What I Tell My Patients: Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials

Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress

Ovarian Cancer

Friday, April 28, 2023 12:15 PM – 1:45 PM

Faculty

Courtney Arn, CNP David M O'Malley, MD Richard T Penson, MD, MRCP Jaclyn Shaver, MS, APRN, CNP, WHNP Moderator Neil Love, MD



Faculty



Courtney Arn, CNP The James Cancer Hospital and Solove Research Institute The Ohio State University Columbus, Ohio



Jaclyn Shaver, MS, APRN, CNP, WHNP Section of Gynecologic Oncology Stephenson Cancer Center OU Health Oklahoma City, Oklahoma



David M O'Malley, MD Professor Division Director, Gynecologic Oncology The Ohio State University and The James Cancer Center Columbus, Ohio



Richard T Penson, MD, MRCP Associate Professor of Medicine Harvard Medical School Clinical Director, Medical Gynecologic Oncology Massachusetts General Hospital

Boston, Massachusetts



Moderator Neil Love, MD Research To Practice Miami, Florida



Ms Arn — Disclosures

Speakers Bureau	AstraZeneca Pharmaceuticals LP, Eisai Inc, Genmab US Inc, ImmunoGen Inc, Merck, Seagen Inc
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Dr O'Malley — Disclosures

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Dr Penson — Disclosures

Advisory Committee	AstraZeneca Pharmaceuticals LP, Eisai Inc, GSK, ImmunoGen Inc, Merck, Mersana Therapeutics Inc, Novocure Inc, Roche Laboratories Inc, Sutro Biopharma, VBL Therapeutics
Contracted Research	Array BioPharma Inc, a subsidiary of Pfizer Inc, AstraZeneca Pharmaceuticals LP, Eisai Inc, Genentech, a member of the Roche Group, Regeneron Pharmaceuticals Inc, Sanofi, Tesaro, A GSK Company, VBL Therapeutics
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Ms Shaver — Disclosures

No relevant conflicts of interest to disclose



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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 pre- and postmeeting surveys. Survey questions will be 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 NCPD 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.



Clinicians Attending via Zoom

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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 pre- and postmeeting surveys. Survey questions will be discussed throughout the meeting.



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



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



Clinicians, Please Complete the Pre- and Postmeeting Surveys





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, <u>www.ResearchToPractice.com</u>



"What I Tell My Patients" Fifteenth Annual RTP-ONS NCPD Symposium Series ONS Congress, San Antonio, Texas — April 26 to 29, 2023

Wednesday April 26	Cervical and Endometrial Cancer 11:15 AM - 12:45 PM CT (12:15 PM - 1:45 PM ET)	
	Breast Cancer 6:00 PM - 8:00 PM CT (7:00 PM - 9:00 PM ET)	
Thursday April 27	Diffuse Large B-Cell Lymphoma 6:00 AM - 7:30 AM CT (7:00 AM - 8:30 AM ET)	
	Chronic Lymphocytic Leukemia 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)	
	HER2-Targeted Antibody-Drug Conjugates 6:00 PM - 7:30 PM CT (7:00 PM - 8:30 PM ET)	
Friday April 28	Hepatobiliary Cancers 6:00 AM - 7:30 AM CT (7:00 AM - 8:30 AM ET)	
	Ovarian Cancer 12:15 PM - 1:45 PM CT (1:15 PM - 2:45 PM ET)	
	Lung Cancer 6:00 PM - 8:00 PM CT (7:00 PM - 9:00 PM ET)	
Saturday April 29	Acute Myeloid Leukemia, Myelodysplastic Syndromes and Myelofibrosis 6:00 AM - 7:30 AM CT (7:00 AM - 8:30 AM ET)	
	Prostate Cancer 12:15 PM - 1:45 PM CT (1:15 PM - 2:45 PM ET)	



What I Tell My Patients 2023 ONS Congress San Antonio, Texas

Symposia Themes

- New agents and therapies; ongoing trials related to specific clinical scenarios
- Patient education: Preparing to receive new therapies
- The bond that heals
- THANKS! (Great job)



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?



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Richard T Penson, MD, MRCP Associate Professor of Medicine Harvard Medical School Clinical Director, Medical Gynecologic Oncology Massachusetts General Hospital

Boston, Massachusetts



Moderator Neil Love, MD Research To Practice Miami, Florida



Agenda

Module 1: Overview of Ovarian Cancer

Module 2: Initial Management of Advanced Ovarian Cancer

Module 3: Up-Front PARP Inhibitor Maintenance Therapy

Module 4: Side Effects and Toxicities of PARP Inhibitors

Module 5: Antibody-Drug Conjugates

Module 6: Future Directions — Tumor Treating Fields



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46-year-old woman with gBRCA1 mutation-positive ovarian cancer who received carboplatin/paclitaxel followed by maintenance olaparib s/p resection





Dr O'Malley Columbus, Ohio

Clinical Research Background



Dr Penson Boston, Massachusetts

- Overview of ovarian cancer
 - Staging
 - Symptoms
 - Palliation



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

Stages of Epithelial OC



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

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50-year-old woman with gBRCA1 mutation-positive ovarian cancer who received first-line maintenance niraparib





Dr O'Malley Columbus, Ohio

Clinical Research Background



Dr Penson Boston, Massachusetts

- Initial management of advanced ovarian cancer
 - Surgical debulking
 - Genomic subsets



New Advanced Ovarian Cancer



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
- Homologous recombination deficiency (HRD) gene mutations 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





MMR = mismatch repair



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67-year-old morbidly obese woman with sBRCA1 mutationpositive ovarian cancer who received carboplatin/paclitaxel followed by maintenance olaparib s/p resection





Dr O'Malley Columbus, Ohio

Clinical Research Background



Dr Penson Boston, Massachusetts

- Up-front PARP inhibitor maintenance therapy
 - Olaparib
 - Niraparib
 - Olaparib/bevacizumab



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



Overall Survival With Maintenance Original Olaparib at a 7-Year Follow-Up in Patients With Newly Diagnosed Advanced Ovarian Cancer and a BRCA Mutation: The SOL01/GOG 3004 Trial

- Paul DiSilvestro, MD¹; Susana Banerjee, MD, PhD²; Nicoletta Colombo, MD, PhD³; Giovanni Scambia, MD⁴; Byoung-Gie Kim, MD, PhD⁵;
- Ana Oaknin, MD, PhD⁶; Michael Friedlander, MD⁷; Alla Lisyanskaya, MD⁸; Anne Floquet, MD^{9,10}; Alexandra Leary, MD^{10,11};
- ² Gabe S. Sonke, MD, PhD¹²; Charlie Gourley, MD, PhD¹³; Amit Oza, MD¹⁴; Antonio González-Martín, MD, PhD^{15,16}; Carol Aghajanian, MD¹⁷; William Bradley, MD¹⁸; Cara Mathews, MD¹; Joyce Liu, MD¹⁹; John McNamara, MSc²⁰; Elizabeth S. Lowe, MD²¹; Mei-Lin Ah-See, MB BChir, MD²²; and Kathleen N. Moore, MD²³; on behalf of the SOLO1 Investigators

J Clin Oncol 2023;41:609-17



SOLO-1: 7-Year Overall Survival





DiSilvestro P et al. J Clin Oncol 2023;41:609-617

PRIMA/ENGOT-OV26/GOG-3012 Study: Updated Long-term PFS and Safety

Gonzalez-Martin A et al. ESMO 2022;Abstract 530P.



PRIMA: Updated PFS in the Overall Population



mPFS, median progression-free survival; PFS, progression-free survival.



PRIMA: Updated PFS in the HRd Population



HRd, homologous recombination-deficient; mPFS, median progression-free survival; PFS, progression-free survival.




Abstract LBA29

Final overall survival results from the Phase III PAOLA-1/ENGOT-ov25 trial evaluating maintenance olaparib plus bevacizumab in patients with newly diagnosed advanced ovarian cancer

<u>Isabelle Ray-Coquard</u>,¹ Alexandra Leary,² Sandro Pignata,³ Claire Cropet,⁴ Antonio González-Martín,⁵ Gerhard Bogner,⁶ Hiroyuki Yoshida,⁷ Ignace Vergote,⁸ Nicoletta Colombo,⁹ Johanna Mäenpää,¹⁰ Frédéric Selle,¹¹ Barbara Schmalfeldt,¹² Giovanni Scambia,¹³ Eva Maria Guerra Alia,¹⁴ Claudia Lefeuvre-Plesse,¹⁵ Antje Belau,¹⁶ Alain Lortholary,¹⁷ Martina Gropp-Meier,¹⁸ Eric Pujade-Lauraine,¹⁹ Philipp Harter²⁰

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PAOLA-1: Overall Survival (ITT Population)





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Dr O'Malley Columbus, Ohio

Clinical Research Background



Dr Penson Boston, Massachusetts

• Side effects and toxicities of PARP inhibitors



Voluntary Withdrawals of Late-Line Indications of PARP Inhibitors

Niraparib – September 14, 2022

The indication for niraparib has been voluntarily withdrawn for the treatment of advanced ovarian, fallopian tube or primary peritoneal cancer in adult patients who have received 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency status. The decision was made in consultation with the US FDA and based on a totality of information from PARP inhibitors for ovarian cancer in the late-line treatment setting.

Olaparib – August 26, 2022

The indication for olaparib has been voluntarily withdrawn for the treatment of deleterious or suspected deleterious gBRCAm advanced ovarian cancer in adult patients who have received 3 or more prior lines of chemotherapy. The decision was made in consultation with the US FDA after a recent subgroup analysis indicated a potential detrimental effect on overall survival for olaparib compared to the chemotherapy control arm in the subgroup of patients who had received 3 or more prior lines of chemotherapy in the randomized Phase III study SOLO-3.

Rucaparib – June 10, 2022

The indication for rucaparib has been voluntarily withdrawn for the treatment of BRCA-mutated ovarian cancer after 2 or more chemotherapies. The withdrawal is based on discussions with the US FDA following submission of overall survival data from the ARIEL4 trial, which demonstrated an increased risk of death in participants with BRCA-mutated ovarian cancer treated with rucaparib after 2 or more therapies.

https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/57e2a3fa-7b9b-432f-a220-5976a509b534/57e2a3fa-7b9b-432f-a220-5976a509b534_viewable_rendition_v.pdf?medcommid=REF--ALL-004447; https://www.lynparzahcp.com/content/dam/physician-services/us/590-lynparzahcp-branded/hcp-global/pdf/solo3-dhcp-final-signed.pdf; https://www.hayesinc.com/news/market-withdrawal-rubraca-for-third-line-ovarian-cancer-indication/



Biologic Rationale for Combining a PARP Inhibitor with an Immune Checkpoint Inhibitor



Preclinical data demonstrate synergy with PARPi and anti-PD-1 combinations.



Olaparib and Durvalumab Combination Improved Progression-Free Survival in Newly Diagnosed Patients with Advanced Ovarian Cancer without Tumor BRCA Mutations in DUO-O Phase III Trial Press Release: April 5, 2023

"Positive high-level results from a planned interim analysis of the DUO-O Phase III trial showed treatment with a combination of olaparib, durvalumab, chemotherapy and bevacizumab demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) versus chemotherapy plus bevacizumab (control arm) in newly diagnosed patients with advanced high-grade epithelial ovarian cancer without tumor BRCA mutations. Patients were treated with durvalumab in combination with chemotherapy and bevacizumab followed by durvalumab, olaparib, and bevacizumab as maintenance therapy.

In an additional arm, durvalumab, chemotherapy plus bevacizumab showed a numerical improvement in PFS versus the control arm but did not reach statistical significance at this interim analysis. At the time of this planned interim analysis, the overall survival (OS) and other secondary endpoints are immature and will be formally assessed at a subsequent analysis.

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60-year-old woman with ovarian cancer whose disease progressed through several lines of standard therapy receives mirvetuximab soravtansine





60-year-old woman with ovarian cancer who received upifitamab rilsodotin and experienced toxicity but also a good response





Dr O'Malley Columbus, Ohio

Clinical Research Background



Dr Penson Boston, Massachusetts

- Antibody-drug conjugates
 - Mirvetuximab soravtansine
 - Upifitamab rilsodotin



FDA Grants Accelerated Approval for Mirvetuximab Soravtansine for FRα-Positive, Platinum-Resistant Epithelial Ovarian, Fallopian Tube or Peritoneal Cancer Press Release: November 14, 2022

"On November 14, 2022, the Food and Drug Administration granted accelerated approval to mirvetuximab soravtansine-gynx for adult patients with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Mirvetuximab soravtansine-gynx is a folate receptor alpha directed antibody and microtubule inhibitor conjugate. Patients are selected for therapy based on an FDA-approved test.

Today, the FDA also approved the VENTANA FOLR1 (FOLR-2.1) RxDx Assay as a companion diagnostic device to select patients for the above indication.

Efficacy was evaluated in Study 0417 (NCT04296890), a single-arm trial of 106 patients with FRα positive, platinumresistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Patients were permitted to receive up to three prior lines of systemic therapy. All patients were required to have received bevacizumab. The trial enrolled patients whose tumors were positive for FRα expression as determined by the above assay. Patients were excluded if they had corneal disorders, ocular conditions requiring ongoing treatment, Grade >1 peripheral neuropathy, or noninfectious interstitial lung disease."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mirvetuximab-soravtansine-gynx-fra-positive-platinum-resistant



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 antigenmediated 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



Mirvetuximab Soravtansine

Mechanism of action

• Antibody-drug conjugate directed against folate receptor alpha (FRα)

Indication

 For patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens

Recommended dose

 6 mg/kg adjusted ideal body weight administered as an IV infusion q3wk until disease progression or unacceptable toxicity



Upifitamab Rilsodotin (UpRi): First-in-Class ADC Targeting NaPi2b



Antibody: Humanized monoclonal anti-NaPi2b¹

Linker: Polymer scaffold; cleavable ester linker²

Payload: AF-HPA (DolaLock-controlled bystander effect)¹

Drug-to-Antibody Ratio: ~10



Upon ADC internalization into tumor cells and efficient release of payload, AF-HPA payload is metabolized to AF that remains highly potent but loses the ability to cross the cell membrane, locking it in the tumor, controlling the bystander effect, and consequently limiting impact on adjacent healthy cells^{2,3}

NaPi2b Is a Sodium-Dependent Phosphate Transporter Broadly Expressed in Ovarian Cancer With Limited Expression in Healthy Tissues⁴



- NaPi2b expressed by tumor cells in two-thirds of patients with high-grade serous ovarian cancer²
- NaPi2b is a lineage antigen (not an oncogene)¹



NaPi2b IHC assay in development – an optimal diagnostic assay would be robust, predictive, reproducible, easily able to distinguish a wide range of expression using TPS scoring method²



ADC, antibody drug conjugate; AF, Auristatin F; AF-HPA, auristatin F-hydroxypropylamide; IHC, immunohistochemistry; NaPi2b, sodium-dependent phosphate transport protein 2B; TPS, tumor proportion score; UpRi, upifitamab rilsodotin.

1. Bodyak ND et al. *Mol Cancer Ther.* 2021;20(5):885–895. 2. Mersana. Data on File. 2022. 3. Tolcher AW et al. ASCO Annual Meeting 2019; Abstract 3010. 4. Lin K et al. *Clin Cancer Res.* 2015;21(22):5139–5150.



Upifitamab Rilsodotin

Mechanism of action

 Antibody-drug conjugate directed against sodium-dependent transport protein 2b (NaPi2b)

Indication

Investigational

Pivotal clinical data

 Phase II registrational UPLIFT (GOG-3048) cohort evaluating upifitamab rilsodotin for patients with platinum-resistant ovarian cancer, including those with high NaPi2b expression



UpRi Phase Ib Study — Ovarian Cancer Expansion Cohort Study Design

Study Closed for Enrollment

Patient Population: HGSOC^a progressing after standard treatments; measurable disease per RECIST v1.1; ECOG PS 0 or 1

Ovarian Cancer Cohort

- 1–3 prior lines in platinum-resistant
- 4 prior lines regardless of platinum status
- High-grade serous histology
- Archived tumor and fresh biopsy (if medically feasible) for NaPi2b
- Exclusion: Primary platinum-refractory disease

UpRi IV Q4W until disease progression or unacceptable toxicity

36 mg/m² cohort initiated in August 2019

43 mg/m² to a max of ~80 mg cohort initiated in December 2019

Primary Objectives

- Evaluate safety and tolerability of MTD or RP2D
- Assess preliminary efficacy (ORR, DCR)

Secondary Objectives

- Association of tumor NaPi2b expression and objective tumor response using an IHC assay with a broad dynamic range to distinguish tumors with high and low NaPi2b expression
- Further assessment of preliminary anti-neoplastic activity (DoR)

Assessment: Tumor imaging (MRI or CT) at baseline and

every 2nd cycle; response assessed per RECIST v1.1



Best Response by UpRi Dose Group

Similar Tumor Reduction in Both Dose Groups: Two-thirds of Patients Had Reductions in Target Tumor Lesions by RECIST 1.1





UpRi Phase Ib Trial: Treatment-Related Adverse Events (TRAEs) by UpRi Dose Group

Dose Group 36 Had a More Favorable Safety Profile Compared to Dose Group 43



TRAEs ≥20%

- No severe ocular toxicity, neutropenia, or peripheral neuropathy in either dose group
- 4 (14%) patients had treatment-related SAEs in Dose Group 36 vs 18 (27%) in Dose Group 43
- Lower frequencies and lower grade pneumonitis occurred in Dose Group 36 (with no Grade 3+) vs Dose Group 43^a



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Dr O'Malley Columbus, Ohio

Clinical Research Background



Dr Penson Boston, Massachusetts

- Tumor treating fields
 - Mechanism of action
 - Available data and ongoing Phase III evaluation
 - Tolerability



Tumor Treatment Fields





Luo et al. Biomed Pharmacother 2020;127:11013.

Effect of Tumor Treating Fields on Dividing Cancer Cells



Effect of Tumor Treating Fields



MISALIGNED TUBULINS INTERFERE WITH FORMATION OF MITOTIC SPINDLE



TUMOR TREATING FIELDS DISRUPTS CANCER CELL DIVISION



MISALIGNED SEPTINS INTERFERE WITH FORMATION OF THE CONTRACTILE RING





AND TUMOR GROWTH

www.novocure.com/our-therapy/

Tumor Treating Fields

Mechanism of action

 Alternating electric fields that interfere with dividing cells by disrupting mitosis

Indication

Investigational

Pivotal clinical data

 Phase III INNOVATE-3 trial evaluating tumor treating fields in combination with paclitaxel for patients with platinum-resistant ovarian cancer



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





INNOVATE: Tumor Treatment Fields + Paclitaxel

Outcomes (PROC)		TTFields + Paclitaxel (n=31)	
Median OS in months (95% Cl)	NR		
Survival Rates, % (95% CI)	6 months 12 months	90 (72-97) 61 (37-78)	
Median PFS in months (95% C)	8.9 (4.7-NA)	
PFS Rates, % (95% CI)	6 months	57 (37-72)	
Best Response in Patients w/ A Radiologic Data,* n (%)	Available 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



Overall survival (Months)

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

INNOVATE: Select Adverse Events

	TTFields and paclitaxel (N = 31)				
Adverse event	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			



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."





ENGO European Network of INNOVATE-3 (ENGOT-ov50 / GOG-3029) (TTFields, 200 kHz) synaecological Oncological Trial groups

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

use

unknown

BRCA Status

- one prior line
- two prior lines



FOUNDATION

TTFields Pipeline

as of October 2022



Courtesy of Chirag Patel, MD

Future Directions

- Validating molecular and transcriptomic mechanisms in tissue samples from TTFields clinical trials
- Computational modeling
- Examining indirect effects of TTFields on cancer proliferation
 - permeabilizing blood vessels and cancer cell membranes
 - altering tumor metabolism
 - application of multiple TTFields frequencies for a single cancer
 - expanding application to spine and other tumors



A woman with a long history of ovarian cancer well-controlled on bevacizumab develops dementia and passes away



APPENDIX



Ovarian cancer 1L PARPi maintenance trials: design and populations

Trial	PARP inhibitor	Duration	BRCA status	R0 at PDS allowed	% PDS	CR/PR to platinum
SOLO1 ^{1,2}	Olaparib	2 years	BRCAmt only	Yes	62.9	Yes
PRIMA ³	Niraparib	3 years	All comers	No if Stage III	33	Yes
PRIME ⁴	Niraparib	3 years	All comers	Yes	53.1	Yes
PAOLA1 ⁵	Olaparib (w/bevacizumab)	2 years	All comers	Yes	50.7	Yes
	Veliparib (w/chemo)	36 total cycles	All comers	Yes	67.5	No (tx starts with chemo)
ATHENA-MONO7	Rucaparib	2 years	All comers	Yes	48.9	Yes

¹Moore et al., *N Engl J Med* 2018; ²Banerjee et al., 2020 ESMO Congress; ³Gonzalez-Martin et al., *N Engl J Med* 2019; ⁴Li et al., 2022 SGO Annual Meeting; ⁵Ray-Coquard et al., *N Engl J Med* 2019; ⁶Coleman et al., *N Engl J Med* 2019; ⁷Monk et al., 2022 ASCO Annual Meeting



Liu J. ASCO 2022; Highlights of the Day: Gynecologic Cancers.

SOLO-1: Study Design

- Newly diagnosed, FIGO stage III–IV, high-grade serous or endometrioid ovarian, primary peritoneal or fallopian tube cancer
- BRCAm
- ECOG performance status 0–1
- Cytoreductive surgery*
- In clinical complete[†] or partial response after PBC



For up to 2 years or until disease progression[‡]



SOLO-1: 7-Year Safety Follow-Up



Patients with TEAEs (%)



*All grades, frequency ≥20% in either treatment arm; 'Grouped-term TEAEs. All-grade thrombocytopenia (grouped term) occurred in 11.2% of patients in the olaparib group and 3.8% of patients in the placebo group, and grade ≥3 thrombocytopenia (grouped term) occurred in 0.8% and 1.5%, respectively Disilvestro P *et al. J Clin Oncol* 2023;41:609–17



DiSilvestro P et al. J Clin Oncol 2023;41:609-17; Matthews C et al. SGO 2023;Abstract 215.
PRIMA Study Design





PRIMA Updated Safety: TEAEs Reported in ≥20% of Patients



Overall Population (N=728)^a



Gonzalez-Martin A et al. ESMO 2022; Abstract 530P.





Courtesy of Joyce Liu, MD, MPH

PAOLA-1: Phase III Trial of Olaparib with Bevacizumab for Newly Diagnosed Stage III-IV OC





aanaraaa

PAOLA-1: Overall Survival Subgroup Analysis by BRCA Mutation and HRD Status



*By central labs; †Unstable median; <50% data maturity; ‡By Myriad myChoice HRD Plus. NR, not reported.



PAOLA-1: Updated Adverse Events of Special Interest

	Primary PFS analysis (DCO: 22 March 2019)		Final PFS2 analysis (DCO: 22 March 2020)		Final OS analysis (DCO: 22 March 2022)	
	Olaparib + bevacizumab (N=535)	Placebo + bevacizumab (N=267)	Olaparib + bevacizumab (N=535)	Placebo + bevacizumab (N=267)	Olaparib + bevacizumab (N=535)	Placebo + bevacizumab (N=267)
MDS/AML/AA, n (%)	6 (1.1)	1 (0.4)	7 (1.3)	4 (1.5)	9 (1.7)	6 (2.2)
New primary malignancies, n (%)*	7 (1.3)	3 (1.1)	13 (2.4)	5 (1.9)	22 (4.1)	8 (3.0)
Pneumonitis/ILD/bronchiolitis, n (%) †	6 (1.1)	0 (0.0)	6 (1.1)	0 (0.0)	7 (1.3)	2 (0.7)

• All patients had discontinued treatment at PFS2 DCO

AA, aplastic anemia; AML, acute myeloid leukemia; ILD, interstitial lung disease; MDS, myelodysplastic syndrome



GCIG

Ray-Coquard I et al. ESMO 2022;Abstract LBA29.

SGO 2022;Abstract 40

Phase 2 OVARIO Study of Niraparib + Bevacizumab Therapy in Advanced Ovarian Cancer Following Frontline Platinum-Based Chemotherapy with Bevacizumab

Melissa M. Hardesty,¹ Thomas Krivak,² Gail S. Wright,³ Erika Hamilton,⁴ Evelyn L. Fleming,⁵ Jimmy Belotte,⁶ Erika Keeton,⁶ Ping Wang,⁶ Aine Clements,⁷ Heidi J. Gray,⁸ Gottfried E. Konecny,⁹ Richard G. Moore,¹⁰ Debra L. Richardson¹¹



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OVARIO phase II trial of combination niraparib plus bevacizumab maintenance therapy in advanced ovarian cancer following first-line platinum-based chemotherapy with bevacizumab

Melissa M. Hardesty ^{a,*}, Thomas C. Krivak ^b, Gail S. Wright ^c, Erika Hamilton ^d, Evelyn L. Fleming ^e, Jimmy Belotte ^f, Erika K. Keeton ^g, Ping Wang ^f, Divya Gupta ^f, Aine Clements ^h, Heidi J. Gray ⁱ, Gottfried E. Konecny ^j, Richard G. Moore ^k, Debra L. Richardson ¹



OVARIO Study Design

		Patients with new ovarian, fallopia f	ly diagnosed high-grade serous or endometrioid stage IIIB to IV epithelial n tube, or peritoneal cancer who achieved a CR, PR, or NED result after ront-line platinum-based chemotherapy + bevacizumab	
All patients underwent tissue te HRd at enrollment	esting for			
		Nira	aparib (200 or 300 mg QD) + bevacizumab (15 mg/kg Q3W)	
Starting niraparib dose, n (%)	N=105			
200 mg (<77 kg and/or platelet count <150,000/μL)	82 (78)	Endpoint assessment		
200 mg (all others)	22 (22)	Primary endpoint	PFS rate at 18 months (PFS18)	
Soo mg (an others)	25 (22)	Secondary endpoints	 PFS Overall survival RECIST or CA-125 PFS Time to first subsequent therapy Time to second subsequent therapy Safety and tolerability Patient-reported outcome 	
		Exploratory endpoints	PFS rate at 6 months (PFS6) and 12 months (PFS12)	
		Statistical analysis plan	 Efficacy: PFS18 and PFS24 will be estimated by frequency analysis, with corresponding 95% exact CI will be reported The time to event endpoints (PFS, TFST, TSST) will be analyzed using Kaplan-Meier methodology Progression will be assessed by RECIST v1.1 per investigator 	



OVARIO: Investigator-Assessed PFS by HRD Status





Hardesty MM et al. *Gynecol Oncol* 2022;166(2):219-29. Hardesty MM et al. SGO 2022;Abstract 40.

OVARIO: Treatment-Related Adverse Events (TRAEs)

	N=105			TRAEs in ≥20% of patients (N=105)		
Parameter, n (%)	Related	Related to nira	Related to bev	Related to niraparib or bevacizumab		
	to nira or			Preferred term, n (%)	Any Grade	Grade ≥3
	Dev			Thrombocytopenia ^a	74 (70)	41 (39)
Any TRAE	105 (100)	104 (99)	96 (91)	Fatigue	60 (57)	9 (9)
Any Grade ≥3 TRAE	84 <mark>(</mark> 80)	<mark>81 (</mark> 77)	54 (51)	Anemia ^b	55 (52)	36 (34)
Any serious TRAE	21 (20)	19 (18)	7 (7)	Nausea	55 (52)	1 (1)
TRAE leading to	42 (40)	32 (30)	(30) 23 (22)	Hypertension ^c	53 (50)	28 (27)
treatment discontinuation	42 (40)	52 (50)		Proteinuria	41 (39)	5 (5)
TRAE leading to dose reduction	78 (74)	77 (73)	27 (26)	Headache	32 (30)	6 (6)
TRAF leading to		12703000023		Neutropenia ^d	28 (27)	13 (12)
treatment interruption	93 (88)	90 (86)	58 (55)	Leukopenia ^e	24 (23)	0



Research

JAMA Oncol 2019;5(8):1141-9.

JAMA Oncology | Original Investigation

Single-Arm Phases 1 and 2 Trial of Niraparib in Combination With Pembrolizumab in Patients With Recurrent Platinum-Resistant Ovarian Carcinoma

Panagiotis A. Konstantinopoulos, MD, PhD; Steven Waggoner, MD; Gregory A. Vidal, MD; Monica Mita, MD; John W. Moroney, MD; Robert Holloway, MD; Linda Van Le, MD; Jasgit C. Sachdev, MD; Eloise Chapman-Davis, MD; Gerardo Colon-Otero, MD; Richard T. Penson, MD; Ursula A. Matulonis, MD; Young Bae Kim, MD; Kathleen N. Moore, MD; Elizabeth M. Swisher, MD; Anniina Färkkilä, MD; Alan D'Andrea, MD; Erica Stringer-Reasor, MD; Jing Wang, PhD; Nathan Buerstatte, MPH; Sujata Arora, MS; Julie R. Graham, PhD; Dmitri Bobilev, MD; Bruce J. Dezube, MD; Pamela Munster, MD



TOPACIO/KEYNOTE-162: Antitumor Activity of Niraparib in Combination with Pembrolizumab





DCR = disease control rate

Konstantinopoulos PA et al. JAMA Oncol 2019;5:1141-9.



Phase II study of olaparib plus durvalumab with or without bevacizumab (MEDIOLA): final analysis of overall survival in patients with non-germline BRCAmutated platinum-sensitive relapsed ovarian cancer

Susana Banerjee,¹ Martina Imbimbo,² Patricia Roxburgh,³ Jae-Weon Kim,⁴ Min Hwan Kim,⁵ Ruth Plummer,⁶ Salomon M. Stemmer,⁷ Benoit You,⁸ Michelle Ferguson,⁹ Richard T. Penson,¹⁰ David M. O'Malley,¹¹ Kassondra Meyer,¹² Haiyan Gao,¹³ Helen K. Angell,¹⁴ Ana T. Nunes,¹⁵ Susan Domchek,¹⁶ Yvette Drew^{6*}



MEDIOLA: Non-gBRCAm Cohorts Study Design





Banerjee S et al. ESMO 2022; Abstract 529MO.

MEDIOLA Final Analysis: Median Overall Survival and 56-Week Disease Control Rate





Banerjee S et al. ESMO 2022; Abstract 529MO.

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, MD¹; Domenica Lorusso, MD, PhD²; Ana Oaknin, MD, PhD³; Sandro Pignata, MD, PhD⁴;

ort

- Andrew Dean, MBChB, MRCP, FRACP⁵; Hannelore Denys, MD, PhD⁶; Nicoletta Colombo, MD, PhD^{7,8}; Toon Van Gorp, MD, PhD⁹;
- Jason A. Konner, MD¹⁰; Margarita Romeo Marin, MD, PhD¹¹; Philipp Harter, MD, PhD¹²; Conleth G. Murphy, MD¹³; Jiuzhou Wang, PhD¹⁴; Elizabeth Noble, BS¹⁴; Brooke Esteves, BSN¹⁴; Michael Method, MD, MPH, MBA¹⁴; and Robert L. Coleman, MD¹⁵

J Clin Oncol 2023;[Online ahead of print]



SORAYA: ORR and Subgroup Analysis in the Efficacy-Evaluable Population

ORR	Investigator-Assessed	BICR-Assessed
No. of efficacy evaluable patients	n = 105	n = 96
ORR, No. (%) [95% CI] ^a	34 (32.4) [23.6 to 42.2]	29 (30.2) [21.3 to 40.4]
Best overall response, No. (%)		
CR	5 (4.8)	6 (6.3)
PR	29 (27.6)	23 (24.0)
SD	48 (45.7)	54 (56.3)
PD	20 (19.0)	9 (9.4)
NE	3 (2.9)	4 (4.2)
Tumor reduction, No. (%)	75 (71.4)	ND
Disease control rate, No. (%)	54 (51.4)	ND
CA-125 response ^b	n = 86	
No. (%) [95% CI]	40 (46.5) [35.7 to 57.6]	ND
ORR subgroup analysis		
Prior lines of therapy, No. (%) [95% CI] ^a		
1 or 2	n = 51	n = 46
	18 (35.3) [22.4 to 49.9]	15 (32.6) [19.5 to 48.0]
3	n = 53	n = 49
	16 (30.2) [18.3 to 44.3]	14 (28.6) [16.6 to 43.3]
Prior exposure to PARPi, No. (%) [95% CI] $^{\rm a,c}$		
Yes	n = 50	n = 47
	19 (38.0) [24.7 to 52.8]	14 (29.8) [17.3 to 44.9]
No	n = 51	n = 46
	14 (27.5) [15.9 to 41.7]	15 (32.6) [19.5 to 48.0]



Matulonis UA et al. J Clin Oncol 2023;[Online ahead of print].

Mirvetuximab Soravtansine (MIRV) in Patients with Platinum-Resistant Ovarian Cancer with High Folate Receptor Alpha (FRα) Expression: Evaluation of Sequence of Therapy on Anti-Tumor Activity in the SORAYA Study

Robert L Coleman,¹ Ana Oaknin,² Sandro Pignata,³ Hannelore Denys,⁴ Nicoletta Colombo,⁵ Toon Van Gorp,⁶ Jason Konner,⁷ Margarita Romeo Marin,⁸ Philipp Harter,⁹ Conleth Murphy,¹⁰ Brooke Esteves,¹¹ Michael Method,¹¹ Domenica Lorusso,¹² Ursula A. Matulonis¹³

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S^{*}RAYA

SGO ANNUAL MEETING ON WOMEN'S CANCER TAM PA, FL - 2023 PATIMIS- PROFESSION - PROFESSION

SGO 2023;Abstract 139



SORAYA: Final Overall Survival by Investigator in Efficacy-Evaluable Population





Coleman RL et al. SGO 2023;Abstract 139.

Updated Results From the Phase 1b Expansion Study of Upifitamab Rilsodotin (UpRi; XMT-1536), a NaPi2bdirected Dolaflexin Antibody Drug Conjugate (ADC) in Ovarian Cancer

<u>Richardson, Debra L</u>¹; Hamilton, Erika P²; Barve, Minal³; Anderson, Charles K⁴; Taylor, Sara K⁵; Lakhani, Nehal⁶; Buscema, Joseph⁷; Tolcher, Anthony W⁸; Zarwan, Corrine⁹; Werner, Theresa L¹⁰; Hays, John L¹¹; Richards, Paul¹²; Arend, Rebecca¹³; Edenfield, Jeffery¹⁴; Putiri, Emily¹⁵; Bernardo, Patricia¹⁵; Burger, Robert A¹⁵; Matulonis, Ursula A¹⁶

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Salt Lake City, UT; ¹¹Arthur James Cancer Hospital, Ohio State University, Columbus, OH; ¹²US Oncology, Oncology and Hematology Assoc. of Southwest VA, Salem, VA; ¹³University of Alabama at Birmingham, Birmingham, AL; ¹⁴Prisma Health Cancer Institute, Greenville, SC; ¹⁵Mersana Therapeutics, Inc, Cambridge, MA; ¹⁶Dana-Farber Cancer Institute, Boston, MA



SGO 2022; Abstract 76.





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Tumor Treating Fields in combination with paclitaxel in recurrent ovarian carcinoma: Results of the INNOVATE pilot study

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INNOVATE: Phase II Trial Design



Start date: September 2014 Primary completion date: December 2016 Study sites: 5 (Europe)

Primary endpoints:

- AE severity and frequency, No. prematurely DCing TTFields due to skin toxicity **Secondary endpoints:**
- PFS, OS, OS_{1yr}, ORR and DOR, CA-125 response and DOR, TTFields usage



What I Tell My Patients: Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials

Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress

Ovarian Cancer

Friday, April 28, 2023 12:15 PM – 1:45 PM

Faculty

Courtney Arn, CNP David M O'Malley, MD Richard T Penson, MD, MRCP Jaclyn Shaver, MS, APRN, CNP, WHNP Moderator Neil Love, MD



What I Tell My Patients: **Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials** Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress **Lung Cancer Friday, April 28, 2023** 6:00 PM - 8:00 PM Faculty **Stephen V Liu, MD** Tara Plues, APRN, MSN Jillian Thompson, MSN, ANP-BC, AOCNP Anne S Tsao, MD, MBA **Moderator** Neil Love, MD

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