

# SGO 2024 Annual Meeting Scientific Debrief: What Patients Should Know

May 18, 2024 | 11:30 a.m. to 1:30 p.m. CT





# A Special Thank You to the Patient Education Alliance!



# Cervical Cancer SGO 2024 Annual Meeting Updates

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# Assessing barriers to HPV vaccination in patients 27-45 years of age among OB/GYN providers and trainees

Warring, et al.

## Real Life Applications:

There are multiple provider, patient and healthcare system related factors that may be barriers to HPV vaccine administration; a comprehensive solution is needed to improve uptake!

**Purpose:** To determine perceived barriers to HPV vaccination among patients 27-45 years of age.

**Methods:** Surveyed OB/GYN providers and trainees (n=49) at a single institution to assess perceived barriers to HPV vaccine administration among patients 27-45 years old.

## **Results:**

- 26.5% of respondents reported that they never discussed HPV vaccination with unvaccinated patients between the ages of 27-45 (only 18.4% reported discussing this “often”)
- Patient related factors impacting likelihood of recommending vaccination (monogamous partner – 27% less likely; smoking – 61% more likely, etc.)
- Most common perceived barriers to providing vaccination: lack of time (70.2%), limited knowledge to counsel (23.4%), unsure how to facilitate vaccine (19.1%)



# Health disparities in cervical cancer: mapping behavioral and socioeconomic drivers of geographic dispersion of disease burden with the geo-analyzer

Castellano, et al.

## Real Life Applications:

- Social determinants of health (poverty level, race/ethnicity, access to modern treatments) contribute to geographical variations in CC and r/m CC and may drive disparities
- Need to optimize access for all!

**Purpose:** To better understand factors related to observed geographic variations in cervical cancer (CC) and recurrent/metastatic (r/m) CC.

**Methods:** Utilized administrative claims database (CC prevalence, incidence or r/m CC, etc.), US Census Bureau American Community Survey (poverty level, race/ethnicity), and American Brachytherapy Society data (presence of a brachytherapy center) data to quantify association between CC or r/m CC burden with CC screening rates, poverty level, race/ethnicity and brachytherapy access.

## Results:

- Screening rates: higher screening rates associated with decreased CC burden
- Household income: increased low-income households associated with decreased screening and higher CC burden
- Brachytherapy access: presence of at least one center associated with reduction in r/m CC burden

**Pembrolizumab plus chemoradiotherapy for high risk, locally advanced cervical cancer: randomized, double-blind, phase 3 EGNOT-cx11/GOG-3047/KEYNOTE-A18 study**

**Duska, et al.**

**Real Life Applications:**

Pembrolizumab combined with chemoradiotherapy and then continued as maintenance should be considered as a new standard of care for patients with high risk, locally advanced cervical cancer

**Purpose:** To assess the efficacy and safety of pembrolizumab + concurrent chemoradiotherapy for patients with high risk, locally advanced cervical cancer.

**Methods:** Patients (n=1,060) with FIGO 2014 Stage IB2-IIB (node positive) or Stage III-IVA (either node positive or negative) disease were randomized to receive cisplatin + EBRT followed by brachytherapy *plus* pembrolizumab (5 cycles, then maintenance x 15 cycles) versus placebo. Primary endpoints: PFS and OS.

**Results:**

- Improved PFS in patients that received pembrolizumab
- Trend towards improved OS in patients that received pembrolizumab
- Most common AE: anemia, nausea, diarrhea (similar between groups)

## A randomized phase III trial of induction chemotherapy followed by chemoradiation compared with chemoradiation alone in locally advanced cervical cancer

Ledermann, et al.

### Real Life Applications:

- Induction chemotherapy followed by chemoradiation should be considered as a new standard of care for patients with locally advanced cervical cancer
- Which study is best applied to each patient?

**Purpose:** To determine the impact of the addition induction chemotherapy to standard chemoradiation for locally advanced cervical cancer on survival.

**Methods:** Patients (n=500) with FIGO 2008 Stage IB1 (node positive), IB2, II, IIIB and IVA cervical cancer were randomized to receive cisplatin + EBRT followed by brachytherapy +/- induction chemotherapy (weekly carboplatin and paclitaxel x 6 weeks). Primary endpoints: PFS and OS.

### **Results:**

- PFS improved with addition of induction chemotherapy (5 year PFS: 73 vs. 64%)
- OS improved with addition of induction chemotherapy (5 year OS: 80 vs. 72%)
- Induction chemotherapy was associated with more hematologic toxicity, but did not compromise the delivery of radiation

**Primary results from BEATcc, a randomized phase 3 trial of first line atezolizumab combined with bevacizumab and a platinum doublet for metastatic (Stage IVB), recurrent or persistent cervical cancer**

**Ledermann, et al.**

**Real Life Applications:**

Atezolizumab in combination with bevacizumab added to platinum-based chemotherapy should be considered a new first-line therapy options for patients with metastatic, recurrent or persistent cervical cancer

**Purpose:** To determine the impact of dual PD-L1 and VEGF blockade on survival in metastatic, recurrent or persistent cervical cancer.

**Methods:** Patients (n=410) with metastatic, recurrent or persistent cervical cancer not amenable to curative therapy randomized to bevacizumab + paclitaxel +cis-/carbo-platin *with or without* atezolizumab. Primary endpoints: PFS and OS.

**Results:**

- PFS improved with addition of atezolizumab (median PFS: 13.7 vs. 10.4 months)
- OS improved with addition of atezolizumab (median OS: 33.1 VS. 22.8 months)
- Predictable and acceptable safety profile with no new safety signals



# Endometrial/Uterine Cancer SGO 2024 Annual Meeting Updates

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## Endometrial Pathology in premenopausal patients seeking emergency care for abnormal uterine bleeding: high risk of endometrial malignancy and premalignancy

Grubman, et al.

### Conclusions:

- Patients seeking emergency gynecologic cancer for abnormal bleeding have risk of pre-malignant endometrial abnormalities and endometrial cancer.
- Expedited work-up is needed especially for patients who have anovulation and elevated BMI who have increased risk

**Purpose:** To evaluate patient characteristics associated with benign, intermediate, and malignant endometrial pathology among premenopausal individuals presenting to the emergency department with abnormal uterine bleeding prompting same day workup

**Methods:** Cross-sectional study, OB/GYN ER 2013-2022,

*Inclusion criteria:* age 18-50, moderate to severe abnormal uterine bleeding, Gyn US & endometrial sampling within 24 hours

*Exclusion criteria:* postmenopausal bleeding and/or previously diagnosed gynecologic cancer

### Results:

- 1618 evaluable patients

<b>Benign</b>	<b>1303 (80.5%)</b>
<b>Intermediate</b>	<b>281 (17.4%)</b>
	Disordered proliferative -- 224 (13,8%) Hyperplasia without atypia -- 57 (3.5%)
<b>Malignant</b>	<b>34 (2.1%)</b>
	Atypical hyperplasia/EIN 16 -- (0.99%) Invasive cancer 18 -- (1.1%)

- Anovulatory bleeding, higher BMI, and younger age associated with higher risk of intermediate or malignant pathology

**Overall survival in patients with primary advanced or recurrent endometrial cancer treated with dostarlimab plus chemotherapy in Part 1 of the ENGOT-EN6-NSGO/GOG-3031/Ruby trial**

**Powell, et al.**

**Conclusions:**

Chemotherapy with immunotherapy is a new standard of care for advanced or recurrent endometrial cancer

**Purpose:** Initial Ruby trial showed improved PFS in dMMR/MSI-H and overall populations

This study updated OS, PFS2, and safety results

**Methods:** Stage III-IV or first recurrent EC

Randomized to paclitaxel/carboplatin/dostarlimab 500 mg followed by dostarlimab 1000 mg IV q 6 weeks up to 3 years versus paclitaxel/carboplatin/placebo followed by placebo.

494 pts randomized: 245 dostarlimab and 249 placebo

**Results:**

- 16.4 months improved median OS in all patients and 7 month median OS benefit in patient with MMRp/MSS tumors
- Patients with dMMR/MSI-H tumor had unprecedented OS benefit
- PFS2 data was consistent with OS
- No new safety concerns



# Durvalumab +carboplatin/paclitaxel followed by durvalumab with or without olaparib as first-line treatment for endometrial cancer(DUO-E/GOG-3041/ENGOT-EN10): objective response rate and duration of response by mismatch repair status

Hye Sook Chon, et al.

**Purpose:** Chemotherapy plus immunotherapy has shown benefit in endometrial cancer. Could the addition of a PARP-I to immunotherapy in the maintenance setting add benefit

**Methods:** Stage III-IV or recurrent endometrial cancer, all histologies except sarcoma

718 patients randomized to:

- Carboplatin/paclitaxel/placebo +placebo maintenance
- Carboplatin/paclitaxel/durvalumab(1120mg)+ durvalumab (1500 mg) maintenance
- Carboplatin/paclitaxel/durvalumab (1120 mg) + durvalumab (1500 mg)/Olaparib (300 mg) maintenance

## **Results:**

- 80% proficient MMR 20 % deficient MMR
- Improved objective response rate in from 55.1% (CP) to 61.9% (CP+D) to 63.6% (CP+D+O) in the intent to treat population
- Duration of response increased from 7.7 mo (CP) to 13.1 mo (CP+D) to 21.3 mo (CP+D+O)
- Patients with deficient MMR had improved PFS, ORR, and DoR versus chemotherapy alone
- In patients with pMMR, the addition of durvalumab to CP improved PFS and increased the median duration of response by 3 months versus chemotherapy alone ( 7.6 months to 10.6 months)
- In patients with proficient MMR, the addition of olaparib improved PFS and increased the median duration of response by 8.1 months versus chemotherapy plus durvalumab ( 10.6 months to 18.7 months)

## **Efficacy and safety of trastuzumab deruxtecan in patients with HER2-expressing solid tumors: biomarker and subgroup analyses from the cervical, endometrial, and ovarian cancer cohorts of the DESTINY-PanTumor02 study**

**Makker, et al.**

### **Conclusions:**

T-DXd is a potential treatment for patients with HER2 expressing gynecologic cancers that have progressed on other therapies

**Purpose:** HER2 is expressed in a range of solid tumors and is associated with a biologically aggressive phenotype

Trastuzumab deruxtecan is a drug antibody conjugate

**Methods:** Destiny-PanTumor02 study is a phase 2 study

HER2 expressing tumors ( IHC 3+or 2+)

- Endometrial 6-17% (3+) 13-39% (2+)
- Cervical 4-11% (3+) 18% (2+)
- Ovarian 2-5% (3+) 8-18% (2+)

### **Results:**

Objective response rates:

- Endometrial (57.5%) IHC3+( 84.6%)
- Cervical (50%) IHC3+ (75%)
- Ovarian (45%) IHC3+ (63.6%)

Response was seen in heavily pretreated patients, patients with previous HER2 or TOP 1 inhibitor therapies

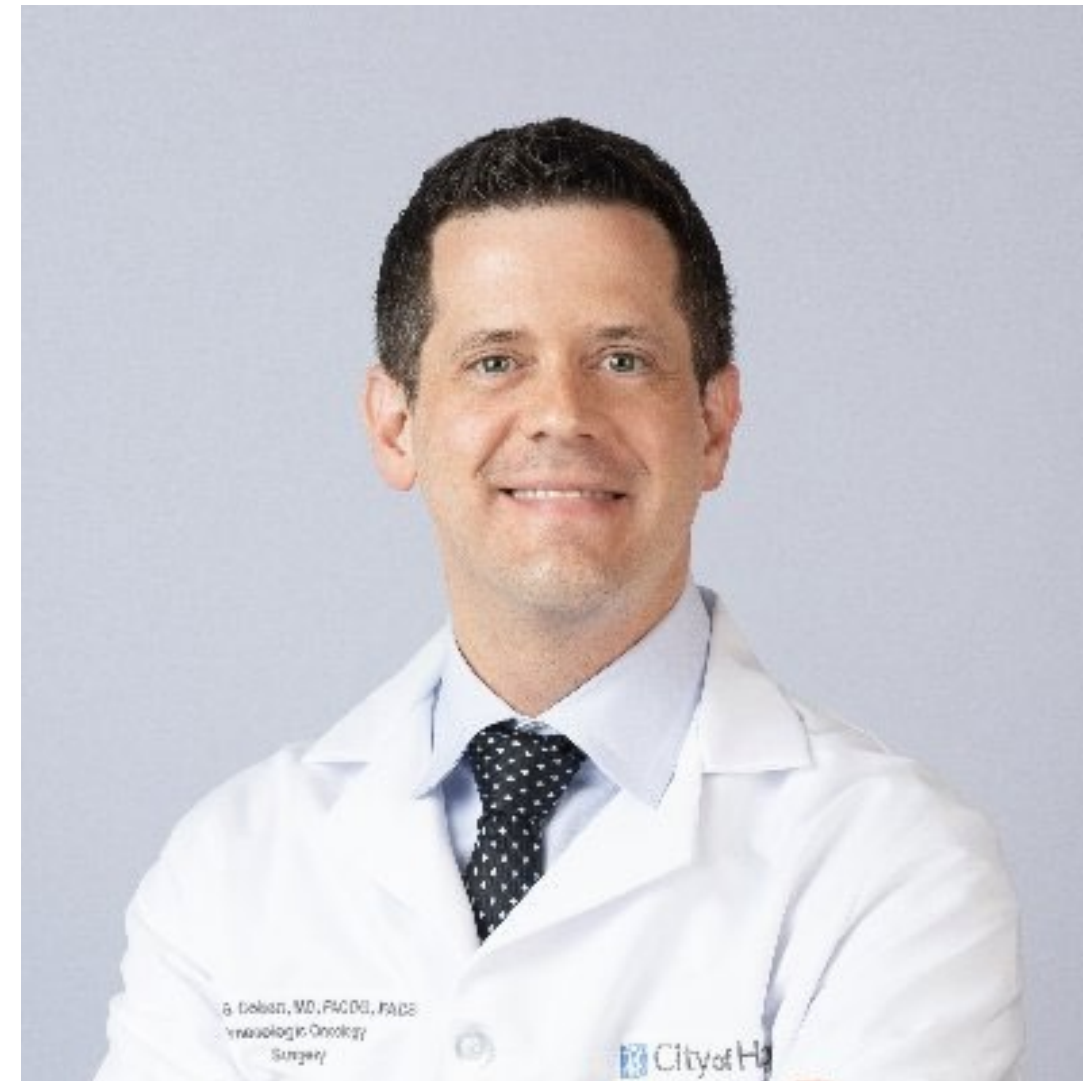
Most common side effects- nausea, fatigue and diarrhea

# Ovarian Cancer SGO 2024 Annual Meeting Updates

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# Avutometinib plus defactinib in recurrent, low-grade serous ovarian cancer: A subgroup analysis of ENGOT-ov60/GOG-3052/RAMP 201 Part A

Banerjee, et al.

## Caveats to Consider

- **KRAS mutation impact on response rates**
- **Comparison of this regimen to hormonal therapy or standard of care chemotherapy**
- **Common TEAEs included nausea; diarrhea; blood creatine phosphokinase increase; edema peripheral; vomiting; vision blur; dermatitis acneiform; fatigue; rash; aspartate aminotransferase increase; dry skin; and blood bilirubin increase.**
- **GOG-3097/ENGOT-ov81/NCRI/RAMP 301: A Phase 3, Randomized, Open-Label Study of Combination Therapy with Avutometinib plus Defactinib Versus Investigator's Choice of Treatment in Patients with Recurrent LowGrade Serous Ovarian Cancer**

**Hypothesis:** Avutometinib (VS-6766) monotherapy and in combination with defactinib may have clinical benefit for patients with recurrent Low-Grade Serous Ovarian Cancer (LGSOC)

- The ENGOT-OV60/GOG-3052/RAMP 201 study is a phase 2 clinical trial evaluating the efficacy and safety of avutometinib (a unique small molecule RAF/MEK clamp) alone and in combination with defactinib (a FAK inhibitor) in patients with recurrent LGSOC.
- A planned subgroup analysis of RAMP 201 (April 6, 2023 data cutoff) was performed to assess the efficacy (Part A; confirmed ORR, blinded independent central review; n=29) and safety (all treated patients; n=81) of avutometinib + defactinib in the context of 1) lines of prior systemic therapy (lines of treatment; 1–3, ≥4) and 2) best response to most recent prior treatment in the metastatic/recurrent setting (partial response/complete response [PR/CR], no PR/CR; investigator-assessed)
- Similar ORRs were observed among patients treated with 1–3 (5/11; 45.5%) and ≥4 (8/18; 44.4%) lines of treatment
- Treatment with avutometinib + defactinib in 3/4 patients who previously received MEKi achieved confirmed PRs
- The safety profiles of avutometinib + defactinib were similar in the 1–3 and ≥4 lines of treatment subgroups and were consistent with previously reported safety data.

## Conclusion & Real-World Application:

- Avutometinib + defactinib achieved high response rates in heavily pre-treated recurrent LGSOC, regardless of the previous line of therapy
- Tumor regression was observed in the majority of patients, including those with stable disease or progressive disease with the last line of therapy, including previous MEK inhibitor
- The majority of treatment-related adverse events (TRAEs) were mild to moderate, manageable/reversible.

## Phase I analysis from the PYNNACLE phase I/II study of PC14586 in the subgroup of patients with advanced ovarian cancer harboring a TP53 Y220C mutation

Schram, et al.

### Caveats to Consider

- In the overall population, 67 patients, including this subset of patients with ovarian cancer, were assessed. The most frequent treatment-related adverse events (TRAEs) were nausea (51%), vomiting (43%), and increased blood creatinine (27%). The frequency and severity of TRAEs were similar in the ovarian cancer population compared with the overall population
- TP53 Y220c mutation present in 2.9% of ovarian cancers
- Only 22 patients in ovarian cohort, sample size is small
- The PYNNACLE Phase 2 clinical trial (NCT04585750) is ongoing and will assess rezatapopt as monotherapy in patients with TP53 Y220C and KRAS wild-type advanced solid tumors

**Hypothesis:** Mutations in the TP53 gene leading to p53 inactivation are the most common mutations across human cancers. Rezatapopt (PC14586) is a first-in-class p53 reactivator that selectively binds to the mutated p53 Y220C protein and restores wild-type (WT) activity.

- The Phase 1 PYNNACLE trial (NCT04585750) showed that rezatapopt has a favorable safety profile and promising efficacy in heavily pre-treated patients across multiple tumor types
- Patients with locally advanced or metastatic ovarian cancer with a TP53 Y220C mutation were eligible.
- As of September 5, 2023, the median age of patients with ovarian cancer (n=22) was 66 years (range: 49–81 years).
- The median number of prior lines of systemic therapy was 4 (range: 1–9). At study entry, 19 patients were platinum resistant, 2 were refractory, and 1 was platinum-sensitive. Of the 15 patients with measurable disease at baseline, 7 had partial response (PR), 7 had stable disease (SD), and 1 had progressive disease.
- The median duration of response was 7 months. Of 15 patients with measurable serum CA-125 at baseline, 6 had a CA-125 response. Among these, 4 patients achieved radiographic PR, and 2 had SD.

### Conclusion & Real-World Application:

- Rezatapopt showed promising efficacy in heavily pre-treated patients with TP53 Y220C advanced ovarian cancer
- Rezatapopt has a favorable safety profile in the overall population and the ovarian cancer subset

**Durvalumab plus paclitaxel/carboplatin plus bevacizumab followed by durvalumab, bevacizumab plus olaparib maintenance among patients with newly-diagnosed advanced ovarian cancer without a tumor BRCA1/BRCA2 mutation: Updated results from DUO-O/ENGOT-OV46/GOG-3025 Trial**

Harter, et al.

**Caveats to Consider**

- **Is the added toxicity with durvalumab worth potential clinical benefit**
- **What is the true contribution of adding durvalumab**
- **The financial toxicity that may come with the trial regimen**
- **Neither the median value or tail of curve in arm 2 (durvalumab alone) differs from the control curve**
- **Minimal difference between the ITT analysis DUO-O arm 3 and the exploratory non-BRCA analysis of adding olaparib in PAOLA-1**

**Hypothesis:** The addition of durvalumab and Olaparib in the upfront setting may impact progression free survival and overall survival for patients with ovarian cancer

Patients had newly diagnosed FIGO stage III or IV high-grade epithelial, non-tBRCAm advanced ovarian cancer; primary or planned interval debulking surgery; and 1 cycle of paclitaxel/carboplatin ± bevacizumab. At cycle 2, patients were randomized 1:1:1 to Arm 1 (control): paclitaxel/carboplatin + bevacizumab + durvalumab placebo (PBO) (up to 6 cycles) followed by bevacizumab (total 15 months) + durvalumab PBO (total 24 months) + olaparib PBO (total 24 months) maintenance; Arm 2: paclitaxel/carboplatin + bevacizumab + durvalumab followed by bevacizumab + durvalumab + olaparib PBO maintenance; or Arm 3: paclitaxel/carboplatin + bevacizumab + durvalumab followed by bevacizumab + durvalumab + olaparib maintenance

- A total of 1,130 patients were randomized: 378 Arm 1, 374 Arm 2, and 378 Arm 3. At this updated PFS analysis (DCO2 September 18, 2023), a sustained improvement was observed for Arm 3 versus Arm 1 in the non-tBRCAm HRD-positive population: HR 0.46 (95% CI: 0.33–0.65), with a median (m)PFS of 45.1 versus 23.3 months, and PFS rate at 24 months of 72.9% versus 46.5%, respectively, and for Arm 3 versus Arm 1 in the non-tBRCAm ITT population: HR 0.61 (95% CI: 0.51–0.73), with mPFS of 25.1 versus 19.3 months, and PFS rate at 24 months of 53.0% versus 33.2%, respectively
- A PFS benefit continued to be observed for Arm 3 versus Arm 1 in the HRD-negative population (HR: 0.68; 95% CI: 0.54–0.85). A numerical improvement in PFS was shown for Arm 2 versus Arm 1 (non-tBRCAm ITT), but statistical significance was not reached in this final PFS analysis
- The interim OS analysis for Arm 3 versus Arm 1 was not statistically significant in the non-tBRCAm ITT population (HR: 0.95; 95% CI: 0.76–1.20; P=0.68; 39% maturity); however, a positive OS trend was noted in the non-tBRCAm HRD-positive population (23% maturity); no further testing was performed per MTP.
- Overall, the most common grade ≥3 AEs in Arm 3 were neutropenia (31% vs 28% in Arm 2 and 26% in Arm 1) and anemia (25% vs 8% in Arm 2 and 8% in Arm 1)

**Conclusion & Real-World Application:**

DUO-O continued to demonstrate clinically meaningful PFS benefit with first-line durvalumab + chemotherapy + bevacizumab followed by durvalumab, bevacizumab + olaparib maintenance (Arm 3) versus control (Arm 1) — mPFS of 45.1 months in Arm 3 is the longest observed for non-tBRCAm HRD-positive patients in the first-line setting to date



## **Efficacy and safety of trastuzumab deruxtecan among patients with HER2-expressing solid tumors: Biomarker and subgroup analyses from the cervical, endometrial, and ovarian cancer cohorts of the DESTINYPanTumor02 study**

**Makker, et al.**

### **Caveats to Consider**

- **What is the best scoring system to use of Her2 IHC?**
- **ILD/pneumonitis remains an important identified risk; proactive monitoring, early detection, and active management are critical in preventing high-grade ILD/pneumonitis**
- **The three most commonly reported drug-related treatment emergent adverse events were nausea, fatigue, and diarrhea**
- **What about for patients with IHC 1+, is there benefit for this cohort**
- **Where is this drug best used in the treatment of ovarian cancer**

**Hypothesis:** In DESTINY-PanTumor02, T-DXd demonstrated clinically meaningful response rates, progression-free survival, and overall survival in HER2-expressing tumors, including gynecologic tumors.

This is an open-label phase II study (NCT04482309) evaluated T-DXd (5.4 mg/kg Q3W) among patients with HER2-expressing (immunohistochemistry [IHC] 3+/2+ by local [with retrospective central testing] or central testing) locally advanced/metastatic disease after  $\geq 1$  systemic treatment, or without alternative treatment.

- 40 ovarian cancer (OC) patients, 19 patients IHC 2+ and 11 patients IHC 3+
- In this HER2-expressing population, the prevalence of BRCA1/2m and HRRm in the OC cohort was 18.4% (7/38) and 21% (8/38), respectively
- 18/40 response (45%), IHC 3+ 7/11 (63.6%), IHC 2+ 36.8%
- Grade  $\geq 3$  drug-related adverse events occurred in 54/120 (45.0%) patients with EC, CC, and OC.
- Adjudicated treatment-related interstitial lung disease/pneumonitis occurred in 13/120 (10.8%) patients with EC, CC, and OC (n=12, grade  $\leq 2$ ; n=1, grade 5).

### **Conclusion & Real-World Application:**

- T-DXd demonstrated clinically meaningful ORR among patients with HER2-expressing gynecologic tumors, irrespective of the number of prior lines of therapy, use of prior HER2 or TOP1 inhibitor therapy, and presence or absence of biomarkers relevant to individual cohorts.
- The safety of T-DXd was consistent with the known profile. These data support T-DXd as a potential treatment for patients with gynecologic HER2-expressing tumors who have progressed on prior therapy.

# Patient-reported outcome results from phase III MIRASOL trial of mirvetuximab soravtansine versus investigator's choice of chemotherapy in FR $\alpha$ -positive, platinum-resistant ovarian cancer

Konecny, et al.

## Caveats to Consider

- **IV chemotherapy regimens are associated with inflammatory abdominal symptoms, including partial SBO, due to targeting of peritoneal and serosal tumor deposits (such as PEG-liposomal doxorubicin, gemcitabine, and paclitaxel)**
- **Delayed collection of PROs at week 8/9 may have minimized the impact of treatment-related toxicity**
- **Would the addition of bevacizumab change these results**
- **Given the PRO favor mirvetuximab, should patients with less than 75% IHC expression have access to this drug as a single agent**

**Hypothesis:** Mirvetuximab soravtansine (MIRV), an antibody-drug conjugate targeting folate receptor-alpha (FR $\alpha$ ), is the first novel treatment to demonstrate a benefit in overall survival (OS) in platinum-resistant ovarian cancer (PROC) in a phase III trial. MIRASOL is the confirmatory, randomized, global phase III trial of MIRV versus standard of care chemotherapy among patients with PROC, which met its primary and key secondary endpoints with statistically significant results in progression-free survival (PFS; INV), objective response rate (ORR; INV), and OS.

Primary patient reported outcomes (PROs) from the European Organization for Research and Treatment of Cancer (EORTC) QLQ-OV28 for patients enrolled in MIRASOL

- A total of 453 FR $\alpha$ -positive PROC patients (Roche FOLR1 Assay) with 1-3 prior lines of therapy were randomized 1:1 to MIRV 6 mg/kg, adjusted ideal body weight, day 1 of a 21-day cycle or investigator's choice (IC) of paclitaxel, pegylated liposomal doxorubicin, or topotecan. The primary PRO assessment was defined as the number of patients achieving at least 15-point improvement at week 8/9 in the abdominal/GI symptom scale of EORTC QLQ-OV28.
- A total of 21% of MIRV patients and 15.3% of IC Chemotherapy patients met the threshold of a 15-point improvement at week 8/9 (P=0.2611). At all time points, statistically significant differences favoring MIRV over IC on the abdominal/GI symptom scale occurred in mean change from baseline at week 8/9 with a difference of -5.0 (95% CI: -8.3 – -1.6; P= 0.0041) with continuous improvement at week 24 of -6.0 (-10.2 – -1.8; P= 0.0056)
- Anchor-based analyses demonstrated that an 11-point change in subscale score was clinically meaningful. Sensitivity analysis using the 11-point threshold showed that 29% of MIRV patients and 18% of IC Chemotherapy patients met the improvement threshold at week 8/9 (P=0.0318).

## Conclusion & Real-World Application:

- Patients treated with mirvetuximab soravtansine experienced better health-related quality of life (HRQOL) compared with the investigator's choice of chemotherapy based on assessments with several validated PRO measures.
- Patients treated with MIRV are more likely to maintain or improve on ovarian cancer-specific measures of HRQOL, with statistically significant improvements observed relative to IC across all time points in abdominal/GI symptoms.
- The efficacy and safety of MIRV are supported by PRO data from the MIRASOL trial and position MIRV as a new standard of care for patients with FR $\alpha$ -positive PROC



# Vaginal/Vulvar Cancer SGO 2024 Annual Meeting Updates

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# Utility of ctDNA as an early predictive biomarker of response to RT/CRT in gynecologic malignancies

Wernicke, et al.

## Real Life Applications

- We need prospective validation
- Does “tumor-informed” ctDNA remain applicable across a treatment course?
- Could this ultimately identify patients for who we could de-escalate treatment?
- Cost?

## Purpose:

To assess the correlation of clinical response in GYN patients receiving radiation (RT) or chemotherapy-radiation (CRT) to ctDNA detection and dynamics.

## Methods:

- Retrospective analysis of patients with vulvar, cervical and recurrent endometrial cancer treated with RT/CRT between 2022-2023
- ctDNA was collected pre-treatment, mid-treatment, end of treatment
- Post-treatment testing at 1, 3, 6 months and then every 6 months using **tumor-informed** ctDNA assay

## Results:

- n=15, 34% were vulvar/vaginal cancer patients
- Strong correlation between elevated ctDNA and measurable disease on imaging pre-treatment
- Patients with undetectable ctDNA at mid-RT and end of RT remained no evidence of disease with undetectable ctDNA at follow up
- ctDNA demonstrates feasibility as a predictive biomarker of response to RT/CRT in patients with GYN malignancies and correlated with response to treatment by imaging and clinical exams

**Outcomes of low-volume metastatic disease among patients with early-stage squamous cell carcinoma undergoing sentinel lymph node biopsy: Results from the International Vulvar Cancer Consortium (IVUCCO)**

**Nasioudis, et al.**

**Real Life Applications**

- Low volume metastatic disease appears to be clinically relevant
- Real-world outcomes may differ from clinical trial
- Macrometastatic disease may benefit from the addition of radiosensitizing chemotherapy to reduce recurrence risk

**Purpose:**

To investigate the outcomes of patients with early-stage vulvar cancer who underwent sentinel lymph node biopsy and had lymph node mets  $\leq 2$ mm in size ("micromet").

**Methods:**

- Retrospective study including 19 academic institutions
- Inclusion criteria: unifocal squamous cell carcinoma of the vulva,  $> 1$ mm depth of invasion, tumor size  $< 4$ cm, successful inguinal sentinel lymph node biopsy
- Exclusion: non-squamous histology, clinically enlarged inguinal lymph nodes, concern for distant disease

**Results:**

- Groin recurrence rate 7% in patients with negative sentinel lymph nodes
- Macromets (tumor  $> 2$ mm) in sentinel lymph nodes: recurrence rate was 22.6%
  - EBRT + chemo reduced risk of recurrence from 30.3% to 17.1% ( $p=0.15$ )
- Micromet in sentinel lymph nodes: recurrence rate was 23.3%.
  - Micromet in sentinel lymph node, recurrence risk with no additional treatment = 40%
  - Micromet in sentinel lymph node, recurrence risk with EBRT = 15.4%

# Outcomes of groin recurrence in vulvar cancer after primary treatment with a sentinel lymph node procedure

Cornel, et al.

## Real Life Applications

- Groin recurrence after SLNBx is not uniformly fatal, particularly if they have not had prior radiation
- Repeat resection may be an option if no prior radiation
- Need to account for selection bias in a retrospective study that higher risk patients were more likely to get adjuvant radiation.
- Prospective data is needed to help guide treatment decisions

## Purpose:

Evaluate treatment outcomes in patients with recurrent vulvar cancer who had previous sentinel lymph node (SLN) procedures.

## Methods:

- Single institution, retrospective cohort study of all patients with recurrent vulvar cancer who had previously underwent a SLN procedure

## Results:

- N=298 had vulvar cancer who underwent SLNBx
  - 42.4% underwent adjuvant treatment
  - N=85 (28.5%) developed recurrence, 10.4% patients recurred in the groins, 20.5% in the vulva
- Disease-free survival by recurrence location: 117 months vulva, 8.9 months groin, 4.4 months distant.
- Treatment of groin recurrence: 60% surgical resection if no prior radiation whereas no patients had surgery if they had prior radiation
- Groin recurrence outcomes:
  - Without prior radiation: 80% alive at 25 months
  - With prior radiation: 63.6% died of disease, median OS 1.6 months



# Disparity in vulvar cancer survival between rural, urban and metropolitan residence: A National Cancer Database Analysis 2012-2019

Gruner, et al.

## Real Life Applications

- Retrospective data suggests a disparity in outcomes for vulvar cancer for patients living in rural areas.
- Research is needed to understand the factors driving this disparity
- Education for PCPs on diagnosis of vulvar cancer
- Importance of HPV vaccination

## Purpose:

To summarize and compare overall survival following a vulvar cancer diagnosis by residential location in the US.

## Methods:

- Retrospective cohort study using the National Cancer Database (NCDB) between 2012-2019
- Residence was categorized as rural, urban or metropolitan

## Results:

- 36,135 cases of vulvar cancer between 2012 and 2019
- 81.7% lived in metropolitan areas, 16.3% urban and 2.0% rural
- Histology, stage, node positivity and time to treatment were similar between groups
- Patients in rural areas were LESS likely to be treated at an academic/research program facility than those in urban or metropolitan areas (30.6% vs 38.7% and 39.0%,  $p < 0.001$ ).
- Patients in rural (HR 1.32,  $p < 0.001$ ) and urban (HR 1.07,  $p = 0.019$ ) locations had higher risk of mortality compared to those in metropolitan locations after adjusting for demographic and clinical characteristics.

# Diversity, Health Equity, & Inclusion

## SGO 2024

### Annual Meeting Updates

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**Increase in counseling seen among patients at risk for genetic cancer syndromes with use of a digital risk stratification tool in a historically underserved population- A randomized controlled trial**

**Webster E., et al.**

**Real Life Applications**

In a historically underserved population, a randomized controlled trial demonstrated the use of a digital genetic cancer risk stratification tool was associated with a larger proportion of eligible patients being counseled about their increased genetic risk. The integration of a digital risk stratification tool may work towards mitigating disparities in utilization of genetic services.

**Purpose:**

Compare the proportion of eligible patients recommended for hereditary cancer syndrome genetic testing when risk assessment is performed by a digital tool versus usual clinician interview.

**Methods:**

New gynecology patients at an urban academic clinic were consented and randomized 1:1 to the intervention or control arm prior to their appointments (Figure 1. Study procedure diagram). In the intervention arm, patients were prompted to use an online, patient-facing risk stratification tool to collect and interpret relevant personal and family history. A summary of the tool-generated genetic risk assessment was available to the patient and provider. In the control arm, patients underwent genetic cancer risk assessment via usual provider interview. Eligibility for hereditary cancer syndrome genetics testing was determined using criteria set forth by the National Comprehensive Cancer Network (NCCN). Fisher's exact was used for statistical analysis.

**Results:**

79 patients enrolled in the study; 40 were randomized to genetic cancer risk assessment via digital tool (intervention arm), and 39 were randomized to risk assessment via usual clinician interview (control arm). Twenty-nine (37%) patients self-identified as Hispanic, 19 (24%) as Non-Hispanic White, 15 (19%) as non-Hispanic Black, 9 (11%) as Asian, 2 (3%) as mixed race, and 5 (6%) preferred not to answer. Most patients had Medicaid insurance, and 24 (30%) reported having a household income of less than \$40,000. Use of the genetic cancer risk assessment tool was associated with a higher likelihood of patients receiving counseling regarding their elevated genetic risk . Among patients with elevated genetic risk, 4 (44%) in the intervention arm and 2 (18%) in the control arm proceeded with genetic testing for hereditary cancers at the time of their appointment (p=0.3).





# Engaging endometrial cancer survivors as peer supporters for equitable cancer care: The SISTER Study training process

Moore A., et al.

## Real Life Applications

It is feasible to recruit and train Black EC survivors as peer support facilitators. ECANA has identified social support as a key area of outreach to decrease social isolation during treatment to affect cancer outcomes.

## Purpose:

To develop and execute an effective peer support training program for the SISTER Study of Peer Support delivered by Black EC survivors

## Methods:

Black EC survivors were recruited and trained to deliver cognitive behavior therapy-related support tools and techniques to EC patients on active treatment via virtual one-on-one or group sessions. Recruitment was via email and in person outreach to the Endometrial Cancer Action Network for African Americans (ECANA) membership. All survivors were required to have received prior EC treatment and be more than 6 months out. Two pre-training gatherings and a formal 2-day training were completed via virtual sessions.

## Results:

- Guided discussion of SISTER protocol and aims led by PIs
- Ongoing meetings to maintain skills creates an empowered and durable peer support team with strong long-term retention
- Readiness evaluated through group role play exercises, repeated materials review and 10-question quiz

# Survival disparities among Black patients compared to White patients enrolled in Gynecologic Oncology Group (GOG) randomized clinical trials: An analysis of 1,882 women

Johnson C., et al.

## Real Life Applications

Based on data from randomized clinical trials adjusted for surgery and chemotherapy treatment, Black patients experienced worse overall survival compared to White patients. Further studies are warranted to determine the genetic and social determinants of health based on race among ovarian cancer patients.

## Purpose:

To evaluate racial disparities within ovarian cancer survival in randomized clinical trials from the GOG

## Methods:

Data on stage III and IV epithelial ovarian cancer patients were obtained from four prospective randomized Gynecologic Oncology Group clinical trials (111, 114, 158, 172). Race was categorized as Asian, Black, and White. Statistical models and log-rank tests were performed to determine overall survival (OS).

## Results:

- Of 1,882 ovarian cancer patients (median age: 57 years), 1,658 (91.8%) were White, 116 (6.4%) were Black, and 32 (1.8%) were Asian. Approximately 93.5% of patients had stage III disease and 6.5% had stage IV disease.
- Overall, 5-year OS was 40.6%. Asian and White patients had higher 5-year OS at 42.0% and 41.2% compared to Black patients at 31.2% ( $p=0.039$ ).
- Black patients experienced higher mortality than White patients (HR 1.29; 95% CI 1.045, 1.584;  $p=0.02$ )

# Racial and ethnic inequities in end-of-life care intensity among patients with gynecologic cancers in California

Cruz D., et al.

## Real Life Applications

Further work to understand processes leading to racial and ethnic inequities in EoL care of patients with gynecologic cancers, and whether this care is counter to patient values, is needed.

## Purpose:

High-intensity care among patients with cancer at the end of life (EoL) is associated with poor quality of life. Objective was to assess prevalence of high intensity EoL (HI-EoL) care among patients with cervical, endometrial, and ovarian cancers in California

## Methods:

Population-based retrospective cohort study included deceased patients with cervical, uterine, or ovarian (hereafter gynecologic) cancers diagnosed from 2013-2019 in the California Cancer Registry and linked to inpatient and ambulatory surgery center data. Primary outcomes : > 1 hospitalization, <sup>3</sup>1 emergency department (ED) visit, or <sup>3</sup>1 invasive mechanical ventilation (IMV) in the last 30 days of life, ≤ 3 days in hospice prior to death, and death in the hospital

## Results:

- 1744 (15.2%) with cervical, 4833 (42.1%) with uterine, and 4898 (42.7%) with ovarian cancer
- 6085 (53.0%) were NHW, 1030 (9.0%) NHB, 2728 (23.8%) Hispanic, 1531 (13.4%) API, and 101 (0.9%) AI/AN
- There were significant differences in EoL care metrics by racial and ethnic group category, such as having DNR orders, >1 hospital admission in the last 30 days of life, death in hospital, and having any HI-EoL care
- The adjusted odds of receiving HI-EoL care were 1.50 times higher for NHB patients (95% CI, 1.30, 1.73), 1.18 times higher for Hispanic (95% CI, 1.06, 1.31), and 1.17 times higher for API (95% CI, 1.03, 1.32) vs. NHW patients



# Risk of cancer progression of non-atypical endometrial hyperplasia (NEH) in a diverse patient population: A long-term, follow-up study

Yao B., et al.

## Real Life Applications

Women from racially diverse patient populations harboring non-atypical endometrial hyperplasia were at significantly higher risk of cancer progression than proposed by the World Health Organization (WHO).

## Purpose:

Assess the long-term risk of EC progression from NEH in a diverse patient population

## Methods:

Retrospective study of all women with NEH diagnosis found on endometrial sampling in a large academic institution reviewed between 1995 -2017 with follow-up data available until 2023

## Results:

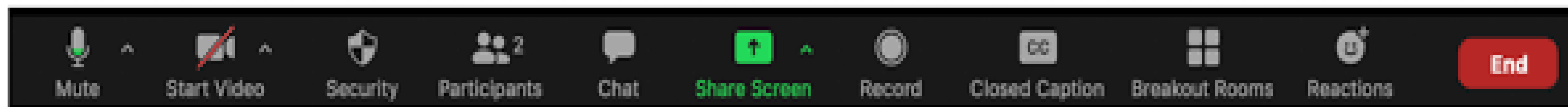
Most common ethnicity/race group were Black patients 32.9% (n=120) followed by Hispanic 26.8% (n=98). Total of 9.9% of patients developed EC, 8.5% progressed to atypical hyperplasia, and 40.1% had persistent NEH or progression to AEH or EC

# Q&A Breakout Rooms

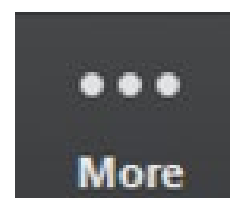
[Ovarian Cancer](#) | [Cervical Cancer](#) | [Endometrial/Uterine Cancer](#) | [Vulvar/Vaginal Cancer](#) |  
[Diversity, Health Equity, & Inclusion](#)

You'll be able to choose whichever breakout room you'd like to enter.  
This is your time to ask questions and dive deeper!

You can switch between the rooms at your leisure using the 'Breakout Room' button on your zoom toolbar.



If you don't see it, try clicking the 'More' button:





# SGO 2025 Annual Meeting on Women's Cancer

in Seattle, WA  
March 15<sup>th</sup> – March 18<sup>th</sup>

## Patient-Focused Events

- Patient & Advocate Education Session
- Patient Advocate's Hope Award Poster Walk
- Coffee, Chat, & Recap





# Foundation for Women's Cancer Educational Resources



## 什么是癌症?

癌症是一个用来定义一系列疾病的词。它们有一个共同的特点，即细胞不受控制地生长，有可能扩散（转移）到身体的其他部位。只有当癌症发生转移时，才属于子宫颈癌、子宫（子宫内膜癌）、卵巢、输卵管。

Tipos de cáncer ginecológico

Cada año se diagnostica a aproximadamente 110,000 mujeres en los Estados Unidos uno de los cinco principales tipos de cáncer ginecológico: de cuello de útero, ovario, endometrio (útero), vulva o vagina. El objetivo de este manual es ayudarlas a comprender los síntomas y minimizar el riesgo de que se desarrollen.

Si se ha diagnosticado cáncer de ovario, endometrio (útero), cuello de útero, vulva o vagina, es importante que un ginecólogo oncológico, médico con capacitación especializada en el tratamiento de estos tipos de cáncer ginecológico, forme parte de su equipo médico para ayudarla a supervisar su atención desde el diagnóstico hasta la finalización del tratamiento.

Cervical • Ovarian • Endometrial/Uterine • Vaginal • Vulvar  
**GYNECOLOGIC CANCER AWARENESS**  
 Know the Symptoms, Reduce the Risk  
 RESEARCH • AWARENESS • OUTREACH • EDUCATION



## Compassionate Caregivers: Navigating Cancer's Challenges

WHAT SHOULD I KNOW?  
**Vulvar and Vaginal Melanoma**  
 Foundation for Women's Cancer

**DESCRIPTION OF THE TUMOR/CANCER TYPE**  
 Vulvar and vaginal melanomas are rare accounting for 5% of vulvar malignancies and 2.4-2.8% of all vaginal malignancies. They develop by malignant transformation of melanocyte cells that are formed in early development as an embryo. Vulvar and vaginal melanomas are considered mucosal melanomas and are more likely to have recurrence and an aggressive clinical course than cutaneous melanomas. Prognostic factors include age, tumor size, thickness of the tumor and lymph node involvement.

**SIGNS & SYMPTOMS**  
 Vulvar and vaginal melanomas can present with a vulvar lesion, vulvar bleeding, irritation or pain. The majority of vulvar and vaginal melanomas are pigmented but may be colorless or have other appearances. Melanomas can have irregular margins or can increase in size.

**SCREENING**  
 There are no screening guidelines for vulvar or vaginal melanoma, but any lesion that is increasing in size, pigmented, has irregular margin especially in a postmenopausal patient should be considered for biopsy or excision.

**TREATMENT AND FOLLOW UP**  
**Role of Surgery:** Surgery has been the standard for treatment of vulvar and vaginal melanoma. For cutaneous melanomas a margin of 1-2 cm is recommended but recent data suggest no improvement in survival in vulvar and vaginal melanoma based on the extent of negative margin. Evaluation of inguinal lymph nodes by sentinel lymph node evaluation is typically done for cutaneous melanomas but because of the rarity of vulvar and vaginal melanoma specific data concerning sentinel lymph node evaluation is limited.

**Role of Radiation Therapy:** Radiation therapy has been utilized in vulvar and vaginal melanoma for patients with lymph node involvement at high risk of recurrence as well as in the setting of recurrence or unresectable disease for relief of symptoms or for patients who are not surgical candidates.

**Role of Chemotherapy:** Targeted therapies or immunotherapy are preferred, but selected chemotherapies are options for patients who are not candidates for targeted therapies or immunotherapy.

**Targeted Therapy options:** In patients with BRAFV600 mutation in the tumor combination therapy with dabrafenib/trametinib versus vemurafenib/cobimetinib versus Encorafenib/bimetinib are options.

Tumors with activating mutations of KIT can be treated with Imatinib.

Larotrectinib or entrectinib for NTRK gene-fusion positive tumors.

NRAS mutated tumors if progression on immunotherapy can be treated with binimetinib.

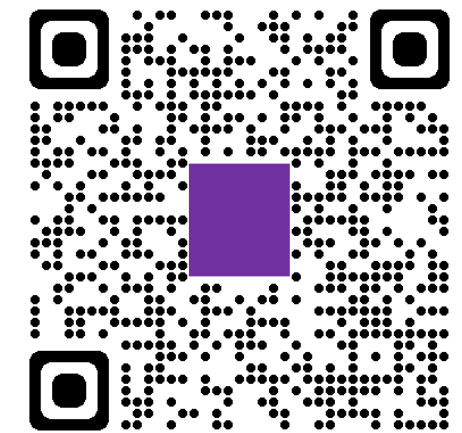
**Immunotherapy options:** If systemic therapy is indicated immunotherapies are the preferred regimens including pembrolizumab or nivolumab versus nivolumab/pIpilimumab. Pembrolizumab/low-dose ipilimumab can be used if progression after anti-PD-1 therapy. Other options include ipilimumab or high dose IL-2 therapy.

**QUESTIONS TO ASK YOUR CARE TEAM**  
 Ask about eligibility for clinical trials if applicable. Clinical and family history may identify patients who are at risk for other melanomas or malignancies and who may benefit from genetic testing.

If you are not already being treated by a gynecologic oncologist, consider seeking a second opinion. Things to consider when getting a second opinion include getting a pathology review by a gynecologic or dermatopathologist as well as presentation to a tumor board.

The Foundation for Women's Cancer (FWC) is a 501(c)(3) nonprofit organization dedicated to supporting research, education and public awareness of gynecologic cancers. [foundationforwomenscancer.org](http://www.foundationforwomenscancer.org)  
 The FWC is the official foundation of the Society of Gynecologic Oncology.

## Rare Tumor One Pagers



**ACCESS ALL FWC RESOURCES HERE!**

**Thank you so much for coming!**

**Thank you again to the Patient Education Alliance and all participants for making this possible!**

