#CO101

Mean Overall Survival from the Phase 3 MIRASOL Trial of Mirvetuximab Soravtansine vs Investigator's Choice of Chemotherapy in Women with FRα-High Platinum-Resistant Ovarian Cancer (GOG 3045/ENGOT-ov55; NCT04209855)

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OBJECTIVE

To estimate the mean overall survival (OS) calculated using restricted mean survival time (RMST) and survival extrapolation, providing an assessment across the entire life span to better capture long-term survival benefit in patients from the Phase 3 MIRASOL trial.

CONCLUSIONS

The 4.11-month mean OS advantage for mirvetuximab soravtansine (MIRV) at 40 months measured with RMST increased to nearly 7 months when modeled to 5 years, substantially exceeding the 3.51-month median OS benefit from the MIRASOL final analysis.

The progression-free survival (PFS) and OS RMST differences between MIRV and investigator's choice of chemotherapy (ICC) continued to increase with longer follow-up, indicating a sustained survival benefit for patients treated with MIRV over ICC.

Mean OS provides an alternative and complementary measure to median OS to assess the magnitude of benefit with an intervention, allowing the capture of long-term survival benefits. With the longer-term survivorship demonstrated in MIRASOL, mean survival provides valuable information for patients, physicians, and health technology assessment bodies and supports MIRV as the standard of care in folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer (PROC).

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INTRODUCTION

MIRASOL Study Background

- MIRASOL (NCT04209855)[1] is a global, open-label, confirmatory, randomized Phase 3 study of MIRV vs ICC in patients with FRα-positive[a] PROC following 1-3 prior lines of therapy
- At the final data cutoff (Sep. 26, 2024), median follow-up for OS was 30.5 months in the intent-to-treat population (ITT; N=453: MIRV, n=227; ICC, n=226); MIRV significantly improved median OS vs ICC (16.85 vs 13.34 months, Δ3.51 months; hazard ratio [HR] 0.68; *P*=.0004)[2]
- To better characterize the survival benefit associated with MIRV in the MIRASOL trial, additional analyses were performed
  - While median OS and HRs are common in oncology trials, they only reflect the timepoint when 50% mortality is reached and can mislead if proportional hazards are not met in the presence of long-term survivors
  - Mean OS, calculated using RMST and survival extrapolation, provides an assessment across the entire follow-up period to better capture long-term survival benefit

[a]FRα expression measured by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay (Roche Diagnostics).

METHODS

RMST Rationale

- RMST is increasingly used in health technology assessment and supplementary clinical trial analyses to provide a more complete picture of survival benefit, alongside traditional median-based analyses using hazard ratios[3]
  - RMST is calculated using the mean area under the Kaplan-Meier (KM) survival curve, and is expressed in units of time, such as months or years
  - It is robust to violations of the proportional hazards assumption, making it more appropriate for studies where treatment benefit changes over time

RMST Calculation

- RMST for MIRV and ICC were obtained from the area under the KM PFS and OS curves using follow-up data from MIRASOL (up to 40 months)

Parametric Modeling

- Parametric extrapolation models were generated to extrapolate the number of life years for the MIRV and ICC treatment arms at 48, 60, and 120 months, and lifetime
  - Seven distributions were tested: exponential, Weibull, log-normal, log-logistic, Gompertz, gamma, and generalized gamma
- All 7 models were evaluated using the framework described by Latimer (2013)[4] including Akaike information criterion (AIC) and Bayesian information criterion (BIC) ranking
- Independent expert clinicians in PROC reviewed model outputs for clinical plausibility and visual fitting

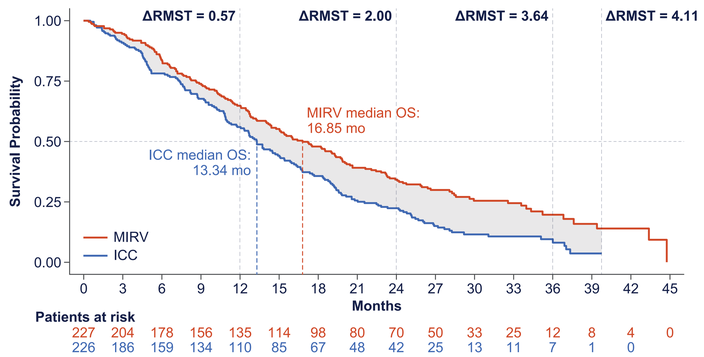
Model Selection

- The final models were selected under 2 scenarios:
  - An approach based on the best-fitting model to the study data by using KM curves until the point where too few patients remained at risk to form statistically-sound future predictions[5,6]
  - Using the Weibull distribution for both study arms, based on a similar analysis from the literature[3]; this is a conservative approach that may underestimate the survival benefit observed with MIRV

RESULTS

MIRASOL RMST

Figure 1. Mean Difference in OS in MIRASOL as Estimated by RMST



ICC, investigator's choice of chemotherapy; MIRV, mirvetuximab soravtansine; OS, overall survival; RMST, restricted mean survival time.

Table 1. RMST Values for the MIRASOL Phase 3 Trial

Timepoint	Treatment Arm	PFS RMST, months	PFS ΔRMST, months	OS RMST, months	OS ΔRMST, months
12 months	*MIRV* *ICC*	6.17 4.69	**1.48**	10.06 9.49	**0.57**
24 months	*MIRV* *ICC*	7.29 4.97	**2.32**	15.80 13.80	**2.00**
32 months	*MIRV* *ICC*	7.53 5.05	**2.48**	18.12 14.97	**3.15**
36 months	*MIRV* *ICC*			19.03 15.39	**3.64**
40 months	*MIRV* *ICC*			19.70 15.59	**4.11**

ICC, investigator's choice of chemotherapy; MIRV, mirvetuximab soravtansine; OS, overall survival; PFS, progression-free survival; RMST, restricted mean survival time.

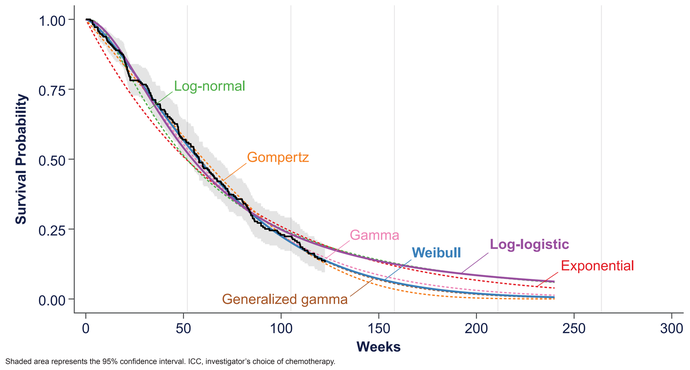
- Median follow-up time in MIRASOL was 28.35 months (95% CI: 24.97, NE) for PFS RMST calculation, and 30.49 months (95% CI: 28.75, 33.68) for OS RMST calculation
- Mean PFS and OS differences as measured with RMST favored MIRV over ICC at all time points (log rank *P*<.0001 for PFS; *P*=.0004 for OS) (**Table 1**)
- The difference in RMST PFS at 32 months was 2.48 months
- When considering OS, the difference in RMST between MIRV vs ICC arms progressively increased over the examined time points to a 4.11-month difference at 40 months (**Table 1**, **Figure 1**)
- MIRV and ICC OS RMST indicated a pattern of increasing advantage for patients in the MIRV treatment arm, prompting further examination using parametric modeling

PARAMETRIC MODELIZATION

Parametric Modeling of ICC Study Arm

- Based on visual and statistical fit, the Weibull model was selected as most closely matching the KM OS curve for the MIRASOL ICC arm (**Table 2**, **Figure 2**)

Figure 2. Parametric Extrapolation Models for the MIRASOL ICC Treatment Arm

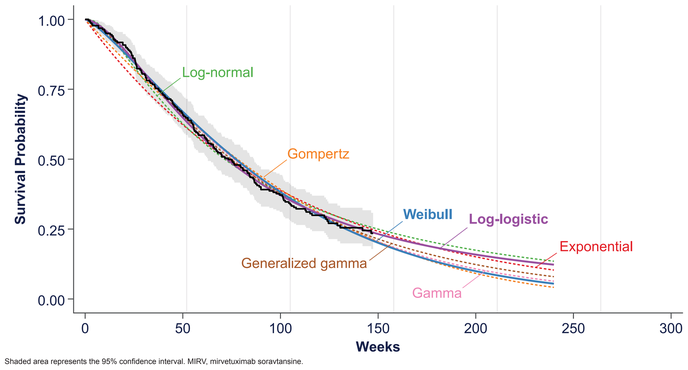


Shaded area represents the 95% confidence interval. ICC, investigator's choice of chemotherapy.

Parametric Modeling of MIRV Study Arm

- Of the 7 distributions tested, the log-logistic model was the best fit, visually and statistically, to the KM survival curve of patients treated with MIRV in the MIRASOL trial (**Figure 3**, **Table 2**)
  - The log-logistic model better matches the shape of the KM curve around week 140, when >20 patients remained in follow-up; after this time point, there was heavy censoring and increased uncertainty
  - The Weibull model was also included in the final model selection based on the literature; it provides a more conservative approach

Figure 3. Parametric Extrapolation Models for the MIRASOL MIRV Treatment Arm



Shaded area represents the 95% confidence interval. MIRV, mirvetuximab soravtansine.

Table 2. Mean Overall Survival for the Weibull and Log-logistic Models

	MIRASOL Clinical Trial Data			Parametric Modeling Data RMST in Months			
				Weibull		Log-logistic	
Timepoint	Treatment Arm	RMST	ΔRMST	mRMST	ΔmRMST	mRMST	ΔmRMST[b]
12 months	*MIRV* *ICC*	10.06 9.49	**0.57**	10.03 9.46	**0.58**	10.03 —	**0.58**
24 months	*MIRV* *ICC*	15.81 13.80	**2.00**	15.96 13.79	**2.17**	15.70 —	**1.91**
36 months	*MIRV* *ICC*	19.04 15.40	**3.64**	19.04 15.31	**3.73**	18.95 —	**3.64**
48 months	*MIRV* *ICC*			20.51 15.76	**4.75**	21.01 —	**5.26**
60 months	*MIRV* *ICC*			21.17 15.86	**5.30**	22.45 —	**6.59**
120 months	*MIRV* *ICC*			21.62 15.90	**5.72**	25.94 —	**10.00**
Lifetime	*MIRV* *ICC*			21.62 15.90	**5.72**	29.21 —	**13.31**

Model Validation

Clinical data are shown here for comparison to the model outputs. Both models produced RMST values close to the actual data.

Model Extrapolation

[b]Defined by Δ = Log-logistic MIRV RMST - Weibull ICC RMST.
ICC, investigator's choice of chemotherapy; MIRV, mirvetuximab soravtansine; mRMST, modeled RMST; OS, overall survival; RMST, restricted mean survival time.

Results in modeled mean overall survival

- Compared with ICC, both models consistently predict an increased number of life years for patients treated with MIRV at different time points (**Table 2**)
  - The survival benefit of MIRV over ICC was predicted to be 6.59 months at 5 years, 10.00 months at 10 years, and 13.31 months over a lifetime horizon with the log-logistic model
  - In comparison, the survival benefit of MIRV was predicted to be 5.30 months at 5 years and 5.72 months at 10 years and over a lifetime horizon with the Weibull model

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Abbreviations

AE, adverse event; AIC, Akaike information criterion; BIC, Bayesian information criterion; CI, confidence interval; FRα, folate receptor alpha; HR, hazard ratio; ICC, investigator's choice of chemotherapy; KM, Kaplan-Meier; MIRV, mirvetuximab soravtansine; PFS, progression-free survival; OS, overall survival; SGO, Society of Gynecologic Oncology; RMST, restricted mean survival time.