Patrik Palacka

Genitourinárne karcinómy

Vyhlásenie o konflikte záujmov autora

Nemám potenciálny konflikt záujmov vo vzťahu k tejto prednáške

Forma finančného prepojenia	Spoločnosť
Participácia na klinických štúdiách/firemnom grante	
Nepeňažné plnenie (v zmysle zákona)	
Prednášajúci	
Akcionár	
Konzultant/odborný poradca	
Ostatné príjmy (špecifikovať)	

Podľa UEMS (upravené v zmysle slovenskej legislatívy)

Prezentáciu podporila agentúra

We Make Media Slovakia s.r.o.

Karcinóm prostaty

Updated Overall Survival Results From PROSPER: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Enzalutamide in Men With Nonmetastatic Castration-Resistant Prostate Cancer

Cora N. Sternberg,[1] Karim Fizazi,[2] Fred Saad,[3] Neal D. Shore,[4] Ugo De Giorgi,[5] David F. Penson,[6] Ubirajara Ferreira,[7] Petro Ivashchenko,[8] Eleni Efstathiou,[9] Katarzyna Madziarska,[10] Michael Kolinsky,[11] Daniel I. G. Cubero,[12] Bettina Noerby,[13] Fabian Zohren,[14] Xun Lin,[14] Katharina Modelska,[15] Jennifer Sugg,[16] Joyce Steinberg,[16] Maha Hussain[17]

PROSPER Study Design

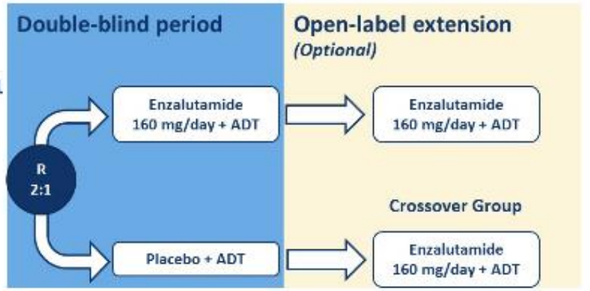
Key Eligibility Criteria

- nmCRPC (central review)
- Rising PSA despite castrate testosterone level (≤ 50 ng/dL)
- Baseline PSA ≥ 2 ng/mL
- PSA doubling time ≤ 10 months

Stratification

- PSA doubling time (< 6 mo vs 6-10 mo)
- Baseline use of bone-targeting agent (Y/N)

N = 1401



Primary endpoint

- MFS (defined as time from randomization to radiographic progression or death within 112 days of treatment discontinuation without evidence of radiographic progression)

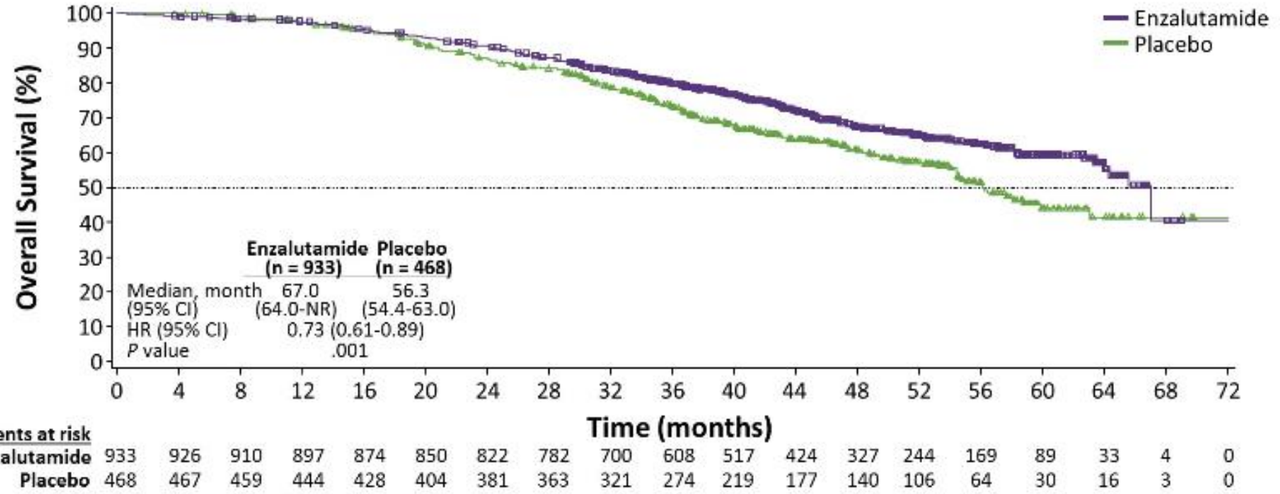
Secondary endpoints

- OS
- Time to PSA progression
- Safety
- PSA response
- Quality of life

ADT, androgen deprivation therapy; MFS, metastasis-free survival; nmCRPC, nonmetastatic castration-resistant prostate cancer; OS, overall
ındomization.

PROSPER Final Overall Survival Analysis

Enzalutamide was associated with a statistically significant 27% reduction in the risk of death



Patients at risk																			
Enzalutamide	933	926	910	897	874	850	822	782	700	608	517	424	327	244	169	89	33	4	0
Placebo	468	467	459	444	428	404	381	363	321	274	219	177	140	106	64	30	16	3	0

CI, confidence interval; HR, hazard ratio; NR, not reached.

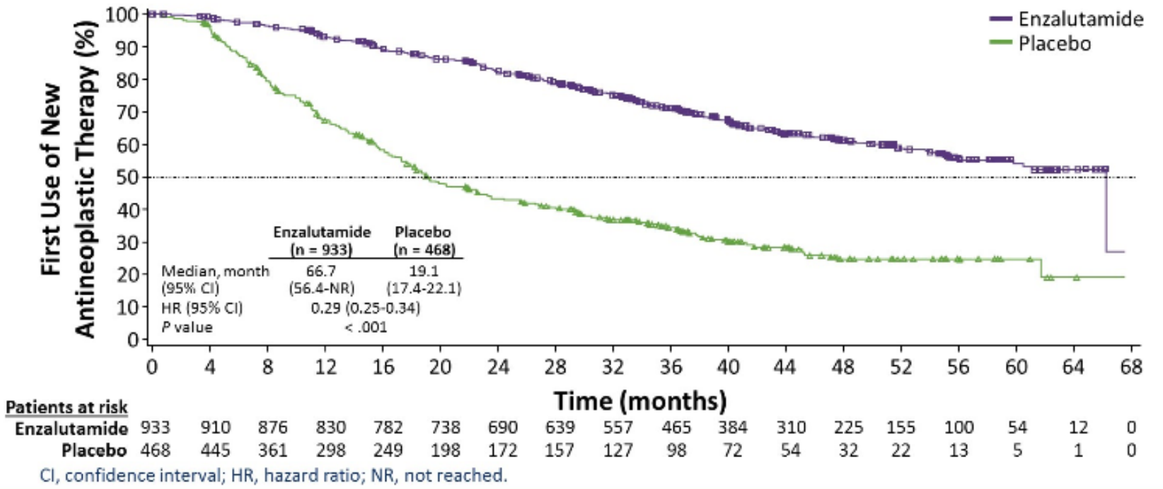
Cora N Sternberg, et al. ASCO©2020. Abstract 5515.

PROSPER Subsequent Antineoplastic Therapy

	Enzalutamide Group (n = 930)	Placebo Group (n = 465)
Patients taking ≥ 1 antineoplastic therapy after treatment discontinuation*	**33%**	**65%**
Subsequent therapies used by ≥ 5% of patients in any treatment group†		
Abiraterone acetate	49%	59%
Docetaxel	60%	47%
Enzalutamide‡	14%	36%
Cabazitaxel	15%	16%
Bicalutamide	9%	14%

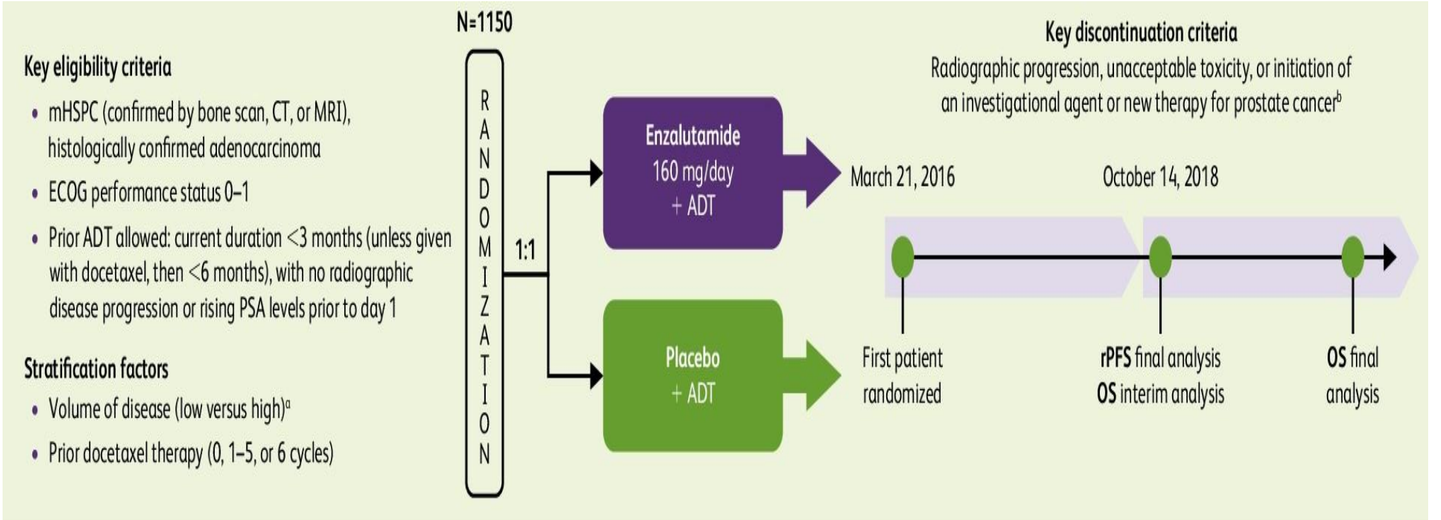
*Percentages based on the total number of patients in each treatment group.
†Percentages based on the number of patients who received ≥ 1 antineoplastic therapy after treatment discontinuation.
‡Does not include the 87 patients who were randomized to placebo and received enzalutamide in the open-label extension.

PROSPER Time to First Use of Subsequent Antineoplastic Therapy



CI, confidence interval; HR, hazard ratio; NR, not reached.

Cora N Sternberg, et al. ASCO © 2020. Abstract 5515.

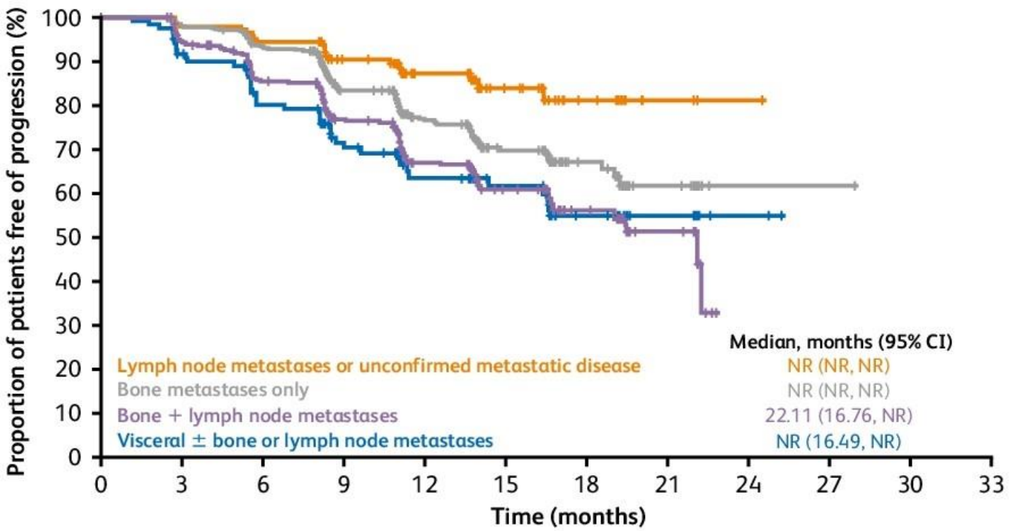


Efficacy of Enzalutamide + Androgen Deprivation Therapy in Metastatic Hormone-Sensitive Prostate Cancer by Pattern of Metastatic Spread: ARCHES *Post Hoc* Analyses

Neal D. Shore,[1] Andrew J. Armstrong,[2] Russell Z. Szmulewitz,[3] Daniel P. Petrylak,[4] Jeffrey Holzbeierlein,[5] Arnauld Villers,[6] Arun Azad,[7,*] Antonio Alcaraz,[8] Boris Alekseev,[9] Taro Iguchi,[10] Francisco Gomez-Veiga,[11] Brad Rosbrook,[12] Ho-Jin Lee,[13] Gabriel P. Haas,[13] Arnulf Stenzl[14]

- ARCHES (NCT02677896): multinational, Phase 3, randomized, double-blind, placebo-controlled trial (**Figure 1**)

Figure 3. Kaplan–Meier of rPFS in the Overall Population by Pattern of Metastatic Spread



CI=confidence interval; NR=not reached; rPFS=radiographic progression-free survival.

Neal D Shore, et al. ASCO © 2020. Abstract 5547.

A randomised phase II trial of ^{177}Lu-PSMA-617 (Lu-PSMA) theranostic versus cabazitaxel in metastatic castration resistant prostate cancer (mCRPC) progressing after docetaxel: Initial results

TheraP (ANZUP 1603)

Michael Hofman, Louise Emmett, Shahneen Sandhu, Amir Iravani, Anthony Joshua, Jeffrey Goh, David Pattison, Hsiang Tan, Ian Kirkwood, Siobhan Ng, Roslyn Francis, Craig Gedye, Natalie Rutherford, Alison Zhang, Margaret McJannett, Martin Stockler, John Violet, Scott Williams, Andrew Martin, Ian Davis

Aim: To determine the activity and safety of ^{177}Lu-PSMA vs cabazitaxel

KEY ELIGIBILITY

- mCRPC post docetaxel suitable for cabazitaxel
- Progressive disease with rising PSA and PSA ≥ 20 ng/mL

^{68}Ga-PSMA + ^{18}F-FDG PET/CT

- PSMA SUVmax > 20 at any site
- Measurable sites SUVmax > 10
- **No FDG positive/PSMA negative sites of disease**
- Centrally reviewed

R

^{177}Lu-PSMA-617
8.5 GBq IV q6 weekly
↓ 0.5GBq each cycle
Up to 6 cycles

→ **SPECT/CT @ 24 hours**
suspend Rx if exceptional response; recommence upon progression

200 men 1:1 randomisation
11 sites in Australia
Stratified by:

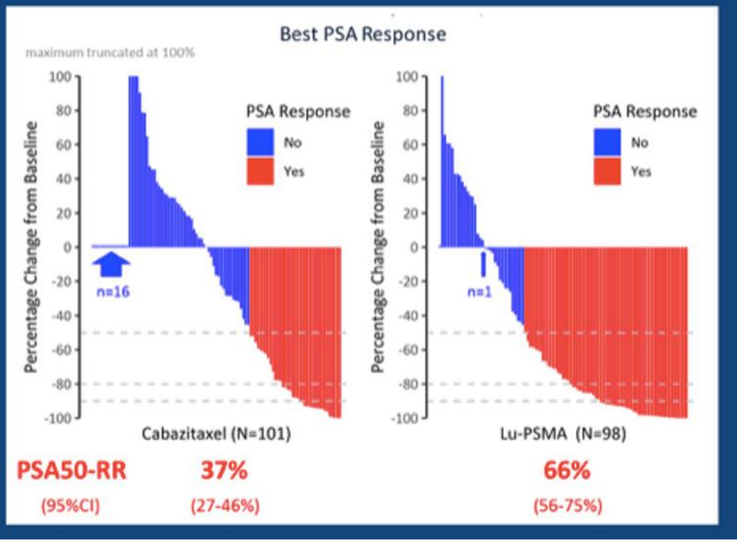
- Disease burden (>20 sites vs ≤ 20 sites)
- Prior enzalutamide or abiraterone
- Study site

CABAZITAXEL
20mg/m^2 IV q3 weekly,
Up to 10 cycles

80% power to detect a true absolute difference of 20% in the PSA response rate (from 40% to 60%), with a 2-sided type 1 error of 5% and allowance of 3% for missing data.

Michael S Hofman, et al. ASCO © 2020. Abstract 5500.

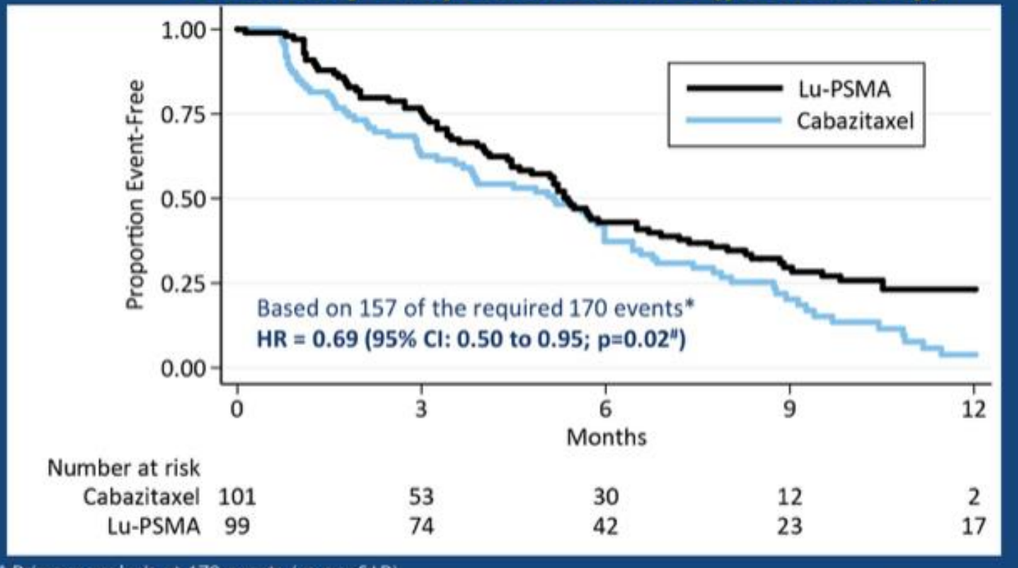
Primary endpoint: PSA ≥ 50% response (PSA50-RR)



Lu-PSMA: 29% absolute (95% CI 16%-42%; p<0.0001) greater PSA50-RR compared to cabazitaxel

For sensitivity analysis per-protocol, the difference was 23% (95% CI 9%-37%; p=0.0016)

Secondary endpoint: PSA PFS (preliminary)



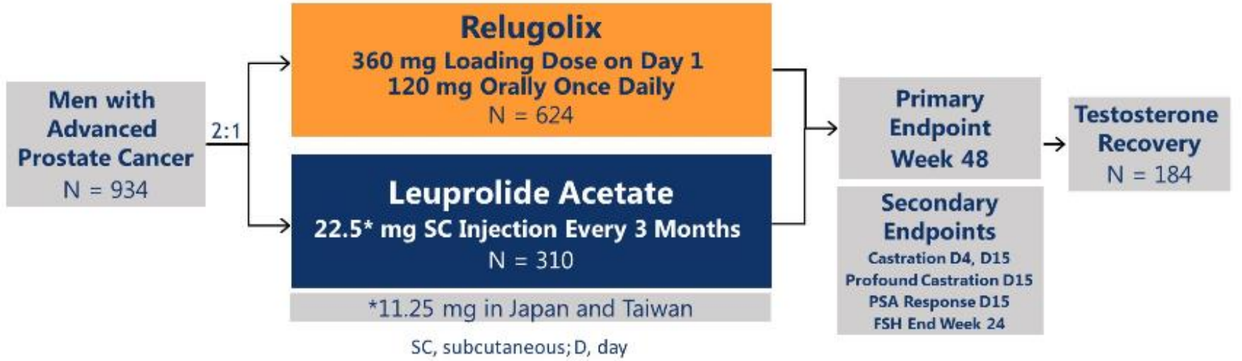
* Primary analysis at 170 events (as per SAP)
# p<0.0027 is required to trigger rejection of null hypothesis prior to planned primary analysis at 170 events (as per SAP)
There have been 71 deaths in total.

Michael S Hofman, et al. ASCO © 2020. Abstract 5500.

HERO

Phase 3 HERO Study Design

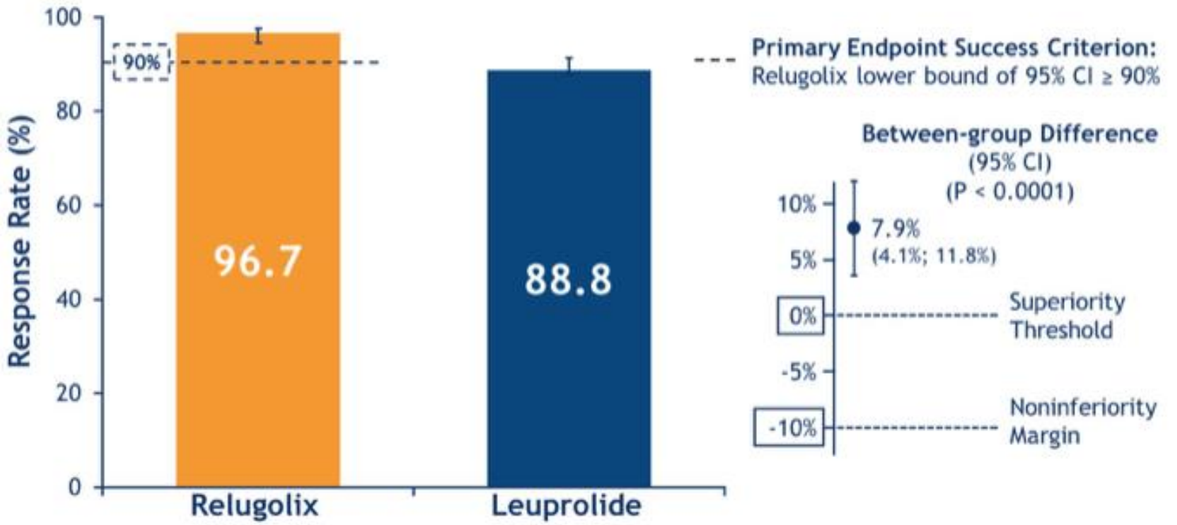
- A multinational phase 3 randomized, open-label, parallel group study to evaluate the safety and efficacy of relugolix in men with advanced prostate cancer
- **Primary Endpoint**: Sustained castration through 48 weeks (< 50 ng/dL)



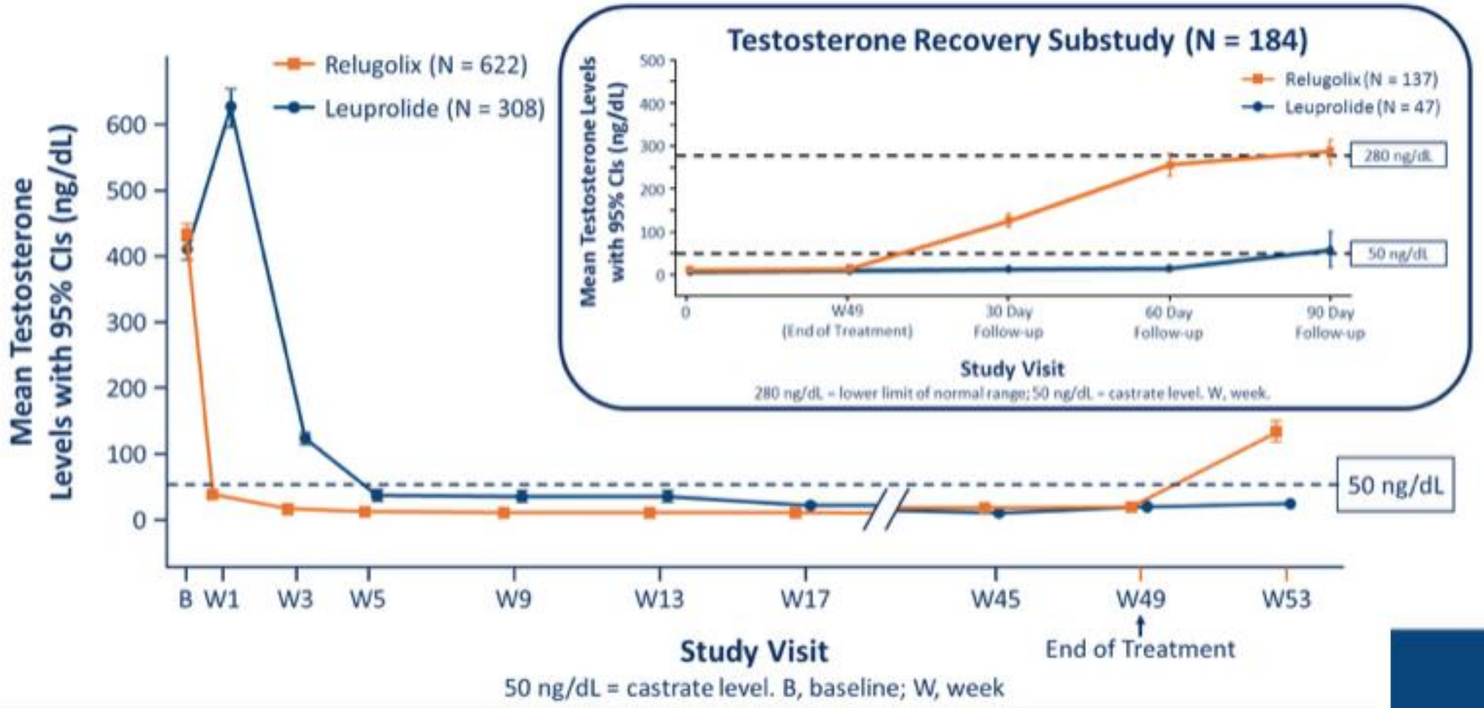
SC, subcutaneous; D, day

HERO

Primary Endpoint – Sustained Castration
Key Secondary Endpoint – Noninferiority to Leuprolide



Neal D Shore, et al. ASCO © 2020. Abstract 5602.



50 ng/dL = castrate level. B, baseline; W, week

	Relugolix (N = 622)	Leuprolide (N = 308)
Adverse Cardiovascular Events	3.9%	7.1%
Major Adverse Cardiovascular Events (MACE)	2.9%	6.2%
Ischemic Heart Disease	2.4%	1.6%

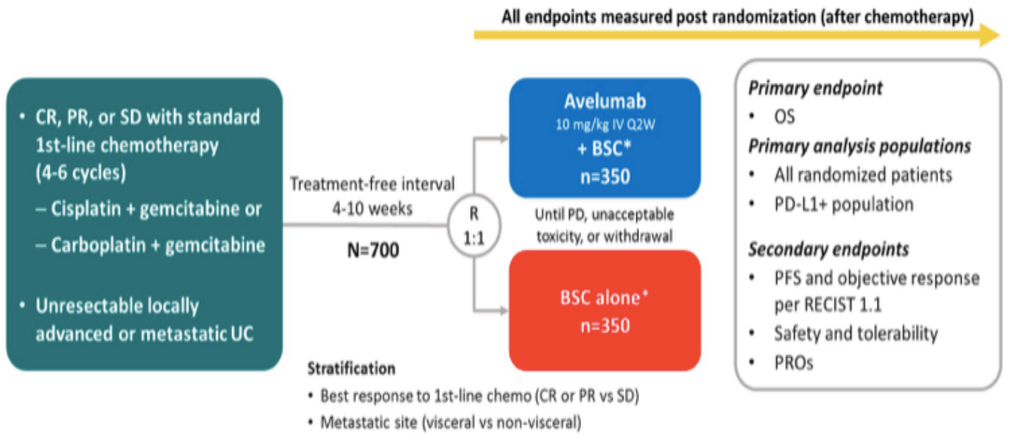
History of MACE	Yes		No	
N (%)	Relugolix 84 (13.5%)	Leuprolide 45 (14.6%)	Relugolix 538 (86.5%)	Leuprolide 263 (85.4%)
MACE	3.6%	17.8%	2.8%	4.2%
Odds Ratio Leuprolide vs Relugolix (95% confidence interval)	5.8 (1.5, 23.3)		1.5 (0.7, 3.4)	

MACE = non-fatal myocardial infarction + non-fatal stroke + all-cause mortality

Neal D Shore, et al. ASCO © 2020. Abstract 5602.

Urotelové karcinómy

JAVELIN Bladder 100 study design (NCT02603432)

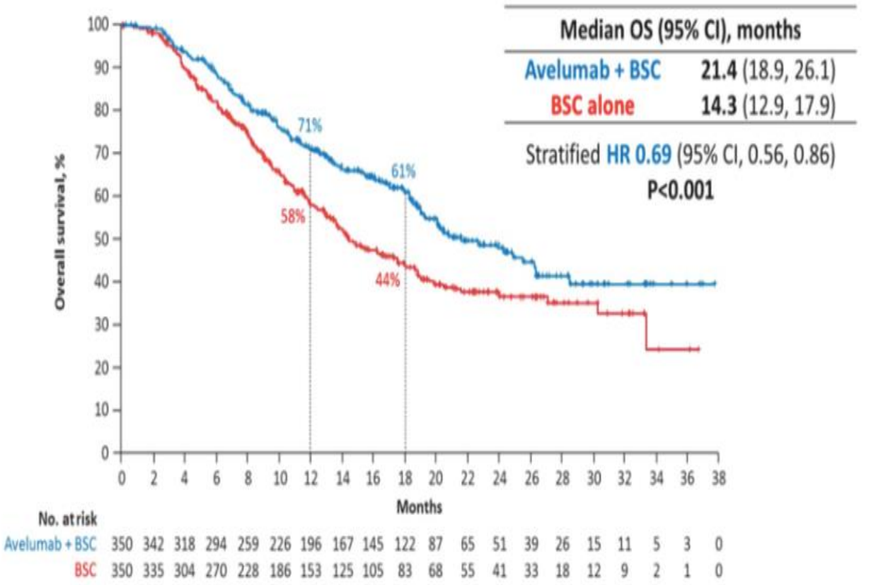


PD-L1+ status was defined as PD-L1 expression in ≥25% of tumor cells or in ≥25% or 100% of tumor-associated immune cells if the percentage of immune cells was >1% or ≤1%, respectively, using the Ventana SP263 assay; 358 patients (51%) had a PD-L1–positive tumor

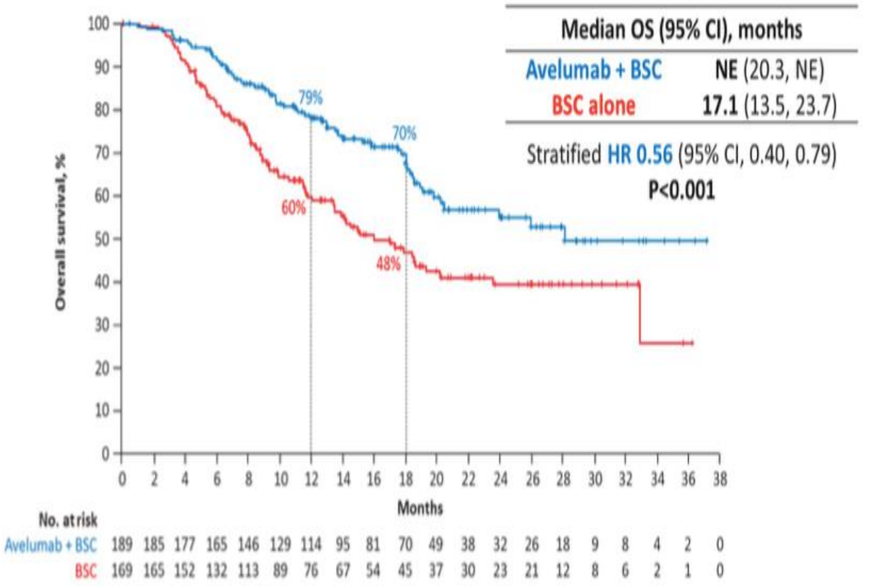
BSC, best supportive care; **CR**, complete response; **IV**, intravenous; **PR**, partial response; **PRO**, patient reported outcome; **Q2W**, every 2 weeks; **R**, randomization; **RECIST 1.1**, Response Evaluation Criteria in Solid Tumors version 1.1; **SD**, stable disease

*BSC (eg, antibiotics, nutritional support, hydration, or pain management) was administered per local practice based on patient needs and clinical judgment; other systemic antitumor therapy was not permitted, but palliative local radiotherapy for isolated lesions was acceptable

OS in the overall population



OS in the PD-L1+ population



OS was measured post randomization (after chemotherapy); the OS analysis crossed the prespecified efficacy boundary based on the alpha-spending function (P<0.0014). **NE**, not estimable

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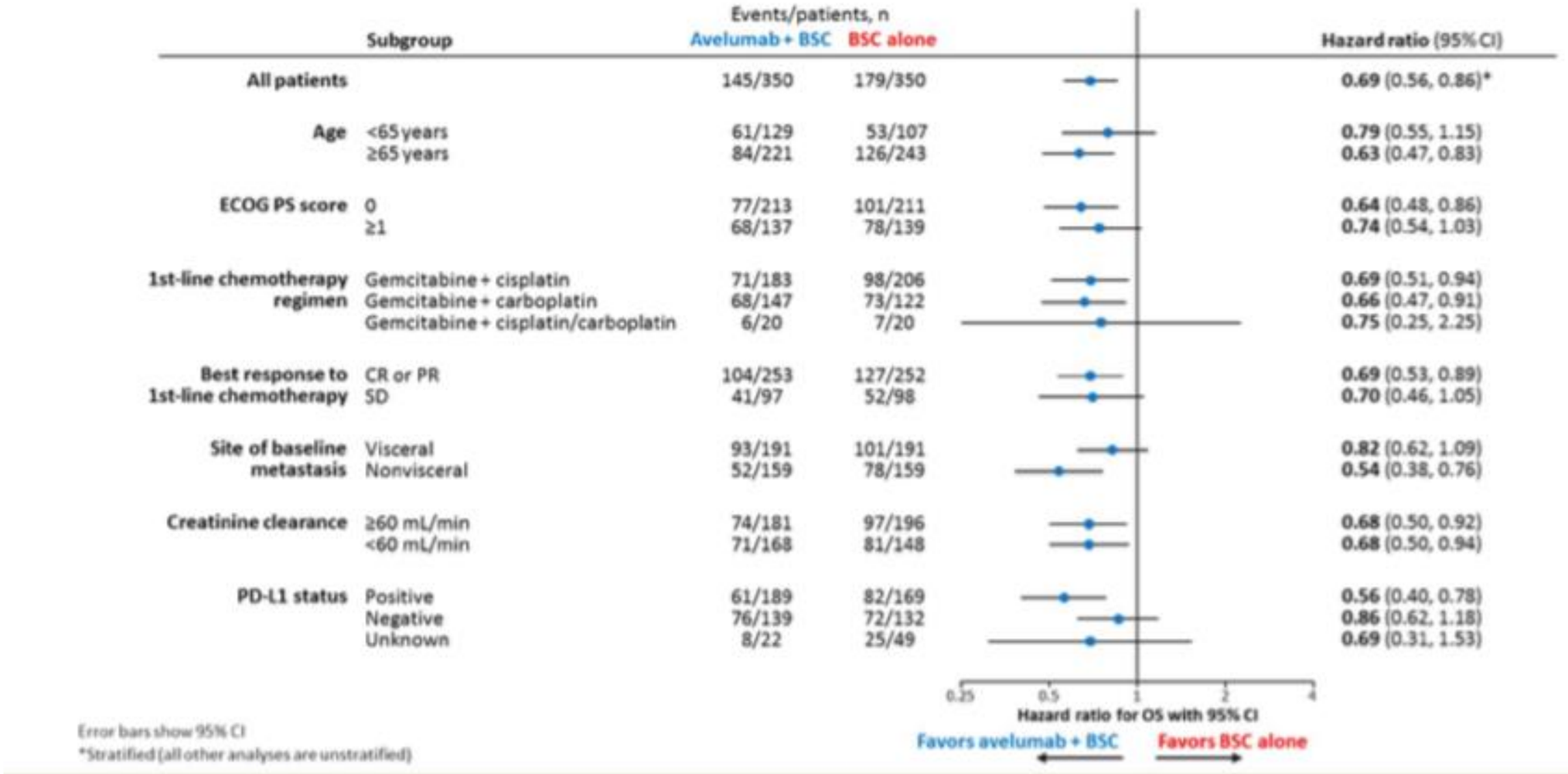
Subgroup analysis of OS in the overall population



Error bars show 95% CI

*Stratified (all other analyses are unstratified)

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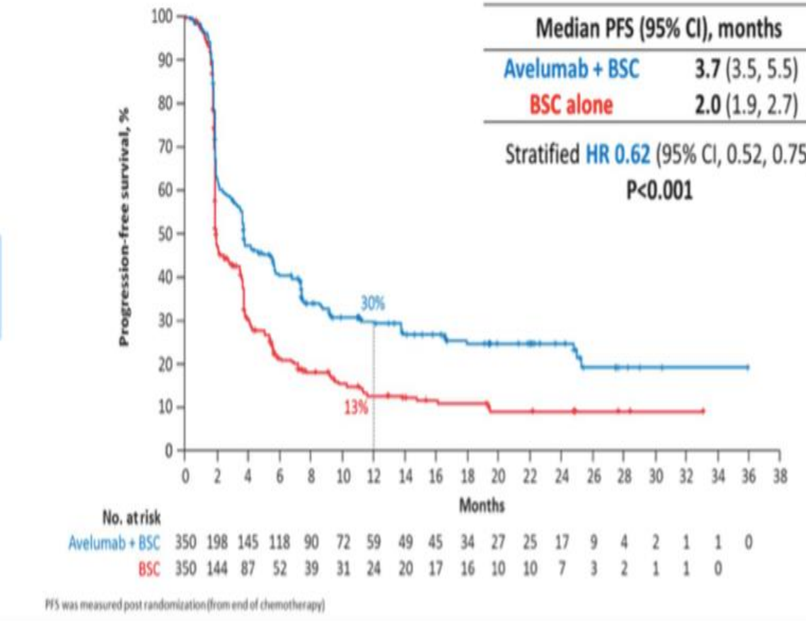
PFS by independent radiology review in the overall population

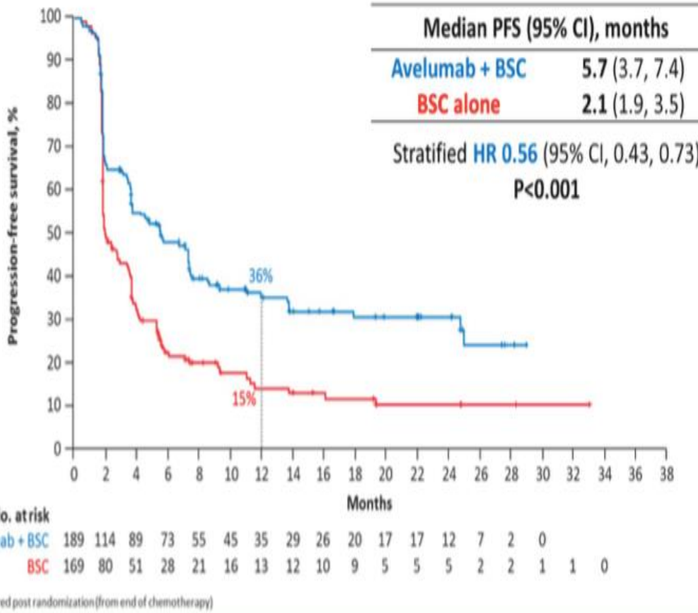


Median PFS (95% CI), months	
Avelumab + BSC	**3.7** (3.5, 5.5)
BSC alone	**2.0** (1.9, 2.7)

Stratified HR 0.62 (95% CI, 0.52, 0.75)
P<0.001

PFS was measured post randomization (from end of chemotherapy)

PFS by independent radiology review in the PD-L1+ population



Median PFS (95% CI), months	
Avelumab + BSC	**5.7** (3.7, 7.4)
BSC alone	**2.1** (1.9, 3.5)

Stratified HR 0.56 (95% CI, 0.43, 0.73)
P<0.001

PFS was measured post randomization (from end of chemotherapy)

Confirmed objective response

Response to maintenance therapy post randomization

	Overall population		PD-L1+ population	
	Avelumab + BSC (N=350)	BSC alone (N=350)	Avelumab + BSC (N=189)	BSC alone (N=169)
ORR, %	**9.7**	**1.4**	**13.8**	**1.2**
(95% CI)	(6.8, 13.3)	(0.5, 3.3)	(9.2, 19.5)	(0.1, 4.2)
Stratified odds ratio (95% CI)	7.464 (2.824, 24.445)		12.699 (3.160, 114.115)	
Best overall response, %				
Complete response	6.0	0.9	9.5	0.6
Partial response	3.7	0.6	4.2	0.6
Stable disease	12.6	13.1	10.1	13.6
Non-CR/non-PD	18.9	12.9	20.1	13.0
Progressive disease	37.1	48.3	31.2	48.5
Not evaluable*	21.7	24.3	24.9	23.7
Disease control, %†	41.1	27.4	43.9	27.8

PD, progressive disease
Objective response was assessed by independent radiology review; in patients with a CR after chemotherapy, best overall response was not evaluable if no evidence of disease at baseline was maintained after randomization, or PD if disease progression occurred after randomization
*Reasons for not evaluable included no evidence of disease at baseline; no post-baseline assessments; SD <6 weeks after randomization; PD >12 weeks after randomization; new anticancer therapy started before first post-baseline assessment; or all post-baseline assessments have objective response of not evaluable
†Patients with a best overall response of CR, PR, SD, or non-CR/non-PD

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IMvigor010 Study Design

Key eligibility[a]
- **High-risk MIUC (bladder, renal pelvis, ureter)**
- **Radical cystectomy/nephroureterectomy with LN dissection** within ≤ 14 weeks
  - **ypT2-T4a or ypN+** for patients treated with **NAC**[b]
  - **pT3-T4a or pN+** for patients **not treated with NAC**[b]
- No postsurgical radiation or AC
- If no prior NAC given, patient had to be ineligible for, or declined, cisplatin-based AC
- ECOG PS 0-2
- **Tissue sample for PD-L1 testing**

R 1:1

Atezolizumab 1200 mg q3w *(16 cycles or 1 year)*

No crossover allowed

Observation[c] **q3w**

Disease recurrence/ survival follow-up

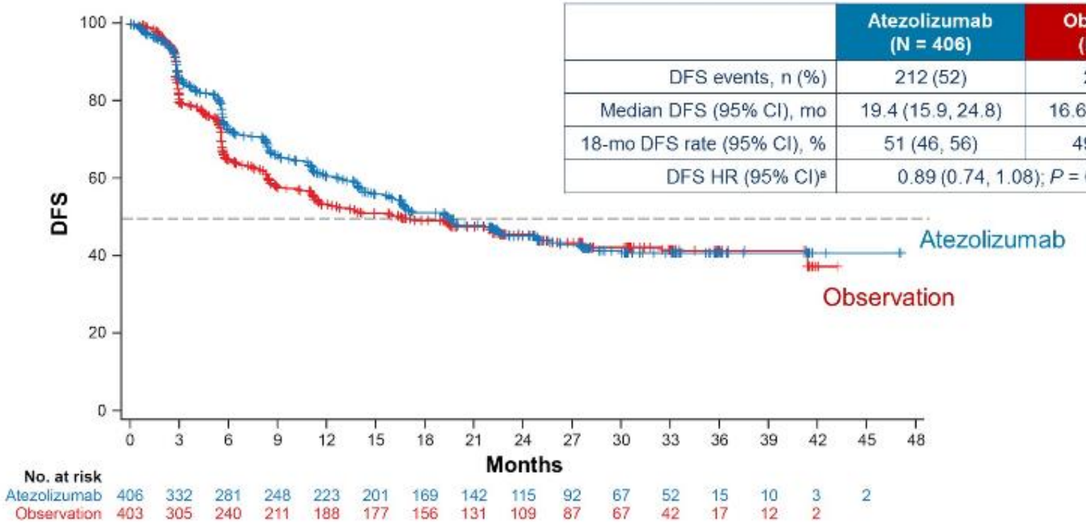
Tumor assessments: q12w for years 1-3, (q24w for years 4-5 and at year 6)

Stratification factors
- Number of LNs resected (< 10 vs ≥ 10)
- Prior NAC (Yes vs No)
- LN status (+ vs –)
- Tumor stage (≤ pT2 vs pT3/pT4)
- PD-L1 status[a] (IC0/1 vs IC2/3)

- **Primary endpoint:** DFS (ITT population)
- **Key secondary endpoint:** OS (ITT population)
- **Exploratory analyses:** Biomarkers including PD-L1 status
- **Safety**

DFS in ITT Population

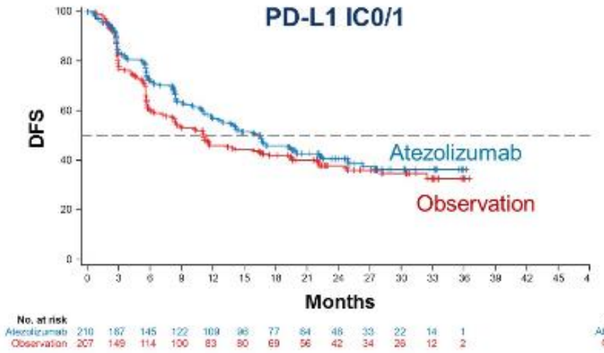
	Atezolizumab (N = 406)	Observation (N = 403)
DFS events, n (%)	212 (52)	208 (52)
Median DFS (95% CI), mo	19.4 (15.9, 24.8)	16.6 (11.2, 24.8)
18-mo DFS rate (95% CI), %	51 (46, 56)	49 (44, 54)
DFS HR (95% CI)[a]	0.89 (0.74, 1.08); *P* = 0.2446[b]	

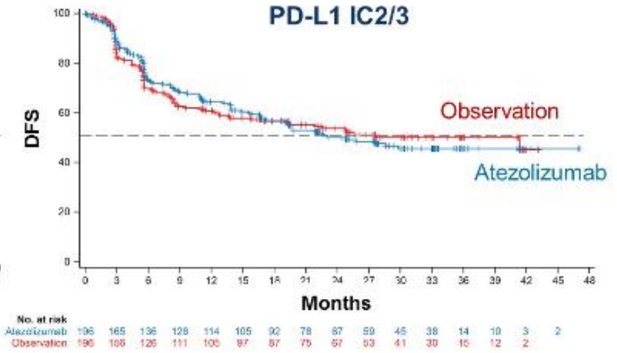


Data cutoff: November 30, 2019. Median follow-up: 21.9 mo. [a] Stratified by post-resection tumor stage, nodal status and PD-L1 status. [b] 2-sided.

Maha HA Hussain, et al. ASCO © 2020. Abstract 5000.

DFS by PD-L1 Status

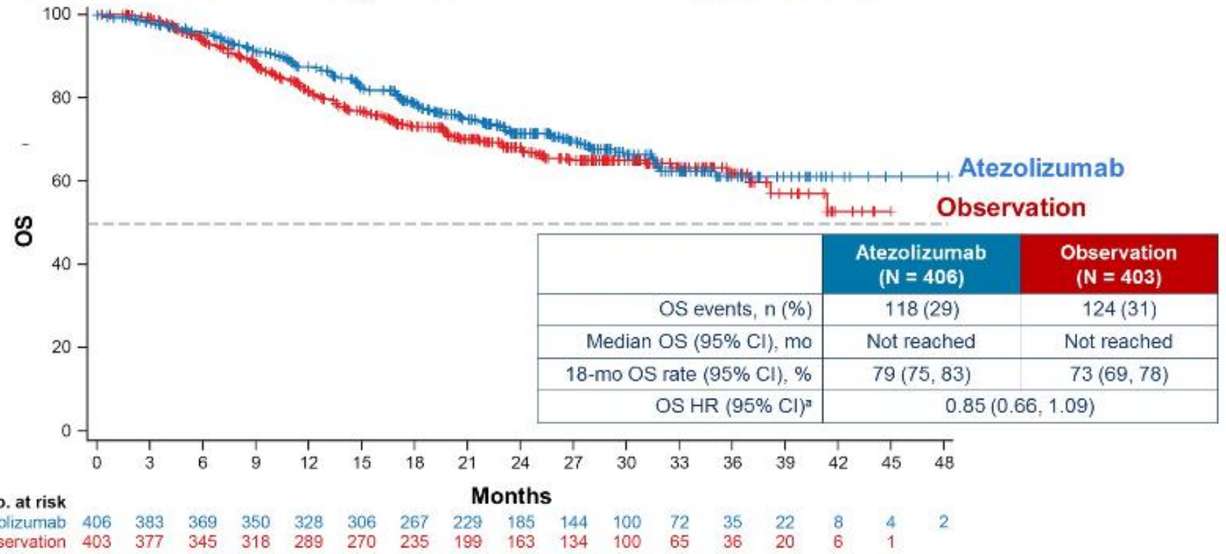




	Atezolizumab (n = 210)	Observation (n = 207)
DFS events, n (%)	118 (56)	120 (58)
HR (95% CI)[a]	0.81 (0.63, 1.05)	

Atezolizumab (n = 196)	Observation (n = 196)
94 (48)	88 (45)
1.01 (0.75, 1.35)	

Interim OS Analysis in ITT Population



	Atezolizumab (N = 406)	Observation (N = 403)
OS events, n (%)	118 (29)	124 (31)
Median OS (95% CI), mo	Not reached	Not reached
18-mo OS rate (95% CI), %	79 (75, 83)	73 (69, 78)
OS HR (95% CI)[a]	0.85 (0.66, 1.09)	

Data cutoff: November 30, 2019. Median follow-up: 21.9 mo. Most common subsequent non-protocol therapies included immunotherapy (9% in atezolizumab arm vs 21% in observation arm), chemotherapy (27% vs 25%) and targeted therapy (5% vs 2%). [a] OS results are shown for descriptive purposes only. HR stratified by tumor stage, nodal status and PD-L1 status.

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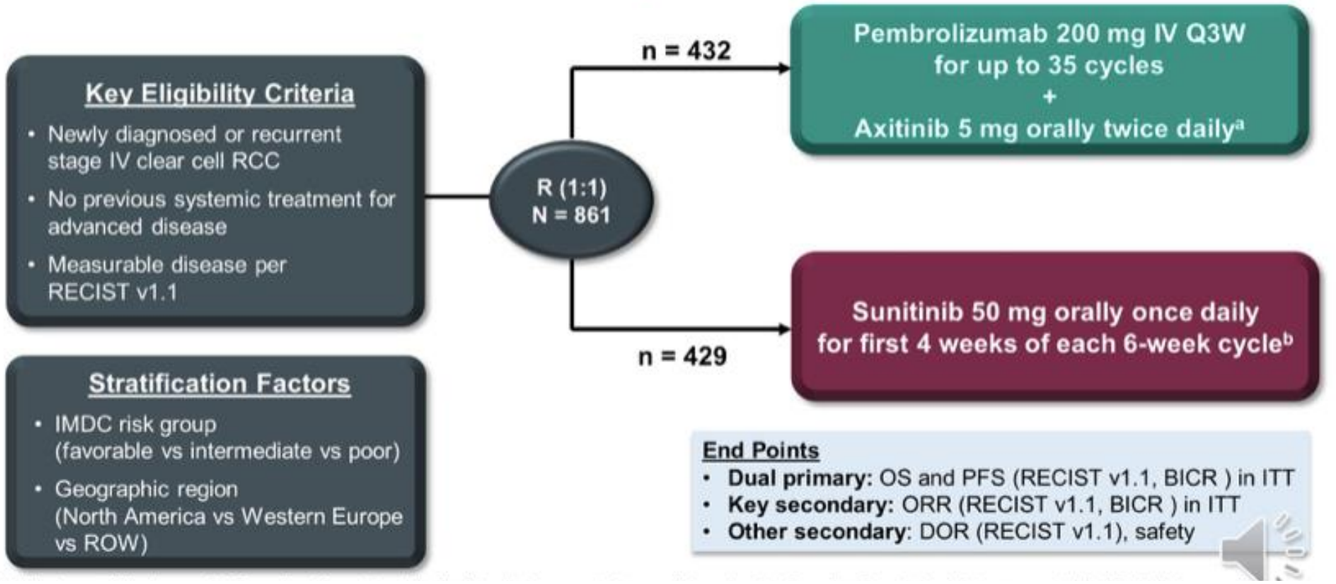
Renálny karcinóm

Pembrolizumab Plus Axitinib Versus Sunitinib as First-Line Therapy for Advanced Renal Cell Carcinoma: Updated Analysis of KEYNOTE-426

E. R. Plimack[1]; B. I. Rini[2]; V. Stus[3]; R. Gafanov[4]; T. Waddell[5]; D. Nosov[6]; F. Pouliot[7]; D. Soulières[8]; B. Melichar[9]; I. Vynnychenko[10]; S. J. Azevedo[11]; D. Borchiellini[12]; R. S. McDermott[13]; J. Bedke[14]; S. Tamada[15]; L. Yin[16]; M. Chen[16]; L. R. Molife[17]; M. B. Atkins[18]; T. Powles[19]

[1]Fox Chase Cancer Center, Philadelphia, PA, USA; [2]Clevland Clinic Taussig Cancer Institute, Cleveland, OH, USA (currently at Vanderbilt-Ingram Cancer Center, Nashville, TN, USA); [3]Dnipropetrovsk Medical Academy of Ministry of Health of Ukraine, Dnipro, Ukraine; [4]Russian Scientific Center of Roentgenoradiology, Moscow, Russia; [7]The Christie NHS Foundation Trust, Manchester, United Kingdom; [6]Central Clinical Hospital With Outpatient Clinic, Moscow, Russia; [7]CHU of Quebec and Laval University, Quebec City, QC, Canada; [8]Centre Hospitalier de l'Universitaire de Montréal, Montréal, QC, Canada; [9]Palacky University Medical School and Teaching Hospital, Olomouc, Czech Republic; [10]Sumy State University, Sumy Regional Oncology Center, Sumy, Ukraine; [11]Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil; [12]Centre Antoine Lacassagne, Université Côte d'Azur, Nice, France; [13]Adelaide and Meath Hospital and University College Dublin, Dublin, Ireland; [14]Eberhard-Karls University Tübingen, Tübingen, Germany; [15]Osaka City University Hospital, Osaka, Japan; [16]Merck & Co., Inc., Kenilworth, NJ, USA; [17]MSD UK, London, United Kingdom; [18]Georgetown Lombardi Comprehensive Cancer Center, Washington, DC, USA; [19]Barts Health NHS Trust and the Royal Free NHS Foundation Trust, Barts Cancer

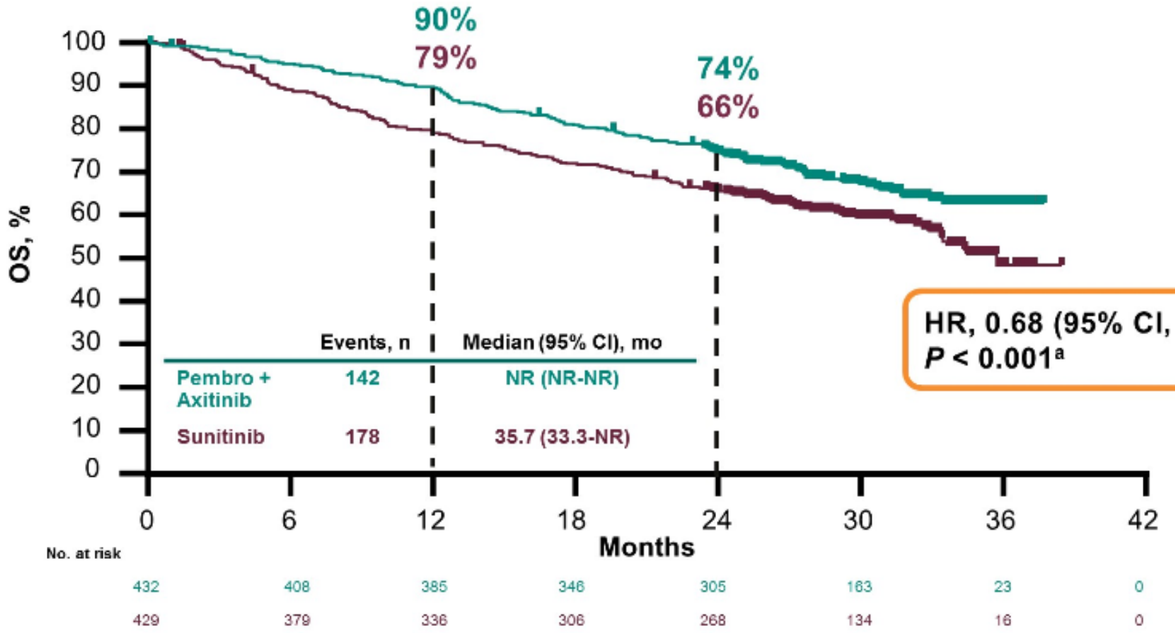
KEYNOTE-426 Study Design



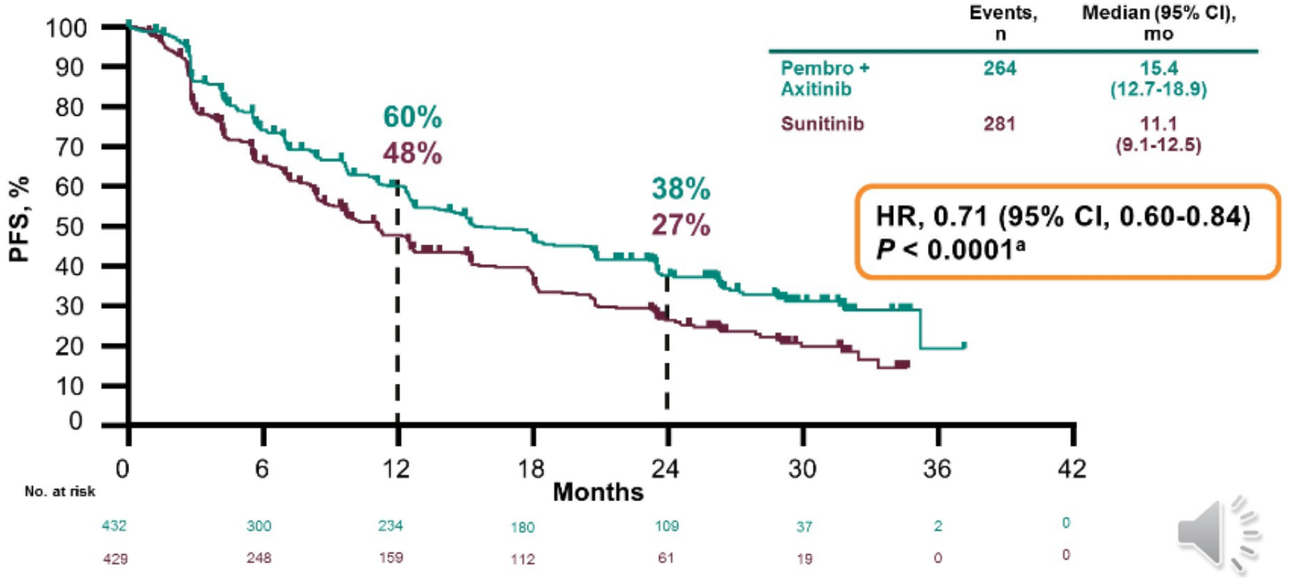
n (%)	Pembrolizumab + Axitinib n = 312	Sunitinib n = 349
Received any subsequent therapy	170 (54.5)	242 (69.3)
By type of treatment		
Any PD-1/PD-L1 inhibitor	25 (8.0)	169 (48.4)
Any VEGF/VEGFR inhibitor	153 (49.0)	159 (45.6)
Other	47 (15.1)	54 (15.5)

Elizabeth R Plimack, et al. ASCO

OS in the ITT Population



PFS in the ITT Population



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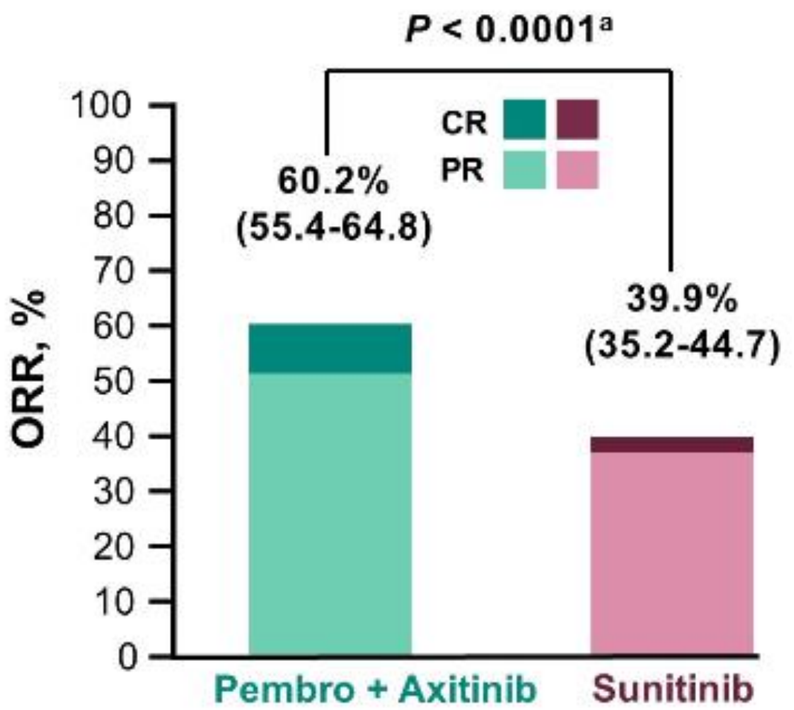
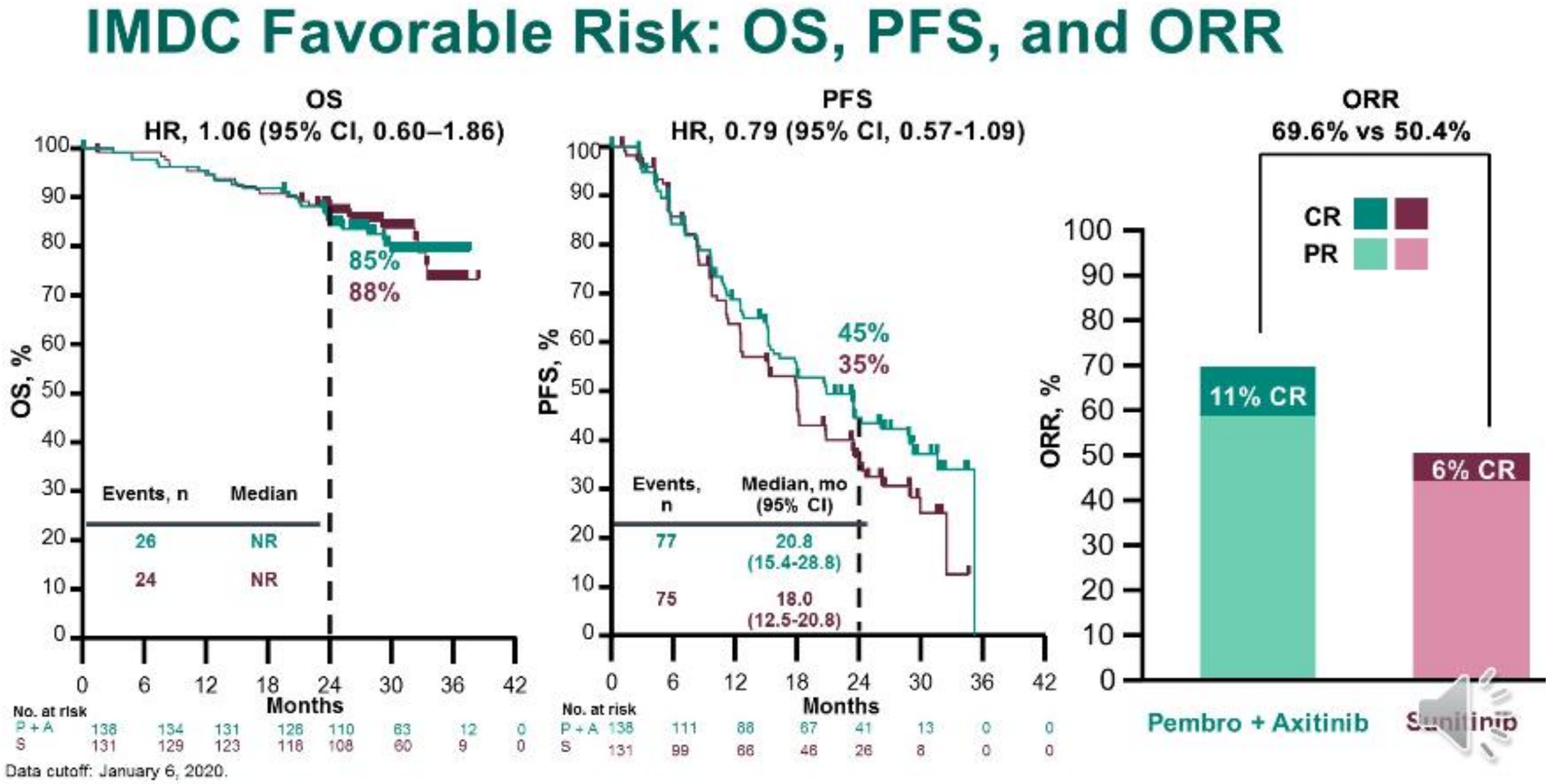
Percento objektívnych odpovedí (ITT populácia)



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

[a]Because superiority of pembrolizumab + axitinib was shown at the first interim analysis, no alpha was allocated to confirmed objective response; only nominal *P* values are reported. [b]Postbaseline assessment available but not evaluable (ie, all postbaseline assessments with insufficient data for assessment of response per RECIST v1.1 or CR/PR/SD <6 weeks from randomization). [c]No postbaseline assessment available for response evaluation; + indicates an ongoing response at time of last disease assessment. Data cutoff: January 6, 2020.

Výsledky podľa prognostických skupín



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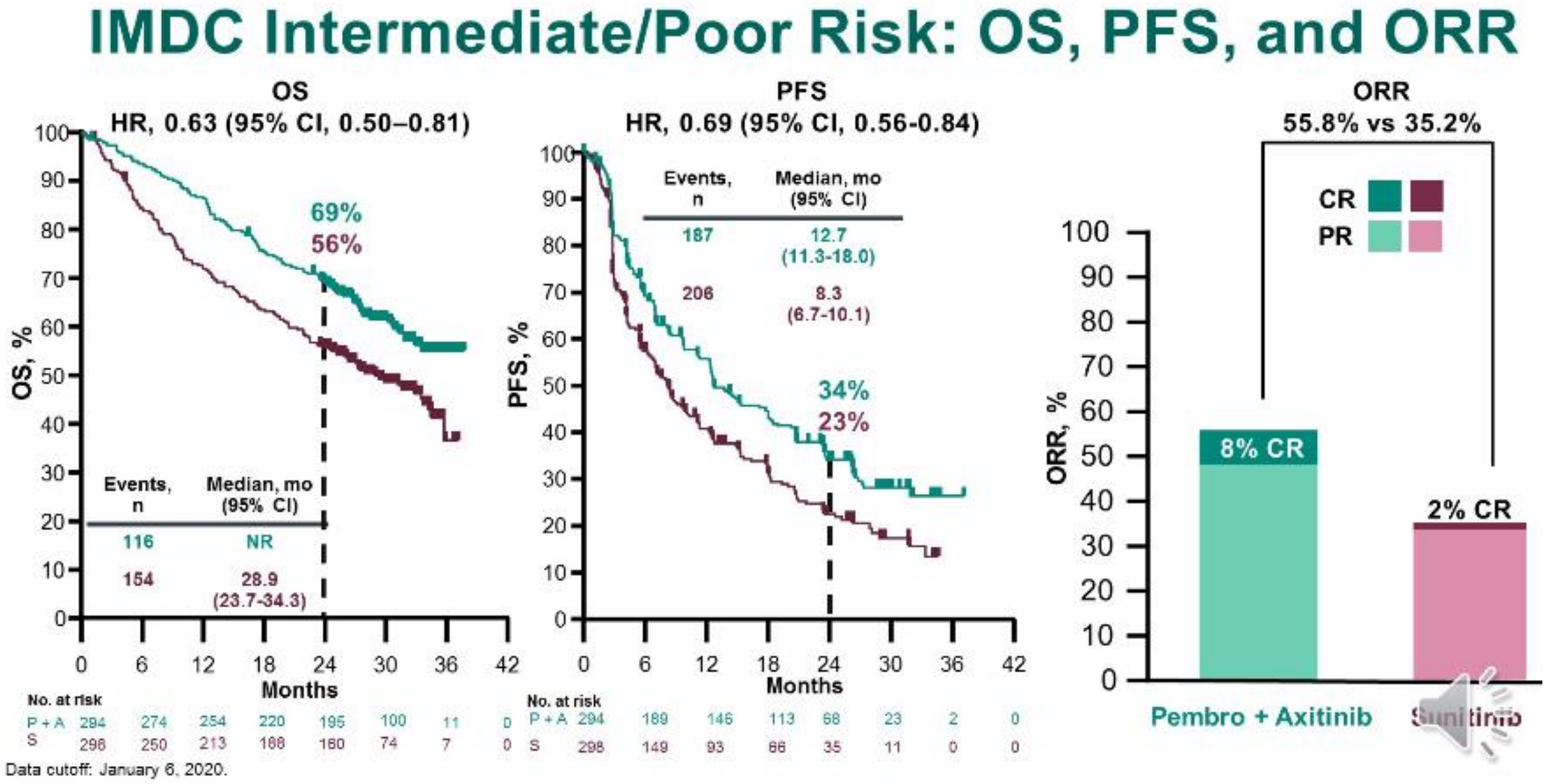
Výsledky podľa prognostických skupín



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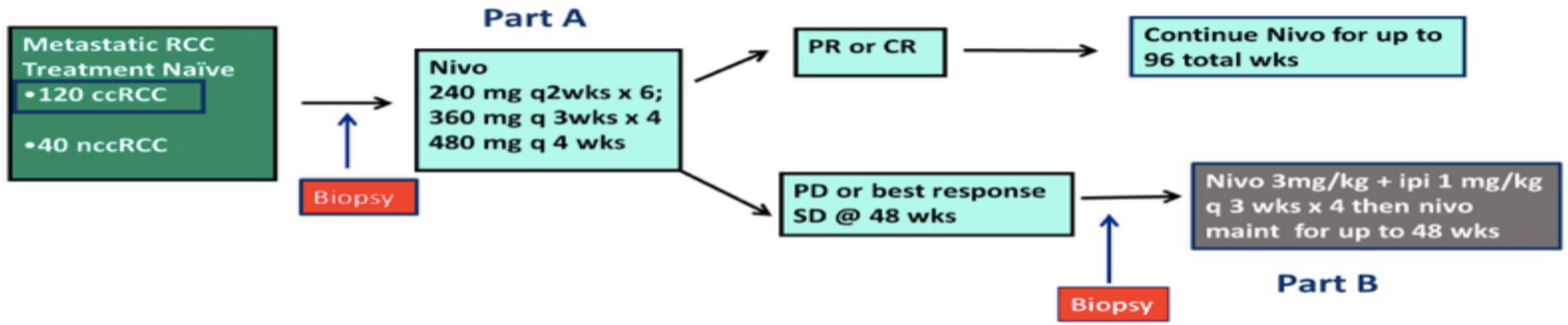
Phase II Study of Nivolumab and Salvage Nivolumab + Ipilimumab in Treatment-Naïve Patients with Advanced Renal Cell Carcinoma (HCRN GU16-260)

Michael B. Atkins[1], Opeyemi A. Jegede[2], Naomi B. Haas[3], David F. McDermott[4], Mehmet A. Bilen[5], Charles G. Drake[6], Jeffrey A. Sosman[7], Robert Alter[8], Elizabeth R. Plimack[9], Brian Rini[10], Michael Hurwitz[11], David Peace[12], Sabina Signoretti[13], Catherine J. Wu[2], Paul J. Catalano[2], Hans Hammers[14]

[1]Georgetown-Lombardi Comprehensive Cancer Center, Washington, DC; [2]Dana Farber Cancer Institute, Boston, MA; [3]University of Pennsylvania Abramson Cancer Center, Philadelphia, PA; [4]Beth Israel Deaconess Medical Center, Boston, MA; [5]Winship Cancer Institute of Emory University, Atlanta GA; [6]Columbia Herbert Irving Comprehensive Cancer Center, New York, NY; [7]Northwestern Lurie Comprehensive Cancer Center, Chicago, IL; [8]John Theurer Cancer Center, Hackensack, NJ; [9]Fox Chase Cancer Center, Philadelphia, PA; [10]Cleveland Clinic Taussig Cancer Institute, Cleveland, OH (currently at Vanderbilt-Ingram Cancer Center, Nashville, TN); [11]Yale-Smilow Comprehensive Cancer Center, New Haven, CT; [12]University of Illinois Chicago, Chicago, IL; [13]Brigham and Women's Hospital Boston, MA, [14]University of Texas Southwestern Sammons Cancer Center, Dallas, TX.

HCRN GU16-260: Study Design

IIT at 12 sites conducted through the HCRN GU Group
Support provided by BMS (CM209-669)



Objective Response Rates: Nivo Monotherapy: Part A

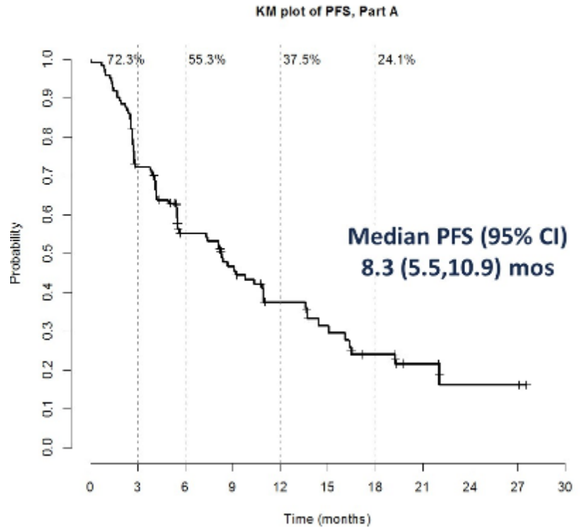
Best Response N (%)	IMDC Risk Category (N)			Total (N= 123) N (%)
	Favor (30) N (%)	Interm (80) N (%)	Poor (12) N (%)	
CR	4 (13.3)	3 (3.8)	0	7 (5.7)
PR*	11 (36.7)	17 (21.2)	3 (25)	32 (26.0)
SD	15 (50.0)	26 (32.5)	5 (42)	46 (37.4)
PD	0	34 (42.5)	4 (33)	38 (30.9)
ORR	15/30 (50)	20/80 (25)	3/12 (25)	39/123 (31.7)
(95% CI) %	(31.3,68.7)	(16.6, 35.1)		(23.6, 40.7)

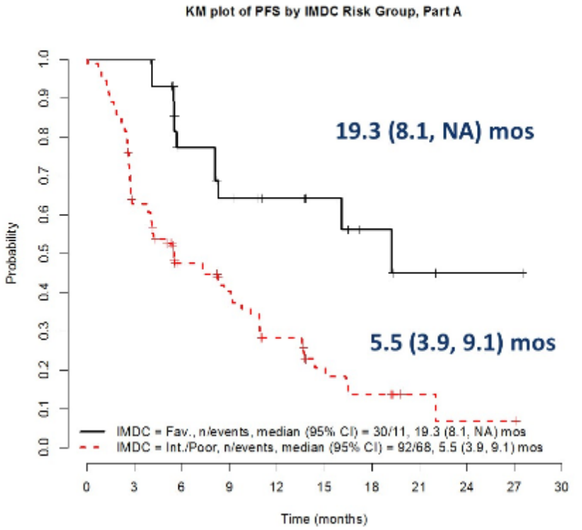
* 1 PR with missing IMDC Risk Category

ORR: 39/123 = 31.7%
95% CI (23.6, 40.7%)

Sarcomatoid RCC ORR:
7/22 = 31.8% (all PRs)
95% CI (13.9, 54.9%)

Progression Free Survival: Nivo Monotherapy (Part A)





Objective Response Rates: Nivo/Ipi Salvage (Part B)

Best Response N (%)	IMDC Risk Category (N=30)			Total N (%)
	Favor (4)	Interm (24)	Poor (2)	
CR	0	0	0	0
PR	2 (50)	2 (8.3)	0	4 (13.3)
SD	1 (25)	6 (25)	0	7 (23.3)
PD	1 (25)	16 (66.7)	2 (100)	19 (63.3)

ORR: 4/30 = 13.3%
95% CI (3.8, 30.7)

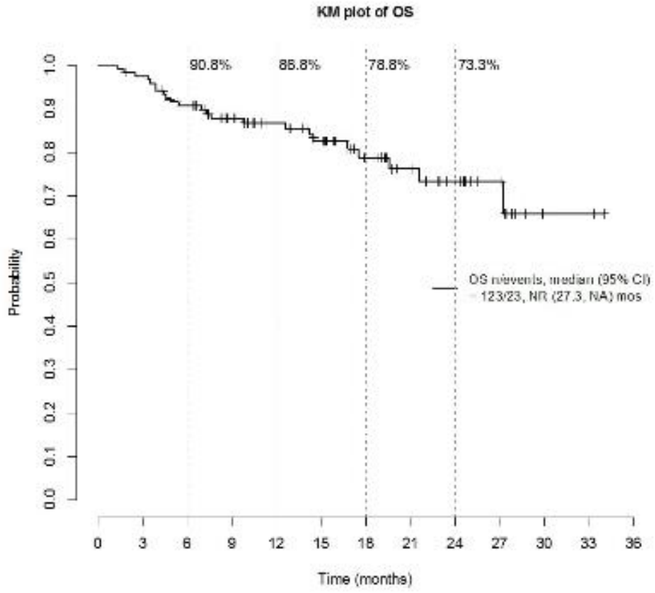
Treatment Emergent Toxicity: Nivo/ipi Salvage (Part B)

N=30	Grade 2: N (%)	Grade ≥ 3: N (%)
Fatigue	5 (17%)	2 (7%)
Colitis/Diarrhea	2 (7%)	4 (13%)
Endocrine	2 (7%)	1 (3%)
Hepatic	0	1 (3%)
Renal	0	2 (7%)
Lipase	6 (20%)	7 (23%)
Pulmonary	1 (3%)	1 (3%)
Myositis/myocarditis	2 (7%)	1 (3%)
Skin	5 (17%)	2 (7%)

Grade ≥ 3 Toxicity
12/30 = 40%

7 of 12 ↑Lipase

Overall Survival: ccRCC



100/123 = 81% of patients remain alive

Ďakujem za pozornosť

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