Drug assessment at a glance: A26-06[1]

Mirvetuximab soravtansine (ovarian cancer)

26 August 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-06. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adult patients with FRα-positive, platinum-resistant high grade serous epithelial ovarian cancer who have received 1 to 3 prior systemic treatment regimens
Intervention	mirvetuximab soravtansine
Comparator	▪ paclitaxel (with or without bevacizumab for bevacizumab-naïve patients) or ▪ pegylated liposomal doxorubicin (PLD) (with or without bevacizumab for bevacizumab-naïve patients) or ▪ topotecan (with or without bevacizumab for bevacizumab-naïve patients)
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	Patients for whom monochemotherapy is a suitable treatment option: ↑↑↑ Patients for whom bevacizumab combination therapy is a suitable treatment option: Ø	★★ –
Morbidity	Ø	–
Symptoms	Ø	–
Health-related quality of life	Ø	–
Side effects	Patients for whom monochemotherapy is a suitable treatment option: ↑↑↑, ↓↓↓ Patients for whom bevacizumab combination therapy is a suitable treatment option: Ø	★★ –
	Ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall:

- Patients for whom monochemotherapy is a suitable treatment option: a large advantage with moderate informative value
- Patients for whom bevacizumab combination therapy is a suitable treatment option: no advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects

- Evidence base:
  - MIRASOL and FORWARD 1 studies: open-label RCTs comparing mirvetuximab soravtansine with chemotherapy (paclitaxel, PLD or topotecan); MIRASOL: N = 227 versus N = 226; FORWARD 1 relevant subpopulation: N = 82 versus N = 34
  - Meta-analysis of both studies based on individual patient data

- In both studies, the comparator arm lacked the option of bevacizumab combination therapy. No data were therefore available for patients for whom this treatment would have been an option.
- The overall survival results from MIRASOL were subject to a high degree of uncertainty, as the proportion of patients who were excluded from the analysis at an early stage was high and varied between the treatment arms.
- The results on side effects from both studies were subject to a high degree of uncertainty, as premedication for paclitaxel in accordance with the summary of product characteristics was not implemented to the required extent, or no data were available on this.

Key study findings

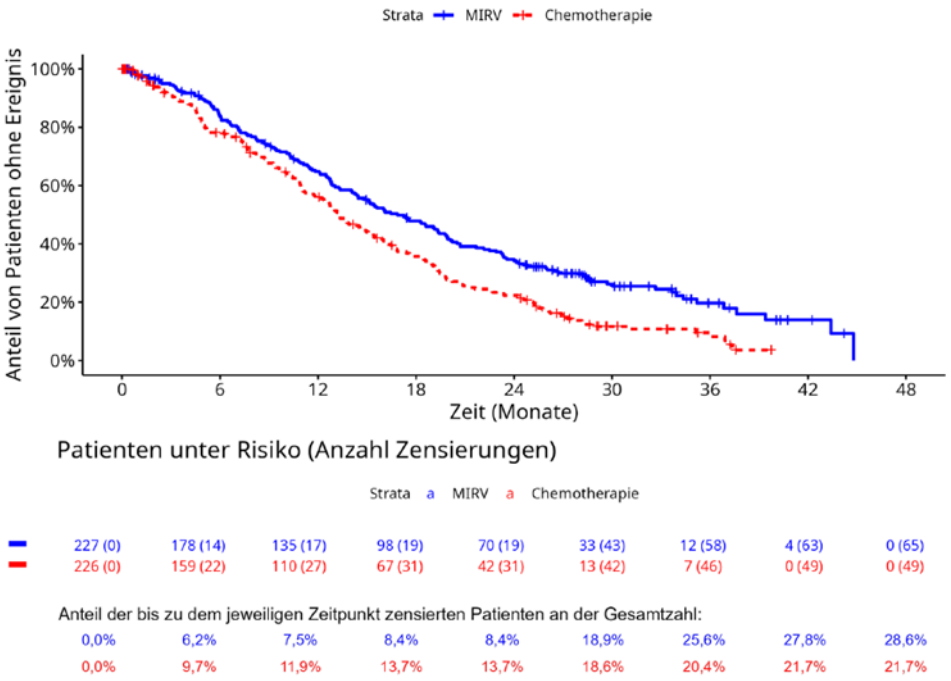
Outcome category Outcome Study	mirvetuximab soravtansine		chemotherapy		mirvetuximab soravtansine vs. chemotherapy
	N	Median time to event in weeks [95% CI] Patients with event n (%)	N	Median time to event in weeks [95% CI] Patients with event n (%)	HR [95% CI]; p-value
Mortality					
Overall survival					
MIRASOL	227	73.3 [62.4; 86.0] 162 (71)	226	58.0 [49.4; 65.9] 177 (78)	0.67 [0.54; 0.84]; < 0.001
FORWARD 1	82	71.4 [54.0; 89.1] 51 (62)	34	49.6 [26.6; 78.7] 25 (74)	0.66 [0.40; 1.08]; 0.104
Total					0.67 [0.55; 0.82]; < 0.001
Side effects					
AEs (supplementary information)					
MIRASOL	218	0.5 [0.3; 0.9] 211 (97)	207	1.0 [0.9; 1.1] 194 (94)	–
FORWARD 1	79	0.4 [0.3; 0.6] 79 (100)	32	0.5 [0.3; 1.0] 32 (100)	–

Outcome category Outcome Study	mirvetuximab soravtansine		chemotherapy		mirvetuximab soravtansine vs. chemotherapy
	N	Median time to event in weeks [95% CI] Patients with event n (%)	N	Median time to event in weeks [95% CI] Patients with event n (%)	HR [95% CI]; p-value
SAEs					
MIRASOL	218	NA [59.9; NC] 55 (25)	207	33.7 [28.6; NC] 69 (33)	0.55 [0.38; 0.79]; 0.001
FORWARD 1	79	97.3 [97.3; NC] 22 (28)	32	30.7 [7.6; NC] 13 (41)	0.44 [0.21; 0.92]; 0.033
Total					0.51 [0.37; 0.71]; 0.001
Severe AEs					
MIRASOL	218	31.6 [21.1; 47.7] 97 (44)	207	14.1 [9.7; 17.7] 113 (55)	0.54 [0.41; 0.72]; < 0.001
FORWARD 1	79	31.9 [19.0; NC] 37 (47)	32	9.0 [3.1; 10.4] 20 (62)	0.44 [0.25; 0.79]; 0.008
Total					0.51 [0.40; 0.66]; < 0.001

Outcome category Outcome Study	mirvetuximab soravtansine		chemotherapy		mirvetuximab soravtansine vs. chemotherapy
	N	Median time to event in weeks [95% CI] Patients with event n (%)	N	Median time to event in weeks [95% CI] Patients with event n (%)	HR [95% CI]; p-value
Discontinuation due to AEs					
MIRASOL	218	NA [73.9; NC] 25 (11)	207	79.1 [55.3; NC] 31 (15)	0.44 [0.25; 0.78]; 0.004
FORWARD 1	79	NA [61.1; NC] 11 (14)	32	NA [18.7; NC] 7 (22)	0.41 [0.15; 1.11]; 0.089
Total					0.44 [0.27; 0.73]; 0.001
Eye disorders (SOC, severe AEs)					
MIRASOL	218	100.7 [98.4; NC] 34 (16)	207	NA 0 (0)	ND; < 0.001
FORWARD 1	79	106.0 [44.7; NC] 11 (14)	32	NA 0 (0)	ND; 0.183
Total					ND; < 0.001

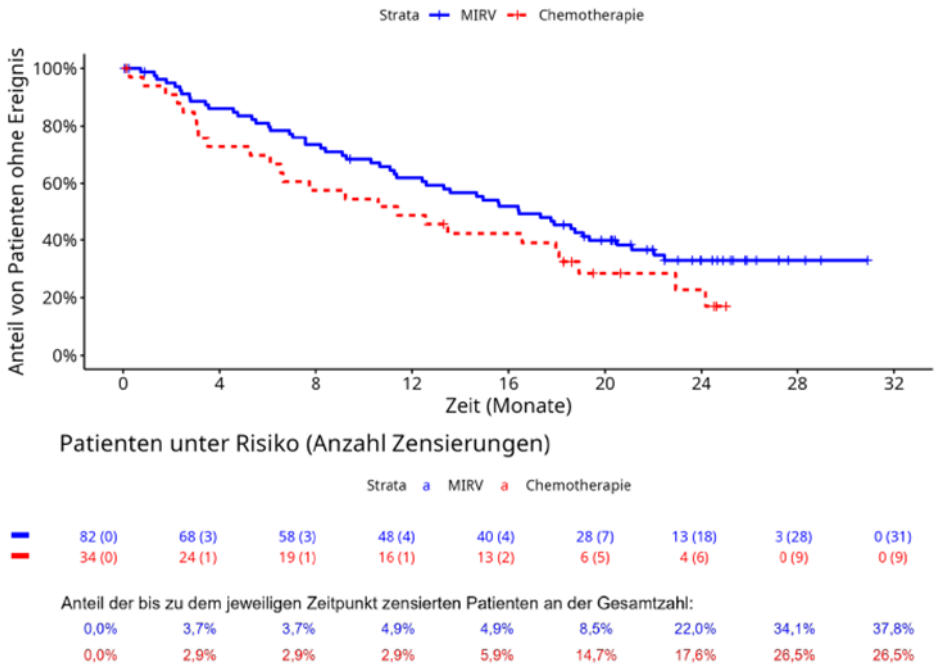
Kaplan-Meier curves on overall survival

MIRASOL study



Anteil der bis zu dem jeweiligen Zeitpunkt zensierten Patienten an der Gesamtzahl: Proportion of censored patients at each timepoint; Anteil von Patienten ohne Ereignis: Proportion of patients without an event; Chemotherapie: chemotherapy; Patienten unter Risiko (Anzahl Zensierungen): Patients at risk (number of censored cases); Zeit (Monate): Time (months)

FORWARD 1 study



Anteil der bis zu dem jeweiligen Zeitpunkt zensierten Patienten an der Gesamtzahl: Proportion of censored patients at each timepoint; Anteil von Patienten ohne Ereignis: Proportion of patients without an event; Chemotherapie: chemotherapy; Patienten unter Risiko (Anzahl Zensierungen): Patients at risk (number of censored cases); Zeit (Monate): Time (months)

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Mirvetuximab-Soravtansin (Ovarialkarzinom); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 06.08.2026]. URL: https://doi.org/10.60584/A26-06.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Mirvetuximab-Soravtansin (Neubewertung Orphan > 30 Mio: Ovarialkarzinom, Eileiterkarzinom oder primäres Peritonealkarzinom, FRα-positiv, platinresistent, nach 1 bis 3 Vortherapien) [online]. 2026 [Accessed: 06.08.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1305/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-06.html.

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