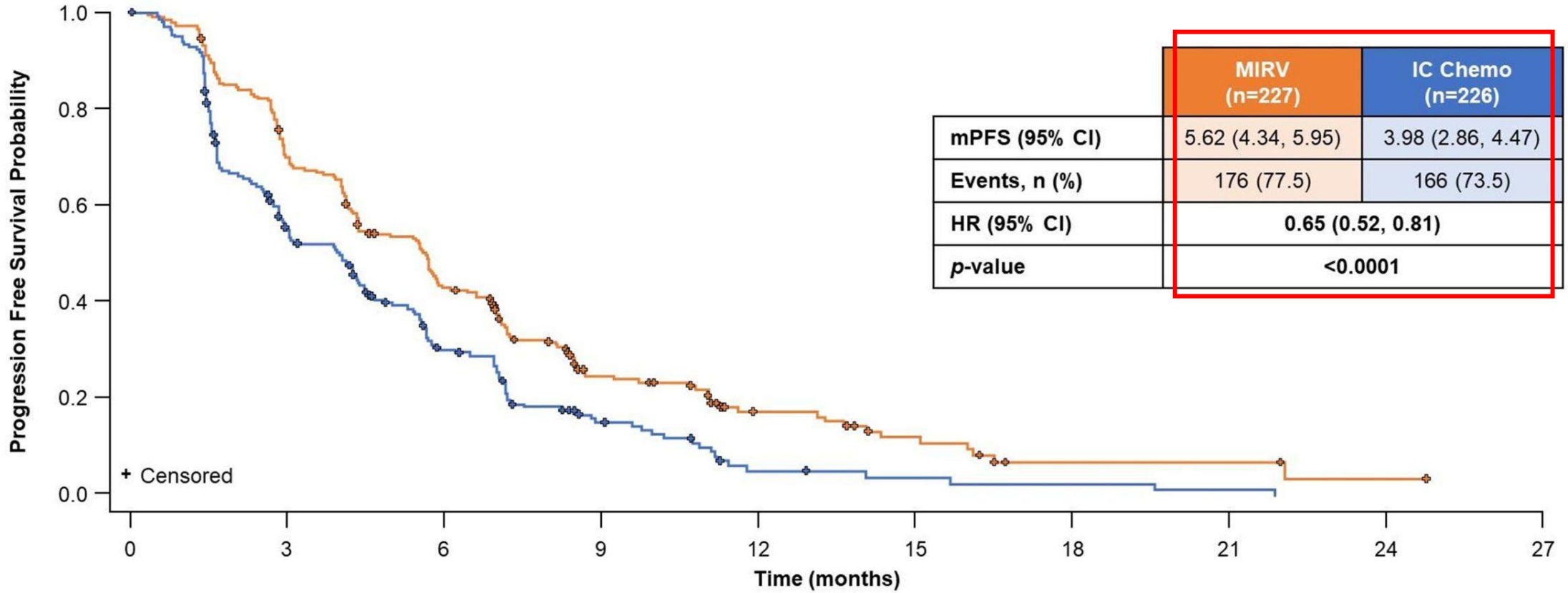
Primary Endpoint: Progression-Free Survival by Investigator



	MIRV (n=227)	IC Chemo (n=226)
mPFS (95% CI)	5.62 (4.34, 5.95)	3.98 (2.86, 4.47)
Events, n (%)	176 (77.5)	166 (73.5)
HR (95% CI)	**0.65 (0.52, 0.81)**	
p-value	**<0.0001**	

No. Participants at Risk

MIRV	227	151	89	38	18	10	3	3	1	0
IC Chemo	226	98	48	19	5	3	2	1	0	

Data cutoff: March 6, 2023

MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; mPFS, median progression-free survival; CI, confidence interval; HR, hazard ratio.

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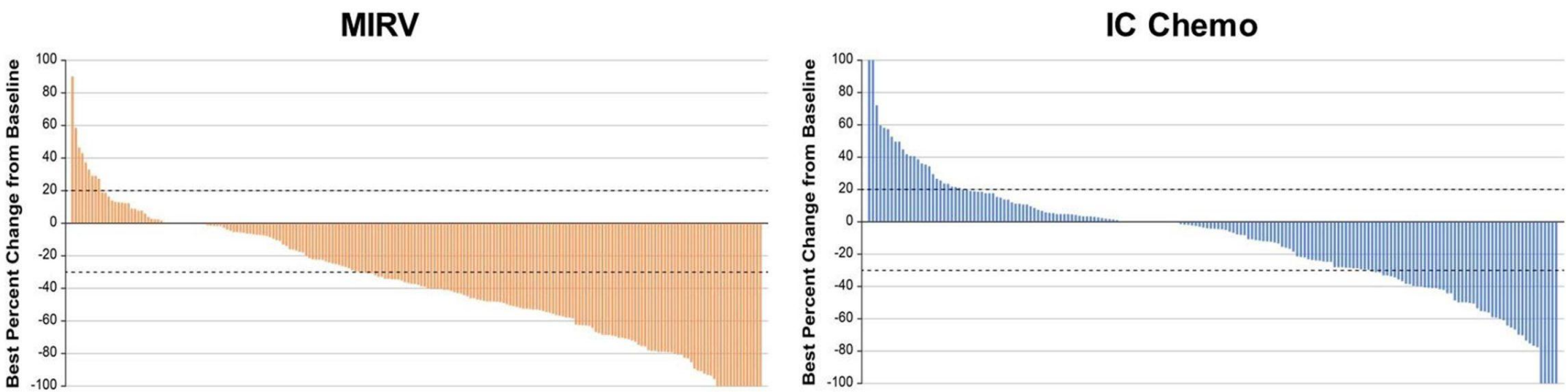
Best Overall Response by Investigator (N=453)

	MIRV (n=227)	IC Chemo (n=226)
ORR, n (%) [95% CI]	96 **(42)** [35.8, 49.0]	36 **(16)** [11.4, 21.4]
Best overall response, n (%)		
CR	12 **(5)**	0
PR	84 **(37)**	36 **(16)**
SD	86 (38)	91 (40)
PD	31 (14)	62 (27)
Not evaluable	14 (6)	37 (16)



Data cutoff: March 6, 2023

MIRV, mirvetuximab soravtansine; IC chemo, investigator's choice chemotherapy; ORR, objective response rate; CI, confidence interval; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; DCR, disease control rate.

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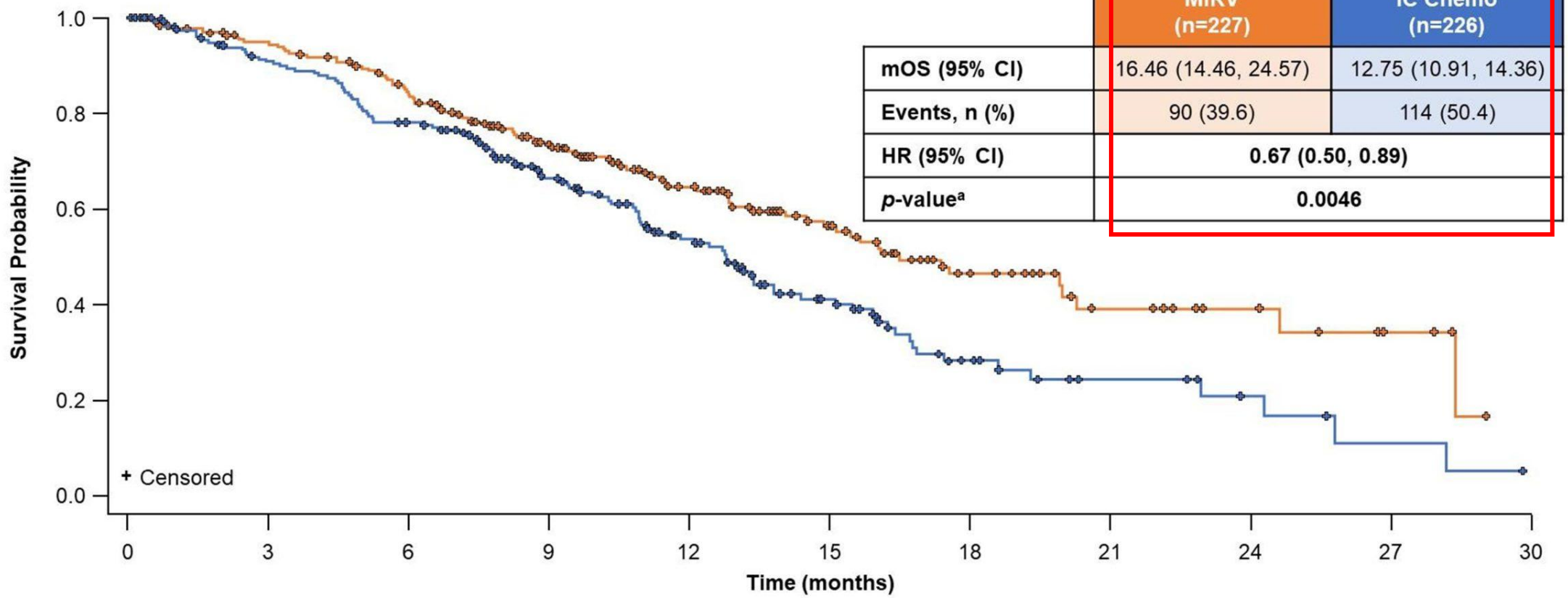
Overall Survival

	MIRV (n=227)	IC Chemo (n=226)
mOS (95% CI)	16.46 (14.46, 24.57)	12.75 (10.91, 14.36)
Events, n (%)	90 (39.6)	114 (50.4)
HR (95% CI)	0.67 (0.50, 0.89)	
p-value[a]	0.0046	



No. Participants at Risk

MIRV	227	204	175	128	82	53	28	15	9	4	0
IC Chemo	226	185	157	107	68	39	18	9	5	2	0

Data cutoff: March 6, 2023

MIRV, mirvetuximab soravtansine; IC Chemo, investigator choice chemotherapy; mOS, median overall survival; CI, confidence interval; HR, hazard ratio.

[a]Overall survival is statistically significant based on pre-specified boundary p-value at interim analysis = 0.01313

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Safety Summary (N=425)

MIRV has a tolerable safety profile compared with IC Chemo

	MIRV (n=218)	IC Chemo (n=207)
Any TEAE, n (%)	210 (96)	194 (94)
Grade 3+ TEAEs, n (%)	91 (42)	112 (54)
SAEs, n (%)	52 (24)	68 (33)
Deaths on study drug or within 30 days of last dose, n (%)	5 (2)	5 (2)
Dose reductions due to TEAEs, n (%)	74 (34)	50 (24)
Dose delays due to TEAEs, n (%)	117 (54)	111 (54)
Discontinuations due to TEAEs, n (%)	20 (9)	33 (16)

Data cutoff: March 6, 2023
The safety population comprises all patients who received at least one dose of MIRV or IC Chemo
TEAEs, treatment-emergent adverse events; MIRV, mirvetuximab soravtansine; IC, investigator choice; Chemo, Chemotherapy.

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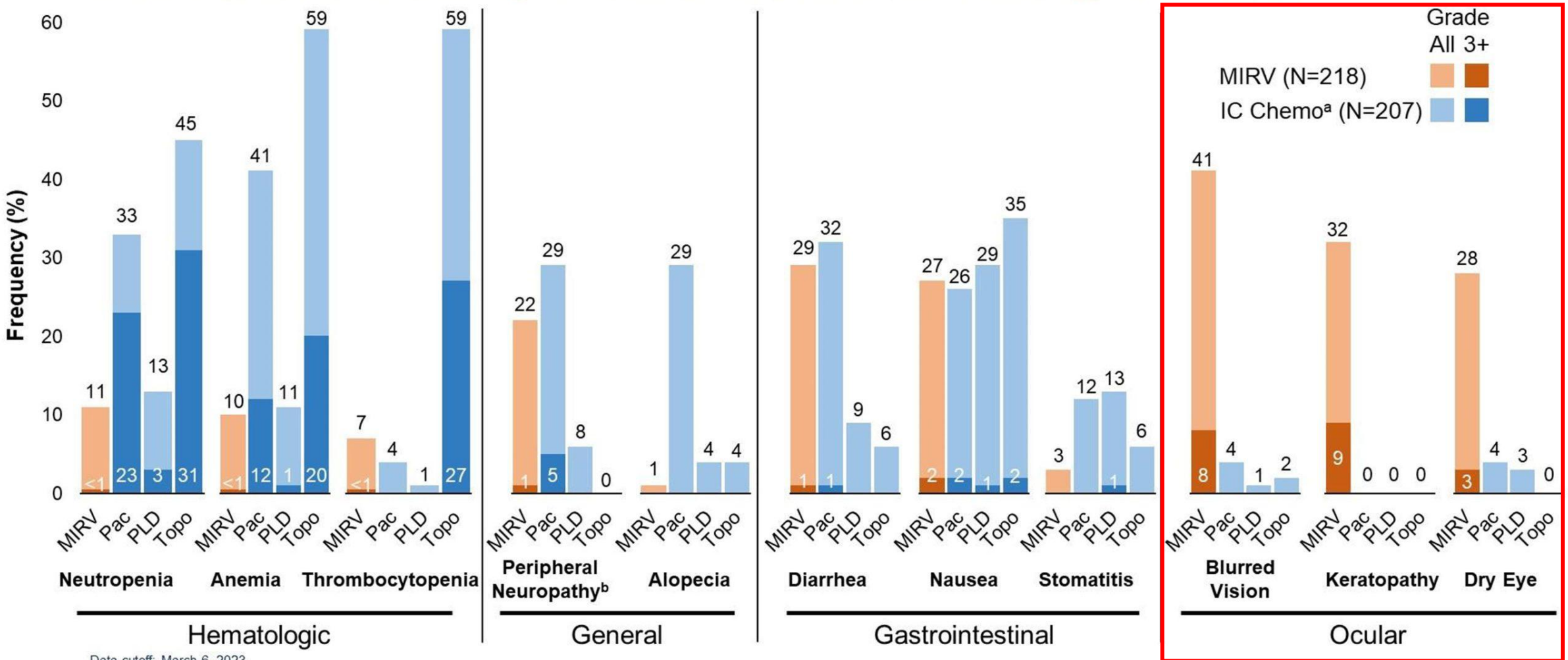
Differentiated Safety Profile: Treatment-Emergent Adverse Events



Data cutoff: March 6, 2023

MIRV, mirvetuximab soravtansine; IC Chemo: investigator's choice of chemotherapy; Pac, paclitaxel; PLD, pegylated liposomal doxorubicin; Topo, topotecan.

[a]Pac n=82, PLD n=76, Topo n=49. [b]Grade 2+ peripheral neuropathy events were observed in 12% and 16% of patients that received MIRV or paclitaxel, respectively.

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MIRASOL Conclusions

- MIRV demonstrated statistically significant and clinically meaningful improvements in **PFS, ORR,** and **OS** compared to IC chemotherapy
- MIRV is the FIRST:
  - Treatment to demonstrate an OS benefit in a phase III trial in PROC
  - FDA-approved ADC for PROC with efficacy confirmed, regardless of prior BEV use in MIRASOL
  - Biomarker-directed therapy for ovarian cancer since PARPi
- With a safety database of more than 1000 patients, MIRV continues to demonstrate a differentiated safety profile consisting predominantly of low-grade ocular, gastrointestinal, and neuropathy events
  - No new safety signals were identified in MIRASOL
- Compared to IC chemotherapy, MIRV was associated with lower rates of:
  - Grade 3 or greater treatment-emergent adverse events (TEAEs) (42% vs 54%)
  - Serious adverse events (24% vs 33%)
  - TEAEs leading to discontinuation of study drug (9% vs 16%)
- These efficacy data, along with the well-characterized safety profile, are practice-changing and position MIRV as a new standard of care for patients with FRα-positive PROC

MIRV, mirvetuximab soravtansine, PFS, progression-free survival; ORR, objective response rate; OS, overall survival; IC, investigator choice; PROC, platinum-resistant ovarian cancer; FDA, Food and Drug Administration; ADC, antibody-drug conjugate; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; TEAEs, treatment-emergent adverse events; FRα, folate receptor alpha.

1. Pujade-Lauraine et al. *J Clin Oncol*. 2014;32(13):1302-1308. **2.** Richardson et al. *JAMA Oncol*. 2023;10.1001/jamaoncol.2023.0197.

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Pembrolizumab vs Placebo Plus Weekly Paclitaxel With or Without Bevacizumab for Platinum-Resistant Recurrent Ovarian Cancer: Results from the Randomized, Double-Blind Phase 3 ENGOT-ov65/ KEYNOTE-B96 Study

Nicoletta Colombo[1,2], Emese Zsiros[3], Alexandra Sebastianelli[4], Mariusz Bidzinski[5], Carlos Gallardo[6], Emad Matanes[7], Kosei Hasegawa[8], Fatih Kose[9], Manuel Magallanes-Maciel[10], Rebecca Herbertson[11], Sumitra Ananda[12], Judith R. Kroep[13], Andreia Cristina de Melo[14], Philip R Debruyne[15], Jae-Weon Kim[16], Xuan Peng[17], Karin Yamada[17], Agata M. Bogusz[17], Thibault De La Motte Rouge[18], and Xiaohua Wu[19] on behalf of the ENGOT-ov65/KEYNOTE-B96 investigators

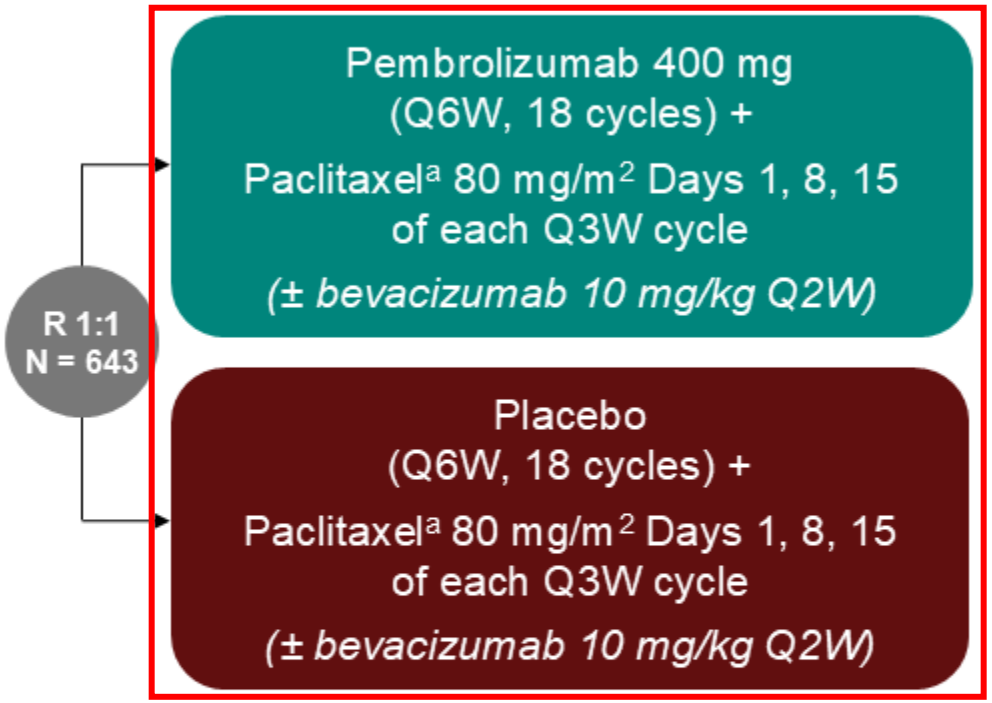
[1]Gynecologic Oncology Program, European Institute of Oncology, IRCCS, Milan, Italy; [2]Department of Medicine and Surgery, University of Milan-Bicocca, Italy; [3]Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA; [4]CHU de Québec-Université Laval, Québec, Canada; [5]Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie, Warsaw, Poland; [6]Bradford Hill Clinical Research Center, Santiago, Chile; [7]Rambam Health Care Campus and Ruth and Bruce Rappaport Faculty of Medicine, Technion, Haifa, Israel; [8]Saitama Medical University International Medical Center, Hidaka, Japan; [9]Başkent University, Ankara, Turkey; [10]Centro Oncologico Internacional, Mexico City, Mexico; [11]University Hospitals Sussex NHS Foundation Trust, West Sussex, United Kingdom; [12]Epworth Healthcare and Peter MacCallum Cancer Centre, Melbourne, Australia; [13]Leiden University Medical Center on behalf of the Dutch Gynecology Oncology Group (DGOG), Leiden, Netherlands; [14]Brazilian National Cancer Institute (INCA), Rio de Janeiro, Brazil; [15]Kortrijk Cancer Centre, AZ Groeninge, Kortrijk, and Belgium and Luxembourg Gynaecological Oncology Group (BGOG), Leuven, Belgium; [16]Seoul National University, Seoul, South Korea; [17]Merck & Co., Inc., Rahway, NJ, USA; [18]Centre Eugene Marquis, Rennes, France; [19]Fudan University Shanghai Cancer Center, Shanghai, China

18 October 2025

ENGOT-ov65/KEYNOTE-B96 Study Design (NCT05116189)

Key Eligibility Criteria

- Histologically confirmed epithelial ovarian, fallopian tube, or primary peritoneal carcinoma
- 1 or 2 prior lines of therapy; at least 1 platinum-based chemotherapy
  - Prior anti-PD-1 or anti-PD-L1, PARPi and bevacizumab permitted
- Radiographic progression within 6 months after the last dose of platinum-based chemotherapy
- ECOG PS 0 or 1



Stratification Factors

- Planned bevacizumab use (yes vs no)
- Region (US vs EU vs ROW)
- PD-L1 CPS (<1 vs 1 to <10 vs ≥10)[b]

Primary Endpoint: PFS per RECIST v1.1 by investigator

Key Secondary: OS

[a]Docetaxel (75 mg/m² Q3W) may be considered in participants with severe hypersensitivity reaction to paclitaxel or an adverse event requiring discontinuation of paclitaxel after consultation with the Sponsor.
[b]The combined positive score (CPS) was assessed at a central laboratory using PD-L1 IHC 22C3 pharmDx and defined as the number of PD-L1 CPS ≥1 cells (tumor cells, lymphocytes, macrophages) divided by the total number of tumor cells × 100.

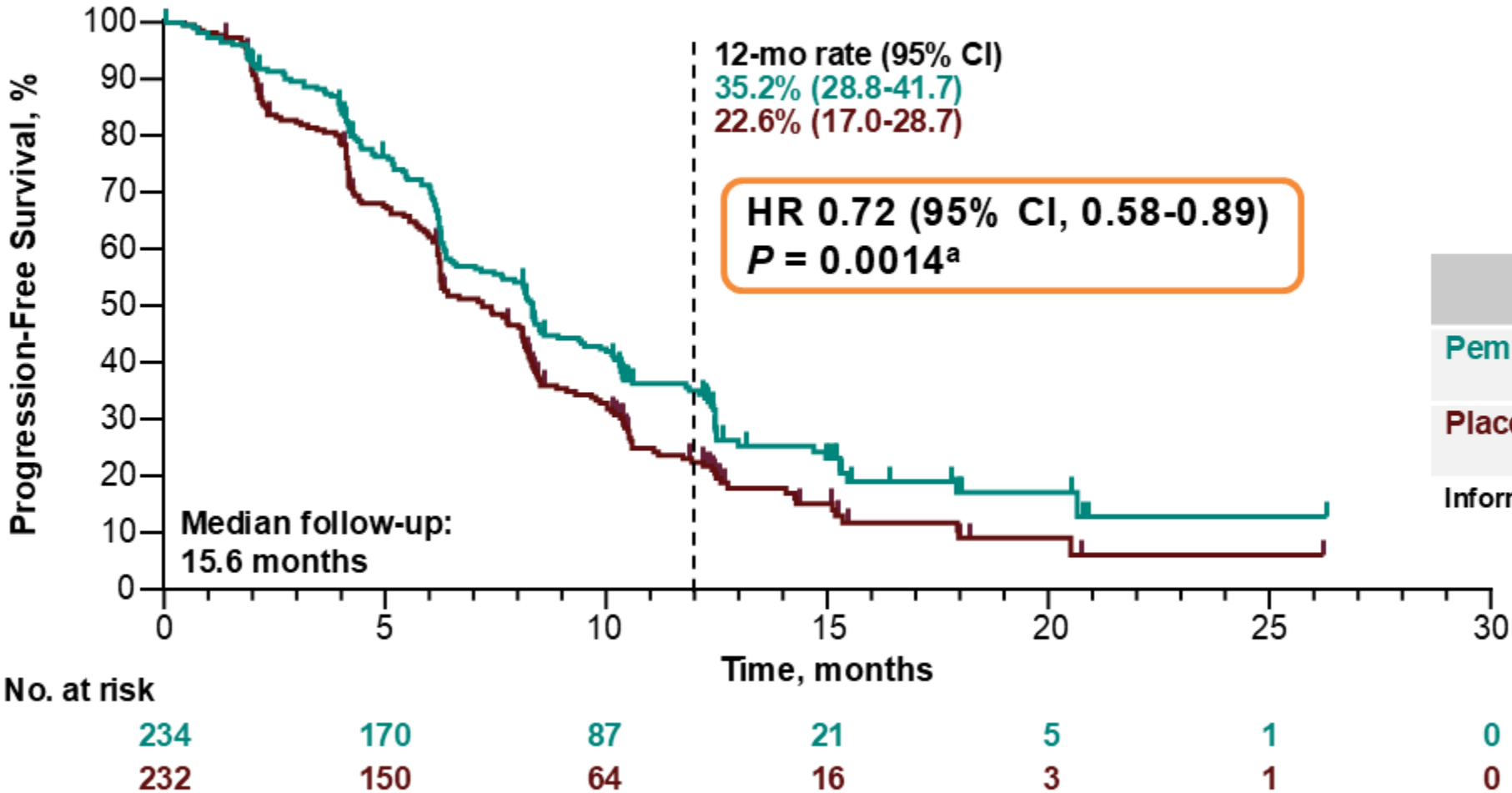
Baseline Characteristics

	Pembro Arm (N = 322)	Placebo Arm (N = 321)
Age, median (range)	62 y (37-85)	61 y (37-82)
Race[a]		
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		
<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)		
IA-IIB	25 (7.8%)	26 (8.1%)
III-IIIC	183 (56.8%)	189 (58.9%)
IVA-IVB	114 (35.4%)	106 (33.0%)

	Pembro Arm (N = 322)	Placebo Arm (N = 321)
ECOG PS 1	142 (44.1%)	144 (44.9%)
High-grade serous histology[b]	278 (86.3%)	275 (85.7%)
Bevacizumab use	235 (73.0%)	236 (73.5%)
Prior lines of therapy[c]		
1 line	121 (37.6%)	113 (35.2%)
2 lines	200 (62.1%)	207 (64.5%)
Prior anticancer therapy		
Anti-PD-1 or PD-L1	7 (2.2%)	7 (2.2%)
Bevacizumab	149 (46.3%)	146 (45.5%)
PARP inhibitor	112 (34.8%)	123 (38.3%)
Platinum-free interval[d]		
<3 mo	137 (42.5%)	162 (50.5%)
≥3 to ≤6 mo	183 (56.8%)	154 (48.0%)
>6 mo	2 (0.6%)	4 (1.2%)

[a]44 participants had missing information for race, 22 (6.8%) in the pembro arm and 22 (6.9%) in the placebo arm. [b]Other histology subtypes in the pembro 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%). [c]2 participants had 3 prior lines of therapy, 1 (0.3%) in each treatment arm. [d]1 participant in the placebo arm had missing information for platinum-free interval. Data cutoff date: March 5, 2025.

Progression-Free Survival in the CPS ≥1 Population at IA1

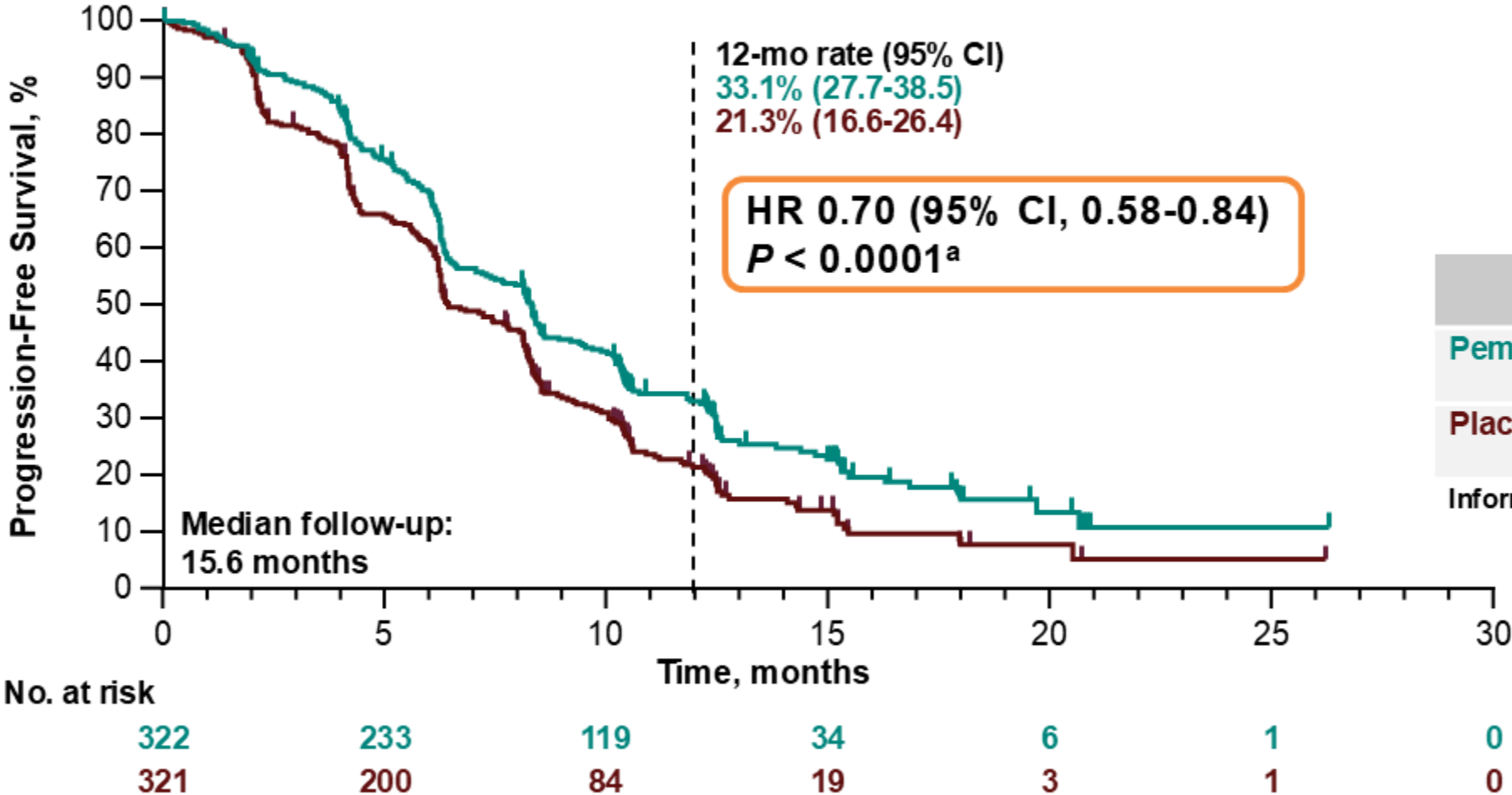


	Pts w/ Event	Median, mo (95% CI)
Pembro Arm	69.2%	8.3 (7.0-9.4)
Placebo Arm	77.6%	7.2 (6.2-8.1)

Information fraction: 87.9%

Response assessed per RECIST v1.1 by investigator review. [a]Hazard ratio (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 0.0116 at this planned first interim analysis; because the success criterion of the PFS hypothesis was met, no formal testing of PFS will be performed at later analyses. Data cutoff date: April 3, 2024.

Progression-Free Survival in the ITT Population at IA1



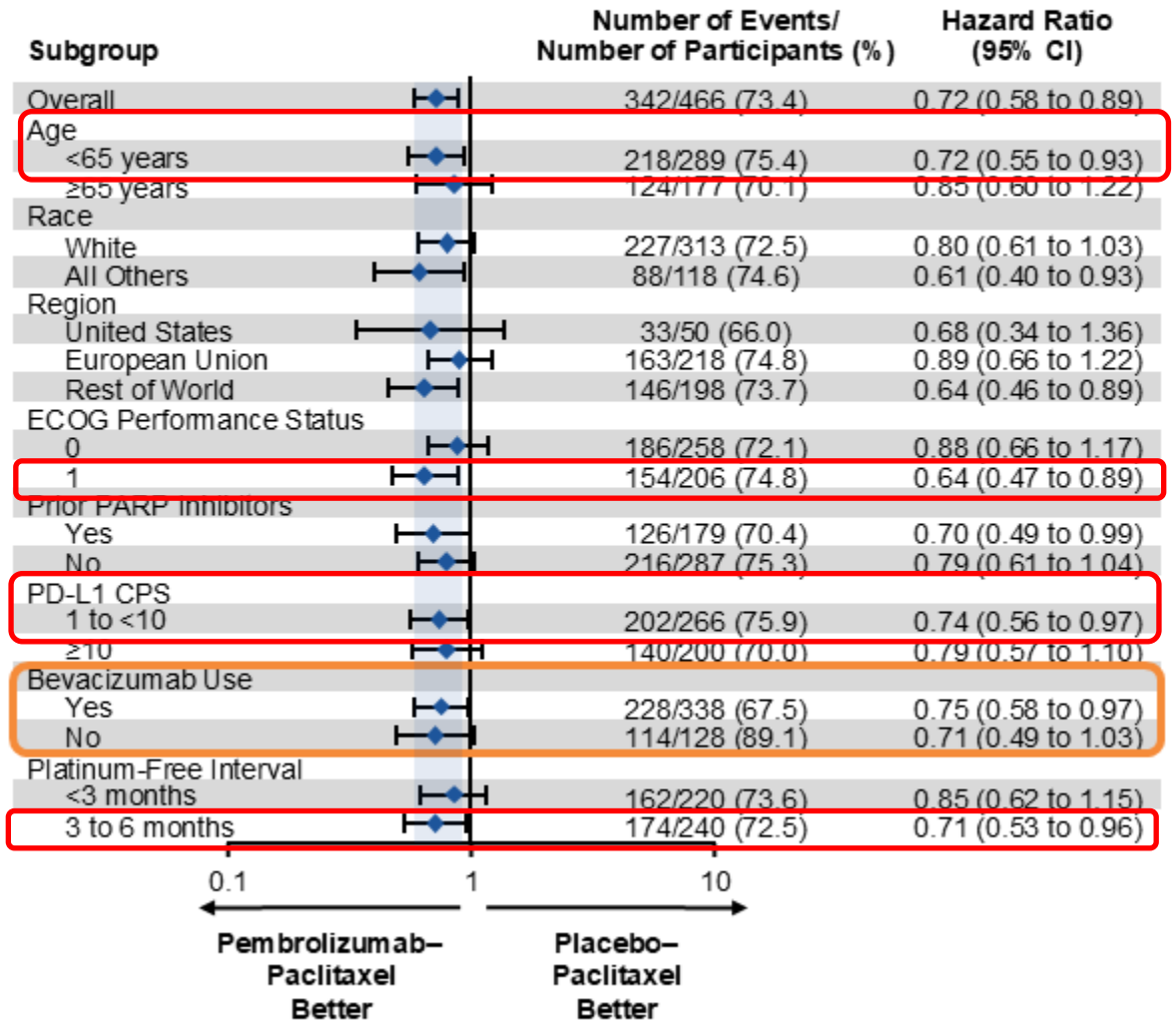
	Pts w/ Event	Median, mo (95% CI)
Pembro Arm	71.7%	8.3 (7.2-8.6)
Placebo Arm	78.8%	6.4 (6.2-8.1)

Information fraction: 89.5%

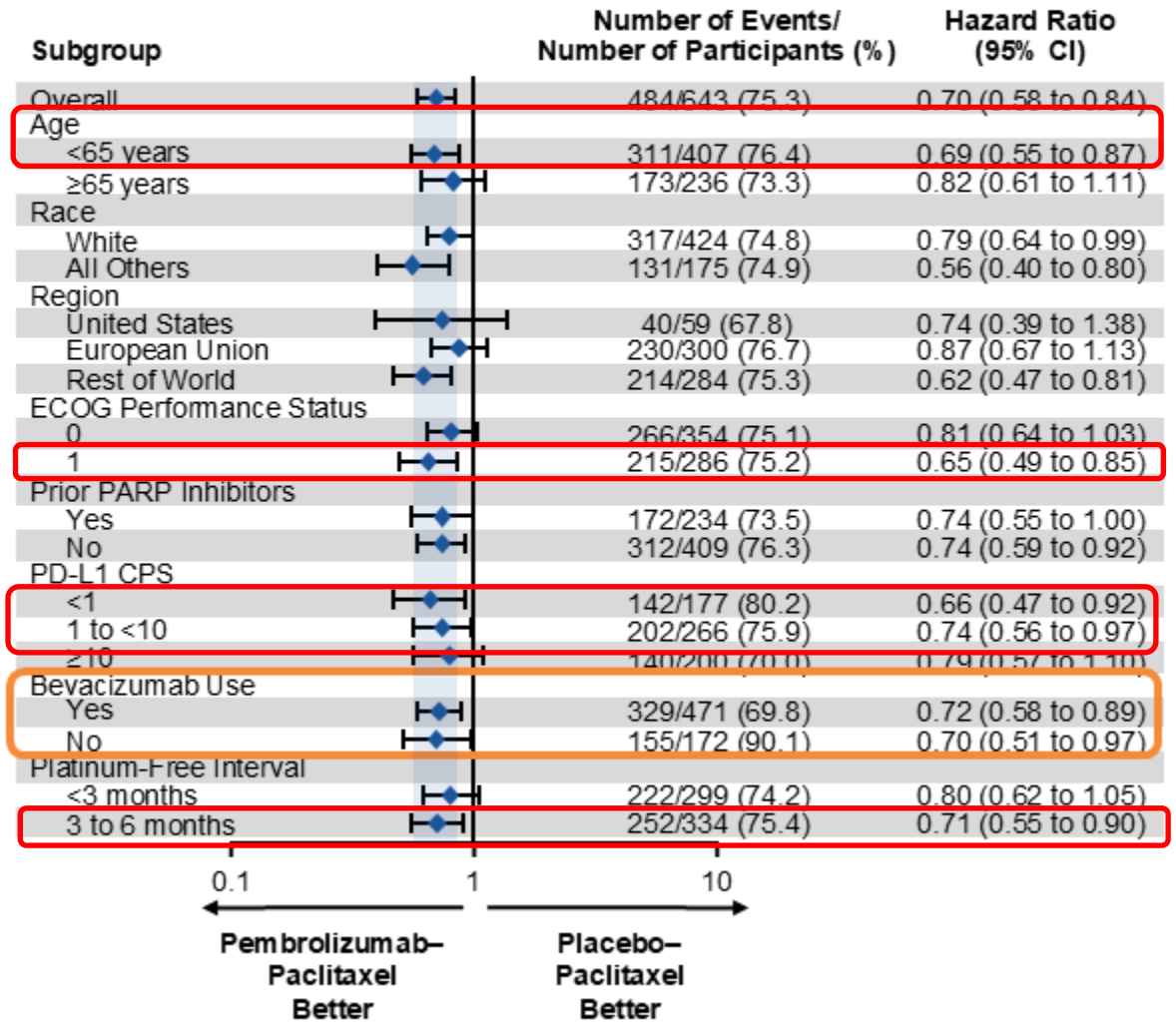
Response assessed per RECIST v1.1 by investigator review. [a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. The observed p-value crossed the prespecified nominal boundary of 0.0023 at this planned first interim analysis; because the success criterion of the PFS hypothesis was met, no formal testing of PFS will be performed at later analyses. Data cutoff date: April 3, 2024.

Progression-Free Survival in Subgroups in the CPS ≥1 and ITT Populations at IA1

CPS ≥1 Population



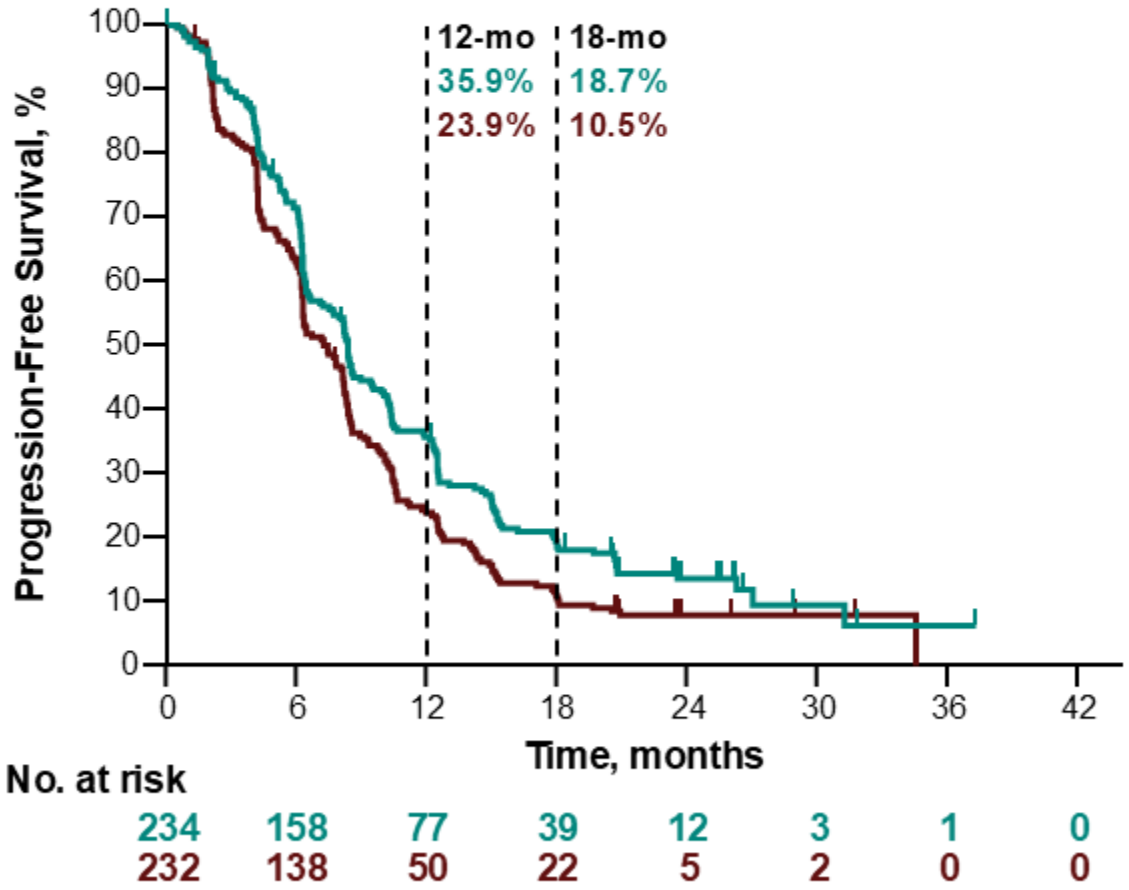
ITT Population



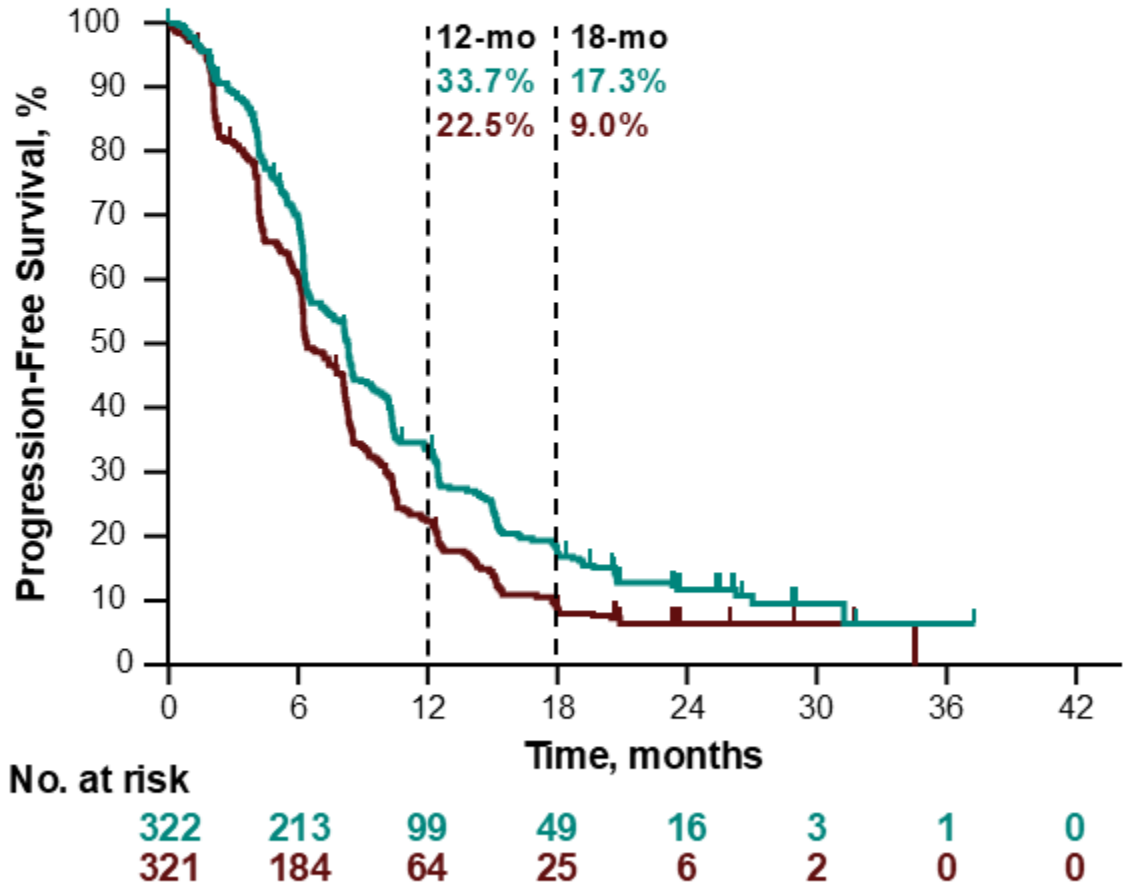
Response assessed per RECIST v1.1 by investigator review. The subgroup results shown in the forest plot were based on an unstratified Cox model, so the results for CPS ≥1 may differ slightly compared with those of the primary analysis, which were based on a stratified Cox model. Data cutoff date: April 3, 2024.

Progression-Free Survival in the CPS ≥1 and ITT Populations at IA2

CPS ≥1 Population	Median, months	Events	HR (95% CI)
Pembro Arm	8.3	81.6%	0.75[a] (0.61-0.91)
Placebo Arm	7.2	86.6%	



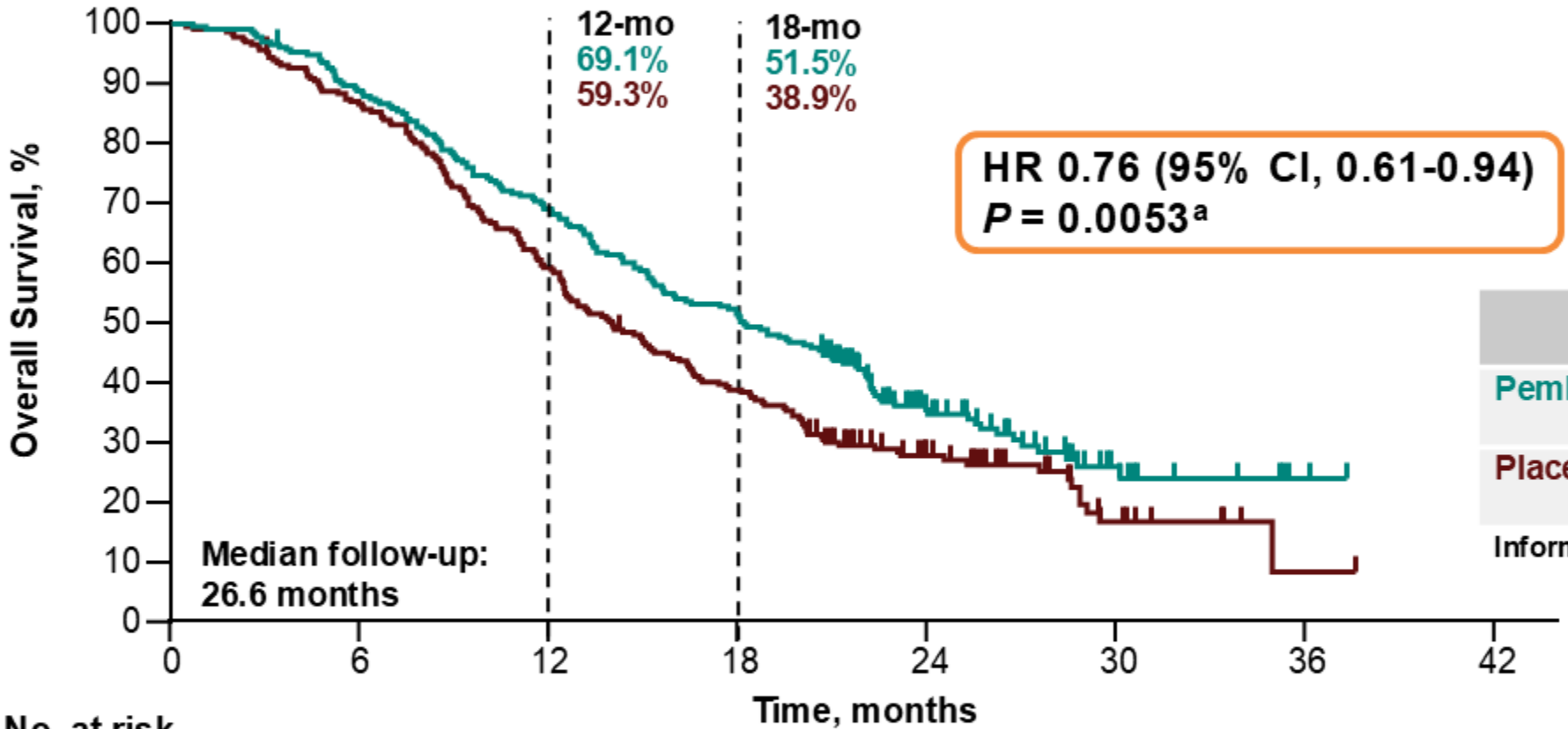
ITT Population	Median, months	Events	HR (95% CI)
Pembro Arm	8.3	83.2%	0.73[a] (0.62-0.86)
Placebo Arm	6.4	87.2%	



Median follow-up: 26.6 months

Response assessed per RECIST v1.1 by investigator review. [a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. No statistical testing for PFS was done at this analysis because significance was achieved at IA1. Data cutoff date: March 5, 2025.

Key Secondary Endpoint: Overall Survival in the CPS ≥1 Population at IA2



HR 0.76 (95% CI, 0.61-0.94)
***P* = 0.0053[a]**

	Pts w/ Event	Median, mo (95% CI)
Pembro Arm	67.1%	18.2 (15.3-21.0)
Placebo Arm	75.4%	14.0 (12.5-16.1)

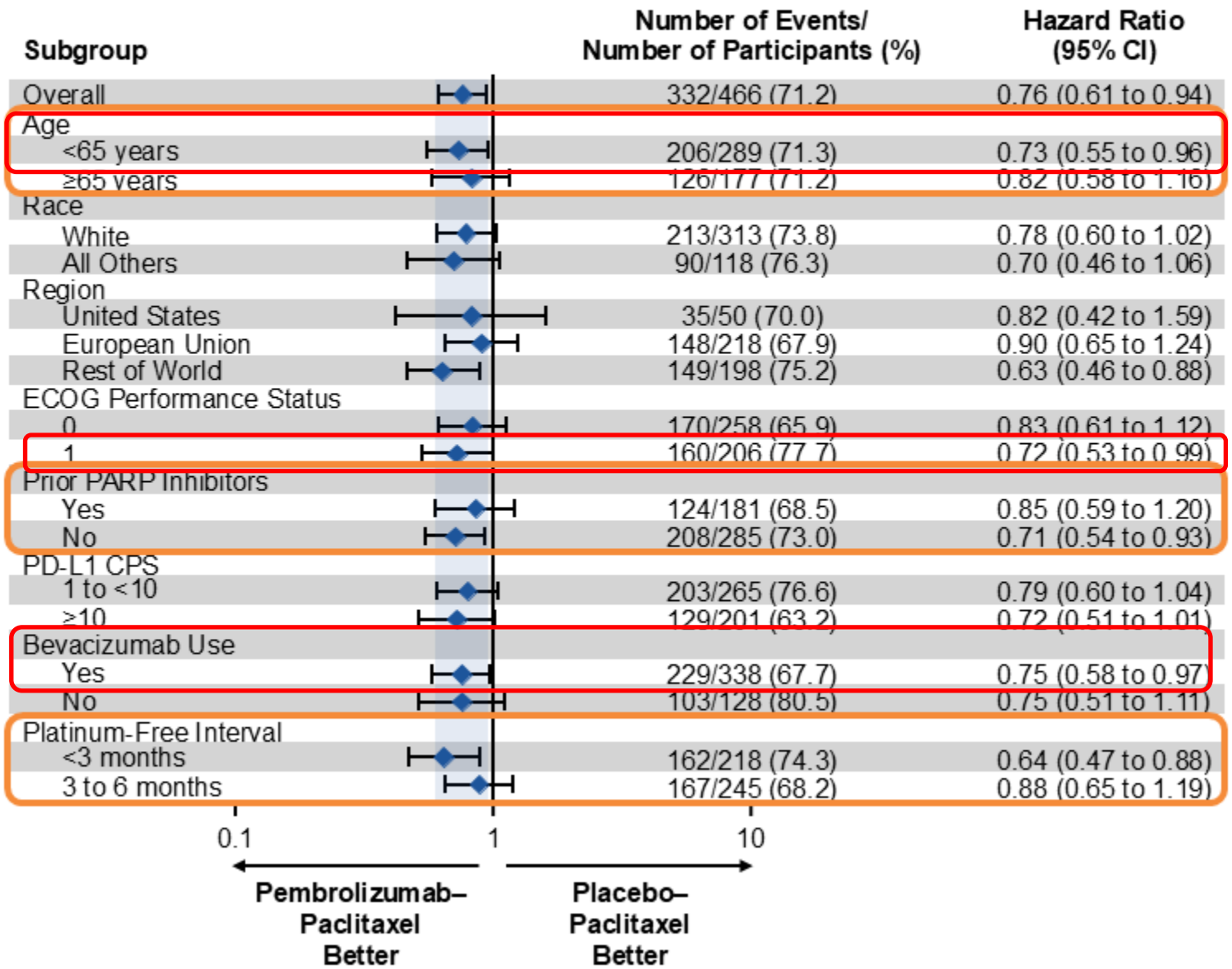
Information fraction: 90.0%

No. at risk

234	207	161	120	49	13	3	0
232	200	137	89	41	10	1	0

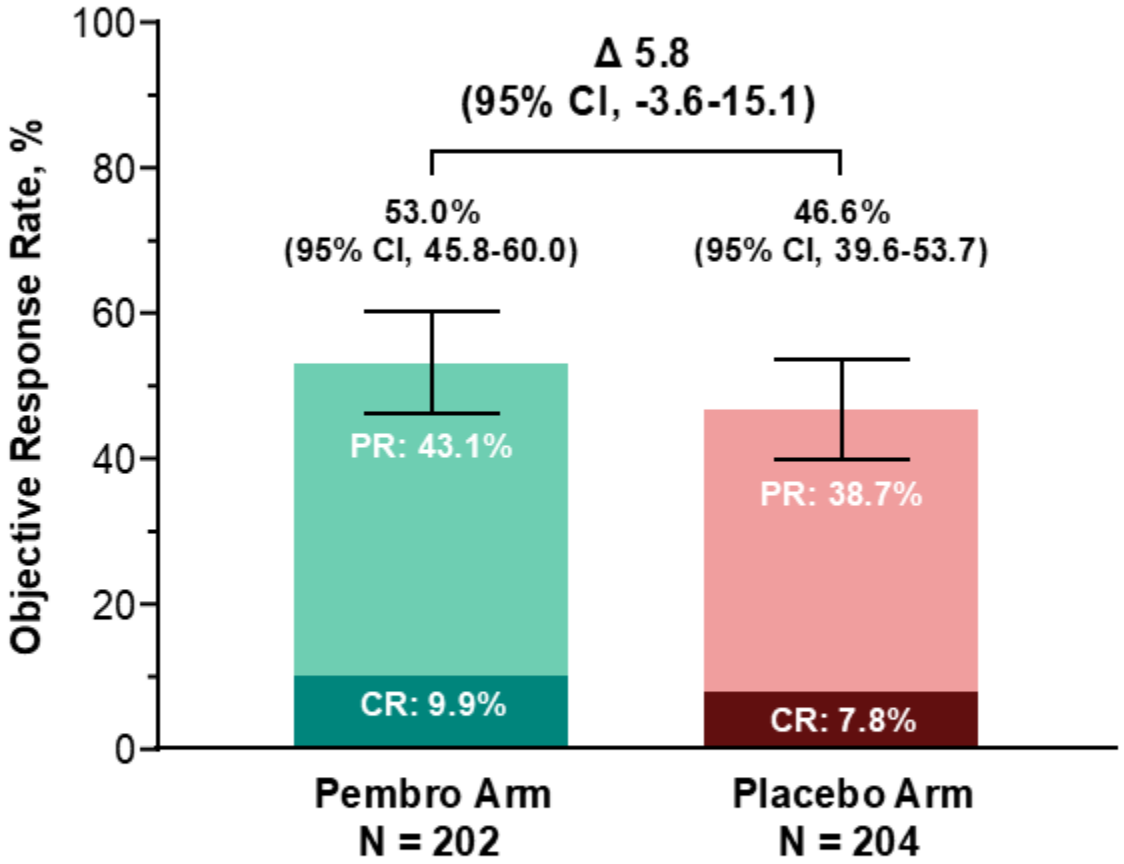
[a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. The observed p-value crossed the prespecified nominal boundary of 0.0083 at this planned second interim analysis. Data cutoff date: March 5, 2025.

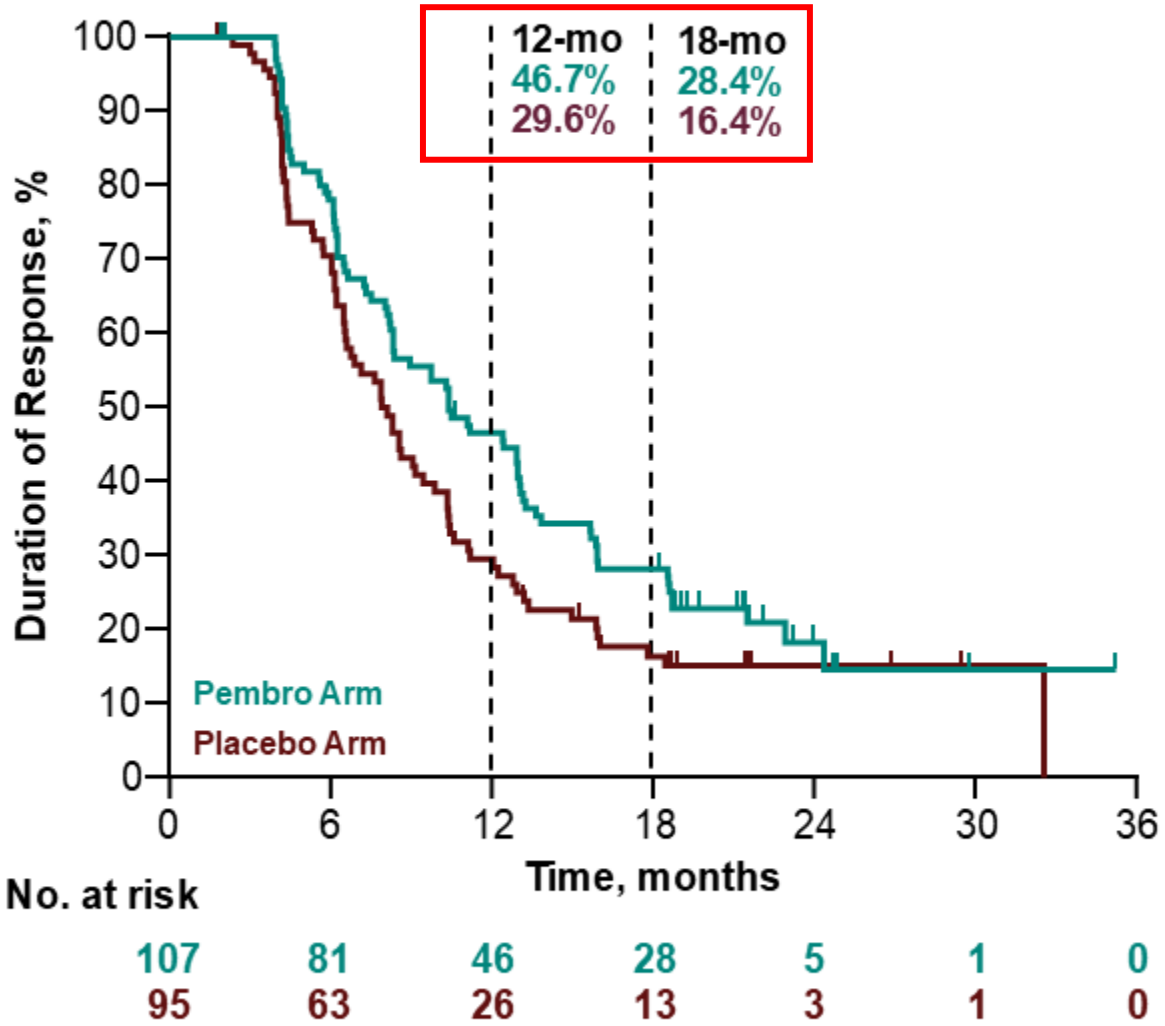
Overall Survival in Subgroups in the CPS ≥1 Population at IA2



Data cutoff date: March 5, 2025.

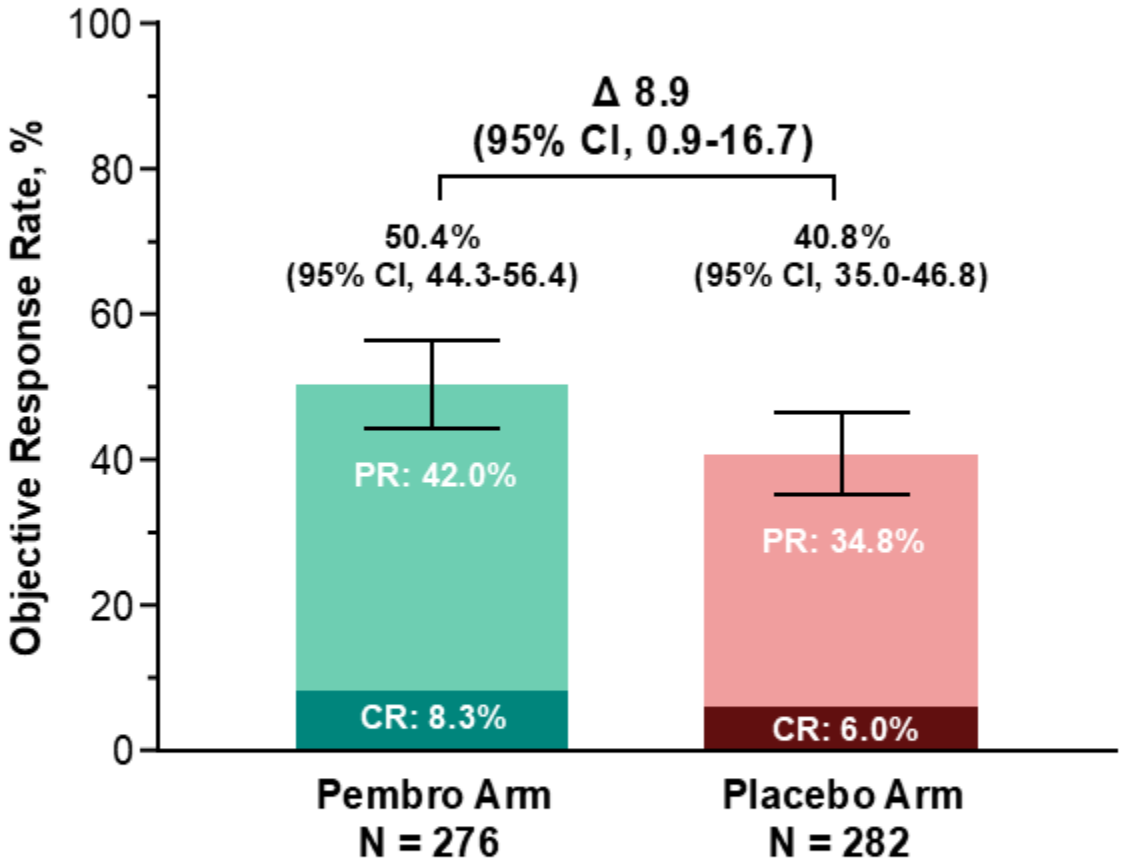
Objective Response Rate and Response Duration in CPS ≥1 Population at IA2

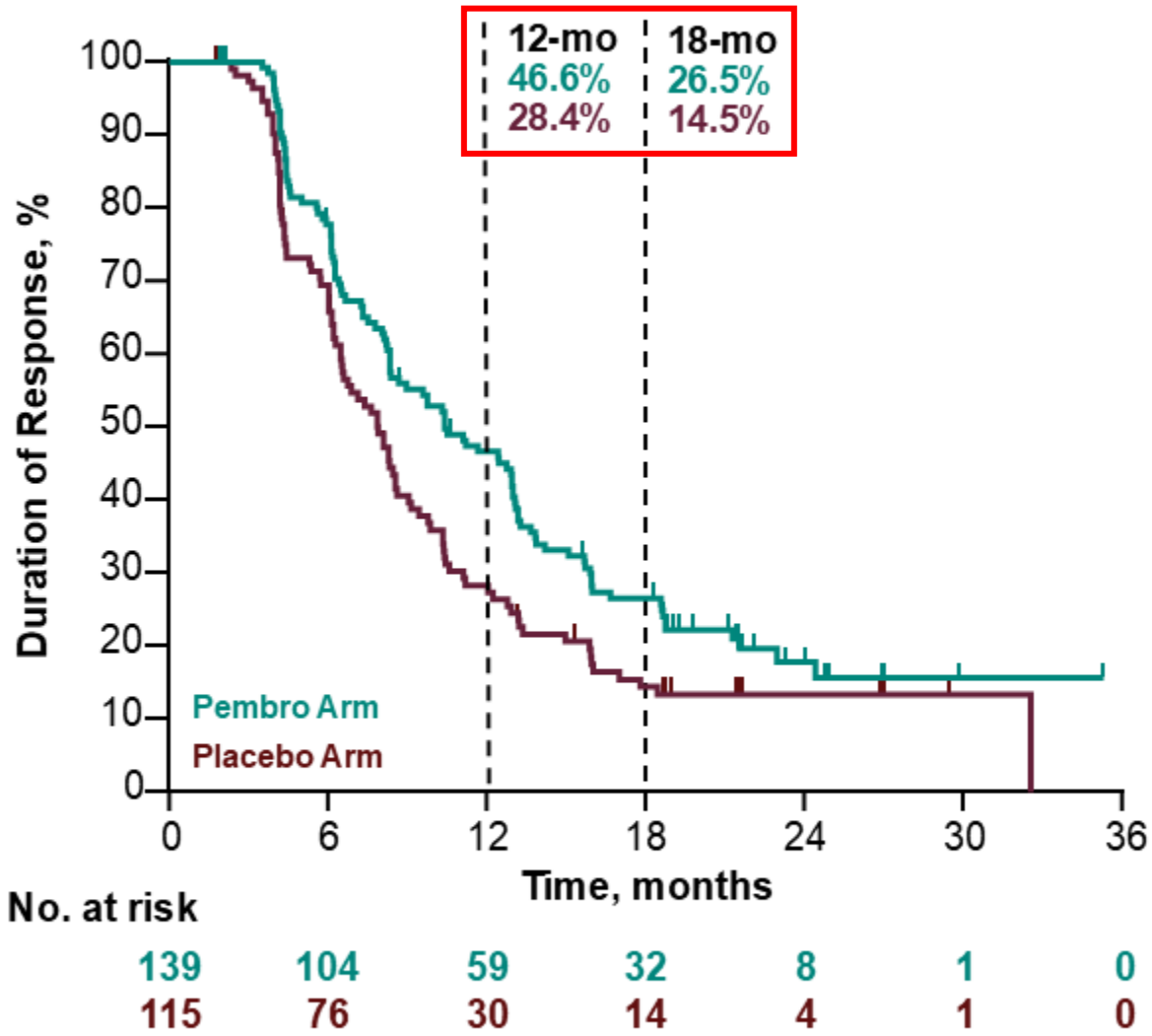




Response assessed per RECIST v1.1 by investigator review. Data cutoff date: March 5, 2025.

Objective Response Rate and Response Duration in ITT Population at IA2





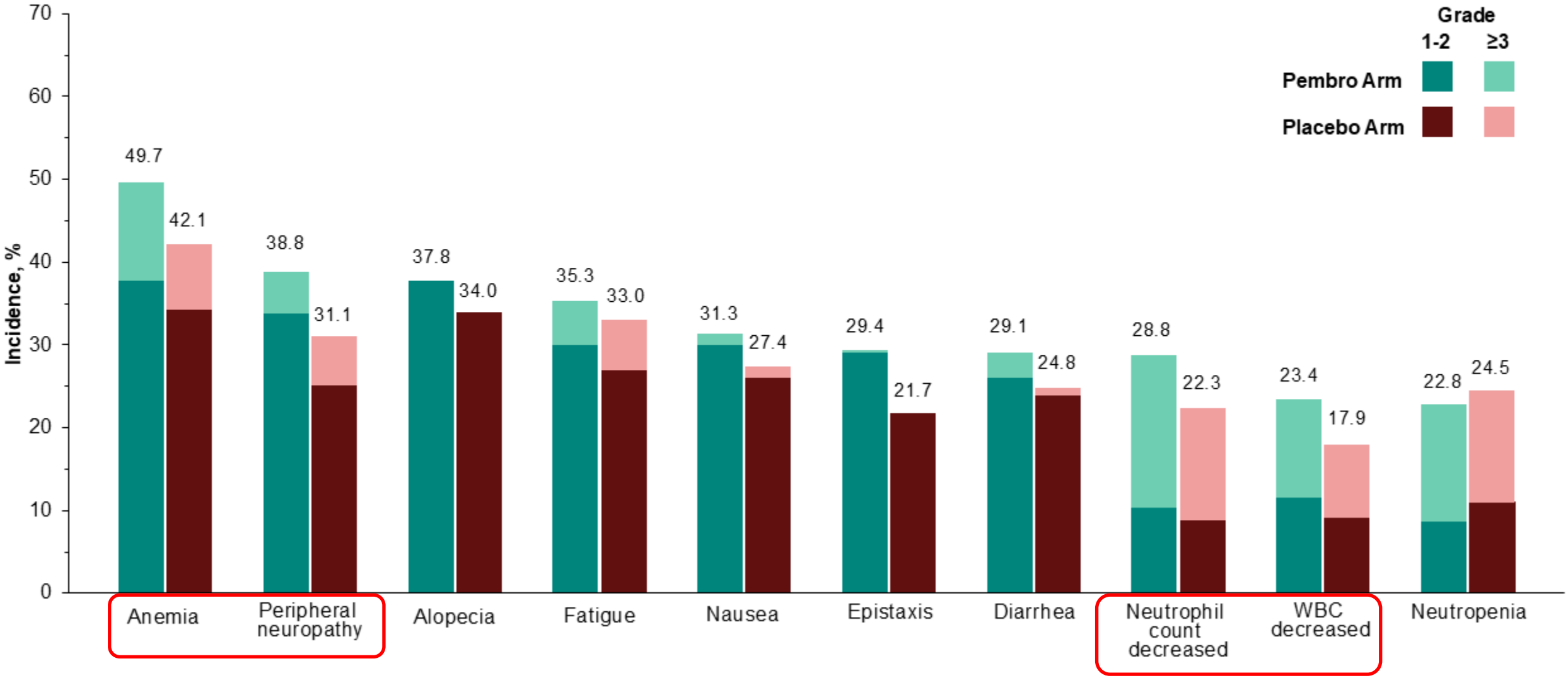
Response assessed per RECIST v1.1 by investigator review. Data cutoff date: March 5, 2025.

Summary of Adverse Events at IA2

	All-Cause AEs		Treatment-Related AEs[a]		Immune-Mediated AEs[b]	
	Pembro Arm (N = 320)	Placebo Arm (N = 318)	Pembro Arm (N = 320)	Placebo Arm (N = 318)	Pembro Arm (N = 320)	Placebo Arm (N = 318)
Any grade	318 (99.7%)	316 (99.4%)	313 (97.8%)	303 (95.3%)	125 (39.1%)	60 (18.9%)
Grade ≥3	264 (82.5%)	225 (70.8%)	216 (67.5%)	176 (55.3%)	37 (11.6%)	11 (3.5%)
Serious	178 (55.6%)	122 (38.4%)	106 (33.1%)	62 (19.5%)	35 (10.9%)	7 (2.2%)
Led to death	15 (4.7%)	14 (4.4%)	3 (0.9%)[c]	5 (1.6%)[d]	2 (0.6%)[e]	0
Led to discontinuation of any treatment	132 (41.3%)	108 (34.0%)	115 (35.9%)	89 (28.0%)	22 (6.9%)	8 (2.5%)

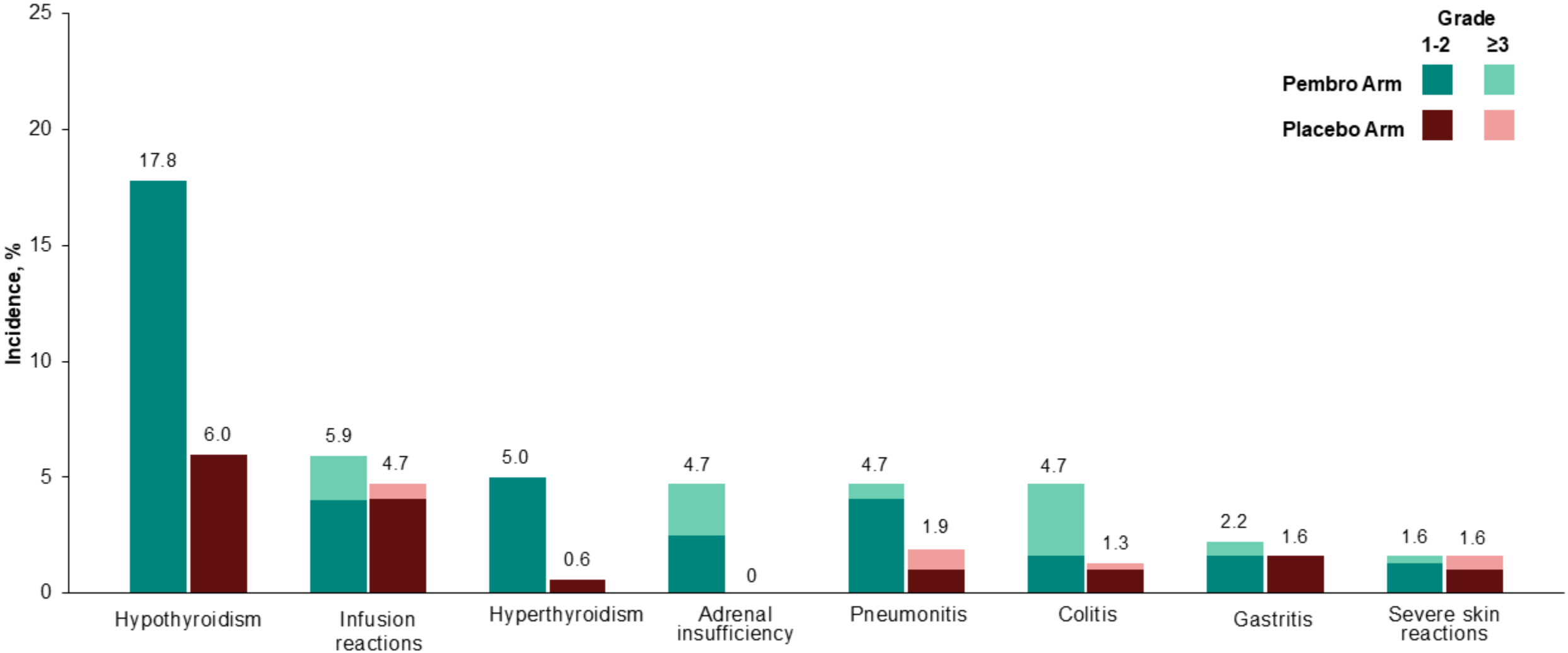
The median duration of therapy was 33 weeks in the pembro arm and 28 weeks in the placebo arm. [a]Per investigator assessment. [b]Events were based on a list of preferred terms intended to capture the known risks of pembrolizumab and considered regardless of attribution to treatment by the investigator. [c]Colitis, interstitial lung disease, and intestinal perforation. [d]Cardiac failure, intestinal perforation (in 2), and large intestine perforation (in 2). [e]Colitis and pneumonitis (reported by the investigator as treatment-related interstitial lung disease). Data cutoff date: March 5, 2025.

Treatment-Related Adverse Events at IA2, Incidence ≥20% in Either Arm



Data cutoff date: March 5, 2025.

Immune-Mediated Adverse Events and Infusion Reactions at IA2, 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: March 5, 2025.

KNB96 vs MIRSOL

Study	Study Design	Patient Population	Analysis Stage	PFS		OS		Notes
				Median, mo	HR (95% CI)	Median, mo	HR (95% CI)	
KEYNOTE-B96	Pem + w-P (+/- bev) vs. Placebo + w-P (+/- bev) in PRROC	• **1-2** Prior Lines • **Primary PFI < 1mo** was **excluded** • **all epithelial OC**	IA1 (median f/u: 15.6 mo)	• CPS ≥ 1 population : **8.3** vs. 7.2 • ITT population : 8.3 vs. 6.4	• CPS ≥ 1 population : 0.72 (0.58-0.89) • ITT population : 0.70 (0.58-0.84)	NR	NR	Presented at ESMO 2025
			IA2 (median f/u: 26.6 mo)	• CPS ≥ 1 population : **8.3** vs. 7.2 • ITT population : 8.3 vs. 6.4	• CPS ≥ 1 population : 0.73 (0.61-0.91) • ITT population : 0.70 (0.62-0.86)	• CPS ≥ 1 population : **18.2** vs. 14.0	• CPS ≥ 1 population : 0.76 (0.61-0.94)	
MIRASOL	Mirv vs. Investigator's Choice Chemo (Pacli, PLD, or Topo) in FR alpha high PRROC	• **1-3** Prior Lines • **Primary PFI < 3mo** was **excluded** • **Only High Grade Serous Histology**	IA (median f/u: 13.1 mo)	**5.62** vs. 3.98	0.65 (0.52-0.81)	**16.46** vs. 12.75	0.67 (0.50-0.89)	Presented at ASCO 2023
			FA (median f/u: 30.5 mo)	**5.59** vs. 3.98	0.63 (0.51-0.79)	**16.85** vs. 13.34	0.68 (0.54-0.84)	Presented at SGO 2025

백금 저항성 재발 치료 요약

표준 기본 치료

- 단일 약제 비백금 화학요법이 기본 치료
- 페길화 리포좀 독소루비신(PLD), 파클리탁셀, 젬시타빈
- 베바시주맙 병용 시 반응률 및 PFS 개선 (AURELIA 연구)
- 낮은 반응률(10-15%)과 짧은 PFS(3-4개월)가 한계점

ADC

- Mirvetuximab soravtansine: FRα-high 환자에서 표준 치료 대비 우수한 효과
- MIRASOL 연구: 전체 생존기간 2년 돌파 (OS 개선)
- Fam-trastuzumab deruxtecan: HER2 발현 난소암 표적 특이성과 강력한 세포독성 약물 전달의 시너지 효과

면역요법

- KNB98 시험: 펨브롤리주맙 + 파클리탁셀 ± 베바시주맙 병용요법
- CPS ≥ 1 및 65세 미만 환자에서 더 큰 이점
- 면역 체크포인트 억제제와 항혈관신생제의 시너지 효과
- 면역 미세환경 조절을 통한 항암 효과 증대

환자 맞춤형 접근

- 분자 프로파일링 기반 치료 선택의 중요성 증가
- 이전 치료력(특히 PARP 억제제, 베바시주맙)에 따른 맞춤 접근
- 잔존 독성(신경병증/신장) 및 전신 상태 고려
- 환자의 치료 목표와 삶의 질 균형 유지

Conclusion

1. Evolution of Treatment Selection

Beyond the 6-Month Cutoff:
Transition from a binary Platinum-Free Interval (PFI) to a **"Continuum of Sensitivity"** model

Biomarker-Driven Strategy:
Treatment is now dictated by **molecular profiles** (BRCA, HRD, and **FRα expression**) rather than clinical timing alone

2. Strategic Therapeutic Updates

Platinum-Sensitive:

Focus on **platinum doublets** followed by **PARP inhibitors or Bevacizumab maintenance** to prolong remission.

Platinum-Resistant (The New Standard):

단일 약제 비백금 화학요법이 기본 치료

ADC Breakthrough: Mirvetuximab Soravtansine is the preferred choice for **FRα-high**

IO Synergy (KEYNOTE-B96): Pembrolizumab + Paclitaxel ± Bevacizumab significantly improves OS, particularly in **CPS ≥ 1** and patients **< 65 years**

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2026년 대한부인종양학회 제7회 동계학술대회 with Chemo-TIP Review

일자 2026년 1월 17일 (토)

장소 세종대학교 컨벤션센터

Thank you for your attention!

대한부인종양학회
Korean Society of Gynecologic Oncology