

# OPTIMIZING THE MANAGEMENT OF NEWLY DIAGNOSED OVARIAN CANCER INCLUDING MAINTENANCE

TRICIA I. FREDERICKS MD, MPH  
NOVEMBER 7, 2023



# WELCOME



**60-minute LIVE  
Webinar**



**All Guests on Mute**



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# WELCOME TODAY'S MODERATOR AND SPEAKER



**Timothy Mullett, MD, MBA, FACS**

**Professor**  
Division of Cardiothoracic Surgery and  
Medical Director, University of  
Kentucky, Markey Cancer Center  
Network Development



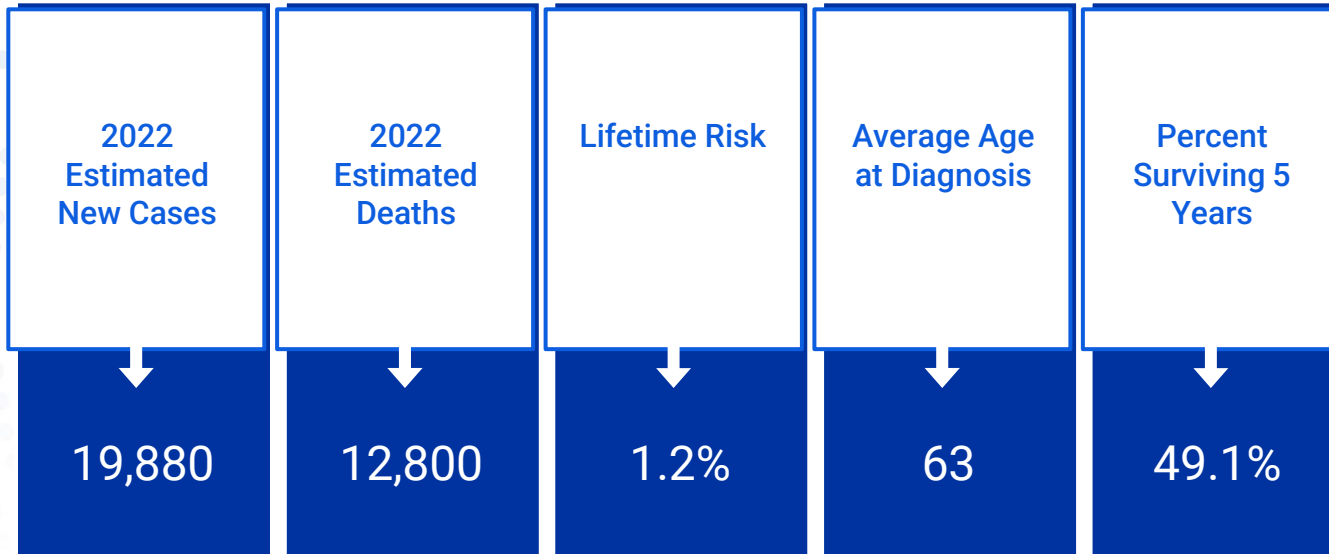
**Tricia Fredericks, MD, MPH**

**Assistant Professor**  
Obstetrics and Gynecology  
University of Kentucky Markey Cancer  
Center

# LEARNING OBJECTIVES

- Optimizing management of patients with newly diagnosed ovarian cancer
- Strategies to manage toxicities of novel ovarian cancer therapies
- Strategies to better manage patients with ovarian cancer at platinum resistant relapse
- Management of treatment options using a multidisciplinary care approach and the value of tumor boards
- Importance of clinical trial participation

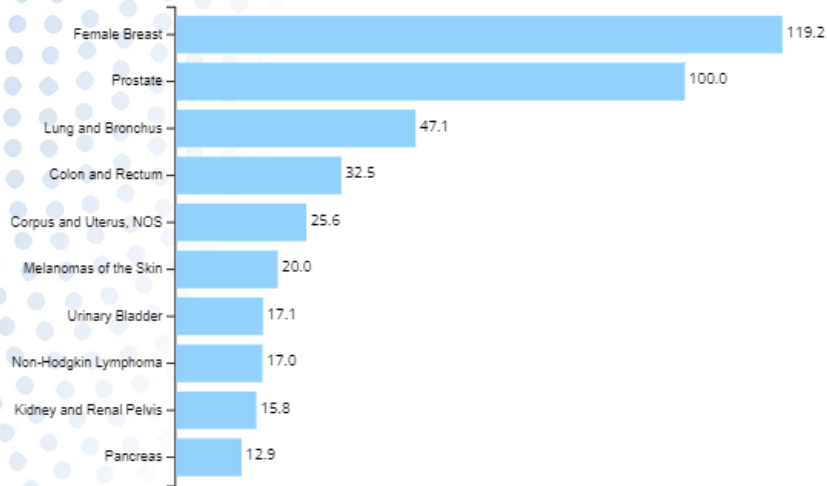
# OVARIAN CANCER KEY FACTS



SEER Cancer Statistics Factsheets: Ovarian Cancer. National Cancer Institute.

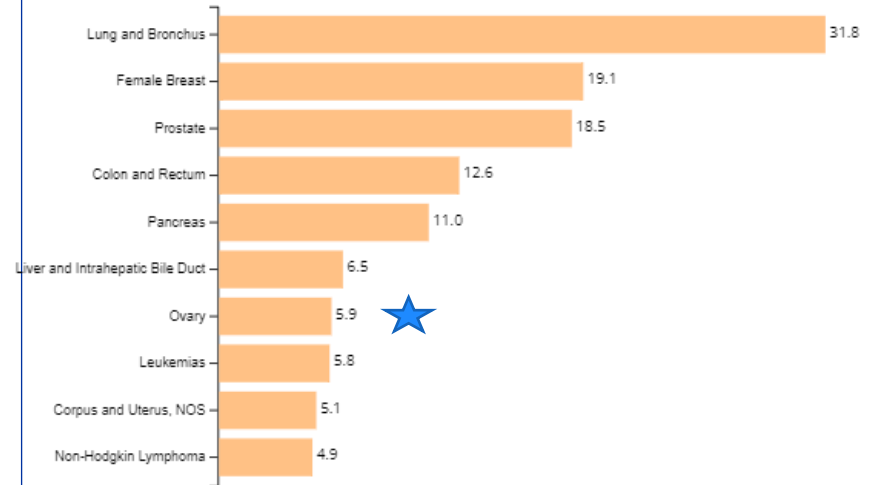
# OVARIAN CANCER MORTALITY

Top 10 Cancers by Rates of New Cancer Cases  
United States, 2020, All Races and Ethnicities,  
Male and Female



Rate per 100,000 people

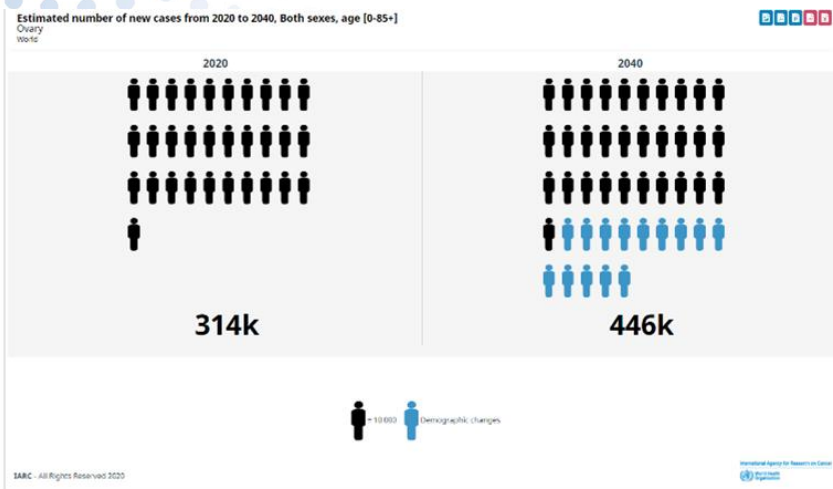
Top 10 Cancers by Rates of Cancer Deaths  
United States, 2020, All Races and Ethnicities,  
Male and Female



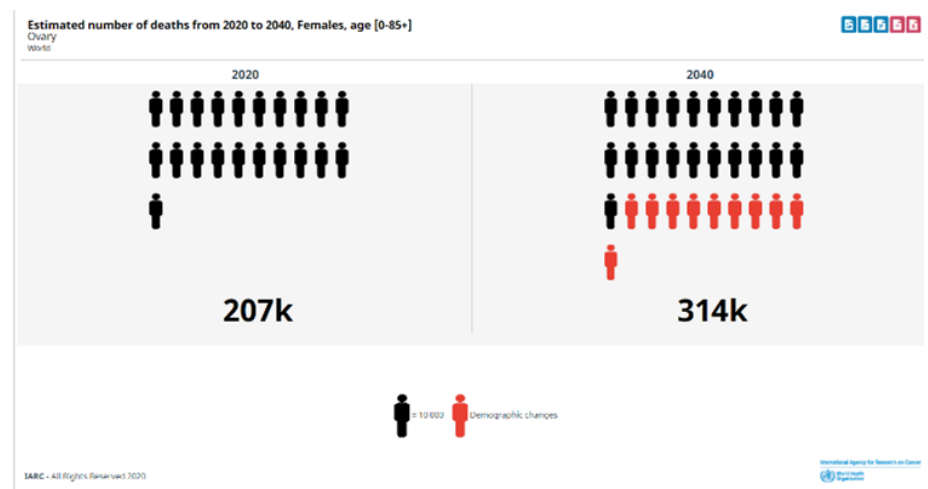
Source - U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020):  
U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute;  
<https://www.cdc.gov/cancer/dataviz>, released in June 2023.

# OVARIAN CANCER

## ESTIMATED WORLDWIDE BURDEN



Incidence 2020 ->2040



Mortality 2020 -> 2040

<https://gco.iarc.fr/tomorrow>

# POLLING QUESTION

What gynecologic malignancy has the highest mortality rate?

- a) Endometrial
- b) Ovarian
- c) Cervical
- d) Vulvar



# NEWLY DIAGNOSED OVARIAN CANCER

# NEWLY DIAGNOSED OVARIAN CANCER

- Initial assessment
- Can I feasibly perform a debulking surgery for the patient to no visible residual disease given current disease status?
- Can the patient tolerate surgery?
- Yes: Primary debulking surgery
- No: Neoadjuvant chemotherapy
- Is the patient able to tolerate/accept chemotherapy after surgery?
  - If no: recommend palliative care approach
- \*\*\*Germline and somatic genetic testing for every new diagnosis

Bristow, Robert E., Isha Puri, and Dennis S. Chi. *Gynecologic oncology* 112.1 (2009): 265-274.  
Hoskins, William J., et al. *American journal of obstetrics and gynecology* 170.4 (1994): 974-980.  
Wright, Alexi A., et al. *Gynecologic oncology* 143.1 (2016): 3-15.

# OVARIAN CANCER CYTOREDUCTIVE SURGERY

- Total abdominal hysterectomy
- Bilateral salpingo-oophorectomy
- Omentectomy
- Grossly visible disease
- Do not routinely remove lymph nodes only if grossly enlarged or disease appears confined to an ovary

# LIMITATIONS TO PRIMARY SURGERY

- Stage IV Disease (Pleural effusions, metastatic lung nodules, liver, spleen parenchymal disease)
  - Bulky upper abdominal disease
  - Porta hepatis
  - Enlarged high aortic lymph nodes
  - Diffuse miliary disease
  - Mesenteric disease
  - Fixed pelvic mass
  - Stomach
- 
- Medical co-morbidities: cardiac, pulmonary, hepatic, recent DVT/PE

# PRIMARY SURGERY

- Assess ability to successfully perform a debulking surgery with goal no visible residual disease
  - Imaging
  - Laparoscopy
- Surgery followed by:
- Carboplatin AUC 6 + Paclitaxel 175 mg/m<sup>2</sup> iv q 21 days for 6 cycles
  - Various regimens: dose dense, IP regimens tested without survival benefit but increased toxicity
  - GOG 172, GOG 252, ICON 8, GOG 262

Katsumata, Noriyuki, et al. *The Lancet* 374.9698 (2009): 1331-1338.  
Clamp, Andrew R., et al. *The Lancet Oncology* 23.7 (2022): 919-930.  
Chan, John K., et al. *New England Journal of Medicine* 374.8 (2016): 738-748.  
Walker, Joan L., et al. *Journal of Clinical Oncology* 37.16 (2019): 1380.  
Armstrong, Deborah K., et al. *New England Journal of Medicine* 354.1 (2006): 34-43.

# NEOADJUVANT CHEMOTHERAPY

- Carboplatin AUC 6 + Paclitaxel 175 mg/m<sup>2</sup> iv q 21 days for 3 cycles
- Consideration of interval debulking surgery
  - Has there been a good response to chemotherapy?
  - Can we technically debulk to no visible residual disease?
  - Are they healthy enough for surgery and willing to receive more chemotherapy after surgery?
- After surgery, additional Carboplatin AUC 6 + Paclitaxel 175 mg/m<sup>2</sup> iv q 21 days for 3 cycles

Vergote, Ignace, et al. *New England Journal of Medicine* 363.10 (2010): 943-953.

Kehoe, Sean, et al. *The Lancet* 386.9990 (2015): 249-257.

Wright, Alexi A., et al. *Gynecologic oncology* 143.1 (2016): 3-15.

# BEVACIZUMAB IN PRIMARY SETTING

GOG 218, ICON7

- Primary surgery followed by chemotherapy
  - Add bevacizumab starting cycle 2 after surgery if suboptimal debulking
  - Can continue with bevacizumab maintenance
- Neoadjuvant with good response and no visible residual after surgery
  - No bevacizumab
- Neoadjuvant chemotherapy with suboptimal interval debulking
  - Consider addition of bevacizumab with second cycle after surgery
- Neoadjuvant chemotherapy with response but not able to debulk
  - Consider addition of bevacizumab

Perren, Timothy J., et al. *New England Journal of Medicine* 365.26 (2011): 2484-2496.  
Burger, Robert A., et al. *New England Journal of Medicine* 365.26 (2011): 2473-2483.

# MAINTENANCE?

- Bevacizumab can be continued as maintenance if it was used in the upfront setting
- PARP inhibitors approved in those with complete or partial response to platinum agents for maintenance
  - Germline or somatic BRCA 1/2, HRD pathway mutations
  - Evidence of HRD+ on Next Gen sequencing
  - All comers?
- Do not recommend chemotherapy for maintenance

Perren, Timothy J., et al. " *New England Journal of Medicine* 365.26 (2011): 2484-2496.  
Burger, Robert A., et al. *New England Journal of Medicine* 365.26 (2011): 2473-2483.  
DiSilvestro, Paul, et al. *Journal of Clinical Oncology* 41.3 (2023): 609.  
González-Martín, Antonio, et al. *New England Journal of Medicine* 381.25 (2019): 2391-2402.  
Markman, Maurie, et al. *Gynecologic oncology* 114.2 (2009): 195-198.



# RECENT ASCO PARP INHIBITOR UPDATE

## Recommendation Update

PARPi	First remission: maintenance	Second or greater remission: maintenance <sup>b</sup>
Olaparib	<b>g/sBRCA</b>	<b>g/sBRCA</b>
Olaparib combined with bevacizumab	<b>g/sBRCA<sup>a</sup></b>	No
Niraparib	<b>g/sBRCA; HRD; wt</b>	<b>g/sBRCA; HRD; wt</b>
Rucaparib	<b>g/sBRCA; HRD; wt</b>	<b>g/sBRCA; HRD; wt</b>
Abbreviations. g/sBRCA, germline or somatic BRCA1/2 mutation; HRD, homologous recombination deficiency; wt, BRCA1/2 wild-type.		

Tew, William P., Christina Lacchetti, and Elise C. Kohn. *Journal of Clinical Oncology* 40.33 (2022): 3878-3881.

# SOLO1

- "results indicate a clinically meaningful, albeit not statistically significant according to prespecified criteria, improvement in OS"

**SOLO-1: A Phase III Trial of Olaparib Monotherapy for BRCA-Mutated Ovarian Cancer**

**Accrual (n = 397)**

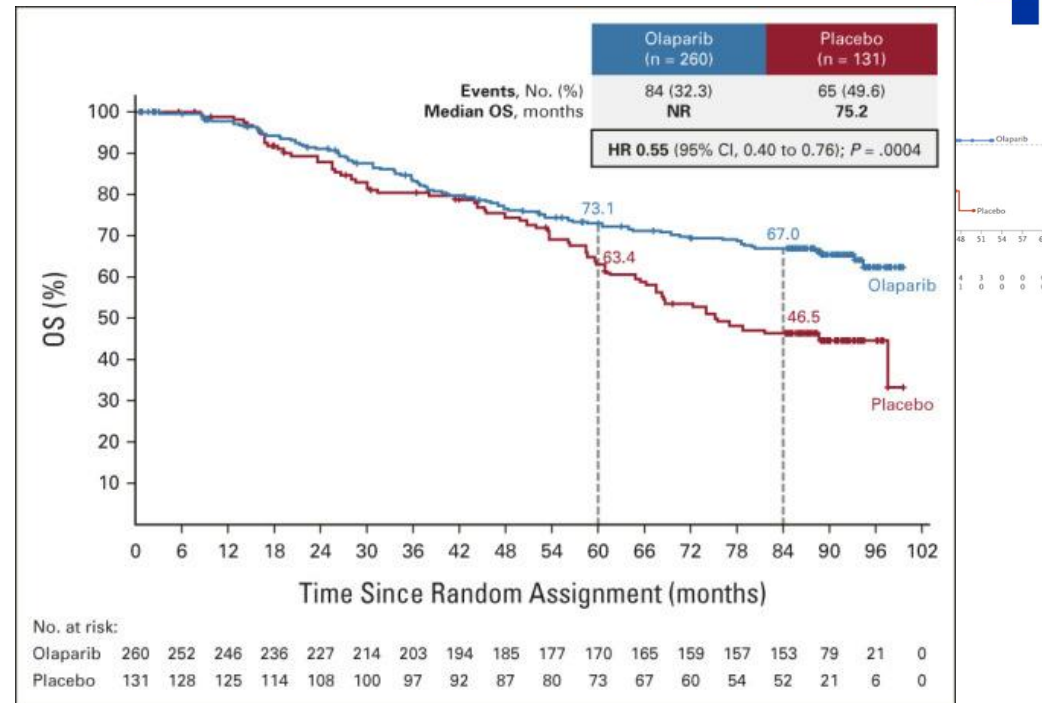
- Newly diagnosed, high-risk ovarian cancer
- Prior platinum-based chemotherapy
- Presence of deleterious or suspected deleterious BRCA/2 mutation

**R**

- Olaparib (300 mg BID)
- Placebo (300 mg BID)

**Primary endpoint: PFS**

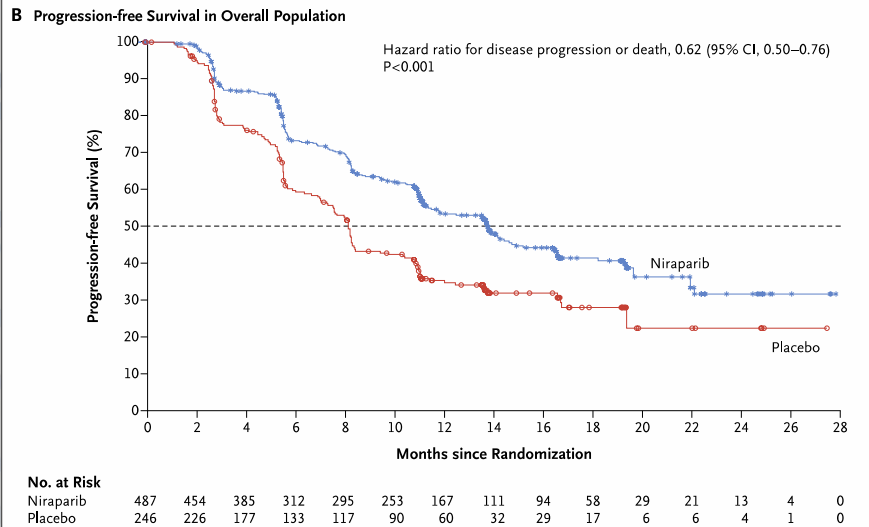
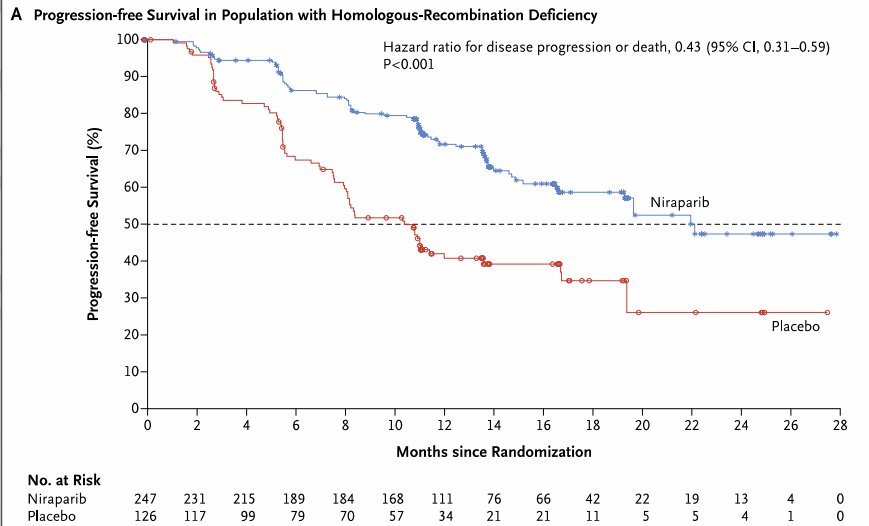
Clinicaltrials.gov; NCT01844986



OS HR 0.55 (95% CI 0.40 to 0.76) p = .0004 with p < .0001 to declare statistical significance.

DiSilvestro, Paul, et al. *Journal of Clinical Oncology* 41.3 (2023): 609.

# PRIMA



## ADVANCED OVARIAN CANCER AFTER RESPONSE TO PLATINUM BASED CHEMOTHERAPY ASSIGNED 2:1 NIRAPARIB MAINTENANCE VS PLACEBO

### OVERALL

PFS 13.8 MO VS 8.2 MO

HR 0.62 (95% CI 0.50-0.76) P<0.001

### HRD

PFS 21.9MO VS 10.4MO

HR 0.43 (95% CI 0.31-0.59) P<0.001

### HR PROFICIENT

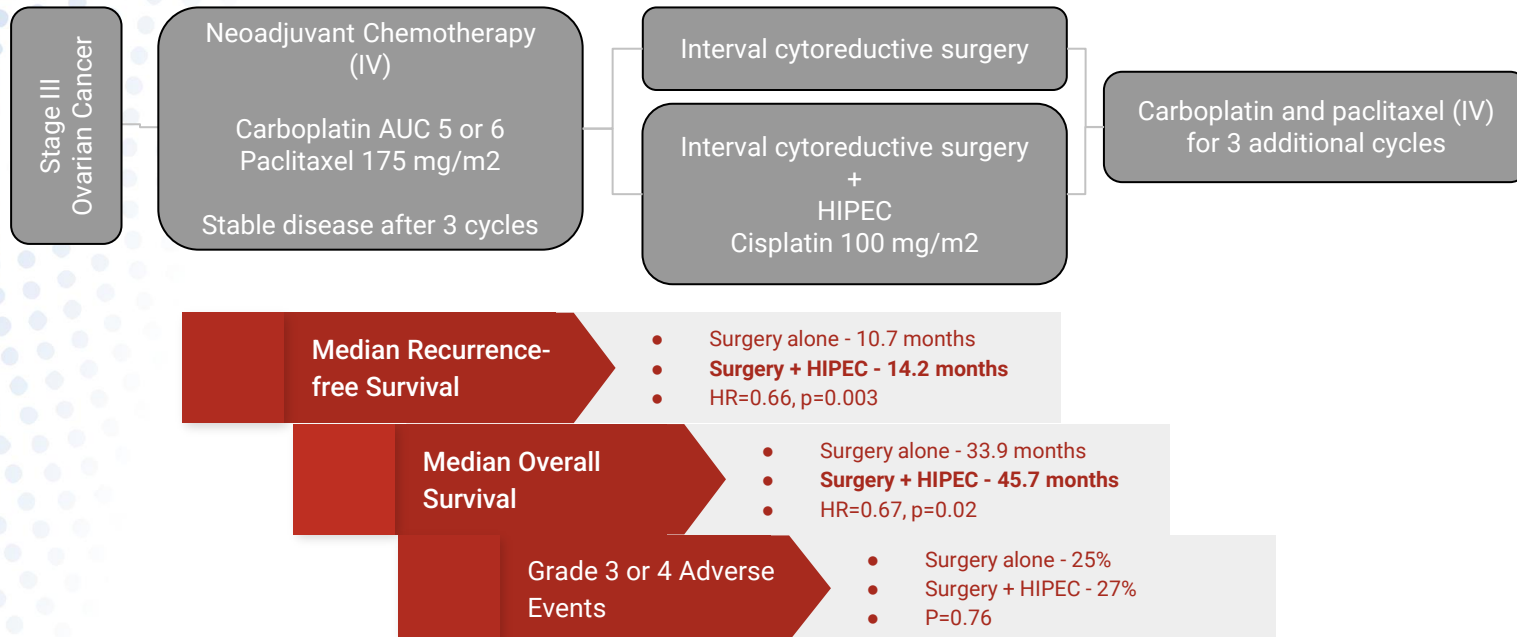
PFS 8.1 VS 5.4MO

HR 0.68 (95% CI 0.49-0.94)

González-Martín, Antonio, et al. *New England Journal of Medicine* 381.25 (2019): 2391-2402.

# HIPEC IN OVARIAN CANCER

Benefit of HIPEC still under investigation



Van Driel, Willemien J., et al. *New England Journal of Medicine* 378.3 (2018): 230-240.

# POLLING QUESTION

What findings would limit the ability to have a primary debulking surgery?

- a) Enlarged ovary
- b) Ascites
- c) 1.2 cm external iliac lymph node
- d) Multiple liver parenchymal metastases

# TOXICITIES OF NOVEL OVARIAN CANCER THERAPIES



# TOXICITIES OF NOVEL OVARIAN CANCER THERAPIES

## PARP INHIBITORS

- PARP inhibitors approved in those with complete or partial response to platinum agents for maintenance
- Nausea:
  - take with food
  - anti-emetics
- Anemia:
  - Continue vs hold with hemoglobin 8-10
  - hold for hemoglobin <8, start back at lower dose if recovered within 4 weeks
- Thrombocytopenia
  - 75-100,000: hold until recovers >100,000
  - 25-75,000: hold until >100,000 dose reduce
  - <25,000: hold anticoagulation, hold until >100,000, dose reduce
- Neutropenia
  - 500-1000, continue PARPi, monitor for signs of infection
  - <500: if lasts 5-7 days, hold until ANC <1500, resume with dose
- Fatigue
  - Evaluate anemia, integrative medicine, hold then dose reduce if interfering with ADLs, consider stimulants

# TOXICITIES OF NOVEL OVARIAN CANCER THERAPIES

## MIRVETUXIMAB

- Transfusion reaction
  - Pretreat with dexamethasone, diphenhydramine, acetaminophen, 5-HT3 serotonin receptor antagonist
- Dry/blurry eyes, changes in vision, corneal ulceration
  - Eye exam before starting and at least every other cycle
  - Dexamethasone and lubricating eye drops starting the day before the infusion and continuing for 8 days after the infusion
- Nausea
  - Anti-emetics
- Diarrhea
  - Loperamide
- Pneumonitis
  - Grade 2 hold until grade 1 then dose reduce
- Peripheral neuropathy
  - Grade 2 hold until grade 1 then dose reduce



# POLLING QUESTION

What is not a side effect of mirvetuximab?

- a) Thrombocytopenia
- b) Dry/blurry eyes
- c) Nausea
- d) Transfusion reaction

# PLATINUM RESISTANT RECURRENCE



# PLATINUM RESISTANT RECURRENCE

- Platinum resistant recurrence: <6 months since last platinum agent
- Standard of Care cytotoxic chemotherapy options
  - Dose-dense paclitaxel RR 21% SD 46%
  - Liposomal doxorubicin RR 20%
- Add bevacizumab if they did not get in upfront setting as long as no history of bowel obstruction or malignant bowel involvement (Aurelia trial with improved RR)
- Other chemotherapy options
  - Single agent bevacizumab RR 21%
  - Gemcitabine RR 19% SD 55%
  - Topotecan RR 17%
  - Oral Etoposide RR 27%
  - Oral Cytoxan + bevacizumab RR 24%
- Next Generation Sequencing if has not previously been done
  - Consider referral to the molecular tumor board
  - Mirvetuximab (targeted agent to folate receptor-alpha) RR 32%

Pujade-Lauraine, Eric, et al. *Obstetrical & Gynecological Survey* 69.7 (2014): 402-404.

Tewari, Krishnansu S., et al. *Journal of Clinical Oncology* 37.26 (2019): 2317.

Lund, Birthe, et al. *JNCI: Journal of the National Cancer Institute* 86.20 (1994): 1530-1533.

Sehouli, Jalid, et al. *Journal of Clinical Oncology* 29.2 (2011): 242-248.

Rose, Peter G., et al. *Journal of Clinical Oncology* 16.2 (1998): 405-410.

Matulonis, Ursula A., et al. *Obstetrical & Gynecological Survey* 78.6 (2023): 343-344.

Garcia, Agustin A., et al. *Journal of Clinical Oncology* 26.1 (2008): 76-82.

## RECENT ASCO UPDATE:

PARP inhibitors are no longer indicated as treatment for ovarian cancer due to no overall survival benefit

Tew, William P., Christina Lacchetti, and Elise C. Kohn. *Journal of Clinical Oncology* 40.33 (2022): 3878-3881.

# POLLING QUESTION

What PARP inhibitor does ASCO recommend for treatment of Ovarian Cancer?

- a) Niraparib
- b) Olaparib
- c) Rucaparib
- d) None of above

# Markey Cancer Center Molecular Tumor Board

Jill Kolesar, PharmD, MS  
Professor, College of Pharmacy  
Co-Director, Molecular Tumor Board

Rachel W. Miller, MD  
Professor Gynecologic Oncology  
Co-Director, Molecular Tumor Board

# MCC MOLECULAR TUMOR BOARD

- MTB is a **free** statewide service available to physicians at UK HealthCare & regional affiliates.
- Forum for expert clinicians, pathologists & scientists to discuss and analyze tumor genotypes & molecular abnormalities in order to recommend patient specific targeted therapies.

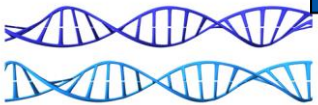
**Meetings occur 1st and 3rd Tuesdays at 12:00 (zoom).**



# MOLECULAR TUMOR BOARD TIMELINE

## Genomic Report:

Gene 1 – mutation detected  
Gene 2  
Gene 3 – mutation detected  
Gene 4



**UK HealthCare**  
MARKEY CANCER CENTER  
An NCI-Designated Cancer Center

Case Submission Form: Molecular Tumor Board

Please complete the case submission and submit the Genomic Report to Jill Kolesar, PharmD, Co-Director of the MTB by email at [jill.kolesar@uky.edu](mailto:jill.kolesar@uky.edu)

Physician Information			
Requested Swiftnave for presentation at MTB			
How would you like to receive recommendation letter?			
Patient Demographics			
MRN#			
MRN#			
Date of birth:			
Gender:			
Diagnosis:			
Stage:			
Performance status:			
Metastatic location:			
Metastatic location:			
Comorbidity:			
How far willing to travel for clinical visit:			
Zip code of home address:			
Prior Therapies (Most recent first)			
Current Therapy (if any)			
Location of Measurable Disease (if any)			



## STEP 1

Physician orders genomic report on patient through any vendor.

## STEP 2

Physician requests MCC MTB consult

## STEP 3

MCC MTB Manager informs requesting physician of case approval & meeting information

## STEP 4

MCC MTB reviews patient's case at the meeting & sends physician treatment recommendation



# HOW TO SUBMIT A CASE TO THE MOLECULAR TUMOR BOARD

# WHO CAN BE REFERRED?

- PATIENTS FOR WHOM YOU PLAN TO OR HAVE ALREADY ORDERED GENOMIC TESTING
  - Any vendor is acceptable
- MCC MTB MAY BE UTILIZED IN FIRST-LINE OR REFRACTORY SETTING
- ONLY REQUIREMENT FOR PRESENTATION AT MCC MTB IS A COMPLETE GENOMIC REPORT

**FOUNDATIONONE** Report Date: 05.29.2012    Diagnosis: Colorectal Cancer

Date of Birth	11/14/1962	Client	Mercy Hospital	Specimen Received	05/15/2012
Gender	Female	Physician	Dr. Smith	Specimen Site	Colon
FMI Case #	1062100092	Additional Recipient	N/A	Collection Method	Core biopsy
Medical Record #	12345	FMI Client #	FMI0001	Specimen Date	10/1/2011
Block ID	JH32145	Pathologist	Dr. Jones	Specimen Type	Block

**About the Test:**  
FoundationOne is a next-generation sequencing (NGS) based assay which identifies genomic alterations within hundreds of cancer-related genes.

**Patient Results** Tumor Type: Colorectal Cancer

3 genomic alterations	pp1-2	<b>Genomic alterations identified</b> PTEN Loss KRAS G12D APC E941*, E1552
2 therapies associated with clinical benefit	pp3-4	
2 therapies with lack of response	pp3-4	
50+ clinical trials	pp5-6	

**Additional disease-relevant genes with no reportable alterations detected**  
*BRAF*

**Therapeutic Implications**

Genomic Alterations Detected	FDA Approved Therapies (In patient's tumor type)	FDA Approved Therapies (In another tumor type)	Potential Clinical Trials
<i>PTEN</i> Loss	None	Temsirolimus Everolimus	Yes. See Clinical Trials section.
<i>KRAS</i> G12D	(-) Panitumumab† (-) Cetuximab†	None	Yes. See Clinical Trials section.
<i>APC</i> E941*, E1552*	None	None	Yes. See Clinical Trials section.
<i>BRAF</i> No alteration detected			

(-) Patient may be resistant to therapy

Note: Genomic alterations detected may be associated with activity of certain FDA approved drugs; however, the agents listed in this report may have varied clinical evidence in the patient's tumor type. Neither the therapeutic agents nor the trials identified are ranked in order of potential or predicted efficacy for this patient, nor are they ranked in order of level of evidence for this patient's tumor type.

Electronically Signed by Jeffrey S. Ross | May 29, 2012 | CLIA Number: 2202027631  
Foundation Medicine, Inc. - One Kendall Square Ste. 5001, Cambridge, MA 02139

Page 1 of 1

# MCC MTB CASE PRESENTATION

- PATIENTS PRESENTATIONS TAKE APPROXIMATELY 15 MINUTES, INCLUDING DISCUSSION
- PRESENTATIONS CONSIST OF :
  - Clinical information (Referring physician or other delegate)
  - Pathology slide review (UK pathologist)
  - Genomic report with review of clinically relevant mutations (Dr. Kolesar)
  - Summary of available therapies and clinical trials (Pharmacist)
  - Discussion and vote (MCC MTB)



HealthCare  
MARKEY CANCER CENTER



A Cancer Center Designated by the  
National Cancer Institute

**Jill M. Kolesar, PharmD, MS**  
Clinical Pharmacologist  
Co-Director, Molecular Tumor Board

**Rachel Miller, MD**  
Gynecological Oncologist  
Co-Director, Molecular Tumor Board

**Susanne Arnold, MD**  
Medical Oncologist  
Associate Director for Translational Research

**Justine Pickarski, MS**  
Genetics Counselor

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### Molecular Tumor Board Recommendation

Dear Dr. Fredericks:

The Markey Cancer Center Molecular Tumor Board has administratively reviewed your patient, \_\_\_\_\_ (serous carcinoma of the ovary). After reviewing the genomic report and clinical characteristics of the case, the MTB recommends consideration of the following:

1. If progression, consider on-label mirvetuximab soravtansine-gynx targeting the FOLR1 positivity of 80%. This is a category 1 evidence level recommendation.
2. If patient is appropriate for maintenance therapy following front line therapy, consider screening for the following clinical trial at Markey Cancer Center:
  - a. NCT04805333 (GYN-08): Phase 1 Dose Escalation of ArtemiCoffee
3. Consider germline testing due to tumor type. This is a category 1 evidence level recommendation.

For questions or concerns regarding the clinical trial at UK, please contact Jeri Reynolds at (859) 218-0131.

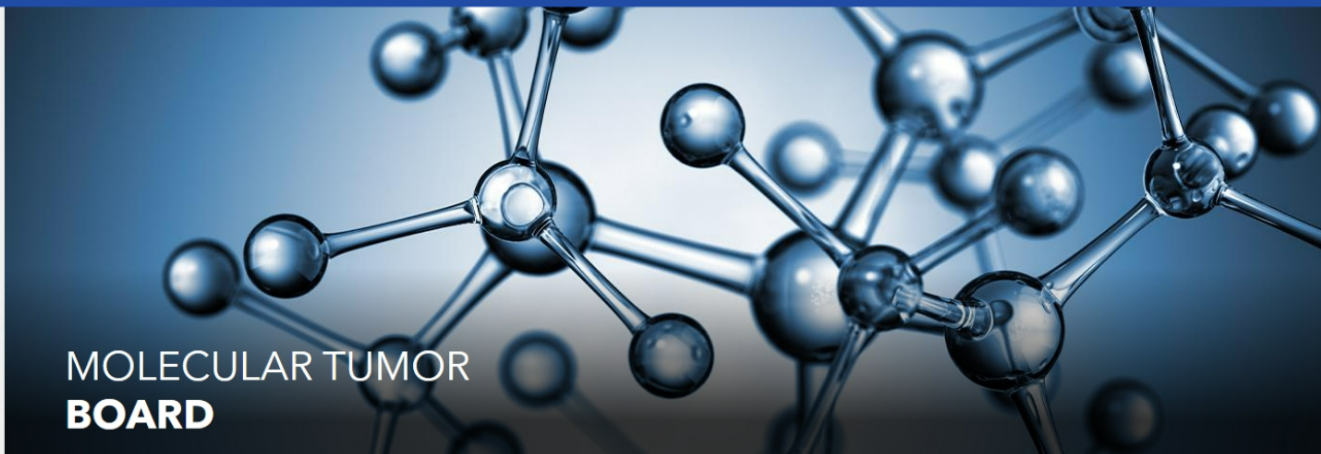
For questions concerning germline testing, please contact [Justine.cooper@uky.edu](mailto:Justine.cooper@uky.edu)

Thank-you for submitting this case to the Markey Cancer Center MTB.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



Home / Markey Cancer Center / Research



The Markey Cancer Center Molecular Tumor Board (MTB) is a statewide service available to physicians at UK HealthCare and regional affiliates.

The MTB provides a forum for expert clinicians, pathologists and scientists to discuss and analyze tumor genotypes and molecular abnormalities in order to recommend patient-specific targeted therapies.

The MTB is intended to supplement oncology tumor boards and includes a broad range of expert panel members.

Clinicians can order a genomic report and submit a case study to be presented for review by the MTB during their twice-monthly meetings. For an overview of the MTB, download the referral flyer below.

[Download our referral flyer \(PDF, 295 KB\)](#)

### Leadership Contact Information

- Jill Kolesar, PharmD, MS, Co-Director
- Rachel Miller, MD, Co-Director

[Click here to contact the tumor board by email, or email Dr. Kolesar directly.](#)



#### Administrative Office

Abigail Anderson, PhD, [aman239@uky.edu](mailto:aman239@uky.edu)  
MTB Project Manager

Rebecca Carpenter, [rebecca.carpenter@uky.edu](mailto:rebecca.carpenter@uky.edu)  
Administrative Support Associate

## Meetings

The Molecular Tumor Board (MTB) meets:

- 12 p.m.
- Every first and third Tuesday

MTB meetings are currently held via Zoom. Please email either [Abigail Anderson, PhD](#) or [Rebecca Carpenter](#) for Zoom details to attend.

Some MTB meetings will include a 15-minute informational update on Precision Medicine.

To schedule a case presentation, review the details in the Case Submission section. **All cases must be submitted to MTB seven days prior to the meeting date.**

## 2023 MTB Meeting Schedule

Month	Day / Tues	Location
June	20	Zoom
July	4	Canceled
July	18	Zoom
August	1	Zoom
August	15	Zoom
September	5	Zoom
September	19	Zoom
October	3	Zoom
October	17	Zoom
November	7	Zoom
November	21	Zoom
December	5	Zoom
December	19	Zoom

## Continuing Medical Education (CME)

If clinicians or pharmacists want to obtain CE Credit for this meeting, they must attend the meeting in person or via teleconference, then enter the provided access code on the [CE Central website](#). Any questions or concerns regarding CE Credit can be directed to the MTB Manager at [mtb@uky.edu](mailto:mtb@uky.edu).

## Policy on Disclosure

It is the policy of the Markey Cancer Center that the faculty, authors, planners and other persons who may influence the content of this CME activity disclose all relevant financial relationships with commercial interests in order to allow CME staff to identify and resolve any potential conflicts of interest. Faculty must also disclose any planned discussions of unlabeled/unapproved uses of drugs or devices during their presentation.

## Case Submission

Cases must be submitted at least seven days prior to the meeting date.

Genomics reports from UK HealthCare or external sources (Foundation, MATCH, etc.) can be submitted.

A patient's genomic report is required for case submission. Please see how to order a genomic report through UK HealthCare under [Order a Genomic Report](#) below.

If you already have a genomic report, fill out the [case submission form](#) online, or download the form below.

[Download form](#)

The patient's genomic report can be sent to [MTB by email](#).

When the case submission and genomic report are received, the MTB manager will schedule the case for presentation and invite the treating clinician to the meeting.

Treatment recommendations will be discussed at the MTB meeting. Recommendation letters will be faxed and/or mailed or uploaded into the electronic health record per the preference of the submitting physician. Specify method of results reporting on the case submission form.

*Note: There is no cost to submit a case to the Markey Cancer Center Molecular Tumor Board.*

# POLLING QUESTION

What is the only requirement to submit a case to the Markey Cancer Center Molecular Tumor Board?

- a) First-line treatment question
- b) Genomics report
- c) PS 0-1
- d) Refractory treatment setting

# CLINICAL TRIAL PARTICIPATION





# IMPORTANCE OF CLINICAL TRIAL PARTICIPATION

From Society of Gynecologic Oncology:

“When new treatments for cancer are developed, they are tested through clinical trials. Major advances in the treatment of gynecologic cancer have all been based on the results of these trials.

Trials are important because it helps us to know whether the practices should be added to the standard treatment options offered to patients.

Participation in gynecologic cancer clinical trials allows patients access to cutting-edge treatment while helping to establish the standard of care for the next generation of women with these diseases.”

[Clinical Trials for Gynecologic Cancer | Society of Gynecologic Oncology \(sgo.org\)](https://www.sgo.org)

# OVARIAN CANCER TRIALS OPEN AT MCC

20-GYN-08 Advanced Ovarian Cancer – Dose Escalation of ArtemiCoffee  
Maintenance trial

Opening soon:

GOG 3068/HOTT

GOG 3078/GLORIOSA

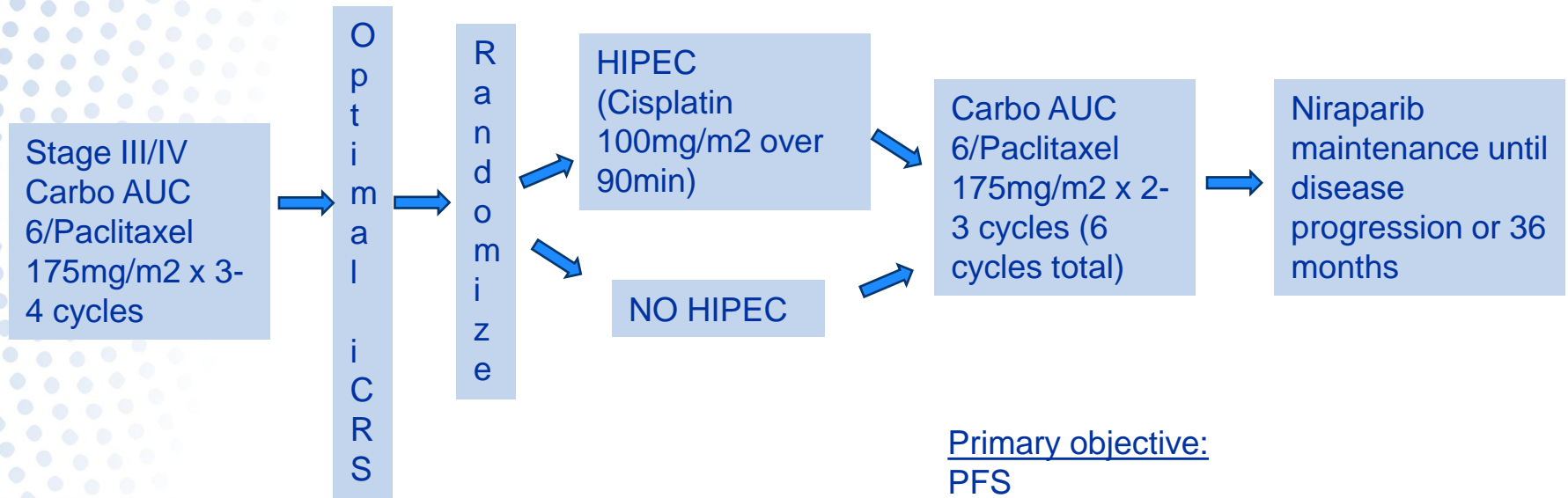
# 20-GYN-08

## PHASE 1 DOSE ESCALATION

- Stage II-IV with complete response to initial therapy
- Phase 1 dose escalation of Artemisia annua decaffeinated coffee
- After the recommended Phase 2 dose is identified, the study will evaluate an expansion cohort to evaluate
  - time to tumor progression or recurrence
  - ability to influence downstream biomarkers NRF2/KEAP1
  - Plasma concentrations of artemisinin and dihydroartemisinin

# GOG-3068/HOTT TRIAL

## SCHEMA



Primary objective:  
PFS

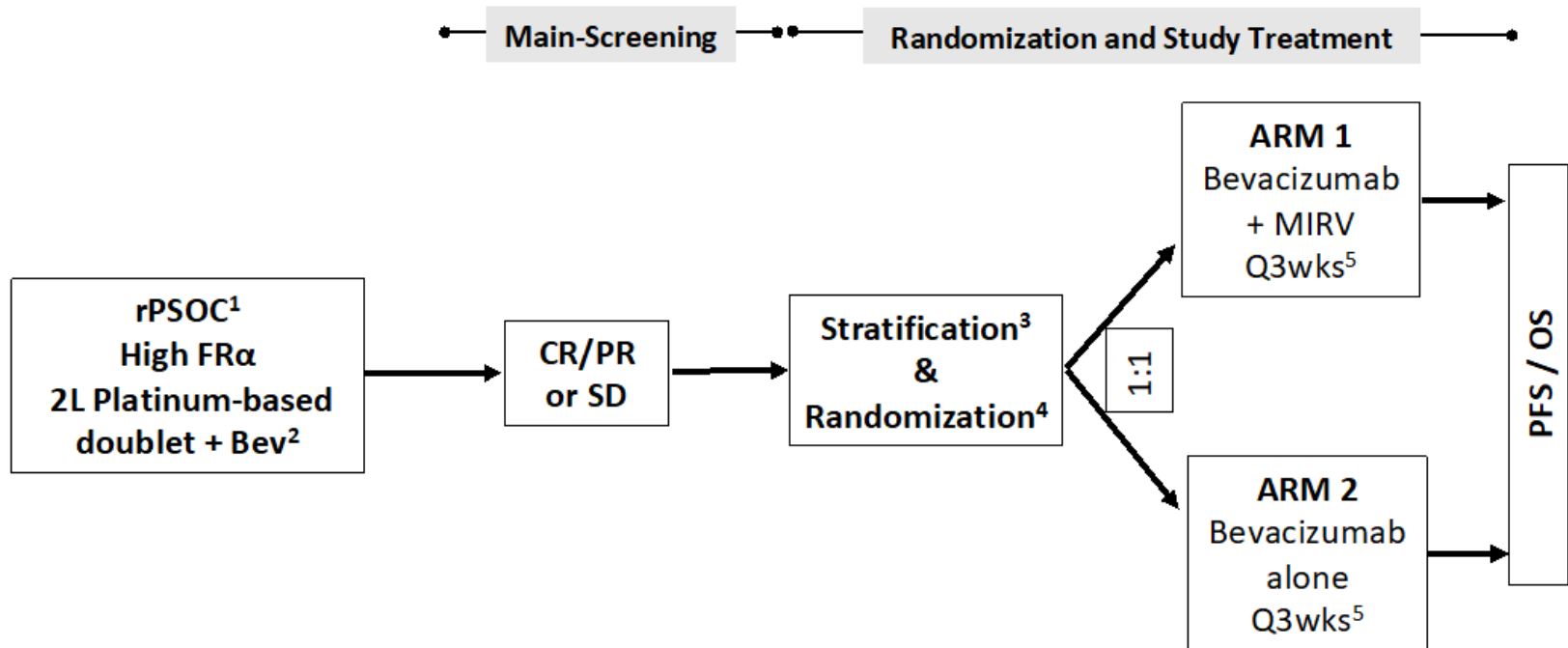
Secondary objectives:  
OS

Adverse events

Effect of HRD, stage, residual disease

# GOG-3078/GLORIOSA TRIAL

## Mirvetuximab Soravtansine With Bevacizumab Versus Bevacizumab as Maintenance in Platinum-sensitive Ovarian, Fallopian Tube, or Peritoneal Cancer (GLORIOSA)





# PATIENT SCENARIO



# PATIENT MCC

- 61 YO F PRESENTING WITH ABDOMINAL DISTENTION, DECREASED APPETITE
- CA125 1499
- EXAM FINDINGS WITH A FIXED PELVIC MASS
- CT GUIDED BIOPSY – HIGH GRADE SEROUS CARCINOMA
- NEXT GEN SEQUENCING – BRCA1 MUTATION, FOLR1+



# PATIENT MCC

- With a fixed pelvic mass and carcinomatosis
  - Start with neoadjuvant carboplatin + paclitaxel x 3 cycles
- Excellent response with normalization of CA125
- Interval debulking surgery with no visible residual disease (R0)
  - carboplatin + paclitaxel x 3 cycles
- Parp inhibitor maintenance with BRCA1+



# PATIENT MCC

- 3 months later, increase in CA125, imaging obtained with recurrence
  - consider referral to molecular tumor board
  - chemotherapy vs targeted therapy (mirvetuximab for FOLR1+)

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# Audience Q&A Session



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