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

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ENGOT European Network of Gynaecological Oncological Trial groups

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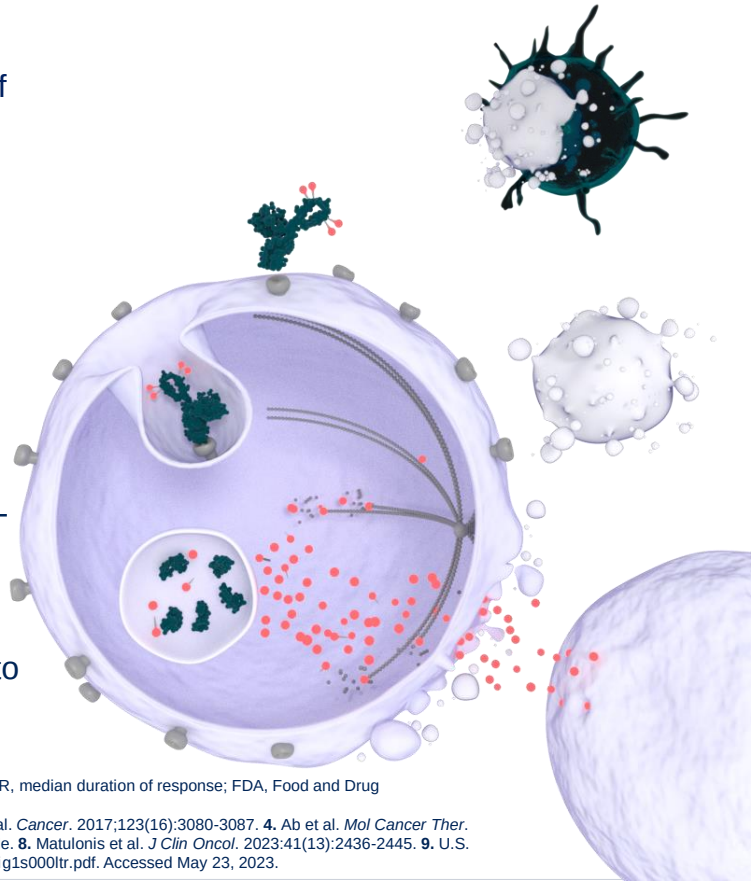
Background

- 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 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 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.

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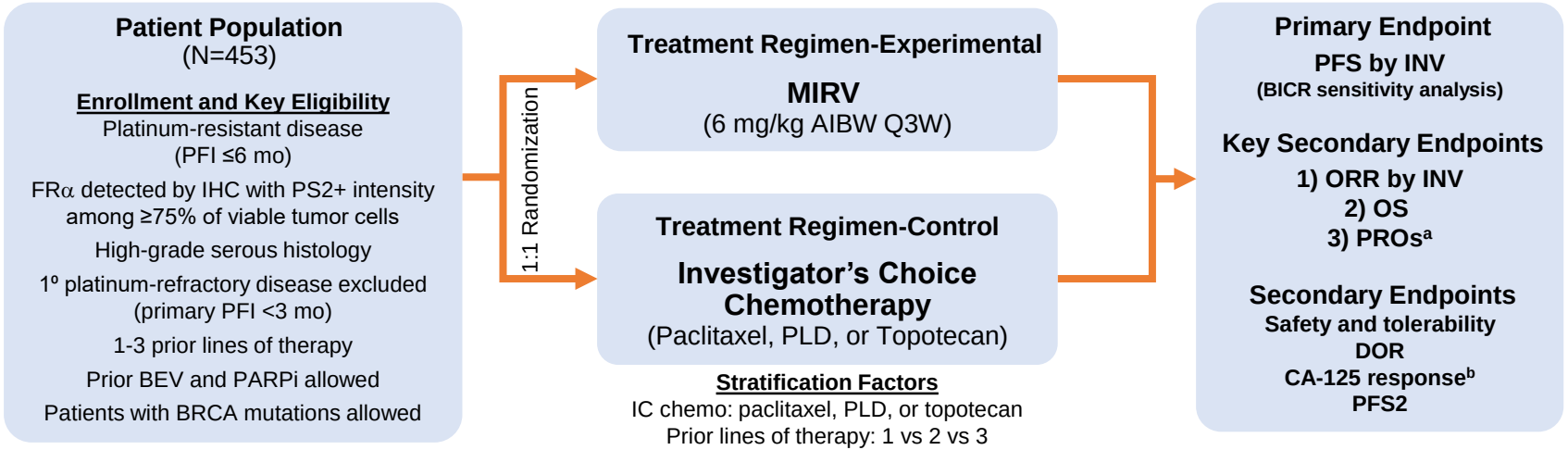
MIRASOL (NCT04209855) – Study Design[1,2]

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.

Baseline Demographics and Stratification Factors (N=453)

Characteristics		MIRV (n=227)	IC Chemo (n=226)
Age, median (range)	Age in years	63 (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)
Platinum-free interval, n (%)[c]	≤ 3 months > 3 - ≤6 months	88 (39) 138 (61)	99 (44) 124 (55)
Stratification Factor **No. of prior systemic therapies, n (%)**	1 2 3	31 (14) 91 (40) 105 (46)	32 (14) 91 (40) 103 (46)
Stratification Factor **Investigator Choice of Chemotherapy**	Paclitaxel PLD Topotecan	93 (41) 82 (36) 52 (23)	92 (41) 81 (36) 53 (23)

Data cutoff: March 6, 2023. **14% of patients remain on MIRV; 3% remain on IC Chemo**

BRCA, BReast CAncer gene; PARPi, poly (ADP-ribose) polymerase inhibitors; MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; PLD, pegylated liposomal doxorubicin,.

[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 MIRV arm and 3 patients (1%) in the IC chemo arm enrolled with platinum-free interval of >6 months

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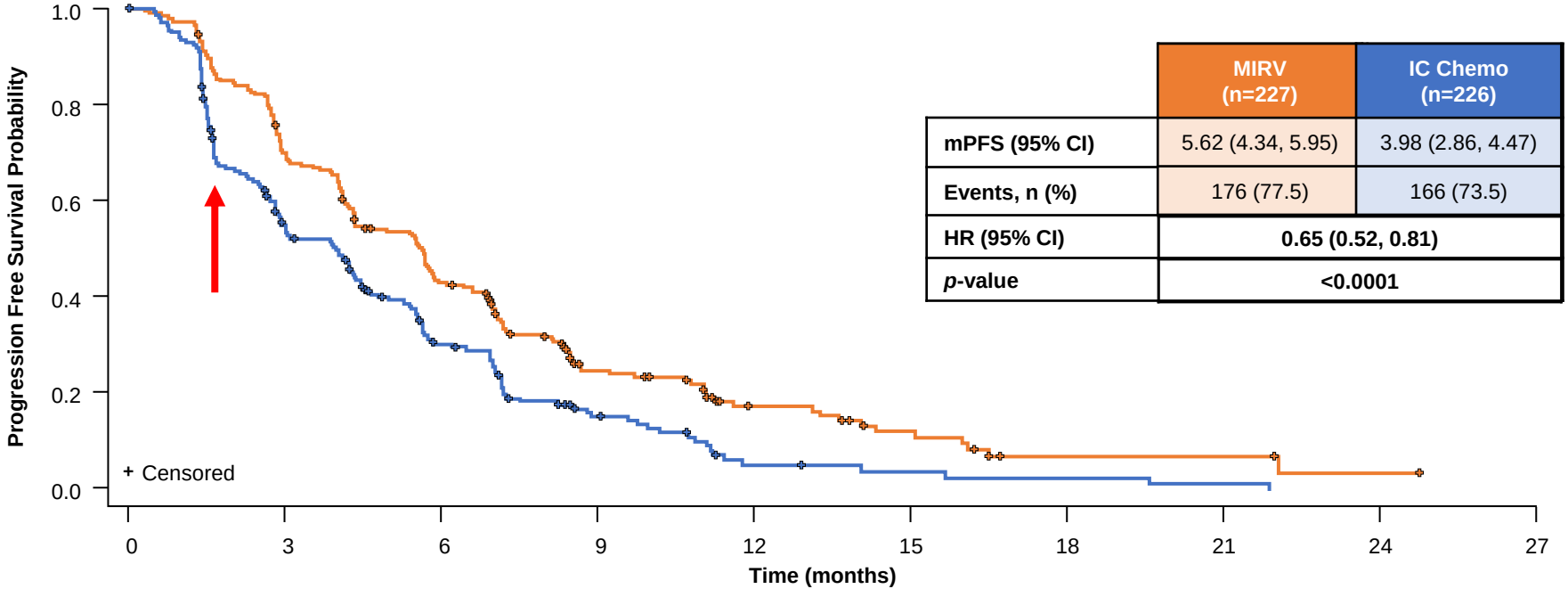
Primary Endpoint: Progression-Free Survival by Investigator



	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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Overall Response Rate by Investigator (N=453)

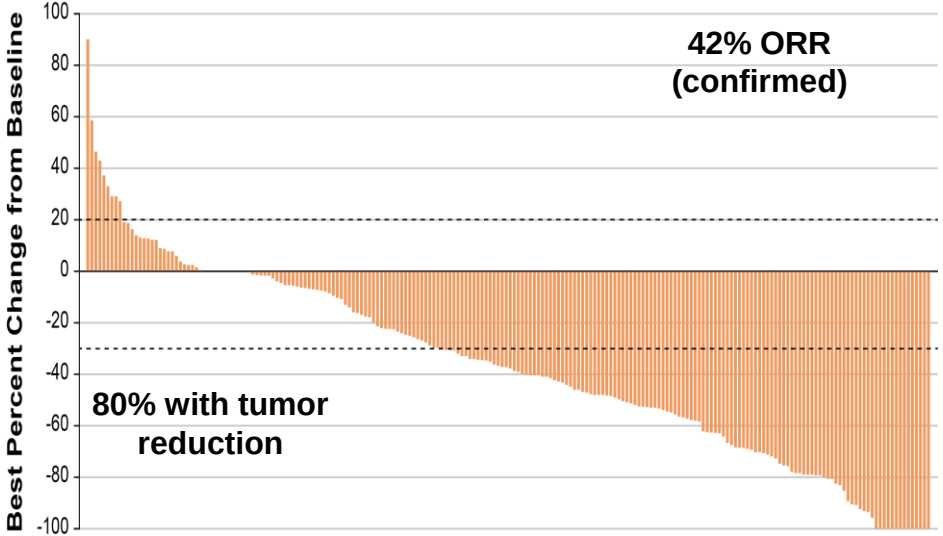
	MIRV (n=227)	IC Chemo (n=226)
ORR **n, 95% CI**	**42%** 96, (35.8, 49.0)	**16%** 36, (11.4, 21.4)
Best overall response, n (%)		
CR	12 (5%)	0
PR	84 (37%)	36 (16%)
SD	86 (38%)	91 (40%)
PD	31 (14%)	62 (27%)
Not evaluable	14 (6%)	37 (16%)

ORR Difference 26.4% (18.4, 34.4)
OR 3.81 (2.44, 5.94)
***p*<0.0001**

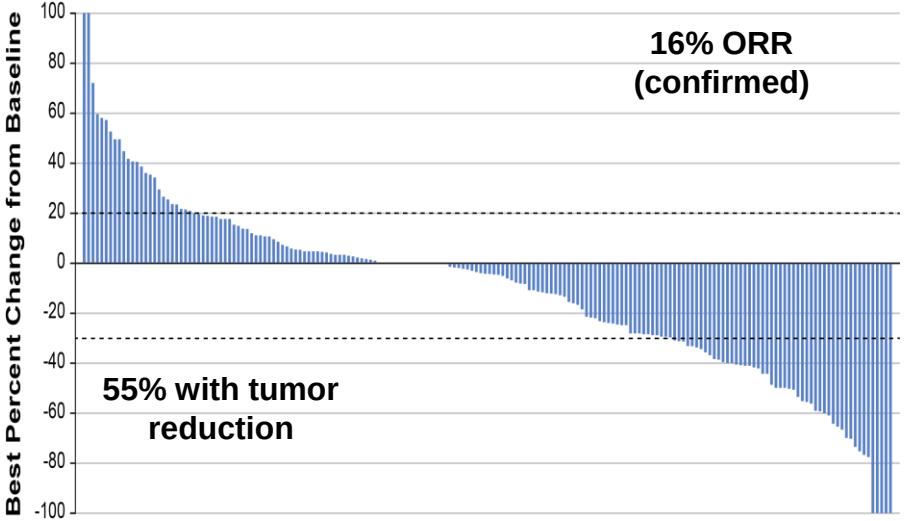
Data cutoff: March 6, 2023
MIRV, mirvetuximab soravtansine; IC chemo, investigator's choice chemotherapy; ORR, objective response rate; CI, confidence interval; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; OR, odds ratio.

Maximum Percentage Change in Target Lesion Size from Baseline by Investigator (N=453)

MIRV



IC Chemo



Data cutoff: March 6, 2023
MIRV, mirvetuximab soravtansine; IC chemo, investigator's choice chemotherapy; ORR, objective response rate.

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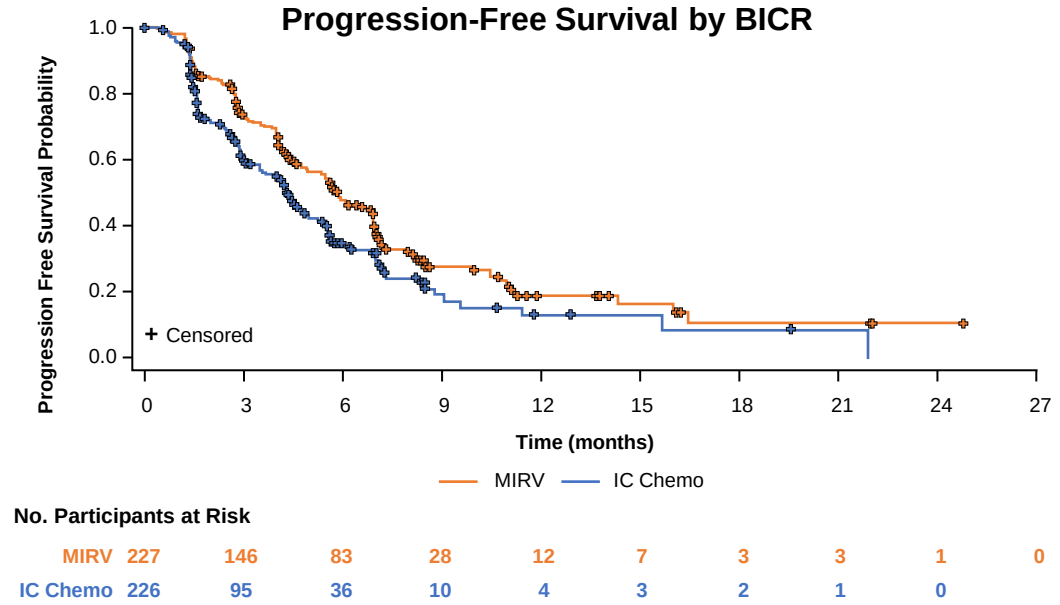
Progression-Free Survival and Objective Response Rate by Blinded Independent Central Review



	MIRV (n=227)	IC Chemo (n=226)
mPFS (95% CI)	5.9 (4.9, 7.0)	4.3 (3.5, 5.0)
Events, n (%)	146 (64)	123 (54)
HR (95% CI)	**0.72 (0.56, 0.92)**	
***p*-value**	**0.0082**	

	MIRV (n=227)	IC Chemo (n=226)
ORR, n (%) (95% CI)	82 (36) (30, 43)	33 (15) (10, 20)
OR (95% CI)	**3.22 (2.04, 5.09)**	
***p*-value**	**<0.0001**	

BICR for PFS and ORR were concordant with investigator assessment

Data cutoff: March 6, 2023

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

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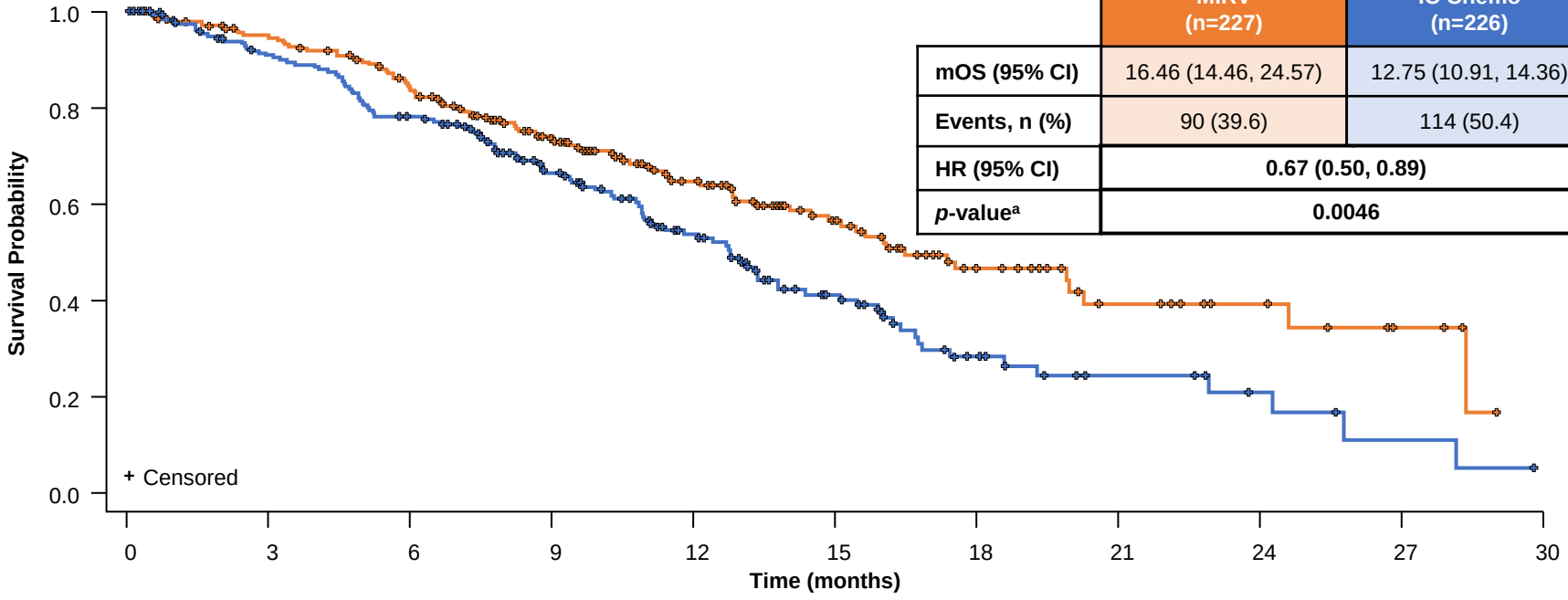
Overall Survival

	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; median follow-up time: 13.11 months

MIRV, mirvetuximab soravtansine; IC Chemo, investigator's 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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Progression-Free and Overall Survival in Bevacizumab-Naïve and Prior Bevacizumab-Treated Subsets by Investigator

	Bev-Naïve		Prior Bev	
	MIRV	IC Chemo	MIRV	IC Chemo
mPFS (95% CI)	7.0 (5.6, 8.4)	5.6 (3.0, 6.5)	4.4 (4.0, 5.8)	3.0 (2.5, 4.3)
Events n (%)[a]	65 (73.0)	57 (69.0)	111 (80.4)	109 (76.2)
HR (95% CI)	**0.66 (0.46, 0.94)**		**0.64 (0.49, 0.84)**	
Nominal *p*-value	0.0210		0.0011	
mOS (95% CI)	20.2 (14.8, NE)	14.4 (11.8, 16.7)	15.4 (11.3, 17.5)	10.9 (9.4, 13.3)
Events n (%)[a]	23 (25.8)	39 (47.0)	67 (48.6)	75 (52.4)
HR (95% CI)	**0.51 (0.31, 0.86)**		**0.74 (0.54, 1.04)**	
Nominal *p*-value	0.0099		0.0789	

Data cutoff: March 6, 2023

[a]Percentage of events was calculated out of the total number of patients in each treatment arm: n=227 for MIRV and n=226 for IC Chemo.

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

MIRASOL Efficacy Summary

- Compared to IC chemo, MIRV:
  - Demonstrated a **35% improvement in PFS** with a HR of 0.65, *p*<0.0001
  - More than doubled the ORR, 42% vs 16%, *p*<0.0001 with 12 CRs compared to zero with IC chemo
  - Provided a **33% improvement in OS** with a HR of 0.67, *p*=0.0046
- BICR PFS and ORR results are concordant with investigator assessment
- Results from both BEV-naïve and BEV-pretreated subgroups demonstrated a consistent benefit with MIRV in patients with PROC

Data cutoff: March 6, 2023
PFS, progression-free survival; inv, investigator; BICR, blinded independent central review; ORR, objective response rate; MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; HR hazard ratio; BICR, blinded independent central review; BEV, bevacizumab; PROC, platinum-resistant ovarian cancer; CR, complete response; OS, overall survival.

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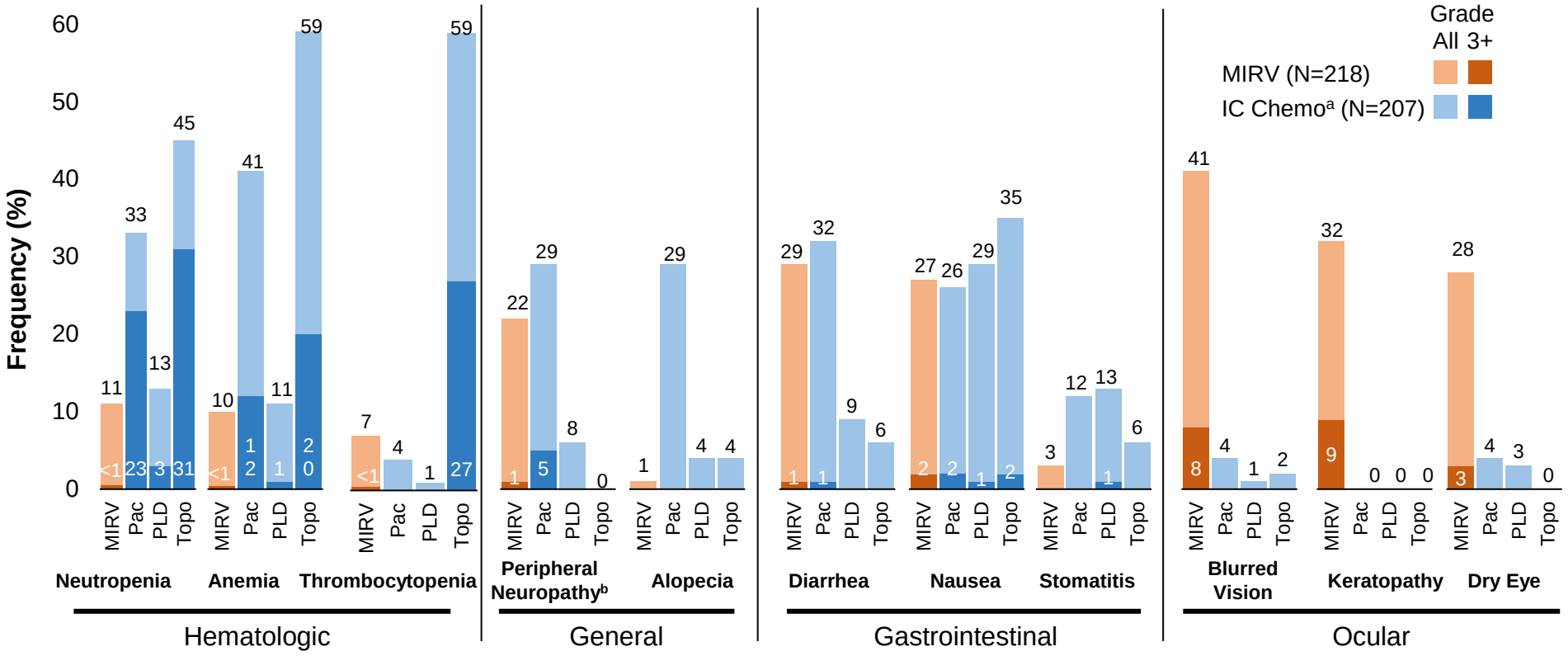
Safety Summary (N=425)

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

Differentiated Safety Profile: Treatment-Emergent Adverse Events



Data cutoff: March 6, 2023

MIRV, mirvetuximab soravtansine; IC Chemo: investigator's choice chemotherapy; 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.

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MIRASOL Conclusions

- MIRV is the first novel treatment to **demonstrate a benefit in overall survival** in platinum-resistant ovarian cancer in a phase 3 trial
- MIRV demonstrated statistically significant and clinically meaningful **improvement in PFS, ORR, and OS** compared to IC chemotherapy, 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

MIRV, mirvetuximab soravtansine, PFS, progression-free survival; ORR, objective response rate; OS, overall survival; IC, investigator's choice chemotherapy; ADC, antibody-drug conjugate; FRα, folate receptor alpha

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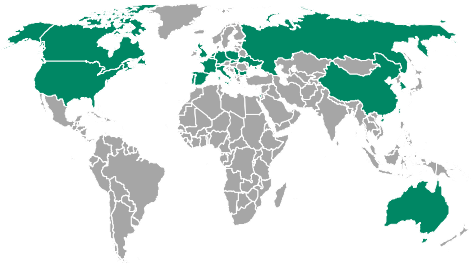
Acknowledgments

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.



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