ASCO news

Melanom -adjuvance

	stádia	No	Design	Výsledky
KEYNOTE-054 Pembro placebo	IIIA-C	1019	200 mg a 3 t / 1 rok -	3-letý RFS 63,7% HR 0,56 44,1%
CHECKMATE 238 Nivo Ipi	IIIB-C IV	906	3 mg/kg a 2 t / 1 rok 10 mg/kg a 3 t 4x – a 3 m / 1 rok	4-letý RFS 51,7% HR 0,71 41,2%
COMBI-AD Taf/Mek placebo	IIIA-IIIC	870	150 mg bid / 2 mg odd / 1 rok -	5-letý RFS 52% HR 0,51 36%

Melanom -adjuvance

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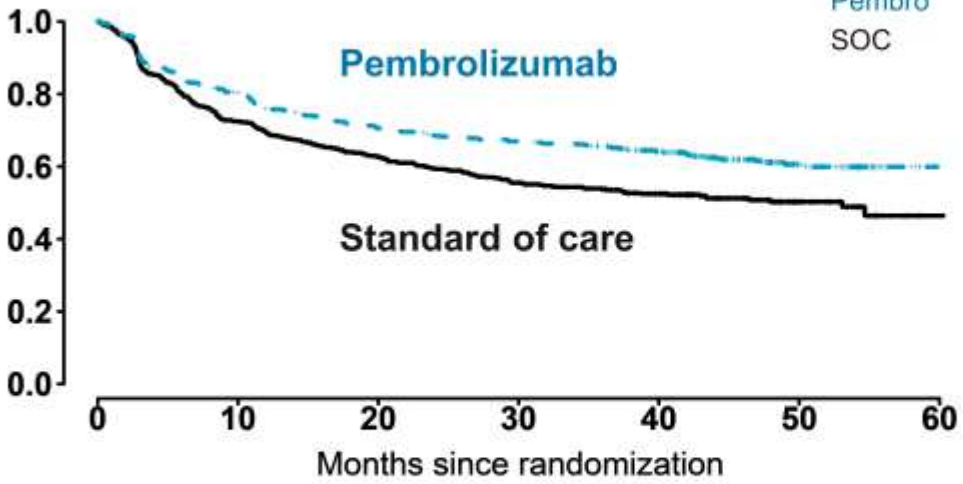
COMBI-AD Taf/Mek placebo	IIIA-IIIC	870	150 mg bid / 2 mg odd / 1 rok -	5-letý RFS 52% HR 0,51 36%
S1404 Pembro HD INF Ipi	IIIA-IV	1303	200 mg a 3 t / 1 rok 20 MU/m2/D1-5 1-4t, 10 MU/m2 D1,3,5 5-52t 10 mg / kg / 3 roky	RFS 63% HR 0,74 51%

Melanom -adjuvance

Relapse-free survival



	Total N	N with Events	Hazard Ratio (99.62% CI)
Pembro	648	240	0.74 (0.57, 0.96)
SOC	655	272	

Log-rank p-value <0.001

Pembro	648	609	410	410	344	86
SOC	655	396	336	290	227	61

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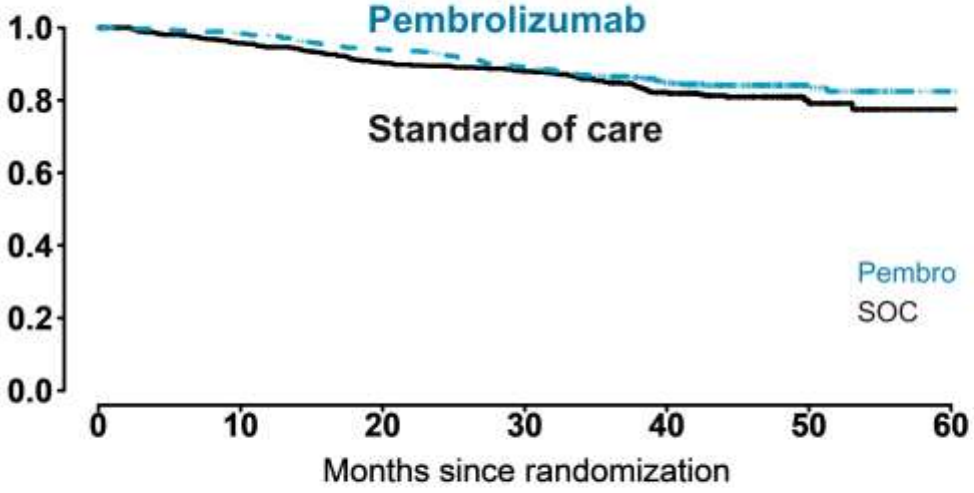
Overall survival (ITT)



	Total N	N with Events	Hazard Ratio (96.3% CI)
Pembro	648	98	0.84 (0.62, 1.13)
SOC	655	101	

Log-rank p-value = 0.21

Pembro	648	624	587	548	427	108	1
SOC	655	524	485	460	343	86	2

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Melanom -adjuvance

Study	RFS	HR for RFS	OS	HR for OS
EORTC 18071[1] Ipilimumab 10mg/kg vs. Placebo	39.2% at 7 years 30.9% at 7 years	**0.75 (0.63-0.88)**	60% at 7 years 51.3% at 7 years	**0.73 (0.60-0.89)**
Combi-AD[2] Dabrafenib+Trametinib vs. Placebo	52% at 5 years 36% at 5 years	**0.51 (0.42-0.61)**	86% at 3 years 77% at 3 years	**0.57 (0.42-0.79)**
CM-238[3] Nivolumab vs. Ipilimumab 10mg/kg	52% at 4 years 41% at 4 years	**0.71 (0.6-0.86)**	78% at 4 years 77% at 4 years	0.87 (0.66-1.14)
Keynote-054[4] Pembrolizumab vs. Placebo	63.7% at 3 years 44.1% at 3 years	**0.56 (0.47-0.68)**		
CM-915[5] Ipilimumab+Nivolumab vs. Nivolumab	64.6% at 2 years 63.2% at 2 years	0.92 (0.77-1.09)		NEFUNGUJE
S1404[6] Pembrolizumab vs. SOC		**0.74 (0.57-0.96)**		0.84 (0.62-1.13)

1: Eggermont et al. Eur J Cancer 2019; 119: 1-10; 2: Hauschild et al. ASCO 2020 Abstract 10001, 3: Weber et al. ESMO 2020 Abstract 10760; 4: Eggermont et al. ASCO 2020 Abstract 10000, 5: Long et al. AACR 2021 Abstract CT004, 6: Grossman et al. ASCO 2021 Abstract 9501

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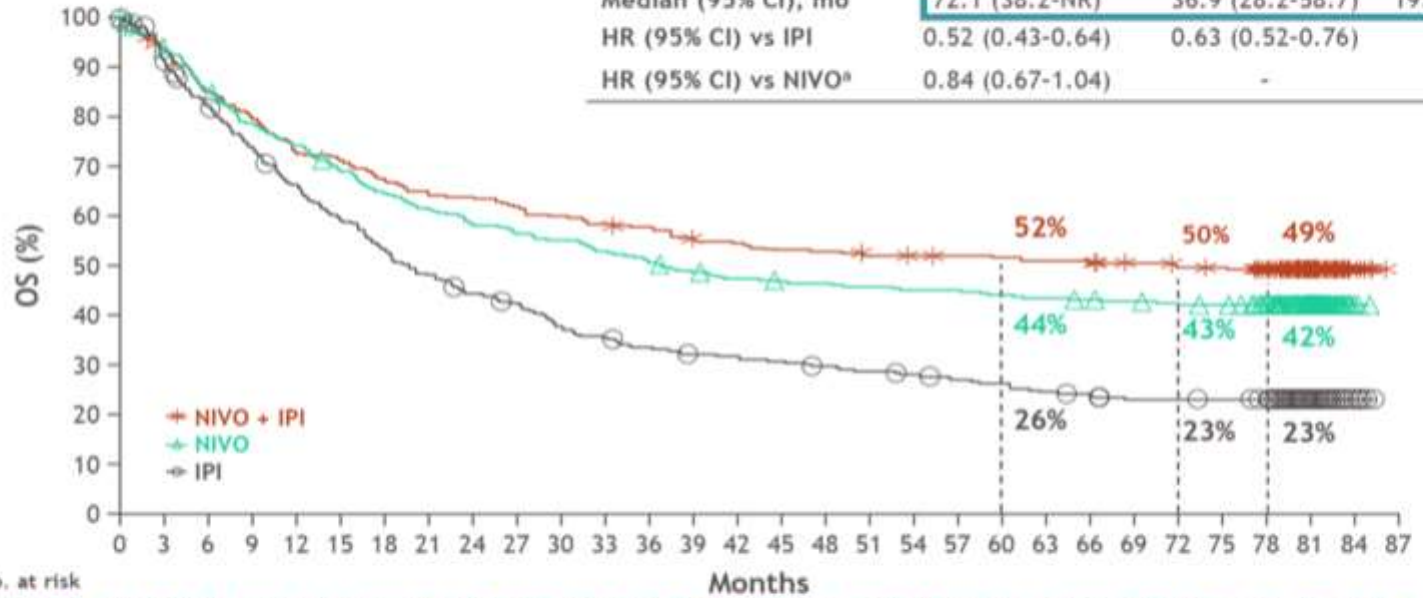
Melanom -paliace

Overall survival

6.5 yr OS for CheckMate 067

Wow.

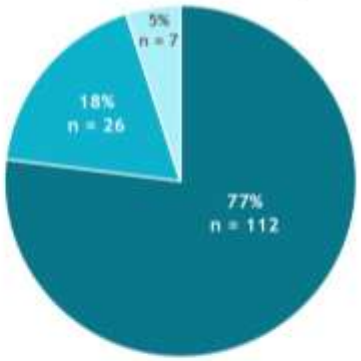
	NIVO + IPI (n = 314)	NIVO (n = 316)	IPI (n = 315)
Median (95% CI), mo	72.1 (38.2-NR)	36.9 (28.2-58.7)	19.9 (16.8-24.6)
HR (95% CI) vs IPI	0.52 (0.43-0.64)	0.63 (0.52-0.76)	-
HR (95% CI) vs NIVO[a]	0.84 (0.67-1.04)	-	-



No. at risk

NIVO + IPI	314	292	265	248	227	222	210	201	199	193	187	181	179	172	169	164	163	159	158	157	156	154	153	150	147	145	138	66	10	0
NIVO	316	292	266	245	231	214	201	191	181	175	171	164	158	150	145	142	141	139	137	137	134	132	130	128	126	124	117	59	3	0
IPI	315	285	253	227	203	181	163	148	135	128	113	107	100	95	94	91	87	84	81	77	75	70	68	64	64	63	61	32	7	0

NIVO + IPI (n = 145)



77% of ipi/nivo treated patients didn't require additional therapy

[a]Descriptive analysis.

Presented By:
Adapted from Wolchock et al. ASCO 2021, Abstract 9506

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2021 ASCO ANNUAL MEETING

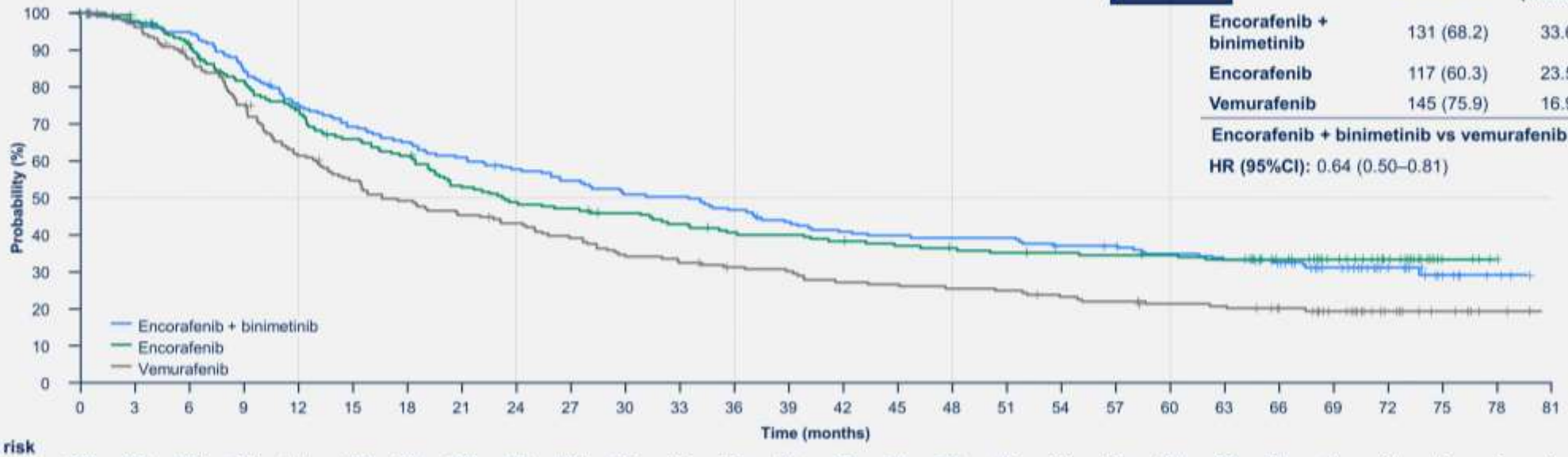
Melanom -paliace

5-Year Overall Survival

OS rate (%)	Year 1	Year 2	Year 3	Year 4	Year 5
Encorafenib + binimetinib	75.5	57.7	46.5	39.1	34.7
Encorafenib	74.6	49.1	40.9	36.8	34.9
Vemurafenib	63.1	43.2	31.4	25.6	21.4

	Events (%)	Median (months)
Encorafenib + binimetinib	131 (68.2)	33.6
Encorafenib	117 (60.3)	23.5
Vemurafenib	145 (75.9)	16.9

Encorafenib + binimetinib vs vemurafenib:
HR (95%CI): 0.64 (0.50–0.81)

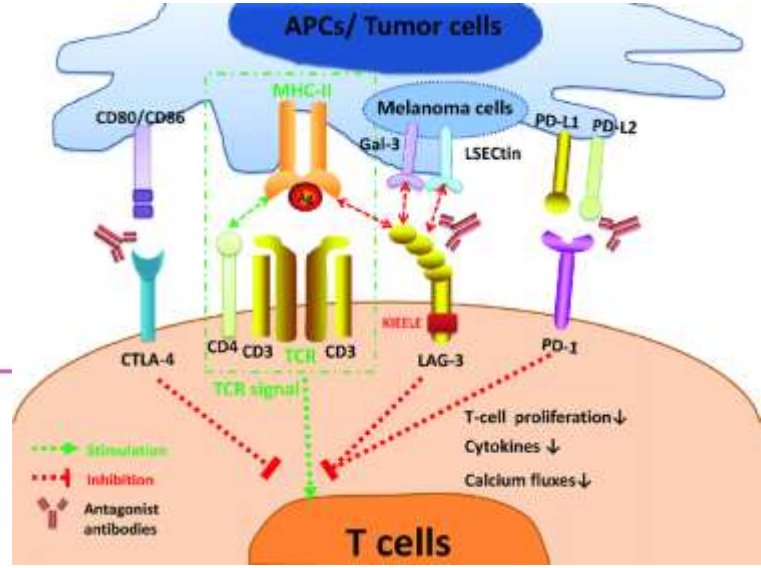


Patients at risk																												
Encorafenib + binimetinib	192	188	182	166	144	132	124	116	109	103	96	95	88	81	76	74	73	73	68	66	62	59	51	41	21	8	3	0
Encorafenib	194	181	168	147	133	117	109	94	86	83	79	74	69	68	65	62	60	58	57	56	55	53	44	34	24	5	0	0
Vemurafenib	191	184	166	141	115	100	89	83	77	71	62	58	54	52	47	45	44	43	39	37	34	32	29	22	13	6	2	0

Melanom –paliace, BRAFmut populace

	5-year OS	5-year OS with baseline LDH > ULN
CM-067 (BRAF mutant)[1,2]		
Ipilimumab + Nivolumab	60%	38%
Nivolumab	46%	28%
Ipilimumab	30%	15%
COLUMBUS[3]		
Encorafenib + Binimetinib	34.7%	9.1%
Encorafenib	34.9%	
Vemurafenib	21.4%	
COMBI-d + COMBI-v[4]		
Dabrafenib + Trametinib	34%	16%

Melanom –paliace, nová první linie?



Study design

- **RELATIVITY-047** is a global, randomized, double-blind, phase 2/3 study

Key eligibility criteria
- Previously untreated unresectable or metastatic melanoma[a]
- ECOG PS 0–1

Stratification factors
- LAG-3[b]
- PD-L1[c]
- *BRAF*
- AJCC v8 M stage

N = 714

R 1:1

- RELA 160 mg + NIVO 480 mg fixed-dose combination (FDC) IV Q4W
- NIVO 480 mg IV Q4W

Primary endpoint
- PFS by BICR[d]

Secondary endpoints
- OS
- ORR by BICR[d]

Relatlimab – Lag-3 inhibitor

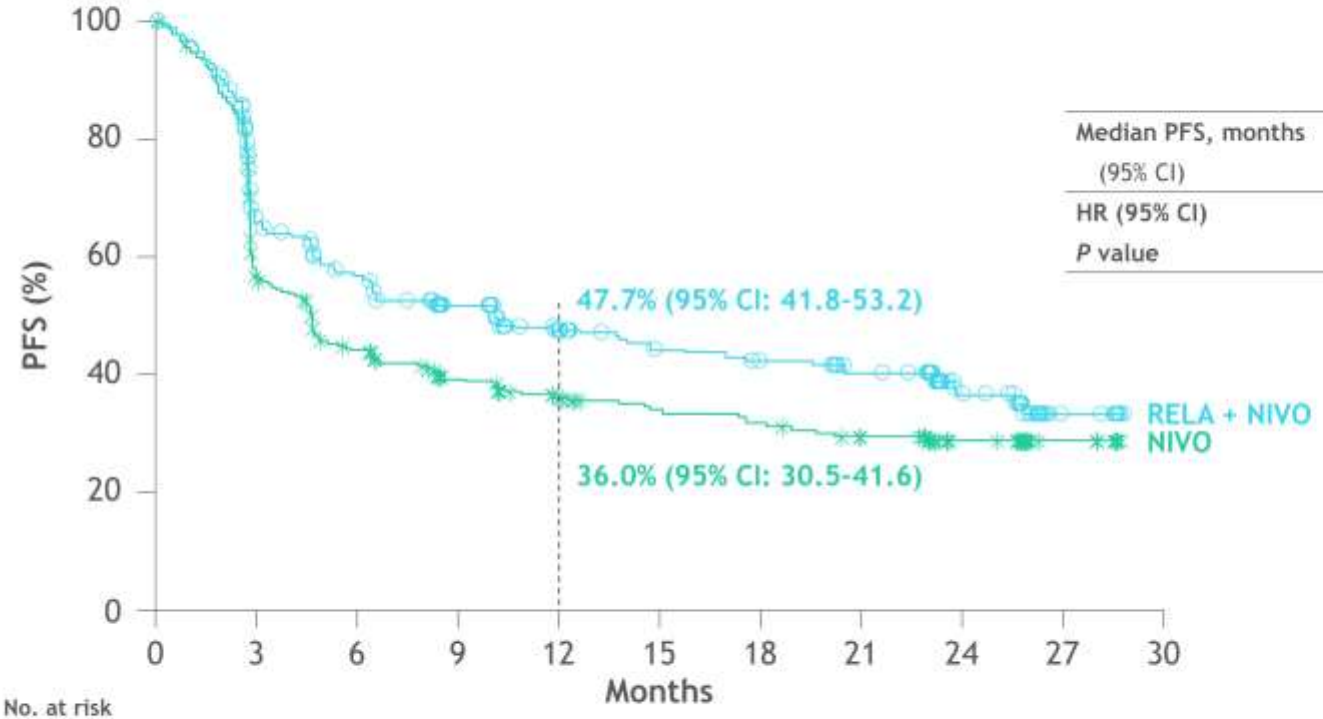
AJCC, American Joint Committee on Cancer; BICR, blinded independent central review; CTLA-4, cytotoxic T lymphocyte antigen-4; ECOG PS, Eastern Cooperative Oncology Group performance status; IHC, immunohistochemistry; IV, intravenous; ORR, overall response rate; Q4W, every 4 weeks; R, randomization.
ClinicalTrials.gov: NCT03470922; Lipson E, et al. Poster presentation at ESMO Congress; October 19-23, 2018; Munich, Germany. Abstract 1302TiP.
[a]Prior adjuvant/neoadjuvant treatment permitted (anti-PD-1 or anti-CTLA-4 permitted if at least 6 months between the last dose and recurrence; interferon therapy permitted if the last dose was at least 6 weeks before randomization); [b]LAG-3 expression on immune cells was determined using an analytically validated IHC assay (LabCorp); [c]PD-L1 expression on tumor cells was determined using the validated Agilent/Dako PD-L1 IHC 28-8 pharmDx test; [d]First tumor assessment (RECIST v1.1) performed 12 weeks after randomization, every 8 weeks up to 52 weeks, and then every 12 weeks. Database lock date: March 9, 2021.

Lipson et al. ASCO 2021 Abstract 9503

Melanom –paliace, nová první linie?

RELATIVITY-047

RELATIVITY 047 demonstrated superior PFS benefit by BICR for RELA + NIVO FDC vs NIVO



	RELA + NIVO (n = 355)	NIVO (n = 359)
Median PFS, months	10.12	4.63
(95% CI)	(6.37-15.74)	(3.38-5.62)
HR (95% CI)	0.75 (0.62-0.92)	
P value	0.0055	

No. at risk											
RELA + NIVO	355	201	163	132	99	81	75	67	30	6	0
NIVO	359	174	124	94	72	61	57	49	27	6	0

Relatlimab – Lag-3 inhibitor

CI, confidence interval; HR, hazard ratio.
All randomized patients. Statistical model for HR and *P* value: stratified Cox proportional hazard model and stratified log-rank test. Stratified by LAG-3 (≥ 1% vs < 1%), *BRAF* (mutation positive vs mutation wild-type), AJCC M stage (M0/M1any[0] vs M1any[1]). PD-L1 was removed from stratification because it led to subgroups with < 10 patients.

Lipson et al. ASCO 2021 Abstract 9503

Karcinom ledvin

KEYNOTE-564 Study Design

Key Eligibility Criteria

- Histologically confirmed clear cell renal cell carcinoma
- Nephrectomy ≤12 weeks prior to randomization
- No prior systemic therapy
- ECOG PS 0 or 1
- Tissue sample for PD-L1 assessment

Stratification Factors

- M0 vs M1 NED
- M0 group further stratified:
  - ECOG PS 0 vs 1
  - US vs non-US

R (1:1)

Pembrolizumab 200 mg Q3W for ~1 year[a]

Placebo Q3W for ~1 year[a]

- Primary end point: DFS per investigator
- Key secondary end point: OS
- Other secondary end points: Safety

DFS, disease-free survival; Q3W, every 3 weeks.
[a]≤17 cycles of treatment were equivalent to ~1 year.

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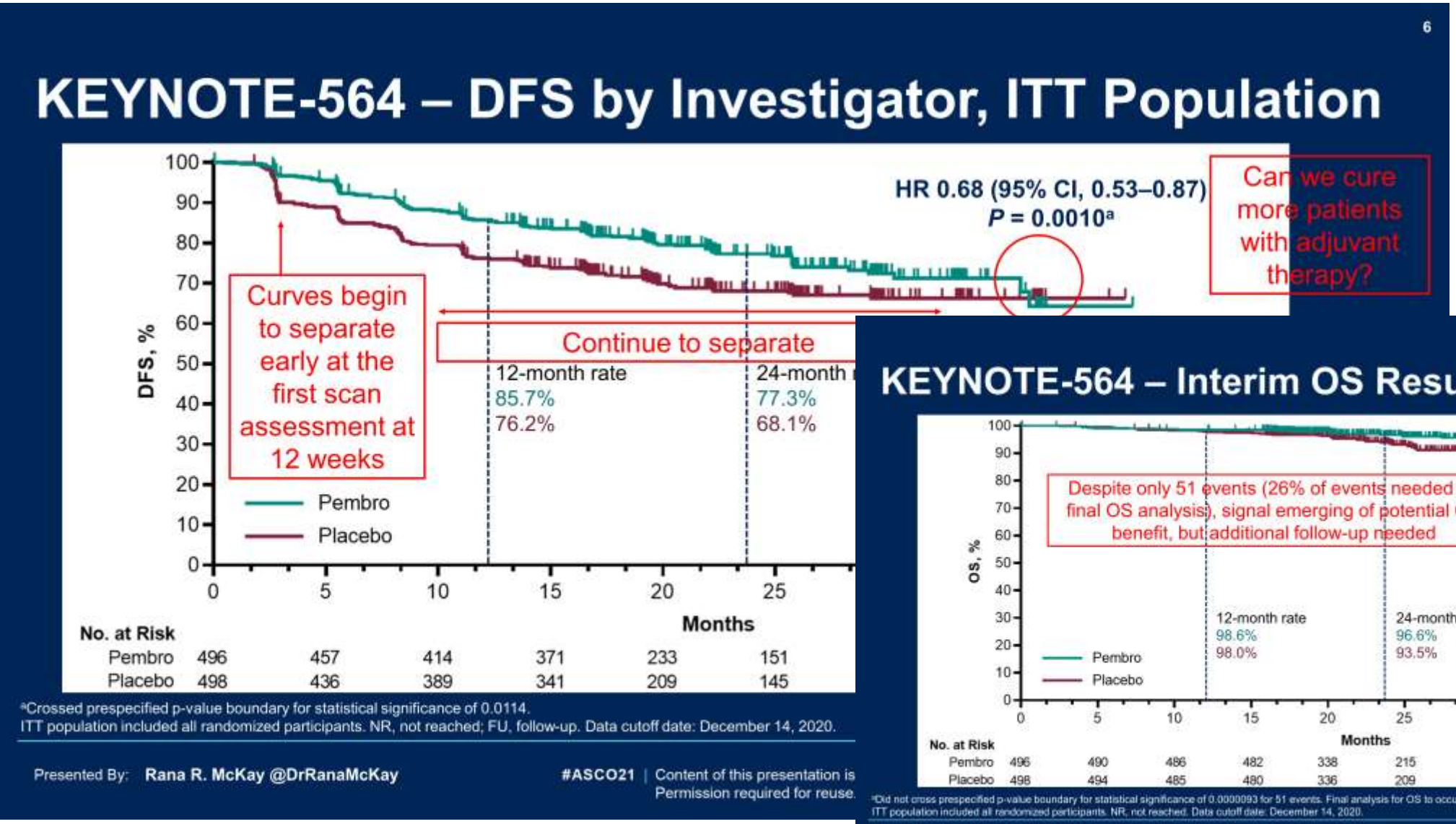

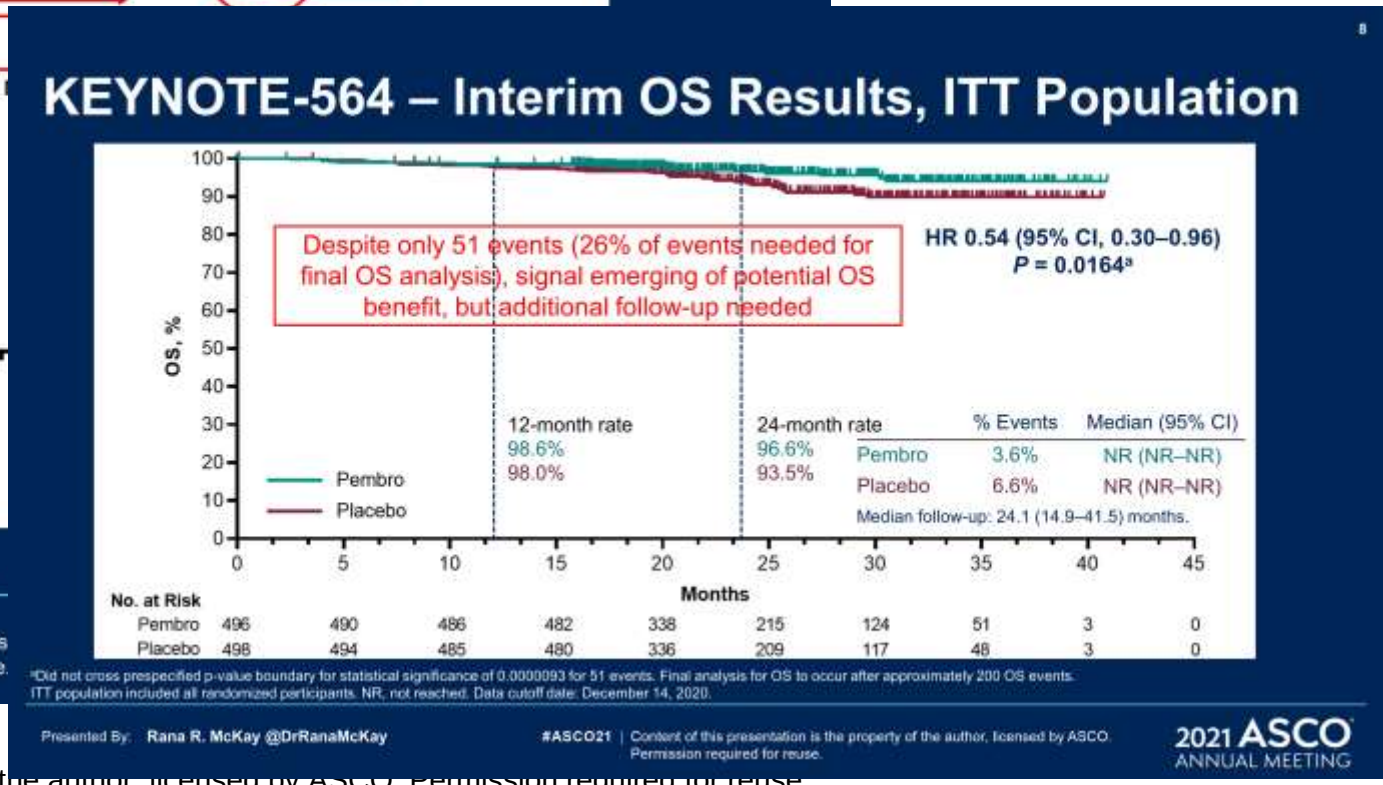

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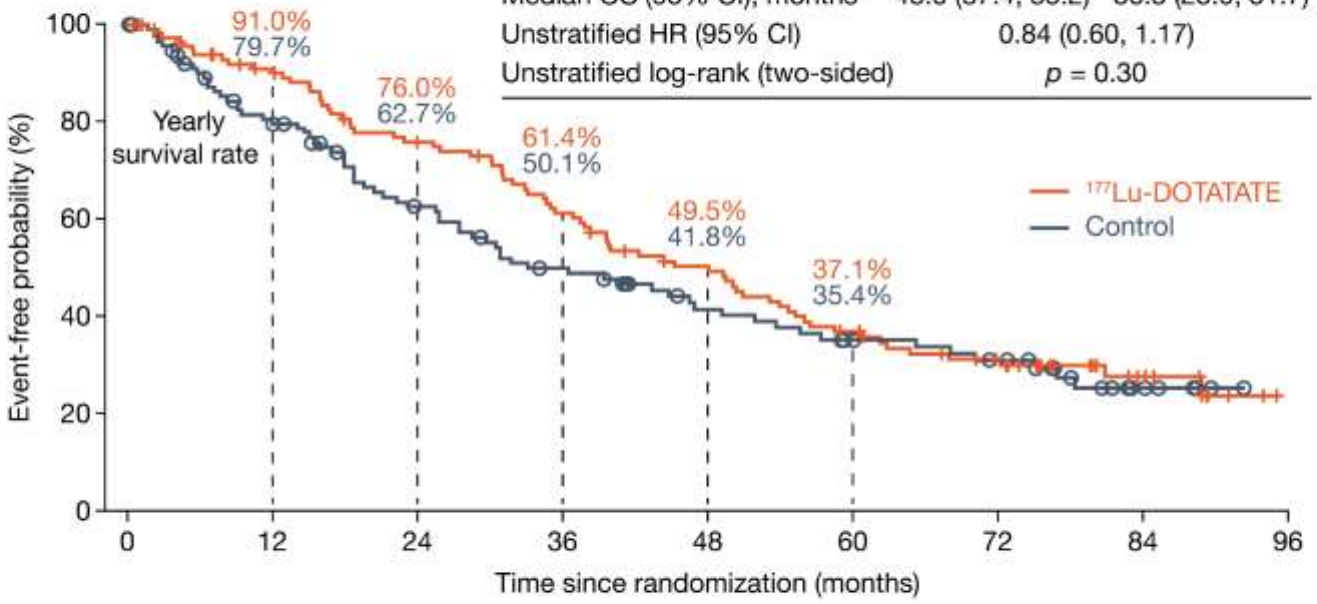
Karcinom ledvin

	HR ve vztahu k DFS
KEYNOTE 564	0,68
S-TRAC	0,76
PROTECT	0,86
ACRIN	0,97

Neuroendokrinní nádory

NETTER-1: overall survival in the intention-to-treat population

	^{177}Lu-DOTATATE	Control
Median OS (95% CI), months	48.0 (37.4, 55.2)	36.3 (25.9, 51.7)
Unstratified HR (95% CI)	0.84 (0.60, 1.17)	
Unstratified log-rank (two-sided)	$p = 0.30$	



No. patients still at risk:

	0	12	24	36	48	60	72	84	96
^{177}Lu-DOTATATE	117	98	79	63	48	35	25	10	0
Control	114	84	61	45	33	25	21	6	0

CI, confidence interval; HR, hazard ratio; OS, overall survival.

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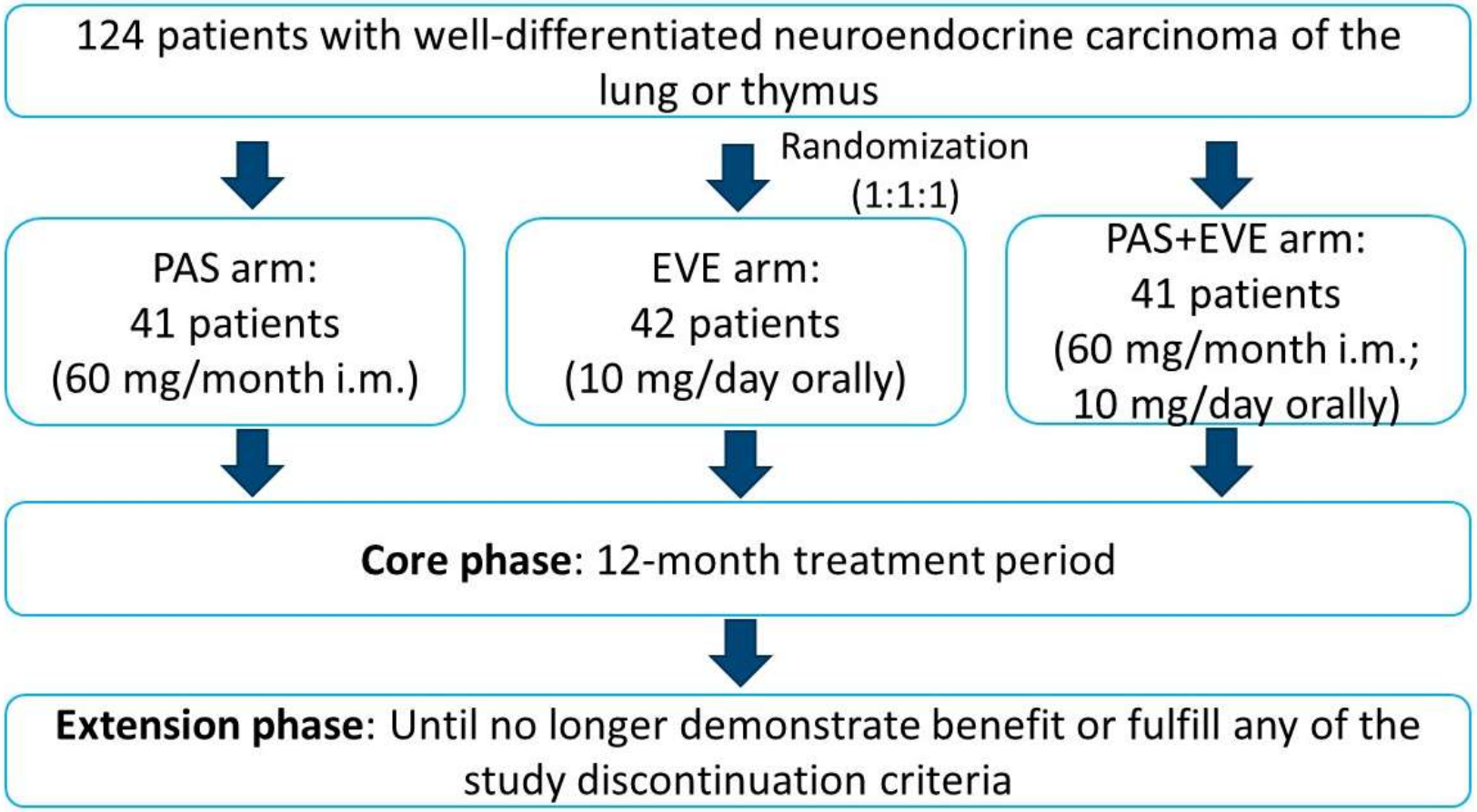
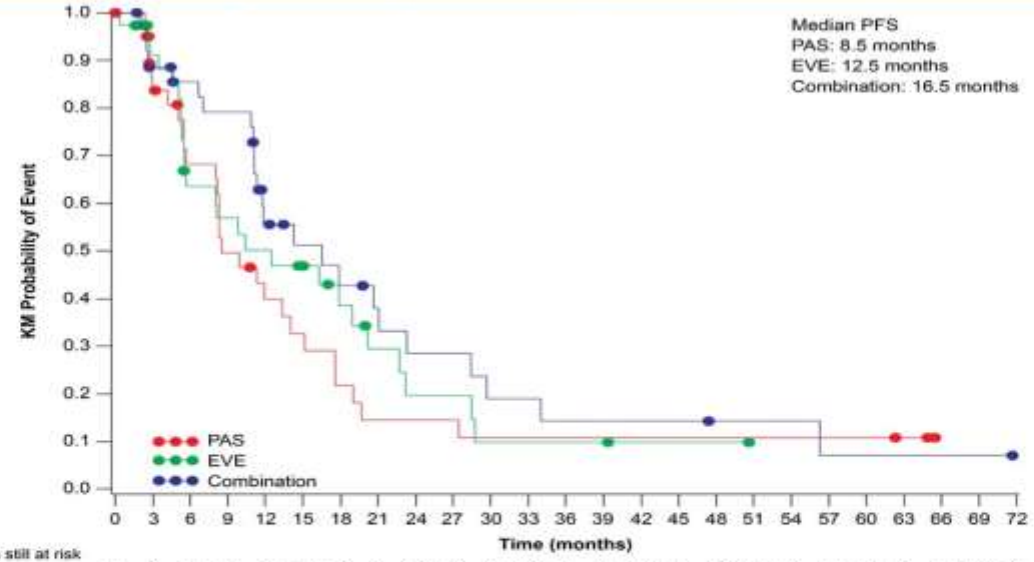
Study Design



Neuroendokrinní nádory

PFS and BPFS

Figure 1. PFS per investigator radiological review by treatment (FAS for the entire study)



No. of patients still at risk

Time (months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	54	60	63	66	69	72
Pasireotide LAR	41	29	22	16	11	9	6	4	4	4	3	3	3	3	3	3	3	3	3	3	3	2	0	0	0
Everolimus	42	30	19	17	15	13	9	6	4	4	2	2	2	2	1	1	1	0	0	0	0	0	0	0	0
Combination	41	30	27	25	15	12	10	8	6	6	4	4	3	3	3	3	2	2	2	1	1	1	1	1	0

BPFS

- The median BPFS for the PAS and EVE arms was 2.9 months (95% CI, 2.79-5.49) and 2.9 months (95% CI, 2.79-3.52), respectively
- The median BPFS for the PAS+EVE combination arm was 5.6 months (95% CI, 3.19-8.31)

BPFS, biochemical progression-free survival; CI, confidence interval; EVE, everolimus; FAS, full analysis set; PAS, pasireotide; PFS, progression-free survival.

Poster presented at the 2020 ASH Annual Meeting & Exposition, held virtually on 5–8 December 2020

Karcinom jícnu

CheckMate 577 study design

- CheckMate 577 is a global, phase 3, randomized, double-blind, placebo-controlled trial[a]

Key eligibility criteria
- Stage II/III EC/GEJC
- Adenocarcinoma or squamous cell carcinoma
- Neoadjuvant CRT + surgical resection (R0,[b] performed within 4-16 weeks prior to randomization)
- Residual pathologic disease
  - ≥ ypT1 or ≥ ypN1
- ECOG PS 0-1

Stratification factors
- Histology (squamous versus adenocarcinoma)
- Pathologic lymph node status (≥ ypN1 versus ypN0)
- Tumor-cell PD-L1 expression (≥ 1% versus < 1%[c])

N = 794

R 2:1

n = 532

Nivolumab
240 mg Q2W × 16 weeks then 480 mg Q4W

n = 262

Placebo
Q2W × 16 weeks then Q4W

Total treatment duration of up to 1 year[d]

Primary endpoint:
- DFS[e]

Secondary endpoints:
- OS[f]
- OS rate at 1, 2, and 3 years

Exploratory endpoints included:
- Safety
- DMFS[g]
- PFS2[h]
- QoL

- Median follow-up was 24.4 months (range, 6.2-44.9)[i]
- Geographical regions: Europe (38%), United States and Canada (32%), Asia (13%), rest of the world (16%)

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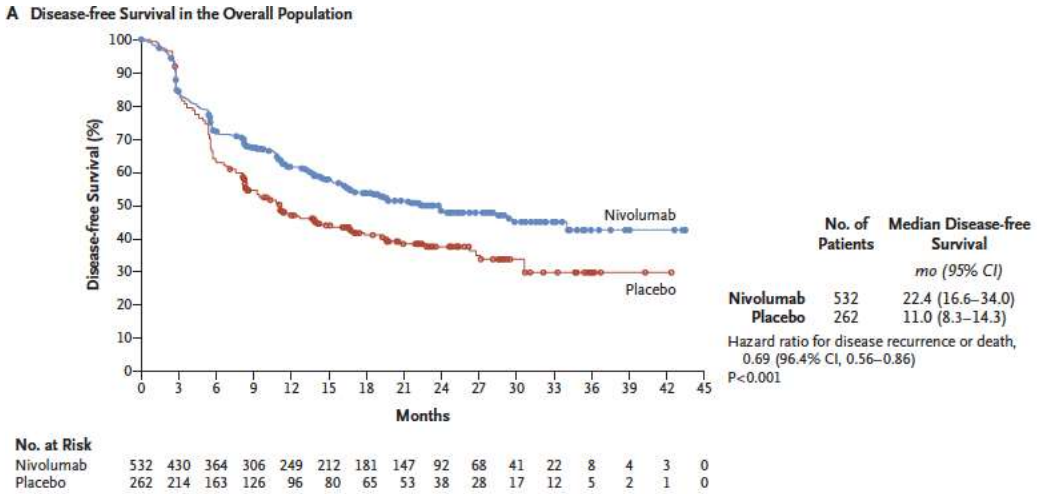
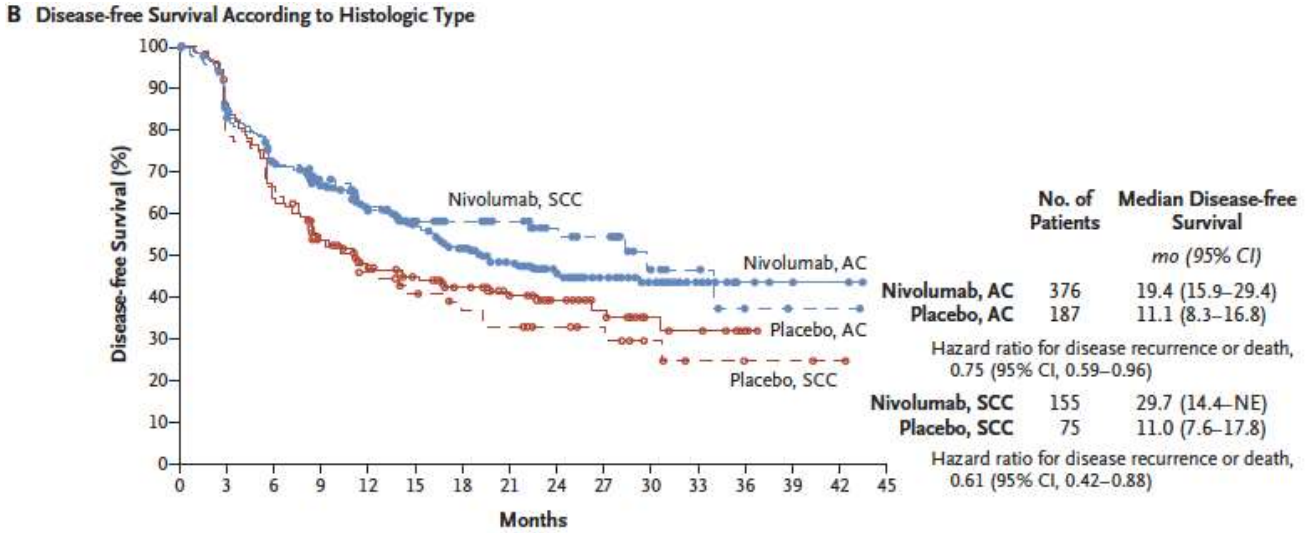
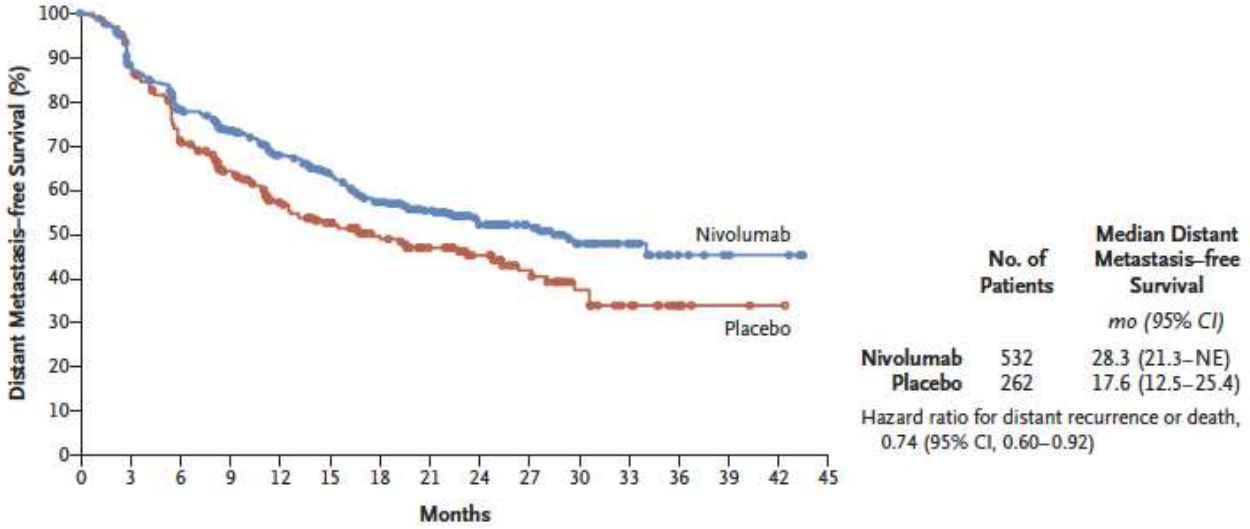
Karcinom jícnu / GEJ







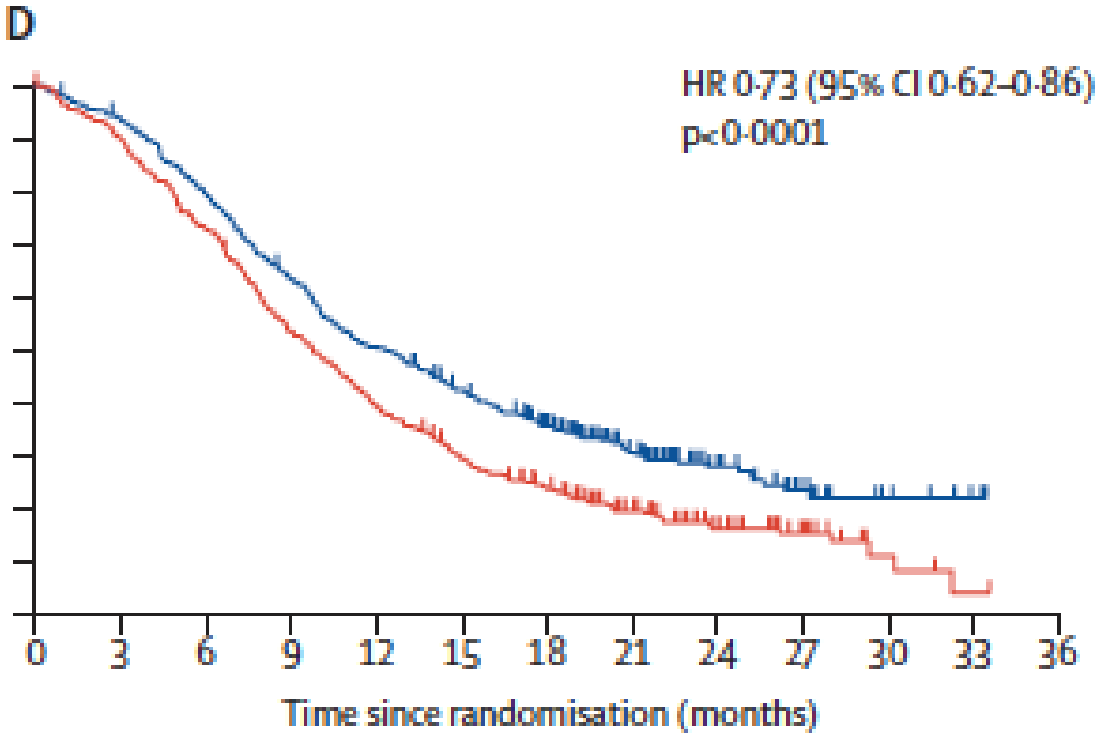
Karcinom jícnu

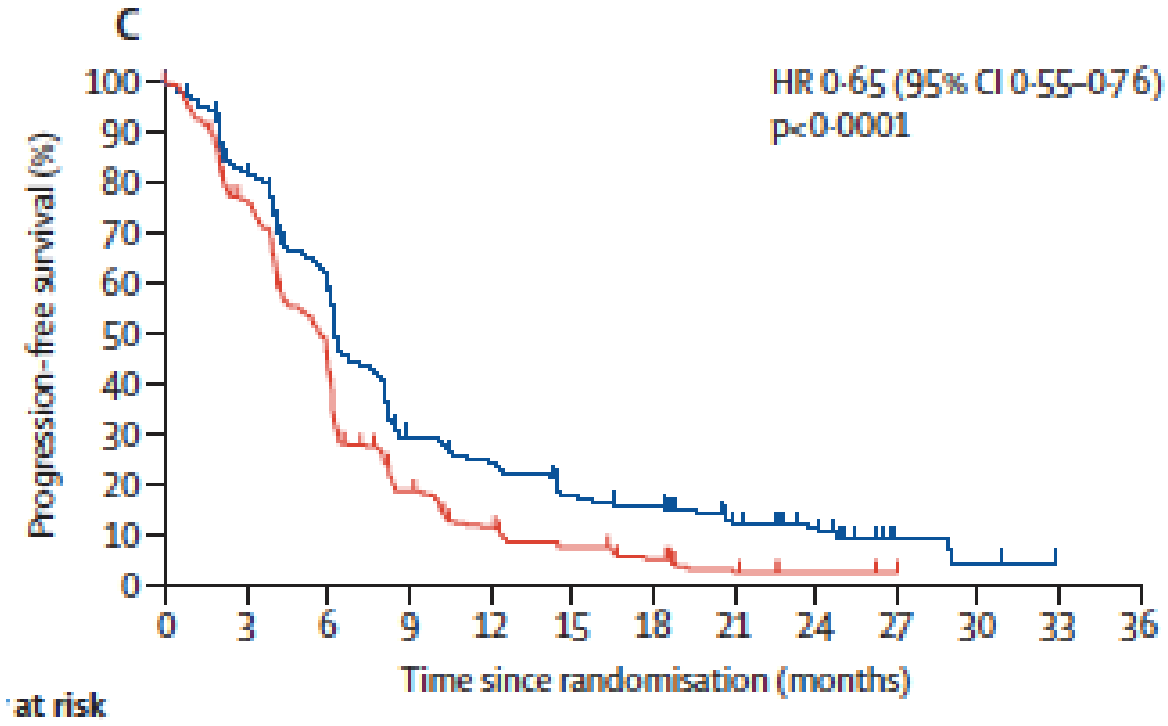
MOS All randomized patients

Pembro + CHT vs CHT

12,6 vs 9,8 pro SCC histologii

12,4 vs 9,8 pro all randomized pat





Karcinom žaludku

CheckMate 649 study design

- CheckMate 649 is a global, randomized, open-label, phase 3 study[a]

Key eligibility criteria
- Previously untreated, unresectable, advanced or metastatic gastric/GEJ/ esophageal adenocarcinoma
- No known HER2-positive status
- ECOG PS 0-1

Stratification factors
- Tumor cell PD-L1 expression (≥ 1% vs < 1%[b])
- Region (Asia vs United States/Canada vs ROW)
- ECOG PS (0 vs 1)
- Chemo (XELOX vs FOLFOX)

R 1:1:1[c]

n = 789 → **NIVO1 + IPI3** Q3W × 4 then NIVO 240 mg Q2W[d]

n = 792 → **NIVO 360 mg + XELOX[e] Q3W[d] or NIVO 240 mg + FOLFOX[f] Q2W[d]** / **XELOX[e] Q3W[d] or FOLFOX[f] Q2W[d]**

N = 1581, including 955 patients (60%) with PD-L1 CPS ≥ 5

Dual primary endpoints:
- **OS** and **PFS[g]** (PD-L1 CPS ≥ 5)

Secondary endpoints:
- **OS** (PD-L1 CPS ≥ 1, all randomized)
- **OS** (PD-L1 CPS ≥ 10)
- **PFS[g]** (PD-L1 CPS ≥ 10, ≥ 1, all randomized)
- **ORR[g]**

Exploratory endpoints:
- **Safety**
- **QoL** (TTSD, FACT-Ga GP5)

- At data cutoff (May 27, 2020), the minimum follow-up was 12.1 months[h]

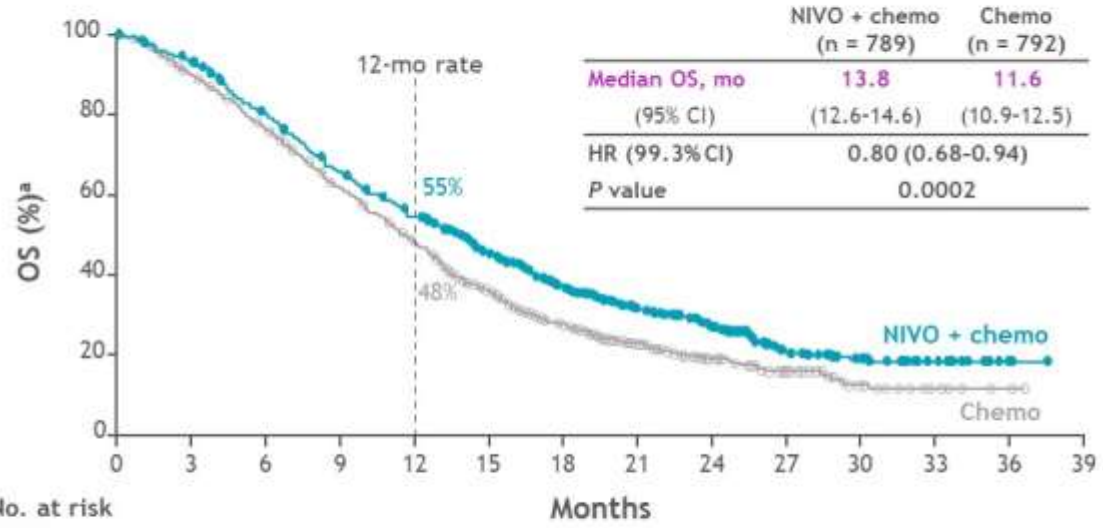
[a]ClinicalTrials.gov number. NCT02872116; [b]PD-L1 < 1% includes indeterminate tumor cell PD-L1 expression; determined by PD-L1 IHC 28-8 pharmDx assay (Dako); [c]After NIVO + chemo arm was added and before new patient enrollment in the NIVO1+IPI3 group was closed; [d]Until documented disease progression (unless consented to treatment beyond progression for NIVO + chemo), discontinuation due to toxicity, withdrawal of consent, or study end. NIVO is given for a maximum of 2 years; [e]Oxaliplatin 130 mg/m² IV (day 1) and capecitabine 1000 mg/m² orally twice daily (days 1-14); [f]Oxaliplatin 85 mg/m², leucovorin 400 mg/m², and FU 400 mg/m² IV (day 1) and FU 1200 mg/m² IV daily (days 1-2); [g]BICR assessed; [h]Time from concurrent randomization of the last patient to NIVO + chemo vs chemo to data cutoff.

Karcinom žaludku

CheckMate 649

Overall survival and progression-free survival in all randomized patients

Overall survival

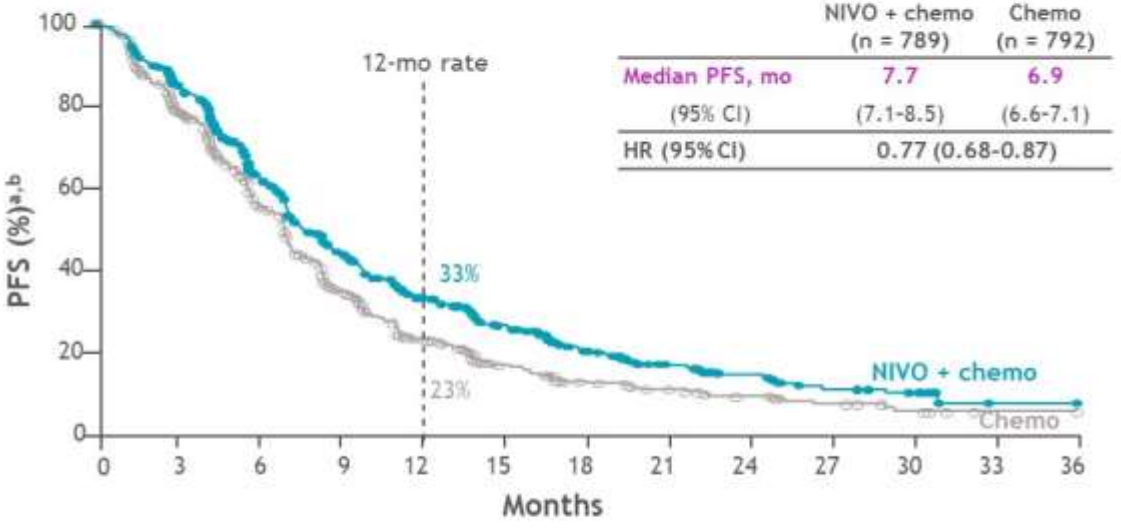


	NIVO + chemo (n = 789)	Chemo (n = 792)
Median OS, mo	13.8	11.6
(95% CI)	(12.6-14.6)	(10.9-12.5)
HR (99.3% CI)	0.80 (0.68-0.94)	
P value	0.0002	

No. at risk

NIVO + chemo	789	731	621	506	420	308	226	147	100	49	34	14	2	0
Chemo	792	697	586	469	359	239	160	94	59	35	15	7	2	0

Progression-free survival



	NIVO + chemo (n = 789)	Chemo (n = 792)
Median PFS, mo	7.7	6.9
(95% CI)	(7.1-8.5)	(6.6-7.1)
HR (95% CI)	0.77 (0.68-0.87)	

789	639	429	287	197	136	83	51	31	15	11	1	0
792	544	351	202	120	65	38	28	18	12	6	1	0

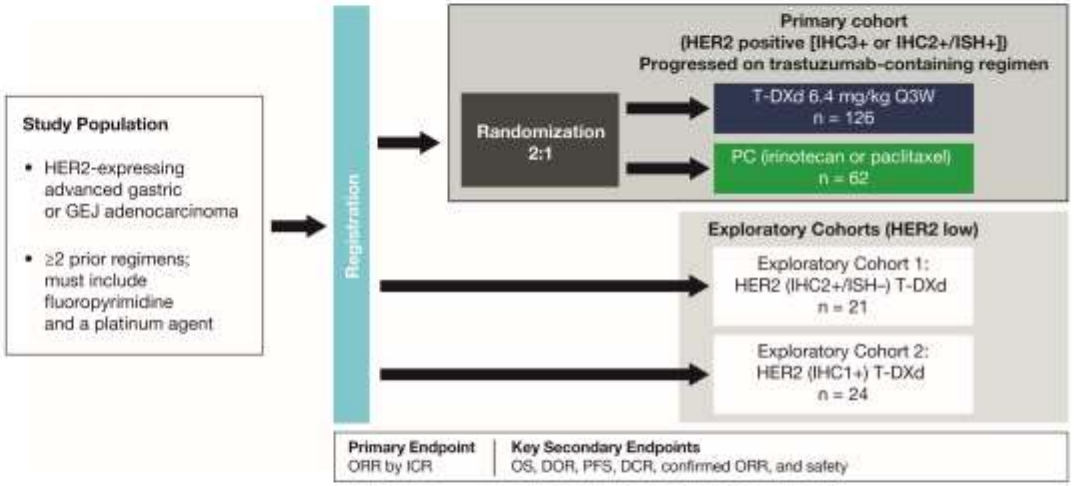
- Superior OS benefit and clinically meaningful PFS improvement in all randomized patients with NIVO + chemo vs chemo
- Median OS with NIVO + chemo vs chemo in patients with PD-L1 CPS ≥ 5 was 14.4 vs 11.1 months and median PFS was 7.7 vs 6.0 months[1]

Karcinom žaludku a GEJ

Background and Study Design

- T-DXd is an antibody–drug conjugate comprising an anti-HER2 antibody, a cleavable tetrapeptide-based linker, and a topoisomerase I inhibitor payload (DXd)[1] approved in the United States and Japan for adult patients with advanced HER2+ gastric or GEJ adenocarcinoma[2,3]
- In the primary DESTINY-Gastric01 analysis, T-DXd exhibited statistically significant ORR and OS benefit vs standard chemotherapy
- Here, we present final OS results as well as updated efficacy and safety data
- Patients had a median of 2 prior lines of therapy (range, 2-9); 44.4% of patients had ≥3 previous lines
- As of June 3, 2020, 10 patients (8%) receiving T-DXd and no patients receiving PC remained on treatment

DESTINY-Gastric01 Study Design



Key secondary endpoint of OS was to be statistically evaluated hierarchically if the primary endpoint was statistically significant

DCR, disease control rate; DOR, duration of response; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; ICR, independent central review; IHC, immunohistochemistry; ISH, in situ hybridization; ORR, objective response rate; OS, overall survival; PC, physician's choice; PFS, progression-free survival; Q3W, every three weeks; T-DXd, trastuzumab deruxtecan.

1. Shitara K et al. Trastuzumab deruxtecan in previously treated HER2-positive gastric cancer. *N Engl J Med*. 2020;382:2419-2430. 2. Enhertu. Prescribing information. Daiichi Sankyo Inc.; 01/2021. 3. Enhertu. Summary of product characteristics. Daiichi Sankyo Co. LTD.; 2020.

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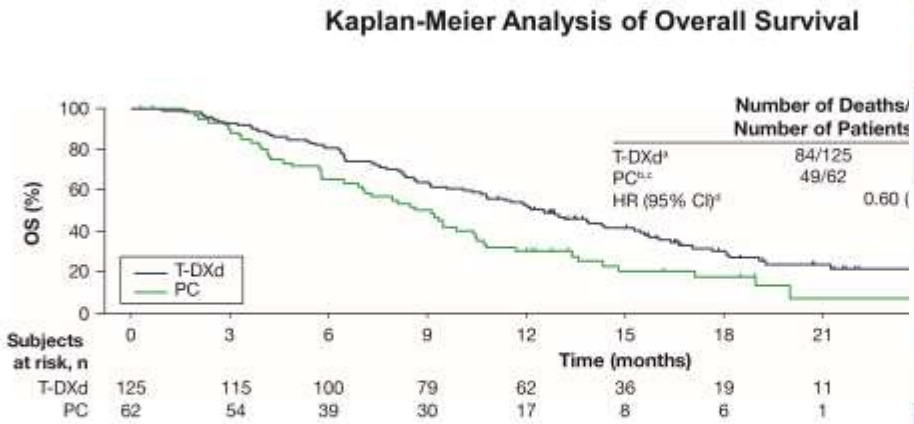
Karcinom žaludku a GEJ

Results: Overall Survival



As in the primary analysis (101 OS events; 54.0% maturity), in this updated analysis (13
T-DXd showed superior antitumor activity compared to PC

HR, hazard ratio; OS, overall survival; PC, physician's choice; T-DXd, trastuzumab deruxtecan.

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	T-DXd n = 119	PC Overall n = 56
ORR (CR + PR) by ICR, n (%)[a]	61 (51.3) 95% CI, 41.9-60.5	8 (14.3) 95% CI, 6.4-26.2
	$P < 0.0001$[b]	
CR	11 (9.2)	0
PR	50 (42.0)	8 (14.3)
SD	42 (35.3)	27 (48.2)
PD	14 (11.8)	17 (30.4)
Not evaluable	2 (1.7)	4 (7.1)
Confirmed ORR (CR + PR) by ICR, n (%)[a]	50 (42.0) 95% CI, 33.0-51.4	7 (12.5) 95% CI, 5.2-24.1
CR	10 (8.4)	0
PR	40 (33.6)	7 (12.5)
SD	52 (43.7)	28 (50.0)
PD	14 (11.8)	17 (30.4)
Not evaluable	3 (2.5)	4 (7.1)
Confirmed DCR (CR + PR + SD), n (%)[a]	102 (85.7) 95% CI, 78.1-91.5	35 (62.5) 95% CI, 48.5-75.1
Confirmed DOR, median, months	12.5 95% CI, 5.6-NE	3.9 95% CI, 3.0-4.9
PFS, median, months	5.6 95% CI, 4.3-6.9	3.5 95% CI, 2.0-4.3
	$P = 0.0003$[c]	
TTR, median, months	1.5 95% CI, 1.4-1.7	1.6 95% CI, 1.3-1.7

complete response; DCR, disease control rate; DOR, duration of response; ICR, independent central review; NE, not estim
onse; SD, stable disease; T-DXd, trastuzumab deruxtecan; TTR, time to response. [a]Includes data for the response-evaluat
een T-DXd and PC overall using Cochran-Mantel-Haenszel test stratified by region. [c]Comparison between T-DXd and PC

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Karcinom vaječníků

Trial design
AGO-OVAR 17 BOOST / GINECO OV118 / ENGOT Ov-15

- Histologically confirmed epithelial ovarian, fallopian tube, or peritoneal cancer (excluding non-epithelial and borderline tumors)
- FIGO stage IIB–IV (any grade/ histologic subtype)
- Primary debulking surgery ≤8 weeks before treatment start, >4 weeks before first BEV dose
- Adequate coagulation parameters, bone marrow, liver, and renal function
- ECOG PS 0–2
- Standard BEV exclusion criteria

n= 927 Nov 2011 – Aug 2013

R 1:1

BEV 15 mg/kg q3 weeks for 22 cycles (15 months)

Paclitaxel 175 mg/m²

Carboplatin AUC5 q3 weeks

BEV15 (standard arm)

BEV 15 mg/kg q3 weeks for 44 cycles (30 months)

Paclitaxel 175 mg/m²

Carboplatin AUC5 q3 weeks

BEV30 (experimental arm)

Stratification factors

FIGO IIB–IIIC and no residual tumor

versus

FIGO IIB–IIIC with residual tumor *or* FIGO IV

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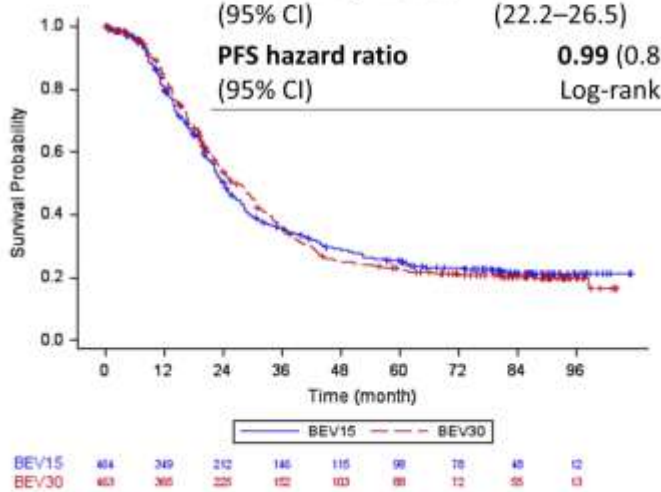
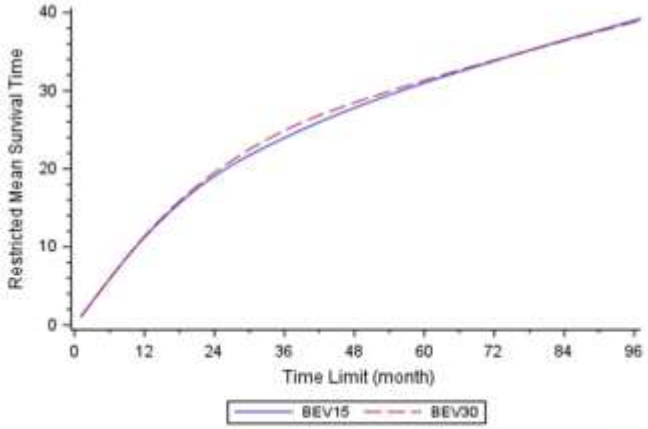
Karcinom vaječníků

Primary endpoint: PFS

	BEV15 n=464	BEV30 n=463
PFS events, n (%)	333 (72)	340 (73)
Median PFS, months (95% CI)	**24.2** (22.2–26.5)	**26.0** (23.7–29.7)
PFS hazard ratio (95% CI)	**0.99** (0.85–1.15) Log-rank p=0.90	



	BEV15 n=464	BEV30 n=463
Restricted mean PFS, months (95% CI)*	**39.5** (36.3–42.7)	**39.3** (36.2–42.4)
* Restricted at last event time	p=0.92	



Presented By: **Jacobus Pfisterer,** AGO Study Group & Gynecologic Oncology Center, Kiel, Germany on behalf of AGO Study Group, GINECO and NSGO

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2021 ASCO ANNUAL MEETING

Roche provides update on Tecentriq US indication for PD-L1-positive, metastatic triple-negative breast cancer

Basel, 27 August 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the company has made the decision to voluntarily withdraw the US accelerated approval for Tecentriq® (atezolizumab) in combination with chemotherapy (Abraxane®, albumin-bound paclitaxel; nab-paclitaxel) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) whose tumours express PD-L1, ….