What I Tell My Patients:
New Treatments and Clinical Trial Options

An NCPD Hybrid Symposium Series
Held During the 47th Annual ONS Congress

Ovarian Cancer

Thursday, April 28, 2022
12:15 PM – 1:45 PM PT

Faculty

Jennifer Filipi, MSN, NP
Kathleen N Moore, MD, MS
Krishnansu S Tewari, MD
Deborah Wright, MSN, APRN, AGCNS-BC

Moderator

Neil Love, MD

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Faculty

Jennifer Filipi, MSN, NP
Department of Gynecologic Oncology
Massachusetts General Hospital Cancer Center
Boston, Massachusetts

Kathleen N Moore, MD, MS
Virginia Kerley Cade Chair in Developmental Therapeutics
Associate Director for Clinical Research
Director, Early Phase Drug Development
Stephenson Cancer Center at the University of Oklahoma HSC
Professor, Section of Gynecologic Oncology
Associate Program Director, Gynecologic Oncology Fellowship
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Krishnansu S Tewari, MD
Professor and Division Director
Division of Gynecologic Oncology
University of California, Irvine
Irvine, California

Deborah Wright, MSN, APRN, AGCNS-BC
Clinical Nurse Specialist
TSET Phase I Program
Lead Advanced Practice Provider
Clinical Trials Office
Stephenson Cancer Center
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

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Ms Filipi — Disclosures

No relevant conflicts of interest to disclose.

Dr Moore — Disclosures

Advisory Committee	Alkermes, Aravive Inc, AstraZeneca Pharmaceuticals LP, Blueprint Medicines, Eisai Inc, Elevar Therapeutics, EMD Serono Inc, Genentech, a member of the Roche Group, Hengrui Therapeutics Inc, I-Mab Biopharma, ImmunoGen Inc, IMXmed, Lilly, Merck, Mereo BioPharma, Mersana Therapeutics Inc, Novartis, Onconova Therapeutics Inc, OncXerna Therapeutics Inc, Tarveda Therapeutics, Tesaro, A GSK Company, VBL Therapeutics
Consulting Agreement	AstraZeneca Pharmaceuticals LP
Contracted Research	Lilly, Merck, PTC Therapeutics
Data and Safety Monitoring Board/Committee	SQZ Biotech

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Dr Tewari — Disclosures

Advisory Committee	AbbVie Inc, AstraZeneca Pharmaceuticals LP, Clovis Oncology, Eisai Inc, Genentech, a member of the Roche Group, Merck, Regeneron Pharmaceuticals Inc, Tesaro, A GSK Company
Contracted Research (to Institution)	AbbVie Inc, Clovis Oncology, Genentech, a member of the Roche Group, Merck, Regeneron Pharmaceuticals Inc
Data and Safety Monitoring Board/Committee	Iovance Biotherapeutics
Speakers Bureau	AstraZeneca Pharmaceuticals LP, Clovis Oncology, Eisai Inc, Merck

Ms Wright — Disclosures

No relevant conflicts of interest to disclose.

Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, GlaxoSmithKline, Merck, and Novocure Inc.

Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Clinicians in the Meeting Room

Networked iPads are available.

Review Program Slides: Tap the Program Slides button to review speaker presentations and other program content.

Answer Survey Questions: Complete the premeeting survey before the meeting. Survey results will be presented and discussed throughout the meeting.

Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

Complete Your Evaluation: Tap the CME Evaluation button to complete your evaluation electronically to receive credit for your participation.

For assistance, please raise your hand. Devices will be collected at the conclusion of the activity.

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Clinicians Attending via Zoom

Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.

Answer Survey Questions: Complete the premeeting survey before the meeting. Survey results will be presented and discussed throughout the meeting.

Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.

Get CME Credit: A CME credit link will be provided in the chat room at the conclusion of the program.

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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based video/PowerPoint program.
  An email will be sent to all attendees when the activity is available.
- To learn more about our education programs, visit our website, **www.ResearchToPractice.com**

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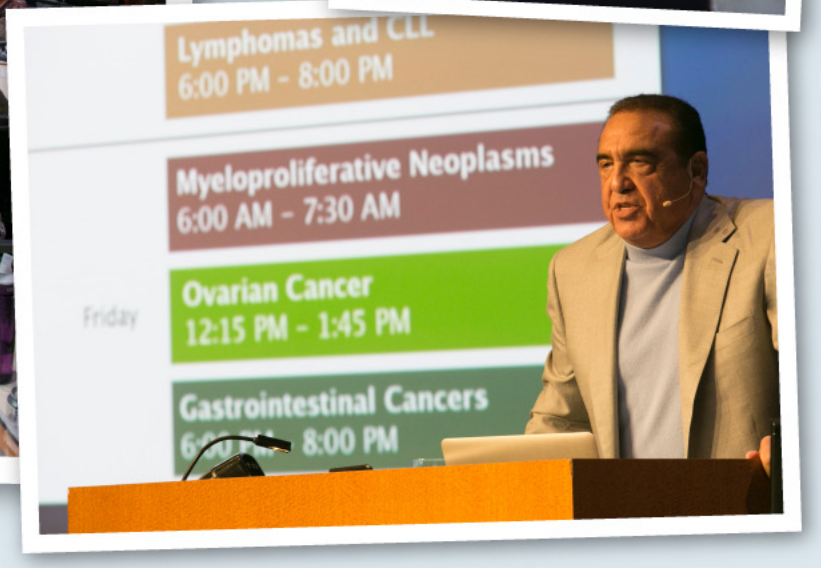
Oncology Grand Rounds

2009-2022

75 Symposia 311 Faculty

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20 YEARS IN THE DESERT
A YOUTUBE ORIGINAL DOCUMENTARY
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"What I Tell My Patients"
14th Annual RTP-ONS NCPD Symposium Series
ONS Congress, Anaheim, California — April 27 - May 1, 2022

Thursday April 28	**Prostate Cancer** 6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)
	Ovarian Cancer 12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)
	Non–Small Cell Lung Cancer 6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)
	Hepatobiliary Cancers 8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)
Friday April 29	**Small Cell Lung Cancer** 6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)
	Chronic Lymphocytic Leukemia 12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)
	Breast Cancer 6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)
	Acute Myeloid Leukemia and Myelodysplastic Syndromes 8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)
Saturday April 30	**Cervical and Endometrial Cancer** 6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)
	Bladder Cancer 12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

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What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

An NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Prostate Cancer

Thursday, April 28, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Kathy D Burns, RN, MSN, AGACNP-BC, OCN
Robert Dreicer, MD, MS
Sandy Srinivas, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

Non-Small Cell Lung Cancer

Thursday, April 28, 2022
6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty
Edward B Garon, MD, MS
Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Anne S Tsao, MD, MBA

Ovarian Cancer

Thursday, April 28, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Jennifer Filipi, MSN, NP
Kathleen N Moore, MD, MS
Krishnansu S Tewari, MD
Deborah Wright, MSN, APRN, AGCNS-BC

Hepatobiliary Cancers

Thursday, April 28, 2022
8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

Faculty
Richard S Finn, MD
Amanda K Wagner, APRN-CNP, AOCNP

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

An NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Small Cell Lung Cancer

Friday, April 29, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Marianne J Davies, DNP, MSN, RN, APRN
Matthew Gubens, MD, MS
Lowell L Hart, MD
Chaely J Medley, MSN, AGNP

Breast Cancer

Friday, April 29, 2022
6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty
Jamie Carroll, APRN, MSN, CNP
Sara A Hurvitz, MD
Kelly Leonard, MSN, FNP-BC
Hope S Rugo, MD

Chronic Lymphocytic Leukemia

Friday, April 29, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Lesley Camille Ballance, MSN, FNP-BC
Amy Goodrich, CRNP
Anthony R Mato, MD, MSCE
Susan O'Brien, MD

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Friday, April 29, 2022
8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

Faculty
Ilene Galinsky, NP
Eunice S Wang, MD

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

An NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Cervical and Endometrial Cancer

Saturday, April 30, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Paula J Anastasia, MN, RN, AOCN
Robert L Coleman, MD
David M O'Malley, MD
Jaclyn Shaver, MS, APRN, CNP, WHNP

Bladder Cancer

Saturday, April 30, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Monica Averia, MSN, AOCNP, NP-C
Shilpa Gupta, MD
Brenda Martone, MSN, NP-BC, AOCNP
Sumanta Kumar Pal, MD

Join Us After ONS for Our Series Continuation

What I Tell My Patients —
A 2-Part NCPD Webinar Series

Hodgkin and Non-Hodgkin Lymphomas

Date and time to be announced

Gastroesophageal Cancers

Wednesday, May 18, 2022

5:00 PM – 6:00 PM ET

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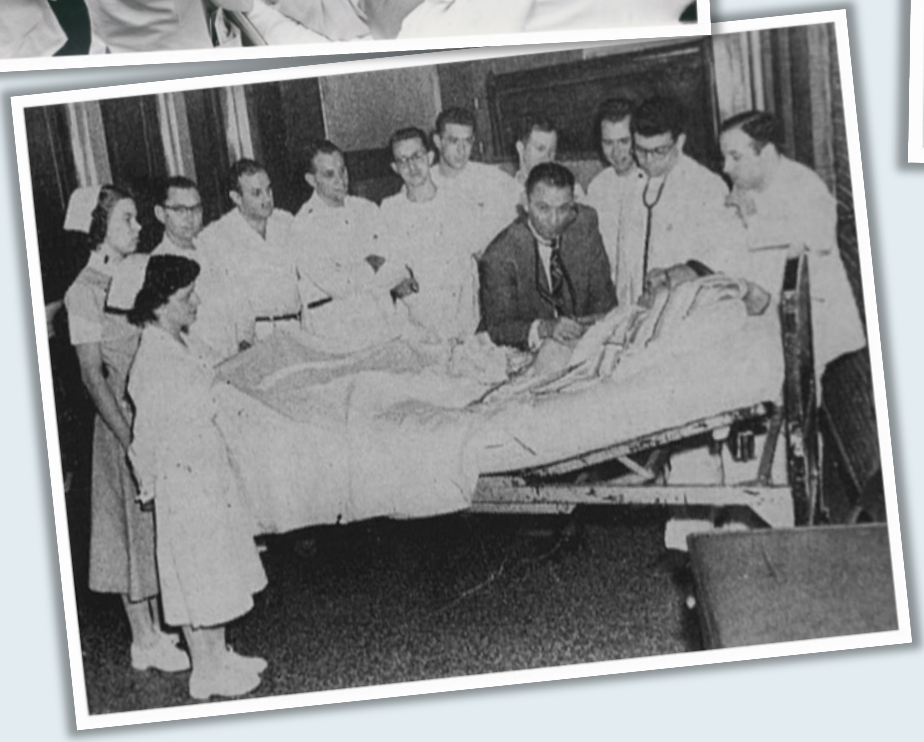

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The Core Oncology Triad
Developing an Individualized Oncology Strategy

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Oncology Grand Rounds
2022 ONS Congress
Anaheim, California

Symposia Themes

Personalized oncology: Implementing an individualized oncologic strategy

- Tumor factors (eg, biomarkers, numeracy)
- Biopsychosocial factors (eg, adherence, available family support, comorbidities, mood)

Novel agents and treatment strategies

- The new-agents revolution (beginning of the end?)

The bond that heals (both ways)

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How was it different to take care of this patient versus another patient in the same oncologic setting?

What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

When was the last time someone asked you, “Why are you in oncology? Isn’t it depressing?”

1. This week
2. This month
3. This year
4. Never

Faculty

Jennifer Filipi, MSN, NP
Department of Gynecologic Oncology
Massachusetts General Hospital Cancer Center
Boston, Massachusetts

Kathleen N Moore, MD, MS
Virginia Kerley Cade Chair in Developmental Therapeutics
Associate Director for Clinical Research
Director, Early Phase Drug Development
Stephenson Cancer Center at the University of Oklahoma HSC
Professor, Section of Gynecologic Oncology
Associate Program Director, Gynecologic Oncology Fellowship
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Krishnansu S Tewari, MD
Professor and Division Director
Division of Gynecologic Oncology
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Irvine, California

Deborah Wright, MSN, APRN, AGCNS-BC
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TSET Phase I Program
Lead Advanced Practice Provider
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University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

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Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Agenda

Module 1 – Primary Ovarian Cancer: Neoadjuvant and Adjuvant Chemotherapy

Module 2 – PARP Inhibitor Maintenance Therapy

Module 3 – Management of Ovarian Cancer in Patients Receiving PARP Inhibitors

Module 4 – Novel Strategies and Clinical Trials

Agenda

Module 1 – Primary Ovarian Cancer

Module 2 – PARP Inhibitor Maintenance Therapy

Module 3 – Adherence in the Maintenance Setting

Module 4 – Novel Strategies and Clinical Trials

SELF-ASSESSMENT QUIZ

Most patients with ovarian cancer have surgery as their initial intervention followed by systemic therapy.

1. Agree
2. Disagree
3. I don’t know

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SELF-ASSESSMENT QUIZ

In addition to neoadjuvant chemotherapy, what other agent is typically added for patients with ovarian cancer who present with ascites?

1. Aflibercept
2. Bevacizumab
3. Lenvatinib
4. Olaparib
5. Niraparib
6. Rucaparib
7. I don’t know

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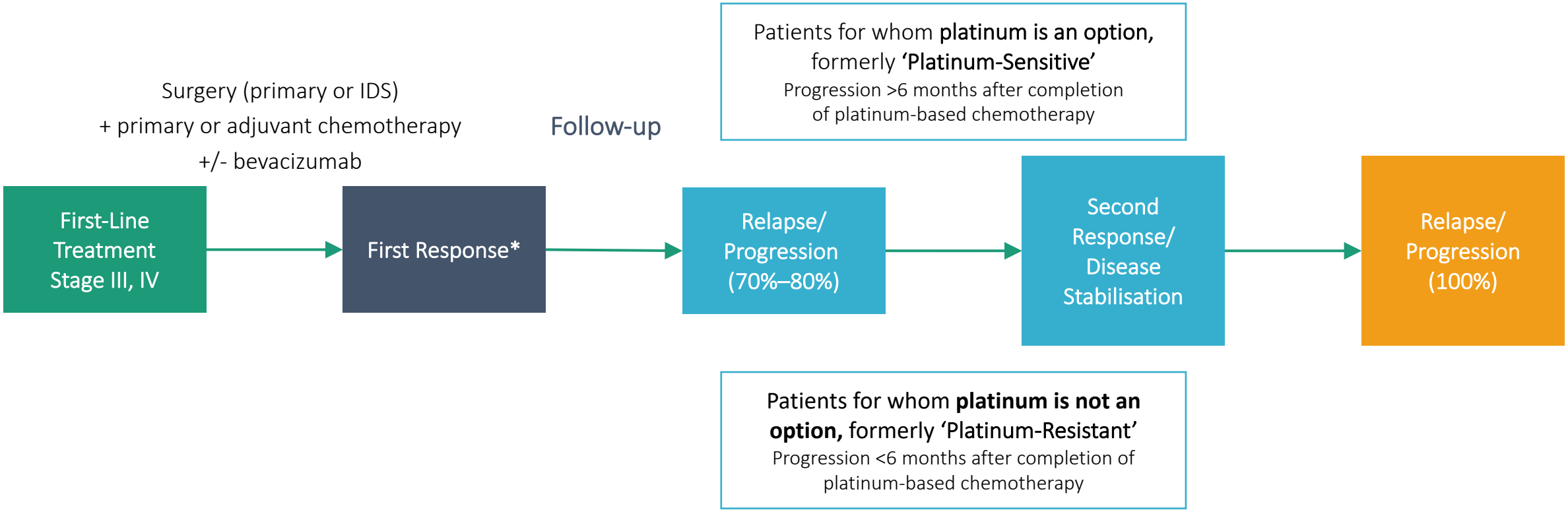
The Typical Course of Advanced Ovarian Cancer

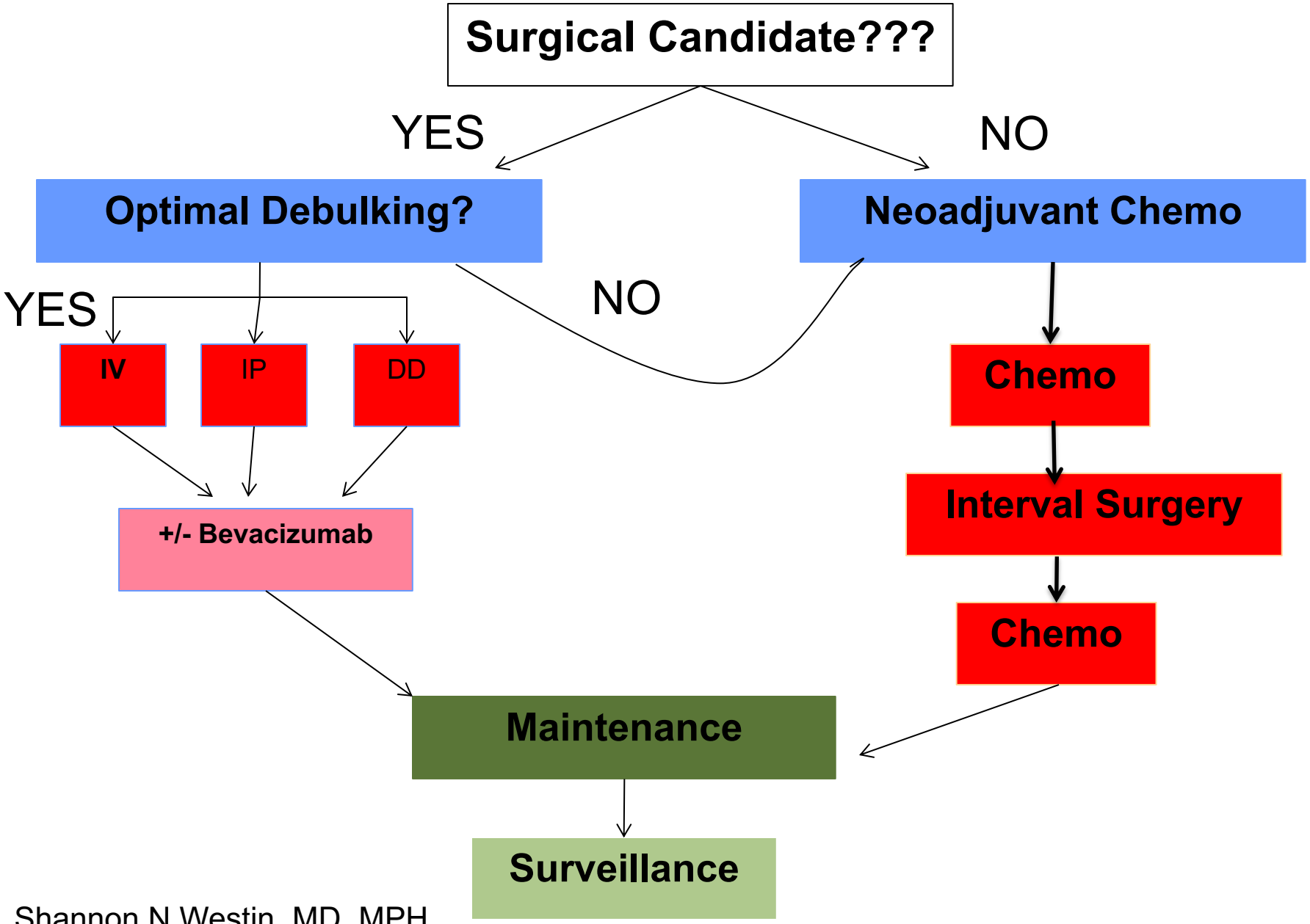


*Around 5% of patients are primary treatment-refractory, meaning disease progressed during therapy or within 4 weeks after the last dose.
IDS=interval debulking surgery.

1. Ledermann JA et al. *Ann Oncol.* 2013;24(Suppl 6):vi24-vi32. 2. Giornelli GH. *Springerplus*. 2016;5(1):1197. 3. Pignata S et al. *Ann Oncol.* 2017;28(suppl_8):viii51-viii56. 4. du Bois A et al. *Cancer*. 2009;115(6):1234-1244.
5. Wilson MK et al. *Ann Oncol*. 2017;28(4):727-732.

Courtesy of Kathleen N Moore, MD, MS

New Advanced Ovarian Cancer



Courtesy, Shannon N Westin, MD, MPH

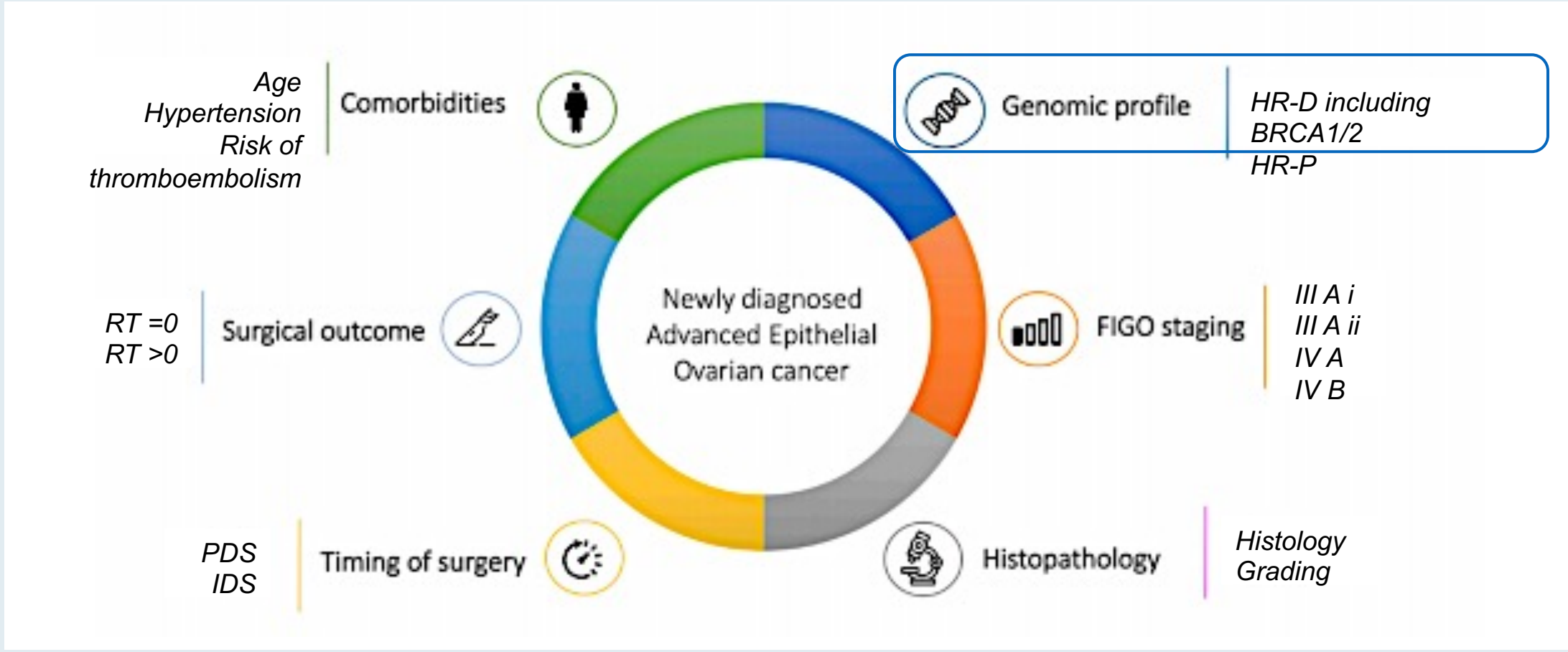
Questions — Kathleen N Moore, MD, MS

Patients presenting with primary ovarian cancer: Role of surgery, neoadjuvant and adjuvant chemotherapy

- **What therapies are used to treat primary ovarian cancer?**
- **How is treatment selected?**

Commentary — Kathleen N Moore, MD, MS

Considerations for Selection of Front-Line Therapy for Ovarian Cancer



Nero et al. Cancers 2021, JAMA Oncol. 2021;7(6):853-86113; 1298, Horowitz et al. J Clin Oncol, 33(8), 2015; Romero I et al. Endocrinology 2012; 153: 1593-1602; Medscape: https://www.medscape.org/viewarticle/776491; Figure adapted from Konstantinopoulos PA, et al. *Cancer Discov*. 2015;5(11):1137–54.

Questions — Jennifer Filipi, MSN, NP

Patients presenting with primary ovarian cancer: Role of surgery, neoadjuvant and adjuvant chemotherapy

- **What are some of the clinical issues that arise for patients with primary ovarian cancer?**
- **How do you discuss expected benefits and toxicities with patients prior to starting treatment?**
- **What are some of the psychosocial issues that arise in this situation?**

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Commentary — Jennifer Filipi, MSN, NP

Patients presenting with primary ovarian cancer: Role of surgery, neoadjuvant and adjuvant chemotherapy

- **Clinical issues:**
  - **Comorbidities – can the patient safely receive chemotherapy/undergo surgery?**
    - **Bevacizumab considerations**
  - **Age/functional status – weekly chemo vs q21 day chemo**
  - **Unresectable disease (poor prognostic factor)**
- **Key discussion points (expected benefits and treatment toxicities):**
  - **Aiming to cure, 80% of patients will recur**
  - **Toxicities: N/v, fatigue, low blood counts, hair loss, neuropathy, myalgias**
    - **Added bevacizumab toxicities: HA, myalgias, HTN, epistaxis, hoarse voice, proteinuria**

Commentary — Jennifer Filipi, MSN, NP

- **Instructive examples (see handout on next slide)**
  - **Extended CINV – dexamethasone taper, SL lorazepam, clinic visits for IV hydration**
  - **Neuropathy – when to dose reduce**
- **Psychosocial:**
  - **Limited support at home**
  - **Patient as caregiver for another (patient example: 66-year-old with 99-year-old mother with dementia)**
  - **Language barriers**
    - **Example: patient continued to take dexamethasone the whole cycle**

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Commentary — Jennifer Filipi, MSN, NP

Cycle 1 (Treatment week) Carboplatin containing regimens	Night before chemotherapy	Day of Chemotherapy (Day 1)	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Notes:
Day of Week:									
Dexamethasone (Decadron)	20mg (5 Tabs)	20mg (5 tabs) in AM	8mg (2 Tabs)	8mg (2 Tabs)					We may change the way you take this medicine next cycle depending on the symptoms you report
Senokot (Senna)		17.2mg (2 tablets) in PM	17.2mg (2 tablets) in AM and PM	17.2mg (2 tablets) in AM and PM					**May continue to take 1-2x/day or back off depending on regularity of bowel movements **If no bowel movement after 2+ days you may take 3TBSP of Milk of Magnesia (over the counter medication). If no effect, you may repeat in 4-6 hours
Docusate sodium (Colace)		200mg (2 tablets) in PM	200mg (2 tablets) in AM and PM	200mg (2 tablets) in AM and PM					
Olanzapine (zyprexa)		2.5-5mg (1 tab) before bed	2.5-5mg (1 tab) before bed	2.5-5mg (1 tab) before bed	2.5-5mg (1 tab) before bed	2.5-5mg (1 tab) before bed	2.5-5mg (1 tab) before bed	2.5-5mg (1 tab) before bed	Take for 5-7 days
Take as needed:									
Ondansetron (Zofran)		Given in infusion center prior to chemo	8mg twice daily **as needed** for nausea at any time during chemotherapy cycle						
Lorazepam (Ativan)	0.5mg (1 tab) every 6 hours **as needed** for nausea at any time during chemotherapy cycle								

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Agenda

Module 1 – Primary Ovarian Cancer

Module 2 – PARP Inhibitor Maintenance Therapy

Module 3 – Adherence in the Maintenance Setting

Module 4 – Novel Strategies and Clinical Trials

SELF-ASSESSMENT QUIZ

There is no evidence that PARP inhibitors will benefit patients who do not have BRCA or BRCA-like germline or somatic mutations.

1. Agree
2. Disagree
3. I don’t know

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SELF-ASSESSMENT QUIZ

For patients with ovarian cancer and BRCA mutations who receive olaparib or niraparib, the chance of experiencing disease relapse at 5 years is reduced…

1. 10% to 20%
2. 20% to 50%
3. More than 70%
4. I don’t know

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SELF-ASSESSMENT QUIZ

What was the duration of treatment with olaparib and niraparib in the Phase III trials evaluating maintenance therapy with PARP inhibitors after debulking surgery and first-line platinum-based chemotherapy?

1. 2 years for both
2. 3 years for both
3. 2 years for olaparib, 3 years for niraparib
4. 2 years for niraparib, 3 years for olaparib
5. I don’t know

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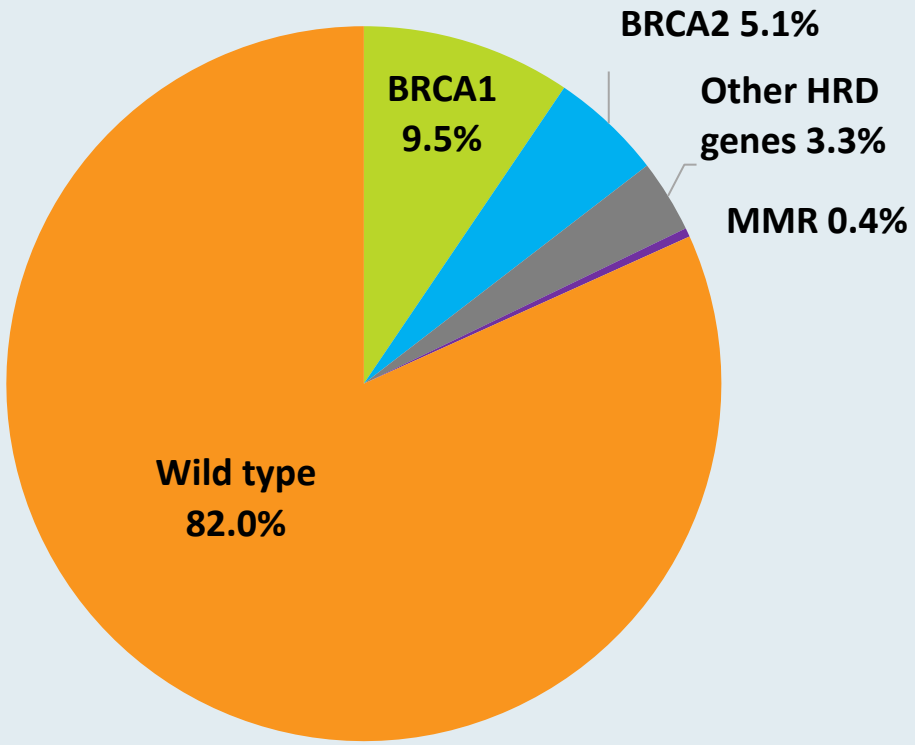
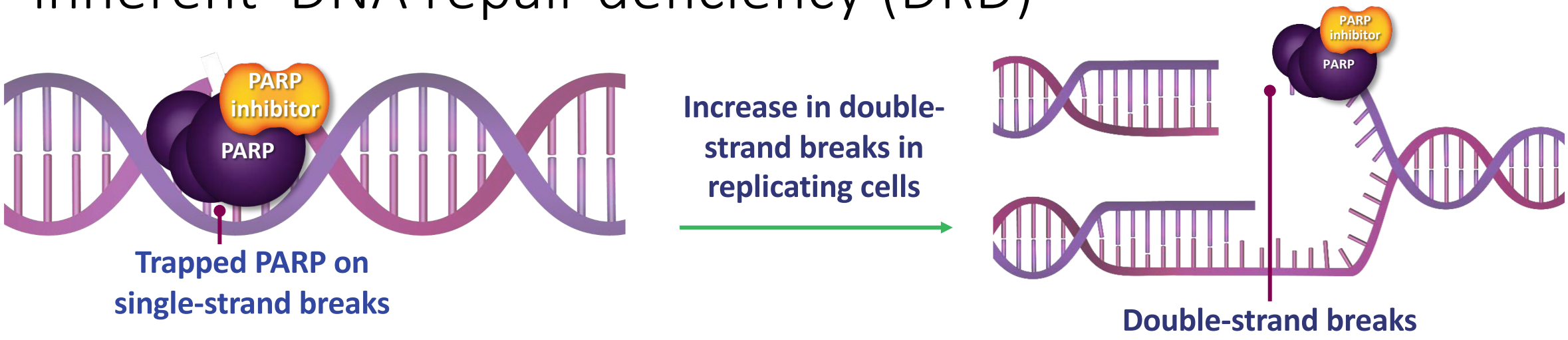
Genetic Mutations in Ovarian Cancer

- Germline mutations in women with OC
  - Germline DNA sequenced from women with OC (N = 1,915) using a targeted capture and multiplex sequencing assay
- Mutations in HRD genes may be a risk for OC
- Somatic mutations: BRCA1/2: 6%,
  HRD genes: 17%
- Patients with mutations in HRD genes are more sensitive to platinum-based chemotherapy, PARP inhibitors



Norquist BM et al. *JAMA Oncol* 2016;2(4):482-90; Aghajanian C et al. ASCO 2017;Abstract 5545; Hennessy B et al. *J Clin Oncol* 2010;28(22):3570-6.

PARPi Exploits the baseline vulnerability of cells with inherent DNA repair deficiency (DRD)



HRR, homologous recombination repair.

O'Connor MJ. *Mol Cell*. 2015.

Phase III First-Line PARPi Maintenance Trials

Study Design	SOLO-1 (N=451)	PAOLA-1 (N=612)	PRIMA (N=620)	VELIA (N=1140)
Treatment arms vs placebo	**Olaparib (n=260)**	**Bevacizumab ± Olaparib**	**Niraparib**	**Veliparib**
Patient Population	*BRCA* mutation	All comers	All comers	*All comers*
Treatment Duration	24 months	15 months for Bev 24 months for Olaparib	36 months or until PD	24 months

Burger RA, *N Engl J Med* 2011; Norquist B *Clin Cancer Res* 2018*; Bevacizumab* prescribing information; Moore K, NEJM 2018; Gonzalez-Martin NEJM 2019; Ray-Coquard NEJM 2019; Coleman NEJM 2019

Courtesy of Shannon N Westin, MD, MPH

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Rucaparib Significantly Improves Progression-Free Survival in First-Line Maintenance Treatment for Women with Ovarian Cancer Regardless of Biomarker Status: The Phase III ATHENA-MONO Trial

Press Release – March 31, 2022

"The manufacturer of rucaparib announced positive top-line data from the monotherapy arm of the ATHENA (GOG 3020/ENGOT-ov45) trial (ATHENA-MONO) demonstrating that **rucaparib as maintenance treatment successfully achieved the primary endpoint of significantly improved investigator-assessed progression-free survival (PFS) compared to placebo.** Benefit was observed in both primary efficacy analyses of patients with newly diagnosed advanced ovarian cancer after successful treatment with platinum-based chemotherapy: Those who had homologous recombination deficiency (HRD-positive), including deleterious BRCA mutations, in addition to all patients randomly assigned in the trial (ITT). Benefit in PFS was also seen in the exploratory subgroups of patients with HRD-negative and BRCA-mutant tumors. The safety of rucaparib observed in the ATHENA-MONO study was consistent with both the US and European labels."

https://www.businesswire.com/news/home/20220331005384/en/Clovis-Oncology's-Rubraca®-Rucaparib-Significantly-Improves-Progression-Free-Survival-in-First-line-Maintenance-Treatment-in-Women-with-Ovarian-Cancer-Regardless-of-Their-Biomarker-Status-in-Phase-3-ATHENA-MONO-Trial

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Questions — Krishnansu S Tewari, MD

Patients who are s/p surgery and chemotherapy: Role of maintenance therapy

- **What therapies are used to treat ovarian cancer in the maintenance setting?**

Commentary — Krishnansu S Tewari, MD

Patients who are s/p surgery and chemotherapy: Role of maintenance therapy

- **Available strategies**
  - **Anti-angiogenesis: Bevacizumab**
  - **PARP inhibitors: Olaparib or Niraparib**
  - **Combinations: Olaparib plus Bevacizumab**
- **Selecting a maintenance therapy**
  - **Bevacizumab use during chemoRx?**
  - **Germline BRCA1/2 testing**
  - **Somatic BRCA 1/2 testing**
  - **Homologous recombination deficiency (HRD) testing**

Commentary — Krishnansu S Tewari, MD

- **Clinical experience**
  - **HRD+ gBRCA-1MUT Stage IIIC Optimal Cytoreduction – received ChemoRx**
  - **HRD+ gBRCAWT Stage IV – received ChemoRx plus BEV**
  - **HRD+ gBRCAWT Stage III Optimal Cytoreduction – received ChemoRx**
  - **HRD Proficient Stage III Suboptimal Cytoreduction – received ChemoRx plus BEV (proteinuria, htn)**

Questions — Deborah Wright, MSN, APRN, AGCNS-BC

Patients who are s/p surgery and chemotherapy: Role of maintenance therapy

- **What are some of the clinical issues that arise for patients receiving maintenance therapy?**
- **How do you discuss expected benefits of therapy with your patients?**
- **What are some of the psychosocial issues that arise in this situation?**

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Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

Patients who are s/p surgery and chemotherapy: Role of maintenance therapy

Clinical issues or aspects that should be taken into consideration when counseling an ovarian cancer patient regarding maintenance therapy intervention.

- **Patient understanding of rationale for maintenance therapy: Keeping the cancer under control for as long as possible after initial treatment.**
- **Patient understanding of risk/benefit of planned maintenance therapy:**
  - **Bevacizumab**
  - **PARPi**
  - **Combination of both bev and PARPi**
- **Information regarding short-term and long-term side effects.**
- **Important to refer to genetic counseling if patient has a germline BRCA mutation**

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Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

Examples of key discussion points prior to starting treatment in terms of expected benefits.

- **The goal of first-line maintenance therapy is to keep cancer controlled for an extended period of time following a complete or partial response to primary therapy.**
- **Studies using bevacizumab and PARPi have demonstrated a PFS advantage with manageable side effect profile versus surveillance alone. (Madariaga 2019)**
- **Maintenance treatment is generally well tolerated.**
- **PARPi are dosed at home and require no IV infusions or extra visits to infusion center**

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Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

Challenges in counseling women regarding maintenance therapy, taking into consideration the psychosocial impact of this diagnosis.

- **Pearl of Wisdom: As physicians and oncology nurses we all know the evidence points to the benefit of maintenance therapy in potentially prolonging PFI and OS. However, a patient who has recovered from surgery and chemotherapy is wanting a return to normalcy — patients often tell me "they want their life back." (Lammers, 2000).**
  - **Listen closely to the patient's experiences during diagnosis and treatment, accept the stories as truth, create a partnership with the patient so they know they are not alone in their cancer journey.**
- **Encourage the patient and her caregivers to express their fears and concerns regarding maintenance therapy and her ovarian cancer diagnosis.**

RTP RESEARCH TO PRACTICE

Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

- **Ovarian cancer is associated with uncertainty, anxiety and depression. (Lammers, 2000)**
- **Roles at home, school and work can be affected. Ovarian cancer greatly impacts the emotional health of the patients, their families and caregivers. Accepting an ovarian cancer diagnosis is a process, not an event. (Lammers, 2000).**
- **Anticipate and discuss with women and their partners, if appropriate, potential fears associated with sexuality and intimacy.**
- **Financial toxicity**

Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

- **Patient example: 45 yr old female BRCA 1 mutation carrier with STG IVA HGSOC initially diagnosed in March 2020. Given the Covid pandemic, decision was made to proceed with NAC instead of assessing for surgical resectability, and the patient started neo-adjuvant chemotherapy Carboplatin/Paclitaxel. Patient had a PR and underwent IVCRS to NGR followed by 3 cycles of Carbo/Paclitaxel (total 6 cycles). Patient is a full-time cardiovascular nurse and continued to work full time during chemotherapy. Dispositioned to Olaparib 300 mg po bid, only reported AE has been Grade 1 Fatigue. Patient is followed via telemedicine, monthly labs — Olaparib is shipped directly to her home.**
- **CA 125 6.6 <- baseline 2946**
- **Refused prophylactic bilateral mastectomies, followed with breast MRI q 6 months and high risk screening protocol with breast oncology team.**
- **Med hx was significant for**
  - **Bicuspid Aortic Valve**
  - **Anxiety**

RTP RESEARCH TO PRACTICE

Agenda

Module 1 – Primary Ovarian Cancer

Module 2 – PARP Inhibitor Maintenance Therapy

Module 3 – Adherence in the Maintenance Setting

Module 4 – Novel Strategies and Clinical Trials

SELF-ASSESSMENT QUIZ

A woman who weighs 135 pounds and has a normal platelet count is about to begin niraparib. What is the optimal starting dose?

1. 300 mg daily
2. 200 mg daily
3. 100 mg daily
4. I don’t know

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SELF-ASSESSMENT QUIZ

Which of the following questions would you consider to be most effective when assessing patient adherence?

1. Are you taking your medication(s) as prescribed?
2. How many pills have you missed this month?
3. When was the last time you refilled your prescription(s)?
4. I don’t know

RTP RESEARCH TO PRACTICE

Side Effects of PARP Inhibitors

- Common side effects with all PARP inhibitors
  - Gastrointestinal: nausea, vomiting, constipation
  - Hematologic: anemia, thrombocytopenia*, neutropenia
  - Fatigue, insomnia
- Other adverse events of special interest
  - Pneumonitis: <1% of patients on olaparib
  - MDS, AML: olaparib <1.5%, rucaparib 0.5%, niraparib 1.4%
  - Creatinine increase: rucaparib 92%, olaparib 44%
  - Cardiovascular side effects: niraparib
  - Embryo-fetal toxicity

* Occurs more frequently with niraparib

Niraparib FDA insert revised 3/2017; Rucaparib FDA insert revised 12/2016; Olaparib FDA insert revised 1/2018

Tolerability of PARP Inhibitors

- Fatigue: usually plateaus after two weeks
- Nausea: may require daily anti-emetics – have used transdermal patch in a few patients
- Hematologic: monitor monthly, may consider weekly for 1st month. Hold dose for grade 2 hematologic events, Reduce dose in half if dose delay
- AML/MDS: refer patient to hematologist if blood counts do not return within 4 weeks. 2% study subjects were diagnosed

Courtesy of Paula J Anastasia, MN, RN, AOCN

Summary of toxicity in maintenance PARPi trials (first line)

	GOG-218	SOLO-1	PAOLA-1	PRIMA
Administration	IV q3weeks 15 months	Oral BID 2 years	Oral BID 2y + IV q3w 15m	Oral QD 3 years
% dose reduction	-	28.5	41	70.9
% dose interruption	-	51.9	54	79.5
% discontinuation	**17**	**11.5**	**20**	**12**
Most frequent Grade ≥ 3 AE	Neut G4 (64%) HT G ≥2 (23%)	Anaemia (22%) Neut. (9%) Asthenia (4%)	HT (19%) Anaemia (17%) Lymph (7%)	Anaemia (31%) Plates. (28%) Neut. (12.8%)

Burger. *NEJM* 2011; Moore. *NEJM* 2018; Ray-Coquard. *NEJM* 2019; Gonzalez-Martin. *NEJM* 2019

Questions — Kathleen N Moore, MD, MS

Patients on PARP maintenance

- **How do you approach prevention and management of side effects/toxicity when using PARP inhibitors in the maintenance setting?**

Commentary — Kathleen N Moore, MD, MS

Tolerability of Front-Line Maintenance

	SOLO-1[1]		PAOLA-1[2]		PRIMA[3-5]		
	Olaparib (n=260)	Placebo (n=131)	Olaparib + bevacizumab (n=535)	Placebo + bevacizumab (n=269)	Niraparib all patients (n=484)	Niraparib modified dosing (n=169)	Placebo (n=244)
Median treatment duration (months)	24.6	13.9	17.3	15.6	11.0	11.0	NR
AE (%)	98	92	99	96	99	NR	92
Grade ≥3 AE (%)	40	19	57	51	70	76	19
Dose adjustments							
AE leading to dose interruption (%)	52	17	54	24	80	72	18
AE leading to dose reduction (%)	29	3	41	7	71	62	8
AE leading to treatment discontinuation (%)	12	3	20	6	12	14	2

Comparisons across trials should not be made as trials were not head-to-head

In PAOLA-1 the trial sponsor queried 'subject decision leading to discontinuation' and encouraged reporting of AEs. This approach was not used in SOLO-1 or PRIMA

AE=adverse event; NR=not reported

1. Banerjee S, et al. Presented at ESMO Virtual Congress 2020. 19-21 September. Abstract #811MO; 2. Ray-Coquard I, et al. N Engl J Med. 2019;381:2416-2428; 3. Gonzalez-Martin A, et al. N Engl J Med. 2019;381:2391-2402; 4. Gonzalez-Martin A, et al. Presented at ESGO Congress 2019. 2-5 November. Athens, Greece; 5. Mirza MR, et al. Presented at ASCO Virtual Scientific Program 2020. 29-31 May. Abstract #6050

Commentary — Kathleen N Moore, MD, MS

Patient Counseling and Dosing Compliance

- Selecting appropriate patients for PARPi therapy and setting expectations are key

Select appropriate patients

Basic counseling re: oral regimens

Specific toxicity management

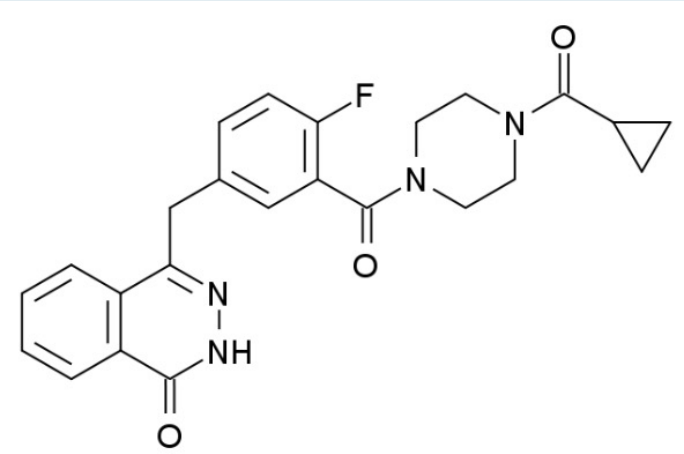

Image from: https://www.drugdevelopment-technology.com/projects/lynparza-olaparib-cancer/attachment/lynparza-olaparib-cancer2/ [Accessed August 2018]

RTP RESEARCH TO PRACTICE

Commentary — Kathleen N Moore, MD, MS

Patient Counseling and Dosing Compliance

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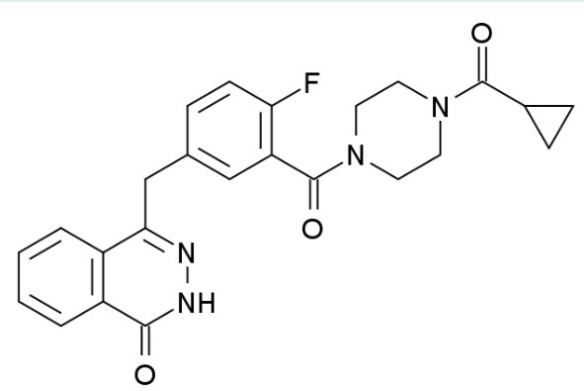


- Complete or partial response to platinum-based chemotherapy[1,2]
- Able to tolerate oral medication[1,2]
- No significant hepatic (bili >1.5 xULN) or renal dysfunction[1]

Image from: https://www.drugdevelopment-technology.com/projects/lynparza-olaparib-cancer/attachment/lynparza-olaparib-cancer2/ [Accessed August 2018]

1. Lynparza 50 mg hard capsules Summary of Product Characteristics (2018); 2. Lynparza 100 mg and 150 mg film-coated tablets Summary of Product Characteristics (2018)

Commentary — Kathleen N Moore, MD, MS

Patient Counseling and Dosing Compliance

- Selecting appropriate patients for PARPi therapy and setting expectations are key

Select appropriate patients

Basic counseling re: oral regimens

Specific toxicity management

CYP3A4 inhibitors
Erythromycin[3]
Diltiazem[3]
Fluconazole[4]
Ciprofloxacin[4]

- Instruct patient on:
  - Missed doses (don't repeat)[1,2]
  - Extra doses (notify provider)
  - No chewing tablets[2]
- Dosing around meals vs fasting
  - No sig food effects – tablet[2]
  - Take 1 hour after food, no food for up to 2 hours afterwards – capsule[1]
- Importance of reporting concomitant meds
  - Some PARPi are metabolised by CYP3A4
    - Use of inhibitors will ↑ PARPi concentrations[1,2]

1. Lynparza 50 mg hard capsules Summary of Product Characteristics (2018); 2. Lynparza 100 mg and 150 mg film-coated tablets Summary of Product Characteristics (2018); 3. Zhou SF. Curr Drug Metab 2008;9(4):310-22; 4. Derungs A et al. Clin Pharmacokinet 2016;55:79-91

Commentary — Kathleen N Moore, MD, MS

Patient Counseling and Dosing Compliance

- Selecting appropriate patients for PARPi therapy and setting expectations are key

Select appropriate patients

Basic counseling re: oral regimens

Specific toxicity management

- Fatigue[1,2]
- Gastrointestinal[1,2]
  - Nausea / emesis
  - Diarrhea
  - Dysgeusia
- Hematologic[1,2]
  - Anemia
  - Neutropenia/Thrombocytopenia
- AML/MDS[1,2]

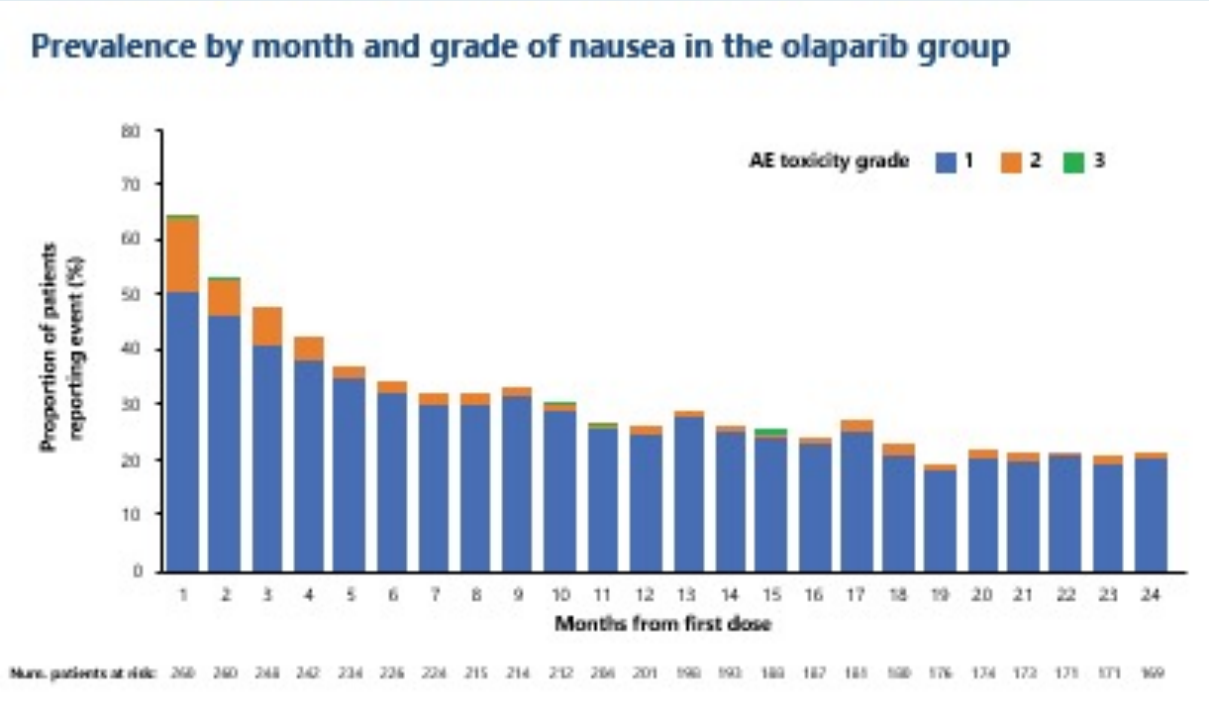
1. Lynparza 50 mg hard capsules Summary of Product Characteristics (2018); 2. Lynparza 100 mg and 150 mg film-coated tablets Summary of Product Characteristics (2018)

RTP RESEARCH TO PRACTICE

Commentary — Kathleen N Moore, MD, MS

Patient Counseling and Dosing Compliance

- **Patient counseling is key**
- **Symptoms are more common at beginning[1]**
- **Improve with time[1]**
- **Evaluation and treatment of N / V**
- **Rule out other causes[2]**
- **Pre-emptive prescriptions for prochlorperazine, lorazepam or metoclopramide[2]**
- **Avoid aprepitant (CYP3A inhibitor)[2]**
- **Dose interruption (G1/2)[2]**
- **Dose reduction (G3/recurrent)[2]**



1. Friedlander M et al. *Asia Pacific Journal of Clinical Oncology* 2016;12:323-31; 2. Moore KN, Monk BJ. *Oncologist* 2016;21(8):954-63

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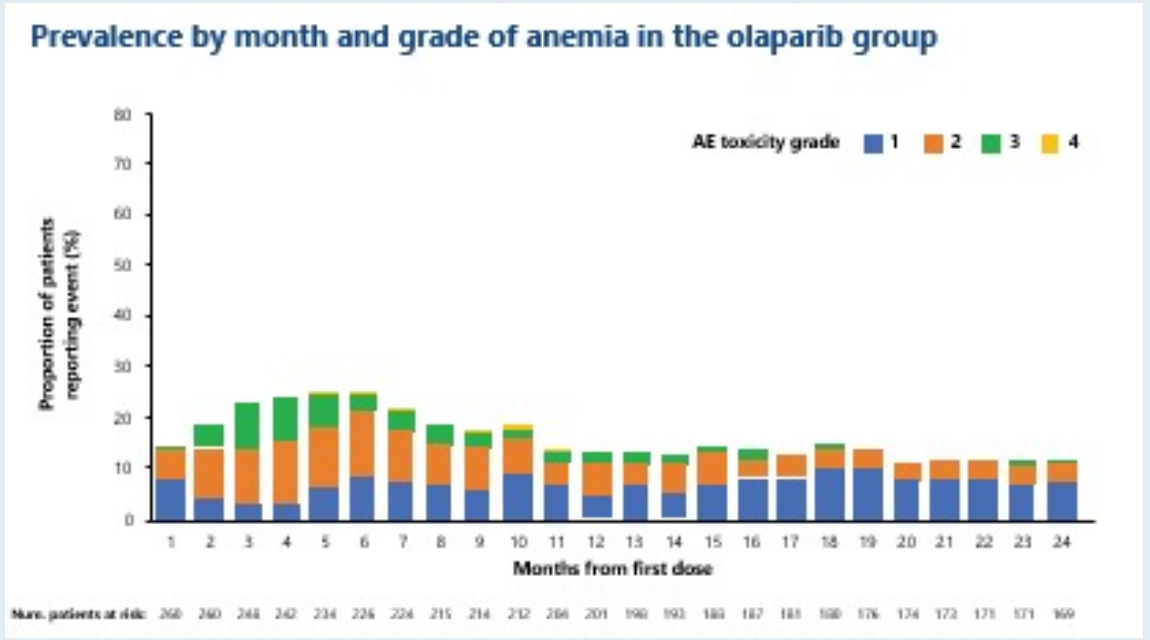
Commentary — Kathleen N Moore, MD, MS

Patient Counseling and Dosing Compliance

Management of hematological toxicities

- **Labs should be checked monthly x 12[1]**
  - **Check baseline iron and folate levels**
  - **Can reduce lab checks to q 3 months[1]**
  - **Anemia is main side effect[1]**
    - **Does not appear cumulative[2]**
- **Evaluation and treatment of anemia**
  - **Rule out other causes[1]**
  - **Mostly managed with dose interruption as long as 28 days (until back to G1)[1]**
  - **Can transfuse w/o interruption or dose modification unless G3/4[1]**
  - **If anemia is still an issue after 2 dose reductions, consider referral[1]**



1. Friedlander M et al. *Asia Pacific Journal of Clinical Oncology* 2016;12:323-31; 2. Moore KN, Monk BJ. *Oncologist* 2016;21(8):954-63

RTP RESEARCH TO PRACTICE

Questions — Jennifer Filipi, MSN, NP

Patients on PARP maintenance

- **What are some of the clinical issues that arise for patients receiving PARP inhibitors in the maintenance setting?**
- **How do you discuss treatment toxicities with patients prior to starting treatment?**
- **What are some of the psychosocial issues that arise in this situation?**

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Commentary — Jennifer Filipi, MSN, NP

Patients on PARP maintenance

- **Clinical issues:**
  - **Benefits to patients with *BRCA* mutations vs HRD vs HRP**
  - **HRP patients: Think about QOL more (least benefit)**
    - **How much extra time will this buy me? Example: patient wanting to go home to Africa**
- **Treatment toxicities:**
  - **Oral chemo is still chemo!**
    - **Nausea, vomiting, GI upset**
    - **Fatigue**
  - **Weekly labs with niraparib x4 weeks (PLTs), olaparib monthly**

RTP RESEARCH TO PRACTICE

Commentary — Jennifer Filipi, MSN, NP

- **Instructive examples/actual clinical experiences**
  - **Fatigue – one of the hardest symptoms to manage**
    - **Niraparib – insomnia.**
  - **Nausea: “moderately to highly emetogenic” NCCN**
    - **Usually improves after 4-6 weeks.**
    - **Olanzapine, ondansetron, etc.**
  - **Anemia (patient examples: acute vs chronic)**
- **Psychosocial issues**
  - **Insurance coverage**
  - **More appointments (virtual visits, local labs)**
  - **Support at home**
    - **If limited, hard to come to clinic**
    - **Toxicity management: patient example – unable to pick up a med at pharmacy, then couldn’t open pill bottle**

RTP RESEARCH TO PRACTICE

Agenda

Module 1 – Primary Ovarian Cancer

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SELF-ASSESSMENT QUIZ

In general, if you have a patient with whom you are discussing a clinical trial who is eligible for a trial, does that patient usually go on a clinical trial?

1. Yes
2. No
3. I don't know

RTP RESEARCH TO PRACTICE

SELF-ASSESSMENT QUIZ

Which of the following drug descriptions best reflects the mechanism of action of mirvetuximab soravtansine, an investigational agent with promising response rates in platinum-resistant ovarian cancer?

1. Anti-PD1 antibody
2. Anti-angiogenic agent
3. Antibody-drug conjugate
4. Tyrosine kinase inhibitor
5. I don’t know

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SELF-ASSESSMENT QUIZ

Which of the following was the main challenge reported for patients with recurrent ovarian cancer receiving TTFs (tumor treating fields) in combination with paclitaxel on the pilot INNOVATE study?

1. Dermatitis
2. Nausea and vomiting
3. Peripheral neuropathy
4. Hepatic dysfunction
5. I don’t know

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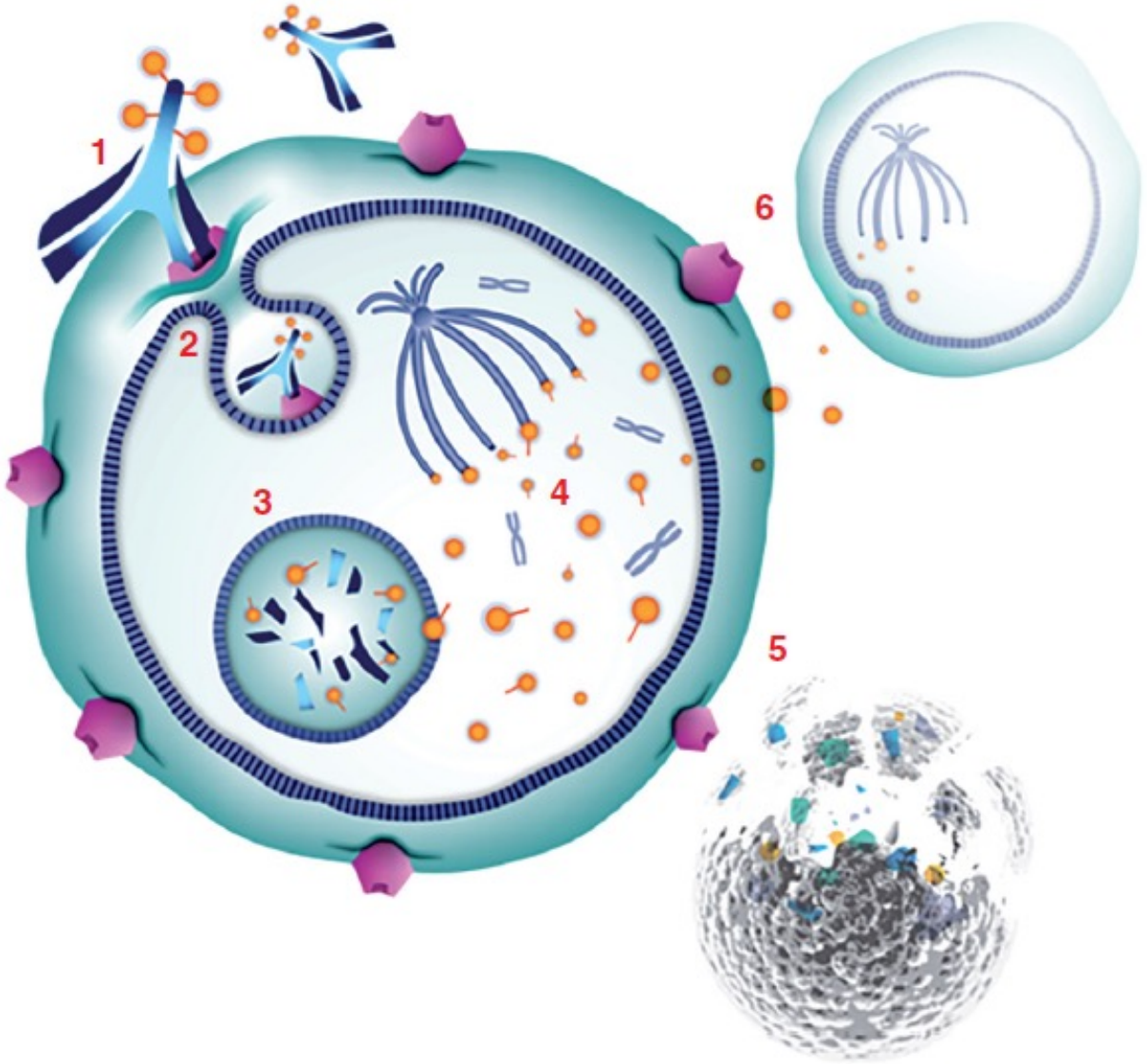
SELF-ASSESSMENT QUIZ

Tumor treating fields involve the use of…

1. Radiation therapy
2. Cryotherapy
3. Electromagnetic therapy
4. Hyperthermia
5. I don’t know

Mirvetuximab Soravtansine: Mechanism of Action



(1) Mirvetuximab soravtansine binds with high affinity to FRα expressed on the tumor cell surface

(2) The antibody-drug conjugate (ADC)/receptor complex becomes internalized via antigen-mediated endocytosis

(3) Lysosomal processing releases active DM4 catabolites from the ADC molecule

(4) These maytansinoid derivatives inhibit tubulin polymerization and microtubule assembly

(5) The potent antimitotic effects result in cell-cycle arrest and apoptosis

(6) Active metabolites can also diffuse into neighboring cells and induce further cell death — in other words, bystander killing

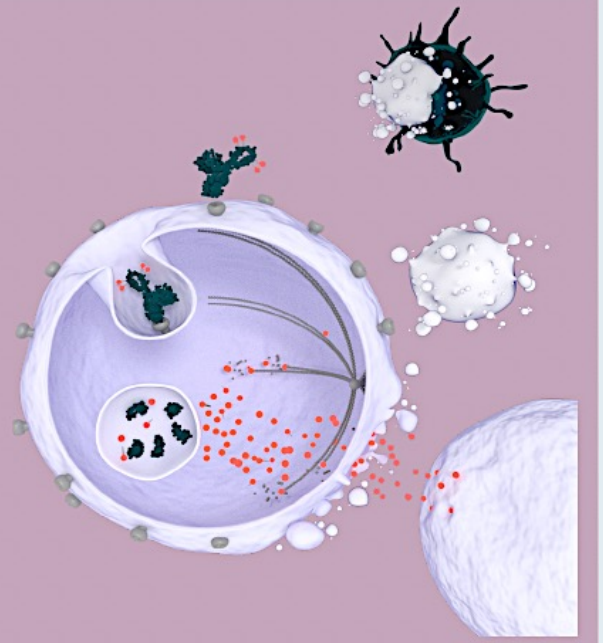
Moore K et al. *Future Oncol* 2018:14(2);123-36.

RTP RESEARCH TO PRACTICE

Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study

Ursula A. Matulonis,[1] Domenica Lorusso,[2] Ana Oaknin,[3] Sandro Pignata,[4] Hannelore Denys,[5] Nicoletta Colombo,[6] Toon Van Gorp,[7] Jason A. Konner,[8] Margarita Romeo Marin,[9] Philipp Harter,[10] Conleth G. Murphy,[11] Jiuzhou Wang,[12] Elizabeth Noble,[12] Brooke Esteves,[12] Michael Method,[12] Robert L. Coleman[13]

[1]Dana-Farber Cancer Institute, Boston, MA, USA; [2]Fondazione Policlinico Universitario A. Gemelli, IRCCS and Catholic University of Sacred Heart, Rome, Italy; [3]Gynaecologic Cancer Programme, Vall d'Hebron Institute of Oncology (VHIO), Hospital Universitari Vall d'Hebron, Vall d'Hebron Barcelona Hospital Campus, Barcelona, Spain; [4]Istituto Nazionale Tumori di Napoli Fondazione G Pascale IRCCS, Naples, Italy; [5]Ghent University Hospital, Ghent, Belgium; [6]European Institute of Oncology IRCCS, Milan, Italy and University of Milan-Bicocca, Milan, Italy; [7]University Hospital Leuven, Leuven Cancer Institute, Leuven, Belgium; [8]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [9]Institut Català d'Oncologia, Badalona, Spain; [10]Ev. Kliniken Essen-Mitte, Essen, Germany; [11]Bon Secours Hospital and Cancer Trials, Cork, Ireland; [12]ImmunoGen, Inc., Waltham, MA, USA; [13]US Oncology Research, Texas Oncology, The Woodlands, TX, USA



SORAYA

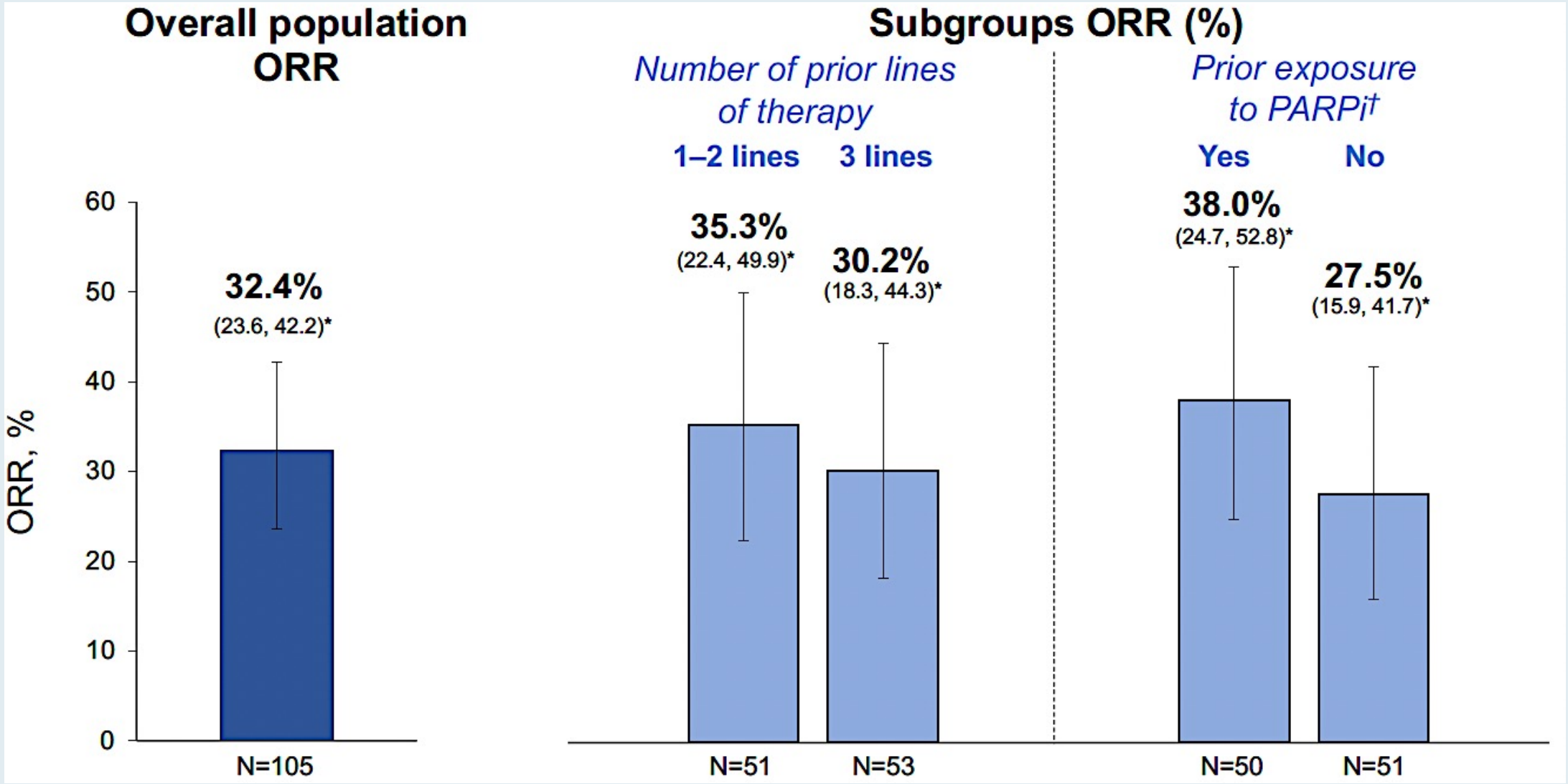
ANNUAL MEETING ON WOMENS' CANCER®
BUILDING BRIDGES // BREAKING BARRIERS
SGO // PHOENIX, ARIZONA // MARCH 18 - 21, 2022

Society of Gynecologic Oncology

SGO 2022;Abstract LBA4

RTP RESEARCH TO PRACTICE

SORAYA: Investigator-Assessed Objective Response Rate by Prior Therapy



Matulonis UA et al. SGO 2022;Abstract LBA4.

SORAYA: Treatment-Related Adverse Events (≥10%)

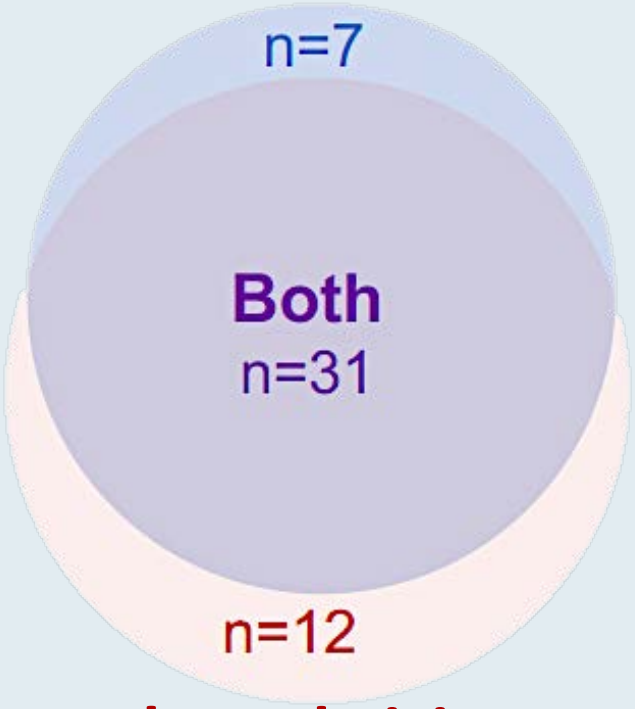
TRAEs, n (%)	All Grades	Grade 3	Grade 4
Patients with any event	91 (86)	29 (27)	1 (1)
Blurred vision	43 (41)	6 (6)	0 (0)
Keratopathy*†	38 (36)	8 (8)	1 (1)
Nausea	31 (29)	0 (0)	0 (0)
Dry eye	24 (23)	2 (2)	0 (0)
Fatigue	24 (23)	1 (1)	0 (0)
Diarrhea	23 (22)	2 (2)	0 (0)
Asthenia	16 (15)	1 (1)	0 (0)
Photophobia	15 (14)	0 (0)	0 (0)
Peripheral neuropathy	13 (12)	0 (0)	0 (0)
Decreased appetite	13 (12)	1 (1)	0 (0)
Vomiting	12 (11)	0 (0)	0 (0)
Neutropenia	11 (10)	1 (1)	0 (0)

- Most AEs were low-grade, reversible ocular and GI events
- Serious Grade ≥3 TRAEs were reported in 8% of patients
- TRAEs led to dose delay in 32% and dose reduction in 19%
- 7 patients (7%) discontinued treatment due to TRAEs
- 1 death was recorded as possibly related to study drug
  - Respiratory failure
  - Autopsy: No evidence of drug reaction; lung metastases

Matulonis UA et al. SGO 2022;Abstract LBA4.

Unique Events Associated with Mirvetuximab Soravtansine: Keratopathy and Blurred Vision

Events developed in 50/106 (47%) patients: mostly low grade



Proactive supportive care
– Lubricating artificial tears
– Corticosteroid eye drops

Predictable
– Median time to onset: cycle 2 (~1.5 months)

Manageable with dose modifications, if needed
– 22% of patients (23/106) had dose delay and/or reduction

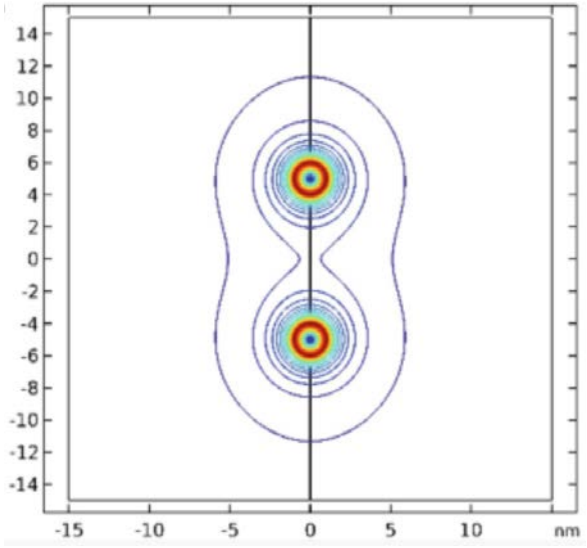
Reversible
– At data cutoff: >80% of Grade 2-3 events had resolved to Grade 0-1
  – 9 patients still receiving mirvetuximab soravtansine or being followed up for resolution

<1% discontinuation due to ocular events
– 1 of 106 patients discontinued due to Grade 4 keratopathy, which resolved within 15 days

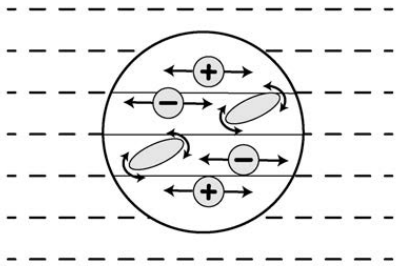
Matulonis UA et al. SGO 2022;Abstract LBA4.

Tumor Treatment Fields

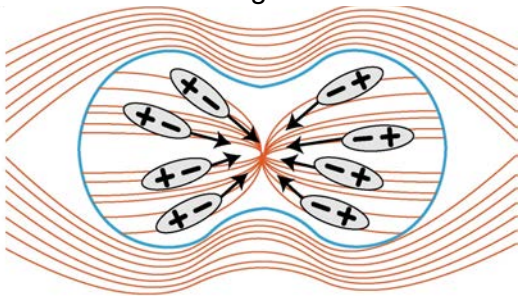
Dividing Cell under TTF
Selective Electric Field Sensitivity

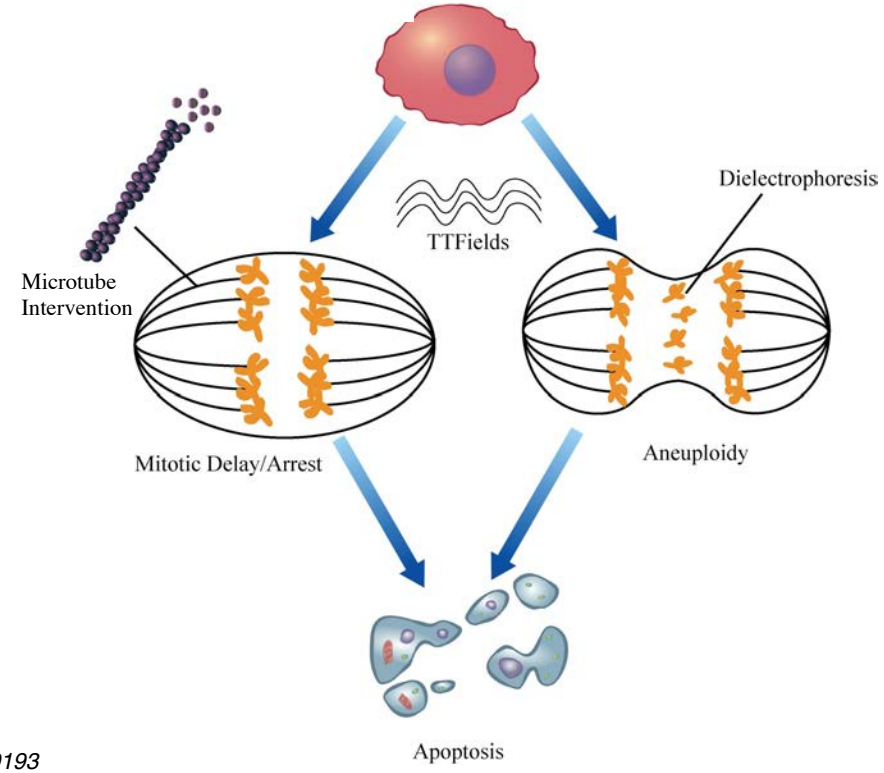


Non-dividing Cells



Dividing Cells

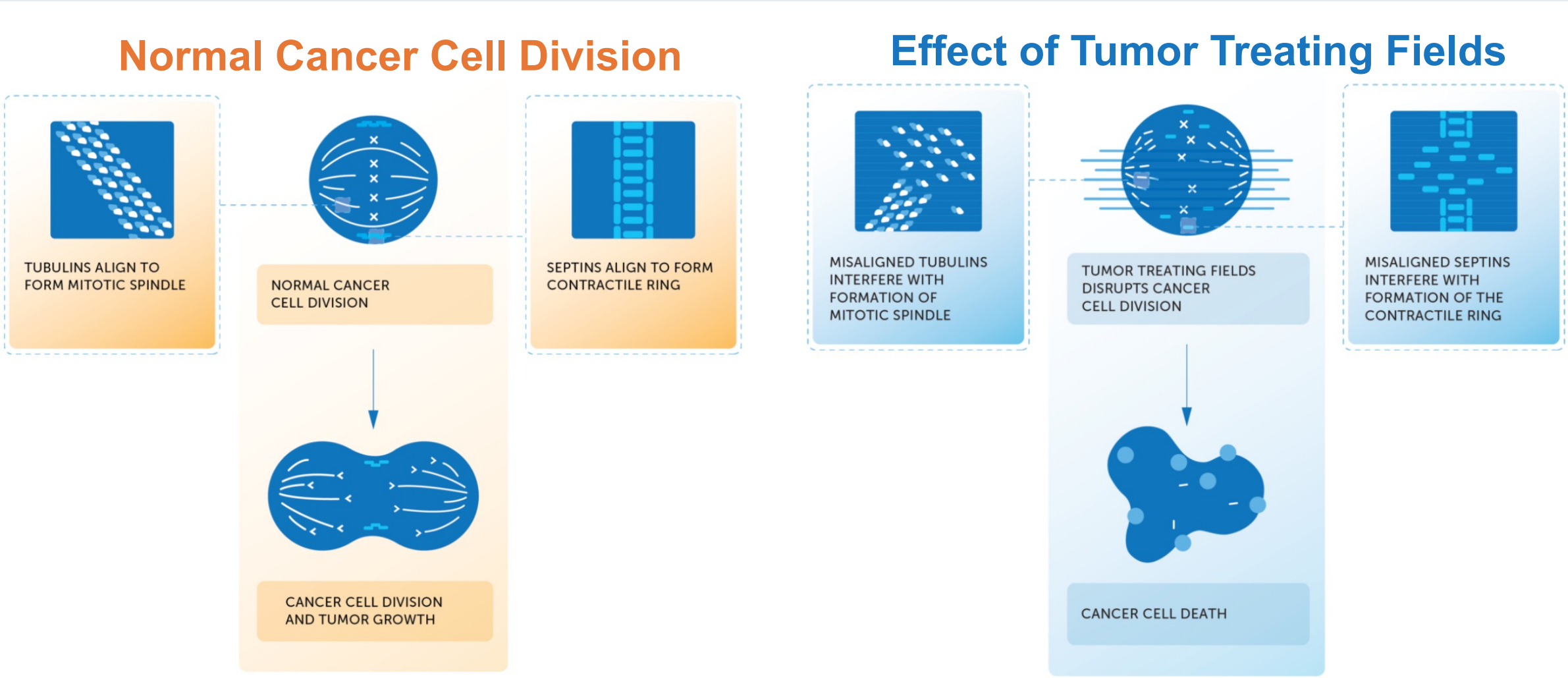




Luo et al. *Biomedicine and Pharmocotherapy 2020; 127:110193*

Luo et al. *Biomedicine and Pharmacotherapy* 2020;127:11013.

Effect of Tumor Treating Fields on Dividing Cancer Cells



www.novocure.com/our-therapy/

RTP RESEARCH TO PRACTICE

NovoTTF-100L™(O) System: A Portable Medical Device That Allows Normal Daily Activities

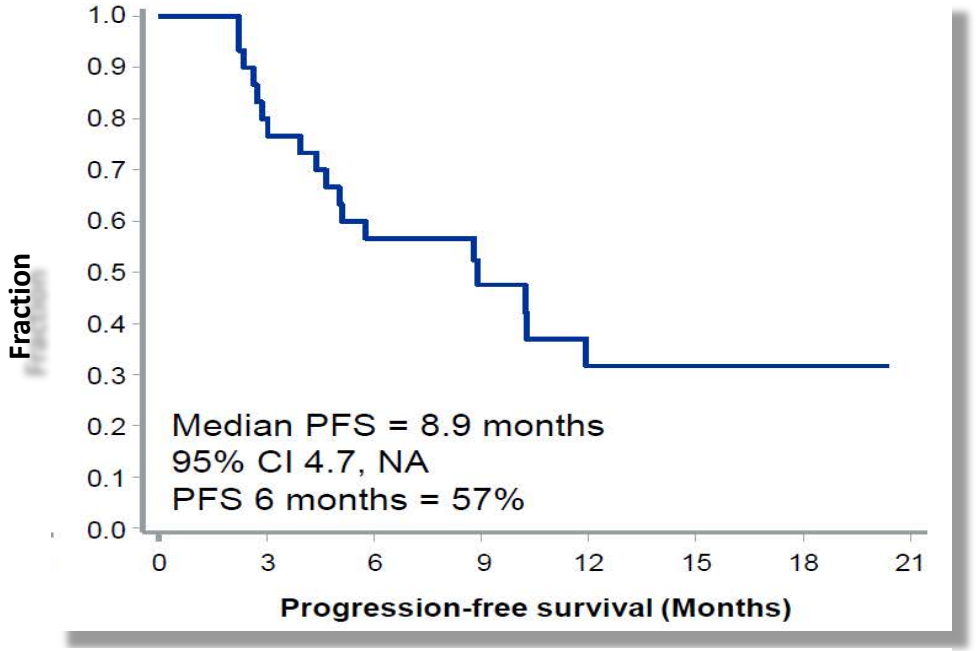
Vergote I et al. *Gynecol Oncol* 2018;150(3):471-7.

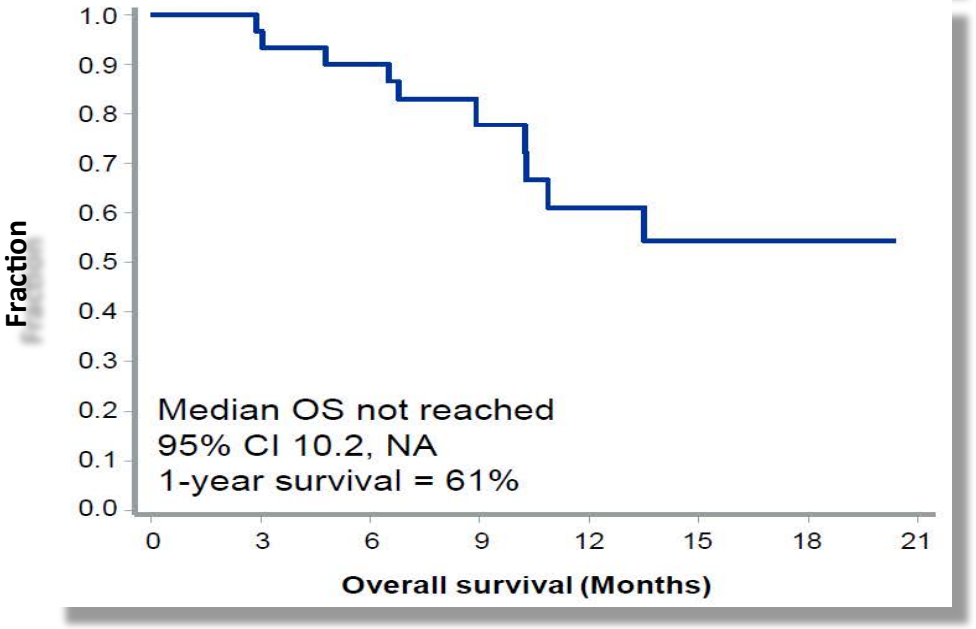
RTP RESEARCH TO PRACTICE

INNOVATE: Tumor Treatment Fields + Paclitaxel

Outcomes (PROC)	TTFields + Paclitaxel (n=31)
Median OS in months (95% CI)	NR
Survival Rates, % (95% CI) 6 months 12 months	 90 (72-97) 61 (37-78)
Median PFS in months (95% CI)	8.9 (4.7-NA)
PFS Rates, % (95% CI) 6 months	 57 (37-72)
Best Response in Patients w/ Available Radiologic Data,* n (%) CR PR SD PD CBR	28 (90%) 0 (0) 7 (25%) 13 (46%) 8 (29%) 20 (71%)

*CT scans were performed every 2 months and stable disease was defined as at least for 2 months





Vergote I et al. *Gynecol Oncol* 2018;150(3):471-7.

INNOVATE: Select Adverse Events

Adverse event	TTFields + paclitaxel (N = 31)	
	Grade 1-2	Grade 3-4
Skin irritation	26 (84%)	2 (6%)
Abdominal pain	13 (42%)	0
Constipation	8 (26%)	0
Diarrhea	15 (48%)	2 (6%)
Nausea	13 (42%)	0
Vomiting	7 (23%)	0
Fatigue	10 (32%)	0
Edema	14 (45%)	0
Dysgeusia	8 (26%)	0
Neuropathy	14 (45%)	0

Vergote I et al. *Gynecol Oncol* 2018;150(3):471-7.

Recommendation Announced to Continue the Phase III Pivotal INNOVATE-3 Study of Tumor Treating Fields for Ovarian Cancer

Press Release — March 23, 2022

"The results of a pre-specified interim analysis for the phase 3 pivotal INNOVATE-3 study evaluating the safety and efficacy of Tumor Treating Fields (TTFields) together with paclitaxel for the treatment of patients with platinum-resistant ovarian cancer were announced today.

An independent data monitoring committee (DMC) reviewed the safety data for all platinum-resistant ovarian cancer patients enrolled on the trial. In addition, an analysis of overall survival was performed on the first 540 patients randomized. The interim analysis did not indicate a need to increase the sample size and the DMC recommended that the study should continue to final analysis as planned."

www.yahoo.com/now/novocure-announces-favorable-recommendation-continue-120000088.html

RTP RESEARCH TO PRACTICE

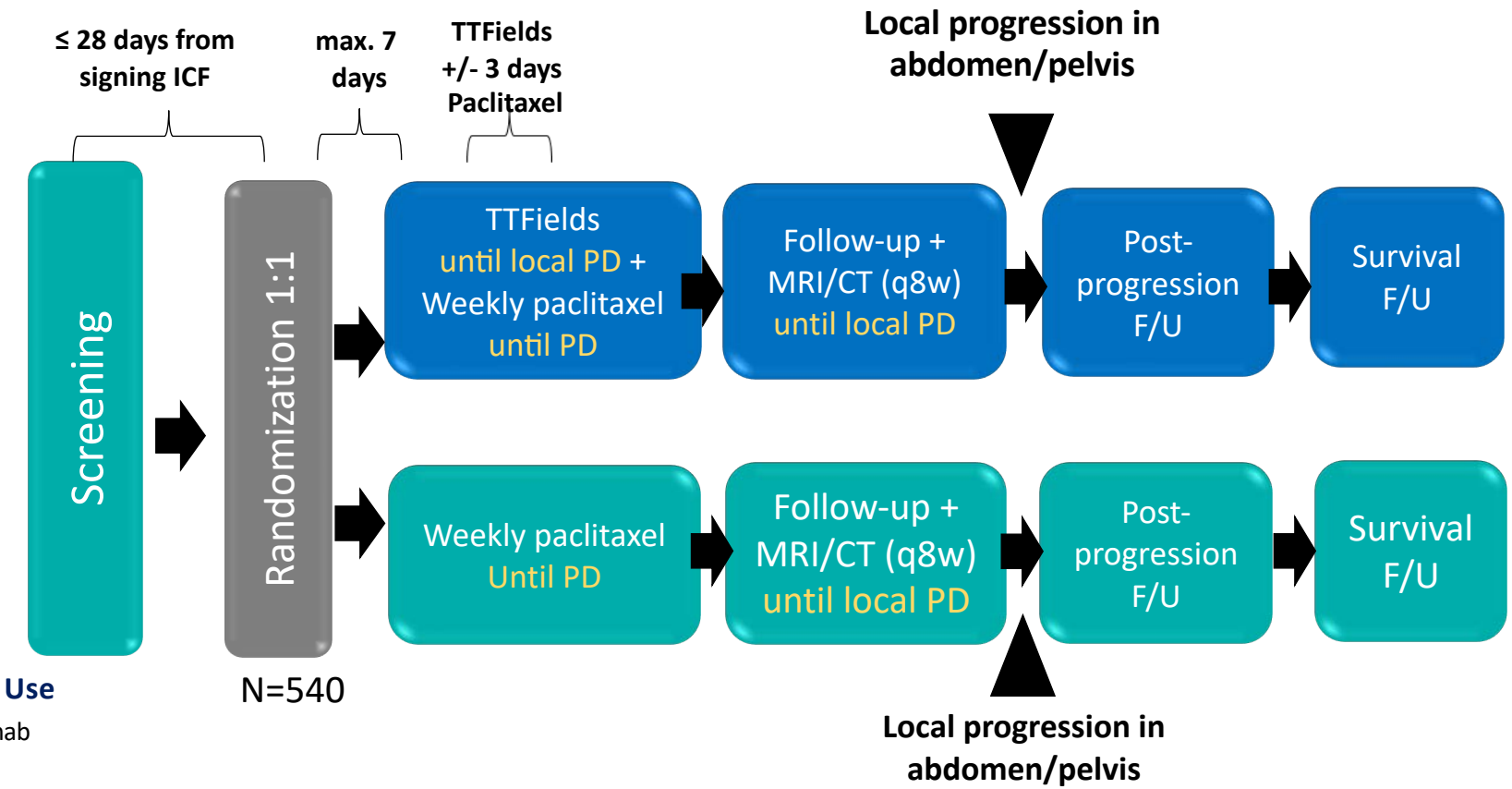
INNOVATE-3 (ENGOT-ov50 / GOG-3029) (TTFields, 200 kHz)

Enrollment target (n=540)

Number of sites (n=110)

- ENGOT enrollment began March 2019
- GOG enrollment began February 2020

Enrollment Closed October 2020



Stratification

- **Prior therapy**
  - no prior systemic therapy following PROC
  - one prior line
  - two prior lines
- **Prior Bevacizumab Use**
  - prior bevacizumab use
  - no prior bevacizumab
- **BRCA Status**
  - mutated BRCA
  - wild type BRCA/ unknown

https://clinicaltrials.gov/ct2/show/NCT03940196

Questions — Krishnansu S Tewari, MD

The patient with advanced disease and no approved treatment options

- **What are some of the strategies being tested in clinical trials that you are most excited about?**
- **When was a time you believe a patient in your care benefited from clinical trial participation?**

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Commentary — Krishnansu S Tewari, MD

The patient with advanced disease and no approved treatment options

- **Combined PARPi + Immunologic Checkpoint Blockade**
  - **ATHENA**
    - **NCT03522246**
    - **Rucaparib plus Nivolumab as frontline maintenance therapy**
- **Combined Anti-VEF + PARPi + Checkpoint**
  - **FIRST**
    - **NCT03602859**
    - **Bevacizumab plus Niraparib and Dostarlimab for primary maintenance therapy**
  - **DUO-O**
    - **NCT03737643**
    - **Bevacizumab plus Olaparib and Durvalumab for primary maintenance therapy**

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Questions — Deborah Wright, MSN, APRN, AGCNS-BC

The patient with advanced disease and no approved treatment options

- **What are some of the obstacles you encounter in having patients participate in clinical trials?**
- **When was a time you believe a patient in your care benefited from clinical trial participation?**
- **What are some of the psychosocial issues that arise in this situation?**

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Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

The patient with advanced disease and no approved treatment options

What are some of the obstacles you encounter in having patients participate in clinical trials?

- **Burden of Financial Toxicity**
  - **Routine care costs, copayments, coinsurance, deductibles**
  - **Time away from work for frequent visits and travel to the site of the clinical trial**
  - **Lodging, meals, dependent care and transportation (fuel costs, wear and tear)**
  - **Unknown adverse effects of investigational treatment and unexpected expenses related to the treatment of AEs (supportive care, medications, ER visits, hospitalizations)**

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Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

Decision-Making

- **Informed consent process**
- **Uncertainty about risk may reduce willingness to participate in clinical trials**
- **Communication breakdowns between providers and patients – use of patient navigators can help reduce patients lost to follow-up, decrease time delays in receiving diagnostic resolution and minimize time lags in starting treatment**
- **Language barrier**
- **Cultural considerations**

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Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

Cite examples from your practice where you believe a patient benefited by clinical trial participation?

- **68 yr old with recurrent metastatic endometrial cancer (adenocarcinoma with clear cell features). Did not tolerate taxane well in second line with platinum, patient wanted a clinical trial immunotherapy option after CT scan confirmed recurrence. PR+, HER2-, MS-stable, PIK3CA on Foundation. Recurred in abdomen/pelvis/nodal regions. Enrolled on study using a combination of anti-PD1 + anti-VEGF/ANG study drugs. ECOG 1. As of 4/13/2022 she has completed 24 cycles of treatment with a durable PR and tolerable AEs, primarily fatigue (Gr1), hypertension (Gr2, now Gr1), constipation (gr1). Sponsor approves patient to continue on study after completing 18 cycles per protocol.**

Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

- **50 yr old with recurrent LGSOC, measurable disease in pelvis. S/p 2 lines of carbo/paclitaxel followed by letrozole maintenance. Foundation testing with no actionable mutations. Enrolled on clinical trial using a novel ADC attached to MMAE. ECOG 0, working full time. Foundation testing with no actionable mutations. 4/22/2022 has completed 14 cycles with a confirmed Complete Response. AEs reported: nausea (Gr1), mucositis (Gr1), arthralgia (Gr1), headache (Gr1), vomiting (Gr2) improved with anti-emetics now Gr 1, fever (Gr1) first 2 cycles only, resolved with APAP.**

Commentary — Deborah Wright, MSN, APRN, AGCNS-BC

- **Patients with advanced cancer who no longer have approved options and are considering clinical trials can experience the following psychosocial issues.**
  - **Declining PS, difficulty completing ADLs, iADLs causing increased fear, anxiety, hopelessness.**
  - **Inability to continue working and earning a wage, lack of advocacy and resources to apply for Social Security Disability, Medicaid.**
  - **Feelings of loneliness, abandonment, marginalization.**
  - **Distress has been referred to as the Sixth Vital sign in cancer care. (Grassi 2017).**

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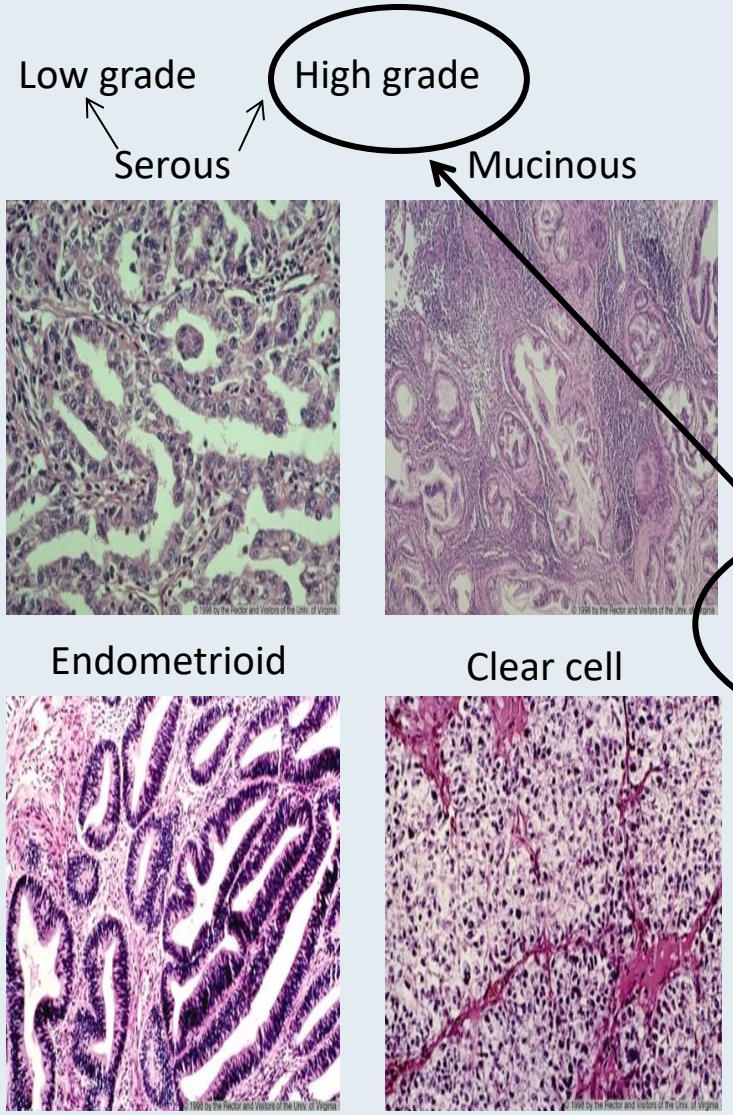
Appendix of Recent Data Sets

OC Is Separated into Histological Categories



Specific molecular features define these categories and shape clinical trial design:

Mucinous tumors
KRAS mutations

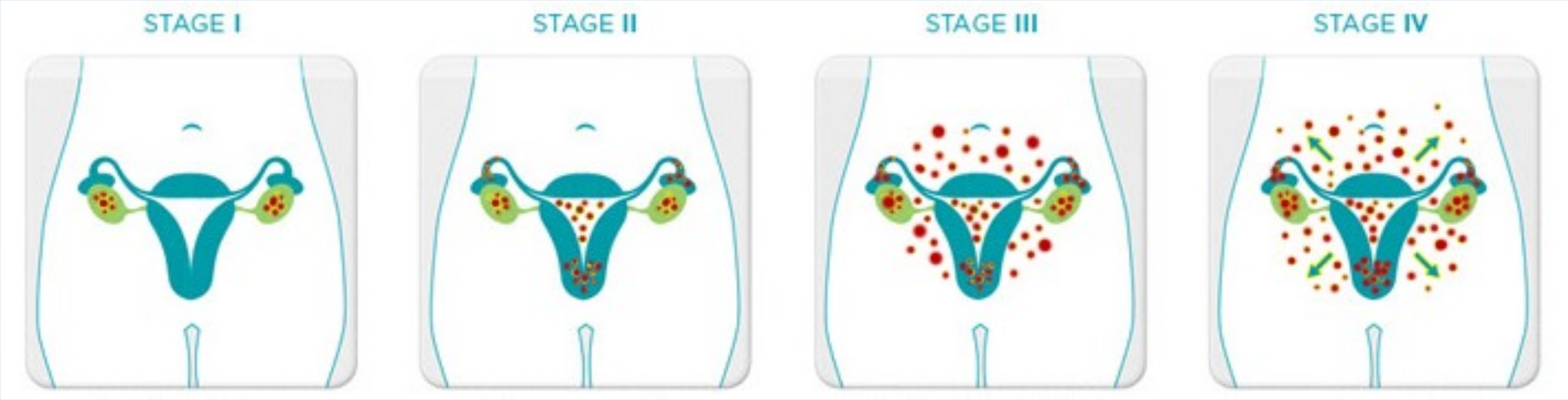
High-grade serous cancers
Homologous recombination deficiency (HRD) is common and thus displays a high rate of platinum sensitivity

Low-grade serous cancers
KRAS mutations; usefulness of MEK inhibitors

Clear cell cancers
Chemotherapy insensitivity, PIK3CA mutations and sensitivity to VEGFR-2 inhibitors

Courtesy of Ursula Matulonis, MD

Stages of Epithelial OC



Confined to ovaries | Spread to pelvis | Spread to abdomen | Spread to distant sites

15% of patients present with Stage I

85% of patients present with Stage II-IV

5 y survival: 90% | 70% | 39% | 17%

http://ovarian.org/about-ovarian-cancer/what-is-ovarian-cancer/types-a-stages; https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html;
Howlander N et al. SEER Cancer Statistics Review 1975-2014, http://seer.cancer.gov/csr/1975_2014/

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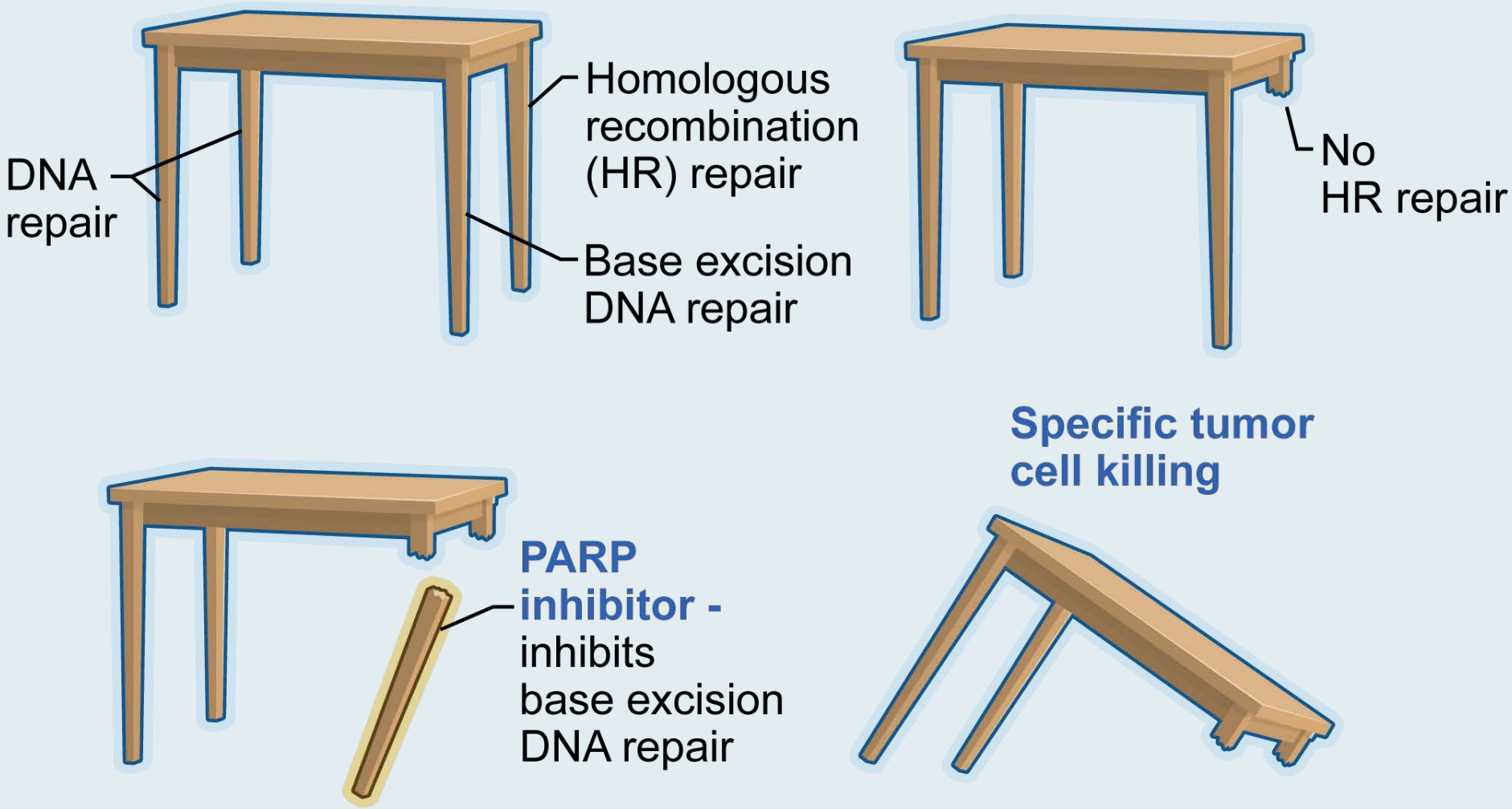
Mechanism of Cell Death from Synthetic Lethality Induced by PARP Inhibition



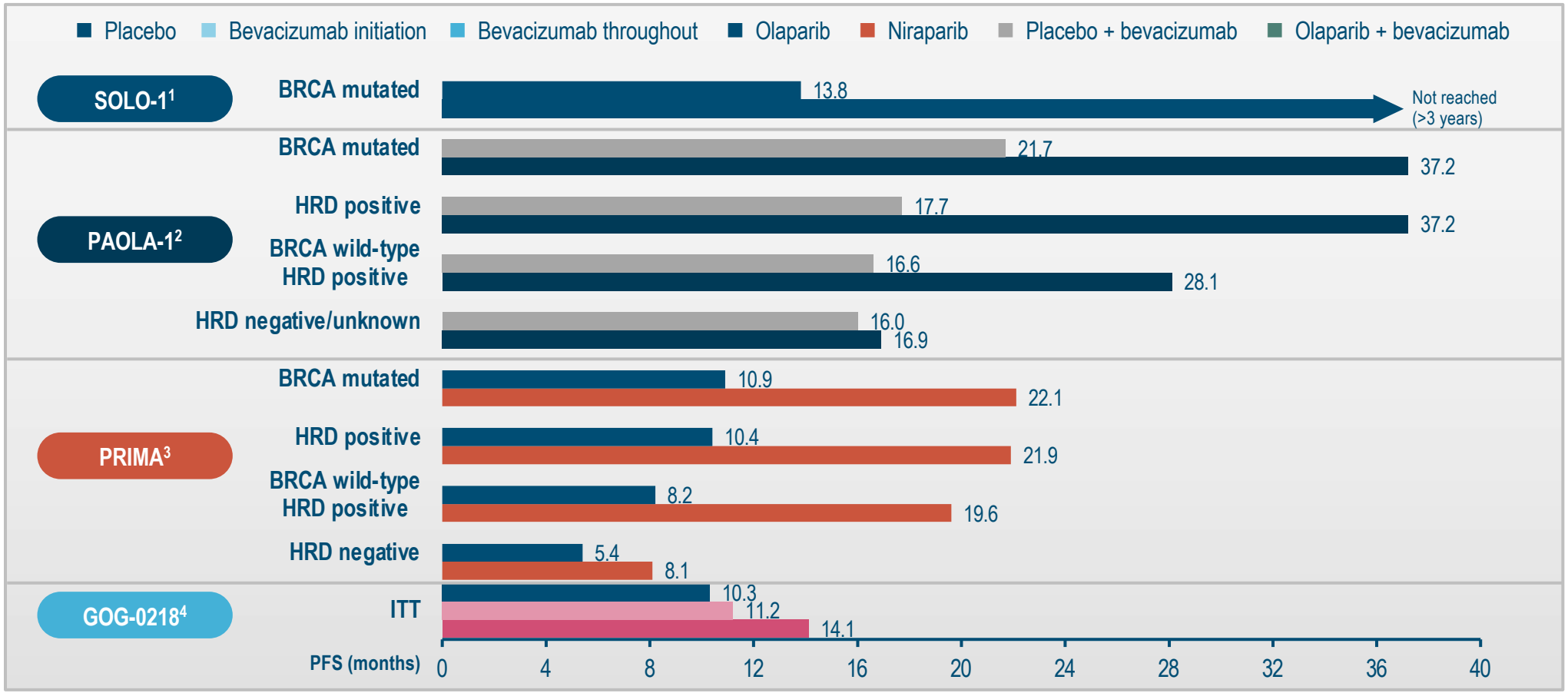
Courtesy of Jenny C Chang, MD

Current FDA-Approved and Investigational PARP Inhibitors: Differences

PARP inhibitor	FDA approvals	PARP trapping potency	PARPi target selectivity (strength of binding)	Dose
Olaparib	Ovarian, breast, pancreatic, prostate	1	Potent PARP1 inhibitor, less selective	300 mg BID
Rucaparib	Ovarian, prostate	1	Potent PARP1 inhibitor, less selective	600 mg BID
Niraparib	Ovarian	~2	Selective inhibitor of PARP1 and 2	300 mg qd
Veliparib	None	<0.2	Potent PARP1 inhibitor, less selective	400 mg BID
Talazoparib	Breast	~100	Potent PARP1 inhibitor, less selective	1 mg qd

Lim JSJ, Tan DSP. *Cancers* 2017;9(8):pii:E109.

SUMMARY OF APPROVED MAINTENANCE STUDIES IN THE FIRST LINE



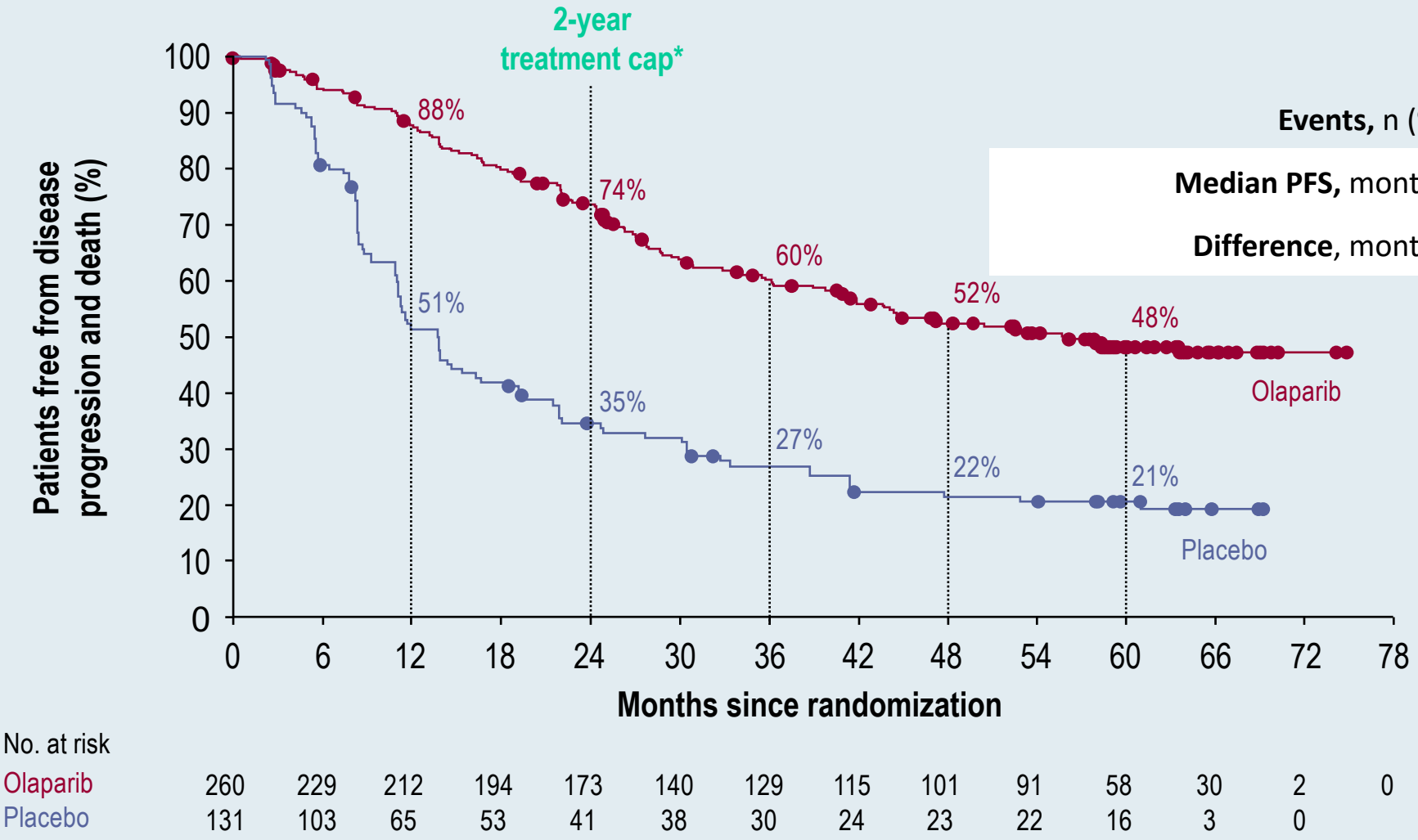
Comparisons across trials should not be made as trials were not head-to-head.

BRCA, breast cancer gene; HRD, homologous recombination deficiency; ITT, intent-to-treat; PFS, progression-free survival

1. Moore K, et al. N Engl J Med 2018;379:2495–2505; 2. Ray-Coquard IL, et al. N Engl J Med 2019; 381:2416–2428; 3. Gonzalez-Martin A, et al. N Engl J Med 2019;381:2391–2402; 4. Burger RA, et al. N Engl J Med 2011;365:2473–2483

Courtesy of Robert L Coleman, MD

SOLO-1: Updated PFS (60 Months Follow-Up)



	Olaparib (N=260)	Placebo (N=131)
Events, n (%)	118 (45)	100 (76)
Median PFS, months	**56.0**	**13.8**
Difference, months	42.2	

HR 0.33 (95% CI 0.25–0.43)

Median treatment duration:
Olaparib, 24.6 months
Placebo†, 13.9 months

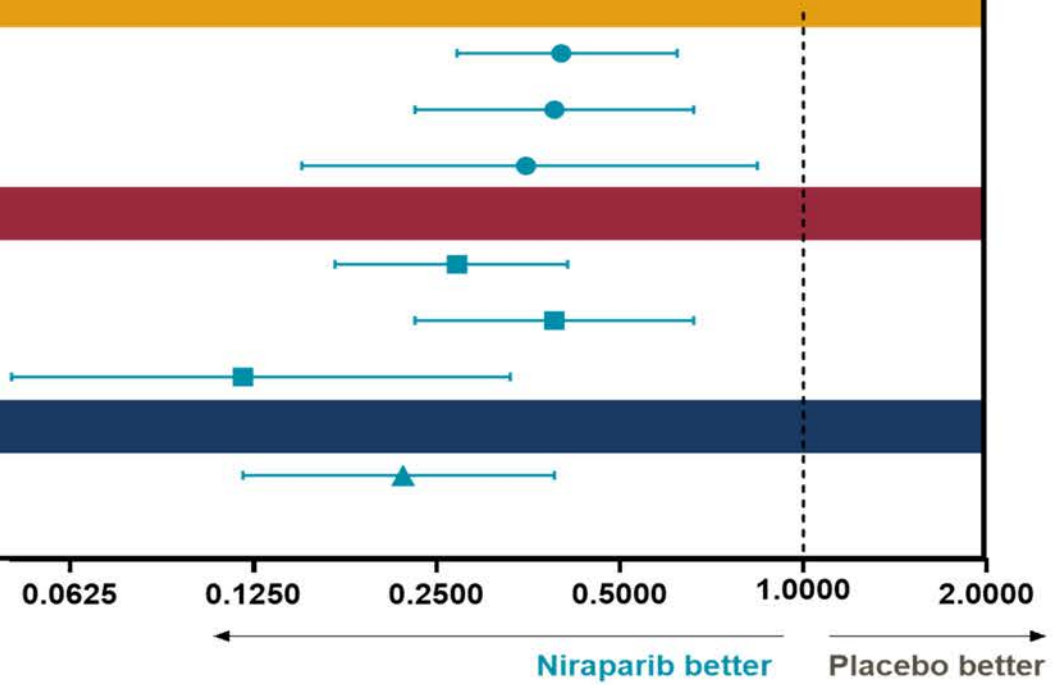
Bradley WH et al. SGO 2021;Abstract 10520.

RTP RESEARCH TO PRACTICE

ASCO 2021 UPDATE - PRIMA

Progression-Free Survival in Patients with *BRCA*m Ovarian Cancer

	Niraparib		Placebo		Hazard ratio for PFS (95% CI)
	n/N	mPFS, mo	n/N	mPFS, mo	
PRIMA (1L maintenance)					
*BRCA*m	49/152	22.1	40/71	10.9	0.40 (0.27–0.62)
BRCA1	40/105	19.6	26/43	8.4	0.39 (0.23–0.66)
BRCA2	9/47	NE	14/28	13.6	0.35 (0.15–0.84)
NOVA (2L maintenance)					
g*BRCA*m	59/138	21.0	44/65	5.5	0.27 (0.17–0.41)
BRCA1	41/84	12.9	27/43	5.8	0.39 (0.23–0.66)
BRCA2	16/50	NE	13/18	5.4	0.12 (0.05–0.33)
NORA[1] (2L maintenance)					
g*BRCA*m[a]	24/65	NE	28/35	5.5	0.22 (0.12–0.39)



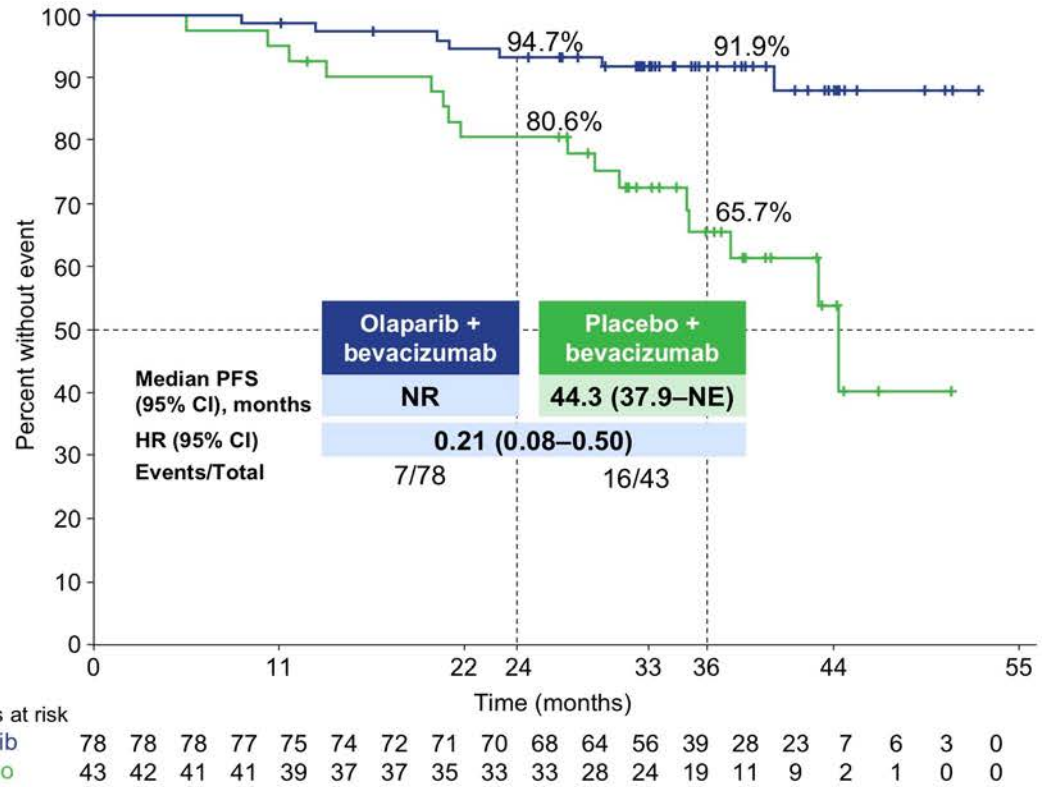
PFS was measured by blinded independent central review. Horizontal lines represent 95% CIs.
[a]*BRCA1* and *BRCA2* data are not currently available.
1L, first-line; 2L, second-line; g, germline; m, mutated; mPFS, median progression-free survival; NE, not estimable; PFS, progression-free survival.
[1]Wu XH, et al. *Ann Oncol* 2021;32(4):512–521.

Courtesy of Michael J Birrer, MD, PhD

ASCO 2021 UPDATE – PAOLA-1

PFS2 by FIGO stage and surgical outcome in patients with HRD-positive tumors

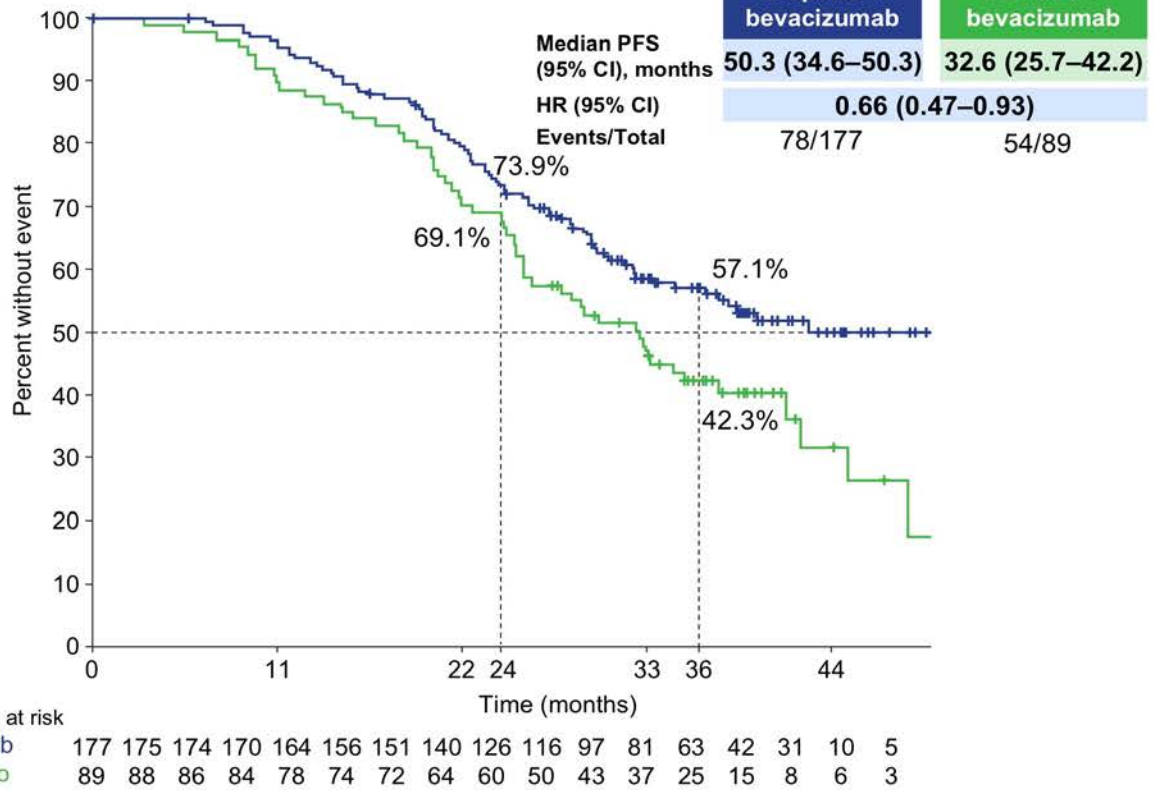
Lower risk*



Patients at risk

Olaparib	78	78	78	77	75	74	72	71	70	68	64	56	39	28	23	7	6	3	0
Placebo	43	42	41	41	39	37	37	35	33	33	28	24	19	11	9	2	1	0	0

Higher risk†



Patients at risk

Olaparib	177	175	174	170	164	156	151	140	126	116	97	81	63	42	31	10	5		
Placebo	89	88	86	84	78	74	72	64	60	50	43	37	25	15	8	6	3		

The median time from the first cycle of chemotherapy to randomization was 7 months. *Patients with HRD-positive tumors who had stage III disease and complete resection following upfront surgery (median follow-up overall: 37.0 months); †Stage III patients with residual disease after upfront surgery or who received neoadjuvant chemotherapy, or HRD-positive stage IV patients (median follow-up overall: 37.5 months).
NR, not reached; PFS2, second progression-free survival.

Courtesy of Michael J Birrer, MD, PhD

OVARIO: Efficacy of niraparib and bevacizumab in patients at high risk is comparable to that in other first-line maintenance treatment trials

OVARIO: PFS rate at 6, 12, and 18 months				
Parameter	**Overall N=105**	**HRd n=49**	**HRp n=38**	**HRnd n=18**
Events at 6 months, n	11	1	7	3
6-month PFS rate, % (95% CI)	90 (82-95)	98 (89-100)	82 (66-92)	83 (59-96)
Events at 12 months, n	26	6	13	7
12-month PFS rate, % (95% CI)	75 (66-83)	88 (75-95)	66 (49-80)	61 (36-83)
Events at 18 months, n	40	12	20	8
18-month PFS rate, % (95% CI)	62 (52-71)	76 (61-87)	47 (31-64)	56 (31-78)

- OVARIO is a Phase II single-arm study of niraparib + bevacizumab therapy in advanced ovarian cancer following frontline platinum-based chemotherapy with bevacizumab
- The study enrolled a high-risk population of patients with OC (N = 105); despite the high-risk population, results were favorable compared with other up-front maintenance treatment trials
- At the 18-month analysis, 62% of patients in the overall population remained progression free
- The safety of niraparib + bevacizumab was consistent with the known side effects of each drug as monotherapy; **no new safety signals were observed**

Dosing: Niraparib (200 or 300 mg QD) + bevacizumab (15 mg/kg Q3W).
The 6-,12-, and 18-month PFS efficacy population (N=105) includes all OVARIO patients dosed ≥6, ≥12, and ≥18 months, from the data cutoff dates of August 14, 2019; February 14, 2020; and August 14, 2020 (last patient enrolled February 14, 2019). Median follow-up was 8.6, 12.8, and 16.0 months.

CI, confidence interval; HRd, homologous recombination deficient; HRnd, homologous recombination not determined; HRp, homologous recombination proficient; n, number of patients; OC, ovarian cancer; PARPi, poly(ADP-ribose polymerase) inhibitor; PFS, progression-free survival.
Hardesty MM et al. SGO Virtual Congress 2021;Poster 22.

Articles

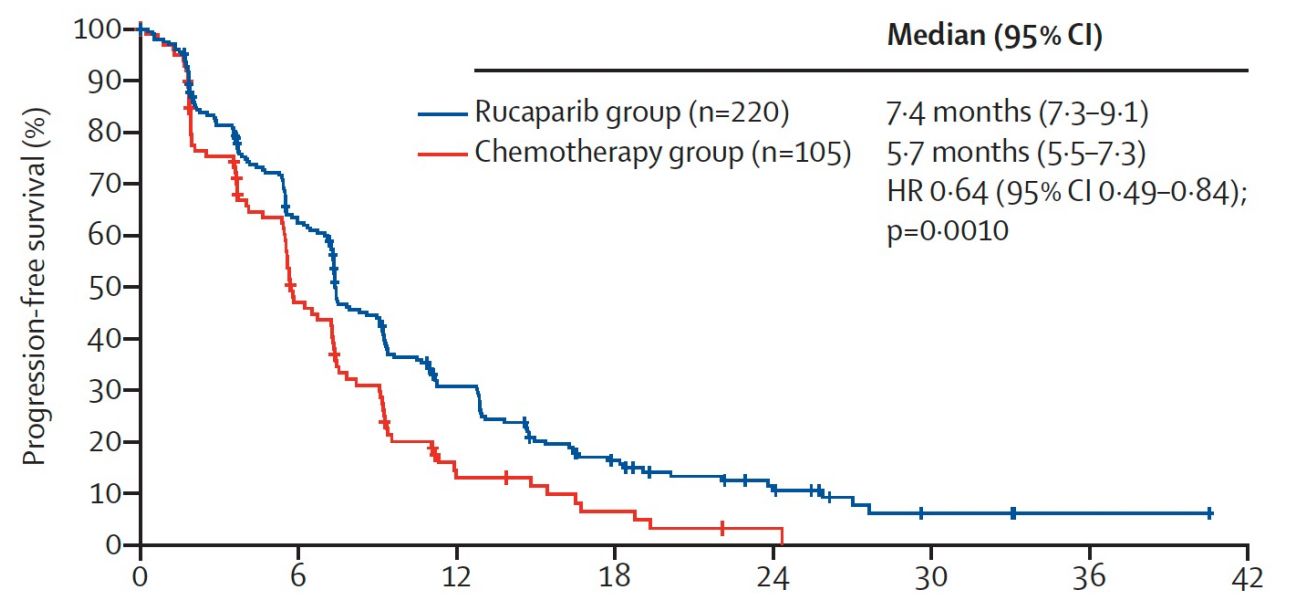
Lancet Oncol 2022;23(4):465-78.

Rucaparib versus standard-of-care chemotherapy in patients with relapsed ovarian cancer and a deleterious *BRCA1* or *BRCA2* mutation (ARIEL4): an international, open-label, randomised, phase 3 trial

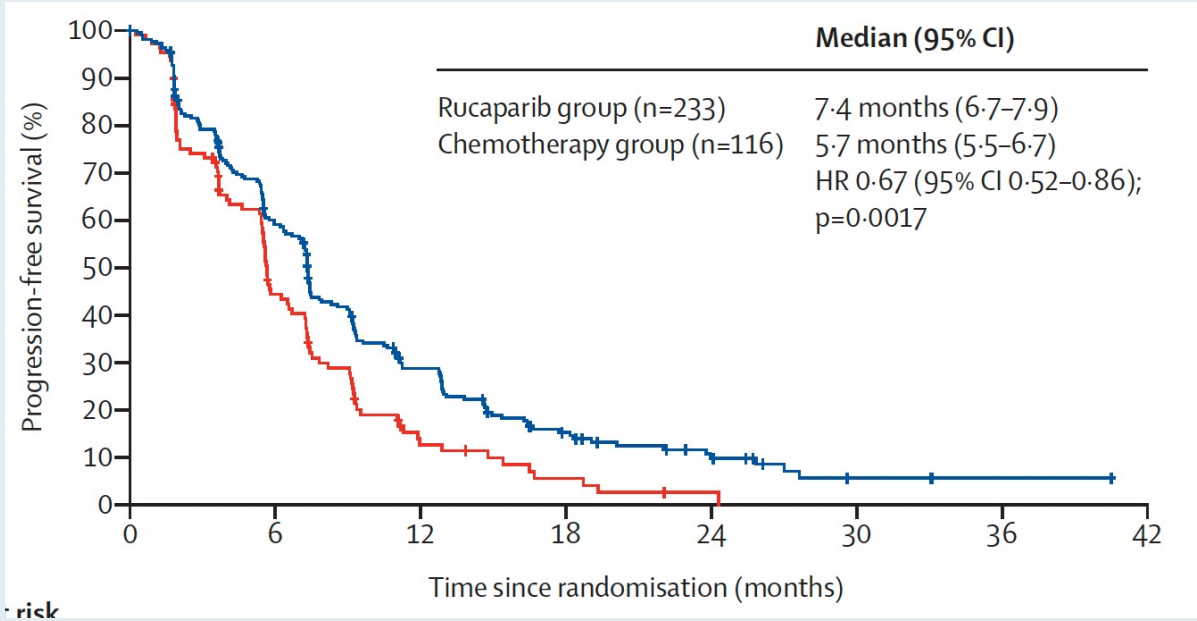
Rebecca Kristeleit, Alla Lisyanskaya, Alexander Fedenko, Mikhail Dvorkin, Andreia Cristina de Melo, Yaroslav Shparyk, Irina Rakhmatullina, Igor Bondarenko, Nicoletta Colombo, Valentyn Svintsitskiy, Luciano Biela, Marina Nechaeva, Domenica Lorusso, Giovanni Scambia, David Cibula, Róbert Póka, Ana Oaknin, Tamar Safra, Beata Mackowiak-Matejczyk, Ling Ma, Daleen Thomas, Kevin K Lin, Karen McLachlan, Sandra Goble, Amit M Oza

ARIEL4

Efficacy



Intent to treat



Kristeleit et al. *Lancet Oncol* 2022;23(4):465-78.

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ARIEL4

	Efficacy population			ITT population		
	Rucaparib group	Chemotherapy group	p value	Rucaparib group	Chemotherapy	p value
RECIST-evaluable patients	211/220 (96%)	96/105 (91%)	..	224/233 (96%)	106/116 (91%)	..
Objective response rate per RECIST	85 (40%; 95% CI 34–47)	31 (32%; 95% CI 23–43)	0·13	85 (38%; 95% CI 32–45)	32 (30%; 95% CI 22–40)	0·13
Complete response	10 (5%)	2 (2%)	..	10 (4%)	2 (2%)	..
Partial response	75 (36%)	29 (30%)	..	75 (33%)	30 (28%)	..
Stable disease	77 (36%)	38 (40%)	..	83 (37%)	43 (41%)	..
Progressive disease	25 (12%)	15 (16%)	..	31 (14%)	19 (18%)	..
Not evaluable	24 (11%)	12 (13%)	..	25 (11%)	12 (11%)	..
Median duration of objective response per RECIST, months	9·4 (95% CI 7·5–11·1)	7·2 (95% CI 4·0–11·4)	..	9·4 (95% CI 7·5–11·1)	7·2 (95% CI 3·9–9·4)	..
HR (95% CI)	0·59 (0·36–0·98)	..	..	0·56 (0·34–0·93)	..	..
RECIST-evaluable or CA-125-evaluable patients	217/220 (99%)	101/105 (96%)	..	230/233 (99%)	111/116 (96%)	..
Objective response rate per RECIST or CA-125	110 (51%; 95% CI 44–58)	44 (44%; 95% CI 34–54)	..	110 (48%; 95% CI 41–55)	45 (41%; 95% CI 31–50)	..

All data are n/N (%), n (%), or estimate with 95% CI in parentheses, unless otherwise stated. p values were calculated using a stratified Cochran-Mantel-Haenszel test. p values for objective response rate per RECIST or CA-125 and duration of objective response are not presented due to the hierarchical step-down analysis being broken (ie, because there was no significant difference in objective response rate between the groups). HR=hazard ratio. ITT=intention-to-treat. RECIST=Response Evaluation Criteria in Solid Tumors version 1.1.

Table 2: **Investigator-assessed objective response rates in patients who were evaluable for RECIST or CA-125 response with measurable disease at baseline in the efficacy and ITT population**

Patient Education for Olaparib

- **Reinforce common side effects: fatigue and nausea, but short lived**
- **Obtain Baseline CBC, Plt, Diff, Comprehensive Metabolic Panel, CA 125; Then monthly After 3 months may continue q 3 month labs and physical exam**
- ***Our practice* monitors weekly CBC, Plt, Diff x 4 weeks**
- **We hold dose one week if Plts < 75K, Hgb < 9.0g/dl, ANC < 1500/mm3**
- **If blood counts are held a week and return to less than grade 1, package insert recommends dose reduction. We dose 150mg q am and 300mg at hs. PI recommends 150mg and 100mg in am and pm**
- **We provide blood transfusion if Hgb < 9.0g/dl and or symptomatic**
- **Consider daily folate, and monthly Vitamin B12 injection, especially if elevated MCV**
- **For fatigue (r/o anemia, hypothyroid, dehydration) encourage exercise and mobility. Fatigue can be due to deconditioning.**
- **Nausea may occur in form of queasiness: recommend prophylactic antiemetic initially then may taper If not needed**
- **Small frequent meals and grazing**
- **May benefit from PPI or anti-acid which can mitigate nausea**
- **Alternative options include behavior modification, acupuncture, CBD oil**
- **If significant nausea where patient is not adequately hydrating or losing weight, hold drug one week; if improvement then consider dose reduction**
- **Recommended guidelines: Discontinue PARP inhibitor maintenance therapy after 2 years (or recurrence)**

Courtesy of Paula J Anastasia, MN, RN, AOCN

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Monitoring Patients on Niraparib

- **Bone Marrow Suppression:**
  - **Test complete blood counts weekly for the first month, monthly next 11 months and periodically thereafter.**

- **Cardiovascular Effects:**
  - **Monitor blood pressure, heart rate monthly for the first year and periodically thereafter.**
  - **Closely monitor patients with cardiovascular disorders.**
  - **Manage hypertension with antihypertensives and dose adjustment.**

Niraparib package insert, revised 3/2017

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Strategies for Managing Nausea/Vomiting

- Prophylactic antiemetics
- Dose interruption
- Dose reduction
- Behavioral modification
  - Avoid sweet or spicy foods
  - Rest but do not lie flat for at least 2 hours after finishing a meal
  - 5 to 6 smaller meals, rather than 3 large meals, throughout the day

Adverse Events: Class Effects and Specific Drug Differences

	Notes	Olaparib	Niraparib	Rucaparib	Talazoparib	Veliparib
Fatigue	50%-70%, mainly Gr1-2	✓	✓	✓	✓	✓
Hematologic AEs						
Anemia	40%-60%	✓	✓	✓	✓	✓--
Thrombocytopenia	Niraparib dose adjustment, based on platelet counts	✓	✓++	✓	✓	✓
Neutropenia	~20%	✓	✓	✓	✓	✓
Gastrointestinal AEs						
Nausea/vomiting	Moderately emetic >30%	✓	✓	✓	✓	✓
Diarrhea	~33%	✓	✓	✓	✓	✓
Laboratory abnormalities						
ALT/AST elevation	5%-10% olaparib, niraparib; 34% rucaparib	✓--	✓--	✓++	✓++	?
Creatinine elevation	10%-12%	✓	✓	✓	NR	NR

NR = not reported

Olaparib PI, rev 5/2020; Niraparib PI, rev 4/2020; Rucaparib PI, rev 5/2020; Talazoparib PI, rev 3/2020;
Madariaga A et al. *Int J Gyn Cancer* 2020 April 9;[Online ahead of print]; Litton JK et al. *NEJM* 2018;379:753-63.

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Adverse Events: Class Effects and Specific Drug Differences

	Notes	Olaparib	Niraparib	Rucaparib	Talazoparib	Veliparib
Respiratory disorders						
Dyspnea +/- cough	10%-20%, usually Gr 1-2	✓	✓	✓	✓	**NR**
Nasopharyngitis	~10%	✓	✓	✓	✓	**NR**
Nervous system and psychiatric disorders						
Insomnia/headache	10%-25%, usually Gr 1-2	✓	✓	✓	✓	✓
Dermatologic toxicity						
Rash, photosensitivity		**<1%**	✓	✓++	**NR**	**NR**
Cardiovascular toxicity						
Hypertension, tachycardia, palpitation		**1%**	✓++	**NR**	**NR**	**NR**
Rare AEs						
MDS/AML	~1% of pts	✓	✓	✓	✓	✓

NR = not reported

Olaparib PI, rev 5/2020; Niraparib PI, rev 4/2020; Rucaparib PI, rev 5/2020; Talazoparib PI, rev 3/2020; Madariaga A et al. *Int J Gyn Cancer* 2020 April 9;[Online ahead of print]; Litton JK et al. *NEJM* 2018;379:753-63.

RTP RESEARCH TO PRACTICE

Dose Adjustments for Adverse Events

Olaparib dose reductions	Dose (tablet)
Starting dose	300 mg BID
First dose reduction	250 mg BID
Second dose reduction	200 mg BID

Niraparib dose reductions	Dose
Starting dose	300 mg daily
First dose reduction	200 mg daily
Second dose reduction	100 mg daily

Rucaparib dose reductions	Dose
Starting dose	600 mg twice daily
First dose reduction	500 mg twice daily
Second dose reduction	400 mg twice daily
Third dose reduction	300 mg twice daily

Courtesy, Shannon N Westin, MD, MPH

FDA Prescribing Information.

Novel Strategies: Summary

		Phase	Regimen	Prior total Therapies	Prior therapies for PROC	Tumor testing/ Prevalence
Taxanes	**GOG-3018 (OVAL)**	**3**	VB-111/placebo D1 (56 day cycle) + weekly paclitaxel vs. weekly Paclitaxel	≤ 5	<3	no
	GOG-3029 (INNOVATE-3)	**3**	TTFields >18 hr/day + weekly paclitaxel vs. weekly Paclitaxel	≤ 5	<3	no
	GOG-3044 (PROFECTA)	**2**	Afuresertib PO QD + Paclitaxel D1,8,15 Q3W vs. weekly Paclitaxel	1-3 prior platinum	0	yes
	GOG-3059 (AXLerate)	**3**	AVB-S6-500 (D1 & 15) + weekly paclitaxel (D 1, 8, 15 on a 28d cycle) vs. weekly Paclitaxel	1-4	not defined (no prior taxanes for recurrence	no
Antibody Drug Conjugates	**GOG-3045 (MIRASOL)**	**3**	Mirvetuximab vs Investigator Choice chemotherapy	1-3	Not defined	yes
	GOG-3048 (UPLIFT)	**1b**	XMT-1536 every 4 weeks	1-3 permis. (Can be granted for 4 prior)	not defined (only 2 prior taxanes allowed)	no
Immunotherapy	**NRG-GY009**	**2/3**	PLD/Atezo (D1&15) vs. PLD/Bev(D1&15)/Atezo (D1&15) vs. PLD/Bev (D1&15)	1-2	Not defined	no
	GOG 3063 (ARTISTRY-7)	3	Nemvaleukin & Pembro vs. Pembro vs. Nemvaleukin vs. IC	Unlimited (prior bev req.)	<6	no
Targeting Replication Stress/PARPi Resistance	**NRG-GY029**	**2**	IC vs olaparib and copanlisib (PARPI resistant)	Unlimited PSOC ≤ 2 PROC, bev req	≤ 2	no
	NRG-GY030	**2/3**	Gemcitabine vs. Gemcitabine + Berzosertib	Unlimited PSOC, 1 PROC, prior bev req	1	no

SORAYA: Efficacy Endpoints Assessed by Investigator and BICR

Endpoints	Investigator-Assessed (N=105)	BICR-Assessed (N=95)
ORR, n (%)	**34 (32.4)**	**30 (31.6)**
95% CI	[23.6, 42.2]	[22.4, 41.9]
Best overall response, n (%)		
Complete response	**5 (4.8)**	**5 (5.3)**
Partial response	29 (27.6)	25 (26.3)
Stable disease	48 (45.7)	53 (55.8)
Progressive disease	20 (19.0)	8 (8.4)
Not evaluable	3 (2.9)	4 (4.2)
mDOR, months	**6.9**	**11.7**
95% CI	[5.6, 8.1]	[5.0, NR]
mPFS, months	**4.3**	**5.5**
95% CI	[3.7, 5.1]	[3.8, 6.9]

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What I Tell My Patients:
New Treatments and Clinical Trial Options

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Held During the 47th Annual ONS Congress

Non-Small Cell Lung Cancer

Thursday, April 28, 2022
6:00 PM – 8:00 PM PT

Faculty

Edward B Garon, MD, MS
Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Anne S Tsao, MD, MBA

Moderator

Neil Love, MD

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