Bridging Clinical Trial Evidence and Real-World Practice : The Role of Zejula

최민철
산부인과
서울아산병원

Disclaimer

The information, views and opinions presented herein are those of the presenter, and the presenter is solely responsible for the materials being introduced in this presentation. Such information, views and opinions of the presenter do not necessarily reflect the views and opinions of Takeda Pharmaceuticals Korea Co., Ltd.
Takeda Pharmaceuticals Korea Co., Ltd does not recommend the use of any product in any different manner than as described in the prescribing information.
Physicians are advised to consult the relevant local prescribing information issued by the manufacturers before prescribing any drug discussed or described at this meeting.
Although patient cases mentioned herein are actual cases, it may differ from local prescribing information.
The information on this material is intended for healthcare professionals only.
Meeting funded by Takeda.

Disclosures

- Takeda Korea

TABLE OF CONTENTS

01 Why Maintenance Therapy Matters

02 Long-term Evidence from PRIMA

03 From Clinical Trials to Real-World Practice

04 Real-World Evidence with Niraparib in Korea

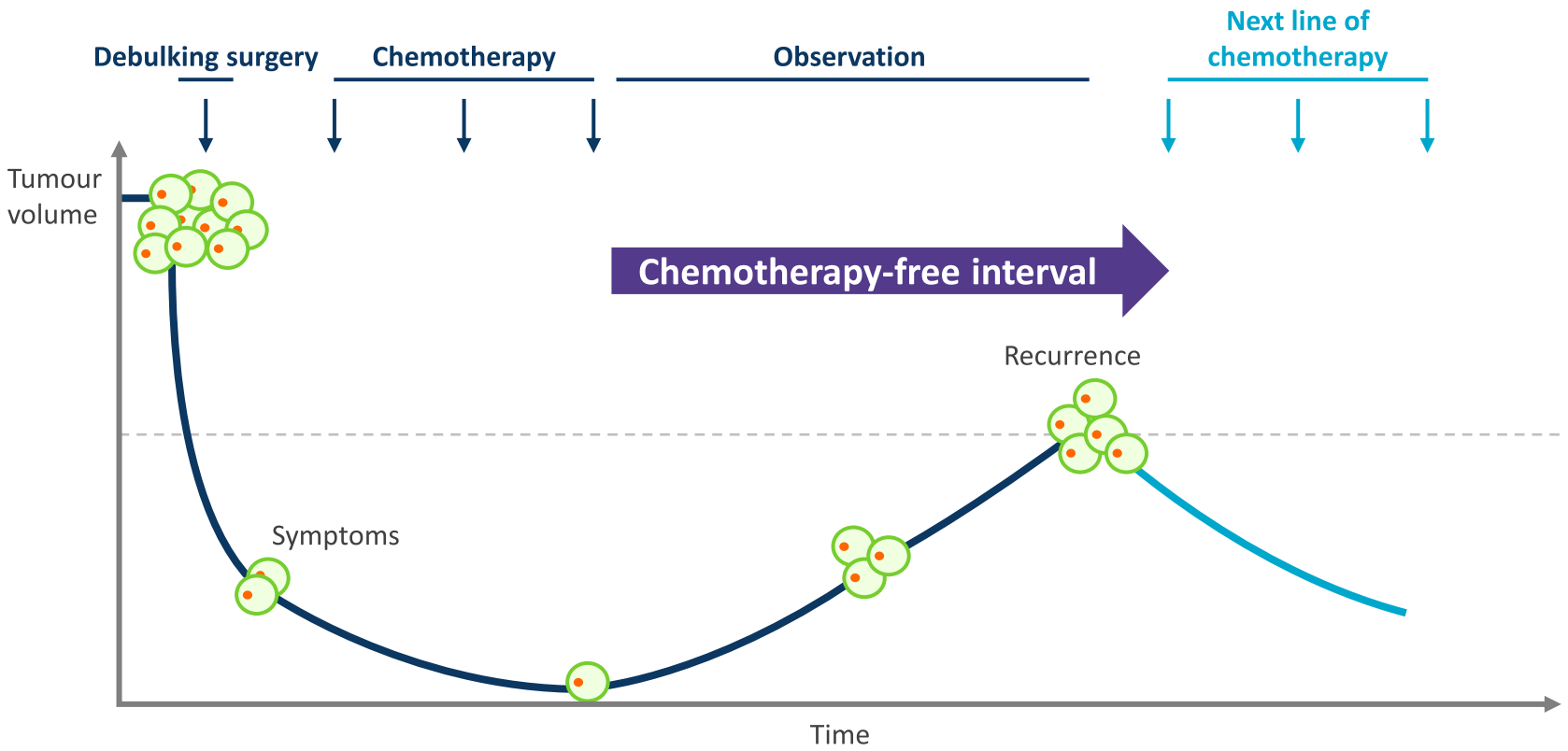
05 Cases Review

06 Advantages of AEJULA® (Niraparib)

Why Maintenance Therapy Matters

Maintenance therapy with PARPis have brought forward a paradigm shift, altering the natural course of disease in ovarian cancer by extending PFS

Management of OC:[1]

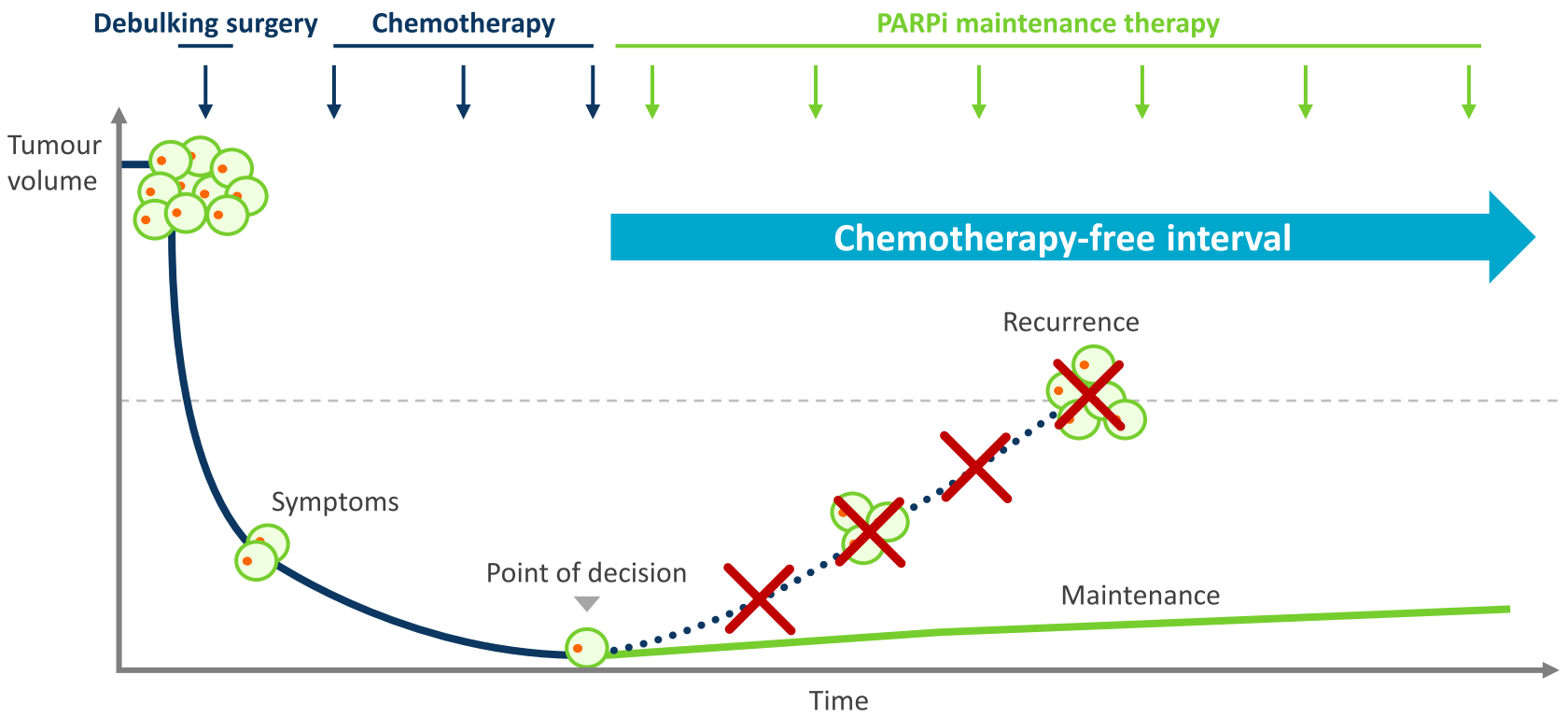


>70% of patients with advanced OC will recur within 3-5 years in the absence of 1L maintenance thearpy[2,3]

Figure is for illustrative purposes only.
1L, first-line; OC, ovarian cancer
1. DiSilvestro P, Alvarez Secord A. *Cancer Treat Rev* 2018;69:53-65. 2. Ledermann JA, *et al. Ann Oncol* 2013;24:vi24-vi32. 3. du Bois A, *et al. Cancer* 2009;115:1234-44.

Maintenance therapy with PARPis have brought forward a paradigm shift, altering the natural course of disease in ovarian cancer by extending PFS

Management of OC:[1]



Goals of Maintenance therapy

1. Prolong benefit following surgery and chemotherapy
2. Improve survival (PFS and hopefully OS)
3. Manageable toxicity and no negative effects on QoL

Figure is for illustrative purposes only.
OC, ovarian cancer; OS, overall survival; PARPi, poly (ADP-ribose) polymerase inhibitor; PFS, progression-free survival; QoL, quality of life.
1. DiSilvestro P, Alvarez Secord *A. Cancer Treat Rev* 2018;69:53-65.

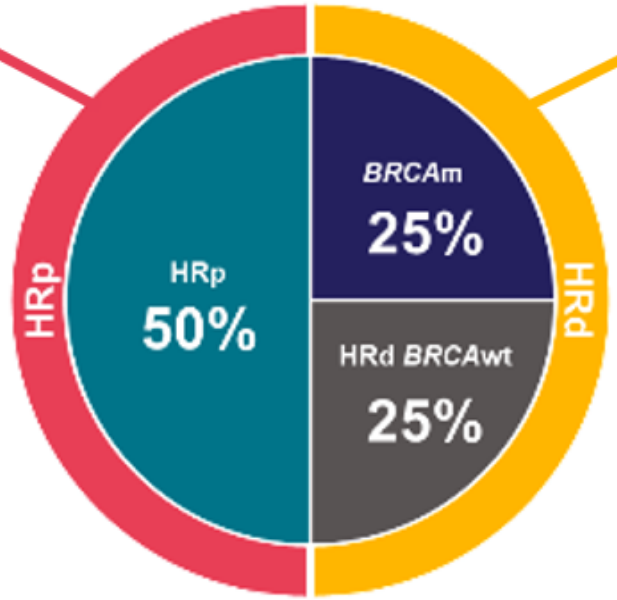
Approximately 50% of high-grade ovarian cancers are HRd[1]

Proportion of patients with genomic mutations in ovarian cancer[1]

HRp defined as "no detectable deficiency in DNA repair"[1]

In a meta-analysis of the studies PAOLA-1, PRIMA, SOLO-1 and VELIA, HRp was associated with higher risk of progression in patients treated with PARPi maintenance therapy[2]

- Risk of progression in HRp patients is 0.83 (95% CI: 0.67–1.03)
- Risk of progression in HRd patients is 0.39 (95% CI: 0.29–0.53)



HRD defined as "deficiency in DNA repair "[1]

HRD can arise from mutations in multiple components of the HR pathway, most frequently in *BRCA* genes[1–3]

- About 50% of patients with OC are HRd
- Within the group of patients with HRD, about half are *BRCA*m and half *BRCA*wt
- HRD is associated with good prognosis and response to PARPi and platinum-based therapies
- *BRCA*m is associated with even better prognosis and response to PARPi and platinum-based therapies

1. Konstantinopoulos PA, Ceccaldi R, Shapiro GI, *et al*. Cancer Discov. 2015;5(11):1137–1154.
2. Cheng H, Yang J, Liu H, *et al*. Arch Gynecol Obstet. 2021;304(2):285–296.
3. Ngoi NYL and Tan DSP. ESMO Open. 2021;6(3):100144.

Differences in study populations

High-risk factors:*[1]

- Stage IV disease
- Visible residual disease or no surgery
- IDS/NACT or no surgery
- PR to chemotherapy[2]
- *BRCA*wt, *BRCA*nd, or missing

	Stage IV disease	Visible residual disease†	Neoadjuvant chemotherapy	PR to chemotherapy	*BRCA*wt
PRMIA[3-5]	35%	47%‡	67%	31%	70%‡‡
PAOLA-1[6,7]	30%	40%	42%	27%††	70%
PRIME[8]	28%	22%§	47%	18%	67%§§
ATHENA-MONO[9]	25%	25%**	51%	18%	79%
SOLO1[10,11]	17%	24%	35%	18%	0%

CLINICAL RISK

1st Quartile | 2nd Quartile | 3rd Quartile | 4th Quartile

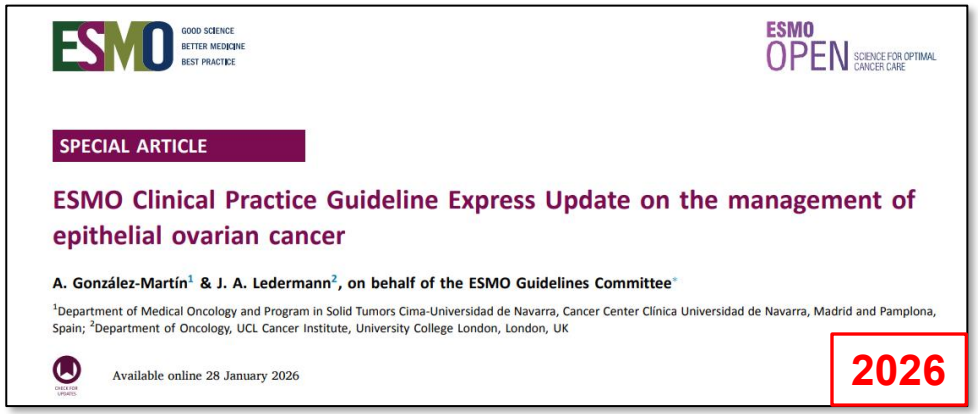
The colours are to indicate the proportion of 'higher-risk patients', where green represents the lowest proportion and red represents the highest population. ‡PRIMA did not include patients with stage III RO after PDS

There are no completed direct head-to-head-trials of these products. These data are from different clinical trials, and since there are inherent limitations in cross-study comparisons, caution should be exercised in interpreting data. Theses data are for information purposes only and are not intended to imply or infer the noninferiority or superiority of either product, in terms of efficacy or safety.

PRIME was sponsored by Zai Lab (Shanghai) Co., Ltd. *Classification based on known risk factors for progression of advanced OC: disease stage, therapy modality, visible residual disease surgery, and BRCA mutation status. †Includes patients who did not receive surgery. §R2 or missing (postoperative residual disease status). **visible disease after chemotherapy. ††Chemotherapy plus bevacizumab. BRCA, breast cancer gene; BRCAnd, BRCA status not determined. ‡‡Including BRCA not determined. §§Germline BRCAwt only. BRCAwt, BRCA wild-type; IDS, interval debulking surgery; NACT, neoadjuvant chemotherapy; OC, ovarian cancer; PARPi, poly (ADP-ribose) polymerase inhibitor; PDS, primary debulking surgery; PR, partial response; R0, no residual disease; R2; >10 mm residual disease.

1. Chase DM., *et al.* presented at ESMO 2021.16-21 Sep (virtual). 2. www.uptodate.com/contents/medical-treatment-for-relapsed-epithelial-ovarian-fallopian-tube-or-peritoneal-cancer-platinum-sensitive-disease#disclaimerContent 3. González-Martin A, *et al. N Engl J Med* 2019:381:2391- 402. 4. González-Martin A, *et al.* presented at ESGO 2019, 2-5 Nov, Athens, Greece. 5, Braicu EI, *et al.* presented at ESGO SoA 2020. 14-16 Dec (virtual). 6. Ray-Coquard I, *et al.* N Engl J Med 2019:381:2416-28. 7. Ray-Coquard I. *et al. N Engl J Med* 2019:381:2416-28 (Supplementary Appendix). 8. Li N. *et al.* presented at SGO 2022.18-21 Mar. Phoenix. AZ. 9. Monk BJ, *et al.* J Clin Oncol 2022; https://doi.org/10.1200/JC0.22.01003. 10. Moore K. *et al. N Engl J Med* 2018:379:2495-505. 11. Moore K. *et al. N Engl J Med* 2018;379:2495-505 (Supplementary Appendix).

Current practice guidelines


ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO OPEN SCIENCE FOR OPTIMAL CANCER CARE

SPECIAL ARTICLE

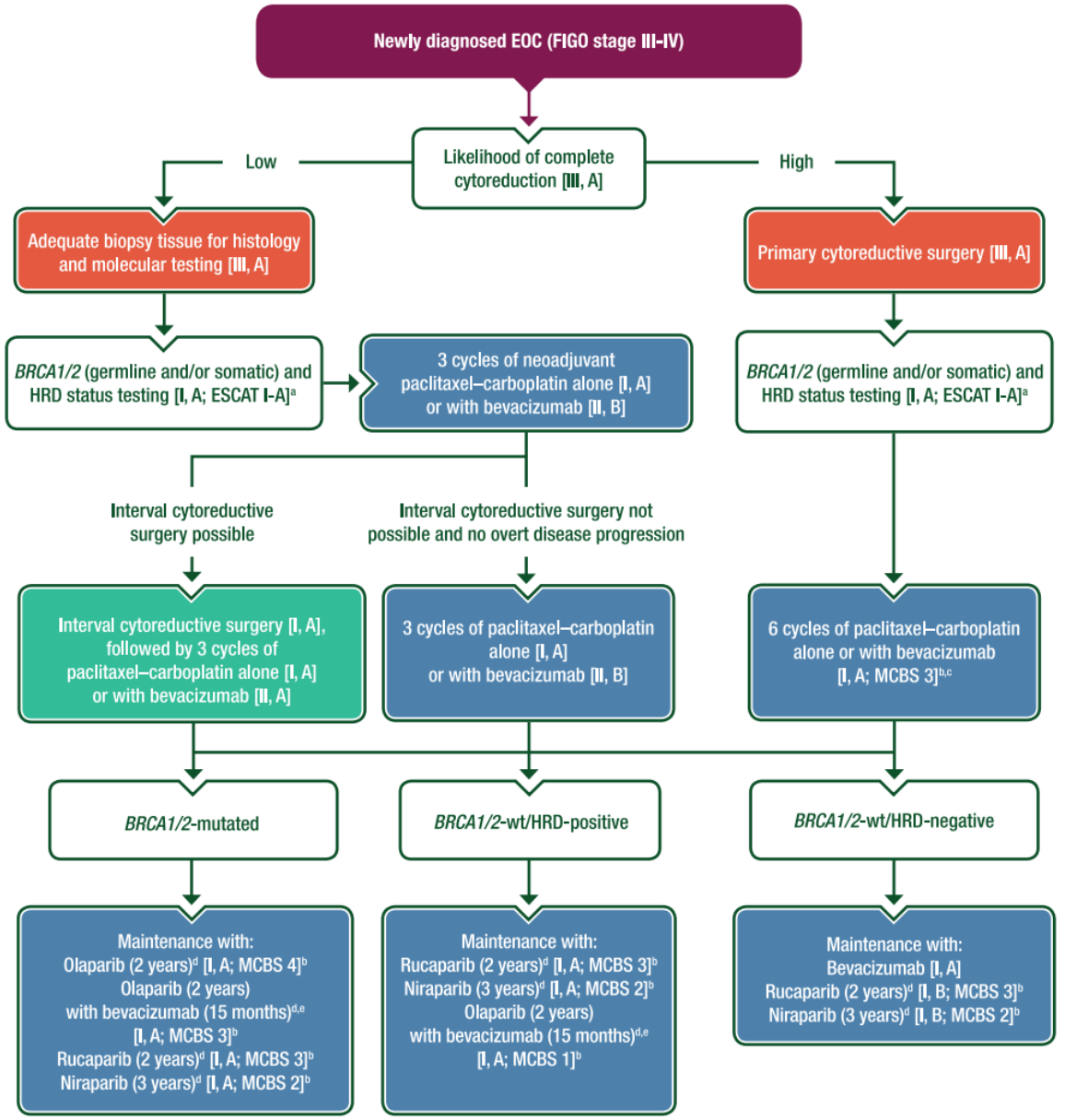
ESMO Clinical Practice Guideline Express Update on the management of epithelial ovarian cancer

A. González-Martín[1] & J. A. Ledermann[2], on behalf of the ESMO Guidelines Committee*

[1]Department of Medical Oncology and Program in Solid Tumors Cima-Universidad de Navarra, Cancer Center Clínica Universidad de Navarra, Madrid and Pamplona, Spain; [2]Department of Oncology, UCL Cancer Institute, University College London, London, UK

Available online 28 January 2026

2026

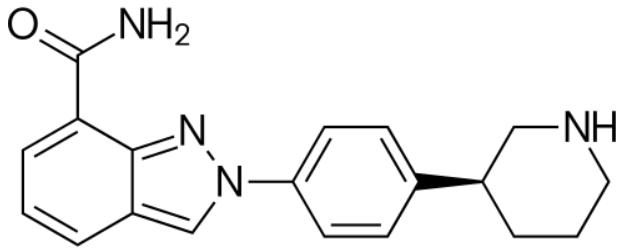


1. ESMO Clinical Practice Guideline Express Update on the management of epithelial ovarian cancer. ESMO Open. 2026;11(2):106032. González-Martín A and Ledermann JA, on behalf of the ESMO Guidelines Committee

Niraparib is a small molecule PARP inhibitor indicated for the treatment of ovarian cancer

Type of drug[1,2]

- Antineoplastic agent
- Inhibitor of PARP-1 and PARP-2



Indication[3]

- Niraparib is indicated for **the maintenance treatment of adult patients with recurrent high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy**

Dosage and administration[3]

- Recommended dose of **200 mg** per day for patients of **<77 kg** or baseline **platelet count <150,000/µL**
- Recommended dose of **300 mg** per day for all other patients
- **Start treatment of niraparib no later than 8 weeks** after the most recent platinum-containing regimen
- Orally once daily
- Administration at **any time of day, without regard to meals**

1. Tesaro Inc. Zejula U.S. Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208447lbl.pdf (Accessed April 2019)
2. European Medicines Agency. Zejula Summary of Product Information. Available at: https://www.ema.europa.eu/documents/product-information/zejula-epar-product-information_en.pdf (Accessed in April 2026).
3. 제줄라® 정 국내 허가사항. https://nedrug.mfds.go.kr/pbp/CCBBB01/getItemDetailCache?cacheSeq=202401351aupdateTs2026-02-13%2011:32:57.0b Accessed in Apr 2026

Long-term Evidence from PRIMA

PRIMA study

- **PRIMA was a landmark Phase III trial in advanced ovarian cancer**

Study Design

Patients with newly-diagnosed OC at high risk for recurrence after response to 1L platinum-based chemotherapy

2:1 Randomization

Niraparib | **Placebo**

Endpoint assessment

Primary Endpoint: Progression-free survival by BICR
Key Secondary Endpoint: Overall survival
Secondary Endpoints: PFS2, TFST, PRO, Safety

Stratification Factors

- NACT administered: Yes or no
- Best response to first platinum therapy: CR or PR
- Tumor homologous recombination test status: deficient or proficient/not-determined

The PRIMA study protocol was modified to prospectively investigate a starting dose of either 300 mg or 200 mg of niraparib (or placebo) based on baseline body weight and/or platelet counts (individualized starting dose).

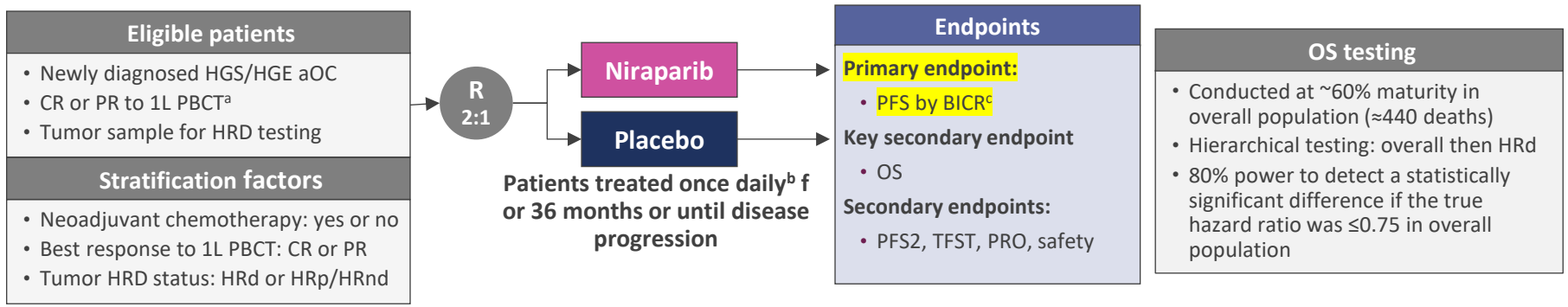
1L first-line BICR blinded independent central review CR complete response NACT neoadjuvant chemotherapy OC ovarian cancer OS overall survival PFS2 progression-free survival 2 PR partial response PRO patient-reported outcomes TFST time to first subsequent therapy.

1. González-Martín A et al. Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. N Engl J Med 2019;381:2391-402

PRIMA 6.2 year updated long-term analysis

PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib 1L maintenance

Phase 3 PRIMA trial enrolled patients with newly diagnosed aOC **at a high risk for disease recurrence** with stage IV disease, residual disease, and NACT.



Key risk characteristics of PRIMA population[1,2]

Disease stage		Residual disease		Tumor HRD/*BRCA* status	
35.1%	stage IV disease at diagnosis	**>99%**	stage III disease at diagnosis with residual disease after primary debulking surgery	**50.9%**	HRd
Initial treatment				**30.4%**	HRd/*BRCA*m
66.7%	received neoadjuvant chemotherapy	**47.5%**	postoperative visible residual disease or no debulking surgery	**34.0%**	HRp
30.6%	achieved partial response to 1L PBCT				

PRIMA/ENGOT-OV26/GOG-3012 trial (NCT02655016). aPatients must have either had CA-125 in the normal range or a ≥90% decrease in CA-125 during 1L treatment that was stable for at least 7 days. At baseline, 7.1% of the overall population had CA-125 above the upper limit of normal. bAt study start, all patients received a fixed starting dose of 300 mg once daily. Subsequently, the protocol was updated to use an individualized starting dose adjusted according to baseline body weight/platelet count. cPrimary endpoint of PFS by BICR assessed by hierarchical testing, first in patients with HRd tumors and then in the overall population. 1L, first-line; aOC, advanced ovarian cancer; BICR, blinded independent central review; BRCAm, BRCA-mutated; CA-125, cancer antigen 125; CR, complete response; HGE, high-grade endometrioid; HGS, high-grade serous; HRD, homologous recombination deficiency; HRd, homologous recombination deficient; HRnd, homologous recombination status not determined; HRp, homologous recombination proficient; OS, overall survival; PBCT, platinum-based chemotherapy; PFS, progression-free survival; PFS2, progression-free survival 2; PR, partial response; PRO, patient-reported outcomes; TFST, time to first subsequent therapy.

1. González-Martín A, et al. N Engl J Med. 2019;381(25):2391–2402. 2. O'Cearbhaill RE, et al. Gynecol Oncol. 2022;166(1):36–43.

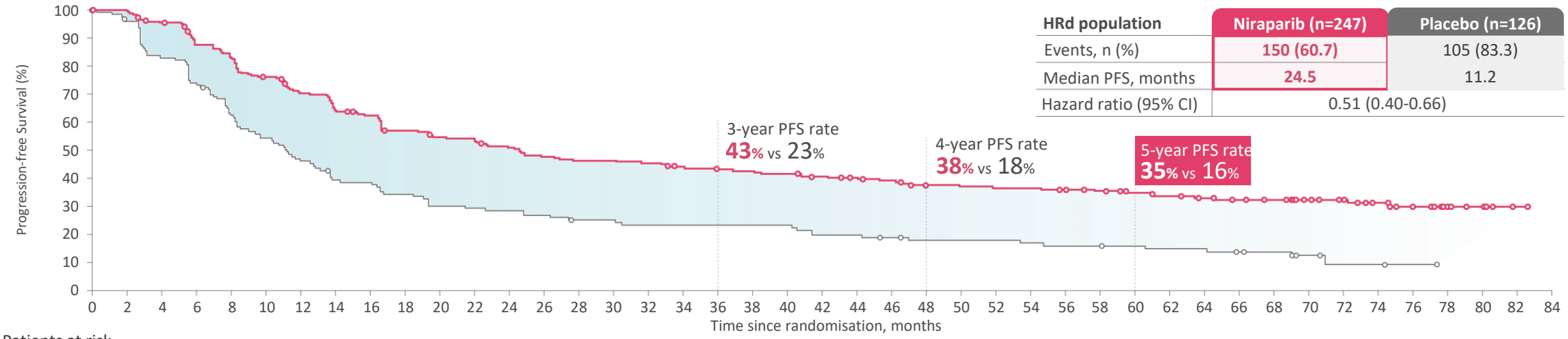
PRIMA 6.2 year updated long-term analysis

- **Updated long-term PFS[a,b]** (ad hoc, investigator-assessed)

Data cutoff date, 8 April 2024; median follow-up, 6.2 years

↳ **Niraparib PFS benefit sustained with additional follow-up in the HRd populations**

Investigator-assessed PFS in HRd



HRd population	Niraparib (n=247)	Placebo (n=126)
Events, n (%)	150 (60.7)	105 (83.3)
Median PFS, months	24.5	11.2
Hazard ratio (95% CI)	0.51 (0.40-0.66)	

Patients at risk

Niraparib	247	235	221	200	189	173	158	143	138	125	119	116	110	103	100	100	98	93	91	89	87	83	79	77	69	68	67	67	64	62	58	55	52	49	46	33	29	24	15	10	8	1	0
Placebo	126	118	102	91	76	66	57	47	46	41	36	35	34	32	28	28	26	26	26	26	26	22	22	20	18	18	18	17	16	16	15	14	14	12	11	5	3	3	2	0			

- **Among patients alive at 5 years in the HRd population, patients who received niraparib were twice as likely to be progression free (35%) than patients who received placebo (16%)**
- **Delaying progression is critical to maintain health-related quality of life[1]**

[a] At study start, patients were monitored for disease progression (CT/MRI) every 12 weeks (3 cycles); in August 2019, the protocol was amended to monitor patients who stayed on study treatment for more than 2 years for disease progression every 24 weeks (6 cycles).
[b] PFS hazard ratios and associated 95% CI calculated using stratified Cox proportional hazards model. For all analyses, stratification factors were those used in randomization.

CT computed tomography HRd homologous recombination deficient HRp homologous recombination proficient MRI magnetic resonance imaging Nir niraparib PBO placebo PFS progression-free survival.

1. Monk BJ, et al. Niraparib first-line maintenance therapy in patients with newly diagnosed advanced ovarian cancer: final overall survival results from the PRIMA/ENGOT-OV26/GOG-3012 trial. Ann Oncol. 2024 Nov;35(11):981-992.

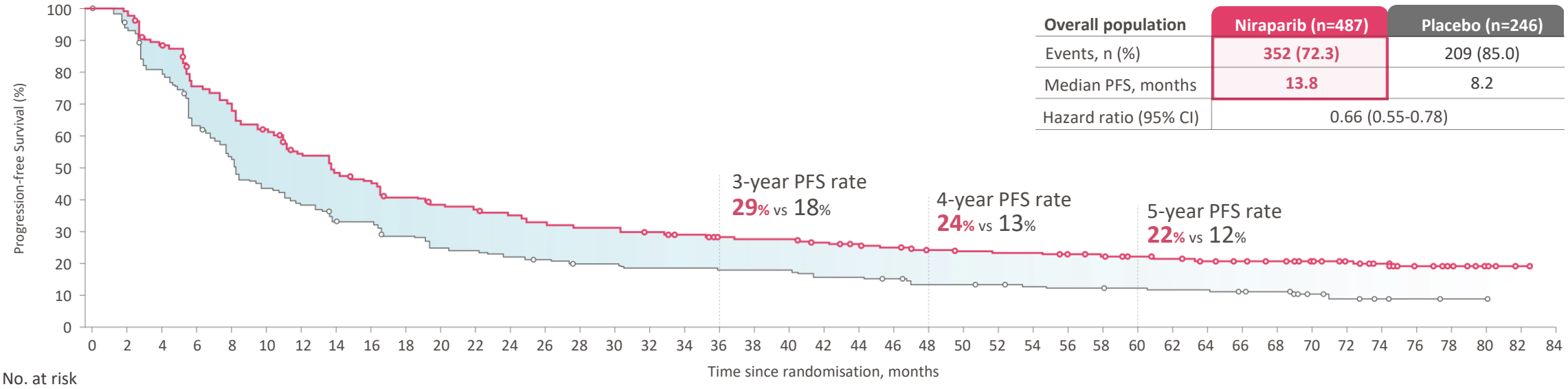
PRIMA 6.2 year updated long-term analysis

- **Updated long-term PFS[a,b]** (ad hoc, investigator-assessed)

Data cutoff date, 8 April 2024; median follow-up, 6.2 years

Niraparib PFS benefit sustained with additional follow-up in the Overall populations

Investigator-assessed PFS in overall



Overall population	Niraparib (n=487)	Placebo (n=246)
Events, n (%)	352 (72.3)	209 (85.0)
Median PFS, months	13.8	8.2
Hazard ratio (95% CI)	0.66 (0.55-0.78)	

No. at risk

Niraparib	487	461	406	342	316	278	243	216	204	181	168	162	153	141	135	134	128	122	118	116	114	108	103	99	89	86	85	85	82	79	74	70	66	63	60	41	35	28	16	11	8	1	0
Placebo	246	226	191	150	125	103	92	78	77	66	57	55	51	48	43	43	40	40	39	39	39	34	34	32	27	27	26	24	23	23	22	21	21	19	18	8	6	4	3	1	1	0	

[a] At study start, patients were monitored for disease progression (CT/MRI) every 12 weeks (3 cycles); in August 2019, the protocol was amended to monitor patients who stayed on study treatment for more than 2 years for disease progression every 24 weeks (6 cycles).
[b] PFS hazard ratios and associated 95% CI calculated using stratified Cox proportional hazards model. For all analyses, stratification factors were those used in randomization.

CT computed tomography HRd homologous recombination deficient HRp homologous recombination proficient MRI magnetic resonance imaging Nir niraparib PBO placebo PFS progression-free survival.

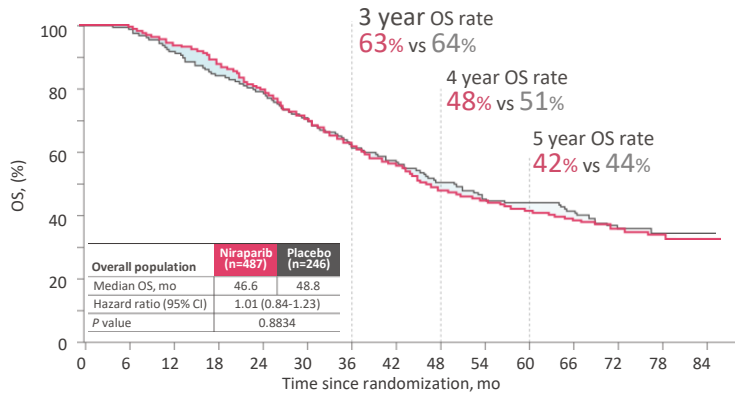
1. Monk BJ, et al. Niraparib first-line maintenance therapy in patients with newly diagnosed advanced ovarian cancer: final overall survival results from the PRIMA/ENGOT-OV26/GOG-3012 trial. Ann Oncol. 2024 Nov;35(11):981-992.

PRIMA 6.2 year updated long-term analysis

- **Final OS** (62.5% maturity in overall population)

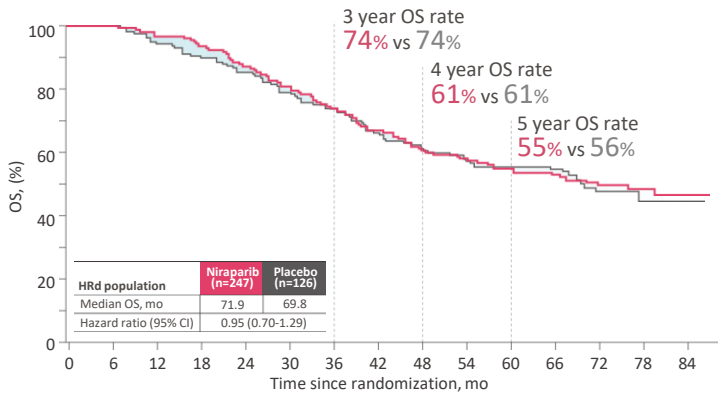
↳ **No difference in OS between niraparib and placebo arms in the overall, HRd, and HRp populations**

Overall[a]



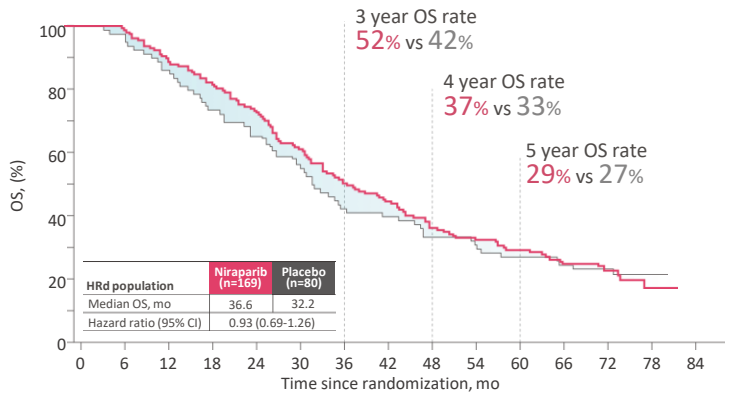
Niraparib	487	480	451	418	378	334	294	261	227	208	192	177	115	39	5
Placebo	246	242	223	204	191	171	153	138	121	111	105	100	62	17	3

HRd[a]



Niraparib	247	245	238	224	207	191	173	156	143	134	126	121	75	31	5
Placebo	126	126	118	112	107	98	91	82	75	70	68	67	40	14	3

HRp[b]



Niraparib	169	164	148	134	120	101	84	73	60	53	47	40	29	5	
Placebo	80	76	67	57	51	44	33	31	26	25	21	19	14	2	

↳ OS results for all prespecified biomarker-defined subgroups consistent with overall population[c]

↳ **However, assessment of long-term efficacy outcomes in high-risk aOC may be complicated by multiple factors**

- **Patient population**
- **Extended Post-progression survival**
- **Subsequent therapy**

[a] Hazard ratios and 95% CIs for overall and HRd populations calculated using stratified Cox proportional hazards model with randomization stratification factors. [b] Hazard ratio and 95% CI for HRp population calculated using unstratified Cox proportional hazards model. [c] OS results for the HRnd population (unstratified): hazard ratio (95% CI), 1.39 (0.88–2.19).

aOC advanced ovarian cancer HRd homologous recombination deficient HRnd homologous recombination status not determined HRp homologous recombination proficient OS overall survival Nir niraparib PBO placebo

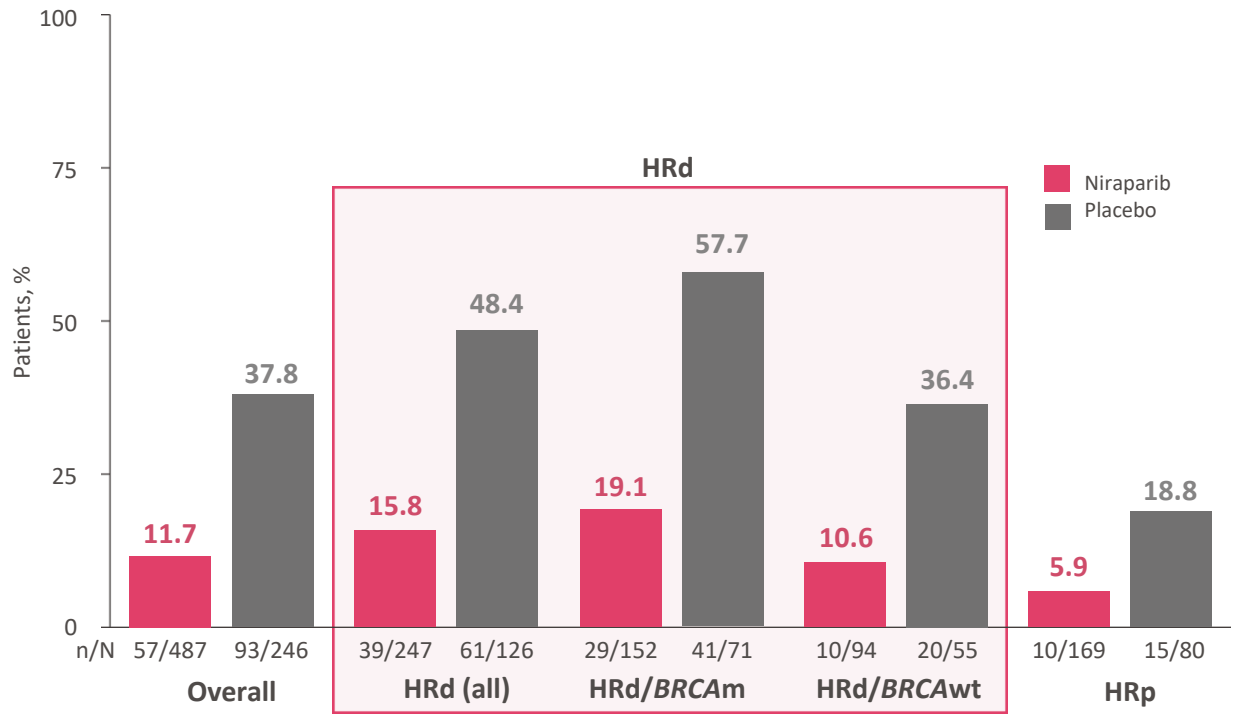
1. González-Martín A, et al. Final Overall survival in patients with newly diagnosed advanced ovarian cancer treated with niraparib first-line maintenance: results from PRIMA/ENGOT-OV26/GOG-3012. presented at ESMO 2024, Barcelona, Spain, Sep 13-17, 2024.

PRIMA 6.2 year updated long-term analysis

- **Subsequent PARP inhibitor therapy**

↳ **3-fold higher subsequent PARP inhibitor use in placebo arm than niraparib arm across populations**

Subsequent PARP inhibitor therapy[a]



Subsequent PARP inhibitor use

- **Most predominant in HRd population, with highest use in HRd/*BRCA*m population.**
- **Most patients initiated in the 2L setting**

Any subsequent PARP inhibitor by treatment line, %[a]	Overall		HRd	
	Niraparib (n=487)	Placebo (n=246)	Niraparib (n=247)	Placebo (n=126)
Any treatment line	11.7	37.8	15.8	48.4
2L	8.2	30.5	13.0	37.3
3L+	3.5	7.3	2.8	11.1

[a] Percentages calculated out of the total number of patients in each population, not the number of patients who experienced disease progression.

2L second-line 3L+ third-line and beyond BRCAm BRCA-mutated BRCAwt BRCAwild-type HRd homologous recombination deficient HRp homologous recombination proficient Nir niraparib PARP poly(ADP-ribose) polymerase PBO placebo.

1. Monk BJ, et al. Niraparib first-line maintenance therapy in patients with newly diagnosed advanced ovarian cancer: final overall survival results from the PRIMA/ENGOT-OV26/GOG-3012 trial. Ann Oncol. 2024 Nov;35(11):981-992. & supplementary.

What Have We Learned from PRIMA?

- **Conclusions for PRIMA final analysis**

Median follow-up, 6.2 years

- **PRIMA enrolled patients with advanced high-grade serous/endometrioid OC at high risk for recurrence**
- **Sustained PFS benefit observed with niraparib with additional follow-up in the overall and HRd populations**
  - **Among patients who were alive at 5 years in the HRd population, those who received niraparib were twice as likely to be progression free as patients who received placebo (35% vs 16%)**
  - **Remaining progression free is critical to maintain health-related quality of life**
    No difference in OS between niraparib and placebo arms in overall population
- **No difference in OS between niraparib and placebo arms in overall population and by HRd status**
  - **3-fold higher subsequent PARP inhibitor use in placebo arm than niraparib arm across populations (HRd: 48.4% vs 15.8%)**
- **Long-term safety remained consistent with the identified safety profile of niraparib**
- **Long-term data support the benefit of niraparib as 1L maintenance therapy regardless of HRd status**

But do these benefits translate into routine clinical practice?

1L first-line HRD homologous recombination deficiency HRd homologous recombination deficient OC ovarian cancer OS overall survival PARP poly(ADP-ribose) polymerase PFS progression-free survival.

1. Monk BJ, et al. Niraparib first-line maintenance therapy in patients with newly diagnosed advanced ovarian cancer: final overall survival results from the PRIMA/ENGOT-OV26/GOG-3012 trial. Ann Oncol. 2024 Nov;35(11):981-992. & supplementary Appendix.

Quality-adjusted progression-free survival and quality-adjusted time without symptoms of disease or toxicity results from the PRIMA/ENGOT-OV26/GOG-3012 final analysis

QA-PFS and Q-TWiST results from PRIMA study

ESMO ANNALS OF ONCOLOGY DRIVING INNOVATION IN ONCOLOGY

ESMO Journals Articles Publish Topics Multimedia About Contact Subscribe

ABSTRACT ONLY · Volume 36, Supplement 2, S718-S719, September 2025

1070P Quality-adjusted progression-free survival (QA-PFS) and quality-adjusted time without symptoms of disease or toxicity (Q-TWiST) results from the PRIMA/ENGOT-OV26/GOG-3012 final analysis

H. Denys [1] · D.M. Chase [2] · B. Pardo Búrdalo [3] · ... · S. Kim [18] · A. González-Martín [19] · B.J. Monk [20] ... Show more

Quality-adjusted progression-free survival and quality-adjusted time without symptoms of disease or toxicity results from the PRIMA/ENGOT-OV26/GOG-3012 final analysis

- **Results (Long-term Benefit Beyond PFS: Quality-adjusted Survival)**
  - **The QA-PFS and Q-TWiST gains observed with niraparib treatment** in the primary analysis were extended in the final analysis

Comparison of QA-PFS and Q-TWiST outcomes in the primary and final analyses

	Restricted mean duration difference between niraparib and placebo (95% CI), mo	
	Primary analysis[6]	Final analysis
Overall[a]		
QA-PFS gain	4.1 (2.2, 5.8)	**7.9 (4.7, 11.4)**
Q-TWiST gain	3.5 (1.7, 5.6)	**9.0 (5.4, 13.4)**
HRd[b]		
QA-PFS gain	6.5 (3.9, 8.9)	**14.1 (8.5, 19.2)**
Q-TWiST gain	5.9 (3.5, 8.6)	**15.9 (9.3, 21.6)**
HRp[c]		
QA-PFS gain	1.2 (-1.0, 3.8)	2.2 (–1.8, 6.7)
Q-TWiST gain	1.5 (-0.6, 4.0)	2.7 (–1.8, 7.8)

[a]At 27.8 months for the primary analysis; 80.1 months for the final analysis.
[b]At 27.8 months for the primary analysis; 77.4 months for the final analysis.
[c]At 22.1 months for the primary analysis; 74.7 months for the final analysis.

HRd, homologous recombination-deficient; HRp, homologous recombination-proficient; QA-PFS, quality-adjusted profession-free survival; Q-TWiST, quality-adjusted time without symptoms of disease or toxicity.
Reference 1. H. Denys, et al. presented at 2025 EMSO Annual Meeting, Sep 2025 2. Barretina-Ginesta M-P, et al. Ther Adv Med Oncol. 2022;14:1–13.

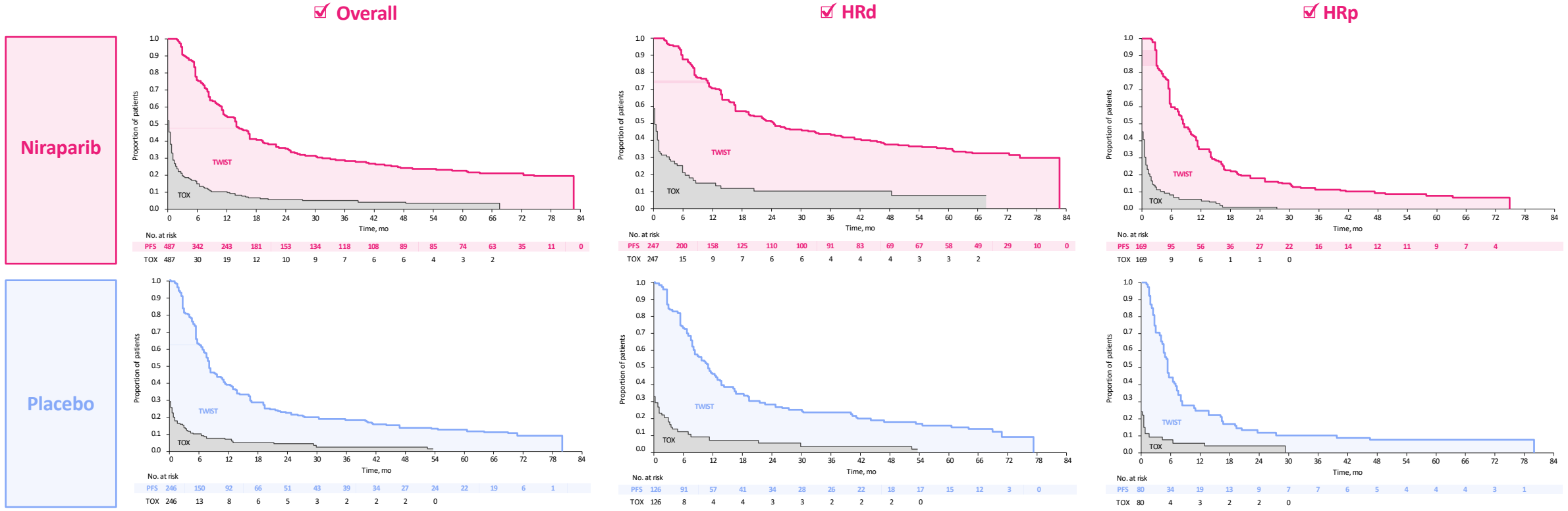
Quality-adjusted progression-free survival and quality-adjusted time without symptoms of disease or toxicity results from the PRIMA/ENGOT-OV26/GOG-3012 final analysis

- **Results**

Q-TWiST

- Partitioned survival curves for the overall, HRd, and HRp populations are shown in Figure

Partitioned survival curves



TOX included grade ≥2 AEs of interest (fatigue or asthenia, nausea, vomiting, abdominal pain, and abdominal bloating). Overall, HRd, and HRp populations had a maximum PFS of 80.1, 77.4, and 74.7 months, respectively.

AE, adverse event; HRd, homologous recombination-deficient; HRp, homologous recombination-proficient; PFS, progression-free survival; TOX, time before PFS during which patients experienced grade ≥2 AEs; TWiST, time without symptoms of disease or toxicity.

Reference 1. H. Denys, et al. presented at 2025 EMSO Annual Meeting, Sep 2025

Quality-adjusted progression-free survival and quality-adjusted time without symptoms of disease or toxicity results from the PRIMA/ENGOT-OV26/GOG-3012 final analysis

Conclusions

- In the PRIMA final analysis, **niraparib first-line maintenance treatment was associated with significant gains in restricted mean QA-PFS and Q-TWiST durations vs placebo in the overall, HRd, and HRp** populations
- Niraparib treatment gains for restricted mean duration of QA-PFS and Q-TWiST were extended from the primary to final analysis, likely because PFS gains were sustained with longer follow-up while the majority of treatment-emergent AEs occur within the first 3 months of niraparib treatment
- By integrating the quantity and quality of progression-free time, these findings further support the **clinical benefit of niraparib** versus placebo **for the maintenance treatment of patients with newly diagnosed advanced OC that responded to first-line platinum based chemotherapy**

AE, adverse event; HRd, homologous recombination-deficient; HRp, homologous recombination-proficient; PFS, progression-free survival; Q-TWiST, quality-adjusted time without symptoms of disease or toxicity; TOX, time before PFS during which patients experienced grade ≥2 AEs; TWiST, time without symptoms of disease or toxicity.

Reference 1. H. Denys, et al. presented at 2025 EMSO Annual Meeting, Sep 2025

From Clinical Trials to Real-World Practice

Real-world outcomes in patients with epithelial ovarian cancer who received first-line maintenance niraparib: final results from the 1NSPIRE chart review study

ESMO ANNALS OF ONCOLOGY DRIVING INNOVATION IN ONCOLOGY

ESMO Journals Articles Publish Topics Multimedia About Contact Subscribe

ABSTRACT ONLY · Volume 36, Supplement 2, S794-S795, September 2025

1227eP Real-world (rw) outcomes in patients (pts) with epithelial ovarian cancer (EOC) who received first-line maintenance (1LM) niraparib: Final results from the 1NSPIRE chart review study

F.B. Musa [1] · B.J. Rimel [2] · J. Lim [3] · ... · A. Golembesky [8] · P.H. Thaker [9] · L.M. Landrum [10] ... Show more

Real-world outcomes in patients with epithelial ovarian cancer who received first-line maintenance niraparib: final results from the 1NSPIRE chart review study

• Results_Patients

☑ All patients	☑ Patients with CR/PR to 1L PBCT
Age Median age, **67 y** (IQR, **60-73 y**) Age group at index: <75 y, **80.7%** ≥75 y, **19.3%**	**Age** Median age, **68 y** (IQR, **60–73 y**) Age group at index: <75 y, **79.8%** ≥75 y, **20.2%**
Race **12.4%** black/ African American/ other minority race **5.0%** Hispanic or Latino	**Race** **12.4%** Black/ African American/ other minority race **5.6%** Hispanic or Latino
Region **46.8%** Midwest **27.5%** South **25.7%** Northeast **0%** West	**Region** **49.4%** Midwest **26.4%** South **24.2%** Northeast **0%** West
Practice type **57.3%** Community based **38.1%** University based **3.7%** Both	**Practice type** **57.3%** Community based **37.6%** University based **4.5%** Both
Insurance type **25.2%** Employer based **51.8%** Medicare **22.9%** Other/ unknown/uninsured	**Insurance type** **21.9%** Employer based **56.2%** Medicare **21.9%** Other/ unknown/uninsured

Characteristic	All patients (N=218)	Patients with CR/PR to 1L PBCT (n=178)
ECOG PS at index		
0–1	192 (88.1)	156 (87.6)
2	7 (3.2)	5 (2.8)
Missing	19 (8.7)	17 (9.6)
Stage at initial diagnosis		
I-II	11 (5.0)	7 (3.9)
III	132 (60.6)	107 (60.1)
IV	39 (17.9)	33 (18.5)
Unknown	36 (16.5)	31 (17.4)
Histology		
Serous	194 (89.0)	158 (88.8)
Other[a]	24 (11.0)	20 (11.2)
Biomarker status		
HRd	**82 (37.6)**	**62 (34.8)**
***BRCA*m**	**24 (11.0)**	**21 (11.8)**
***BRCA*wt**	**49 (22.5)**	**35 (19.7)**
***BRCA* unknown**	**9 (4.1)**	**6 (3.4)**
HRp	57 (26.1)	47 (26.4)
*BRCA*wt/HRD status unknown	66 (30.3)	57 (32.0)
Both *BRCA* and HRD status unknown	13 (6.0)	12 (6.7)
Type of surgery		
PCS	85 (39.0)	66 (37.1)
ICS	110 (50.5)	96 (53.9)
No surgery	18 (8.3)	13 (7.3)
Unknown/missing	5 (2.3)	3 (1.7)
Residual disease status[b]		
Visible residual disease	45 (23.1)	35 (21.6)
No visible residual disease	114 (58.5)	96 (59.3)
Unknown/missing	39 (20.0)	33 (20.4)
Received 1L platinum-containing regimen	217 (99.5)	178 (100.0)
Received 1L bev-containing regimen	19 (8.7)	18 (10.1)
Follow-up time, median (IQR), mo	22.6 (16.1-33.5)	23.6 (16.4-33.8)

Values in table are n (%) unless noted otherwise.
[a]Other includes clear cell, mucinous, endometrioid, epithelial not otherwise specified, or unknown.
[b]Among patients who received cytoreductive surgery.

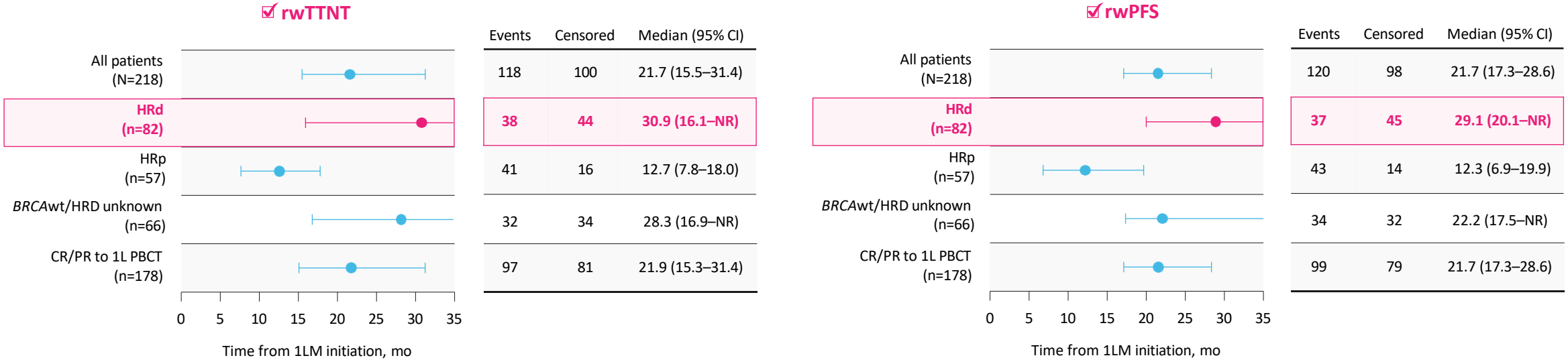
- **This final analysis included data from 218 patients across 18 US sites**
  – Median (IQR) follow-up time was 22.6 months (16.1–33.5 months)
- Overall, 178 patients (81.7%) had a CR/PR to 1L PBCT, and 31 (14.2%) had stable disease
- Demographic and clinical characteristics were similar between the overall patient population and the subgroup of patients with a CR/PR
- Overall, **37.6% of patients had HRd, 26.1% had HRp, and 30.3% had BRCAwt/HRD status unknown**
  – Both BRCA and HRD status were unknown for 6.0% of patients overall

1L, first-line; bev, bevacizumab; BRCAm, BRCA-mutated; BRCAwt, BRCA wild-type; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; HRD, homologous recombination deficiency; HRd, homologous recombination deficient; HRp, homologous recombination proficient; ICS, interval cytoreductive surgery; PBCT, platinum-based chemotherapy; PCS, primary cytoreductive surgery; PR, partial response.
Reference 1. F. B. Musa, et al. presented at 2025 EMSO Annual Meeting, Sep 2025

Real-world outcomes in patients with epithelial ovarian cancer who received first-line maintenance niraparib: final results from the 1NSPIRE chart review study

- **Results**
  - Overall, the observed median rwTTNT and rwPFS were both 21.7 months for all patients (Figure 3)
  - **When examining real-world outcomes by biomarker subgroup, the longest observed median rwTTNT and rwPFS were among patients with HRd status**
  - Observed median rwTTNT and rwPFS among patients in the subgroup of patients with CR/PR to 1L PBCT were similar to those in the overall population

Real-world outcomes among all patients, stratified by biomarker status, and among patients with CR/PR to 1L PBCT



1LM, first-line maintenance; BRCAwt, BRCA wild-type; CR, complete response; HRD, homologous recombination deficiency; HRd, homologous recombination deficient; HRp, homologous recombination proficient; NR, not reached; PBCT, platinum-based chemotherapy; PR, partial response; rwPFS, real-world progression-free survival; rwTTNT, real-world time to next treatment.

Reference 1. F. B. Musa, et al. presented at 2025 EMSO Annual Meeting, Sep 2025

Real-world outcomes in patients with epithelial ovarian cancer who received first-line maintenance niraparib: final results from the 1NSPIRE chart review study

• Conclusions

- **Real-world outcomes aligned with expectations for key biomarker subgroups, with numerically longer rwTTNT and rwPFS observed in the HRd subgroup** versus the overall population

- For patients with advanced EOC receiving 1LM niraparib monotherapy in routine clinical practice, real-world outcomes exceeded expectations based on the PRIMA trial results. This was true in all biomarker subgroups, including patients with HRp status
  - This finding may be due to:
    · The inclusion of patients with stage III EOC and no visible residual disease in the 1NSPIRE study
    · Clinicians' ability to identify those most likely to benefit from niraparib in routine clinical practice

- Compared with all patients, **baseline demographic and clinical outcomes were similar in the subgroup of patients with a CR or PR to 1L PBCT**

Reference 1. F. B. Musa, et al. presented at 2025 EMSO Annual Meeting, Sep 2025

04

Real-World Evidence with Niraparib in Korea

Real-world clinical study

REFIRM

PI : Jeong-Yeol Park, Asan Medical Center

The **R**eal world **E**fficacy and sa**F**ety of n**I**rapa**R**ib in Korean women with pri**M**ary and recurrent epithelial ovarian cancer, (Multicenter, retrospective cohort and chart-review study)

- **Objective:**
  - ✓ To evaluate the efficacy and safety of niraparib in Korean women with primary and recurrent epithelial ovarian cancer who underwent niraparib maintenance therapy
  - ✓ To evaluate the efficacy and safety of salvage niraparib therapy in Korean women with heavily pretreated epithelial ovarian cancer.

Observation cohort

Cohort A (n=682)

Who did not receive any kind of maintenance therapy for primary epithelial ovarian cancer

Treatment cohort

Epithelial ovarian cancer patients who treated with **Niraparib**

Cohort B (n=281)

niraparib maintenance therapy for Primary epithelial ovarian cancer in **1st line** setting

Cohort C (n=184)

niraparib maintenance therapy for recurrent epithelial ovarian cancer in **2nd or 3rd** line setting.

Cohort D (n=73)

salvage niraparib therapy for recurrent epithelial ovarian cancer in **4th line or more** line setting

Endpoint

- Primary : PFS
- Secondary : Safety, OS

PFS, progression-free survival; OS, overall survival

https://classic.clinicaltrials.gov/ct2/show/NCT06086665 accessed on 27 Jan 204

Study Background

- It has been three years since niraparib was introduced into Korea, and about 600 Korean patients with epithelial ovarian cancer have been treated with this drug.
- The efficacy and safety of niraparib in primary and recurrent epithelial ovarian cancer were well demonstrated in the NOVA trial and the PRIMA trial, and the efficacy and safety of niraparib in heavily pretreated epithelial ovarian cancer patients were confirmed in the -QUADRA trial.
- However, safety and efficacy data in Korean women are still scanty.
- The purpose of this study was to evaluate the safety and efficacy of niraparib in Korean women with primary and recurrent epithelial ovarian cancer.

Study Institutions and Study Period

- Study Institutions : 9 tertiary centers in Korea
  - Asan Medical Center
  - National Cancer Center
  - Seoul St. Mary’s Hospital
  - Seoul National University Hospital
  - Samsung Medical Center
  - Severance Hospital
  - Keimyung University Hospital
  - Pusan National University Hospital
- Study Period
  - Clinicopathologic data were gathered from patient who treated **between December 2019 and October 2022**.

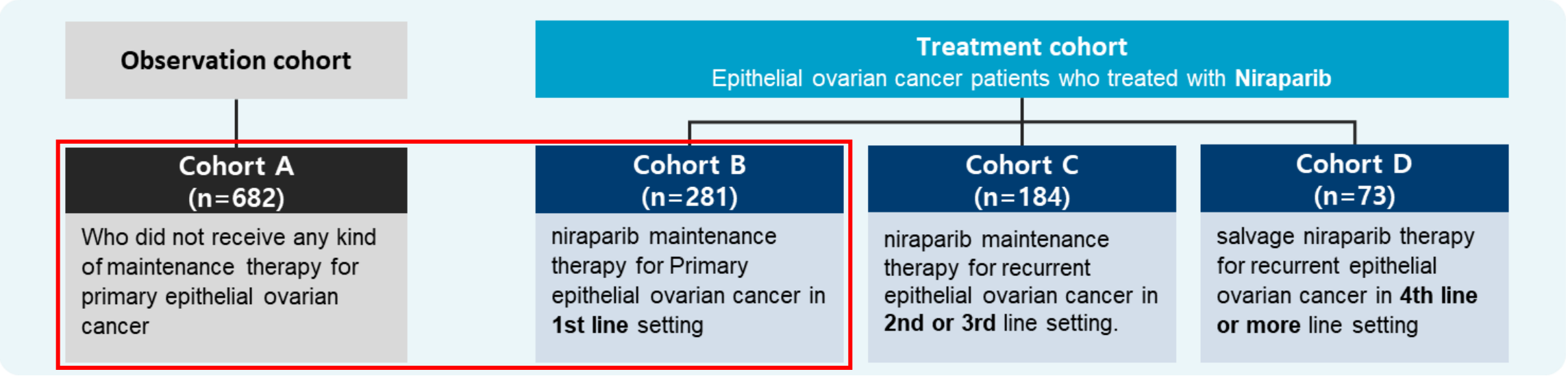
REFIRM Study : Cohort A & B

Cohort A &B

REFIRM

PI : Jeong-Yeol Park, Asan Medical Center

The **R**eal world **E**fficacy and sa**F**ety of n**I**rapa**R**ib in Korean women with pri**M**ary and recurrent epithelial ovarian cancer, (Multicenter, retrospective cohort and chart-review study)



Inclusion Criteria

- Histologically confirmed primary epithelial ovarian, fallopian tube, or primary peritoneal cancer with known germline and/or somatic BRCA mutation status who completed first-line platinum-based chemotherapy and showed partial or complete response between December 2019 and October 2022
- Cohort A : patients who received first-line maintenance niraparib

  Cohort B : Patients who did not receive any maintenance therapy

Statistical Analysis

- **Unmatched overall cohort**
  - Baseline characteristics were compared between groups using the chi-square or Fisher’s exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables.
  - PFS and OS were estimated using the Kaplan–Meier method and compared between groups using the log-rank test.
- **Matched cohort**
  - To reduce potential confounding, 1:1 propensity score matching (PSM) was performed using the nearest-neighbor algorithm with a caliper of 0.4, implemented via the MatchIt package in R (version 4.5.0).
  - Matching was based on age at diagnosis, receipt of neoadjuvant chemotherapy, and BRCA mutation status.

Unmatched Overall Cohort : Baseline Characteristics

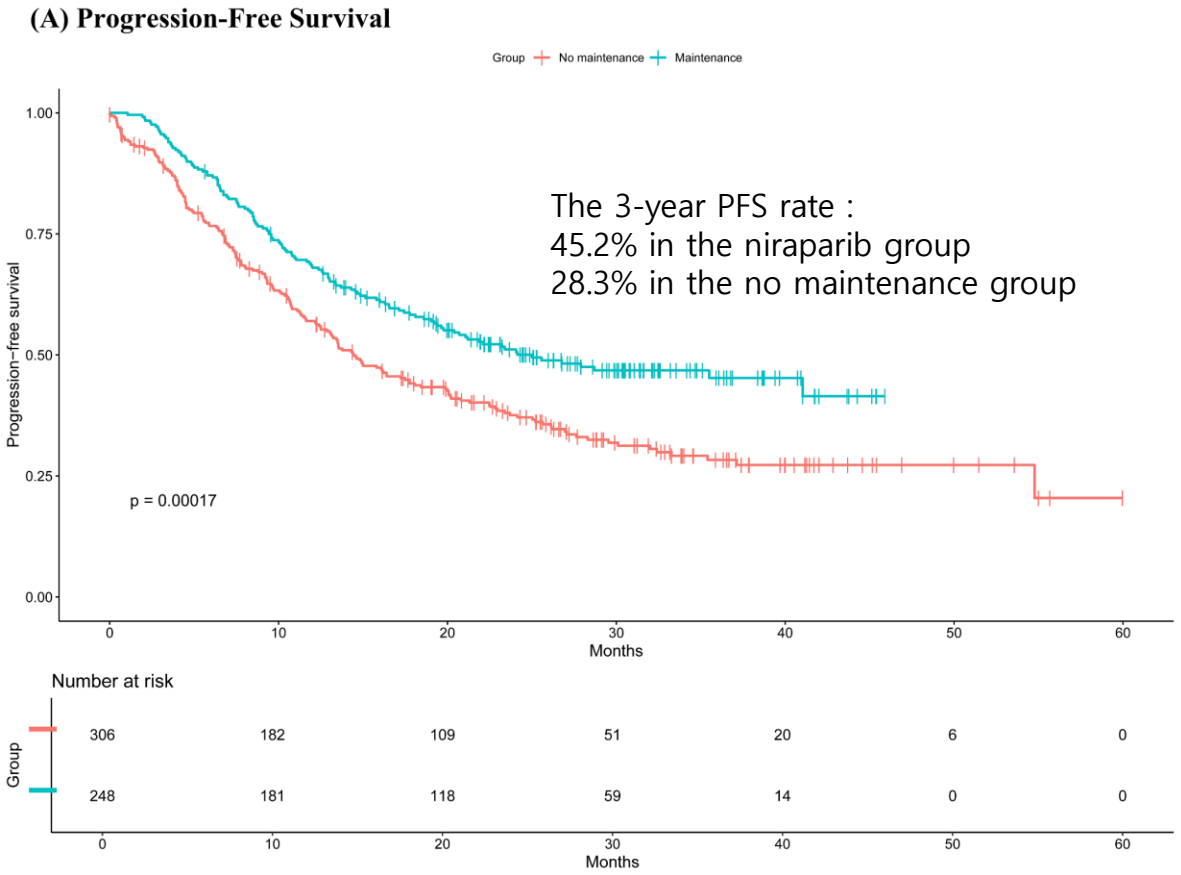
Characteristics	No Maintenance (n = 306)	Niraparib (n =248)	P
Age			
median (range)	59 (19–85)	56 (33–91)	0.01
Histology			0.009
Serous	264 (86.3%)	230 (92.7%)	
Endometrioid	14 (4.6%)	12 (4.8%)	
Clear cell	15 (4.9%)	6 (2.4%)	
Mixed	12 (3.9%)	0 (0.0%)	
Others†	1 (0.3%)	0 (0.0%)	
Stage			0.18
Stage III			
A	33 (10.8%)	18 (7.3%)	
B	25 (8.2%)	16 (6.5%)	
C	136 (44.4%)	103 (41.5%)	
Stage IV	112 (36.6%)	111 (44.8%)	
Reciept of neoadjuvant chemotherapy			0.012
No	207 (67.6%)	141 (56.9%)	
Yes	99 (32.4%)	107 (43.1%)	
Outcomes of cytoreductive surgery (n,%)			
Primary cytoreductive surgery			0.21
Complete	150 (72.5%)	93 (66.0%)	
Optimal (Residual < 1cm)	34 (16.4%)	34 (24.1%)	
Suboptimal (Residual ≥ 1cm)	23 (11.1%)	14 (9.9%)	
Interval debulking surgery			0.099
Complete	63 (63.6%)	74 (69.2%)	
Optimal (Residual < 1cm)	26 (26.3%)	30 (28.0%)	
Suboptimal (Residual ≥ 1cm)	10 (10.1%)	3 (2.8%)	
No. of cycles of platinum-based CTx			0.042
6	226 (73.9%)	175 (70.6%)	
7-9	54 (17.6%)	62 (25.0%)	
10-12	9 (2.9%)	6 (2.4%)	
others††	17 (5.6%)	5 (2.0%)	
Response to platinum-based CTx			0.96
Complete response	239 (78.1%)	195 (78.6%)	
Partial response	67 (21.9%)	53 (21.4%)	
BRCA status†††			< 0.001
Mutated	44 (15.1%)	100 (40.3%)	
Wild type	247 (84.9%)	148 (59.7%)	

Patients in the niraparib group were

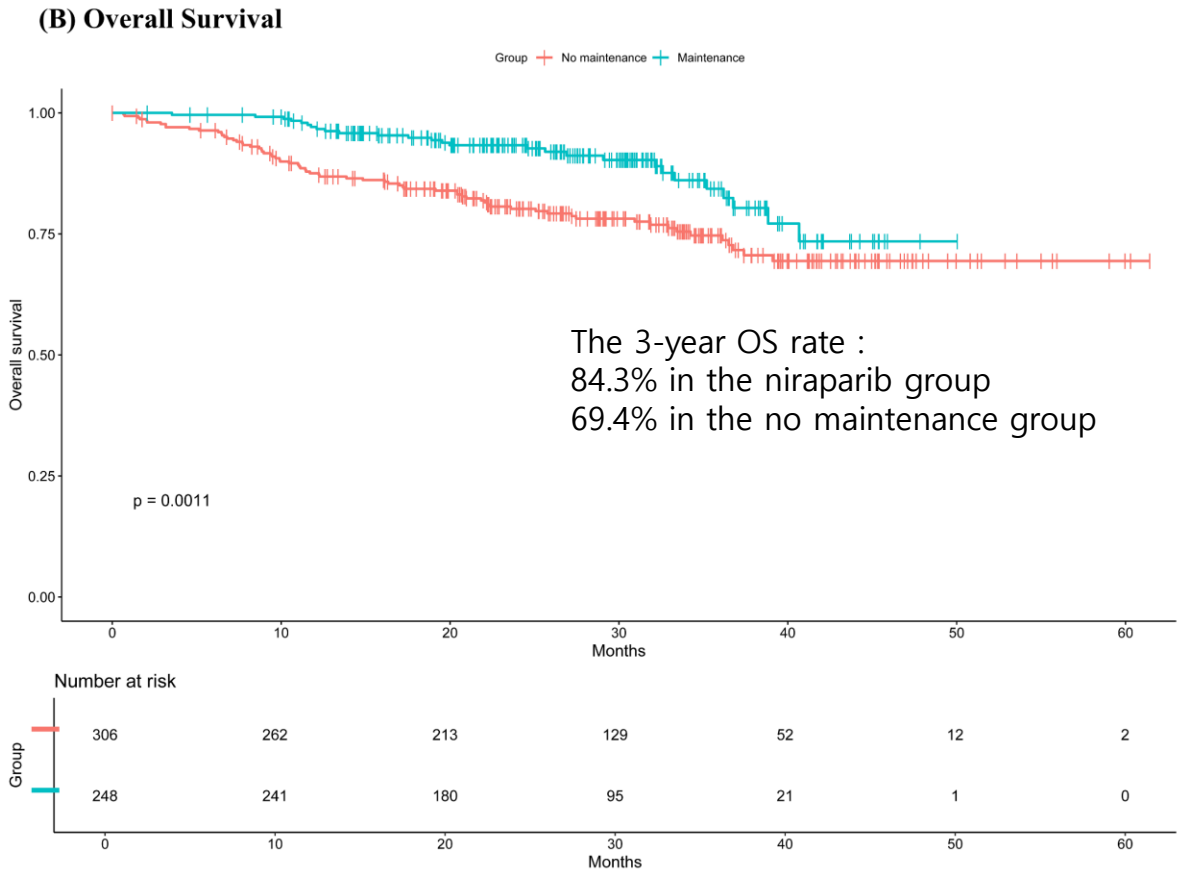
- younger (median age 56 vs. 59 years, p = 0.01),
- had a higher proportion of serous histology (92.7% vs. 86.3%, p = 0.009),
- were more likely to receive neoadjuvant chemotherapy (43.1% vs. 32.4%, p = 0.012),
- and had a higher prevalence of BRCA mutations (40.3% vs. 15.1%, p < 0.001).

Values are mean ± standard deviation or number (%).
BMI, body mass index; CA-125, cancer antigen 125; CTx, chemotherapy;
† Others: Poorly differentiated squamous cell carcinoma, ovarian origin
†† Others includes 3, 4, 5, 13, and 15 cycles of platinum-based chemotherapy.
††† BRCA testing was not performed in 15 patients in the no adjuvant group.

Unmatched Overall Cohort : PFS & OS



The 3-year PFS rate :
45.2% in the niraparib group
28.3% in the no maintenance group



The 3-year OS rate :
84.3% in the niraparib group
69.4% in the no maintenance group

The median duration of follow-up : 26.6 months, 26.3 months, and 26.6 months for all patients, niraparib maintenance group, and no maintenance group

Matched Cohort : Baseline Characteristics

Characteristics	No maintenance (n = 189)	Niraparib (n =189)	P
Age			
median (range)	57 (35–81)	56 (35–81)	0.58
Histology			0.13
Serous	168 (88.9%)	175 (92.6%)	
Endometrioid	9 (4.8%)	8 (4.2%)	
Clear cell	9 (4.8%)	6 (3.1%)	
Mixed	3 (1.6%)	0 (0.0%)	
Stage			0.085
Stage III	122 (64.6%)	104 (55.0%)	
A	20 (10.6%)	9 (4.8%)	
B	12 (6.3%)	10 (5.2%)	
C	90 (47.6%)	85 (45.0%)	
Stage IV	67 (35.4%)	85 (45.0%)	
Reciept of neoadjuvant chemotherapy			0.53
No	118 (62.4%)	111 (58.7%)	
Yes	71 (37.6%)	78 (41.3%)	
Outcomes of cytoreductive surgery (n,%)			
Primary debulking surgery			0.12
Complete	89 (75.4%)	72 (64.98%)	
Optimal (Residual < 1cm)	17 (14.4%)	28 (25.2%)	
Suboptimal (Residual ≥ 1cm)	12 (10.2%)	11 (9.9%)	
Interval debulking surgery			0.49
Complete	47 (66.2%)	55 (70.5%)	
Optimal (Residual < 1cm)	18 (25.4%)	20 (25.6%)	
Suboptimal (Residual ≥ 1cm)	6 (8.5%)	3 (3.8%)	
No. of cycles of platinum-based CTx			0.32
6	144 (76.2%)	136 (72.0%)	
7-9	40 (21.2%)	48 (25.4%)	
10-12	5 (2.6%)	3 (1.6%)	
others†	0 (0.0%)	2 (1.1%)	
Response to platinum-based CTx			0.80
Complete response	147 (77.8%)	150 (79.3%)	
Partial response	42 (22.2%)	39 (20.6%)	
BRCA status			0.08
Mutated	42 (22.2%)	58 (30.7%)	
Wild type	147 (77.7%)	131 (69.3%)	

To address baseline imbalances between treatment groups, propensity score matching was performed using age at diagnosis, receipt of neoadjuvant chemotherapy, and BRCA mutation status as matching variables.

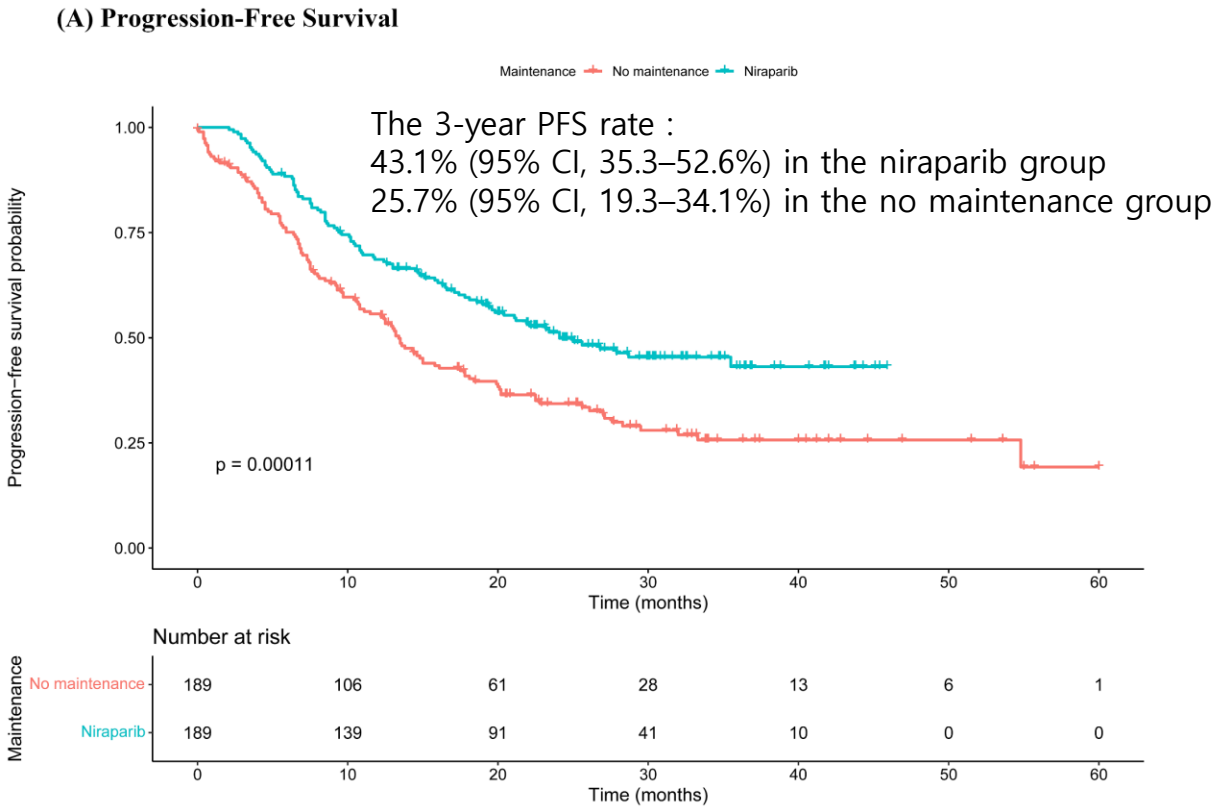
A caliper width of 0.4 was selected based on preliminary matching assessments.

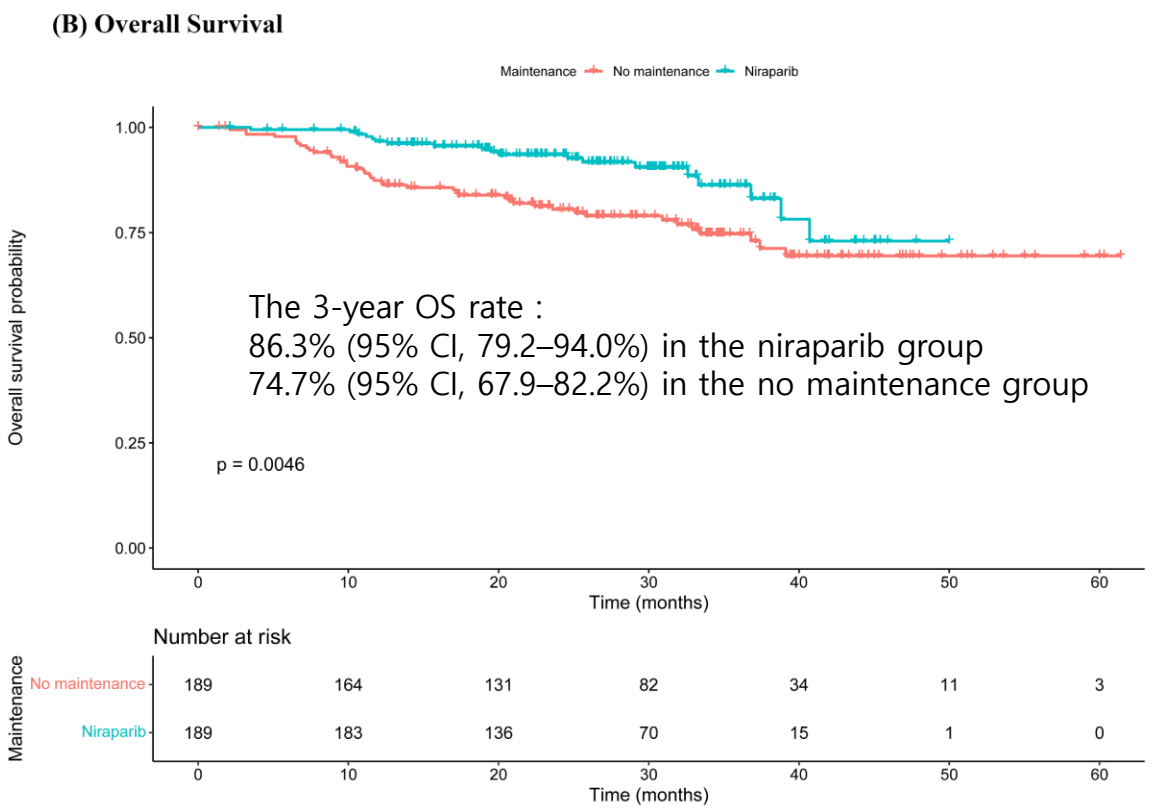
Values are mean ± standard deviation or number (%).
BMI, body mass index; CA-125, cancer antigen 125; CTx, chemotherapy;
†Others includes 5, and 13 cycles of platinum-based chemotherapy.

Matched Cohort : BRCA Mutation Status

Characteristics	No maintenance (n =189)	Niraparib (n =189)
No. of patients who underwent BRCA test (%)		
Germline BRCA	79 (41.8%)	58 (30.7%)
Somatic BRCA	3 (5.9%)	22 (11.6%)
Germline & Somatic BRCA	107 (56.6%)	109 (57.7%)
BRCA status (n%)		
BRCA wildtype	147 (77.7%)	131 (69.3%)
BRCA1 mutation	30 (15.9%)	27 (14.3%)
BRCA2 mutation	11 (5.8%)	31 (16.4%)
BRCA1&2 mutation	1 (0.5%)	0 (0.0%)

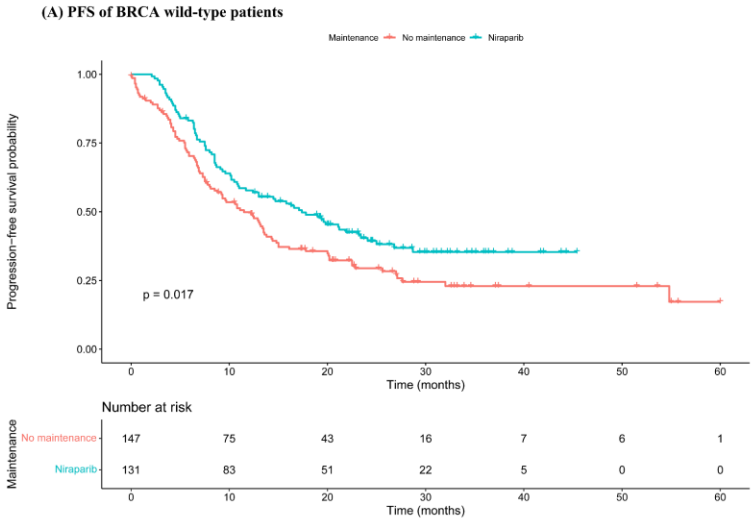
Matched Cohort : PFS & OS

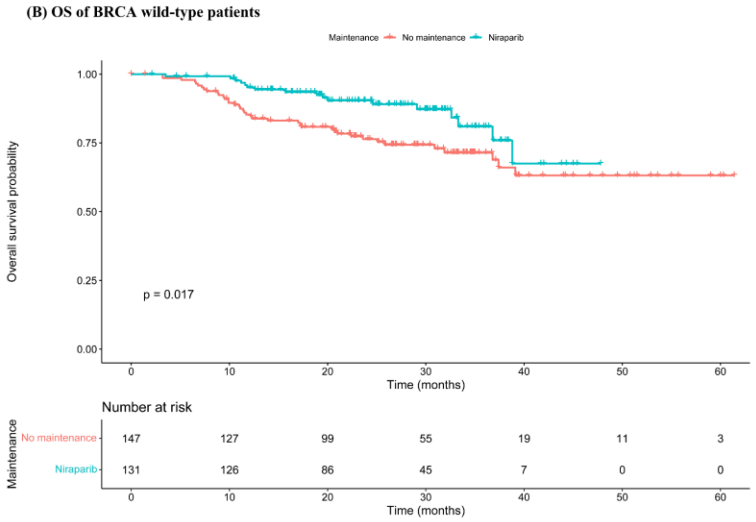


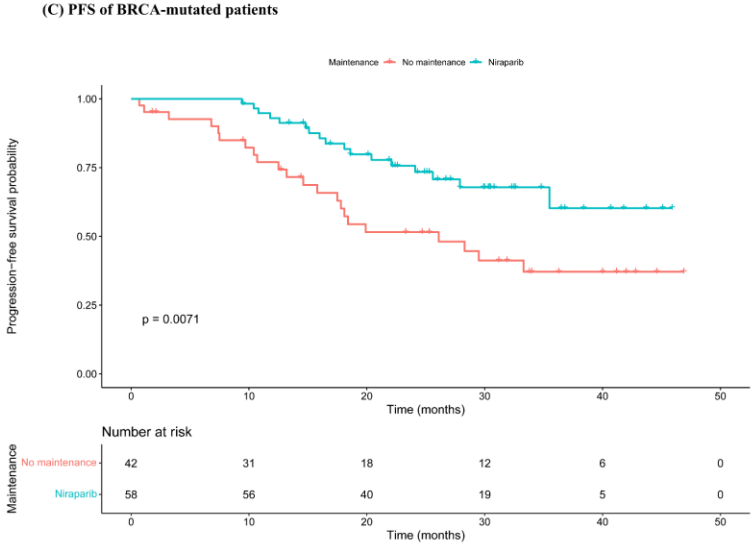


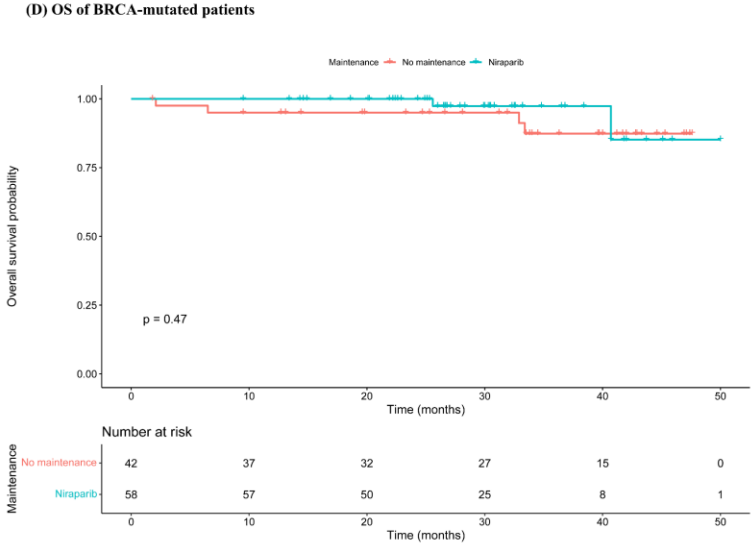
The median duration of follow-up : 26.5 months, 26.3 months, and 26.6 months for all patients, niraparib maintenance group, and no maintenance group

Matched Cohort : PFS & OS according to BRCAm status









Conclusion in Cohort A & B

- This real-world study supports the clinical effectiveness of first-line niraparib maintenance therapy in Korean women with advanced epithelial ovarian cancer.
- Niraparib was associated with prolonged progression-free survival compared with no maintenance therapy, with consistent benefit observed in both BRCA-mutated and BRCA wild-type patients.
- An overall survival benefit was also observed in the matched overall population and was particularly evident among patients with BRCA wild-type tumors with minimal crossover to post-progression PARPi.

CASES REVIEW

CASE I, high risk HRD +

- F/56, Ov cancer, HGSC Stage IIIC
  <<Steroid allergy : 근이완제 사용불가>>

- 2024' NAC Paclitaxel/Carbo #3
- 2024.9 : IDS ➔ not R0
- 2024.11 : Paclitaxel/Carbo #3

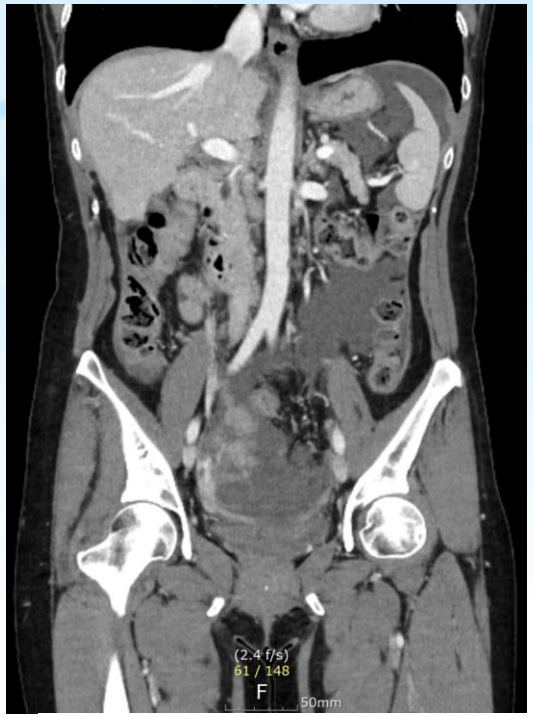
- CA125 : 13, AP-CT : PR

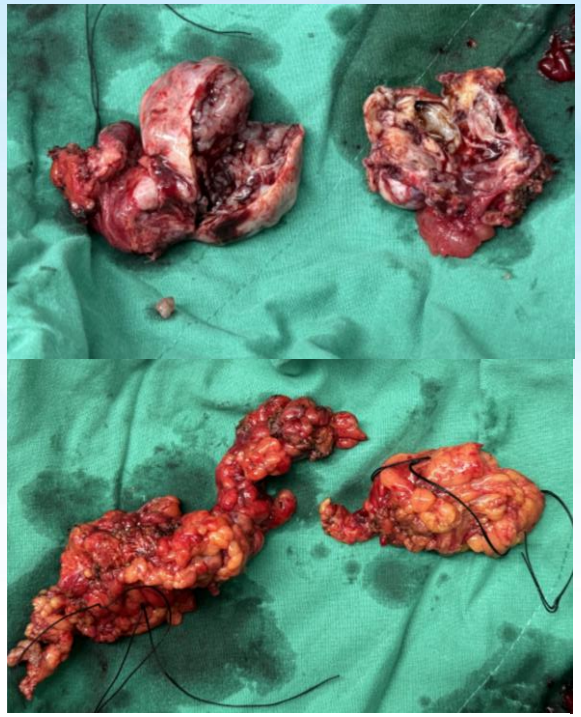
➔ tissue ***BRCA*^{wild}, HRD(GIS 45)**
➔ Niraparib start

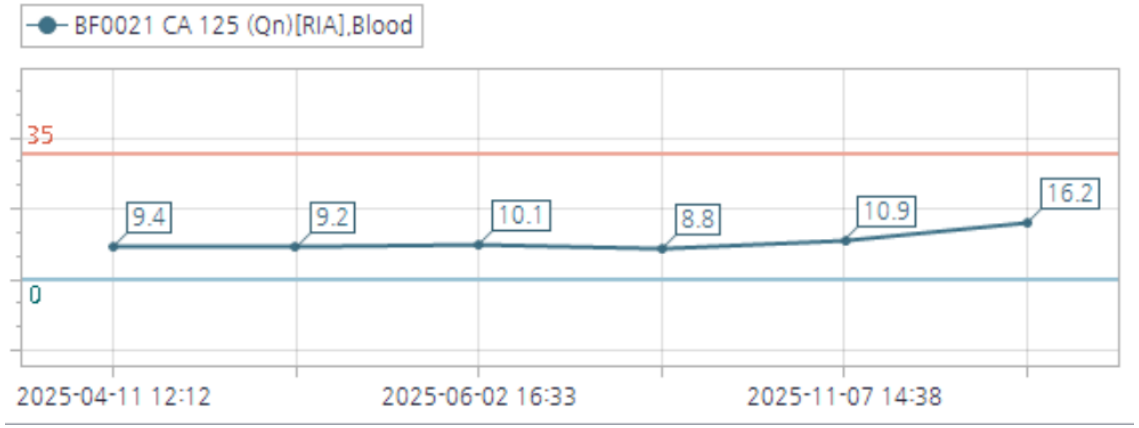
<< 1Y 6Mo >> stable status

2026.3 : peritoneal recurrence

➔ OP X, 2nd T/C/bev #5







CASE II, high risk *BRCA*m/HRD +

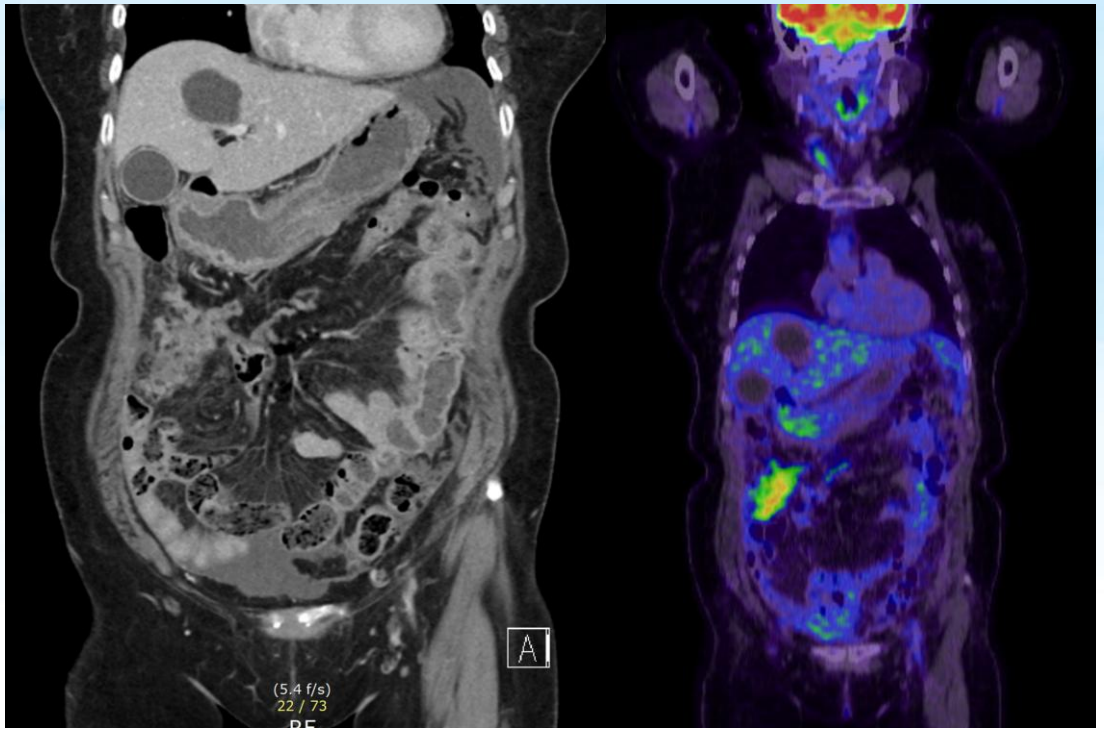
- **F/72, PPSC, HGSC Stage IIIC**

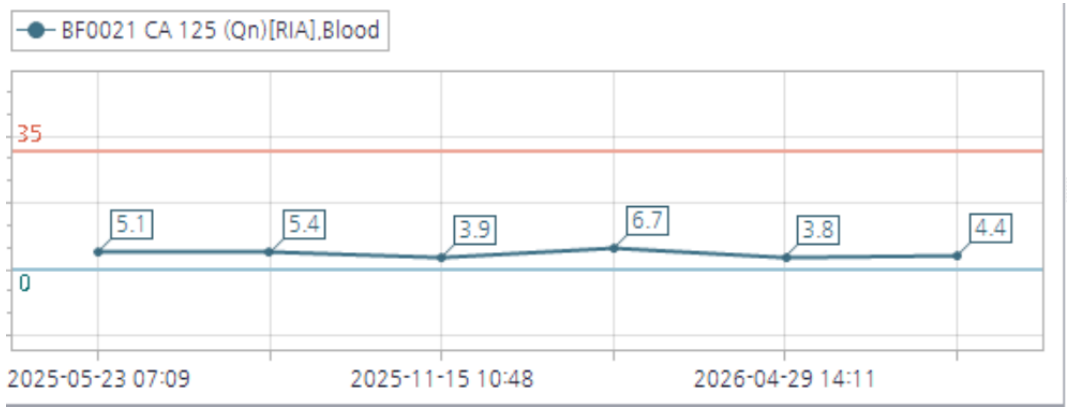
- **2024' NAC Paclitaxel/Carbo #3**
- **2024.8 : IDS with GS CO-OP (Rt. Hemi-colectomy) : PCI 16 ➔ R0**
- **2024.11 : Paclitaxel/Carbo #3**

- **CA125 : 8, AP-CT : CR**

➔ **tissue *BRCA*^{mut}, HRD(GIS 74)**
➔ **Niraparib start**

NED until now <<1Y 8Mo>>





CASE III, high risk *BRCA* -/HRD +

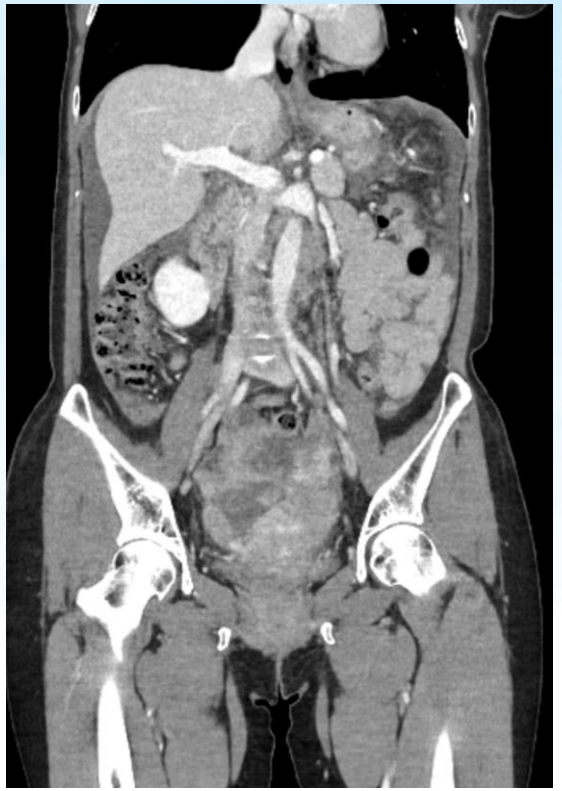
- F/52, OV CA, HGSC Stage IVB
  Lt SCLN, cardiphrenic LN +

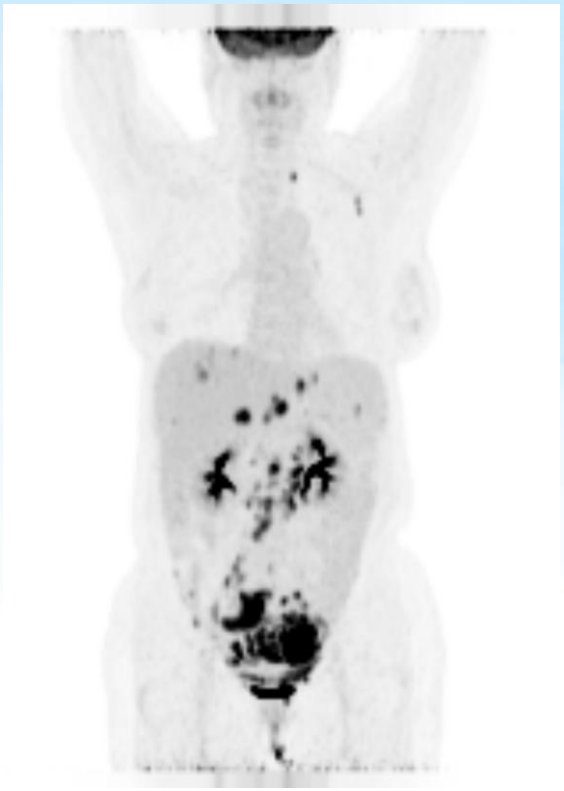
- 2026.3 : NAC Paclitaxel/Carbo #3
- 2026.5 : IDS ➔ R1
- 2026.7 : Paclitaxel/Carbo #3

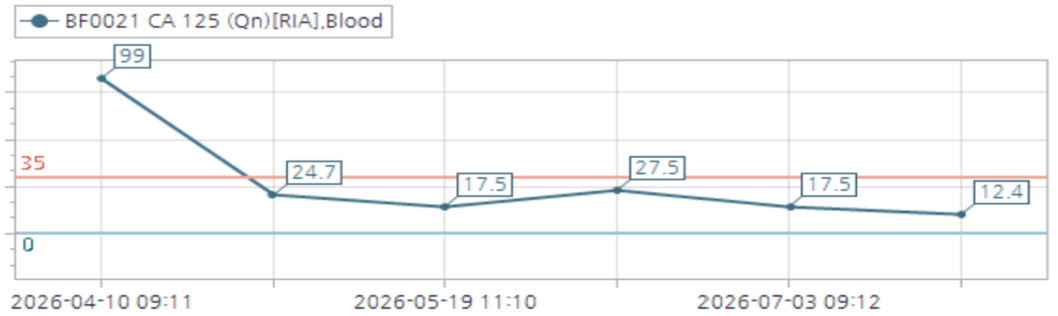
- CA125 : 12, AP-CT : PR

➔ g*BRCA* -/-, HRD +, HER2 3+
➔ PRIMA VS PAOLA1

➔ maintenance niraparib 예정







CASE IV, high risk HRP

- F/68, Tubal CA, HGSC, Stage IIIC

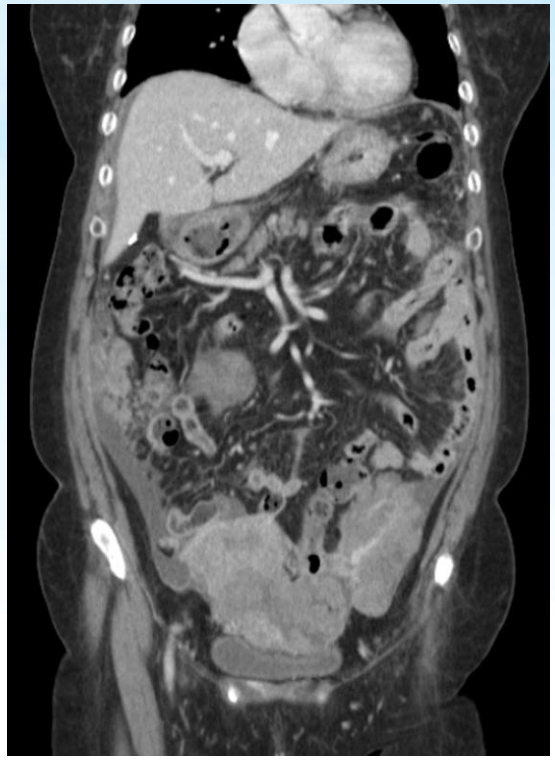
- 2025.10 : NAC Paclitaxel/Carbo #3
- 2025.12 : IDS with LAR (GS CO-OP)
  ➔ R0
- 2026.3 : Paclitaxel/Carbo #3

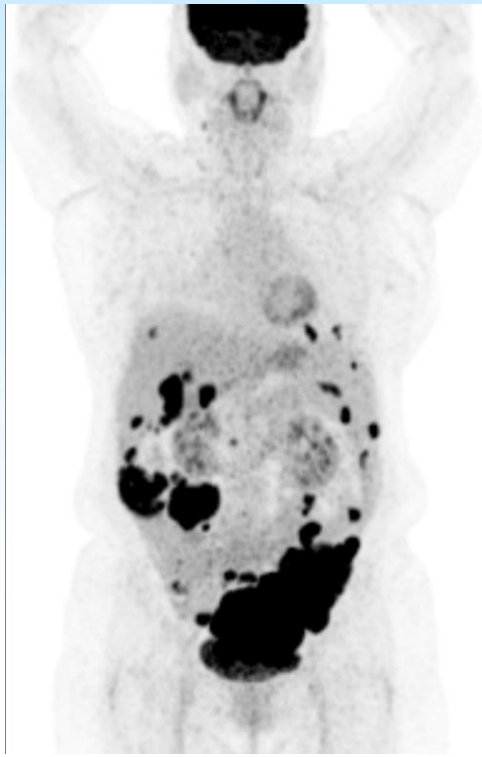
- CA125 : 7, AP-CT : CR

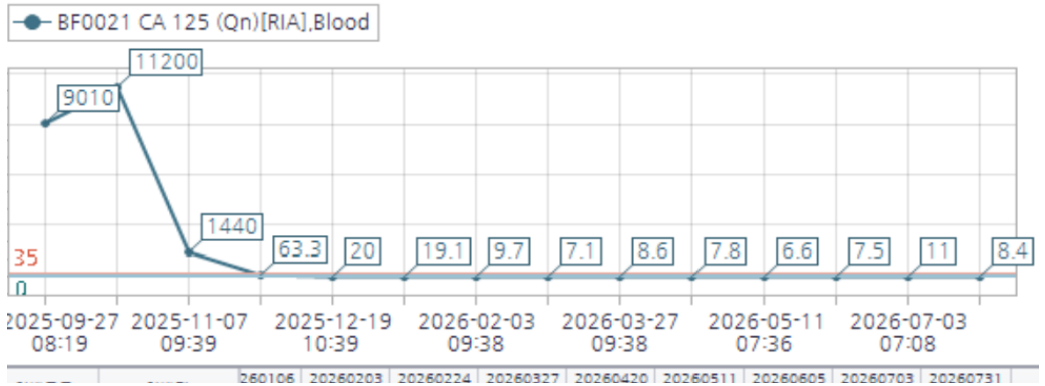
Results:
- HRD (상동재조합결핍): 음성 (score: 41)
- BRCA 변이: 음성 (25-11-18)

➔ gBRCA -/-, HRD – (GIS 41)

➔ maintenance niraparib 진행







CASE V, Low grade serous, HRD +

- F/58, Ovary CA, Low grade serous, Stage IIIC

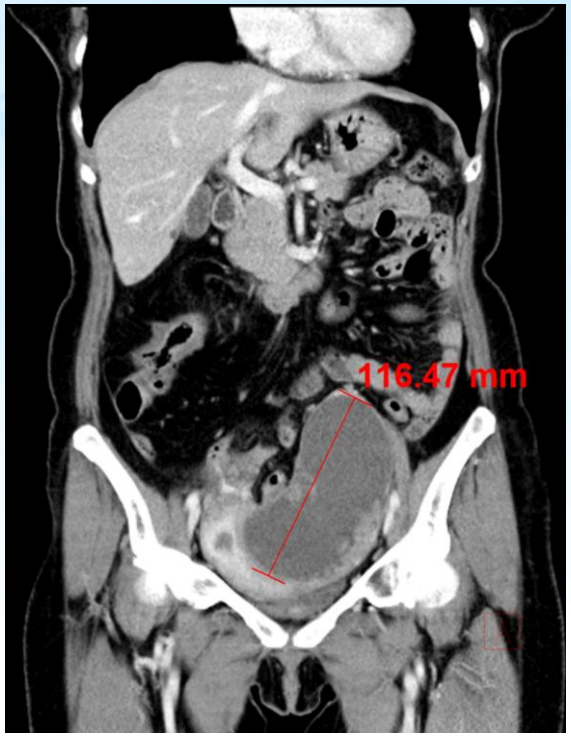
- Intestinal TBc medication
- 2025.12 : PDS with LAR (GS CO-OP) ➔ R0
- 2026.4 : Paclitaxel/Carbo #6

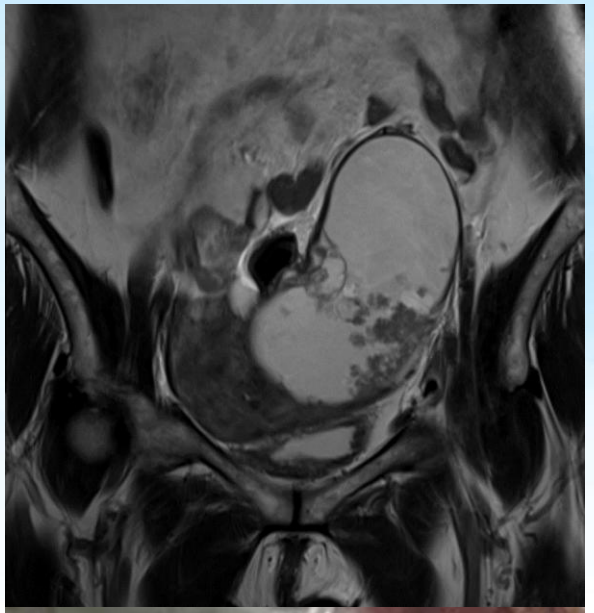
- CA125 : 7, AP-CT : CR

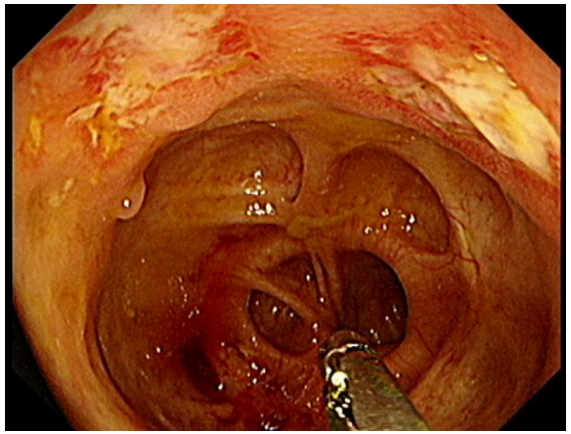
➔ **Initial plan : maintenance hormone therapy (aromatase inhibitor)**

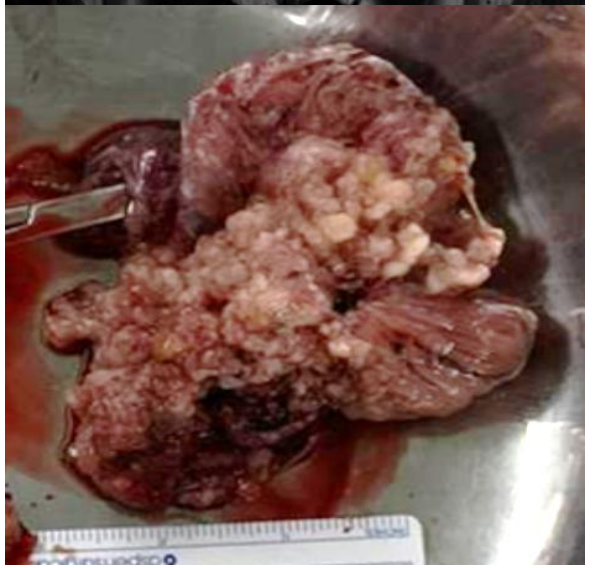
Tissue BRCA -/- HRD + (GIS 52) MMRp HER2 2+

➔ maintenance niraparib start









Advantages of ZEJULA® (niraparib)

ZEJULA ®

ZEJULA®는 바이오마커에 상관 없이 모든 난소암 환자에서 사용이 가능하며,
난소암 1차 단독 유지요법으로 유일하게 *BRCA*m, HRd/*BRCA*wt 환자 모두에서 급여가 가능한 PARP 억제제입니다.†

↳ 제줄라® 투여 가능 환자[1,2]

	HRd		HRp
	*BRCA*m	*BRCA*wt	*BRCA*wt
1차 단독 유지요법 (백금기반요법에 반응)	☑	☑	✓
2차 이상 단독 유지요법 (백금기반요법에 반응)	☑	✓	✓

☑ 보험급여 대상 환자 ✓ 국내 허가받은 적응증

† As of Apr 2026
1. 제줄라® 정 국내 허가사항. https://nedrug.mfds.go.kr/pbp/CCBBB01/getItemDetailCache?cacheSeq=202401351aupdateTs2026-02-13%2011:32:57.0b Accessed in Apr 2026 2. 건강보험심사평가원 공고 제2024-129호(시행일: 2024년 10월 1일)

ZEJULA®

ZEJULA®는 바이오마커에 상관 없이 모든 난소암 환자에서 사용이 가능하며, 난소암 1차 단독 유지요법으로 유일하게 *BRCA*m, HRd/*BRCA*wt 환자 모두에서 급여가 가능한 PARP 억제제입니다.†

국내 허가된 PARP 억제제 1차 치료 시 급여조건 비교[1,2]

항암요법	제줄라®	A
투여대상	1차 백금기반요법에 반응(CR 또는 PR)한 진행성 **상동재조합결핍 양성(*BRCA* 변이 또는 유전체 불안정성)** 상피성 난소암, 난관암, 일차 복막암 # 유지요법 시행 직전 투여된 백금기반요법은 bevacizumab 포함 요법을 제외하며, 이전에 PARP 억제제를 투여받은 적이 없어야 함.	1차 백금기반요법에 반응(CR 또는 PR)한 진행성 *BRCA* 변이 **고도 상피성** 난소암, 난관암, 일차 복막암 # 유지요법 시행 직전 투여된 백금기반요법은 bevacizumab 포함 요법을 제외하며, 이전에 PARP 억제제를 투여받은 적이 없어야 함.
투약기간	백금계 항암제 완료 후 **12주 이내 투여**	백금계 항암제 완료 후 **8주 이내 투여**
급여 인정 기간	**제한 없음**	최초 투여 후 **2년까지**

† As of Apr 2026

1. 제줄라® 정 국내 허가사항. https://nedrug.mfds.go.kr/pbp/CCBBB01/getItemDetailCache?cacheSeq=202401351aupdateTs2026-02-13%2011:32:57.0b Accessed in Apr 2026
2. 건강보험심사평가원 공고 제2024-129호(시행일: 2024년 10월 1일)

Thank you for your attention

• **제품관련 의약정보(학술)문의 |** Tel: 080 908 0971 / e-mail: medinfoAPAC@takeda.com
• **이상사례보고 |** AE.SouthKorea@takeda.com

▲제줄라캡슐 100mg ▲제줄라정 100mg

제줄라® 제품 정보

제줄라 제품설명서 전문은 식약처 의약품안전나라의 제품허가사항 또는 QR 코드를 참고하시기 바랍니다.