Immunotherapy for Kidney Cancer

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Disclosures

- **Consulting:** Octane Global, Defined Health, Dedham Group, Adept Field Solutions, Slingshot Insights, Blueprint Partnership, Charles River Associates, Schlesinger Group, Imprint Science, Insight Strategy, Trinity Group, Adnovate Strategies, Catenion, Cello BioHealth Consulting, PWW Consulting, Haymarket, AbbVie
- **Advisory boards:** Exelixis, AVEO, Bristol Myers Squibb (nonfinancial)
- **Educational:** KidneyCAN / National Kidney Foundation, LM Education and Exchange, MDedge, Cancer Expert Now, CancerNetwork, OncLive, Aptitude, Health, ASCO Post, Targeted Oncology
- **Research funding:** Exelixis, AstraZeneca
- I will be discussing non-FDA approved indications during my presentation.

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Pre-Test Question:
A 63-year-old gentleman with microscopic hematuria is found to have a 10cm left renal mass and >10 bilateral pulmonary nodules on CT imaging. He has had unintentional weight loss and fatigue, but is still active (KPS 80-90). His labs are notable for anemia and thrombocytosis, but are otherwise unremarkable. Biopsy of a lung nodule shows **clear cell renal cell carcinoma**. Which of the following would you choose as a first-line systemic therapy:

A. Sunitinib
B. Combination therapy regimen containing an immune checkpoint inhibitor, such as nivolumab + ipilimumab
C. Temsirolimus
D. Bevacizumab plus interferon alfa

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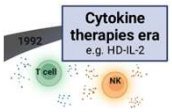
The evolving landscape of systemic therapy for advanced RCC



Braun & Kashima, Urol Clin N Am, 2023

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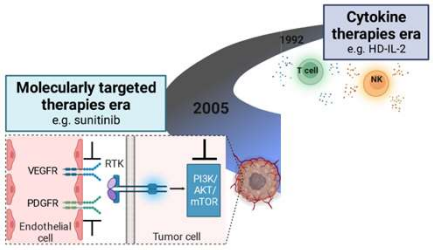
The evolving landscape of systemic therapy for advanced RCC



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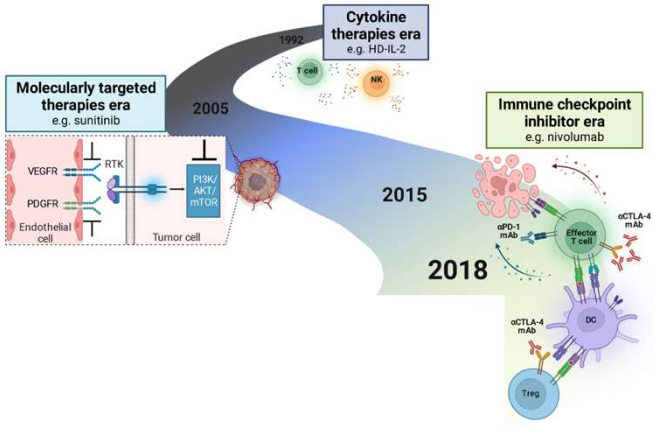

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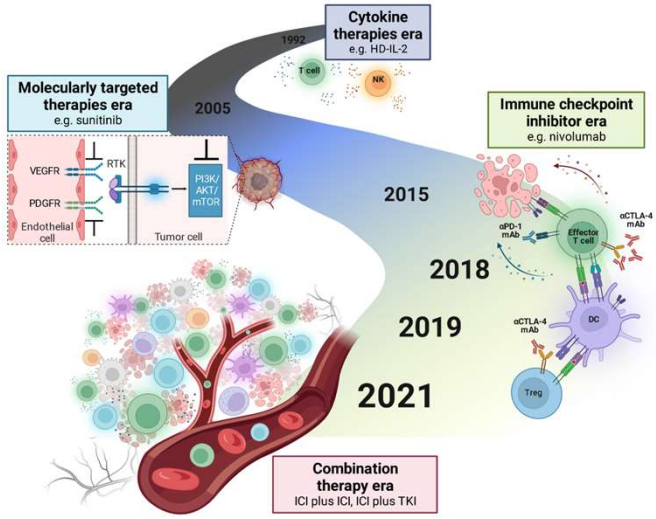

Braun & Kashima, Urol Clin N Am, 2023

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Systemic therapies for clear cell RCC: Where are we now?

	First-line systemic therapies			Subsequent therapies			
	IO + IO	IO + TKI	*TKI alone*	IO-based	TKI alone	mTORi	TKI + mTORi
Favorable		pembrolizumab + axitinib *avelumab + axitinib (immature OS)* nivolumab + cabozantinib pembrolizumab + lenvatinib	*(for select patients only)* *sunitinib* *pazopanib (favorable)* *cabozantinib (intermediate / poor)*	nivolumab (if no prior IO) *IO-based combinations (in specific circumstances)*	cabozantinib axitinib tivozanib *pazopanib* *sunitinib* *sorafenib*	everolimus	lenvatinib + everolimus
Intermediate / Poor	**IO + IO** nivolumab + ipilimumab (*intermediate / poor risk only*)						

Adapted from Braun, GU ASCO, 2021

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Systemic therapies for clear cell RCC: Where are we now?

First-line systemic therapies

	IO + IO	IO + TKI	TKI alone
Favorable		pembrolizumab + axitinib *avelumab + axitinib (immature OS)*	*(for select patients only)* *sunitinib* *pazopanib (favorable)*
Intermediate / Poor	nivolumab + ipilimumab (*intermediate / poor risk only*)	nivolumab + cabozantinib pembrolizumab + lenvatinib	*cabozantinib (intermediate / poor)*

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CheckMate-214: nivolumab + ipilimumab

Key eligibility criteria
- Treatment naïve, inoperable, locally advanced, or metastatic RCC
- Clear-cell histology
- KPS ≥70%

Stratification
- IMDC prognostic score (0 vs 1-2 vs 3-6)
- Region (United States vs Canada/Europe vs rest of the world)

N = 1,096

R

1:1

Nivolumab 3 mg/kg IV every 3 wk **+ ipilimumab** 1 mg/kg IV every 3 wk x 4 doses, then **nivolumab** 3 mg/kg every 2 wk

Sunitinib 50 mg orally daily (4 wk on, 2 wk off)

Endpoints
- **Coprimary:** PFS, OS, ORR (intermediate/poor risk)
- **Secondary:** PFS, OS, ORR (ITT)
- **Exploratory:** PFS, OS, ORR (favorable risk)

Motzer et al, *N Engl J Med*, 2018

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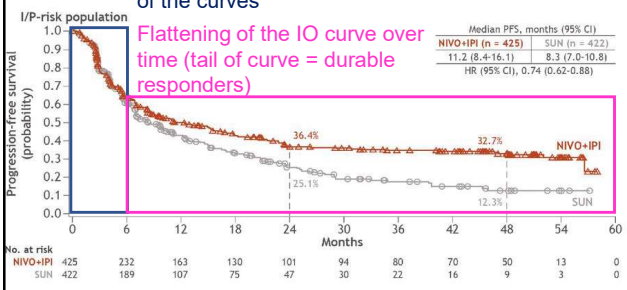
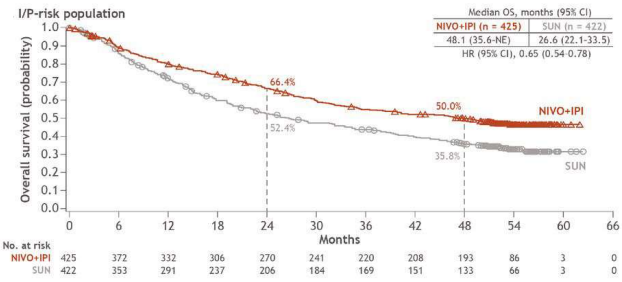
Long-term follow-up: durable responses for a subset of patients

No early separation of the curves

Flattening of the IO curve over time (tail of curve = durable responders)





Albiges et al, *ESMO Open*, 2020

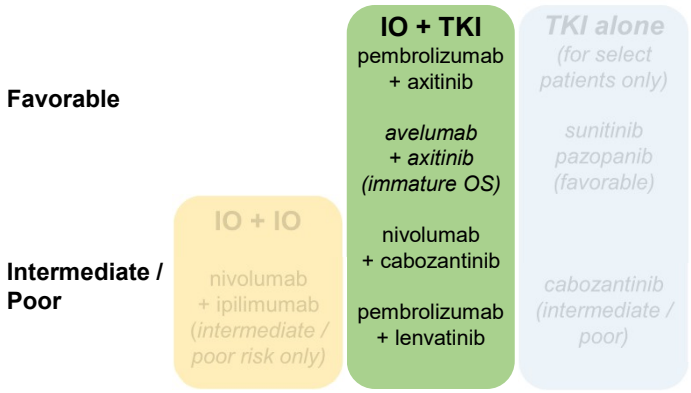
CheckMate-214: higher primary PD rates

	Intermediate-/Poor-Risk		ITT		Favorable-Risk	
	NIVO + IPI (n = 425)	SUN (n = 422)	NIVO + IPI (n = 550)	SUN (n = 546)	NIVO + IPI (n = 125)	SUN (n = 124)
Confirmed ORR (95% CI), %	41.9 (37-47)	26.8 (23-31)	39.1 (35-43)	32.4 (29-37)	29.6 (22-38)	51.6 (43-61)
P	<.0001		.0134		.0005	
Best overall response, n (%)						
CR	44 (10.4)	6 (1.4)	59 (10.7)	14 (2.6)	15 (12.0)	8 (6.5)
PR	134 (31.5)	107 (25.4)	156 (28.4)	163 (29.9)	22 (17.6)	56 (45.2)
SD	131 (30.8)	187 (44.3)	198 (36.0)	230 (42.1)	67 (53.6)	43 (34.7)
PD	82 (19.3)	71 (16.8)	97 (17.6)	77 (14.1)	15 (12.0)	6 (4.8)
NE	32 (7.5)	48 (11.4)	38 (6.9)	57 (10.4)	6 (4.8)	9 (7.3)
NR	2 (0.5)	3 (0.7)	2 (0.4)	5 (0.9)	0	2 (1.6)
Ongoing response, n (%)	n = 178 116 (65.2)	n = 113 56 (49.6)	n = 215 140 (65.1)	n = 177 92 (52.0)	n = 37 24 (64.9)	n = 64 34 (56.3)

Albiges et al, *ESMO* 2020, Abstract 711P

Systemic therapies for clear cell RCC: Where are we now?

First-line systemic therapies



Front-line IO+TKI combinations

KEYNOTE 426[1]	Treatment-naive clear-cell RCC; KPS ≥ 70%; (N = 861)	**Pembrolizumab** 200 mg IV Q3W + **Axitinib** 5 mg PO BID **Sunitinib** 50 mg PO QD (4/2)	1º EP: PFS/OS
JAVELIN Renal 101[2]	Treatment-naive clear-cell RCC; ECOG PS 0 or 1; (N = 886)	**Avelumab** 10 mg/kg IV Q2W + **Axitinib** 5 mg PO BID in 6-wk cycles **Sunitinib** 50 mg PO (4/2)	1º EP: PFS/OS PD-L1+ pts
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Slide adapted from T. Choueiri
1. Rini et al. *NEJM*, 2019 2. 3. Motzer et al. *NEJM*, 2019 3. Choueiri et al. NEJM 2021; 4. Motzer et al, NEJM 2021

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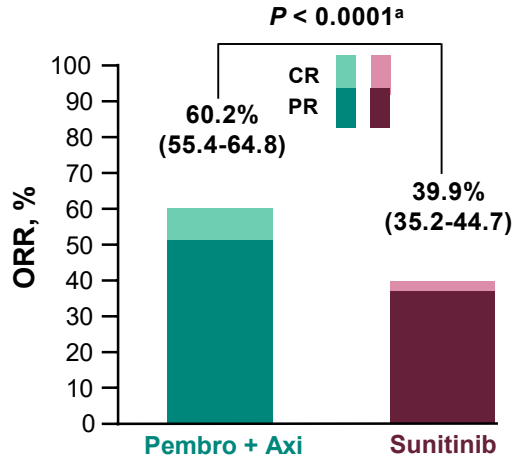
Pembrolizumab+axitinib: higher response rates



	Pembro + Axi n = 432	Sunitinib n = 429
Best Response, n (%)		
CR	38 (8.8)	13 (3.0)
PR	222 (51.4)	158 (36.8)
SD	100 (23.1)	150 (35.0)
PD	49 (11.3)	74 (17.2)
NE[b]	16 (3.7)	28 (6.5)
NA[c]	7 (1.6)	6 (1.4)
Median (range) duration of response, mo	23.5 (1.4+ to 34.5+)	15.9 (2.3 to 31.8+)

[a]As superiority of pembrolizumab plus axitinib was demonstrated at the first interim analysis, no alpha was allocated to confirmed objective response; only nominal p-values are reported. [b]Post-baseline assessment(s) available however not being evaluable (i.e., all post-baseline assessment(s) with insufficient data for assessment of response per RECIST 1.1. or CR/PR/SD <6 weeks from randomization). [c]No post-baseline assessment available for response evaluation; + indicates an ongoing response at time of last disease assessment. Data cutoff: January 6, 2020.

1. Plimack et al. Updated Analysis of KN-426. ASCO 2020. Abstract no. 5001

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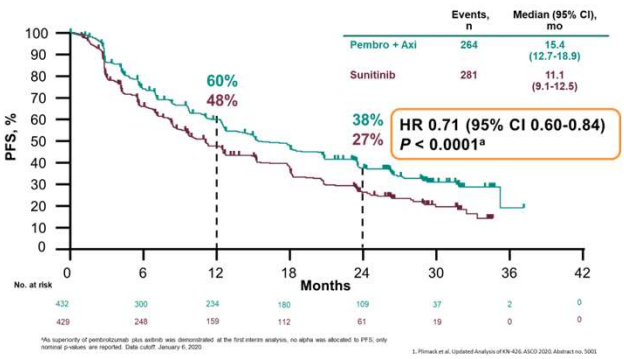
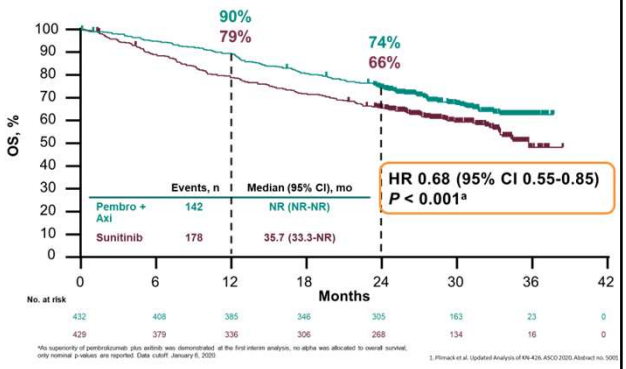
Pembrolizumab+axitinib: survival





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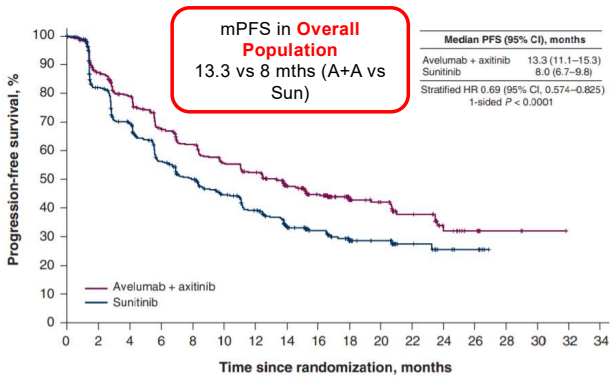
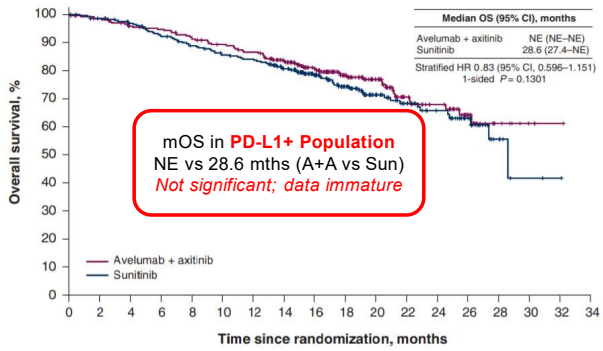
Avelumab+axitinib: survival





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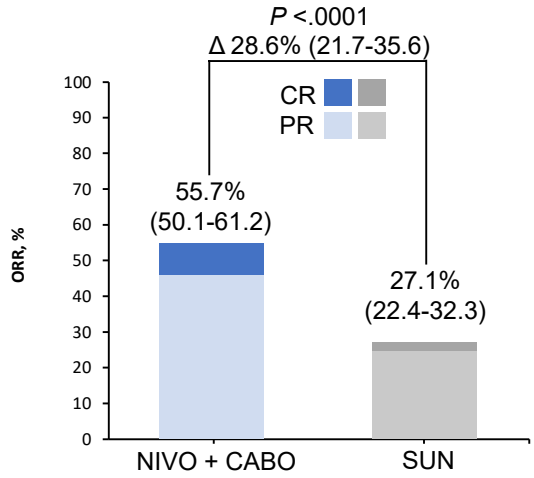
Nivolumab+cabozantinib: high CR/PR, low PD



Outcome, %	Nivolumab + Cabozantinib (n = 323)	Sunitinib (n = 328)
CR	8.0	4.6
PR	47.7	22.6
SR	32.2	42.1
PD	5.6	13.7
NE/NA[b]	6.5	17.1
Median time to response (range), mo[c]	2.8 (1.0-19.4)	4.2 (1.7-12.3)
Median duration of response (95% CI), mo[c]	20.2 (17.3-NE)	11.5 (8.3-18.4)

[a] BICR-assessed ORR and BOR by RECIST v1.1. [b] Includes patients who were never treated, those who discontinued/died before disease assessment, those without measurable disease at baseline per BICR, or other reason not reported/specified. [c] Median time to and duration of response were calculated for patients who had a complete or partial response (n = 180 with NIVO + CABO, n = 89 patients with SUN). 1. Choueiri TK et al. ESMO 2020. Abstract 696O_PR.

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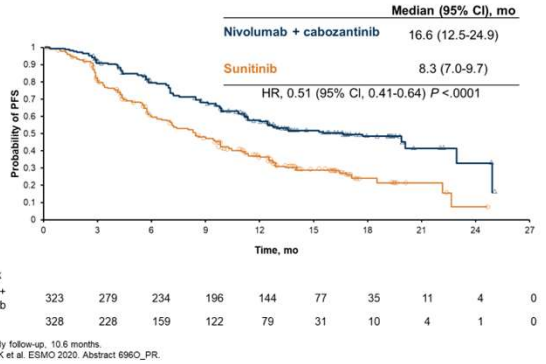
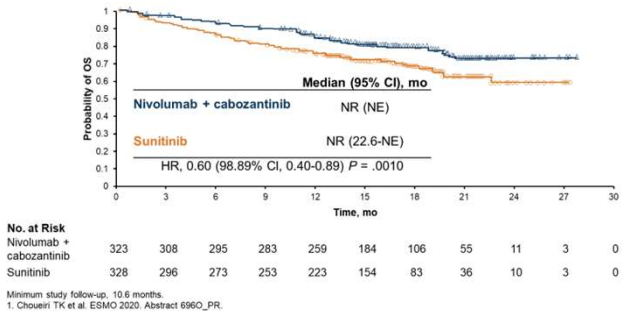
Nivolumab+cabozantinib: survival





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Nivolumab+cabozantinib: survival over time

Median follow-up (months)	18[1]	23.5[2]	32.9[3]	44.0[4]
OS, months	NR	NR	37.7	49.5
HR (95% CI)	0.60 (0.40-0.89)	0.66 (0.50-0.87)	0.70 (0.55-0.90)	0.70 (0.56-0.87)
PFS, months	16.6	17.0	16.6	16.6
HR (95% CI)	0.51 (0.41-0.64)	0.52 (0.43-0.64)	0.56 (0.46-0.68)	0.58 (0.48-0.71)
ORR(%)/CR(%)	55.7/8.0	56.5/8.5	55.7/12.4	55.7/12.4

1. Choueiri et al, ESMO 2020, *NEJM*, 2021. 2. Motzer R.J. et al., ASCO GU Cancer Symposium, 2021. 3. Powles et al, ASCO GU Cancer Symposium, 2022 and Motzer et al, Lancet Oncol, 2022. 4. Burotto M. et al., ASCO GU Cancer Symposium, 2023

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Pembrolizumab+lenvatinib: high response rates

	Lenvatinib + Pembrolizumab (N = 355)	Sunitinib (N = 357)
Objective response rate, n (%)	252 (71.0)	129 (36.1)
95% CI[a]	(66.3, 75.7)	(31.2, 41.1)
Difference (%) (95% CI)[a]	34.9 (28.0, 41.7)	
Relative risk[b]	1.97 (1.69, 2.29)	
Best overall response, n (%)		
Complete response	61 (17.2)	15 (4.2)
Partial response	191 (53.8)	114 (31.9)
Stable disease[c]	68 (19.2)	136 (38.1)
Progressive disease	19 (5.4)	50 (14.0)
Unknown/Not evaluable	16 (4.5)	42 (11.8)
Median duration of objective response, mo (95% CI)	26.0 (22.2, 41.4)	14.7 (9.4, 16.8)

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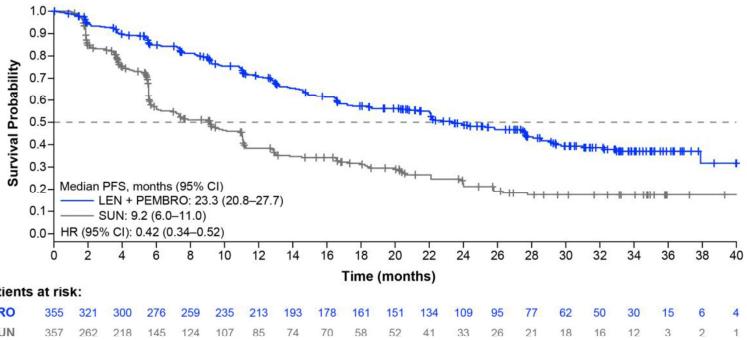
Pembrolizumab+lenvatinib: survival

PFS



	MSKCC			IMDC		
	Poor risk	Intermediate risk	Favorable risk	Poor risk	Intermediate risk	Favorable risk
LEN +PEMBRO vs SUN HR (95% CI)	0.18 (0.08–0.42)	0.46 (0.35–0.60)	0.43 (0.29–0.64)	0.30 (0.14–0.62)	0.41 (0.30–0.54)	0.47 (0.32–0.69)

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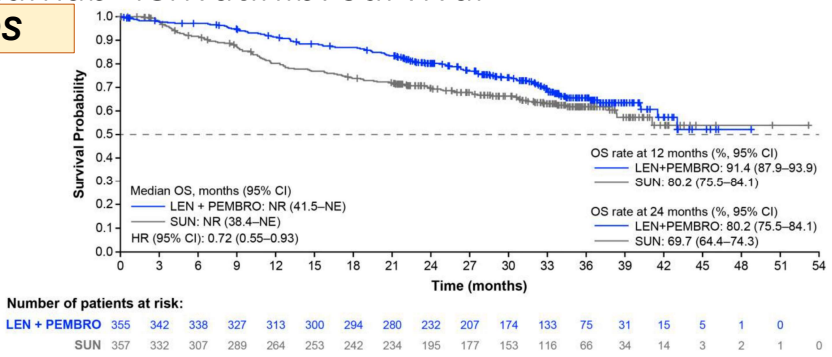
Pembrolizumab+lenvatinib: survival

OS



	MSKCC			IMDC		
	Poor risk	Intermediate risk	Favorable risk*	Poor risk	Intermediate risk	Favorable risk*
LEN +PEMBRO vs SUN HR (95% CI)	0.50 (0.25–1.02)	0.71 (0.52–0.97)	1.00 (0.51–1.96)	0.39 (0.20–0.77)	0.72 (0.52–1.00)	1.22 (0.66–2.26)*

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Immunotherapy combinations for first-line treatment of advanced clear cell RCC: *the next generation*

First-line systemic therapies

	IO + IO	IO + TKI	TKI alone	
Favorable		pembrolizumab + axitinib *avelumab + axitinib (immature OS)*	*(for select patients only)* *sunitinib* *pazopanib (favorable)*	**Triplet therapy?** *IO+IO+TKI* *IO+TKI +Other*
Intermediate / Poor	nivolumab + ipilimumab *(intermediate / poor risk only)*	nivolumab + cabozantinib pembrolizumab + lenvatinib	*cabozantinib (intermediate / poor)*	

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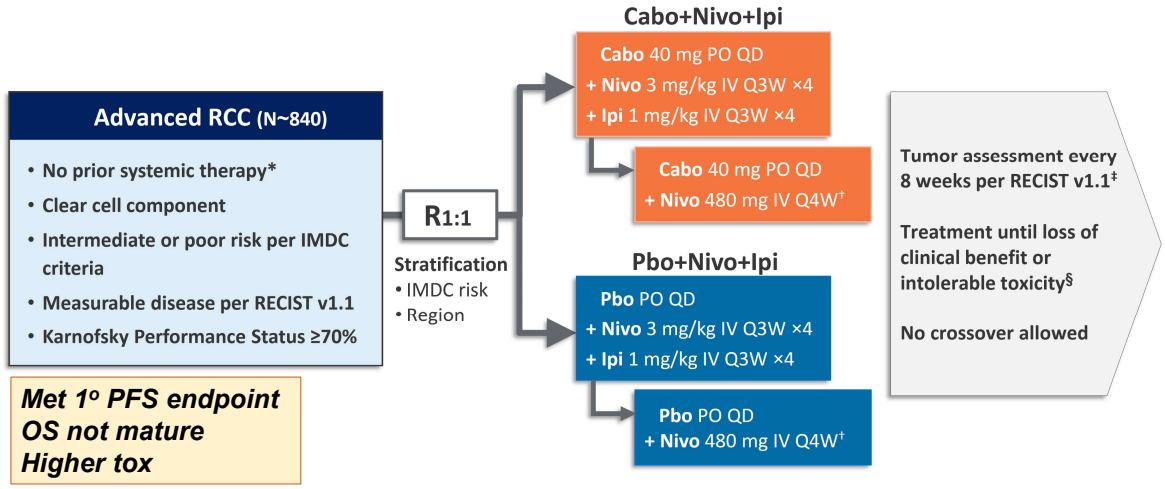
COSMIC-313: nivolumab + ipilimumab ± cabozantinib



Met 1º PFS endpoint
OS not mature
Higher tox

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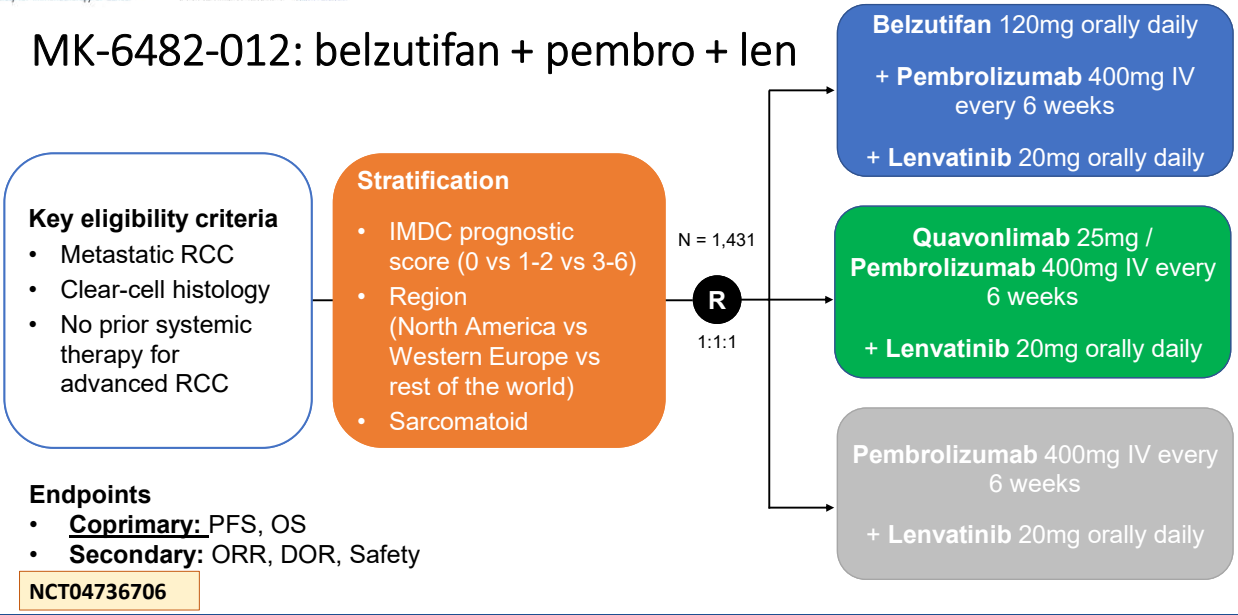
MK-6482-012: belzutifan + pembro + len



Endpoints
- **Coprimary:** PFS, OS
- **Secondary:** ORR, DOR, Safety

NCT04736706

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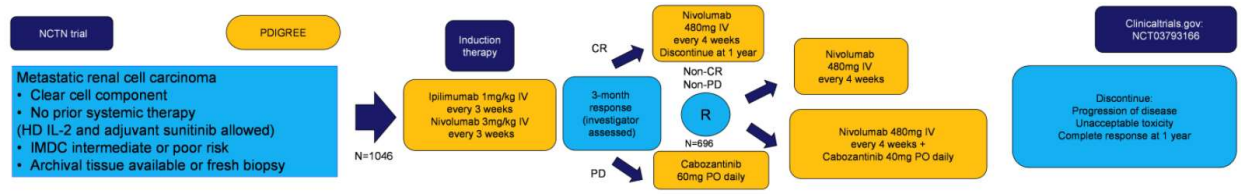
Addressing toxicity: adaptive trial designs for combination therapy

PDIGREE: nivo + ipi, add* cabo if needed *(NCT03793166)



Source: UroToday

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Adjuvant therapy for RCC in the ICI era

PROSPER	Sample Size	Inclusion Criteria	Treatment	Primary Endpoint	Statistically Significant?
Keynote-564	994	pT2G4, pT3aG3-4, pT3b-T4Gx, pTxN1, pTxNxM1 (resected to NED within 1 year); clear cell	Pembrolizumab vs placebo	DFS	YES DFS HR 0.63 OS HR: 0.52 (n.s.)
IMmotion010	778	pT2G4, pT3aG3-4, pT3b-T4Gx, pTxN1, pTxNxM1 (resected to NED*); clear cell	Atezolizumab vs. placebo	DFS	No
CheckMate-914	1600	pT2aG3-4N0, pT2b-T4GxN0, pTxGxN1; clear cell	Nivolumab + ipilimumab vs. nivolumab + placebo vs. placebo (6 months)	DFS	No (Part A; nivo+ipi)
PROSPER	766	T2Nx, TxN1, TxNxM1 (resected to NED); any RCC histology	*Perioperative/adjuvant* nivolumab vs. observation	EFS	No
RAMPART	*1750*	*Leibovich score 3-11; any RCC histology*	*Durvalumab + tremelimumab vs. durvalumab vs. observation*	*DFS, OS*	*7/2024*

Adapted from:
McKay, ASCO Annual Meeting, 2021
Choueiri, IKCS, 2021

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KEYNOTE-564: adjuvant pembrolizumab

~87% of patients

Intermediate-High Risk		High Risk		M1 NED
pT2	pT3	pT4	Any pT	NED after resection of oligometastatic sites ≤1 year from nephrectomy
Grade 4 or sarcomatoid	Any grade	Any grade	Any grade	
N0	N0	N0	N+	
M0	M0	M0	M0	

Key Eligibility Criteria
- Histologically confirmed clear cell renal cell carcinoma
- Nephrectomy ≤12 weeks prior to randomization
- No prior systemic therapy
- ECOG PS 0 or 1
- Tissue sample for PD-L1 assessment

R (1:1)

- Pembrolizumab 200 mg Q3W for ~1 year
- Placebo Q3W for ~1 year

Stratification Factors
- M0 vs M1 NED
- M0 group further stratified:
  - ECOG PS 0 vs 1
  - US vs non-US

- Primary end point: DFS per investigator
- Key secondary end point: OS
- Other secondary end points: Safety

Adapted from: Choueiri, ASCO Annual Meeting, 2021

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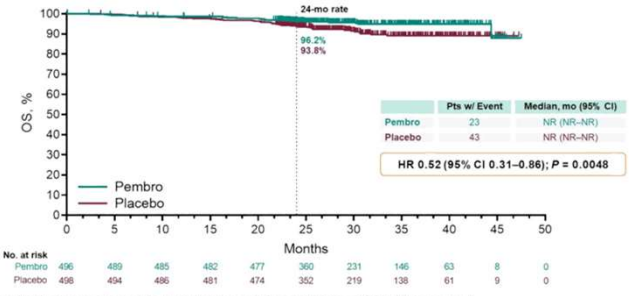
KEYNOTE-564: adjuvant pembrolizumab prolongs DFS (30 mo f/u)



- *P*-value did not cross the prespecified boundary for statistical significance of 0.000095 (one-sided)

24-month DFS: 78.3 vs 67.3%

OS not mature (66 of 200 events)

Choueiri, GU ASCO, 2022
Choueiri, Lancet Oncology, 2022

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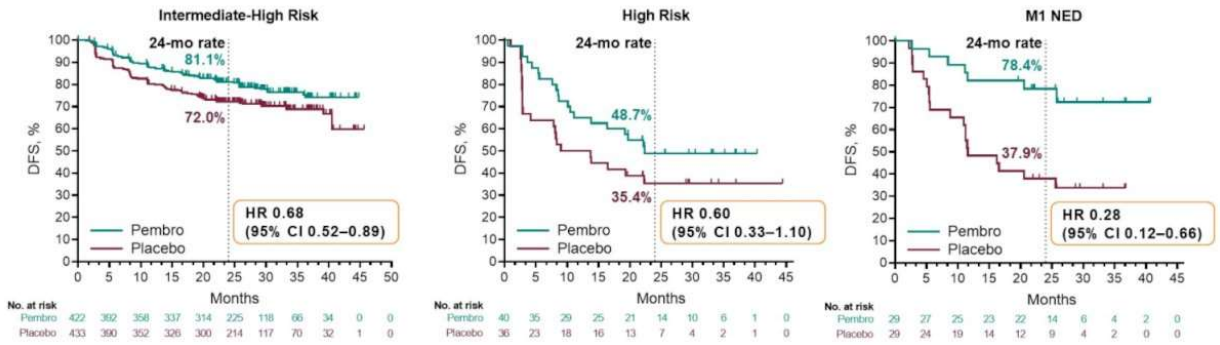
KEYNOTE-564: benefit scales with risk

pT2 grade 4 or pT3	pT4 or N1	M1 NED



Choueiri, GU ASCO, 2022
Choueiri, Lancet Oncology, 2022

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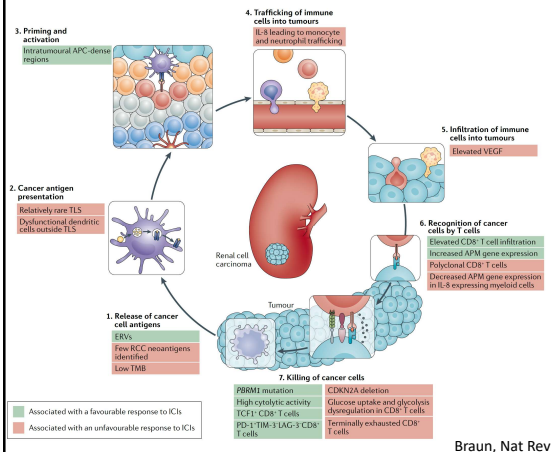
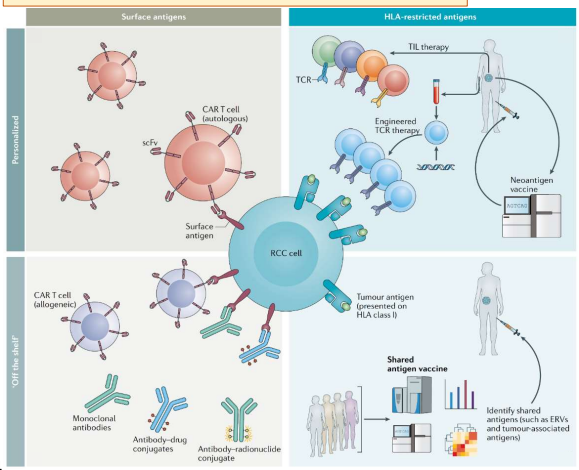
Novel therapeutic approaches in RCC

Novel therapies will require an understanding of RCC-specific immunobiology	*Antigen-specific approaches as a next generation IO*





Braun, Nat Rev Clin Oncol, 2021

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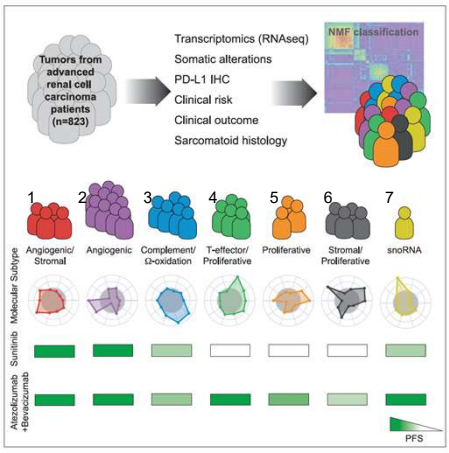
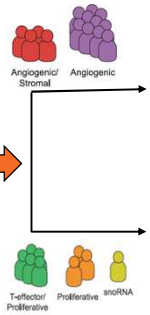
Future approaches: precision immunotherapy





NCT05361720

Ipilimumab + Nivolumab IV every 21 days for 4 cycles.

Nivolumab IV on day 1 + **Cabozantinib** PO QD every 4 weeks.

Endpoints
- **Coprimary:** ORR
- **Secondary:** PFS, DOR, irAEs

Conclusions and future directions

- IO-based combination therapy is the standard-of-care for most patients with advanced ccRCC
- No head-to-head comparison of IO+IO vs IO+TKI
  - IO+IO (nivo + ipi) with longer follow-up, demonstrated durability
  - IO+TKI with higher response rates, lower primary PD rates
  - Toxicities: higher irAE (IO+IO) vs chronic TKI toxicity
- The triplet era is coming, but toxicity will be a challenge
  - Adaptive design (PDIGREE)?
- Adjuvant IO is approved; decisions should be individualized per patient
- Novel therapies and precision immunotherapy are on the horizon

Acknowledgments

- Toni Choueiri
- Sabina Signoretti
- Brad McGregor
- Rana McKay
- Eli Van Allen
- David McDermott
- Michael Hurwitz
- Harriet Kluger
- Mario Sznol
- **Patients and their families**

Interested in working together?
BraunLab is actively recruiting and looking for collaborations
david.braun@yale.edu

@BraunMDPhD

Post-Test Question:
A 63-year-old gentleman with microscopic hematuria is found to have a 10cm left renal mass and >10 bilateral pulmonary nodules on CT imaging. He has had unintentional weight loss and fatigue, but is still active (KPS 80-90). His labs are notable for anemia and thrombocytosis, but are otherwise unremarkable. Biopsy of a lung nodule shows **clear cell renal cell carcinoma**. Which of the following would you choose as a first-line systemic therapy:

A. Sunitinib
B. Combination therapy regimen containing an immune checkpoint inhibitor, such as nivolumab + ipilimumab
C. Temsirolimus
D. Bevacizumab plus interferon alfa

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