

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

In Partnership with Project Echo® and Florida Cancer Specialists

**Wednesday, June 2, 2021
5:00 PM – 6:00 PM ET**

Faculty

**Walter Stadler, MD
Vikas Malhotra, MD**

Moderator

Neil Love, MD

Faculty



Walter Stadler, MD

Fred C Buffett Professor of Medicine
Dean for Clinical Research

Deputy Director, Comprehensive Cancer Center
The University of Chicago
Chicago, Illinois



Vikas Malhotra, MD

Staff Medical Oncologist-Hematologist
Florida Cancer Specialists and Research Institute
Spring Hill, Florida

Steering Committee



Chung-Han Lee, MD, PhD

Assistant Attending Physician
Genitourinary Oncology Service
Memorial Sloan Kettering Cancer Center
New York, New York



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



Sumanta K Pal, MD

Clinical Professor, Department of Medical Oncology
City of Hope Comprehensive Cancer Center
Duarte, California



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Dean for Clinical Research
Deputy Director, Comprehensive Cancer Center
The University of Chicago
Chicago, Illinois

Commercial Support

This activity is supported by an educational grant from Pfizer 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 companies: AbbVie Inc, Adaptive Biotechnologies Corporation, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, Genentech, a member of the Roche Group, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc and Verastem Inc.

Research To Practice CME Planning Committee Members, Staff and Reviewers

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

Project ECHO® Disclosure

Project ECHO collects registration, participation, questions/answers, chat comments, and poll responses for some teleECHO® programs. Your individual data will be kept confidential. These data may be used for reports, maps, communications, surveys, quality assurance, evaluation, research, and to inform new initiatives.

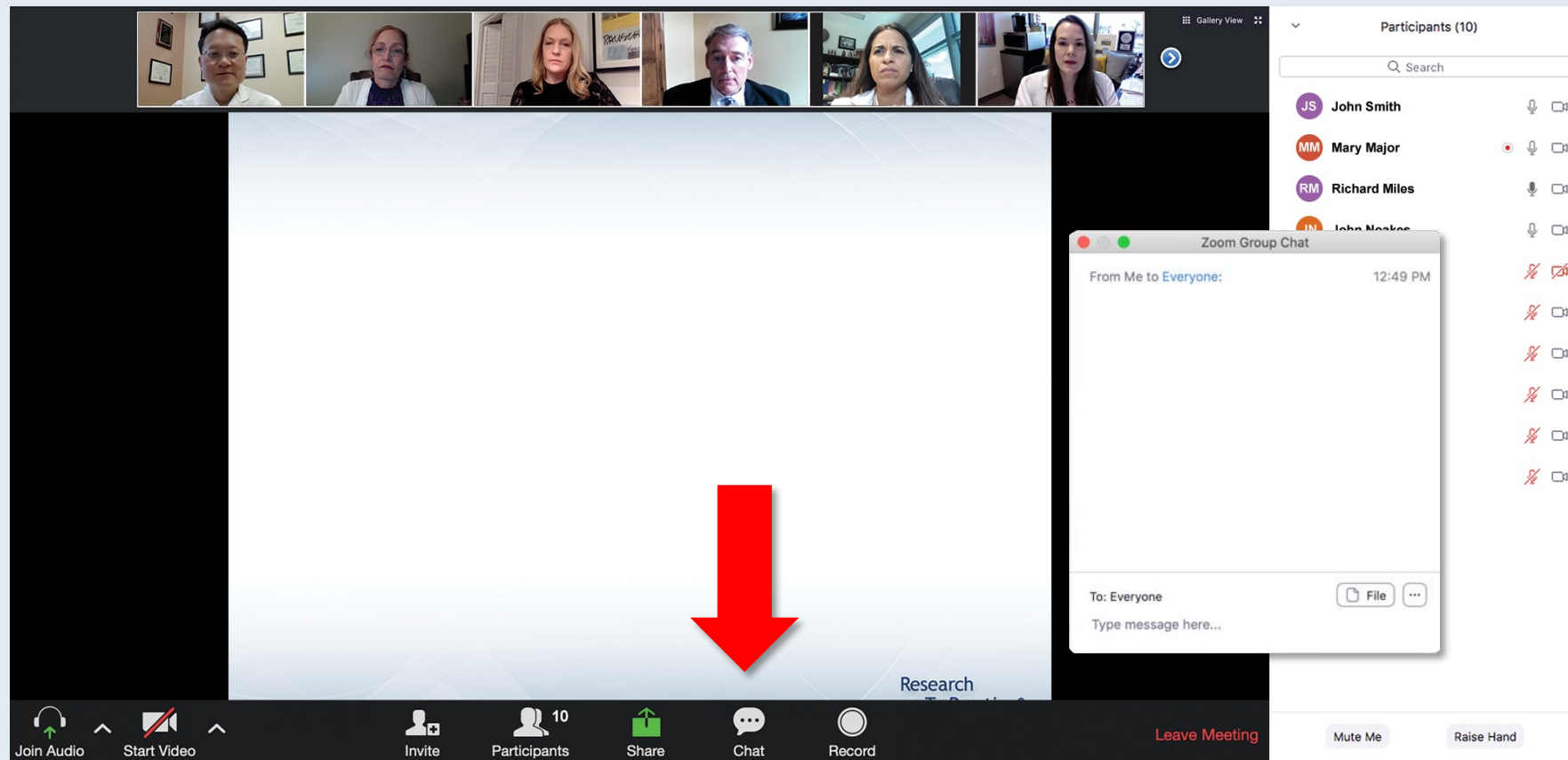
Dr Stadler — Disclosures

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Dr Malhotra — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



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Familiarizing Yourself with the Zoom Interface

How to answer poll questions

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What is your usual treatment recommendation for a patient with MM who has been followed by ASCT for 1-5 years who then experiences an asymptomatic relapse?

Quick Poll

- ☐ Carfilzomib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Carfilzomib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
- ☐ Elotuzumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Ixazomib + Rd
- ☐ Other

Submit

Co-provided by USF Health Research To Practice®

Participants (10)

Name	Microphone	Video
JS John Smith	On	On
MM Mary Major	On	On
RM Richard Miles	On	On
JN John Noakes	On	On
AS Alice Suarez	Off	Off
JP Jane Perez	Off	Off
RS Robert Stiles	Off	Off
JF Juan Fernandez	Off	Off
AK Ashok Kumar	Off	Off
JS Jeremy Smith	Off	Off

When a poll question pops up, click your answer choice from the available options.
Results will be shown after everyone has answered.

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot displays a Zoom meeting interface. At the top, a video bar shows participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the video bar, a presentation slide titled "Meet The Professor Program Steering Committee" is visible. The slide lists six members of the steering committee with their photos and titles:

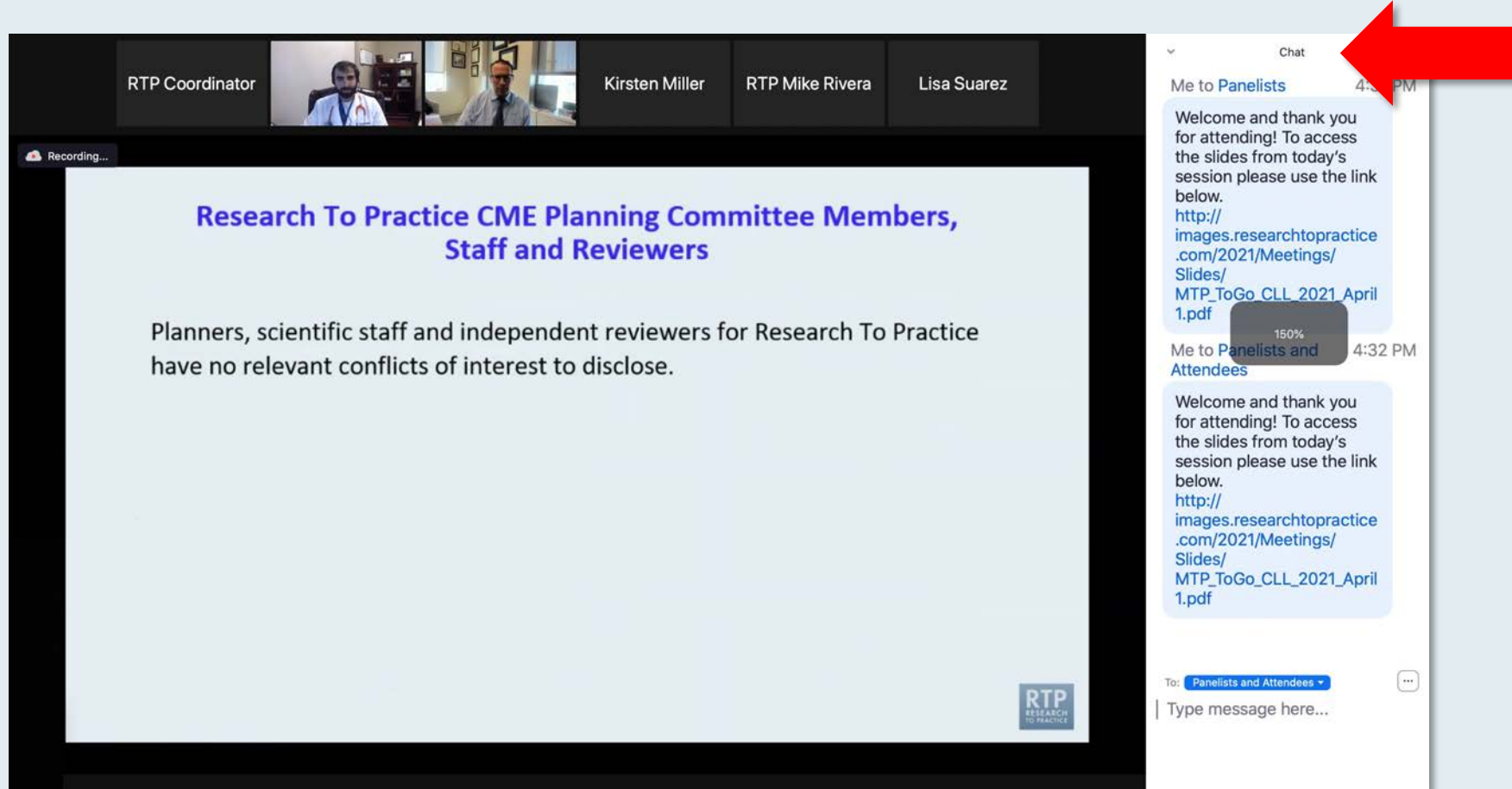
- John N Allan, MD**
Assistant Professor of Medicine
Weill Cornell Medicine
New York, New York
- Ian W Flinn, MD, PhD**
Director of Lymphoma Research Program
Sarah Cannon Research Institute
Tennessee Oncology
Nashville, Tennessee
- Steven Coutre, MD**
Professor of Medicine (Hematology)
Stanford University School of Medicine
Stanford, California
- Prof John G Gribben, MD, DSc, FMedSci**
Chair of Medical Oncology
Barts Cancer Institute
Queen Mary University of London
Charterhouse Square
London, United Kingdom
- Matthew S Davids, MD, MMSc**
Associate Professor of Medicine
Harvard Medical School
Director of Clinical Research
Division of Lymphoma
Dana-Farber Cancer Institute
Boston, Massachusetts
- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

The chat window on the right is expanded, showing messages from "Me to Panelists" and "Me to Panelists and Attendees". A red arrow points to the white line above the chat submission box, indicating where to drag to expand the box.

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

Familiarizing Yourself with the Zoom Interface

Increase chat font size



**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

Renal Cell Carcinoma



DR CHUNG-HAN LEE
MEMORIAL SLOAN KETTERING CANCER CENTER
NEW YORK, NEW YORK



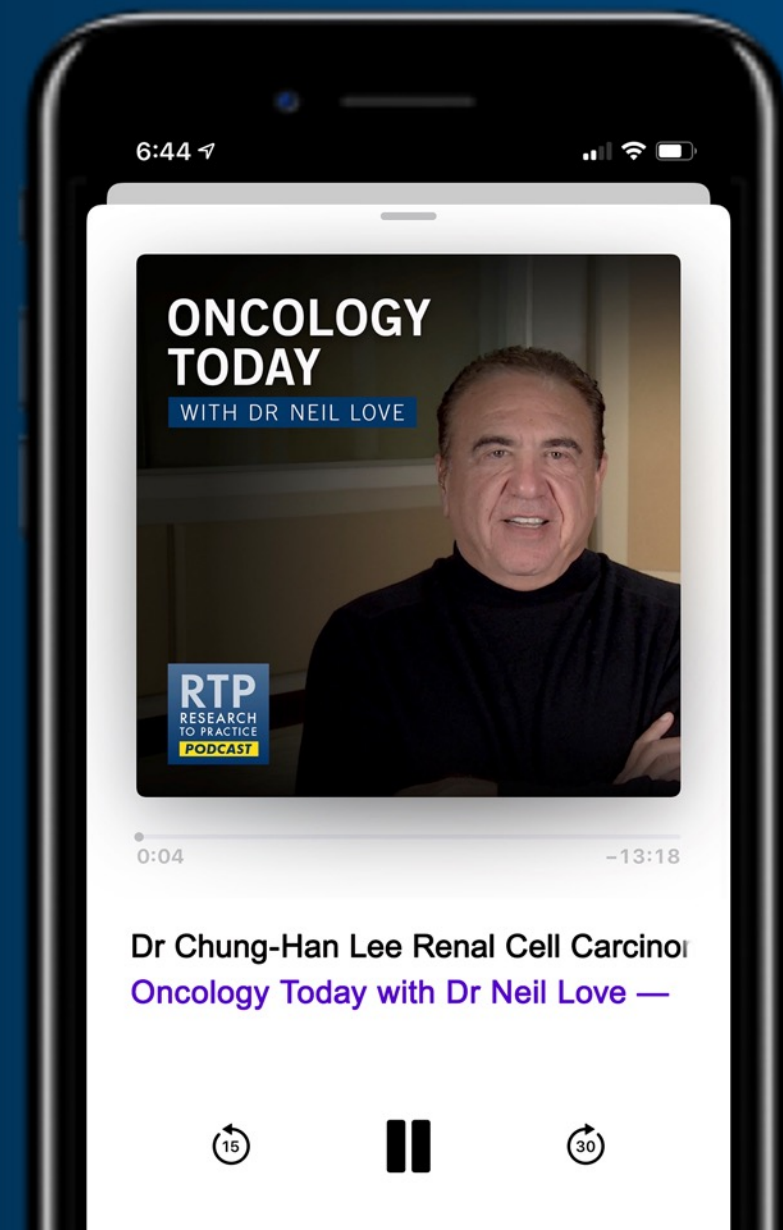
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Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Advanced Gastrointestinal Cancers

**Monday, June 7, 2021
5:00 PM – 6:00 PM ET**

Faculty

Kristen K Ciombor, MD, MSCI

Moderator

Neil Love, MD

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Wednesday, June 16, 2021

5:00 PM – 6:00 PM ET

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Moderator

Neil Love, MD

ASCO Highlights and More: Investigators Review Recent Data Sets and Provide Perspectives on Current Oncology Care

*A Daylong Multitumor Educational Webinar in Partnership
with the Texas Society of Clinical Oncology (TxSCO)*

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Webinar 1 – Tuesday, April 6, 2021

Faculty

Sumanta K Pal, MD

Webinar 3 – Wednesday, June 2, 2021

Faculty

Walter Stadler, MD

Webinar 2 – Tuesday, May 4, 2021

Faculty

Chung-Han Lee, MD, PhD

Webinar 4 – Tuesday, July 6, 2021

Faculty

David I Quinn, MBBS, PhD

Thank you for joining us!

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

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Sumanta K Pal, MD

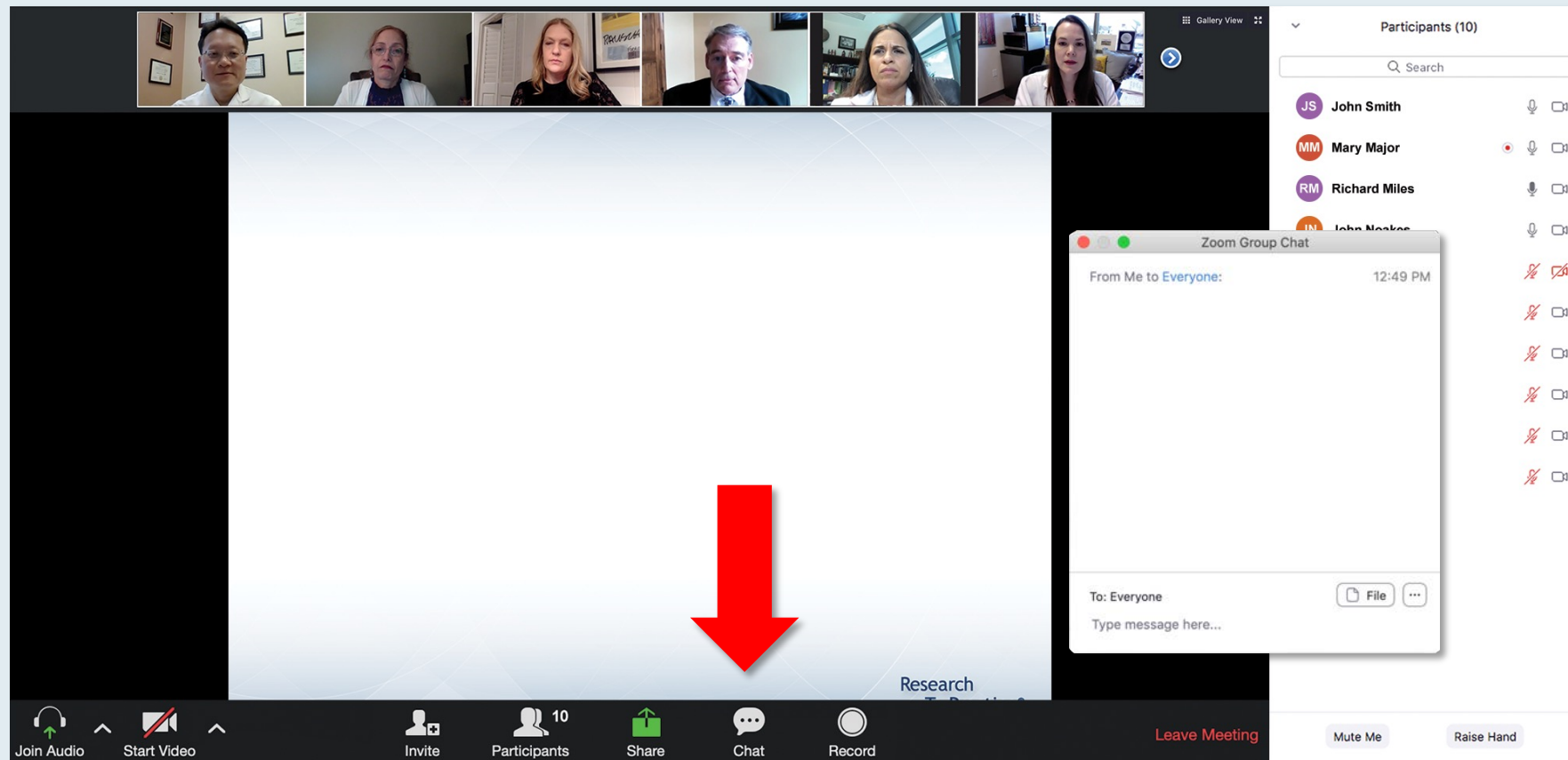
Clinical Professor, Department of Medical Oncology
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What is your usual treatment recommendation for a patient with MM who has been followed by ASCT for 1-5 years who then experiences an asymptomatic relapse?

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2. Pomalidomide +/- dexamethasone
3. Carfilzomib + pomalidomide +/- dexamethasone
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8. Daratumumab + bortezomib +/- dexamethasone
9. Ixazomib + Rd
10. Other

Co-provided by USF Health Research To Practice®

Participants (10)

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- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
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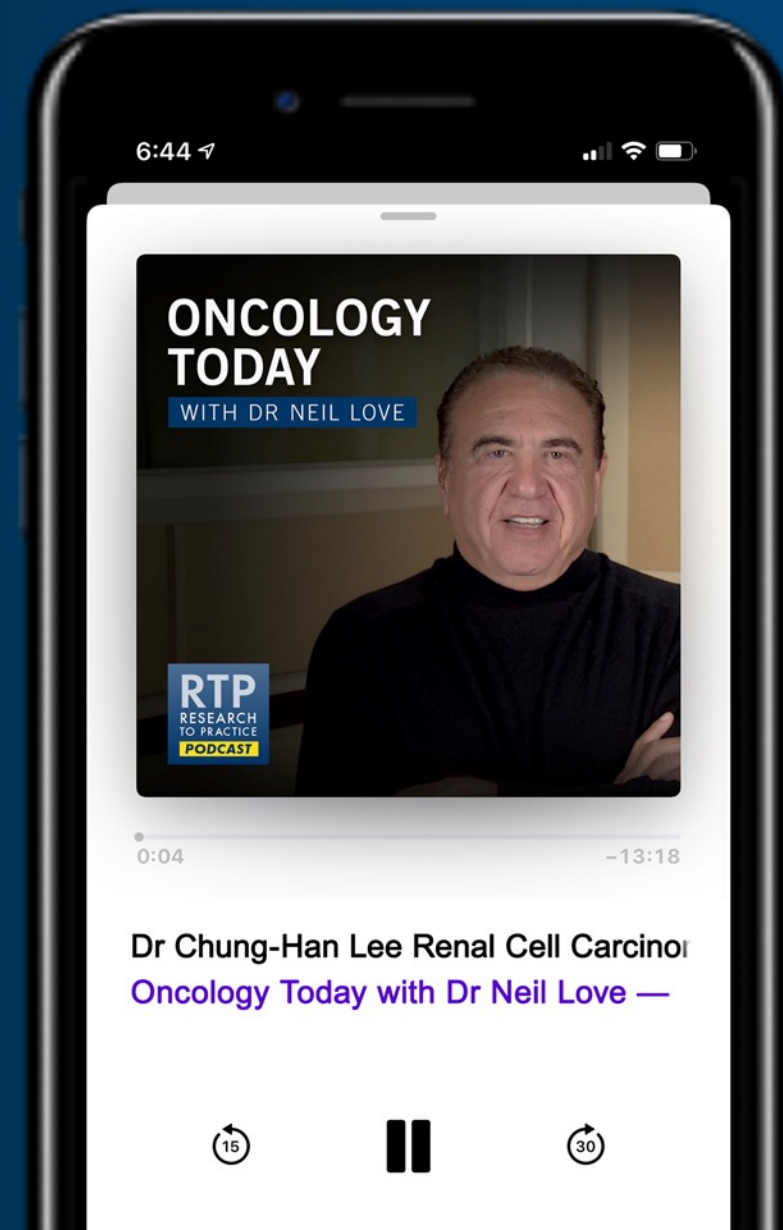
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Agenda

MODULE 1: Cases from the Practice of Dr Malhotra

- A 75-year-old man with metastatic RCC treated with axitinib/nivolumab
- A 65-year-old man RCC with extensive bone and lung metastases
- A 70-year-old man with RCC with 3 small lung metastases

MODULE 2: Consensus or Controversy – Clinical Investigator Approaches to Clinical Scenarios

MODULE 3: Renal Cell Carcinoma Journal Club with Dr Stadler

MODULE 4: Key Data Sets

MODULE 5: Other Recent Data Sets

Pembrolizumab Demonstrated Superior Disease-Free Survival Compared with Placebo as Adjuvant Therapy for Patients with RCC Following Surgery

Press Release: April 8, 2021

“The pivotal Phase 3 KEYNOTE-564 trial evaluating pembrolizumab met its primary endpoint of disease-free survival (DFS) for the potential adjuvant treatment of patients with RCC following nephrectomy or following nephrectomy and resection of metastatic lesions.

Based on an interim analysis conducted by an independent Data Monitoring Committee, pembrolizumab monotherapy demonstrated a statistically significant and clinically meaningful improvement in DFS compared with placebo. The trial will continue to evaluate overall survival (OS), a key secondary endpoint.

The safety profile of pembrolizumab in this trial was consistent with that observed in previously reported studies. Results will be presented at an upcoming medical meeting and will be submitted to regulatory authorities.”

Pembrolizumab versus Placebo as Post-Nephrectomy Adjuvant Therapy for Patients with Renal Cell Carcinoma: Randomized, Double-Blind, Phase III KEYNOTE-564 Study

Choueiri TK et al.

ASCO 2021;Abstract LBA5.

Plenary Session: Sunday, June 6, 1:00 PM - 4:00 PM EDT

Agenda

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Case Presentation — Dr Malhotra: A 75-year-old man with metastatic RCC treated with axitinib/nivolumab

75-year-old male who presented with hematuria and CT scans showed 5 cm left kidney mass. He had left nephrectomy in January 2017. In May 2018 he presented with extensive lung mets, biopsy proven. Motzer score was low with anemia. He was started on axitinib and nivolumab with excellent ongoing response for 3 years. Dose of axitinib had to be reduced to 5 mg once daily due to hand-foot syndrome.

Question

- How do the faculty members handle dose of axitinib?

Case Presentation — Dr Malhotra: A 65-year-old man with RCC with extensive bone and lung metastases

65-year-old male presented with left flank pain and CT showed large 12 cm left kidney mass. Work up showed extensive bone and lung mets. He was started on axitinib and avelumab. He had very good partial response and continues with good response. His Motzer score was low with anemia and hypercalcemia.

Question

- How does the faculty decide between this regimen and ipi/nivo?

Case Presentation — Dr Malhotra: A 70-year-old man with RCC with 3 small lung metastases

70-year-old male with right kidney mass — biopsy proven RCC with three 1 cm lung mets — hypermetabolic on PET. Low risk. He had 4 cycles of ipi/nivo with excellent response.

Question

- Would the faculty consider nephrectomy?

Agenda

MODULE 1: Cases from the Practice of Dr Malhotra

- A 63-year-old man with metastatic renal cell carcinoma (RCC) treated with ipilimumab/nivolumab
- A 67-year-old man with metastatic RCC and high-risk oncocytic features who responded to ipilimumab/nivolumab
- A 65-year-old man with Stage III RCC

MODULE 2: Consensus or Controversy – Clinical Investigator Approaches to Clinical Scenarios

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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 renal cell carcinoma (RCC) who on routine follow-up 3 years later is found to have asymptomatic bone metastases (PS 0)?

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

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 renal cell carcinoma (RCC) who on routine follow-up 3 years later is found to have asymptomatic bone metastases (PS 0)?



Dr Lee

Pembrolizumab/lenvatinib



Dr Pal

Nivolumab/cabozantinib



Dr Quinn

Nivolumab/cabozantinib



Dr Stadler

Cabozantinib

Regulatory and reimbursement issues aside, which first-line therapy would you recommend for a 65-year-old patient who presents with clear cell RCC with multiple painful bone metastases and hemoglobin (Hb) of 11.4 g/dL (PS 1)?

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

Regulatory and reimbursement issues aside, which first-line therapy would you recommend for a 65-year-old patient who presents with clear cell RCC with multiple painful bone metastases and a hemoglobin (Hb) of 11.4 g/dL (PS = 1)?



Dr Lee

Nivolumab/cabozantinib



Dr Pal

Nivolumab/cabozantinib



Dr Quinn

Cabozantinib



Dr Stadler

Nivolumab/ipilimumab

In general, what would you recommend as second-line treatment for a 65-year-old patient (PS 0) with metastatic clear cell RCC who receives first-line ipilimumab/nivolumab and experiences disease progression after 12 months?

1. TKI monotherapy
2. Everolimus
3. Lenvatinib + everolimus
4. Avelumab/axitinib
5. Pembrolizumab/axitinib
6. Nivolumab/cabozantinib
7. Anti-PD-1/PD-L1 monotherapy
8. Other

In general, what would you recommend as second-line treatment for a 65-year-old patient (PS 0) with metastatic clear cell RCC who receives first-line ipilimumab/nivolumab and experiences disease progression after 12 months?



Dr Lee

Cabozantinib



Dr Pal

Cabozantinib



Dr Quinn

Cabozantinib or axitinib



Dr Stadler

Cabozantinib

In general, what would you recommend as second-line treatment for a 65-year-old patient (PS 0) with metastatic clear cell RCC who receives first-line nivolumab/cabozantinib and experiences disease progression after 12 months?



Dr Lee

Lenvatinib + everolimus



Dr Pal

Lenvatinib + everolimus



Dr Quinn

Axitinib



Dr Stadler

Axitinib

What would be your most likely third-line systemic therapy recommendation for a 65-year-old patient with metastatic RCC who experienced disease progression on first-line pembrolizumab/axitinib and second-line cabozantinib (PS 0)?



Dr Lee

Lenvatinib + everolimus



Dr Pal

Lenvatinib + everolimus



Dr Quinn

Tivozanib



Dr Stadler

Lenvatinib + everolimus

In general, how would you compare the efficacy of tivozanib to that of other commercially available tyrosine kinase inhibitors (TKIs) (eg, axitinib, cabozantinib, lenvatinib) in patients with relapsed metastatic RCC?



Dr Lee

Other commercially available TKIs are more efficacious



Dr Pal

Efficacy is about the same



Dr Quinn

Efficacy is about the same



Dr Stadler

Efficacy is about the same

In general, how would you compare the tolerability of tivozanib to that of other commercially available TKIs (eg, axitinib, cabozantinib, lenvatinib) in patients with relapsed metastatic RCC?



Dr Lee

Tivozanib is more tolerable



Dr Pal

Tivozanib is more tolerable



Dr Quinn

Tivozanib is more tolerable



Dr Stadler

Tolerability is about the same

Agenda

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MODULE 3: Renal Cell Carcinoma Journal Club with Dr Stadler

- Active surveillance of metastatic RCC: Results from a prospective observational study (MaRCC)
- Optimized management of nivolumab and ipilimumab in advanced RCC: A response-based Phase II study (OMNIVORE)

MODULE 4: Key Data Sets

MODULE 5: Other Recent Data Sets

Active Surveillance of Metastatic Renal Cell Carcinoma: Results From a Prospective Observational Study (MaRCC)

Michael R. Harrison, MD ¹; Brian A. Costello, MD²; Nrupen A. Bhavsar, PhD¹; Ulka Vaishampayan, MD³; Sumanta K. Pal, MD ⁴; Yousef Zakharia, MD⁵; Heather S. L. Jim, PhD ⁶; Mayer N. Fishman, MD⁶; Ana M. Molina, MD⁷; Christos E. Kyriakopoulos, MD⁸; Che-Kai Tsao, MD⁹; Leonard J. Appleman, MD¹⁰; Benjamin A. Gartrell, MD^{11,12}; Arif Hussain, MD¹³; Walter M. Stadler, MD ¹⁴; Neeraj Agarwal, MD¹⁵; Russell K. Pachynski, MD¹⁶; Thomas E. Hutson, DO¹⁷; Hans J. Hammers, MD¹⁸; Christopher W. Ryan, MD¹⁹; Brant A. Inman, MD ¹; Jack Mardekian, PhD²⁰; Azah Borham, PharmD²⁰; and Daniel J. George, MD¹

Cancer 2021;127(11):1827-35.

Optimized Management of Nivolumab and Ipilimumab in Advanced Renal Cell Carcinoma: A Response-Based Phase II Study (OMNIVORE)

Rana R. McKay, MD¹; Bradley A. McGregor, MD²; Wanling Xie, MS²; David A. Braun, MD, PhD²; Xiao Wei, MD²; Christos E. Kyriakopoulos, MD³; Yousef Zakharia, MD⁴; Benjamin L. Maughan, MD, PharmD⁵; Tracy L. Rose, MD⁶; Walter M. Stadler, MD⁷; David F. McDermott, MD⁸; Lauren C. Harshman, MD²; and Toni K. Choueiri, MD²

Agenda

MODULE 1: Cases from the Practice of Dr Malhotra

MODULE 2: Consensus or Controversy – Clinical Investigator Approaches to Clinical Scenarios

MODULE 3: Renal Cell Carcinoma Journal Club with Dr Stadler

- Active surveillance of metastatic RCC: Results from a prospective observational study (MaRCC)
- Optimized management of nivolumab and ipilimumab in advanced RCC: A response-based Phase II study (OMNIVORE)

MODULE 4: Key Data Sets

MODULE 5: Other Recent Data Sets

Pembrolizumab (Pembro) plus Axitinib (Axi) versus Sunitinib as First-Line Therapy for Advanced Clear Cell Renal Cell Carcinoma (ccRCC): Results from 42-Month Follow-Up of KEYNOTE-426

Rini BI et al.

ASCO 2021;Abstract 4500.

Genitourinary Cancer – Kidney and Bladder: Monday, June 7, 8:00 AM - 11:00 AM

Phase 2 Study of Belzutifan (MK-6482), an Oral Hypoxia-Inducible Factor 2 α (HIF-2 α) Inhibitor, for Von Hippel-Lindau (VHL) Disease-Associated Clear Cell Renal Cell Carcinoma (ccRCC)

Srinivasan R et al.

ASCO 2021;Abstract 4555.

Genitourinary Cancer – Kidney and Bladder: Monday, June 7, 8:00 AM - 11:00 AM

A Phase 1b/2 Umbrella Study of Investigational Immune and Targeted Combination Therapies as First-Line Therapy for Patients with Advanced Renal Cell Carcinoma (RCC)

Plimack ER et al.

ASCO 2021;Abstract TPS4594.


Genitourinary Cancer – Kidney and Bladder: Monday, June 7, 8:00 AM - 11:00 AM

Indirect comparison of the 4 regimens available.

	CheckMate 214 (Ipi/Nivo) ¹ (n=550 vs n=546)	KEYNOTE-426 (Axi/Pembro) ² (n=432 vs n=429)	CheckMate 9ER (Cabo/Nivo) ³ (n=323 vs n=328)	CLEAR (Len/Pembro) ⁴ (N=355 vs n=357)
mOS, months HR (CI);	NR vs 38.4 0.69 (0.59–0.81);	NR vs 35.7 0.68 (0.55–0.85);	NR vs NR 0.60 (0.40–0.89);	NR vs NR 0.66 (0.49–0.88)
Landmark OS 12 mo	83% vs. 78%	90% vs. 79%	87% vs. 78% (est)	90% vs 79% (est.)
Landmark OS 24 mo	71% vs. 61%	74% vs. 66%	74% vs 60% (est)	79% vs. 70%
mPFS, months HR (CI)	12.2 vs 12.3 0.89 (0.76–1.05)	15.4 vs 11.1 0.71 (0.60–0.84)	16.6 vs 8.3 0.51 (0.41–0.64)	23.9 vs 9.2 0.39 (0.32–0.49)
ORR, %	39 vs 32	60 vs 40	56 vs 27	71 vs 36
CR, %	11 vs 3	9 vs 3	8 vs 5	16 vs 4
Med f/u, months	55	30.6	18.1	27
Prognostic risk, %				
Favorable	23	32	23	31
Intermediate	61	55	58	59
Poor	17	13	19	9
Prior nephrectomy	82%	83%	69%	74%
Subsequent systemic therapies for sunitinib arm, %	Overall (69%) IO (42%)	Overall (69%) IO (48%)	Overall (40%) IO (29%)	NR

Please handle with care....



Indirect comparison of the 4 regimens available.

	CheckMate 214 (Ipi/Nivo) ¹ (n=550 vs n=546)	KEYNOTE-426 (Axi/Pembro) ² (n=432 vs n=429)	CheckMate 9ER (Cabo/Nivo) ³ (n=323 vs n=328)	CLEAR (Len/Pembro) ⁴ (N=355 vs n=357)
mOS, months HR (CI);	NR vs 38.4 0.69 (0.59–0.81);			
Landmark OS 12 mo	83% vs. 78%			
Landmark OS 24 mo	71% vs. 61%			
mPFS, months HR (CI)	12.2 vs 12.3 0.89 (0.76–1.05)			
ORR, %	39 vs 32			
CR, %	11 vs 3			
Med f/u, months	55			
Prognostic risk, %				
Favorable	23			
Intermediate	61			
Poor	17			
Prior nephrectomy	82%			
Subsequent systemic therapies for sunitinib arm, %	Overall (69%) IO (42%)			

Please handle with care....

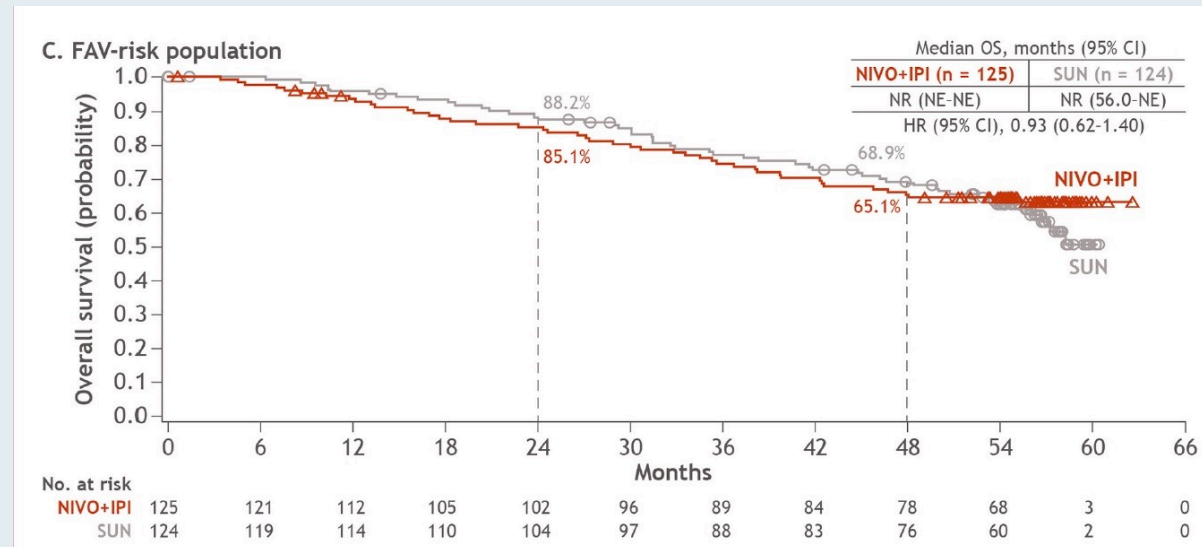
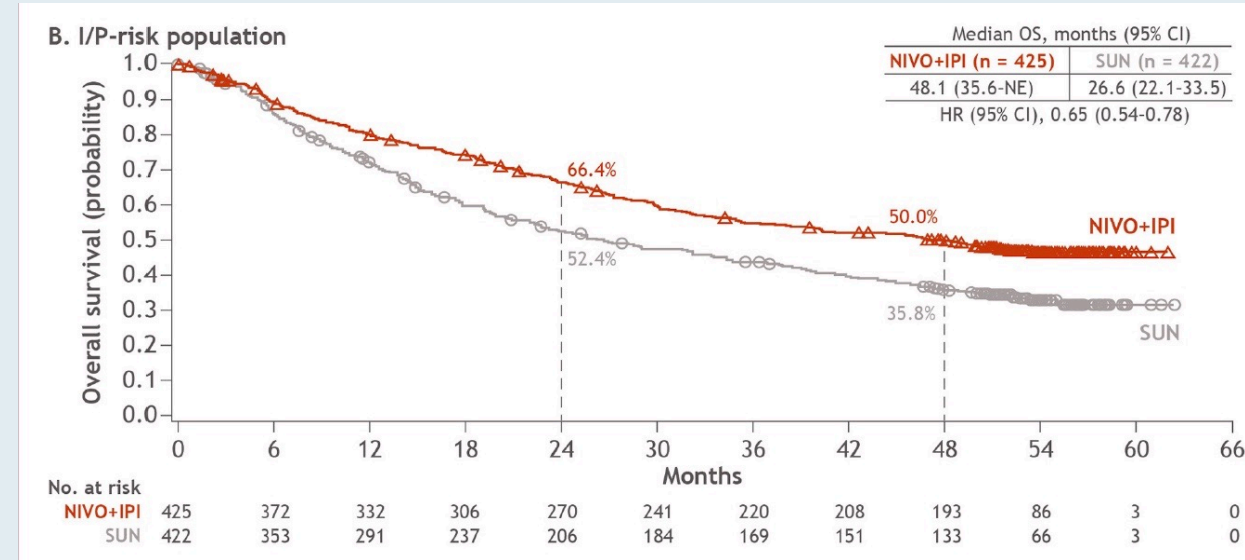
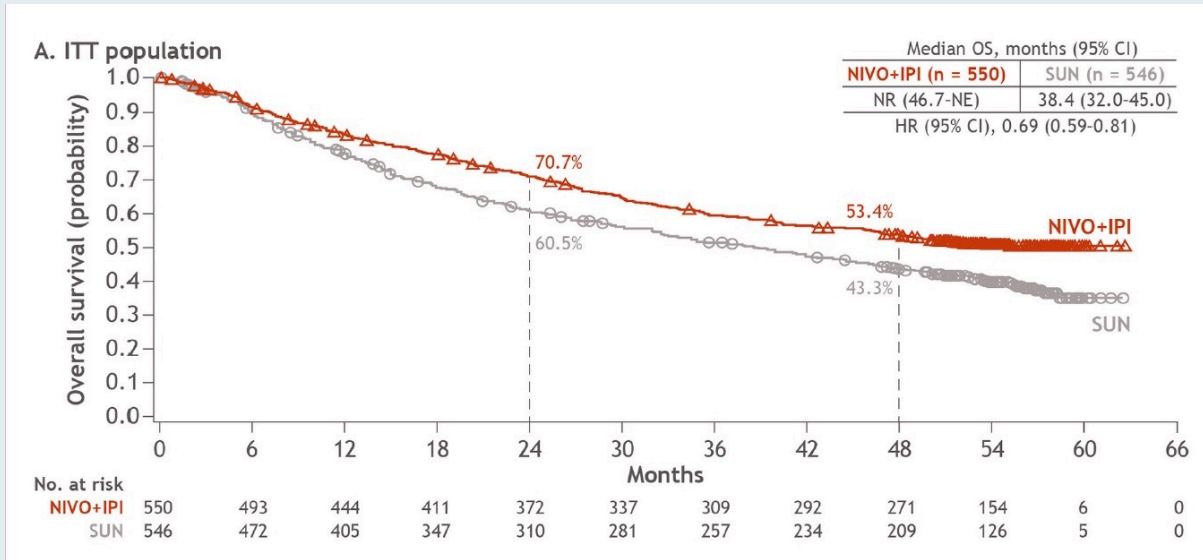


Nivolumab plus ipilimumab versus sunitinib for first-line treatment of advanced renal cell carcinoma: extended 4-year follow-up of the phase III CheckMate 214 trial

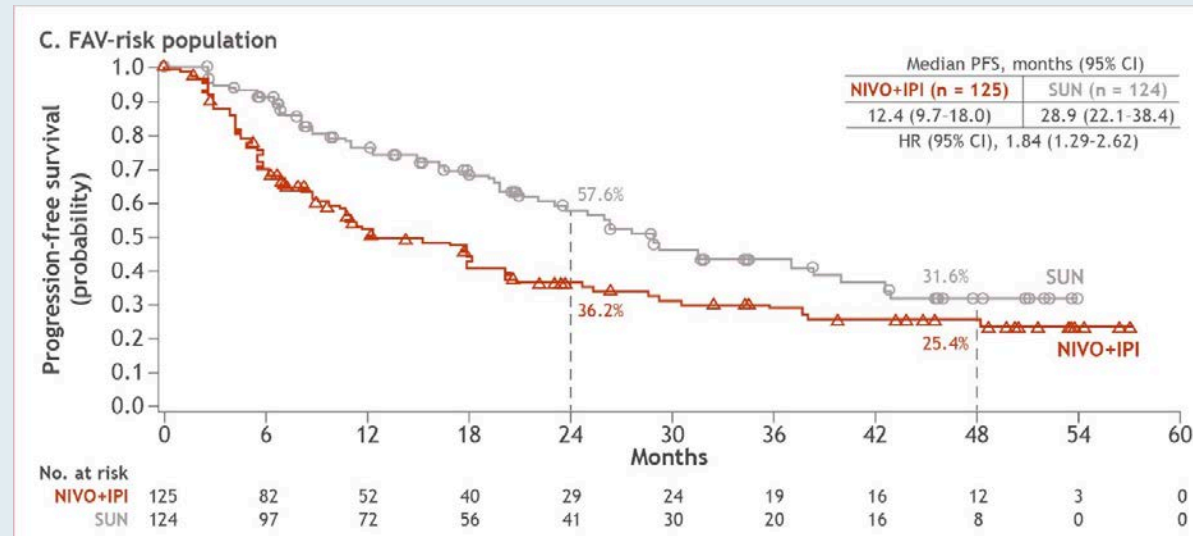
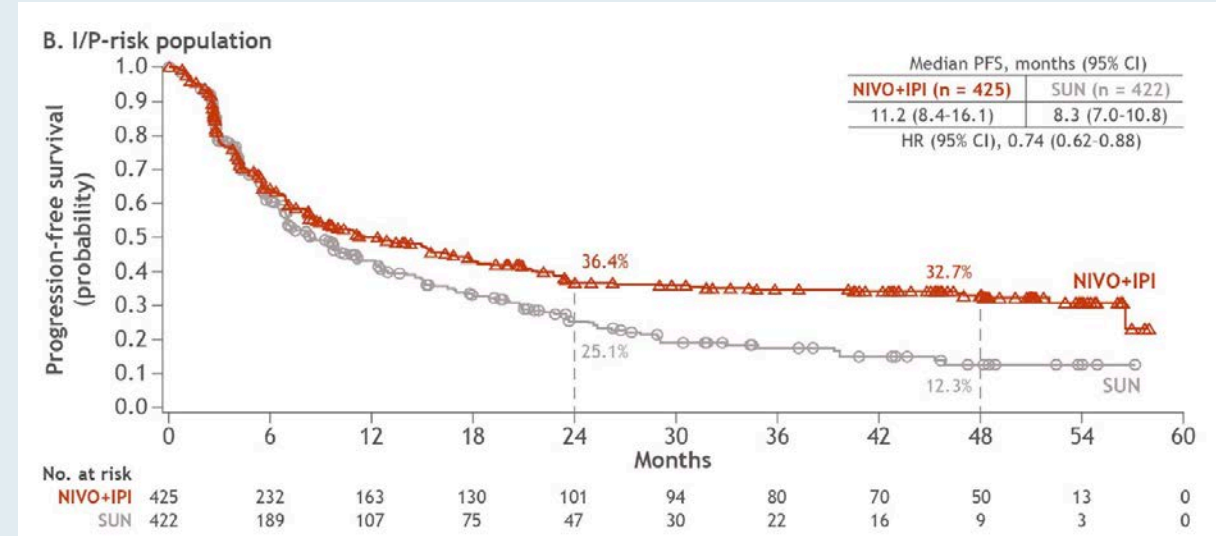
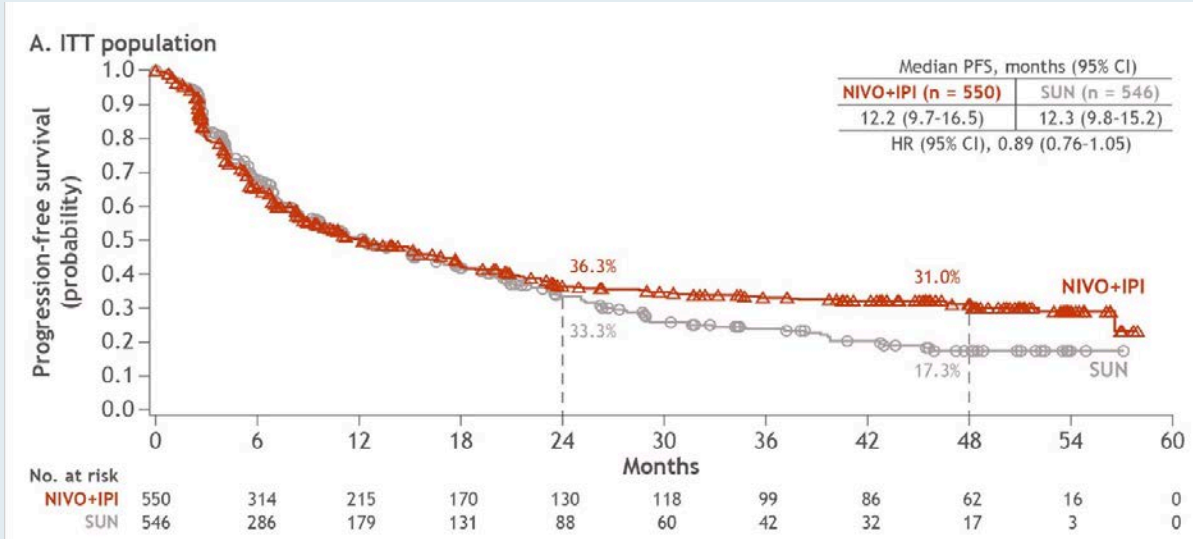
Laurence Albiges ¹, Nizar M Tannir,² Mauricio Burotto,³ David McDermott,^{4,5} Elizabeth R Plimack,⁶ Philippe Barthélémy,^{7,8} Camillo Porta ⁹, Thomas Powles,^{10,11} Frede Donskov,¹² Saby George,¹³ Christian K Kollmannsberger,¹⁴ Howard Gurney,^{15,16} Marc-Oliver Grimm,¹⁷ Yoshihiko Tomita,¹⁸ Daniel Castellano,¹⁹ Brian I Rini,²⁰ Toni K Choueiri,²¹ Shruti Shally Saggi,²² M Brent McHenry,²³ Robert J Motzer²⁴

ESMO Open 2020;5(6):e001079

CheckMate 214: OS in ITT, Intermediate/Poor-Risk and Favorable-Risk Populations



CheckMate 214: PFS in ITT, Intermediate/Poor-Risk and Favorable-Risk Populations



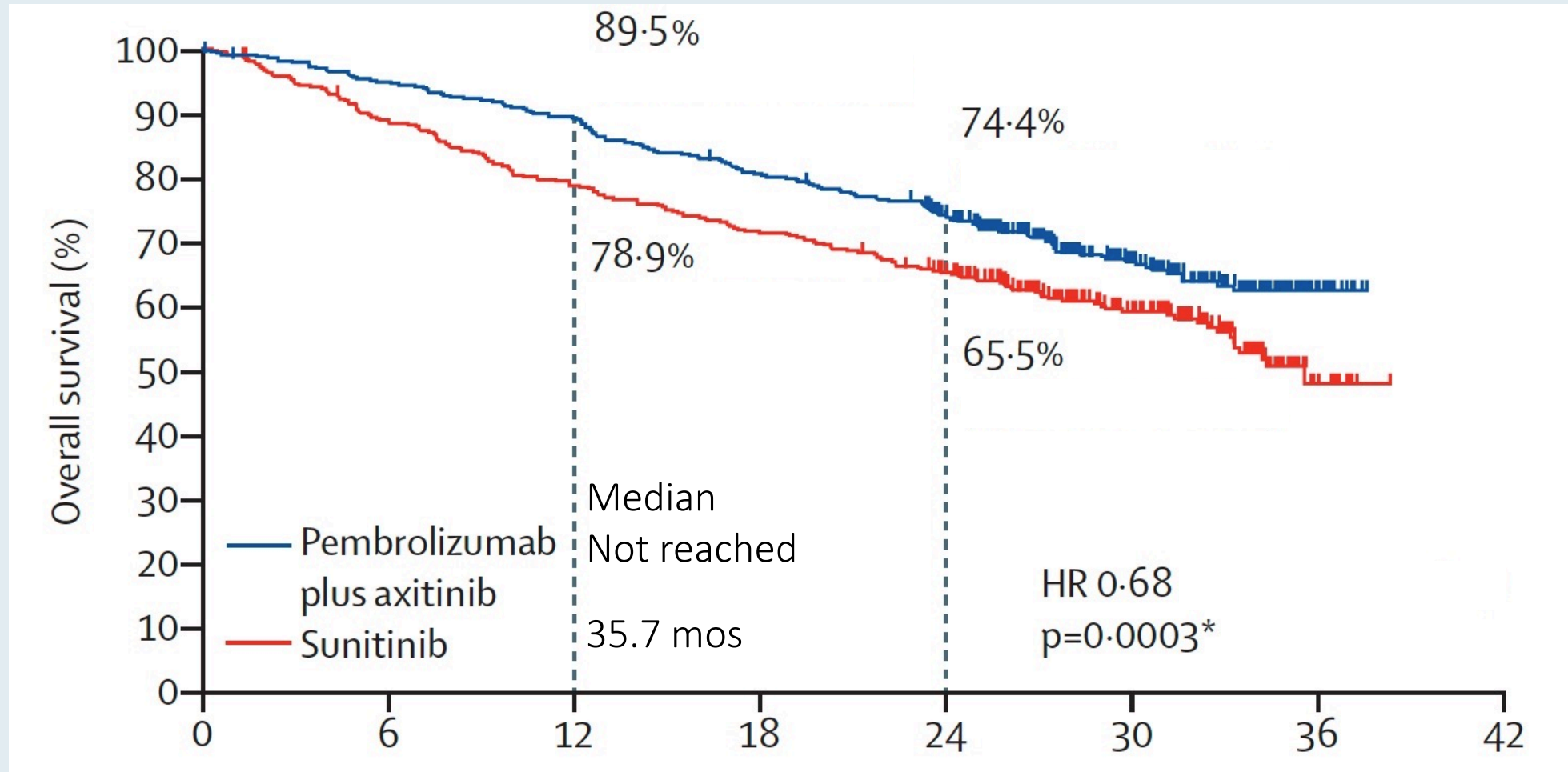
Lancet Oncol 2020;21:1563-73

Pembrolizumab plus axitinib versus sunitinib monotherapy as first-line treatment of advanced renal cell carcinoma (KEYNOTE-426): extended follow-up from a randomised, open-label, phase 3 trial



Thomas Powles, Elizabeth R Plimack, Denis Soulières, Tom Waddell, Viktor Stus, Rustem Gafanov, Dmitry Nosov, Frédéric Pouliot, Bohuslav Melichar, Ihor Vynnychenko, Sergio J Azevedo, Delphine Borchellini, Raymond S McDermott, Jens Bedke, Satoshi Tamada, Lina Yin, Mei Chen, L Rhoda Molife, Michael B Atkins, Brian I Rini

KEYNOTE-426: Overall Survival with Extended Follow-Up



***N Engl J Med* 2021;384(9):829-41**

The NEW ENGLAND JOURNAL of MEDICINE

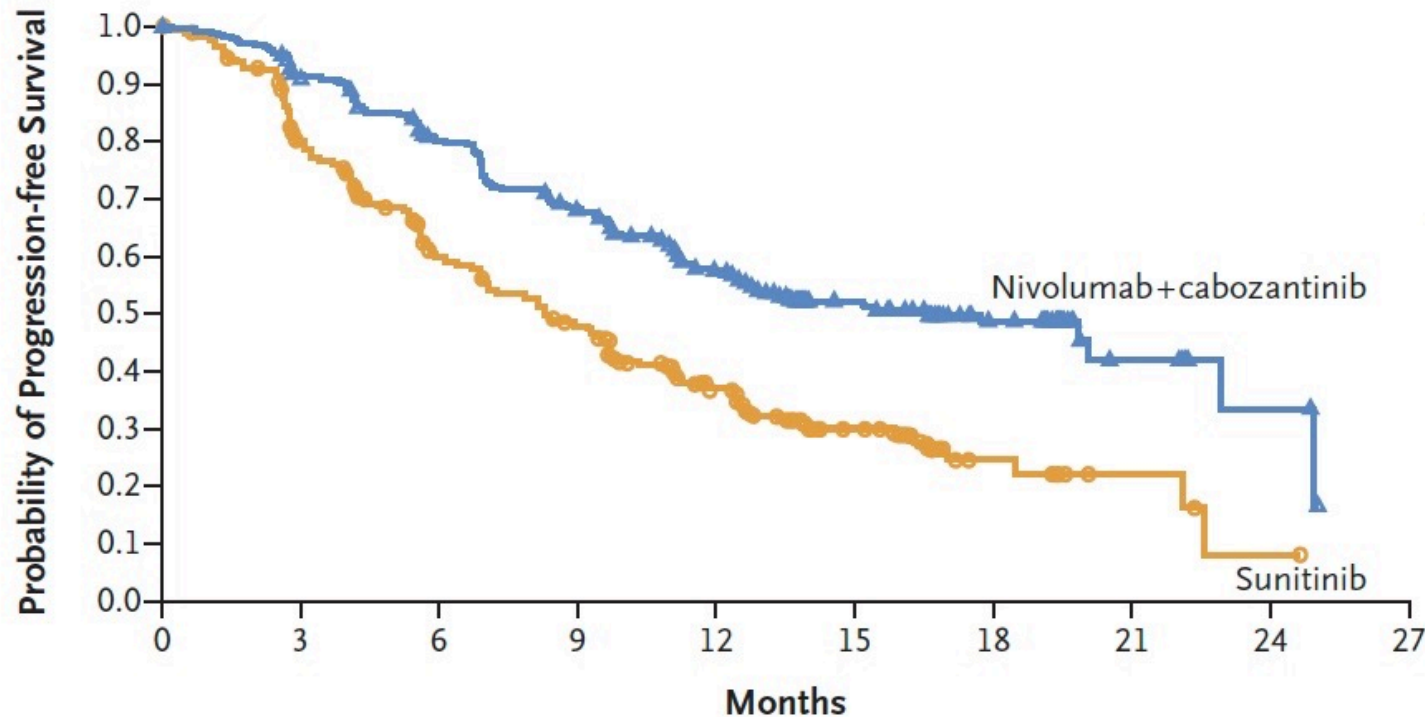
ORIGINAL ARTICLE

Nivolumab plus Cabozantinib versus Sunitinib for Advanced Renal-Cell Carcinoma

T.K. Choueiri, T. Powles, M. Burotto, B. Escudier, M.T. Bourlon, B. Zurawski, V.M. Oyervides Juárez, J.J. Hsieh, U. Basso, A.Y. Shah, C. Suárez, A. Hamzaj, J.C. Goh, C. Barrios, M. Richardet, C. Porta, R. Kowalyszyn, J.P. Feregrino, J. Żołnierek, D. Pook, E.R. Kessler, Y. Tomita, R. Mizuno, J. Bedke, J. Zhang, M.A. Maurer, B. Simsek, F. Ejzykowicz, G.M. Schwab, A.B. Apolo, and R.J. Motzer, for the CheckMate 9ER Investigators*

Progression-Free Survival in the Intention-to-Treat Population

A Progression-free Survival



	No. of Patients	Median (95% CI) mo
Nivolumab+ Cabozantinib	323	16.6 (12.5–24.9)
Sunitinib	328	8.3 (7.0–9.7)

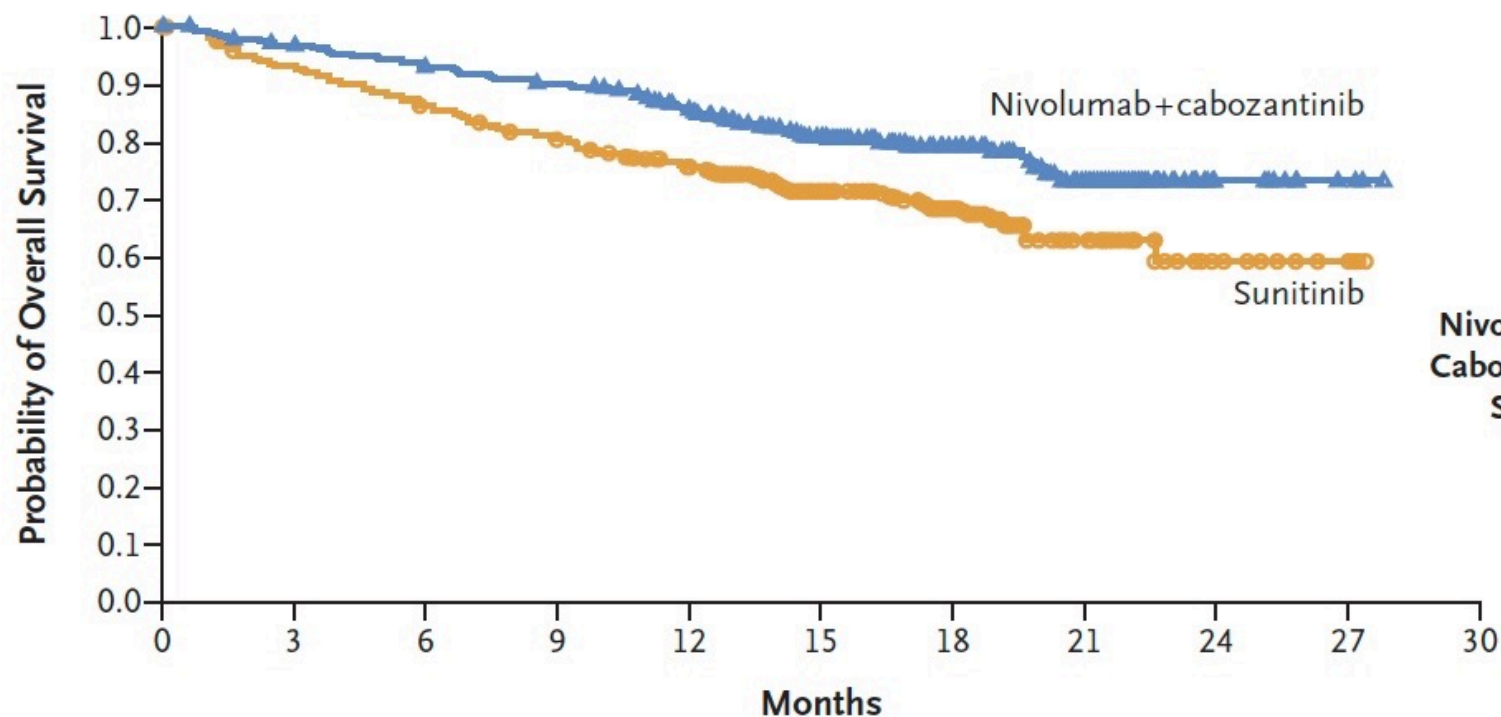
Hazard ratio for disease progression or death, 0.51 (95% CI, 0.41–0.64)
P<0.001

No. at Risk

Nivolumab+cabozantinib	323	279	234	196	144	77	35	11	4	0
Sunitinib	328	228	159	122	79	31	10	4	1	0

Overall Survival in the Intention-to-Treat Population

B Overall Survival



	No. of Patients	Median (95% CI) mo
Nivolumab+ Cabozantinib	323	NR (NE)
Sunitinib	328	NR (22.6–NE)

Hazard ratio for death, 0.60
(98.89% CI, 0.40–0.89)
P=0.001

No. at Risk

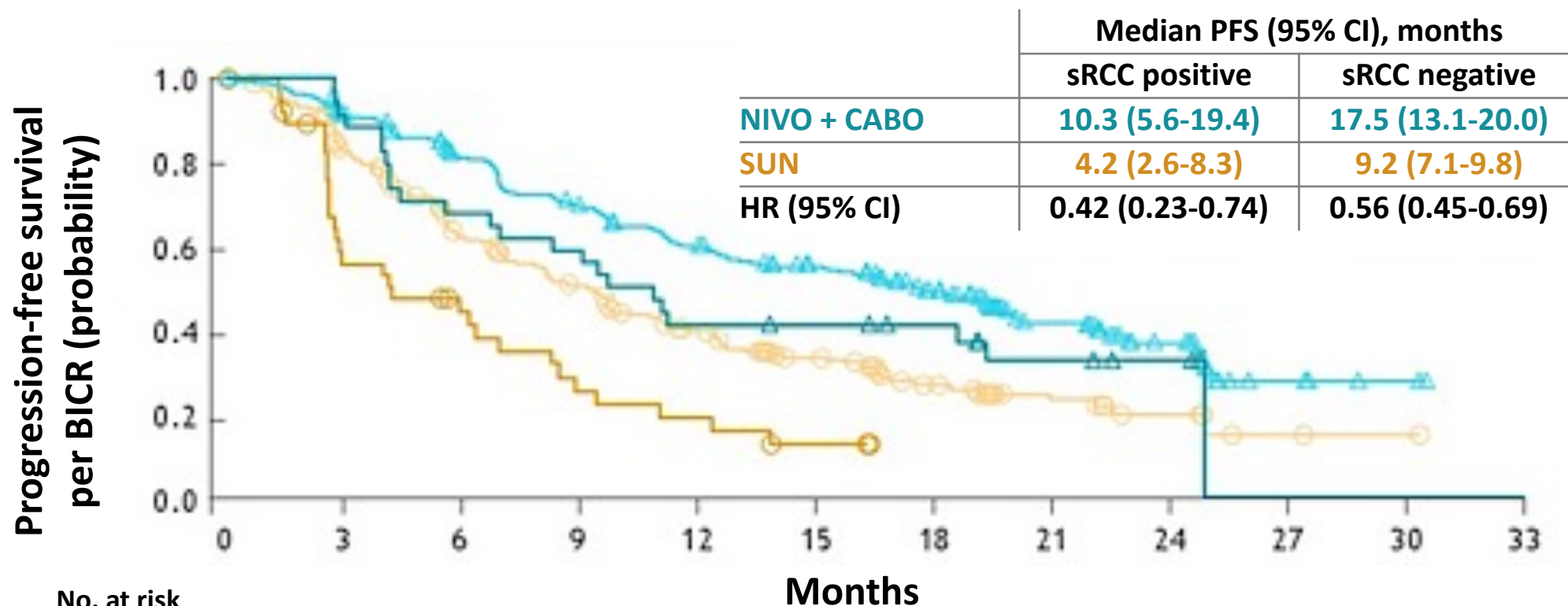
Nivolumab+cabozantinib	323	308	295	283	259	184	106	55	11	3	0
Sunitinib	328	296	273	253	223	154	83	36	10	3	0

Nivolumab + Cabozantinib (NIVO + CABO) versus Sunitinib (SUN) for Advanced Renal Cell Carcinoma (aRCC): Outcomes by Sarcomatoid Histology and Updated Trial Results with Extended Follow-Up of CheckMate 9ER

Motzer RJ et al.

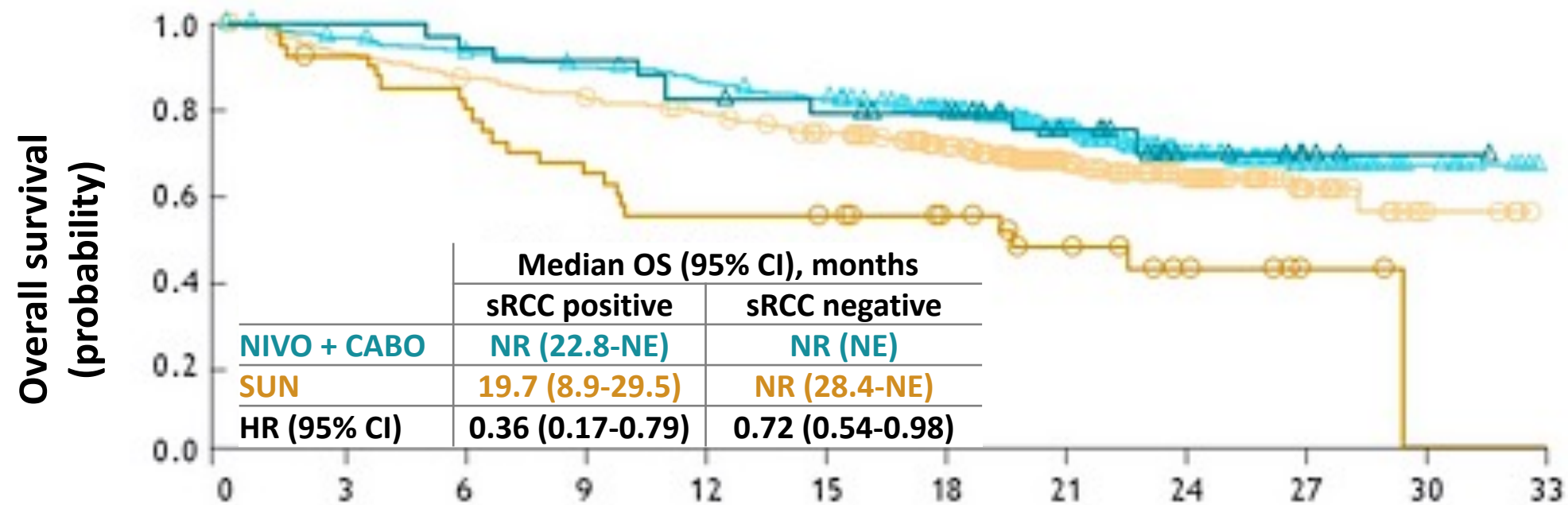
Genitourinary Cancers Symposium 2021;Abstract 308.

Progression-Free Survival per BICR by Sarcomatoid Histology



	No. at risk											
	Months											
NIVO + CABO sRCC positive	34	31	23	20	14	13	11	7	4	0	0	0
SUN sRCC positive	41	20	14	8	6	2	0	0	0	0	0	0
NIVO + CABO sRCC negative	289	249	213	181	152	132	91	49	22	5	2	0
SUN sRCC negative	287	210	146	114	81	59	37	17	7	2	1	0

Overall Survival by Sarcomatoid Histology



No. at risk		Months											
NIVO + CABO	sRCC positive	34	34	32	31	28	26	24	16	7	3	1	0
	SUN sRCC positive	41	37	32	26	22	21	17	12	6	2	0	0
	sRCC negative	289	274	263	252	241	229	196	131	77	37	9	0
	SUN sRCC negative	287	258	240	228	214	196	172	106	56	20	4	0

***N Engl J Med* 2021;[Online ahead of print].**

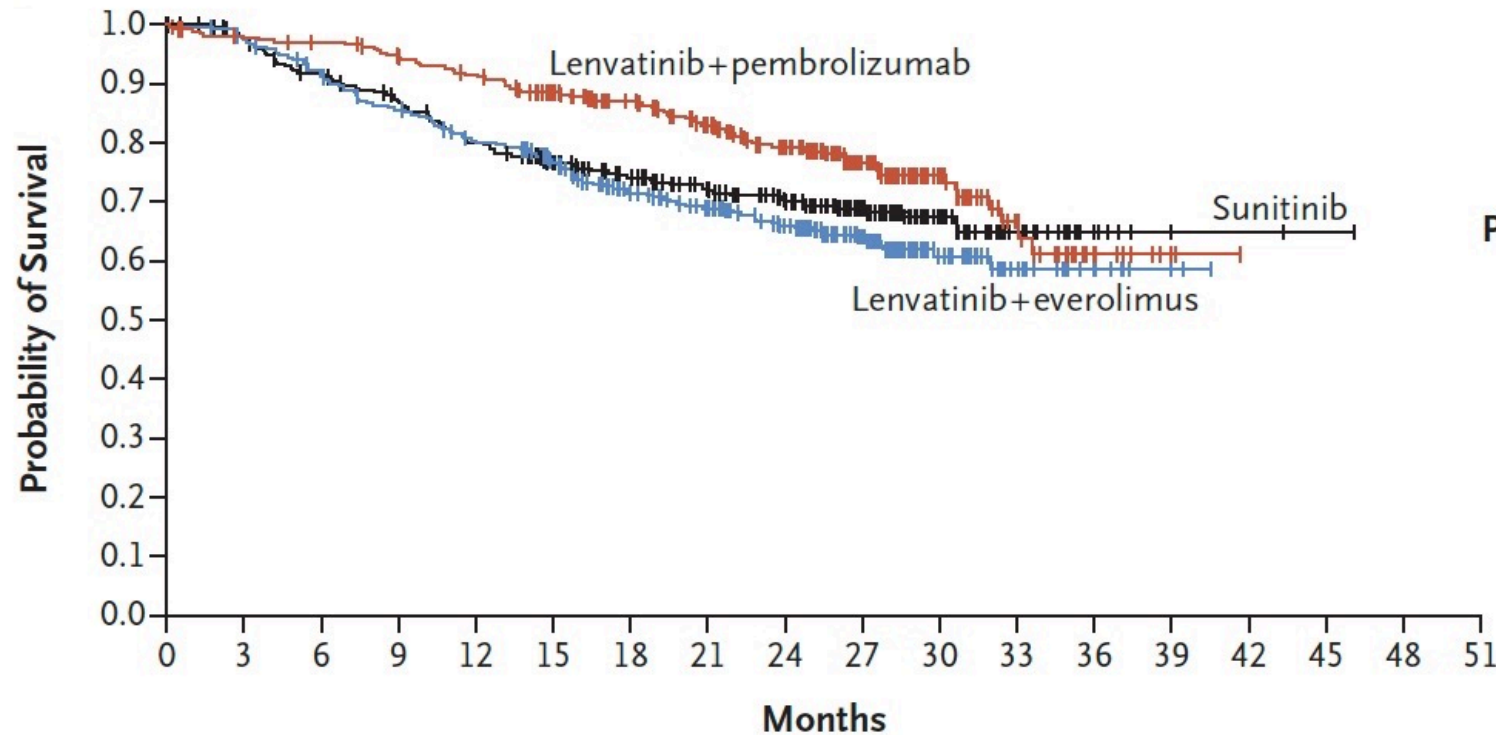
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Lenvatinib plus Pembrolizumab or Everolimus for Advanced Renal Cell Carcinoma

R. Motzer, B. Alekseev, S.-Y. Rha, C. Porta, M. Eto, T. Powles, V. Grünwald, T.E. Hutson, E. Kopyltsov, M.J. Méndez-Vidal, V. Kozlov, A. Alyasova, S.-H. Hong, A. Kapoor, T. Alonso Gordo, J.R. Merchan, E. Winkquist, P. Maroto, J.C. Goh, M. Kim, H. Gurney, V. Patel, A. Peer, G. Procopio, T. Takagi, B. Melichar, F. Rolland, U. De Giorgi, S. Wong, J. Bedke, M. Schmidinger, C.E. Dutcus, A.D. Smith, L. Dutta, K. Mody, R.F. Perini, D. Xing, and T.K. Choueiri, for the CLEAR Trial Investigators*

Kaplan-Meier Analysis of Overall Survival



No. at Risk

Lenvatinib+pembrolizumab	355	342	338	327	313	280	253	222	188	129	66	26	10	2	0		
Lenvatinib+everolimus	357	346	321	299	277	246	205	183	154	109	46	22	8	2	0		
Sunitinib	357	332	307	289	264	236	207	186	160	112	60	25	7	2	2	1	0

Median Overall Survival (95% CI)

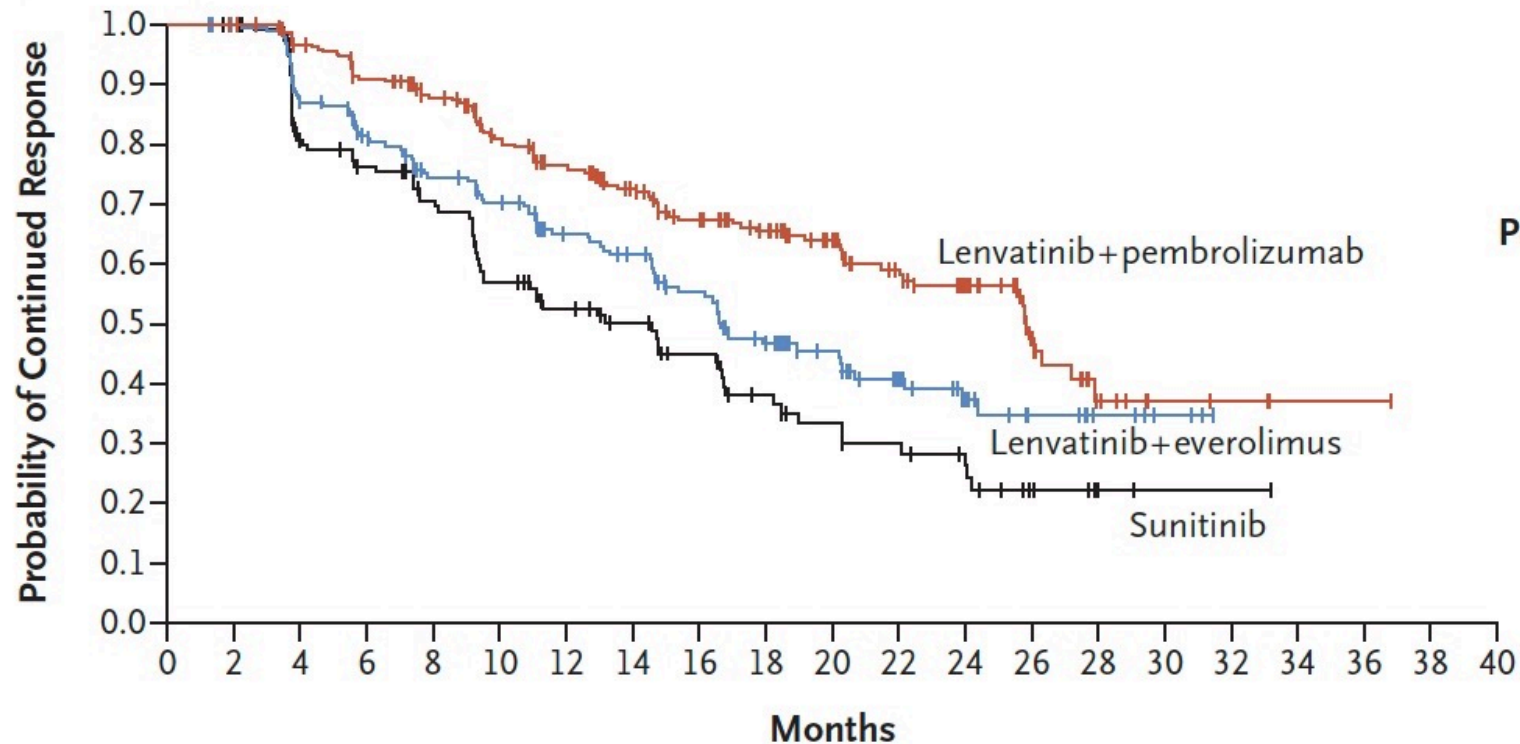
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Lenvatinib+ Pembrolizumab	NR (33.6–NE)
Lenvatinib+ Everolimus	NR (NE–NE)
Sunitinib	NR (NE–NE)

Hazard ratio for death (lenvatinib+ pembrolizumab vs. sunitinib), 0.66 (95% CI, 0.49–0.88); P=0.005

Hazard ratio for death (lenvatinib+ everolimus vs. sunitinib), 1.15 (95% CI, 0.88–1.50); P=0.30

Kaplan-Meier Analysis of Response Duration



No. at Risk

Lenvatinib+pembrolizumab	252	250	234	215	197	172	153	131	112	101	83	63	45	23	9	4	3	1	1	0
Lenvatinib+everolimus	191	186	159	142	125	113	93	83	65	50	39	27	18	11	6	3	0			
Sunitinib	129	125	91	82	73	57	47	40	33	25	20	17	13	7	2	1	1	0		

Confirmed Tumor Responses

Measure	Lenvatinib plus Pembrolizumab (N = 355)	Lenvatinib plus Everolimus (N = 357)	Sunitinib (N = 357)
Objective response (95% CI) — %†	71.0 (66.3–75.7)	53.5 (48.3–58.7)	36.1 (31.2–41.1)
Relative risk vs. sunitinib (95% CI)	1.97 (1.69–2.29)	1.48 (1.26–1.74)	Reference
Best overall response — no. (%)			
Complete response	57 (16.1)	35 (9.8)	15 (4.2)
Partial response	195 (54.9)	156 (43.7)	114 (31.9)
Stable disease	68 (19.2)	120 (33.6)	136 (38.1)
Progressive disease	19 (5.4)	26 (7.3)	50 (14.0)
Unknown or could not be evaluated‡	16 (4.5)	20 (5.6)	42 (11.8)
Median time to response (range) — mo	1.94 (1.41–18.50)	1.91 (1.41–14.36)	1.94 (1.61–16.62)
Median duration of response (95% CI) — mo	25.8 (22.1–27.9)	16.6 (14.6–20.6)	14.6 (9.4–16.7)

Selected Adverse Events of Any Cause That Emerged or Worsened During Treatment in at Least 25% of the Patients in Any Treatment Group

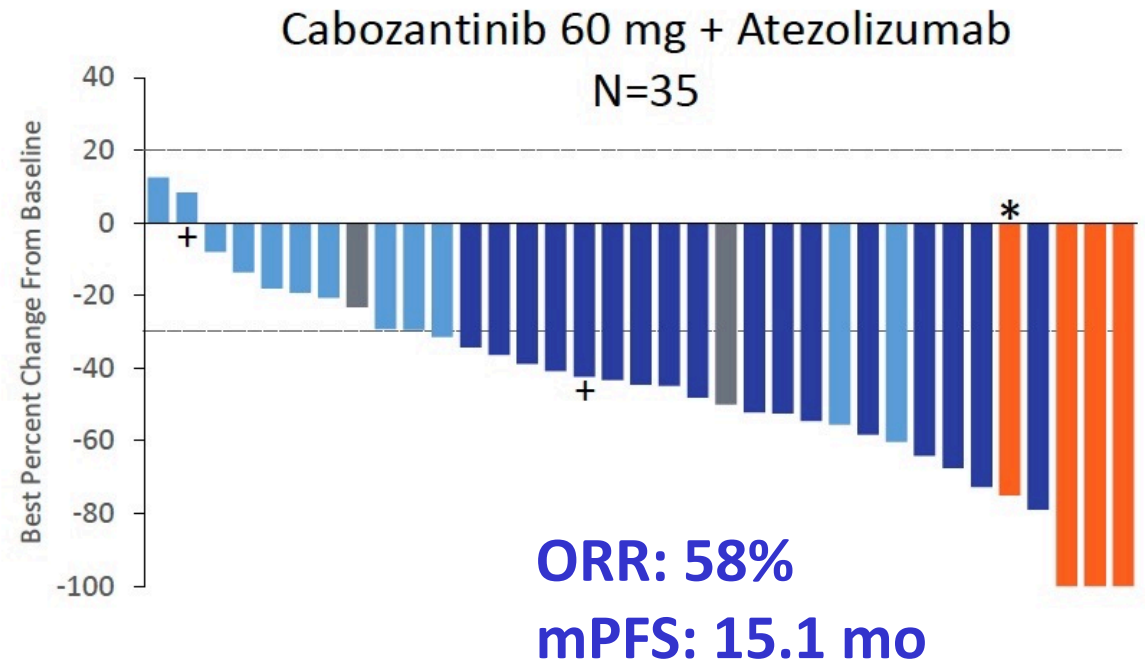
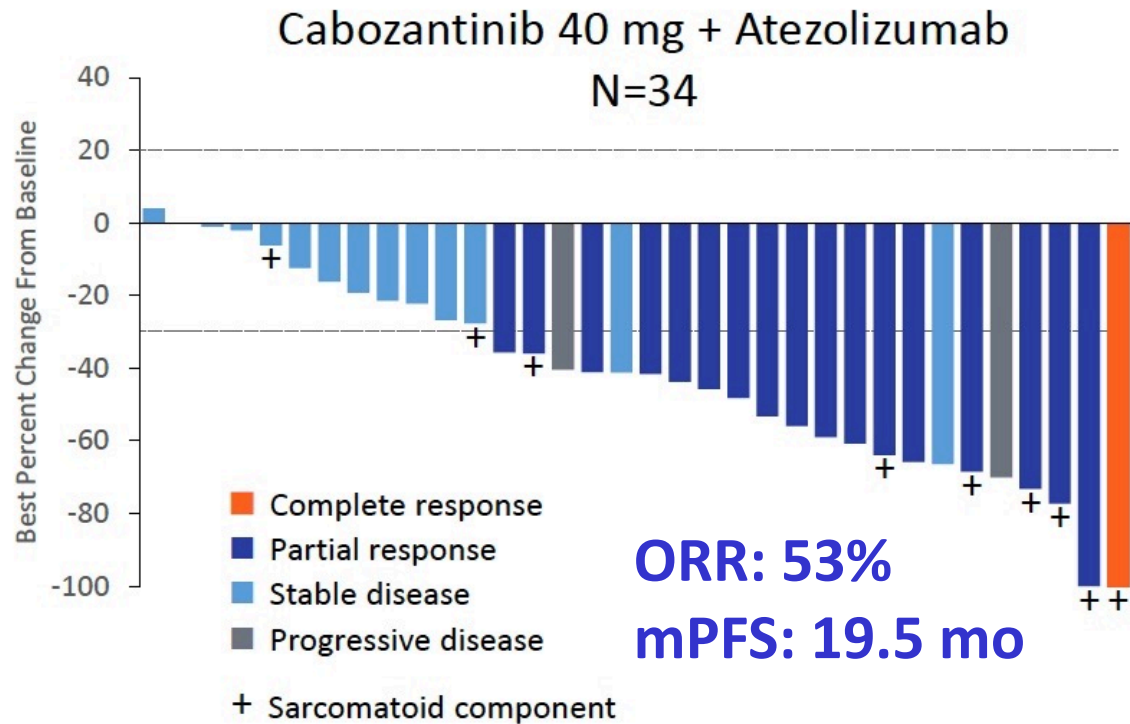
Event	Lenvatinib plus Pembrolizumab (N = 352)		Lenvatinib plus Everolimus (N = 355)		Sunitinib (N = 340)	
	Any Grade	Grade ≥ 3 [†]	Any Grade	Grade ≥ 3 [†]	Any Grade	Grade ≥ 3 [†]
	<i>number of patients (percent)</i>					
Any event	351 (99.7)	290 (82.4)	354 (99.7)	295 (83.1)	335 (98.5)	244 (71.8)
Diarrhea	216 (61.4)	34 (9.7)	236 (66.5)	41 (11.5)	168 (49.4)	18 (5.3)
Hypertension	195 (55.4)	97 (27.6)	162 (45.6)	80 (22.5)	141 (41.5)	64 (18.8)
Hypothyroidism [‡]	166 (47.2)	5 (1.4)	95 (26.8)	2 (0.6)	90 (26.5)	0
Decreased appetite	142 (40.3)	14 (4.0)	144 (40.6)	22 (6.2)	105 (30.9)	5 (1.5)
Fatigue	141 (40.1)	15 (4.3)	149 (42.0)	27 (7.6)	125 (36.8)	15 (4.4)

Cabozantinib (C) in Combination with Atezolizumab (A) as First-Line Therapy for Advanced Clear Cell Renal Cell Carcinoma (ccRCC): Results from the COSMIC-021 Study

Pal S et al.

ESMO 2020;Abstract 7020.

COSMIC-021: Cabozantinib/Atezolizumab for Previously Untreated Advanced ccRCC



Select, Ongoing Phase III Clinical Trials for Previously Untreated Metastatic Renal Cell Carcinoma

Study acronym	Target accrual	Randomization	Primary endpoint(s)	Estimated primary completion
COSMIC-313	840	<ul style="list-style-type: none"> Cabozantinib + nivolumab + ipilimumab (4 doses) → cabozantinib + nivolumab Placebo + nivolumab + ipilimumab (4 doses) → placebo + nivolumab 	PFS	Nov 2021
PDIGREE	1,046	After Induction nivolumab/ipilimumab <ul style="list-style-type: none"> Pts with CR → Nivolumab <ul style="list-style-type: none"> Pts with non-CR or non-PD, <u>randomized</u> <ul style="list-style-type: none"> → Nivolumab → Nivolumab + Cabozantinib Pts with PD → Cabozantinib 	OS	Sept 2021

FDA Approves Tivozanib for Relapsed or Refractory Advanced RCC

Press Release: March 10, 2021

“On March 10, 2021, the Food and Drug Administration approved tivozanib, a kinase inhibitor, for adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

Efficacy was evaluated in TIVO-3 (NCT02627963), a randomized (1:1), open-label, multicenter trial of tivozanib versus sorafenib in patients with relapsed or refractory advanced RCC who received two or three prior systemic treatments, including at least one VEGFR kinase inhibitor other than sorafenib or tivozanib.

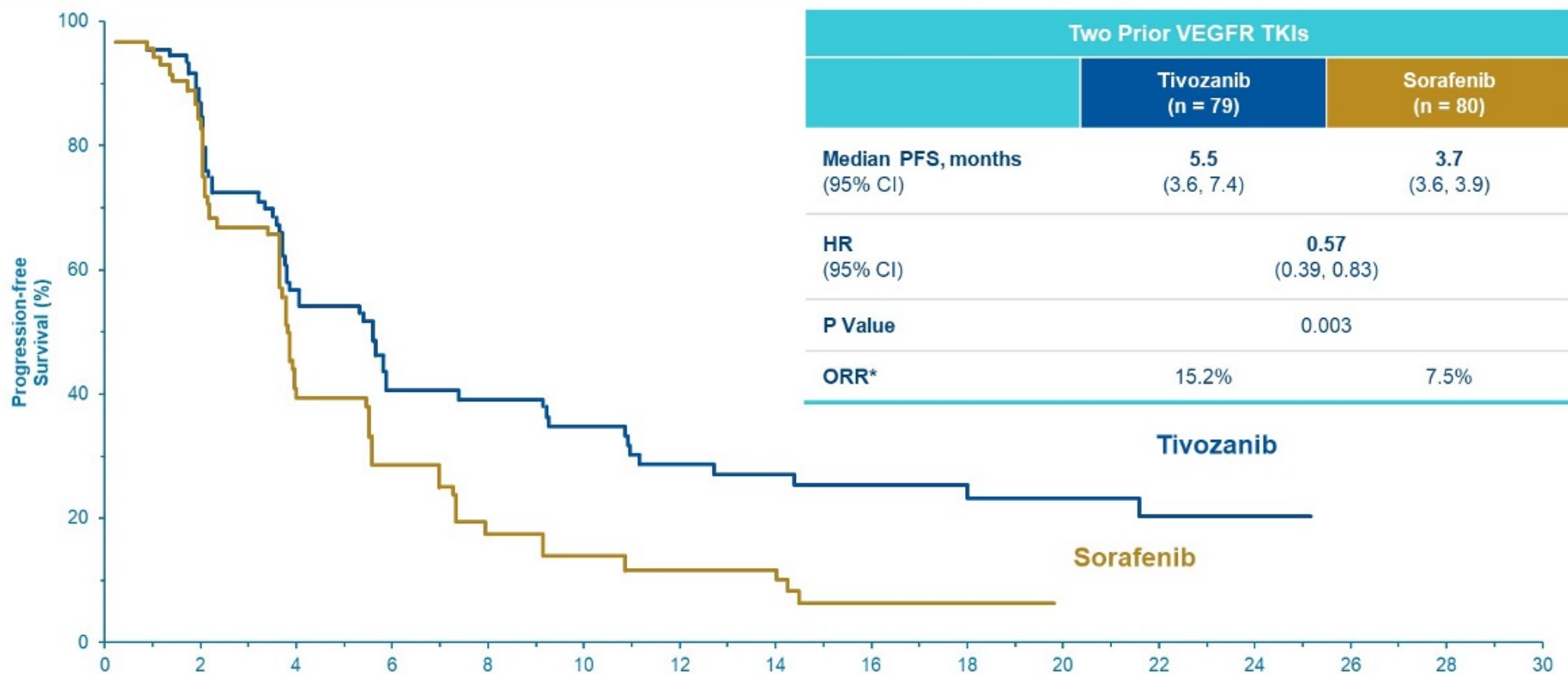
The recommended tivozanib dose is 1.34 mg once daily (with or without food) for 21 consecutive days every 28 days until disease progression or unacceptable toxicity.”

Tivozanib in Patients with Advanced Renal Cell Carcinoma (aRCC) Who Have Progressed After Prior Treatment of Axitinib: Results from TIVO-3

Rini BI et al.

Genitourinary Cancers Symposium 2021;Abstract 278.

TIVO-3: Progression-Free Survival and ORR in Patient Subgroup with 2 Prior TKIs



TIVO-3: Tivozanib After Axitinib

RCC Population	N (subjects)		mPFS (months)		HR	ORR	
	<u>Tivo</u>	<u>Sor</u>	<u>Tivo</u>	<u>Sor</u>		<u>Tivo</u>	<u>Sor</u>
ITT	175	175	5.6	3.9	0.73	18%	8%
3 rd Line Any Prior Axitinib	47	46	5.5	3.9	0.71	16%	6%
4 th Line Any Prior Axitinib	36	43	5.5	3.6	0.64	11%	10%
3 rd and 4 th Line Any Prior Axitinib	83	89	5.5	3.7	0.68	13%	8%

Lancet 2021;397:695-703

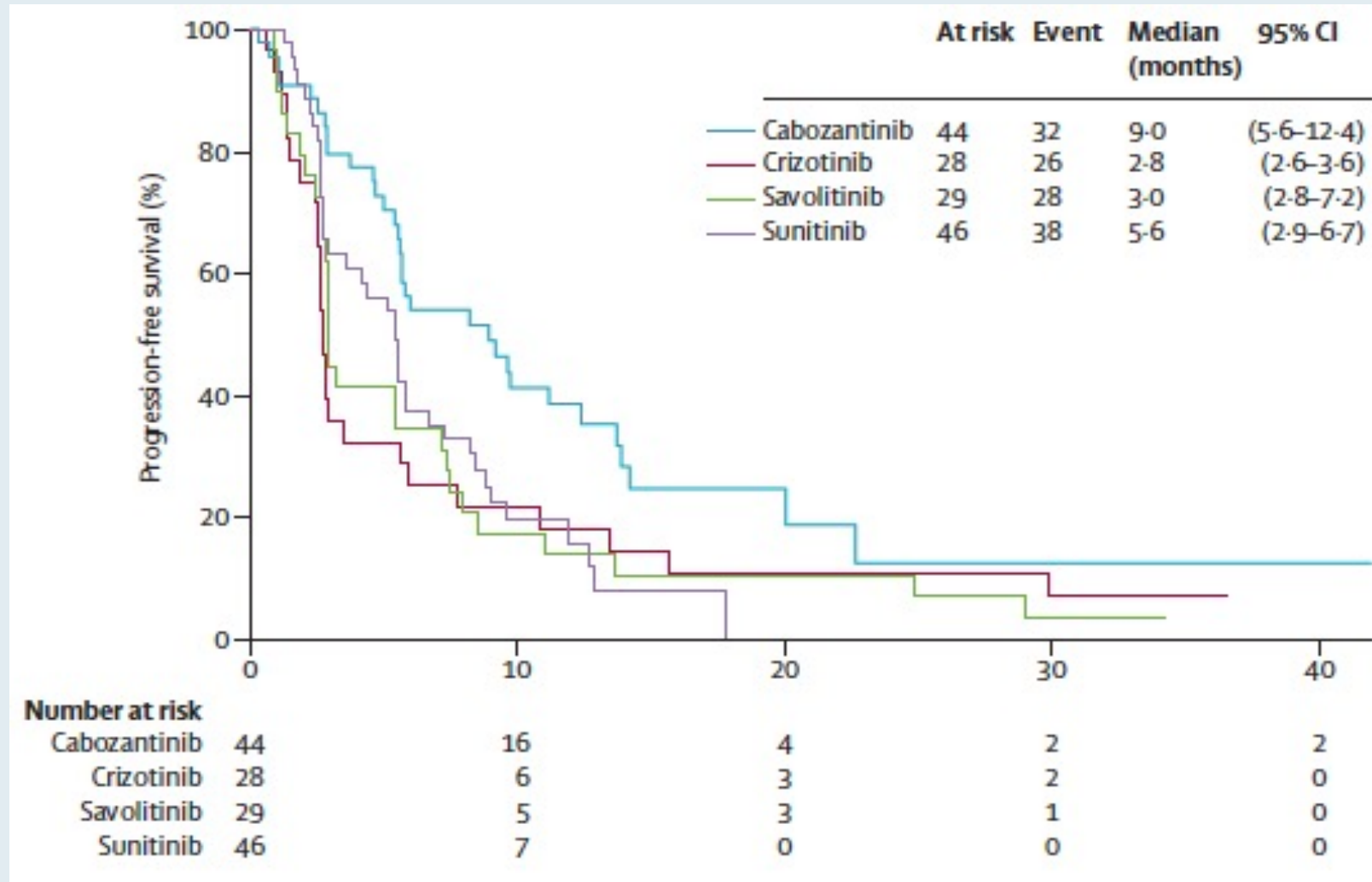
Articles

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

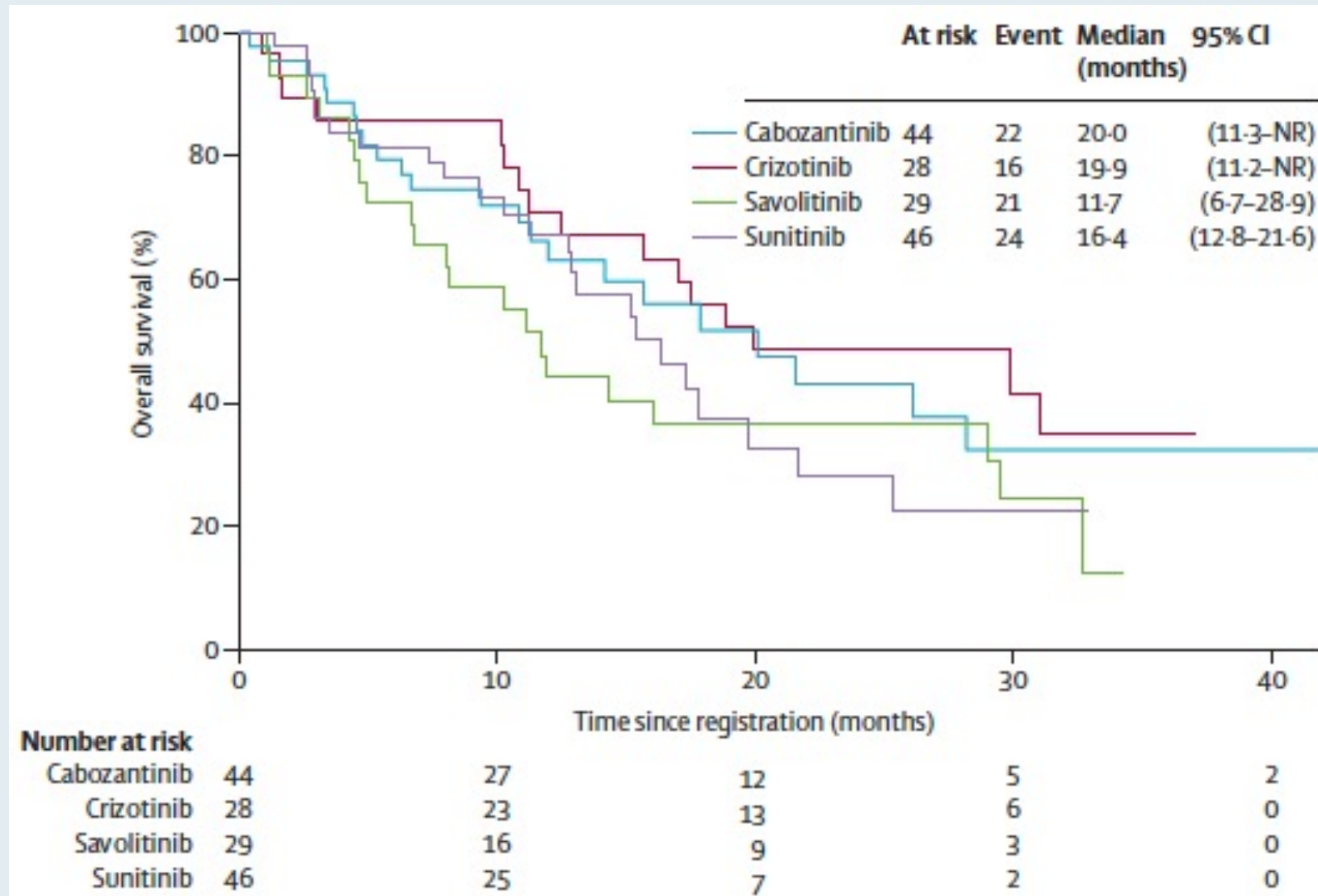


Sumanta K Pal, Catherine Tangen, Ian M Thompson Jr, Naomi Balzer-Haas, Daniel J George, Daniel Y C Heng, Brian Shuch, Mark Stein, Maria Tretiakova, Peter Humphrey, Adebowale Adeniran, Vivek Narayan, Georg A Bjarnason, Ulka Vaishampayan, Ajjai Alva, Tian Zhang, Scott Cole, Melissa Plets, John Wright,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

Kaplan-Meier Analysis of Progression-Free Survival



Kaplan-Meier Analysis of Overall Survival



FDA Grants Priority Review to Belzutifan for von Hippel-Lindau Disease-Associated RCC

Press Release – March 16, 2021

“The FDA accepted a new drug application for belzutifan to treat von Hippel-Lindau disease-associated renal cell carcinoma and granted it priority review based on response rate results from a phase 2 trial.

A new drug application for belzutifan was accepted by the FDA and granted priority review for the treatment of patients with von Hippel-Lindau (VHL) disease-associated renal cell carcinoma (RCC), not requiring immediate surgery...

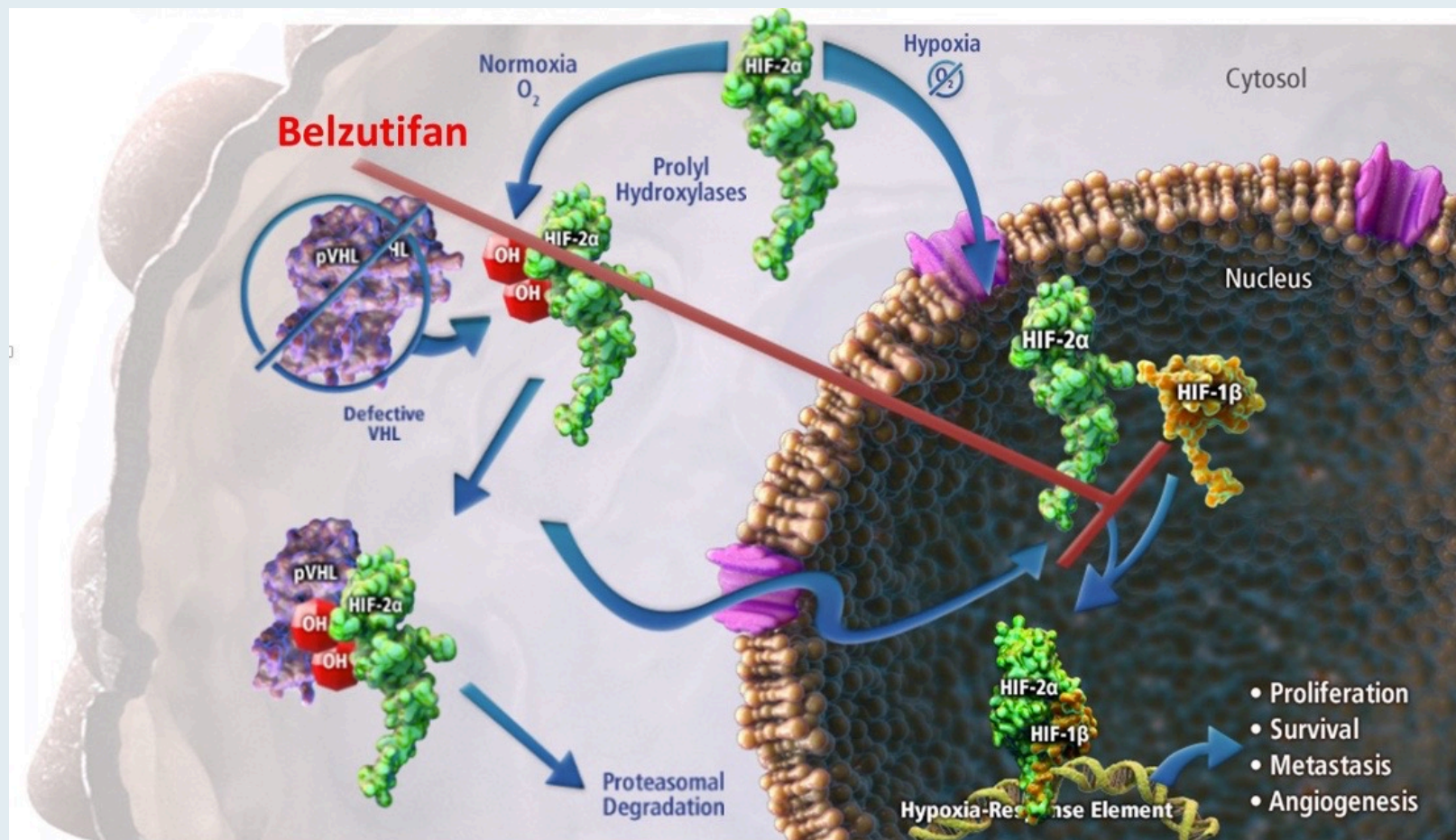
The application is based on results of a phase 2 trial, Study-004 (NCT03401788), of belzutifan in the treatment of VHL disease-associated RCC, with a primary end point of objective response rate and secondary measures of disease control rate, duration of response, time to response, progression-free survival, time to surgery, and safety. Patients treated on the trial must have had at least 1 measurable solid tumor localized to the kidneys and were not in need of immediate surgical intervention.”

The Oral HIF-2 α Inhibitor Belzutifan (MK-6482) in Patients With Advanced Clear Cell Renal Cell Carcinoma: Updated Follow-up of a Phase 1/2 Study

Todd Michael Bauer,¹ Toni K. Choueiri,² Kyriakos P. Papadopoulos,³ Elizabeth R. Plimack,⁴
Jaime R. Merchan,⁵ David F. McDermott,⁶ M. Dror Michaelson,⁷ Leonard Joseph Appleman,⁸
Sanjay Thamake,⁹ Rodolfo F. Perini,⁹ Eric Kristopher Park,⁹ Eric Jonasch¹⁰

¹Sarah Cannon Research Institute/Tennessee Oncology, PLLC, Nashville, TN, USA; ²Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA, USA; ³South Texas Accelerated Research Therapeutics (START), San Antonio, TX, USA; ⁴Fox Chase Cancer Center, Philadelphia, PA, USA; ⁵University of Miami, Miami, FL, USA; ⁶Beth Israel Deaconess Medical Center, Boston, MA, USA; ⁷Massachusetts General Hospital, Boston, MA, USA; ⁸University of Pittsburgh Medical Center, Pittsburgh, PA; ⁹Merck & Co., Inc., Kenilworth, NJ, USA; ¹⁰The University of Texas MD Anderson Cancer Center, Houston, TX, USA

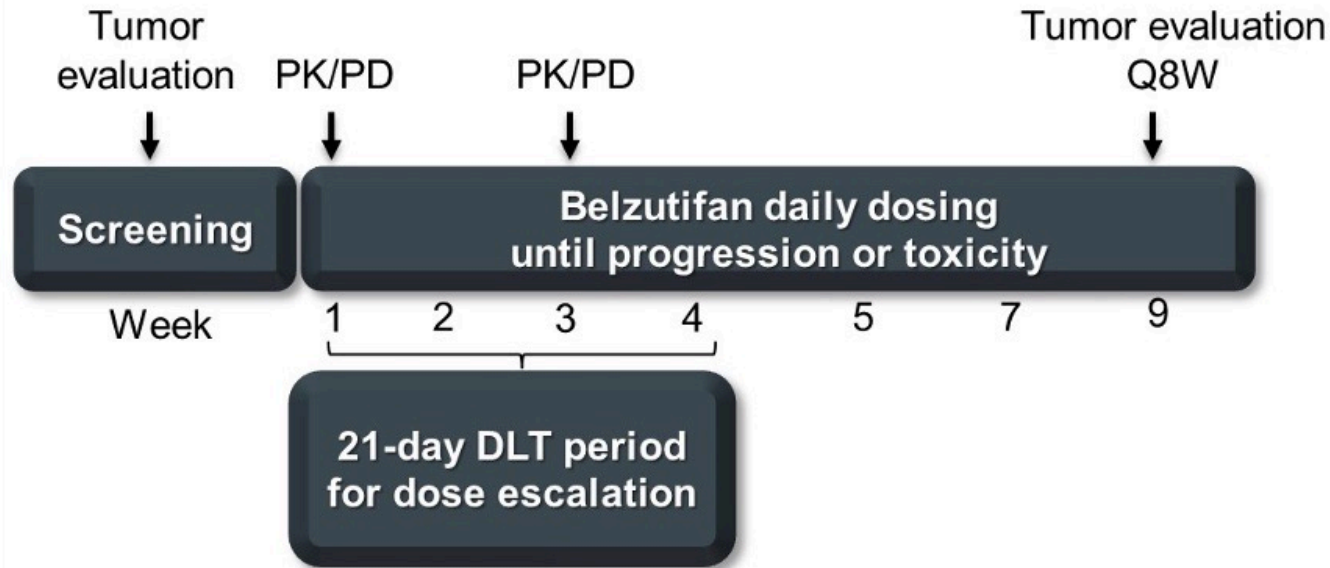
pVHL Deficiency Results in HIF-2-alpha Activation



- 90% of patients with sporadic ccRCC have defective pVHL function¹
- Loss of pVHL function results in constitutive activation of HIF-2α²
- Belzutifan is a potent, selective, small molecule HIF-2α inhibitor

1. Linehan WM, Ricketts CJ. *Nat Rev Urol*. 2019;16:539-552. 2. Couvé S et al. *Cancer Res*. 2014;74:6554-6564.

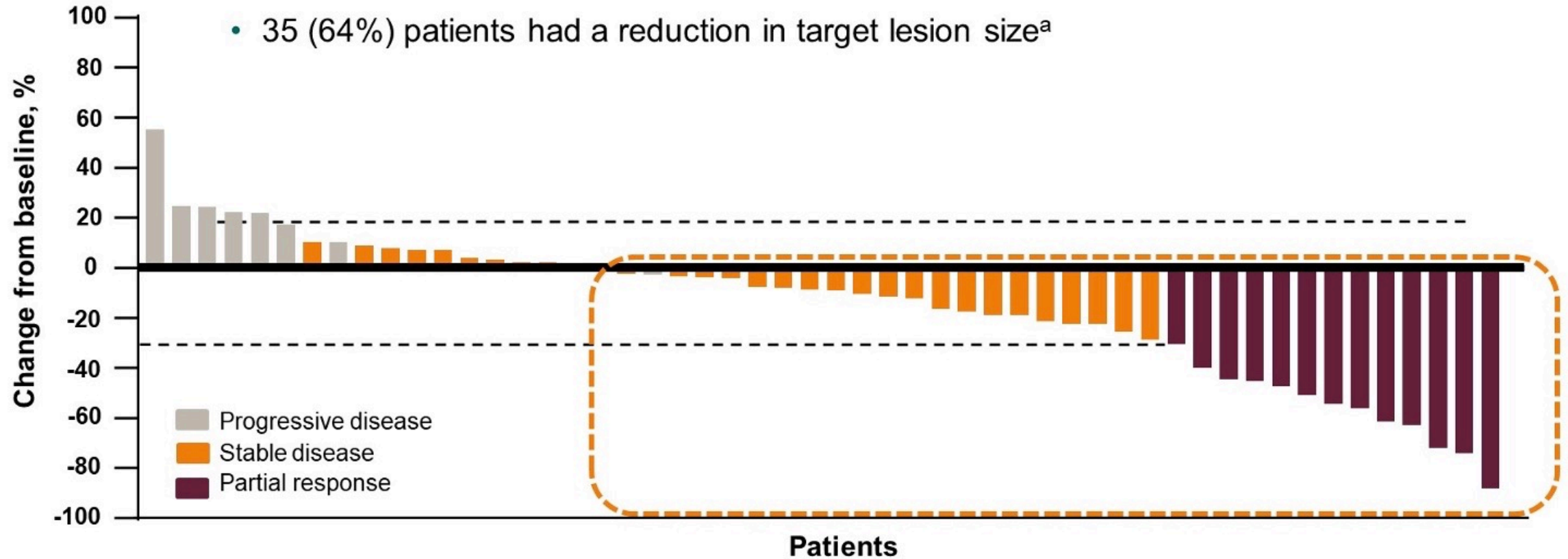
Study Design



- Dose of 120 mg once daily selected for further clinical development from the dose-escalation cohort
- **55 patients with previously treated advanced ccRCC enrolled at 120 mg orally once daily in the dose-expansion cohort**
 - 44 (80%) discontinued
 - Most common reason was disease progression: 60%
 - 11 (20%) have treatment ongoing
- Median (range) follow-up:
 - 27.7 (24.8-34.3) months

- Dose-escalation cohort for patients with advanced solid tumors
- Dose-expansion cohort for patients with advanced ccRCC who previously received ≥ 1 therapy
 - Key end points: Safety, objective response rate, duration of response

Best Tumor Change from Baseline (Investigator Assessment in the ccRCC Cohort)



^a3 patients were nonevaluable. Data cutoff: June 1, 2020.

Genitourinary Cancers Symposium 2021;Abstract 272.

Phase 2 Study of the Oral Hypoxia-Inducible Factor 2 α Inhibitor Belzutifan (MK-6482) in Combination With Cabozantinib in Patients With Advanced Clear Cell Renal Cell Carcinoma

Toni K. Choueiri¹; Todd M. Bauer²; David F. McDermott³; Edward Arrowsmith⁴; Ananya Roy⁵; Rodolfo Perini⁵; Donna Vickery⁵; Scott S. Tykodi⁶

¹Dana-Farber Cancer Institute, Boston, MA, USA; ²Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN, USA;

³Beth Israel Deaconess Medical Center, Boston, MA, USA; ⁴Tennessee Oncology, Chattanooga, TN, USA;

⁵Merck & Co., Inc., Kenilworth, NJ, USA; ⁶University of Washington and Fred Hutchinson Cancer Research Center, Seattle, WA, USA

Study Design

Key Eligibility Criteria

- Advanced or metastatic ccRCC
- Either treatment naive or has received prior PD-1/L1 immunotherapy and ≤ 2 regimens for locally advanced or metastatic RCC
- ECOG PS 0 or 1

Cohort 1:
Treatment-naïve
belzutifan 120 mg/day +
cabozantinib 60 mg/day
N \approx 50

Cohort 2:
Prior immunotherapy treatment
belzutifan 120 mg/day +
cabozantinib 60 mg/day
N \approx 50

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

Assessments

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

Posttreatment

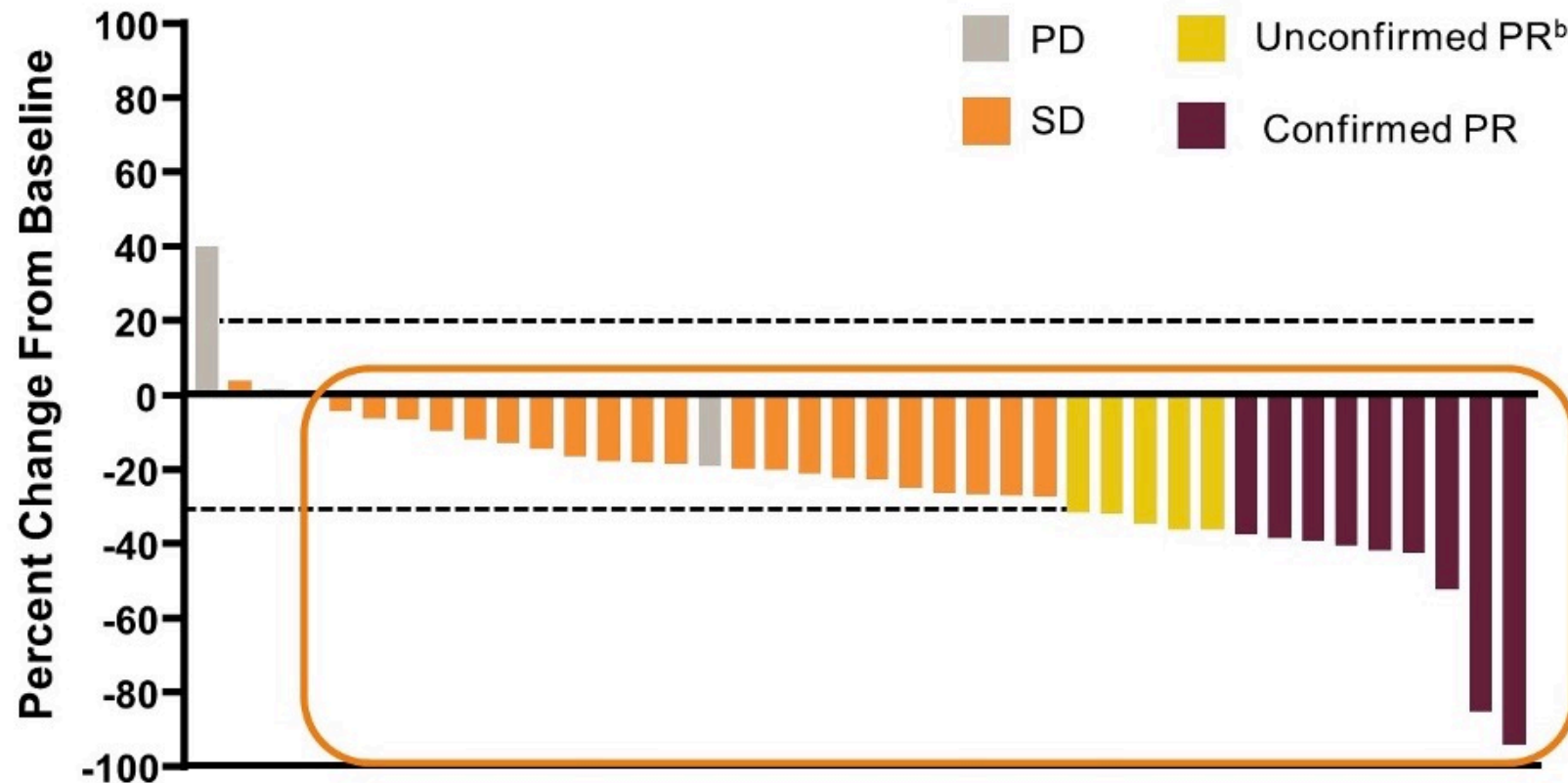
- 28-day safety follow-up
- Follow-up visits every 6 months

End Points

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

Best Tumor Change from Baseline

- 36 of 41 patients (88%) experienced a reduction in target lesion size^a



Treatment-Related Adverse Events

Treatment-Related AEs in ≥15% of Patients	Safety Analysis Set N = 52			
	Any Grade		Grade 3	
	Event, n	n (%)	Event, n	n (%)
Any	742	51 (98)	60	31 (60)
Anemia	92	40 (77)	8	6 (12)
Fatigue	67	35 (67)	10	6 (12)
Hand-foot syndrome	56	28 (54)	1	1 (2)
Diarrhea	49	23 (44)	2	2 (4)
Hypertension	52	23 (44)	15	12 (23)
Nausea	24	18 (35)	1	1 (2)
ALT increased	48	17 (33)	7	3 (6)
AST increased	34	17 (33)	2	2 (4)
Decreased appetite	22	15 (29)	1	1 (2)
Dysgeusia	19	12 (23)	1	1 (2)
Headache	12	10 (19)	0	0 (0)
Hypophosphatemia	18	9 (17)	2	2 (4)
Stomatitis	10	8 (15)	0	0 (0)

^aAll patients who received ≥1 dose of treatment. Data cutoff: October 15, 2020.

- There were no grade 4/5 treatment-related AEs
- Of all 742 AEs, 92% were grade 1 or 2 in severity
- Treatment-related hypoxia, considered an on-target AE for belzutifan, occurred in 2 patients (4%) (both were grade 3 AEs)

Agenda

MODULE 1: Cases from the Practice of Dr Malhotra

MODULE 2: Consensus or Controversy – Clinical Investigator Approaches to Clinical Scenarios

MODULE 3: Renal Cell Carcinoma Journal Club with Dr Stadler

- Active surveillance of metastatic RCC: Results from a prospective observational study (MaRCC)
- Optimized management of nivolumab and ipilimumab in advanced RCC: A response-based Phase II study (OMNIVORE)

MODULE 4: Key Data Sets

MODULE 5: Other Recent Data Sets

ORIGINAL ARTICLE

Updated efficacy results from the JAVELIN Renal 101 trial: first-line avelumab plus axitinib versus sunitinib in patients with advanced renal cell carcinoma

T. K. Choueiri^{1*}, R. J. Motzer², B. I. Rini^{3†}, J. Haanen⁴, M. T. Campbell⁵, B. Venugopal⁶, C. Kollmannsberger⁷, G. Gravis-Mescam⁸, M. Uemura⁹, J. L. Lee¹⁰, M.-O. Grimm¹¹, H. Gurney¹², M. Schmidinger¹³, J. Larkin¹⁴, M. B. Atkins¹⁵, S. K. Pal¹⁶, J. Wang¹⁷, M. Mariani¹⁸, S. Krishnaswami¹⁹, P. Cislo²⁰, A. Chudnovsky²¹, C. Fowst¹⁸, B. Huang¹⁹, A. di Pietro²² & L. Albiges²³

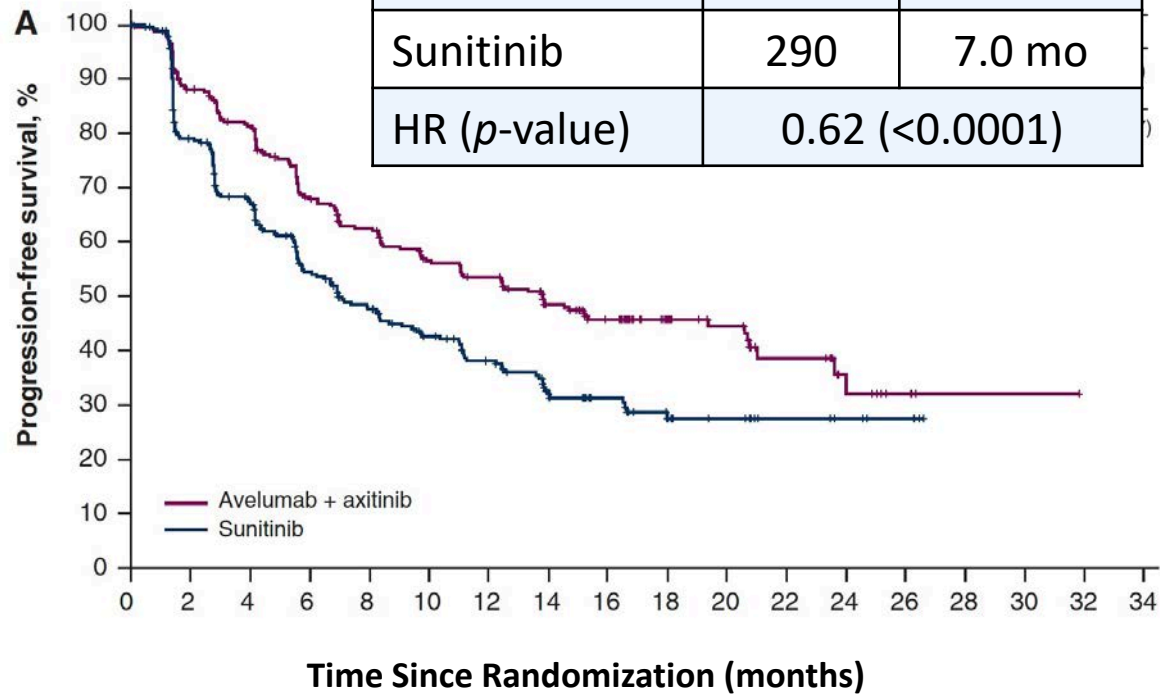
JAVELIN Renal 101: Overall Response and Best Response Rate in the PD-L1-Positive and Overall Populations

	PD-L1-positive		Overall	
	Avelumab + axitinib (n = 270)	Sunitinib (n = 290)	Avelumab + axitinib (n = 442)	Sunitinib (n = 444)
Confirmed ORR	55.9%	27.2%	52.5%	27.3%
CR	5.6%	2.4%	3.8%	2.0%
PR	50.4%	24.8%	48.6%	25.2%
Stable disease	27.0%	41.4%	28.3%	43.7%
Progressive disease	11.5%	22.4%	12.4%	19.4%
Ongoing response	55.6%	53.2%	54.3%	50.4%

JAVELIN Renal 101: PFS in the PD-L1+ and Overall Populations

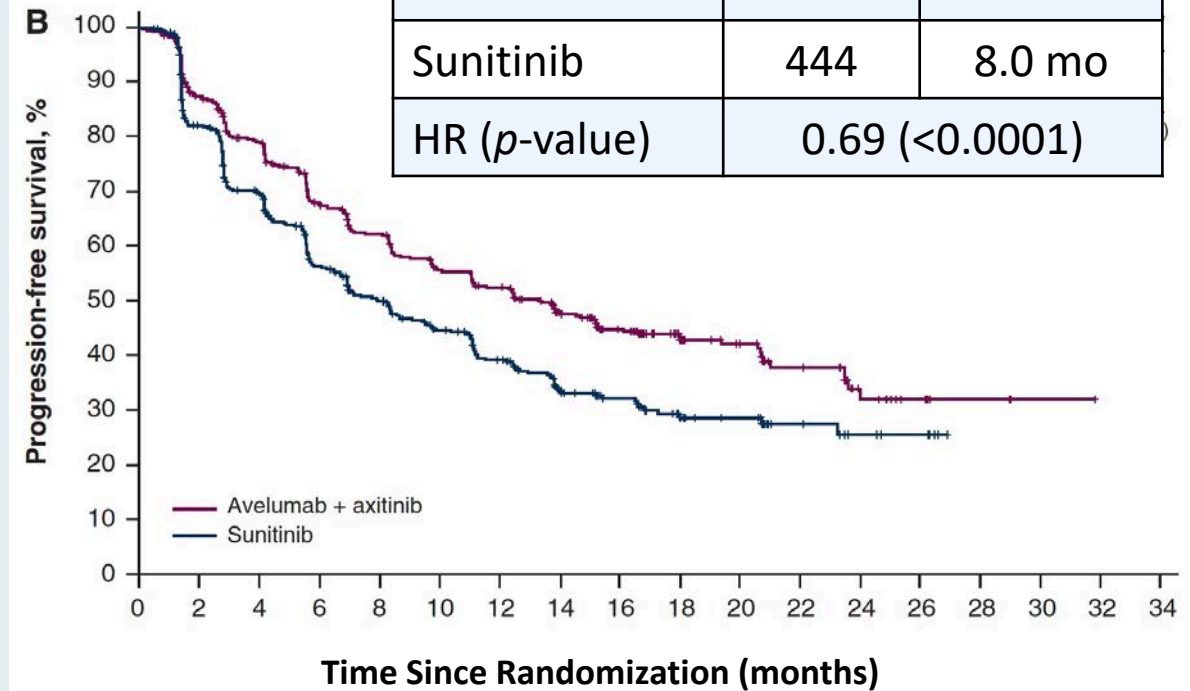
PD-L1 $\geq 1\%$ Population

	N	mPFS
Avelumab + axitinib	270	13.8 mo
Sunitinib	290	7.0 mo
HR (p-value)	0.62 (<0.0001)	

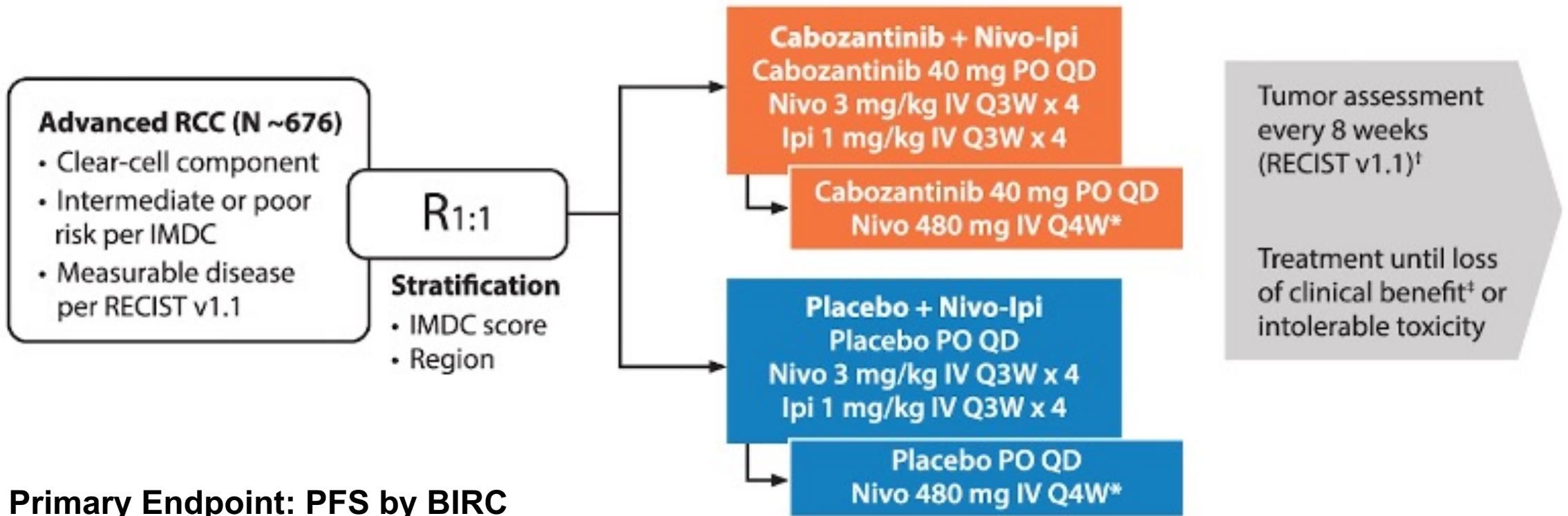


Overall Population

	N	mPFS
Avelumab + axitinib	442	13.3 mo
Sunitinib	444	8.0 mo
HR (p-value)	0.69 (<0.0001)	



COSMIC-313 Phase III Schema



<https://www.urotoday.com/conference-highlights/asco-2020/asco-2020-kidney-cancer/121877-asco-2020-cosmic-313-phase-iii-study-of-cabozantinib-in-combination-with-nivolumab-and-ipilimumab-in-patients-with-previously-untreated-advanced-renal-cell-carcinoma-of-intermediate-or-poor-risk.html>

Sequencing of Therapy for Patients with Relapsed/Refractory (R/R) RCC; Novel Approaches Under Investigation

Salvage Ipilimumab and Nivolumab in Patients With Metastatic Renal Cell Carcinoma After Prior Immune Checkpoint Inhibitors

Anita Gul, MD¹; Tyler F. Stewart, MD^{2,3}; Charlene M. Mantia, MD⁴; Neil J. Shah, MD⁵; Emily Stern Gatof, MD⁴; Ying Long, PharmD²; Kimberly D. Allman, MSN, CNP¹; Moshe C. Ornstein, MD, MA¹; Hans J. Hammers, MD, PhD⁶; David F. McDermott, MD⁴; Michael B. Atkins, MD⁵; Michael Hurwitz, MD, PhD²; and Brian I. Rini, MD¹

J Clin Oncol 2020;38:3088-94.

Salvage Ipilimumab/Nivolumab for mRCC After Prior ICI Therapy

Variable	No. (%)
No. of prior lines of systemic therapy	
1	9 (20)
2	12 (27)
3	8 (18)
4	6 (13)
> 4	10 (22)
Prior VEGF receptor inhibitor ^a	27 (60)
Prior immunotherapy	
Anti-PD-1 ^b	34 (76)
Anti-PD-L1 ^b	11 (24)
IL-2 ^c	14 (31)
Best response to prior ICI	
PR	24 (53)
SD	12 (27)
PD	9 (20)

BOR to Prior ICI	No. (%)	BOR to Salvage Ipilimumab and Nivolumab	No. (%)
PR	24 (53)	PR	4 (17)
		SD	2 (8)
		PD	17 (71)
		NE	1 (4)
SD	12 (27)	PR	3 (25)
		SD	5 (42)
		PD	4 (33)
PD	9 (20)	PR	2 (22)
		PD	7 (78)

Abbreviations: BOR, best objective response; ICI, immune checkpoint inhibitor; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease.

A Pooled Analysis of the Efficacy and Safety of Cabozantinib Post Immunotherapy in Patients with Advanced Renal Cell Carcinoma

Oya M et al.

ASCO 2020;Abstract 5089.

Efficacy of Cabozantinib with or without Prior Immunotherapy

	Prior IO (N = 33)	No Prior IO (N = 332)
Objective response rate	21.2%	17.2%
Clinical benefit rate	75.8%	83.7%
Median PFS	Not reached	7.4 mo
6-months PFS	65.5%	58.3%
Median PFS	19.5 mo	21.9 mo
6-months OS	90.8%	90.6%

Phase II Trial of Lenvatinib (LEN) plus Pembrolizumab (PEMBRO) for Disease Progression After PD-1/PD-L1 Immune Checkpoint Inhibitor (ICI) in Metastatic Clear Cell Renal Cell Carcinoma (mccRCC)

Lee C-H et al.

ASCO 2020;Abstract 5008.

Efficacy of Lenvatinib/Pembrolizumab in Patients Previously Treated with Immunotherapy

	Anti-PD-1/PD-L1 (N = 104)	Anti-PD-1/PD-L1 and anti-VEGF (n = 68)	Nivolumab + ipilimumab (n = 38)
ORR	55%	59%	47%
Median DOR	12 mo	9 mo	Not reached
Median PFS (irRECIST)	11.7 mo	Not reported	Not reported
OS at 12 months	77%	Not reported	Not reported

Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Advanced Gastrointestinal Cancers

**Monday, June 7, 2021
5:00 PM – 6:00 PM ET**

Faculty

Kristen K Ciombor, MD, MSCI

Moderator

Neil Love, MD

Thank you for joining us!

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