ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

EFFICACY OF MIRVETUXIMAB SORAVTANSINE IN FOLATE RECEPTOR ALPHA HIGH, PLATINUM-RESISTANT OVARIAN CANCER BY TYPE AND NUMBER OF PRIOR TREATMENT REGIMENS: AN EXPLORATORY ANALYSIS

Toon Van Gorp[1], Renaud Sabatier[2], Gottfried E. Konecny[3], Dominique Berton[4], Gordon Jayson[5], Sandro Pignata[6], Shibani Nicum[7], Nicoletta Colombo[8], John Moroney[9], Lainie P. Martin[10], Jung-Yun Lee[11], Andrzej Roszak[12], Shani Breuer[13], Ingrid Boere[14], Petronella B. Ottevanger[15], Olivier Tredan[16], Sophie Abadie Lacourtoisie[16], Diane Provencher[17], Laura Farrelly[18], Lucy Mcavan[19], Charles A. Leath III[20], Yuemei Wang[21], Michael Method[21], Domenica Lorusso[22], Kathleen N. Moore[23]

[1]University Hospital Leuven Leuven Cancer Institute, Leuven, Belgium; [2]Institut Paoli Calmettes, Marseille, France; [3]UCLA Jonsson Comprehensive Cancer Center, Los Angeles, CA, USA; [4]Institut de Cancérologie de l'Ouest, Centre René Gauducheau, Saint Herblain, France; [5]The Christie, Manchester, United Kingdom; [6]Istituto Nazionale Tumori- G. Pascale, Naples, Italy; [7]University College of London, London, United Kingdom; [8]European Institute of Oncology IRCCS, Milan, Italy and University of Milan-Bicocca, Milan, Italy; [9]The University of Chicago, Chicago, IL, USA; [10]University of Pennsylvania Penn Medicine, Philadelphia, PA, USA; [11]Severance Hospital, Seoul, South Korea; [12]Wielkopolskie Centrum Onkologii, Poznan, Poland; [13]Hadassah Ein Kerem – Sharett, Jerusalem, Israel; [14]Erasmus Medical Center, Rotterdam, The Netherlands; [15]Radboud UMC, Nijmegen, The Netherlands; [16]Institut de Cancérologie de l'Ouest, Centre Paul Papin, Angers, France; [17]University of Montreal Hospital Center, Montreal, Canada; [18]University College of London, London, United Kingdom; [19]University Hospitals Coventry and Warwickshire NHS Trust, Conetry, United Kingdom; [20]University of Alabama, Birmingham, AL, USA; [21]ImmunoGen, Inc., Waltham, MA, USA, [22]Fondazione Policlinico Universitario A. Gemelli, IRCCS and Catholic University of Sacred Heart, Rome, Italy; [23]Stephenson Cancer Center University of Oklahoma College of Medicine, Oklahoma City, OK, USA

congress.esgo.org

Date: September 28, 2023
Name: Toon Van Gorp, MD

ENGOT European Network of Gynaecological Oncological Trial groups
GOG FOUNDATION® Transforming the standard of care™

Mirvetuximab Soravtansine Demonstrates Longer Overall Survival And Progression-Free Survival By Prior Lines Of Therapy Vs Chemotherapy In Platinum-Resistant Ovarian Cancer And High Folate Receptor Alpha Expression In The MIRASOL Trial

Toon Van Gorp, Renaud Sabatier, Gottfried E. Konecny, Gordon Jayson, Sandro Pignata, Nicoletta Colombo, John Moroney, Lainie P. Martin, Jung-Yun Lee, Andrzej Roszak, Shani Breuer, Ingrid Boere, Olivier Tredan, Diane Provencher, Laura Farrelly, Charles A. Leath III, Yuemei Wang, Michael Method, Domenica Lorusso, Kathleen N. Moore

Mirvetuximab Soravtansine Demonstrates Efficacy Over Investigator's Choice Chemotherapy Regardless Of Prior PARPi Exposure In Phase III MIRASOL Trial

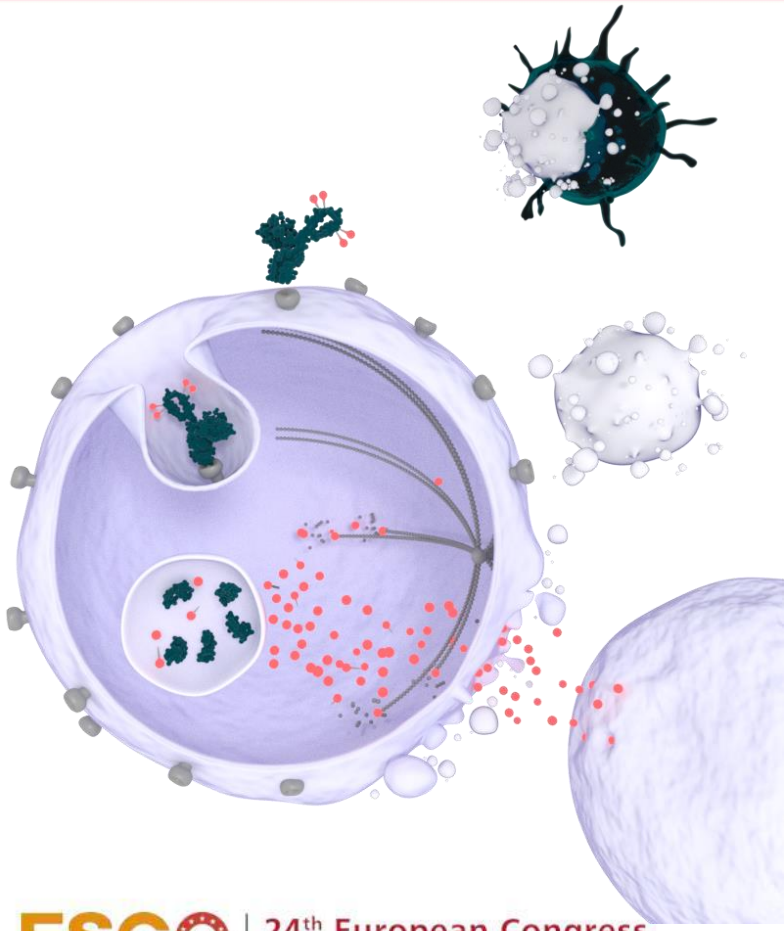
Kathleen N. Moore, Dominique Berton, Gottfried E. Konecny, Shibani Nicum, Sandro Pignata, Nicoletta Colombo, John Moroney, Lainie P. Martin, Jung-Yun Lee, Andrzej Roszak, Shani Breuer, Petronella B. Ottevanger, Sophie Abadie-Lacourtoisie, Diane Provencher, Lucy Mcavan, Charles A. Leath III, Yuemei Wang, Michael Method, Domenica Lorusso, Toon Van Gorp

Declaration of Interests

- Consulting/Advising with AstraZeneca, Eisai, GSK, ImmunoGen, MSD/Merck & Co, OncXerna Therapeutics, Seagen, and Tubulis
- Travel, accommodations, and/or expenses from AstraZeneca, ImmunoGen, MSD/Merck, and PharmaMar
- Research funding from Amgen, AstraZeneca, and Roche
- All payments institutional

Background

- Prior to MIRASOL, no randomized phase 3 trial has shown an overall survival (OS) benefit of a novel therapy in platinum-resistant ovarian cancer (PROC)[1,2]
- Mirvetuximab Soravtansine (MIRV) is an ADC comprising an 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 approval worldwide



PFS, progression-free survival; OS, overall survival; FRα, folate receptor alpha; ORR, objective response rate; ADC, antibody-drug conjugate; mDOR, median duration of response; FDA, Food and Drug Administration; BEV, bevacizumab; US, United States; EU, Europe. **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.

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

Patient Population
(N=453)

Enrollment and Key Eligibility
Platinum-resistant disease (PFI ≤6 mo)
FRα detected by IHC with PS2+ intensity among ≥75% of viable tumor cells
High-grade serous histology
1º platinum-refractory disease excluded (primary PFI <3 mo)
1-3 prior lines of therapy
Prior BEV and PARPi allowed
Patients with BRCA mutations allowed

1:1 Randomization

Treatment Regimen-Experimental
MIRV
(6 mg/kg AIBW Q3W)

Treatment Regimen-Control
Investigator's Choice Chemotherapy
(Paclitaxel, PLD, or Topotecan)

Stratification Factors
IC chemo: paclitaxel, PLD, or topotecan
Prior lines of therapy: 1 vs 2 vs 3

Primary Endpoint
PFS by INV
(BICR sensitivity analysis)

Key Secondary Endpoints
1) ORR by INV
2) OS
3) PROs[a]

Secondary Endpoints
Safety and tolerability
DOR
CA-125 response[b]
PFS2

Exploratory Endpoints
Additional PRO assessments[c]

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; EORTC, European Organisation for Research and Treatment of Cancer; EQ5D-5L, EuroQoL 5 Dimension 5 Level; 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; PGIS, Patient Global Impression of Severity; PLD, pegylated liposomal doxorubicin; PRO, patient-reported outcome; PS2+, positive staining intensity ≥2; Q3W, every 3 weeks; QLQ-C30, Quality of Life Questionnaire Core 30; QLQ-OV28, Quality of Life Questionnaire Ovarian Cancer Module.

[a]The primary PRO assessment utilizes the EORTC QLQ-OV28 abdominal/gastrointestinal symptom subscale to determine the number of participants demonstrating ≥15% (or equivalently, a 15-point) improvement at week 8/9.

[b]Gynecological Cancer InterGroup (GCIG) criteria.

[c]Includes analyses of PROs from the EORTC QLQ-OV28 (analyses in addition to the primary PRO assessment), EORTC QLQ-C30, EQ5D-5L, and PGIS instruments.

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

References: 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.

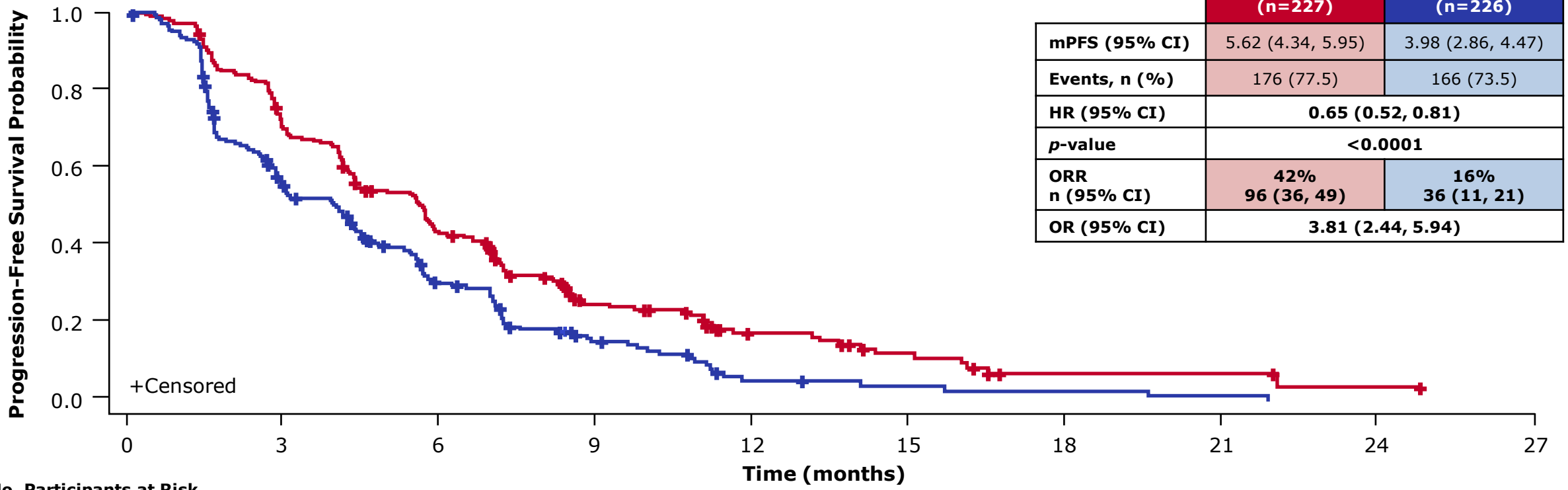
Baseline Demographics and Stratification Factors (N=453)

Baseline Characteristics		MIRV (n=227)	IC Chemo (n=226)
Age, median (range)	Age in years	64 (32-88)	62 (29-87)
Stage at initial diagnosis, n (%)[a]	I-II III IV	9 (4) 137 (60) 76 (33)	9 (4) 147 (65) 65 (29)
BRCA mutation, n (%)	Yes No/Unknown	29 (13) 198 (87)	36 (16) 190 (84)
Prior exposure, n (%)	Bevacizumab PARPi Taxanes	138 (61) 124 (55) 227 (100)	143 (63) 127 (56) 224 (99)
Primary platinum-free interval, n (%)[b]	≤ 12 months > 12 months	146 (64) 80 (35)	142 (63) 84 (37)
Most Recent Platinum-free interval, n (%)[c]	≤ 3 months > 3 - ≤6 months	88 (39) 138 (61)	99 (44) 124 (55)
Stratification Factors			
No. prior systemic therapies, n (%)	1 2 3	31 (14) 91 (40) 105 (46)	32 (14) 91 (40) 103 (46)
Investigator Choice of Chemotherapy	Paclitaxel PLD Topotecan	93 (41) 82 (36) 52 (23)	92 (41) 81 (36) 53 (23)

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; NA, not applicable; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitors. [a]Five patients (2%) in the MIRV arm and five patients in the IC chemo arm (2%) were missing information for stage at initial diagnosis [b]One patient (<1%) in the MIRV arm was missing information on primary platinum-free interval. [c]One patient (1%) in the PARPi Naive IC Chemo arm, 1 patient (<1%) in the PARPi treated MIRV arm, 2 patients (2%) in the PARPi treated IC chemo arm, 2 patients (2%) in the 1-2 prior lines of therapy IC Chemo arm, 1 patient (<1%) in the 3 prior lines of therapy MIRV arm, and 1 patient (<1%) in the 3 prior lines of therapy IC Chemo arm enrolled with platinum-free interval of >6 months.

Progression-Free Survival and Objective Response Rate 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**	
ORR n (95% CI)	**42% 96 (36, 49)**	**16% 36 (11, 21)**
OR (95% CI)	**3.81 (2.44, 5.94)**	

No. Participants at Risk

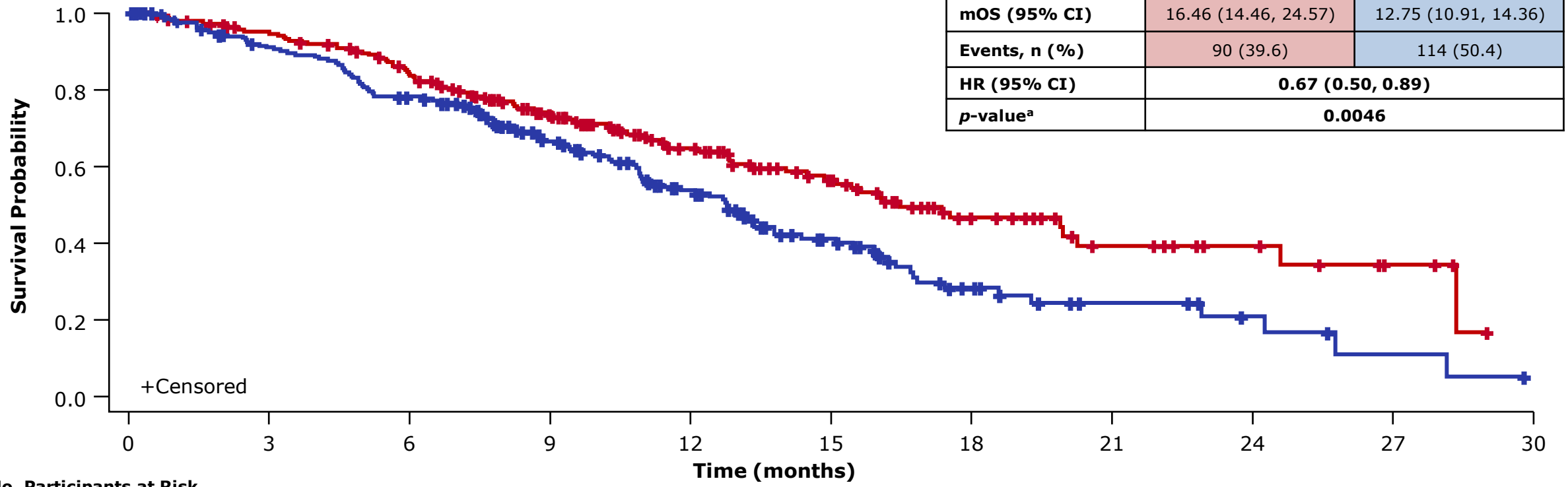
MIRV	**227**	**151**	**89**	**38**	**18**	**10**	**3**	**3**	**1**	**0**
IC Chemo	**226**	**98**	**48**	**19**	**5**	**3**	**2**	**1**	**0**	

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mPFS, median progression-free survival; ORR, objective response rate; HR, hazard ratio; OR, odds ratio.

Key Secondary Endpoint: 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; median follow-up time: 13.11 months.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mOS, median overall survival.
[a]Overall survival was statistically significant based on pre-specified boundary *p*-value at interim analysis = 0.01313.

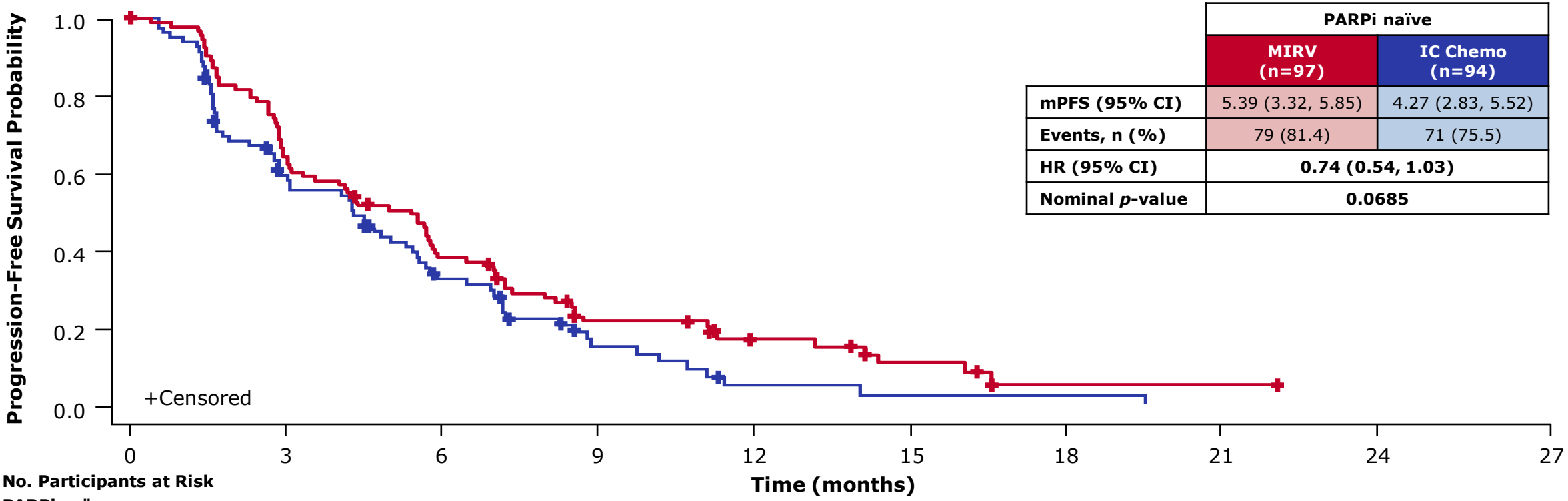
Baseline Demographics by PARPi Naïve, PARPi Treated, and Prior Lines of Therapy Subsets

Baseline Characteristics		PARPi Naïve		PARPi Treated		1-2 Prior Lines		3 Prior Lines	
		MIRV (n=97)	IC Chemo (n=94)	MIRV (n=124)	IC Chemo N=127)	MIRV (n=122)	IC Chemo (n=123)	MIRV (n=105)	IC Chemo (n=103)
BRCA mutation, n (%)	Yes No/Unknown	1 (1) 96 (99)	3 (3) 91 (97)	28 (23) 96 (77)	33 (26) 94 (74)	16 (13) 106 (87)	15 (12) 108 (88)	13 (12) 92 (88)	21 (20) 82 (80)
Immediately Prior exposure, n (%)	Bevacizumab Taxanes	30 (31) 42 (43)	28 (30) 40 (43)	25 (20) 25 (20)	21 (17) 29 (23)	33 (27) 44 (36)	29 (24) 47 (38)	23 (22) 25 (24)	21 (20) 25 (24)
No. prior systemic therapies, n (%)	1 2 3	15 (15) 39 (40) 43 (44)	23 (24) 35 (37) 36 (38)	14 (11) 48 (39) 62 (50)	10 (8) 52 (41) 65 (51)	29 (24) 89 (73) 4(3)	34 (28) 87 (71) 2 (2)	0 1 (<1) 104 (99)	0 1 (<1) 102 (99)
Primary platinum-free interval, n (%)[a]	≤ 12 months > 12 months	70 (72) 27 (28)	69 (73) 25 (27)	73 (59) 50 (40)	70 (55) 57 (45)	92 (75) 30 (25)	89 (72) 34 (28)	54 (51) 50 (48)	53 (51) 50 (49)
Platinum-free interval, n (%)[b]	≤ 3 months > 3 - ≤6 months	40 (41) 57 (59)	29 (31) 64 (68)	44 (35) 79 (64)	67 (53) 58 (46)	35 (29) 87 (71)	35 (28) 86 (70)	53 (50) 51 (49)	64 (62) 38 (37)
Best Response to Last Line, n (%)	CR PR SD PD Unknown/NA	9 (9) 33 (34) 17 (18) 32 (33) 6 (6)	15 (16) 32 (34) 22 (23) 22 (23) 3 (3)	9 (7) 43 (35) 27 (22) 41 (33) 4 (3)	10 (8) 34 (27) 33 (26) 45 (35) 5 (4)	16 (13) 52 (43) 22 (18) 28 (23) 4 (3)	19 (15) 45 (37) 29 (24) 27 (22) 3 (2)	3 (3) 25 (24) 24 (23) 47 (45) 6 (6)	7 (7) 23 (22) 27 (26) 40 (39) 6 (6)

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; NA, not applicable; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitors. [a]One patient (<1%) in the PARPi treated MIRV arm and one patient (<1%) in the 3 prior lines of therapy MIRV arm were missing information on primary platinum-free interval. [b]One patient (<1%) in the PARPi treated MIRV arm, 2 patients (2%) in the PARPi treated IC chemo arm, 2 patients (2%) in the 1-2 prior lines of therapy IC Chemo arm, 1 patient (<1%) in the 3 prior lines of therapy MIRV arm, and 1 patient (<1%) in the 3 prior lines of therapy IC Chemo arm enrolled with platinum-free interval of >6 months.

Progression-Free Survival: PARPi Naïve



	PARPi naïve	
	MIRV (n=97)	IC Chemo (n=94)
mPFS (95% CI)	5.39 (3.32, 5.85)	4.27 (2.83, 5.52)
Events, n (%)	79 (81.4)	71 (75.5)
HR (95% CI)	**0.74 (0.54, 1.03)**	
Nominal *p*-value	**0.0685**	

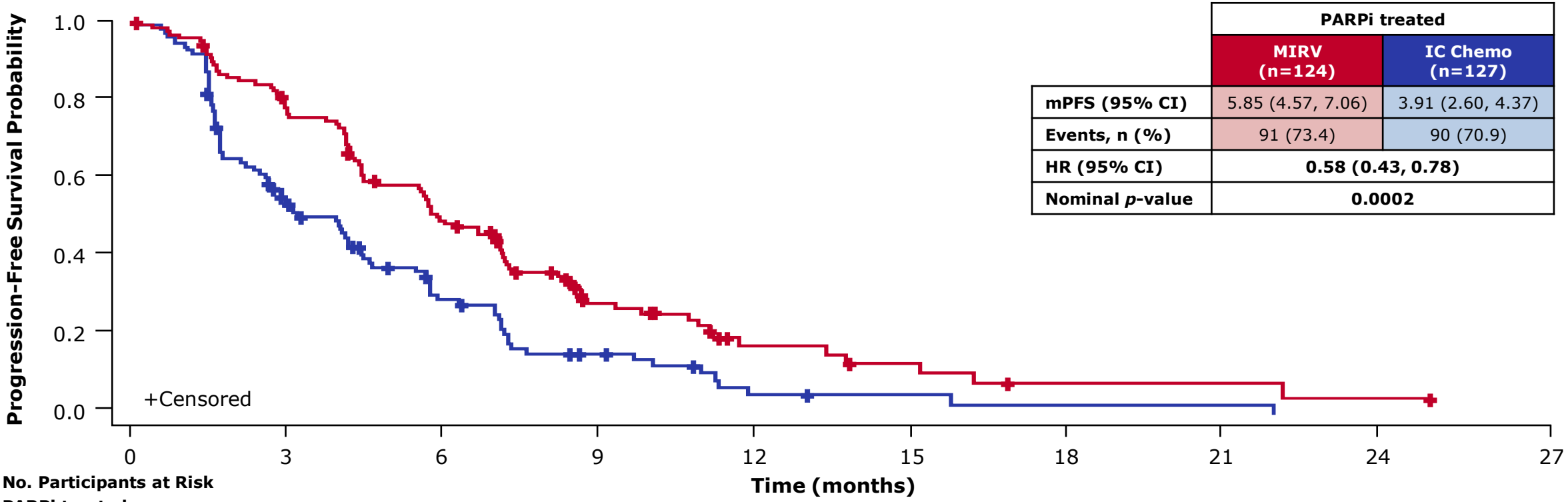
No. Participants at Risk

PARPi naïve									
MIRV	**97**	**61**	**35**	**17**	**10**	**5**	**1**	**1**	**0**
IC Chemo	**94**	**45**	**23**	**8**	**2**	**1**	**1**	**0**	

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mPFS, median progression-free survival; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitors.

Progression-Free Survival: PARPi Treated



	PARPi treated	
	MIRV (n=124)	IC Chemo (n=127)
mPFS (95% CI)	5.85 (4.57, 7.06)	3.91 (2.60, 4.37)
Events, n (%)	91 (73.4)	90 (70.9)
HR (95% CI)	**0.58 (0.43, 0.78)**	
Nominal *p*-value	**0.0002**	

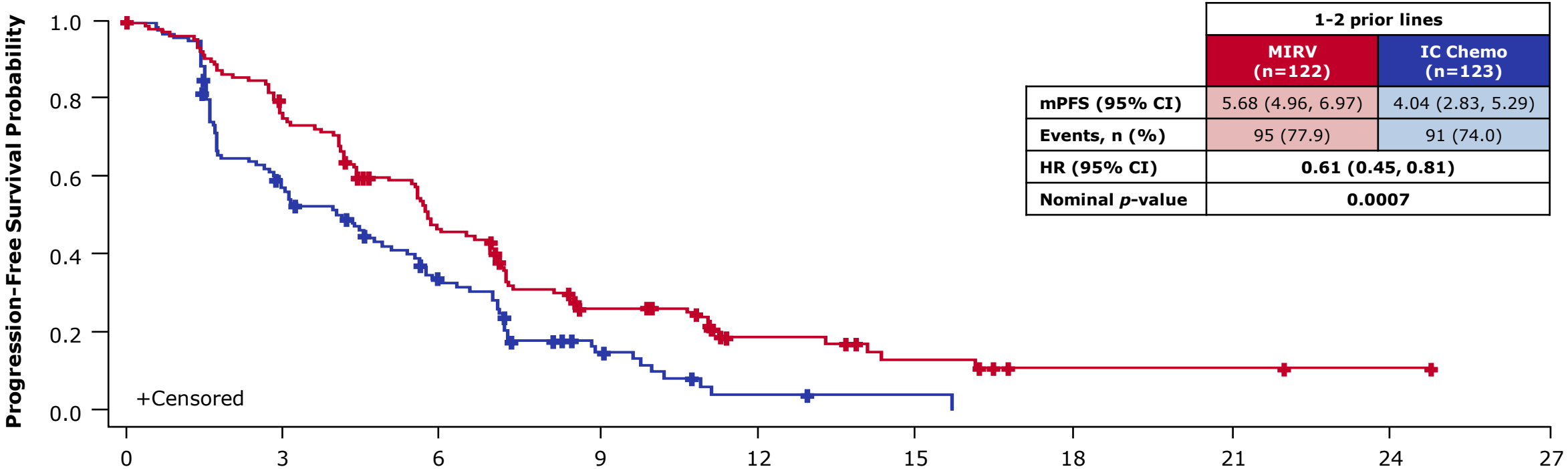
No. Participants at Risk

PARPi treated										
MIRV	**124**	**88**	**54**	**21**	**8**	**5**	**2**	**2**	**1**	**0**
IC Chemo	**127**	**52**	**25**	**11**	**3**	**2**	**1**	**1**	**0**	

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mPFS, median progression-free survival; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitors.

Progression-Free Survival: 1-2 Prior Lines of Therapy



	1-2 prior lines	
	MIRV (n=122)	IC Chemo (n=123)
mPFS (95% CI)	5.68 (4.96, 6.97)	4.04 (2.83, 5.29)
Events, n (%)	95 (77.9)	91 (74.0)
HR (95% CI)	**0.61 (0.45, 0.81)**	
Nominal *p*-value	**0.0007**	

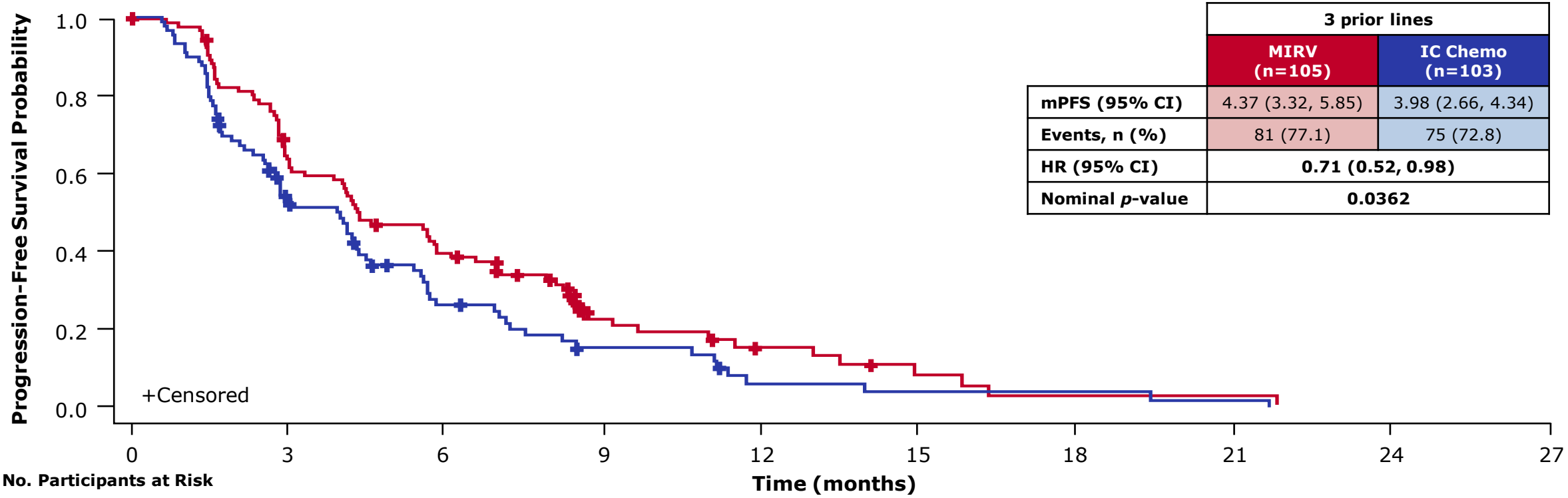
No. Participants at Risk

1-2 prior lines										
MIRV	**122**	**90**	**52**	**25**	**11**	**6**	**2**	**2**	**1**	**0**
IC Chemo	**123**	**58**	**30**	**10**	**2**	**1**	**0**			

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mPFS, median progression-free survival.

Progression-Free Survival: 3 Prior Lines of Therapy



	3 prior lines	
	MIRV (n=105)	IC Chemo (n=103)
mPFS (95% CI)	4.37 (3.32, 5.85)	3.98 (2.66, 4.34)
Events, n (%)	81 (77.1)	75 (72.8)
HR (95% CI)	0.71 (0.52, 0.98)	
Nominal *p*-value	0.0362	

No. Participants at Risk

3 prior lines									
MIRV	105	61	37	13	7	4	1	1	0
IC Chemo	103	40	18	9	3	2	2	1	0

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mPFS, median progression-free survival.

Key Secondary Endpoint: Objective Response Rate by Investigator (N=453)

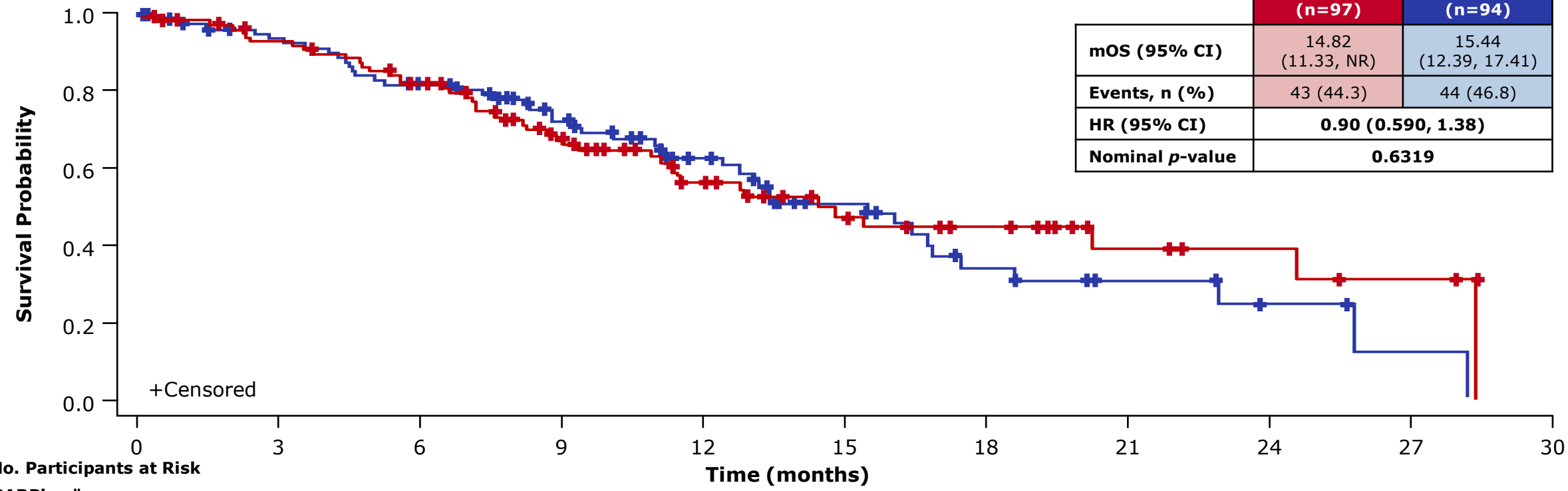
Overall Population ORR (95% CI)
MIRV: 42% (36, 49) vs **IC Chemo: 16%** (11, 21)
ORR Difference: 26% (18, 34)
OR: 3.81 (2.44, 5.94)
***p*<0.0001**

	PARPi naïve		PARPi treated		1-2 prior lines		3 prior lines	
	MIRV (n=97)	**IC Chemo (n=94)**	**MIRV (n=124)**	**IC Chemo (n=127)**	**MIRV (n=122)**	**IC Chemo (n=123)**	**MIRV (n=105)**	**IC Chemo (n=103)**
ORR, % n, 95% CI	**40** 39 (30, 51)	**14** 13 (8, 23)	**45** 56 (36, 54)	**17** 22 (11, 25)	**46** 56 (37, 55)	**15** 18 (9, 22)	**38** 40 (29, 48)	**18** 18 (11, 26)
	ORR Diff: 26% (14, 38) **OR: 4.19** (2.06, 8.54) **Nominal *p*<0.0001**		**ORR Diff: 28%** (17, 39) **OR: 3.93** (2.20, 7.02) **Nominal *p*<0.0001**		**ORR Diff: 31%** (20, 42) **OR: 4.95** (2.68, 9.14) **Nominal *p*<0.0001**		**ORR Diff: 21%** (9, 33) **OR: 2.91** (1.53, 5.53) **Nominal *p*=0.0009**	
Best overall response, n (%)								
CR	5 (5)	0	7 (6)	0	10 (8)	0	2 (2)	0
PR	34 (35)	13 (14)	49 (40)	22 (17)	46 (38)	18 (15)	38 (36)	18 (18)
SD	38 (39)	44 (47)	44 (36)	47 (37)	46 (38)	53 (43)	40 (38)	38 (37)
PD	14 (14)	25 (27)	16 (13)	36 (28)	18 (15)	35 (29)	13 (12)	27 (26)
Not evaluable	6 (6)	12 (13)	8 (7)	22 (17)	2 (2)	17 (14)	12 (11)	20 (19)

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; CR, complete response; IC chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; OR, odds ratio; ORR, objective response rate; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitors; PD, progressive disease; PR, partial response; SD, stable disease.

Overall Survival: PARPi Naïve



	PARPi naïve	
	MIRV (n=97)	IC Chemo (n=94)
mOS (95% CI)	14.82 (11.33, NR)	15.44 (12.39, 17.41)
Events, n (%)	43 (44.3)	44 (46.8)
HR (95% CI)	0.90 (0.590, 1.38)	
Nominal *p*-value	0.6319	

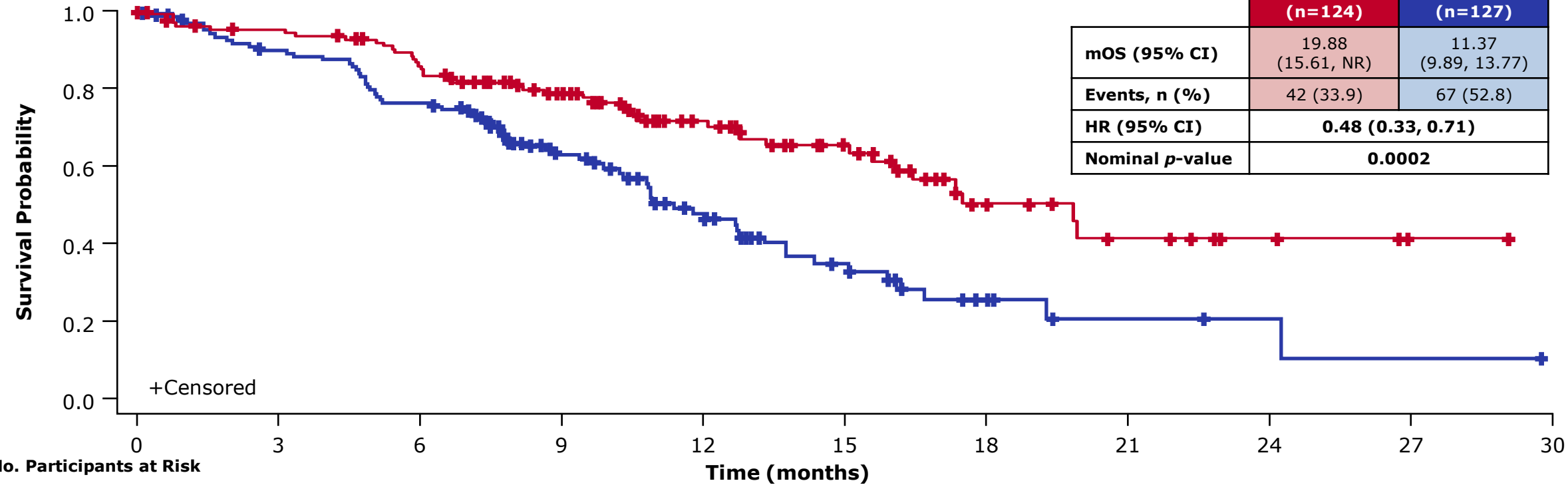
No. Participants at Risk

PARPi naïve											
MIRV	97	86	73	49	32	19	14	7	5	3	0
IC Chemo	94	78	66	50	34	21	11	6	3	1	0

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mOS, median overall survival; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; NR, not reached.

Overall Survival: PARPi Treated



	PARPi treated	
	MIRV (n=124)	IC Chemo (n=127)
mOS (95% CI)	19.88 (15.61, NR)	11.37 (9.89, 13.77)
Events, n (%)	42 (33.9)	67 (52.8)
HR (95% CI)	0.48 (0.33, 0.71)	
Nominal *p*-value	0.0002	

No. Participants at Risk

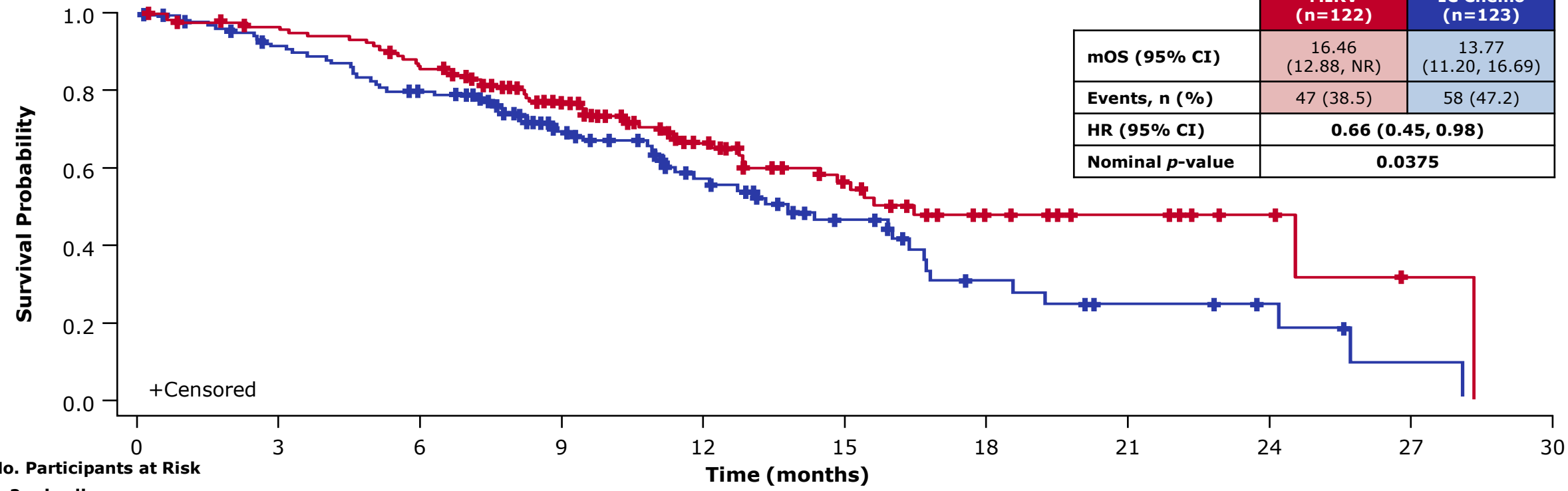
PARPi treated											
MIRV	124	113	99	76	47	32	13	8	4	1	0
IC Chemo	127	105	89	56	34	18	7	3	2	1	0

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mOS, median overall survival; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; NR, not reached.

Overall Survival: 1-2 Prior Lines of Therapy

	1-2 prior lines	
	MIRV (n=122)	IC Chemo (n=123)
mOS (95% CI)	16.46 (12.88, NR)	13.77 (11.20, 16.69)
Events, n (%)	47 (38.5)	58 (47.2)
HR (95% CI)	**0.66 (0.45, 0.98)**	
Nominal *p*-value	**0.0375**	



No. Participants at Risk

1-2 prior lines

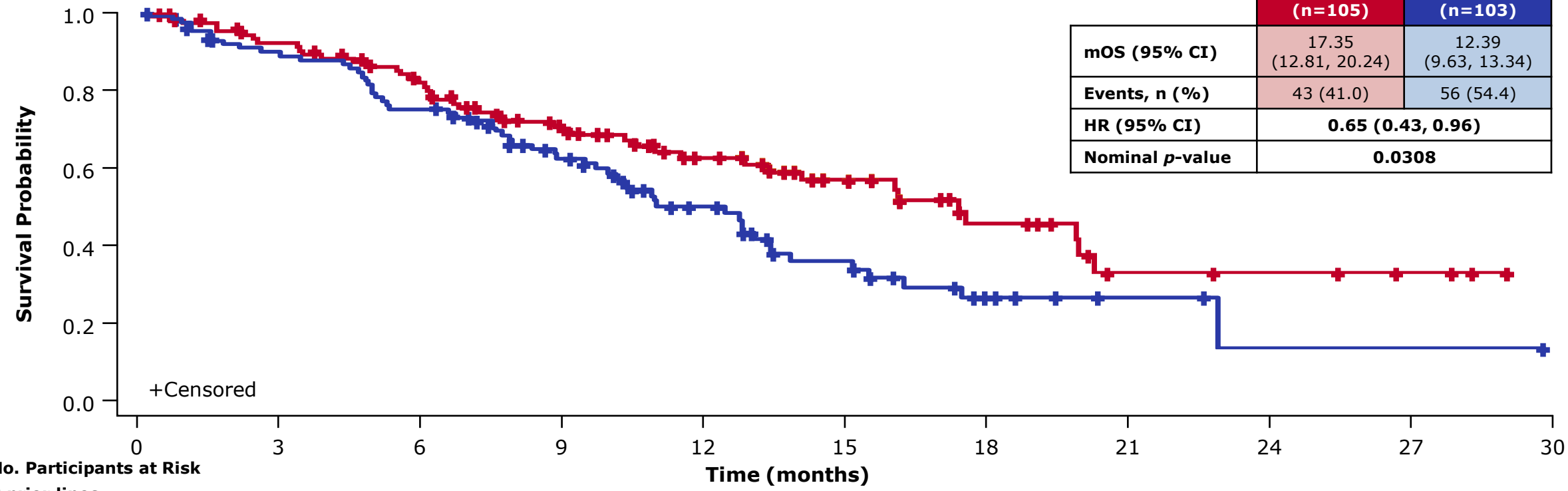
MIRV	**122**	**113**	**100**	**73**	**45**	**29**	**14**	**9**	**4**	**1**	**0**
IC Chemo	**123**	**101**	**86**	**58**	**37**	**21**	**10**	**6**	**4**	**1**	**0**

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mOS, median overall survival; NR, not reached.

Overall Survival: 3 Prior Lines of Therapy

	3 prior lines	
	MIRV (n=105)	IC Chemo (n=103)
mOS (95% CI)	17.35 (12.81, 20.24)	12.39 (9.63, 13.34)
Events, n (%)	43 (41.0)	56 (54.4)
HR (95% CI)	0.65 (0.43, 0.96)	
Nominal *p*-value	0.0308	



No. Participants at Risk

3 prior lines											
MIRV	105	91	75	55	37	24	14	6	5	3	0
IC Chemo	103	84	71	49	31	18	8	3	1	1	0

ESGO European Society of Gynaecological Oncology | 24th European Congress on Gynaecological Oncology Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

Data cutoff: March 6, 2023.
CI, confidence interval; HR, hazard ratio; IC Chemo, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; mOS, median overall survival; NR, not reached.

Safety Summary (N=425)

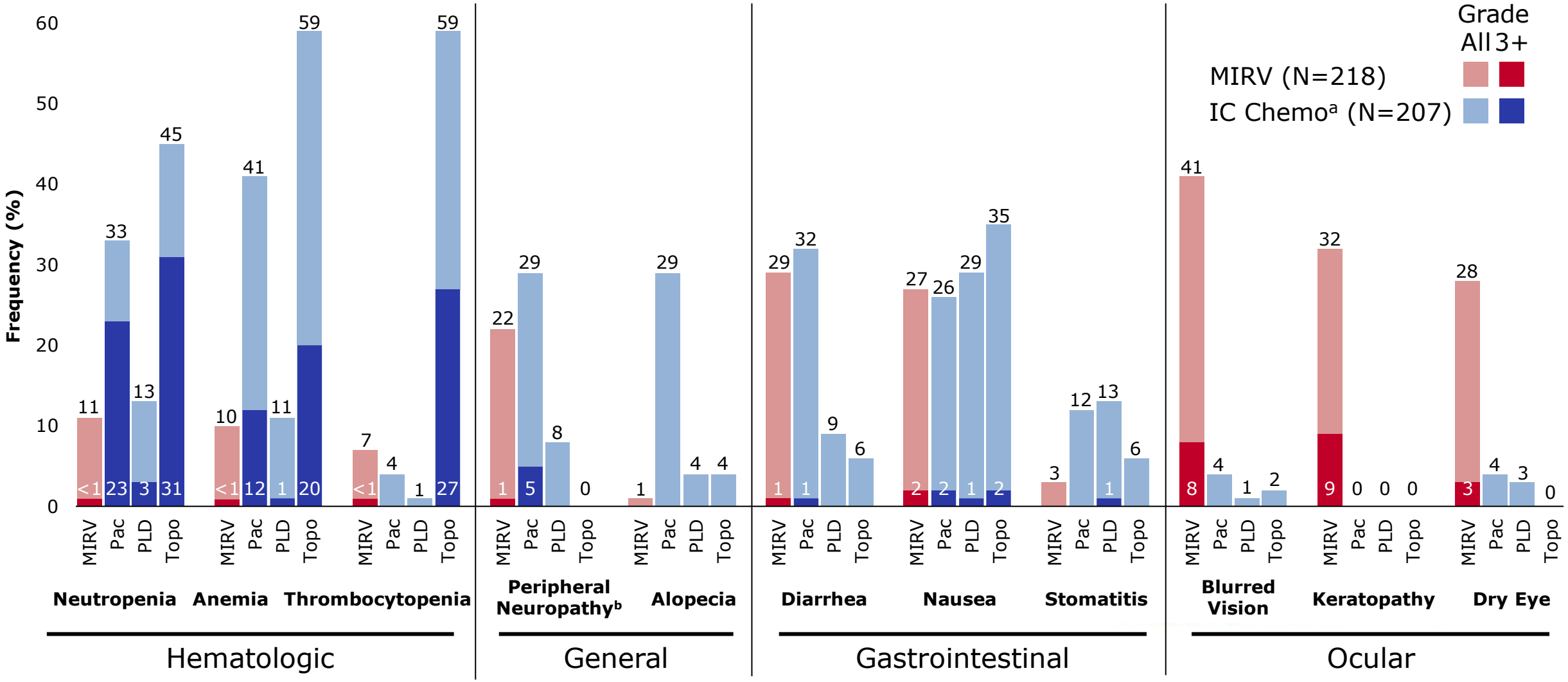
MIRV has a tolerable safety profile compared with IC Chemo

	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)

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye

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; SAEs, serious adverse events; MIRV, mirvetuximab soravtansine; IC, investigator's choice chemotherapy.

Differentiated Safety Profile: Treatment-Emergent Adverse Events



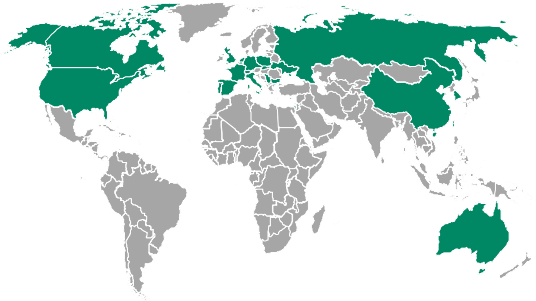
Data cutoff: March 6, 2023.
IC Chemo: investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine; Pac, paclitaxel; PLD, pegylated liposomal doxorubicin; Topo, topotecan.
[a]Pac n=82 (39%), PLD n=76 (37%), Topo n=49 (24%). [b]Grade 2+ peripheral neuropathy events were observed in 12% and 16% of patients that received MIRV or paclitaxel, respectively.

Conclusions

- MIRV is the first novel treatment to **demonstrate an overall survival benefit** in platinum-resistant ovarian cancer in a phase 3 trial
- MIRV also demonstrated clinically meaningful **improvements in PFS, ORR, and OS** compared to IC chemotherapy, regardless of prior lines of therapy or prior PARPi treatment, with a differentiated safety profile consisting predominantly of low-grade ocular and gastrointestinal events
- MIRV is the **first ADC for ovarian cancer** with proven efficacy and is the only FDA-approved biomarker-directed therapy for platinum-resistant ovarian cancer
- These data are practice-changing and position MIRV as a **new standard of care** for patients with FRα-positive PROC

Acknowledgments

This presentation is dedicated to the patients and their families who participated in the MIRASOL clinical trial.
Thank you to the clinical investigators and research teams who supported the MIRASOL trial at over 250 sites in 21 countries across North America, Europe, Asia, and Australia.



GOG FOUNDATION

K Moore
C Cosgrove
G Matina-Smaldone
E Hamilton
A Jewell
R Boothby
C Leath
G Konecny
M Gold
L Martin
S Sharma
P Rose
J Wright
A Santin
J Barter
R Morris
B Orr
M Gordinier
K Wade
S Zweizig
M Oliver
Y Zhuo
D Sonnenburg
M Teneriello
N Cloven
D Richards
B Monk
J Buscema
KS LyBarger
R Littell
D Black
C Lee

S Lewin
M Sundborg
K Resnick
T Myers
M Indermaur
R Wehnham
L Duska
G Colon-Otero
J Moroney
J Schorge
E Teplinsky
V Galvan-Turner
S Ratnam
U Sobol
G Westhoff
J Burke
C Anderson
R Marsh
E Salinas
K Schuler
C Chua
C Tin-U
K Ward
T Pustilnik
C Aylesworth
M Hardesty
S Chambers
A Santillan-Gomez
J Thomes-Pepin
L Ma
T Moore
T Krivak
E Alvarez

A Mendivil
M Zakhour
J Lucci
G Harrer
R Liu
M Carney
L Hart
G Wright
D Spitz
K Butler
J Weroha
M Ellison
R Littell
E Whitman
P Lim

GEICO Grupo Español de Investigación en Cáncer de Ovario

M Romeo Marín
A Barquín
J Martinez
Y García
A Yubero
P Estévez

A Santaballa
N Ruiz
S González
M Merino Salvador
F Galvez
J Cueva

AGO Studiengruppe

N deGregorio
C Haenle
F Schochter
F Hilpert
F Trillsch
P Wimberger
M Gropp-Meier
B Schmalfeldt
G Bauerschmitz
H Bronger
A Lehnert

T Fehm
L Hanker
H Voss
M Klar
N Akyol
A Mustea
I Meinhold-Heerlein
A A-Balat

GINECO

C Lebreton
A Floquet
D Berton-Rigaud
J Alexandre
A Leary
DB Roufai
A Angelergues
L Gladieff
E Kalbacher

S Abadie-Lacourtoisie
B You
A Hardy-Bessard
S Becourt
M Kaminsky
O Tredan
R Sabatier

MaNGO

N Colombo
G Tasca
A Bologna
A Ardizzoia

A Ferrero
G Tognon
P Zola

MITO

D Lorusso
C Zamagni
S Pignata

E Geuna
G Valabrega
F Roila
P Scollo

NCRI National Cancer Research Institute

R Miller
S Banerjee
R Glasspool
C Gourley
C Barlow

J Gordon
L McAvan
S Ayers
K Scatchard
S Crusz

Y Kim
J Kim
M Lim

J Lee
Y Kim
J Lee

M Dvorkin
E Poddubskaya
O Lipatov
O Mikheeva

D Provencher
P Ghatage
L Gilbert
A Covens
A Oza
J Weberpals
S Pin
P Bessette

P Wang
C Chang
S Hsiao

LAM Costa
M de Lurdes Batarda
MSR Casa-Nova Peres
JB e Sá
M Nave

G Richardson
CI Diakos
M Oehler
A Bonaventura
YC Lee
K Webber
A Dean

H Dechev
N Stefanova
J Arabadjiev
N Conev
B Robev

X Wu
G Lou
B Xia
D Wang
K Wang
A Lin
Y Chen
Y Huang
H Qiu
X Wang
R An
G Li
H Wen
K Song

Y Gao
Q Chen
Z Liang
J Liu
L Wang
L Yao
Y Yue
S Yao
H Zhang
Y Zhang
L Chen
Y Wu

CEEGOG Central and Eastern European Gynecologic Oncology Group

D Cibula
J Klat
M Pospiskova
M Milovic-Kovacevic
A Mandic
J Nedovic

D Ryspayeva
Z Oleksandr
P Tetiana
V Sukhin
A Kryzhanivska
V Paramonov

BGOG

T Van Gorp
M De Bock
W Demey
S Altintas
V Renard
G Huygh

nvog

J Tromp
I Boere
N Ottevanger
R Lalisang

PGOG

W Bednarek
M Sikorska
A Chudecka-Głaz
P Derlatka
D Klasa-Mazurkiewicz
A Roszak

ISGO

R Shapira
M Beiner
S Breuer
I Ben-Shachar
A Yachnin
T Levy

ESGO European Society of Gynaecological Oncology
24th European Congress on Gynaecological Oncology
Sep 28 – Oct 1, 2023 | Istanbul, Türkiye