GONORTE
Grupo Oncológico

Presentaciones más destacadas en cáncer renal

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- CR LOCALIZADO:
  - LITESPARK 022
  - PROS RAMPART TRIAL
- CR AVANZADO:
  - LITESPARK 011
  - CYTOSHRINK
- BIOMARCADORES:
  - The K-COMPASS model
  - MONSTAR-SCREEN-3
- CR NO CELULAS CLARAS
- POSTERS

ASCO Genitourinary Cancers Symposium

Adjuvant Pembrolizumab Plus Belzutifan Versus Pembrolizumab for Clear Cell Renal Cell Carcinoma: The Randomized Phase 3 LITESPARK-022 Study

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Background

- Pembrolizumab is the adjuvant standard of care for patients with ccRCC at increased risk of recurrence following nephrectomy[1]
  - The phase 3 KEYNOTE-564 study showed that adjuvant pembrolizumab significantly improved DFS and OS compared with placebo[2,3]
  - Nevertheless, additional adjuvant therapy options are needed, as ~40% of patients treated with adjuvant pembrolizumab experienced death or recurrence within 5 years of nephrectomy[4]
- Belzutifan is a potent, selective HIF-2α inhibitor with established efficacy in patients with advanced RCC treated with prior immunotherapy and VEGFR-TKI therapy[5]
  - Adjuvant combination strategies incorporating belzutifan may improve outcomes in RCC
- The randomized, double-blind, phase 3 LITESPARK-022 study evaluated pembrolizumab + belzutifan vs pembrolizumab + placebo in participants with resected ccRCC at increased risk of recurrence

ccRCC, clear cell renal cell carcinoma; DFS, disease-free survival; OS, overall survival; VEGFR-TKI, vascular endothelial growth factor receptor tyrosine kinase inhibitor.

1. NCCN Kidney cancer (Version 1.2026); 2. Choueiri TK, et al. *N Engl J Med* 2021;385(8):683-694; 3. Choueiri TK, et al. *N Engl J Med* 2024;390(16):1359-1371; 4. Haas N, et al. *J Clin Oncol* 2025;43(16_suppl):4514-4514; 5. Choueiri TK, et al. *N Engl J Med* 2024;391(8):710-721.

Study Design: LITESPARK-022 (NCT05239728)

Key Eligibility Criteria

- Histologically confirmed ccRCC with no prior systemic therapy
- Surgery ≤12 weeks prior to randomization
- ECOG PS 0 or 1
- One of the following:
  - Intermediate-high risk of recurrence (M0):
    - pT2, grade 4 or sarcomatoid, N0
    - pT3, any grade, N0
  - High risk of recurrence (M0):
    - pT4, any grade, N0
    - Any pT, any grade, N+
  - M1 NED

Median follow-up (data cutoff, Aug 23, 2025):
28.4 months (range, 15.0–40.1)

R 1:1

N = 921 → **Pembrolizumab** 400 mg Q6W for ~1 year (≤9 cycles) + **belzutifan** 120 mg QD for ≤54 weeks

N = 920 → **Pembrolizumab** 400 mg Q6W for ~1 year (≤9 cycles) + **placebo** QD for ≤54 weeks

Stratification Factors

- Intermediate-high vs high vs M1 NED
- Tumor grade 1-2 vs 3-4

Primary endpoint: DFS by investigator
Key secondary endpoint: OS
Other secondary endpoints include: safety

NED, no evidence of disease; QD, daily; Q6W, every six weeks.

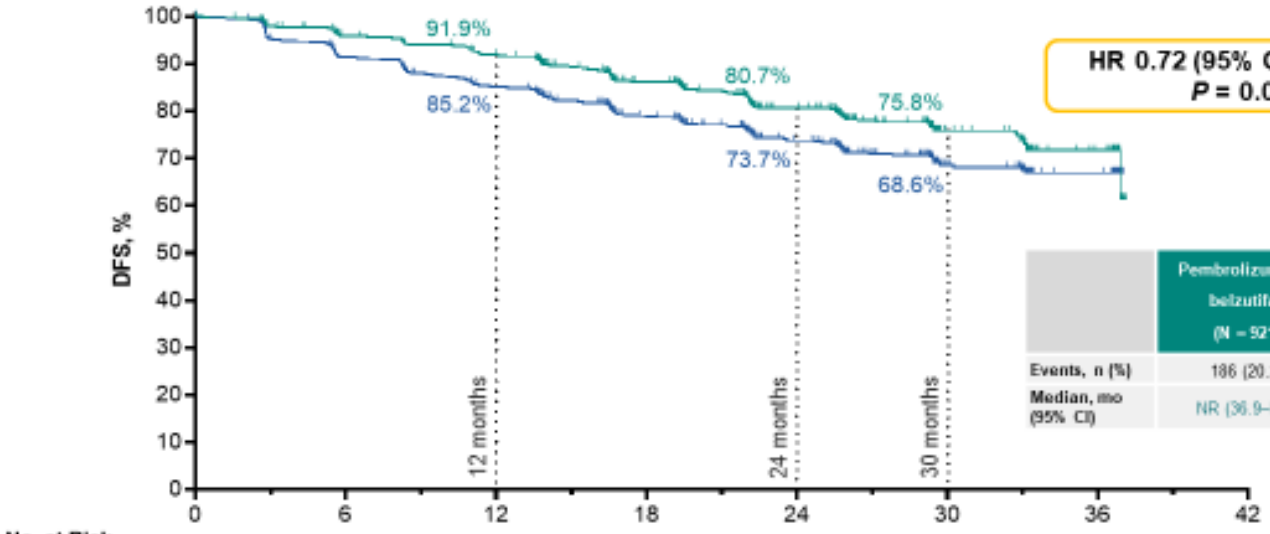
Baseline Characteristics

Characteristic, n (%)	Pembrolizumab + belzutifan (N = 921)	Pembrolizumab + placebo (N = 920)
Age, median (range), yrs	59.0 (20–91)	60.0 (24–86)
Sex		
Male	673 (73.1)	642 (69.8)
Female	248 (26.9)	278 (30.2)
US Region		
US	140 (15.2)	115 (12.5)
Non-US	781 (84.8)	805 (87.5)
Race		
White	576 (62.5)	581 (63.2)
All others	303 (32.9)	315 (34.2)
Missing	42 (4.6)	24 (2.6)
ECOG PS		
0	788 (85.6)	777 (84.5)
1	133 (14.4)	143 (15.5)

Characteristic, n (%)	Pembrolizumab + belzutifan (N = 921)	Pembrolizumab + placebo (N = 920)
Risk Category[a]		
Intermediate-to-High	779 (84.6)	782 (85.0)
High	58 (6.3)	53 (5.8)
M1 NED	84 (9.1)	84 (9.1)
Sarcomatoid features		
Present	104 (11.3)	84 (9.1)
Absent	730 (79.3)	724 (78.7)
Unknown	87 (9.4)	112 (12.2)
Tumor grade		
1-2	322 (35.0)	328 (35.7)
3-4	599 (65.0)	592 (64.3)
PD-L1 status[b]		
CPS <1	222 (24.1)	217 (23.6)
CPS ≥1	547 (59.4)	502 (54.6)
Not available[c]	152 (16.5)	201 (21.8)

[a]One participant had stage 2 (T2, N0, M0), grade 2 disease and was thus ineligible for these categories. [b]Programmed death ligand 1 (PD-L1) combined positive score (CPS) was determined via the number of PD-L1–staining cells (tumor cells, lymphocytes, and macrophages) divided by the total number of viable tumor cells, multiplied by 100. [c]Includes participants with missing or non-evaluable assessment of PD-L1 status.
Data cutoff: August 23, 2025.

DFS by Investigator, ITT Population



HR 0.72 (95% CI, 0.59–0.87)
P = 0.0003*

	Pembrolizumab + belzutifan (N = 921)	Pembrolizumab + placebo (N = 920)
Events, n (%)	186 (20.2)	246 (26.7)
Median, mo (95% CI)	NR (36.9–NR)	NR (NR–NR)

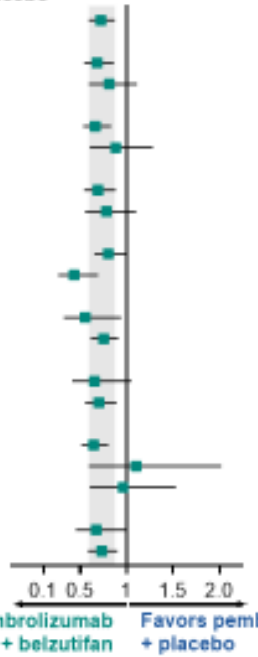
No. at Risk

Pembrolizumab + belzutifan	921	850	805	669	451	153	35	0
Pembrolizumab + placebo	920	823	759	619	417	140	38	0

*Denotes statistical significance by stratified log-rank test (p-value boundary, 0.01632).
NR, not reached. ITT population comprised all randomized participants. HRs and 95% CI estimated via stratified Cox proportional hazard model.
Median follow-up: 28.4 months (range, 15.0–40.1).
Data cutoff: August 23, 2025.

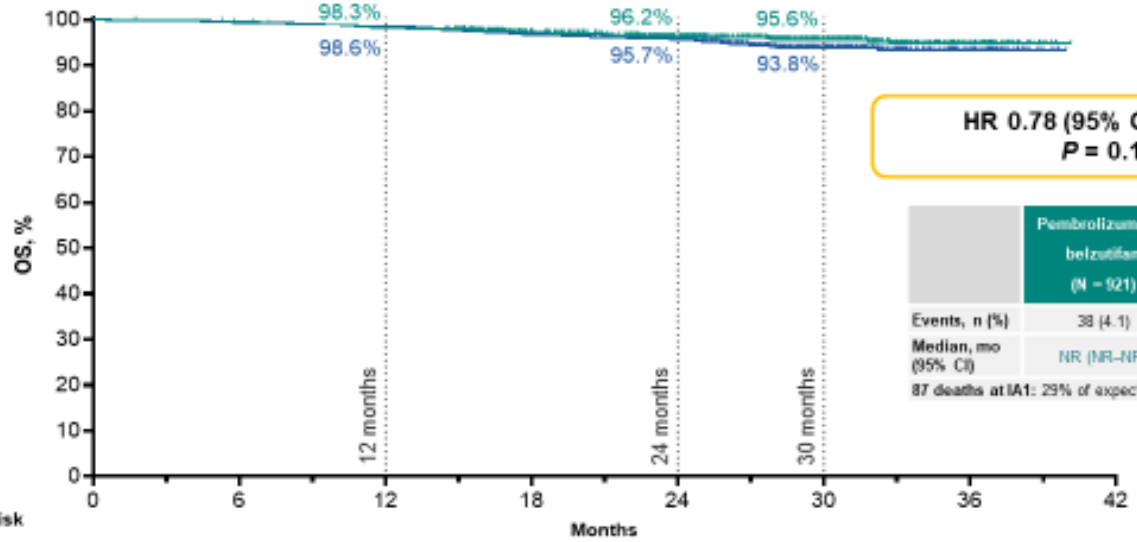
DFS by Investigator in Subgroups, ITT Population

	Events/Participants		Hazard Ratio (95% CI)
	Pembro + bel	Pembro + placebo	
Overall	186/921	246/920	0.72 (0.59–0.87)
Age			
<65 yrs	118/638	160/622	0.68 (0.54–0.86)
≥65 yrs	68/283	86/298	0.81 (0.59–1.11)
Sex			
Male	138/673	184/642	0.66 (0.53–0.83)
Female	48/248	62/278	0.88 (0.60–1.28)
Race			
White	116/576	159/581	0.69 (0.54–0.88)
All Others	58/303	76/315	0.78 (0.55–1.10)
ECOG PS			
0	162/788	193/777	0.80 (0.65–0.99)
1	24/133	53/143	0.43 (0.26–0.69)
Geographic Region			
United States	24/140	32/115	0.55 (0.32–0.94)
Outside United States	162/781	214/805	0.75 (0.61–0.91)
PD-L1 status			
CPS <1	30/222	41/217	0.65 (0.41–1.05)
CPS ≥1	119/547	149/502	0.70 (0.55–0.89)
Risk category			
Intermediate-to-High	129/779	191/782	0.64 (0.51–0.80)
High	21/58	20/53	1.10 (0.59–2.02)
M1 NED	36/84	35/84	0.96 (0.60–1.53)
Tumor grade			
1 or 2	42/322	62/328	0.67 (0.45–0.99)
3 or 4	144/599	184/592	0.73 (0.58–0.90)



Data cutoff: August 23, 2025.

Interim OS Results, ITT Population



HR 0.78 (95% CI, 0.51–1.19)
P = 0.1220*

	Pembrolizumab + belzutifan (N = 921)	Pembrolizumab + placebo (N = 920)
Events, n (%)	38 (4.1)	49 (5.3)
Median, mo (95% CI)	NR (NR–NR)	NR (NR–NR)

87 deaths at IA1: 29% of expected events at final analysis

No. at Risk

Pembrolizumab + belzutifan	921	914	900	805	631	319	70	0
Pembrolizumab + placebo	920	914	907	807	638	319	69	0

*Did not reach statistical significance by stratified log-rank test (p-value boundary, 0.00003).
Final analysis for OS to occur after approximately 300 OS events. HRs and 95% CI estimated via stratified Cox proportional hazard model.
Data cutoff: August 23, 2025.

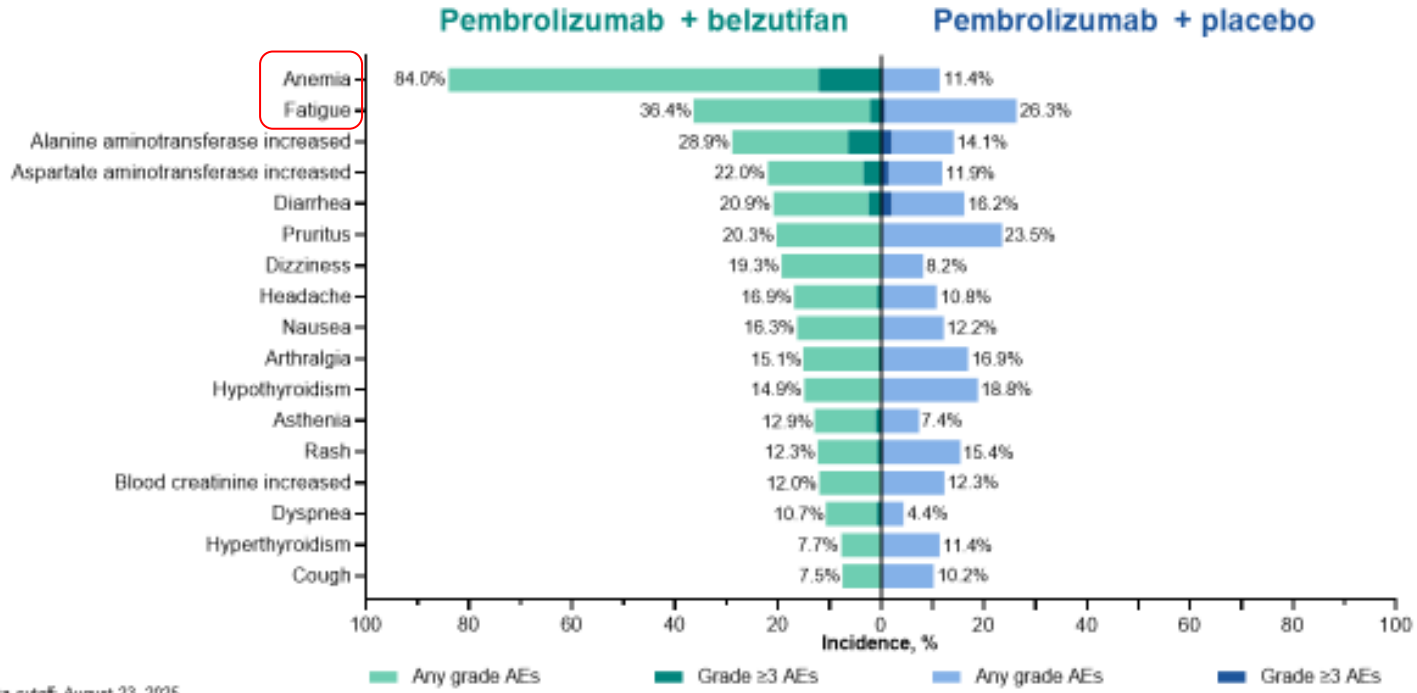
Median follow-up: 28.4 months (range, 15.0–40.1).

Summary of Safety Results, As-Treated Population

Participants, n (%)	Pembrolizumab + belzutifan[a,b] (N = 915)	Pembrolizumab + placebo[a,b] (N = 913)
Median duration on study therapy, mo (range)	12.4 (0.03–20.1)	12.4 (0.3–18.9)
Treatment-emergent AEs	905 (98.9)	863 (94.5)
Grade ≥3	477 (52.1)	276 (30.2)
Led to discontinuation of all study treatment	109 (11.9)	82 (9.0)
Led to death	10 (1.1)	11 (1.2)
Serious[c]	270 (29.5)	182 (19.9)
Serious[c] and led to discontinuation of all study treatment	59 (6.4)	43 (4.7)
Treatment-related AEs	884 (96.6)	737 (80.7)
Grade ≥3	386 (42.2)	163 (17.9)
Led to discontinuation of all study treatment	93 (10.2)	67 (7.3)
Led to death	3 (0.3)	3 (0.3)
Immune-mediated AEs or infusion reactions	324 (35.4)	353 (38.7)
Grade ≥3	86 (9.4)	76 (8.3)

*Me
141.
existing hospitalization, resulted in persistent or significant disability or incapacity, was a congenital anomaly or birth defect, or was judged by the investigator to be a serious adverse event.
Safety was assessed in all participants who received ≥1 dose of study treatment.
Data cutoff: August 23, 2025

Treatment-Emergent AEs with Incidence ≥10%, As-Treated Population



Data cutoff: August 23, 2025.

Summary and Management of Anemia[a], As-Treated Population

Participants, n (%)	Pembrolizumab + belzutifan (N = 915)	Pembrolizumab + placebo (N = 913)
TEAEs of anemia[a]	771 (84.3)	107 (11.7)
Grade ≥3	111 (12.1)	5 (0.5)
Led to interruption of belzutifan/placebo	226 (24.7)	6 (0.7)
Led to dose reduction of belzutifan/placebo	158 (17.3)	0
Led to discontinuation of belzutifan/placebo	37 (4.0)	1 (0.1)
Supportive therapy for anemia		
Treated with blood transfusions only	41 (4.5)	6 (0.7)
Treated with ESA only	65 (7.1)	2 (0.2)
Treated with ESA and blood transfusions	10 (1.1)	0 (0.0)

[a]Includes participants with anemia and decreased hemoglobin.
ESA, erythropoiesis-stimulating agent.
Data cutoff: August 23, 2025.

Summary and Management of Hypoxia, As-Treated Population

Participants, n (%)	Pembrolizumab + belzutifan (N = 915)	Pembrolizumab + placebo (N = 913)
TEAEs of hypoxia	64 (7.0)	1 (0.1)
Grade ≥3	42 (4.6)	0
Led to interruption of belzutifan/placebo	23 (2.5)	1 (0.1)
Led to dose reduction of belzutifan/placebo	32 (3.5)	0
Led to discontinuation of belzutifan/placebo	15 (1.6)	0
Supportive therapy for hypoxia		
Treated with oxygen therapy	30 (3.3)	0
Median time to onset of oxygen therapy, days (range)	103.5 (16 to 356)	-

Data cutoff: August 23, 2025.

Summary and Conclusions

- Pembrolizumab + belzutifan showed a statistically significant and clinically meaningful DFS improvement vs pembrolizumab monotherapy in participants with ccRCC at increased risk of recurrence post nephrectomy
  - DFS benefit was generally consistent across prespecified subgroups
- Additional follow-up is planned for the key secondary endpoint of OS
- The safety profile of pembrolizumab + belzutifan was manageable with a low rate of AEs leading to the discontinuation of both study drugs
  - Overall safety was consistent with the expected profiles of each individual drug
- LITESPARK-022 is the first adjuvant phase 3 trial in RCC to show a significant benefit for a combination treatment vs an active immunotherapy comparator
- These results support the addition of belzutifan to standard-of-care adjuvant pembrolizumab for patients with ccRCC at increased risk of recurrence

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Patient-reported outcomes in resected renal cell carcinoma: adjuvant durvalumab and tremelimumab versus active monitoring in the RAMPART trial

Sophie Merrick[1], Laura Murphy[1], Elena Frangou[1], Hannah L Rush[1,2], Hannah Plant[1], Matt Nankivell[1], Duncan C Gilbert[1], Paul Nathan[3], Grant D Stewart[4], Craig Gedye[5], Axel Bex[6,7], Tim Eisen[8], Ian D Davis[9,10], Balaji Venugopal[11], Thomas Powles[12], Max Parmar[1], Martin Stockler[13,14], James Larkin[15], Angela Meade[1], on behalf of the RAMPART investigators.

1. MRC Clinical Trials Unit at UCL, UK 2. Guy's and St Thomas' NHS Foundation Trust, UK 3. Mount Vernon Cancer Centre, UK 4. University of Cambridge, UK 5. University of Newcastle, Australia, 6. Royal Free London NHS Foundation Trust, UK 7. Netherland Cancer Institute, Netherlands 8. Cambridge University Hospitals NHS Foundation Trust 9. Monash University, Australia 10. Eastern Health, Australia 11. University of Glasgow, UK 12. St Bartholomew's Hospital, UK 13. University of Sydney, Australia 14. ANZUP Cancer Trials Group, Australia 15. Royal Marsden UK

RAMPART Trial

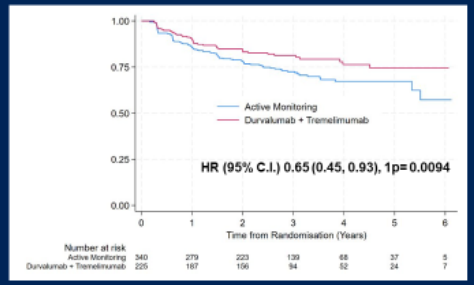
- Open label
- 2 comparisons
- Patient reported outcome (PRO) analysis presented today:
  - DT (Arm C) vs AM (Arm A)

Confirmed RCC and high or intermediate risk of relapse (Leibovich risk score),
or with fully resected synchronous ipsilateral adrenal metastases,
or with a single fully resected soft tissue metastasis (within 6-24 months post nephrectomy)

Randomization
Allocation ratio 3:2:2
N=790

Arm A	Arm B	Arm C
active monitoring (AM) N=340	durvalumab 1500mg q4w for 1 year N=225	durvalumab 1500mg q4w for 1 year and tremelimumab (DT) 75mg at day 1 and week 4 N=225

RAMPART Disease Free Survival (ITT Population)



3-year DFS	
Durvalumab and Tremelimumab (N=225)	**Active Monitoring (N=340)**
81%	73%
Median Follow Up: 3 years	

RAMPART Quality of Life Study

- Optional sub-study in English-speaking countries.
- EORTC QLQ-C30 completed at baseline, week 16 and month 15.
- Recall period: Past 7 days

Scale/ Item Group	Interpretation
Overall health and quality of life (2 items)	Higher score = better QoL
Functional domains (5)	Higher score = better functioning
Symptom and single-item scales (9)	Higher score = worse symptoms/financial problems

All scale scores were linearly transformed to a 0 to 100 range.
Clinically meaningful differences were predefined by item and scale[1].

1. Cocks K et al. *J Clin Oncol*. 2011.

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Results

- **254** participants were included in the PRO analysis (**104** DT, **150** AM).
- Baseline characteristics: overall trial and QoL sub-study → broadly similar.
- Baseline characteristics: DT (Arm C) vs AM (Arm A) → broadly similar, some minor differences.
  - Sex:
    - 74% male in DT vs 68% male in AM.
  - Performance status (PS):
    - PS 0: 88% DT vs 80% AM.
    - PS 1: 12% DT vs 20% AM.

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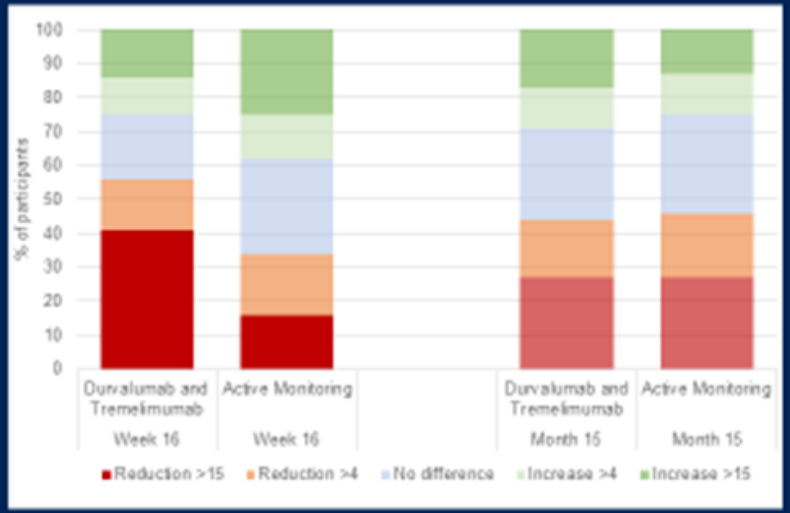
Proportion of Participants with Clinically Meaningful Change in OHQL

- At Week 16 a higher proportion of participants in the DT arm experienced a large clinically meaningful reduction in OHQL (odds ratio 3.7, 95% CI 1.9 to 7.1, p=0.0001).
- At Month 15 proportions were similar between treatment arms.

All analyses were exploratory.



CMD = clinically meaningful difference.
Small CMD = >3 points. Large CMD = >15 points.

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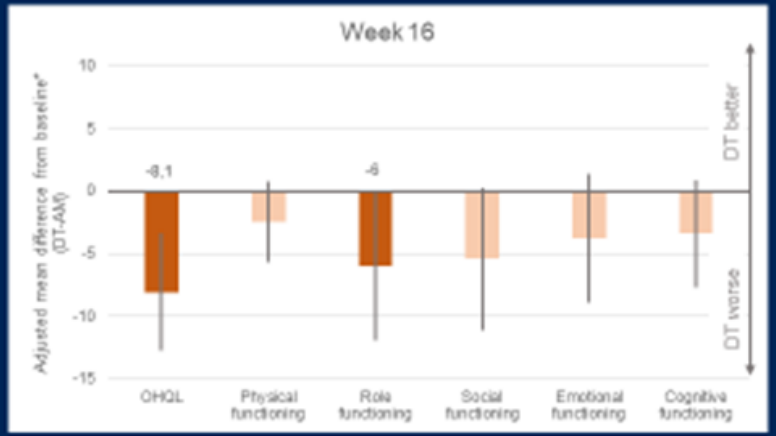
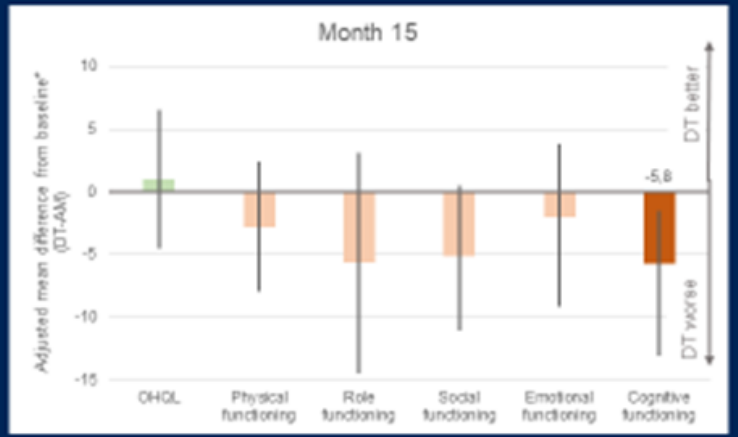
OHQL & Functional scores

- **Week 16:** OHQL and role functioning were worse with DT, exceeding clinically meaningful thresholds.
- **Month 15:** Early differences appeared to improve. Cognitive functioning was worse with DT exceeding clinically meaningful thresholds.





Higher scores = better OHQL/functioning with DT.
* Adjusted for baseline QoL score and sex; all analyses were exploratory.

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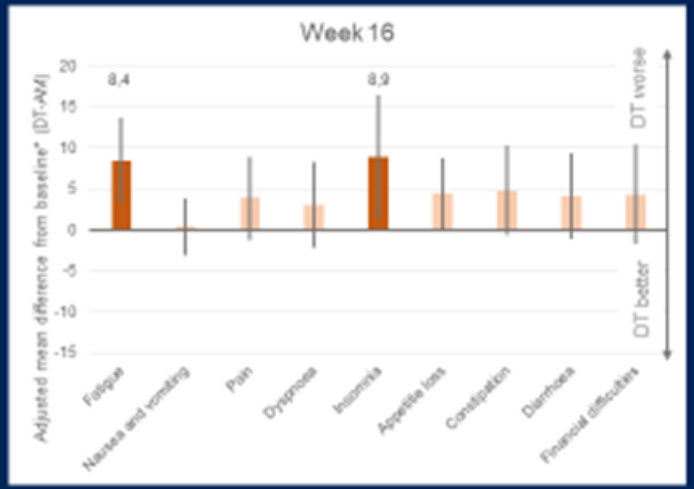
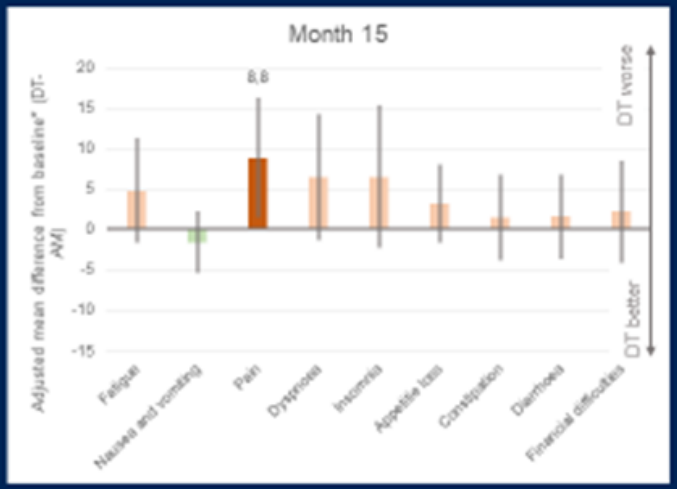
Symptoms and Financial Difficulties

- **Week 16:** Fatigue and insomnia were worse with DT, exceeding clinically meaningful thresholds.
- **Month 15:** Pain was worse with DT, exceeding clinically meaningful thresholds.





Higher scores = worse symptoms/financial difficulties.
* Adjusted for baseline QoL score and sex; all analyses were exploratory.

Conclusions

- **At Week 16, DT was associated with worse QoL**, with clinically meaningful declines in OHQL, role functioning, fatigue and insomnia. **These early effects appeared to improve by Month 15.**
- **At Month 15, DT was associated with new clinically meaningful declines in pain and cognitive function.**
- These findings should be considered alongside the DFS benefit when interpreting the trial results.

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- POSTERS

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Belzutifan Plus Lenvatinib Versus Cabozantinib for Advanced Renal Cell Carcinoma After Anti–PD-(L)1 Therapy: Open-Label Phase 3 LITESPARK-011 Study

Robert J. Motzer,[1] Se Hoon Park,[2] Ray McDermott,[3] Camillo Porta,[4] Daniel Y.C. Heng,[5] Mauricio Burotto,[6] Roberto Iacovelli,[7] Elena Verzoni,[8] Hernan J. Cutuli,[9] John B.A.G. Haanen,[10] Cristina Suárez,[11] Guillermo de Velasco,[12] Begoña Pérez-Valderrama,[13] Hans Westgeest,[14] Sammy Yuan,[15] Rodolfo F. Perini,[15] Ding Wang,[15] Manuela Schmidinger[16]

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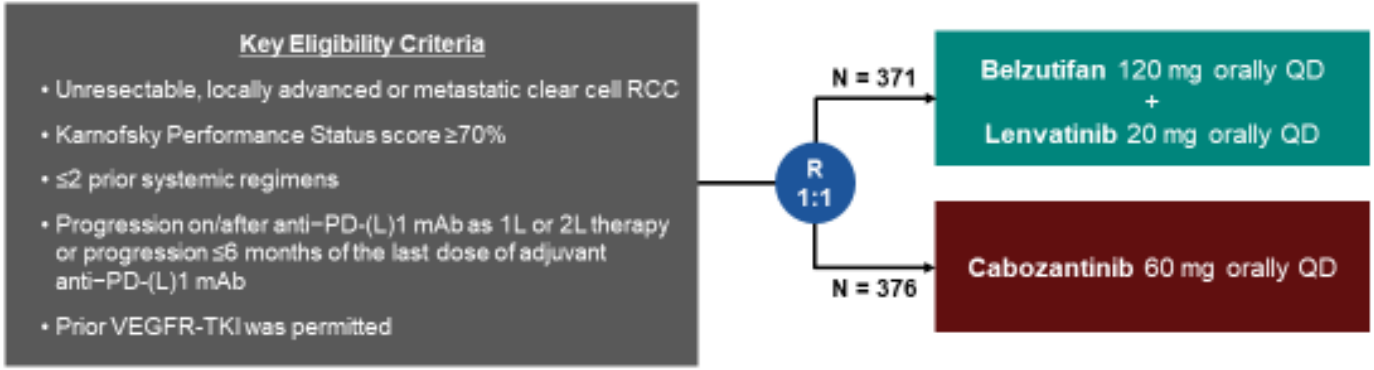
PRESENTED BY: Robert J. Motzer

LITESPARK-011 Study (NCT04586231)



Stratification Factors
- IMDC prognostic score:[a] 0 vs. 1-2 vs. 3-6
- Line of treatment for prior anti−PD-(L)1: 1L, adjuvant, neoadjuvant-adjuvant vs. 2L
- Geographic region: North America vs. western Europe vs. rest of world

Dual Primary Endpoints:
- PFS per RECIST 1.1 by BICR
- OS

Key Secondary Endpoint:
- ORR per RECIST 1.1 by BICR

Other Secondary Endpoints Include:
- DOR per RECIST 1.1 by BICR
- Safety

Exploratory Endpoints Include:
- Time to deterioration in patient-reported outcomes

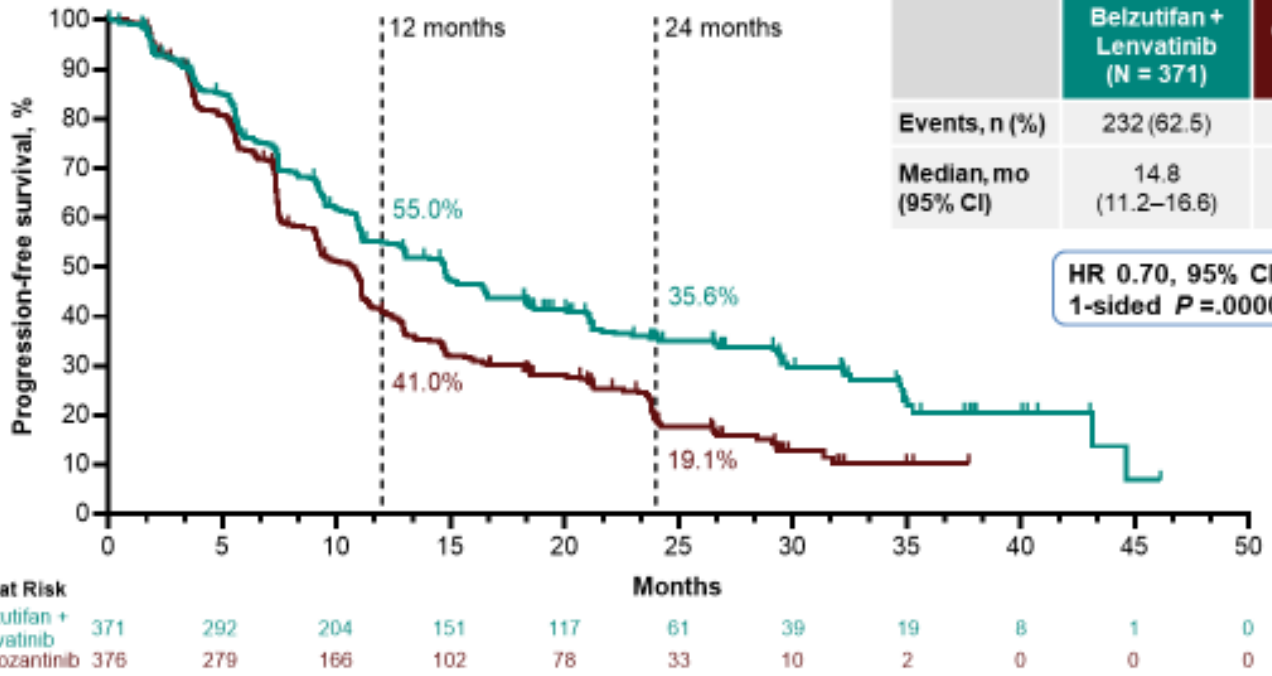
BICR, blinded independent central review; QD, daily.
[a]Based on the number of present risk factors (KPS score <80%; time from diagnosis to 1L treatment <1 year; low hemoglobin; high corrected serum calcium; high neutrophils; high levels of platelets) according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC).

Baseline Characteristics

Characteristic, n (%)	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Median age (range), years	63.0 (30–85)	62.5 (30–86)
Sex		
Male	273 (73.6)	292 (77.7)
Female	98 (26.4)	84 (22.3)
KPS score		
90 or 100	276 (74.4)	277 (73.7)
70 or 80	95 (25.6)	99 (26.3)
Geographic region		
North America	64 (17.3)	63 (16.8)
Western Europe	221 (59.6)	216 (57.4)
Rest of world	86 (23.2)	97 (25.8)
IMDC prognostic risk categories		
Favorable (score 0)	84 (22.6)	95 (25.3)
Intermediate (score 1-2)	226 (60.9)	215 (57.2)
Poor (score 3-6)	61 (16.4)	66 (17.6)
Prior lines of therapy		
Adjuvant only	15 (4.0)	18 (4.8)
1	252 (67.9)	251 (66.8)
2	100 (27.0)	107 (28.5)
3	4 (1.1)	0
Number of prior VEGFR-TKIs		
0	158 (42.6)	165 (43.9)
1	203 (54.7)	205 (54.5)
2	10 (2.7)	6 (1.6)

Data cutoff date, IA2: 9 April 2025

Primary Endpoint: PFS per RECIST 1.1 by BICR



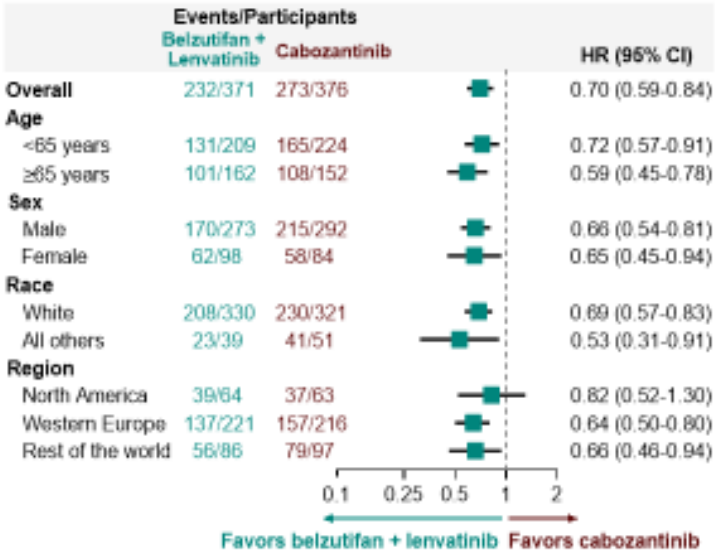
	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Events, n (%)	232 (62.5)	273 (72.6)
Median, mo (95% CI)	14.8 (11.2–16.6)	10.7 (9.2–11.1)

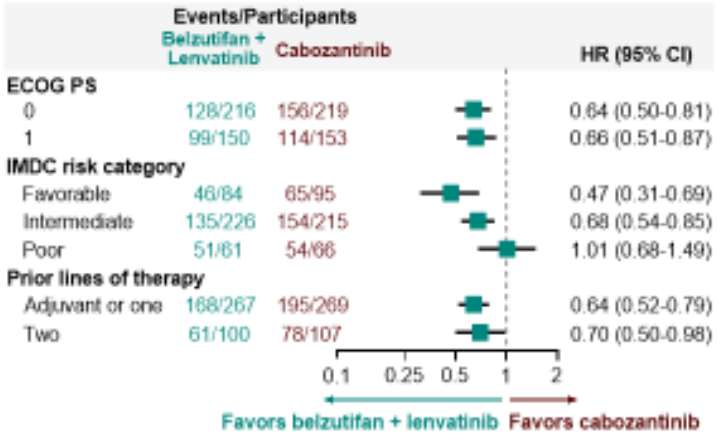
HR 0.70, 95% CI 0.59–0.84, 1-sided *P* =.00007*

* denotes statistical significance (1-sided boundary 0.0047).

Data cutoff date, IA2: 9 April 2025

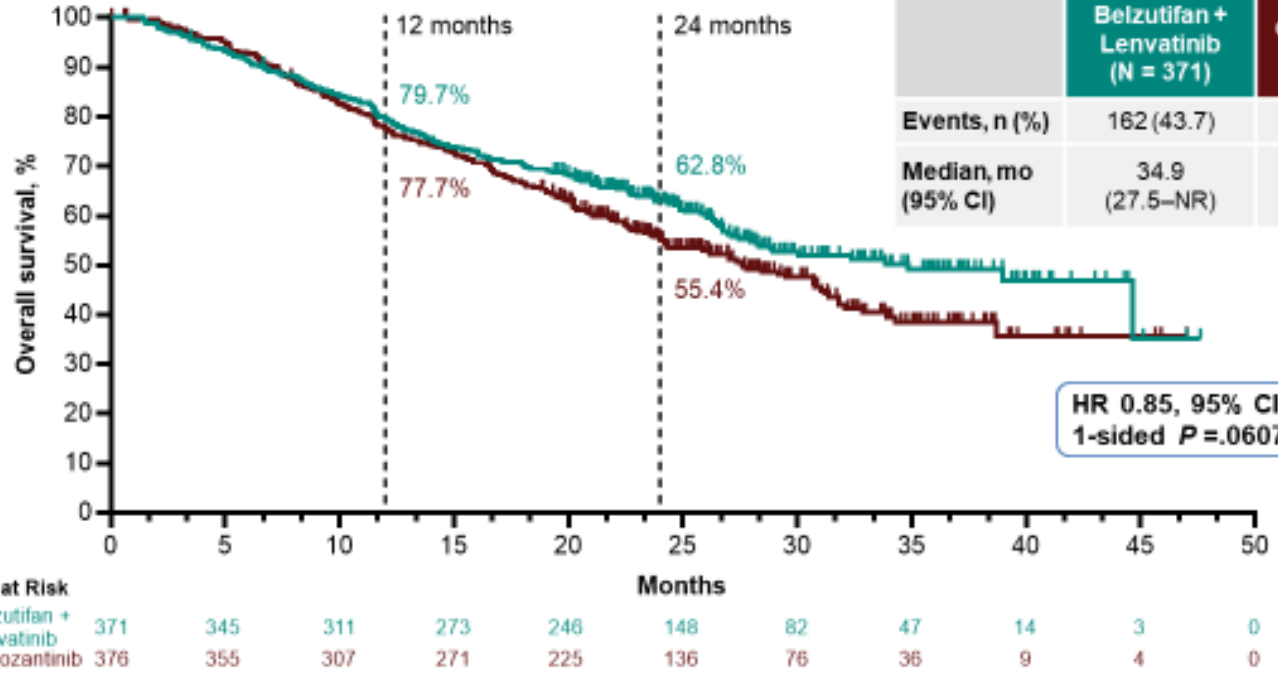
PFS by BICR in Key Subgroups





Data cutoff date, IA2: 9 April 2025

Primary Endpoint: OS



	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Events, n (%)	162 (43.7)	192 (51.1)
Median, mo (95% CI)	34.9 (27.5–NR)	27.6 (24.0–31.4)

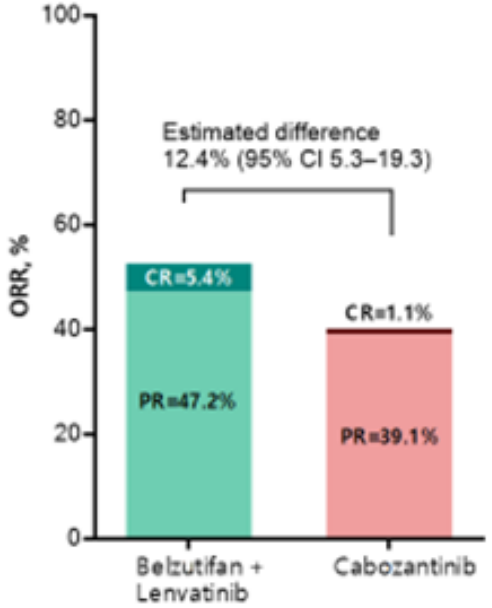
HR 0.85, 95% CI 0.68–1.05,
1-sided *P* =.06075

NR, not reached. OS did not reach statistical significance (1-sided boundary 0.0115).

Data cutoff date, IA2: 9 April 2025

Key Secondary Endpoint: ORR per RECIST 1.1 by BICR

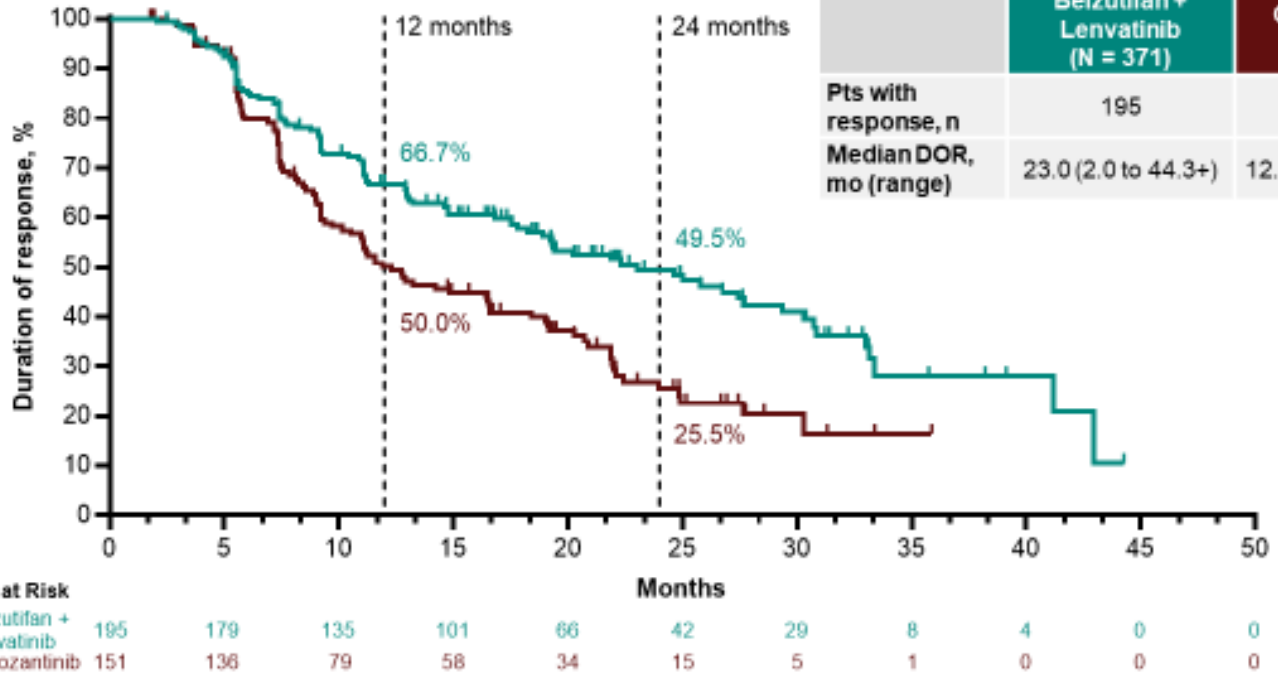
	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
ORR, % (95% CI)	52.6 (47.3–57.7)	40.2 (35.2–45.3)
Estimated difference, % (95% CI)	12.4 (5.3–19.3)[a]	
Best overall response		
CR	20 (5.4)	4 (1.1)
PR	175 (47.2)	147 (39.1)
SD	143 (38.5)	186 (49.5)
PD	21 (5.7)	22 (5.9)
Not evaluable[b]	4 (1.1)	7 (1.9)
No assessment[c]	8 (2.2)	10 (2.7)



[a]ORR not tested again at IA2, and was statistically significant at IA1 (52.6% vs 39.6%; 1-sided *P*=.0002).
[b]Including pts with insufficient data for response assessment or no evidence of disease by BICR per RECIST 1.1.
[c]Including pts without post-baseline assessment by the data cutoff date.

Data cutoff date, IA2: 9 April 2025

Secondary Endpoint: DOR per RECIST 1.1 by BICR



	Belzutifan + Lenvatinib (N = 371)	Cabozantinib (N = 376)
Pts with response, n	195	151
Median DOR, mo (range)	23.0 (2.0 to 44.3+)	12.3 (1.8+ to 35.9+)

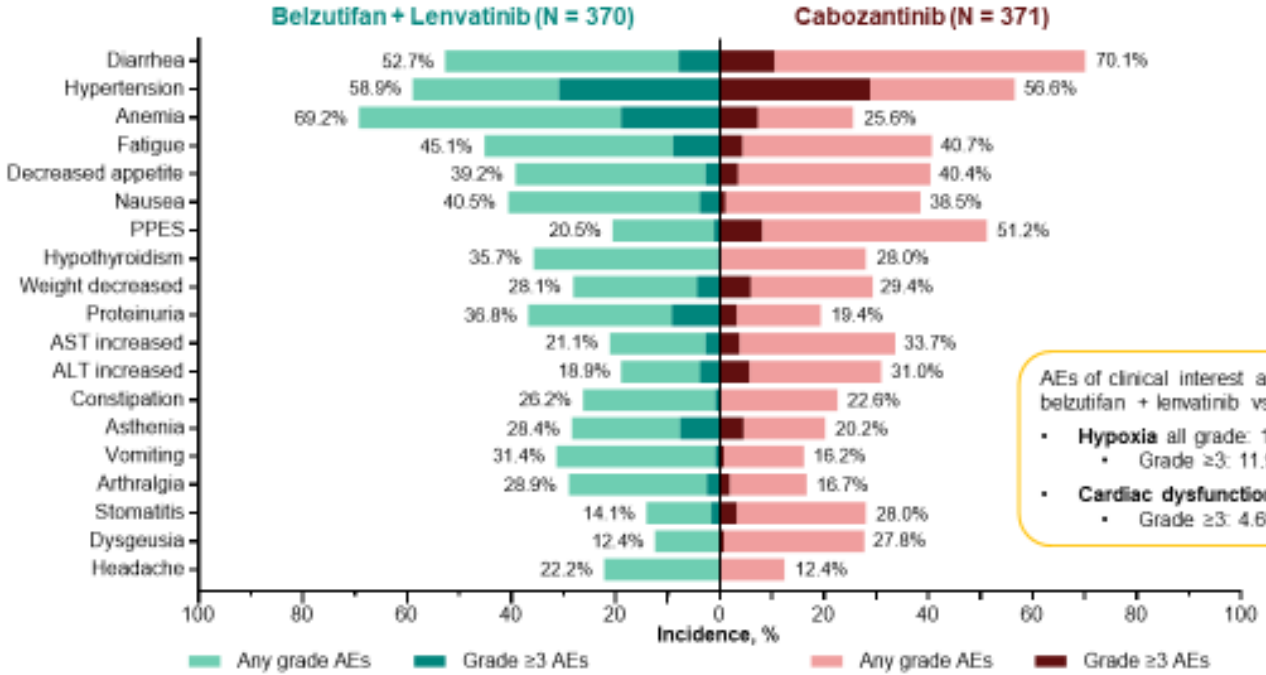
No. at Risk											
Belzutifan + Lenvatinib	195	179	135	101	66	42	29	8	4	0	0
Cabozantinib	151	136	79	58	34	15	5	1	0	0	0

DOR, duration of response.

Data cutoff date, IA2: 9 April 2025

Common Treatment-Emergent AEs[a]

Incidence ≥20% in Any Arm



AEs of clinical interest and incidence <20% with belzutifan + lenvatinib vs cabozantinib included:

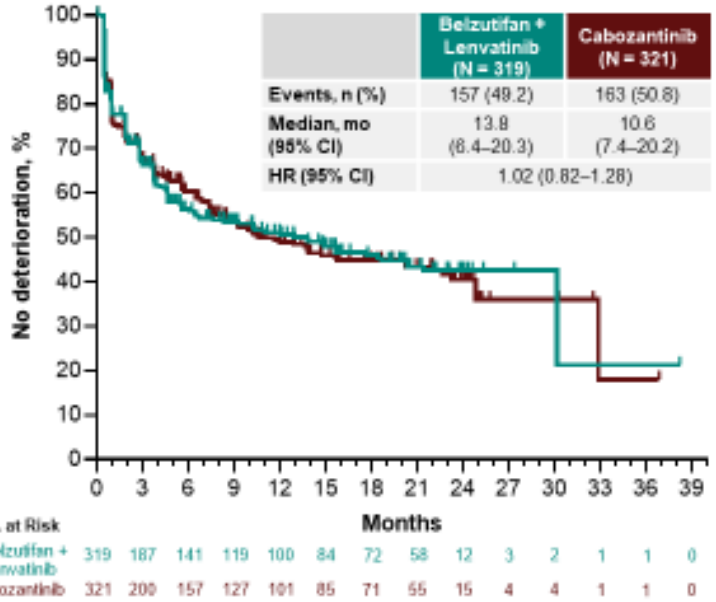
- **Hypoxia** all grade: 15.4% vs 0%
  - Grade ≥3: 11.9% vs 0%
- **Cardiac dysfunction** all grade: 7.0% vs 1.1%
  - Grade ≥3: 4.6% vs 0.5%

ALT, alanine aminotransferase; AST, aspartate aminotransferase; PPES, palmar-plantar erythrodysesthesia syndrome.
[a]Collected up to 30 days after cessation of study treatment.

Data cutoff date, IA2: 9 April 2025

Exploratory Endpoint: Time to Deterioration in Patient-Reported Outcomes

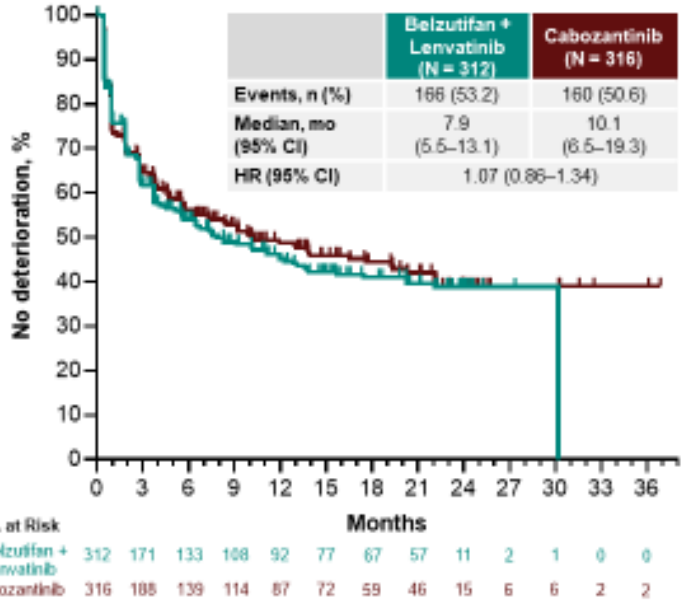
FKSI-DRS



	Belzutifan + Lenvatinib (N = 319)	Cabozantinib (N = 321)
Events, n (%)	157 (49.2)	163 (50.8)
Median, mo (95% CI)	13.8 (8.4–20.3)	10.6 (7.4–20.2)
HR (95% CI)	1.02 (0.82–1.28)	

No. at Risk														
Belzutifan + Lenvatinib	319	187	141	119	100	84	72	58	12	3	2	1	1	0
Cabozantinib	321	200	157	127	101	85	71	55	15	4	4	1	1	0

EORTC QLQ-C30 GHS/QOL



	Belzutifan + Lenvatinib (N = 312)	Cabozantinib (N = 316)
Events, n (%)	166 (53.2)	160 (50.6)
Median, mo (95% CI)	7.9 (5.5–13.1)	10.1 (6.5–19.3)
HR (95% CI)	1.07 (0.86–1.34)	

No. at Risk														
Belzutifan + Lenvatinib	312	171	133	108	92	77	67	57	11	2	1	0	0	
Cabozantinib	316	188	139	114	87	72	59	46	15	6	6	2	2	

Time to confirmed deterioration defined as time from baseline to first onset of ≥3 points for FKSI-DRS or ≥10 points for GHS/QOL with confirmation of the deterioration at the subsequent visit.
EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire; FKSI-DRS, Functional Assessment of Cancer Therapy Kidney Symptom Index – Disease-Related Symptoms; GHS, global health status; QOL, quality of life. Data cutoff date, IA2: 9 April 2025

Summary and Conclusions

- Belzutifan + lenvatinib demonstrated superior PFS and ORR vs cabozantinib in participants with advanced clear cell RCC following anti–PD-(L)1 therapy
- OS favored belzutifan + lenvatinib but did not reach statistical significance and will be tested further at final analysis
- The safety profile of belzutifan + lenvatinib was generally consistent with the profiles of the individual drugs
- Time to worsening in disease-specific symptoms and quality of life were similar between belzutifan + lenvatinib vs cabozantinib
- LITESPARK-011 is the first phase 3 study of a HIF-2α inhibitor plus a VEGFR-TKI, and the first phase 3 study in RCC in the post–PD-(L)1 setting to show improved outcomes vs a contemporary VEGFR-TKI
- Belzutifan + lenvatinib addresses an unmet clinical need and represents a potential new treatment option for patients with RCC that progressed after anti–PD-(L)1 therapy

ASCO Genitourinary Cancers Symposium

CYTOSHRINK: A Randomized Phase II trial of Cytoreductive Stereotactic Hypofractionated Radiotherapy with Ipilimumab/Nivolumab for Metastatic Kidney Cancer

Aly-Khan A. Lalani[1], Gregory R. Pond[2], Shankar Siva[3], William Chu[4], Darin Gopaul[5], Scott Morgan[6], Naveen S. Basappa[7], Eric Winquist[8], Michael Bonert[9], Jonathan Bramson[10], Michael Surette[11], Arun Azad[3], Lavinia Spain[3], Georg Bjarnason[12], Dominick Bossé[6], Mark Levine[2], Jim Wright[2], Sebastien J. Hotte[1], Anand Swaminath[1]

[1]Juravinski Cancer Centre, McMaster University, Hamilton ON; [2]Ontario Clinical Oncology Group, McMaster University, Hamilton ON; [3]Peter MacCallum Cancer Centre, Melbourne AUS; [4]Durham Regional Cancer Centre, Oshawa ON; [5]Grand River Hospital, Kitchener ON; [6]The Ottawa Hospital Cancer Centre, Ottawa ON; [7]Cross Cancer Institute, Edmonton AB; [9]Verspeeten Family Cancer Centre, London ON; [9]St. Joseph's Healthcare, Hamilton ON; [10]McMaster Immunology Research Center, Hamilton ON; [11]Farncombe Family Digestive Health Research Institute, Hamilton ON; [12]Odette Cancer Centre, Toronto ON

Abstract #416

Hypotheses

1. SBRT to the primary kidney mass will enhance the efficacy of Nivo/Ipi and provide a safe upfront primary cytoreductive treatment

2. SBRT + Nivo/Ipi will lead to upregulation of key components of immune modulation as well as unique perturbation of the host microbiome

Phase II CYTOSHRINK study design (NCT04090710)

POPULATION INCLUDED:
1. Biopsy proven untreated aRCC
2. IMDC Intermediate or poor risk
3. Primary kidney lesion amenable to SBRT (up to 20 cm)
4. Eligible for Nivolumab / Ipilimumab

STRATIFICATION FACTORS:
IMDC intermediate (1-2) vs poor (3-6) prognostic groups

RANDOMIZATION

2:1

Experimental arm:
Cycle 1 Nivolumab / Ipilimumab
↓
SBRT to primary kidney lesion (30-40 Gy in 5 fractions)
↓
Cycle 2-4 Nivolumab / Ipilimumab
Maintenance Nivolumab per standard of care

Control arm:
Cycle 1-4 Nivolumab / Ipilimumab
Maintenance Nivolumab per standard of care

Primary Outcome:
1-year PFS

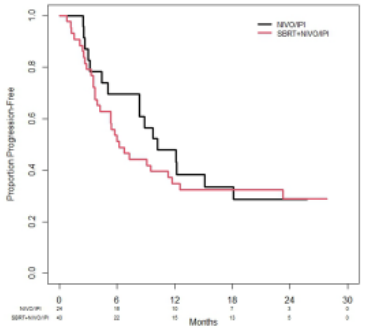
Secondary outcomes:
Safety
Objective response rate (ORR)
Overall Survival (OS)
Health-related Quality of Life (QOL)

Correlative analyses:
Baseline tissue biopsy
Blood immune signatures
Gut microbiome

Baseline Characteristics

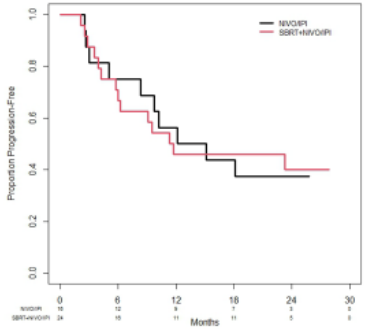
Characteristic, N (%)		Nivo / Ipi (N=24)	SBRT + Nivo / Ipi (N=43)
Study Centre	Canada	19 (79)	35 (81)
	Australia	5 (21)	8 (19)
IMDC Criteria	Intermediate 1-2	14 (58)	25 (58)
	Poor 3-6	10 (42)	18 (42)
Sex	N (%) Male	18 (75)	31 (72)
Age	Mean (sd)	66 (7.9)	62 (9.3)
Body-Mass Index	Median (range)	28 (18.3, 42.2)	28 (19.5, 51.6)
KPS	≥80	13 (75)	39 (91)
	<80	6 (25)	4 (9)
Histology	Clear Cell	21 (88)	39 (91)
T Stage	T1-T2	13 (54)	13 (30)
	T3-T4	11 (46)	30 (70)
Number of Measurable Lesions at Baseline	1	11 (46)	5 (12)
	2	4 (17)	14 (33)
	3	5 (21)	9 (21)
	≥4	4 (16)	15 (35)
Size of Largest Lesion, mm	Median (range)	87.5 (36, 158)	97 (36, 178)
Cumulative Size of Lesions, mm	Median (range)	116.5 (36, 385)	141 (36, 410)
Target Lesions	Left Kidney	13 (54)	25 (58)
	Right Kidney	14 (58)	19 (44)
	Lung/pulmonary	10 (42)	30 (70)
	Bone/Skeletal	0 (0)	4 (9)
	Liver	2 (8)	10 (23)
	LN – short axis	7 (29)	14 (33)
	Muscle/connective tissue	0 (0)	1 (2)
	Pancreas	1 (4)	2 (5)
	Other	5 (21)	22 (51)

PFS in the ITT population



	Nivo / Ipi N=24	SBRT + Nivo / Ipi N=43
Events, n (%)	16 (66.7)	30 (69.8)
Median, mo (95% CI)	10.2 (5.1-18.1)	6.3 (3.9-11.7)
1-year PFS, % (95% CI)	47.8 (26.8-66.1)	34.9 (21.2-48.9)
HR 1.20 (95% CI 0.65-2.21), p-value=0.56		

PFS in PP population (4 cycles of Nivo / Ipi)



	Nivo / Ipi N=16	SBRT + Nivo / Ipi N=24
Events, n (%)	10 (62.5)	14 (58.3)
Median, mo (95% CI)	13.7 (5.1-NR)	11.5 (5.8-NR)
1-year PFS, % (95% CI)	56.3 (29.5-76.2)	45.8 (25.6-64.0)
HR 1.07 (95% CI 0.46-2.45), p-value=0.88		

Summary and next steps

- CYTOSHRINK is the first randomized trial testing the addition of early cytoreductive SBRT to first-line Nivo/Ipi for *de novo* aRCC patients
- 12-month PFS was not improved compared to Nivo/Ipi alone, though there were notable baseline imbalances
- The addition of SBRT to Nivo/Ipi was safe with no new safety signals noted
- Further follow up of OS, QOL, as well as correlative biomarker analyses (baseline tissue, serial blood and gut microbiome samples) are ongoing

- CR LOCALIZADO:
  - LITESPARK 022
  - PROS RAMPART TRIAL
- CR AVANZADO:
  - LITESPARK 011
  - CYTOSHRINK
- BIOMARCADORES:
  - The K-COMPASS model
  - MONSTAR-SCREEN-3
- CR NO CELULAS CLARAS
- POSTERS

ASCO Genitourinary Cancers Symposium

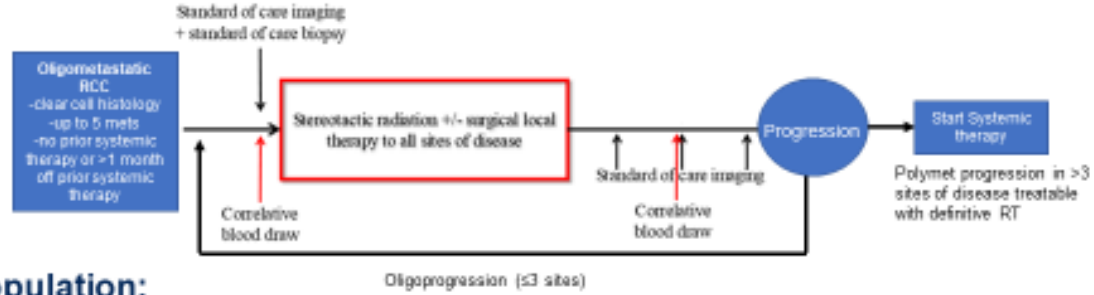
Circulating KIM-1 and ctDNA as prognostic markers in oligometastatic clear cell renal cell carcinoma (ccRCC): The K-COMPASS model

Chad Tang, Aaron Seo, Alex D Sherry, Peng Yang, Kieko Hara, Kanishka Sircar, Giannicola Genovese, Eric Jonasch, Amishi Y Shah, Sarah Ratzel, Ashley Acevedo, Christopher J Battey, Clara Steiner, Liliana Ascione, Xiaowen Liu, Nizar Tannir, Toni K Choueiri, Pavlos Msaouel, Wenxin Xu

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

Dana-Farber Cancer Institute

Methods



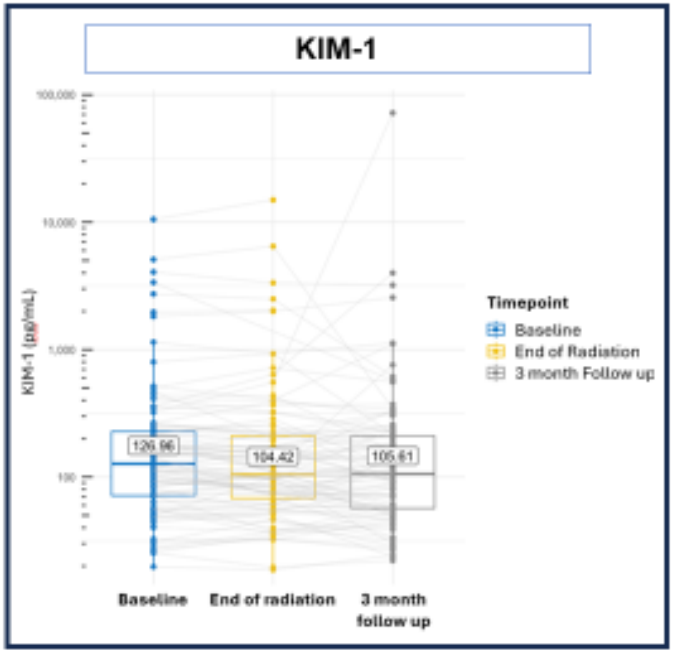
Patient Population:

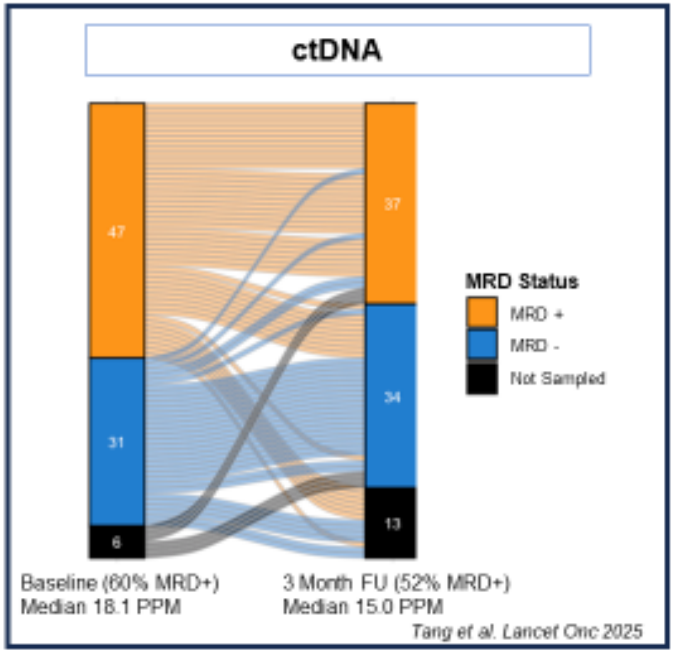
- Phase II trial investigating metastasis directed radiation therapy without systemic therapy (*Tang et al. Lancet Onc 2025* and *Tang et al. Lancet Onc 2021*)
- 112/120 (93%) had **KIM-1** and 89/120 (74%) had **ctDNA**

Assays

- ELISA-based assay to measure plasma **KIM-1** protein levels
- Customized **ctDNA** panels of ≤2000 somatic variants from WGS (Precise MRD, Myriad Genetics)

Baseline KIM-1 and ctDNA

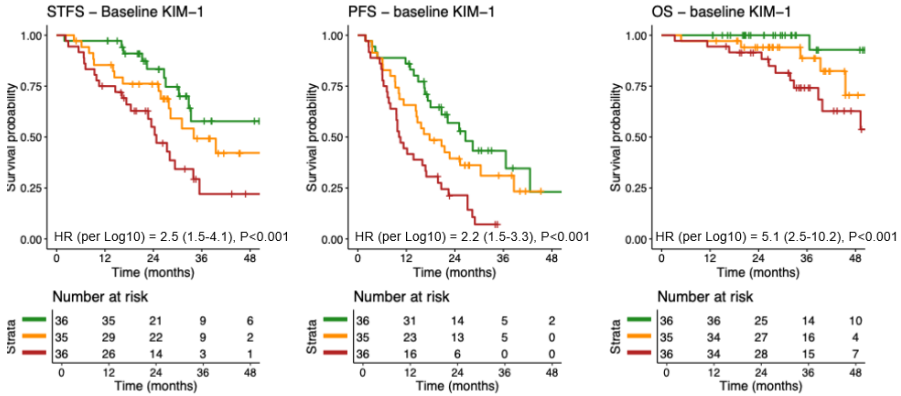




Systemic Therapy Free Survival– Baseline KIM-1 and ctDNA

Parameter	Baseline		3-Month Follow-Up	
	Univariable	**Multivariable**	Univariable	**Multivariable**
KIM-1 (per log10[pg/mL])	2.5 (1.5–4.1) P<0.001	**1.9 (1.0–3.6)** **P=0.041**	3.22 (1.91–5.43) P<0.001	**2.22 (1.09–4.51)** **P=0.03**
ctDNA (MRD+ vs MRD–)	2.8 (1.3–5.9) P=0.0089	**2.47 (1.1–5.6)** **P=0.03**	4.42 (2.09–9.50), P<0.001	**2.70 (1.09–6.67)** **P=0.03**

Baseline KIM-1 and outcomes



K-COMPASS model

- Elastic net-penalized Cox regression selected top 6 out of 21 variables
- Final K-COMPASS consisted of 6 variables fit with Weibull regression
- K-COMPASS exhibited strong discrimination for STFS (C-index 0.76) and outperformed the 4 variable clinical model (C-index 0.66)

		Parameters	Selection frequency
Clinical Model	K-COMPASS Model	KIM-1 (per log10[pg/mL])	100%
		ctDNA MRD (MRD+ vs MRD-)	100%
		Prior lines of systemic therapy at baseline (per line)	100%
		ECOG score (per 1 point)	66%
		Number of metastatic lesions at baseline (per 1 lesion)	66%
		Time from diagnosis to metastasis (per 1 month)	55%

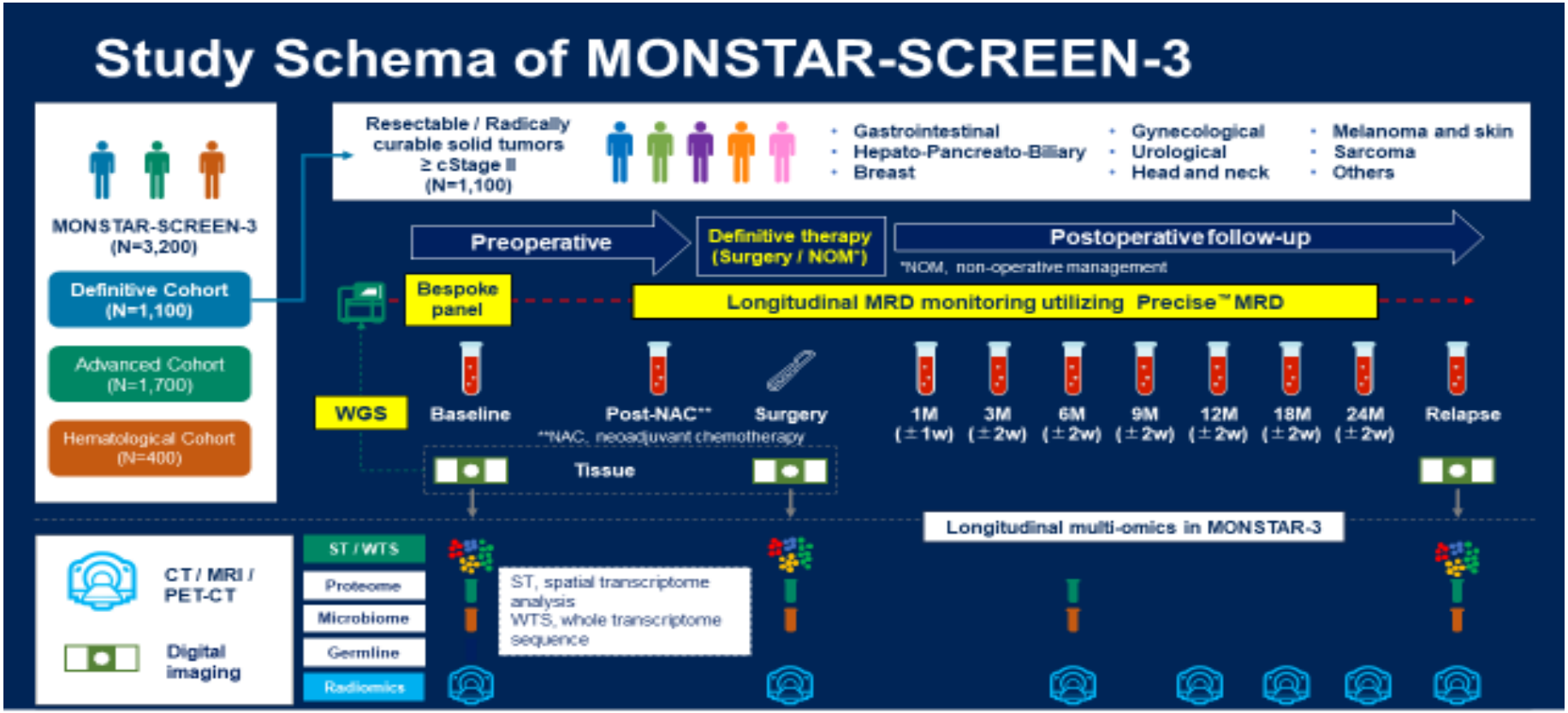
ASCO Genitourinary Cancers Symposium

Ultra-Sensitive Whole-Genome Sequencing-Based Molecular Residual Disease Detection in Resectable Renal Cell Carcinoma: Preliminary Results from the MONSTAR-SCREEN-3 Study

Taigo Kato, MD, PhD

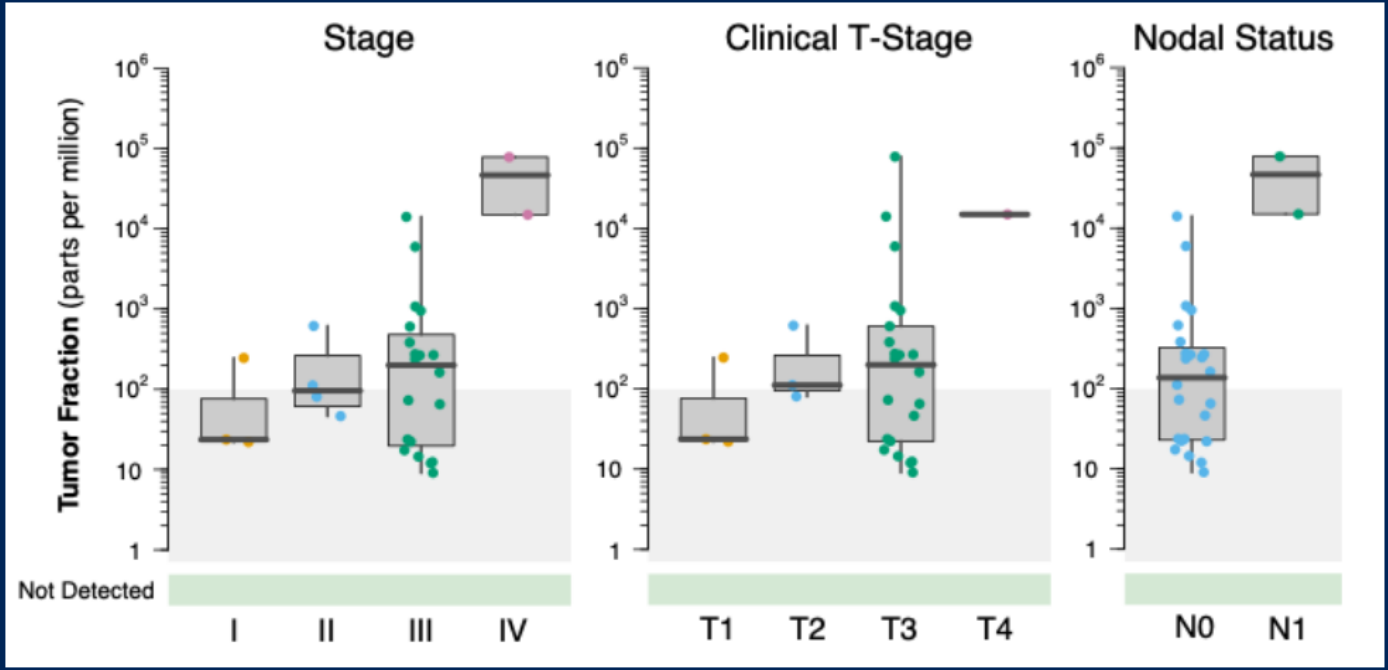
The University of Osaka Graduate School of Medicine, Osaka, Japan

Shugo Yajima, Masaki Shiota, Takahiro Osawa, Takahiro Kojima, Yujiro Hayashi, Nobuyuki Tanaka, Mototsugu Oya, Masashi Nakayama, Takashige Abe, Masatoshi Eto, Hitoshi Masuda, Jeff Jasper, Dale Muzzey, Katie Johansen Taber, Tadayoshi Hashimoto, Shin Kobayashi, Eiji Oki, Takayuki Yoshino, Norio Nonomura


Study Schema of MONSTAR-SCREEN-3
MONSTAR-SCREEN-3
(N=3,200)
Definitive Cohort
(N=1,100)
Advanced Cohort
(N=1,700)
Hematological Cohort
(N=400)
Resectable / Radically curable solid tumors
≥ cStage II
(N=1,100)
Gastrointestinal
Hepato-Pancreato-Biliary
Breast
Gynecological
Urological
Head and neck
Melanoma and skin
Sarcoma
Others
Preoperative
Definitive therapy (Surgery / NOM*)
Postoperative follow-up
*NOM, non-operative management
Bespoke panel
Longitudinal MRD monitoring utilizing Precise™ MRD
WGS
Baseline
Post-NAC**
Surgery
**NAC, neoadjuvant chemotherapy
1M (±1w)
3M (±2w)
6M (±2w)
9M (±2w)
12M (±2w)
18M (±2w)
24M (±2w)
Relapse
Tissue
Longitudinal multi-omics in MONSTAR-3
CT / MRI / PET-CT
Digital imaging
ST / WTS
Proteome
Microbiome
Germline
Radiomics
ST, spatial transcriptome analysis
WTS, whole transcriptome sequence

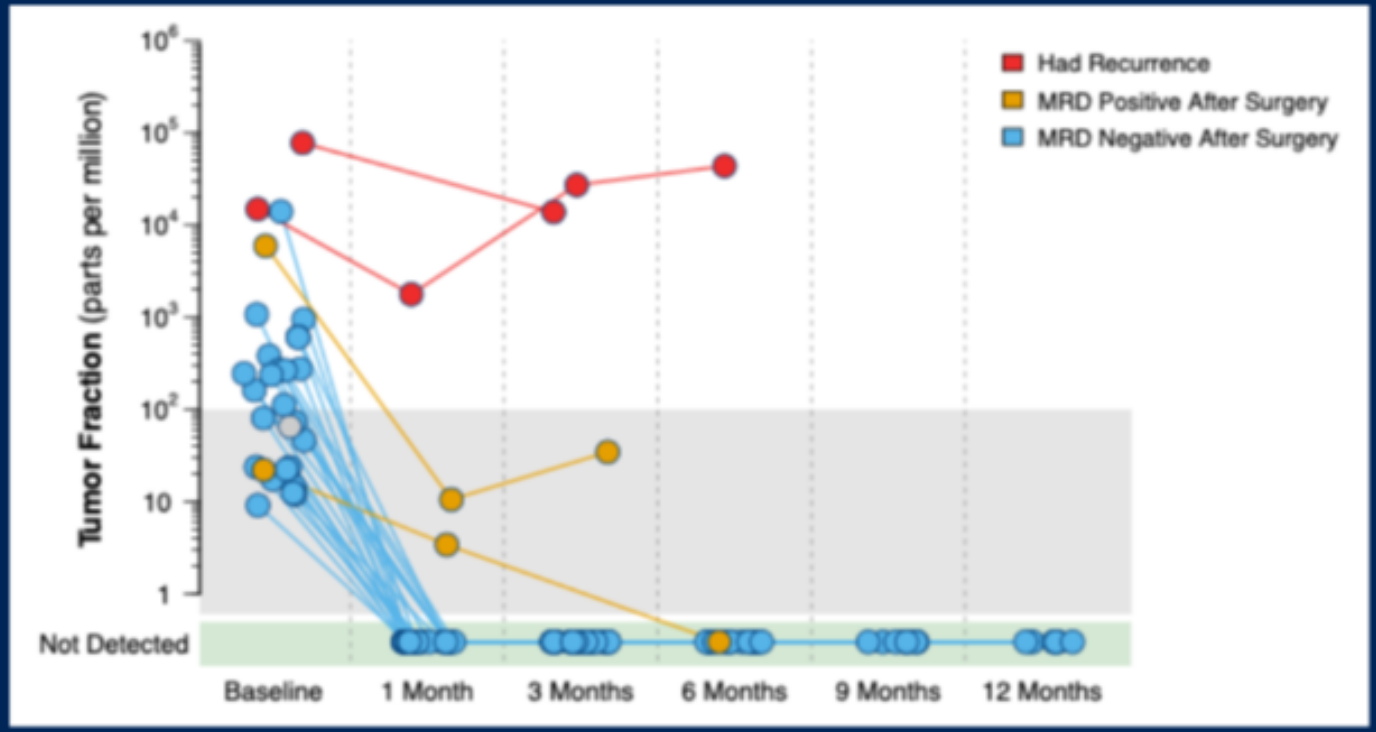
Baseline ctDNA tumor fraction

- 100% baseline detection (range 9.1- 78,177 PPM), 13/29 in the ultra-sensitive range <100 PPM
- ctDNA levels was associated with stage, size, and nodal status



ctDNA stratifies patients at risk of recurrence

- 25 patients became MRD negative after surgery and have remained negative
- 4 patients were MRD positive after surgery and 2 have recurred clinically



Conclusions

- MONSTAR-SCREEN-3 successfully implemented tumor informed WGS-based ctDNA assay for MRD detection across a diverse spectrum of tumor types, including renal cell carcinoma.
- We demonstrated robust detection capabilities with 100% baseline sensitivity and 11.1% MRD positivity at 1-month post-surgery, with 50.0% of positive cases detected at ultra-sensitive levels.
- Patients with recurrence had persistently ctDNA-positive after the radical surgery. We will carefully follow up patients with ctDNA-positive at ultra-sensitive levels.
- ctDNA levels were associated with stage, size, and nodal status.
- Additional validation with extended follow-up and an expanded cohort is necessary to confirm these promising initial findings.

- CR LOCALIZADO:
  - LITESPARK 022
  - PROS RAMPART TRIAL
- CR AVANZADO:
  - LITESPARK 011
  - CYTOSHRINK
- BIOMARCADORES:
  - The K-COMPASS model
  - MONSTAR-SCREEN-3
- CR NO CELULAS CLARAS
- POSTERS

Real World Comparative Effectiveness of First-line Cabozantinib versus Cabozantinib with Nivolumab in Patients with Metastatic Papillary Renal Cell Carcinoma

Micah Ostrowski MD[1], Yeonjung Jo PhD[2], Georges Gebrael MD[1], Zeynep Irem Ozay MD[1], Roberto Nussenzveig, PhD[1], Chadi Hage Chehade MD[1], Krishnam Goel[1], Patrick Campbell MD[1], Tanner Hardy MD[1], Gabriel Hooper MD[1], Haoran Li MD, PhD[3], Vinay Mathew Thomas MD[1], Benjamin L. Maughan MD, PharmD[1], Umang Swami MD, MS[1], Neeraj Agarwal MD, FASCO[1]

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Abstract #461

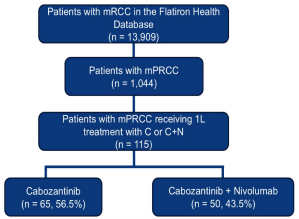
Introduction

- Papillary renal cell carcinoma is the most common non-clear cell renal cell carcinoma.
- Standard of care options for metastatic papillary renal cell carcinoma (mPRCC) include both cabozantinib (C) and cabozantinib with nivolumab (C+N) (NCCN Guidelines V1.2026) due to a lack of randomized clinical trial results in this setting and are currently being investigated in PAPMET2 (NCT05411081).
- Real world data comparing C and C+N in patients with mPRCC are lacking.
- This study aims to evaluate the comparative effectiveness of first line (1L) C versus C+N in patients with mPRCC using a large, real-world database.

Methods

- This is an IRB approved retrospective study using the US-based, electronic health record-derived deidentified Flatiron Health Research Database.
- Eligibility: patients with mPRCC who received 1L treatment with C+N or C monotherapy from 04/29/2017-07/16/2024. Patients were classified into two groups based on treatment with C+N or C.
- Endpoints: real-world overall survival (rwOS) and real-world time to next therapy (rwTTNT), summarized via Kaplan-Meier survival estimates and their 95% confidence intervals (CIs) and compared in the context of propensity score (PS) matching weighted analysis with the Cox proportional hazard model.
- The PS was constructed using logistic regression with the baseline covariates: age, race-ethnicity, gender, region, socioeconomic status, practice type, insurance, smoking status, prior nephrectomy, IMDC risk score, and 1L start year.

Study Population



Results

Table 1. Baseline characteristics of patients receiving C and patients receiving C+N.

Baseline Characteristics	C (n=65)	C+N (n=50)	SMD before PS	SMD after PS
Age, median (IQR), years	69 (63-77)	69 (58.75-73)	0.216	0.076
Race-Ethnicity, n (%)			0.32	0.052
Asian non-Hispanic	0 (0)	1 (2.0)		
Black non-Hispanic	11 (16.9)	11 (22.0)		
Hispanic-Latino	1 (1.5)	1 (2.0)		
White non-Hispanic	40 (61.5)	30 (60.0)		
Other	4 (6.2)	1 (2.0)		
Unknown	9 (13.8)	6 (12.0)		
Gender, n (%)			0.157	0.009
Male	50 (76.9)	35 (70.0)		
Female	15 (23.1)	15 (30.0)		
Region, n (%)			0.364	0.036
Northeast	5 (7.7)	7 (14.0)		
Midwest	7 (10.8)	3 (6.0)		
South	26 (40.0)	23 (46.0)		
West	3 (4.6)	4 (8.0)		
Unknown	24 (36.9)	13 (26.0)		
SES Quintile, n (%)			0.489	0.073
1	9 (13.8)	11 (22.0)		
2	11 (16.9)	4 (8.0)		
3	10 (15.4)	7 (14.0)		
4	15 (23.1)	13 (26.0)		
5	10 (15.4)	12 (24.0)		
Unknown	10 (15.4)	3 (6.0)		
Practice Type, n (%)			0.57	0.009
Academic	16 (24.6)	13 (26.0)		
Community	40 (61.5)	37 (74.0)		
Unknown	9 (13.8)	0 (0)		
Insurance, n (%)			0.371	0.029
Commercial Health plan	43 (66.2)	34 (68.0)		
Medicare/Other Governmental Program	16 (24.6)	8 (16.0)		
Medicaid	2 (3.1)	1 (2.0)		
Others	1 (1.5)	4 (8.0)		
Unknown	3 (4.6)	3 (6.0)		
Smoking Status, n (%)			0.043	0.078
No history of smoking	30 (46.2)	22 (44.0)		
History of smoking	35 (53.8)	28 (56.0)		
Prior Nephrectomy, n (%)			0.283	0.029
Yes	44 (67.7)	27 (54.0)		
No	21 (32.3)	23 (46.0)		
IMDC Risk Group, n (%)			0.381	0.082
Poor/Intermediate Risk	46 (70.8)	41 (82.0)		
Favorable Risk	2 (3.1)	3 (6.0)		
Unknown	17 (26.2)	6 (12.0)		
First line start year centered median, n (IQR)	0 [-1.00-1.00]	0 [-1.00-0.92]	0.904	0.003

* SMD = Standardized mean difference

Figure 1. Kaplan Meier Estimates of real-world time to next treatment (rwTTNT) from first-line therapy after propensity score matching weighting.

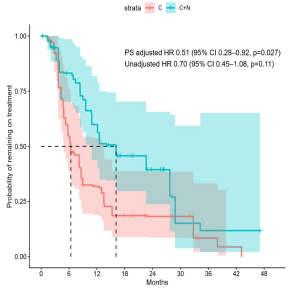


Figure 2. Kaplan Meier Estimates of real-world overall survival (rwOS) from first-line therapy after propensity score matching weighting.

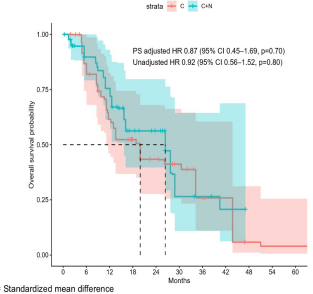


Table 2. Median rwTTNT, Median rwOS, and hazard ratio (HR) of patients treated with 1L C and C+N both before and after propensity score matching weighting.

	C	C+N	HR (95% CI)	p value
rwTTNT	6.4 mo	11 mo	0.70 (0.45 – 1.08)	0.11
rwTTNT after PS matching weighting	6.4 mo	16 mo	0.51 (0.28 – 0.92)	0.027
rwOS	19 mo	27 mo	0.92 (0.56 – 1.52)	0.8
rwOS after PS matching weighting	20 mo	26 mo	0.87 (0.45 – 1.69)	0.7

Conclusion

- In this study of patients with mPRCC, following PS matching weighting analysis, first-line C+N was associated with improved rwTTNT as compared to C monotherapy. However, there was no evidence of significant difference in rwOS between both groups.
- These data support the need for randomized trials to validate these findings and may help inform clinicians in decision-making and patient counseling.

Limitations

- Retrospective nature of the study
- Data missingness in certain endpoints
- Lack of detailed pathologic information including the presence of sarcomatoid features

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Actualizaciones tras el Congreso Americano de Oncología Clínica GU

GONORTE Grupo Oncológico

Abstract 448: Real-world analysis of renal cell carcinoma with sarcomatoid differentiation treated with first-line immunotherapy: Results from the International mRCC Database Consortium (IMDC)

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Affiliations: 1. University of Calgary, Calgary, AB; 2. Arthur JE Child Comprehensive Cancer Centre, Calgary, AB; 3. Dana-Farber Cancer Institute, Boston, MA; 4. Barts Cancer Institute, London, England; 5. Asan Medical Center, Seoul, South Korea; 6. Hospital Universitario Marques de Valdecilla, Santander, Spain; 7. Claraspital Basel, Basel, Switzerland; 8. Hospital Universitario 12 de Octubre, Madrid, Spain; 9. Val d'Hebron Institute of Oncology, Barcelona, Spain; 10. University of Kansas Cancer Center, Kansas City, KS; 11. Canberra Hospital, Canberra, Garran, Australia; 12. Austin Hospital, Heidelburg, Australia; 13. UCSD Health Moores Cancer Center, San Diego, CA; 14. CancerCare Manitoba, Winnipeg, MB

Arthur J.E. Child Comprehensive Cancer Centre

imdc

Background

- Sarcomatoid renal cell carcinoma (sRCC) is an aggressive histologic subtype associated with poor prognosis and high unmet need.
- First-line immunotherapy combinations, including dual checkpoint blockade (nivolumab-ipilimumab) and immune-VEGF regiments are standard in metastatic RCC.
- Patients with poor-risk sarcomatoid differentiation are under-represented in trials, leading to unclear real-world comparative outcomes in intermediate and poor-risk sRCC.

Methods

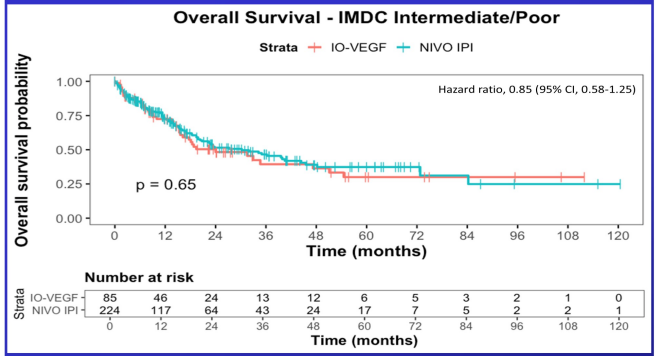
- Using the IMDC, we identified intermediate and poor-risk patients with sarcomatoid renal cell carcinoma treated with first-line immunotherapy combinations (either nivolumab - ipilimumab or immune-VEGF therapy).
- We evaluated:
  - Baseline clinical characteristics, Overall Survival (OS), Time to Next Treatment (TTNT), Treatment duration, and Overall Response Rate (ORR)
- Survival outcomes were estimated using Kaplan-Meier methods and compared using log-rank tests, with multivariable Cox regression adjusting for key prognostic factors.

Baseline Characteristics	Treatment Type		p value
	IO + VEGF (n=87)	Nivo + Ipi (n=250)	
Intermediate risk patients, n (%)	55 (63.20%)	142 (56.80%)	0.358
Poor risk patients, n (%)	32 (36.80%)	108 (43.20%)	
Median Age, n (standard deviation)	62.5	62.1	0.817
Sex (Male), n (%)	65 (74.71%)	187 (74.80%)	0.987
IMDC risk factors, n (%)			
KPS < 80%	16 (18.39%)	35 (14.00%)	0.325
TDTI <1 yr	76 (87.36%)	230 (92.00%)	0.197
Calcium level > ULN	12 (13.79%)	44 (17.60%)	0.411
Hemoglobin level < LLN	51 (58.62%)	169 (67.60%)	0.130
Platelet count > ULN	19 (21.84%)	56 (22.4%)	0.914
Neutrophil count > ULN	24 (27.59%)	64 (25.6%)	0.716
Sites of metastasis, n (%)			
Lung	58 (66.67%)	176 (71.26%)	0.422
Bone	28 (32.56%)	81 (32.53%)	0.996
Brain	8 (9.30%)	21 (8.50%)	0.821

Conclusions

In this real-world cohort of intermediate/poor-risk sRCC, we found:

- **Comparable overall survival and TTNT between IO-VEGF and nivolumab-ipilimumab**
- **Nearly identical overall response rate across regimens**
- **Performance status and bone metastases, rather than regimen choice, were the strongest predictors of outcomes**



Results

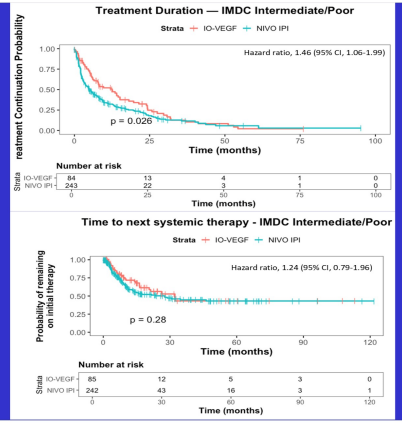
- **No statistically significant difference in OS** between IO-VEGF and nivolumab–ipilimumab; Log-rank p = 0.65; Adjusted Cox model: **HR 0.85 (95% CI 0.58-1.25), p = 0.40.** Median OS: **24.0 months (IO-VEGF)** vs **30.2 months (NIVO-IPI).**
- TTNT: log-rank p = 0.28; adjusted HR 1.24 (p = 0.35).
- Treatment duration: log-rank p = 0.026; adjusted **HR 1.46 (p = 0.019; time-varying).**
- ORR: ~49% in **both groups** (p = 1.00).
- Clear cell RCC: 70.6%
- Non-clear cell RCC: 23.7%

Key Prognostic Findings

- Bone metastases predicted worse outcomes: TTNT HR **2.05** (95% CI 1.39–3.03), **p < 0.001**; OS HR **2.03** (95% CI 1.42–2.90), **p < 0.001**
- KPS <80% was associated with worse OS (HR **1.70**, p = 0.022)

Future Directions:

- Develop risk-adapted first-line strategies for sRCC patients with bone metastases.
- Incorporate metastatic burden and functional status into trial stratification and treatment selection



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PREDICTING CLEAR CELL SUBTYPE FOR KIDNEY TUMORS FROM CROSS-SECTIONAL IMAGING USING ARTIFICIAL INTELLIGENCE

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Cleveland Clinic

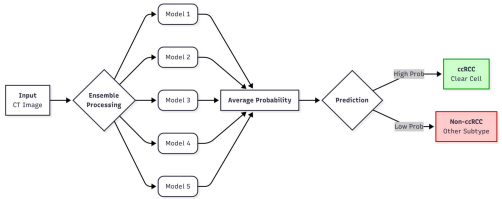
AIM–HI Lab

Artificial Intelligence in Medicine and Health Imaging

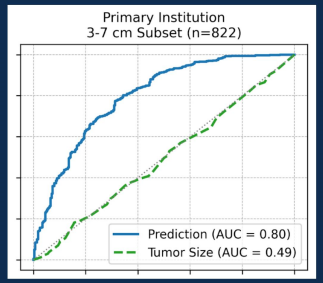
Background

Clear cell renal cell carcinoma (ccRCC) is the most common subtype of kidney cancer, yet the specific diagnosis is typically unknown prior to surgery.
While **renal mass biopsy** can aid diagnosis, it suffers from imperfect performance due to tumor heterogeneity and is invasive.
We sought to determine if **artificial intelligence (AI)** could predict the clear cell subtype directly from standard **preoperative CT imaging**.
A specific focus was placed on **3-7 cm tumors**, a clinical "grey zone" where decision-making between surveillance and surgery is often difficult.

Methods



We retrospectively reviewed **1,642 patients** from a primary institution and **536 patients** from an external validation cohort.
A **ResNet-50 convolutional neural network** was fine-tuned to predict the presence of clear cell histology.
To ensure robustness, we utilized **5-fold cross-validation** and an **ensemble of 5 models** for the external predictions.
We compared the AI model's performance against **tumor size alone**, utilizing DeLong's tests to assess statistical significance.



Computer-vision based models can predict clear cell subtype for renal tumors from cross-sectional imaging

This may be especially useful in small-to-medium size lesions where diagnostic uncertainty is highest

Results

		Number ccRCC	Model AUC	Tumor Size AUC	p (ΔAUC)
Primary Institution	Whole Cohort (n=1642)	1004	**0.71**	0.54	**6.6e-21**
	3-7cm Cohort (n=822)	534	**0.80**	0.49	**1.2e-26**
External Validation	Whole Cohort (n=536)	349	**0.56**	0.53	0.43
	3-7cm Cohort (n=237)	160	**0.59**	0.44	**0.009**

In the **primary cohort**, the AI model achieved an **AUC of 0.71**, significantly outperforming tumor size (AUC 0.54, p<0.001).
The model was most effective in the **3-7 cm subset**, achieving a strong **AUC of 0.80** compared to a random **AUC of 0.49** for tumor size.
In the **external validation cohort**, the model successfully outperformed tumor size in the **3-7 cm subset** (AUC 0.59 vs 0.44, p=0.009).
While generalization remains a challenge in the whole external cohort, the **significant improvement** in the 3-7 cm group highlights the model's potential utility in indeterminate masses.

Future Directions

We aim to improve **generalizability** across institutions to address the performance drop seen in the whole external cohort.

Future iterations will attempt to classify **specific non-ccRCC subtypes** (e.g., papillary, chromophobe) rather than grouping them together.

Abstract #440: Comparative efficacy of immune checkpoint inhibitor combination therapies by metastatic site in metastatic renal cell carcinoma.

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1.Department of Urology, Kindai University School of Medicine, 2. Department of Urology, Jikei University School of Medicine, 3.Department of Urology,Osaka Medical and Pharmaceutical University, 4.Department of Urology,Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, 5.Department of Urology, Fujita-Health University School of Medicine, 6.Department of Urology, Kawasaki University School of Medicine, 7.Department of Urology, Hamamatsu University School of Medicine.

Background

Previous evidence suggests that treatment efficacy may vary by metastatic organ site. For instance, an extended analysis of the CheckMate 9ER trial demonstrated organ-specific differences in target lesion responses with nivolumab plus cabozantinib compared with sunitinib [Powles, T. et al. *J. Clin. Oncol.* 2022]..Nevertheless, the prognostic implications of organ-specific metastases and the comparative efficacy of IO–IO versus IO–TKI therapy remain insufficiently defined [Dudani, S. *et al. JAMA Netw. Open* 4 2021. Wei, H. *et al. Sci. Rep.* 11 2021].

Therefore, in this multicenter retrospective study, we evaluated the therapeutic outcomes of IO–IO and IO–TKI combination therapies according to metastatic sites in patients with mRCC.

Conclusion

- **The efficacy of IO combination therapy may depend on the site of metastasis.**
- **IO–TKI combination therapy could be a more appropriate first-line treatment option than IO–IO therapy for patients with mRCC involving bone or liver metastases.**
- **IO–IO combination therapy may be a more appropriate treatment option for patients with lymph node or lung metastases.**

Methods

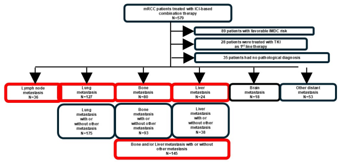
This retrospective analysis included data from **579 patients with mRCC** who received first-line combination immunotherapy from September 2018 to December 2024 in a multicentre study in Japan conducted by the JK-FOOT Study Group.

The metastatic sites analyzed included the lymph nodes, lungs, bones, liver and brain.

Eligible patients were those with intermediate or poor risk according to the IMDC criteria.

The primary outcomes were progression-free survival **(PFS)** and overall survival **(OS)**, and **the secondary outcome** was the objective response rate**(ORR)**.

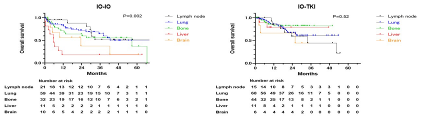
Flowchart of patient selection for the study



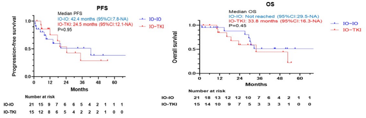
Results

	Lymph node			Lung			Bone			Liver			Liver and/or bone		
	IO-IO (n=21)	IO-TKI (n=15)	P-value	IO-IO (n=62)	IO-TKI (n=70)	P-value	IO-IO (n=34)	IO-TKI (n=46)	P-value	IO-IO (n=11)	IO-TKI (n=11)	P-value	IO-IO (n=63)	IO-TKI (n=82)	P-value
Age, median, (range)	70 (27-87)	70 (26-85)		70 (32-86)	70 (44-89)		70 (25-86)	70 (45-85)		70 (54-74)	70 (58-80)		70 (53-79)	70 (53-83)	
Sex	18/3	11/4	0.24	48/14	49/21	0.43	29/5	37/9	0.77	8/3	9/2	1.0	52/11	63/19	0.42
eGFR, median, (range)	50 (5-84)	50 (16-79)		50 (4-102)	50 (5-91)		50 (4-102)	50 (5-98)		50 (8-77)	50 (32-102)		50 (4-160)	50 (5-102)	
Metastatic site, n (%)															
Lung	0	0		62 (100)	70 (100)		14 (41.2)	17 (37.0)	0.82	9 (81.8)	6 (54.5)	0.36	33 (52.4)	40 (48.8)	0.74
Bone	0	0		0	0		34 (100)	46 (100)		0 (0)	0 (0)		47 (74.6)	64 (78.0)	0.69
Liver	0	0		0	0		0	0		11 (100)	11 (100)		24 (38.1)	28 (34.1)	0.73
Brain	0	0		0	0		0	0		0 (0)	0 (0)		0 (0)	0 (0)	
Lymph node	21 (100)	15 (100)		14 (22.6)	21 (30)	0.43	7 (20.6)	10 (21.7)	1.0	8 (72.7)	5 (45.5)	0.39	20 (31.7)	27 (32.9)	1.0
Histology, n (%)															
Clear cell	9 (42.9)	6 (40)	0.71	44 (71.0)	56 (80)	0.3	24 (70.6)	33 (71.7)	0.74	9 (81.8)	7 (63.6)	0.47	45 (71.4)	55 (67.0)	0.3
Papillary	4 (19.0)	4 (26.7)		3 (4.8)	3 (4.3)		0 (0)	3 (6.5)		0 (0)	2 (18.2)		1 (1.6)	7 (8.5)	
Unclassified	4 (19.0)	0 (0)		3 (4.8)	1 (1.4)		1 (2.9)	0 (0)		0 (0)	0 (0)		3 (4.8)	2 (0)	
Sarcomatoid component	2 (9.5)	0 (0)	1.0	5 (8.1)	10 (14.3)	0.27	1 (2.9)	3 (6.5)	0.61	1 (9.1)	0 (0)	1.0	2 (3.2)	4 (4.9)	0.27
Comfirmation of histology, n (%)															
Nephrectomy	11(52.3)	7 (46.7)	1.0	29 (46.8)	41 (58.6)	0.16	13 (38.2)	15 (32.6)	0.81	5 (45.5)	4 (36.4)	1.0	23 (36.5)	28 (4.9)	0.16
Biopsy	9 (42.9)	4 (26.7)		24 (38.7)	16 (22.9)		12 (35.3)	19 (41.3)		5 (45.5)	5 (45.5)		24 (38.1)	33 (40.2)	
IMDC at 1st line, n (%)															
Intermediate/Poor	14/7	11/4	0.72	38/24	55/15	0.036	23/11	28/18	0.64	6/5	6/5	1.0	37/26	47/35	

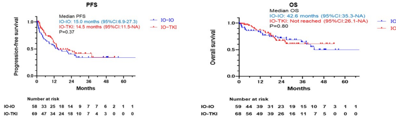
Overall survival by metastatic site



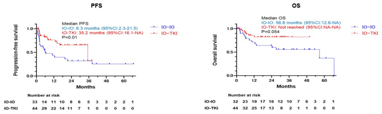
Lymph node metastases



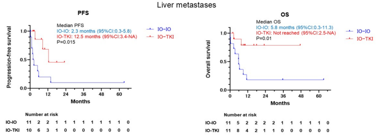
Lung metastases



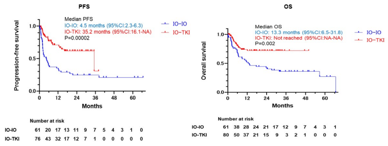
Bone metastases



Liver metastases



Liver and/or bone metastases



	Multivariate			
	Liver		Liver and/or bone	
Variables	Hazard ratio (95% CI)	P-value	Hazard ratio (95% CI)	P-value
Age	1.00 (0.89-1.12)	0.97	0.98 (0.95-1.00)	0.06
IMDC (poor vs intermediate)	1.89 (0.48-7.50)	0.36	2.71 (1.53-4.83)	0.0007
1st line therapy (IO–TKI vs IO–IO)	0.14 (0.02-0.86)	0.033	0.40 (0.22-0.73)	0.003
KPS (<80 vs ≧80)	0.65 (0.08-5.52)	0.69	0.48 (0.22-1.04)	0.06

multivariate Cox regression analysis

	Lymph node (n=36)		Lung (n=132)		Bone (n=80)		Liver (n=22)		Liver and/or bone (n=145)	
Best response, n (%)	IO–IO (n=21)	IO–TKI (n=15)	IO–IO (n=62)	IO–TKI (n=70)	IO–IO (n=34)	IO–TKI (n=46)	IO–IO (n=11)	IO–TKI (n=11)	IO–IO (n=63)	IO–TKI (n=82)
CR	1 (4.8)	1 (6.7)	4 (6.5)	8 (11.4)	0 (0)	2 (4.3)	0 (0)	0 (0)	2 (3.1)	3 (3.7)
PR	9 (42.9)	6 (40)	28 (45.2)	37 (52.9)	12 (35.3)	17 (37.0)	3 (27.2)	4 (36.4)	18 (28.6)	31 (37.8)
SD	7 (33.3)	6 (40)	16 (25.8)	11 (15.7)	8 (23.5)	16 (34.8)	3 (27.2)	3 (27.2)	14 (22.2)	26 (31.3)
PD	3 (14.3)	1 (6.7)	10 (16.1)	10 (14.3)	10 (29.4)	4 (8.7)	3 (27.2)	1 (9.1)	21 (33.3)	8 (9.6)
ORR	10 (47.6)	7 (46.7)	32 (51.6)	45 (64.3)	12 (35.3)	19 (41.3)	3 (27.2)	4 (36.4)	20 (31.7)	34 (41.5)

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Actualizaciones tras el Congreso Americano de Oncología Clínica GU

GONORTE Grupo Oncológico

KCRNC KIDNEY CANCER RESEARCH NETWORK OF CANADA
RRCRC RÉSEAU DE RECHERCHE SUR LE CANCER DU REIN DU CANADA

Head-to-Head Comparison of Pembrolizumab-Axitinib versus Pembrolizumab-Lenvatinib in Metastatic RCC: Real World Data from the Canadian Kidney Cancer Information System (CKCis) database.

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Centre universitaire de santé McGill — McGill University Health Centre

INTRODUCTION

- Management of mRCC has significantly changed due to the advent of ICIs and TKIs.
- Pembrolizumab-axitinib (PA) and pembrolizumab-lenvatinib (PL) have each shown substantial improvements in PFS, OS, and ORR.
- Both PA and PL are widely used but there is no head-to-head data comparing these regimens, leaving clinicians with limited real-world evidence to guide individualized treatment decisions.

METHODS

This multicenter, retrospective cohort study utilized de-identified data from the CKCis Canadian Database.
Eligible patients were adults aged 18 years or older with histologically confirmed mRCC who initiated first-line systemic therapy with IO-TKI combination, either PA or PL, on or after February 2021.
Descriptive statistics were used to summarize patient and disease characteristics. Between-group comparisons employed chi-square tests for categorical variables and t-tests or Mann-Whitney U tests for continuous variables.
Kaplan-Meier survival curves were generated for OS and PFS. Multivariable Cox proportional hazards regression was performed to adjust for potential confounders.
Logistic regression was used to assess predictors of ORR, and Fisher's exact testing was used to compare AE rates.
Prespecified subgroup analyses were conducted for IMDC risk categories, age, sex, and metastatic burden.

Table 1. Demographics

Characteristic	Pembro–Lenvatinib	Pembro–Axitinib	Total
Age, mean (SD), years	64.8 (9.7)	65.9 (10.1)	65.8 (10.0)
Male sex, n (%)	61 (73.5)	404 (73.6)	465 (73.6)
Clear-cell RCC, n (%)	453 (82.5)	63 (75.9)	516 (81.7)
Non–clear-cell RCC, n (%)	96 (17.5)	20 (24.1)	116 (18.3)
Prior nephrectomy, n (%)	61 (73.5)	370 (67.4)	431 (68.2)
Metastasectomy, n (%)	14 (16.9)	124 (22.6)	138 (21.8)
Prior radiation (any), n (%)	31 (37.3)	284 (51.7)	315 (49.8)
≥3 metastatic sites, n (%)†	39 (47.0)	239 (44.0)	278 (45.1)
Lung metastases, n (%)*	53 (63.9)	343 (62.5)	396 (62.7)
Bone metastases, n (%)*	35 (42.2)	178 (32.4)	213 (33.7)
Liver metastases, n (%)*	28 (33.7)	109 (19.9)	137 (21.7)
Brain metastases, n (%)*	7 (8.4)	57 (10.4)	64 (10.1)
KPS ≤70%, n (%)‡	14 (12.4)	71 (14.3)	85 (13.9)
IMDC risk group, n (%)§			
•Favorable	123 (22.2)	18 (18.0)	105 (23.1)
•Intermediate	286 (51.6)	49 (49.0)	237 (52.5)
•Poor	145 (26.2)	33 (33.0)	112 (24.7)

* Patients may have multiple metastatic sites
† Data available for 616 patients; ‡ Data available for 611 patients; § Data available for 554 patients

FIGURES

Figure 1
PFS for entire cohort:

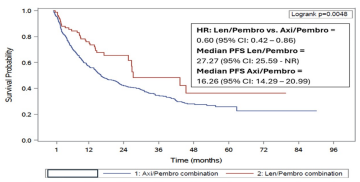


Figure 2
Overall Survival for clear cell‡

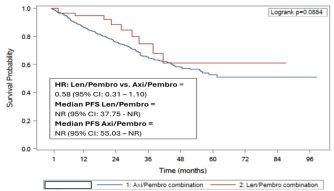


Figure 3
Overall Survival for non-clear cell‡

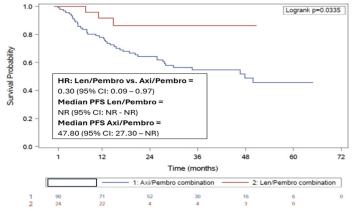


Figure 4
Overall Survival for IMDC - Good Risk:

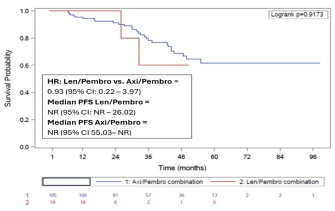
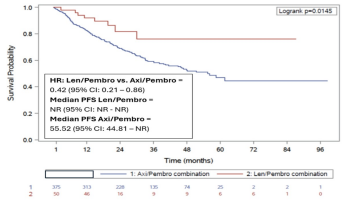


Figure 5
Overall Survival for IMDC – Intermediate/Poor Risk:



We gratefully acknowledge the Canadian Kidney Cancer Information System (CKCIS) for its support.

RESULTS

- 632 patients with mRCC treated with first-line pembrolizumab-based IO-TKI combinations were included, of whom 549 (86.9%) received PA and 83 (13.1%) received PL. Baseline characteristics are summarized in Table 1.
- PFS was significantly longer with PL (Figure 1).
- After adjustment for age and IMDC risk, PA was associated with a higher risk of progression (HR 1.81, P = 0.0036). Intermediate/poor IMDC risk was also independently associated with shorter PFS (HR 1.38, P = 0.015).
- OS showed an even stronger treatment effect, PA was associated with more than double the risk of death compared with PL (HR 2.15, P = 0.019), and IMDC intermediate/poor risk remained an independent adverse prognostic factor (HR 1.94, P = 0.001), while age was not associated with OS.

Table 2 (Figures 2-5). Overall Survival

Subgroup	Time Point	Pembrolizumab–Lenvatinib (PL)	Pembrolizumab–Axitinib (PA)	P value
Clear-cell RCC	12 months	94.9%	86.6%	0.0884
Non–clear-cell RCC	12 months	91.6%	78.0%	0.0335
IMDC Favorable risk	12 months	100%	95.24%	0.9173
	24 months	100%	91.1%	
IMDC Intermediate/Poor risk	12 months	92.0%	82.3%	0.0145
	48 months	75.9%	47.3%	

Table 3. Treatment Dosing and Dose Modifications

Parameter	Pembrolizumab–Lenvatinib (PL)	Pembrolizumab–Axitinib (PA)
Median starting dose	20 mg once daily	5 mg twice daily
Median on-treatment dose	14 mg once daily	5 mg twice daily
Dose reduction	50.0%	35.3%
Dose increase	2.0%	10.2%

Table 4. Treatment-Related Adverse events

Safety Outcome	Pembrolizumab–Lenvatinib (PL)	Pembrolizumab–Axitinib (PA)
Overall toxicity	Frequent but manageable	Frequent but manageable
Common adverse events	Fatigue, diarrhea, anorexia	Fatigue, diarrhea, anorexia
Proteinuria (grade ≥3)	Higher incidence (53.8%)	Lower incidence (14.2%)
Grade 5 TRAEs	None reported	None reported

CONCLUSIONS

- PL was associated with significantly improved PFS compared with PA.
- OS was also significantly improved with PL versus PA.
- PL required more frequent TKI dose modifications than PA.
- Increased dose modifications with PL did not result in higher rates of treatment discontinuation.
- Real-world outcomes with PL are consistent with efficacy observed in randomized clinical trials.
- Findings suggest a potential real-world survival advantage of PL over PA.
- Further prospective comparative studies are needed to refine patient selection.

KCRNC/CKCis Website — Linkedin — @ckcis_ca

Abstract 478: Efficacy of subsequent therapy in patients with metastatic renal cell carcinoma of intermediate and poor risk with disease progression on the 1-line immuno-oncology combinations

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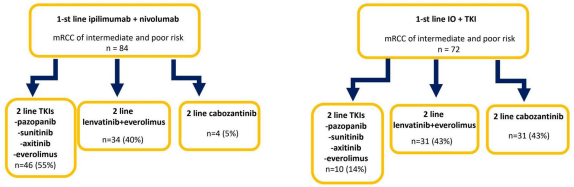
Background

In the era of immune-oncology (IO) combinations, particularly IO+IO and IO plus tyrosine kinase inhibitors (TKIs), overall survival (OS) in patients (pts) with metastatic renal cell carcinoma (mRCC) and intermediate or poor risk per the International mRCC Database Consortium (IMDC) has markedly improved. However, the lack of a universally accepted treatment standard complicates the evaluation of subsequent lines of therapy after disease progression.

Figure 1. Study design



Methods

Multicenter retrospective study included pts with mRCC of IMDC intermediate and poor risk who received subsequent therapy after disease progression on the first-line treatment with either dual immunotherapy (ipilimumab and nivolumab) or IO-TKI between 2020 and 2024. The primary endpoints were objective response rate (ORR) and progression-free survival (PFS).

Results

The median follow-up was 18 months. Median second-line PFS was 7.2 months (95% CI 5.7–8.7) after IO+IO and 7.7 months (95% CI 5.3–10.1) after IO+TKI (HR 1.2, 95% CI 0.8–1.7; Fig. 2). Median PFS with lenvatinib plus everolimus in the second line was similar between groups - 8.4 months after IO+TKI and 10.5 months after IO+IO (HR 1.2, 95% CI 0.7–2.1). However, the ORR to lenvatinib plus everolimus was significantly higher after IO+IO than after IO+TKI (47% vs 19%; OR 0.3, 95% CI 0.1–0.8).

In the overall cohort, irrespective of prior therapy, second-line mPFS did not differ between lenvatinib plus everolimus and cabozantinib - 8.9 months and 8.7 months, respectively (HR 0.7, 95% CI 0.5–1.2). Median PFS with TKI monotherapy (pazopanib/sunitinib/axitinib) was significantly shorter (5.1 months), compared with lenvatinib plus everolimus or cabozantinib (HR 1.5, 95% CI 1.0–2.2; Fig. 3).

Table 1. Baseline characteristics

	Lenvatinib+ Everolimus n=65	Cabozantinib n=35	TKIs n=56
Age, median (IQR), years	63	59	65
ECOG			
-0-1	47 (72%)	23 (66%)	28 (50%)
-2-3	18 (28%)	12 (34%)	28 (50%)
IMDC risk group			
-intermediate	43 (66%)	26 (74%)	39 (70%)
- poor	22 (34%)	9 (26%)	17 (30%)
Prior nephrectomy			
- yes	36 (55%)	23 (66%)	38 (68%)
- no	29 (45%)	12 (34%)	18 (32%)
1L treatment regimens			
- IO+IO	34 (52%)	4 (11%)	46 (82%)
- IO+TKI	31 (48%)	31 (89%)	10 (18%)

Figure 2. Kaplan–Meier curves for PFS on second-line therapy according to the type of first-line treatment.

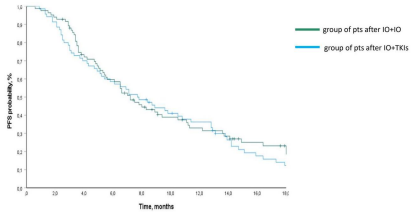


Figure 3. Kaplan–Meier curves for PFS comparing second-line treatment regimens irrespective of prior therapy.

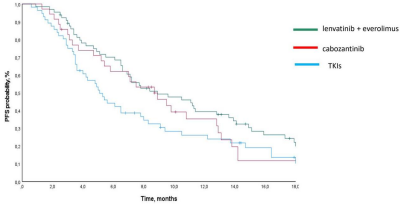


Table 2. Comparison of the efficacy of second-line treatment regimens after progression on IO+IO therapy.

2 line	mPFS, mo	HR (95% CI)	ORR	OR (95% CI)
TKIs	5,4	1,5 (0,9-2,5)	17%	0,4 (0,2-0,6)
Lenvatinib+ everolimus	10,5		47%	

Table 3. Comparison of the efficacy of second-line treatment regimens after progression on IO+TKI therapy.

2 line	mPFS, mo	HR (95% CI)	ORR	OR (95% CI)
Lenvatinib+ everolimus	8,4	0,8 (0,5-1,4)	19%	1,6 (0,4-6,2)
Cabozantinib	8,7		13%	

Conclusions

In real-world clinical practice, lenvatinib plus everolimus and cabozantinib demonstrate comparable progression-free survival and represent reasonable treatment options for patients with metastatic renal cell carcinoma who experience disease progression after immune-oncology combinations.

First-generation TKIs demonstrate lower efficacy in terms of both ORR and PFS.

The authors declare no conflict of interest.

Should you have any questions do not hesitate to contact us by emai: pokia@mail.ru

ASCO Genitourinary Cancers Symposium

Novel Targets in Kidney Cancer

Hans Hammers MD, PhD UT Southwestern

Key Takeaway Points/Conclusions

- **Rich Pipeline of targeted and and immune therapies**
  - HIF1 Inhibitors and Combinations
  - Bispecific Antibodies:
    - VEGF/PD1
    - PDL1/CTLA4
    - BITE (e.g. ENPP3/CD3)
  - CAR-T (CA9, CD70)
  - Small Molecule Immune Modulators (PTPN2, HPK1)
  - mRNA Vaccine (V940)

- **We will see a proliferation of novel combination therapies at various disease stages - with the promise of higher efficacy but also toxicity**


NEWS

7:53 4G

#GU26

Destacados | Más recientes | Personas | Videos

Tom Powles @tompowles1 · 21/1/26

The big renal cancer story ASCO GU #GU26 are the 2 positive R3 belzutifan combination trials. Many feel belzutifan is well placed earlier in RCC which is more angiogenic & in combination due to a good tox profile. LS22 @DrChoueiri show adjuvant bel + pembro is better than pembro while LS11 tests adding belzutifan to lenvatinib vs cabozantinib in pretreated disease @motzermd @OncoAlert

Add to Agenda

8:15 - 8:25 AM PST

Belzutifan (bel) plus lenvatinib (lenva) versus cabozantinib (cabo) for advanced renal cell carcinoma (RCC) after anti–PD-(L)1 therapy: Open-label phase 3 LITESPARK-011 study.

Robert J. Motzer, MD

Memorial Sloan Kettering Cancer Center

Abstract LBA417

Add to Agenda

8:25 - 8:35 AM PST

Adjuvant pembrolizumab plus belzutifan versus pembrolizumab for clear cell renal cell carcinoma (ccRCC): The randomized phase 3 LITESPARK-022 study.

Toni K. Choueiri, MD, FASCO

Dana-Farber Cancer Institute and Harvard Medical School

Abstract LBA418

Toni Choueiri, MD @DrCho... · 22/2/26

ASCO GU 2026 – Top 15 Trials with Potential Practice Impact @ASCO #GU26

- KEYNOTE-B15 / EV-304 – Perioperative enfortumab vedotin + pembrolizumab vs gemcitabine/cisplatin in muscle-invasive bladder cancer.
- PEACE-3 – Final overall survival of enzalutamide ± radium-223 in metastatic castration-resistant prostate cancer with bone metastases.
- PSMAddition – Adding lutetium-177 PSMA-617 to ADT + AR pathway inhibitor in metastatic hormone-sensitive prostate cancer.
- LITESPARK-022 – Adjuvant pembrolizumab + belzutifan vs pembrolizumab alone in clear cell renal cell carcinoma.
- LITESPARK-011 – Belzutifan + lenvatinib vs cabozantinib after prior immunotherapy in advanced renal cell carcinoma.
- PEACE-2 – ADT + radiation ± cabazitaxel in very-high-risk localized prostate cancer.
- IMvigor011 – ctDNA-guided adjuvant atezolizumab strategy in muscle-invasive bladder cancer.
- NIAGARA biomarker analyses – Circulating and urine tumor DNA after perioperative durvalumab in bladder cancer.
- SWOG S1602 – BCG strain comparison and priming strategy in non–muscle-invasive bladder cancer.
- RC48G001 – Disitamab vedotin in HER2-positive advanced urothelial cancer.
- BRCAAway OS update – PARP inhibitor + AR pathway inhibitor strategy in mCRPC with DDR alterations.
- CAPItello-281 PROs – Capivasertib + abiraterone in PTEN-deficient metastatic hormone-sensitive prostate cancer.
- PAnTHa – Actinium-225 PSMA radioligand therapy in metastatic castration-resistant prostate cancer.
- CYTOSHRINK – Stereotactic radiotherapy + nivolumab/ipilimumab in metastatic renal cell carcinoma.
- CLIMATE – miR-371a-3p biomarker for surveillance decisions in stage I testicular cancer.

Prostate Bladder Renal Testis

ASCO y 9 más

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MILA ESKER