Onkologisk behandling av avansert og metastatisk cancer renis: en ny tidsepoke

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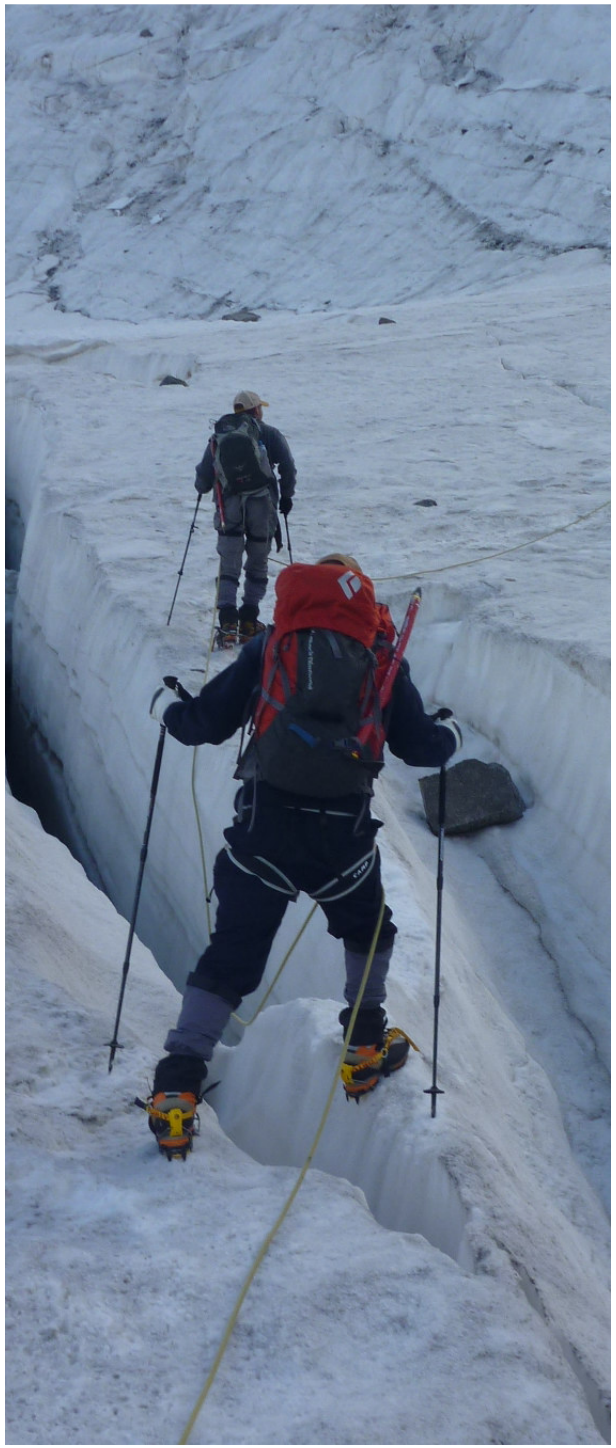
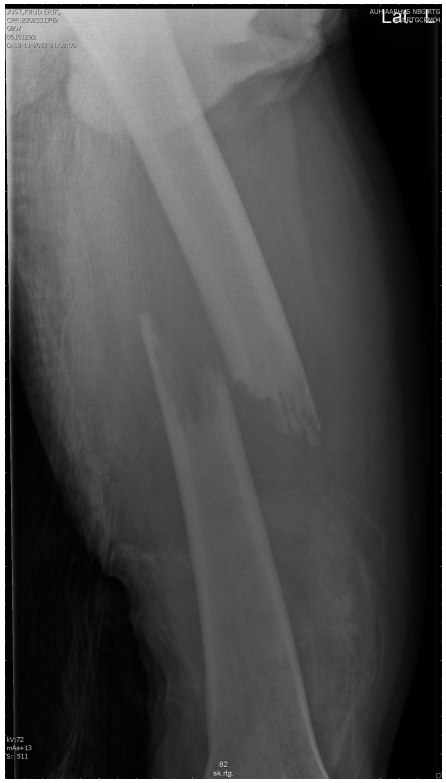
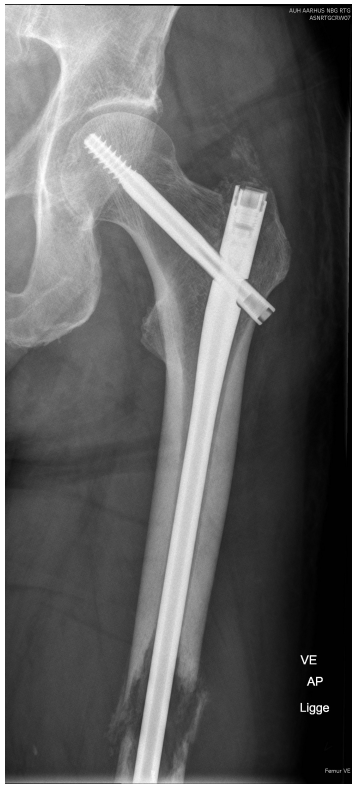
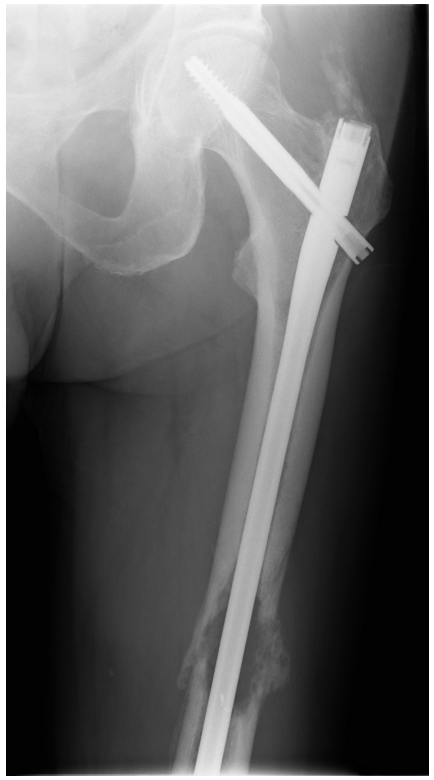
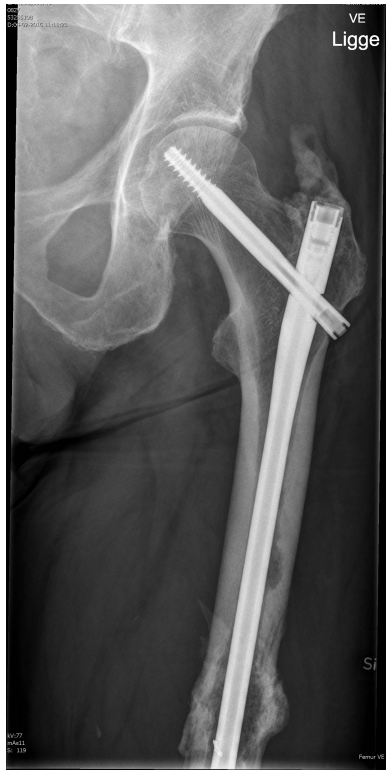



en ny tidsepoke









18.11.2013 **2.1.2014** **12.6.2014** **4.2.2016**

21.11.2013 surgery. Biopsy mRCC. 80 yr male. Primary kidney tumor 5.5 cm + lung + bone mets

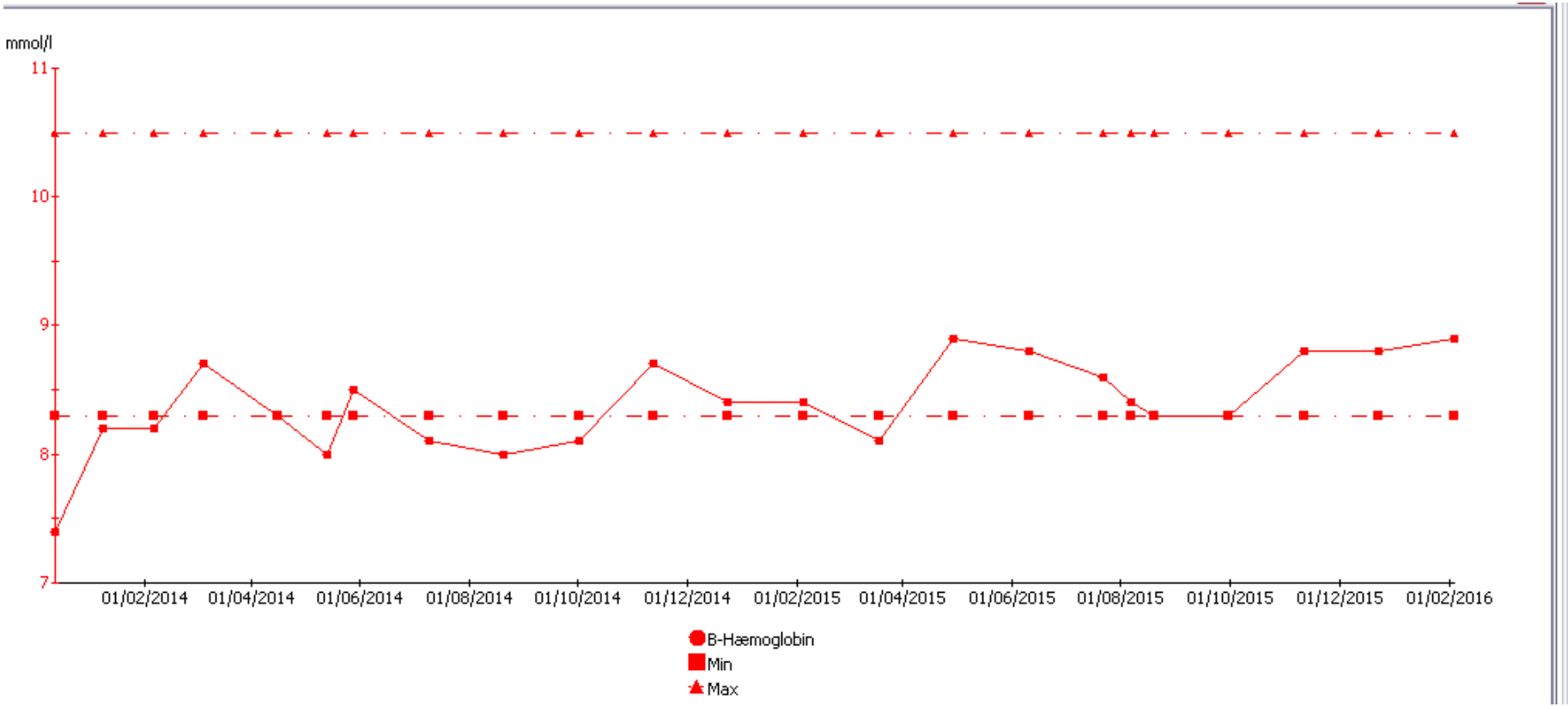
12.12.2013 start pazopanib 600 mg daily

16.1.2014 Rx 20Gy / 4 F

4.2.2014 start zoledronic acid after prior specialist dentist examination

28.5.2014 pazopanib 800 mg daily. Development of hypertension (treated with losartan)

11.6.2015. start rehabilitation with physical exercise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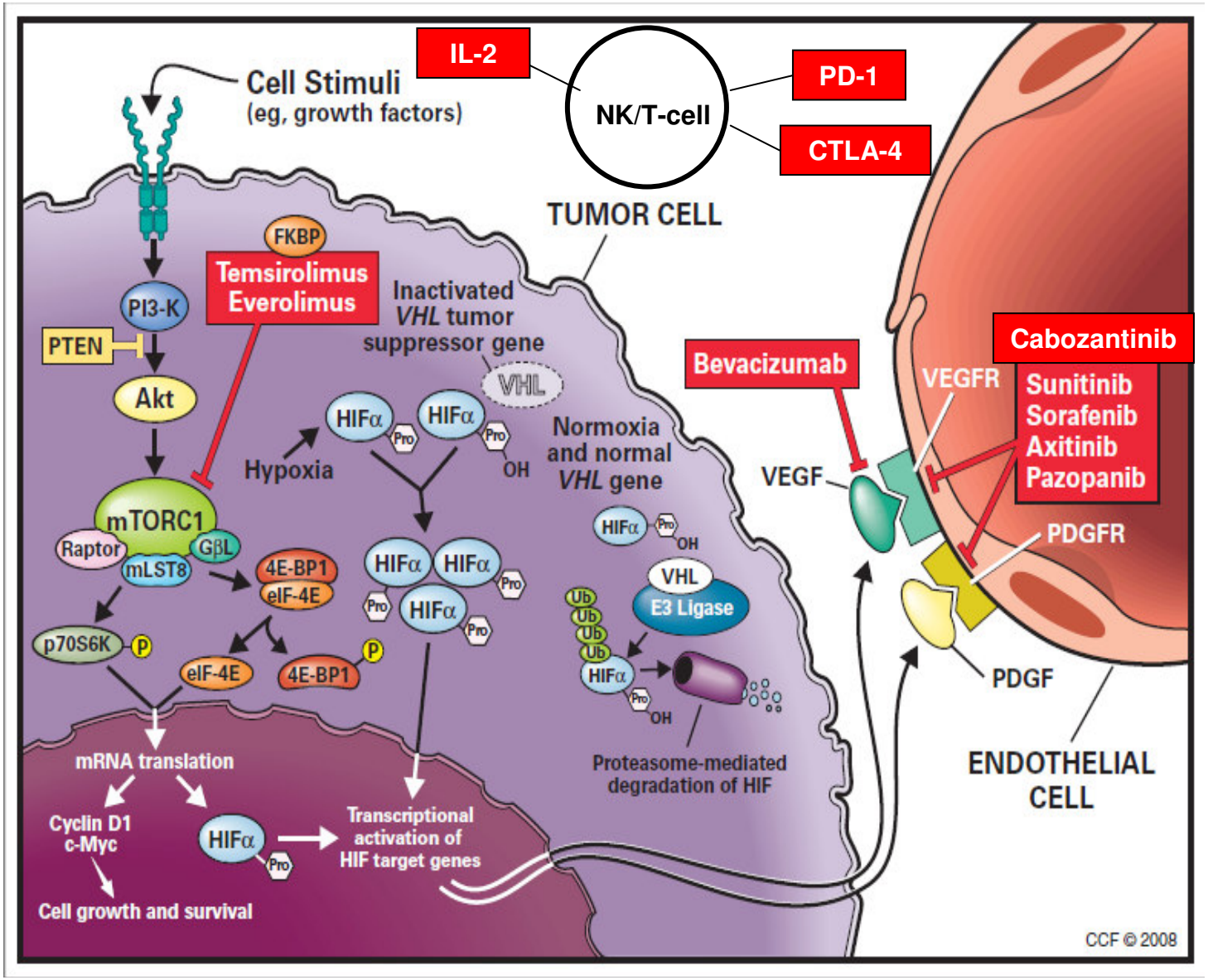
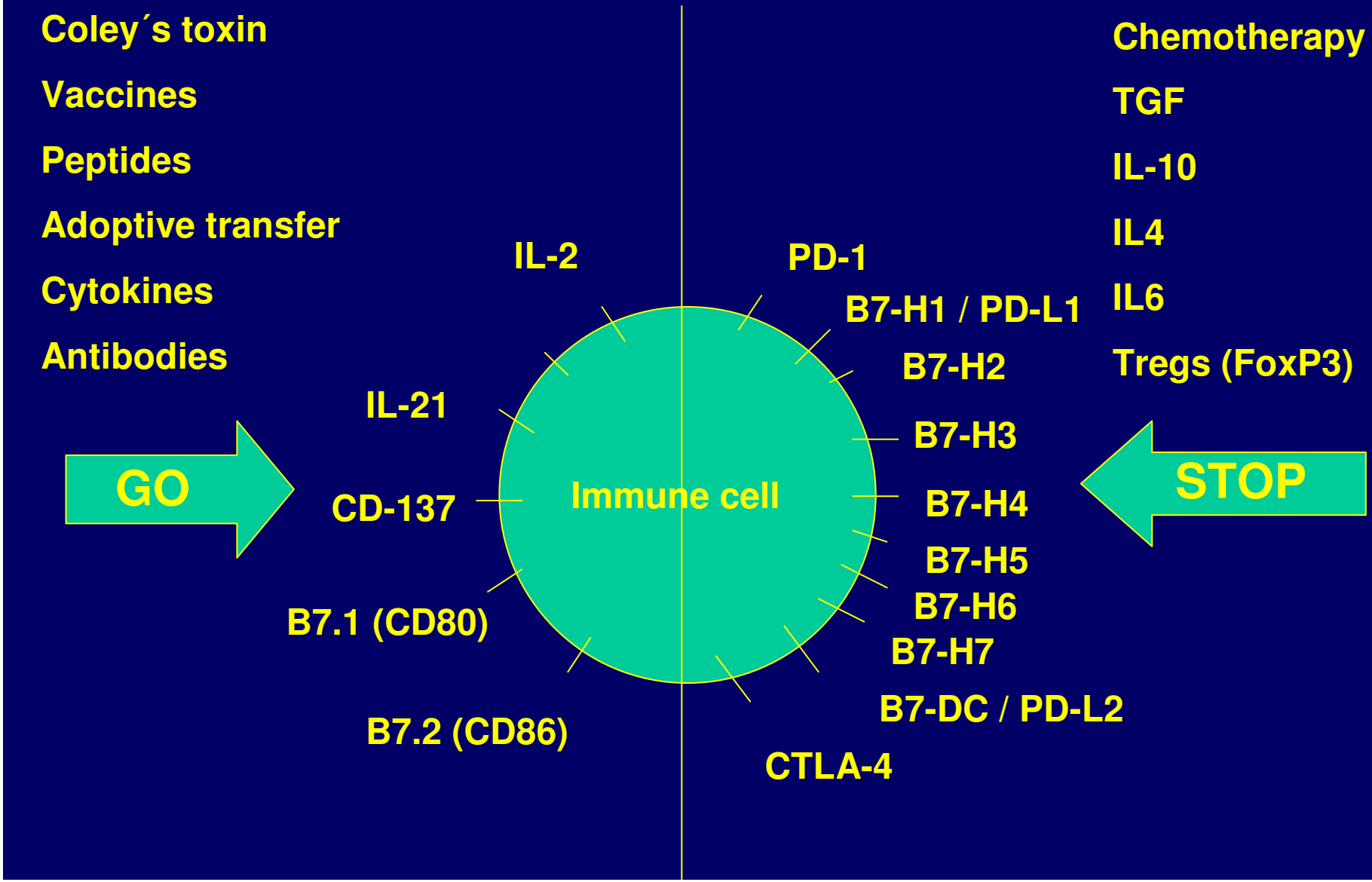
01/02/2016
B-Hæmoglobin
Min
Max

mRCC – major progress in few years

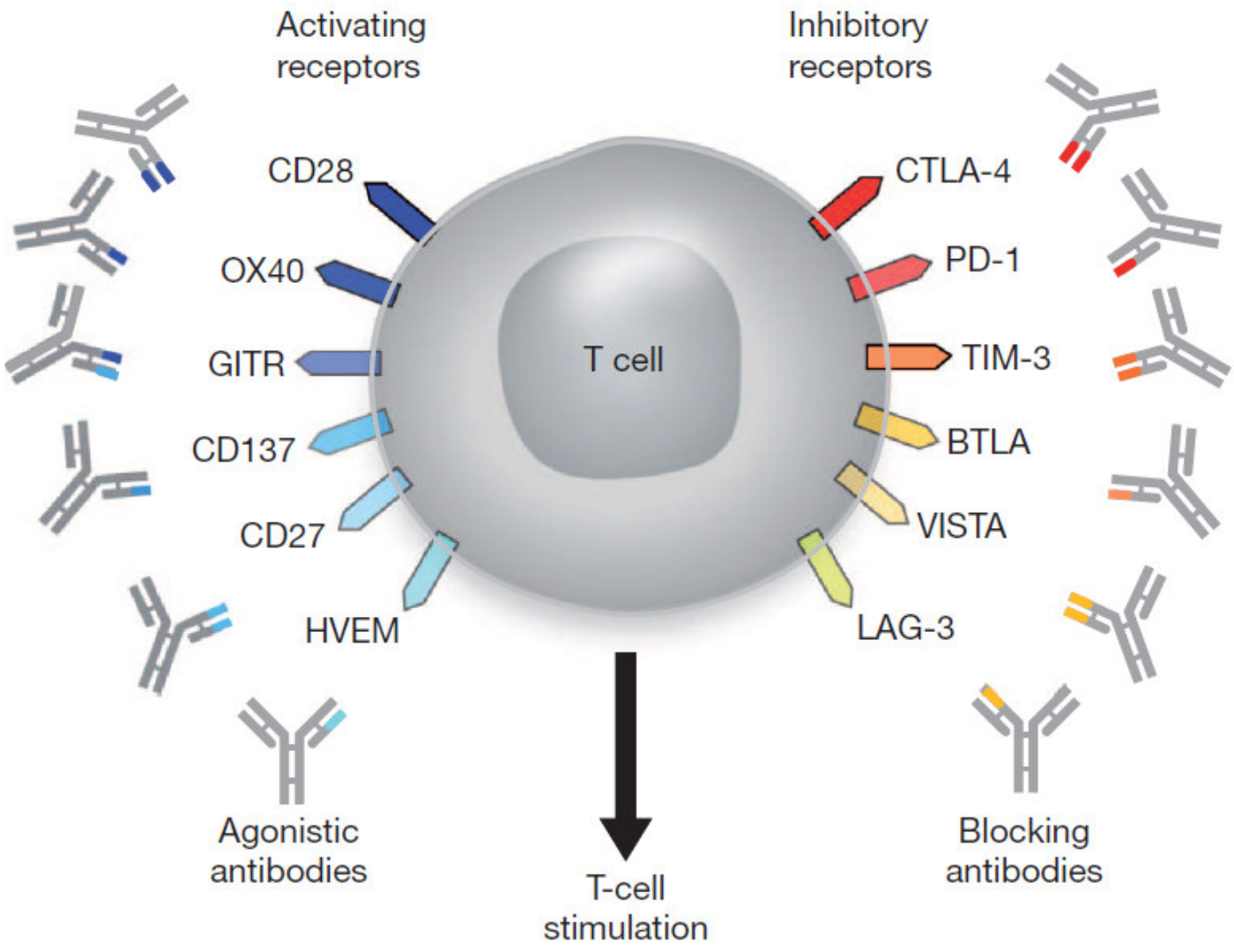


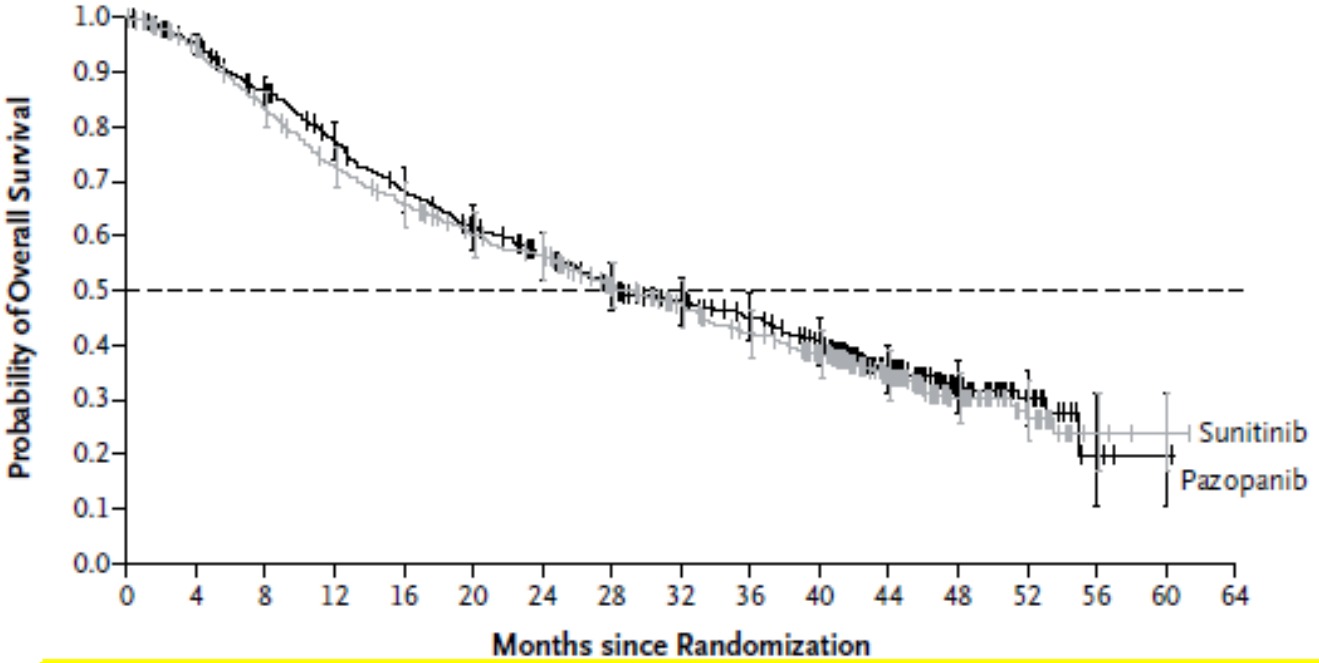
Rini, Lancet 2009

”Stop” & ”Go” signals in immune system



PD1/PDL-1 is just the beginning





	pazopanib	sunitinib
Med OS	28.3 mo	29.1 mo
MSKCC Fav	42.5 mo	43.6 mo
MSKCC Int	26.9 mo	26.1 mo
MSKCC poor	9.9 mo	7.7 mo
Second line	55%	54%
Tx-stop due to AE	24%	20%

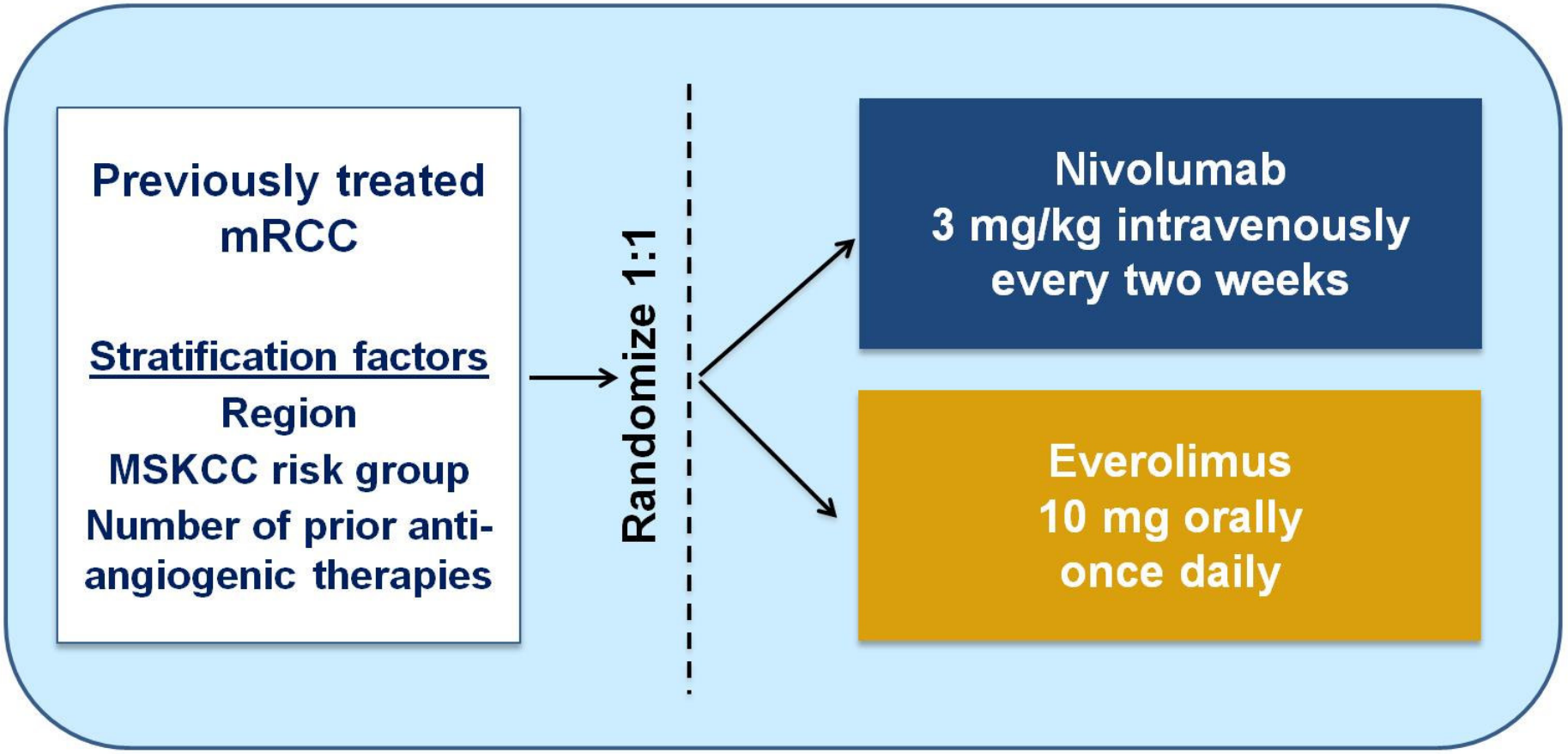
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 5, 2015 VOL. 373 NO. 19

Nivolumab versus Everolimus in Advanced Renal-Cell Carcinoma

R.J. Motzer, B. Escudier, D.F. McDermott, S. George, H.J. Hammers, S. Srinivas, S.S. Tykodi, J.A. Sosman, G. Procopio, E.R. Plimack, D. Castellano, T.K. Choueiri, H. Gurney, F. Donskov, P. Bono, J. Wagstaff, T.C. Gauler, T. Ueda, Y. Tomita, F.A. Schutz, C. Kollmannsberger, J. Larkin, A. Ravaud, J.S. Simon, L.-A. Xu, I.M. Waxman, and P. Sharma, for the CheckMate 025 Investigators*

Study design



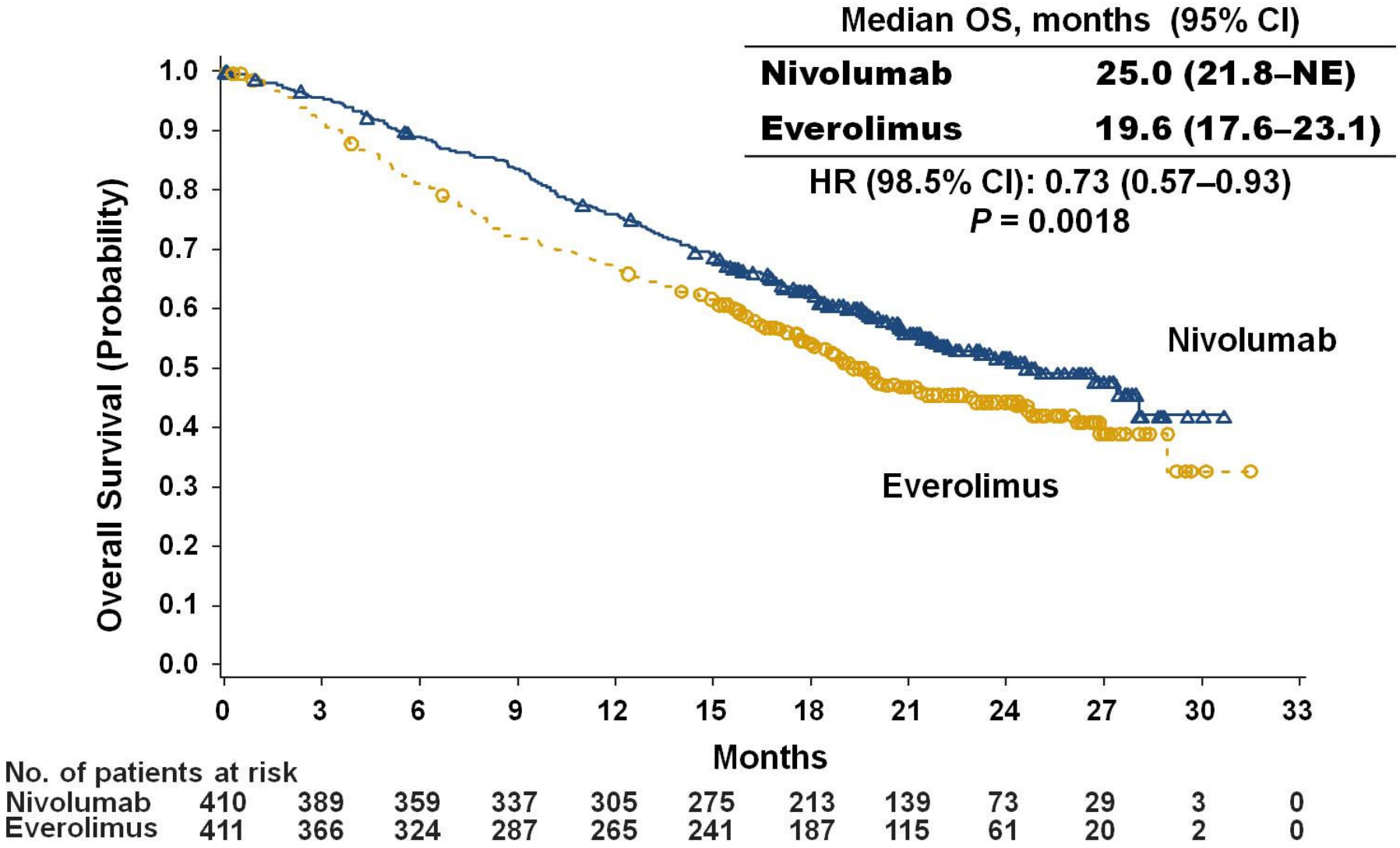
- Patients were treated until progression or intolerable toxicity occurred
- Treatment beyond progression was permitted if drug was tolerated and clinical benefit was noted

MSKCC, Memorial Sloan-Kettering Cancer Center.

Demographics and baseline characteristics

Characteristic	Nivolumab N = 410	Everolimus N = 411
Median age (range), years	62 (23–88)	62 (18–86)
Sex, %		
Female	23	26
Male	77	74
MSKCC risk group, %		
Favorable	35	36
Intermediate	49	49
Poor	16	15
Number of prior anti-angiogenic regimens in advanced setting, %		
1	72	72
2	28	28
Region, %		
US/Canada	42	42
Western Europe	34	34
Rest of the world	23	24

Overall survival



Minimum follow-up was 14 months.

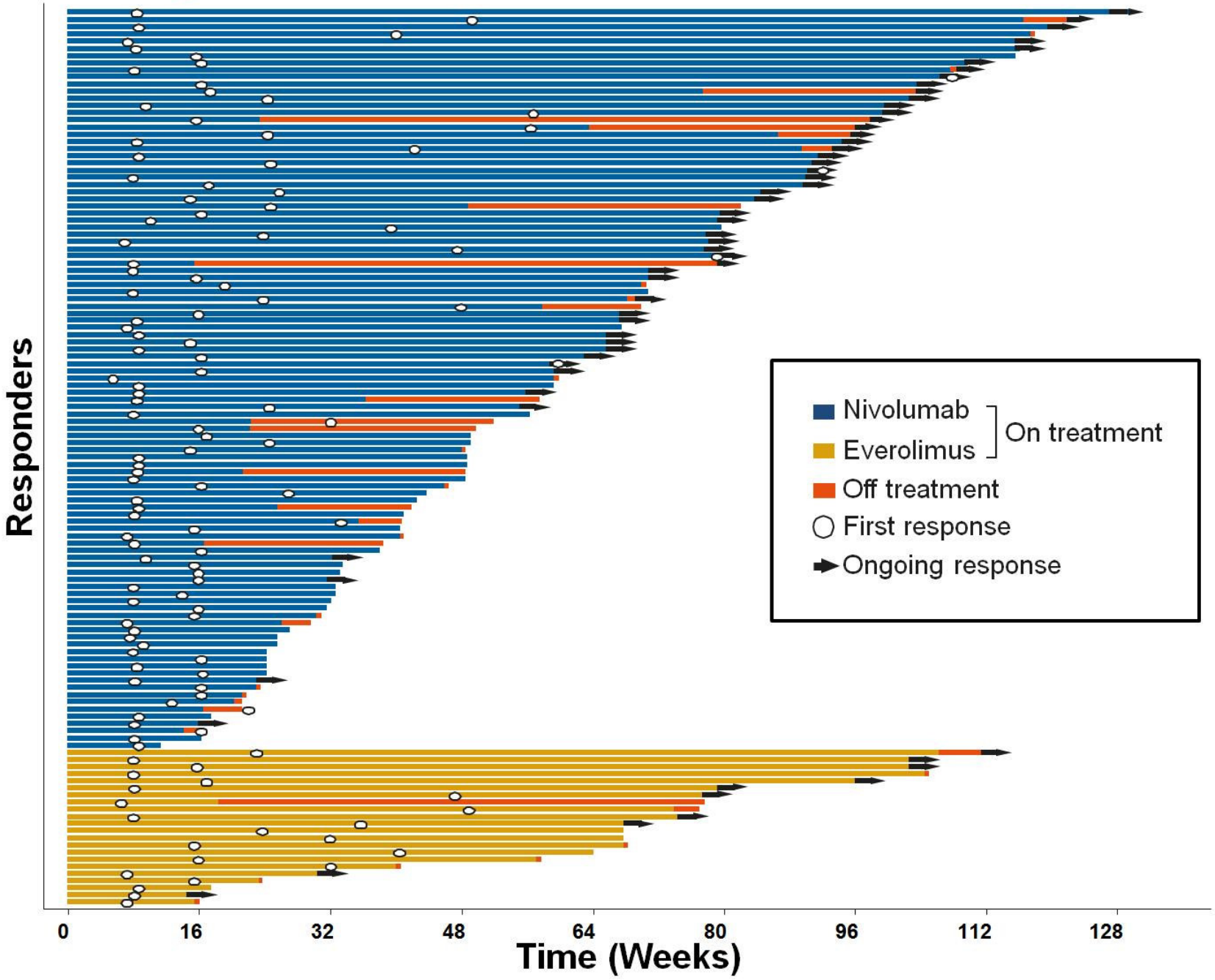
NE, not estimable.

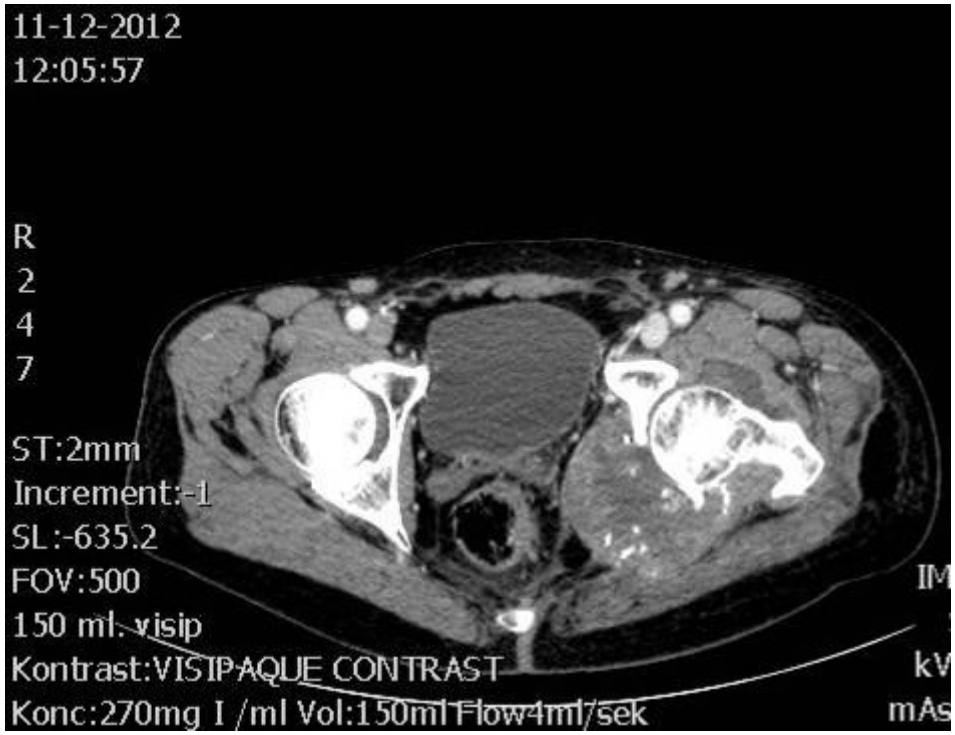
Antitumor activity

	Nivolumab N = 410	Everolimus N = 411
Objective response rate, %	25	5
Odds ratio (95% CI)	5.98 (3.68–9.72)	
P value	<0.0001	
Best overall response, %		
Complete response	1	1
Partial response	24	5
Stable disease	34	55
Progressive disease	35	28
Not evaluated	6	12
Median time to response, months (range)	3.5 (1.4–24.8)	3.7 (1.5–11.2)
Median duration of response, months (range)*	12.0 (0–27.6)	12.0 (0–22.2)
Ongoing response, n/N (%)	49/103 (48)	10/22 (45)

*For patients without progression or death, duration of response is defined as the time from the first response (CR/PR) date to the date of censoring.

Response characteristics

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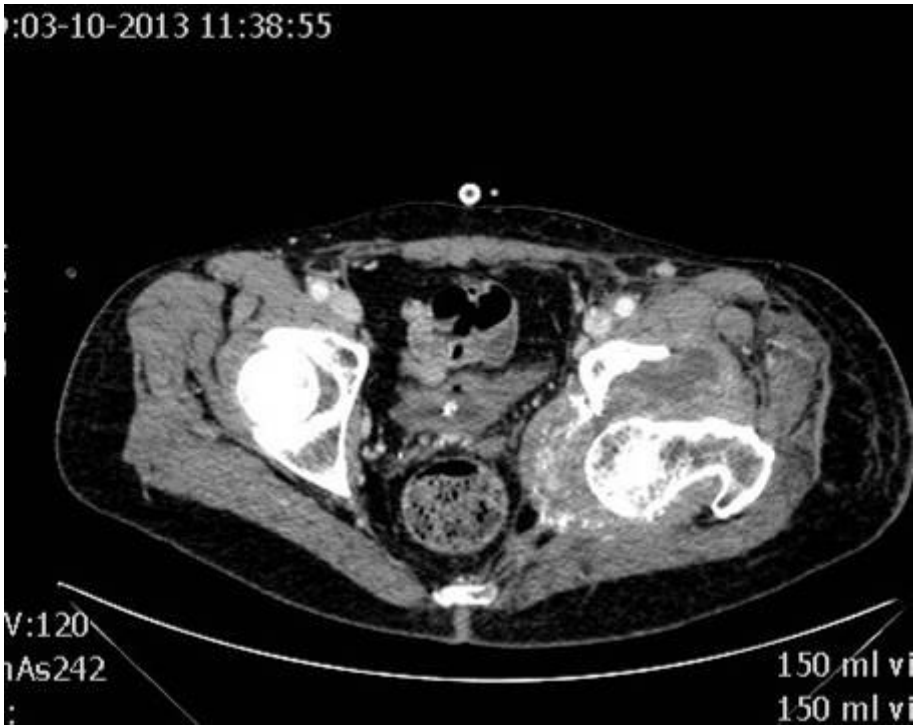
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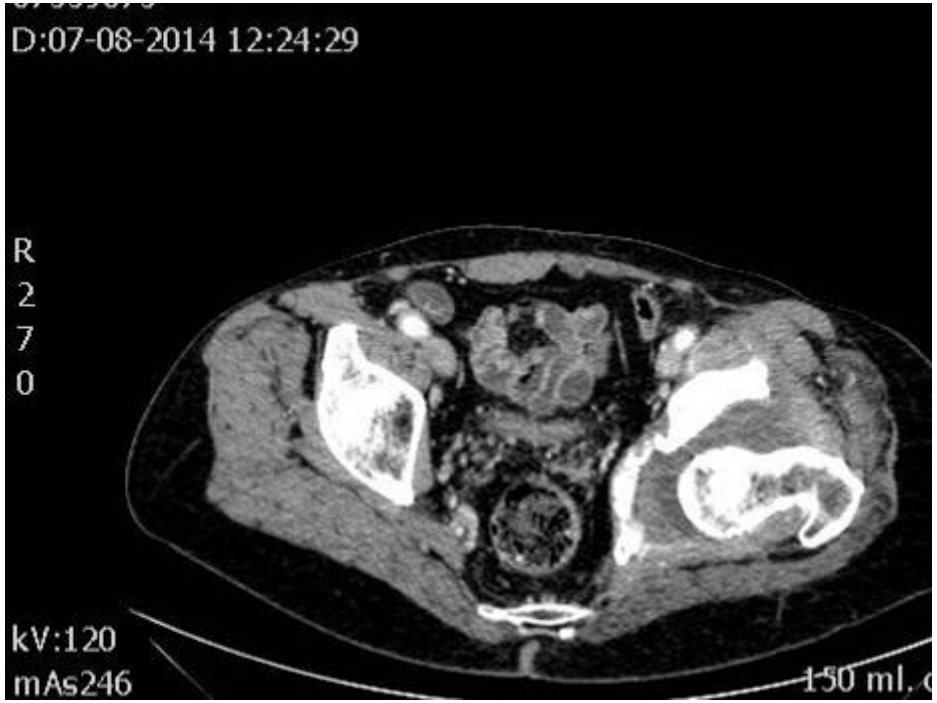
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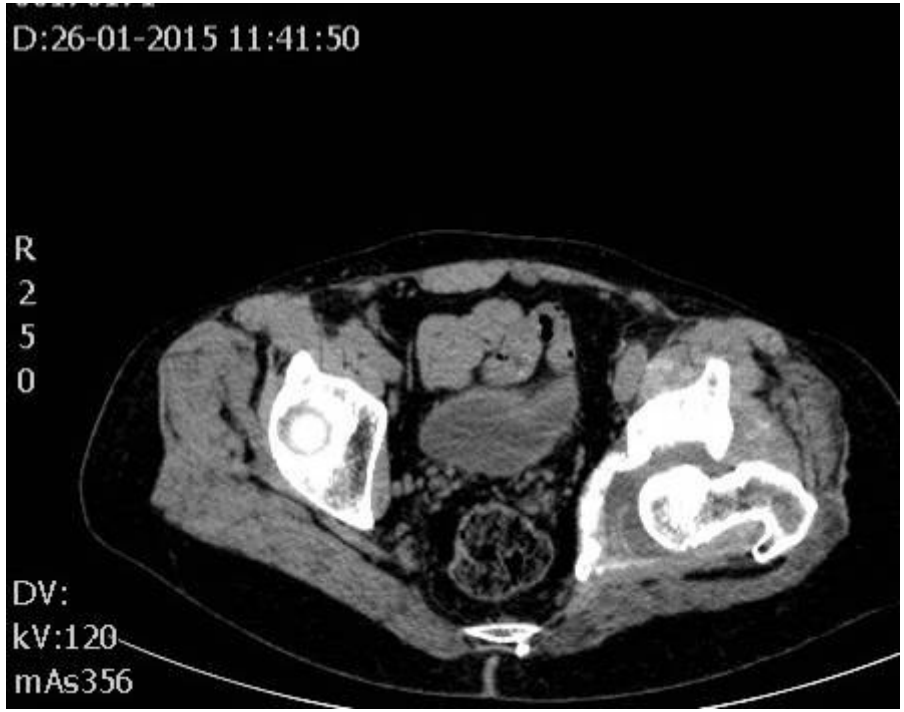
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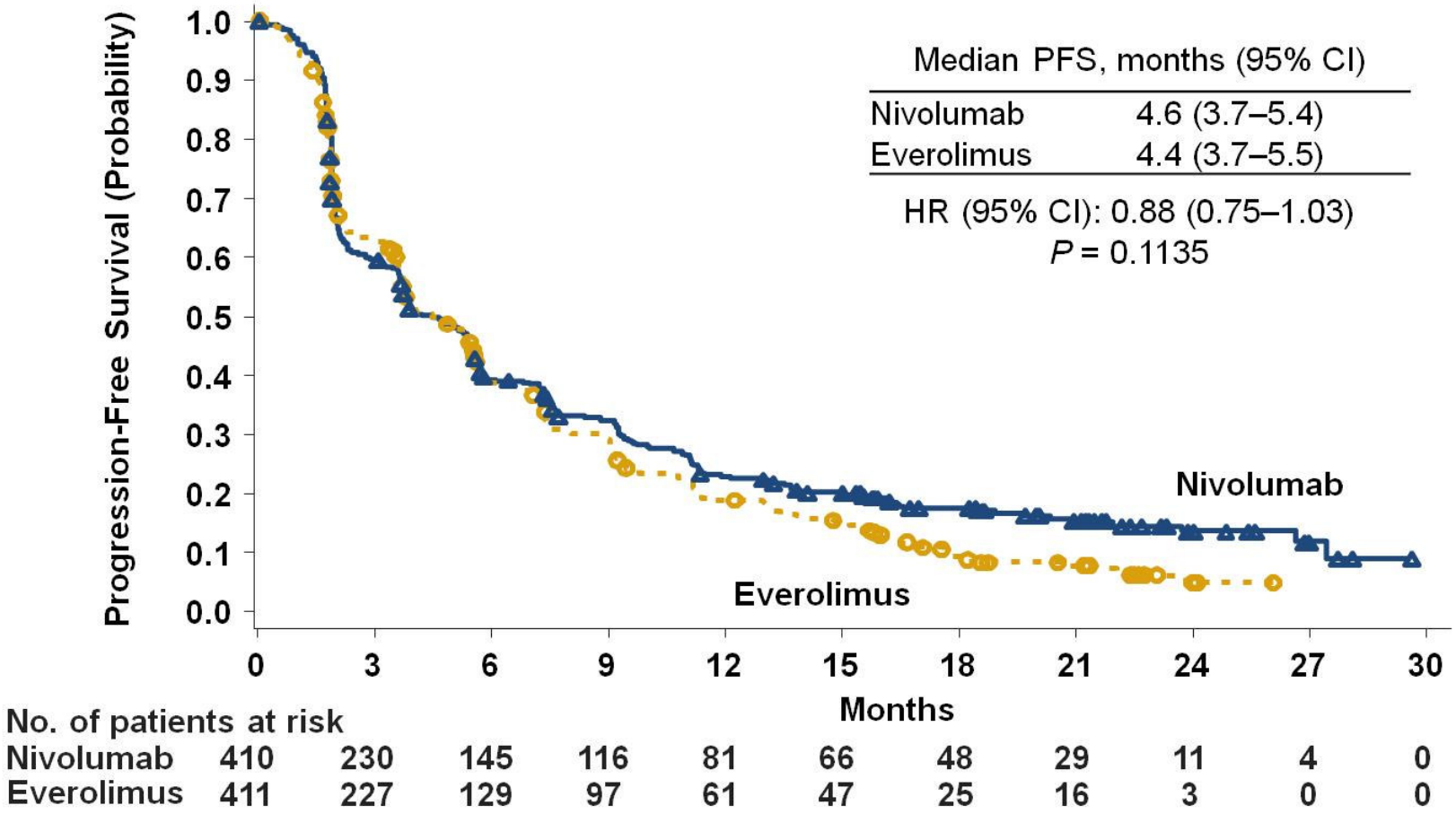
Progression-free survival



- In a post-hoc analysis of patients who had not progressed or died at 6 months, median PFS was 15.6 months for nivolumab vs 11.7 months for everolimus (HR (95% CI): 0.64 (0.47–0.88))

Safety Summary

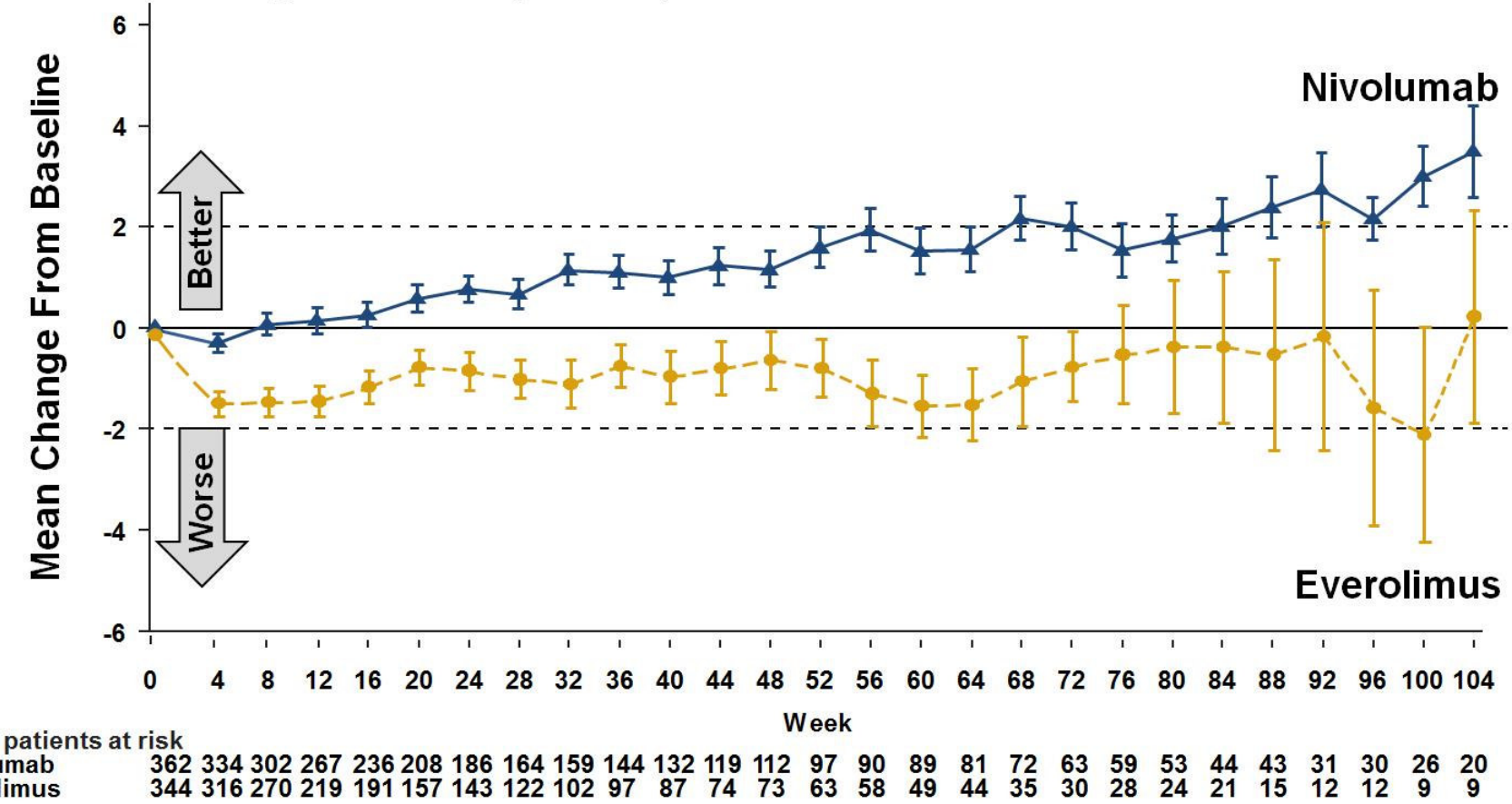
	Nivolumab N = 406		Everolimus N = 397	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
Treatment-related AEs, %	79	19	88	37
Treatment-related AEs leading to discontinuation, %	8	5	13	7
Treatment-related deaths, n	0		2[a]	

- 44% of patients in the nivolumab arm and 46% of patients in the everolimus arm were treated beyond progression

[a] Septic shock (1), bowel ischemia (1).

Change from baseline in quality of life scores on FKSI-DRS

- Mean change from baseline in the nivolumab group increased over time and differed significantly from the everolimus group at each assessment through week 76 ($P<0.05$)



No. of patients at risk

Nivolumab	362	334	302	267	236	208	186	164	159	144	132	119	112	97	90	89	81	72	63	59	53	44	43	31	30	26	20
Everolimus	344	316	270	219	191	157	143	122	102	97	87	74	73	63	58	49	44	35	30	28	24	21	15	12	12	9	9

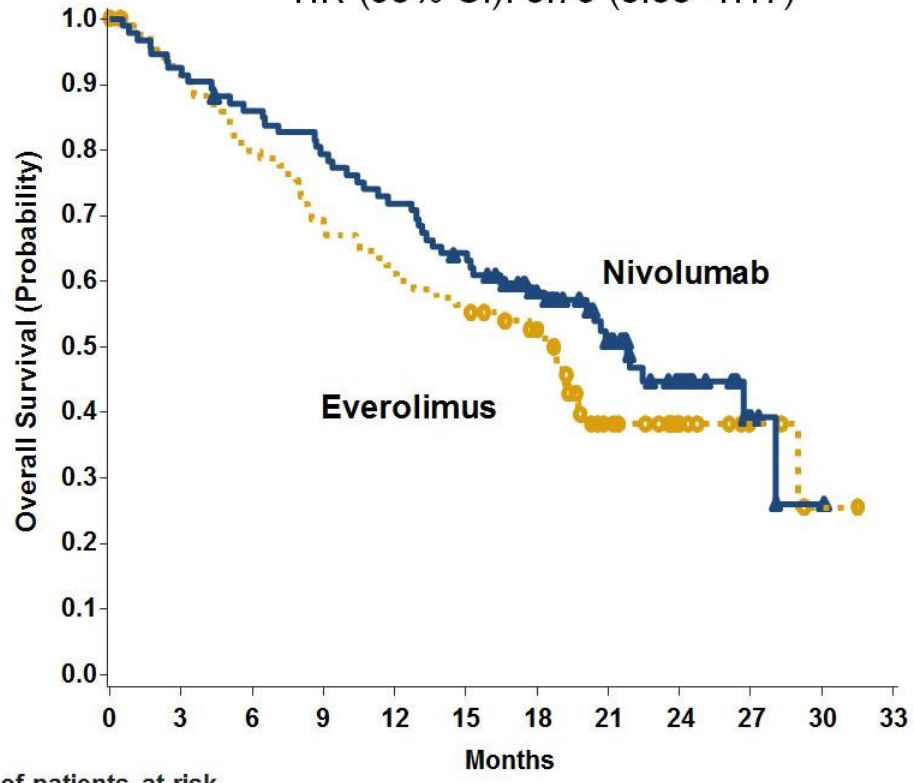
Questionnaire completion rate: ≥80% during the first year of follow-up.

Overall survival by PD-L1 expression

PD-L1 ≥1% (n = 24%)

Median OS, months (95% CI)	
Nivolumab	21.8 (16.5–28.1)
Everolimus	18.8 (11.9–19.9)

HR (95% CI): 0.79 (0.53–1.17)

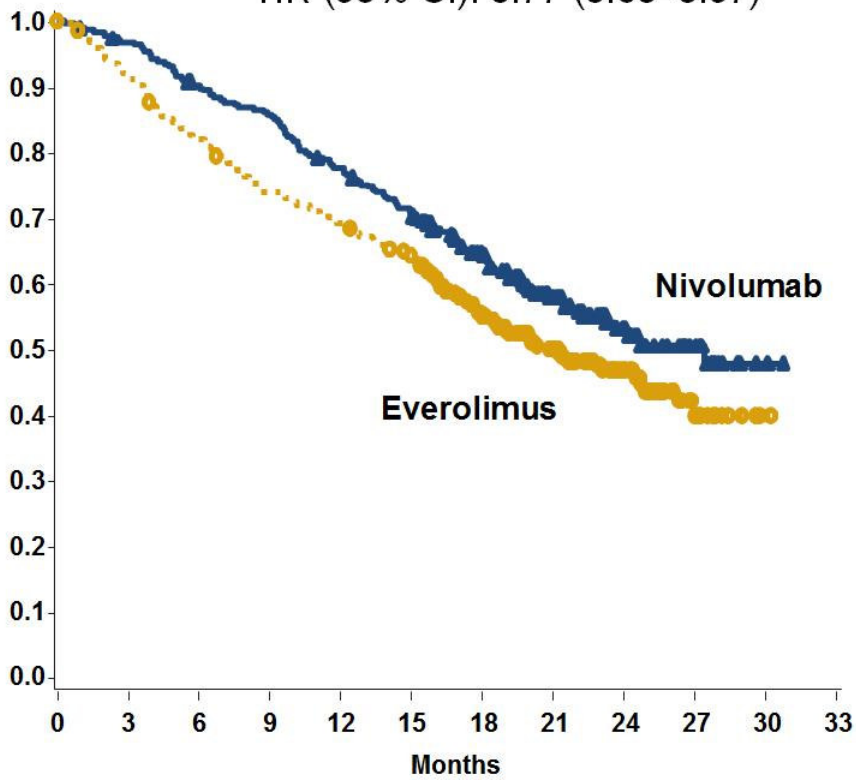


No. of patients at risk												
Nivolumab	94	86	79	73	66	58	45	31	18	4	1	0
Everolimus	87	77	68	59	52	47	40	19	9	4	1	0

PD-L1 <1% (n = 76%)

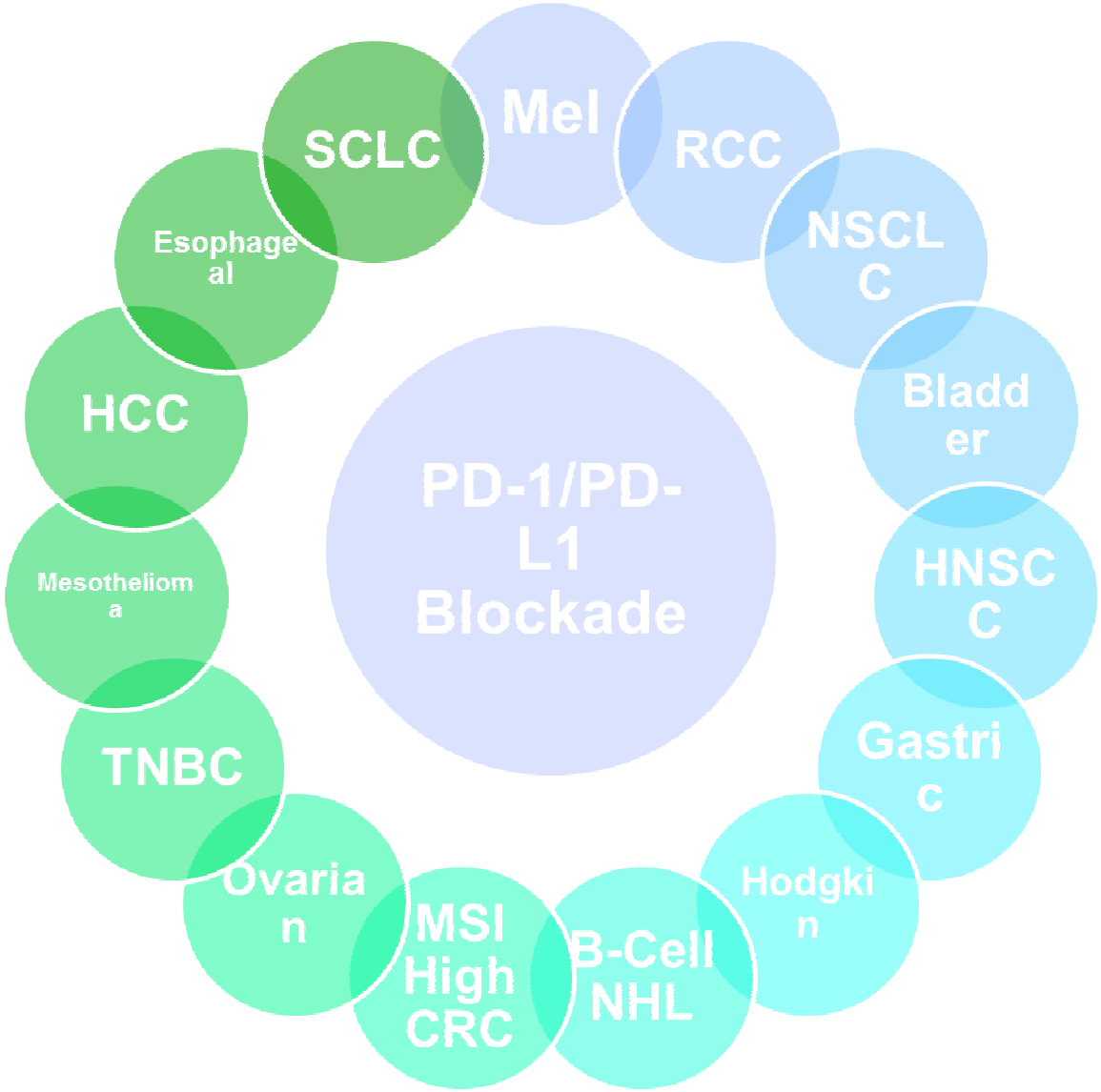
Median OS, months (95% CI)	
Nivolumab	27.4 (21.4–NE)
Everolimus	21.2 (17.7–26.2)

HR (95% CI): 0.77 (0.60–0.97)

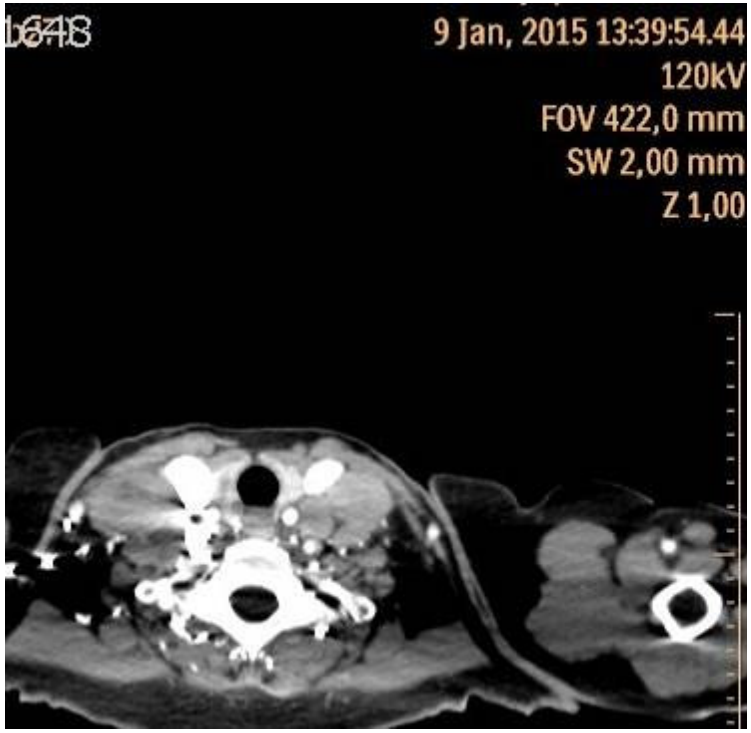


Nivolumab	276	265	245	233	210	189	145	94	48	22	2	0
Everolimus	299	267	238	214	200	182	137	92	51	16	1	0

PD-Lomas



Marabelle A, Routy B, Michels J, Kroemer G, Zitvogel L. Oncoimmunology 2015.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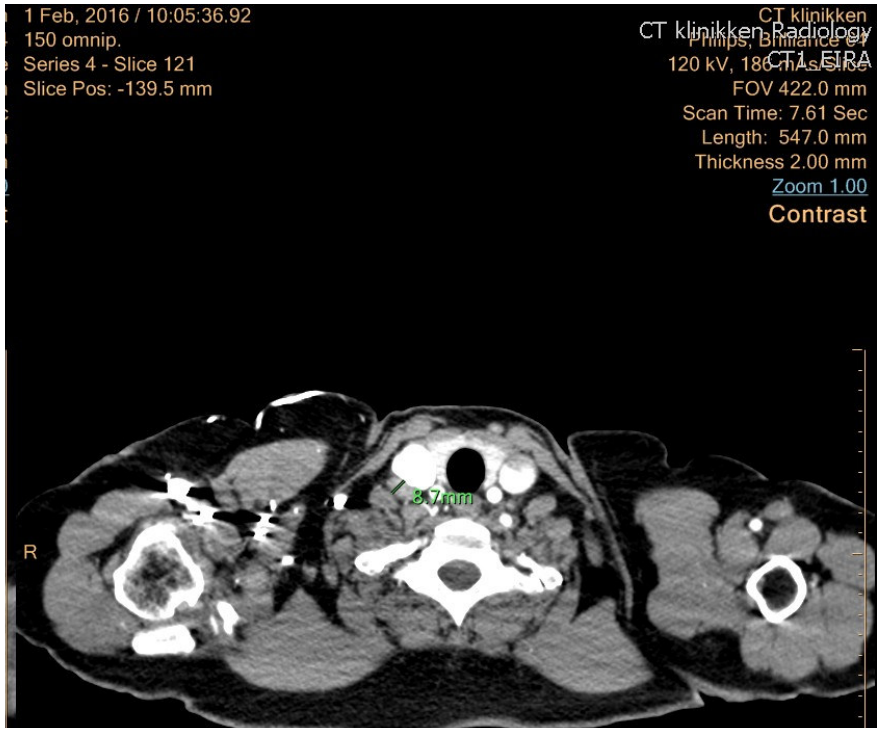
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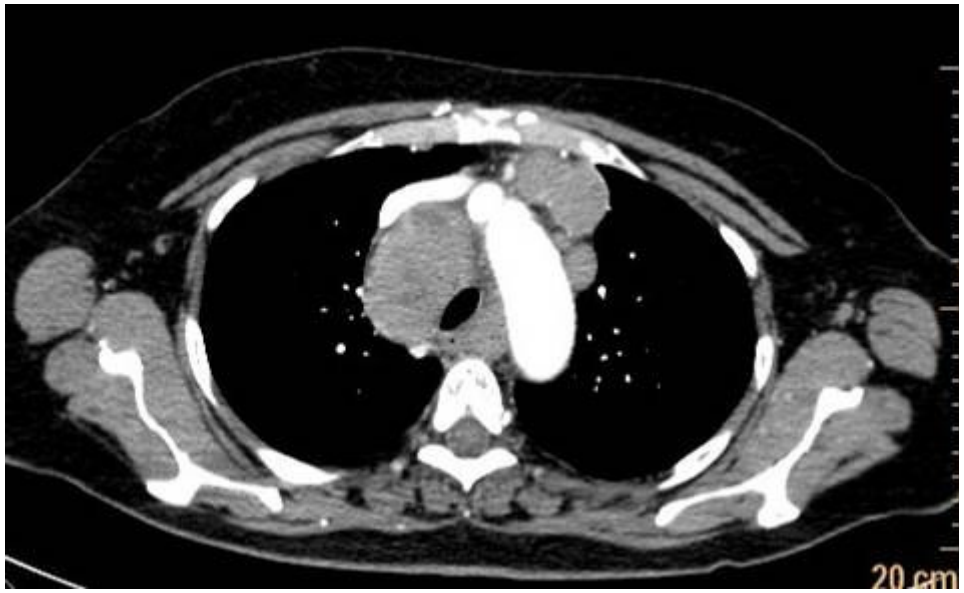
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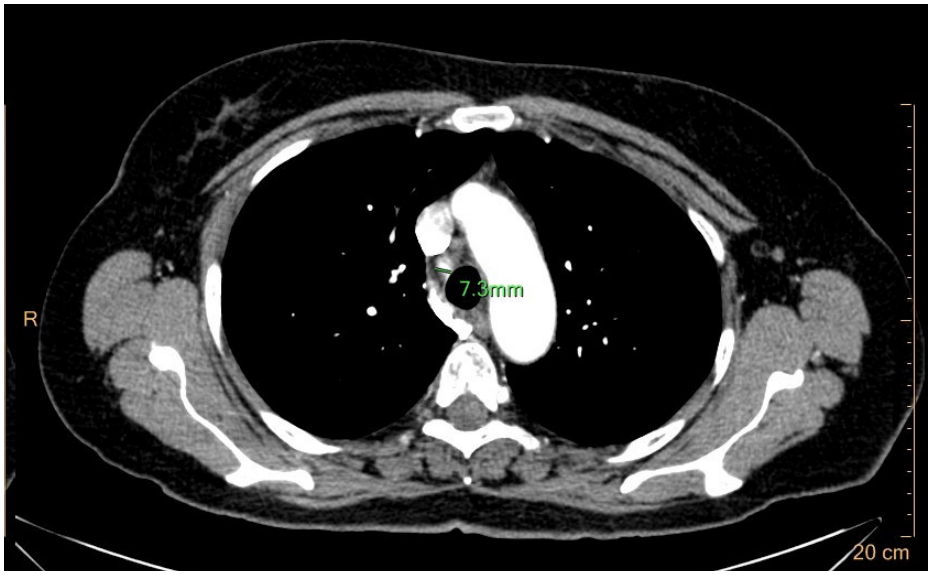
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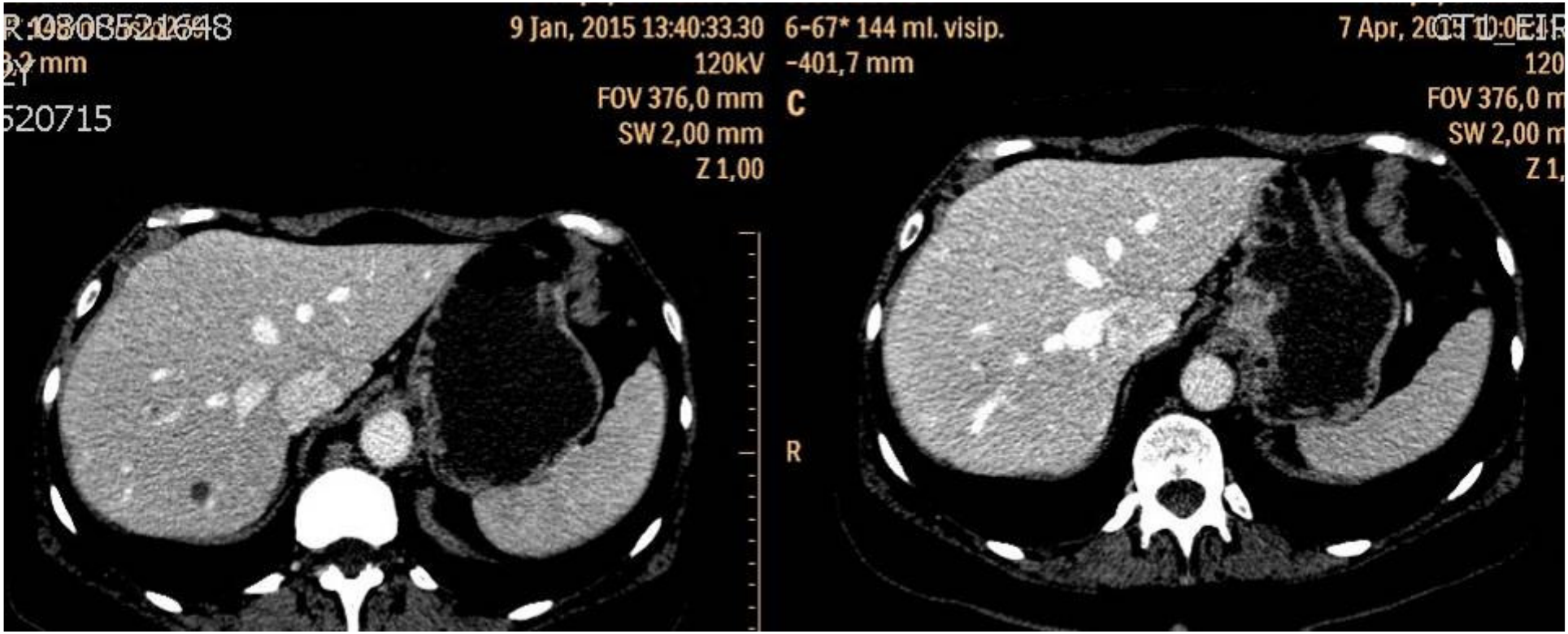
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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cabozantinib versus Everolimus in Advanced Renal-Cell Carcinoma

T.K. Choueiri, B. Escudier, T. Powles, P.N. Mainwaring, B.I. Rini, F. Donskov, H. Hammers, T.E. Hutson, J.-L. Lee, K. Peltola, B.J. Roth, G.A. Bjarnason, L. Géczi, B. Keam, P. Maroto, D.Y.C. Heng, M. Schmidinger, P.W. Kantoff, A. Borgman-Hagey, C. Hessel, C. Scheffold, G.M. Schwab, N.M. Tannir, and R.J. Motzer, for the METEOR Investigators*

N=375 **RR 21% vs 5%**

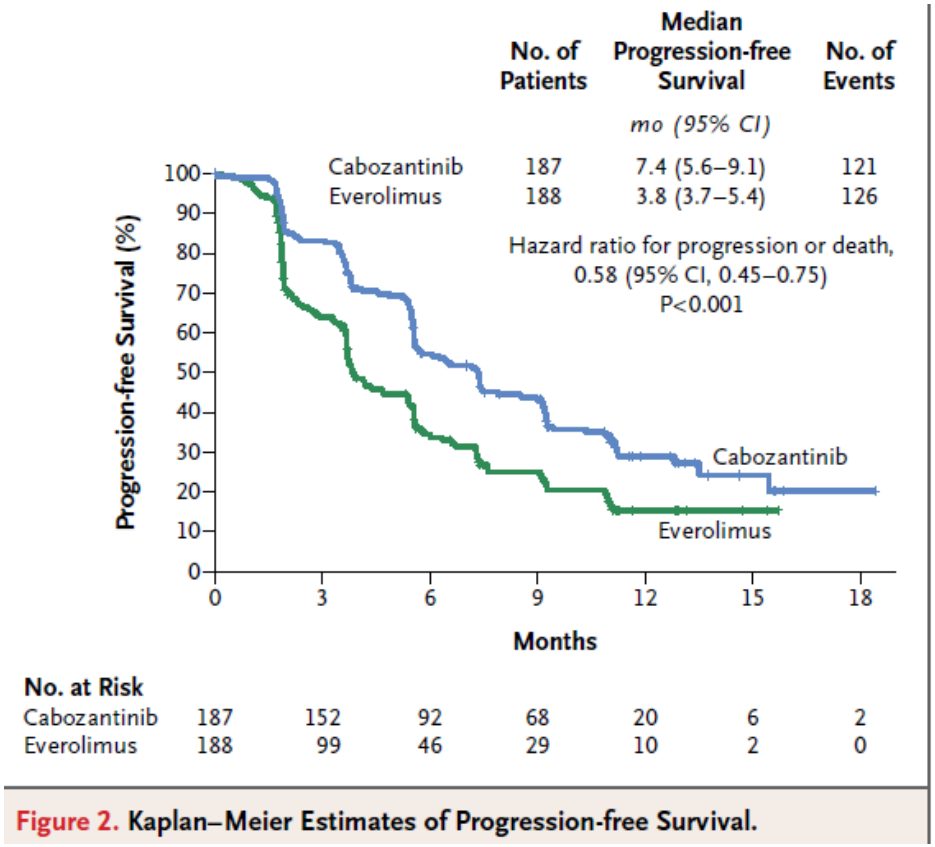

Figure 2. Kaplan–Meier Estimates of Progression-free Survival.

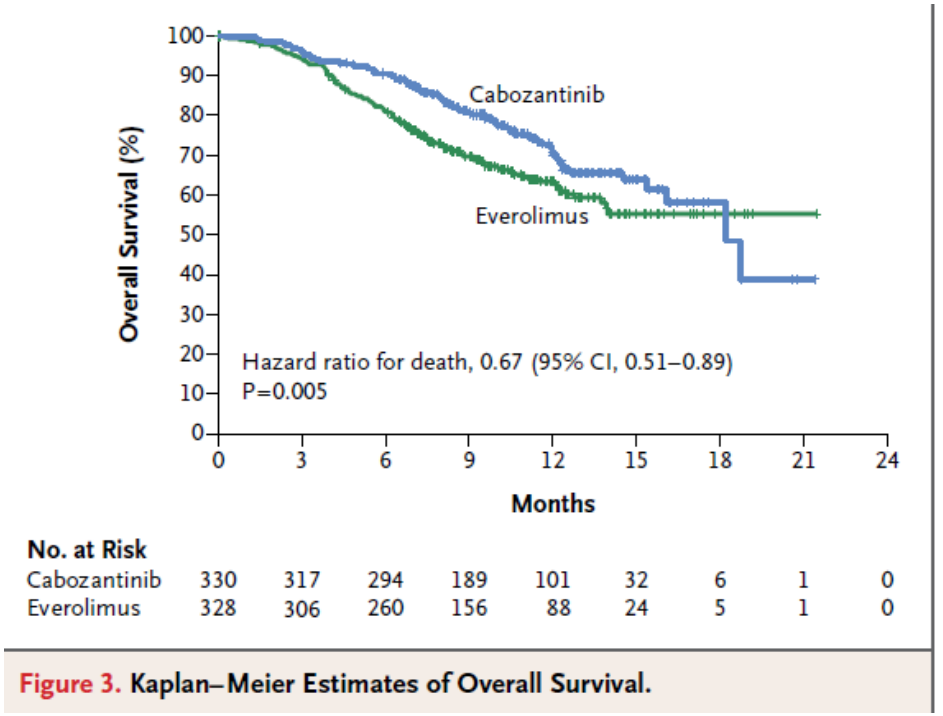

Figure 3. Kaplan–Meier Estimates of Overall Survival.

ASCO GU 2016:

N=658

PFS 7.4 vs 3.9

RR 17% vs 3%

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Exelixis Announces Positive Overall Survival Results from METEOR, the Phase 3 Pivotal Trial of Cabozantinib in Advanced Renal Cell Carcinoma

– Cabozantinib significantly improved overall survival as compared with everolimus –

– First therapy to demonstrate improvement in overall survival, progression-free survival, and objective response rate in a large, pivotal phase 3 study in previously treated renal cell carcinoma patients –

– Exelixis intends to share the data with U.S. and EU regulators, and to present the data at a medical meeting later in 2016 –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 1, 2016-- Exelixis, Inc. (NASDAQ:EXEL) today announced positive overall survival (OS) results from METEOR, the phase 3 pivotal trial comparing cabozantinib to everolimus in 658 patients with advanced renal cell carcinoma (RCC) who have experienced disease progression following treatment with a VEGF receptor tyrosine kinase inhibitor (TKI). In a second interim analysis for OS, a secondary endpoint of the trial, the results showed a highly statistically significant and clinically meaningful increase in OS for patients randomized to cabozantinib as compared to everolimus. Ongoing study monitoring did not identify any new safety signals. Exelixis intends to present these data at a medical meeting later this year.

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Doctor, what is my prognosis?

Table 6. Results of Multivariate Analysis

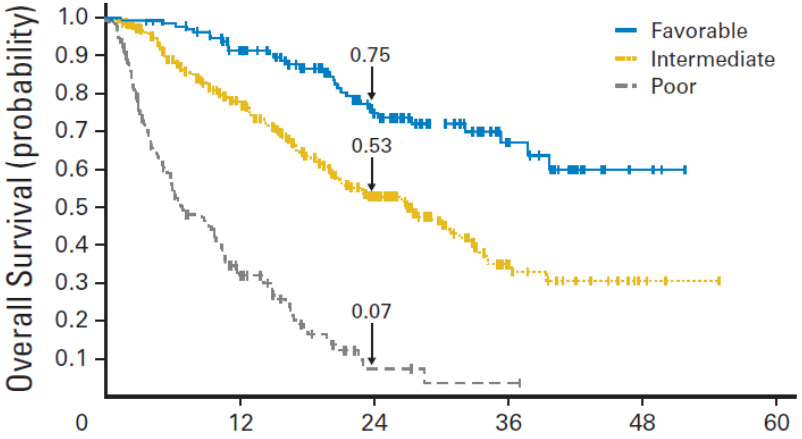
	Parameter Estimate	SE	χ^2	*P*	Risk Ratio	95% CI
Lactate dehydrogenase	0.9019	0.1230	53.74	.0001	2.46	1.94-3.14
Hemoglobin	0.5439	0.0897	36.75	.0001	1.72	1.45-2.05
Corrected calcium	0.5268	0.1147	21.11	.0001	1.69	1.35-2.12
Karnofsky performance status	0.4050	0.0967	17.56	.0001	1.50	1.24-1.81
Prior nephrectomy	0.2992	0.0908	10.87	.001	1.35	1.13-1.61

No. of Risk Factors	% of Patients	% of Patients Alive	Median Survival (months)	95% CI	1-Year Survival (%)	3-Year Survival (%)
0	25	18	19.9	17.1-27.9	71	31
1 or 2	53	7	10.3	8.9-11.4	42	7
3, 4, or 5	22	0.7	3.9	3.4-5.0	12	0

MSKCC (Motzer), JCO 1999; 17:2530-2540

Table 3. Multivariable Analysis and Final Model

Parameter	Parameter Estimate ± SE	Hazard Ratio	95% CI	*P*
Clinical				
KPS < 80%	0.92 ± 0.14	2.51	1.92 to 3.29	< .0001
Time from diagnosis to treatment < 1 year	0.35 ± 0.13	1.42	1.09 to 1.84	.0098
Laboratory				
Hemoglobin < LLN	0.54 ± 0.14	1.72	1.31 to 2.26	.0001
Calcium > ULN	0.59 ± 0.17	1.81	1.29 to 2.53	.0006
Neutrophil count > ULN	0.88 ± 0.17	2.42	1.72 to 3.39	< .0001
Platelet count > ULN	0.40 ± 0.16	1.49	1.09 to 2.03	.0121



IMDC (Heng) JCO 2009; 27: 5794-99

FULL PAPER

BJC

British Journal of Cancer (2015), 1–10 | doi: 10.1038/bjc.2015.368

Keywords: sunitinib; metastatic renal cell carcinoma; biomarkers; adverse events; multivariate; neutropenia; hypertension

Sunitinib-associated hypertension and neutropenia as efficacy biomarkers in metastatic renal cell carcinoma patients

Frede Donskov*[,1], M Dror Michaelson[2], Igor Puzanov[3], Mellar P Davis[4], Georg A Bjarnason[5], Robert J Motzer[6], David Goldstein[7], Xun Lin[8], Darrel P Cohen[8], Robin Wiltshire[9] and Brian I Rini[10]

Table 1. Baseline patient characteristics

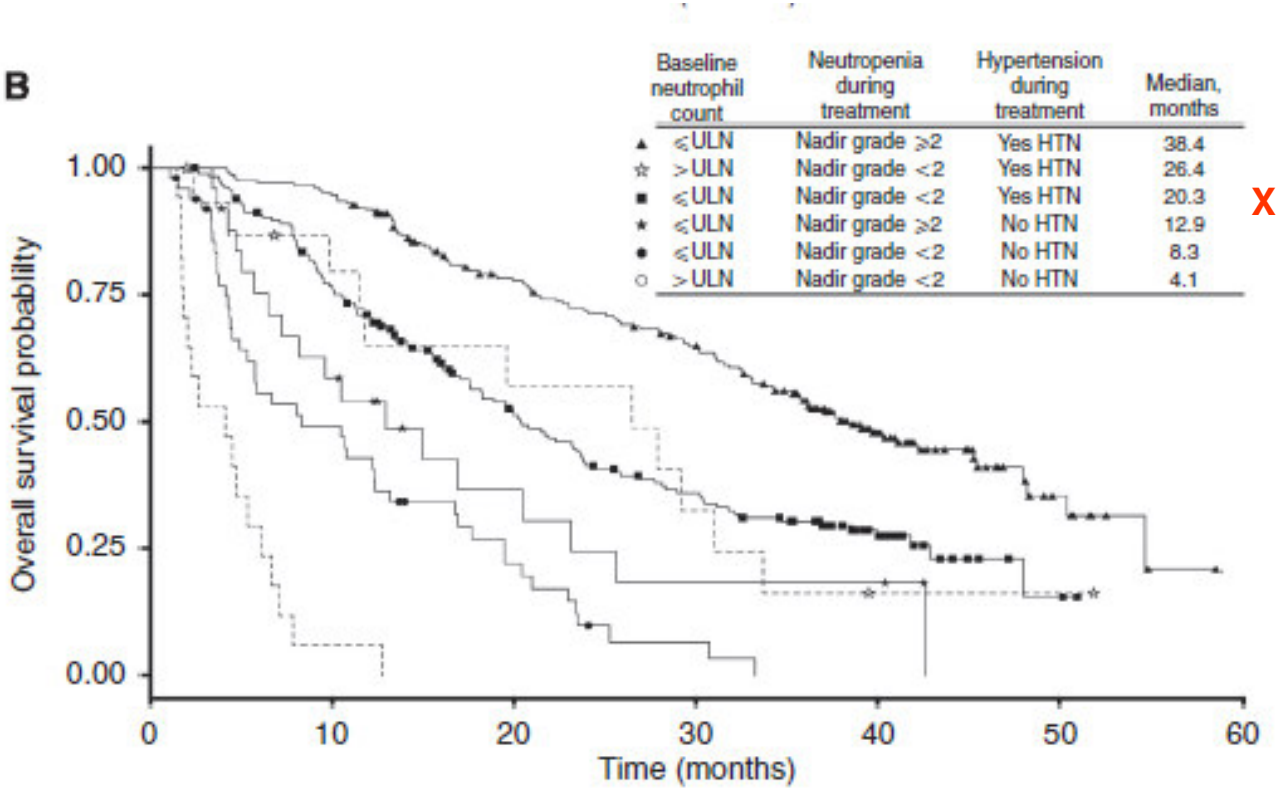
Characteristic	Second-line, Schedule 4/2 phase II trial (Motzer *et al*, 2006a) (*n* = 63)	Second-line, Schedule 4/2 phase II trial (Motzer *et al*, 2006b) (*n* = 106)	First-line, Schedule 4/2 phase III trial (Motzer *et al*, 2009) (*n* = 375)[a]	First-line, Schedule CDD phase II trial (Barrios *et al*, 2012) (*n* = 119)	Second-line, Schedule CDD phase II trial (Escudier *et al*, 2009) (*n* = 107)
Median (range) age, years	60 (24–87)	56 (32–79)	62 (27–87)	58[b] (24–78)	59 (29–80)
Male/female, *n* (%)	68/32	63/37	71/29	76/24	82/18
ECOG PS, *n* (%)					
0	34 (54)	58 (55)	231 (62)	63 (53)	61 (57)
1	29 (46)	48 (45)	144 (38)	56 (47)	45 (42)
⩾2	0	0	0	0	1 (1)
Histology, *n* (%)					
Clear cell	55 (87)	105 (99)	375 (100)	119 (100)	104 (97)
Other	8 (13)	1 (1)	0	0	3 (3)
Prior nephrectomy, *n* (%)	58 (92)	106 (100)	340 (91)	112 (94)	100 (93)
Prior cytokine therapy, *n* (%)	63 (100)	106 (100)	0	0	107 (100)
Prior radiation therapy, *n* (%)	25 (40)	20 (19)	53 (14)	15 (13)	NA
No. of disease sites, *n* (%)					
1	8 (13)	13 (12)	55 (15)	30 (25)	12 (11)
⩾2	55 (87)	93 (88)	320 (85)	87 (73)[c]	95 (89)

N=770

Table 4. Final combined AE multivariate models of associations between adverse events and survival end points for mRCC patients receiving sunitinib on (A) Schedule 4/2 or (B) any dose/schedule

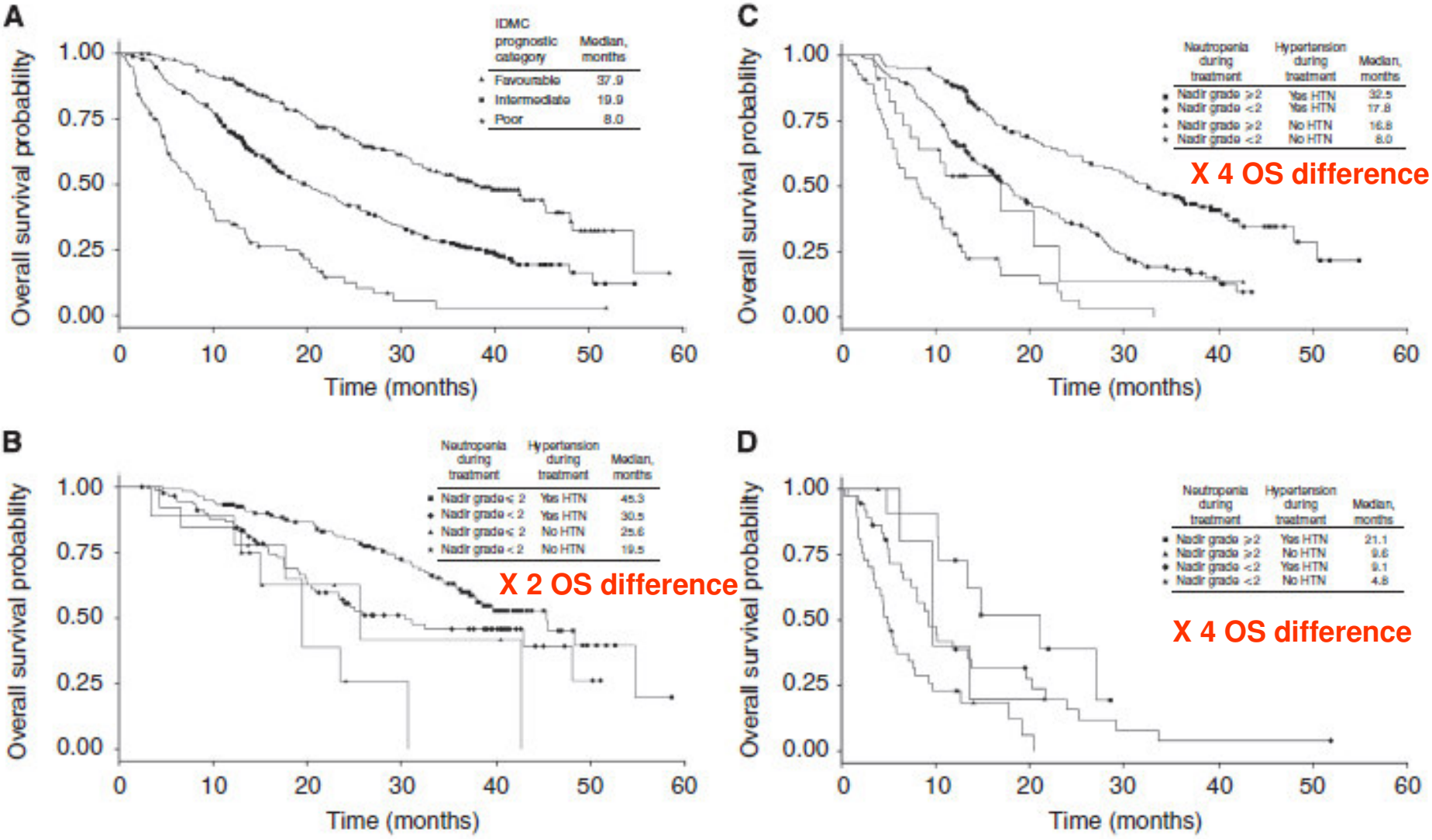
		Adverse event at any time point			Adverse event by the 12-week landmark		
Adverse event	End point	HR	95% CI	*P*-value[a]	HR	95% CI	*P*-value[a]
(A) Schedule 4/2							
Neutropenia	PFS	**0.77**	**0.61–0.97**	**0.0276**	**0.72**	**0.56–0.93**	**0.0130**
	OS	**0.65**	**0.50–0.85**	**0.0014**	**0.71**	**0.55–0.93**	**0.0122**
Hypertension	PFS	**0.37**	**0.27–0.52**	**<0.0001**	0.81	0.61–1.07	0.1305
	OS	**0.36**	**0.27–0.50**	**<0.0001**	**0.68**	**0.53–0.88**	**0.0036**
Hand–foot syndrome	PFS	0.90	0.70–1.15	0.3986	0.83	0.59–1.16	0.2651
	OS	**0.70**	**0.52–0.93**	**0.0152**	**0.64**	**0.44–0.94**	**0.0218**
Asthenia/fatigue	PFS	**0.56**	**0.42–0.74**	**<0.0001**	1.01	0.78–1.30	0.9555
	OS	0.82	0.61–1.10	0.1882	0.99	0.78–1.27	0.9586
Thrombocytopenia	PFS	0.83	0.63–1.10	0.1971	1.05	0.73–1.51	0.7905
	OS	0.96	0.70–1.33	0.8271	1.07	0.74–1.53	0.7233
(B) Any dose/schedule							
Neutropenia	PFS	**0.69**	**0.56–0.85**	**0.0004**	**0.72**	**0.57–0.91**	**0.0062**
	OS	**0.58**	**0.45–0.73**	**<0.0001**	**0.68**	**0.53–0.87**	**0.0019**
Hypertension	PFS	**0.44**	**0.33–0.58**	**<0.0001**	0.98	0.76–1.26	0.8730
	OS	**0.48**	**0.37–0.63**	**<0.0001**	**0.73**	**0.58–0.91**	**0.0063**
Hand–foot syndrome	PFS	0.88	0.70–1.10	0.2495	0.88	0.64–1.19	0.3963
	OS	**0.69**	**0.52–0.90**	**0.0062**	**0.60**	**0.42–0.86**	**0.0049**
Asthenia/fatigue	PFS	**0.69**	**0.54–0.88**	**0.0026**	0.98	0.79–1.23	0.8786
	OS	0.94	0.73–1.22	0.6576	0.96	0.77–1.19	0.7056
Thrombocytopenia	PFS	0.96	0.75–1.24	0.7557	1.09	0.79–1.51	0.5920
	OS	1.00	0.76–1.32	0.9863	1.11	0.81–1.52	0.5096

Neutropenia gr ≥ 2 = <1.5 **Hypertension = systolic BP >140**



X 9 OS difference

Br J Cancer 2015;113:1571-80



Br J Cancer 2015;113:1571-80

BJUI
BJU International

Sunitinib-induced hypertension, neutropaenia and thrombocytopaenia as predictors of good prognosis in patients with metastatic renal cell carcinoma

Juhana Rautiola*†, Frede Donskov‡, Katriina Peltola*, Heikki Joensuu*† and Petri Bono*†

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BJU Int 2016; 117: 110-117

Neutropenia gr ≥ 2 = <1.5 **Thrombocytopenia gr >0 (= < LLN)**

50 mg 4/2	**39 (22%)**
37.5 mg cont	**80 (44%)**
25 mg cont	**62 (34%)**

Hypertension	**60 (33%)**
Neutropenia	**88 (49%)**
Thrombocytopenia	**135 (75%)**

Neutropenia was associated with improved PFS and OS in all sunitinib doses, and a trend was seen for hypertension and thrombocytopenia

MVA: **Hypertension and neutropenia associated with PFS and OS**

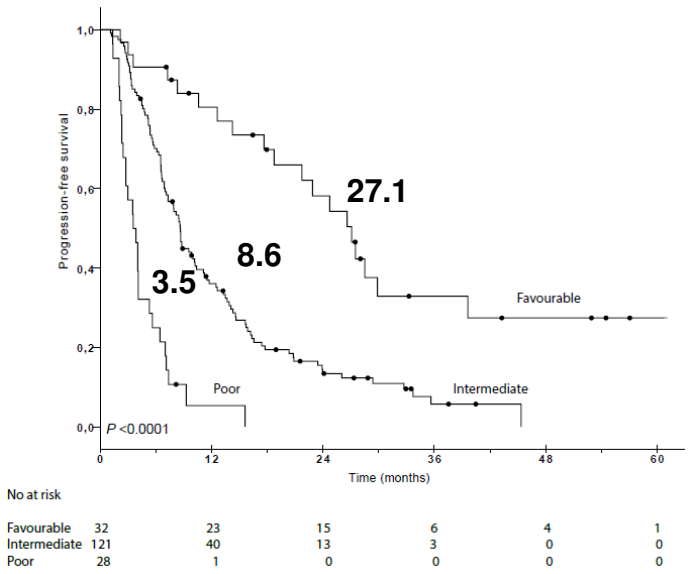
Thrombocytonenia associated with PFS

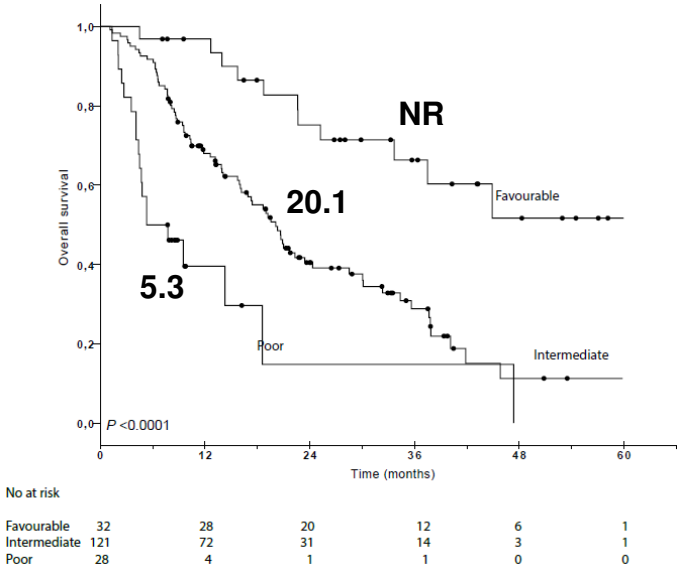
12-week landmark: hypertension and thrombocytopenia associated with PFS and OS

Only 4 patients with baseline neutrophils > ULN achieved neutropenia

BJU Int. 2016 Jan;117(1):110-7

Biomarker profile based on Hypertension, Neutropenia and Thrombocytopenia: Favourable profile: all 3 biomarkers, poor profile: no biomarkers

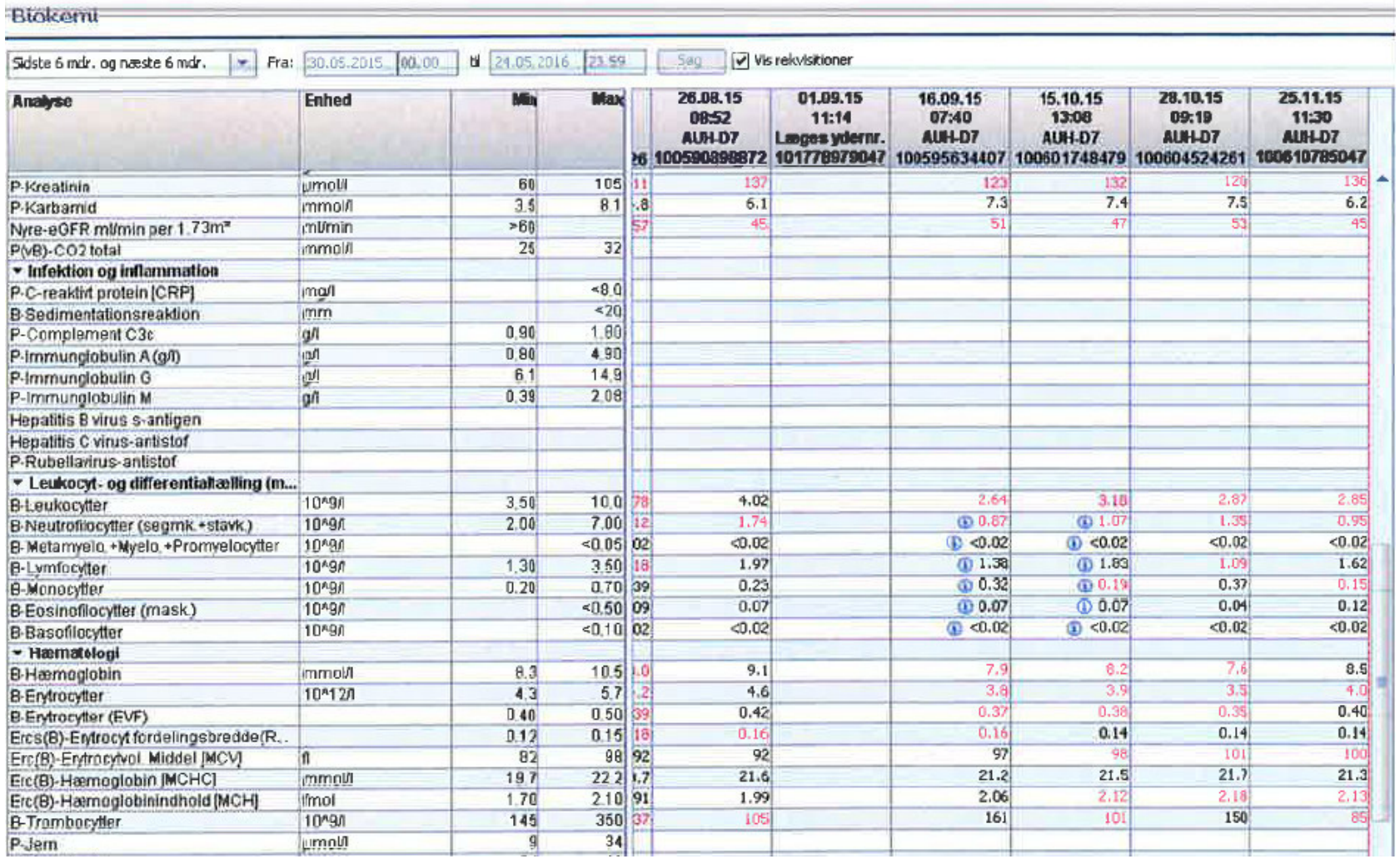




Response Rate: Fav vs Int vs poor biomarker profile: 47% vs 21% vs 4%

BJU Int. 2016 Jan;117(1):110-7

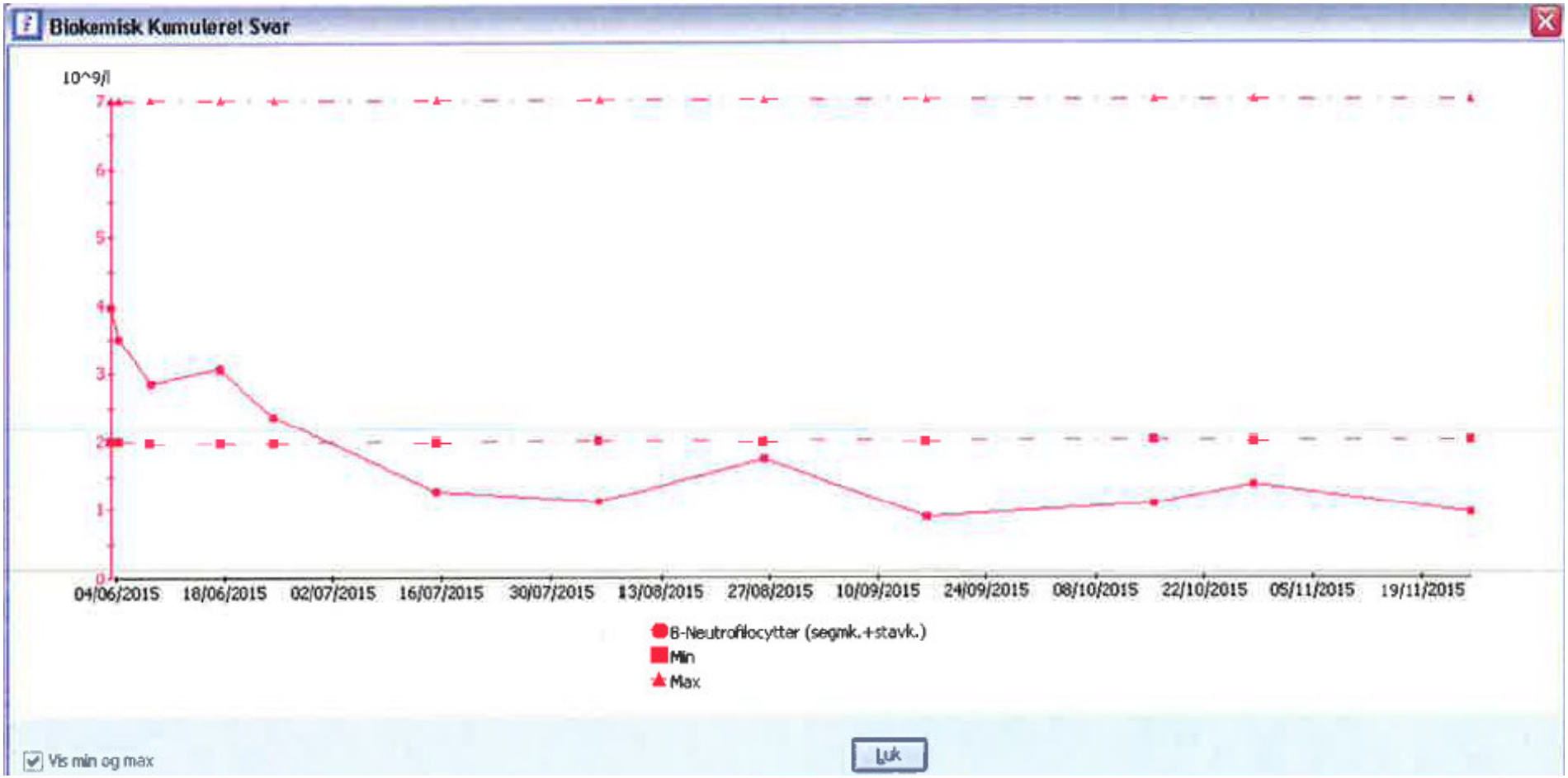
Doctor, what is my prognosis?



Biokemi

Sidste 6 mdr. og næste 6 mdr. | Fra: 30.05.2015 00.00 | til 24.05.2016 23.59 | Søg | Vis rekvisitioner

Analyse	Enhed	Min	Max	26.08.15 08:52 AUH-D7 1005908988872	01.09.15 11:14 Læges ydernr. 101778979047	16.09.15 07:40 AUH-D7 100595634407	15.10.15 13:08 AUH-D7 100601748479	28.10.15 09:19 AUH-D7 100604524261	25.11.15 11:30 AUH-D7 100610785047
P-Kreatinin	µmol/l	60	105	11	137	123	132	120	136
P-Karbamid	mmol/l	3.5	8.1	.8	6.1	7.3	7.4	7.5	6.2
Nyre-eGFR ml/min per 1.73m²	ml/min	>60		57	45	51	47	53	45
P(vB)-CO2 total	mmol/l	25	32						
▼ Infektion og inflammation									
P-C-reaktivt protein [CRP]	mg/l		<8.0						
B-Sedimentationsreaktion	mm		<20						
P-Complement C3c	g/l	0.90	1.80						
P-Immunglobulin A (g/l)	g/l	0.80	4.90						
P-Immunglobulin G	g/l	6.1	14.9						
P-Immunglobulin M	g/l	0.39	2.08						
Hepatitis B virus s-antigen									
Hepatitis C virus-antistof									
P-Rubellavirus-antistof									
▼ Leukocyt- og differentialtælling (m...									
B-Leukocytter	10^9/l	3.50	10.0	78	4.02	2.64	3.18	2.87	2.85
B-Neutrofilocytter (segmk.+stavk.)	10^9/l	2.00	7.00	12	1.74	ⓑ 0.87	ⓑ 1.07	1.35	0.95
B-Metamyelo.+Myelo.+Promyelocytter	10^9/l		<0.05	02	<0.02	ⓑ <0.02	ⓑ <0.02	<0.02	<0.02
B-Lymfocytter	10^9/l	1.30	3.50	18	1.97	ⓑ 1.38	ⓑ 1.63	1.09	1.62
B-Monocytter	10^9/l	0.20	0.70	39	0.23	ⓑ 0.32	ⓑ 0.19	0.37	0.15
B-Eosinofilocytter (mask.)	10^9/l		<0.50	09	0.07	ⓑ 0.07	ⓑ 0.07	0.04	0.12
B-Basofilocytter	10^9/l		<0.10	02	<0.02	ⓑ <0.02	ⓑ <0.02	<0.02	<0.02
▼ Hæmatologi									
B-Hæmoglobin	mmol/l	8.3	10.5	1.0	9.1	7.9	8.2	7.6	8.5
B-Erytrocytter	10^12/l	4.3	5.7	.2	4.6	3.8	3.9	3.5	4.0
B-Erytrocytter (EVF)		0.40	0.50	39	0.42	0.37	0.38	0.35	0.40
Ercs(B)-Erytrocyt fordelingsbredde(R..		0.12	0.15	18	0.16	0.16	0.14	0.14	0.14
Erc(B)-Erytrocytvol. Middel [MCV]	fl	82	98	92	92	97	98	101	100
Erc(B)-Hæmoglobin [MCHC]	mmol/l	19.7	22.2	1.7	21.6	21.2	21.5	21.7	21.3
Erc(B)-Hæmoglobinindhold [MCH]	fmol	1.70	2.10	91	1.99	2.06	2.12	2.18	2.13
B-Trombocytter	10^9/l	145	350	37	105	161	101	150	85
P-Jern	µmol/l	9	34						


Biokemisk Kumuleret Svar
10^9/l
7
6
5
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3
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1
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04/06/2015
18/06/2015
02/07/2015
16/07/2015
30/07/2015
13/08/2015
27/08/2015
10/09/2015
24/09/2015
08/10/2015
22/10/2015
05/11/2015
19/11/2015
B-Neutrofilocytter (segmk.+stavk.)
Min
Max
Vis min og max
Luk

EUROPEAN UROLOGY 68 (2015) 516–522

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European Association of Urology

Kidney Cancer

Health Economic Changes as a Result of Implementation of Targeted Therapy for Metastatic Renal Cell Carcinoma: National Results from DARENCA Study 2

Anne V. Soerensen[a,*], *Frede Donskov*[b], *Jakob Kjellberg*[c], *Rikke Ibsen*[d], *Gregers G. Hermann*[e], *Niels V. Jensen*[f], *Kirsten Fode*[b], *Poul F. Geertsen*[a]

Design, setting, and participants: Costs were measured per patient per year during a 2-yr follow-up during 2002–2005 (immunotherapy only) and 2006–2009 (TT implementation). All Danish patients with a diagnosis code for RCC and a procedure code for TT or immunotherapy were linked to the Danish National Patient Registry (contains information on all contacts with primary and secondary health sector). Health care and productivity costs were retrieved from the Danish case-mix system and Coherent Social Statistics, respectively. Drug costs were calculated separately from procedure codes and retail prices.

5. Conclusions

Different patterns of health care costs were observed after implementation of TT in patients with mRCC, with lower inpatient costs, lower radiotherapy costs, higher outpatient costs, higher radiology costs, and higher medicine costs. However, total health care costs per patient per year did not significantly differ after TT implementation.

Eur Urol 2015; 68: 516-22

WE ARE DOING PROGRESS – BUT STILL MUCH WORK TO DO

Northern European Multidisciplinary RCC meeting in Copenhagen June 17th and 18th 2016

The Northern European Multi-disciplinary RCC meeting will take place at Hotel Phoenix in Copenhagen on June 17th and 18th 2016. http://www.phoenixcopenhagen.dk/
The hotel is located in the center of Copenhagen and is easy accessible from the airport and metro.

Scientific planning committee:
Frede Donskov (DK) Chairman,
Bjarne Kromann (DK),
Petri Bono (FI),
Ulrika Harmenberg (SE),
Christof Müller (NO),
Börje Ljungberg (SE)
Benoit Beuselinck (BE)

Friday 17.00 – Saturday 14.00 **New case-based abstract concept: deadline 13 may**