Year in Review — Clinical Investigators Provide Perspectives on the Most Relevant New Publications, Data Sets and Advances in Oncology:

Bladder Cancer and Renal Cell Carcinoma

Tuesday, February 2, 2021
5:00 PM – 6:00 PM ET

Faculty

Sumanta K Pal, MD
David I Quinn, MBBS, PhD

Moderator

Neil Love, MD

RESEARCH TO PRACTICE
2021
YEAR IN REVIEW

YiR Bladder Cancer and Renal Cell Carcinoma Faculty

Sumanta K Pal, MD
Clinical Professor, Department of Medical Oncology
City of Hope Comprehensive Cancer Center
Duarte, California

David I Quinn, MBBS, PhD
Medical Director
USC Norris Cancer Hospital and Clinics
Head, Section of GU Cancer, Division of Oncology
Associate Professor of Medicine
USC Norris Comprehensive Cancer Center
Keck School of Medicine of USC
Los Angeles, California

Commercial Support

This activity is supported by educational grants from Astellas and Seagen Inc, Bristol-Myers Squibb Company and Exelixis Inc.

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Acerta Pharma — A member of the AstraZeneca Group, Adaptive Biotechnologies Corporation, Agendia Inc, Agios Pharmaceuticals Inc, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Dendreon Pharmaceuticals Inc, Eisai Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Foundation Medicine, Genentech, a member of the Roche Group, Genmab, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Guardant Health, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Lexicon Pharmaceuticals Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, Natera Inc, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sandoz Inc, a Novartis Division, Sanofi Genzyme, Seagen Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, A GSK Company, Teva Oncology, Tokai Pharmaceuticals Inc and Verastem Inc.

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Dr Pal — Disclosures

No relevant conflicts of interest to disclose.

Dr Quinn — Disclosures

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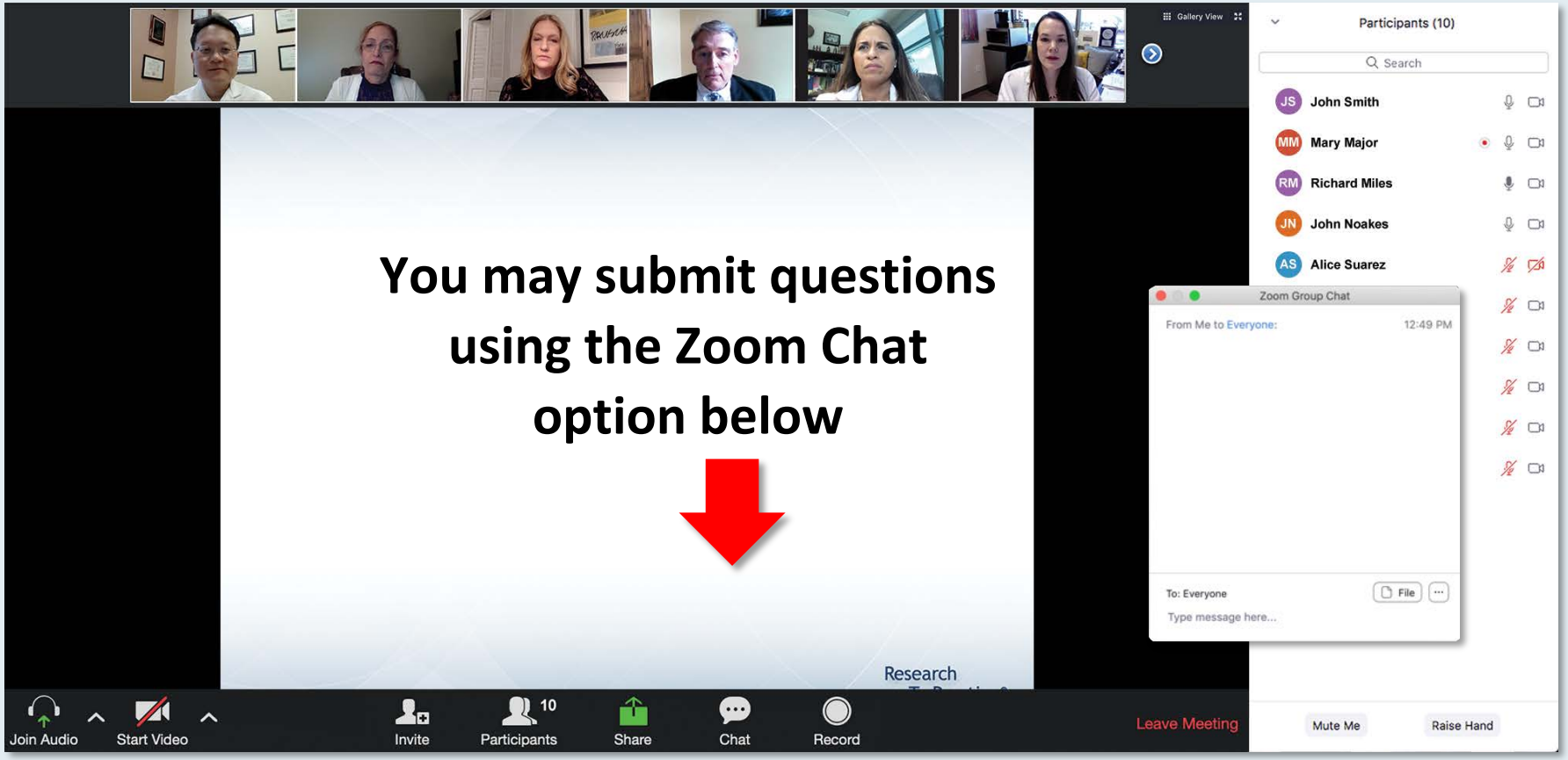
We Encourage Clinicians in Practice to Submit Questions



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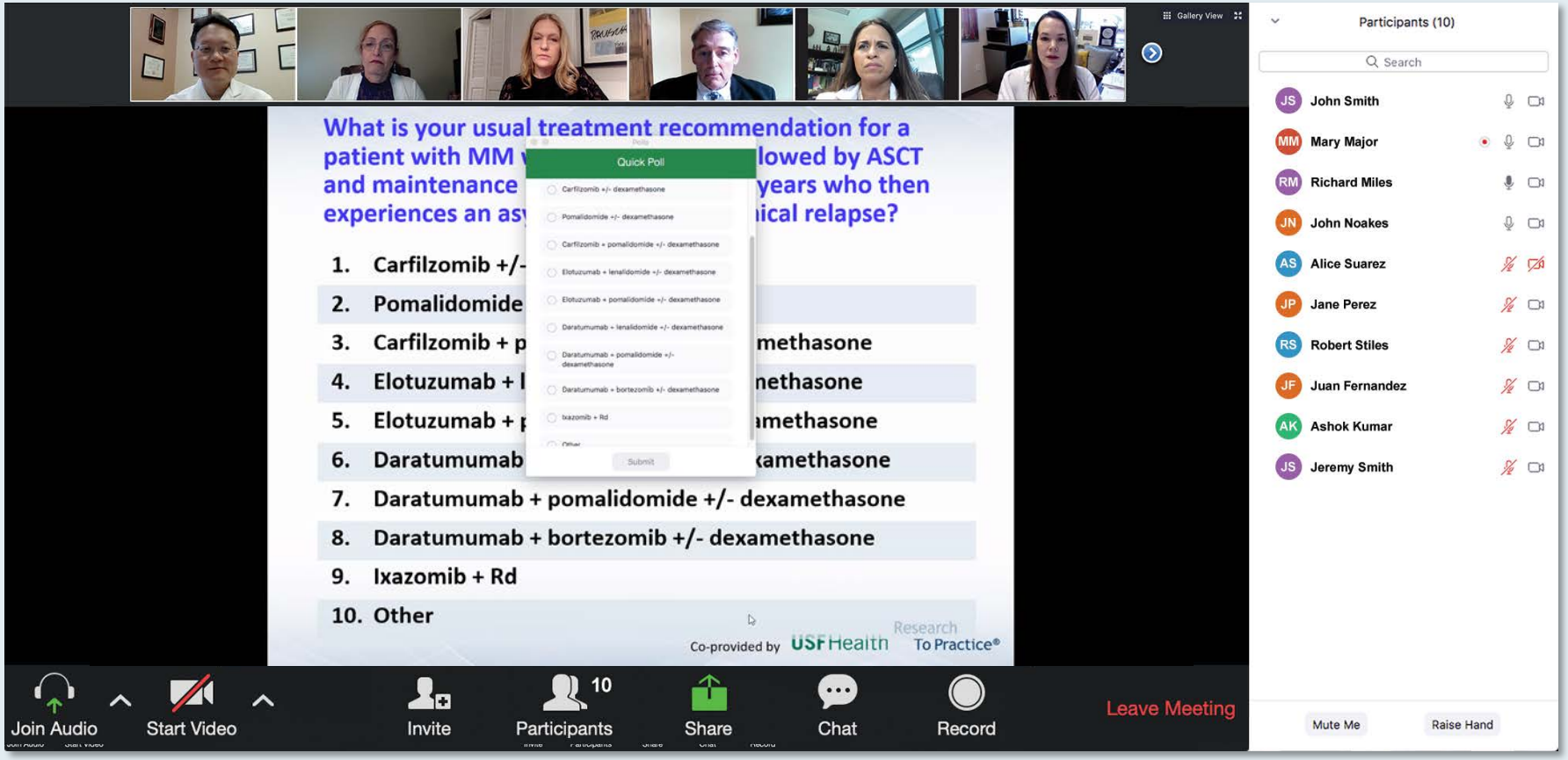

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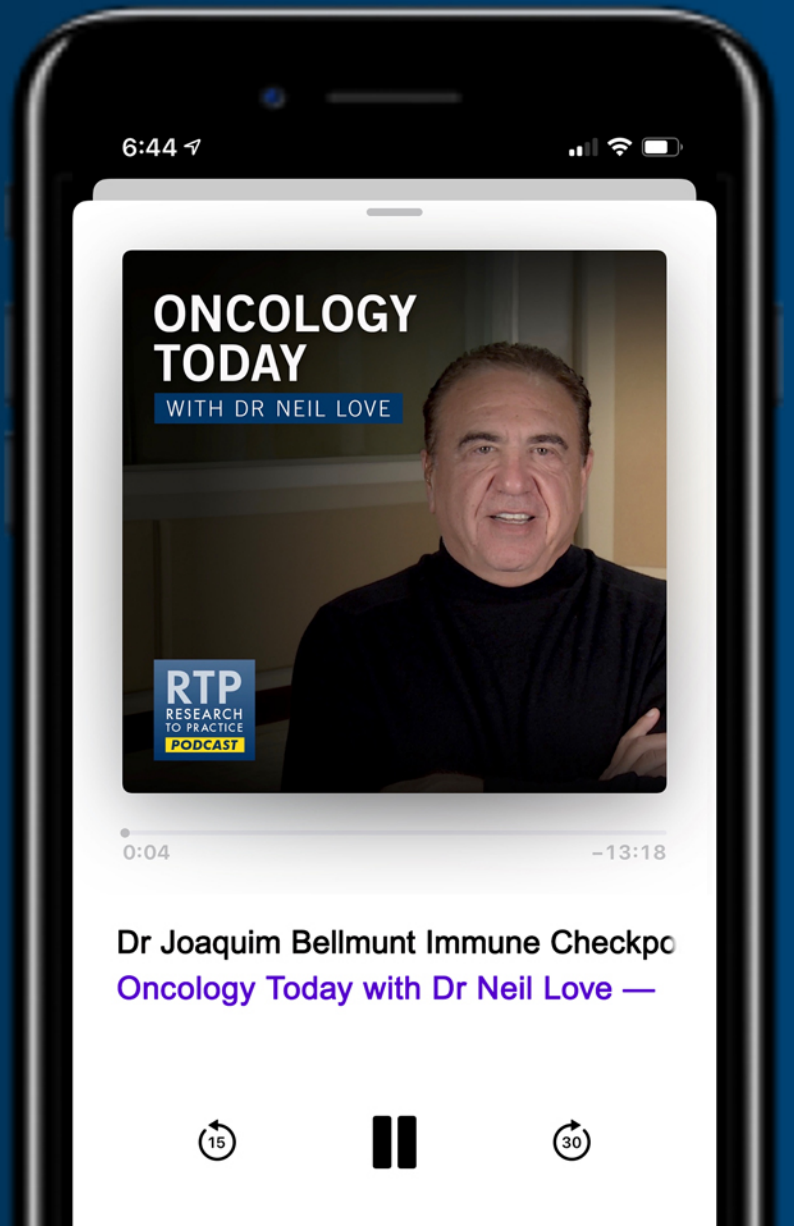

Recent Advances in Hematologic Oncology: A 4-Part Live Webinar Series Reviewing Key Data and Presentations from the 62nd ASH Annual Meeting

Part 2 — Hodgkin and Non-Hodgkin Lymphoma

Wednesday, February 3, 2021
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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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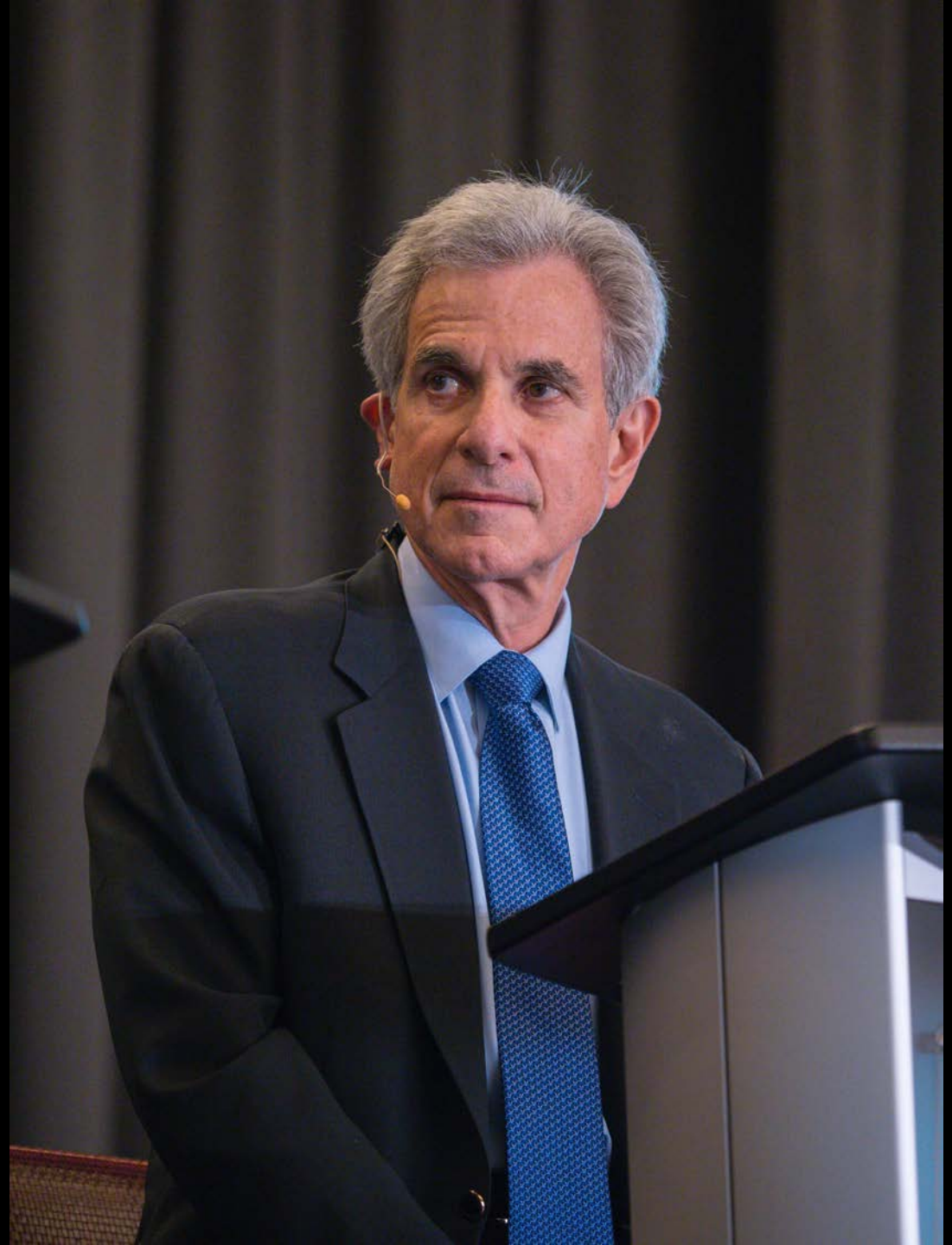
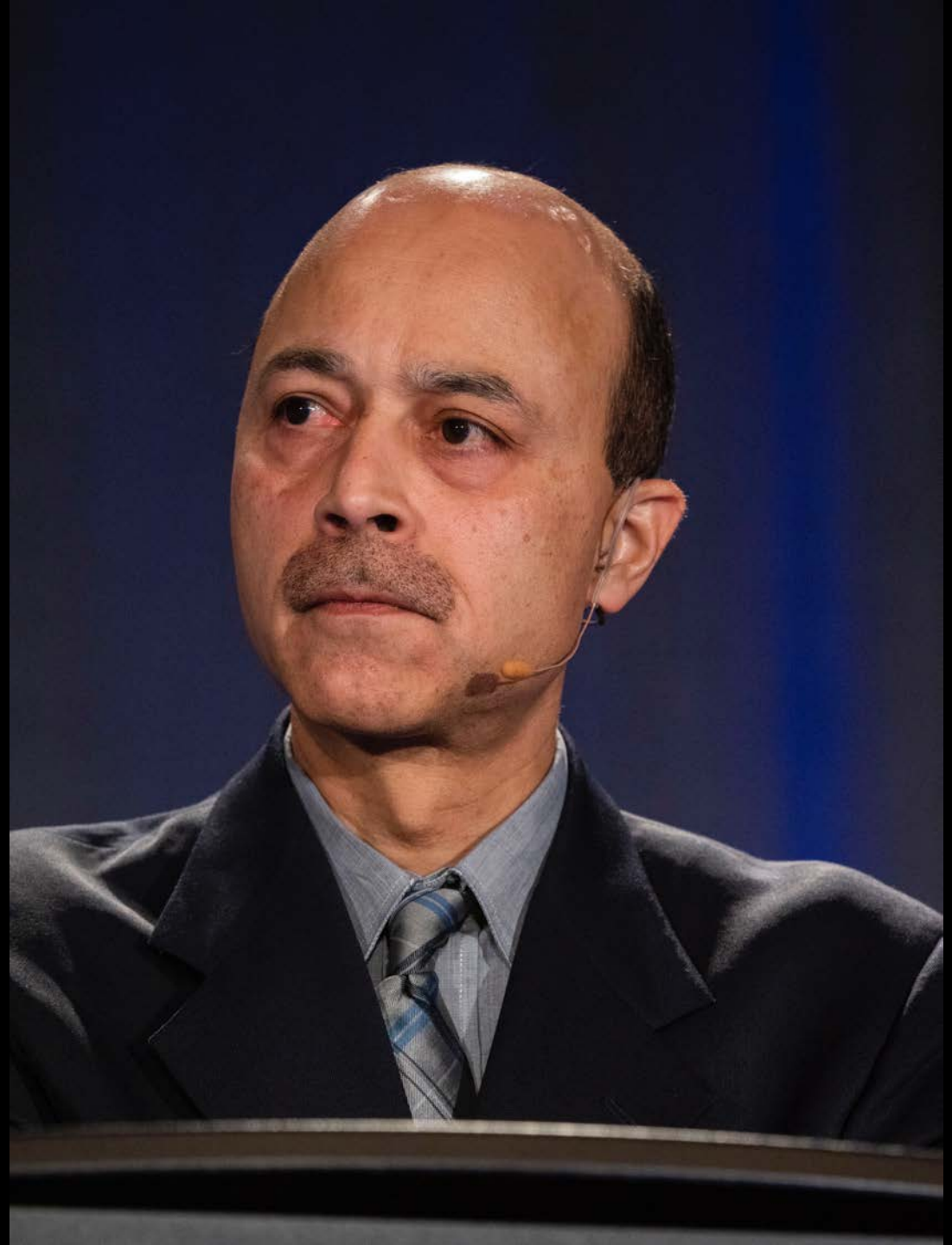



Yes (biochemical recurrence with rapid PSA doubling time)
Yes (M0 disease)
Yes (no significant metastatic disease or high-grade rapid recurrence)


IMvigor210 Cohort 1: accelerated FDA approval
Reserved
Reserved



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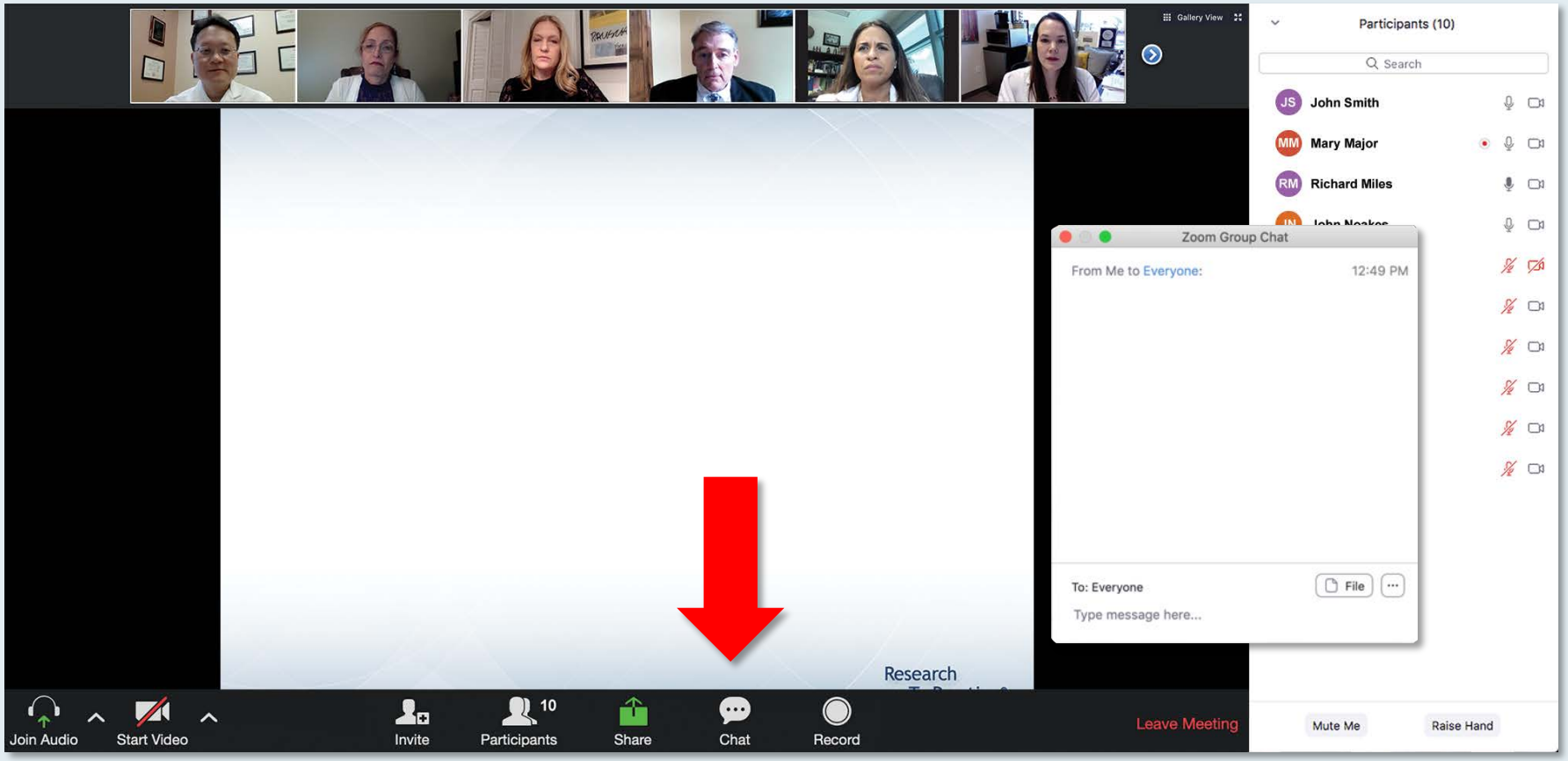

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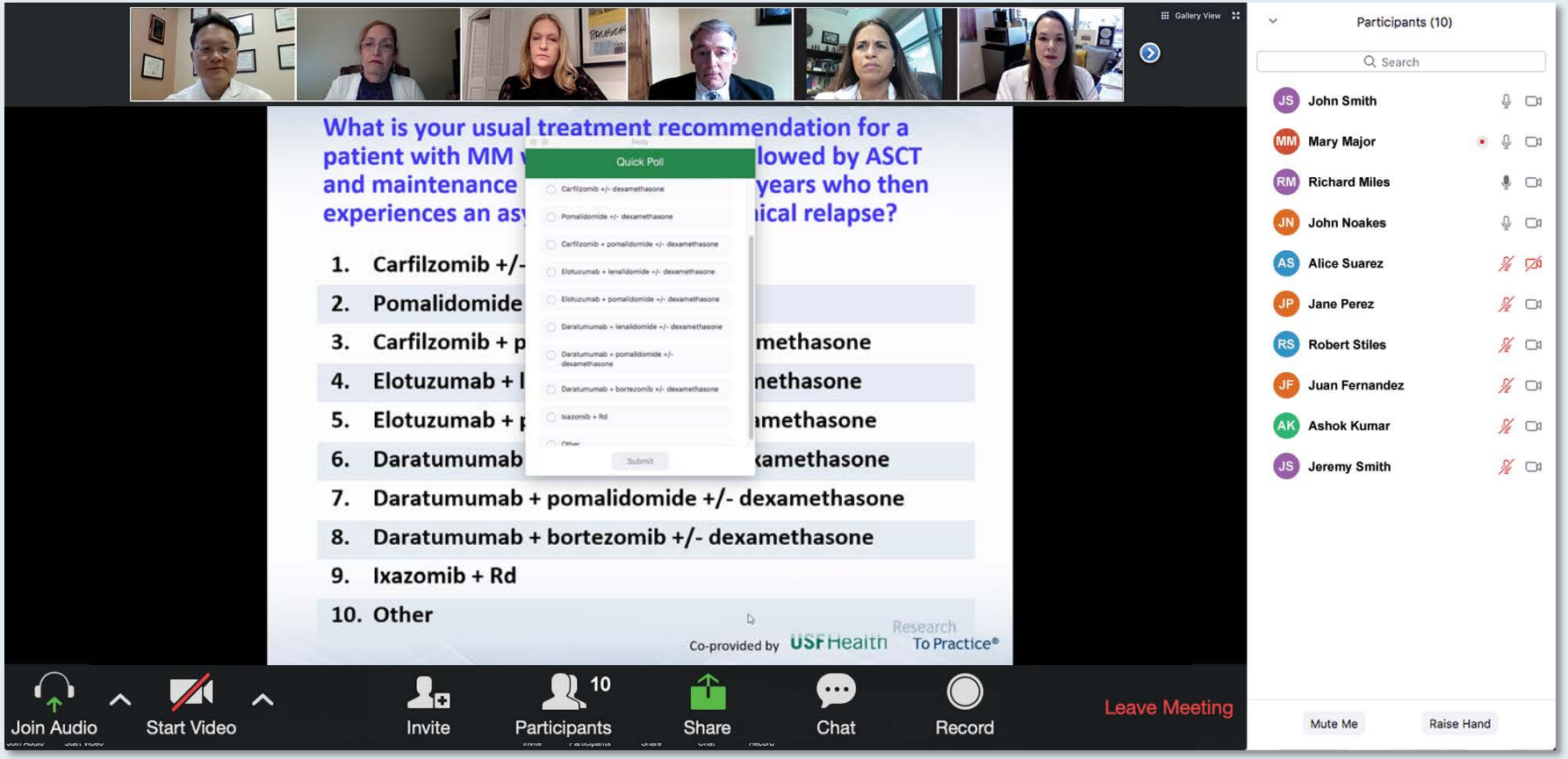

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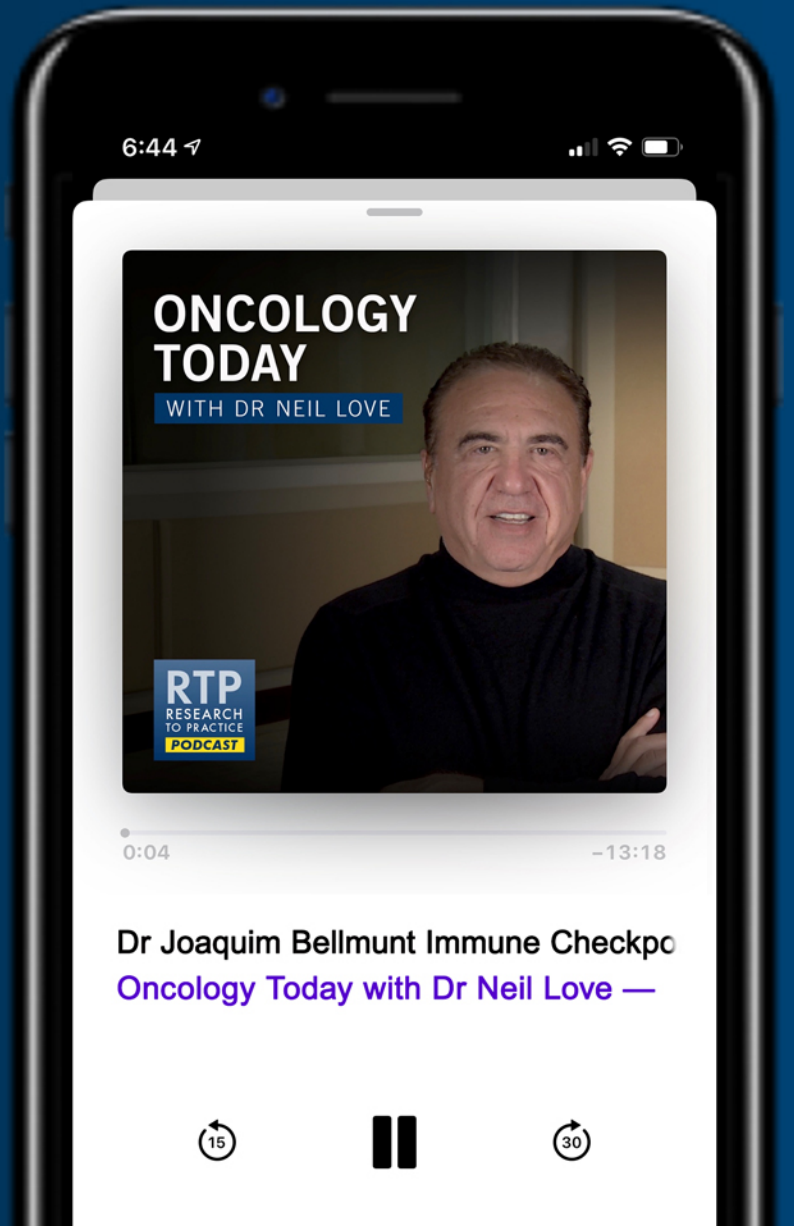

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Agenda

Renal Cell Carcinoma (RCC)

- Module 1: First-line treatment of metastatic RCC
- Module 2: Relapsed disease

Urothelial Bladder Cancer (UBC)

- Module 3: Immune checkpoint inhibitors (ICIs) for non-muscle-invasive UBC
- Module 4: (Neo)adjuvant ICIs
- Module 5: ICIs +/- other systemic therapies; novel strategies
- Module 6: Enfortumab vedotin
- Module 7: Erdafitinib

Agenda

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The Comparison of Cytoreductive Nephrectomy (CN) with Tyrosine Kinase Inhibitor Therapy Alone in Patients with Primary Metastatic Renal Cell Carcinoma (mRCC)

Wheeler SB et al.
Genitourinary Cancers Symposium 2021;Abstract 304.

Long-Term Survival Outcomes of Cytoreductive Nephrectomy Combined with Targeted Therapy for Metastatic Renal Cell Carcinoma: A Systematic Review and Individual Patient Data Meta-Analysis

Esagian SM et al.

Genitourinary Cancers Symposium 2021;Abstract 317.

Cytoreductive Nephrectomy for Favorable Risk Patients with Metastatic Renal Cell Carcinoma? No, Cytoreductive Nephrectomy Should No Longer Be Routinely Performed[1]

Cytoreductive Nephrectomy for Favorable Risk Patients with Metastatic Renal Cell Carcinoma? Yes, Cytoreductive Nephrectomy Should Still Be Considered[2]

[1] Kim HL et al. *Curr Opin Urol* 2020;30(5):743-5.

[2] Meza L et al. *Curr Opin Urol* 2020;30(5):740-2.

Regulatory and reimbursement issues aside, which first-line therapy would you recommend for a 65-year-old patient with a history of nephrectomy for clear-cell RCC who on routine follow-up 4 years later is found to have asymptomatic lung metastases (PS 0)?

1. Nivolumab/ipilimumab
2. Avelumab/axitinib
3. Pembrolizumab/axitinib
4. Nivolumab/cabozantinib
5. Tyrosine kinase inhibitor (TKI) monotherapy
6. Anti-PD-1/PD-L1 monotherapy
7. Other

Regulatory and reimbursement issues aside, which first-line therapy would you recommend for a 65-year-old patient presenting with symptomatic metastatic clear cell RCC with extensive bone involvement?

1. Nivolumab/ipilimumab
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4. Nivolumab/cabozantinib
5. TKI monotherapy
6. Anti-PD-1/PD-L1 monotherapy
7. Other

Regulatory and reimbursement issues aside, which first-line therapy would you recommend for a 65-year-old patient presenting with symptomatic metastatic clear cell RCC with extensive bone involvement who had undergone a kidney transplant?

1. Nivolumab/ipilimumab
2. Avelumab/axitinib
3. Pembrolizumab/axitinib
4. Nivolumab/cabozantinib
5. TKI monotherapy
6. Anti-PD-1/PD-L1 monotherapy
7. Other

Module 1: First-line treatment of metastatic RCC

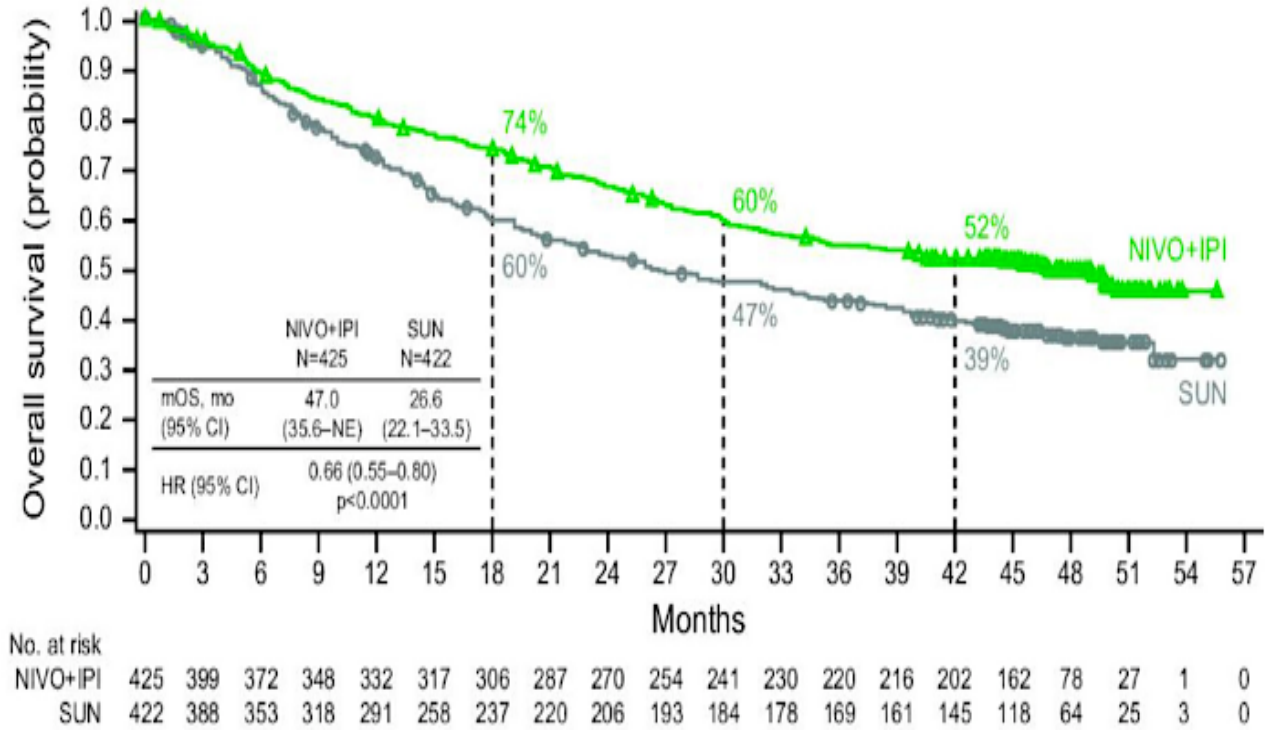
- **Key Relevant Data Sets**
  - CheckMate 214: Nivolumab/ipilimumab (nivo/ipi) vs sunitinib
  - BIONIKK: Nivo/ipi or VEGFR tyrosine kinase inhibitors
  - KEYNOTE-426: Pembrolizumab/axitinib vs sunitinib
  - CLEAR (KEYNOTE-581): Pembrolizumab + lenvatinib
  - JAVELIN Renal 101: Avelumab/axitinib vs sunitinib
  - CheckMate 9ER: Nivolumab/cabozantinib vs sunitinib
  - COSMIC-021: Atezolizumab + cabozantinib

CM 214: Overall Survival 42 Month Min Follow Up by IMDC Risk

Intermediate/poor risk

Median OS, months (95% CI)	
NIVO+IPI	47.0 (35.6–NE)
SUN	26.6 (22.1–33.5)

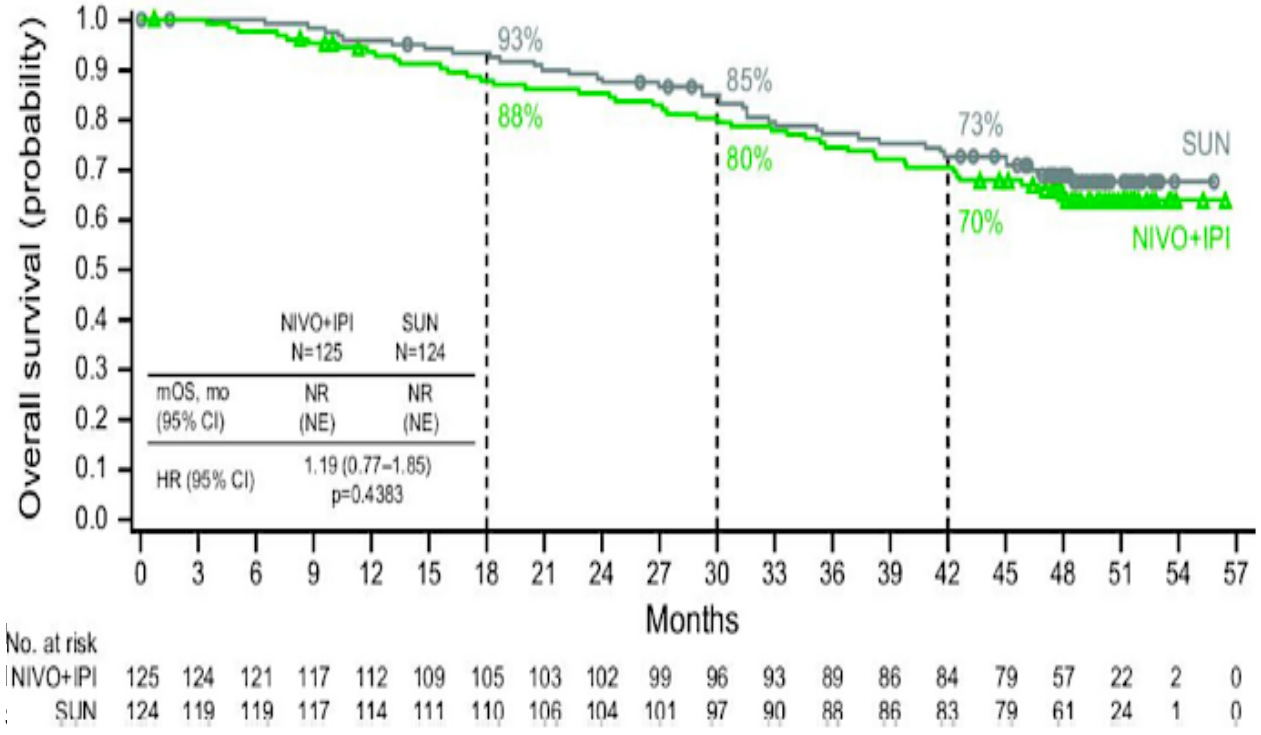
HR (95% CI), 0.66 (0.55–0.80)
P < 0.0001



Favorable risk

Median OS, months (95% CI)	
NIVO+IPI	NR (NE)
SUN	NR (NE)

HR (95% CI), 1.19 (0.73–2.04)
P = 0.4383

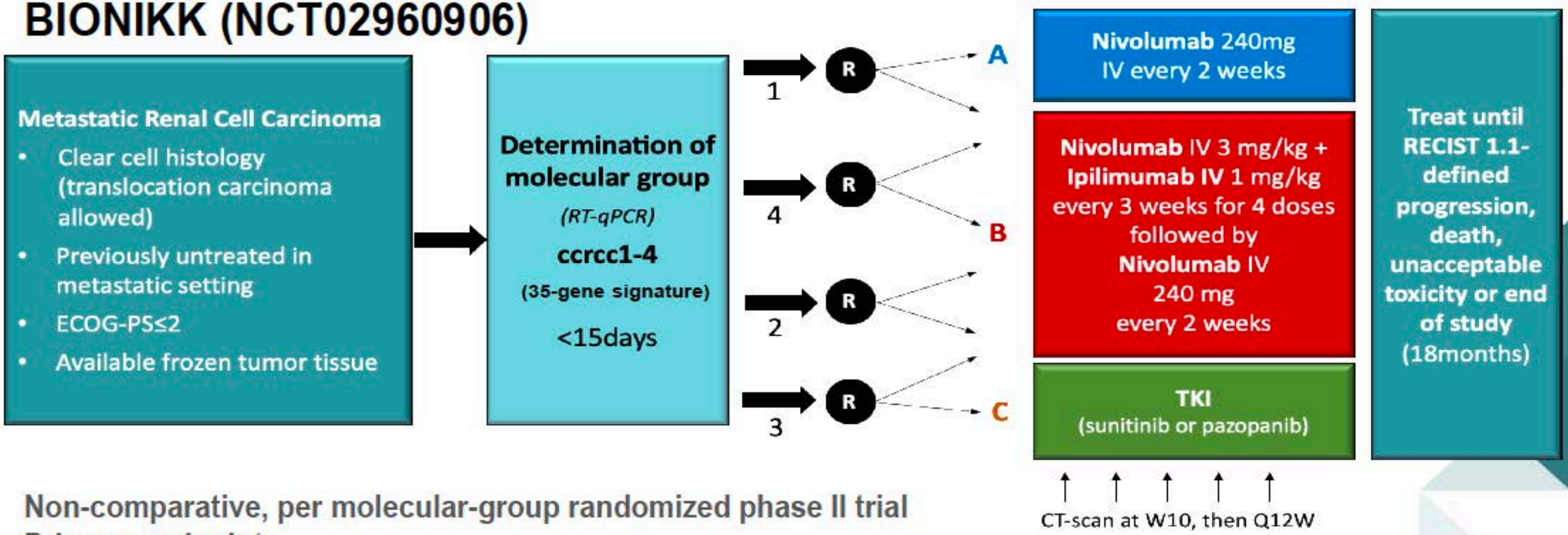


Motzer RJ et al. J Immunother Cancer 2020

Courtesy of David I Quinn, MBBS, PhD

METHODS: study design

BIONIKK (NCT02960906)



Non-comparative, per molecular-group randomized phase II trial

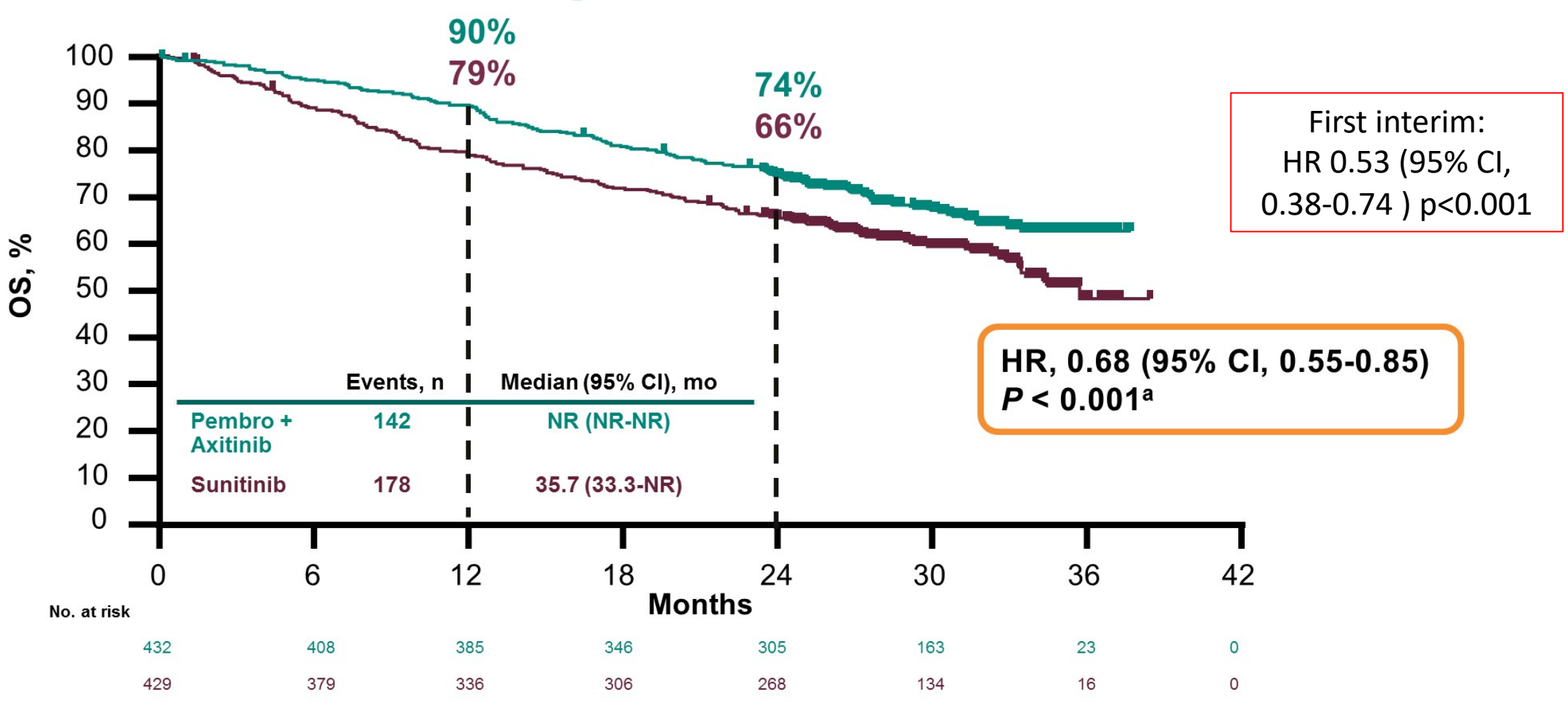
Primary endpoint:

Overall response rate (ORR: CR+PR) using RECIST 1.1 per investigator

Vano Y et al. ESMO 2020;Abstract LBA25.

Courtesy of David I Quinn, MBBS, PhD

KEYNOTE-426: OS in the ITT Population



First interim:
HR 0.53 (95% CI, 0.38-0.74) p<0.001

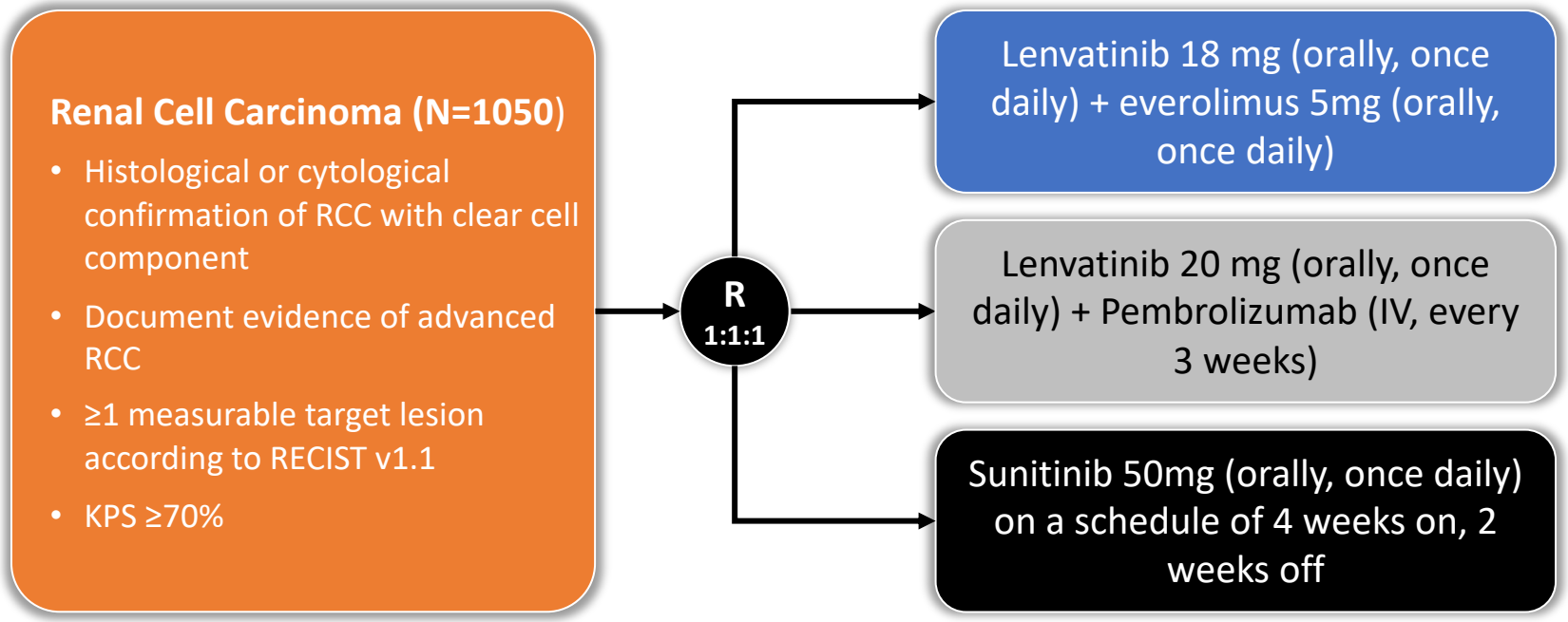
HR, 0.68 (95% CI, 0.55-0.85)
***P* < 0.001[a]**

[a]Because superiority of pembrolizumab + axitinib was shown at the first interim analysis, no alpha was allocated to OS; only nominal *P* values are reported. Data cutoff: January 6, 2020.

Plimack E et al. ASCO 2020;Abstract 5001; Powles T et al. *Lancet Oncol* 2020.

Courtesy of David I Quinn, MBBS, PhD

CLEAR: A Phase III Study Comparing Lenvatinib + Everolimus vs Lenvatinib + Pembrolizumab vs Sunitinib in Patients With Advanced or Metastatic RCC



Study Endpoints

- Primary: PFS
- Secondary: OS, ORR, safety and tolerability, HRQoL

Stratification

- Geographic region (western Europe and North America vs other)
- MSKCC prognostic groups (favorable, intermediate and poor risk)

https://clinicaltrials.gov/ct2/show/NCT02811861

Courtesy of David I Quinn, MBBS, PhD

CLEAR Trial Meets Primary and Secondary Endpoints

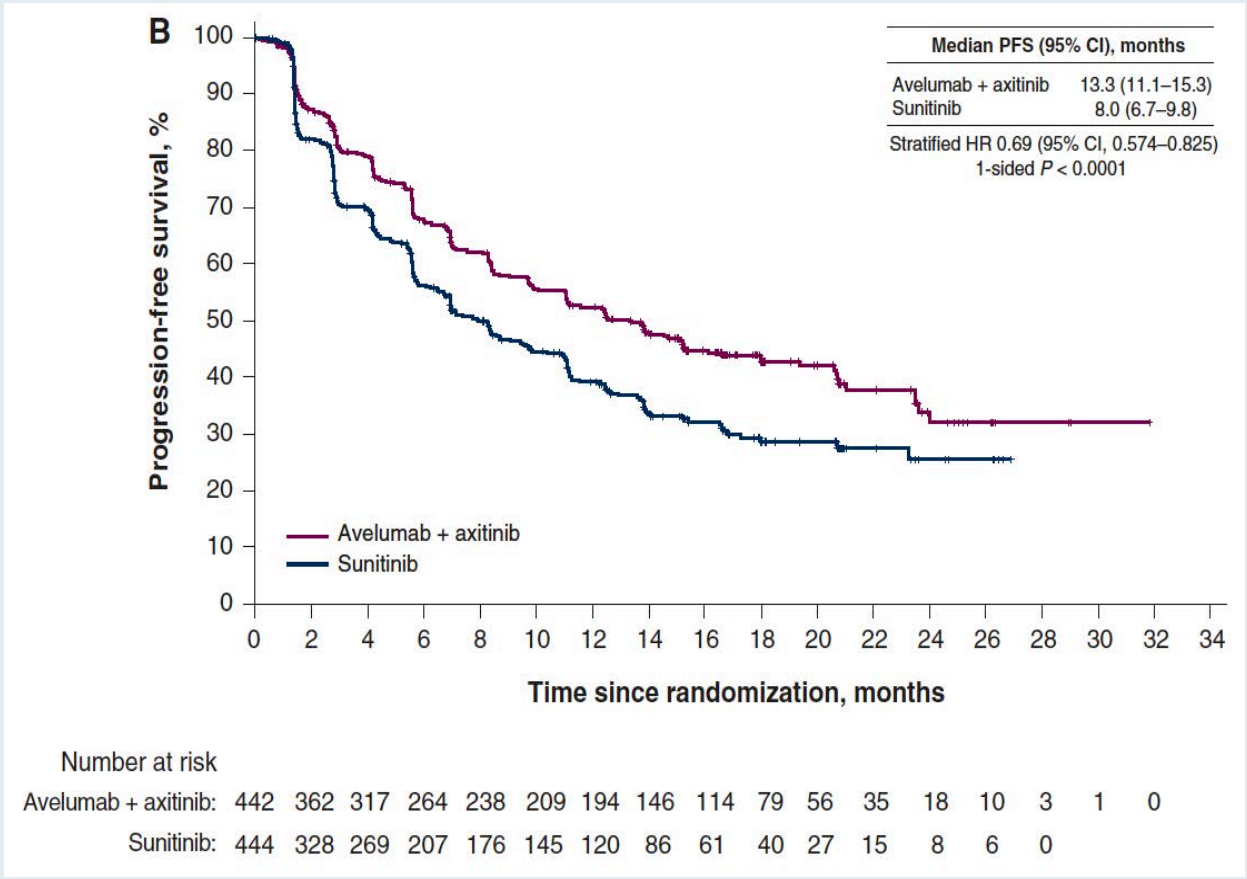
Press Release: November 20, 2020

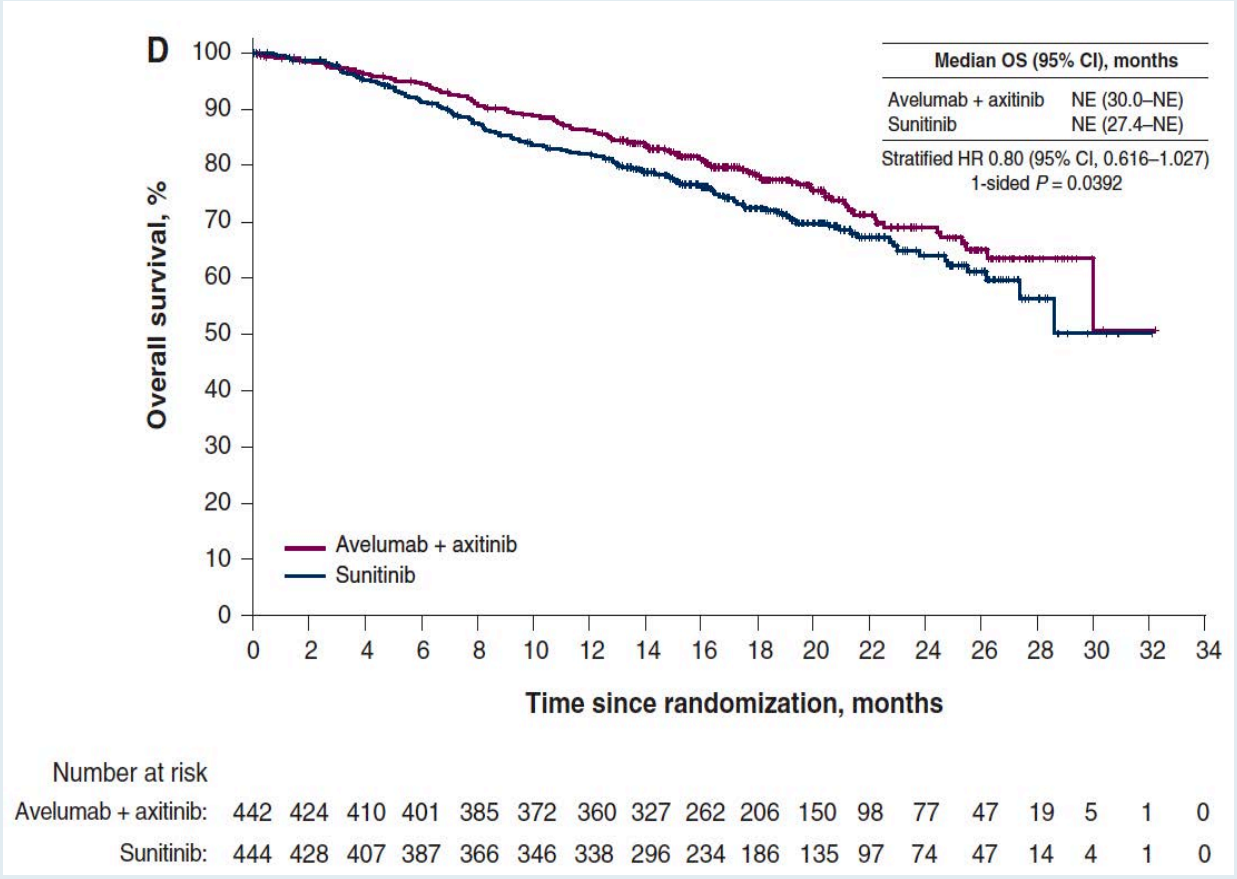
New investigational data were announced demonstrating positive top-line results from the pivotal Phase III CLEAR trial (Study 307)/KEYNOTE-581) evaluating lenvatinib, the orally available multiple receptor tyrosine kinase inhibitor, with pembrolizumab, the anti-PD-1 therapy, as well as lenvatinib with everolimus versus sunitinib for the first-line treatment of advanced renal cell carcinoma (RCC).

Lenvatinib with pembrolizumab met the trial's primary endpoint of progression-free survival (PFS) and its key secondary endpoints of overall survival (OS) and objective response rate (ORR), demonstrating a statistically significant and clinically meaningful improvement in PFS, OS and ORR versus sunitinib in the intention-to-treat (ITT) study population. Lenvatinib with everolimus also met the trial's primary endpoint of PFS and a key secondary endpoint of ORR, demonstrating a statistically significant and clinically meaningful improvement in PFS and ORR versus sunitinib in the ITT study population. The ITT population included patients across all Memorial Sloan Kettering Cancer Center risk groups (favorable, intermediate and poor). The safety profiles of both lenvatinib/pembrolizumab and lenvatinib/everolimus were consistent with previously reported studies. These data will be presented at an upcoming medical meeting.

https://www.eisai.com/news/2020/news202073.html

JAVELIN Renal 101: Avelumab/Axitinib as First-Line Therapy
Updated Efficacy Results





Choueiri TK et al. *Ann Oncol* 2020.

JAVELIN Renal 101: Avelumab/Axitinib as First-line Therapy

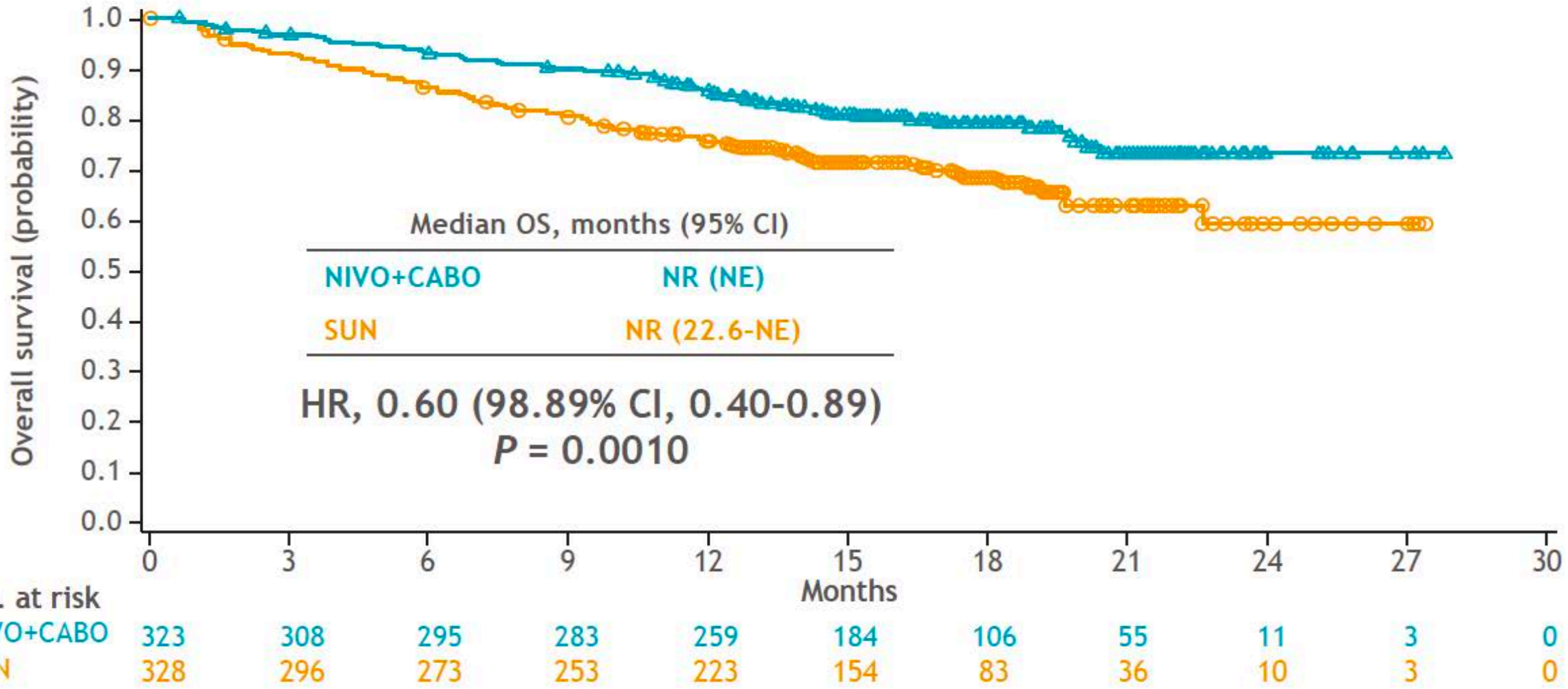
With further follow up, the PFS advantage for AA over SU is very consistent but OS remains elusive.

The lack of OS advantage, relegates the use of AA to a place behind behind NI, PA and CN regimens and possibly LenPem.

Choueiri TK et al. *Ann Oncol* 2020.

Courtesy of David I Quinn, MBBS, PhD

CheckMate 9ER: Overall survival

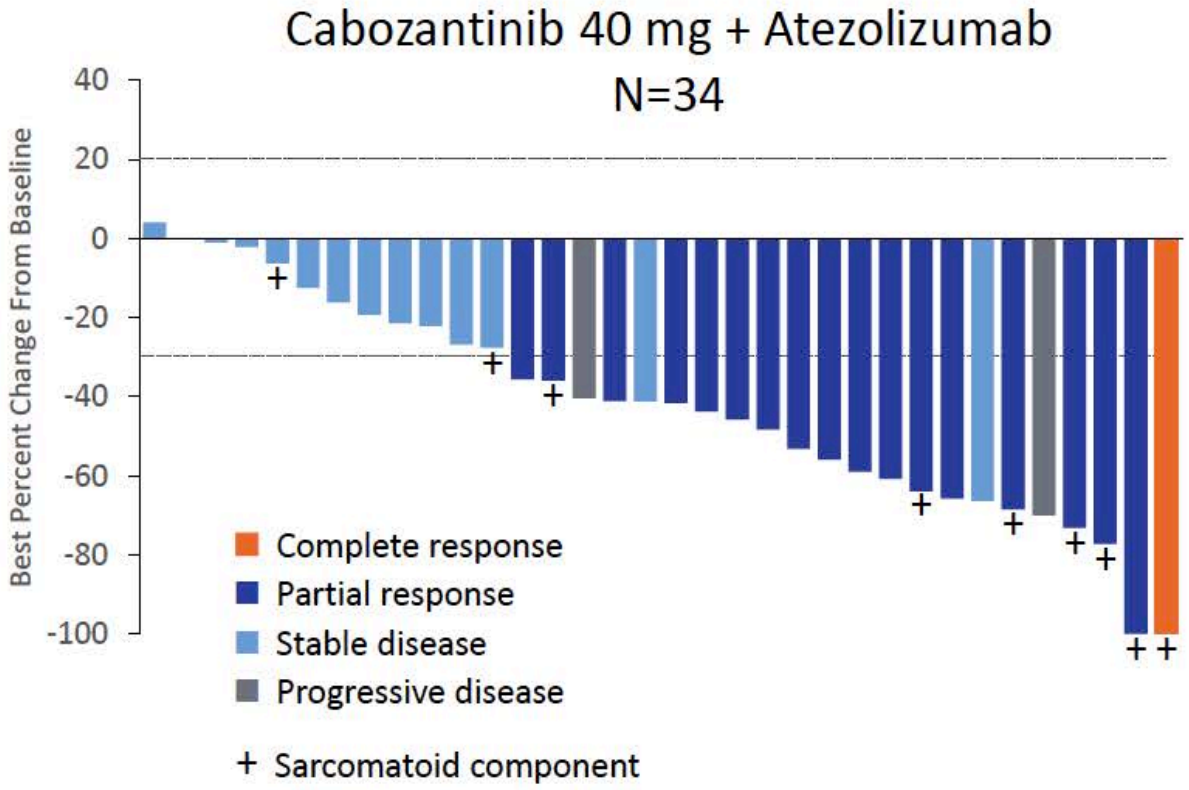


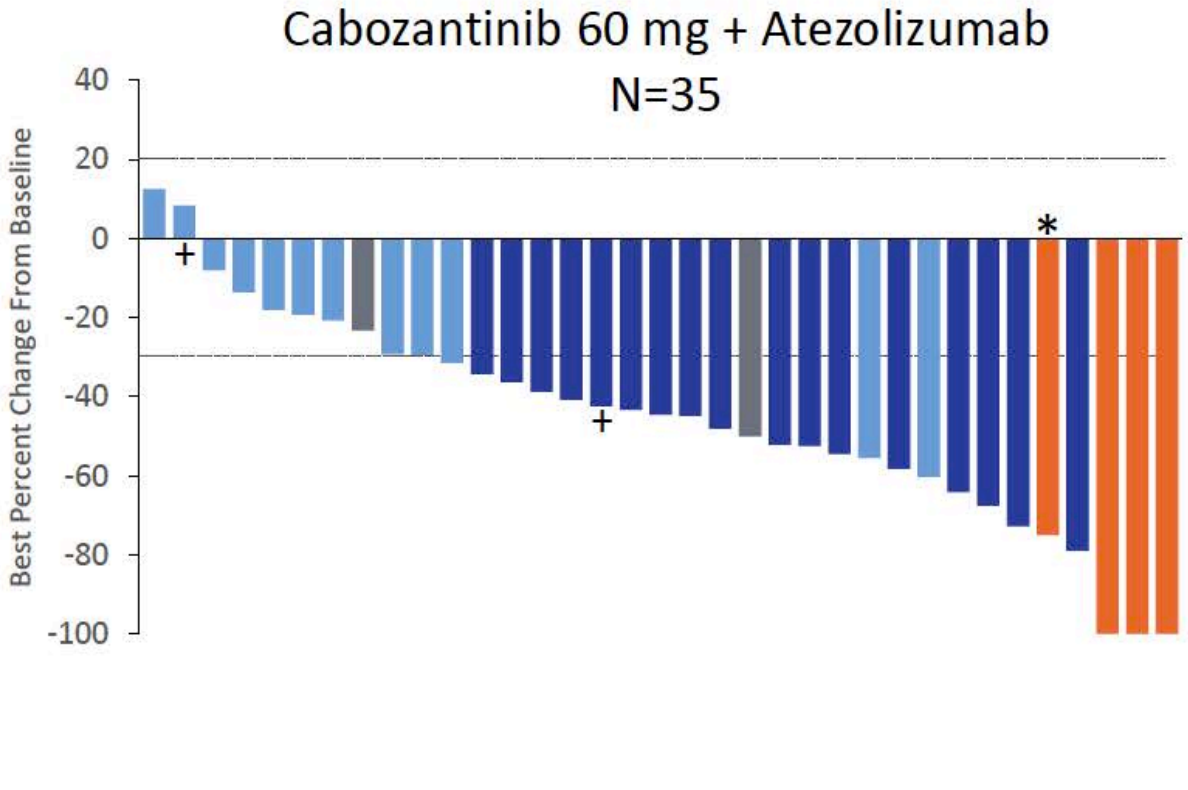
Minimum study follow-up, 10.6 months.
NE, not estimable; NR, not reached.

Choueiri T et al. ESMO 2020;Abstract 696O.

Courtesy of David I Quinn, MBBS, PhD

COSMIC-021: Atezolizumab/Cabozantinib as First-Line Therapy





Pal S et al. ESMO 2020;Abstract 702O.

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- **Module 2: Relapsed disease**

Urothelial Bladder Cancer (UBC)

- Module 3: Immune checkpoint inhibitors (ICIs) for non-muscle-invasive UBC
- Module 4: (Neo)adjuvant ICIs
- Module 5: ICIs +/- other systemic therapies; novel strategies
- Module 6: Enfortumab vedotin
- Module 7: Erdafitinib

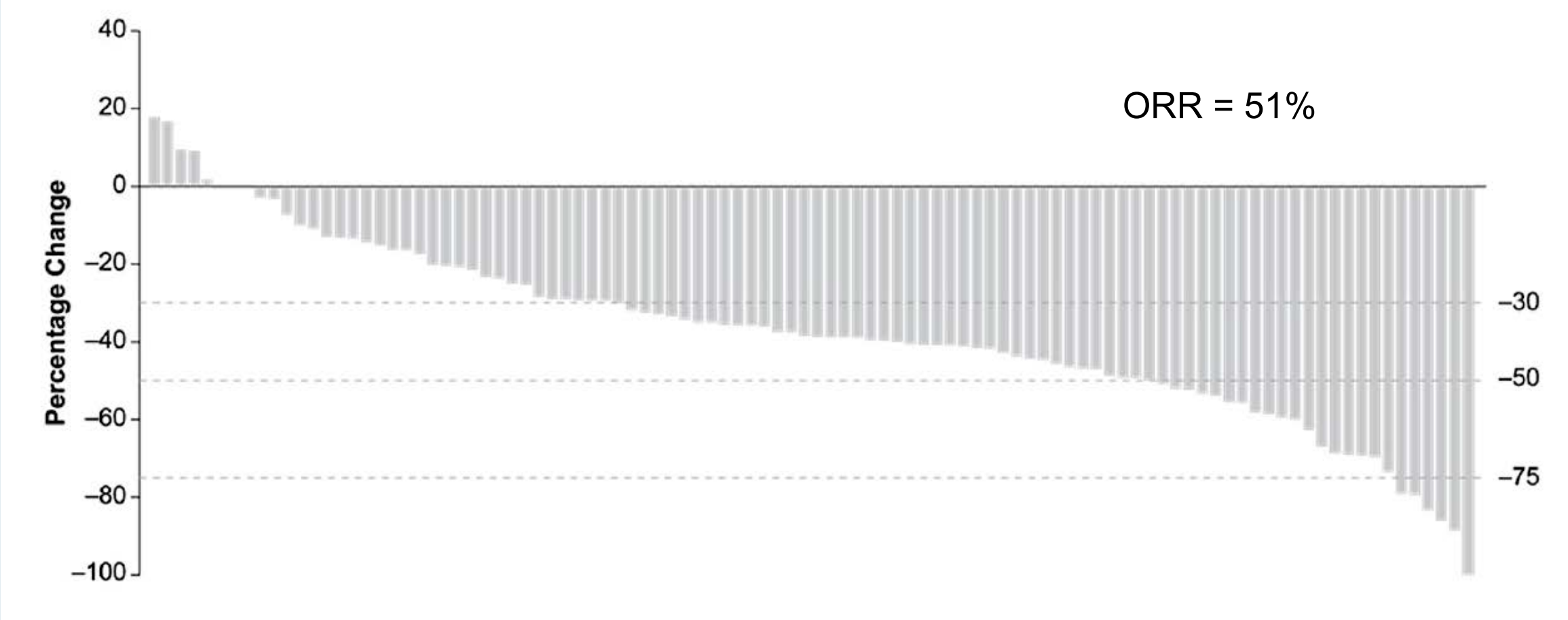
Have you administered or would you administer nivolumab/ipilimumab to a patient with metastatic RCC who had received a prior checkpoint inhibitor either alone or in combination with an anti-angiogenic?

1. I have
2. I have not but would for the right patient
3. I have not and would not

Module 2: Relapsed disease

- **Key Relevant Data Set**
  - Pembrolizumab + lenvatinib after prior ICI therapy

Lenvatinib/Pembrolizumab for Previously Treated Advanced RCC: Response



Lee C-H et al. ASCO 2020;Abstract 5008.

Agenda

Renal Cell Carcinoma (RCC)

- Module 1: First-line treatment of metastatic RCC
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Module 3: Immune checkpoint inhibitors (ICIs) for non-muscle-invasive UBC

- **Key Relevant Data Set**
  - KEYNOTE-057: Pembrolizumab for BCG-unresponsive, high-risk non-muscle invasive bladder cancer

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 (NCT02625961), 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

Pembrolizumab for the Treatment of Patients with High-Risk (HR) Non-Muscle-Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guérin: Extended Follow-Up of KEYNOTE-057 Cohort A

Balar AV et al.

Genitourinary Cancers Symposium 2021;Abstract 451.

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If the administration of adjuvant nivolumab after cystectomy led to a hazard rate of 0.2 for disease-free survival but the data were immature for overall survival, would you want to use nivolumab as adjuvant therapy?

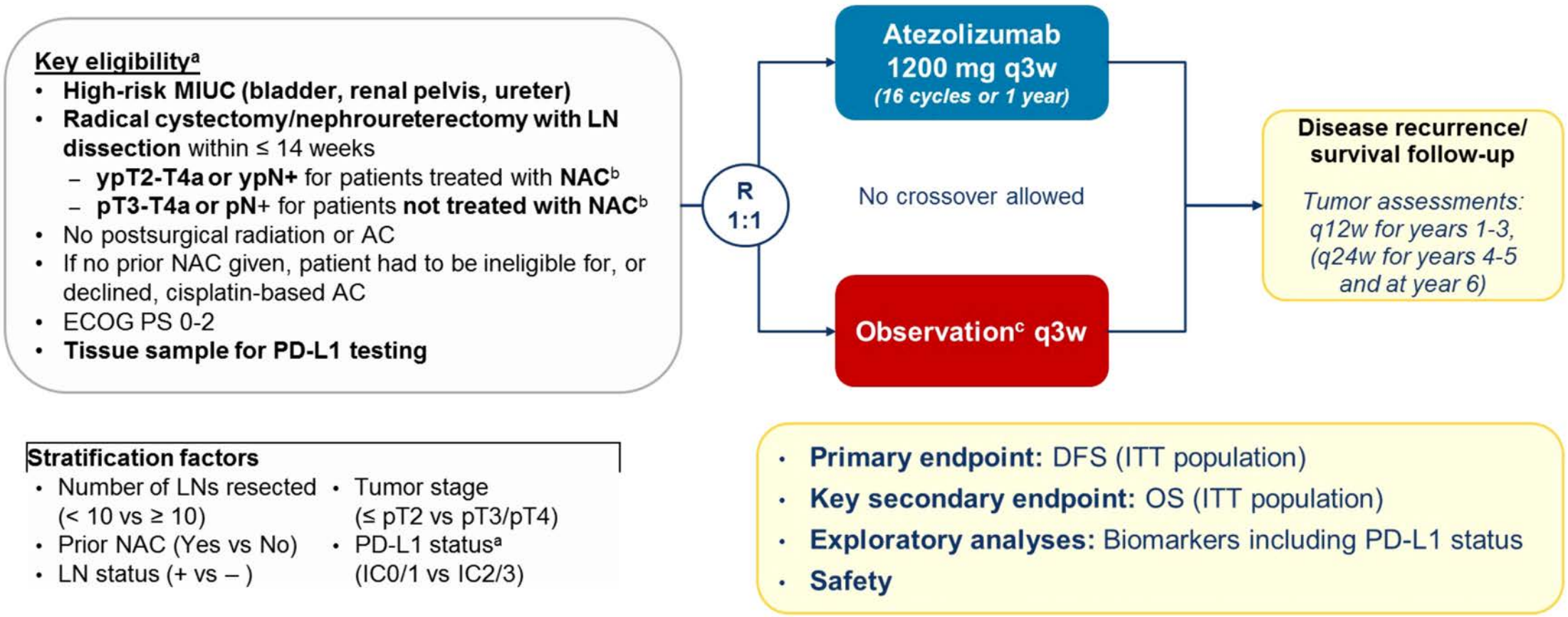
1. Yes
2. No

Module 4: (Neo)adjuvant ICIs

- **Key Relevant Data Sets**
  - IMvigor010: Adjuvant atezolizumab + chemotherapy
  - CheckMate 274: Adjuvant nivolumab vs placebo

Earlier-Stage Disease: IMvigor010

IMvigor010: Primary analysis from a phase III randomized study of adjuvant atezolizumab (atezo) versus observation (obs) in high-risk muscle-invasive urothelial carcinoma (MIUC)



AC, adjuvant chemotherapy; DFS, disease-free survival; ITT, intention to treat; LN, lymph node; MIUC, muscle-invasive UC. [a] Protocol amendments broadened eligibility to "all-comers" (initially, only PD-L1–selected patients were enrolled [IC2/3: PD-L1 expression on tumor-infiltrating immune cells (IC) ≥ 5% of tumor area [VENTANA SP142 IHC assay]) and to patients with MIUC (initially, only patients with muscle-invasive bladder cancer were enrolled). [b] Upper-tract UC staging: ypT2-4 or ypN+ (with NAC) and pT3-4 or pN+ (without NAC). [c] Alternating clinic visits and phone calls.

Hussain MHA et al. Presented at ASCO Annual Meeting 2020 (Abstract 5000)

Courtesy of Sumanta K Pal, MD

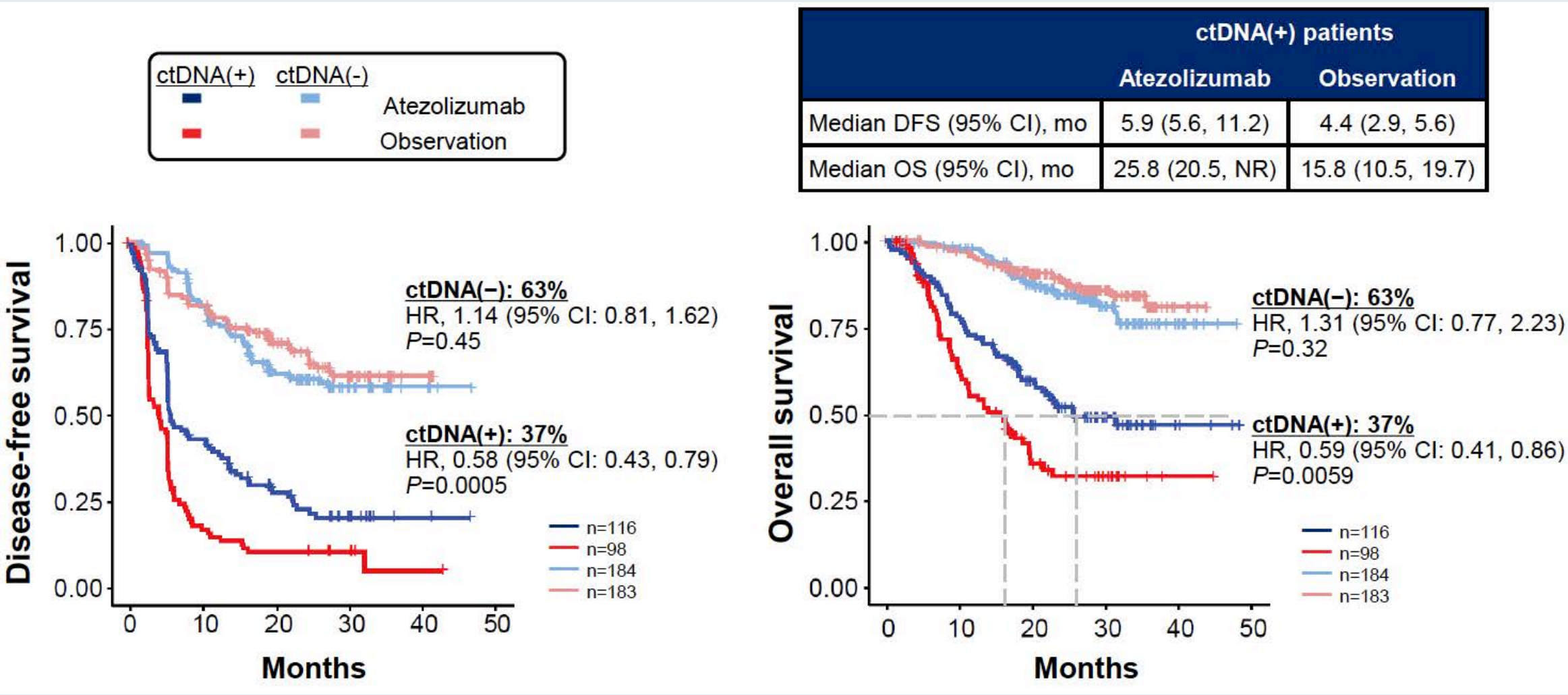
Clinical Outcomes in Post-operative ctDNA-Positive Muscle-Invasive Urothelial Carcinoma Patients After Atezolizumab Adjuvant Therapy

Powles T et al.

ESMO Immuno-Oncology Virtual Congress 2020;Abstract 10.

IMvigor010: Disease-Free and Overall Survival with Atezolizumab versus Observation

	ctDNA(+) patients	
	Atezolizumab	Observation
Median DFS (95% CI), mo	5.9 (5.6, 11.2)	4.4 (2.9, 5.6)
Median OS (95% CI), mo	25.8 (20.5, NR)	15.8 (10.5, 19.7)



Powles T et al. ESMO Immuno-Oncology Virtual Congress 2020;Abstract 10.

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

Press Release – September 24, 2020

In an interim analysis, CheckMate 274, a pivotal Phase III 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 both in 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.

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What would be your preferred first-line treatment regimen for a 65-year-old patient with metastatic UBC?

1. Cisplatin/gemcitabine
2. Carboplatin/gemcitabine
3. PD-1/PD-L1 monotherapy
4. Test PD-L1 level and administer anti-PD-1/PD-L1 monotherapy if PD-L1 positive
5. Cisplatin/gemcitabine → maintenance avelumab
6. Carboplatin/gemcitabine → maintenance avelumab
7. Platinum-based chemotherapy → other anti-PD-1 maintenance
8. Other

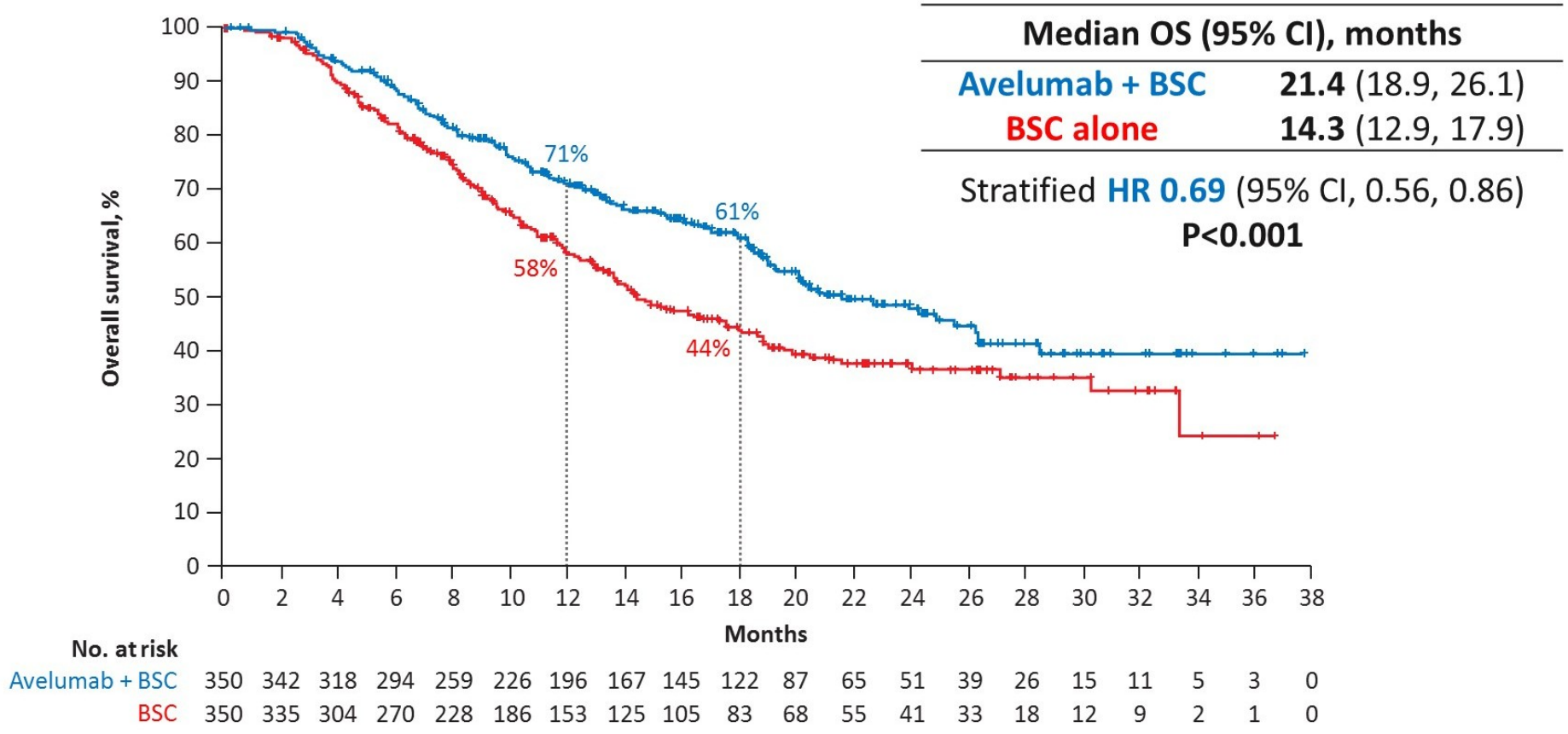
Module 5: ICIs with and without other systemic therapies; novel strategies

- **Key Relevant Data Sets**
  - JAVELIN Bladder 100: Avelumab maintenance therapy
  - KEYNOTE-361: Pembrolizumab +/- chemotherapy
  - DANUBE: Durvalumab +/- tremelimumab vs chemotherapy
  - Phase II trial of single-agent cabozantinib
  - Phase I trial of cabozantinib and nivolumab +/- ipilimumab

Advanced Disease: JAVELIN Bladder 100

Avelumab maintenance therapy for advanced or metastatic urothelial carcinoma

OS in the overall population



Median OS (95% CI), months	
Avelumab + BSC	**21.4** (18.9, 26.1)
BSC alone	**14.3** (12.9, 17.9)

Stratified **HR 0.69** (95% CI, 0.56, 0.86)

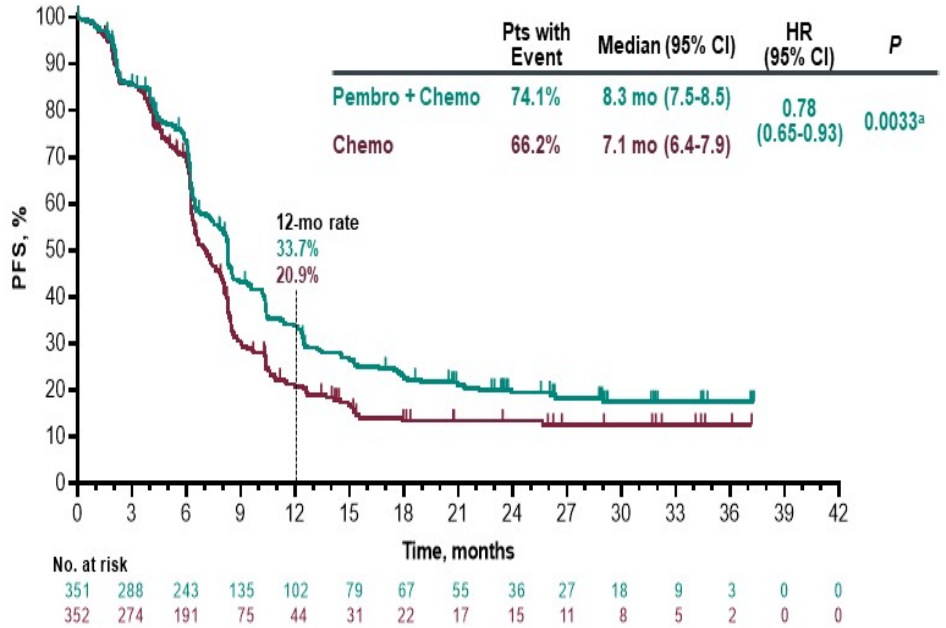
P<0.001

Powles T et al. N Engl J Med 2020 Sep 4;383 (13): 1218-1230; Presented at ASCO Annual Meeting 2020 (Abstract LBA1)

Advanced Disease: First-Line Pembrolizumab

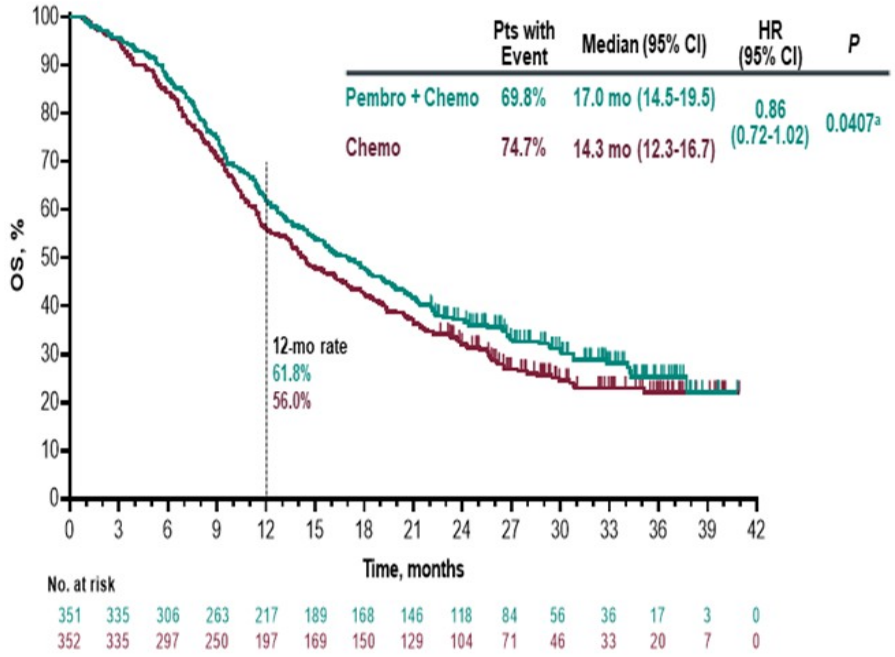
Pembrolizumab (P) combined with chemotherapy (C) vs C alone as first line(1L) therapy for advanced urothelial carcinoma (UC): KEYNOTE-361

PFS by BICR: Pembro + Chemo vs Chemo, ITT Population (Primary Endpoint)



aP-value boundary of significance at final analysis ≤0.0019.
PFS assessed per RECIST v1.1. Data cutoff date: April 29, 2020.

OS: Pembro + Chemo vs Chemo, ITT Population

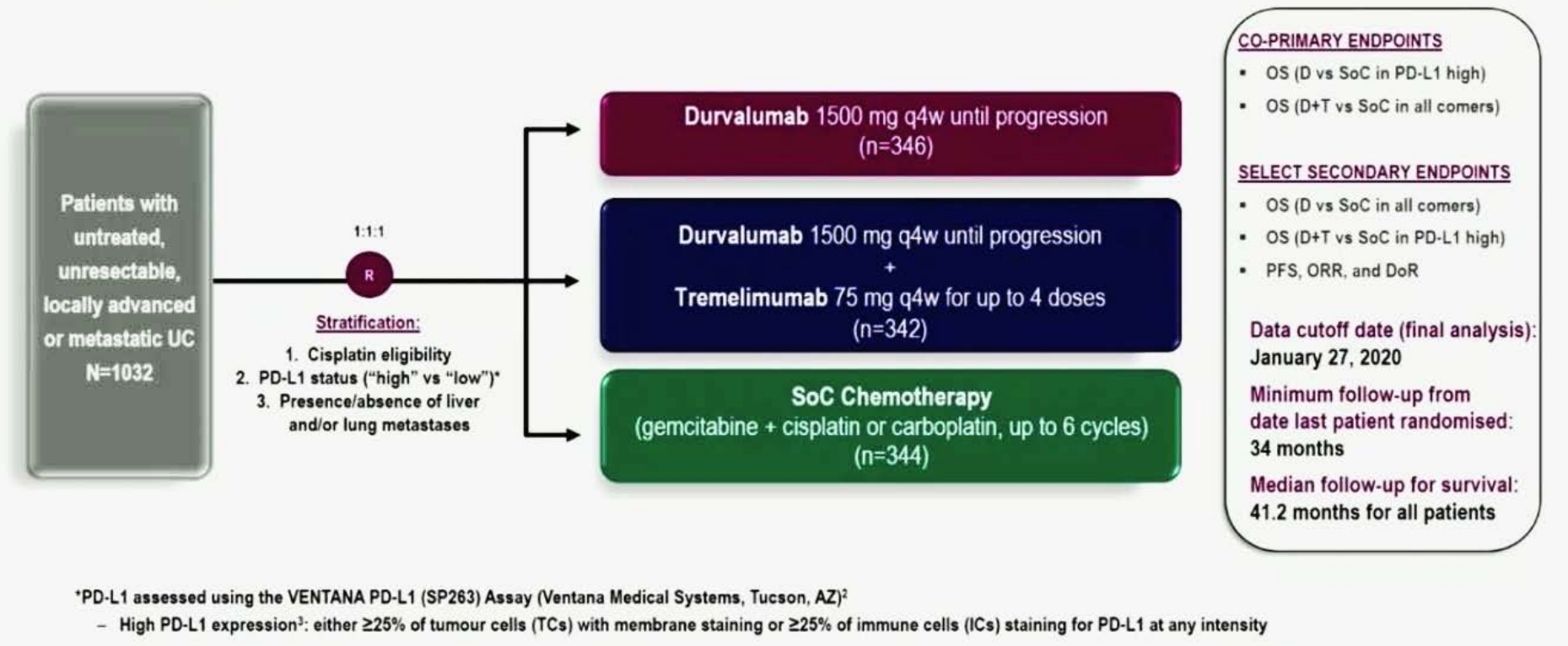


aP-value boundary of significance at final analysis ≤0.0142. Per the statistical analysis plan, no further formal statistical testing was performed.
Data cutoff date: April 29, 2020.

Alva A et al. Presented at the ESMO 2020 Virtual Congress (Abstract LBA23)

Advanced Disease: DANUBE

Durvalumab alone and durvalumab plus tremelimumab versus chemotherapy in previously untreated patients with unresectable, locally advanced or metastatic urothelial carcinoma (DANUBE): a randomised, open-label, multicentre, phase 3 trial

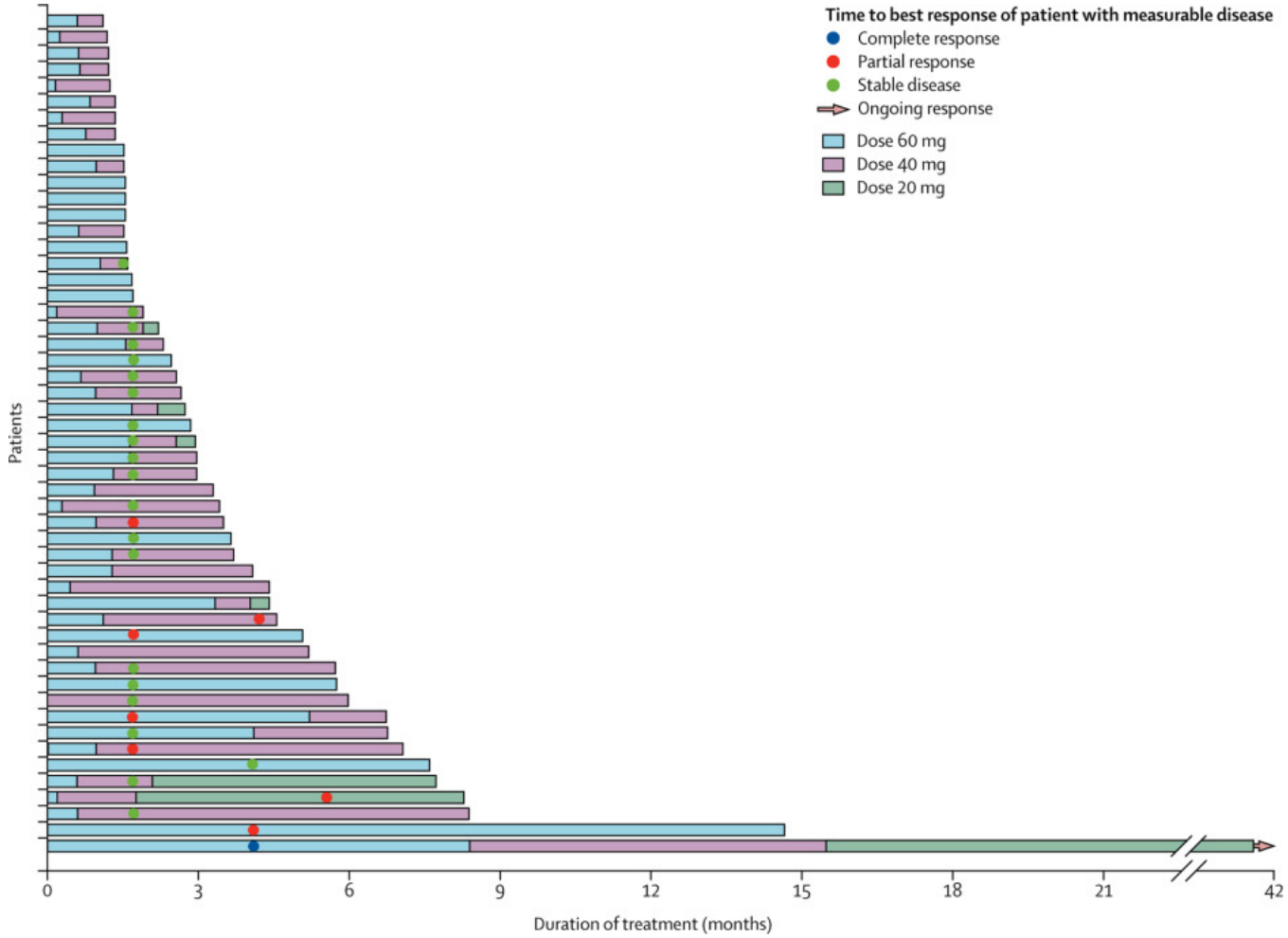


Powles T et al; DANUBE study investigators Lancet Oncol. 2020 Dec;21(12):1574-1588; Presented at the ESMO 2020 Virtual Congress (Abstract 697O)

Courtesy of Sumanta K Pal, MD

Advanced Disease: Platinum-Refractory mUBC

Cabozantinib in patients with platinum-refractory metastatic urothelial carcinoma: an open-label, single-centre, phase 2 trial



Apolo AB et al. Lancet Oncol. 2020 Aug;21(8):1099-1109; Kikuchi E, Hayakawa N. Lancet Oncol. 2020 Aug;21(8):1005-1006

Courtesy of Sumanta K Pal, MD

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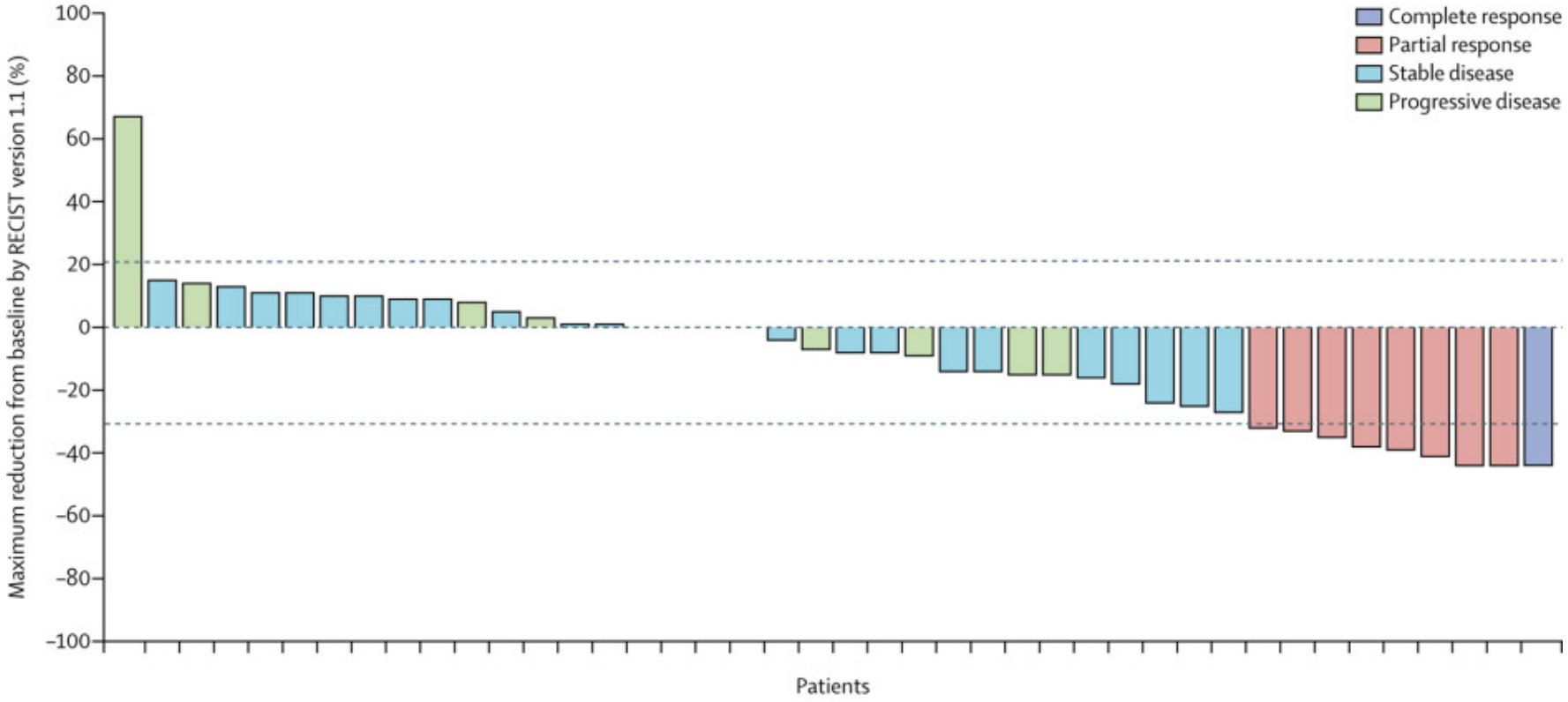

Apolo AB et al. Lancet Oncol. 2020 Aug;21(8):1099-1109; Kikuchi E, Hayakawa N. Lancet Oncol. 2020 Aug;21(8):1005-1006

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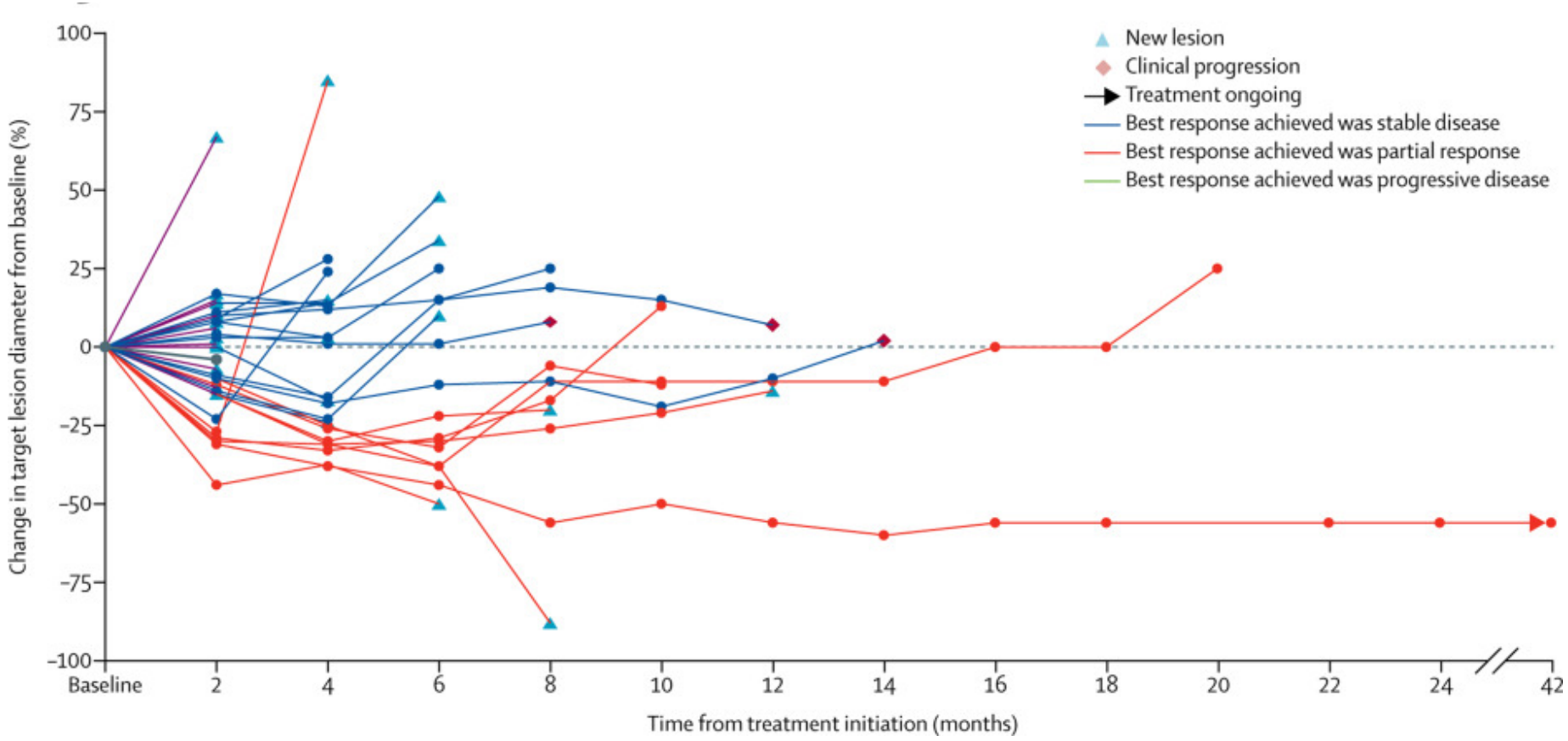
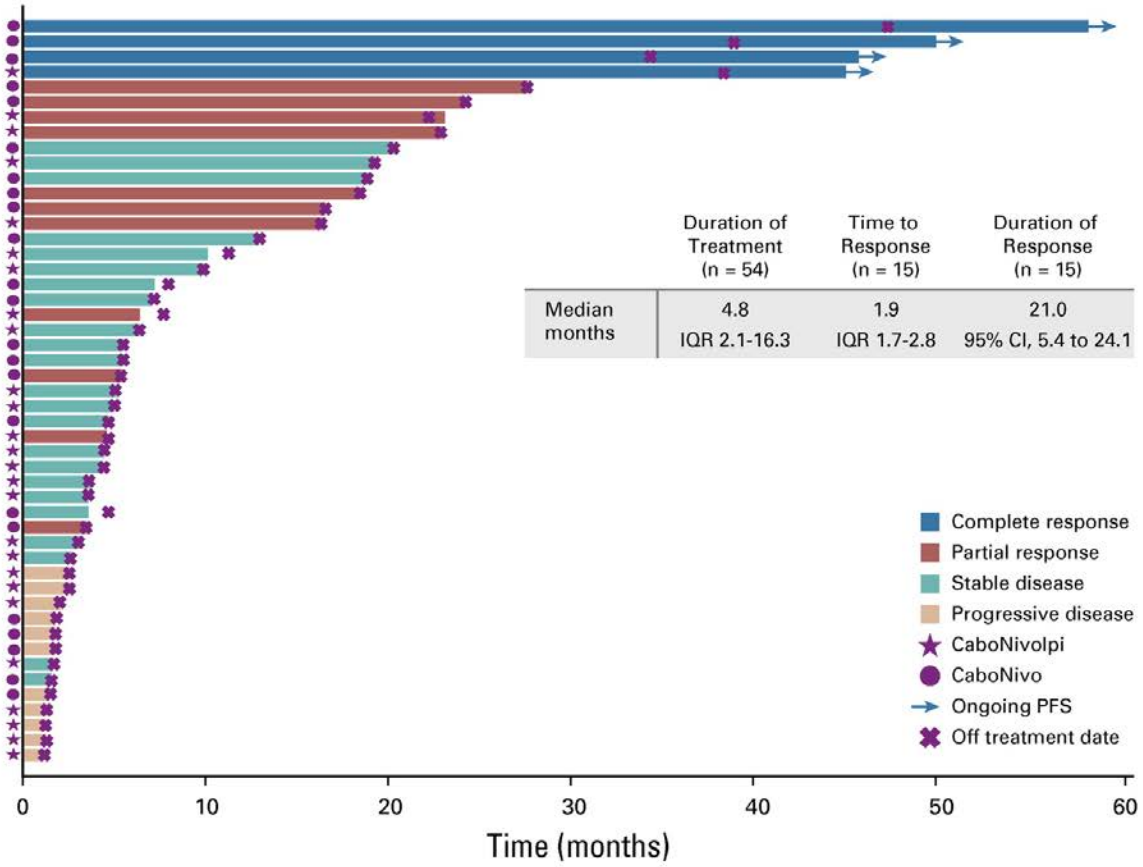


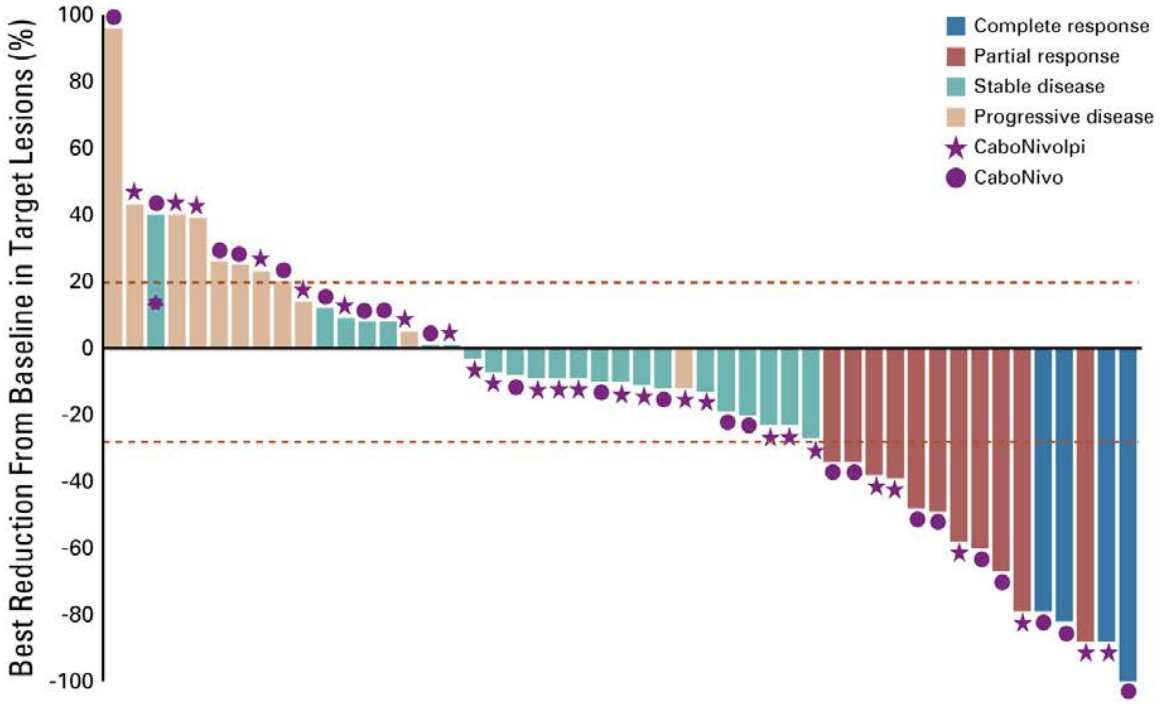
Apolo AB et al. Lancet Oncol. 2020 Aug;21(8):1099-1109; Kikuchi E, Hayakawa N. Lancet Oncol. 2020 Aug;21(8):1005-1006

Courtesy of Sumanta K Pal, MD

Advanced Disease: Platinum-Refractory mUBC

Phase I Study of Cabozantinib and Nivolumab Alone or With Ipilimumab for Advanced or Metastatic Urothelial Carcinoma and Other Genitourinary Tumors





Apolo AB et al. J Clin Oncol. 2020 Nov 1;38(31):3672-3684

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How would you generally sequence enfortumab vedotin and erdafitinib for a patient with metastatic UBC who is eligible to receive both agents?

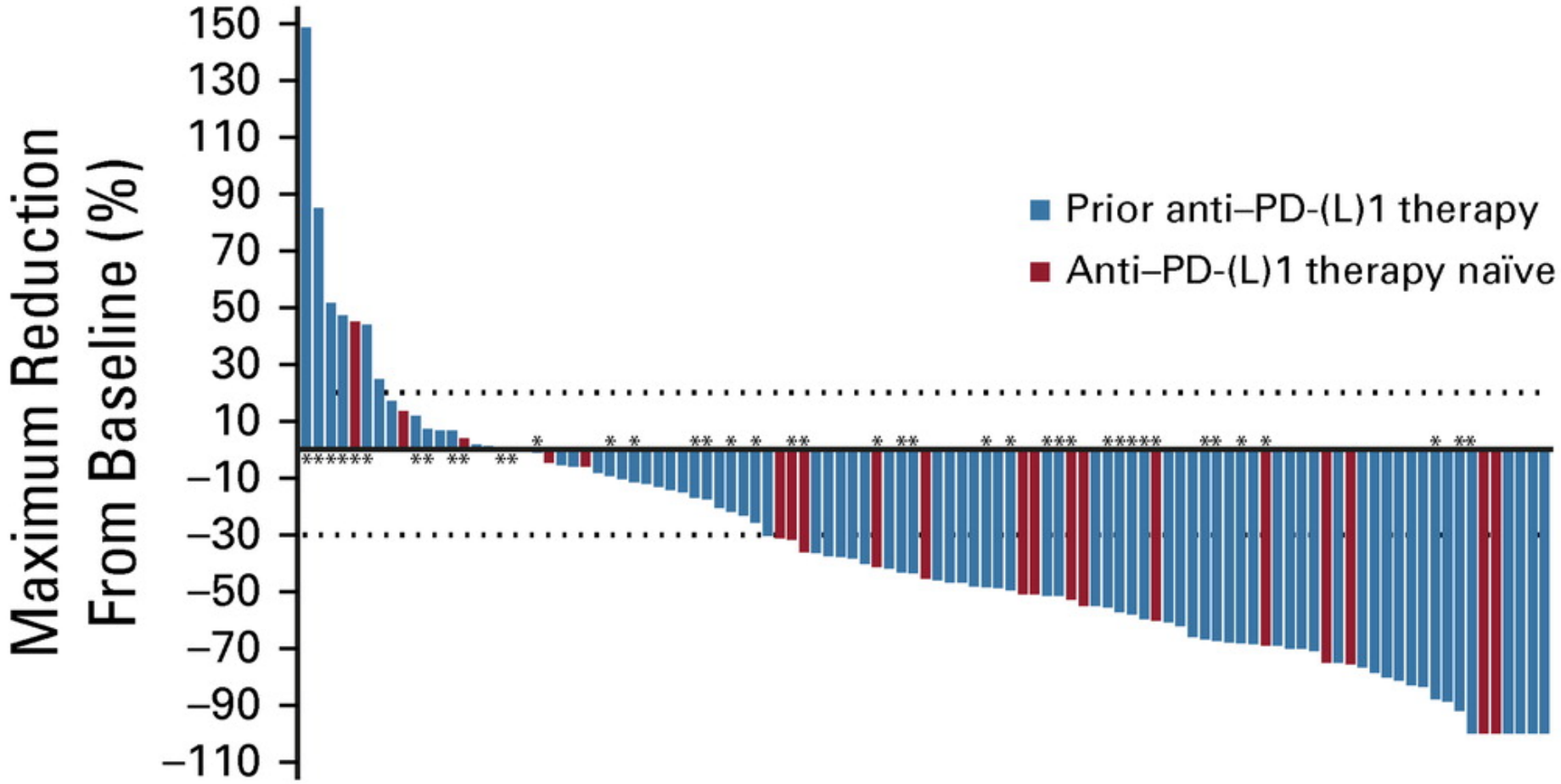
1. Enfortumab vedotin → erdafitinib
2. Erdafitinib → enfortumab vedotin

Module 6: Enfortumab vedotin

- **Key Relevant Data Sets**
  - EV-101: Single-agent enfortumab vedotin
  - EV-103: Enfortumab vedotin + pembrolizumab

Advanced Disease: Enfortumab Vedotin

EV-101: A Phase I Study of Single-Agent Enfortumab Vedotin in Patients With Nectin-4-Positive Solid Tumors, Including Metastatic Urothelial Carcinoma

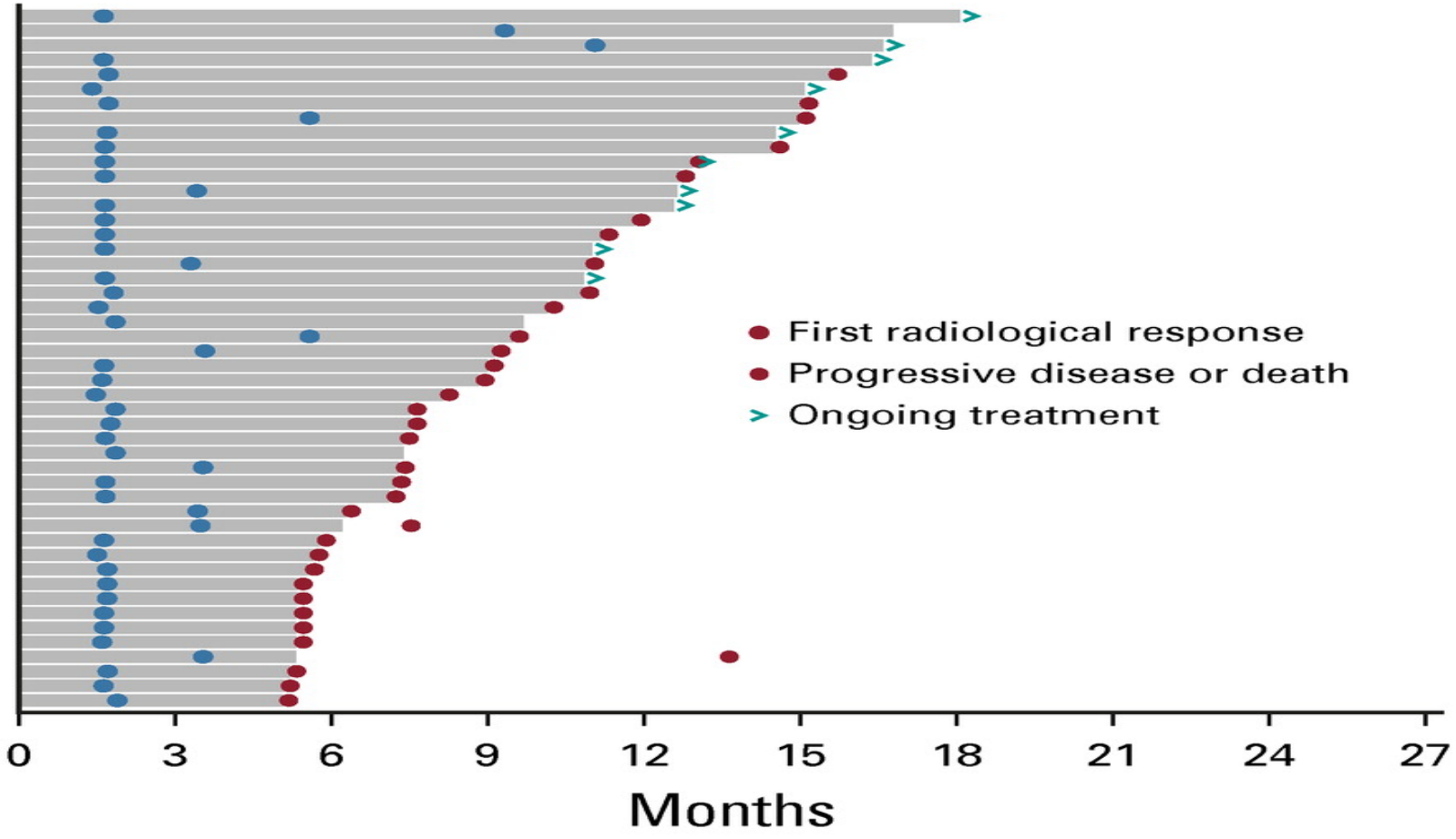


Rosenberg J et al. J Clin Oncol. 2020 Apr 1;38(10):1041-1049

Courtesy of Sumanta K Pal, MD

Advanced Disease: Enfortumab Vedotin

EV-101: A Phase I Study of Single-Agent Enfortumab Vedotin in Patients With Nectin-4-Positive Solid Tumors, Including Metastatic Urothelial Carcinoma



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Courtesy of Sumanta K Pal, MD

Advanced Disease: Enfortumab Vedotin

EV-101: A Phase I Study of Single-Agent Enfortumab Vedotin in Patients With Nectin-4-Positive Solid Tumors, Including Metastatic Urothelial Carcinoma

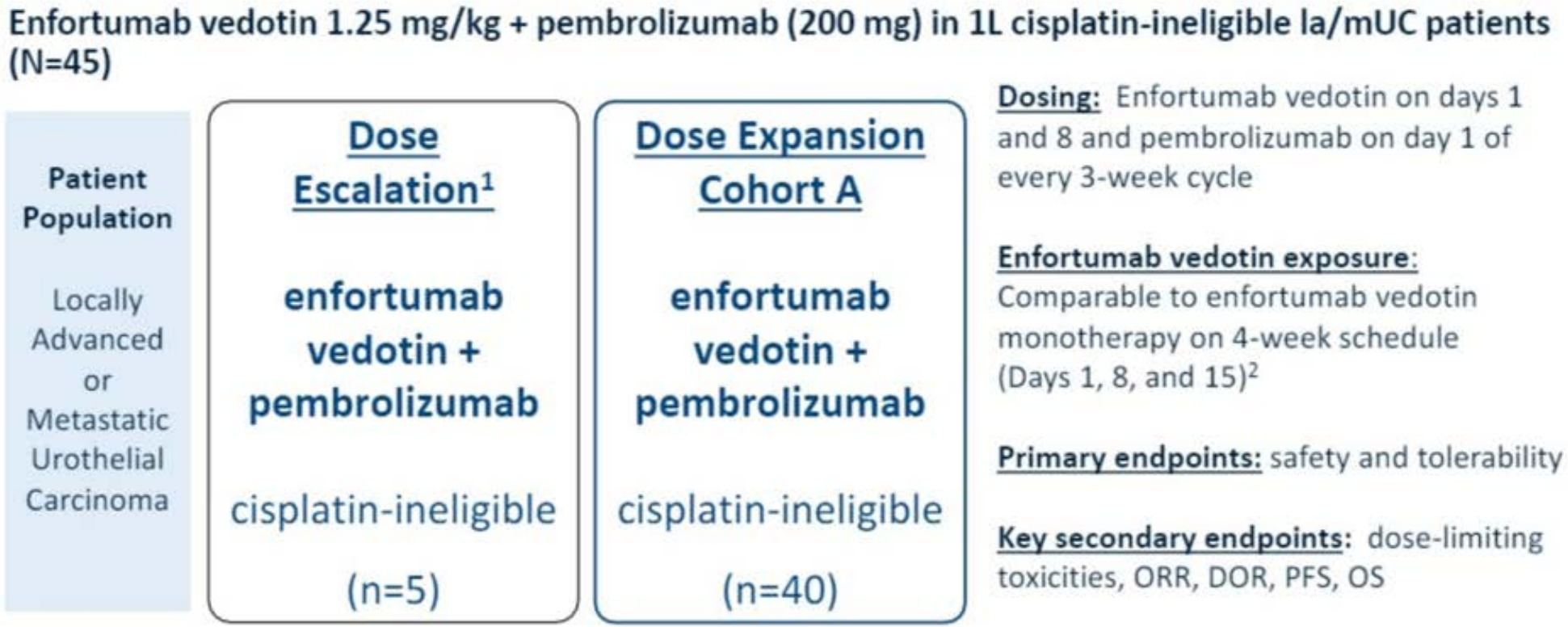
		Prior Anti–PD-(L)1 Therapy, No. (%)	
Response	**Overall mUC, No. (%)**	**Investigator Review[a]**	**Central Review[b]**
No. of patients	112	89	74
Confirmed CR	5 (5)	3 (3)	8 (11)
Confirmed PR	43 (38)	35 (39)	25 (34)
SD	32 (29)	28 (32)	27 (37)
Confirmed ORR,[c] % (95% CI)	43 (33.6 to 52.6)	43 (32.3 to 53.6)	45 (33.0 to 56.6)
DCR,[c] % (95% CI)	71 (62.1 to 79.6)	74 (63.8 to 82.9)	81 (70.3 to 89.3)
Median DoR, months (95% CI)	7.4 (5.6 to 9.6)	7.3 (4.2 to 9.6)	7.5 (5.8 to NR)

Rosenberg J et al. J Clin Oncol. 2020 Apr 1;38(10):1041-1049

Courtesy of Sumanta K Pal, MD

Advanced Disease: Enfortumab Vedotin

EV-103: Preliminary durability results of enfortumab vedotin plus pembrolizumab for locally advanced or metastatic urothelial carcinoma



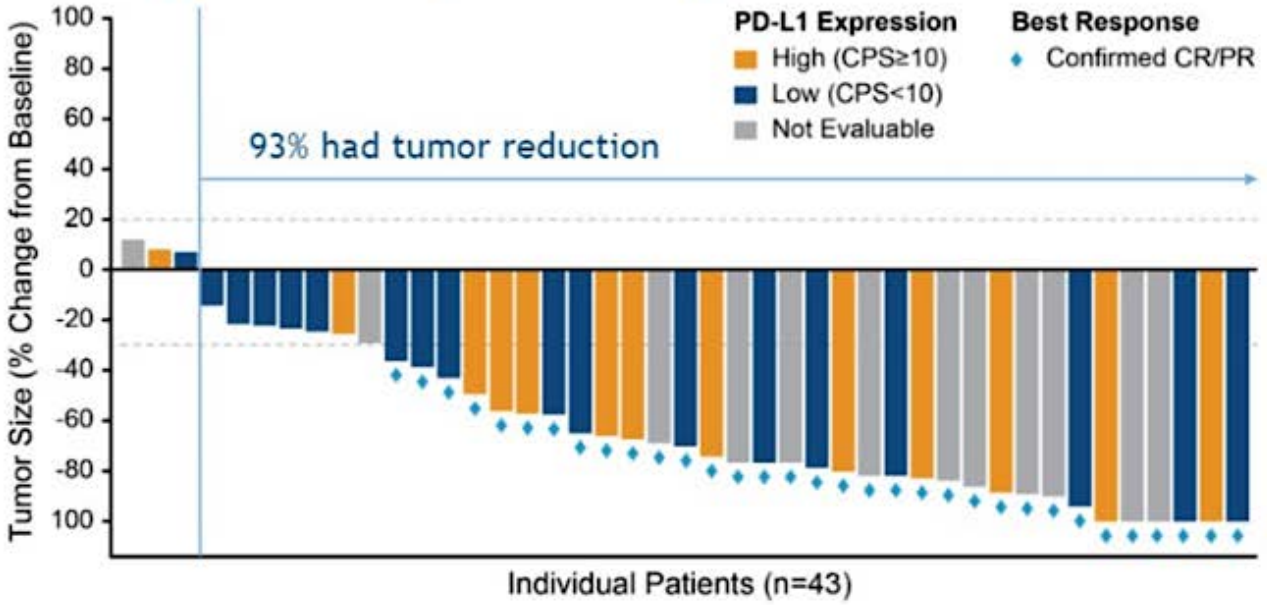
Rosenberg JE et al. Presented at the Genitourinary Cancers Symposium 2020 (Abstract 441)

Courtesy of Sumanta K Pal, MD

Advanced Disease: Enfortumab Vedotin

EV-103: Preliminary durability results of enfortumab vedotin plus pembrolizumab for locally advanced or metastatic urothelial carcinoma

Maximal Target Lesion Reduction by PD-L1 status and Objective Response Rate per Investigator



Confirmed ORR 95% CI	**73.3% (33/45)** (58.1, 85.4)
Complete response	15.6% (7/45)
Partial response	57.8% (26/45)

Best Overall Response Per RECIST v 1.1 by investigator (N=45)

- Responses observed regardless of PD-L1 expression level

Two patients did not have post-baseline response assessments before end-of-treatment: 1 withdrew consent and 1 died before any post-baseline response assessment. These patients are included in the full analysis set used to calculate ORR, but are not included in the figure above.

Horizontal lines at positive 20% and negative 30% denote thresholds for target lesions for disease progression and response, respectively.

Rosenberg JE et al. Presented at the Genitourinary Cancers Symposium 2020 (Abstract 441)

Advanced Disease: Enfortumab Vedotin

EV-103: Preliminary durability results of enfortumab vedotin plus pembrolizumab for locally advanced or metastatic urothelial carcinoma

Treatment-Related Adverse Events of Clinical Interest (AECI)

- Rates of peripheral neuropathy, rash, and hyperglycemia similar to enfortumab vedotin monotherapy
- No new safety signal with the combination

	Patients (N=45) n (%)		Time to first onset (months) median (min, max)
AECI: categorized by related MedDRA terms	Any Grade	≥Grade 3[1]	Any Grade
Peripheral neuropathy	25 (56)	2 (4)	2.3 (1, 12)
Rash	28 (62)	6 (13)	0.7 (0, 12)
Hyperglycemia[2]	5 (11)	3 (7)	0.5 (0, 3)

Rosenberg JE et al. Presented at the Genitourinary Cancers Symposium 2020 (Abstract 441)

Courtesy of Sumanta K Pal, MD

Advanced Disease: Enfortumab Vedotin

EV-103: Preliminary durability results of enfortumab vedotin plus pembrolizumab for locally advanced or metastatic urothelial carcinoma

AECI: determined by investigator	Patients (N=45) n (%)	
	Any Grade	≥Grade 3[1]
Immune-mediated AE requiring systemic steroids	13 (29)	8 (18)[3]

Rosenberg JE et al. Presented at the Genitourinary Cancers Symposium 2020 (Abstract 441)

Courtesy of Sumanta K Pal, MD

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For which of the following adverse events is the risk increased with erdafitinib?

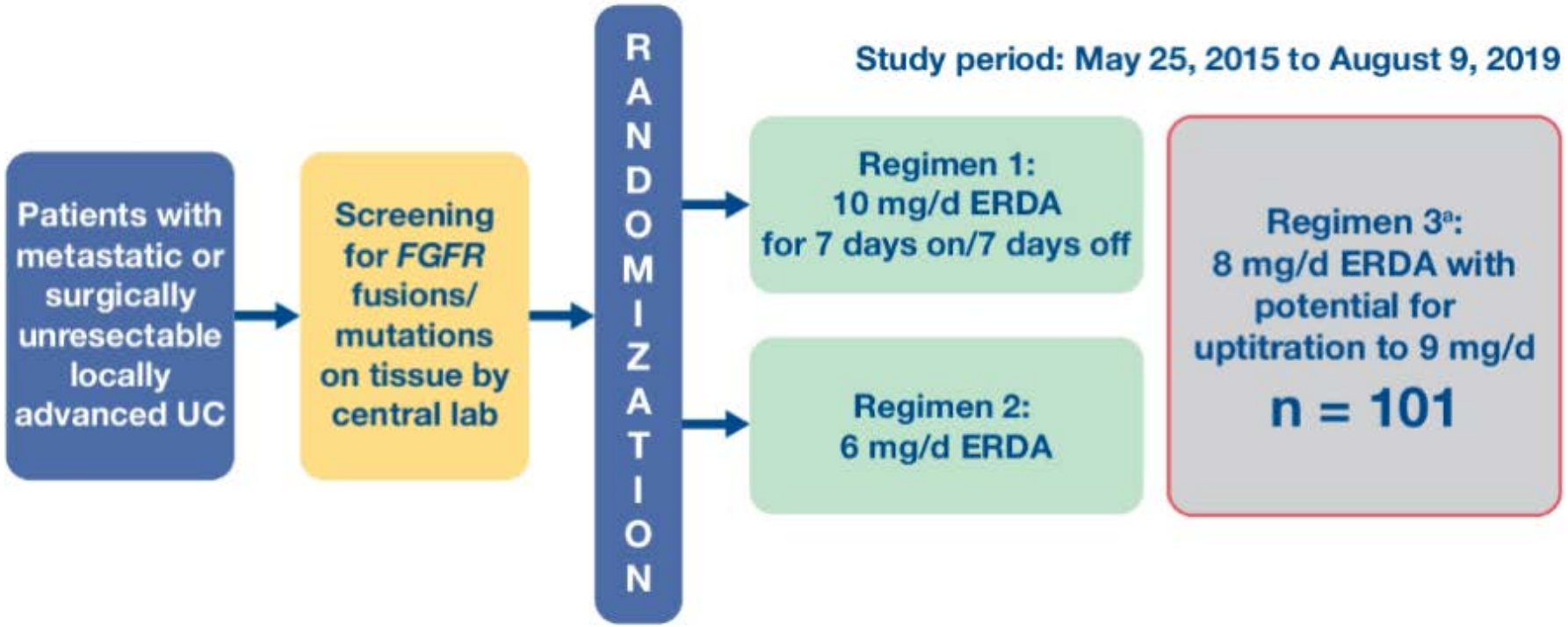
1. Ocular toxicity
2. Hyperphosphatemia
3. Both 1 and 2
4. Neither 1 or 2
5. I don’t know

Module 7: Erdafitinib

- **Key Relevant Data Set**
  - BCL2001: Long-term outcomes

Advanced Disease: Erdafitinib

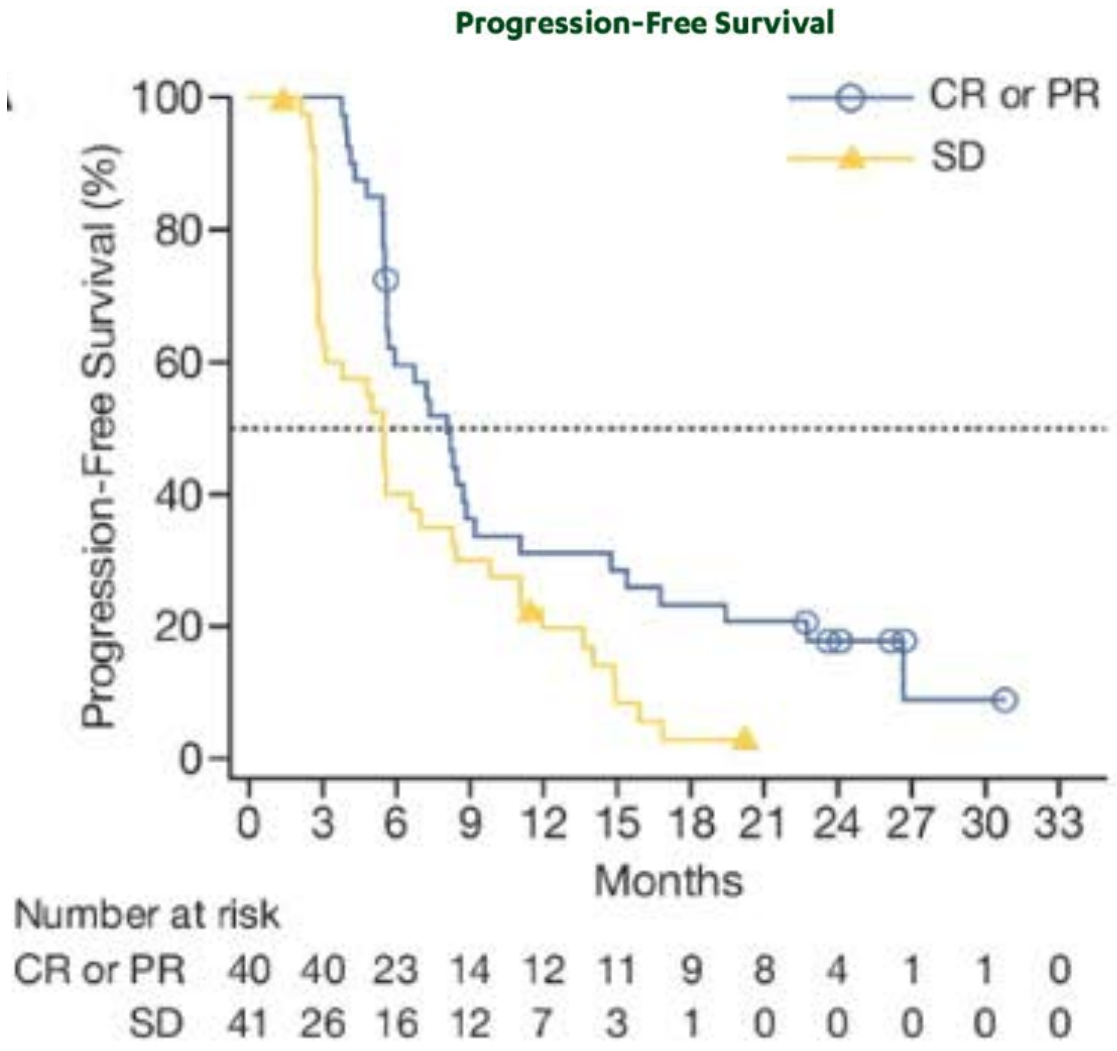
Erdafitinib in locally advanced or mUC: Long-term outcomes in BLC2001



Siefker-Radtke AO et al. Presented at ASCO 2020 (Abstract 5015)

Courtesy of Sumanta K Pal, MD

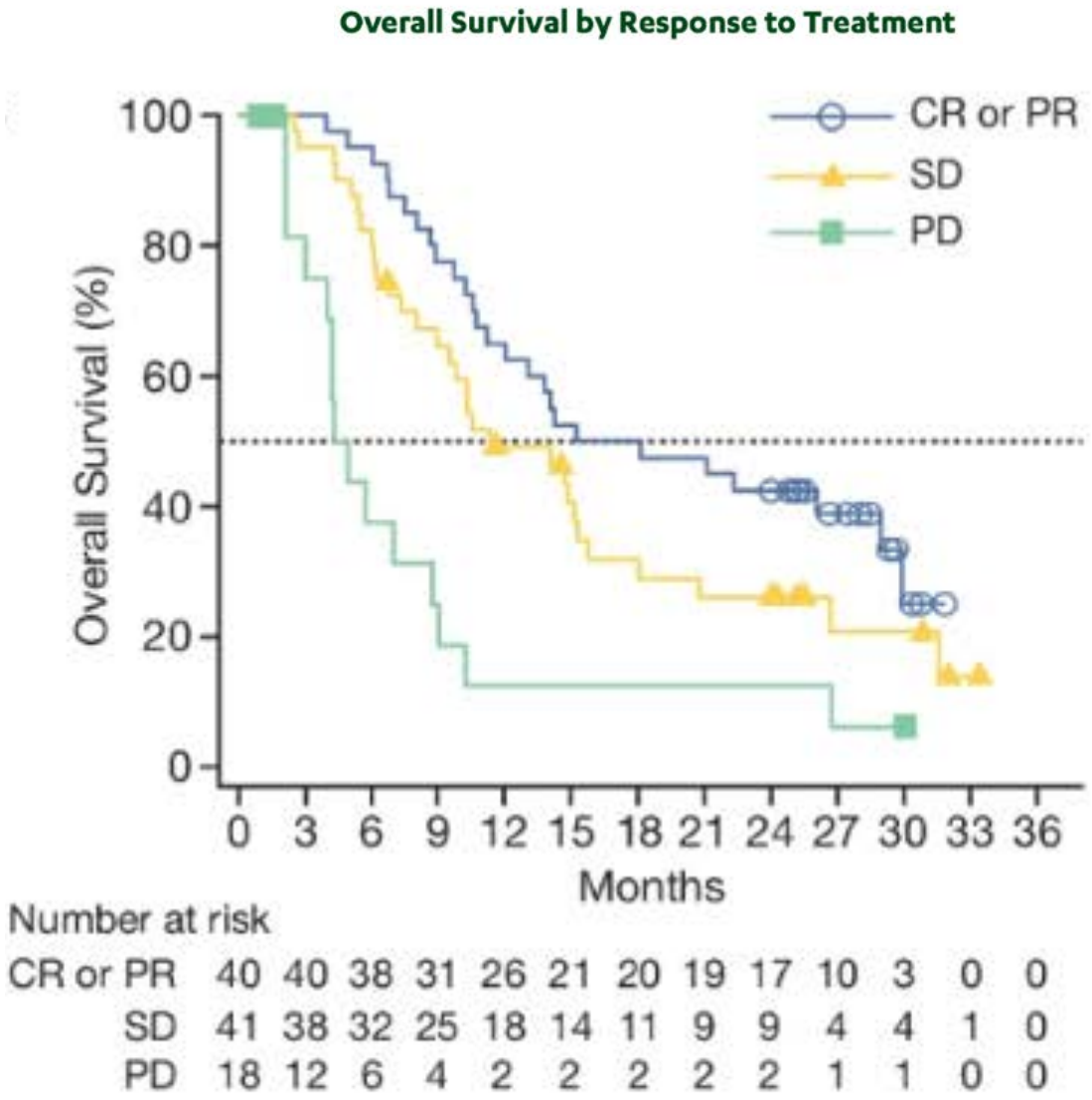
Advanced Disease: Erdafitinib



Siefker-Radtke AO et al. Presented at ASCO 2020 (Abstract 5015)

Courtesy of Sumanta K Pal, MD

Advanced Disease: Erdafitinib



Siefker-Radtke AO et al. Presented at ASCO 2020 (Abstract 5015)

Courtesy of Sumanta K Pal, MD

Recent Advances in Hematologic Oncology: A 4-Part Live Webinar Series Reviewing Key Data and Presentations from the 62nd ASH Annual Meeting

Part 2 — Hodgkin and Non-Hodgkin Lymphoma

Wednesday, February 3, 2021
5:00 PM – 6:00 PM ET

Faculty

John Kuruvilla, MD
John P Leonard, MD
Michael E Williams, MD, ScM

Moderator

Neil Love, MD

RESEARCH TO PRACTICE 2021 YEAR IN REVIEW

Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

RESEARCH TO PRACTICE 2021 YEAR IN REVIEW