13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Urothelial Bladder Carcinoma

Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

Medical Oncologists

Elisabeth I Heath, MD
Daniel P Petrylak, MD

Oncology Nurse Practitioners

Monica Averia, MSN, AOCNP, NP-C
Kathy D Burns, RN, MSN, AGACNP-BC, OCN

Moderator

Neil Love, MD

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Translational Sciences
Chair, Genitourinary Oncology
Multidisciplinary Team
Professor of Oncology and Medicine
Hartmann Endowed Chair for Prostate Cancer Research
Director, Prostate Cancer Research
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Detroit, Michigan

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Yale School of Medicine
New Haven, Connecticut

Oncology Nurse Practitioners

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USC Norris Cancer Center
Los Angeles, California

Kathy D Burns, RN, MSN, AGACNP-BC, OCN
GU Medical Oncology
City of Hope Comprehensive Cancer Center
Duarte, California

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Commercial Support

This activity is supported by an educational grant from Astellas and Seagen Inc.

Dr Love — Disclosures

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Dr Heath — Disclosures

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Consulting Agreement	Astellas
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Speakers Bureau	Sanofi Genzyme

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Dr Petrylak — Disclosures

Consulting Agreements	Advanced Accelerator Applications, Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bicycle Therapeutics, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Clovis Oncology, Exelixis Inc, Incyte Corporation, Janssen Biotech Inc, Lilly, Mirati Therapeutics, Monopteros Therapeutics, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Roche Laboratories Inc, Seagen Inc, UroGen Pharma
Contracted Research	Advanced Accelerator Applications, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, BioXcel Therapeutics Inc, Bristol-Myers Squibb Company, Clovis Oncology, Eisai Inc, Endocyte Inc, Genentech, a member of the Roche Group, Innocrin Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Mirati Therapeutics, Novartis, Pfizer Inc, Progenics Pharmaceuticals Inc, Replimune, Roche Laboratories Inc, Sanofi Genzyme, Seagen Inc
Ownership Interest	Bellicum Pharmaceuticals Inc (sold 7/2020), Tyme Inc (sold 10/2019)

Ms Averia — Disclosures

No relevant conflicts of interest to disclose.

Ms Burns — Disclosures

Advisory Committee	EMD Serono Inc
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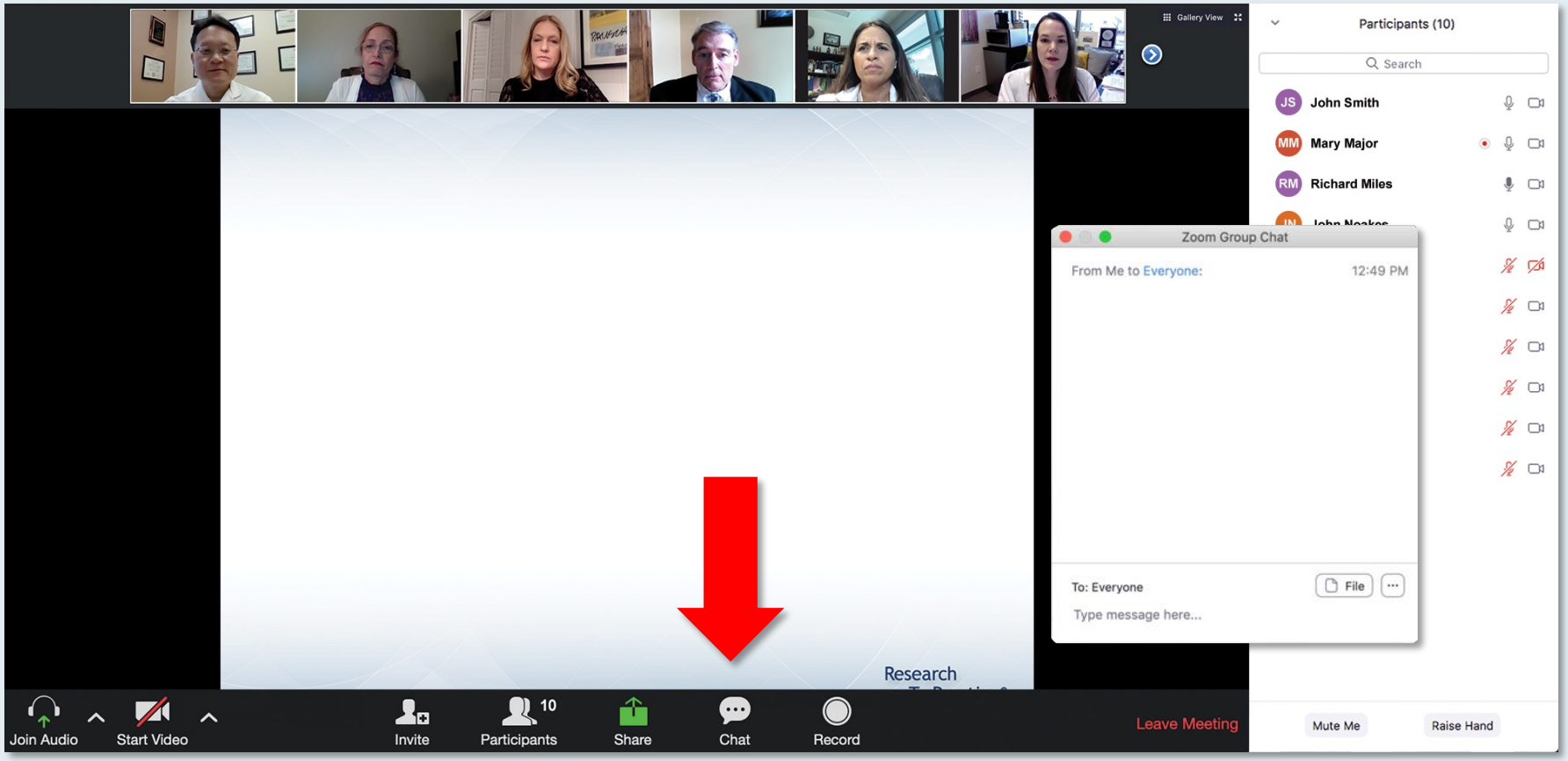
We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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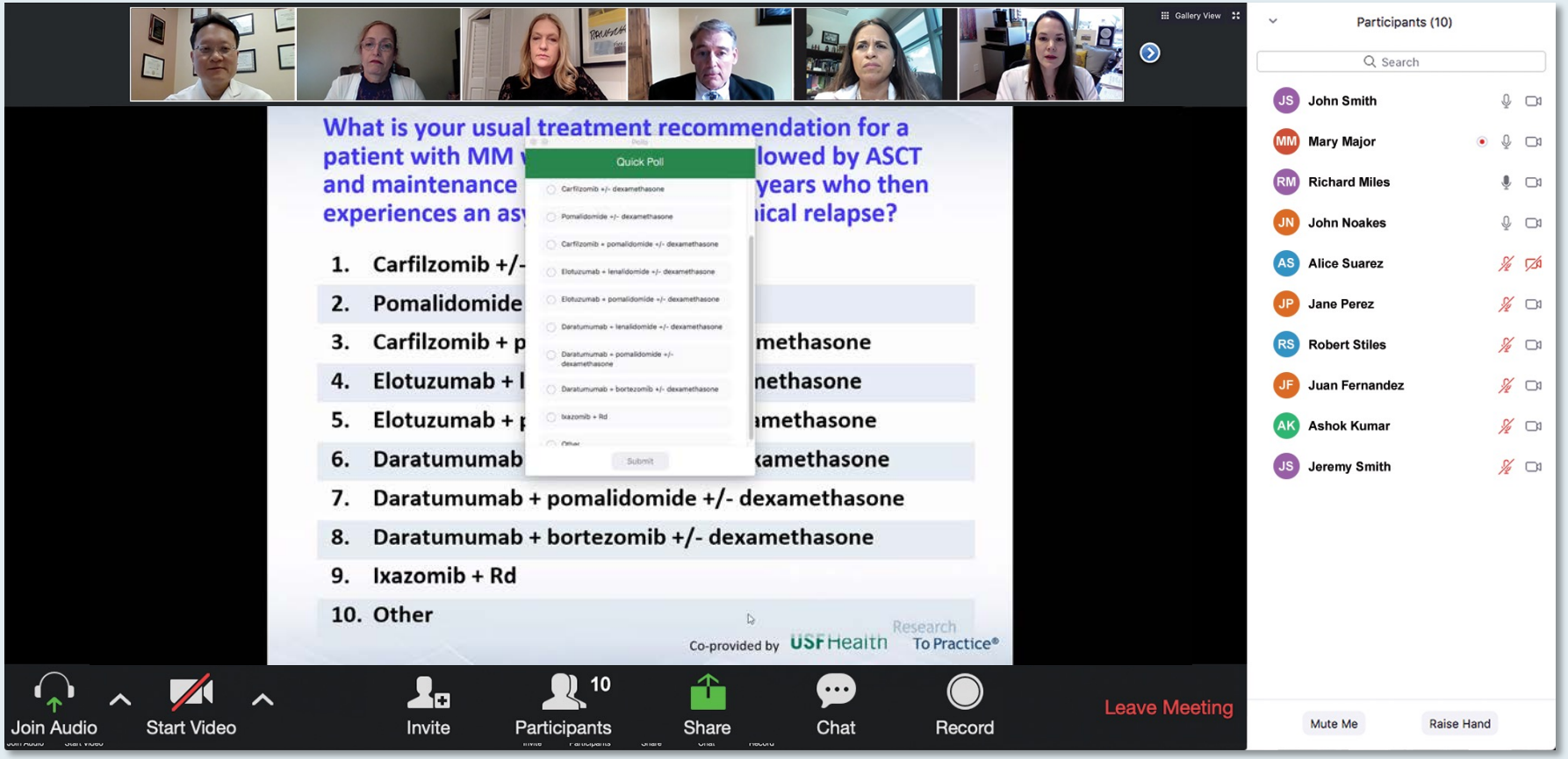

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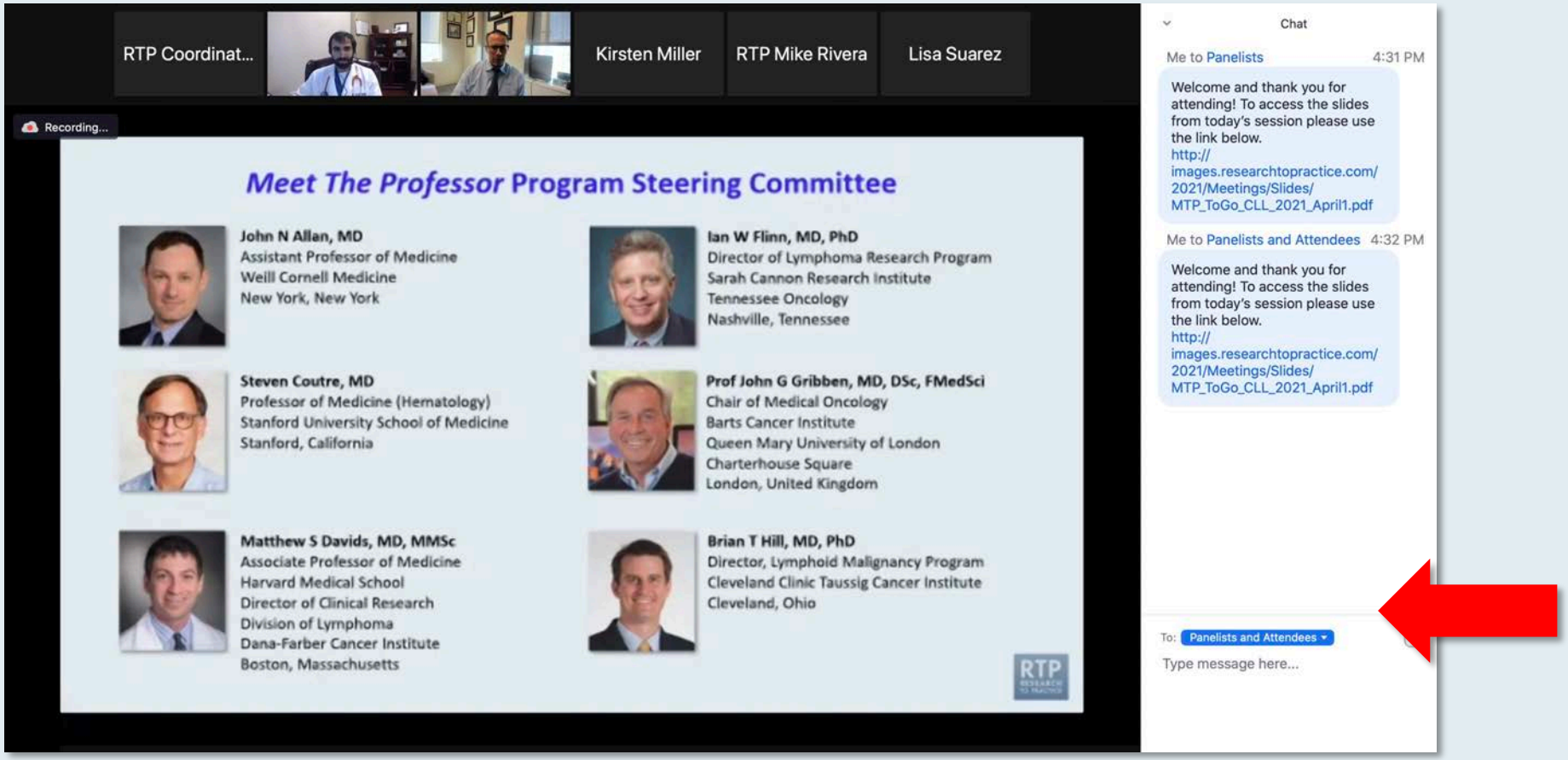

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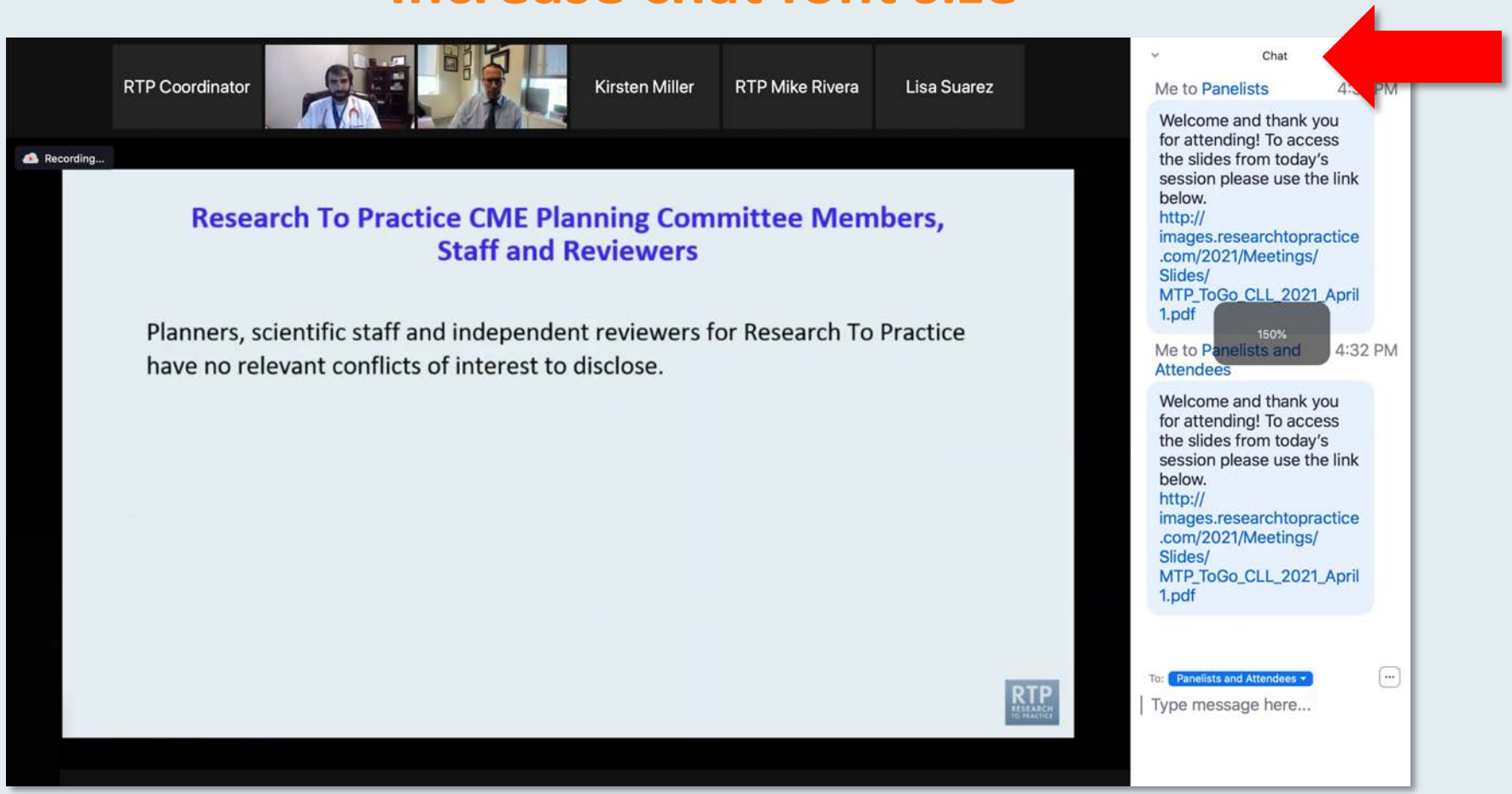

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WITH DR NEIL LOVE

Newly Approved Agents in the Management of Urothelial Bladder Carcinoma

DR MATTHEW GALSKY
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

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13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series Held During the 46th Annual ONS Congress

Breast Cancer
Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET

Non-Small Cell Lung Cancer
Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Acute Myeloid Leukemia
Wednesday, April 21, 2021
12:00 PM – 1:00 PM ET

Colorectal and Gastroesophageal Cancers
Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

Prostate Cancer
Thursday, April 22, 2021
8:30 AM – 10:00 AM ET

Hodgkin and Non-Hodgkin Lymphomas
Thursday, April 22, 2021
5:00 PM – 6:30 PM ET

Multiple Myeloma
Tuesday, April 27, 2021
8:30 AM – 10:00 AM ET

Gynecologic Cancers
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Urothelial Bladder Carcinoma
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Chronic Lymphocytic Lymphoma
Thursday, April 29, 2021
8:30 AM – 10:00 AM ET

Chimeric Antigen Receptor T-Cell Therapy
Thursday, April 29, 2021
5:00 PM – 6:30 PM ET

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Ask the Expert: Clinical Investigators Provide Perspectives on the Management of Renal Cell Carcinoma

In Partnership with Project Echo® and Florida Cancer Specialists

Tuesday, May 4, 2021
5:00 PM – 6:00 PM ET

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

A Daylong Clinical Summit Hosted in Partnership with Medical Oncology Association of Southern California (MOASC)

Saturday, May 15, 2021
10:30 AM – 6:30 PM ET

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Saturday, May 15, 2021

10:30 AM — Breast Cancer
Ruth O'Regan, Tiffany A Traina

11:30 AM — Multiple Myeloma
Kenneth Anderson, Noopur Raje

12:50 PM — Chronic Lymphocytic Leukemia and Lymphomas
Craig Moskowitz, Jeff Sharman

1:50 PM — Genitourinary Cancers
Joaquim Bellmunt, Sumanta Kumar Pal

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Saturday, May 15, 2021

3:15 PM — Gastrointestinal Cancers
Wells A Messersmith, Eileen M O'Reilly

4:15 PM — Acute Myeloid Leukemia and Myelodysplastic Syndromes
Harry Paul Erba, Rami Komrokji

5:35 PM — Lung Cancer
D Ross Camidge, Benjamin Levy

Up for Debate: Oncology Investigators Provide Their Take on Current Controversies in Patient Care

A Daylong Multitumor Educational Webinar
in Partnership with Florida Cancer Specialists

Saturday, May 22, 2021
10:15 AM – 4:15 PM ET

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Saturday, May 22, 2021

10:15 AM — Lung Cancer
John V Heymach, Stephen V Liu

11:30 AM — Genitourinary Cancers
Maha Hussain, Elizabeth R Plimack

12:45 PM — Chronic Lymphocytic Leukemia and Lymphomas
Jonathan W Friedberg, Laurie H Sehn

2:00 PM — Multiple Myeloma
Irene M Ghobrial, Sagar Lonial

3:15 PM — Breast Cancer
Virginia Kaklamani, Nancy U Lin

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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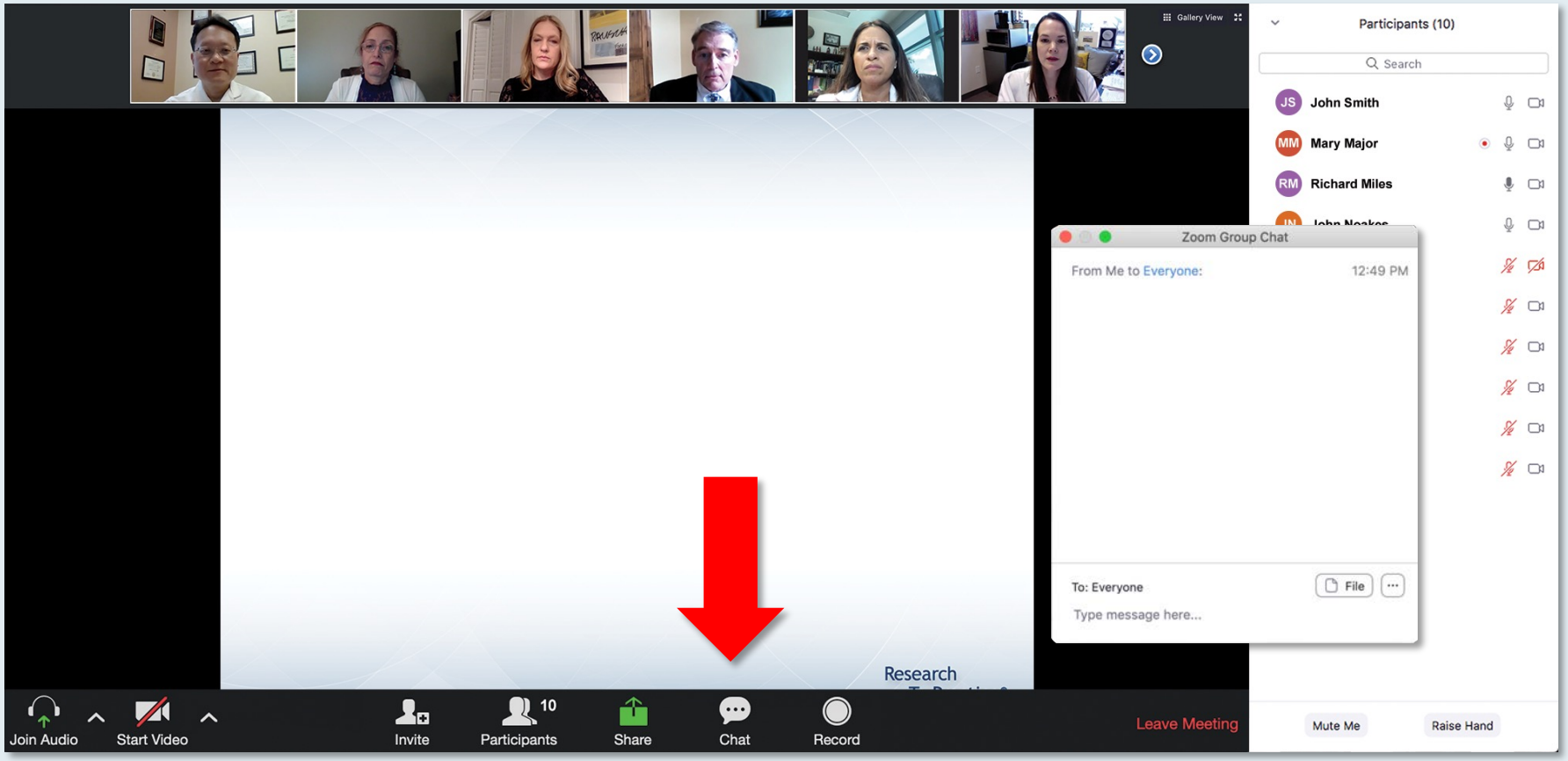

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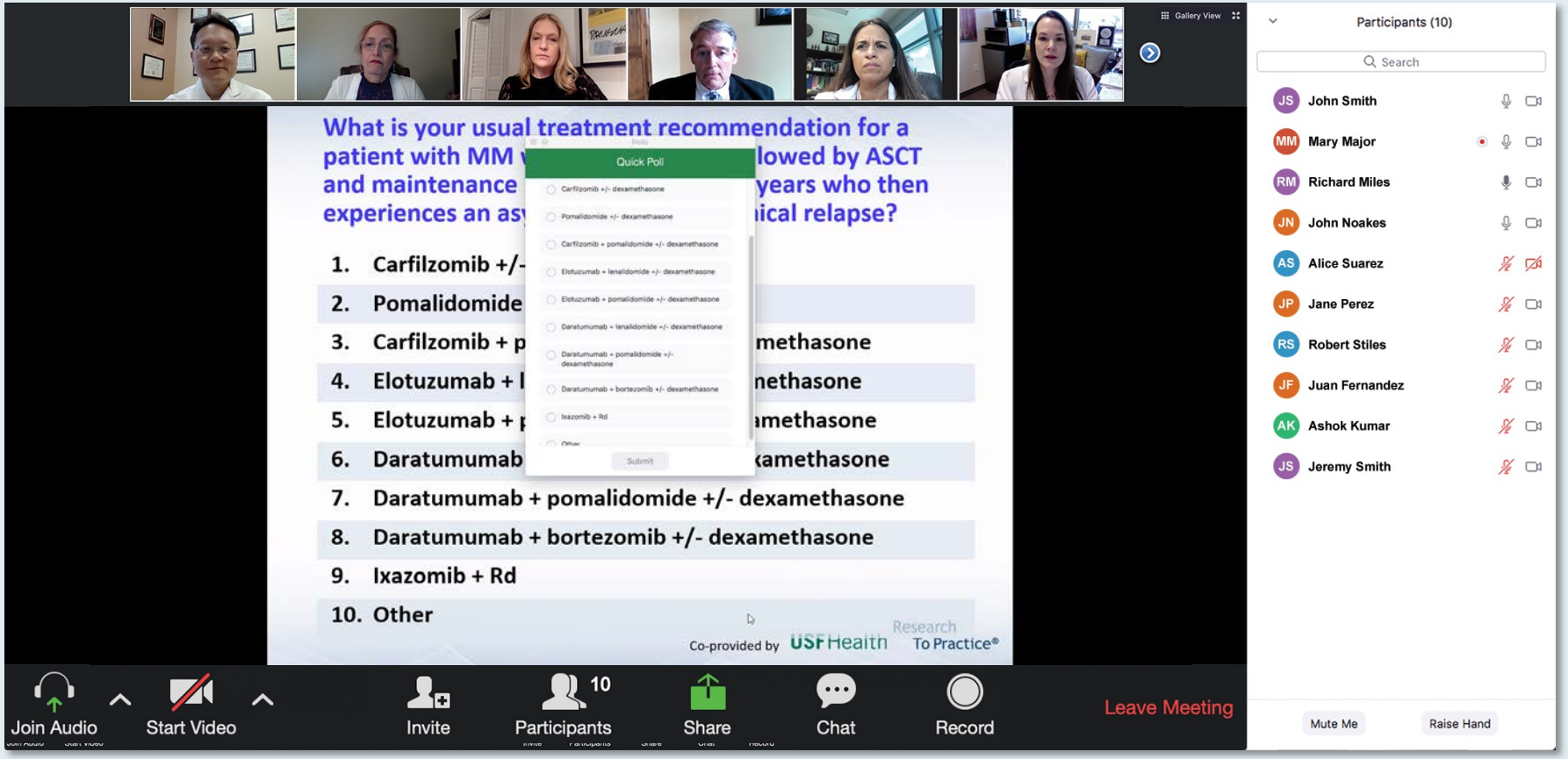

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Oncology Nurse Practitioners

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Oncology Nurse Practitioners

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Ronald Stein, JD, MSN, NP-C, AOCNP
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Victoria Sherry, DNP, CRNP, AOCNP
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Perelman Center for Advanced Medicine
University of Pennsylvania Medical Center
Faculty, University of Pennsylvania School of Nursing
Philadelphia, Pennsylvania

Elizabeth Zerante, MS, AGACNP-BC
APN Inpatient Hematopoietic Cellular Therapy Service
University of Chicago Medicine
Chicago, Illinois

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Oncology Grand Rounds Nursing Webinar Series

Monday	Tuesday	Wednesday	Thursday	Friday
19	20 Breast Ca 8:30 AM Lung Ca 5:00 PM	21 AML 12:00 PM CRC and GE Ca 4:45 PM	22 Prostate Ca 8:30 AM Lymphomas 5:00 PM	23
26	27 Multiple Myeloma 8:30 AM Gynecologic Ca 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM CAR-T 5:00 PM	30

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WITH DR NEIL LOVE

A Personal Experience with COVID-19

DR NOOPUR RAJE

MASSACHUSETTS GENERAL HOSPITAL

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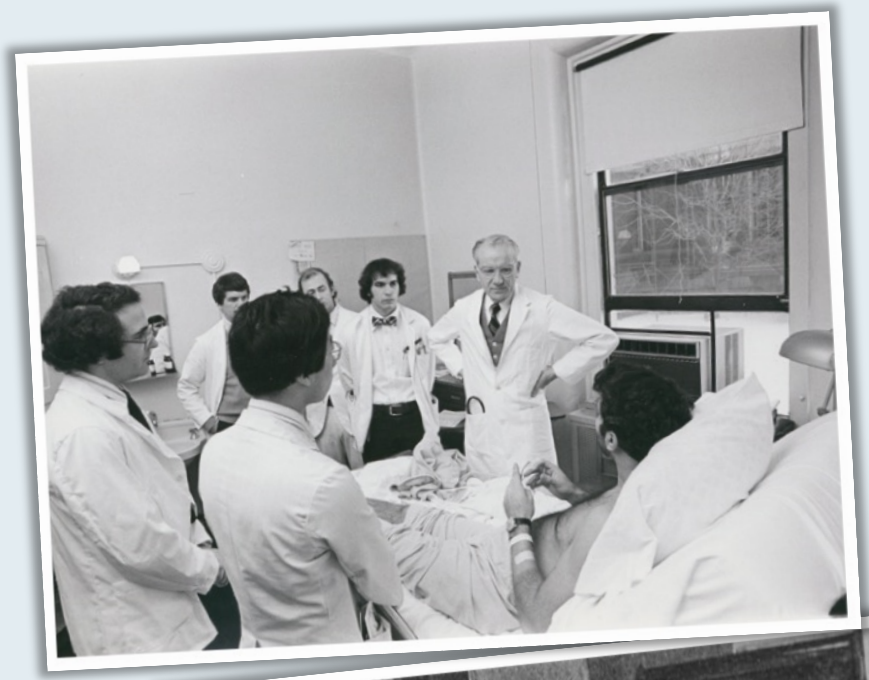

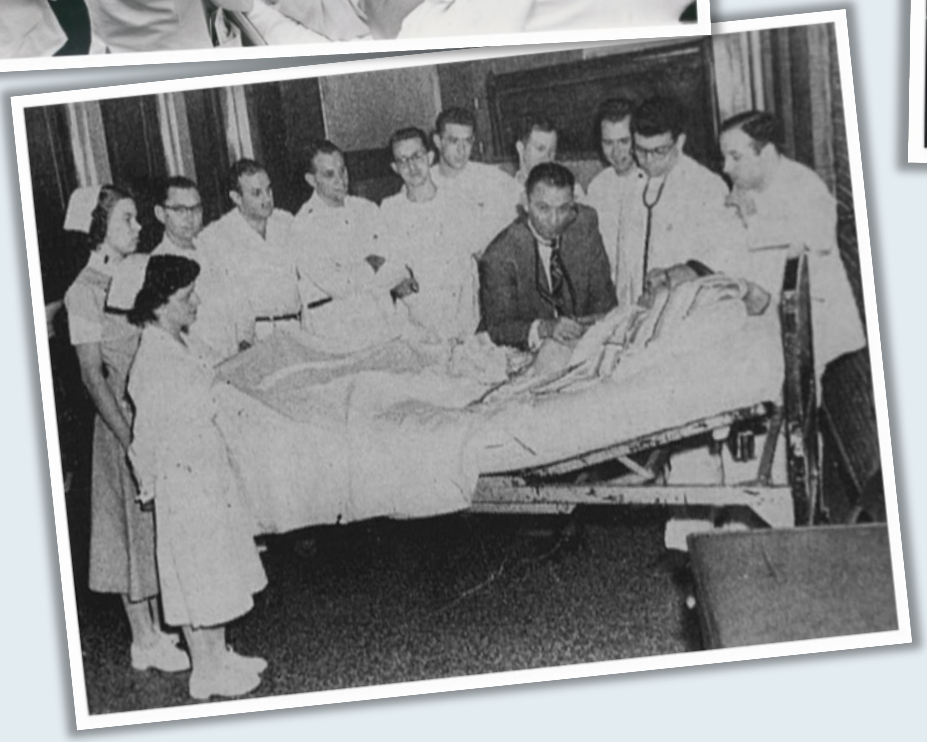


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13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

- Key patient-education issues
- Biopsychosocial considerations:
  - Family/loved ones
  - The bond that heals

Clinical Investigators

Oncology Strategy

- New agents and regimens
- Predictive biomarkers
- Ongoing research and implications

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13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Urothelial Bladder Carcinoma

Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

Medical Oncologists

Elisabeth I Heath, MD
Daniel P Petrylak, MD

Oncology Nurse Practitioners

Monica Averia, MSN, AOCNP, NP-C
Kathy D Burns, RN, MSN, AGACNP-BC, OCN

Moderator

Neil Love, MD

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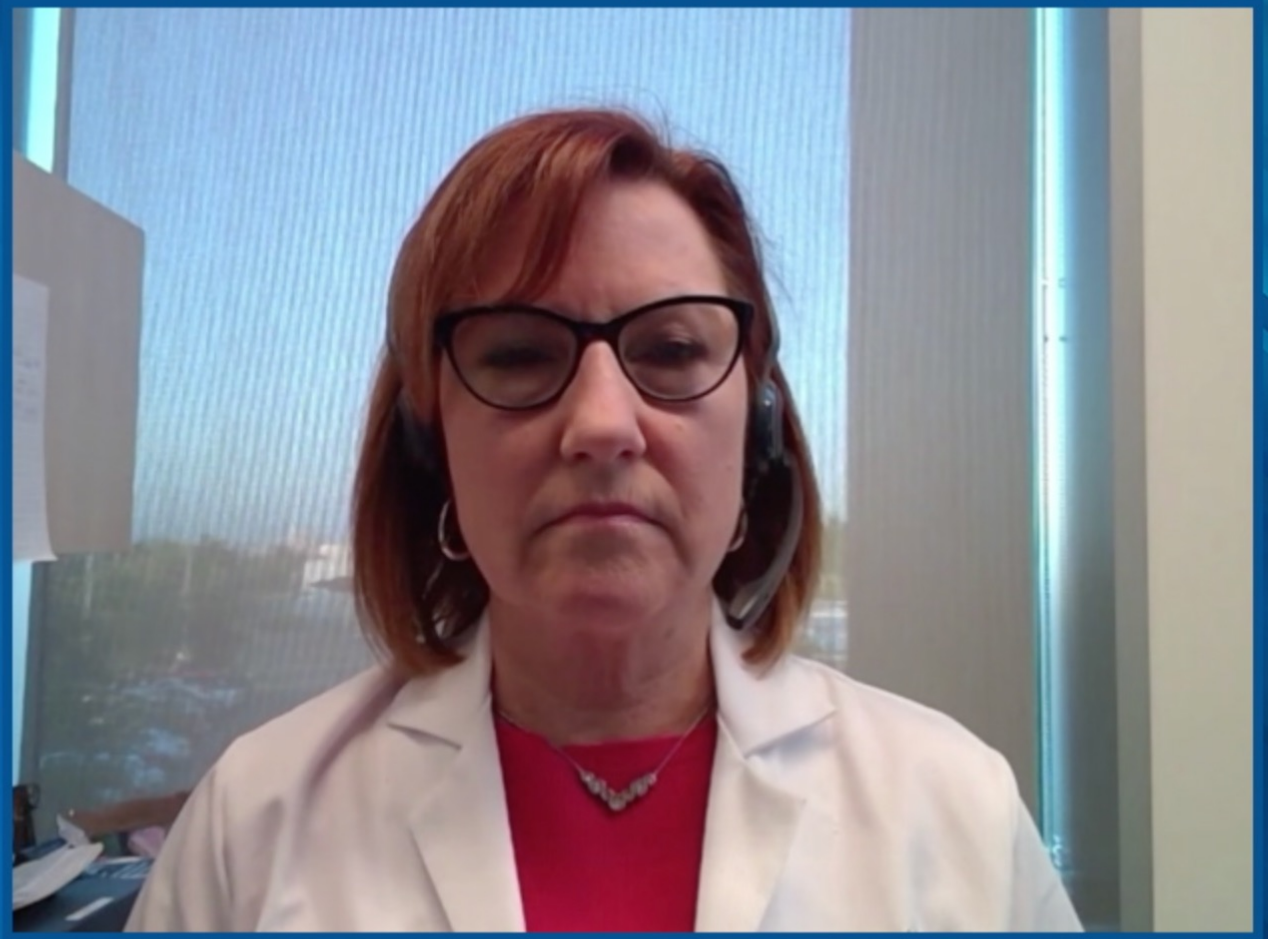
Monica Averia, MSN, AOCNP, NP-C



Kathleen Burns, NP

Agenda

Ms Averia: A 68-year-old woman with newly diagnosed metastatic bladder cancer – PD-L1 CPS 15

Ms Burns: A frail 87-year-old man with relapsed metastatic bladder cancer

Ms Averia: An 81-year-old woman with relapsed, metastatic bladder cancer

Ms Burns: A 51-year-old man with metastatic bladder cancer and an FGFR3 mutation

Which of the following agents is now approved and commonly used as maintenance therapy after first-line chemotherapy for metastatic urothelial bladder cancer?

1. Pembrolizumab
2. Avelumab
3. Enfortumab vedotin
4. Erdafitinib
5. I don’t know

Case Presentation – A 68-year-old woman with newly diagnosed metastatic bladder cancer – PD-L1 CPS 15 (Part 1)

Ms Averia

- Rheumatologist, married with daughter
- Summer 2020: Transferred from another hospital where she had been admitted for acute renal failure
- Diagnosed with metastatic urothelial bladder cancer
  - PD-L1 CPS: 15, PD-L1 IC: 5%
- 9-12/2020: Cisplatin/gemcitabine
- 3/2021 – present: Avelumab
  - Tolerating well, fatigue

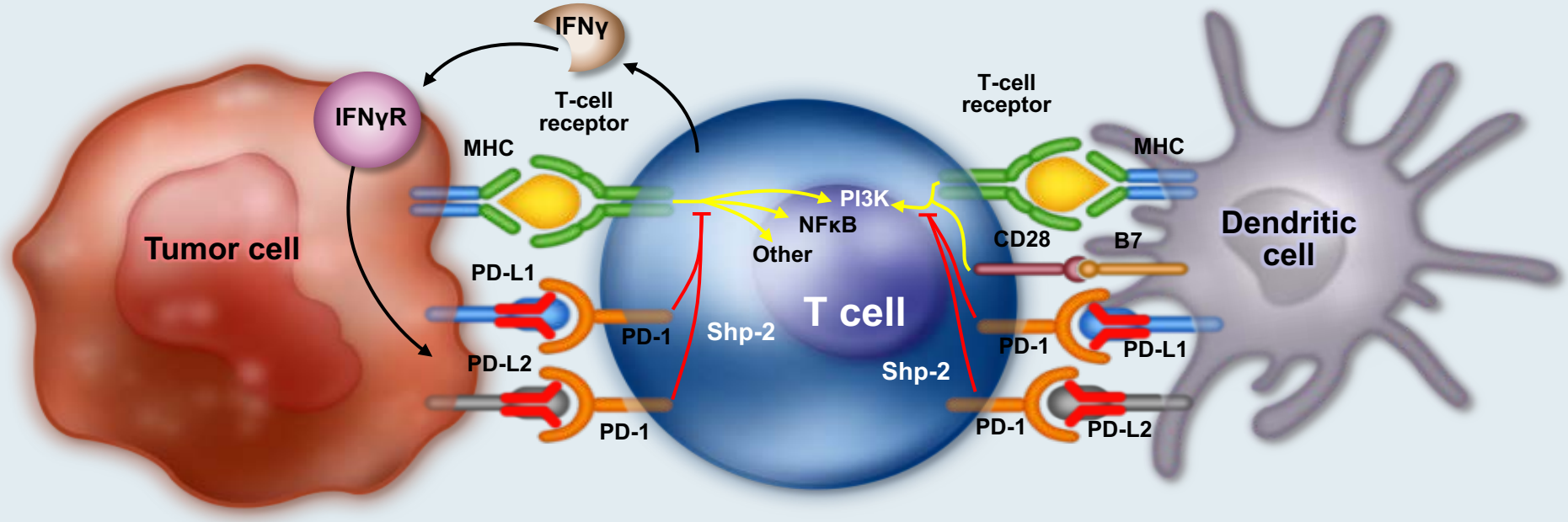
Case Presentation – A 68-year-old woman with newly diagnosed metastatic bladder cancer – PD-L1 CPS 15 (Part 2)

Ms Averia

- Rheumatologist, married with daughter
- Summer 2020: Transferred from another hospital where she had been admitted for acute renal failure
- Diagnosed with metastatic urothelial bladder cancer
  - PD-L1 CPS: 15, PD-L1 IC: 5%
- 9-12/2020: Cisplatin/gemcitabine
- 3/2021 – present: Avelumab
  - Tolerating well, fatigue
- ***Symptom management phone calls multiple times weekly***

Anti-PD-1/PD-L1 Antibodies: Mechanism of Action

- PD-1 expression on tumor-infiltrating lymphocytes is associated with decreased cytokine production and effector function
  - Anti-PD-1 antibodies bind PD-1 receptors on T cells and disrupts negative signaling triggered by PD-L1/PD-L2 to restore T-cell antitumor function
  - Anti-PD-L1 antibodies bind PD-L1 receptors



Current Treatment Paradigms Metastatic Urothelial Ca

- Cisplatin eligible
  - gem/cis
- Cisplatin ineligible
  - immunotherapy (pembro or atezo) if PD-L1+
  - gem/carbo
- Chemotherapy unfit
  - immunotherapy (pembro or atezo)
- Platinum refractory
  - immunotherapy (pembro level 1 evidence)

Courtesy of Peter H O'Donnell, MD

FDA Approves Avelumab for Urothelial Carcinoma Maintenance Treatment

Press Release – June 30, 2020

"The Food and Drug Administration approved avelumab for maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy.

Efficacy of avelumab for maintenance treatment of UC was investigated in the JAVELIN Bladder 100 trial (NCT02603432), a randomized, multi-center, open-label trial that enrolled 700 patients with unresectable, locally advanced or metastatic urothelial carcinoma that had not progressed with four to six cycles of first-line platinum-containing chemotherapy. Patients were randomized (1:1) to receive either avelumab intravenously every 2 weeks plus best supportive care (BSC) or BSC alone. Treatment was initiated within 4-10 weeks after last chemotherapy dose."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-avelumab-urothelial-carcinoma-maintenance-treatment

N Engl J Med 2020;383:1218-30.

The NEW ENGLAND JOURNAL of MEDICINE

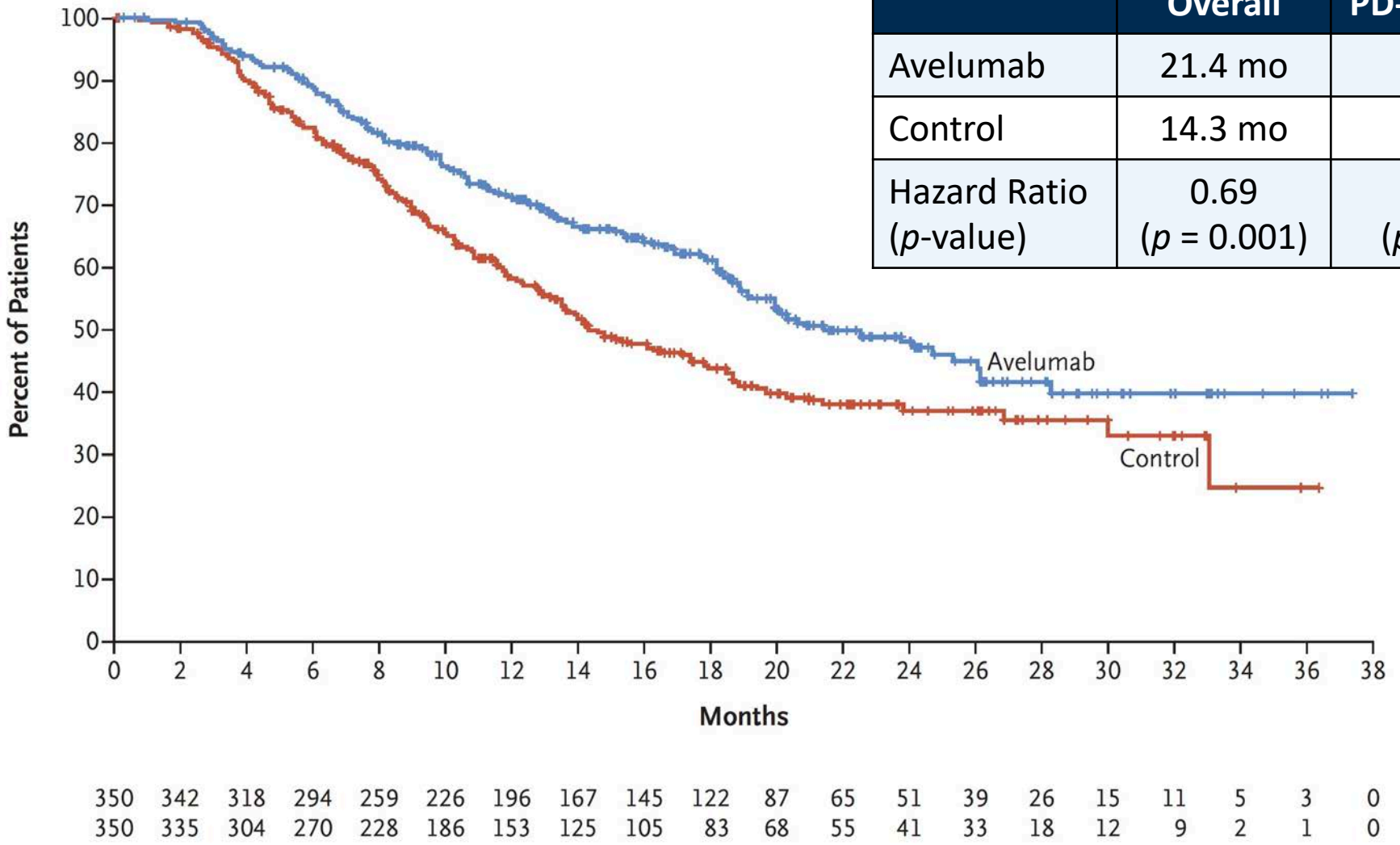
ORIGINAL ARTICLE

Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma

T. Powles, S.H. Park, E. Voog, C. Caserta, B.P. Valderrama, H. Gurney, H. Kalofonos, S. Radulović, W. Demey, A. Ullén, Y. Loriot, S.S. Sridhar, N. Tsuchiya, E. Kopyltsov, C.N. Sternberg, J. Bellmunt, J.B. Aragon-Ching, D.P. Petrylak, R. Laliberte, J. Wang, B. Huang, C. Davis, C. Fowst, N. Costa, J.A. Blake-Haskins, A. di Pietro, and P. Grivas

JAVELIN Bladder 100 Primary Endpoint: Overall Survival

	Overall	PD-L1-positive
Avelumab	21.4 mo	NE
Control	14.3 mo	17.1 mo
Hazard Ratio (*p*-value)	0.69 (*p* = 0.001)	0.56 (*p* < 0.001)



Powles T et al. *N Engl J Med* 2020;383:1218-30.

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FDA-Approved Immune Checkpoint Inhibitors for UBC

Agent	FDA approval date	Indication
Avelumab	6/30/2020	• Maintenance treatment after first-line platinum-containing chemotherapy
Pembrolizumab	1/8/2020	• BCG-unresponsive, high-risk NMIBC in patients ineligible for or electing not to undergo cystectomy
Pembrolizumab*	5/18/2017	• Previously platinum-treated locally advanced or metastatic UBC
Avelumab	5/9/2017	• Previously platinum-treated locally advanced or metastatic UBC
Durvalumab	5/1/2017	*FDA indication voluntarily withdrawn*
Nivolumab	2/2/2017	• Previously platinum-treated locally advanced or metastatic UBC
Atezolizumab*	5/18/2016	*FDA indication voluntarily withdrawn*

NMIBC = non-muscle-invasive bladder cancer

* 6/9/2018: FDA limits use to locally advanced or metastatic UBC not eligible for cisplatin
* 8/16/2018: FDA requires companion diagnostic for specific PD-L1 levels (pembrolizumab CPS ≥10, atezolizumab IC ≥5%); for patients not eligible for any platinum-containing therapy, indication is regardless of PD-L1 expression

https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications

Voluntary Withdrawal of Durvalumab Indication for Advanced Bladder Cancer in the United States

Press Release – February 22, 2021

"The voluntary withdrawal of the durvalumab indication in the US for previously treated adult patients with locally advanced or metastatic bladder cancer [was announced today]. This decision was made in consultation with the Food and Drug Administration (FDA).

In May 2017, durvalumab was granted accelerated approval in the US based on promising tumor response rates and duration of response data from Study 1108, a Phase I/II trial that evaluated the safety and efficacy of durvalumab in advanced solid tumors, including previously treated bladder cancer. Continued approval was contingent on results from the DANUBE Phase III trial in the 1st-line metastatic bladder cancer setting, which did not meet its primary endpoints in 2020. The withdrawal is aligned with FDA guidance for evaluating indications with accelerated approvals that did not meet post-marketing requirements, as part of a broader industry-wide evaluation. This withdrawal does not impact the indication outside the US and does not impact other approved durvalumab indications within or outside the US."

https://www.astrazeneca.com/media-centre/press-releases/2021/voluntary-withdrawal-imfinzi-us-bladder-indication.html

Voluntary Withdrawal of Atezolizumab Indication for Advanced Bladder Cancer in the United States

Press Release – March 7, 2021

The voluntary withdrawal of the atezolizumab indication in the US for prior platinum-treated metastatic urothelial carcinoma was announced on March 7, 2021. “This decision was made in consultation with the US Food and Drug Administration (FDA) as part of an industry-wide review of accelerated approvals with confirmatory trials that have not met their primary endpoint(s) and have yet to gain regular approvals.”

“Atezolizumab was granted accelerated approval in 2016 for the treatment of prior-platinum treated mUC based on the results from the IMvigor210 study (Cohort 2). Continued approval for this indication was contingent upon the results of IMvigor211, the original PMR [post-marketing requirements] for the prior-platinum mUC indication. This study did not meet its primary endpoint of overall survival in the PD-L1 high patient population. Subsequently, the FDA designated the IMvigor130 study as the PMR which will still continue until the final analysis. However, as the treatment landscape in prior-platinum (second-line) mUC has rapidly evolved with the emergence of new treatment options, [the manufacturer] is voluntarily withdrawing this indication in recognition of the principles of the Accelerated Approval Program.”

https://www.gene.com/media/press-releases/14898/2021-03-07/genentech-provides-update-on-tecentriq-u

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Agenda

Ms Averia: A 68-year-old woman with newly diagnosed metastatic bladder cancer – PD-L1 CPS 15

Ms Burns: A frail 87-year-old man with relapsed metastatic bladder cancer

Ms Averia: An 81-year-old woman with relapsed, metastatic bladder cancer

Ms Burns: A 51-year-old man with metastatic bladder cancer and an FGFR3 mutation

RTP RESEARCH TO PRACTICE

Case Presentation – A frail 87-year-old man with relapsed metastatic bladder cancer (Part 1)

Ms Burns

- Active, retired architect and attorney; married with children
- Summer 2020: Diagnosed with metastatic urothelial bladder cancer
  - PD-L1 status: Unknown, PIK3CA mutation
  - Frail, rising creatinine
- Pembrolizumab x 3-4 doses → PD
- Enfortumab vedotin

RTP RESEARCH TO PRACTICE

Case Presentation – A frail 87-year-old man with relapsed metastatic bladder cancer (Part 2)

Ms Burns

- Active, retired architect and attorney; married with children
- Summer 2020: Diagnosed with metastatic urothelial bladder cancer
  - PD-L1 status: Unknown, PIK3CA mutation
  - Frail, rising creatinine
- Pembrolizumab x 3-4 doses → PD
- Enfortumab vedotin
  - ***Cutaneous side effects, "activation of prior skin cancer"; peripheral neuropathy***
  - ***Dose reduction***

RTP RESEARCH TO PRACTICE

Case Presentation – A frail 87-year-old man with relapsed metastatic bladder cancer (Part 3)

Ms Burns

- Active, retired architect and attorney; married with children
- Summer 2020: Diagnosed with metastatic urothelial bladder cancer
  - PD-L1 status: Unknown, PIK3CA mutation
  - Frail, rising creatinine
- Pembrolizumab x 3-4 doses → PD
- Enfortumab vedotin
  - Cutaneous side effects, “activation of prior skin cancer”; peripheral neuropathy
  - Dose reduction
- ***Changing from infusional to oral therapy***
- ***Impact of treatments on quality of life***

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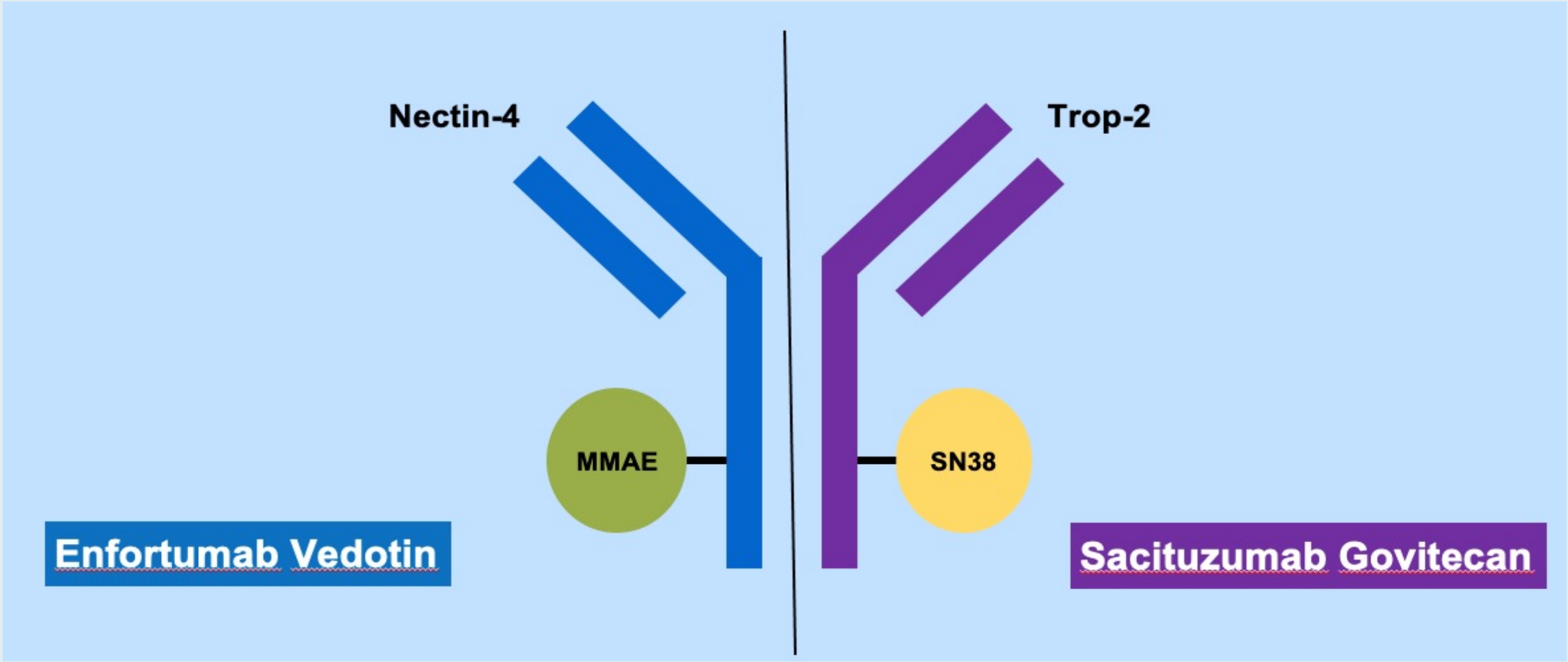
Case Presentation – An 81-year-old woman with relapsed, metastatic bladder cancer

Ms Averia

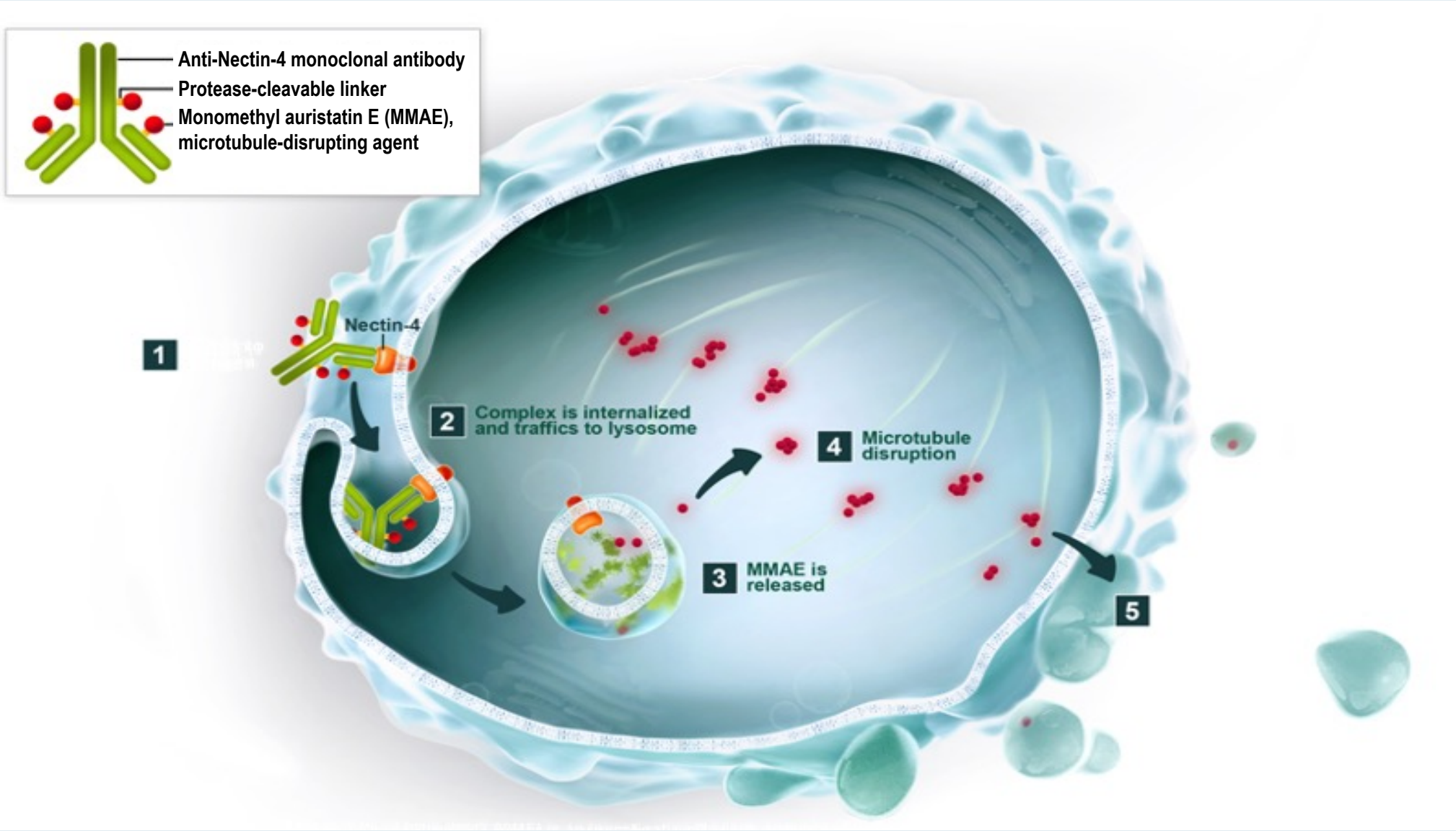
- 2015: BCG
- 2016: Muscle-invasive bladder cancer → cisplatin/gemcitabine x 3
  - "failure to thrive," pancytopenia, prolonged placement in skilled nursing facility
- 2017: Metastases to pelvis and spine → RT to pelvis
- 7/2018-1/2019: Pembrolizumab x 7 → PD
- 2-5/2019: Carboplatin/pemetrexed → PD → RT to pelvis
- Enfortumab vedotin, with response after 3 cycles but extreme fatigue
  - 3-week treatment break, with significant improvement in disposition
- Discussion of stopping treatment and hospice versus continuing treatment

Antibody-Drug Conjugates in UBC



Courtesy of Matthew Galsky, MD.

Enfortumab Vedotin: Nectin-4 Targeted Therapy



Courtesy of Jonathan Rosenberg, MD

Primary Results of EV-301: A Phase III Trial of Enfortumab Vedotin versus Chemotherapy in Patients with Previously Treated Locally Advanced or Metastatic Urothelial Carcinoma

Powles T et al.

Genitourinary Cancers Symposium 2021;Abstract 393.

EV-301: Response and Survival Analyses

	Enfortumab vedotin (n = 301)	Chemotherapy (n = 307)	Hazard ratio	*p*-value
Median OS	12.9 mo	9.0 mo	0.70	0.001
Median PFS	5.6 mo	3.7 mo	0.61	<0.00001
ORR	40.6%	17.9%	—	—
DCR	71.9%	53.4%	—	—

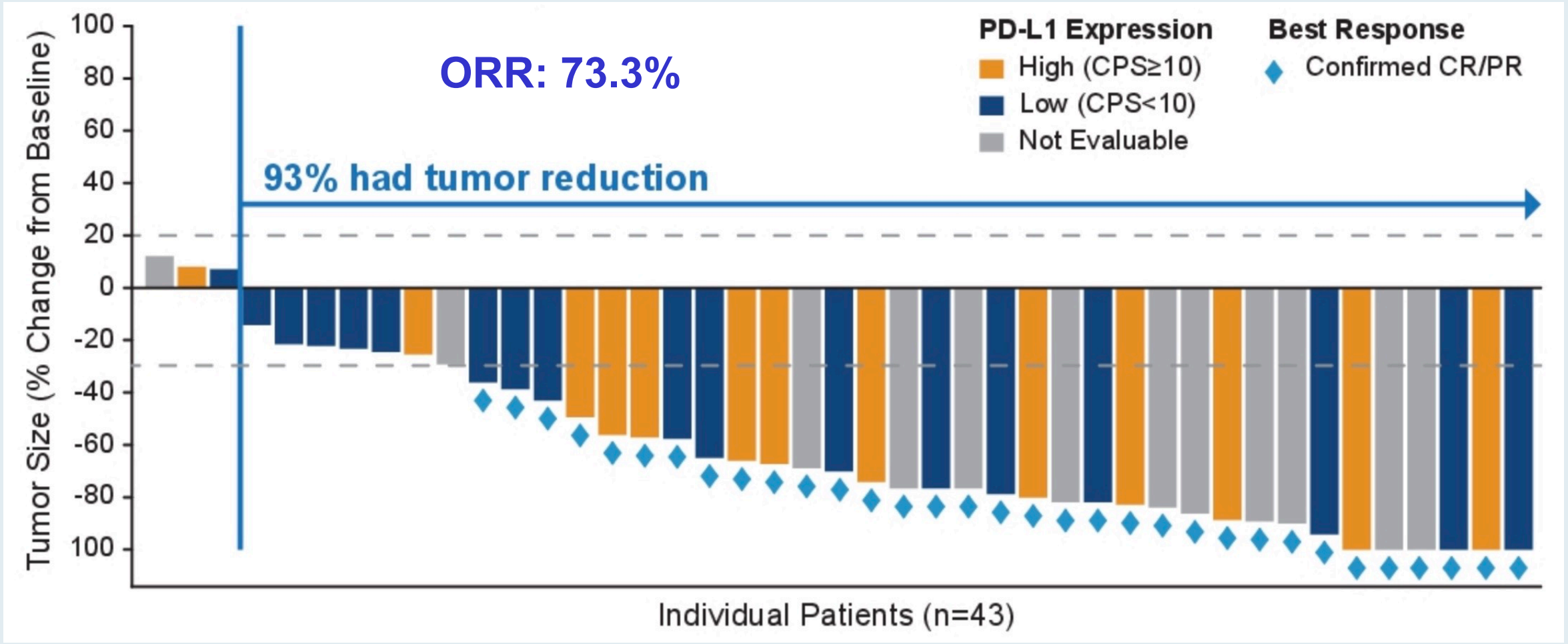
Powles T et al. Genitourinary Cancers Symposium 2021;Abstract 393.

Study EV-103: Durability Results of Enfortumab Vedotin plus Pembrolizumab for Locally Advanced or Metastatic Urothelial Carcinoma

Rosenberg JE et al.

ASCO 2020;Abstract 5044.

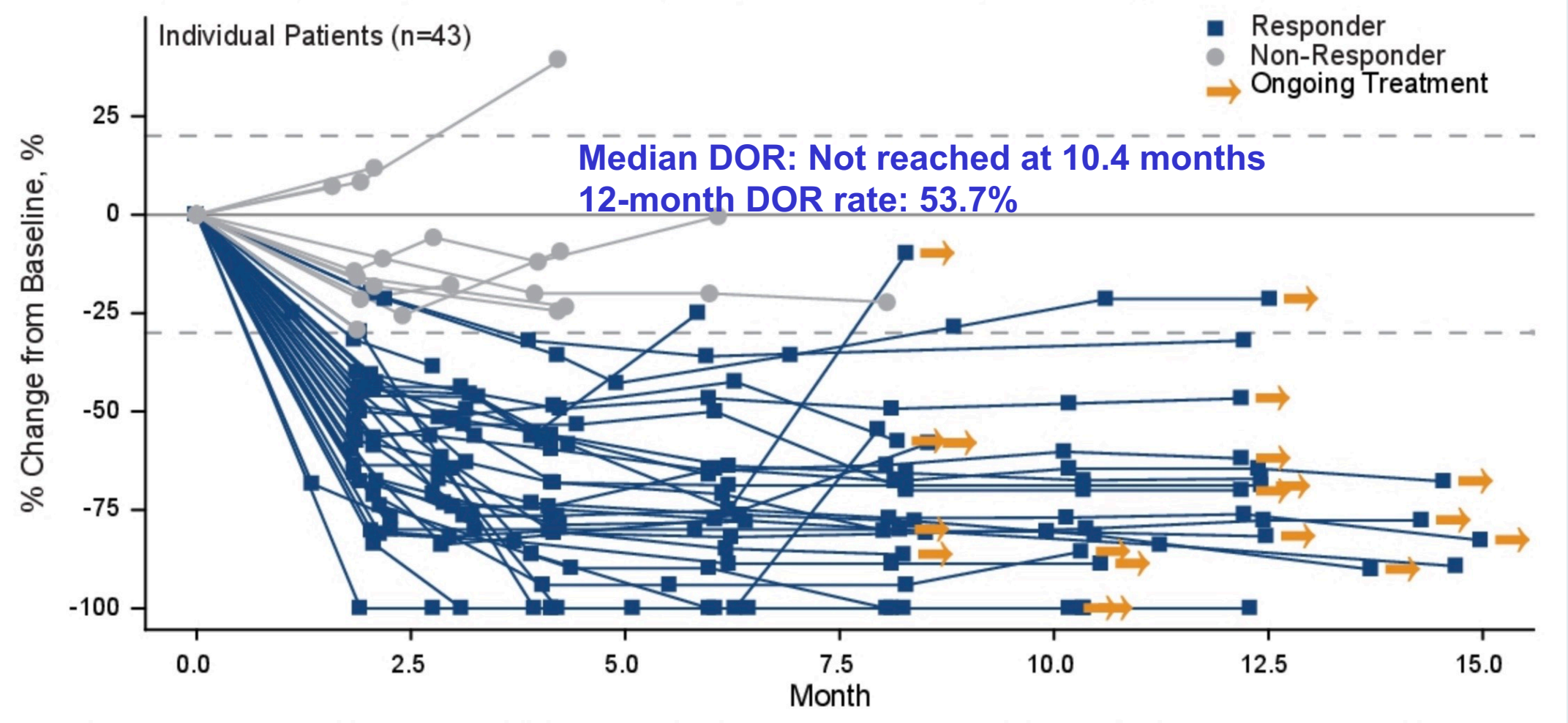
EV-103: Response to Enfortumab Vedotin with Pembrolizumab in the First-Line Setting



Rosenberg JE et al. ASCO 2020;Abstract 5044.

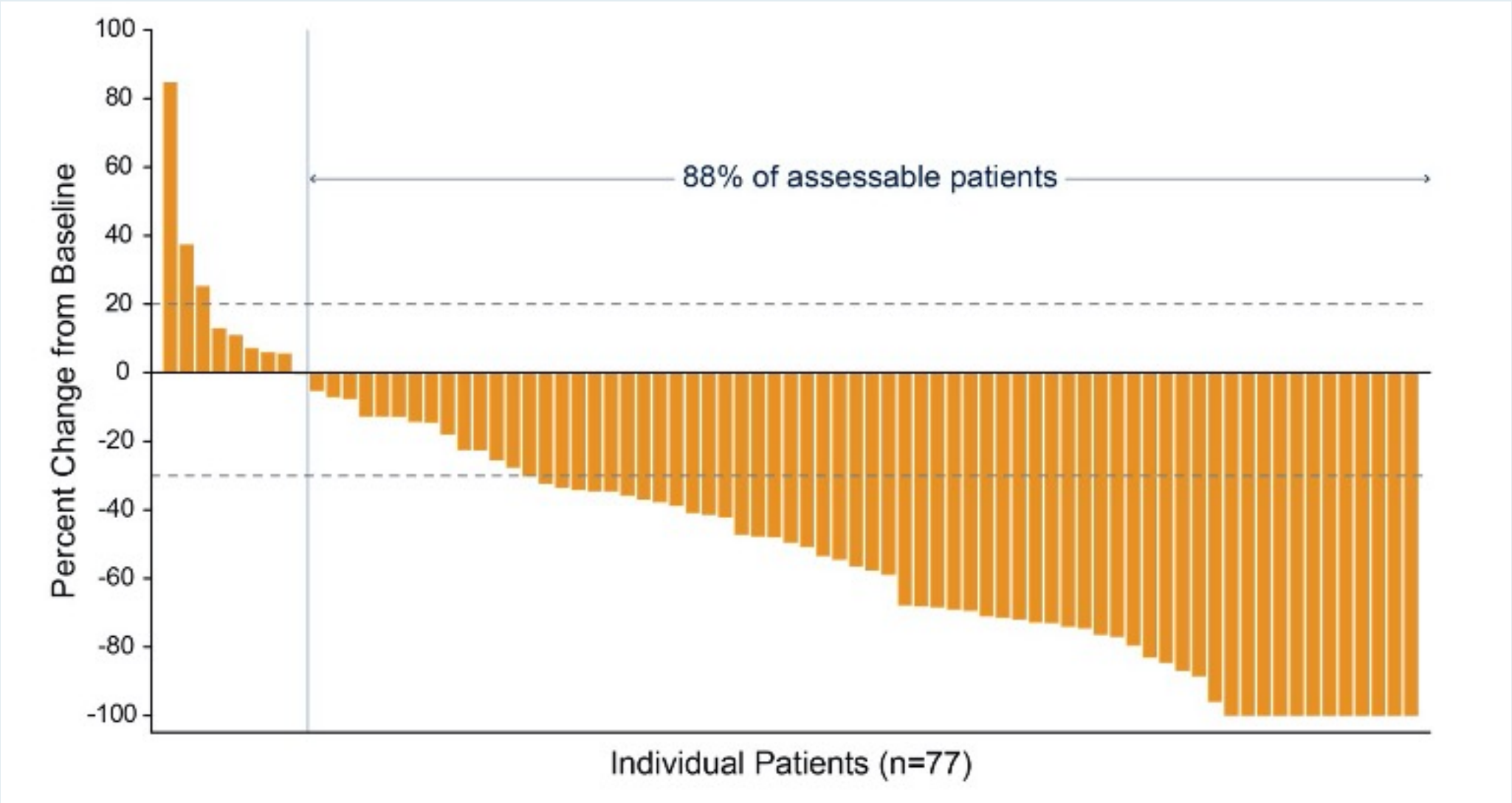
RTP RESEARCH TO PRACTICE

EV-103: Durability of Response to Enfortumab Vedotin with Pembrolizumab in the First-Line Setting



Rosenberg JE et al. ASCO 2020;Abstract 5044.

EV-201 Cohort 2: Change in Tumor Measurements per BICR



Balar AV et al. Genitourinary Cancers Symposium 2021;Abstract 394.

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EV-201 Cohort 2: Treatment-Related Adverse Events of Special Interest

Skin Reactions
61% any grade, 17% ≥Grade 3
Median Onset = 0.5 months[2]
% resolution/improvement[3] = 80%

- No Grade 5 events, 1 Grade 4 event
- 13 patients with severe cutaneous adverse reactions[4]
  - Most ≤Grade 2, no Grade 4 or 5 events
  - 4 patients with Grade 3 events: stomatitis, skin exfoliation, dermatitis bullous, dermatitis exfoliative generalised
  - 1 discontinuation due to severe cutaneous adverse reaction

Peripheral Neuropathy
54% any grade, 8% ≥Grade 3
Median Onset = 2.4 months
% resolution/improvement[3] = 56%

- PN rate was similar in patients with and without pre-existing PN (53% vs 54%)

Hyperglycemia
10% any grade, 6% ≥Grade 3
Median Onset = 0.5 months[2]
% resolution/improvement[3] = 89%

- Higher rate of HG in patients with pre-existing HG than those without pre-existing HG (20% vs. 7%)
- Higher rate of HG in patients with BMI ≥30 kg/m^2 than those with BMI <30 kg/m^2 (23% vs. 8%)

Balar AV et al. Genitourinary Cancers Symposium 2021;Abstract 394.

FDA Grants Accelerated Approval to Sacituzumab Govitecan for Advanced Urothelial Cancer

Press Release – April 13, 2021

"The Food and Drug Administration granted accelerated approval to sacituzumab govitecan for patients with locally advanced or metastatic urothelial cancer (mUC) who previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

Efficacy and safety were evaluated in TROPHY (IMMU-132-06; NCT03547973), a single-arm, multicenter trial that enrolled 112 patients with locally advanced or mUC who received prior treatment with a platinum-containing chemotherapy and either a PD-1 or PD-L1 inhibitor. Patients received sacituzumab govitecan, 10 mg/kg intravenously, on days 1 and 8 of a 21-day treatment cycle."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sacituzumab-govitecan-advanced-urothelial-cancer

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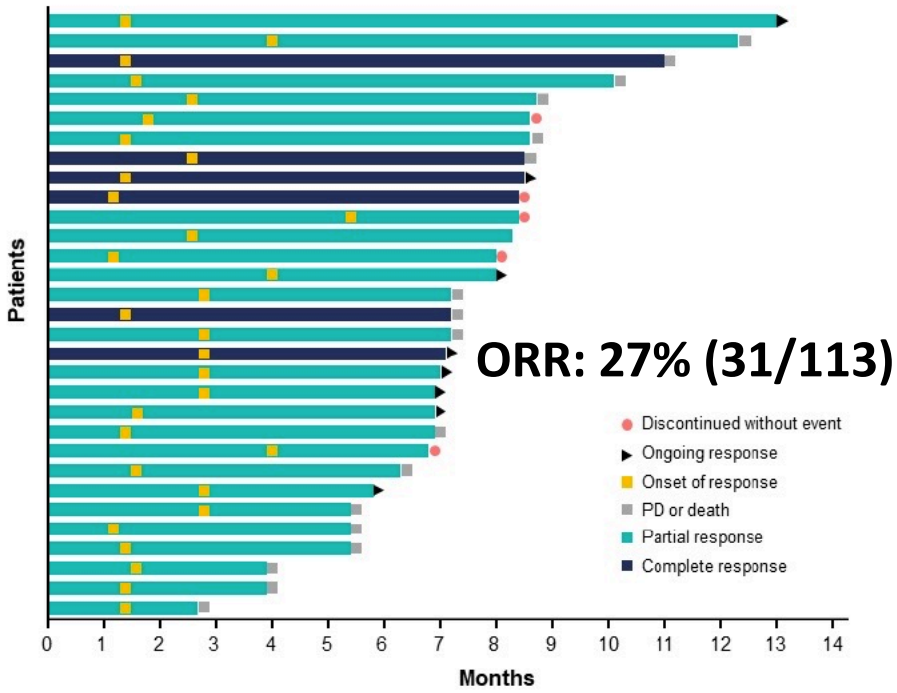
Final Results from TROPHY-U-01 Cohort 1: A Phase 2 Open-Label Study of Sacituzumab Govitecan (SG) in Patients with Metastatic Urothelial Cancer (mUC) and Disease Progression After Platinum (PLT)-Based Regimens and Checkpoint Inhibitors (CPI)

Loriot Y et al.

ESMO 2020;Abstract LBA24.

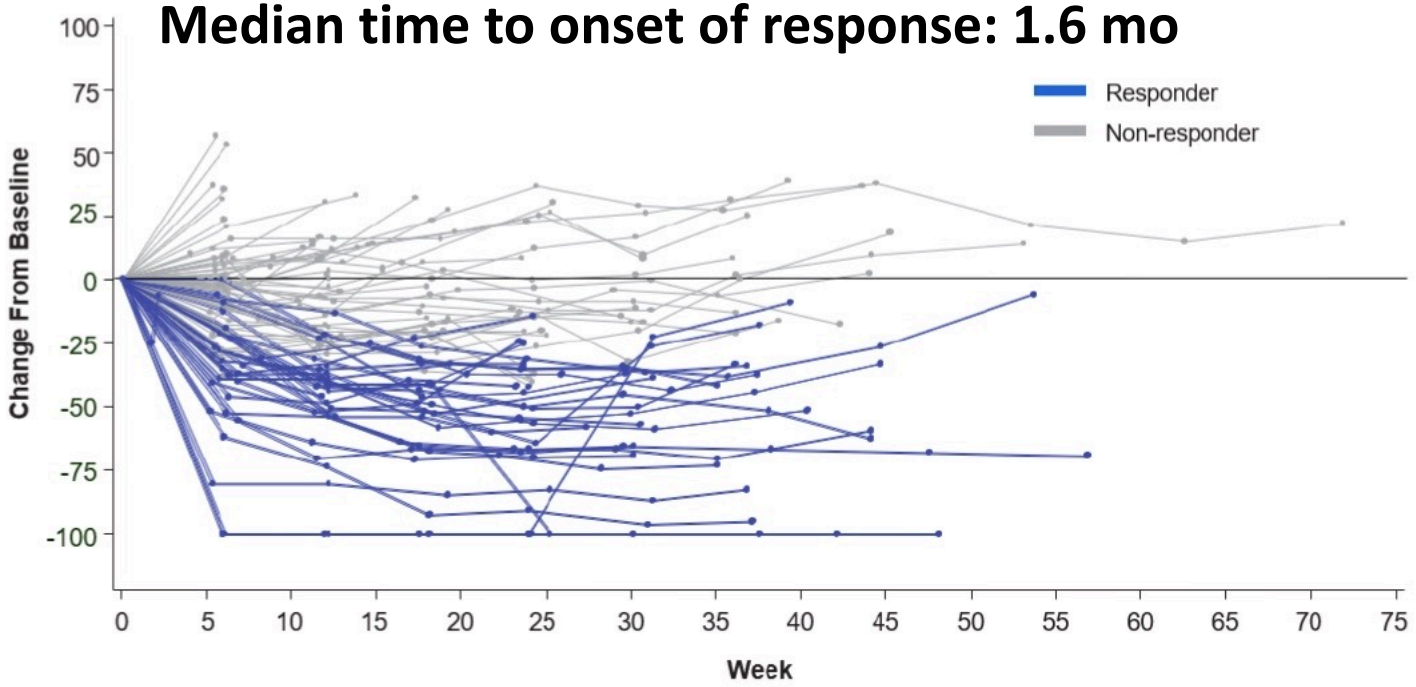
TROPHY-U-01 (Cohort 1): ORR, Duration of Response and Survival



ORR: 27% (31/113)

Median DOR: 5.9 mo

Median time to onset of response: 1.6 mo



- 27 of 31 responders are alive
- 8 of 31 responders have an ongoing response and are still on treatment at data cutoff

Median PFS: 5.4 mo **Median OS: 10.5 mo**

Loriot Y et al. ESMO 2020;Abstract LBA24.

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Agenda

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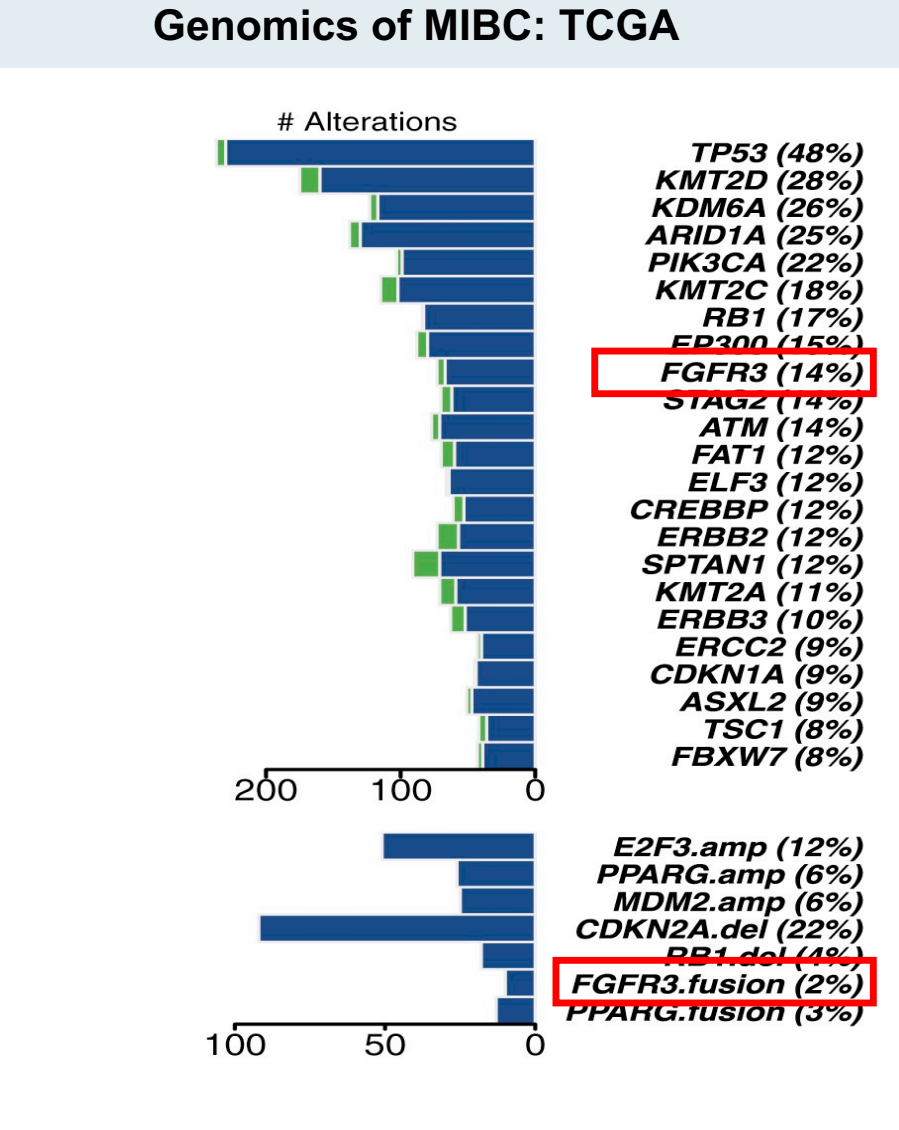
Ms Burns: A 51-year-old man with metastatic bladder cancer and an FGFR3 mutation

Case Presentation – A 51-year-old man with metastatic bladder cancer and an FGFR3 mutation

Ms Burns

- Owner of a landscaping company, wife died of pancreatic cancer during his treatment, lives 2-3 hours from the clinic
- 2016: Diagnosed with bladder cancer, cisplatin/gemcitabine x 4 → PD
- Clinical trial of pembrolizumab/ephrin → recurrence in bladder after a few months
- Intravesicular gemcitabine
- Liver metastases, FGFR3 mutation identified
- 8/2020: Erdafitinib 9 mg → 8 mg x 3 months, with response
  - Fatigue, onycholysis, blurry vision, increased phosphate levels
- Patient seeks alternative therapies

FGFR3 Genomic Alterations in Muscle-Invasive Bladder Cancer



- In muscle-invasive disease, *FGFR3* mutations in ~20% of tumors, but protein and/or gene overexpression in ~50%.
- Activating mutations of *FGFR3* in ~75% of low-grade papillary bladder tumors.
- FGFR3-TACC3 fusions enriched in young, Asian, non-smokers, upper tract tumors (invasive, high grade)
- Preclinical evidence for activity of FGFR inhibitors in selected cells with FGFR alterations

Courtesy of Guru Sonpavde, MD

Robertson AG et al. *Cell* 2017;171(3):540-56; Cappellen D et al. *Nat Genet* 1999;23:18-20; Nassar A et al. *JCO Precis Oncol* 2018; Gust KM et al. *Mol Cancer Ther* 2013;12:1245-54; Grünewald S et al. *Int J Cancer* 2019; Sfakianos JP Eur Urol 2015;68(6):970-7.

Erdafitinib - Toxicities

Most Common Treatment-Related AEs (TRAEs)

Reported in >20% of patients	8 mg continuous dose (n = 99)	
Patients with TRAEs, n (%)	**Any grade**	**Grade 3**
Hyperphosphatemia	72 (73)	2 (2)
Stomatitis	54 (55)	9 (9)
Dry mouth	43 (43)	0
Diarrhea	37 (37)	4 (4)
Dysgeusia	35 (35)	1 (1)
Dry skin	32 (32)	0
Alopecia	27 (27)	0
Decreased appetite	25 (25)	0
Hand-foot syndrome	22 (22)	5 (5)
Fatigue	21 (21)	2 (2)

Most were grade 1 or 2

There were no grade 4 or 5 TRAEs

Serious TRAEs were reported in 9 patients (9%); none was reported in more than 1 patient

Siefker-Radtke AO et al. ASCO 2018;Abstract 4503.

Courtesy of Peter H O'Donnell, MD

Erdafitinib – Key Toxicities

5 WARNINGS AND PRECAUTIONS

5.1 Ocular Disorders

Erdafitinib can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect.

CSR/RPED was reported in 25% of patients treated with Erdafitinib, with a median time to first onset of 50 days. Grade 3 CSR/RPED, involving central field of vision, was reported in 3% of patients. CSR/RPED resolved in 13% of patients and was ongoing in 13% of patients at the study cutoff. CSR/RPED led to dose interruptions and reductions in 9% and 14% of patients, respectively and 3% of patients discontinued Erdafitinib.

Dry eye symptoms occurred in 28% of patients during treatment with Erdafitinib and were Grade 3 in 6% of patients. All patients should receive dry eye prophylaxis with ocular demulcents as needed.

Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms. Ophthalmological examination should include assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography.

Withhold Erdafitinib when CSR occurs and permanently discontinue if it does not resolve within 4 weeks or if Grade 4 in severity. For ocular adverse reactions, follow the dose modification guidelines [*see Dosage and Administration (2.3)*].

5.2 Hyperphosphatemia

Increases in phosphate levels are a pharmacodynamic effect of Erdafitinib [*see Pharmacodynamics (12.2)].* Hyperphosphatemia was reported as adverse reaction in 76% of patients treated with Erdafitinib. The median onset time for any grade event of hyperphosphatemia was 20 days (range: 8 –116) after initiating Erdafitinib. Thirty-two percent of patients received phosphate binders during treatment with Erdafitinib.

Courtesy of Peter H O'Donnell, MD

erdafitinib FDA label

New Directions in UBC

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FDA Approves Pembrolizumab for BCG-Unresponsive, High-Risk Non-Muscle Invasive Bladder Cancer

Press Release – January 8, 2020

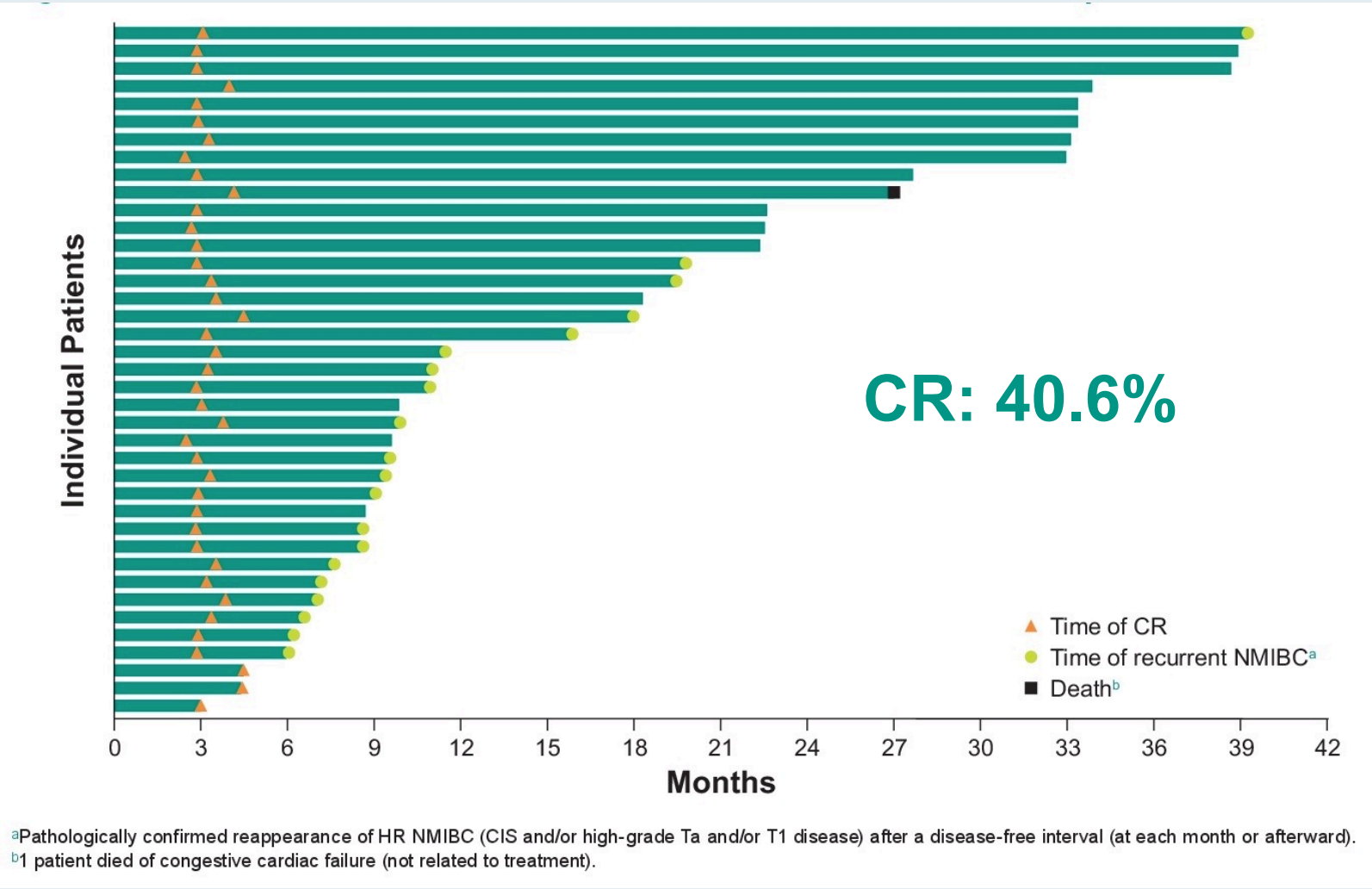
"The Food and Drug Administration approved pembrolizumab for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Efficacy was investigated in KEYNOTE-057 (NCT 02625961), a multicenter, single-arm trial that enrolled 148 patients with high-risk NMIBC, 96 of whom had BCG-unresponsive CIS with or without papillary tumors. Patients received pembrolizumab 200 mg every 3 weeks until unacceptable toxicity, persistent or recurrent high-risk NMIBC or progressive disease, or up to 24 months of therapy without disease progression."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-bcg-unresponsive-high-risk-non-muscle-invasive-bladder-cancer

RTP RESEARCH TO PRACTICE

Extended Follow-Up of KEYNOTE-057: Response, Time to Response and Recurrence of HR NMIBC in Patients Who Experienced a CR



[a]Pathologically confirmed reappearance of HR NMIBC (CIS and/or high-grade Ta and/or T1 disease) after a disease-free interval (at each month or afterward).
[b]1 patient died of congestive cardiac failure (not related to treatment).

Balar AV et al. Genitourinary Cancers Symposium 2021;Abstract 451.

Nivolumab Significantly Improves DFS as Adjuvant Therapy for High-Risk, Muscle-Invasive Urothelial Carcinoma in the Phase III CheckMate 274 Trial

Press Release – September 24, 2020

"[In an interim analysis,] CheckMate 274, a pivotal Phase 3 trial evaluating nivolumab after surgery in patients with high-risk, muscle-invasive urothelial carcinoma, has met its primary endpoints of improving disease-free survival (DFS) versus placebo in both all randomized patients and in patients whose tumor cells express PD-L1 ≥1%.

CheckMate 274 is the first and only Phase III trial in which immunotherapy has reduced the risk of relapse in the adjuvant setting for these patients. The safety profile of nivolumab was consistent with previously reported studies in solid tumors.

The company plans to complete a full evaluation of the CheckMate 274 data, work with investigators to present the results at an upcoming medical conference and submit the data to health authorities. The CheckMate 274 trial will continue as planned to allow for future analyses of secondary endpoints, including overall survival and disease-specific survival."

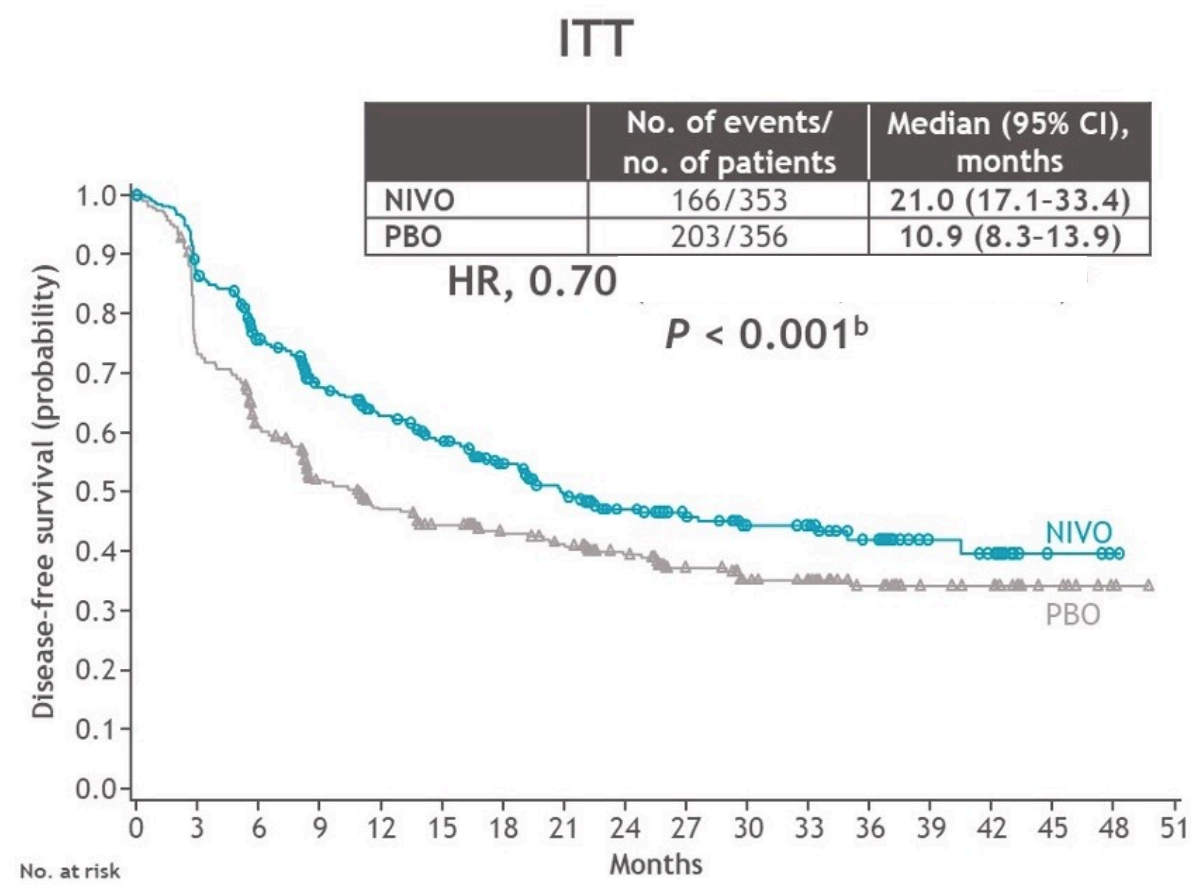
https://news.bms.com/news/corporate-financial/2020/Opdivo-nivolumab-Significantly-Improves-Disease-Free-Survival-vs.-Placebo-as-Adjuvant-Therapy-for-Patients-with-High-Risk-Muscle-Invasive-Urothelial-Carcinoma-in-Phase-3-CheckMate--274-Trial/default.aspx

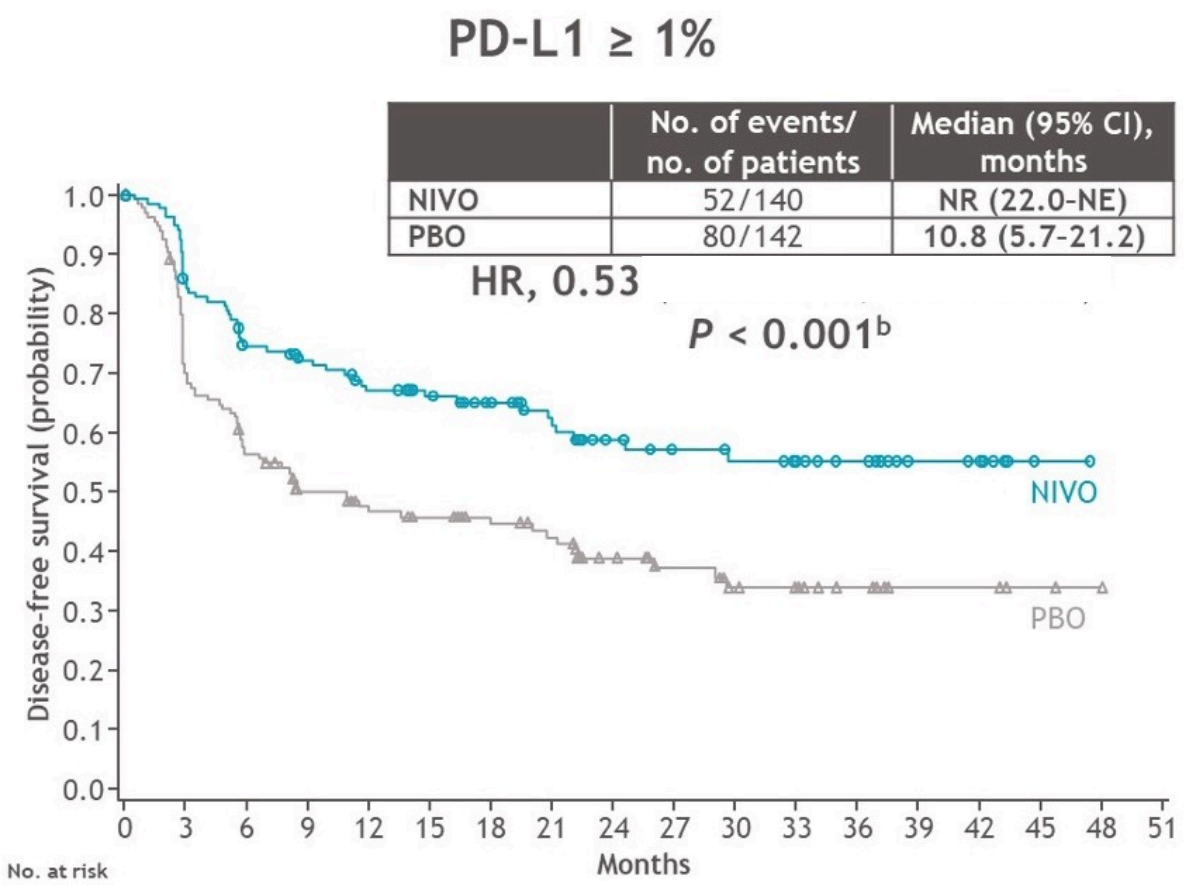
First Results from the Phase 3 CheckMate 274 Trial of Adjuvant Nivolumab vs Placebo in Patients Who Underwent Radical Surgery for High-Risk Muscle-Invasive Urothelial Carcinoma (MIUC)

Bajorin DF et al.

Genitourinary Cancers Symposium 2021;Abstract 391.

CheckMate 274: Disease-Free Survival in the ITT and PD-L1 ≥1% Populations





Bajorin DF et al. Genitourinary Cancers Symposium 2021;Abstract 391.

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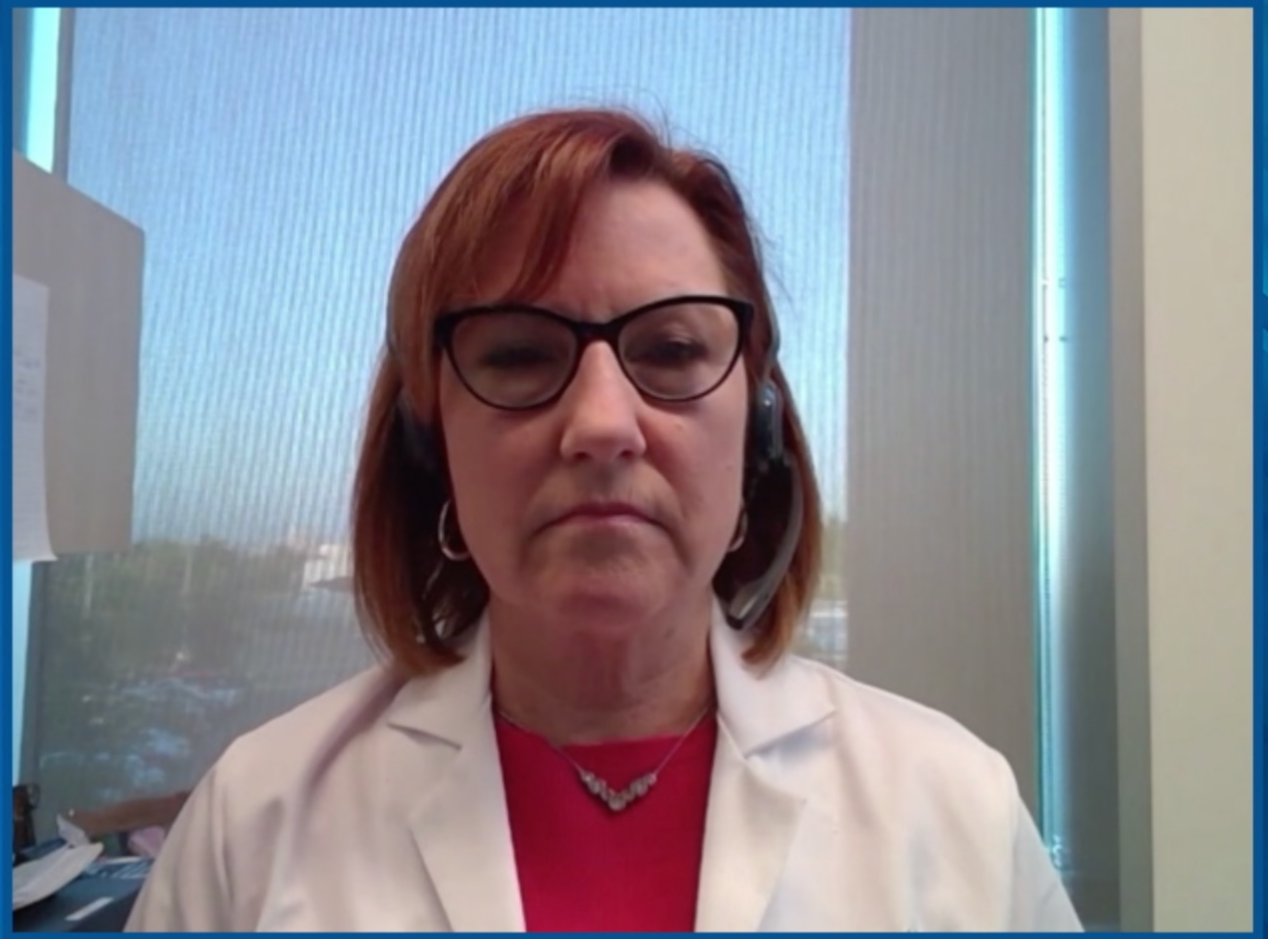
Monica Averia, MSN, AOCNP, NP-C



Kathleen Burns, NP

13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Chronic Lymphocytic Leukemia

Thursday, April 29, 2021
8:30 AM – 10:00 AM ET

Medical Oncologists

Brian T Hill, MD, PhD
John M Pagel, MD, PhD
Jennifer Woyach, MD

Oncology Nurse Practitioners

Lesley Camille Ballance, MSN, FNP-BC
Kristen E Battiato, AGNP-C
Corinne Hoffman, MS, APRN-CNP, AOCNP

Moderator

Neil Love, MD

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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