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Presentaciones más destacadas en cáncer renal

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Disclosures

- **Personal confilcts of interest: Scientific Consultancy Role (speaker and advisory role) and travel grant**: *IPSEN, Pfizer, Roche, Bayer, Sanofi, Janssen, Astellas, Eisai, Adacap, Lilly, Novartis, BMS, MSD, Adium, Asofarma, Recordati Rare diseases, Exelixis.*

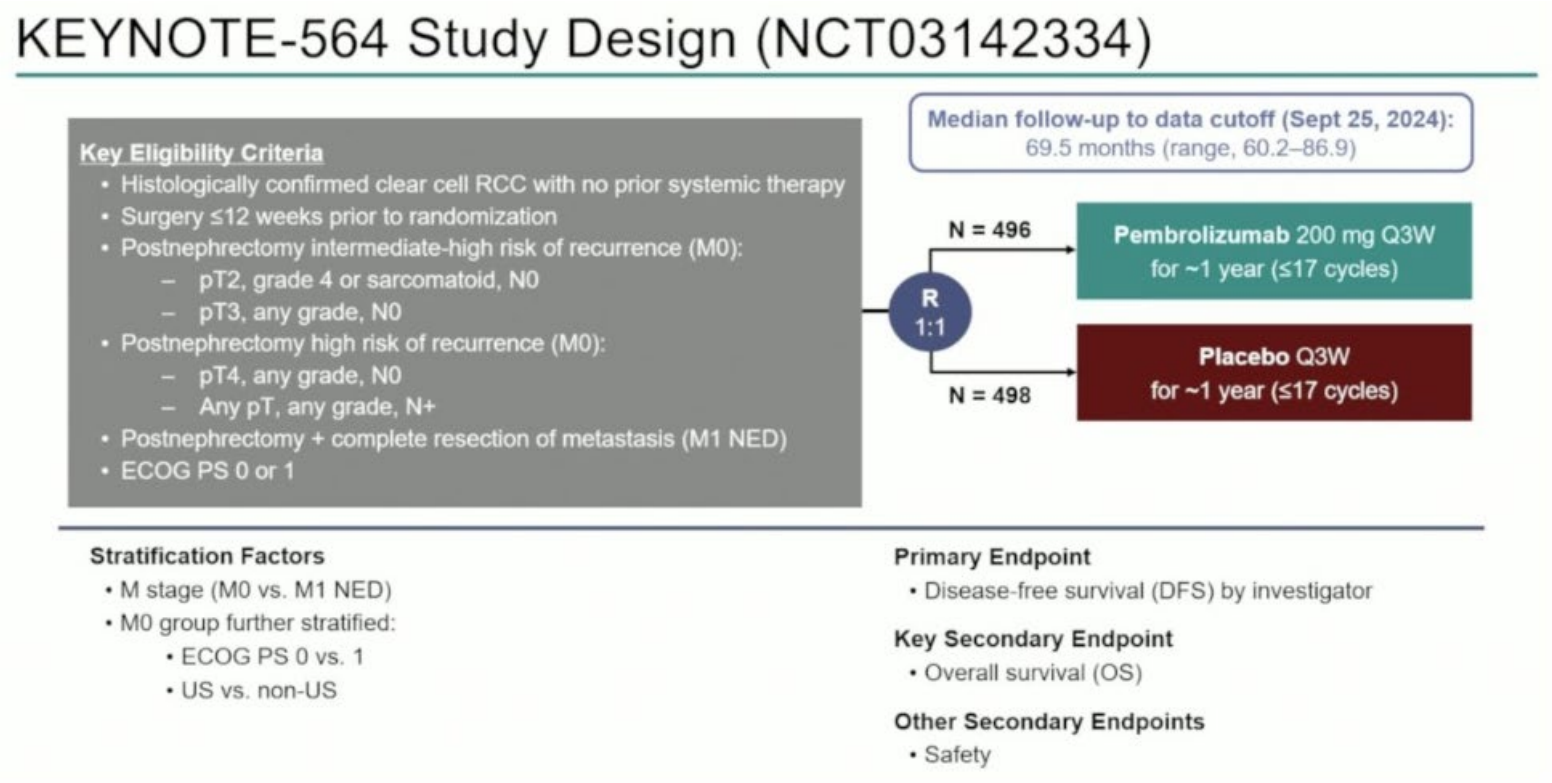
- **Participation in Clinical trials:** *Roche, BMS, MSD, Pfizer, Novartis, IPSEN, Exelixis, Astrazeneca-Medimmune, Janssen, Lilly, Eisai, Astellas.*

- **Research support:** *Roche, Pfizer, IPSEN, Janssen, Exelisis*

Schedule

- ***Adjuvant setting***
- ***Neoadjuvant setting***
- ***Metastatic disease***
- ***Conclusions***

Adjuvant



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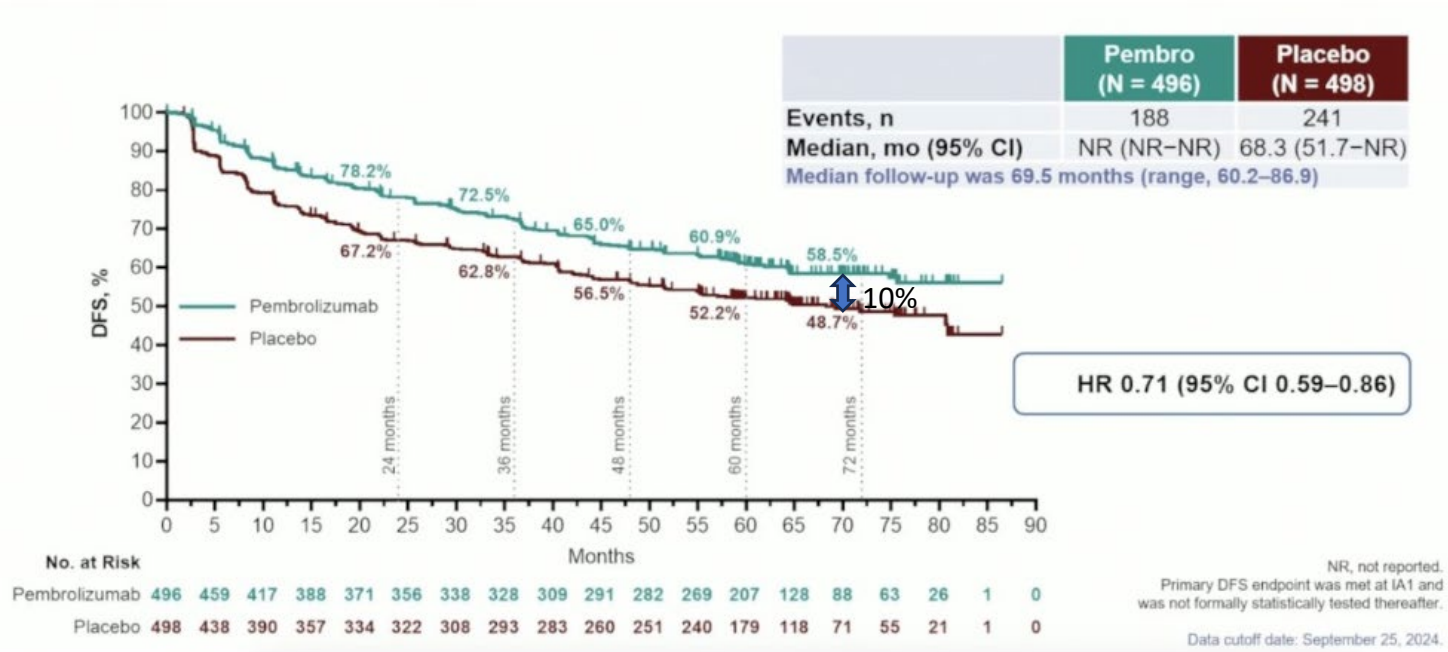
Adjuvant



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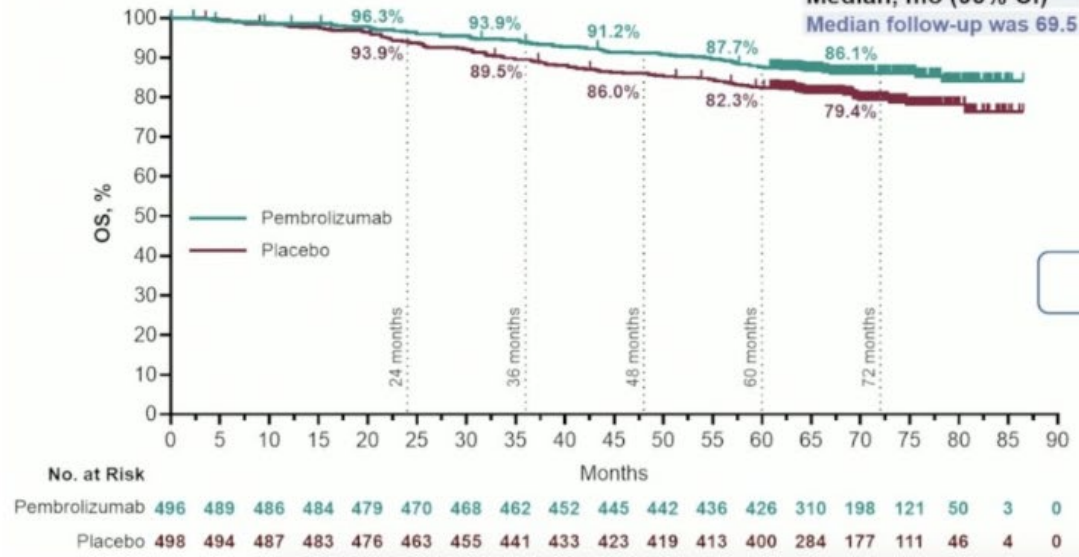
Adjuvant

	Pembro (N = 496)	Placebo (N = 498)
Events, n	68	99
Median, mo (95% CI)	NR (NR–NR)	NR (NR–NR)

Median follow-up was 69.5 months (range, 60.2–86.9)



HR 0.66 (95% CI 0.48–0.90)

Key secondary OS endpoint was met at IA3 and was not formally statistically tested thereafter.

Data cutoff date: September 25, 2024.

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Adjuvant

	Participants with Documented Recurrence, n	
	Pembrolizumab (n = 171)	Placebo (n = 226)
Systemic therapy only	73 (42.7%)	100 (44.2%)
Systemic + surgery/radiation therapy	37 (21.6%)	54 (23.9%)
Surgery/radiation therapy only	33 (19.3%)	30 (13.3%)
No subsequent therapy reported[a]	28 (16.4%)	42 (18.6%)
VEGF/VEGFR inhibitor[b]	101 (59.1%)	133 (58.8%)
Anti–PD-(L)1 therapy[b]	49 (28.7%)	109 (48.2%)

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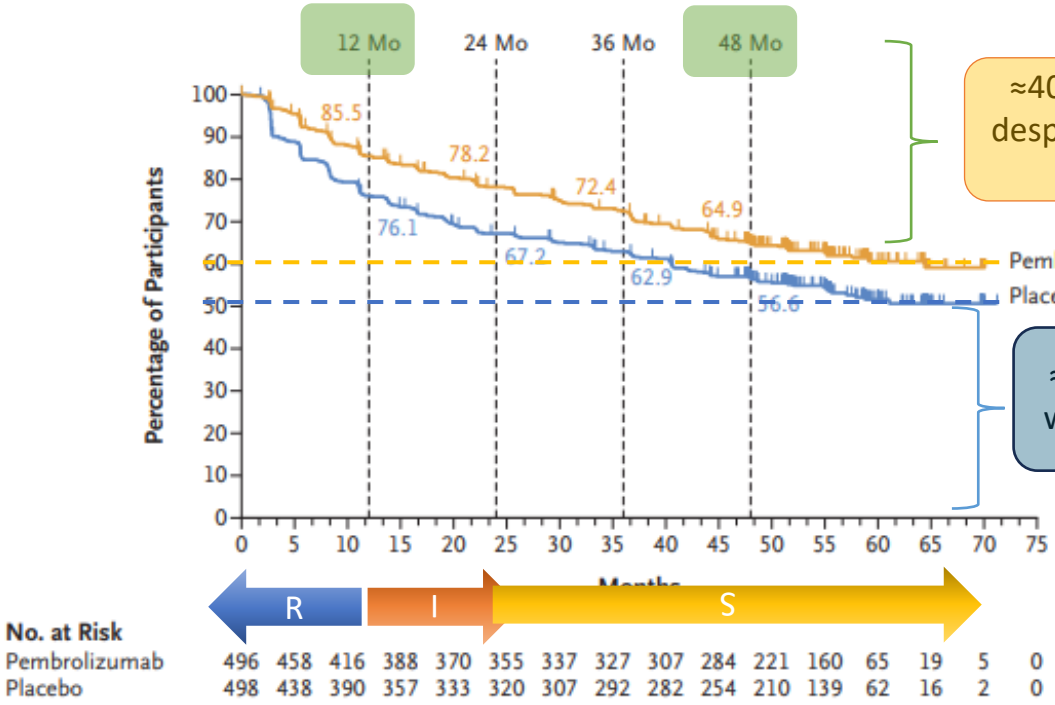
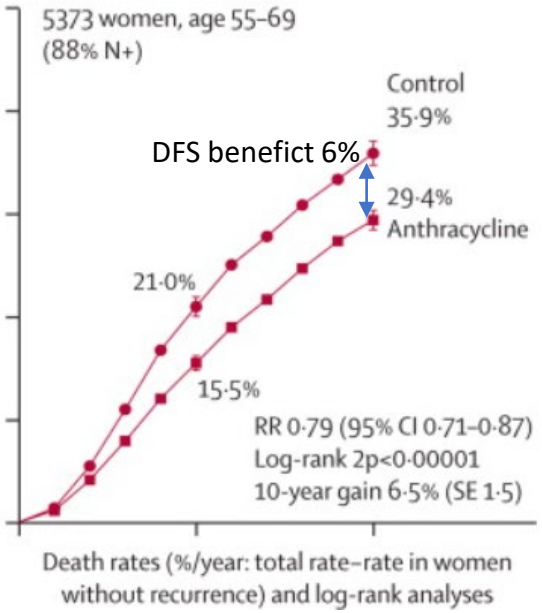
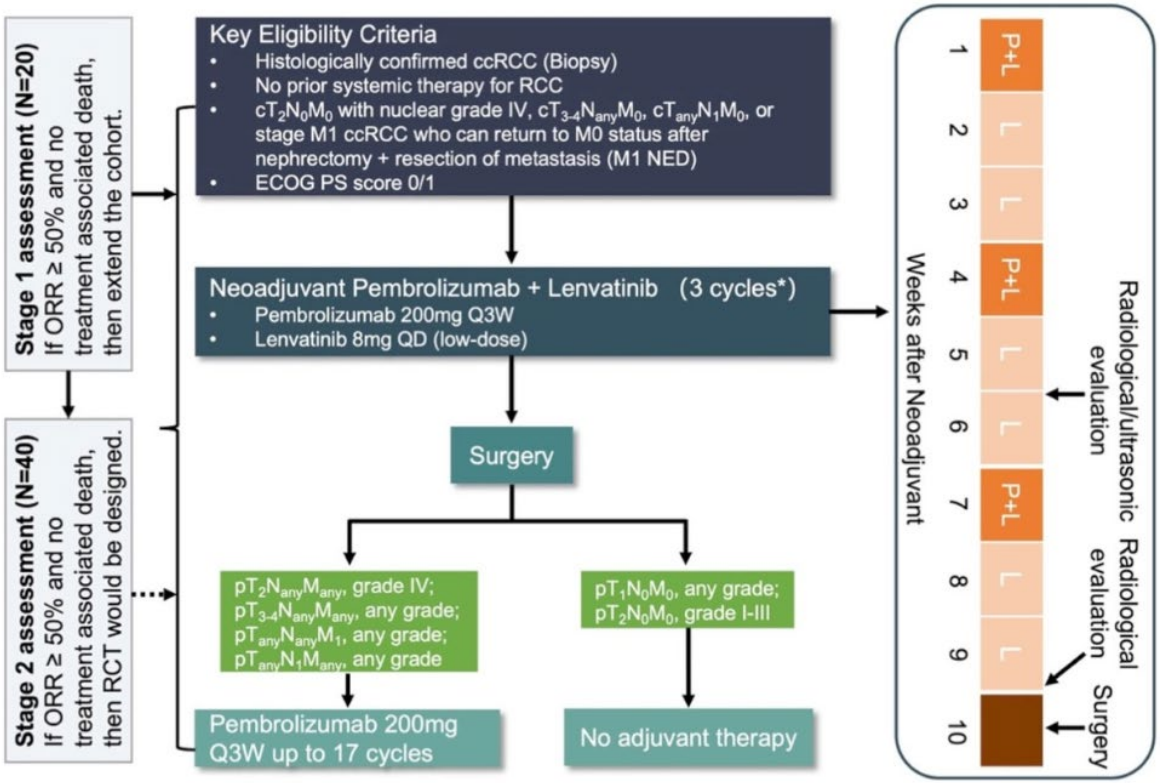
Adjuvant





Haas N et al. ASCO 2025
Choueiri TK, et al. J Clin Oncol 2022
Choueiri TK, et al. N Engl J Med. 2024.

Neoadjuvant



Shimiao Z et al. ASCO 2025.

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Neoadjuvant

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33 patients screened

10 patients excluded
- 6 declined to participant
- 2 ineligible histology
- 1 concomitant prednisone treatment

24 patients enrolled for neoadjuvant therapy

1 patient withdrew before treatment

3 patients refused the 3rd cycle treatment due to good response

20 patients underwent surgery included in Per-protocol analysis
17 patients received 3 cycles of treatment
1 patient received 4 cycles of treatment
1 patient received 5 cycles of treatment
1 patient received 6 cycles of treatment

23 patients underwent surgery included in Intention-to-treat analysis
17 patients received 3 cycles of treatment
1 patient received 4 cycles of treatment
1 patient received 5 cycles of treatment
1 patient received 6 cycles of treatment
3 patients received 2 cycles of treatment

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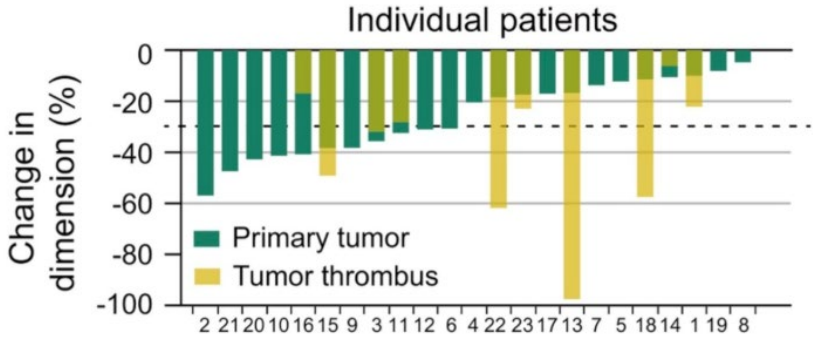
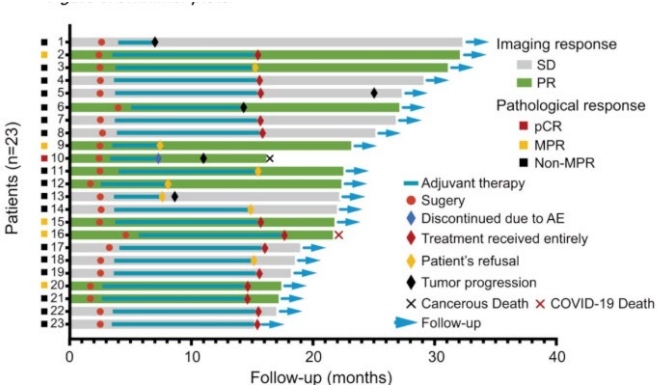
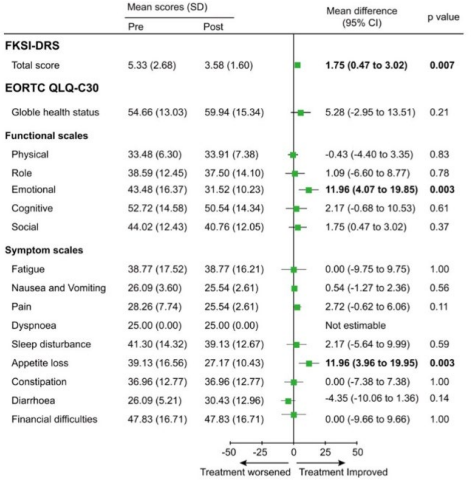
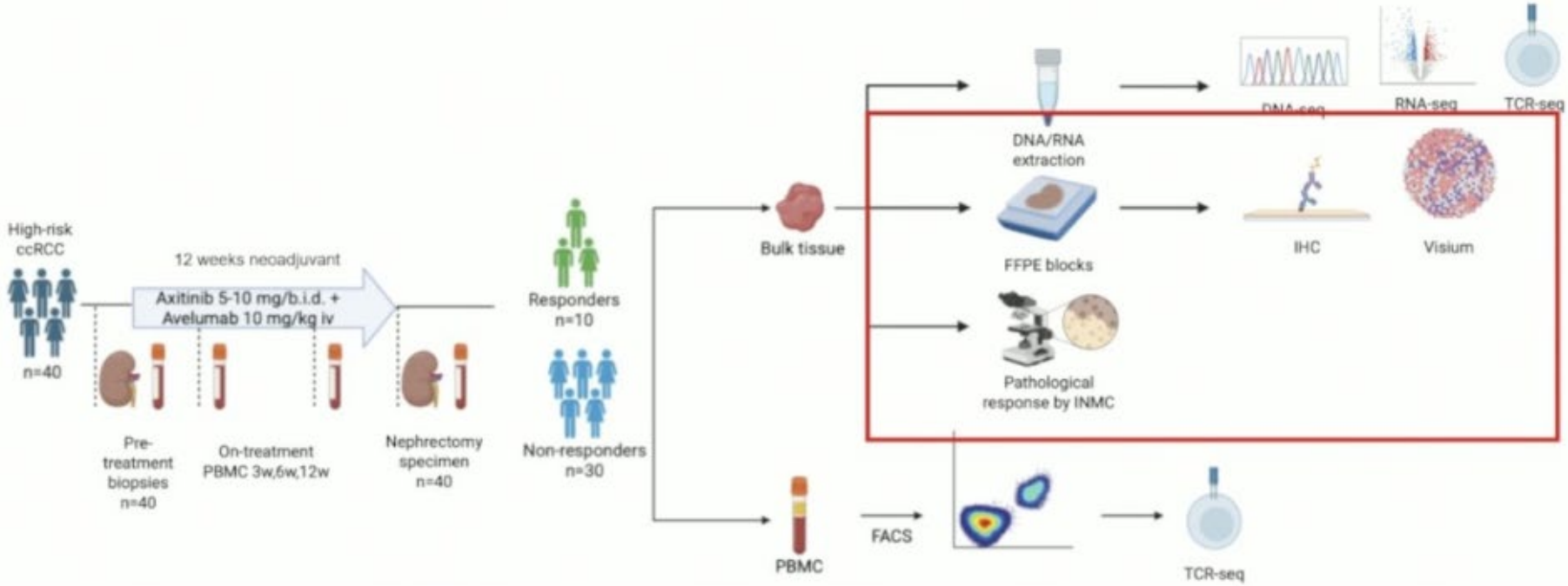






	Mean scores (SD) Pre	Post	Mean difference (95% CI)	p value
FKSI-DRS				
Total score	5.33 (2.68)	3.58 (1.60)	**1.75 (0.47 to 3.02)**	**0.007**
EORTC QLQ-C30				
Globle health status	54.66 (13.03)	59.94 (15.34)	5.28 (-2.95 to 13.51)	0.21
Functional scales				
Physical	33.48 (6.30)	33.91 (7.38)	-0.43 (-4.40 to 3.35)	0.83
Role	38.59 (12.45)	37.50 (14.10)	1.09 (-6.60 to 8.77)	0.78
Emotional	43.48 (16.37)	31.52 (10.23)	**11.96 (4.07 to 19.85)**	**0.003**
Cognitive	52.72 (14.58)	50.54 (14.34)	2.17 (-0.68 to 10.53)	0.61
Social	44.02 (12.43)	40.76 (12.05)	1.75 (0.47 to 3.02)	0.37
Symptom scales				
Fatigue	38.77 (17.52)	38.77 (16.21)	0.00 (-9.75 to 9.75)	1.00
Nausea and Vomiting	26.09 (3.60)	25.54 (2.61)	0.54 (-1.27 to 2.36)	0.56
Pain	28.26 (7.74)	25.54 (2.61)	2.72 (-0.62 to 6.06)	0.11
Dyspnoea	25.00 (0.00)	25.00 (0.00)	Not estimable	
Sleep disturbance	41.30 (14.32)	39.13 (12.67)	2.17 (-5.64 to 9.99)	0.59
Appetite loss	39.13 (16.56)	27.17 (10.43)	**11.96 (3.96 to 19.95)**	**0.003**
Constipation	36.96 (12.77)	36.96 (12.77)	0.00 (-7.38 to 7.38)	1.00
Diarrhoea	26.09 (5.21)	30.43 (12.96)	-4.35 (-10.06 to 1.36)	0.14
Financial difficulties	47.83 (16.71)	47.83 (16.71)	0.00 (-9.66 to 9.66)	1.00

Neoadjuvant



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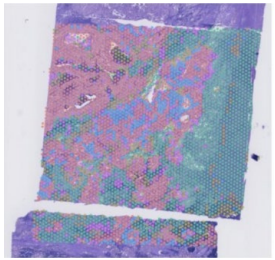
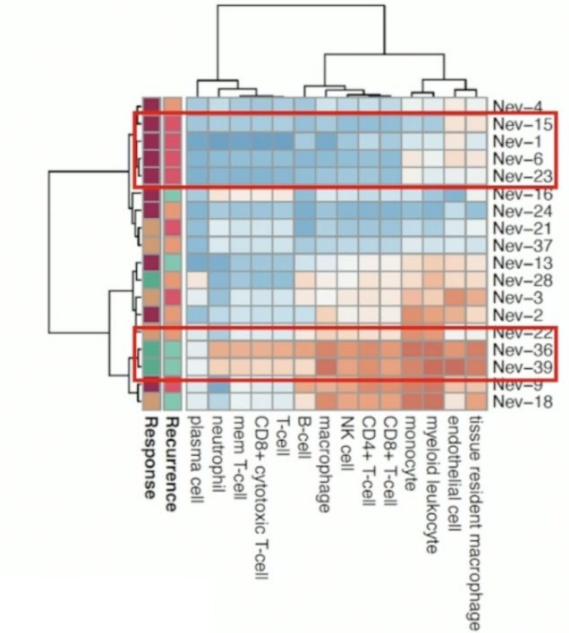
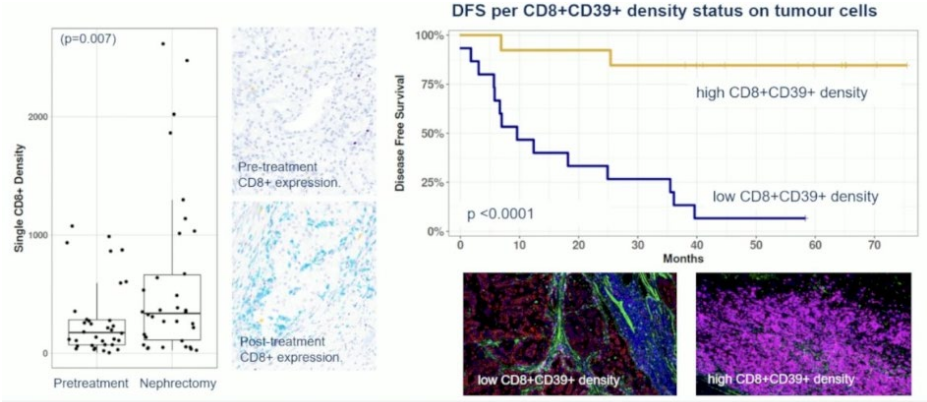
Neoadjuvant







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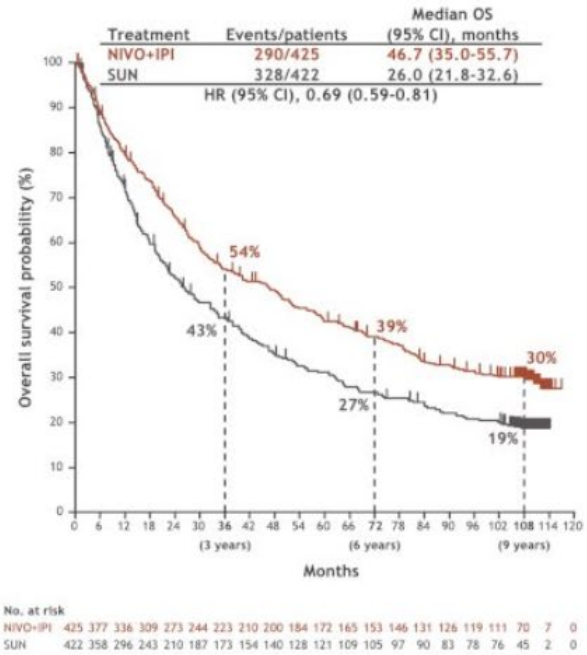
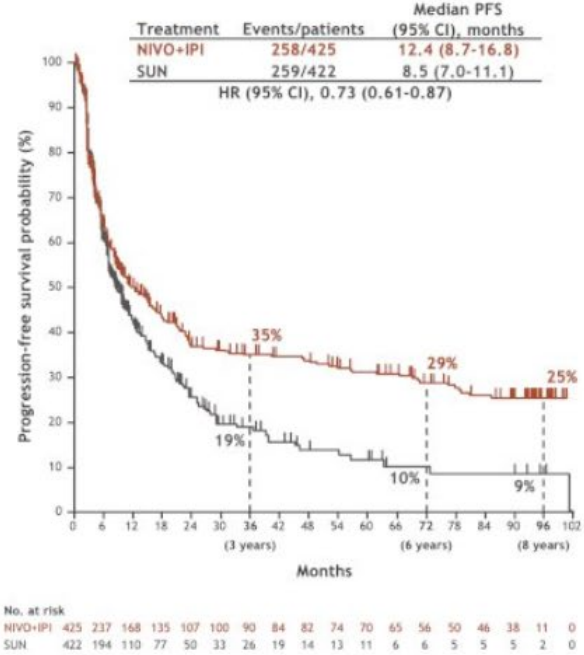
Metastatic disease

INT/POOR

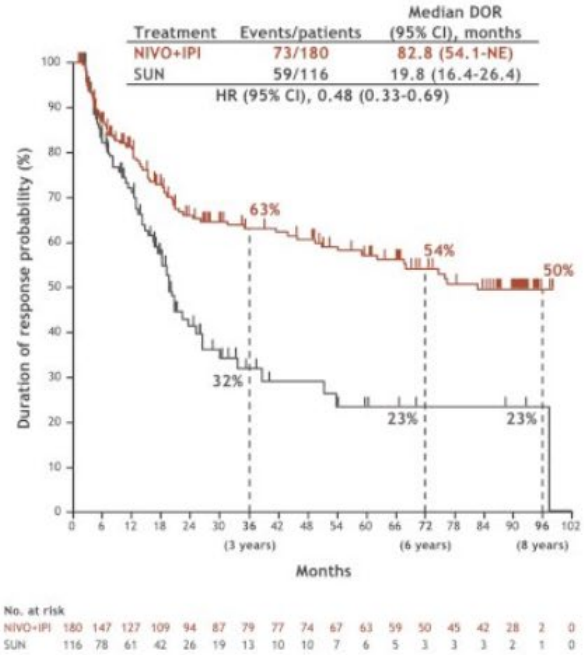
OS



PFS per IRRC[a]



DOR per IRRC[a,b]



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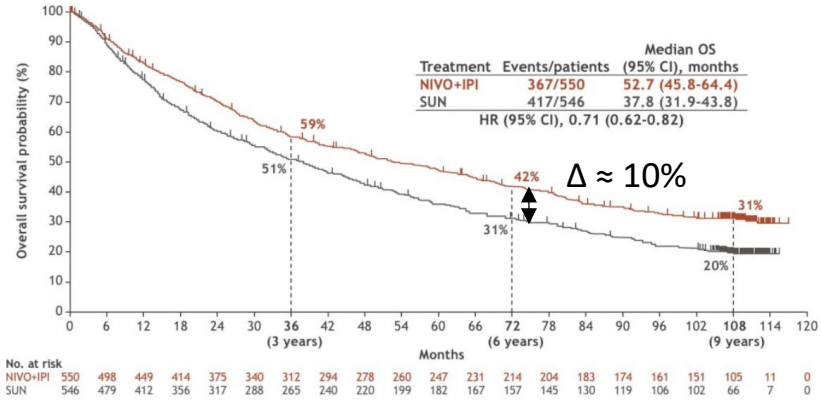
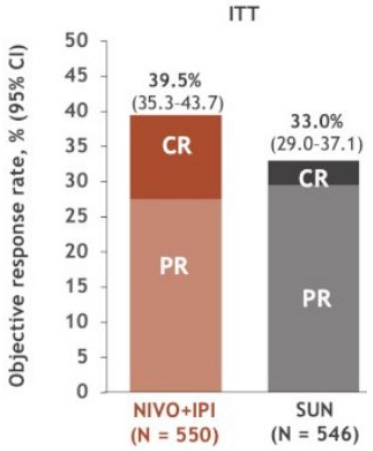
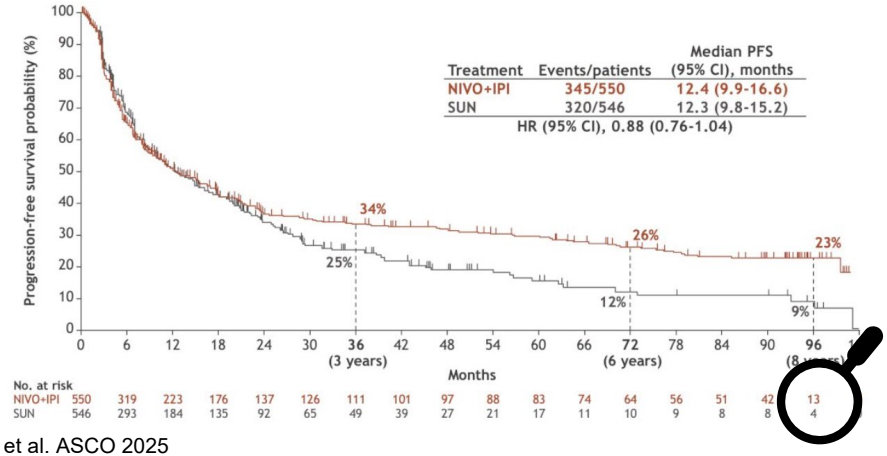
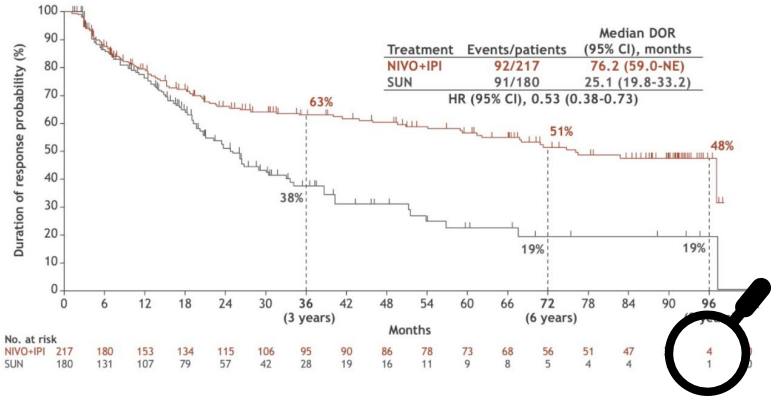
Metastatic disease

ITT









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Metastatic disease

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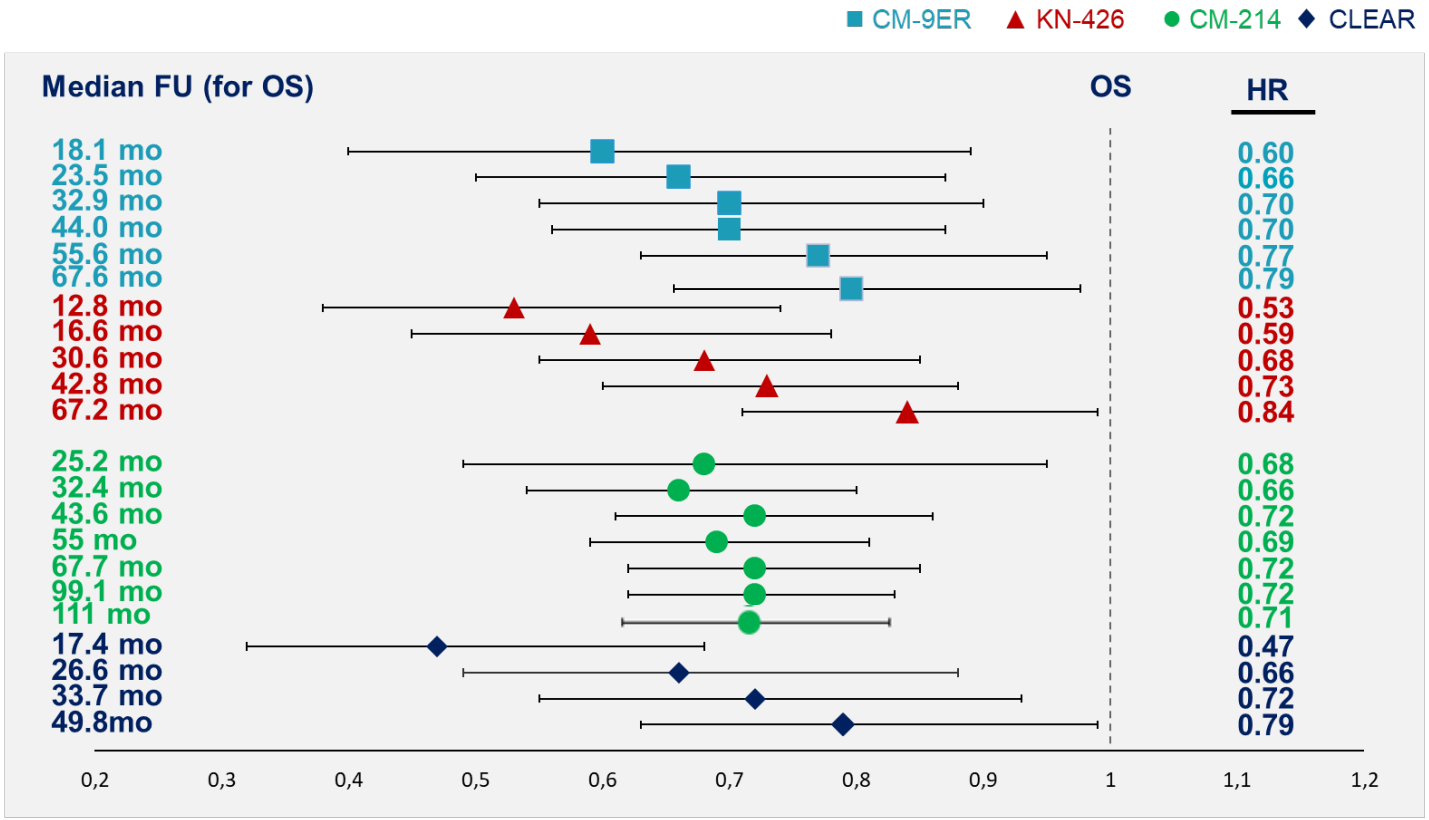

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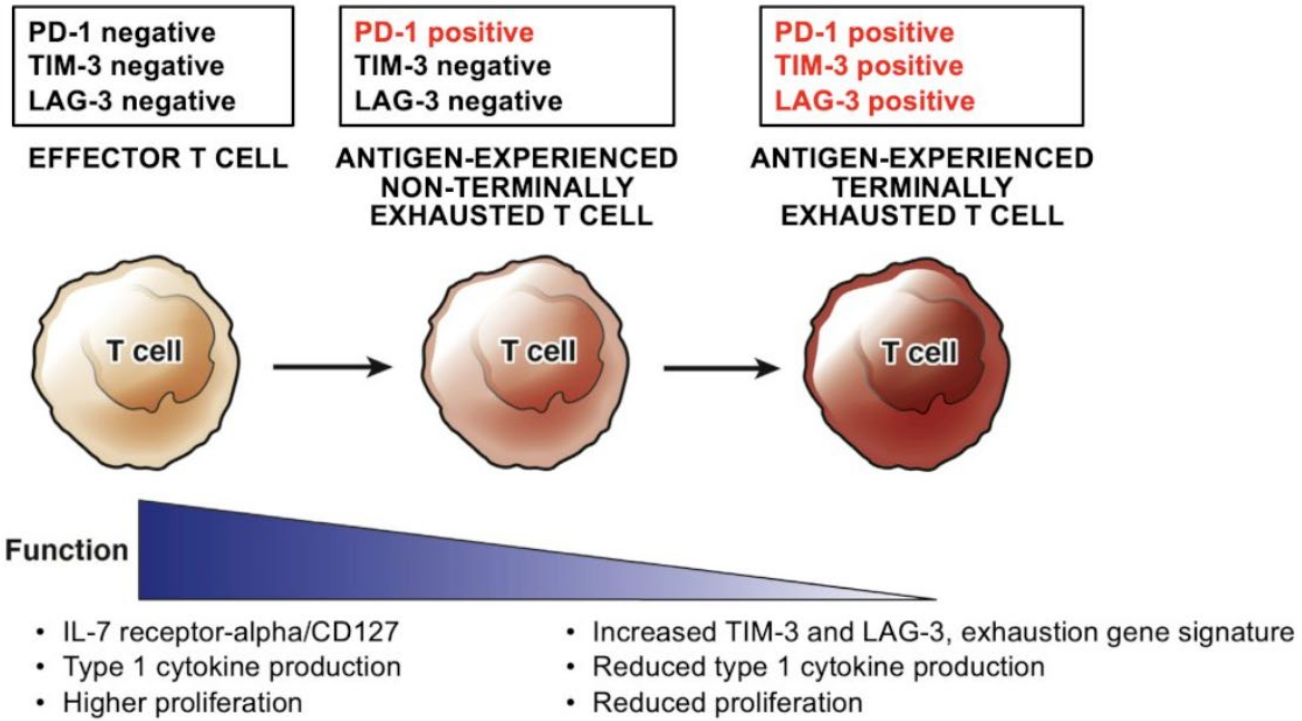
Metastatic disease



McDermott D et al. ASCO 2025

Metastatic disease

Characteristic		Zanzalintinib + Nivo (n=40)	Zanzalintinib + Nivo/Rela (n=40)
Median age, years (range)		68 (48–81)	61 (34–88)
Sex, n (%)	Male / Female	34 (85.0) / 6 (15.0)	35 (87.5) / 5 (12.5)
Prior nephrectomy, n (%)		36 (90.0)	26 (65.0)
Karnofsky Performance Status, n (%)	100 or 90	32 (80.0)	29 (72.5)
	80 or 70	8 (20.0)	11 (27.5)
IMDC risk score, n (%)	Favorable	10 (25.0)	12 (30.0)
	Intermediate or poor	30 (75.0)	28 (70.0)
ccRCC with sarcomatoid features, n (%)		5 (12.5)	0
Number of target lesions at baseline, n (%)	1	7 (17.5)	11 (27.5)
	2	13 (32.5)	13 (32.5)
	≥3	20 (50.0)	16 (40.0)
Sites of metastatic disease at baseline, n (%)	Lung	25 (62.5)	20 (50.0)
	Lymph node	23 (57.5)	15 (37.5)
	Bone	3 (7.5)	13 (32.5)
	Adrenal gland	9 (22.5)	3 (7.5)
	Pancreas	7 (17.5)	6 (15.0)
	Liver	5 (12.5)	3 (7.5)

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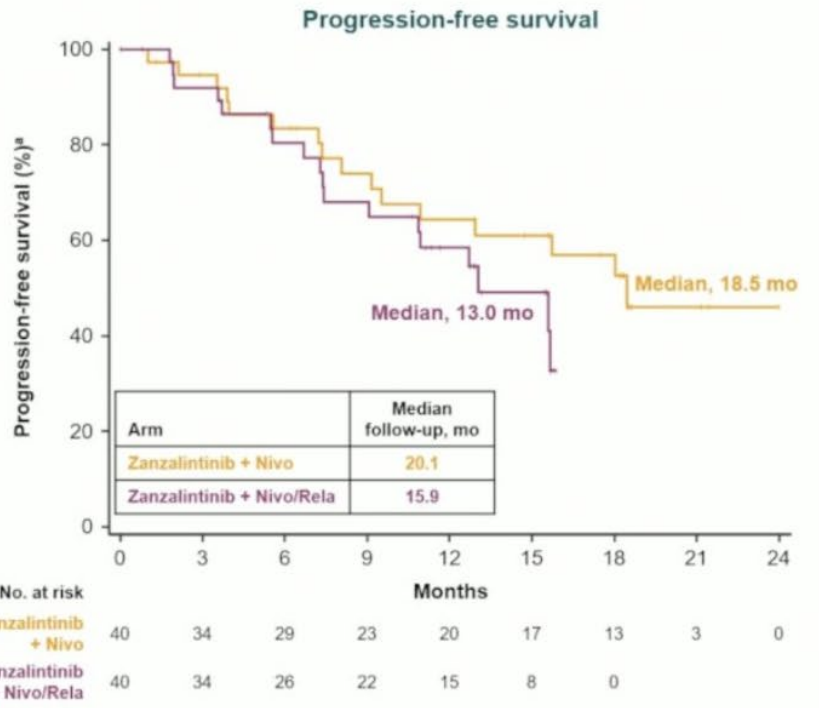
Metastatic disease

	Zanzalintinib + Nivo (n=40)	Zanzalintinib + Nivo/Rela (n=40)
ORR (95% CI), %	**63 (46–77)**	**40 (25–57)**
Confirmed CR, n (%)	3 (8)	1 (3)
Confirmed PR, n (%)	22 (55)	15 (38)
SD, n (%)	11 (28)	20 (50)
PD, n (%)	2 (5)	3 (8)
DCR (95% CI), %	90 (76–97)	90 (76–97)
Median DOR (95% CI), months	NE (11.1–NE)	NE (4.0–NE)
12-month DOR (95% CI), %	73.4 (50.0–87.1)	74.1 (39.1–90.9)
Median TTR (range), months	2.1 (1.7–11.0)	3.6 (1.7–12.8)
Median PFS (95% CI), months	**18.5 (9.5–NE)**	**13.0 (7.4–NE)**
6-month PFS (95% CI), %	83.4 (66.8–92.2)	80.4 (63.1–90.2)
12-month PFS (95% CI), %	64.4 (45.7–78.1)	58.4 (39.9–73.0)



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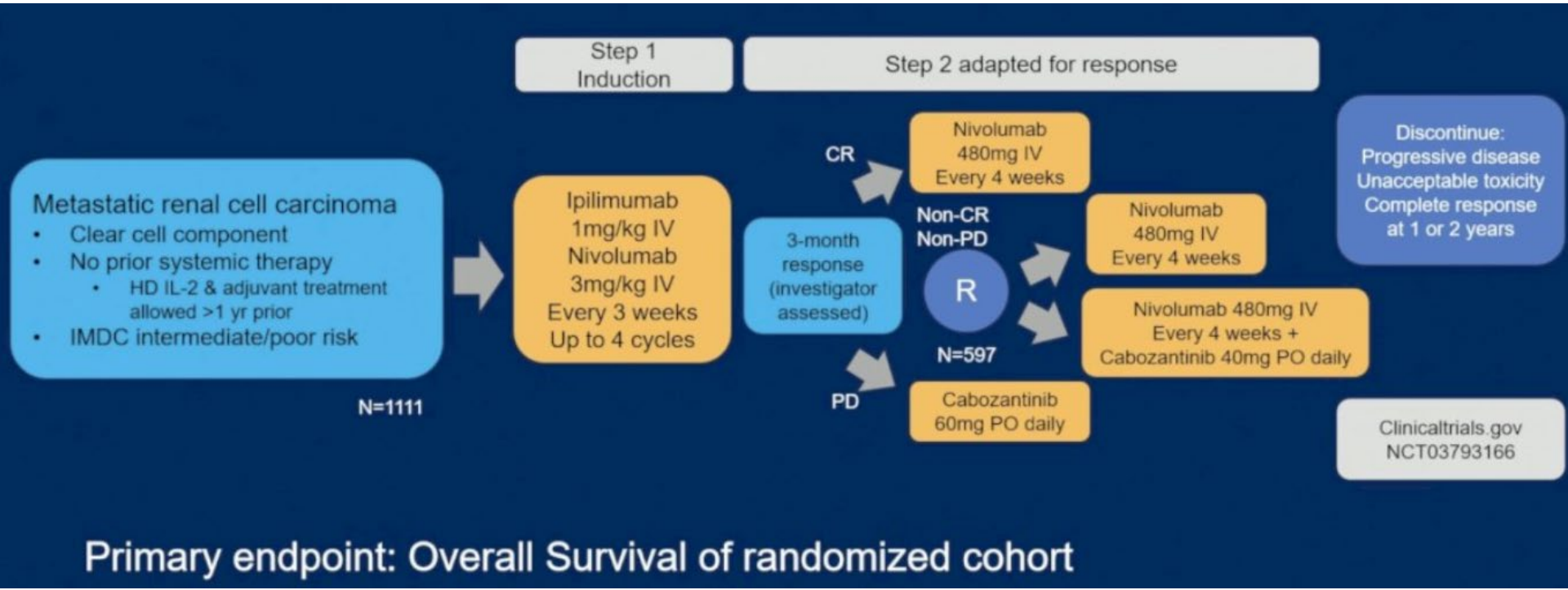
Metastatic disease



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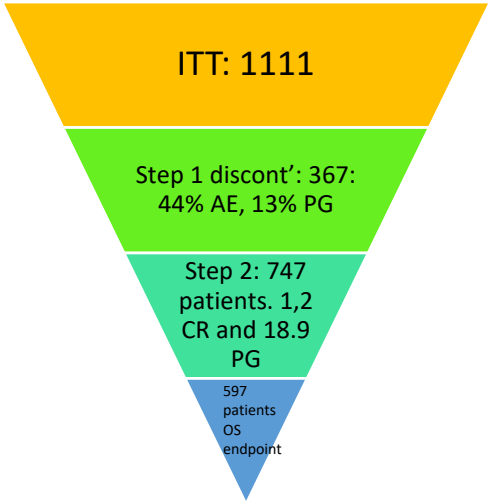
Metastatic disease

Patient Characteristics	ITT (Total =1111)	Step 1 Discontinued Subset (N=364)	Step 2 Subset (N=747)	P-value
Age, Median (range)	64 years (29-86)	64 years (39-86)	63 years (29-85)	0.197
Gender				
Male (%)	819 (73.7%)	255 (70.1%)	564 (75.5%)	0.053
Female (%)	292 (26.3%)	109 (29.9%)	183 (24.5%)	
Ethnicity				
Hispanic/LatinX	115 (10.4%)	27 (7.4%)	88 (11.8%)	0.068
Non-Hispanic	967 (87%)	330 (90.7%)	637 (85.3%)	
Race				
White	945 (85%)	313 (86%)	632 (84.6%)	0.772
Black	47 (4.2%)	16 (4.4%)	31 (4.1%)	
Asian	36 (3.2%)	10 (2.7%)	26 (3.5%)	
American Indian or Alaskan native	14 (1%)	3 (0.8%)	11 (1.5%)	

Disease Characteristics	ITT (Total =1111)	Step 1 Discontinued Subset (N=364)	Step 2 Subset (N=747)	P-value
IMDC risk				
Intermediate	849 (76.8%)	261 (72.3%)	588 (78.9%)	0.0144
Poor	257 (23.2%)	100 (27.7%)	157 (21.1%)	
Bone metastases				
Yes	307 (27.7%)	124 (34.2%)	183 (24.5%)	0.0007
No	803 (72.3%)	239 (65.8%)	564 (75.5%)	
De novo metastases				
Yes	603 (54.3%)	201 (55.2%)	402 (53.8%)	0.66
No	508 (45.7%)	163 (44.8%)	345 (46.2%)	
Enrolling site				
Academic center	458 (41.2%)	143 (39.3%)	315 (42.2%)	0.29
Community oncology	540 (48.6%)	177 (48.6%)	363 (48.6%)	
Regional center	113 (10.2%)	44 (12.1%)	69 (9.2%)	



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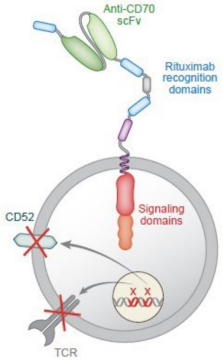
Metastatic disease



TRAVERSE Phase 1b Study Design (NCT04696731)

Key Eligibility Criteria

- Aged ≥18 years with advanced or metastatic ccRCC
- Disease progression after PD-1 axis and VEGF targeted therapies
- CD70 positive by IHC on archival or fresh tumor tissue
- ECOG 0-1
- Adequate pulmonary, cardiac, renal, hepatic, and hematologic function

Phase 1b[a] treatment

Day -5 to Day -3: Standard Lymphodepletion Flu/Cy

Day 0: ALLO-316 80×10^6 CAR+ cells

Follow up through M60: Response and safety assessments

Phase 1b Endpoints

- Primary
  - TEAEs
- Secondary
  - ORR, CRR, DOR, TTR, PFS, OS, CAR T expansion kinetics

Demographics and Disease Characteristics	Phase 1b n = 22[a]	All patients N = 50
Age, median (range), years	56 (35-67)	60 (35-70)
Male sex, n (%)	20 (91)	44 (88)
ECOG PS 0, n (%)	10 (45)	27 (54)
Disease stage IV, n (%)	22 (100)	50 (100)
Prior nephrectomy, n (%)	22 (100)	45 (90)
IMDC risk at screening, n (%)		
Favorable	8 (36)	19 (38)
Intermediate	14 (64)	27 (54)
Poor	0	3 (6)
Not available	0	1 (2)
Treatment timing	**Phase 1b n = 22[a]**	**All patients N = 50**
Time from enrollment to treatment, median (range), days	4 (1-15)	4 (1-15)

Prior Treatment	Phase 1b n = 22[a]	All patients N = 50
Lines of prior therapy, median (range)	4 (1-11)	4 (1-11)
Prior therapies, n (%)		
Anti-PD-(L)1 therapy	22 (100)	50 (100)
Anti-CTLA-4 therapy	12 (55)	31 (62)
Cabozantinib	18 (82)	39 (78)
≥2 TKIs	18 (82)	32 (64)
≥3 TKIs	13 (59)	17 (34)
mTOR inhibitor	15 (68)	20 (40)
Belzutifan	9 (41)	10 (20)
Received CTLA-4 inhibitor, PD-(L)1 inhibitor, TKI, and HIF-2α inhibitor	7 (32)	8 (16)

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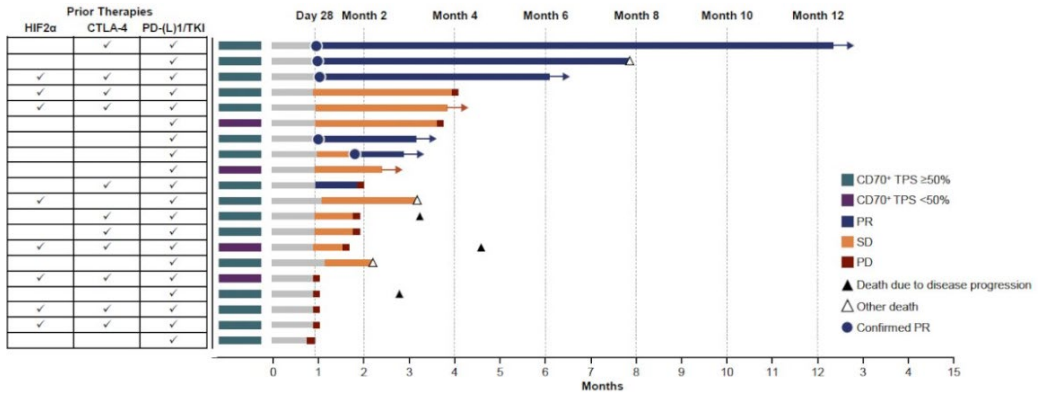
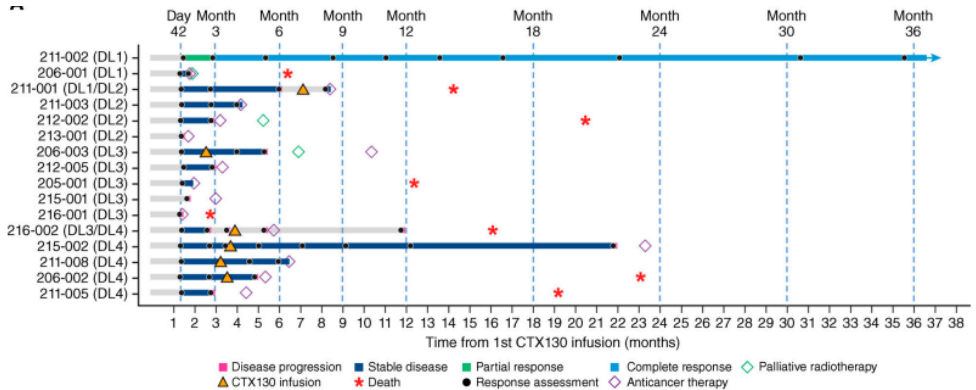
Metastatic disease

¡TEAEs ≥20% incidence in Phase 1b, n (%)	Phase 1b n = 22[a]		All patients N = 50	
	All Grades	Grade ≥3	All Grades	Grade ≥3
Neutropenia	15 (68)	15 (68)	30 (60)	28 (56)
WBC decreased	15 (68)	15 (68)	28 (56)	26 (52)
Anemia	13 (59)	9 (41)	26 (52)	17 (34)
Thrombocytopenia	12 (55)	6 (27)	23 (46)	13 (26)
Nausea	8 (36)	0	25 (50)	0
ALT increased	7 (32)	2 (9)	16 (32)	7 (14)
Peripheral edema	7 (32)	0	17 (34)	0
Pyrexia	7 (32)	0	19 (38)	1 (2)
Arthralgia	6 (27)	0	13 (26)	0

	CD70*[a] patients Phase 1b n = 20	All CD70*[a] patients n = 38
ORR (confirmed CR or PR per RECIST v1.1), n/N (%)	5/20 (25)	8/38 (21)
CD70+ TPS ≥50%	5/16 (31)	8/31 (26)
CD70+ TPS <50%	0/4 (0)	0/7 (0)





Srour S et al. ASCO 2025
Pal S et al. Cancer Discov 2024

Metastatic disease

SUNNIFORECAST

Patient population
- Previously untreated, met. or locally advanced nccRCC
- Eligible for ICI therapy
- Tumor material available
- Measurable disease as per RECIST v1.1
- Karnofski performance status ≥ 70%
- No active CNS metastases

N= 316 pts

R
1:1

Arm A

Nivolumab + Ipilimumab (I/N)
(mx. 4 times)
then Nivolumab (N) maintenance

Arm B

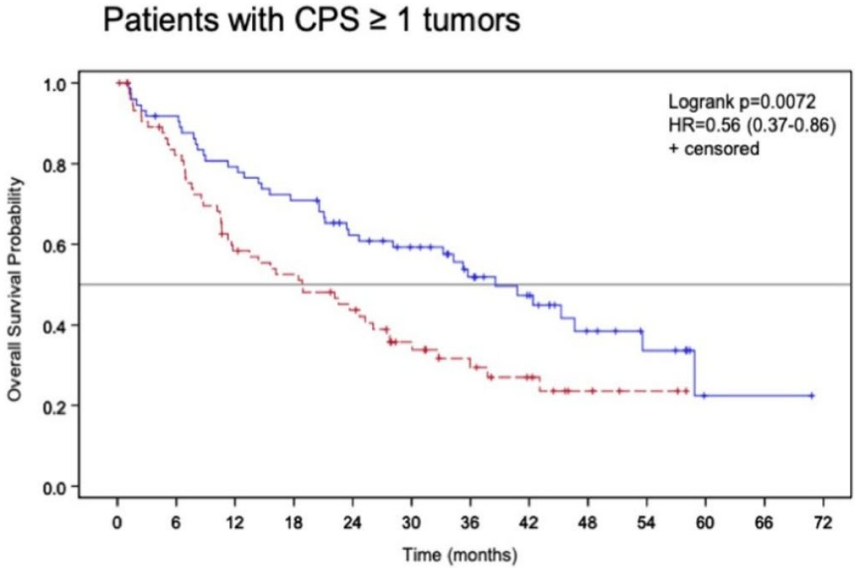
Standard of Care (SOC) therapy

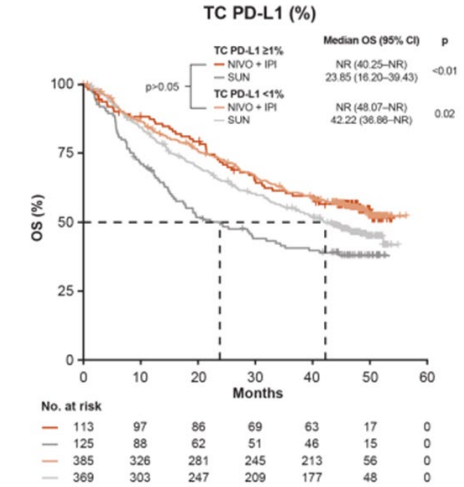
Stratification
- Histology (papillary vs others)
- IMDC score

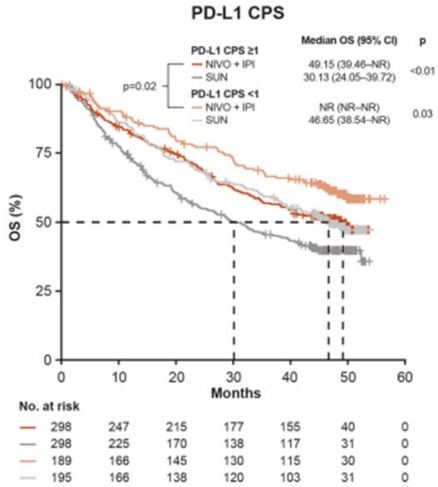
- ***Treatment until disease progression, unacceptable toxicity, or withdrawal of consent***
- ***pts. may be treated beyond progression under protocol-defined circumstances***

Ahrens M et al. ASCO 2025

Metastatic disease



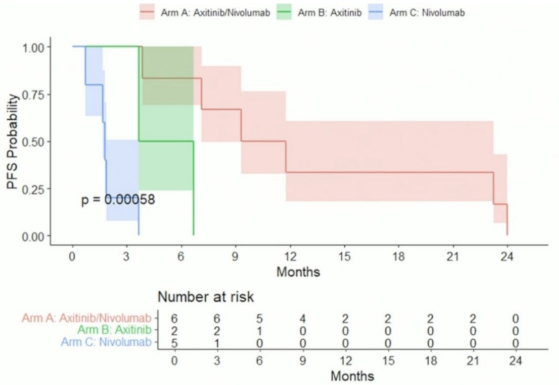




Ahrens M et al. ASCO 2025
Motzer R et al. JTI 2022

Metastatic disease

Characteristic	Arm A: Axitinib/Nivolumab N = 6	Arm B: Axitinib N = 2	Arm C: Nivolumab N = 5	Overall N = 13	p-value[1]
Age (Years)					0.715
Mean (SD)	18 (9)	19 (6)	18 (14)	18 (10)	
Median (Q1, Q3)	16 (10, 21)	19 (15, 23)	15 (12, 16)	16 (12, 21)	
Min, Max	9, 32	15, 23	7, 42	7, 42	
Age Category					>0.999
Age < 18	4 (67%)	1 (50%)	4 (80%)	9 (69%)	
Age 18+	2 (33%)	1 (50%)	1 (20%)	4 (31%)	
Prior Anti-VEGF therapy	1 (17%)	0 (0%)	1 (20%)		>0.999
No prior systemic therapy	5 (83%)	2 (100%)	4 (80%)	11 (85%)	
Best Overall Response					0.019
Partial Response	2 (33%)	0 (0%)	0 (0%)	2 (15%)	
Stable Disease	4 (67%)	2 (100%)	1 (20%)	7 (54%)	
Progressive Disease	0 (0%)	0 (0%)	4 (80%)	4 (31%)	



Geller J et al. ASCO 2025

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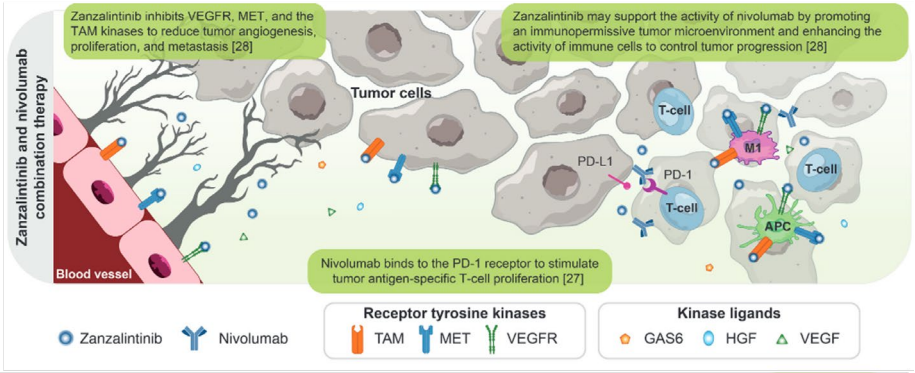
Metastatic disease

CLINICAL TRIAL PROTOCOL

OPEN ACCESS Check for updates

STELLAR-304: a phase III study of zanzalintinib (XL092) plus nivolumab in advanced non-clear cell renal cell carcinoma

Sumanta K. Pal[a], Thomas Powles[b], Ravindran Kanesvaran[c], Javier Molina-Cerrillo[d], Darren R. Feldman[e], Pedro Barata[f], Mohan Liu[g], Aarohi Bhatt[h], Zhong Wang[i], Prachi Nandoskar[h] and Cristina Suarez[j]



VHL

Key Eligibility Criteria

- Diagnosis of VHL disease, based on germline alteration
- ≥1 measurable RCC tumor
- No RCC tumor or other VHL tumor that necessitates immediate surgery[a]
- No prior systemic anticancer therapy
- No metastatic disease
- ECOG PS 0 or 1

N = 61

Belzutifan
120 mg orally once daily[b]

Tumor Assessments

- At screening and every 12 weeks for a minimum of 3 years, then every 24 weeks thereafter

End Points

- Primary: ORR in VHL disease–associated RCC per RECIST v1.1 by IRC
- Secondary: ORR in other VHL disease–associated neoplasms; DOR; TTR per RECIST v1.1 by IRC; and safety

Narayan V et al. ASCO 2025

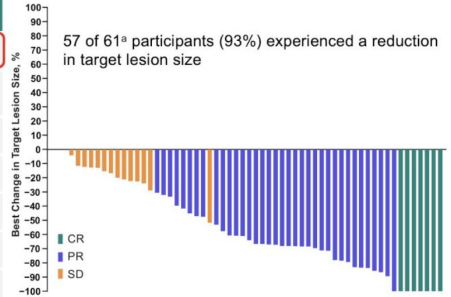
VHL

	N = 61
Age, median (range), years	41 (19-66)
Sex, n (%)	
Male	32 (52)
Female	29 (48)
ECOG PS, n (%)	
0	50 (82)
1	10 (16)
2[a]	1 (2)
No. of participants with non-RCC neoplasms[b] per IRC, n (%)	
pNET	20 (33)
CNS hemangioblastoma	50 (82)
Retinal hemangioblastoma	14 (23)

	N = 61
Prior VHL disease–related surgical procedures,[c] n (%)	
No. of participants who had ≥1 prior surgical procedure	59 (97)
RCC	47 (77)
Pancreatic lesions (serous cystadenoma + pNET)	9 (15)
CNS hemangioblastoma	46 (75)
Retinal hemangioblastoma	26 (43)
Size of target lesions,[d] median (range), mm	
RCC	22 (10-43)
CNS hemangioblastoma	17 (10-87)
pNET	19 (10-52)
***VHL* alteration, n (%)**	
Deletion	18 (30)
Mutation	43 (70)

Variable	Efficacy Population (N=61)
Objective response — no. (% [95% CI])	30 (49 [36 to 62])
Best response — no. (%)	
Complete response	0
Partial response	30 (49)
Stable disease	30 (49)
Disease progression	0
Unable to be evaluated†	1 (2)
Median time to response (range) — mo	8.2 (2.7 to 19.1)
Median duration of response (range) — mo‡	NR (2.8+ to 22.3+)

	RCC N = 61
ORR, % (95% CI)	70 (57-81)
Best response n (%)	
CR	7 (11)
PR	36 (59)
SD	17 (28)
PD	0
NE[a]	1 (2)



Narayan V et al. ASCO 2025
Jonash E et al. NEJM 2021

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VHL

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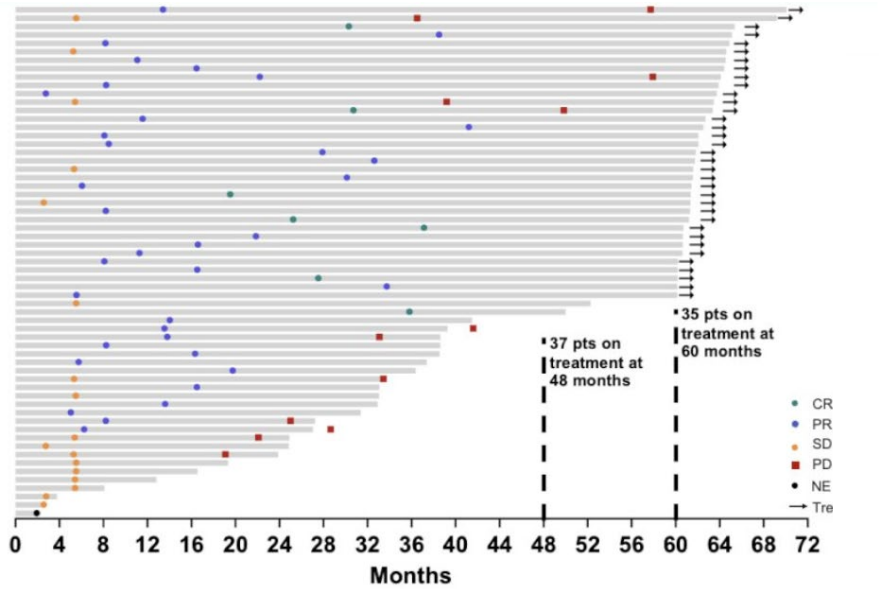

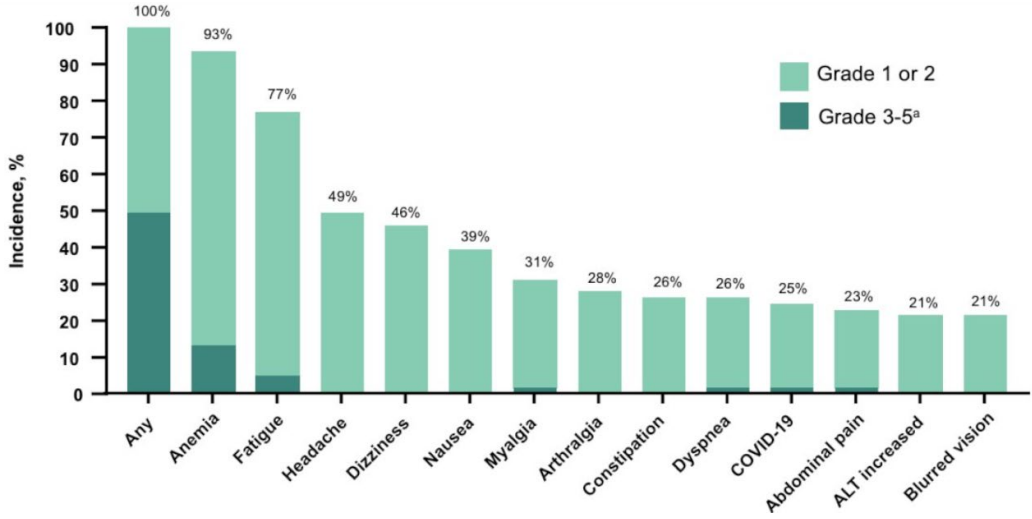

Narayan V et al. ASCO 2025

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VHL

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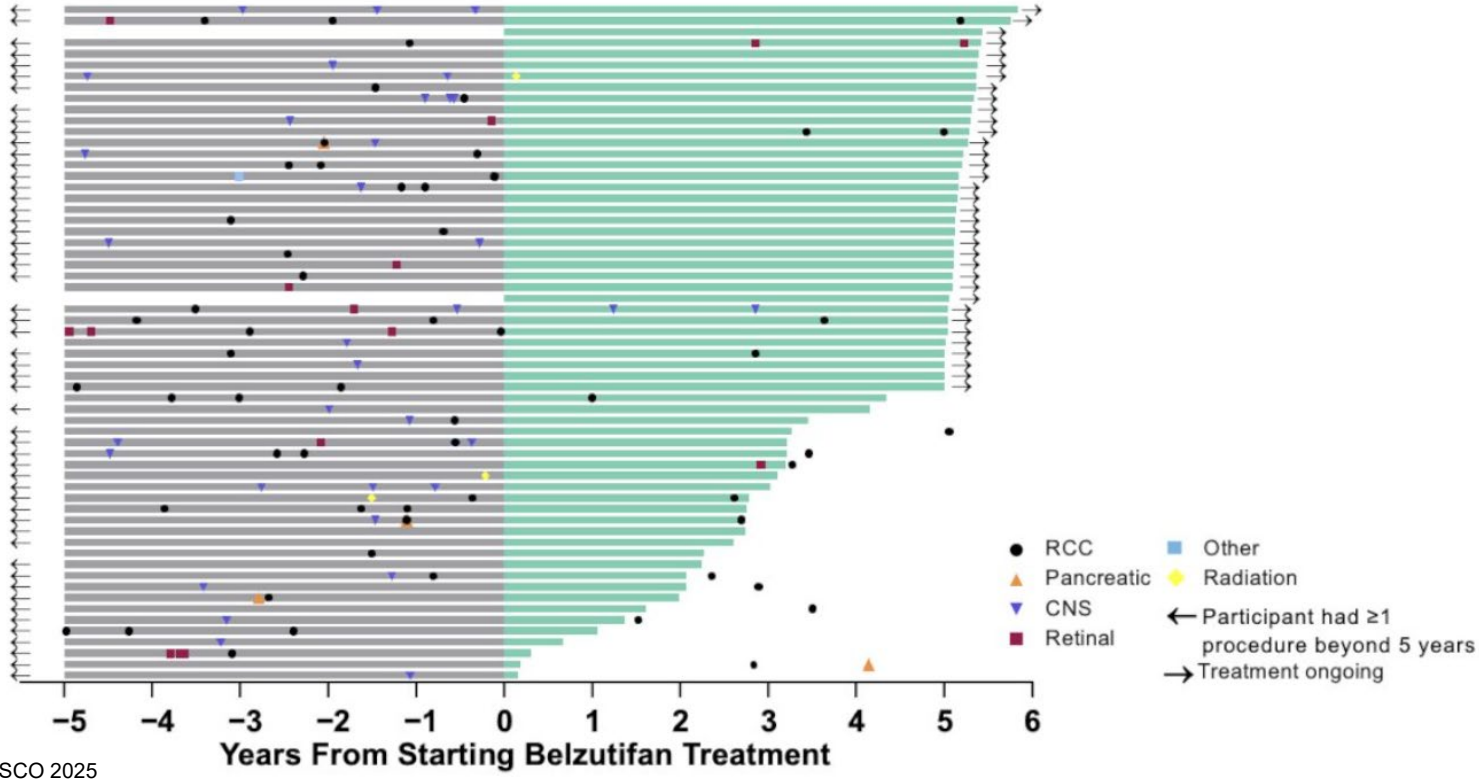
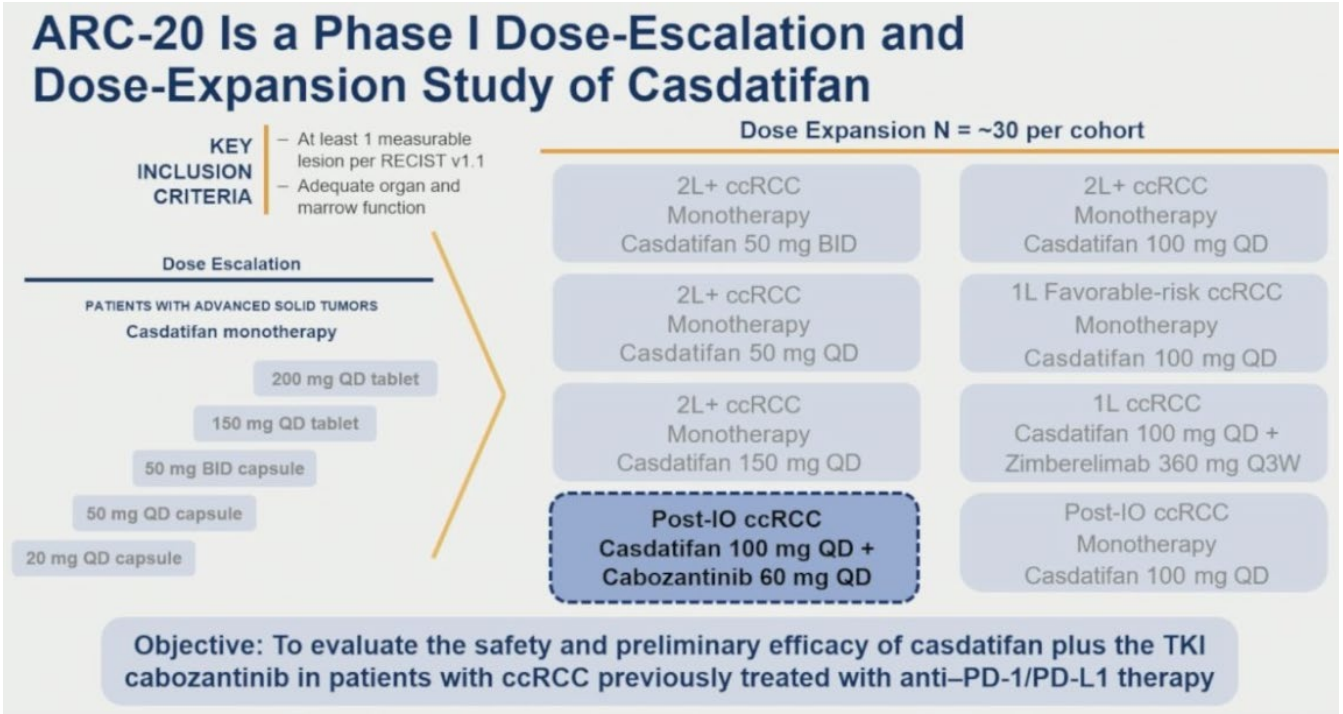


Narayan V et al. ASCO 2025

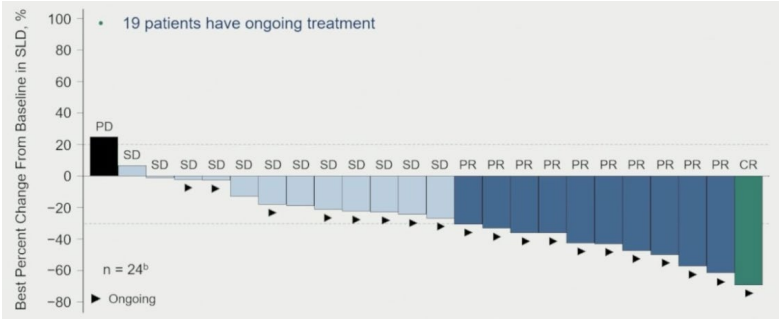
Metastatic disease



Choueiri T et al. ASCO 2025

Metastatic disease

Characteristic	Safety Population[a] (N = 42)
Age, years, median (range)	63 (43–81)
Sex, female/male, n (%)	9 (21%) / 33 (79%)
ECOG PS 0/1, n (%)	29 (69%) / 13 (31%)
IMDC risk score, n (%)	
Favorable	9 (21%)
Intermediate	29 (69%)
Poor	4 (10%)
Number of prior regimens, n (%)	
1	35 (83%)
2+	7 (17%)
Prior treatment, n (%)	
VEGFR-TKI plus IO	17 (40%)
IO only	25 (60%)



	(n = 24)[a]
Follow-up, months, median (range)	5.3 (2.8–9.1)
Confirmed ORR[b], % (n) (95% CI)	**46% (11) (25.6%, 67.2%)**
Best Overall Response, n (%)	
CR	1 (4%)
PR[b]	10 (42%)
SD	12 (50%)
PD	1 (4%)

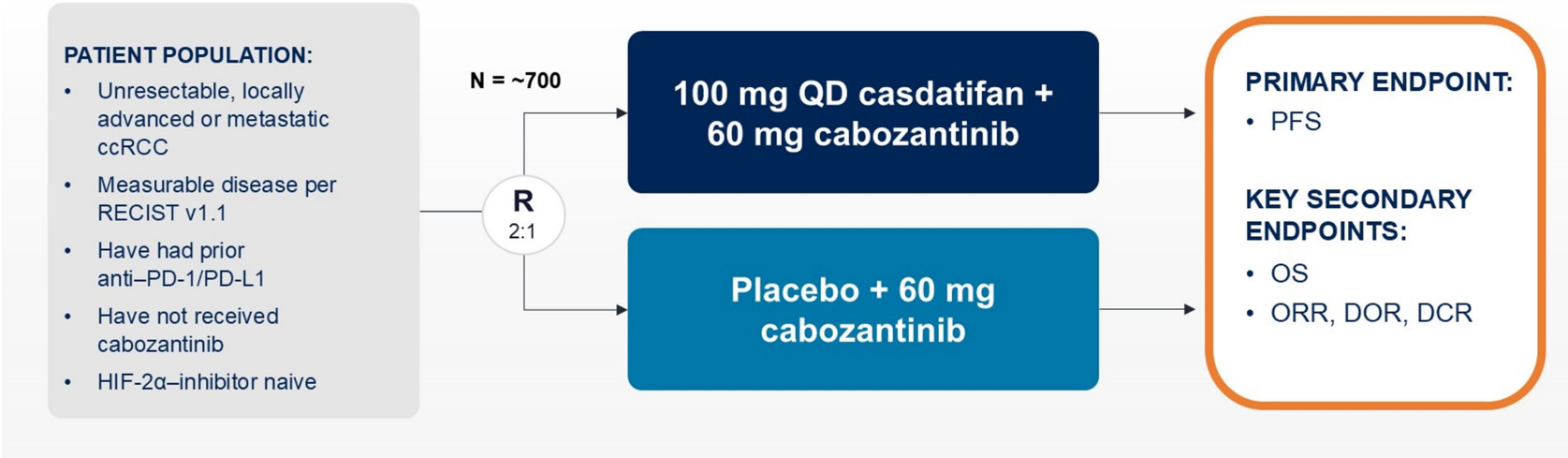
	Safety Population,[a] n (%) (N = 42)		
	AE Related to		
	Casdatifan	Cabozantinib	Any Study Drug
Follow-up, months, median (range)		3.7 (1.1–9.1)	
Patients with any treatment-related AE[b], n (%)	41 (98%)	39 (93%)	41 (98%)
Anemia	29 (69%)	18 (43%)	29 (69%)
Fatigue	20 (48%)	23 (55%)	23 (55%)
Alanine aminotransferase increased	8 (19%)	16 (38%)	16 (38%)
Diarrhea	6 (14%)	15 (36%)	15 (36%)
Aspartate aminotransferase increased	6 (14%)	14 (33%)	14 (33%)
Platelet count decreased	5 (12%)	12 (29%)	12 (29%)
Nausea	5 (12%)	10 (24%)	10 (24%)
Dizziness	7 (17%)	6 (14%)	8 (19%)

Choueiri T et al. ASCO 2025

Metastatic disease

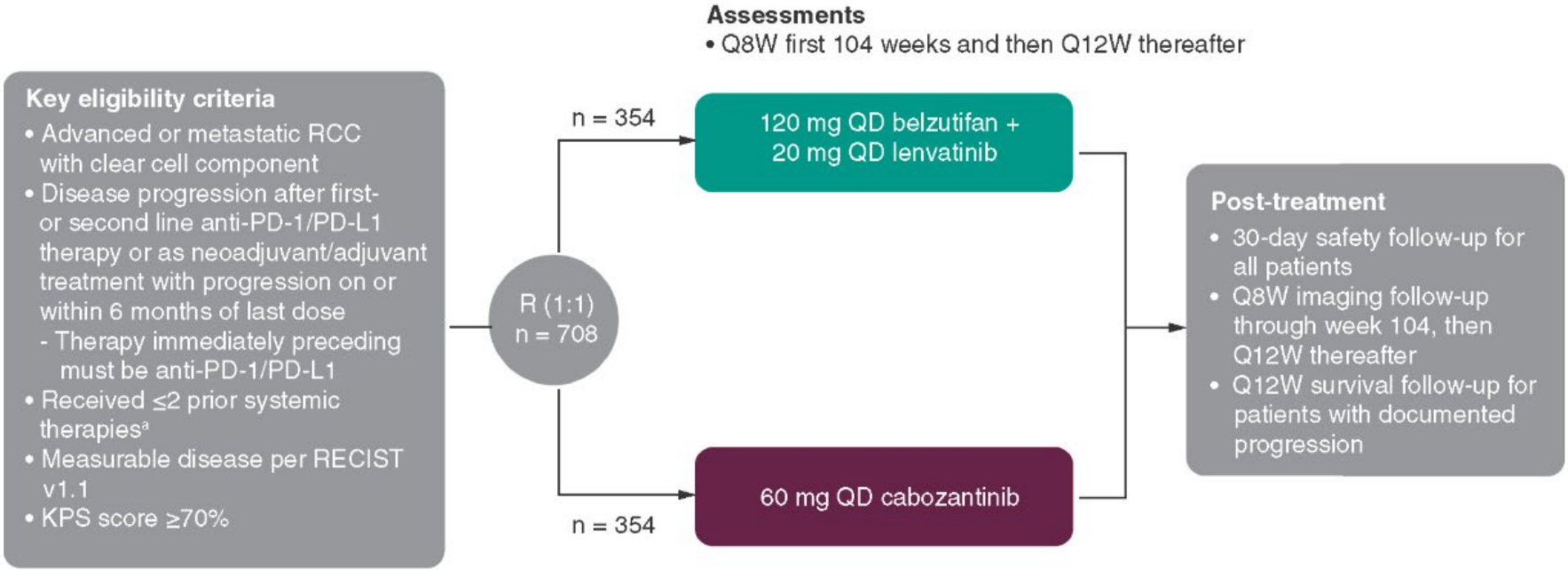
Anticipated first half 2025

PEAK-1

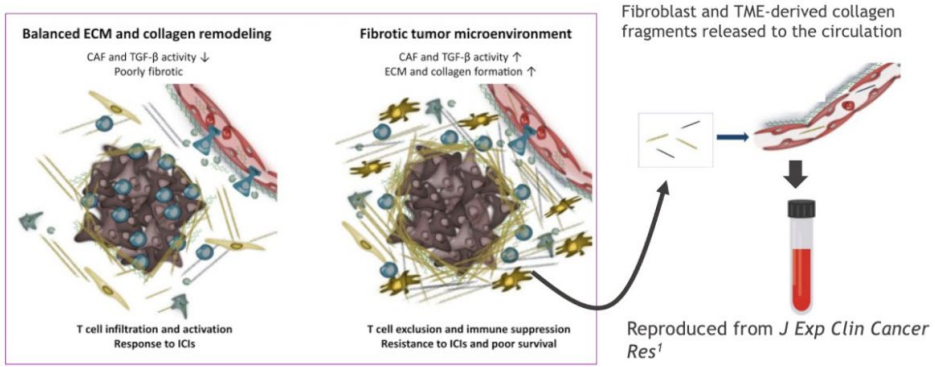


Metastatic disease

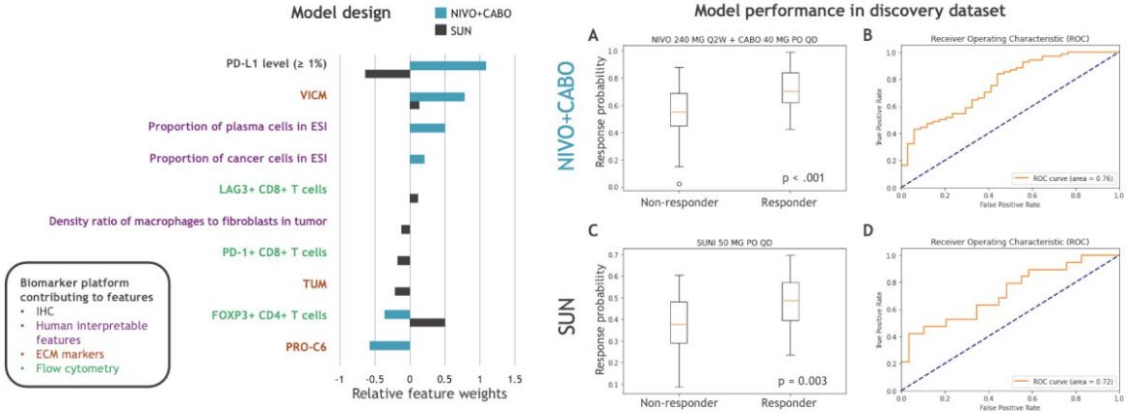
LS 011



Metastatic disease

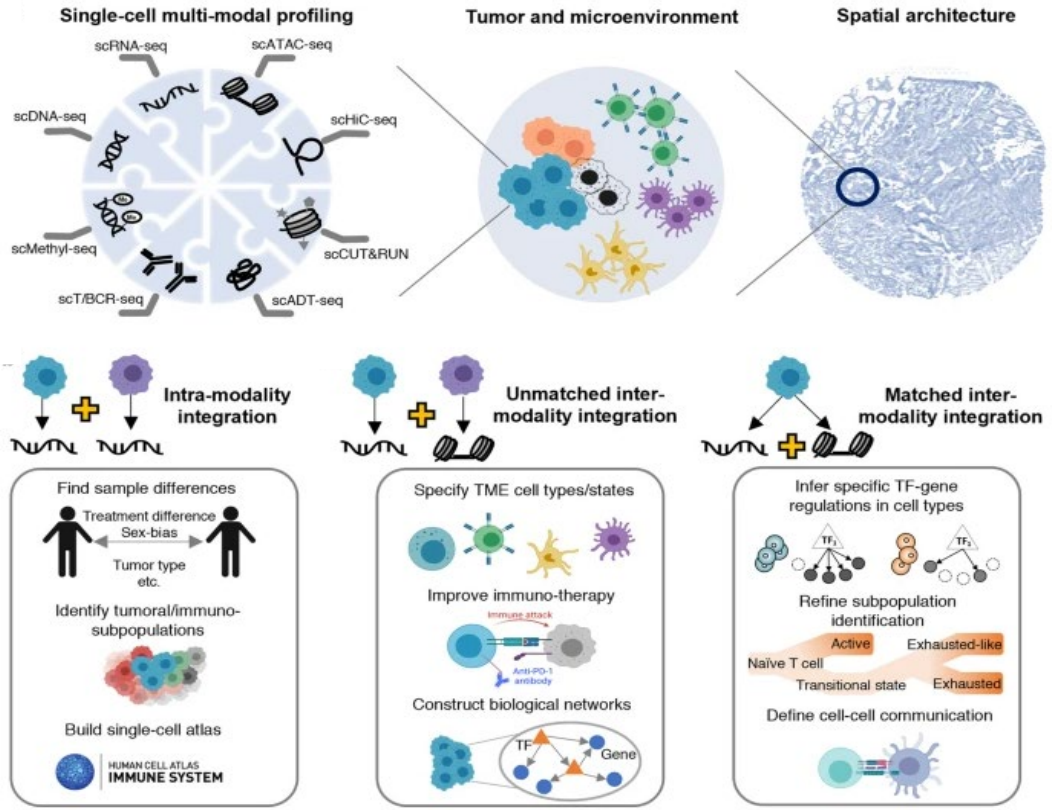


Reproduced from *J Exp Clin Cancer Res*[1]



Braun D et al. ASCO 2025

Metastatic disease



Ma A et al. Nature Comm 2024

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Future

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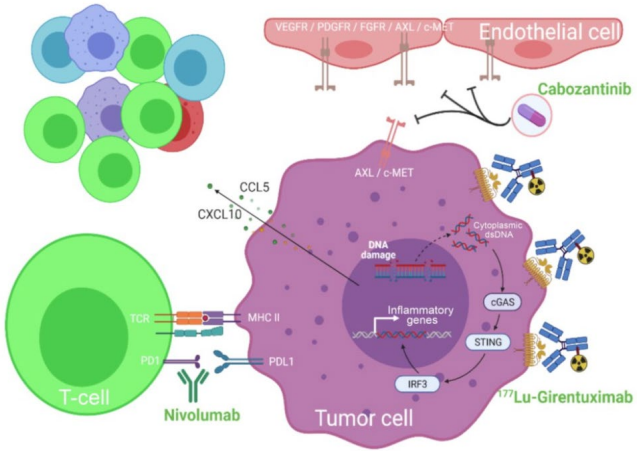
STARLITE-1



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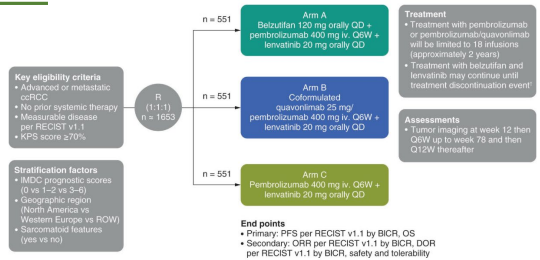

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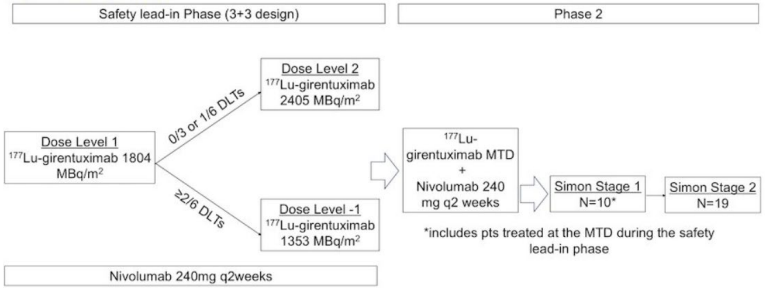
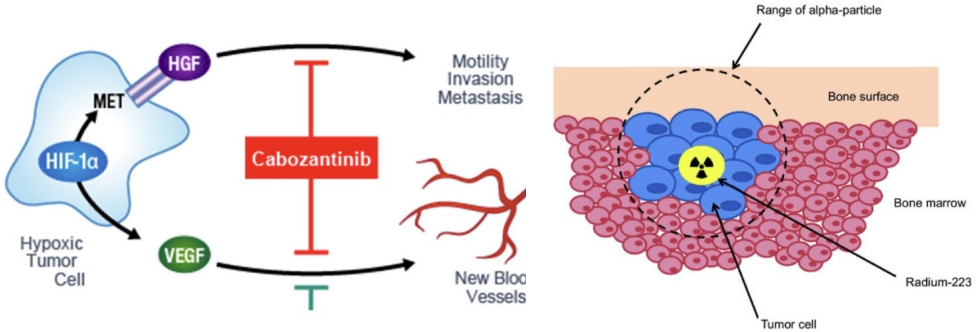


RADICAL



Conclusions

- Nothing clearly change in daily practice after ASCO 2025
- Pembrolizumab is the standard of care in the adjuvant setting afer 5 years of FU KN 564
- The final analysis from the Checkmate 214 continues supporting the significant impact of IO-based combinations in the first line setting.
- How can we improve these data? Triplets will be the answer? Not yet.
- Adaptive trials according to response (ideally molecularly based) will be helpful for clinical practice.
- Promising results in pretreated patients, but based in the same strategies, we need novel MoA in kidney cancer.
- Urgent need of usefull biomarkers

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