Year in Review:
Kidney and Bladder Cancer

Tuesday, March 8, 2022
5:00 PM – 6:00 PM ET

Faculty

Elizabeth R Plimack, MD, MS
Thomas Powles, MBBS, MRCP, MD

Moderator

Neil Love, MD

RTP Year in Review 2022

YiR Kidney and Bladder Cancer Faculty

Elizabeth R Plimack, MD, MS
Chief, Division of Genitourinary Medical Oncology
Director, Genitourinary Clinical Research
Professor, Department of Hematology/Oncology
Fox Chase Cancer Center
Temple Health
Philadelphia, Pennsylvania

Thomas Powles, MBBS, MRCP, MD
Professor of Genitourinary Oncology
Barts Cancer Institute
Director of Barts Cancer Centre
Queen Mary University of London
London, United Kingdom

Commercial Support

This activity is supported by educational grants from Astellas and Seagen Inc, Eisai Inc, Exelixis Inc, and Merck.

Dr Love — Disclosures

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Prof Powles — Disclosures

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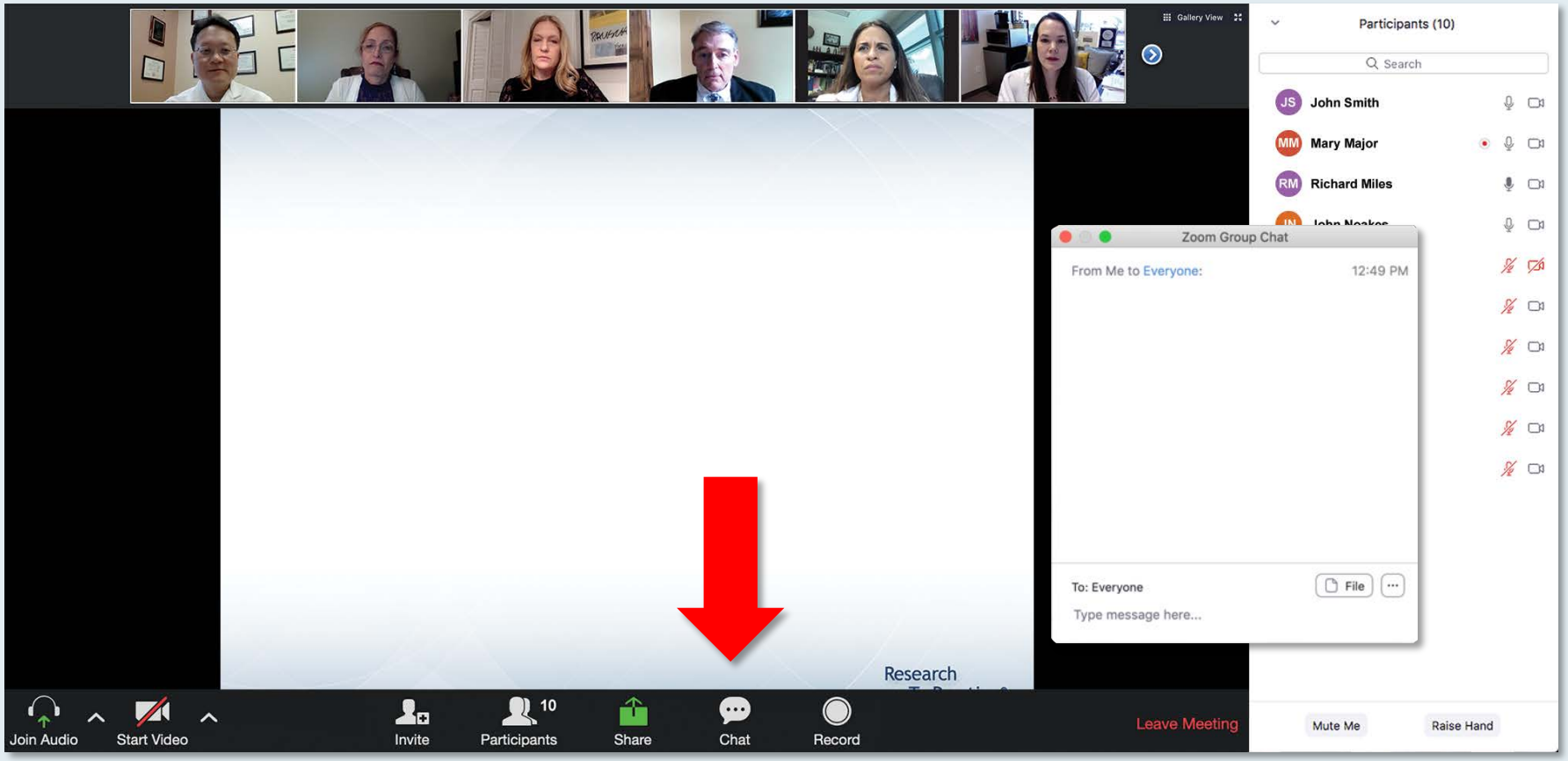
We Encourage Clinicians in Practice to Submit Questions



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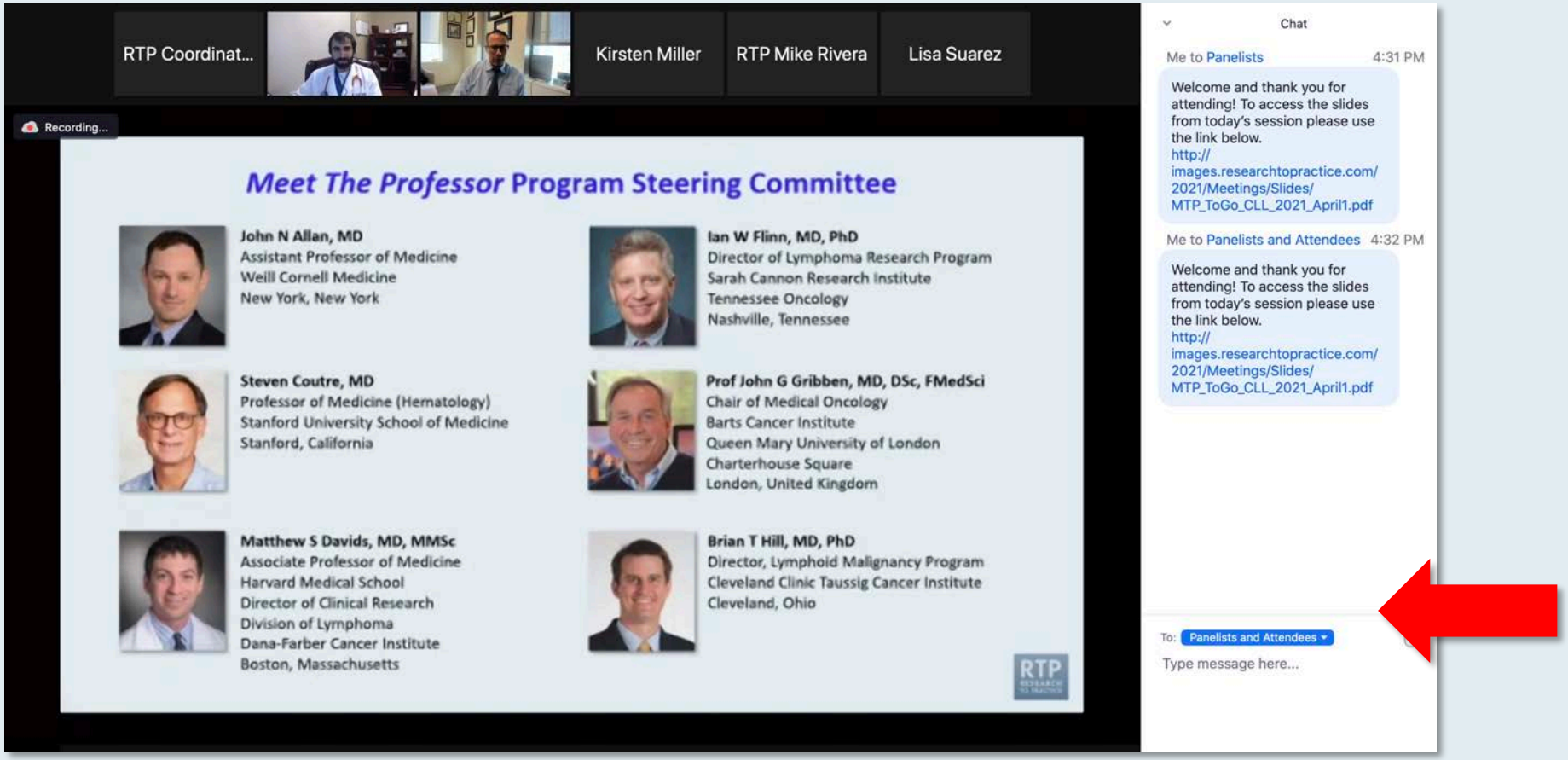
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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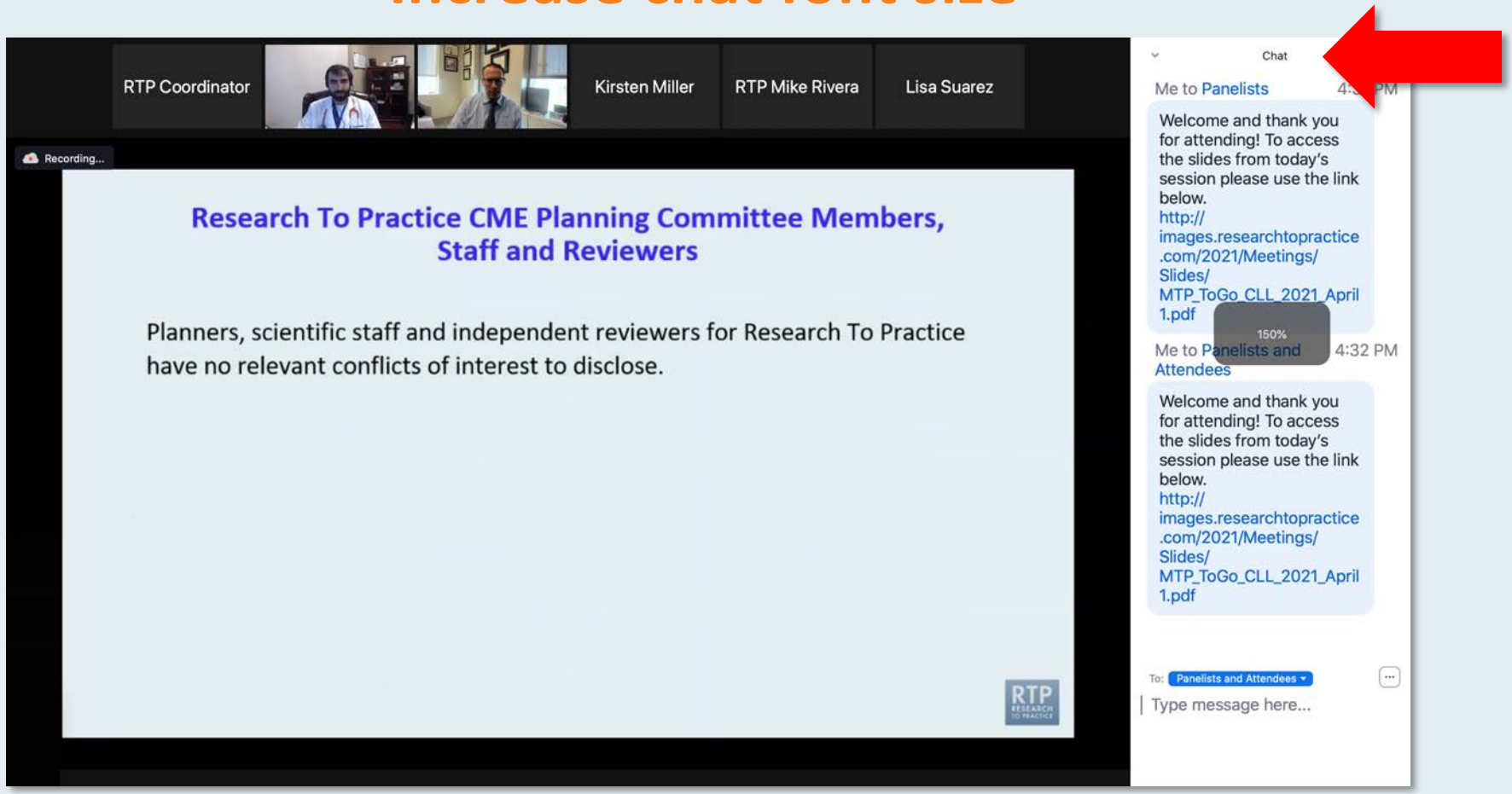

Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

ONCOLOGY TODAY

WITH DR NEIL LOVE

Novel Agents and Strategies for the Treatment of Metastatic Castration-Resistant Prostate Cancer

DR EVAN YU

FRED HUTCHINSON CANCER RESEARCH CENTER

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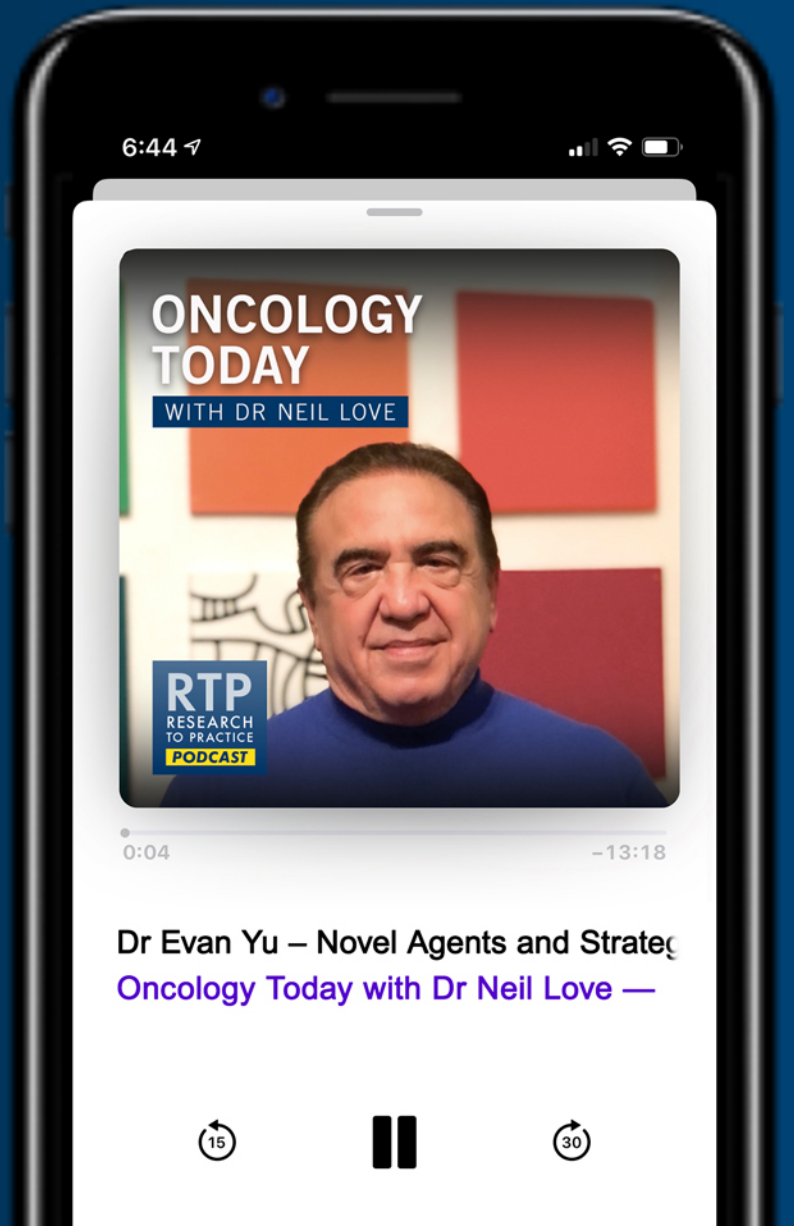

Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia

Wednesday, March 9, 2022
5:00 PM – 6:00 PM ET

Faculty

Rebecca L Olin, MD, MSCE

Moderator

Neil Love, MD

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RESEARCH
TO PRACTICE

Meet The Professor

Current and Future Management of Myelofibrosis

Thursday, March 10, 2022
5:00 PM – 6:00 PM ET

Faculty

Srdan Verstovsek, MD, PhD

Moderator

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Meet The Professor

Optimizing the Clinical Management of Hodgkin and Non-Hodgkin Lymphomas

Tuesday, March 15, 2022
5:00 PM – 6:00 PM ET

Faculty

Sonali M Smith, MD

Moderator

Neil Love, MD

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RESEARCH
TO PRACTICE

Meet The Professor

Current and Future Management of Chronic Lymphocytic Leukemia

Thursday, March 17, 2022
5:00 PM – 6:00 PM ET

Faculty

Peter Hillmen, MB ChB, PhD

Moderator

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Data + Perspectives: Clinical Investigators Discuss the Current and Future Management of Ovarian Cancer

Saturday, March 19, 2022

2:30 PM – 4:00 PM ET

Faculty

Mansoor Raza Mirza, MD
Kathleen N Moore, MD, MS
David M O'Malley, MD

Moderator

Robert L Coleman, MD

RTP
RESEARCH
TO PRACTICE

Meet The Professor

Current and Future Role of Immunotherapy in the Management of Lung Cancer

Wednesday, March 30, 2022
5:00 PM – 6:00 PM ET

Faculty

Sarah B Goldberg, MD, MPH

Moderator

Neil Love, MD

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TO PRACTICE

Thank you for joining us!

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

RTP Year in Review 2022

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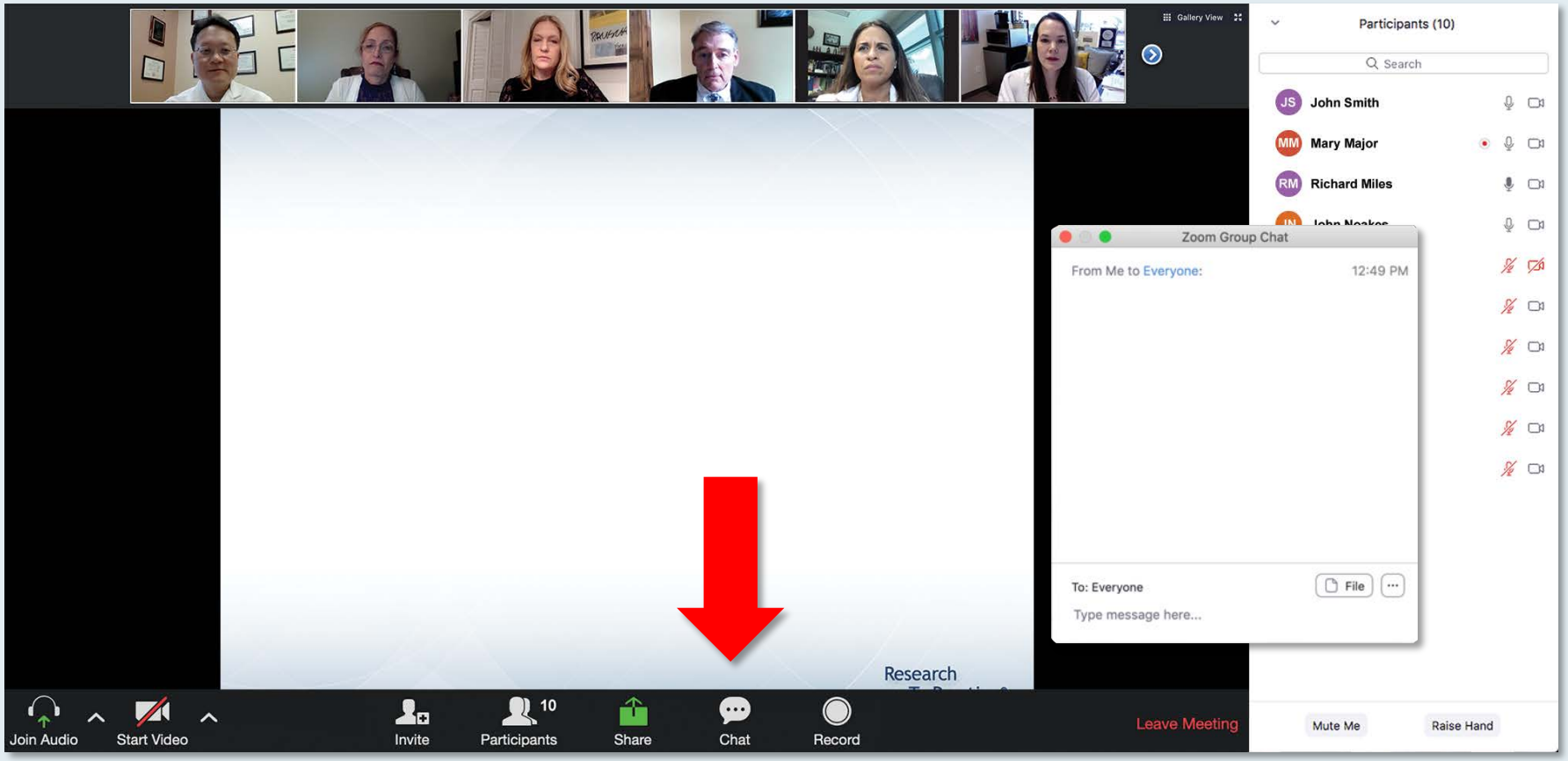

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RTP Year in Review 2022

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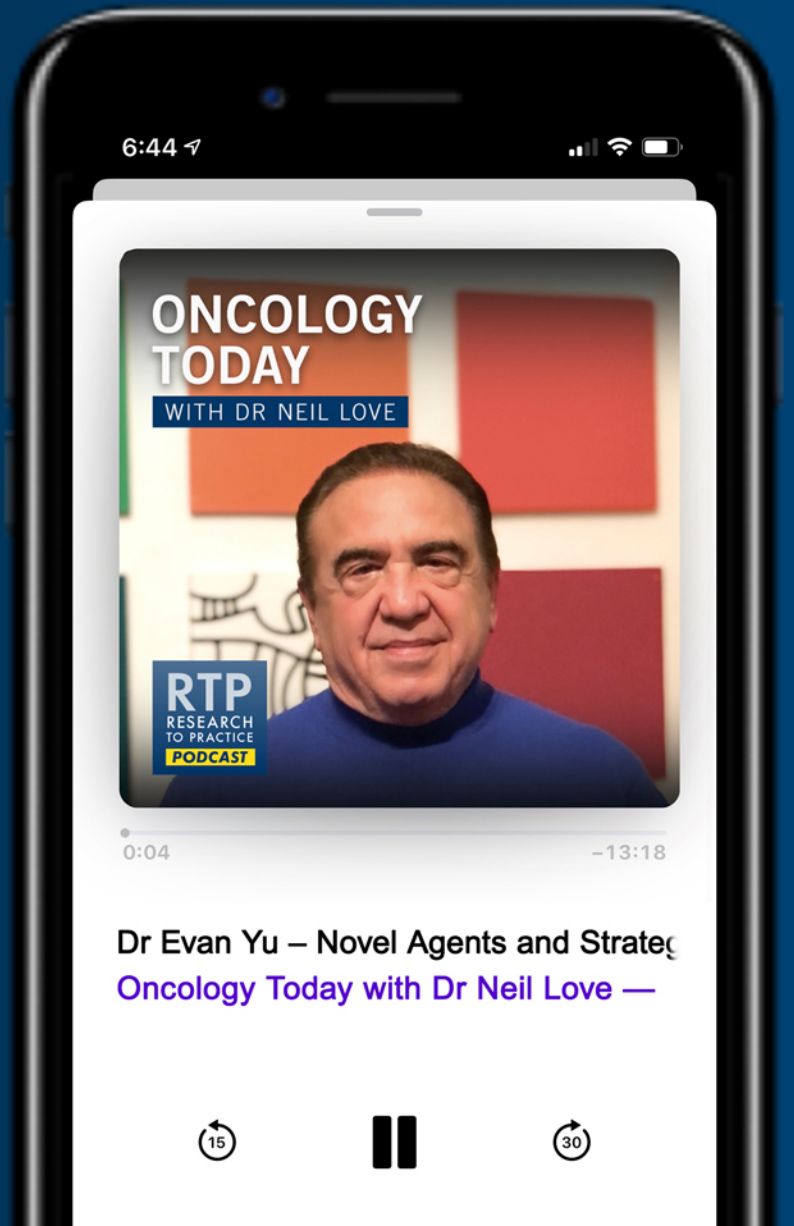

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RTP Year in Review 2022

Advances in metastatic renal cancer

Thomas Powles
Director of Barts Cancer Center.
Professor of Urology Cancer, Barts Cancer Institute.

@tompowles1

@uromigos

2021 YEAR IN REVIEW: UROTHELIAL CARCINOMA

Elizabeth R. Plimack MD MS
Chief, Division of Genitourinary Medical Oncology
Director, Genitourinary Clinical Research
Professor, Hematology/Oncology
Fox Chase Cancer Center, Temple Health
@ERPlimackMD

FOX CHASE CANCER CENTER
TEMPLE HEALTH

Link to updated disclosures https://t.co/ZE7NhaE4io?amp=1 also available in my twitter profile

RTP RESEARCH TO PRACTICE

Agenda

Advances in Metastatic Renal Carcinoma – Prof Powles

Module 1: Adjuvant Therapy in Renal Cell Carcinoma (RCC)

Module 2: First-Line Treatment of Metastatic RCC

Module 3: Belzutifan for von Hippel-Lindau-Associated RCC

Module 4: Non-Clear Cell RCC

2021 Year in Review: Urothelial Carcinoma – Dr Plimack

Module 5: Non-Muscle-Invasive Bladder Cancer (NMIBC)

Module 6: Adjuvant and Neoadjuvant Treatments for NMIBC

Module 7: Sequencing Therapies for Metastatic Urothelial Bladder Cancer

Agenda

Advances in Metastatic Renal Carcinoma – Prof Powles

Module 1: Adjuvant Therapy in Renal Cell Carcinoma (RCC)

- KEYNOTE-564

Module 2: First-Line Treatment of Metastatic RCC

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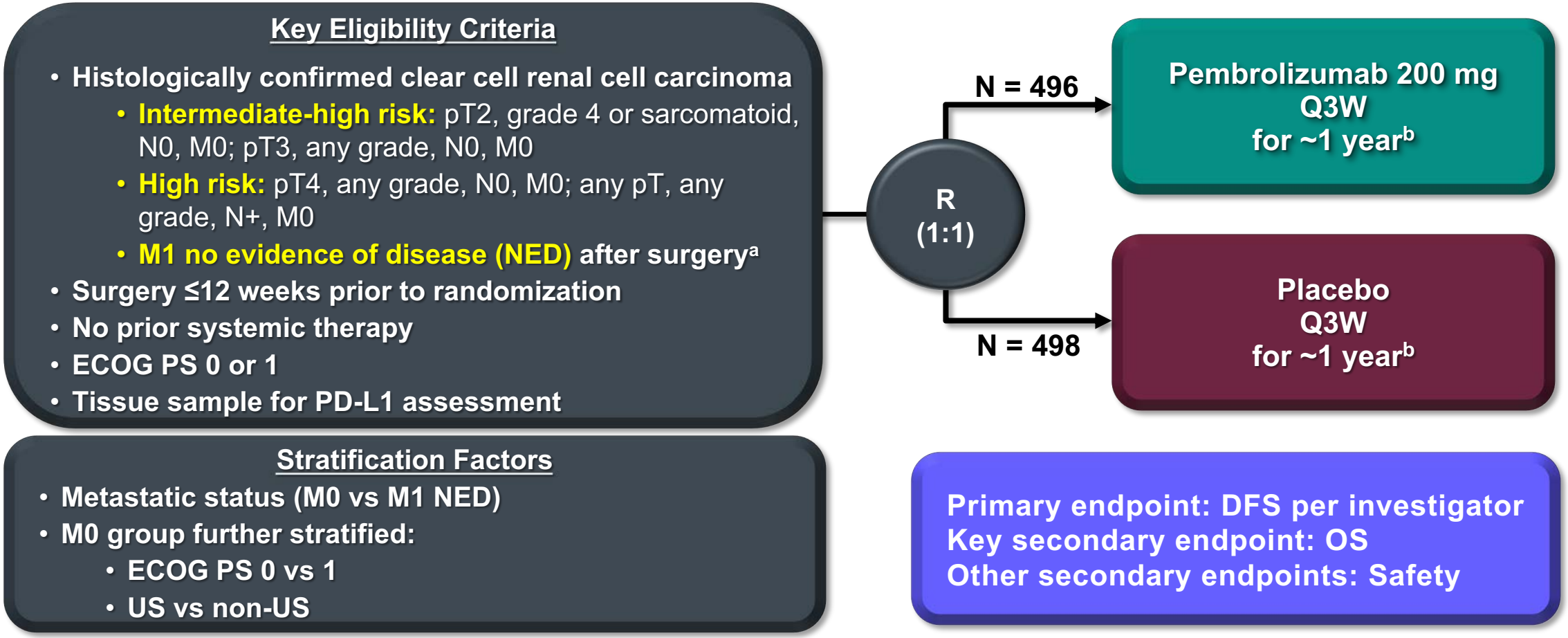
KEYNOTE-564 (NCT03142334) Study Design



- Median (range) time from randomization to cutoff: 30.1 (20.8−47.5) months

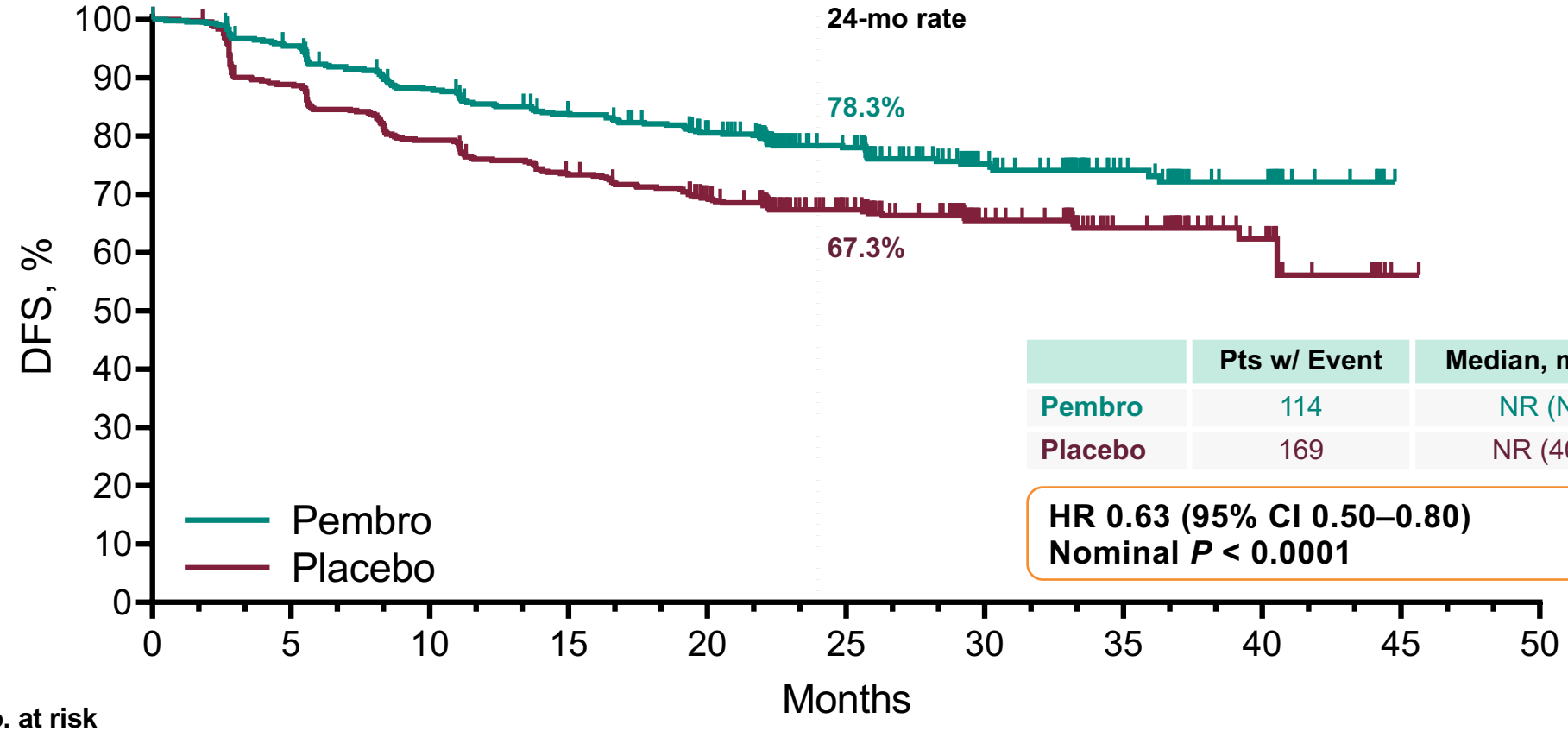
Q3W, every 3 weeks.

[a]M1 NED: no evidence of disease after primary tumor + soft tissue metastases completely resected ≤1 year from nephrectomy; [b]≤17 cycles of treatment were equivalent to ~1 year.

Data cutoff date: June 14, 2021.

Courtesy of Thomas Powles, MBBS, MRCP, MD

KEYNOTE-564: Primary Endpoint – DFS, ITT Population



	Pts w/ Event	Median, mo (95% CI)
Pembro	114	NR (NR–NR)
Placebo	169	NR (40.5–NR)

HR 0.63 (95% CI 0.50–0.80)
Nominal *P* < 0.0001

No. at risk

Pembro	496	458	416	389	361	255	135	77	37	0	0
Placebo	498	437	389	356	325	230	125	74	33	1	0

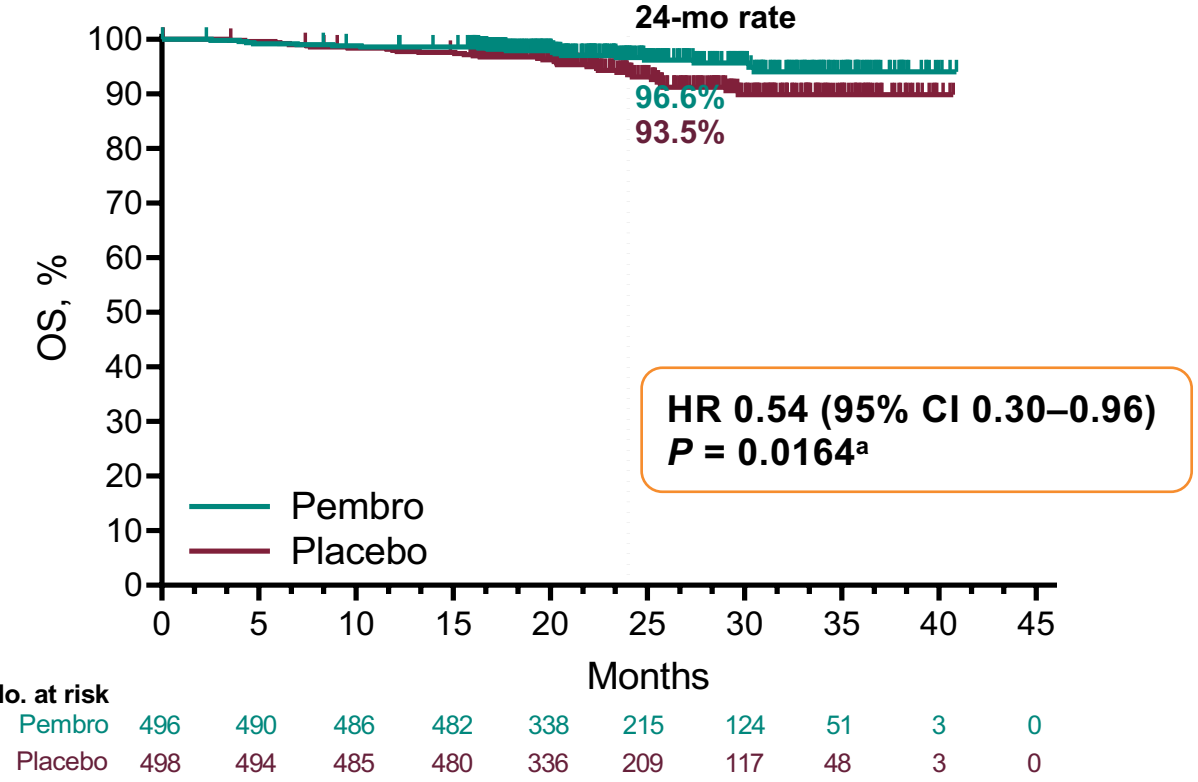
Choueiri K et al. ASCO GU 2022;Abstract 290

Courtesy of Thomas Powles, MBBS, MRCP, MD

ITT population included all randomized participants. DFS, disease-free survival; NR, not reached. Data cutoff date: June 14, 2021.

KEYNOTE-564: Key Secondary Endpoint – OS, ITT Population

Primary Analysis: 24.1 mo Follow-Up

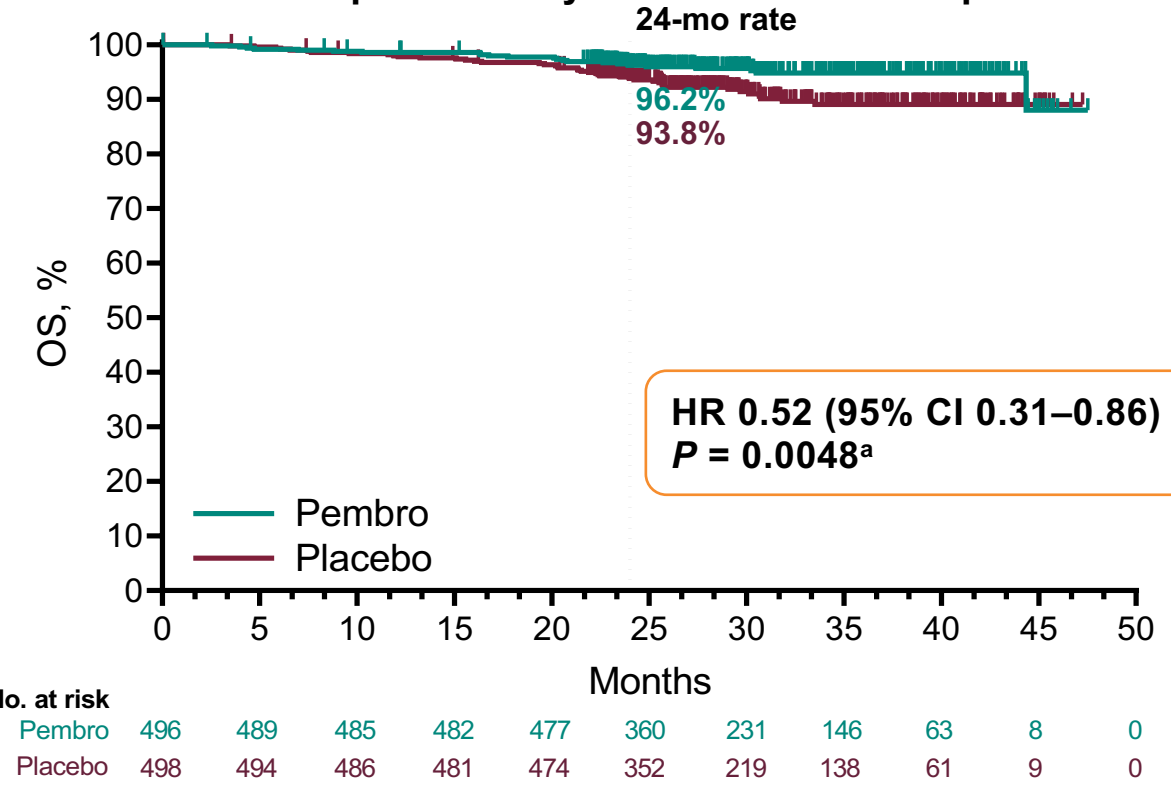


No. at risk

Pembro	496	490	486	482	338	215	124	51	3	0
Placebo	498	494	485	480	336	209	117	48	3	0

	Pts w/ Event	Median, mo (95% CI)
Pembro	18	NR (NR–NR)
Placebo	33	NR (NR–NR)

Updated Analysis: 30.1 mo Follow-Up



No. at risk

Pembro	496	489	485	482	477	360	231	146	63	8	0
Placebo	498	494	486	481	474	352	219	138	61	9	0

	Pts w/ Event	Median, mo (95% CI)
Pembro	23	NR (NR–NR)
Placebo	43	NR (NR–NR)

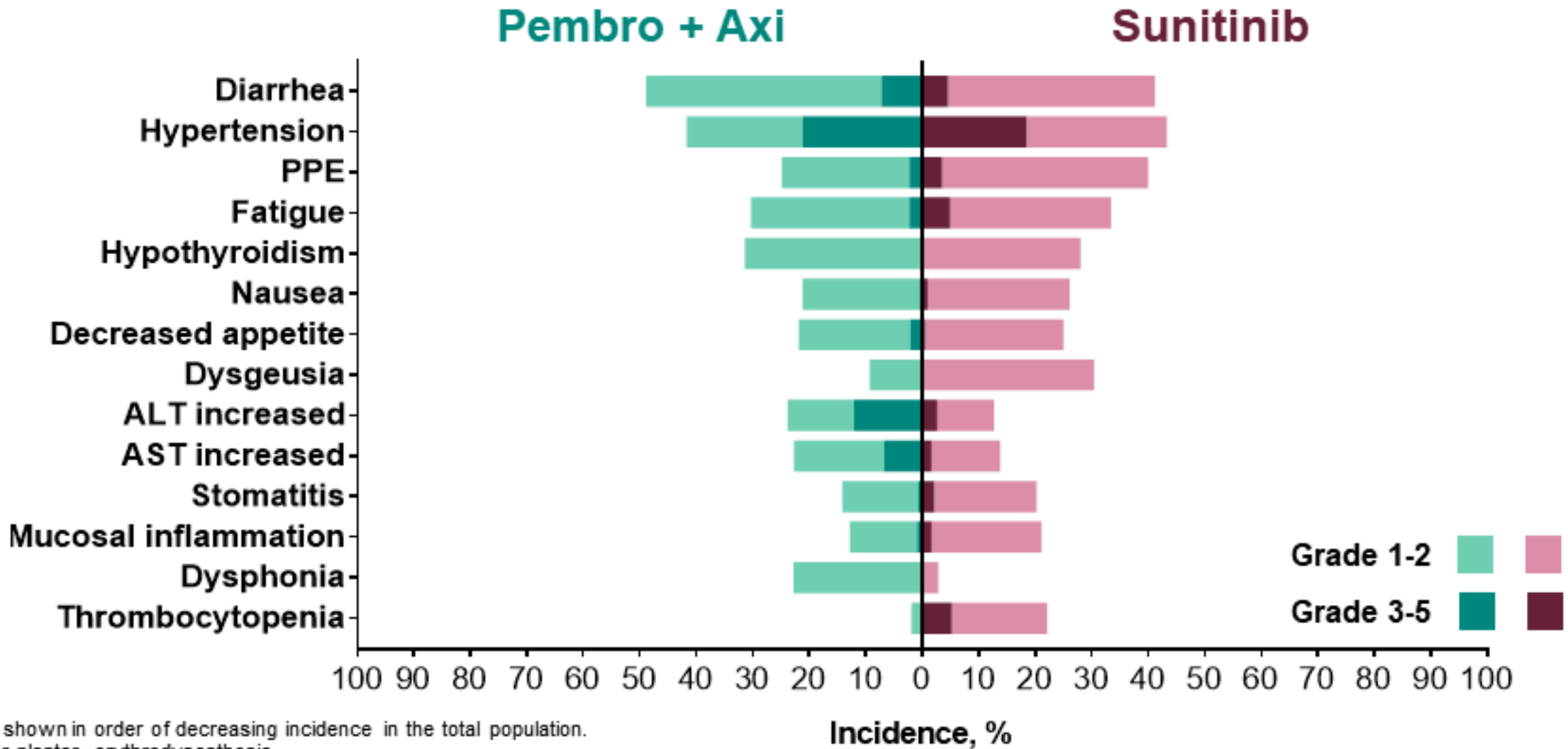
[a]Did not cross prespecified p-value boundary for statistical significance.

ITT population included all randomized participants. NR, not reached. Primary analysis data cutoff date: December 14, 2020. Updated analysis data cutoff date: June 14, 2021.

Choueiri K et al. ASCO GU 2022;Abstract 290

Courtesy of Thomas Powles, MBBS, MRCP, MD

Treatment-Related Adverse Events: Incidence ≥20%



Events are shown in order of decreasing incidence in the total population.
PPE, palmar-plantar erythrodysesthesia.
Data cutoff date: Aug 24, 2018.

Courtesy of Thomas Powles, MBBS, MRCP, MD

Agenda

Advances in Metastatic Renal Carcinoma – Prof Powles

Module 1: Adjuvant Therapy in Renal Cell Carcinoma (RCC)

Module 2: First-Line Treatment of Metastatic RCC

- CheckMate 214, PRISM, CheckMate 9ER, CLEAR/KEYNOTE-581, COSMIC-021

Module 3: Belzutifan for von Hippel-Lindau-Associated RCC

Module 4: Non-Clear Cell RCC

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RTP Year in Review 2022

Ipilimumab + Nivolumab (IO/IO): CheckMate 214

Patients

- **Treatment-naïve advanced or metastatic clear-cell RCC**
- **Measurable disease**
- **KPS ≥70%**
- **Tumor tissue available for PD-L1 testing**

Randomize 1:1

Stratified by
- IMDC prognostic score (favorable vs intermediate vs poor risk)
- Region (US vs Canada/ Europe vs rest of world)

Treatment

Arm A
3 mg/kg nivolumab IV + 1 mg/kg ipilimumab Q3W for 4 doses, then 3 mg/kg nivolumab Q2W

Arm B
50 mg sunitinib orally once daily for 4 weeks (6-week cycles)

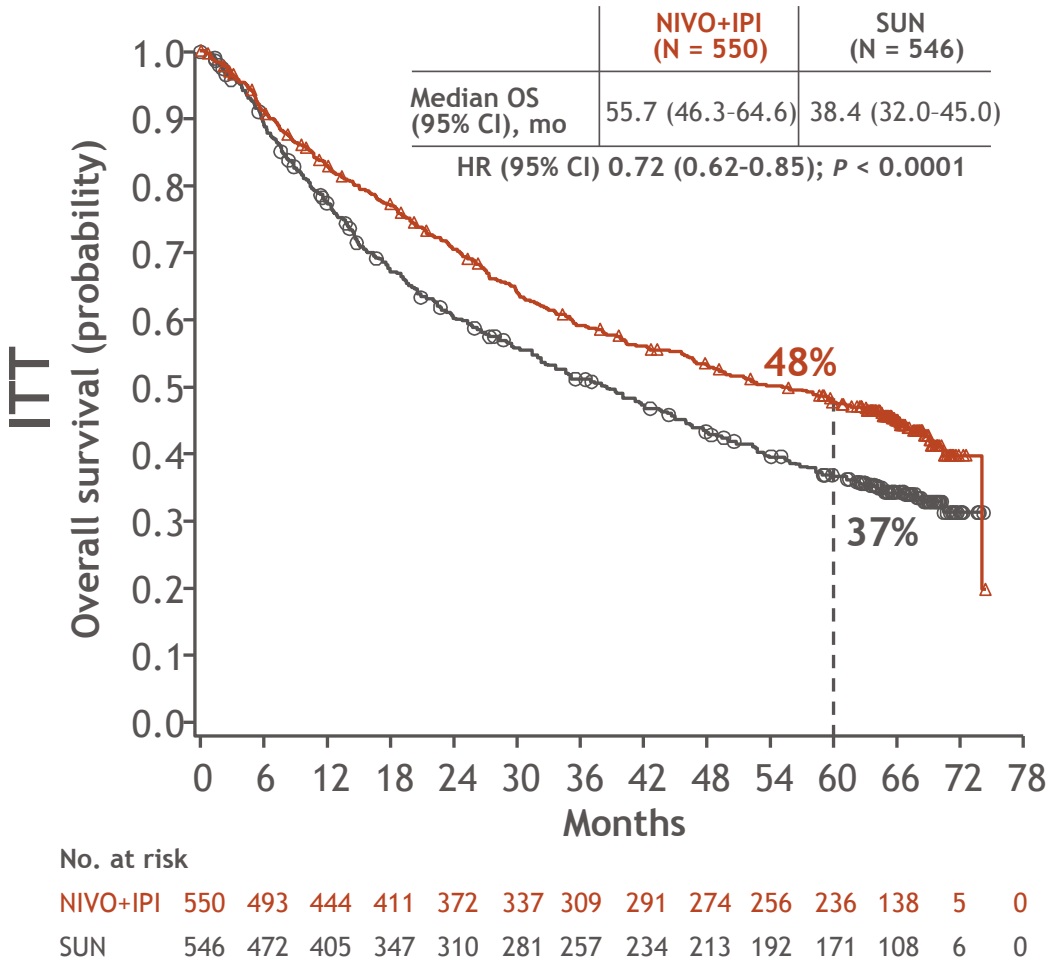
IMDC, International Metastatic RCC Database Consortium; KPS, Karnofsky performance status; Q2W, every 2 weeks; Q3W, every 3 weeks

Motzer RJ et al. *Lancet Oncology.* 2019;20(10):1370-1385;
Motzer RJ et al. *N Engl J Med*. 2018;378:1277-1290.

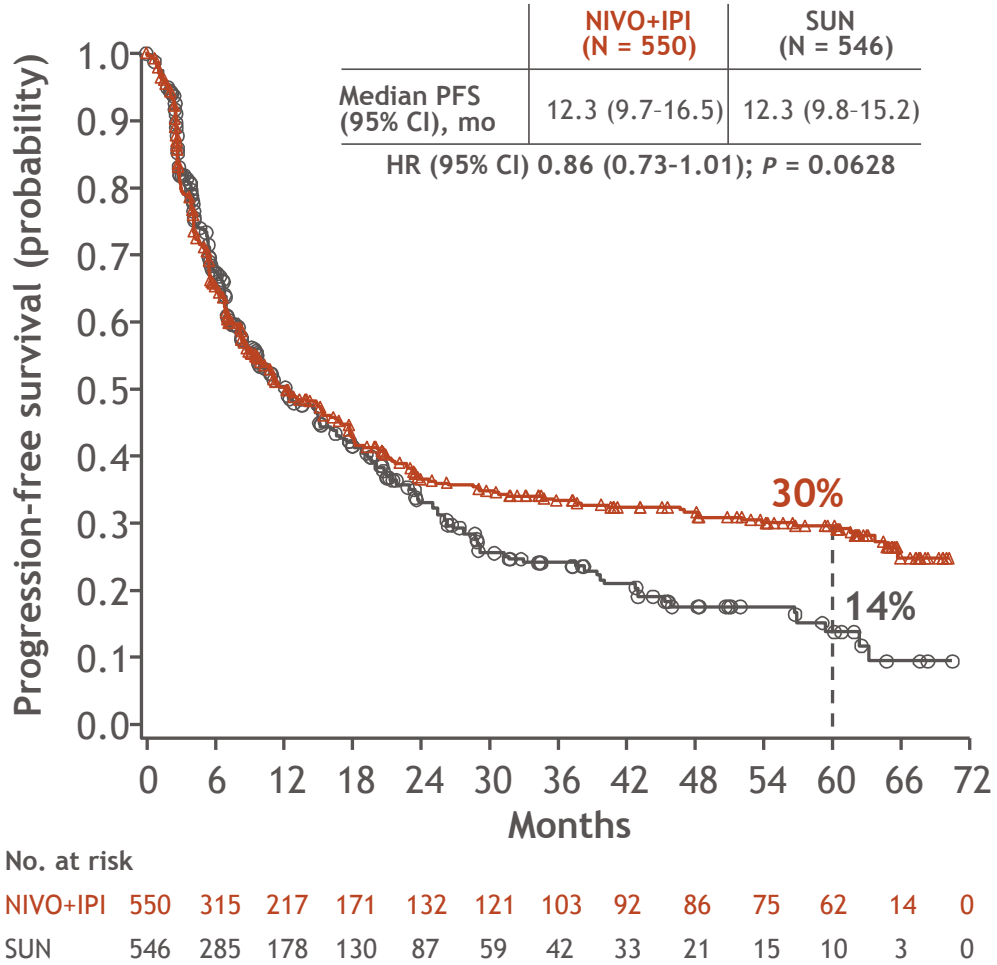
Courtesy of Thomas Powles, MBBS, MRCP, MD

CheckMate 214: OS and PFS in ITT – 5-year Update

Overall survival



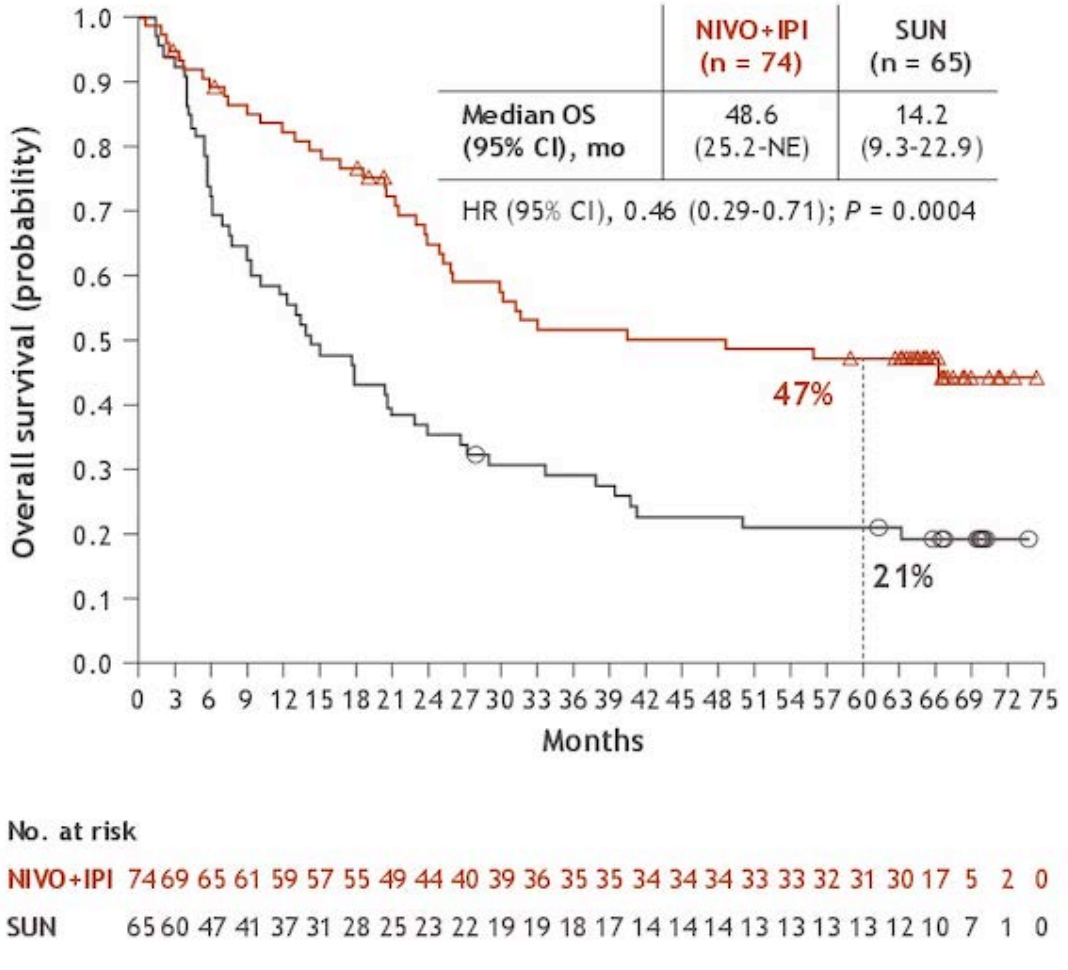
Progression-free survival

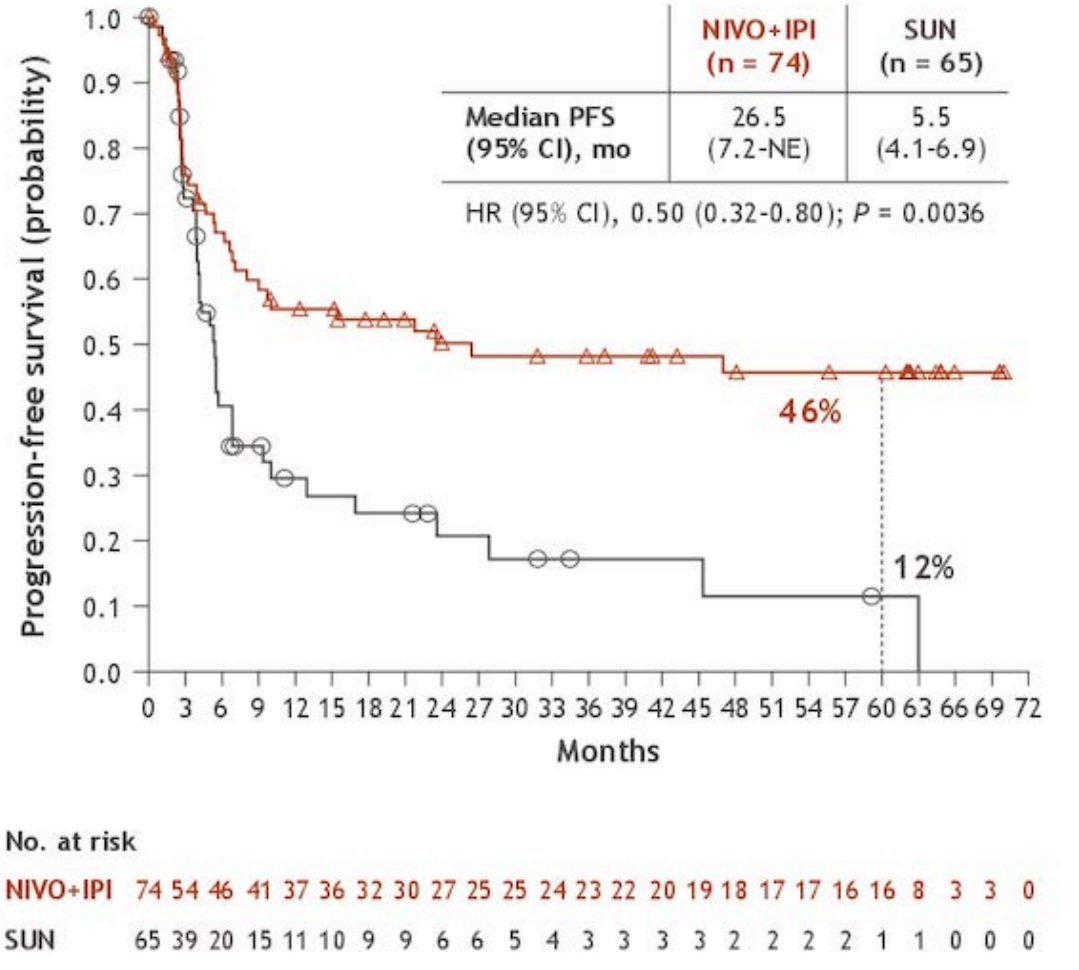


Motzer RJ et al. ESMO 2021. Abstract 661P.

Courtesy of Thomas Powles, MBBS, MRCP, MD

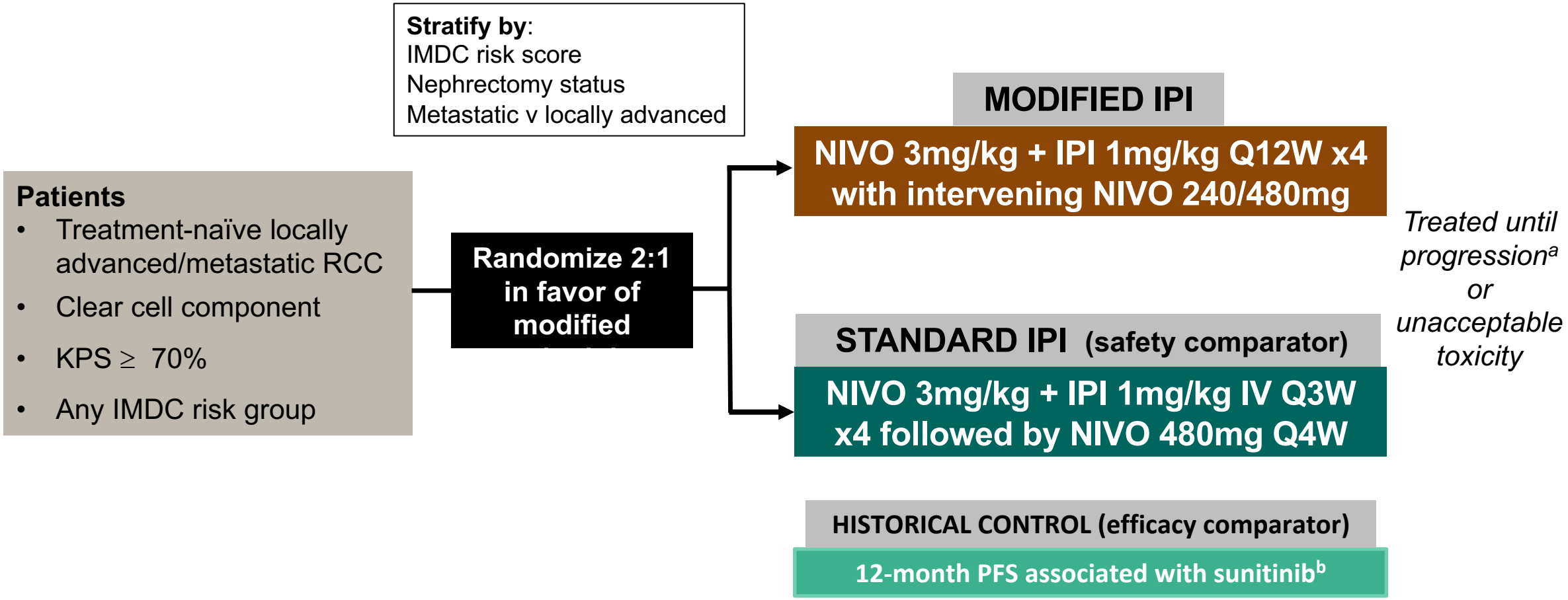
CheckMate 214: OS and PFS for Patients with Intermediate- or Poor-Risk Sarcomatoid RCC





Tannir NM et al. Genitourinary Cancers Symposium 2022;Abstract 352.

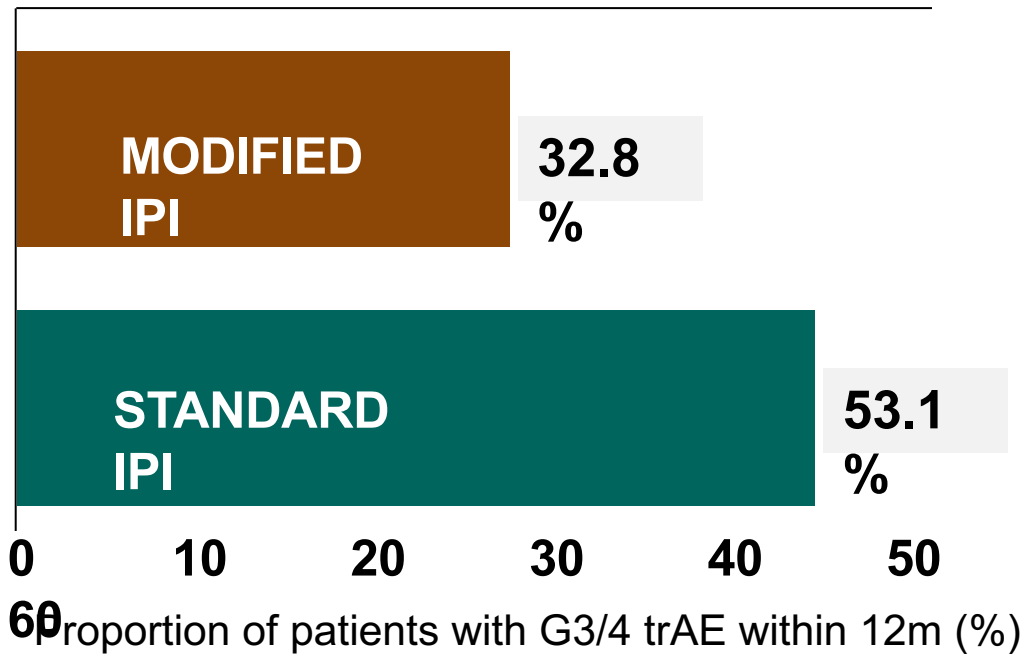
PRISM: Study design



[a] patients were allowed to continue treatment beyond RECIST defined progression if clinically stable and tolerating therapy
[b] Motzer RJ et al. *N Eng J Med* 2013;14:141-8
Q2, 3, 4, 12W – every n weeks; KPS – Karnofsky Performance Status; IMDC – International Metastatic RCC Database Consortium

Courtesy of Thomas Powles, MBBS, MRCP, MD

PRISM: Primary endpoint – Proportion of patients with G3/4 trAE within 12m



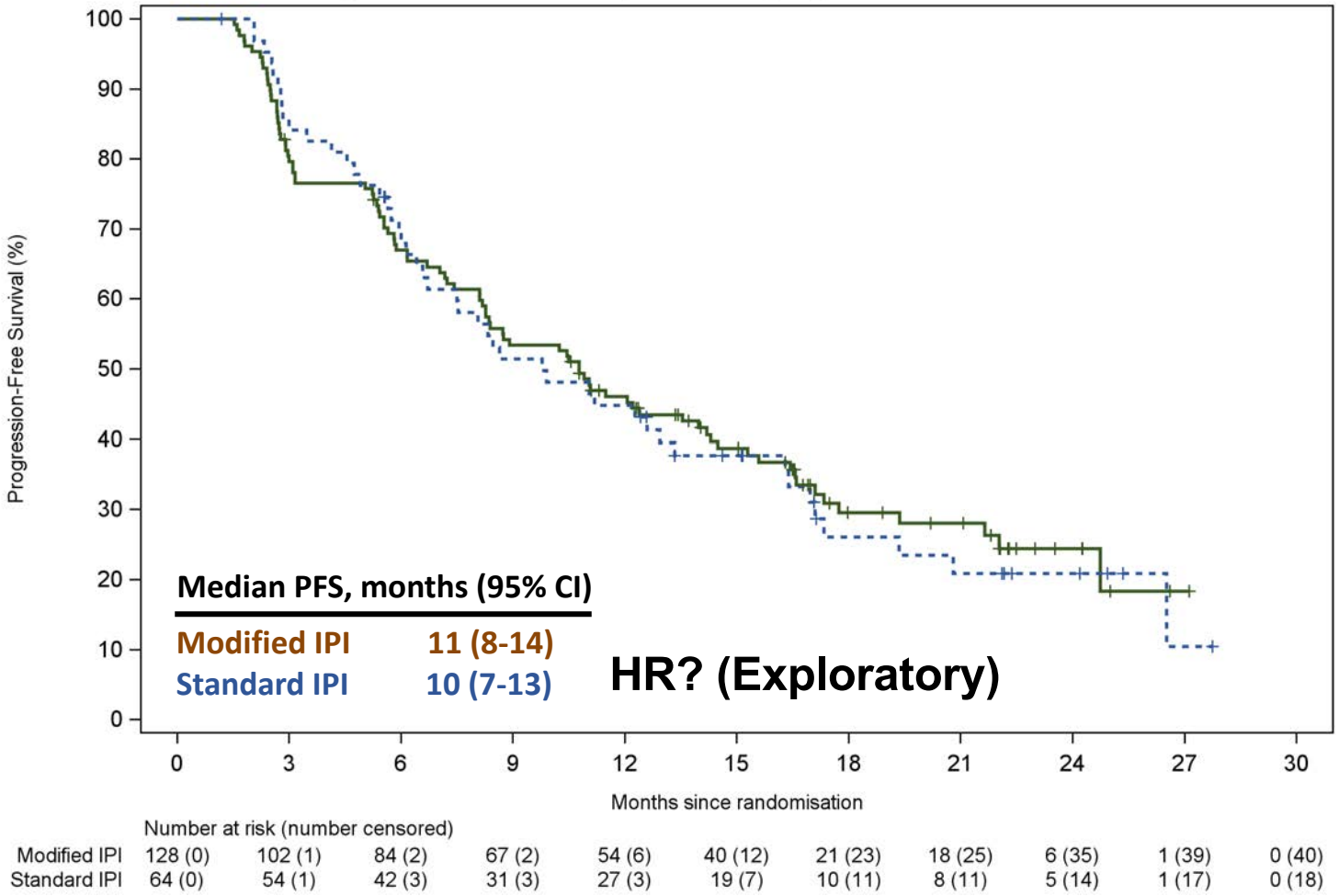
△ -20.3% (90%CI -32.6, -8.0)

OR 0.43 (90% CI 0.25-0.72); p = 0.0075

trAE – treatment-related adverse event

Courtesy of Thomas Powles, MBBS, MRCP, MD

PRISM: Progression-free survival: modified ITT



12m PFS rate (one-sided 90% CI)	
Modified IPI	46.1% (38.6%, 53.2%)
Historical rate	39.7%*

*based on 9m median PFS with sunitinib in COMPARZ trial[a]

The study was not designed to allow formal comparison of PFS between treatment arms, only against historical control.

Modified intention to treat (mITT) population - randomized patients who received at least one dose of trial therapy

[a] Motzer et al. *N Eng J Med* 2013;14:141-8

Courtesy of Thomas Powles, MBBS, MRCP, MD

CheckMate 9ER: Study design

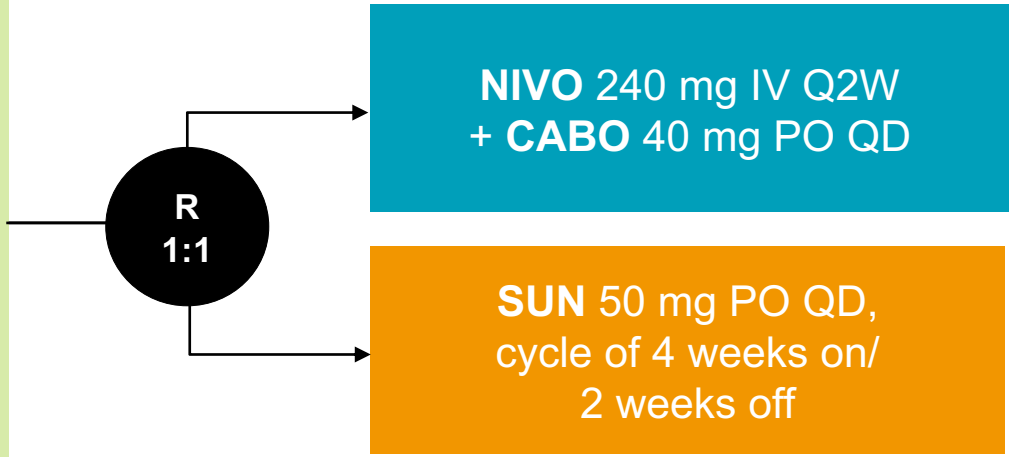
N = 651

Key inclusion criteria[1,2]

- Previously untreated advanced or metastatic RCC with a clear cell component
- Any IMDC risk group
- No prior systemic therapy

Stratification factors:

- IMDC risk score
- Tumor PD-L1 expression[a]
- Geographic region



Treat until RECIST v1.1–defined progression or unacceptable toxicity[b]

Median study follow-up, 18.1 months (range, 10.6–30.6 months)

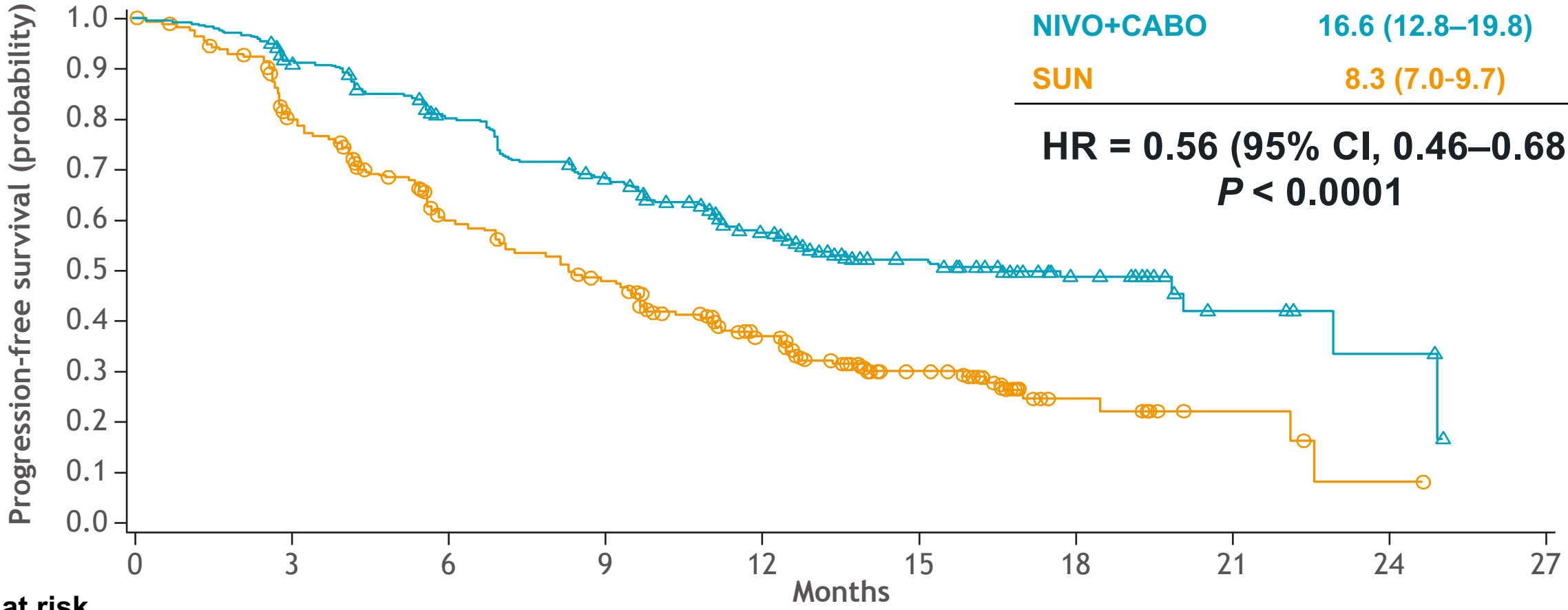
[a]Defined as the percent of positive tumor cell membrane staining in a minimum of 100 evaluable tumor cells per validated Dako PD-L1 immunohistochemistry assay.
[b]NIVO dosing may not exceed a total of 2 years (from cycle 1); CABO and SUN treatment may continue beyond 2 years in the absence of progression or unacceptable toxicity. Patients may be treated beyond progression.
IMDC, International Metastatic Renal Cell Carcinoma Database Consortium; IV, intravenously; PD-L1, programmed death ligand 1; PO, orally; Q2W, every 2 weeks; QD, once daily; RECIST, Response Evaluation Criteria in Solid Tumors.
1. clinicaltrials.gov/ct2/show/NCT03141177. Accessed June 8, 2020; 2. Choueiri et al. Poster presented at the American Society of Clinical Oncology Annual Meeting 2018. TPS4598.

Courtesy of Thomas Powles, MBBS, MRCP, MD

CheckMate 9ER — PFS

Median PFS, months (95% CI)	
NIVO+CABO	16.6 (12.8–19.8)
SUN	8.3 (7.0-9.7)

HR = 0.56 (95% CI, 0.46–0.68)
***P* < 0.0001**



No. at risk

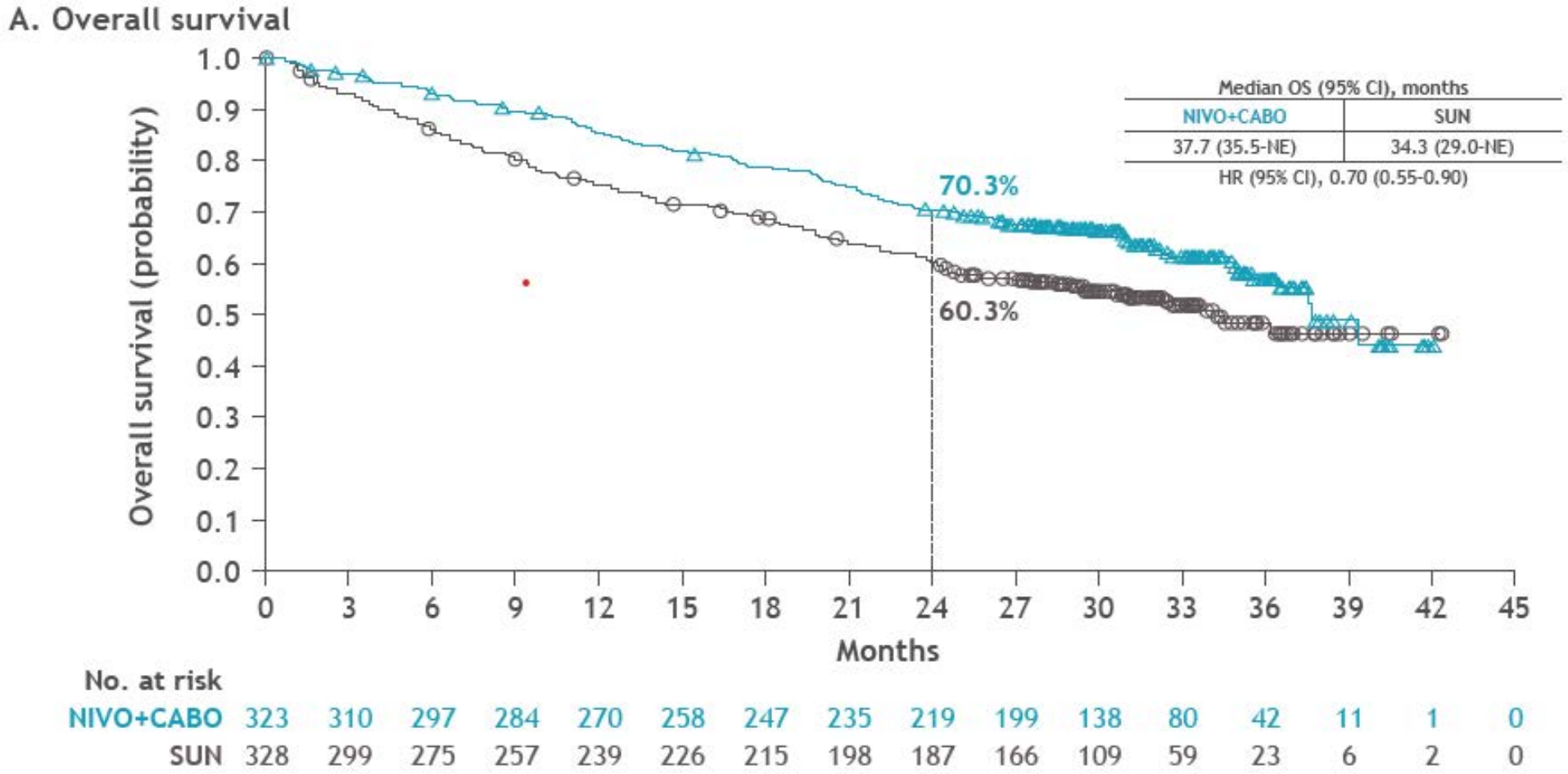
NIVO+CABO	323	279	234	196	144	77	35	11	4	0
SUN	328	228	159	122	79	31	10	4	1	0

Minimum study follow-up, 10.6 months.

Powles T et al. ASCO GU 2022;Abstract 350.

Courtesy of Thomas Powles, MBBS, MRCP, MD

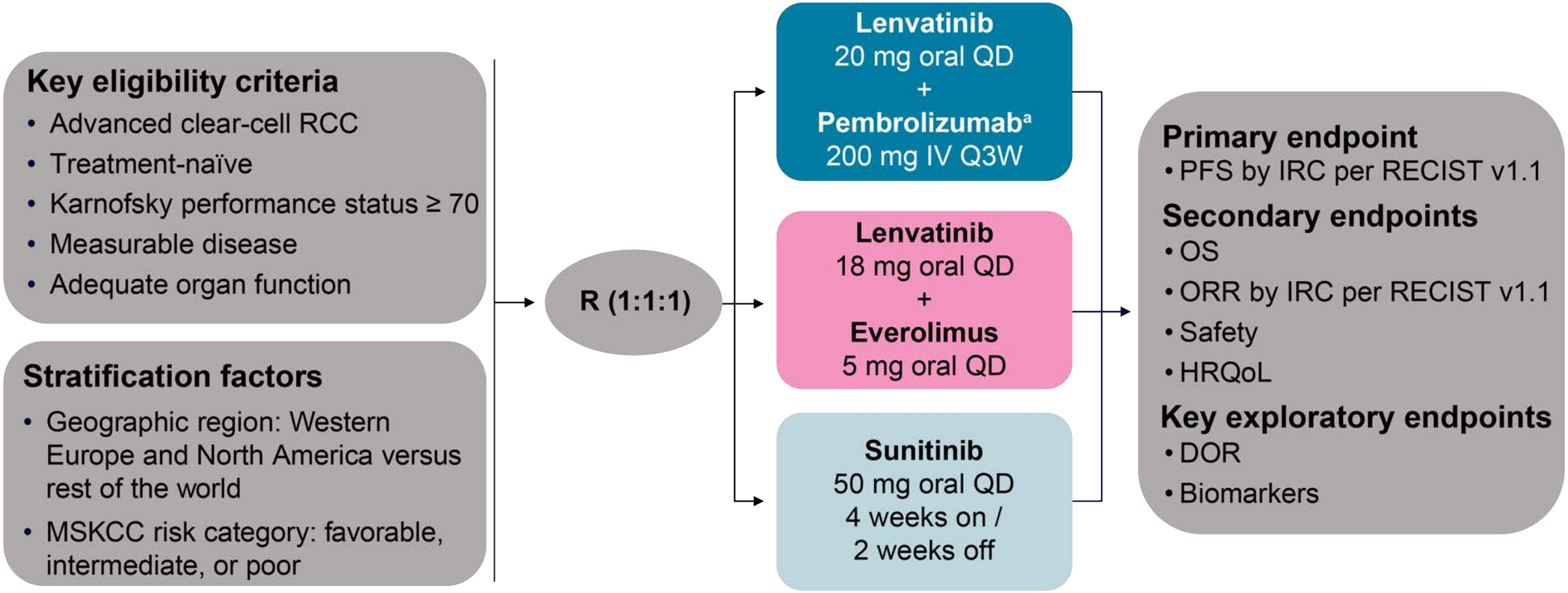
CheckMate 9ER — 24-month OS



Courtesy of Thomas Powles, MBBS, MRCP, MD

Powles T et al. ASCO GU 2022;Abstract 350.

CLEAR Study Design

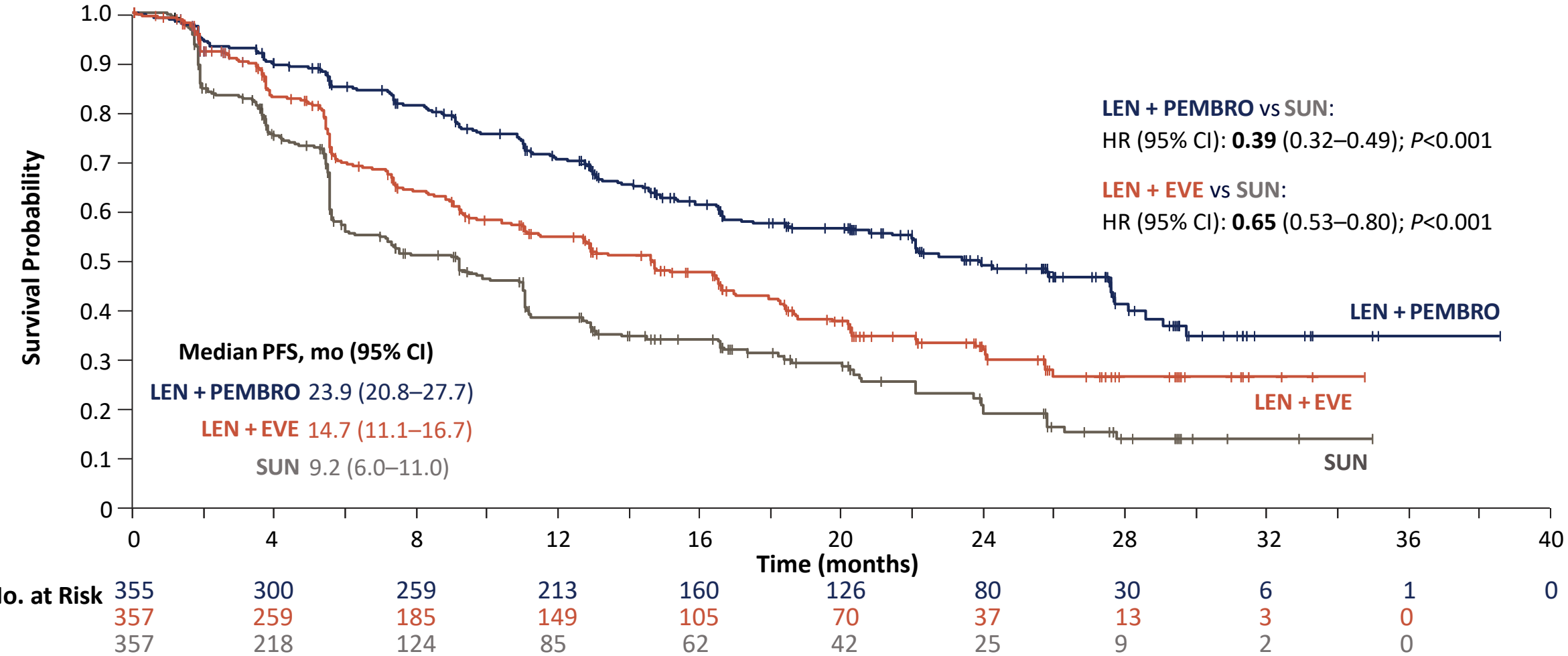


[a]Patients could receive a maximum of 35 pembrolizumab treatments.

DOR, duration of response; HRQoL, health-related quality of life; IRC, independent review committee; IV, intravenous; MSKCC, Memorial Sloan Kettering Cancer Center; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QD, once daily; Q3W, once every 3 weeks; R, randomization; RCC, renal cell carcinoma; RECIST v1.1; Response Evaluation Criteria In Solid Tumors version 1.1.

Courtesy of Thomas Powles, MBBS, MRCP, MD

CLEAR/KEYNOTE-581: PFS

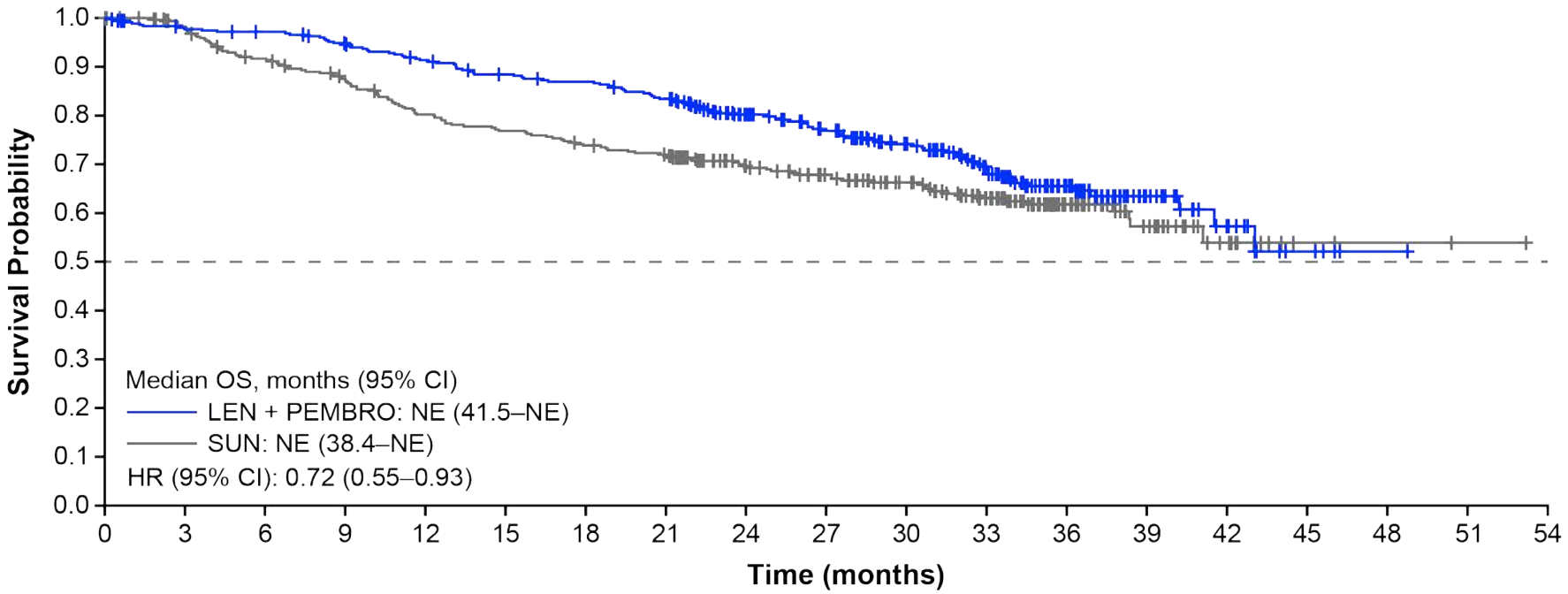


*By Independent Review Committee per RECIST v1.1.
CI, confidence interval; HR, hazard ratio; mo, months; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors.
1. Motzer R et al. Presented at ASCO-GU 2021; 2. Motzer R et al. *N Engl J Med* 2021. doi: 10.1056/NEJMoa2035716. Epub ahead of print.

Adapted from: Motzer R et al. ASCO-GU 2021

Courtesy of Thomas Powles, MBBS, MRCP, MD

CLEAR/KEYNOTE-581: Overall Survival[a]



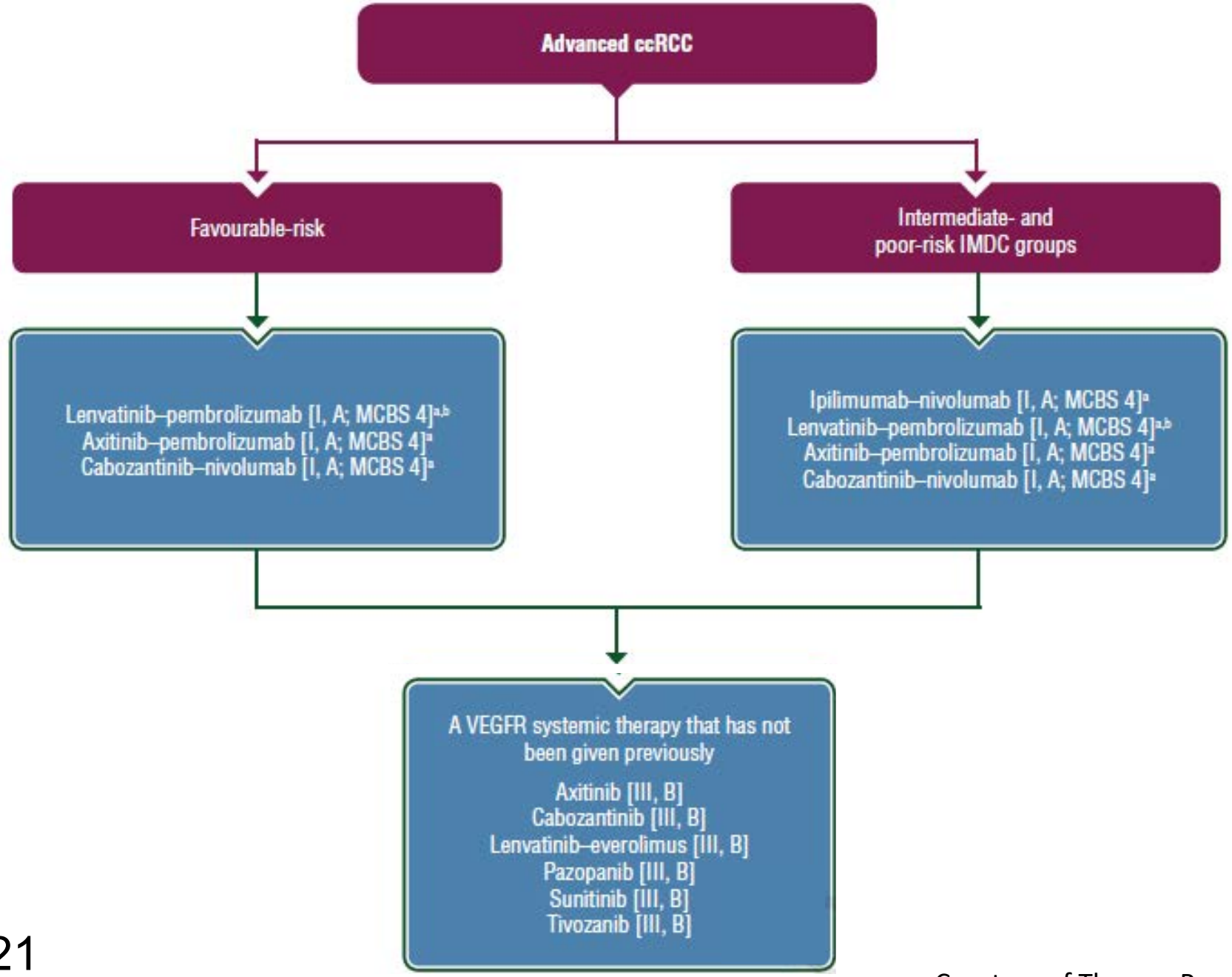
Number of patients at risk:

LEN + PEMBRO	355	342	338	327	313	300	294	280	232	207	174	133	75	31	15	5	1	0
SUN	357	332	307	289	264	253	242	234	195	177	153	116	66	34	14	3	2	1	0

- Median duration of follow-up for OS was 33.7 months (95% CI, 32.8–34.4) in the LEN + PEMBRO arm and 33.4 months (95% CI, 32.5–34.1) in the SUN arm
- 250 (70.4%) and 235 (65.8%) patients in the LEN + PEMBRO and SUN arms were censored, respectively

[a]Data cutoff occurred on March 31, 2021.
CI, confidence interval; HR, hazard ratio; NE, not estimable; OS, overall survival.

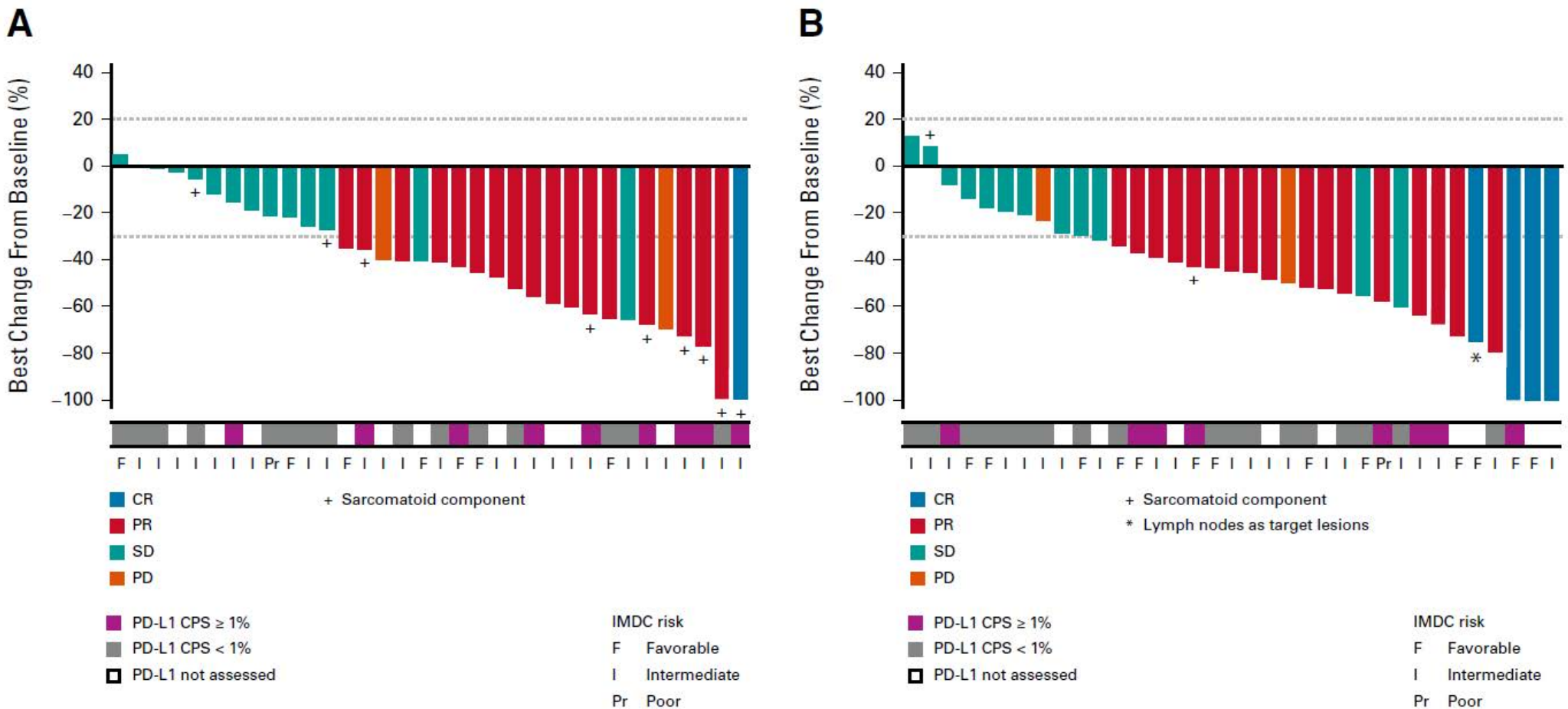
Courtesy of Thomas Powles, MBBS, MRCP, MD



ESMO eUpdate
Powles et al 2021

Courtesy of Thomas Powles, MBBS, MRCP, MD

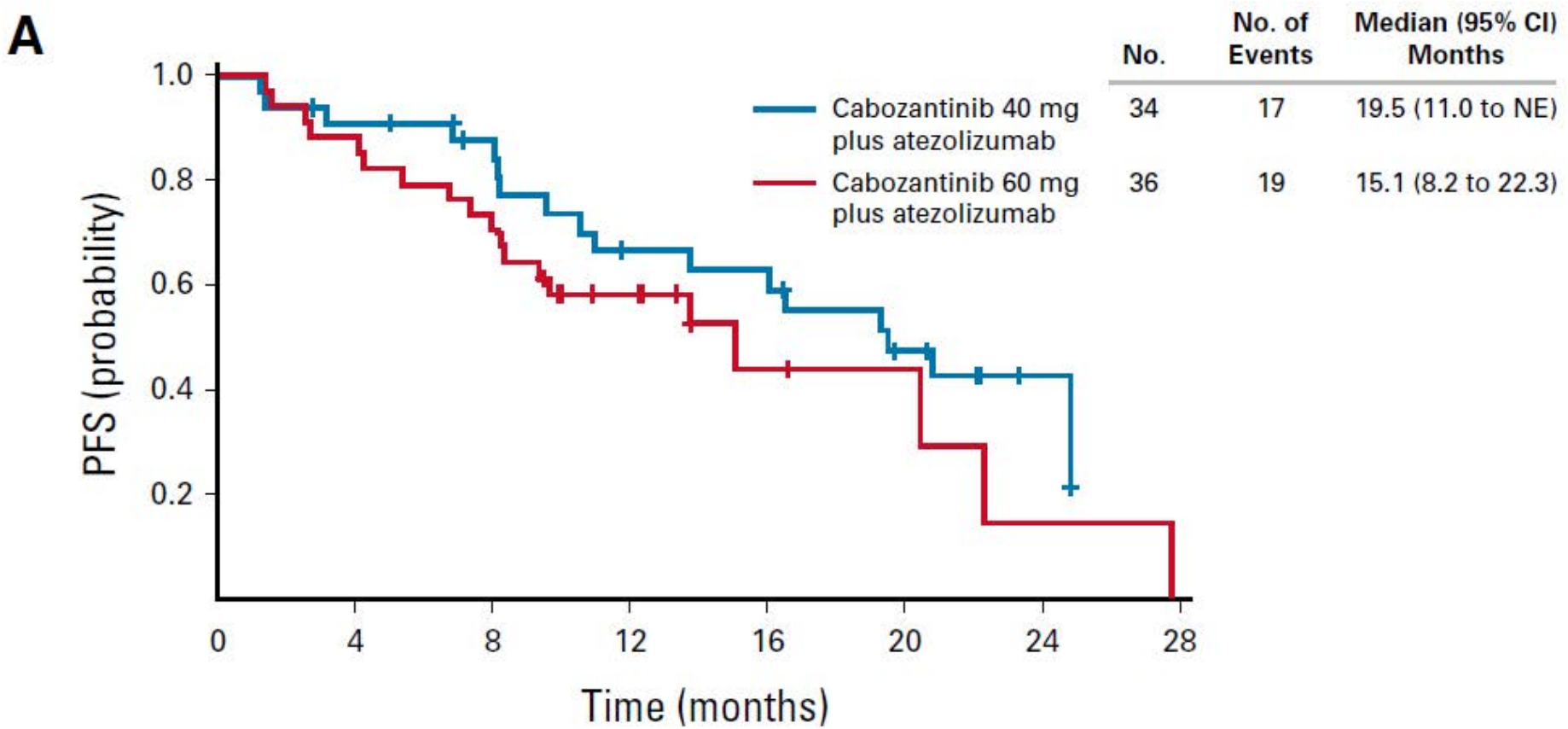
Cabozantinib in Combination With Atezolizumab for Advanced Renal Cell Carcinoma: Results From the COSMIC-021 Study



Courtesy of Thomas Powles, MBBS, MRCP, MD

Pal SK et al. J Clin Oncol 2021;39(33):3725-36.

Cabozantinib in Combination With Atezolizumab for Advanced Renal Cell Carcinoma: Results From the COSMIC-021 Study



	No.	No. of Events	Median (95% CI) Months
Cabozantinib 40 mg plus atezolizumab	34	17	19.5 (11.0 to NE)
Cabozantinib 60 mg plus atezolizumab	36	19	15.1 (8.2 to 22.3)

Courtesy of Thomas Powles, MBBS, MRCP, MD

Pal SK et al. J Clin Oncol 2021;39(33):3725-36.

Agenda

Advances in Metastatic Renal Carcinoma – Prof Powles

Module 1: Adjuvant Therapy in Renal Cell Carcinoma (RCC)

Module 2: First-Line Treatment of Metastatic RCC

Module 3: Belzutifan for von Hippel-Lindau-Associated RCC

- Jonasch E et al. N Engl J Med 2021;385(22):2036-46, Choueiri et al. GU Cancers Symposium #272, McDermott D et al. ESMO 2021;Abstract 656MO.

Module 4: Non-Clear Cell RCC

2021 Year in Review: Urothelial Carcinoma – Dr Plimack

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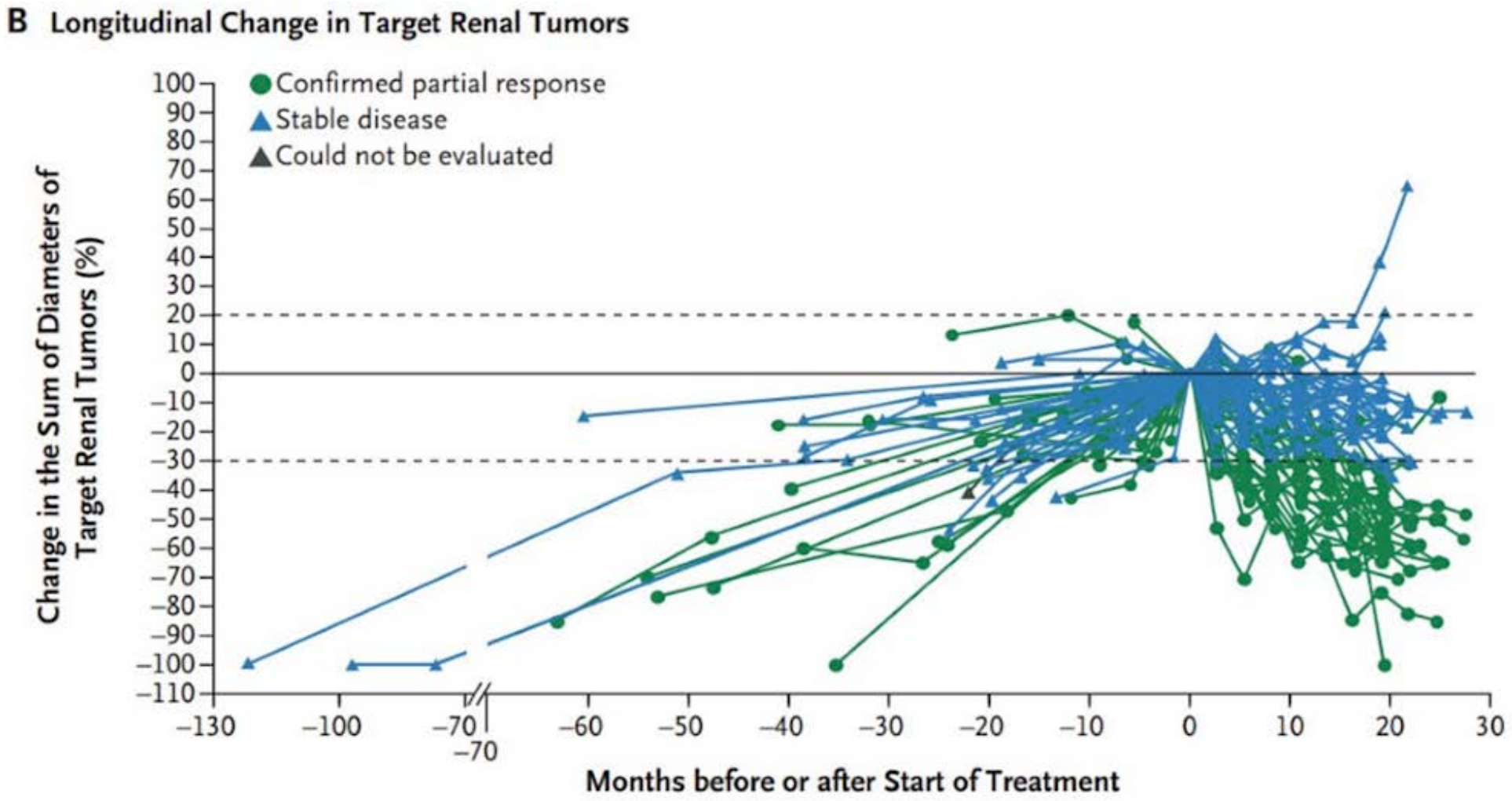
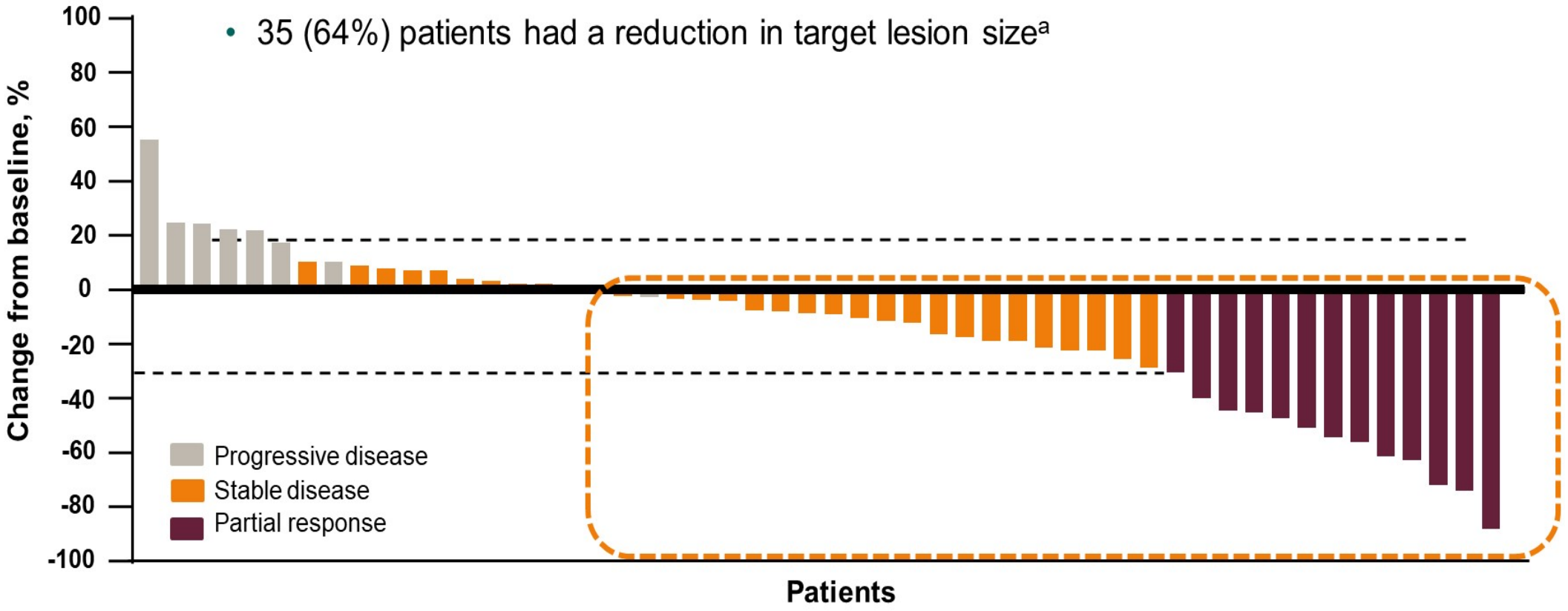
Belzutifan in VHL driven primary renal tumors



Courtesy of Thomas Powles, MBBS, MRCP, MD

Jonasch E et al. N Engl J Med 2021;385(22):2036-46.

Belzutifan in heavily pretreated advanced RCC



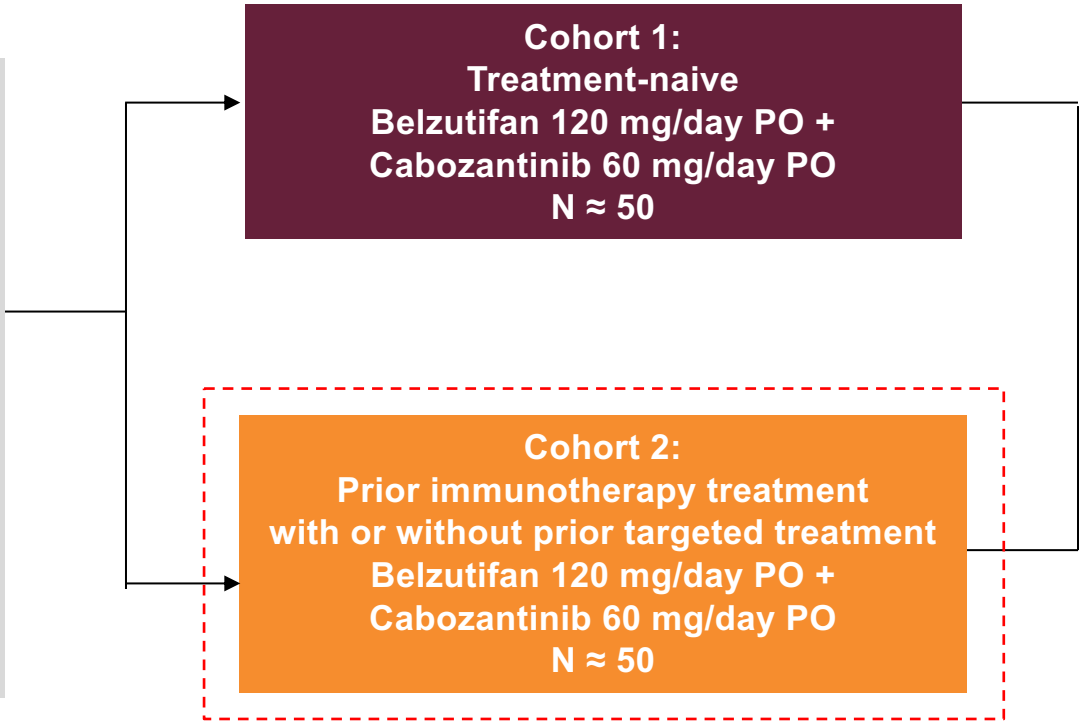
[a]3 patients were nonevaluable. Data cutoff: June 1, 2020.

Choueiri et al. GU Cancers Symposium #272

Courtesy of Thomas Powles, MBBS, MRCP, MD

Phase 2 Study of Belzutifan, an Oral Hypoxia-Inducible Factor 2α Inhibitor, Plus Cabozantinib

Key Eligibility Criteria
- Advanced or metastatic ccRCC
- Being treatment naive or having previously received immunotherapy and ≤2 regimens for locally advanced or metastatic RCC
- ECOG PS 0 or 1
- All IMDC risk categories (favorable/intermediate/poor) allowed



Safety and tolerability were evaluated in the first 6 participants enrolled, irrespective of cohort
- If tolerability was established, enrollment continued
- If tolerability was not established, dose was reviewed

Tumor Assessments
- Q8W after week 9 for 12 months and then Q12W thereafter

End Points
- Primary: ORR
- Secondary: PFS, TTR, DOR, OS, safety/tolerability, PK/PD

Median follow-up[a]
- 15.4 months (range, 8.7-30.6)

[a]Follow-up = the time from first dose to the database cutoff date.
Data cutoff: May 3, 2021.

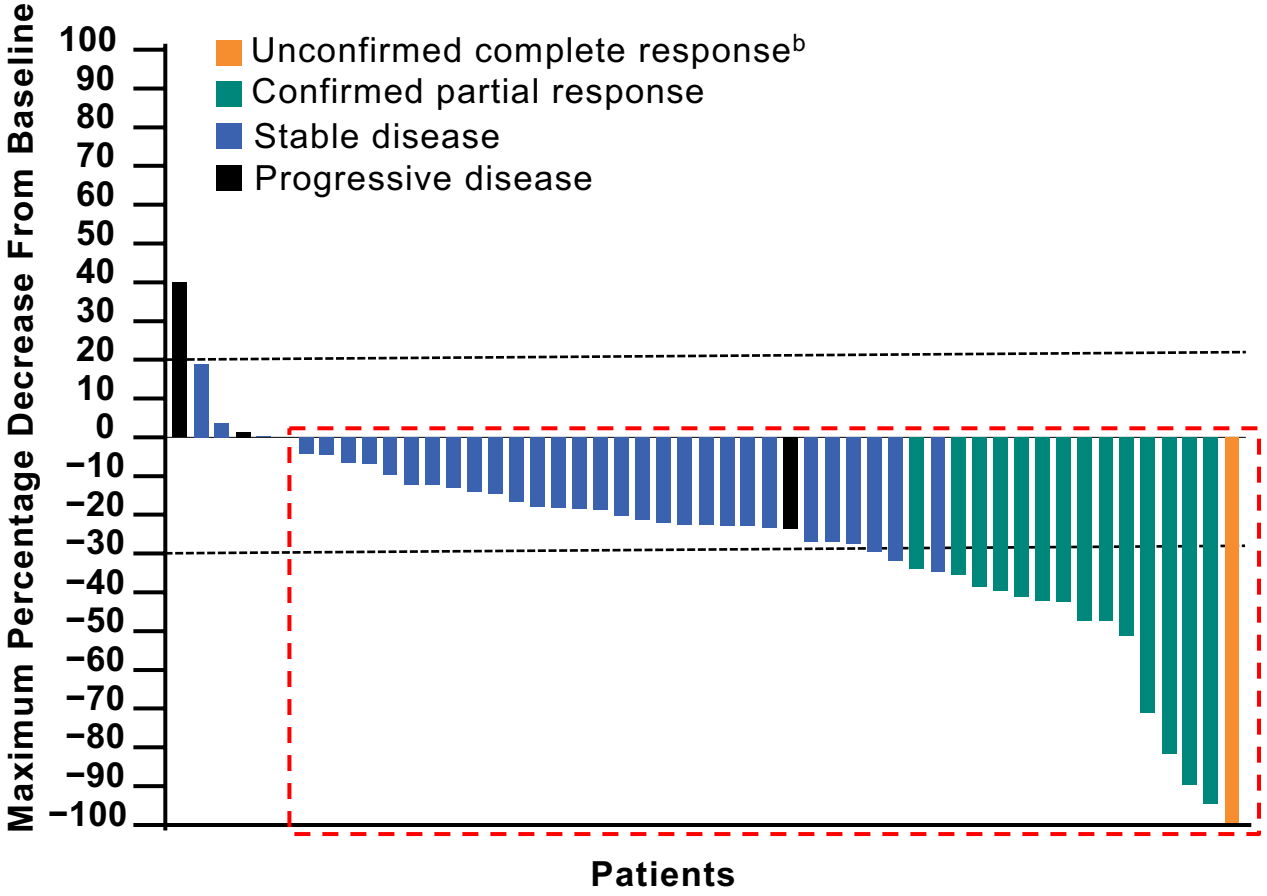
McDermott D et al. ESMO 2021;Abstract 656MO.

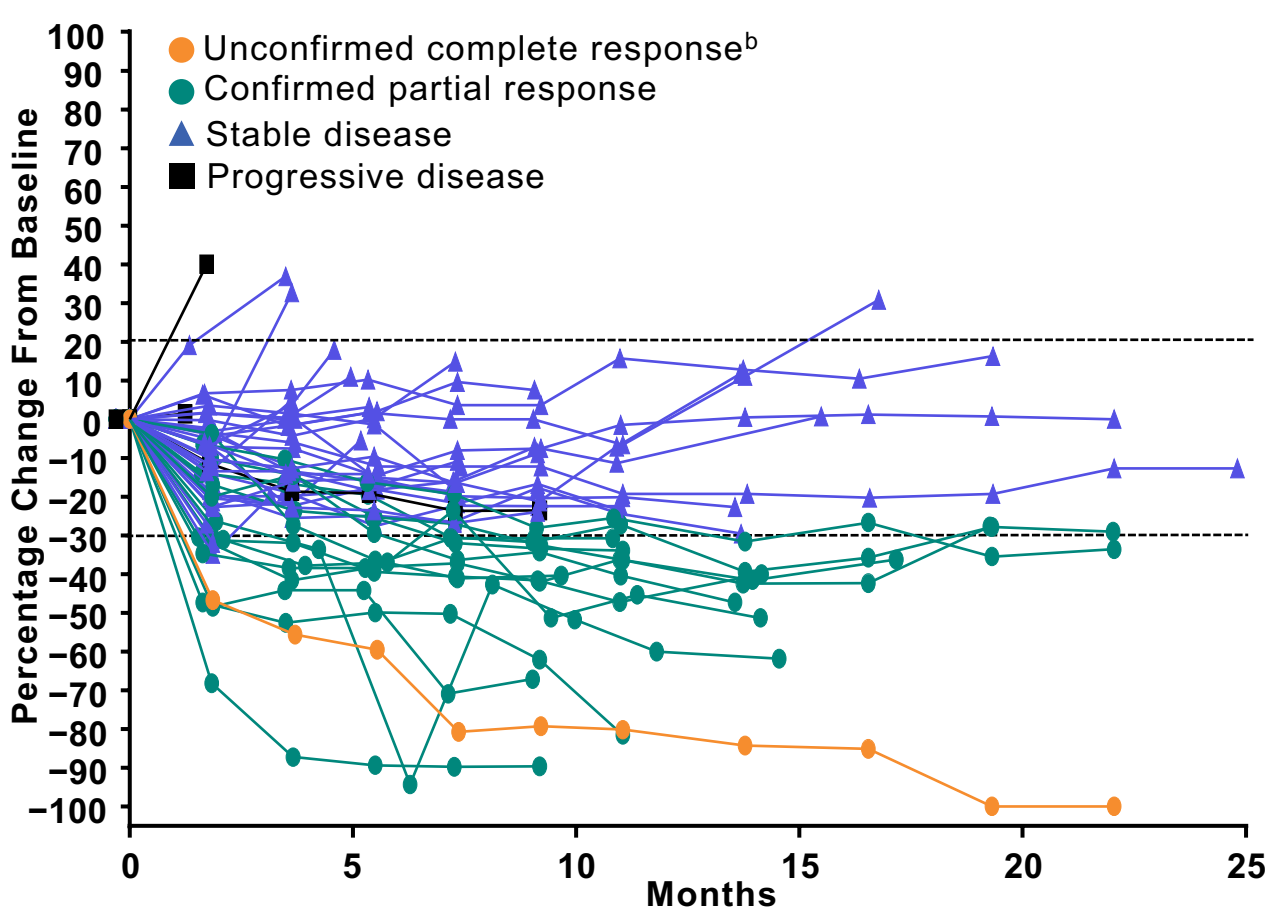
Courtesy of Thomas Powles, MBBS, MRCP, MD

McDermott D et al. ESMO 2021;Abstract 656MO.

Best Tumor Change From Baseline

- 45 of 52 patients (86.5%) experienced a reduction in target lesion size[a]





[a]1 patient had a response of "not available" and was recorded as having no change from baseline value. [b]Documented at a single time point before the data cutoff date; to be confirmed at a subsequent time point. Data cutoff: May 3, 2021.

Courtesy of Thomas Powles, MBBS, MRCP, MD

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Module 4: Non-Clear Cell RCC

- SWOG 1500: PAPMET

2021 Year in Review: Urothelial Carcinoma – Dr Plimack

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Module 6: Adjuvant and Neoadjuvant Treatments for NMIBC

Module 7: Sequencing Therapies for Metastatic Urothelial Bladder Cancer

A comparison of sunitinib with cabozantinib, crizotinib, and savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial

Sumanta K Pal, Catherine Tangen, Ian M Thompson Jr, Naomi Balzer-Haas, Daniel J George, Daniel Y C Heng, Brian Shuch, Mark Stein, Maria Tretiakova, Peter Humphrey, Adebowale Adeniran, Vivek Narayan, Georg A Bjarnason, Ulka Vaishampayan, Ajjai Alva, Tian Zhang, Scott Cole, Melissa Plets, John Wright, Primo N Lara Jr

Lancet 2021;397(10275):695-703.

Agenda

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2021 Year in Review: Urothelial Carcinoma – Dr Plimack

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- KEYNOTE-057

Module 6: Adjuvant and Neoadjuvant Treatments for NMIBC

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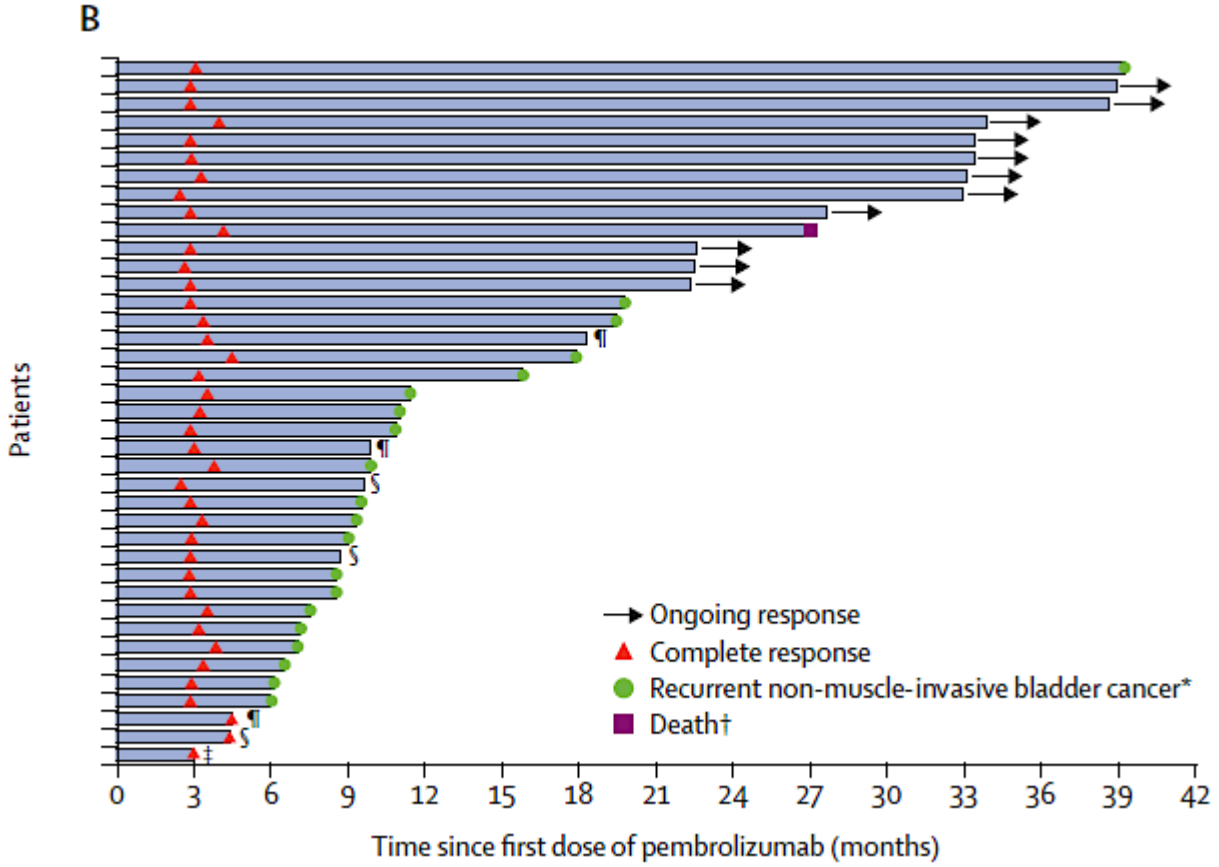
RTP Year in Review 2022

NMIBC: KEYNOTE-057

Time to complete response and recurrence of high-risk non-muscle-invasive bladder cancer in patients with a complete response



Courtesy of Elizabeth R Plimack, MD, MS

Cohort A: BCG unresponsive NMIBC with CIS

- Treated with 1 year of pembrolizumab.
- 96 evaluable for response

This group is at low risk for metastases

This condition is curable with cystectomy

- 41% in CR at 3 months
- 11/96 = 11% maximum durable CR rate

Balar AV et al. Lancet Oncol 2021;22(7):919-30.

Agenda

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2021 Year in Review: Urothelial Carcinoma – Dr Plimack

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Module 6: Adjuvant and Neoadjuvant Treatments for NMIBC

- IMvigor010, CheckMate 274, VESPER EV-103 cohort H

Module 7: Sequencing Therapies for Metastatic Urothelial Bladder Cancer

RTP Year in Review 2022

Adjuvant Therapy for High Risk MIBC: IMvigor010

IMvigor010 Study Design

Key eligibility[a]

- **High-risk MIUC (bladder, renal pelvis, ureter)**
- **Radical cystectomy/nephroureterectomy with LN dissection** within ≤ 14 weeks
  - **ypT2-T4a or ypN+** for patients treated with **NAC[b]**
  - **pT3-T4a or pN+** for patients **not treated with NAC[b]**
- No postsurgical radiation or AC
- If no prior NAC given, patient had to be ineligible for, or declined, cisplatin-based AC
- ECOG PS 0-2
- **Tissue sample for PD-L1 testing**

R 1:1

Atezolizumab 1200 mg q3w *(16 cycles or 1 year)*

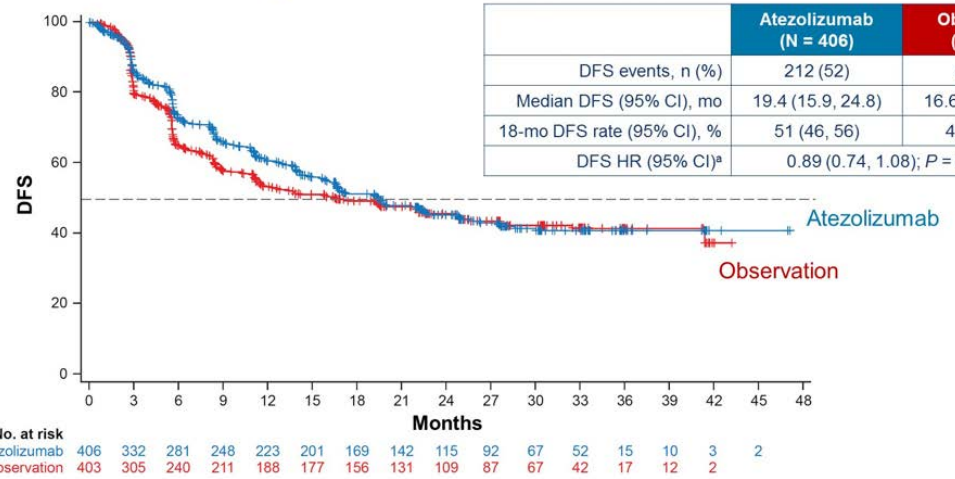
No crossover allowed

Observation[c] q3w

Disease recurrence/ survival follow-up

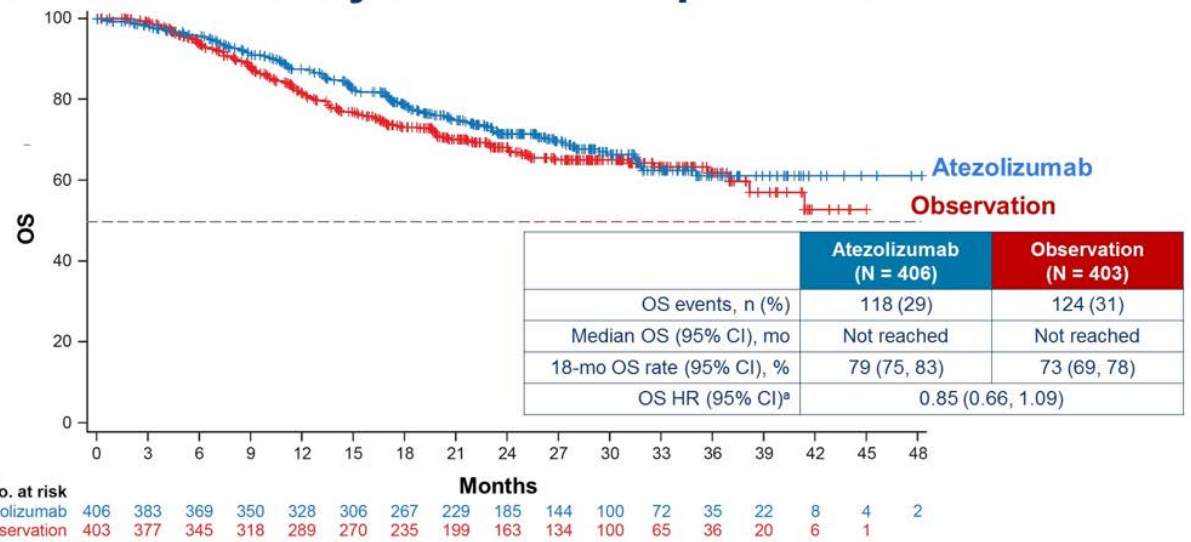
Tumor assessments: q12w for years 1-3, (q24w for years 4-5 and at year 6)

DFS in ITT Population



	Atezolizumab (N = 406)	Observation (N = 403)
DFS events, n (%)	212 (52)	208 (52)
Median DFS (95% CI), mo	19.4 (15.9, 24.8)	16.6 (11.2, 24.8)
18-mo DFS rate (95% CI), %	51 (46, 56)	49 (44, 54)
DFS HR (95% CI)[a]	0.89 (0.74, 1.08); *P* = 0.2446[b]	

Interim OS Analysis in ITT Population

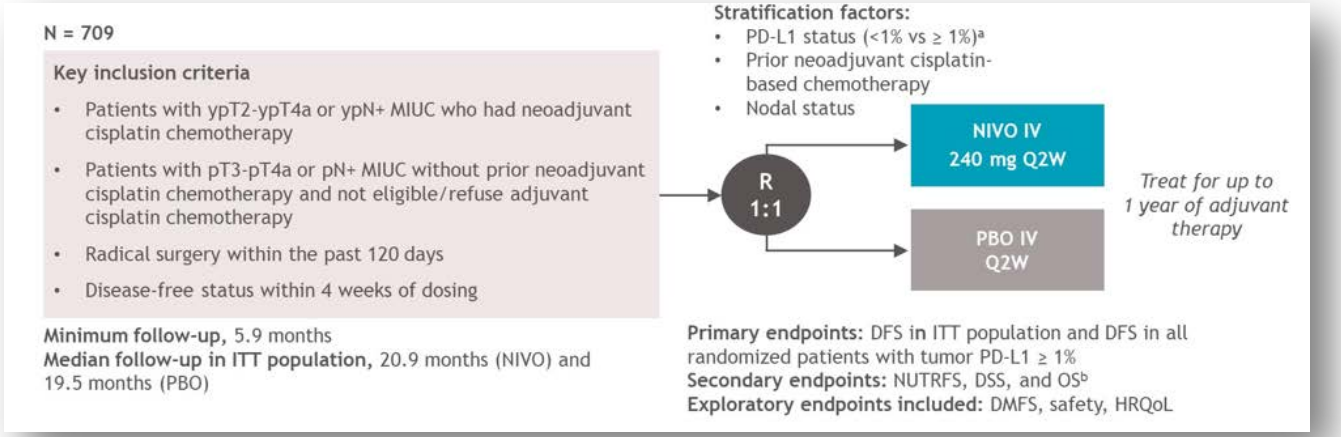


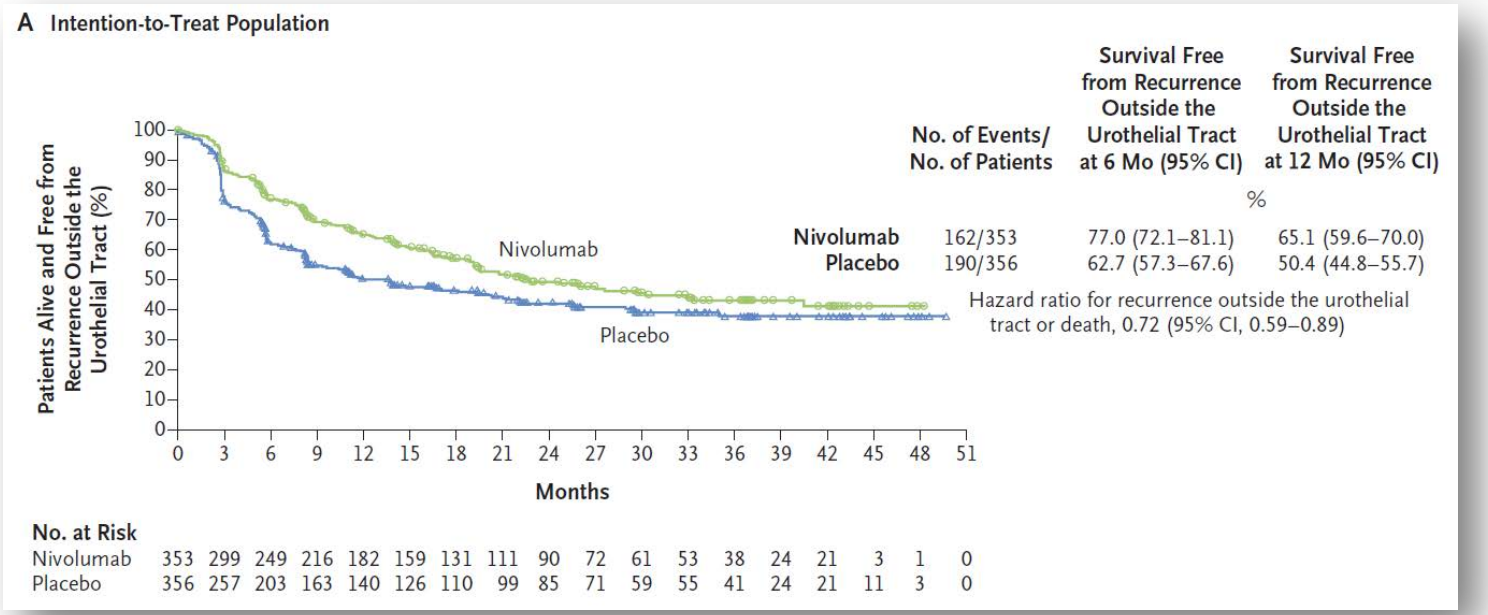
	Atezolizumab (N = 406)	Observation (N = 403)
OS events, n (%)	118 (29)	124 (31)
Median OS (95% CI), mo	Not reached	Not reached
18-mo OS rate (95% CI), %	79 (75, 83)	73 (69, 78)
OS HR (95% CI)[a]	0.85 (0.66, 1.09)	

Courtesy of Elizabeth R Plimack, MD, MS

Bellmunt J et al. Lancet Oncol 2021;22(4):525-37.

Adjuvant Therapy for High Risk MIBC: CM 274





OS data not presented,
Not mature

Bajorin et al. GU ASCO. 2020
Bajorin et al. NEJM 2021

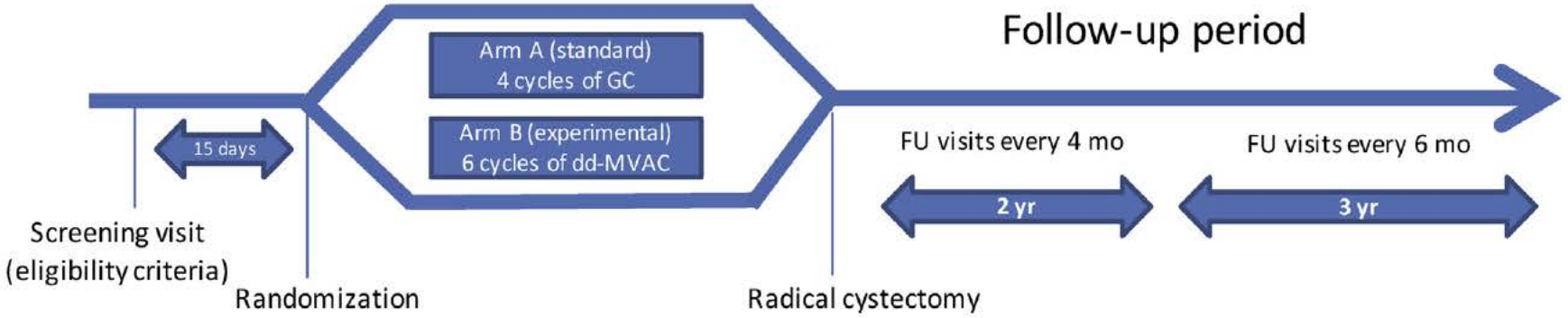
Courtesy of Elizabeth R Plimack, MD, MS

Conclusions: Localized Disease

- NMIBC: KEYNOTE-057
  - Pembrolizumab approved, but low “cure” rate in Cohort A (CIS)
  - Notably cohort B which included higher risk MIBC has not reported
  - Long term results will define clinical utility in this setting.
- MIBC
  - Neoadjuvant Cisplatin-based chemo still SOC. DDMVAC superior results in terms of PFS and ORR vs GC (VESPER)
  - Neoadjuvant EV: ***
- ADJUVANT HIGH RISK RESECTED UC
  - Nivolumab: DFS benefit, no OS benefit (yet) vs placebo
  - Atezolizumab: No DFS or OS benefit vs observation

Courtesy of Elizabeth R Plimack, MD, MS

NEOADJUVANT: VESPER



- Enrolled 437 neoadjuvant patients over 5 years in France
- Randomized 1:1
  - 4 cycles of GC every 3 wks (total 12 weeks)
  - 6 cycles of DDMVAC every 2 wks (total 12 weeks)

Table 5 – Pathological responses observed after neoadjuvant chemotherapy and cystectomy for the dd-MVAC and GC arms

	GC (n = 198)	dd-MVAC (n = 199)	p value
Complete response			
ypT0 pN0	71 (36%)	84 (42%)	0.021
ypTis or ypTa or ypT1 and ypN0		42 (21%)	
≥ypT2 and ypN0	63 (32%)	51 (26%)	
ypN+	35 (18%)	20 (10%)	
Uncertain staging	2	2	
Non-muscle invasive			
<ypT2 pN0	98 (49%)	126 (63%)	0.007
≥ypT2 or ypN+	99 (50%)	72 (36%)	
Uncertain staging	1	1	
Organ-confined disease			
<ypT3 pN0	124 (63%)	154 (77%)	0.001
≥ypT3 or ypN+	73 (37%)	43 (22%)	
Uncertain staging	1	2	

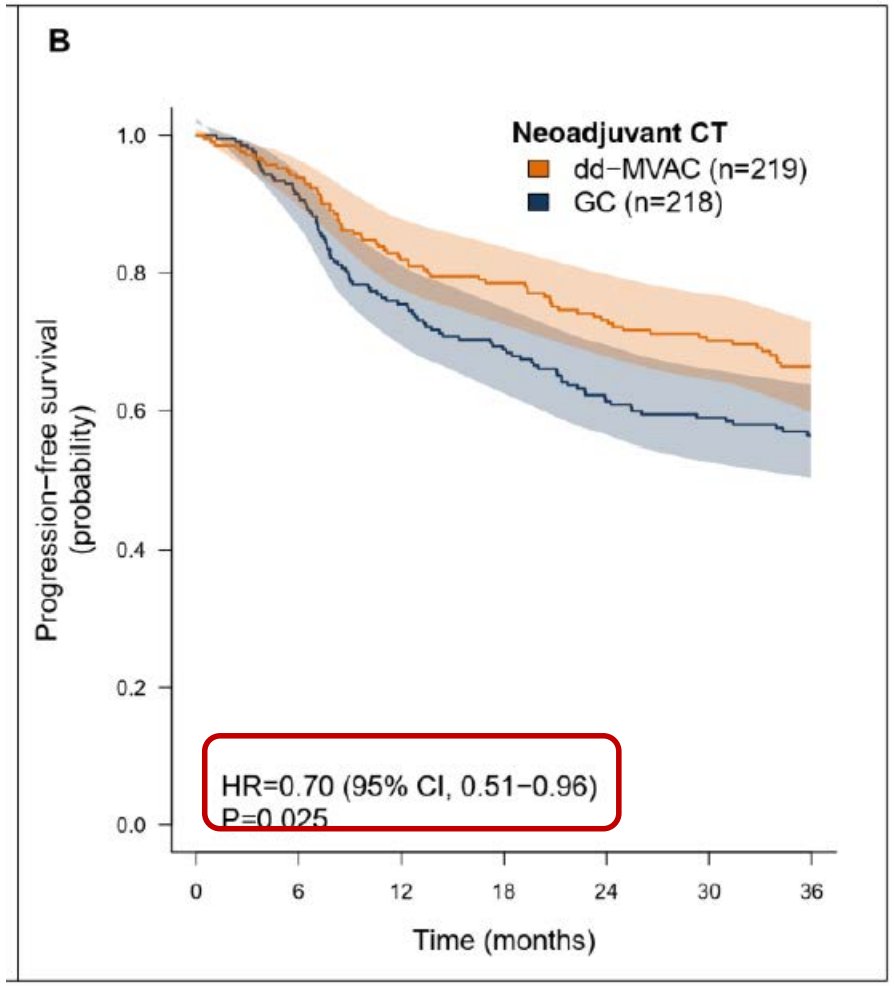
dd-MVAC = dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin; GC = gemcitabine and cisplatin.
Data are presented as frequency (percentage). Comparisons between the GC and dd-MVAC groups are performed with a chi-square test. A p value of <0.05 would assume a statistical difference between the GC and dd-MVAC groups.

Courtesy of Elizabeth R Plimack, MD, MS

Pfister et al. ESMO 2021, abs 652O;Pfister et al. Eur Urol 2021

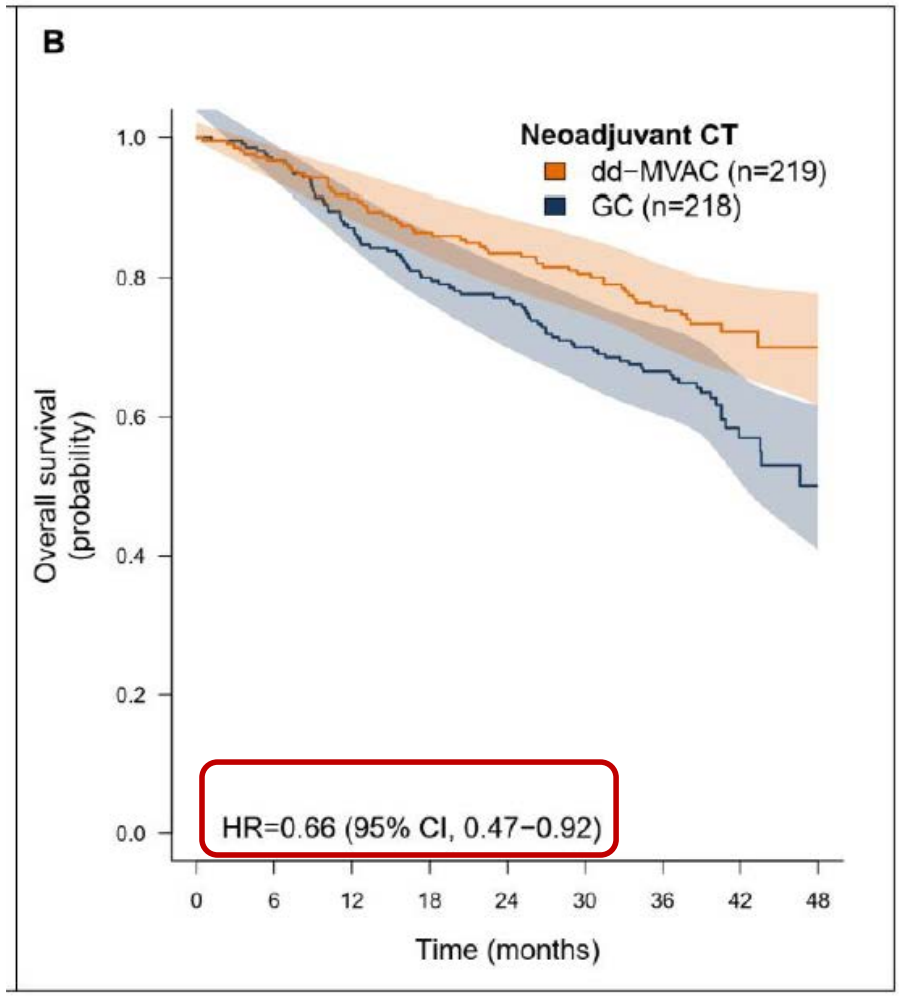
NEOADJUVANT: VESPER

PROGRESSION FREE SURVIVAL (PFS)



Courtesy of Elizabeth R Plimack, MD, MS

OVERALL SURVIVAL (OS)



Pfister et al. ESMO 2021, abs 652O;Pfister et al. Eur Urol 2021

NEOADJUVANT EV: EV-103 COHORT H

EV-related TEAEs seen in ≥20% patients by preferred term	EV Mono (N=22)
Overall (all Grades)	22 (100)
Fatigue	10 (45.5)
Alopecia	8 (36.4)
Dysgeusia	8 (36.4)
Diarrhea	6 (27.3)
Nausea	6 (27.3)
Peripheral sensory neuropathy	6 (27.3)
Dry eye	5 (22.7)
Rash maculo-papular	5 (22.7)

TEAEs are newly occurring AEs or worsening AE after the first dose of study treatment through 30 days after the end of study treatment
Data cut date: 9 Sep 2021
EV: Enfortumab vedotin; RC+PLND: Radical cystectomy plus pelvic lymph node dissection; TEAEs: Treatment-emergent adverse events

- Overall, 4 (18%) patients had Grade ≥3 EV-related TEAEs
  - Grade 3 EV-related TEAEs included: asthenia, dehydration, erythema multiforme, hyperglycemia, post procedural urine leak, rash maculo-papular, small intestinal obstruction
- No EV-related Grade 4 TEAEs or deaths were observed
- 3 deaths occurred on the study:
  - Acute kidney injury
  - Cardiac arrest (related to RC+PLND)
  - Pulmonary embolism (related to RC+PLND)

Courtesy of Elizabeth R Plimack, MD, MS

Petrylak DP et al. ASCO GU 2022;Abstract 435.

NEOADJUVANT EV: EV-103 COHORT H

Pathological Response	Central Pathology Results (N=22) n (%) [95% Confidence Interval]
Pathological Complete Response Rate (defined as absence of any viable tumor tissue: ypT0 and N0)	**8 (36.4%)** [17.2–59.3]
Pathological Downstaging Rate (defined as presence of ypT0, ypTis, ypTa, ypT1, and N0)	**11 (50.0%)** [28.2–71.8]

Courtesy of Elizabeth R Plimack, MD, MS

Petrylak DP et al. ASCO GU 2022;Abstract 435.

Agenda

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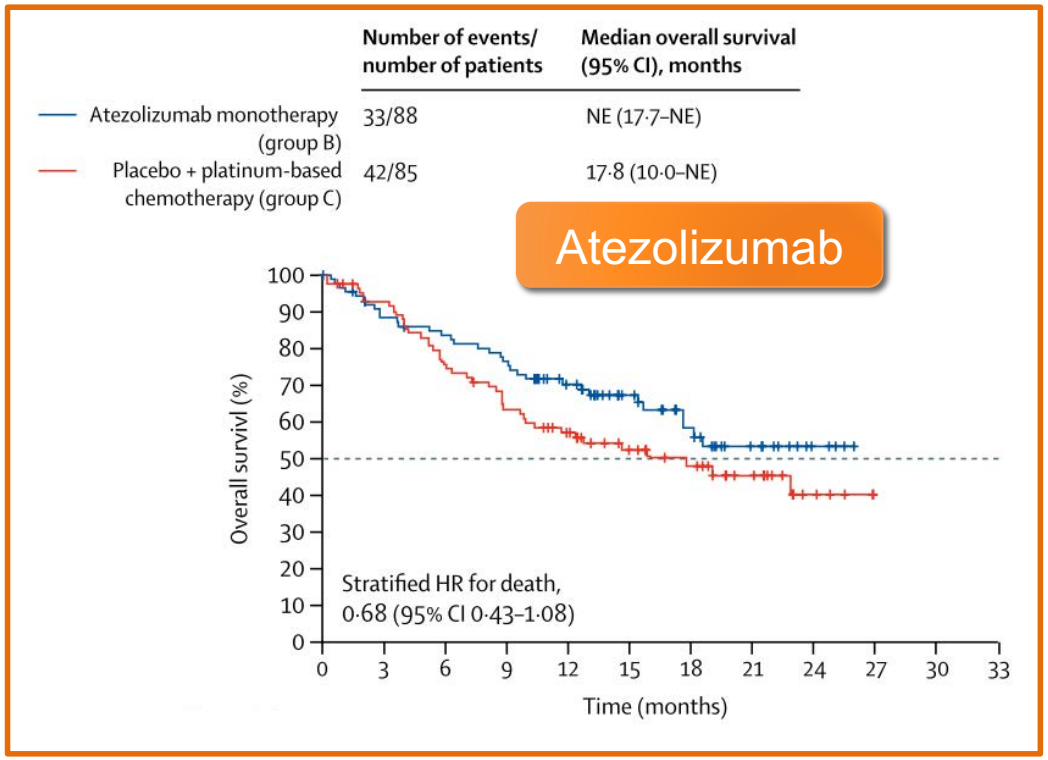
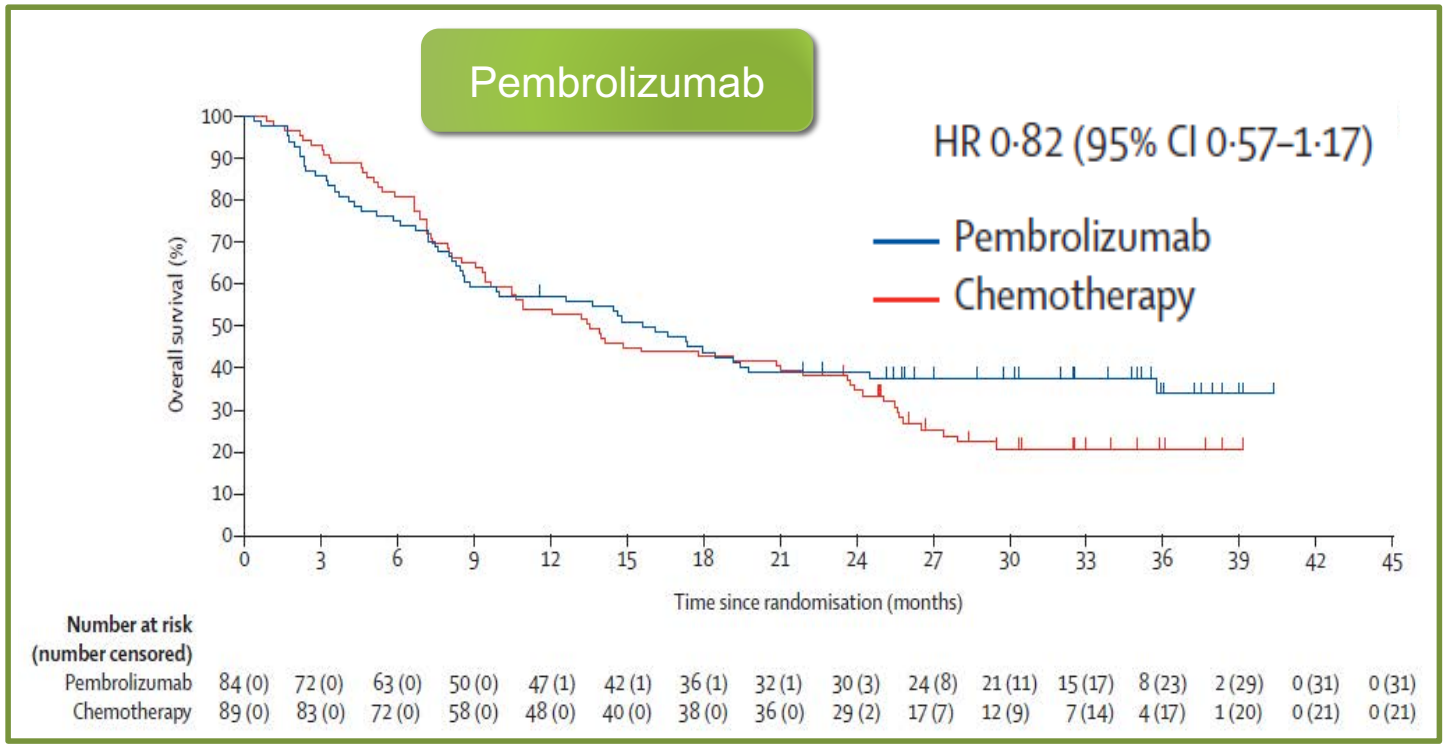
Agenda

Module 7: Sequencing Therapies for Metastatic Urothelial Bladder Cancer

- First-line checkpoint monotherapy versus gemcitabine/platinum for PD-L1-high disease
- EV-103: Dose escalation/expansion cohort A
- JAVELIN Renal 100
- EV-201
- TROPHY-U-01
- Sacituzumab govitecan
- Erdafitinib
- Disitamab vedotin (RC48-ADC)
- DSA201-A-U105: Trastuzumab deruxtecan

PD-L1-High Patients Treated with First-Line Single-Agent Checkpoint vs Gem/Platinum: OS





Galsky MD et al. Lancet 2020;395(10236):1547-57.

Powles T et al. Lancet Oncol 2021;22(7):931-45.

Refs: PubMed PMID: 32416780, 3405117

Courtesy of Elizabeth R Plimack, MD, MS

EV-103: EV Pembro Combo 1L UC

Data from Dose Escalation and Expansion Cohort A

Patient Population

Locally Advanced or Metastatic Urothelial Carcinoma

Dose Escalation*

enfortumab vedotin
+
pembrolizumab

cisplatin-ineligible 1L

(n=5)

Cohort A (Dose Expansion)

enfortumab vedotin
+
pembrolizumab

cisplatin-ineligible 1L

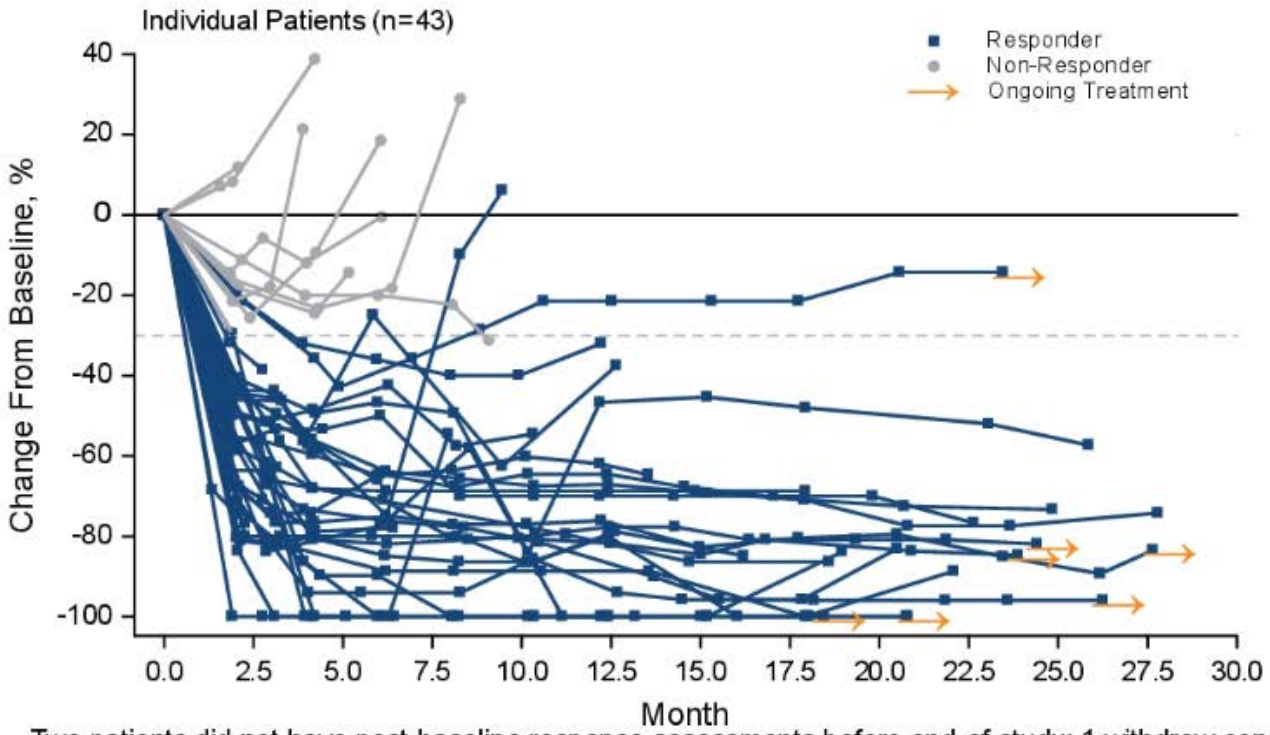
(n=40)

Courtesy of Elizabeth R Plimack, MD, MS

Friedlander TW et al. ASCO 2021;Abstract 4528.

EV-103: EV Pembro Combo 1L UC

Percent Change from Baseline in Sum of Diameters of Target Lesions



- Median number of treatment cycles is 9 (range: 1, 34)
- 87.9% (29/33) of responses observed at first tumor assessment (week 9 ±1 week)
- Median time to response at 2.1 months (range: 1.4, 4.2)

Two patients did not have post-baseline response assessments before end-of-study: 1 withdrew consent and 1 died before any post-baseline response assessment
Dotted horizontal line indicates threshold for partial response (-30%), but is not necessarily indicative of response

Courtesy of Elizabeth R Plimack, MD, MS

Friedlander TW et al. ASCO 2021;Abstract 4528.

EV-103: EV Pembro Combo 1L UC

Treatment-Related Adverse Events of Special Interest (AESI)

AESI[a]	Patients (N=45) n (%)		Median Onset, months (min,max)	Resolution/ Improvement[b] n (%)
	Any Grade	≥Grade 3[c]	Any Grade	Any Grade
Any peripheral neuropathy	28 (62.2)	2 (4.4)	2.4 (0.7,12.5)	19/28 (67.9)
Any skin reactions	30 (66.7)	9 (20.0)	0.7 (0.1,15.7)	27/30 (90.0)
Any hyperglycemia[d]	5 (11.1)	4 (8.9)	0.5 (0.3,3.5)	5/5 (100.0)

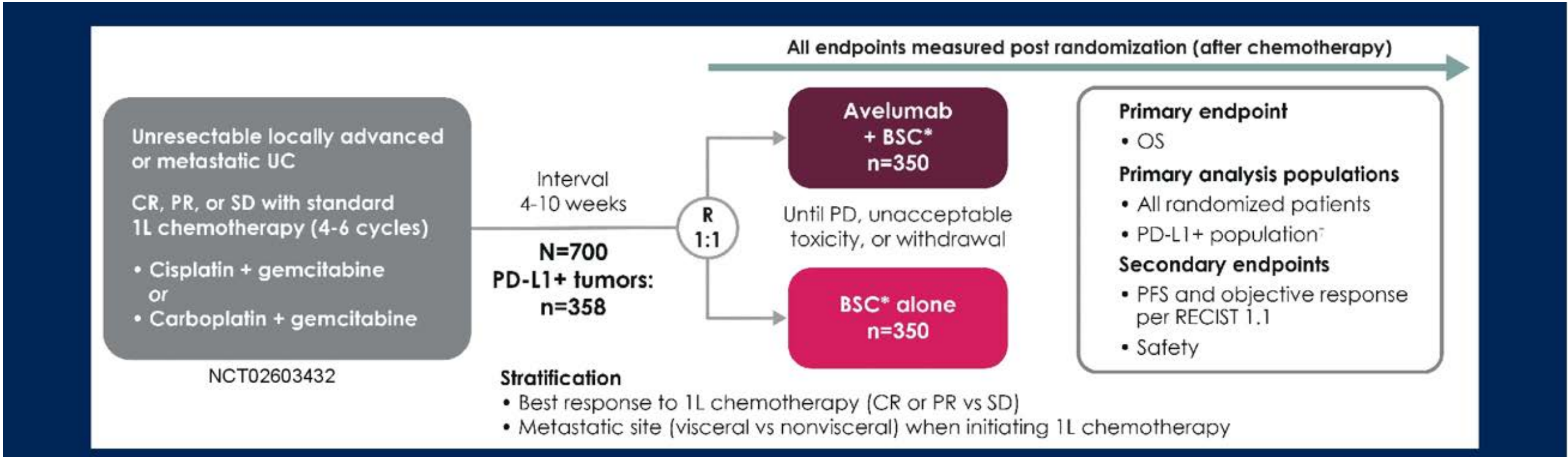
AESI: imAEs[a,e]	Patients (N=45) n (%)	
	Any Grade	≥Grade 3
Immune-mediated AE	20 (44.4)	12 (26.7)[f]

a. Categorized by related Medical Dictionary for Regulatory Activities (MedDRA) terms, MedDRA v. 23.0
b. Resolution/Improvement as of last follow-up. For events that are not resolved, improvement is defined as at least one grade improvement from the worst grade at the last assessment
c. No Grade 5 TRAE of Clinical Interest; two Grade 4 skin reaction events (dermatitis bullous, toxic epidermal necrolysis)
d. Blood glucose assessments were non-fasting

Courtesy of Elizabeth R Plimack, MD, MS

Friedlander TW et al. ASCO 2021;Abstract 4528.

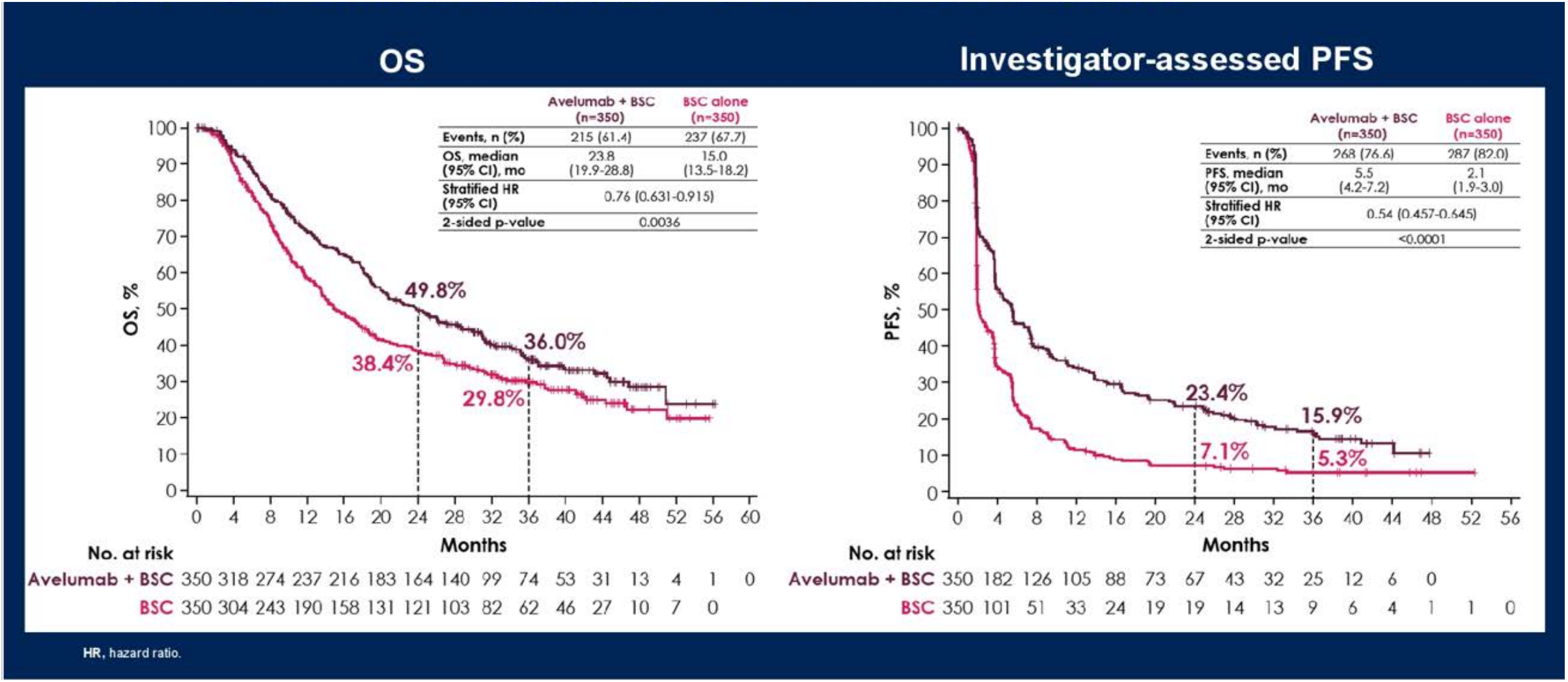
JAVELIN 100 update



Courtesy of Elizabeth R Plimack, MD, MS

Powles T et al. ASCO GU 2022;Abstract 487.

JAVELIN 100 update



Courtesy of Elizabeth R Plimack, MD, MS

Powles T et al. ASCO GU 2022;Abstract 487.

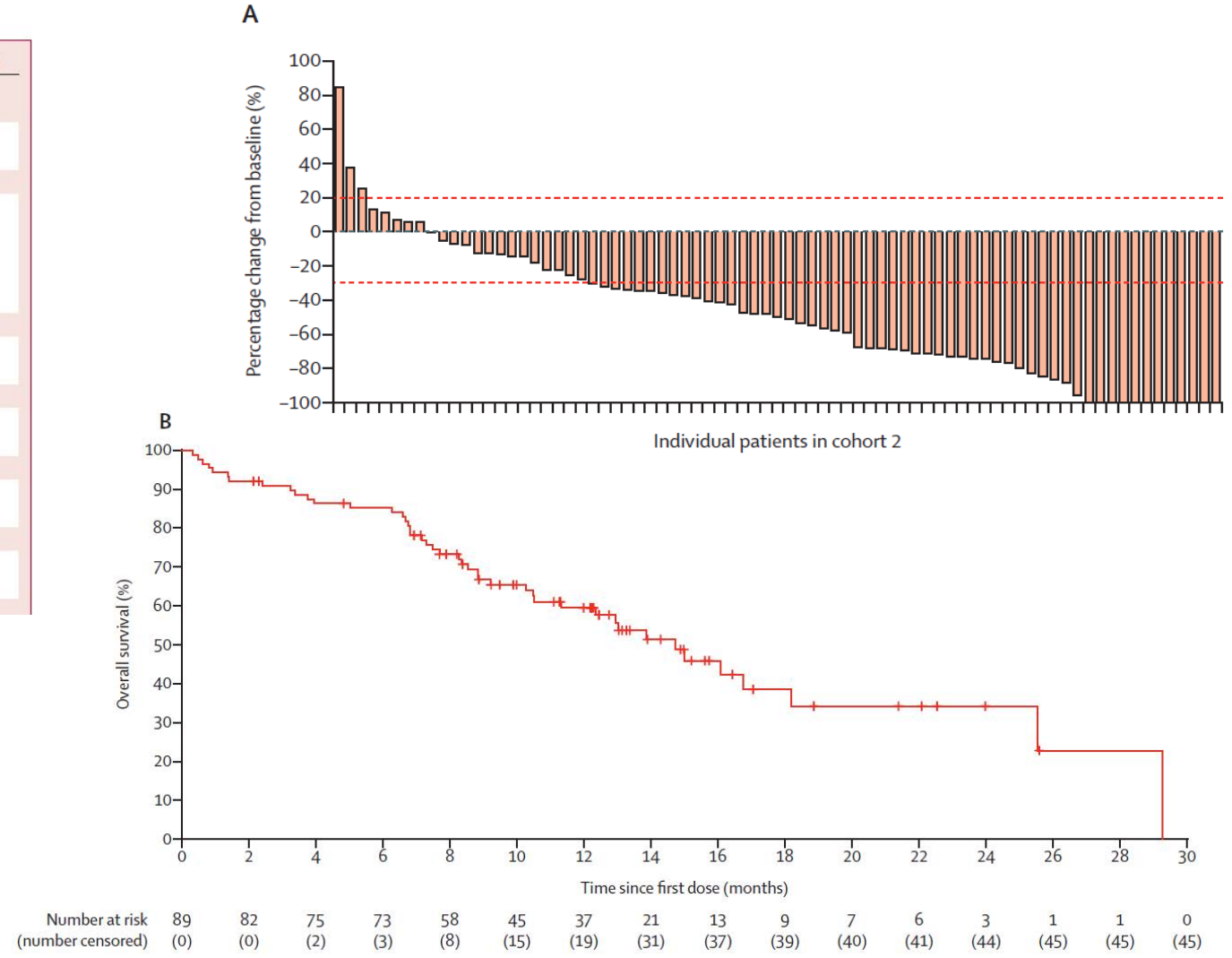
Enfortumab vedotin after PD-1 or PD-L1 inhibitors in cisplatin-ineligible patients with advanced urothelial carcinoma (EV-201): a multicentre, single-arm, phase 2 trial

	Cohort 2 (n=89)
Sex	
Male	66 (74%)
Female	23 (26%)
Age, years	
Median	75 (68–78)
Range	49–90
<75 years	43 (48%)
≥75 years	46 (52%)
Region	
North America	57 (64%)
Asia	18 (20%)
Europe	14 (16%)
ECOG performance status	
0	37 (42%)
1	41 (46%)
Primary tumour location	
Upper tract (renal pelvis and ureter)	38 (43%)
Bladder or other	51 (57%)
Histology type	
Urothelial carcinoma only	62 (70%)
Urothelial carcinoma with squamous differentiation	12 (13%)
Urothelial carcinoma with other histological variants‡	15 (17%)

(Table 1 continues in next column)

	Cohort 2 (n=89)
(Continued from previous column)	
Current extent of disease	
Locally advanced	1 (1%)
Metastatic	88 (99%)
Metastasis sites	
Lymph nodes only	18 (20%)
Visceral disease§	70 (79%)
Bone	22 (25%)
Liver	21 (24%)
Lung	41 (46%)
Number of previous systemic therapies	
Median	1 (1–1)
Range	1–4¶
Response to PD-1 or PD-L1-containing therapy	
Responder	22 (25%)
Non-responder	67 (75%)
Baseline PD-L1 expression	
CPS <10	53/80 (66%)‖
CPS ≥10	27/80 (34%)‖
Baseline Nectin-4 expression, H-score**	
Median	275 (230–296)
Range	0–300

	Cohort 2 (n=89)
Objective response rate	46 (52%)
95% CI	41–62
Best overall response	
Complete response	18 (20%)
Partial response	28 (31%)
Stable disease	27 (30%)
Progressive disease	8 (9%)
Not evaluable*	8 (9%)

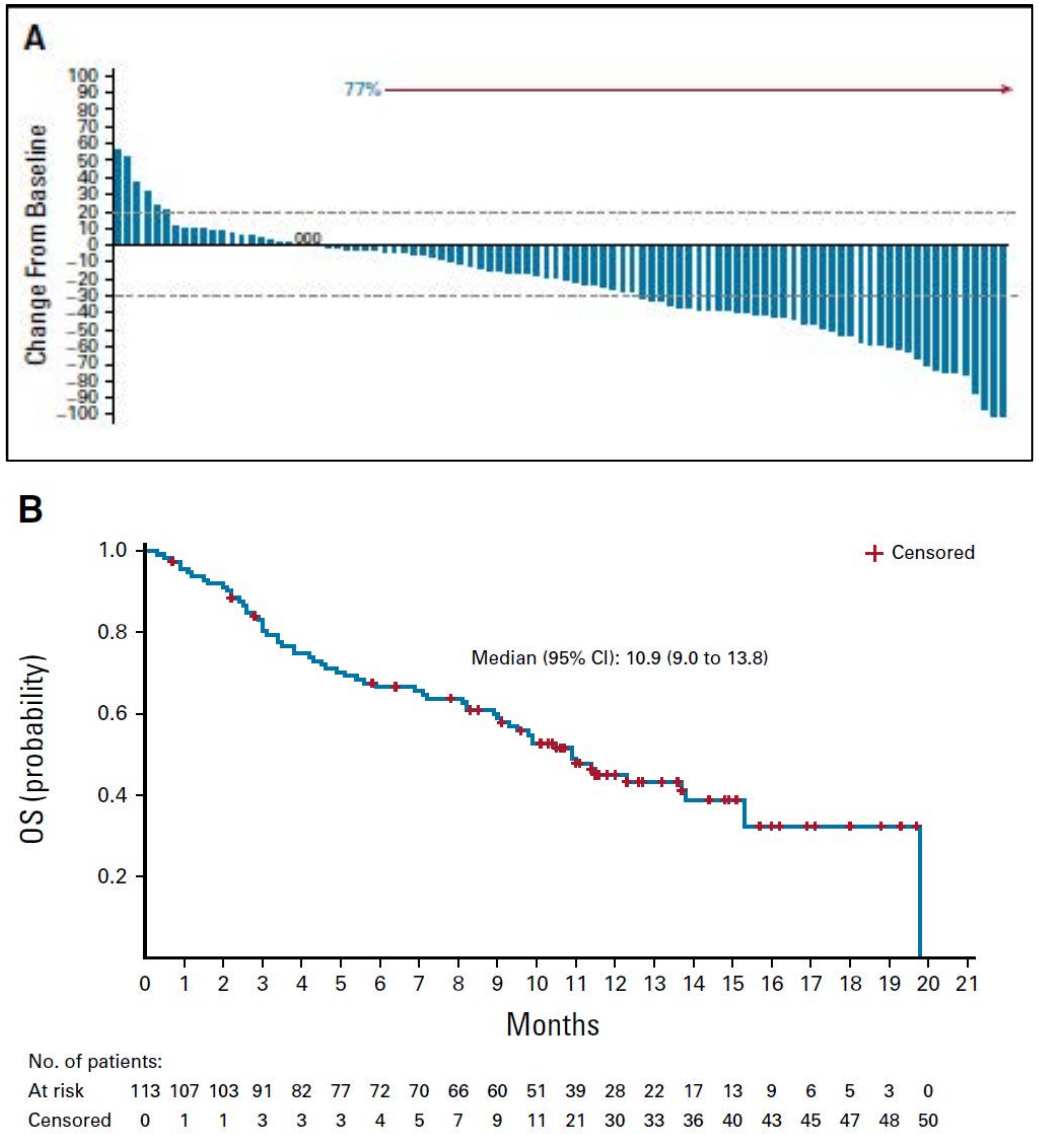


Courtesy of Elizabeth R Plimack, MD, MS

TROPHY-U-01: A Phase II Open-Label Study of Sacituzumab Govitecan in Patients With Metastatic Urothelial Carcinoma Progressing After Platinum-Based Chemotherapy and Checkpoint Inhibitors

TABLE 1. Patient Demographics and Baseline Characteristics

Characteristic	N = 113
Age, median (range), years	66 (33-90)
≥ 75, No. (%)	26 (23)
Male, No. (%)	88 (78)
Race, No. (%)	
White	84 (74)
Black	3 (3)
Asian	3 (3)
Other	1 (1)
Not reported	22 (20)
ECOG PS, No. (%)	
0	32 (28)
1	81 (72)
Type of disease, No. (%)	
Metastatic urothelial cancer	108 (96)
Locally advanced unresectable	4 (3.5)
Missing	1 (0.09)
Visceral metastatic sites, No. (%)[a]	75 (66)
Lung	49 (43)
Liver	38 (34)
Other	15 (13)
Setting of prior systemic therapy, No. (%)	
Adjuvant	22 (19.5)
Metastatic	108 (95.6)
Neoadjuvant	36 (31.9)
Prior CPIs, No. %	112 (99)[b]
Prior platinum anticancer therapy, No. (%)	113 (100)
Cisplatin	89 (79)
Carboplatin	24 (21)
Prior enfortumab vedotin, No. (%)	10 (8.8)
Prior erdafitinib, No. (%)	2 (1.8)
Prior anticancer regimens, median, No. (range)	3.0 (1-8)



Tagawa ST et al. J Clin Oncol 2021;39(22):2474-85.

Courtesy of Elizabeth R Plimack, MD, MS

Sacituzumab govitecan (SG) + Pembro

- Post platinum, checkpoint naïve
  - **SG + Pembro ORR 34%[1]**

  Compare to:
  - Pembro alone ORR 21%[2]
  - SG alone post platinum and CPI ORR 27%[3]
  - EV post platinum and CPI ORR 44%[4]

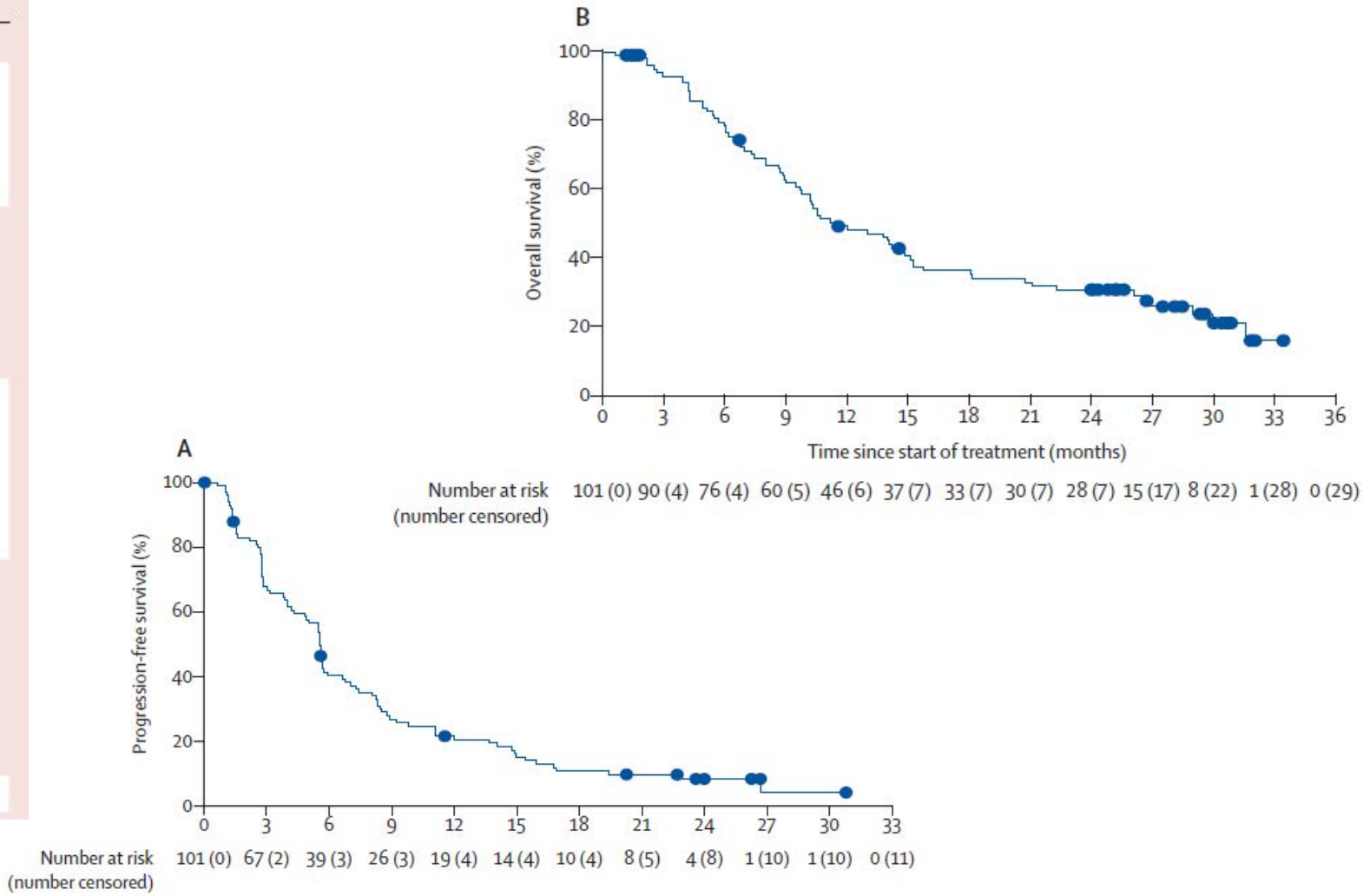
- Additive toxicity
- Combination not likely to enter clinical practice

1. Grivas P et al. ASCO GU 2022;Abstract 434; 2. Bellmunt J et al. NEJM 2017;376(11):1015-26; 3. Loriot Y et al. ESMO 2020;Abstract LBA24; 4.Rosenberg JE et al. JCO 2019;37(29):2592–600.

Courtesy of Elizabeth R Plimack, MD, MS

Efficacy and safety of erdafitinib in patients with locally advanced or metastatic urothelial carcinoma: long-term follow-up of a phase 2 study

	Participants (n=101)*
Age, years	67 (61–73)
ECOG performance status	
0	51 (50%)
1	43 (43%)
2	7 (7%)
Pretreatment†	
Progressed or relapsed after chemotherapy	89 (88%)
Chemotherapy-naive	12 (12%)
Previous immunotherapy	24 (24%)
Number of lines of previous treatment‡	
0	10 (10%)
1	48 (48%)
2	28 (28%)
≥3	15 (15%)
Visceral metastases§	
Present	78 (77%)
Absent	23 (23%)
Liver	20 (20%)
Lung	57 (56%)
Bone	23 (23%)
Lymph node metastases only	9 (9%)



Courtesy of Elizabeth R Plimack, MD, MS

Siefker-Radtke AO et al. Lancet Oncol 2022;23(2):248-58.

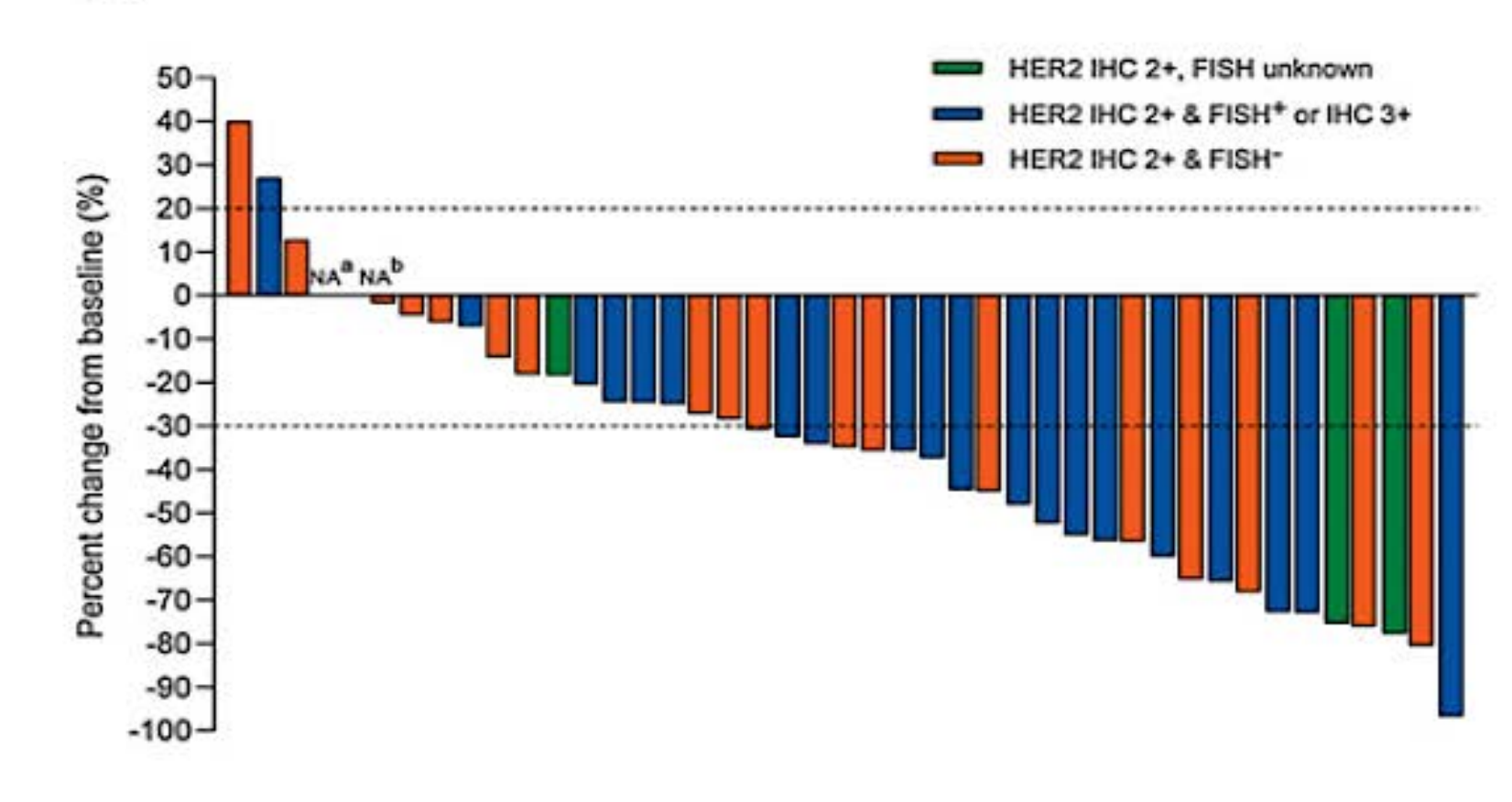
Open-label, Multicenter, Phase II Study of RC48-ADC, a HER2-Targeting Antibody–Drug Conjugate, in Patients with Locally Advanced or Metastatic Urothelial Carcinoma

Xinan Sheng[1], Xieqiao Yan[1], Lin Wang[2], Yanxia Shi[3], Xin Yao[4], Hong Luo[5], Benkang Shi[6], Jiyan Liu[7], Zhisong He[8], Guohua Yu[9], Jianming Ying[10], Weiqing Han[11], Changlu Hu[12], Yun Ling[10], Zhihong Chi[1], Chuanliang Cui[1], Lu Si[1], Jianmin Fang[13,14], Aiping Zhou[2], and Jun Guo[1]

Clin Cancer Res 2021;27(1):43-51.

Courtesy of Elizabeth R Plimack, MD, MS

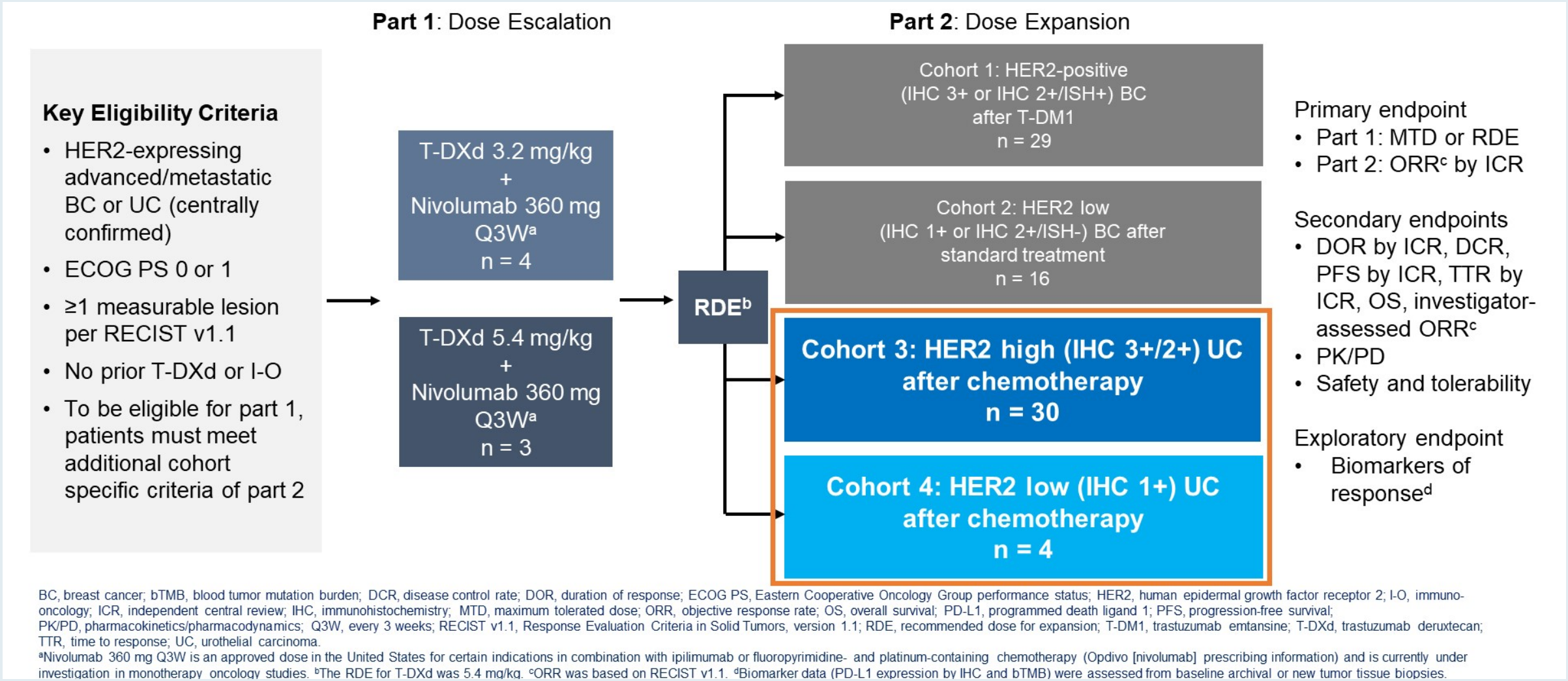
Best Percent Change from Baseline with Disitamab Vedotin (RC48-ADC)



88.4% patients had a decrease in tumor size from baseline as assessed by the BIRC.

Sheng X et al. *Clin Cancer Res* 2021;27(1):43-51.

DS8201-A-U105 Study Design



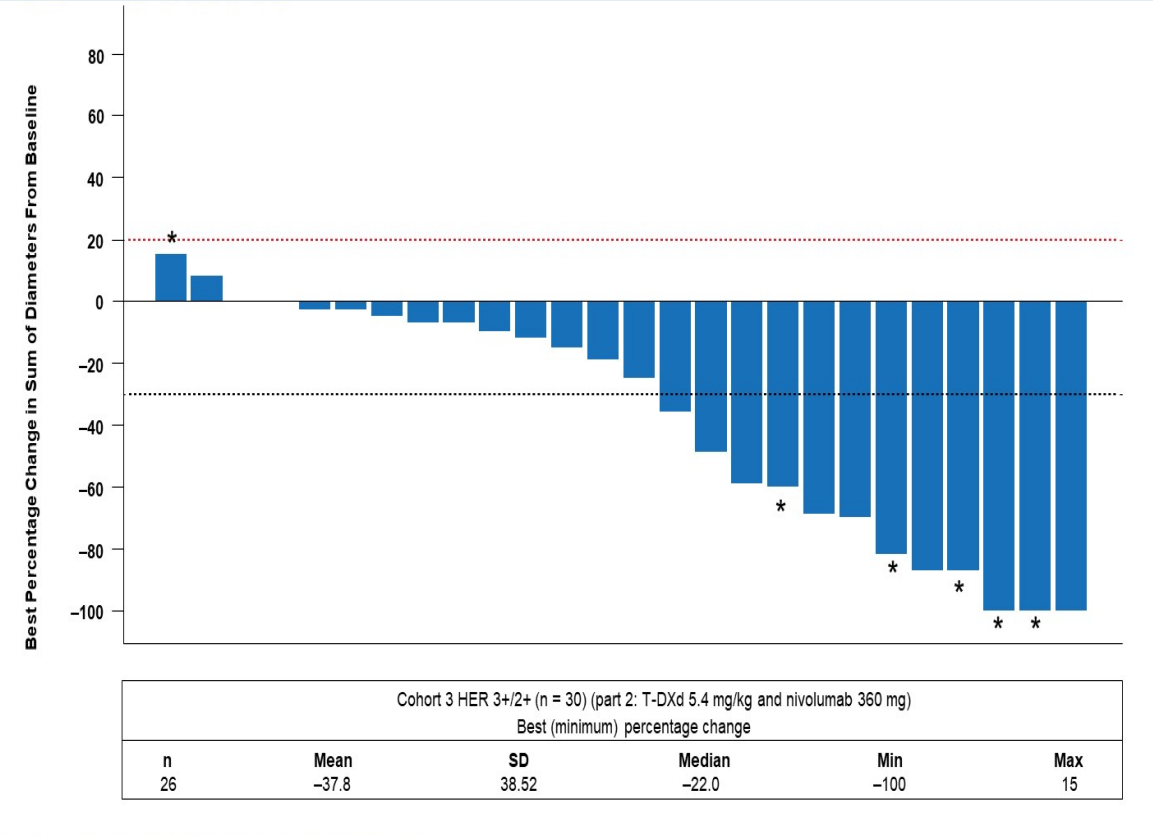
BC, breast cancer; bTMB, blood tumor mutation burden; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; I-O, immuno-oncology; ICR, independent central review; IHC, immunohistochemistry; MTD, maximum tolerated dose; ORR, objective response rate; OS, overall survival; PD-L1, programmed death ligand 1; PFS, progression-free survival; PK/PD, pharmacokinetics/pharmacodynamics; Q3W, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; RDE, recommended dose for expansion; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan; TTR, time to response; UC, urothelial carcinoma.

[a]Nivolumab 360 mg Q3W is an approved dose in the United States for certain indications in combination with ipilimumab or fluoropyrimidine- and platinum-containing chemotherapy (Opdivo [nivolumab] prescribing information) and is currently under investigation in monotherapy oncology studies. [b]The RDE for T-DXd was 5.4 mg/kg. [c]ORR was based on RECIST v1.1. [d]Biomarker data (PD-L1 expression by IHC and bTMB) were assessed from baseline archival or new tumor tissue biopsies.

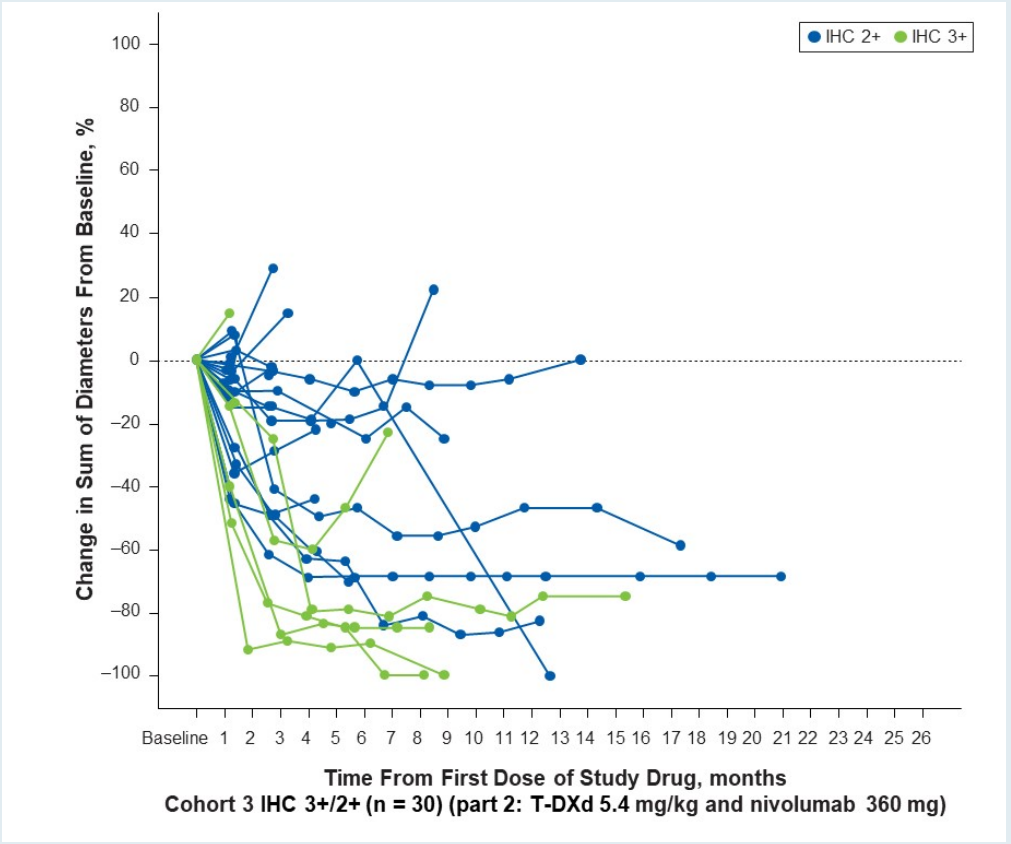
Galsky MD et al. ASCO GU 2022;Abstract 438.

Courtesy of Elizabeth R Plimack, MD, MS

Change in Tumor Size



By ICR in HER2 IHC 3+2/+ Cohort



Over Time in HER2 IHC 3+2/+ Cohort

Galsky MD et al. ASCO GU 2022;Abstract 438.

Courtesy of Elizabeth R Plimack, MD, MS

Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia

Wednesday, March 9, 2022
5:00 PM – 6:00 PM ET

Faculty

Rebecca L Olin, MD, MSCE

Moderator

Neil Love, MD

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Thank you for joining us!

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

RTP Year in Review 2022