Malígny melanóm

novinky z ASCO20© Virtual meeting

MUDr. Silvia Jurišová

Vyhlásenie o konflikte záujmov autora

☐ Nemám potenciálny konflikt záujmov

☐ Deklarujem nasledujúci konflikt záujmov

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

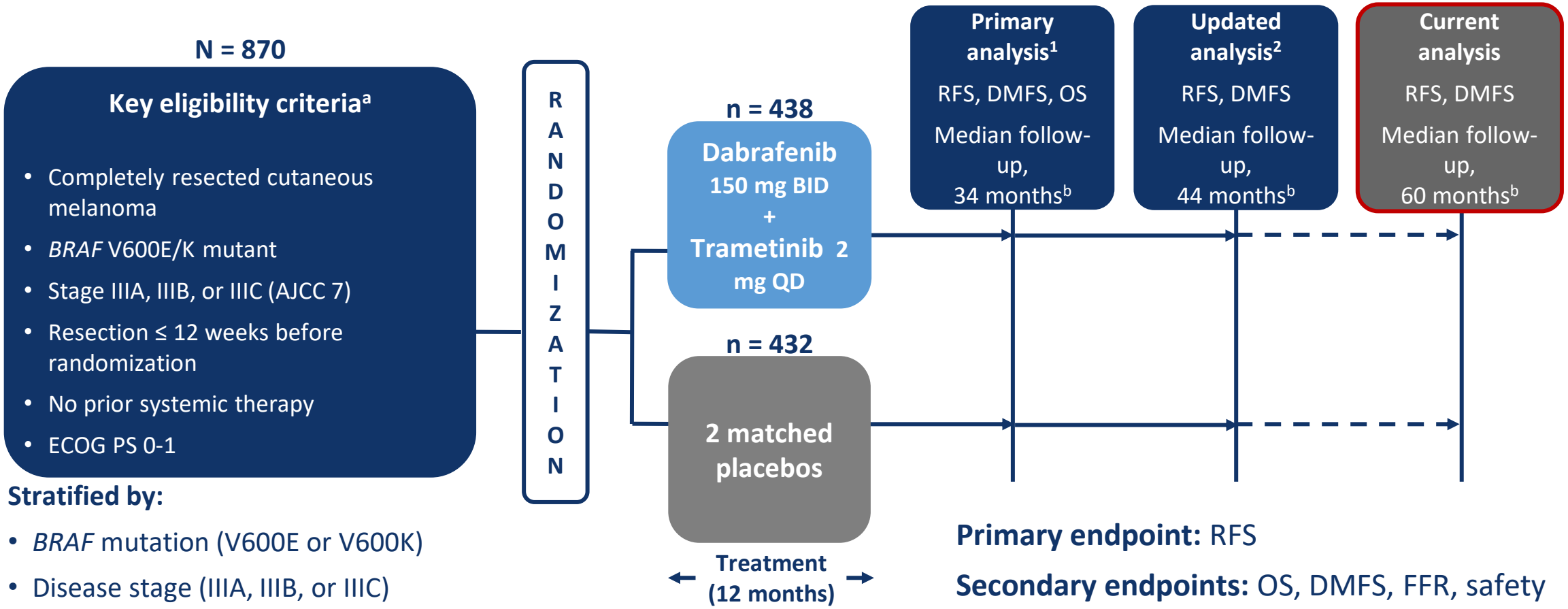
Podľa UEMS (upravené v zmysle slovenskej legislatívy)

Prezentáciu podporila agentúra

We Make Media Slovakia s.r.o.

Long-term benefit of adjuvant dabrafenib plus trametinib in patients with resected stage III BRAF V600–mutant melanoma: 5-year analysis of COMBI-AD

Axel Hauschild, Reinhard Dummer, Mario Santinami, Victoria Atkinson, Mario Mandalà, John M. Kirkwood, Vanna Chiarion Sileni, James Larkin, Marta Nyakas, Caroline Dutriaux, Andrew Haydon, Caroline Robert, Laurent Mortier

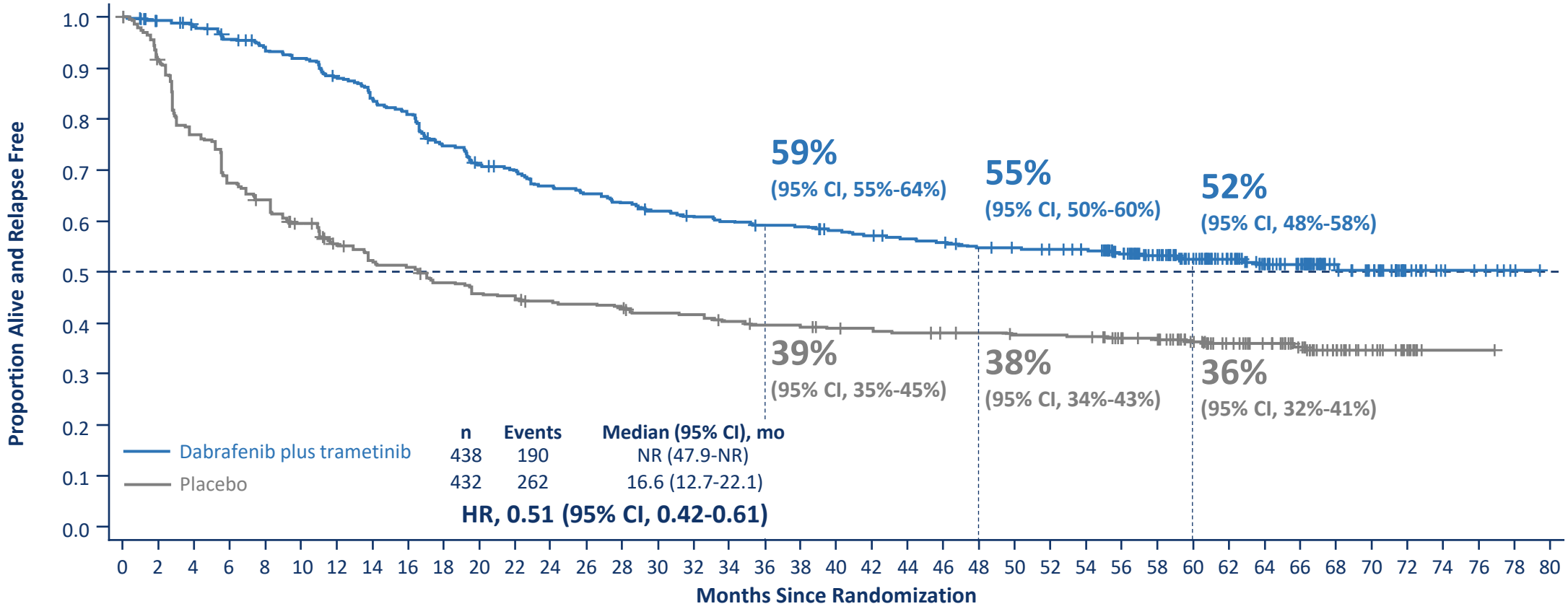


AJCC 7, American Joint Committee on Cancer Staging Manual, 7th edition; BID, twice daily; DMFS, distant metastasis–free survival; ECOG PS, Eastern Cooperative Oncology Group performance status; FFR, freedom from relapse; OS, overall survival; QD, once daily; RFS, relapse–free survival.

[a] COMBI-AD is registered at ClinicalTrials.gov (NCT01682083). [b] Median follow-up shown is for the dabrafenib plus trametinib arm.

Hauschild A, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10001)

COMBI-AD: Relapse-Free Survival



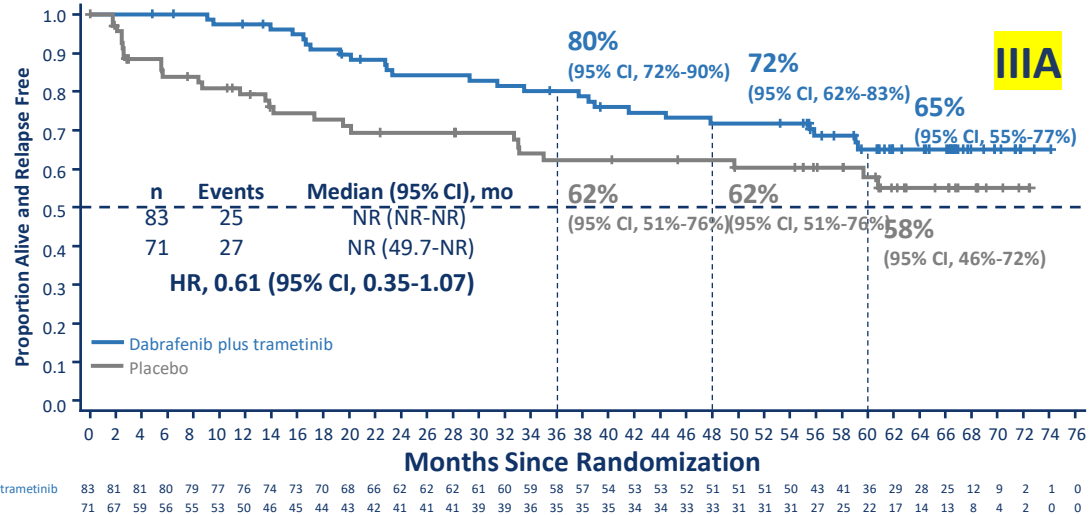
No. at risk

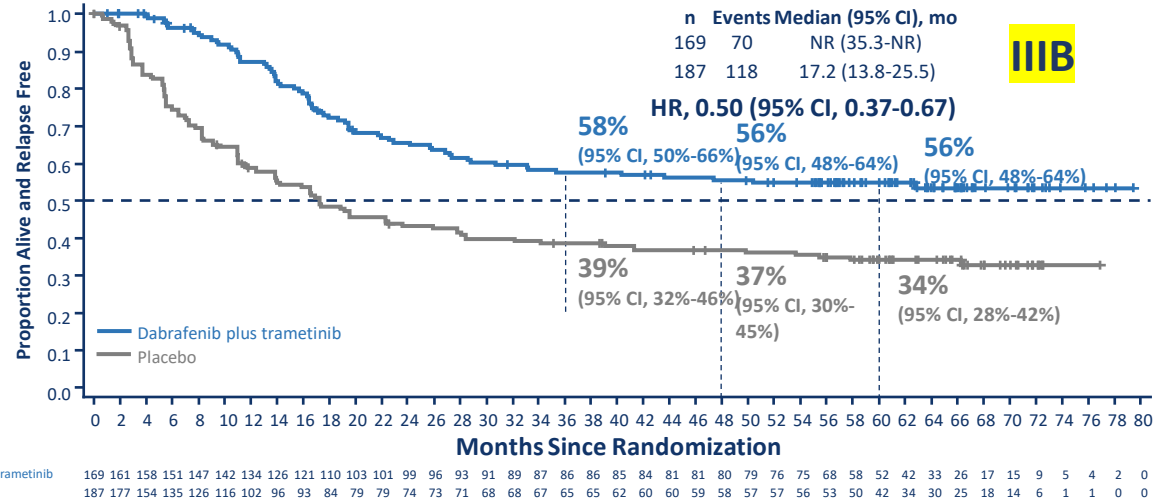
Dabrafenib plus trametinib	438	413	405	391	381	372	354	335	324	298	281	275	262	256	249	242	236	233	229	228	221	217	213	210	204	202	199	195	176	156	133	109	92	80	45	38	17	8	6	2	0
Placebo	432	387	322	280	263	243	219	204	199	185	178	175	168	166	164	158	157	151	147	146	143	140	139	137	136	133	133	132	121	115	99	80	69	56	35	26	13	1	1	0	0

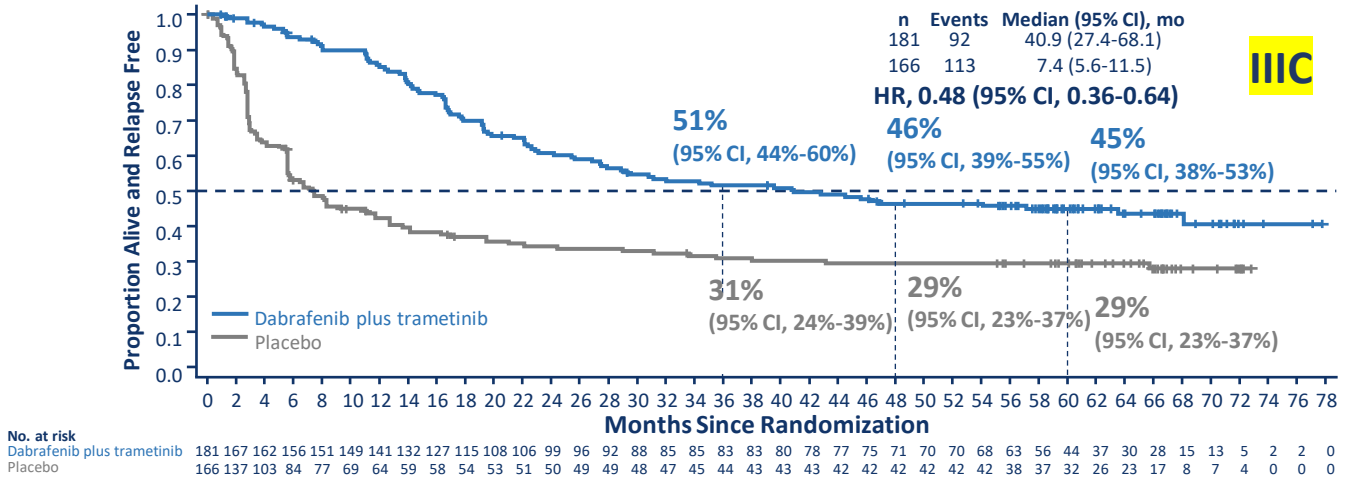
HR, hazard ratio; NR, not reached.

Hauschild A, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10001)

COMBI-AD: Relapse-Free Survival: AJCC 7

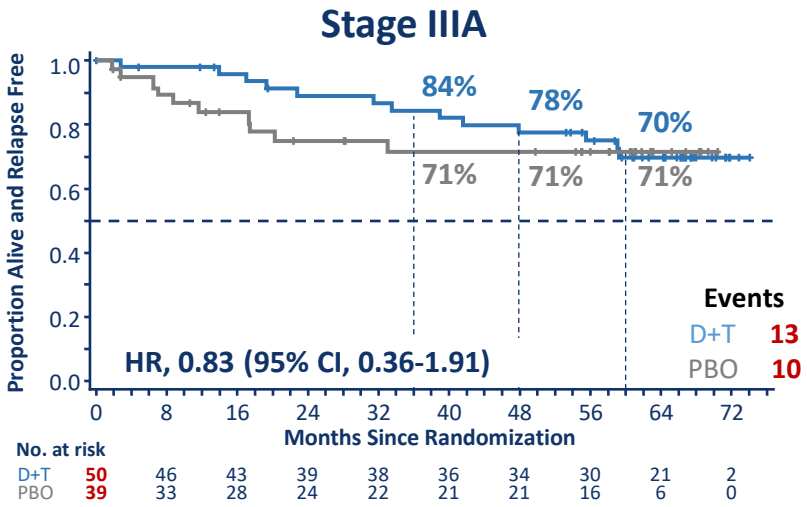


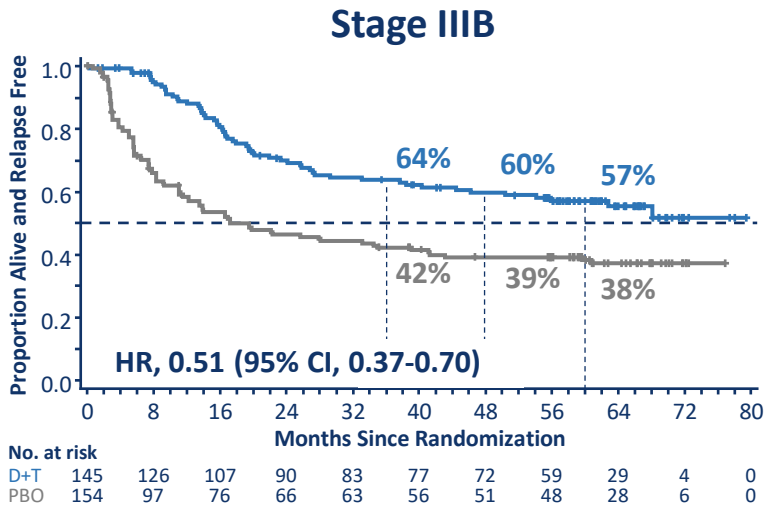


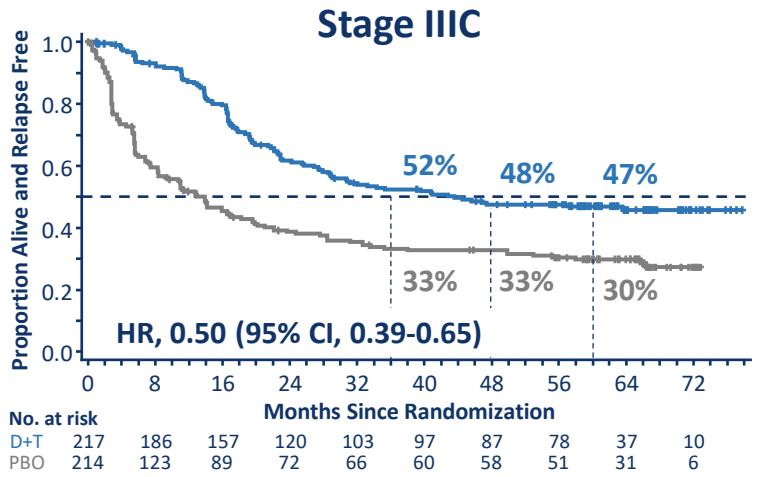


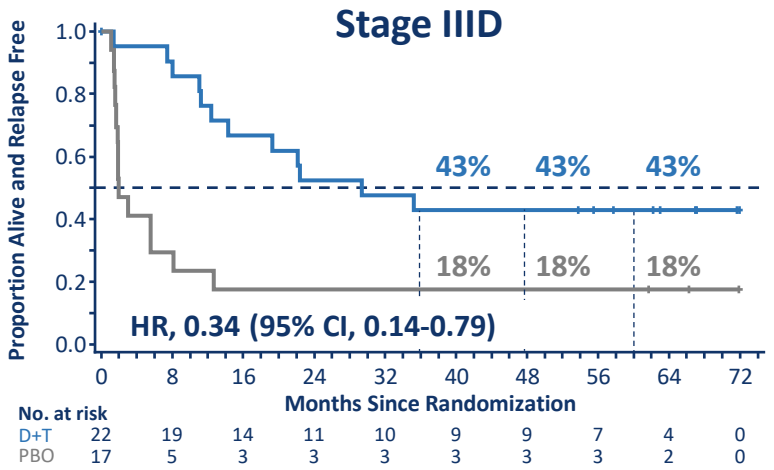
Hauschild A, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10001)

COMBI-AD: Relapse-Free Survival: AJCC 8







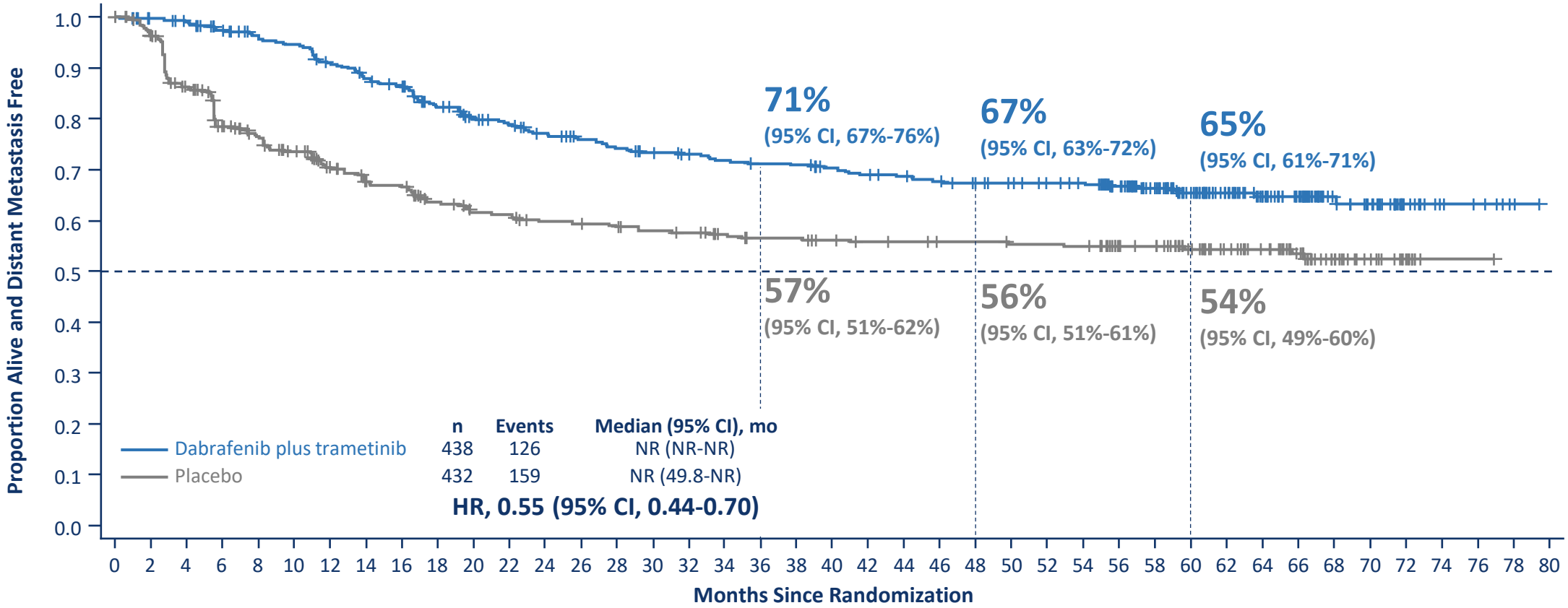


AJCC 8, American Joint Committee on Cancer Staging Manual, 8th edition; D+T, dabrafenib plus trametinib; PBO, placebo.

Hauschild A, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10001)

COMBI-AD: Distant Metastasis–Free Survival

Distant Metastasis as First Relapse Only[a]



No. at risk

Dabrafenib plus trametinib	438	413	407	390	380	373	352	336	327	301	285	278	265	257	251	243	238	234	231	230	223	219	216	212	208	205	201	197	179	158	135	110	93	80	45	38	17	8	6	2	0
Placebo	432	393	329	284	266	247	221	206	202	186	179	176	169	168	165	161	159	153	149	148	145	141	140	138	138	135	135	134	121	116	100	80	69	56	35	26	13	1	1	0	0

[a] Due to informative censoring, patients who had a local or regional first recurrence may not be represented in this analysis. Per protocol, patients with a first relapse at a locoregional site were not required to continue follow-up for distant metastases and were censored at the time of locoregional recurrence if follow-up was not complete.

Hauschild A, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10001)

Long-term benefit of adjuvant dabrafenib plus trametinib in patients with resected stage III BRAF V600–mutant melanoma: 5-year analysis of COMBI-AD

Axel Hauschild, Reinhard Dummer, Mario Santinami, Victoria Atkinson, Mario Mandalà, John M. Kirkwood, Vanna Chiarion Sileni, James Larkin, Marta Nyakas, Caroline Dutriaux, Andrew Haydon, Caroline Robert, Laurent Mortier

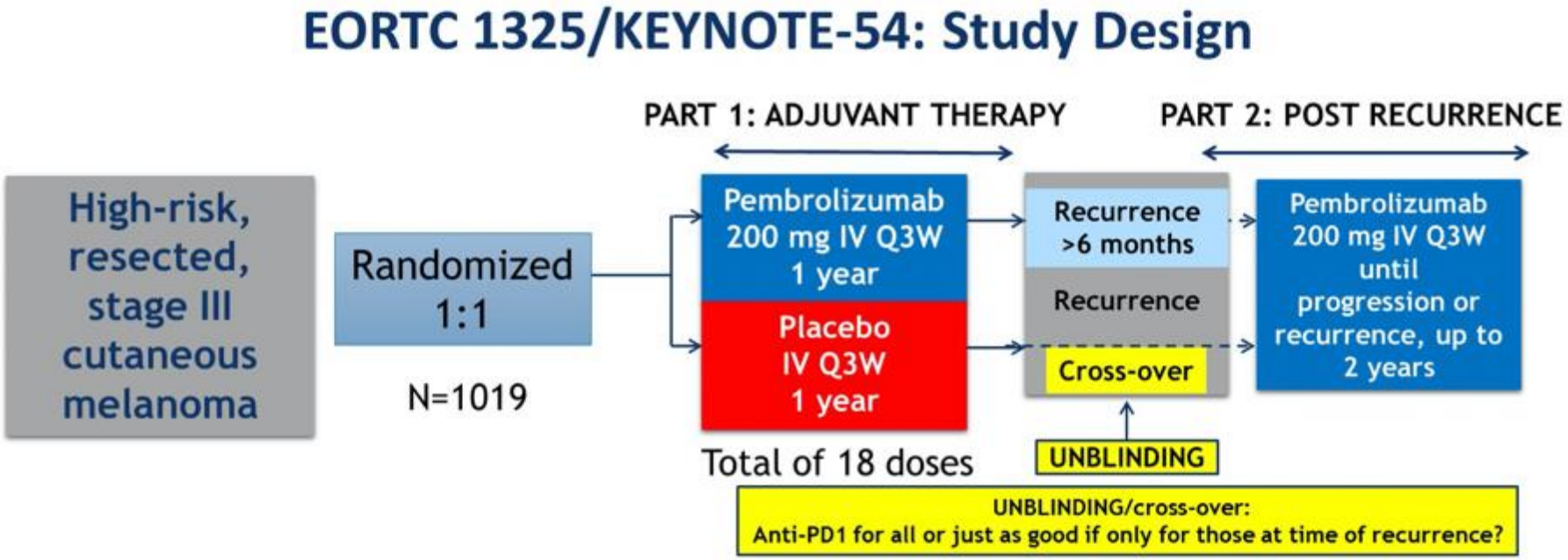
- COMBI-AD patrí medzi najvýznamnejšie adjuvantné štúdie s cielenou liečbou BRAFi a MEKi u pacientov štádia III
- 3-ročné sledovanie - D a T voči placebu RFS 58% voči 39% (HR 0,47)
- 2020 – 5 ročné prežívanie – medián RFS nedosiahnutý
- Pacienti liečení D + T , 4 roky bez relapsu prežívalo 55 %, 5 rokov 52%
- Placebo – 38%, 36%
- Prínos pozorovaný vo všetkých podskupinách : HR III A 0,61 ; IIIB 0,50, III C 0,48
- Medián DMFS nebol dosiahnutý ani u D + T, ani pri placebe, no priaznivejšie trendy boli u D + T (HR 0,55)

Záver: 5 ročná analýza potvrdzuje dlhodobý prínos adjuvantnej terapie D + T u pacientov po operácii malígneho melanómu III BRAFV600E/K mutáciou

Hauschild A, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10001)

Pembrolizumab versus placebo after complete resection of high-risk stage III melanoma: New recurrence-free survival results from the EORTC 1325-MG/Keynote 054 double-blinded phase III trial at three-year median follow-up.

Alexander M. Eggermont, Christian U. Blank, Mario Mandalà, Georgina V. Long, Victoria Atkinson, Stéphane Dalle, Andrew Mark Haydon, Andrey Meshcheryakov, Muhammad Khattak, Matteo S. Carlino



Primary Endpoint: RFS(per investigator) in overall population and RFS in patients with PD-L1 positive tumors

Secondary Endpoints: DMFS and OS in PD-L1 pos. pts, Safety and HRQoL

Eggermont AM, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10000)

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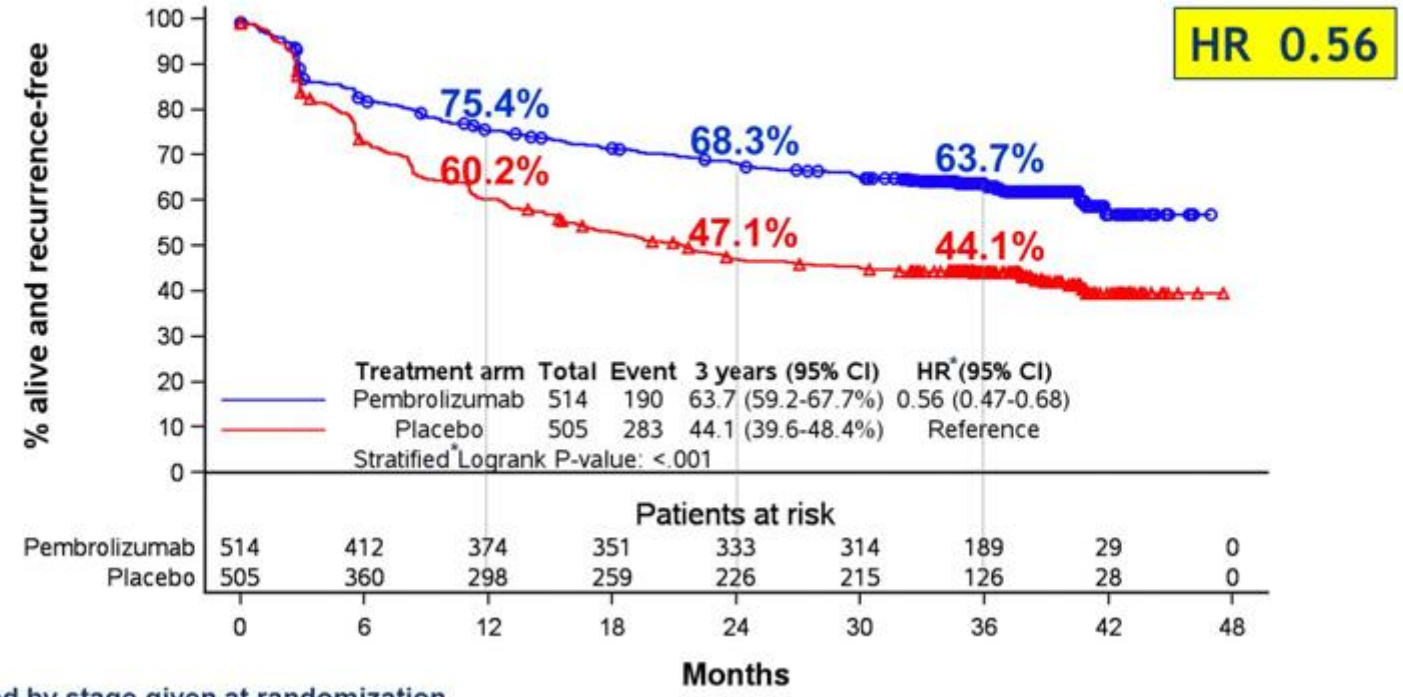
EORTC 1325/KEYNOTE-54: New RFS analysis (ASCO 2020)

- ***Cut-off date*** (30-Sep-2019); duration of follow-up: median **3** years; **473** RFS events



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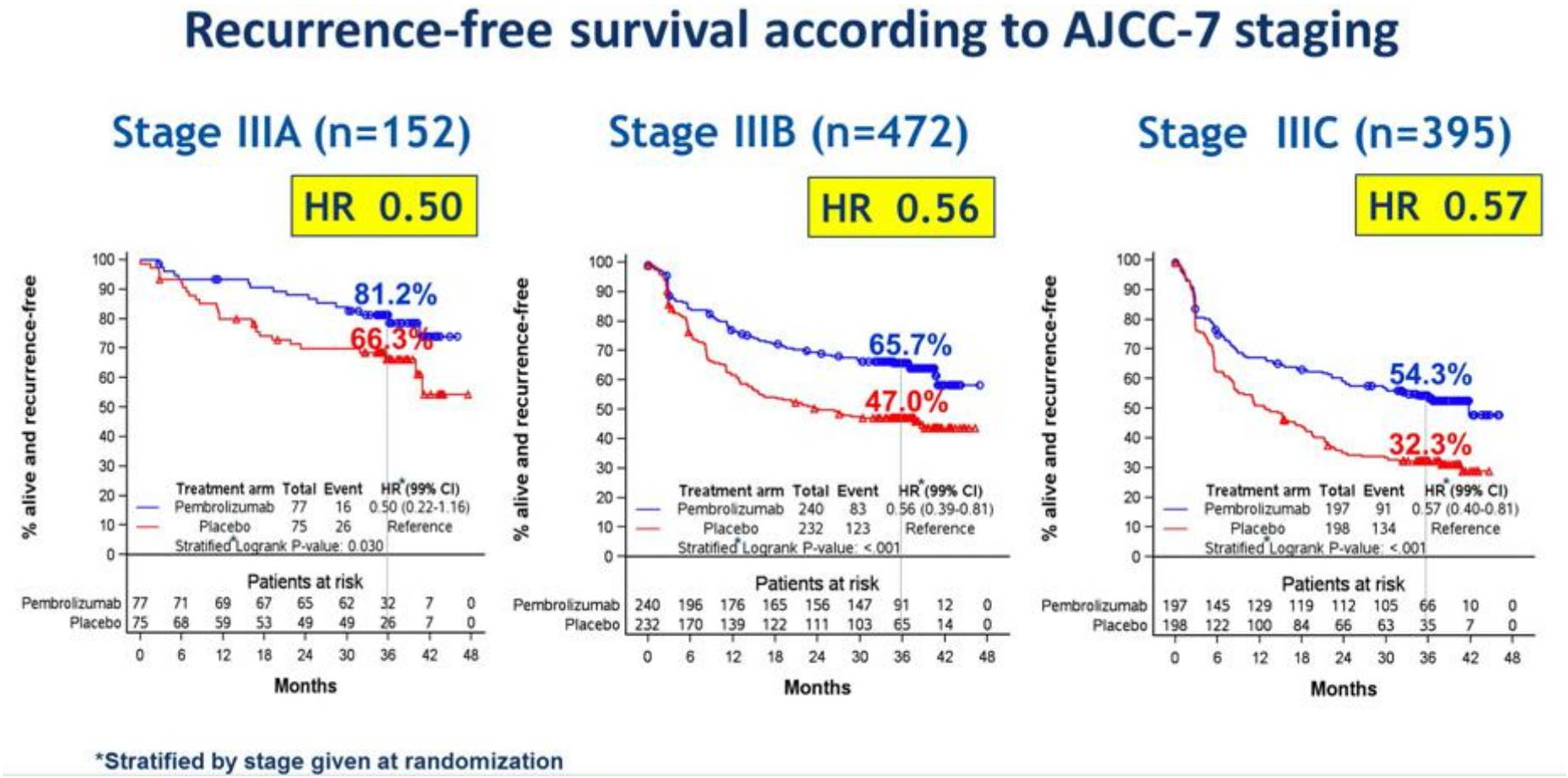

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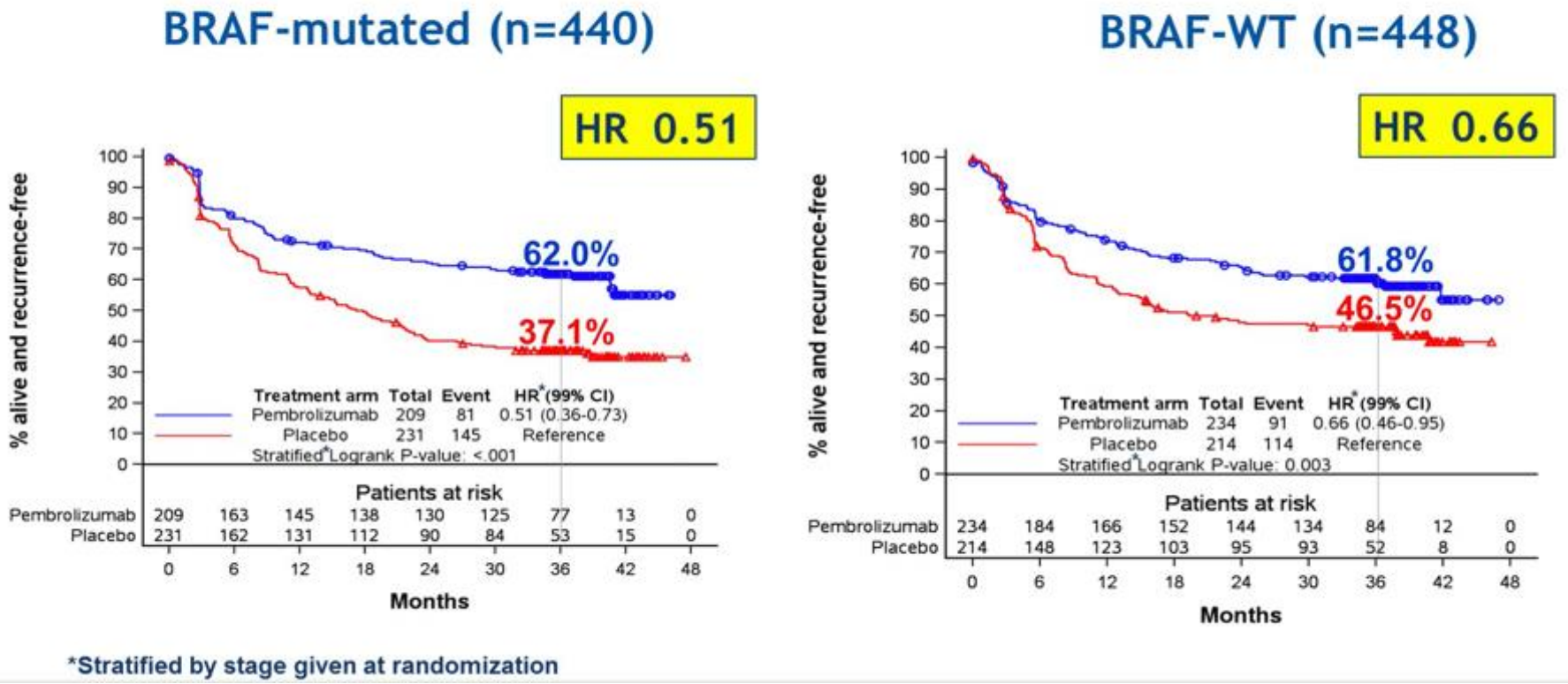
RFS according to BRAF-V600 E-K mutation status



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Immune-Related Adverse Events (irAE)

Regardless of investigator attribution

	Pembrolizumab (N=509)		Placebo (N=502)	
	Grade ≥1 N(%)	Grade ≥3 N(%)	Grade ≥1 N(%)	Grade ≥3 N(%)
ANY IRAE	192 (37.7)	39 (7.7)	45 (9.0)	3 (0.6)
ENDOCRINE DISORDERS	119 (23.4)	8 (1.6)	25 (5.0)	0 (0.0)
RESPIRATORY / THORACIC DISORDERS	25 (4.9)	4 (0.8)	3 (0.6)	0 (0.0)
VITILIGO OR SEVERSE SKIN REATIONS	30 (5.9)	5 (1.0)	8 (1.6)	0 (0.0)
GASTROINTESTINAL DISORDERS	21 (4.1)	11 (2.2)	4 (0.8)	2 (0.4)
HEPATOBILIARY DISORDERS	9 (1.8)	7 (1.4)	1 (0.2)	1 (0.2)
OTHER IMMUNE-RELATED ADVERSE EVENTS	17 (3.3)	6 (1.2)	5 (1.0)	0 (0.0)

Eggermont AM, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10000)

The anti–PD-1 antibody spartalizumab in combination with dabrafenib and trametinib in advanced *BRAF* V600–mutant melanoma: Efficacy and safety findings from parts 1 and 2 of the Phase III COMBI-i trial.

Georgina V. Long, Celeste Lebbe, Victoria Atkinson, Mario Mandalà, Paul D. Nathan, Ana Arance, Erika Richtig, Naoya Yamazaki, Caroline Robert, Dirk Schadendorf, Hussein Abdul-Hassan Tawbi

Cieľ: či cielená liečba BRAF a MEK inhibítormi v kombinácii s imunoterapiou anti PD-1 protilátkou môže zvýšiť účinnosť liečby oproti samotnej imunoterapii , či cielenej liečbe pri akceptovateľnej toxicite

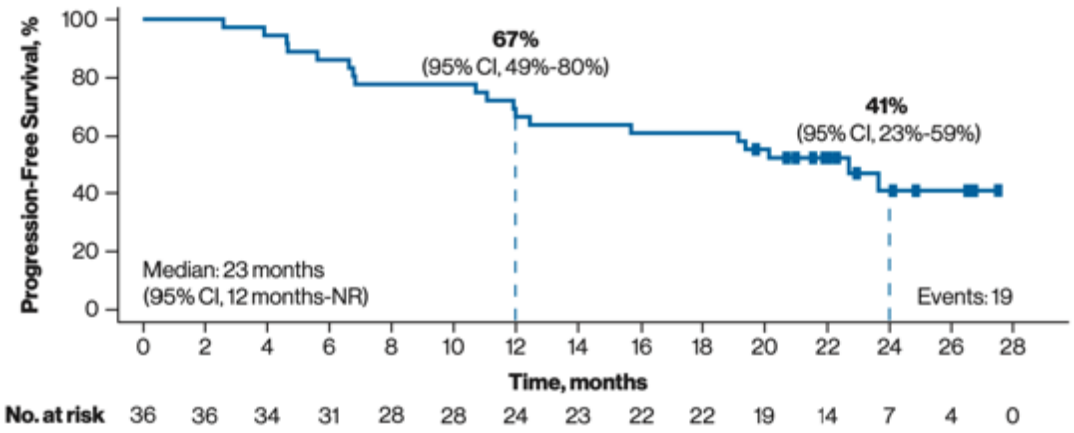
Dávkovanie:
Spartalizumab (anti PD-1) 400 mg i.v. á 4 týždne, dabrafenib 150 mg 2 x denne, trametinib 2 mg 1 x denne

Objective Response Rate

Patients With Measurable Disease at Baseline	N = 36
Best overall response, n (%)	
CR	16 (44)
PR	12 (33)
SD	6 (17)
PD	1 (3)
Unknown	1 (3)
Confirmed ORR (CR + PR), n (%) [95% CI]	28 (78) [61-90]
DCR (CR + PR + SD), n (%) [95% CI]	34 (94) [81-99]
DOR, median (95% CI), months	NR (17-NR)
24-Month DOR rate (95% CI), %	53 (29-73)

CR, complete response; DCR, disease control rate; DOR, duration of response; NR, not reached; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.

Kaplan Meier Estimates of PFS (all patients n= 36, per investigator review)



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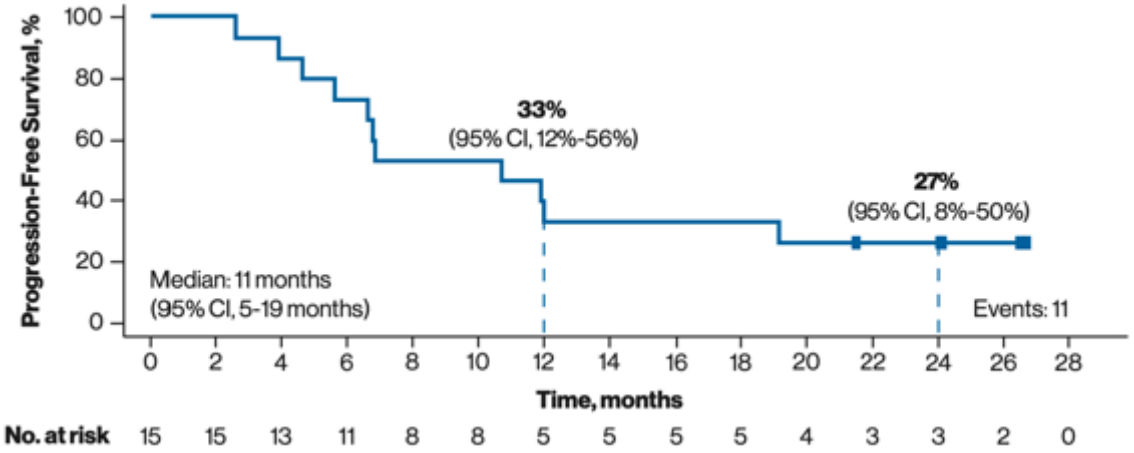
Kaplan Meier Estimates of PFS (patients with LDH ≥ ULN n= 15)



Pacienti s elevaciou LDH :
ORR 67% (CR 27%)
Medián PFS 10,7 mesiaca Medián OS nedosiahnutý
Odhadované 24 mesačné PFS u- 26,7% a OS 52,5%

NÚ: pyrexia, elevácia lipázy, neutropénia, elevácia CK, zvýšená aktivita hepatálnych enzýmov, nové NÚ neboli zaznamenané
17% pacientov ukončené podávanie liekov pre toxicitu

Záver: výsledky klinickej štúdie potvrdili vysokú účinnosť imunoterapie s cielenou liečbou, jednak v počte liečebných odpovedí , aj v dĺžke ich trvania aj u pacientov s nepriaznivou prognózou

Effect of first-line spartalizumab + dabrafenib + trametinib on immunosuppressive features detected in peripheral blood and clinical outcome in patients (pts) with advanced BRAF V600–mutant melanoma.

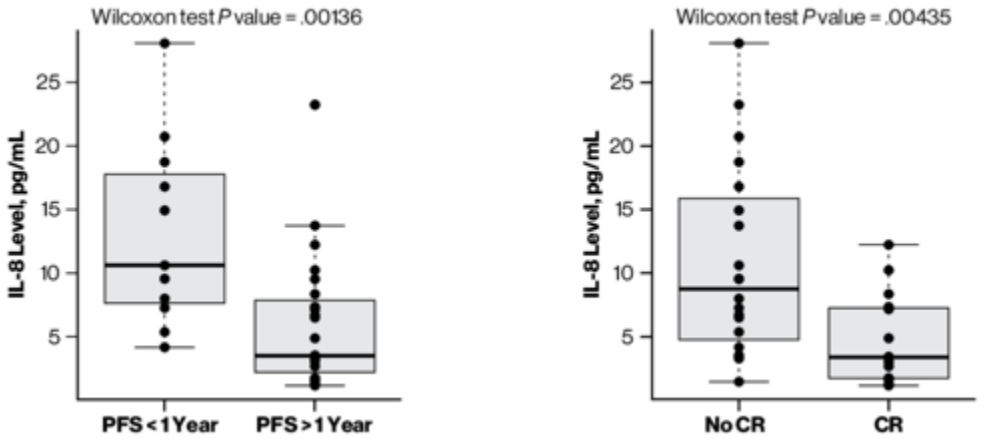
Reinhard Dummer, Kelly Biette, Daniel Gusenleitner, Radha Ramesh, Celeste Lebbe, Victoria Atkinson, Mario Mandalà, Paul D. Nathan, Ana Arance, Erika Richtig, Naoya Yamazaki, Caroline Robert, Dirk Schadendorf…

36 pac. – odber tkanivovej vzorky a krvi – pred zahájením liečby 2., 3., 8., 12. týždeň a pri progresii

Blood Biomarkers Associated With PFS > 1 Year

Parameter	Ratio of Median Level for PFS > 1 year vs PFS < 1 year[a]	*P* Value[b]
LDH level	0.50	.0029
NLR	0.56	.0049
Percentage of neutrophils	0.87	.0057
Percentage of lymphocytes	1.65	.0093
Albumin level	1.10	.0150

LDH, lactate dehydrogenase; NLR, neutrophil to lymphocyte ratio; PFS, progression-free survival.
[a] Wilcoxon test. [b] All *P* values are nominal.



- IL-8 bol s pomedzi 45 sledovaných cytokínov hodnotených pri začatí liečby Spartalizumabom + TakMek identifikovaný ako prognosticky indikátor pre CR a PFS
- Nízke hladiny IL-8 v plazme boli spojené s lepším PFS a dosiahnutím CR a naznačujú, že IL-8 môže pridať nezávislú prediktívnu hodnotu k LDH a NLR pre PFS> 1 rok a CR

Dummer R, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10034)

Risk of disease progression (PD) following discontinuation of BRAF±MEK targeted therapies for reasons other than PD in patients (pts) with metastatic or unresectable melanoma.

Francesca Corti, Giovanni Randon, Marta Bini, Alessandra Raimondi, Sara Manglaviti, Emma Zattarin, Ilaria Bisogno,

abstract 10053

- Pacienti s mts melanómom a prítomnou mutáciou BRAF dosahujú na liečbe kombináciou BRAFi a MEKi dlhodobé remisie, no následky prerušenia liečby z iných dôvodov ako PD nie sú dobre popísané

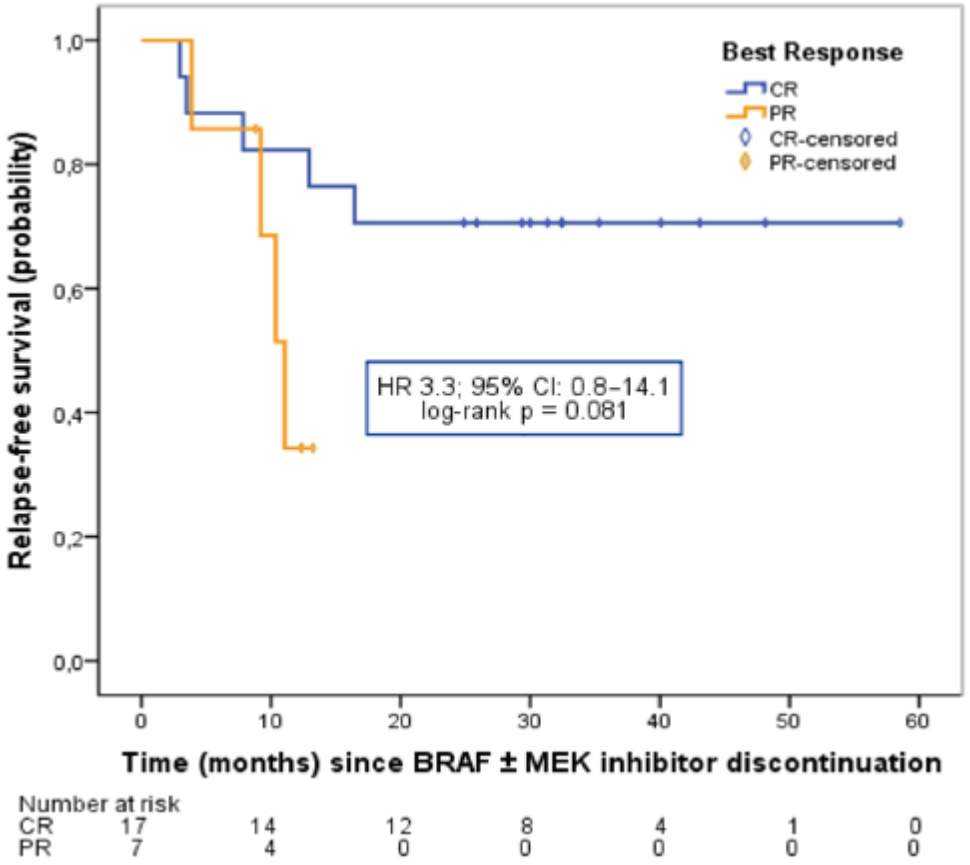
- Retrospektívne hodnotenie 24 pacientov liečených monoterapiou BRAFi , alebo kombináciou BRAFi a MEKi
- LDH v norme , ECOG 0 v čase zahájenia liečby
- 79% dôvod ukončenia liečby toxicita , 21% odvolalo súhlas s liečbou
- CR – 71% ; PR – 29% - v dobe ukončenia liečby
- Medián sledovania 31 mesiacov (8-59)
- Po ukončení liečby došlo u 37,5% k PD, z toho u 22% v doposiaľ nepostihnutom orgán
- Medián času do progresie 9 mesiacov od ukončenia terapie (3-16)

Corti F, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10053)

Risk of disease progression (PD) following discontinuation of BRAF±MEK targeted therapies for reasons other than PD in patients (pts) with metastatic or unresectable melanoma.

Francesca Corti, Giovanni Randon, Marta Bini, Alessandra Raimondi, Sara Manglaviti, Emma Zattarin, Ilaria Bisogno,

abstract 10053

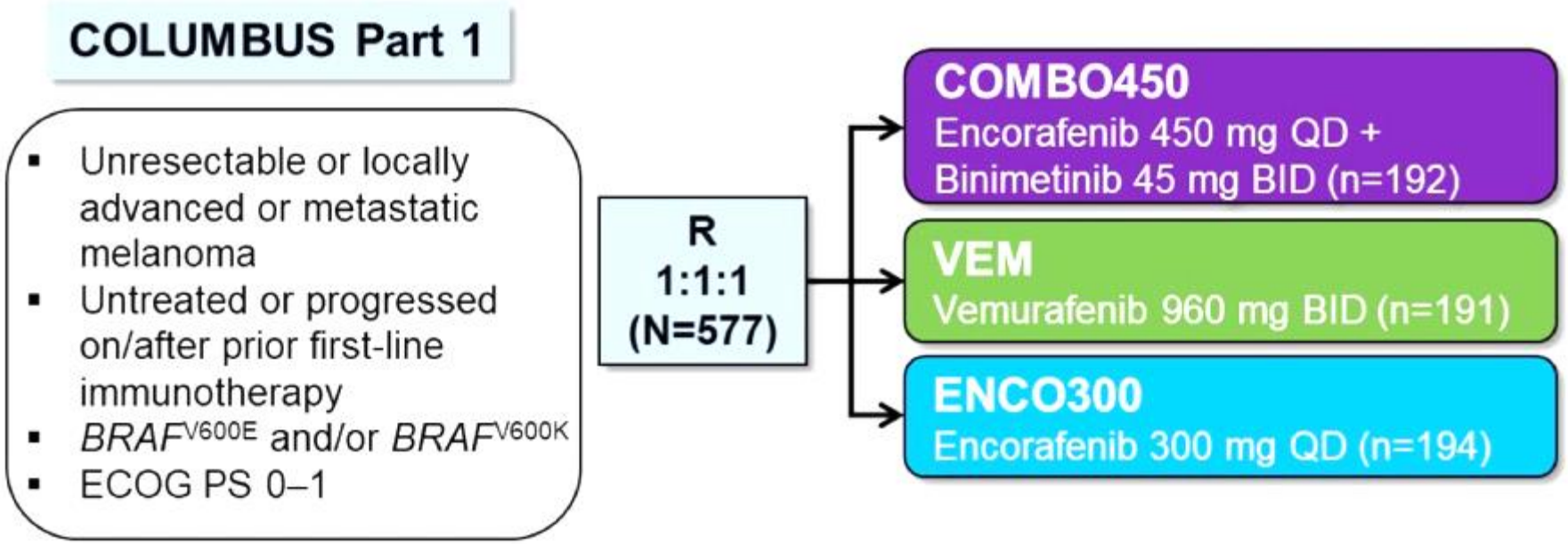


Risk of PD following discontinuation	
12 months	31%
24 months	45%

- Bol zaznamenaný nesignifikantný trend k vyššiemu riziku relapsu u pacientov s reziduálnym ochorením v porovnaní s pacientami s CR
- u všetkých 6 pacientov, ktorí boli pre PD opäť liečení BRAFi a MEKi bola popísaná liečebná odpoveď a u 3/6 došlo ku CR
- Výsledky štúdie poukazujú na to, že aj u pacientov s dobrou prognózou ochorenia a významnou liečebnou odpoveďou je riziko relapsu po ukončení terapie vysoké, a že doposiaľ nepoznáme biomarkery, ktoré by nám ukázali , u ktorých pacientov je vhodné po dosiahnutí CR BRAFi a MEKi ukončiť

Corti F, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10053)

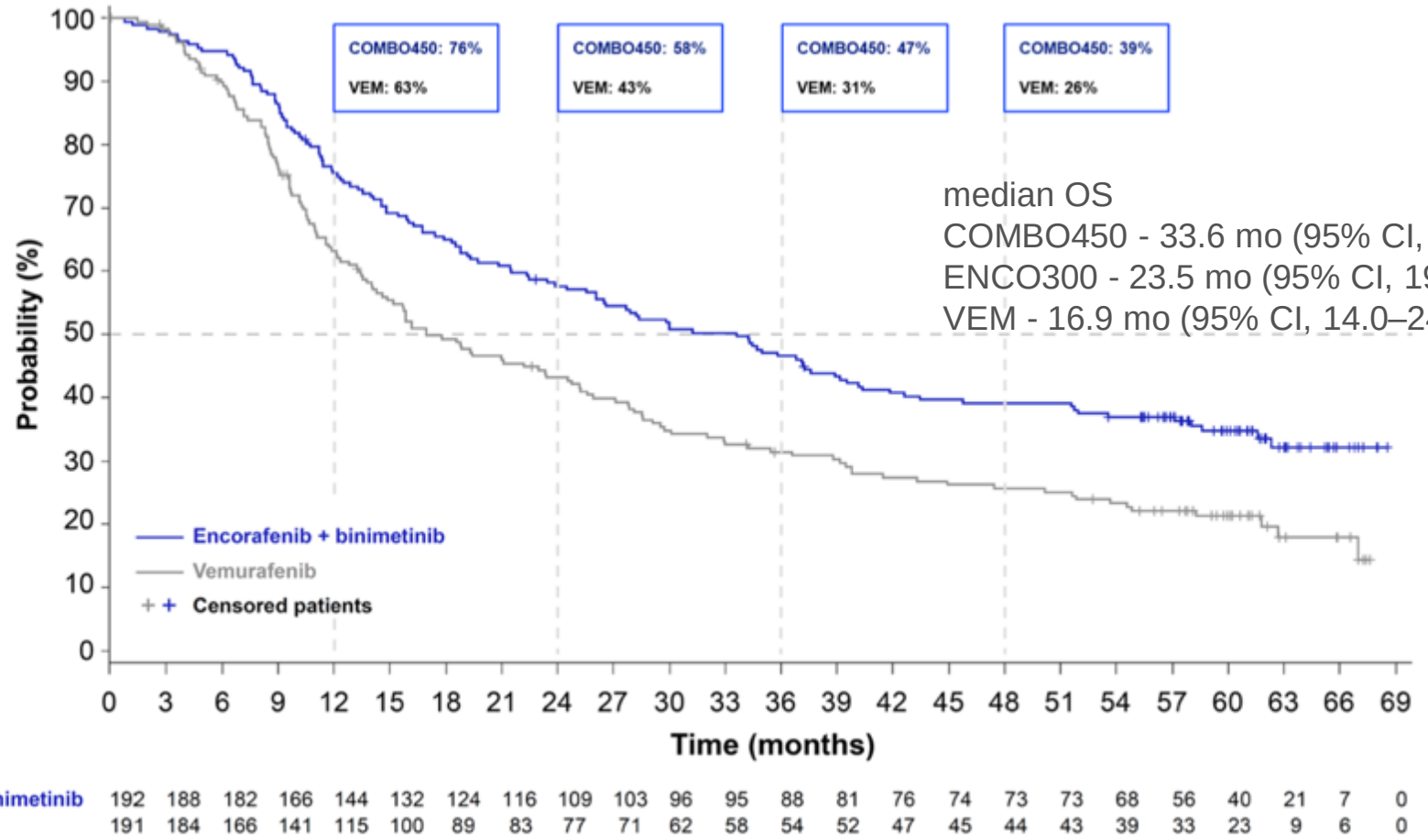
Update on Overall Survival in COLUMBUS: A Randomized Phase 3 Trial of Encorafenib (ENCO) Plus Binimetinib (BINI) vs Vemurafenib (VEM) or ENCO in Patients With BRAF V600–Mutant Melanoma



- A total of 577 patients were randomized in part 1 of the COLUMBUS study(COMB450:192; ENCO300: 194 and VEM: 191)
- landmark analyses of PFS and OS, as well as analyses of some prognostic subgroups from the COLUMBUS study, a 4-year updated, post-hoc analysis with additional follow-up from the COLUMBUS trial was conducted
- data cutoff November 2019

Gogas H, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10012)

COLUMBUS: Overall Survival and 4-Year Landmark Analysis COMBO vs VEM

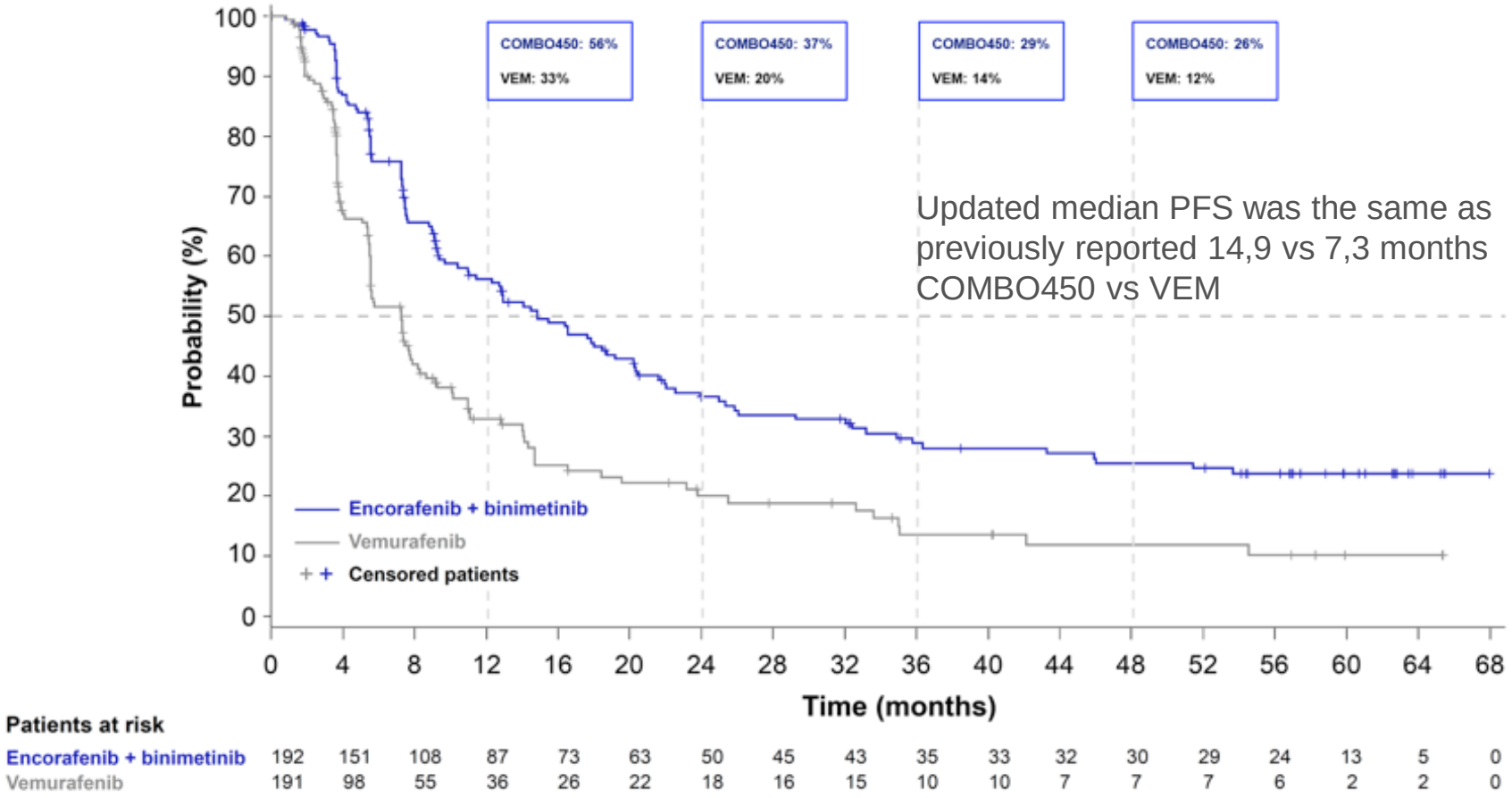


median OS
COMBO450 - 33.6 mo (95% CI, 24.4–39.2)
ENCO300 - 23.5 mo (95% CI, 19.6–33.6)
VEM - 16.9 mo (95% CI, 14.0–24.5)

median follow-up for OS was 60.6 months

Gogas H, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10012)

COLUMBUS: PFS and 4-Year Landmark Analysis: COMBO450 vs VEM (blinded IRC)



Updated median PFS was the same as previously reported 14,9 vs 7,3 months COMBO450 vs VEM

Gogas H, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10012)

Update on overall survival in COLUMBUS: A randomized phase III trial of encorafenib (ENCO) plus binimetinib (BINI) versus vemurafenib (VEM) or ENCO in patients with *BRAF* V600-mutant melanoma.

Helen Gogas, Paolo Antonio Ascierto, Keith Flaherty, Ana Arance, Mario Mandalà, Gabriella Liszkay, Claus Garbe, Dirk Schadendorf, Ivana Krajsova, Ralf Gutzmer ...

Výsledky potvrdzujú dlhodobú účinnosť COMBO 450 u pacientov s BRAFV600 pozit. melanómom

Výsledky podobne v rámci viacerých podskupín pacientov

Výsledky bezpečnosti konzistentné so známym bezpečnostným profilom COMBO450.

- Bez nových bezpečnostných signálov

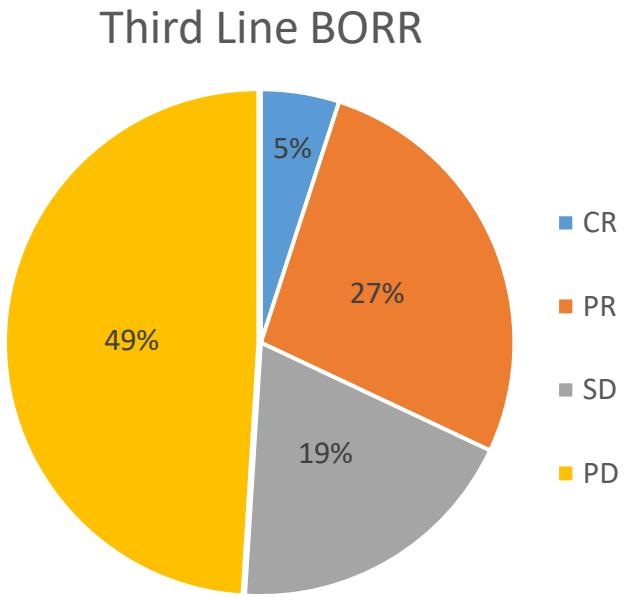
Gogas H, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10012)

Activity and safety of third-line BRAF-targeted therapy (TT) following first-line TT and second-line immunotherapy (IT) in advanced melanoma.

Victoria Atkinson, Kathleen Batty, Georgina V. Long, Matteo S. Carlino, Geoffrey David Peters, Prachi Bhave, Maggie A. Moore, Wen Xu, Lauren Julia Brown, Melissa Arneil, Megan Lyle, Alexander M. Menzies

- Hodnotenie bezpečnosti a účinnosti BRAFi a MEKi po predchádzajúcom zlyhaní cielenej liečby a imunoterapie
- Zaradených 90% pacientov liečených v I. línii cielenou liečbou (80% D + T)

ORR v I. línii : CR 20%, PR 41%, SD 17% , PD 13%
Medián trvania odpovede 7,2 mesiaca
II. línia imunoterapie – 49% monoterapia anti PD-1, 33% komb. Anti PD-1 + anti CTLA - 4, 14% monoterapia anti CTLA-4
III. línia: BRAFi a MEKi D+T41%, V+C33%, E+B 11%
ORR – 28%, medián trvania odpovede 81 dní
Medián OS 1,7 roku a 34% prežívalo v dobe analýzy



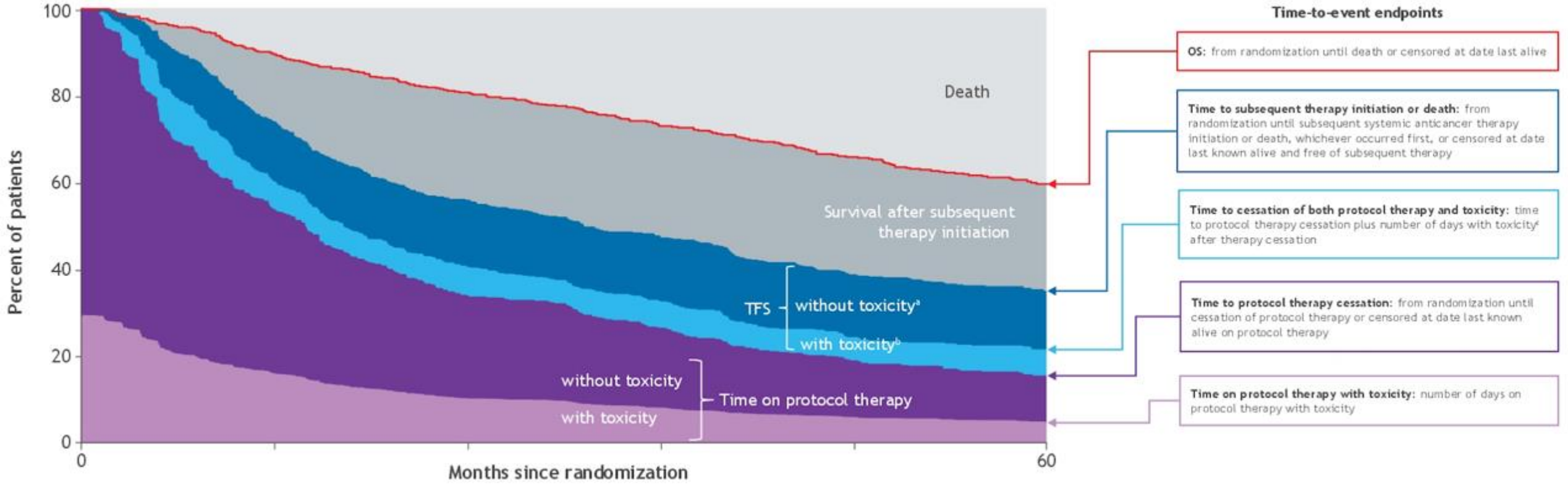
Záver: aj po progresii na predchádzajúcich 2 líniách liečby došlo u pacientov pri podaní cielenej liečby v III. línii k významnej liečebnej odpovedi

Atkinson V, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10049)

Estimating treatment-free survival (TFS) over extended follow-up in patients (pts) with advanced melanoma (MEL) treated with immune-checkpoint inhibitors (ICIs): Five-year follow-up of CheckMate 067.

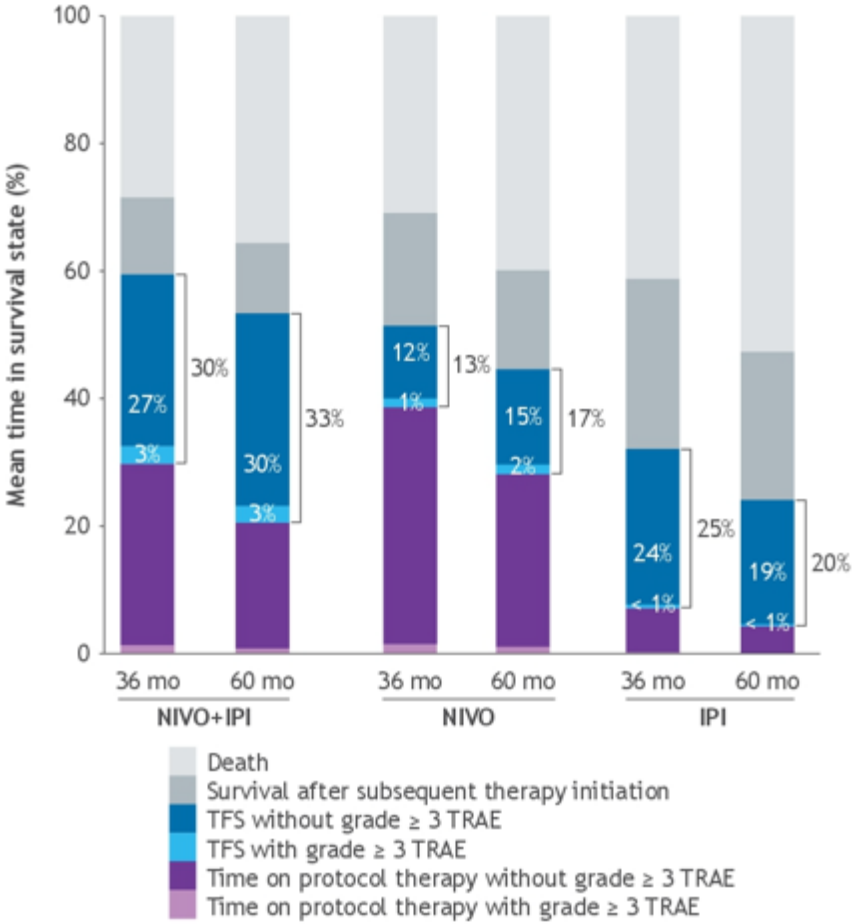
Meredith M. Regan, Charlene Mantia, Lillian Werner, Ahmad A. Tarhini, Sumati Rao, Andriy Moshyk, Corey Ritchings, Jasmine I. Rizzo, Michael B. Atkins, David F. McDermott

Data were analyzed for 937 pts with MEL who started treatment with nivolumab (NIVO) plus ipilimumab (IPI), NIVO, or IPI in CheckMate 067.



Regan M, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10043)

Five-year follow-up of CheckMate 067.



Pri porovnávaní 60 mesačného a 36 mesačného sledovania je zrejmé, že najviac profitujú pacienti liečení kombináciou Nivo a Ipi , ktorí majú TFS 2 x dlhšie ako pacienti po monoterapii Nivo

Jeden z dôvodov je tiež ukončenie kombinovanej liečby pre toxicitu bez progresie ochorenia

Väčšina pacientov strávila TFS bez NÚ stupňa 3

Regan M, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10043)

Response to immune checkpoint inhibitor (ICI) rechallenge after high-grade immune related adverse events (irAE) in patients (pts) with metastatic melanoma (MM).

Payal Shah, Patrick Boland, Anna C. Pavlick

Súčasné odporúčania obmedzujú pokračovania imunoterapie u pacientov so závažnými NÚ
Autoimunita - kontraindikácia

Retrospektívne hodnotených 551 pacientov liečených od 2014 do 2020 imunoterapiou
180 pac (32,7) malo závažné NÚ, 91 (50,6%) pacientom bola po odoznení NÚ opakovane podaná imunoterapia

Medián vzniku prvých NÚ po I. podaní imunoterapie 7, 6 týždňa
- 60% pacientov grade 3
- 40% pacientov grade 4

Shar P, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10045)

Response to immune checkpoint inhibitor (ICI) rechallenge after high-grade immune related adverse events (irAE) in patients (pts) with metastatic melanoma (MM).

Payal Shah, Patrick Boland, Anna C. Pavlick

- Medián doby od vzniku prvých NÚ do nového podania imunoterapie - **9, 7 týždňov**
- Z 56 pac., ktorí boli liečení kombináciou bolo opäť liečených kombináciou 29 pac. (51,8%), 27 pac. (48%) imunoterapiou
- Z 35 pac. liečených monoterapiou znovu liečba imunoterapiou - mono 21 (60%) a 14 (40%) kombináciou
- Medián sledovania 21.1 mes

Kontrola ochorenia u 60,4%

40,7%	CR
11%	PR
8,8%	SD

75.8 %	objavenie sa NÚ
44,9%	iný typ NÚ
31,9%	závažná tox.

Kolitída	27,5%
Hepatitída	23,1%
Kožná toxicita	22,0%
Hypofyzitída	5,5%
Adrenálna insuf	5,5%
Neurologické problémy	4,4%

Záver: opakované podanie imunoterapie môže byť bezpečné a NÚ vzniknuté pri opakovanom podaní sa môžu odlišovať od účinkov pri I. podaní liečby

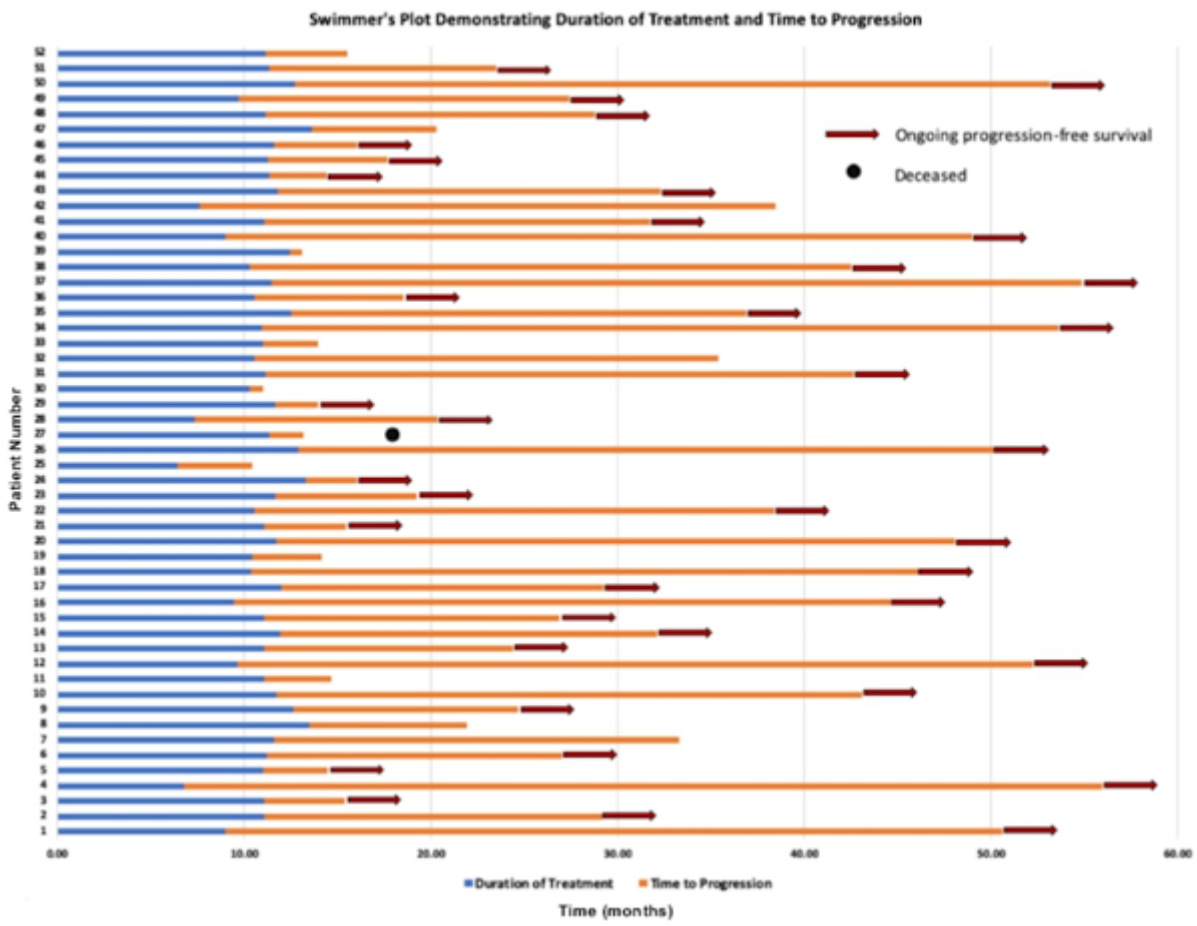
Shar P, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10045)

Clinical outcomes with early-elective discontinuation of PD-1 inhibitors (PDi) at one year in patients (pts) with metastatic melanoma (MM).

Rebecca Pokorny, Jordan P. McPherson, Kenneth F. Grossmann, Carolyn Luckett, Benjamin Newell Voorhies, Daniel S. Sageser, Jocelyn Wallentine, Zachary Tolman, Siwen Hu-Lieskovan, Umang Swami;

- 52 pacientov liečených monoterapiou anti PD-1 protilátkami
- Medián trvania odpovede – 11,1 mesiaca
  - CR 25% pacientov
  - PR 53,8% pacientov
  - SD 21,2% pacientov
- Medián sledovania 20,5 mesiaca, po ukončení liečby 75% pacientov bez progresie
- 13 pacientov – progresia, z nich 5 liečených anti PD-1, u všetkých dosiahnutá kontrola ochorenia

Záver: výsledky tejto štúdie naznačujú , že je možné uvažovať o skrátení podávania liečby anti PD-1 protilátkami, bez toho aby došlo k zníženiu účinnosti liečby, zníži sa toxicita , ktorá liečbu sprevádza



Pokorny R, et al. *J Clin Oncol* 38: 2020 (suppl; abstr 10048)