

**LIVE PODCAST**

# Front-line Therapy in Papillary Renal Cancer



#UROMIGOSLIVE24



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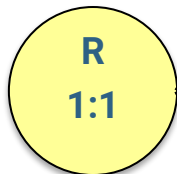
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# SUNNIFORECAST

## Key Inclusion Criteria

- Metastatic or locally advanced nccRCC (>50% ncc component or sarcomatoid, defined for lesions with at least 20% sarcomatoid component)
- No prior systemic therapy for RCC
- Measurable disease RECIST v1.1
- KPS  $\geq$  70%
- No active CNS metastases



**Nivolumab  
+ Ipilimumab**

**Standard of Care agent(s)  
124TKI; 17 IO/TKI; 2 other**

## Stratification

- Histology (papillary vs non-papillary; central path review)
- IMDC score

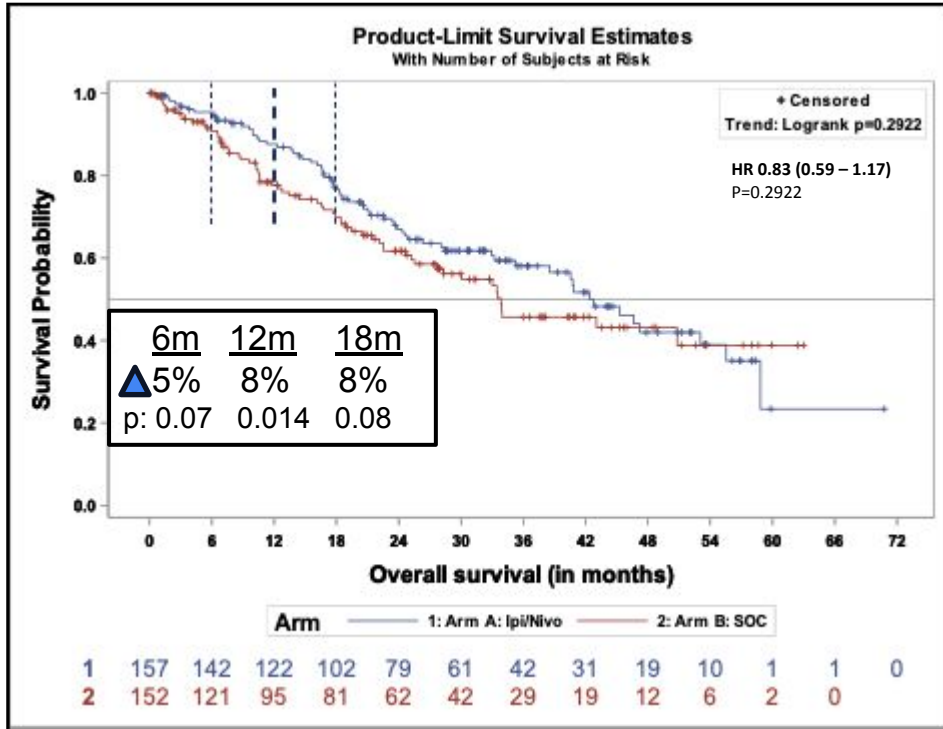
## Primary Endpoint: OS rate at 12 months

**Key Secondary Endpoints:** OS at 6 and 18 months; PFS, ORR, TTP, Safety, QoL

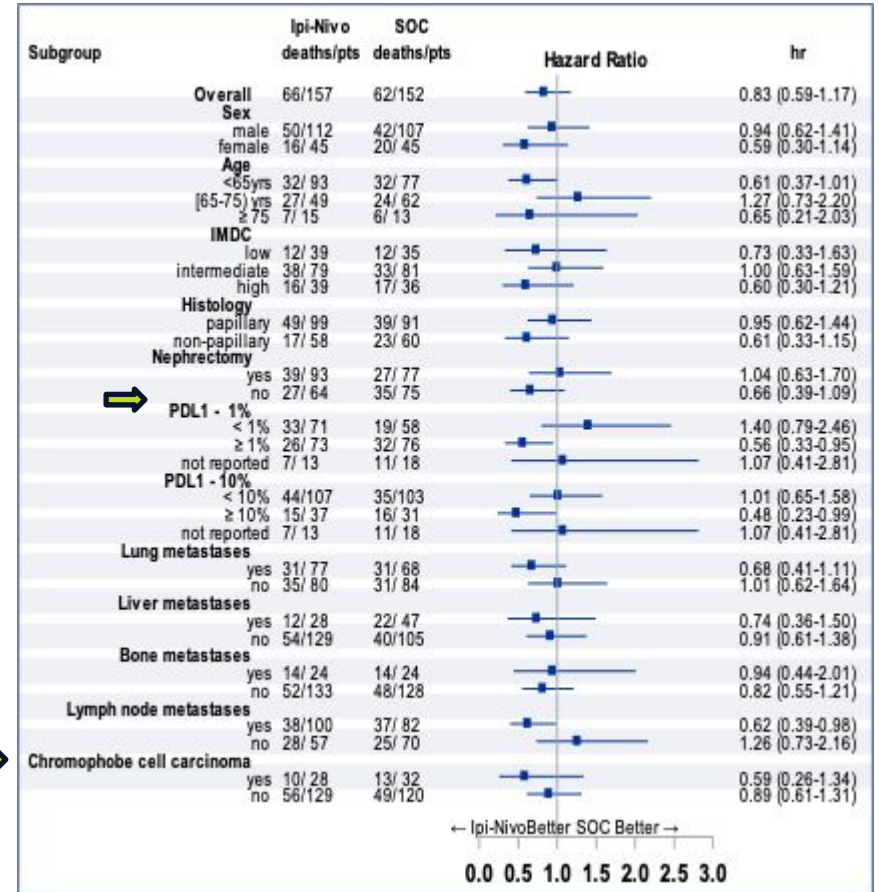
**Exploratory Endpoints:** predictive biomarkers (e.g. PD-L1 expression)

Subtypes of nccRCC	N=309
Papillary RCC	57.6%
Chromophobe RCC	19.4%
MiT family translocation RCC	3.9%
Medullary carcinoma	1.0%
Translocation RCC	1.6%
Tubulocystic RCC	1.0%
Mucinous tubular and spindle cell carcinoma	0.3%
Sarcomatoid	4.5%
Ductal carcinoma	1.0%
Others	6.7 %

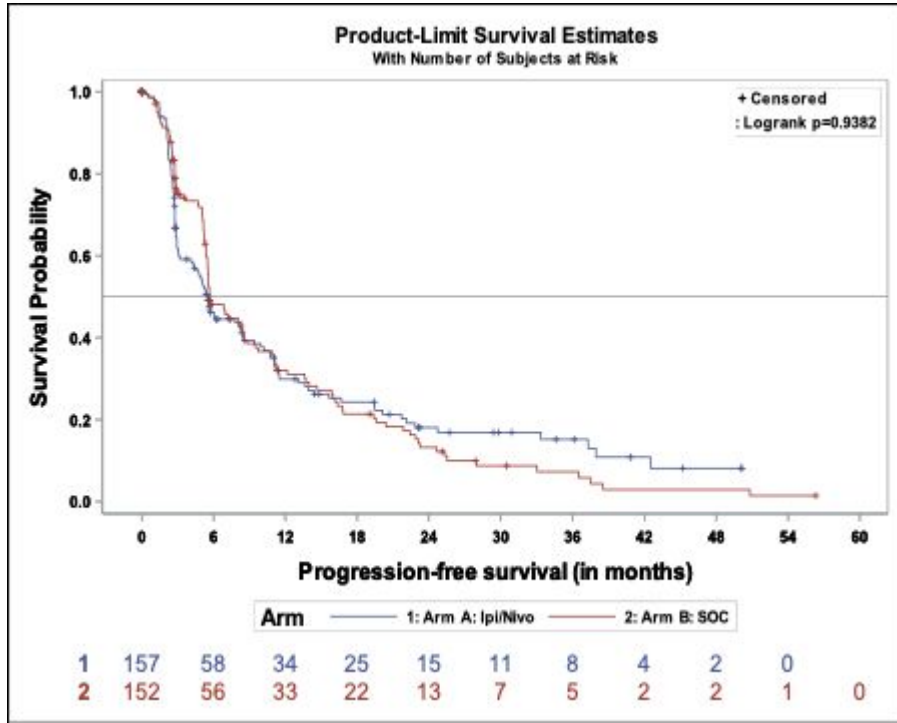
# Overall Survival



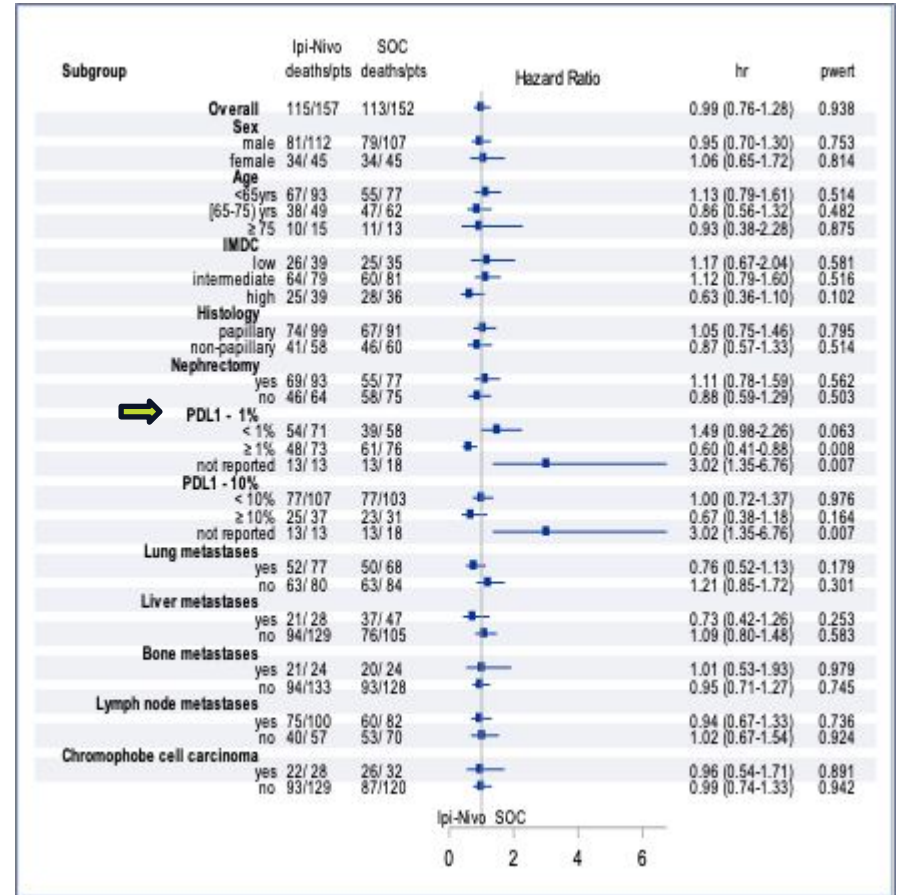
Median follow-up: 24.3 mos (0.5 -70.2)



# Progression-Free Survival



	IPI/Nivo	SOC
<b>Median PFS mos.</b>	<b>5.5</b>	<b>5.7</b>
<b>HR 0.99 (0.76-1.18)</b>		



# Papillary Renal Cell Carcinoma: Summary of select data

	N	ORR	Primary PD rate	PFS (months)
<b>Single Agent VEGF TKI</b>				
Sunitinib <small>(Pal et al. Lancet 2021; Barata et al. JCO 2024)</small>	46	4% (0% CR)	24%	6.0
Cabozantinib	44	23% (5% CR)	9%	7.0
<b>Single Agent IO</b>				
Pembrolizumab <small>(McDermott et al. JCO 2021)</small>	118	29% (6% CR)	32%	5.5
Nivolumab <small>(Atkins et al. JITC 2023)</small>	19	5% (5% CR)	37%	3.9
<b>IO-based Combinations</b>				
Cabo/Atezo <small>(Pal et al. JCO 2021)</small>	15	47% (0% CR)	0%	9.5*
Cabo/Nivo <small>(Fitzgerald et al. E Urol 2024)</small>	32	47% (3% CR)	3%	13.0
Len/Pembro <small>(Voss et al. ASCO GU 2024)</small>	93	51% (8% CR)	11%	17.4
Ipi/Nivo <small>(Bergmann et al. ESMO 2024)</small>	89	29% (10% CR)	33%	5.5*

\* All comers



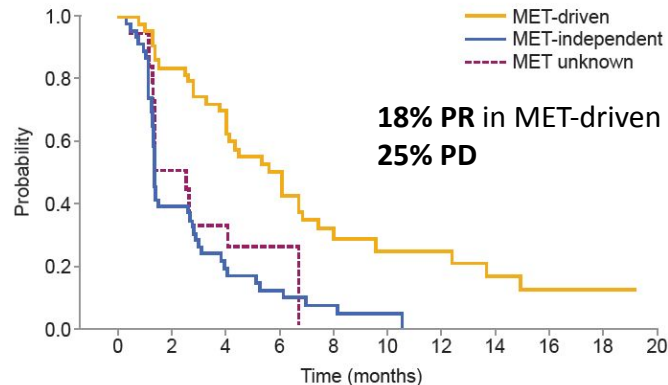
**Brian Rini, MD** @brian\_rini · Sep 14



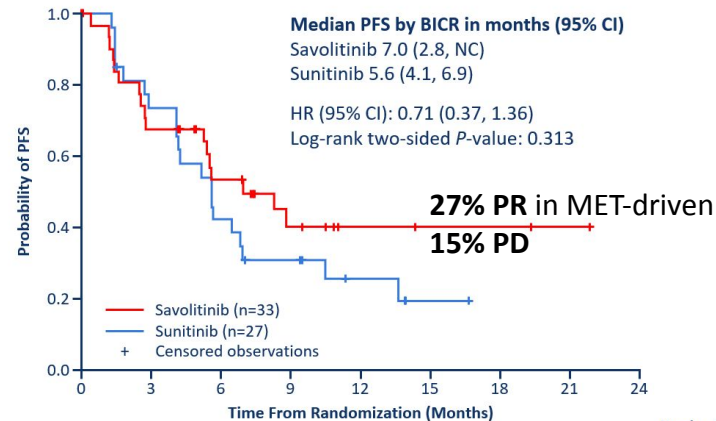
After the SUNNIFORECAST presentation at #ESMO2024, what is the standard of care for front-line, metastatic papillary RCC?



## Savolitinib Phase II Data



Time (months)	0	1.4	2.8	4.1	5.5	6.9	8.3	9.7	11.1	12.5	13.9	15.2	16.6	18.0	19.4
No. at risk															
MET-independent	46	30	15	8	4	3	2	1	0						
MET-driven	44	39	29	20	13	9	6	6	4	3	3	3	0		
MET unknown	19	13	3	2	1	0									

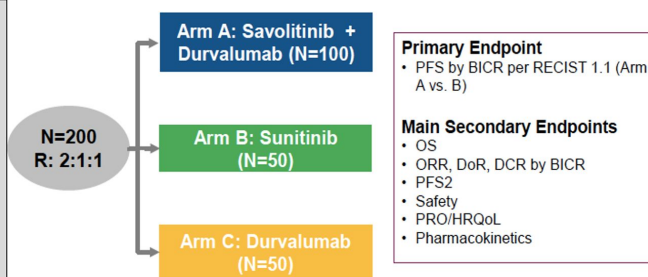


									Number Randomized/ Number of Events
Number of Patients at Risk									
Savolitinib	33	21	15	8	4	3	3	1	0
Sunitinib	27	19	11	7	4	1	0	0	0
									33/17
									27/20

## Phase III SAMETA Trial

### Key Eligibility Criteria

- Locally advanced or metastatic PRCC
- Confirmation of MET-driven PRCC without co-occurring FH mutations using central laboratory validated NGS Assay
- 1L patients (Tx naive in metastatic setting)
- No prior METi, durvalumab or sunitinib
- Measurable disease per RECIST1.1
- Karnofsky Score >70
- Stable/asymptomatic brain mets permitted
- No history of serious liver disease, no active or recent clinically significant cardiac conditions, no active infection, autoimmune or inflammatory disorders\*



## Phase III STELLAR 304 Trial

Previously untreated advanced nccRCC  
(papillary, unclassified, and  
translocation-associated)

N≈291

R2:1

Zanzalitinib + Nivolumab

Sunitinib

- **Dual primary endpoints:** PFS and ORR per RECIST v1.1 by BIRC
- **Secondary endpoint:** OS
- **Other endpoints:** safety, including incidence and severity of AEs