Here, we examine a large, international patient series to identify new adverse prognostic factors.

**Methodology** We evaluated 254 patients treated in Charing Cross Hospital and Mount Vernon Cancer Centre, UK and in Multi-centre Italian Trials in Ovarian Cancer (MITO) group between 1971 and 2018. Descriptive statistical, survival and Cox regression techniques were performed using STATA (StataCorp, v.16, Texas, USA).

**Results** Median age was 26 years (IQR, 20–32). There were 22.4% dysgerminomas, 18.5% immature teratomas, 33.5% yolk sac, 17.7% mixed, 1.2% embryonal, 2.4% choriacarcinoma and 4.3% unclassified. FIGO stage distribution was 24.4%, 65.9% and 7.3% of cases. 

First line chemotherapy consisted of BEP, POMB/ACE or other regimens in 31.5% (IC/M), 12.6% (II), 40.5% (III) and 15.4% (IV). First primary complete cytoreductive surgery (CC0-CC1) was achieved in 30.7% of patients, 22.4% dysgerminomas, 18.5% immature teratomas, 33.5% undifferentiated non-dysgerminoma versus dysgerminoma [HR 12.7, 95%CI (1.7–94.0), p=0.013] were significantly associated with worse cancer-specific survival (CSS). Twenty-year CSS for stage IC/M, II, III, and IV were 94.8%, 82.3%, 83.2% and 84.3%, respectively. In patients relapsing or failing to achieve a complete response, HDCT showed a trend for improved 5-year CSS compared to conventional treatments [HR 0.5, 95%CI (0.2–1.0), p=0.241].

**Conclusion** This study demonstrated that in addition to advanced stage, age ≥35 at presentation [HR 2.3, 95%CI (1.0–5.0), p=0.04], stage [HR 1.5, 95%CI (1.0–2.1), p=0.032], and non-dysgerminoma versus dysgerminoma [HR 12.7, 95%CI (1.7–94.0), p=0.013] were significantly associated with worse cancer-specific survival (CSS). Twenty-year CSS for stage IC/M, II, III, and IV were 94.8%, 82.3%, 83.2% and 84.3%, respectively. In patients relapsing or failing to achieve a complete response, HDCT showed a trend for improved 5-year CSS compared to conventional treatments [HR 0.5, 95%CI (0.2–1.0), p=0.241].
IC: paclitaxel, pegylated liposomal doxorubicin, or topotecan. Primary endpoint was PFS; key secondary endpoints: objective response rate (ORR), OS, and patient-reported outcomes (PRO) (hierarchical order).

**Results** 227 pts were randomized to the MIRV arm; 226 to the IC arm. Baseline characteristics were well balanced; 14% of pts had one, 39% two, and 47% three PLOT. In pts with 1 or 2 PLOT (n=245), PFS hazard ratio (HR), 95% confidence interval was 0.61 (0.45, 0.81) and 3 PLOT (n=208), PFS HR was 0.71 (0.52, 0.98). In patients with 1 or 2 PLOT, OS HR was 0.66 (0.45, 0.98); and 3 PLOT OS HR was 0.65 (0.43, 0.96). Compared with IC, MIRV was associated with lower rates of grade 3+ treatment-emergent adverse events (TEAEs) (42% vs. 54%), serious AEs (24% vs. 33%), and discontinuations due to TEAEs (9% vs. 16%). The key secondary PRO endpoint, EORTC QLC-OV28 (abdominal/GI symptom scale), will be presented.

**Conclusion** MIRV demonstrated a longer OS and PFS vs IC, regardless of the number of PLOT. MIRV is the first treatment to demonstrate both an OS and a PFS benefit in a phase III trial in PRO. These efficacy data, along with the well-characterized safety profile, position MIRV as a new standard of care for pts with FRα-positive PRO.

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**Introduction** Mirvetuximab soravtansine targets folate receptor alpha (FRα), demonstrated an improvement in progression-free survival (PFS) and overall survival (OS) in patients (pts) with platinum-resistant ovarian cancer (PROC) compared to investigator choice chemotherapy (IC) (Moore K et al. ASCO 2023; LBA5507). Here we present efficacy data by prior PARPi gaitor choice chemotherapy (IC) (Moore K et al. ASCO 2023; LBA5507). Here we present efficacy data by prior PARPi gaitor choice chemotherapy (IC) (Moore K et al. ASCO 2023; LBA5507).

**Methodology** 453 PROC pts with high FRα expression with 1–3 priors were randomized 1:1 to MIRV or IC: paclitaxel, pegylated liposomal doxorubicin, or topotecan. Primary efficacy endpoint was PFS; key secondary endpoints: overall response rate (ORR), overall OS, and patient-reported outcomes (hierarchical order).

**Results** 227 pts were randomized to the MIRV arm; 226 to the IC arm. Baseline characteristics were well balanced; 14% of pts had one, 39% two, and 47% three prior lines of therapy; 55% received prior PARPi. In pts with prior PARPi (n=251) PFS HR was 0.58 (95% confidence interval 0.43, 0.78, p-value=0.0002) and ORR 45% vs 17%, p-value <0.0001, favoring MIRV. In the PARPi-naïve subset (n=191), PFS HR was 0.74 (0.54, 1.03, p-value=0.0685) and ORR 40% vs 14%, p<0.0001. In pts with prior PARPi, MIRV had lower rates of grade 3+ treatment-emergent adverse events (TEAEs) (45% vs. 58%), serious TEAEs (21% vs. 35%), and discontinuations due to TEAEs (9% vs. 22%) compared with IC. Additional patient characteristics, safety, and OS data will be presented.

**Conclusion** MIRV is the first treatment to demonstrate both an OS and a PFS benefit compared to IC in a phase III trial in PROC. In this subset analysis, the benefit extends to patients regardless of prior PARPi, with the greatest benefits in pts with prior PARPi exposure. These efficacy data, along with the well-characterized safety profile, position MIRV as a new standard of care for pts with FRα-positive PROC.

### 10. Quality of life after treatment

**#461 PATIENT REPORTED OUTCOMES FROM CCTG CX.5 (SHAPE): RANDOMIZED TRIAL COMPARING RADICAL HYSTERECTOMY (RH) AND PV NODE DISSECTION (PN) VS SIMPLE HYSTERECTOMY (SH) AND PN IN WOMEN WITH LOW-RISK EARLY-STAGE**

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**Introduction** CX.5 (SHAPE) is a Canadian Cancer Trials Group (CCTG) led Gynecologic Cancer Intergroup international randomized phase III randomized non-inferiority trial comparing RH to SH in women with low-risk early-stage cervical cancer. The primary endpoint was pelvic recurrence rate at 3 years. Quality of Life (QoL) and Sexual Health are important survivorship issues for women undergoing this surgery and Patient Reported Outcomes (PROs) were important secondary endpoints in this trial.

**Methodology** PROs included QoL measured by EORTC QLC-C30 with QLC-CX24 and sexual health assessment (SHA) by the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale-Revised (FSDS-R). These were measured at baseline and at 3, 6, 12, 24, and 36 months after the surgery. Change scores from baseline were calculated and analyzed by linear mixed models.