ESMO® 2021
Sekce karcinomu prsu

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MOÚ
Brno

Vybrané studie

- GIM4
- BRIGHTNES
- MONALEESA 2
- Destiny-Breast03

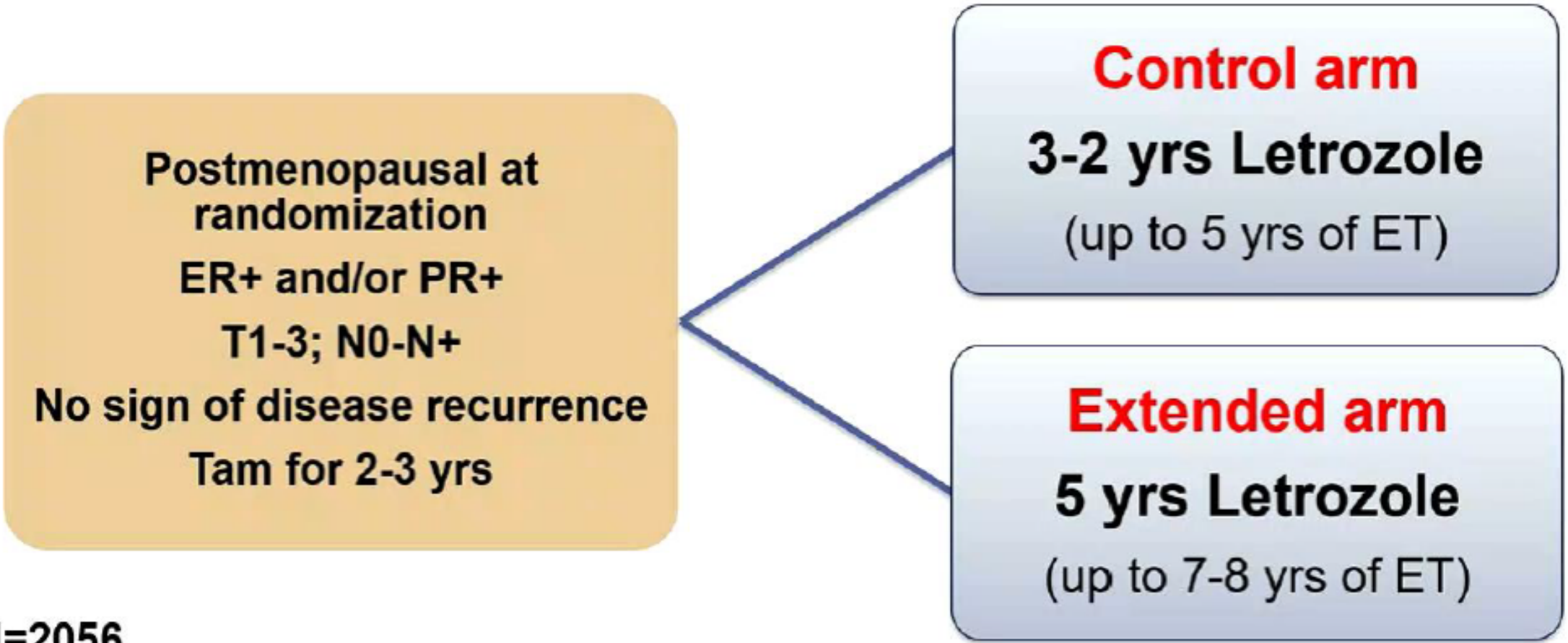
Extended therapy with letrozole as adjuvant treatment of postmenopausal patients with early-stage breast cancer: a randomised, phase 3 trial of the Gruppo Italiano Mammella.

Del Mastro L, Mansutti B, Bisagni G, Ponzone R, Durando A, Amaducci L, Cognetti F, Frassoldati A, Michelotti M, Mura S, Urracci Y, Sanna G, Gori S, De Placido S, Garrone O, Barone C, Bighin C, Poggio F, Lambertini M, Bruzzi P on behalf of GIM investigators

Cíl GIM studie

- Porovnat prodlouženou adjuvanci letrozolem po dobu 5 let oproti standardnímu trvání 2–3 roky u postmenopauzálních pacientek, které již byly léčené 2–3 roky adjuvantní léčbou tamoxifenem

GIM4 study design

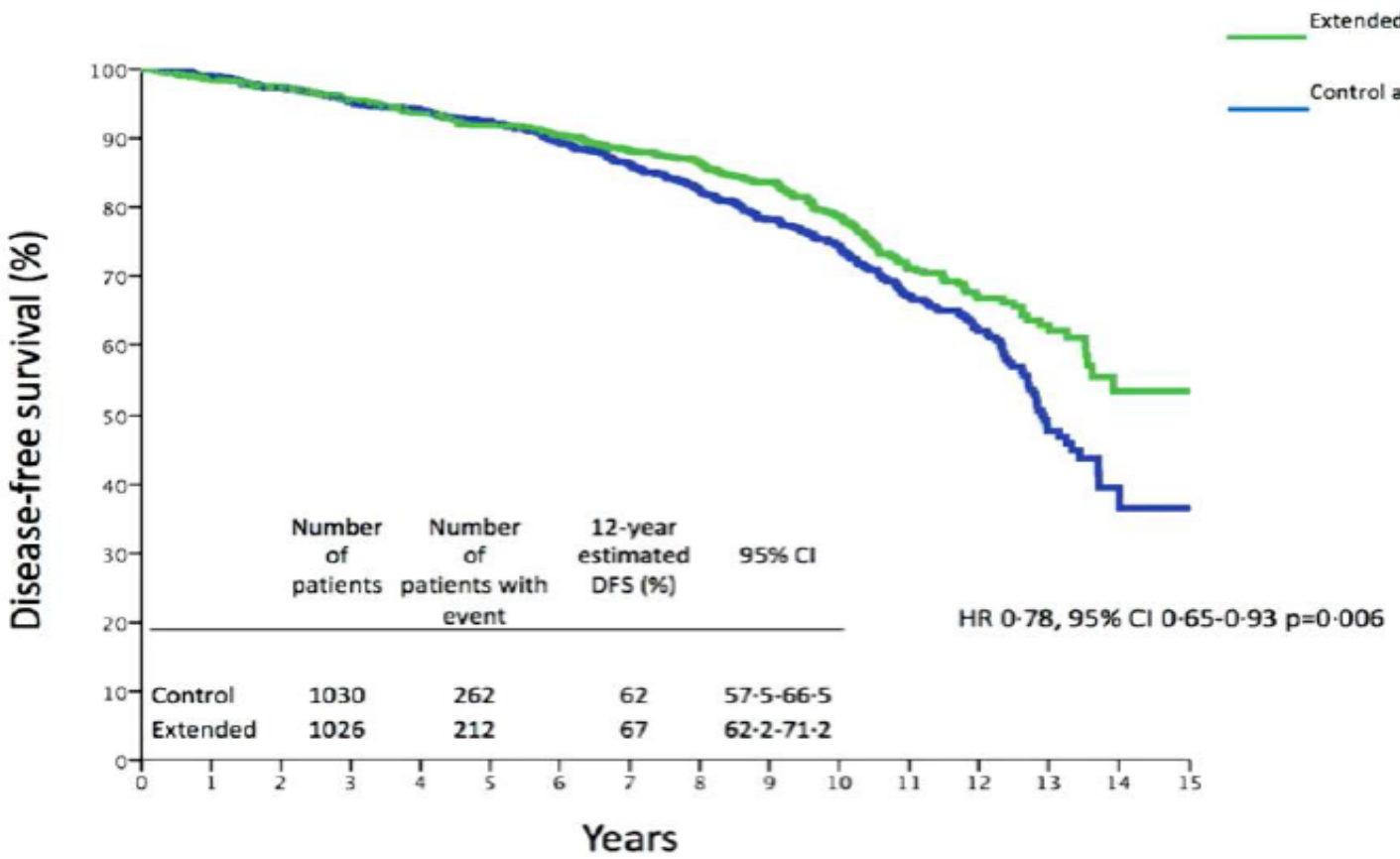


N=2056
Recruitment in 69 centres in Italy (GIM group), 2005-2010
Median follow-up: 11·7 years (IQR 9·5–13·1)

Charakteristika pacientek

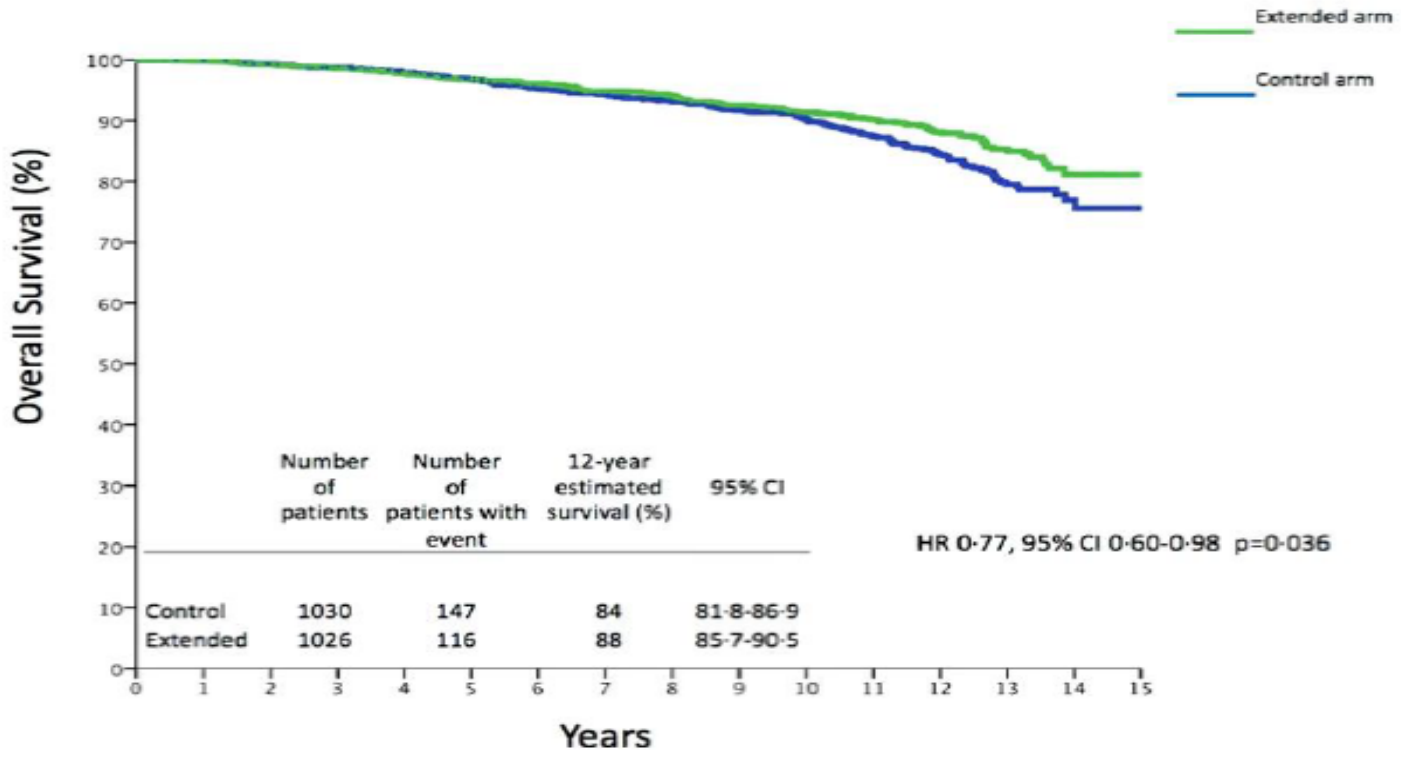
Characteristic		Control arm 2-3 year letrozole (n=1030)	Extended arm 5-year letrozole (n=1026)
Age, median (IQR)		60 (54-67)	61 (54-68)
Tumor size	pT1	704 (68%)	703 (68%)
	pT2	261 (25%)	252 (25%)
	pT3-4	34 (3%)	43 (4%)
	Unknown	31 (3%)	28 (3%)
Nodal status	pN0	581 (56%)	568 (55%)
	pN1-2-3	411 (40%)	428 (42%)
	Unknown	38 (4%)	30 (3%)
Histological grade	G1	156 (15%)	161 (16%)
	G2	564 (55%)	589 (57%)
	G3	221 (21%)	213 (21%)
	Unknown	89 (9%)	63 (6%)
HR status	ER+ and PR+	855 (83%)	866 (84%)
	ER+ or PR+	153 (15%)	146 (14%)
	Uknown	22 (2%)	14 (1%)
HER2 status	Positive	63 (6%)	60 (6%)
	Negative	851 (83%)	833 (81%)
	Unknown	116 (11%)	133 (13%)
Prior (neo)adjuvant CT	No	455 (44%)	450 (44%)
	Yes	557 (54%)	565 (55%)
	unknown	18 (2%)	11 (1%)
Prior duration of tamoxifen, years Median (IQR)		2.4 (1.9-3.3)	2.5 (1.9-3.3)

DFS v mediánu sledování 11,7 roku



Number at risk (censored)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Control 1030 (0)	999 (20)	966 (37)	919 (64)	878 (94)	816 (140)	746 (185)	636 (270)	515 (365)	394 (462)	310 (529)	217 (595)	139 (659)	64 (711)	13 (756)	0 (767)
Extended 1026 (0)	991 (20)	963 (37)	917 (64)	875 (89)	815 (133)	742 (194)	648 (270)	538 (369)	441 (449)	341 (525)	218 (620)	150 (677)	75 (746)	18 (990)	1 (1024)

Celkové přežití v mediánu sledování 11,7 roku

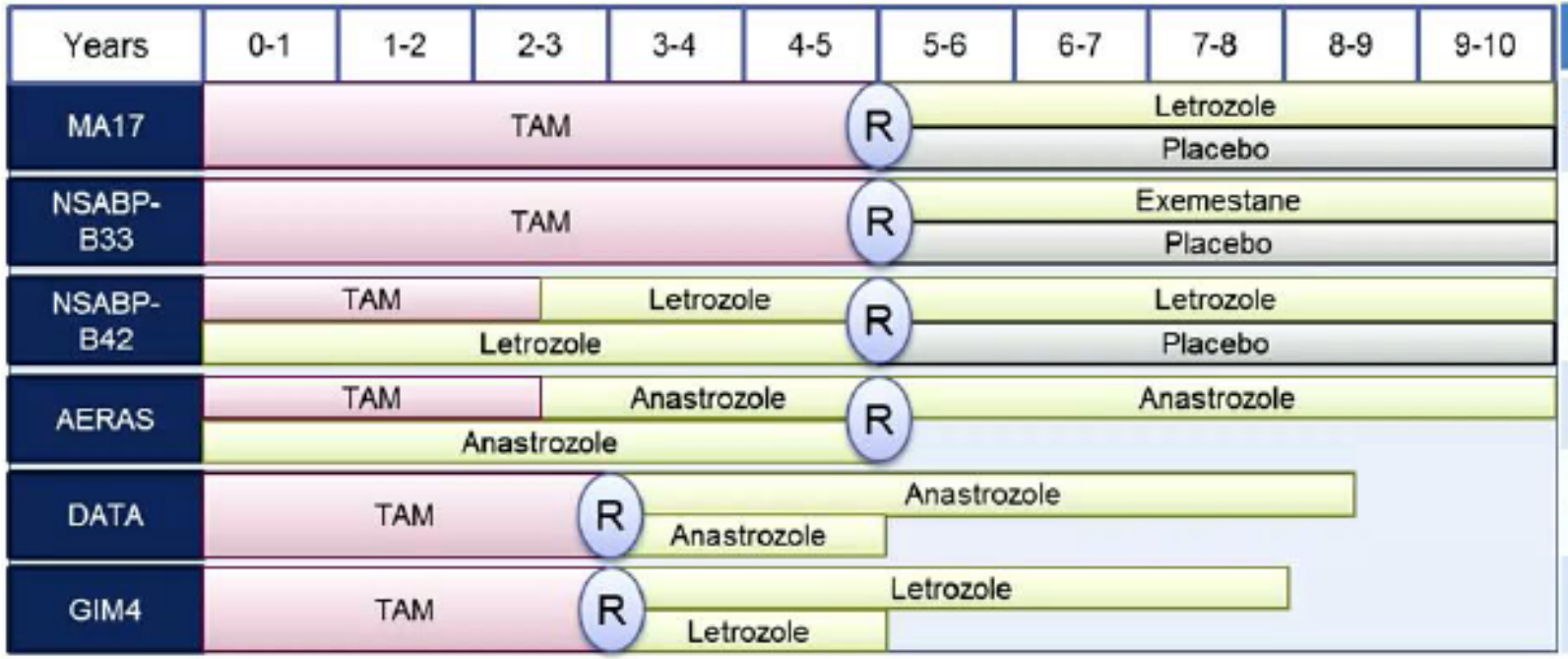


Number at risk (censored)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Control	1030 (0)	1021 (8)	1006 (17)	991 (26)	968 (40)	933 (65)	895 (89)	863 (111)	810 (154)	738 (213)	656 (285)	533 (388)	389 (252)	211 (677)	61 (823)	2 (881)
Extended	1026 (0)	1019 (6)	1006 (12)	988 (23)	965 (38)	941 (52)	916 (70)	868 (107)	823 (146)	755 (200)	682 (264)	568 (370)	416 (511)	231 (686)	60 (850)	3 (907)

Tolerance léčby

	Control arm 2-3 year letrozole (n=968)	Extended arm 5-year letrozole (n=926)
Treatment completed	779 (80%)	582 (63%)
Duration of letrozole, years	2.4 (1.9-2.8)	5.0 (2.5-5.0)
Early treatment discontinuation	189 (19%)	344 (37%)
Toxicity	*87 (9%)*	*133 (14%)*
Patient refusal	*37 (4%)*	*96 (10%)*
Other	*65 (7%)*	*115 (12%)*

Benefit studie GIM 4 v kontextu jiných studií



DFS HR	N Patients (N+)	Benefit in OS?	Median FU (years)
0.58 (0.45 - 0.76) P < .001	5187 (45%)	No (overall) Yes (N+)	2.5
0.68 p=0.07	1598 (48%)	No	2.5
0.84 (0.74-0.96) p=0.011	3966 (43%)	No	9.3
0.548 P=0.0004	1683 (21%)	No	5
0.79 (0.62-1.02) p=0.066	1860 (66-68%)	No	7.2
0.77 (0.65-.93) p=0.006	2056 (44%)	Yes	11.4

- Benefit in subgroups from retrospective analyses and meta-analyses
- No strong recommendation of extended AI in main breast cancer guidelines

Závěr autorů

- Adjuvantní léčba letrozolem, prodloužená na 5 let

u postmenopauzálních pacientek , které již byly léčené 2–3 roky tamoxifenem, signifikantně prodloužila DFS (HR 0,78,95%;

CI 0,65–0,93;p = 0,0064) a OS (HR 0,77; 95% CI 0,65–0,98; p = 0,036)

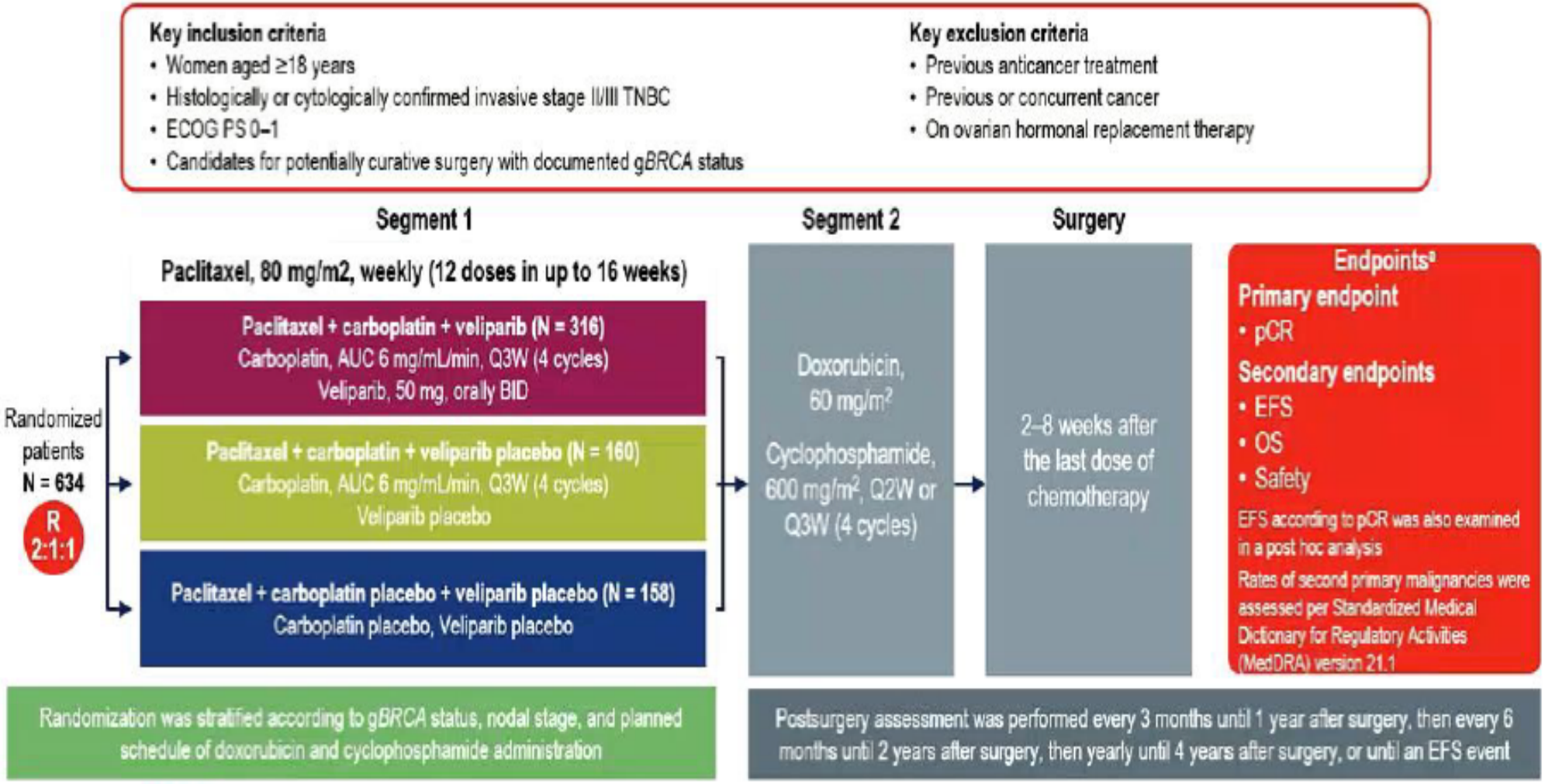
a měla by se stát standardem léčby

EVENT-FREE SURVIVAL, OVERALL SURVIVAL, AND SAFETY OF ADDING VELIPARIB PLUS CARBOPLATIN OR CARBOPLATIN ALONE TO NEOADJUVANT CHEMOTHERAPY IN TRIPLE-NEGATIVE BREAST CANCER AFTER ≥4 YEARS OF FOLLOW-UP: BRIGHTNESS, A RANDOMIZED PHASE 3 TRIAL

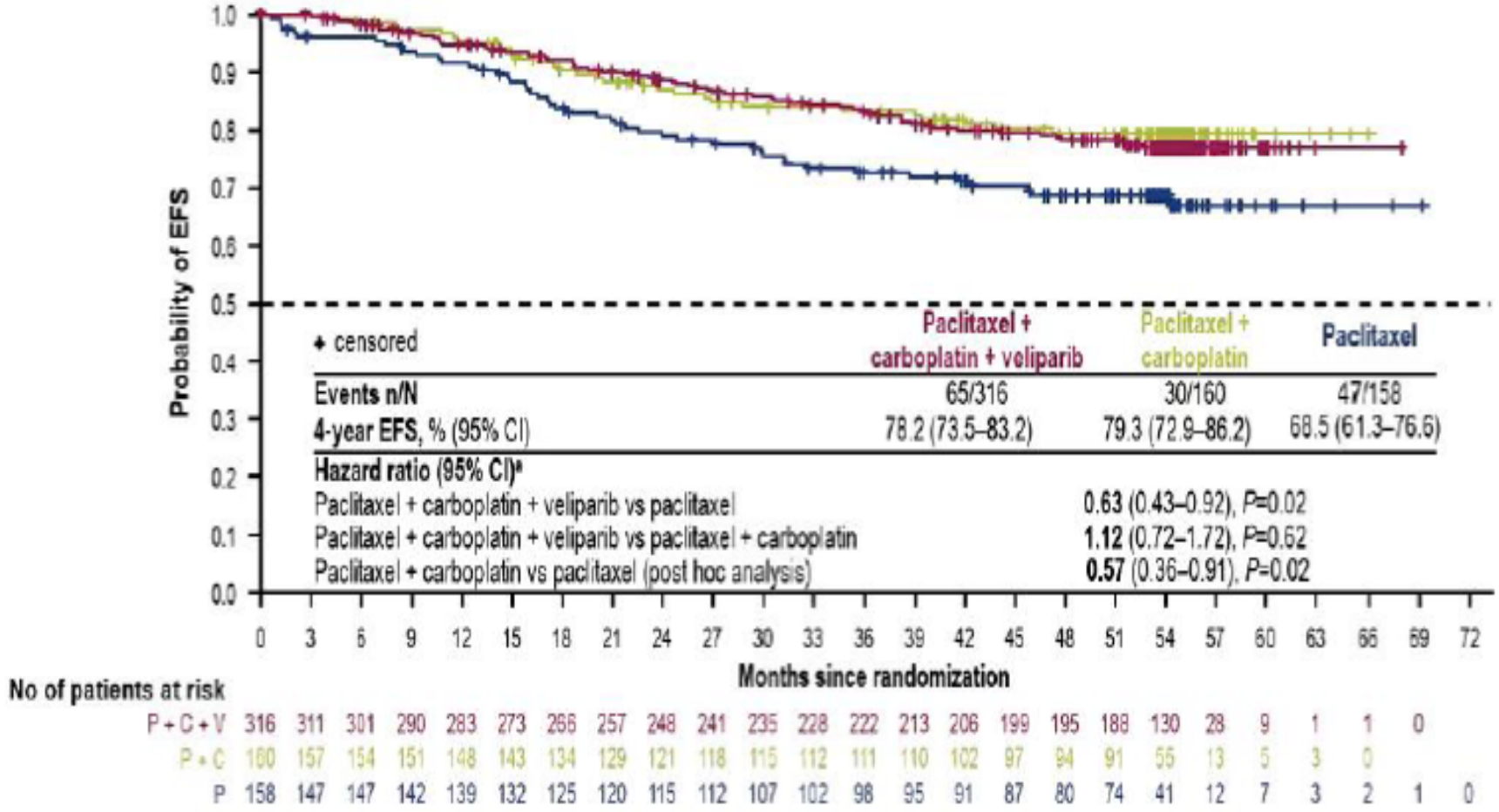
Sibylle Loibl[1,2], William M. Sikov[3], Jens Huober[4], Hope S. Rugo[5], Norman Wolmark[6,7], Joyce O'Shaughnessy[8,9], David Maag[10], Michael Untch[11], Mehra Golshan[12], Jose Ponce Lorenzo[13], Otto Metzger[14], Martin Dunbar[10], W. Fraser Symmans[15], Charles E Geyer Jr[6,16]

[1]German Breast Group, c/o GBG Forschugns GmbH, Neu-Isenburg, Germany; [2]Centre for Hematology and Oncology Bethanien, Frankfurt, Germany; [3]Women & Infants Hospital of Rhode Island, Providence, RI, USA; [4]Breast Center Cantonal Hospital St Gallen, St Gallen, Switzerland; [5]University of California San Francisco Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA; [6]National Surgical Adjuvant Breast and Bowel Project Foundation, Pittsburgh, PA, USA; [7]University of Pittsburgh, Pittsburgh, PA, USA; [8]Texas Oncology, US Oncology, Dallas, TX, USA; [9]Baylor University Medical Center, Dallas, TX, USA; [10]AbbVie Inc., North Chicago, IL, USA; [11]HELIOS Klinikum Berlin-Buch, Berlin, Germany; [12]Yale Cancer Center, Yale School of Medicine, New Haven, CT, USA; [13]University General Hospital of Alicante, ISABIAL, Alicante, Spain; [14]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [15]MD Anderson Cancer Center, Houston, Texas, USA; [16]Houston Methodist Cancer Center, Houston, TX, USA

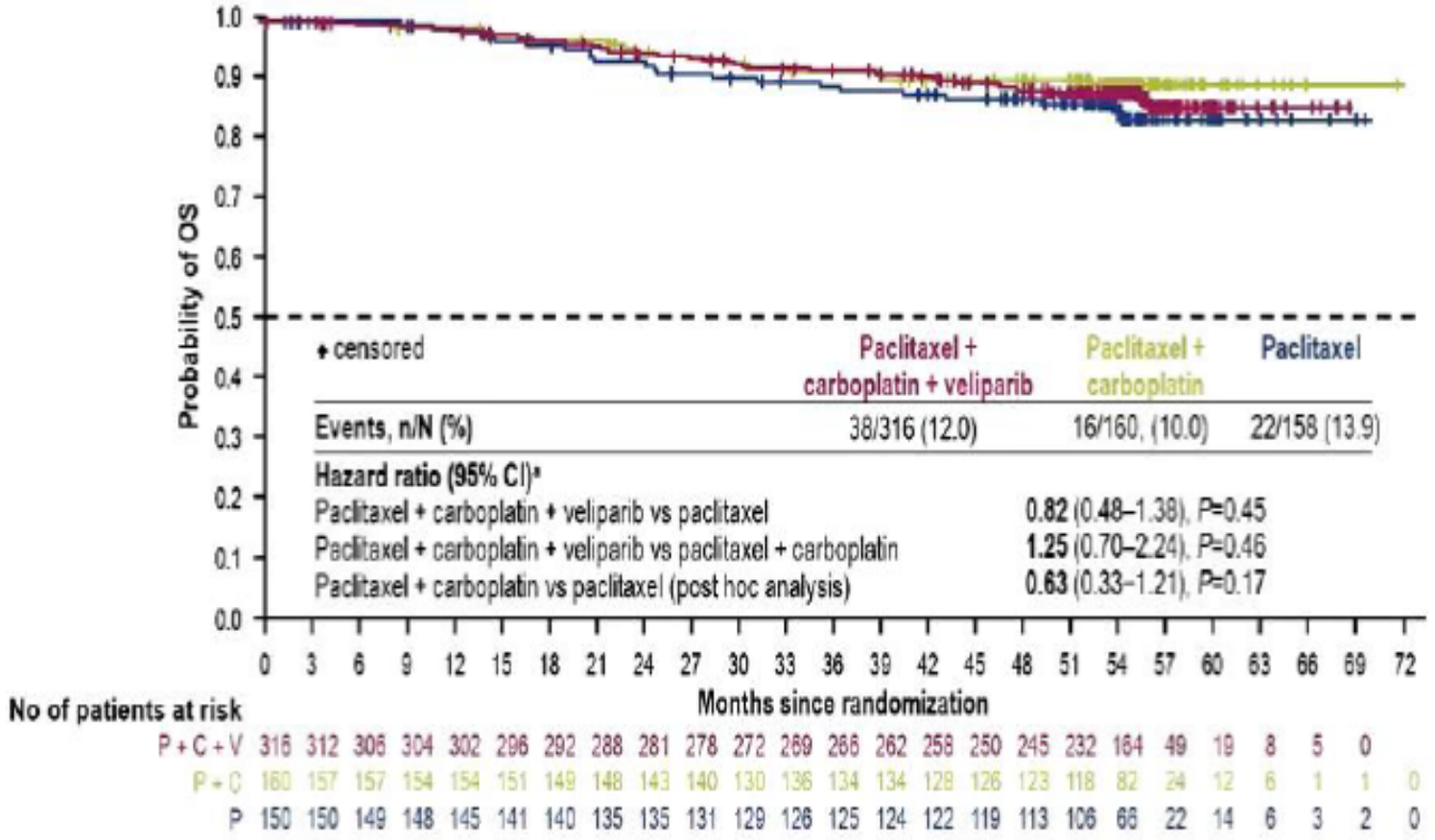
Design studie



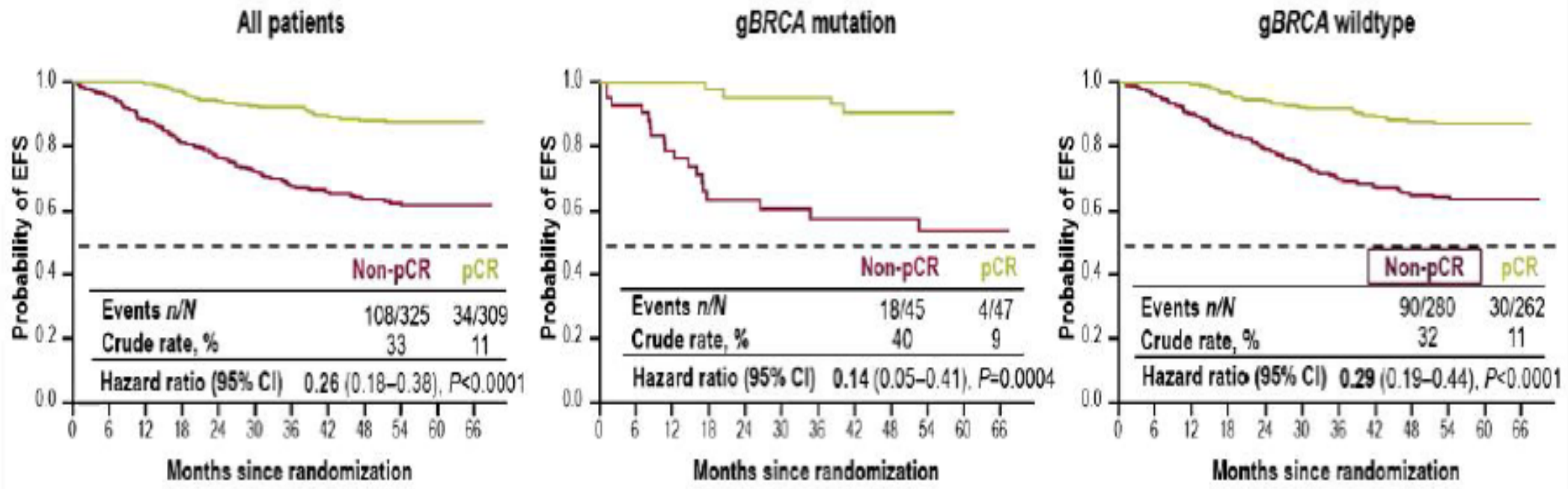
Event-free survival v mediánu sledování 4,5 roku



OS v mediánu sledování 4,5 roku



EFS podle pCR ve všech skupinách pacientek a podle přítomnosti germinální mutace *BRCA*



Patients with pCR had improved EFS compared to those without pCR (HR 0.26, 95% CI 0.18–0.38; P<0.0001), regardless of *BRCA* mutation status

Závěr studie

- Přidání CBDCA k paklitaxelu s následnou léčbou doxorubicinem a cyklofosfamidem signifikantně zlepšilo pCR v mediánu sledování 4,5 roku
- Přidání veliparibu nemělo vliv na dosažení pCR
- Pacientky s pCR měly signifikantně lepší EFS, a to nezávisle na přítomnosti germinální mutace *BRCA* genu u pacientek
- Výskyt MDS, AML a jiných sekundárních malignit byl stejný v rameni s i bez CBDCA
- Výsledky studie podporují přidání CBDCA do NACHT u pacientek s TNBC stadia II–III

2021 ESMO congress

Trastuzumab Deruxtecan (T-DXd) vs Trastuzumab Emtansine (T-DM1) in Patients With HER2+ Metastatic Breast Cancer: Results of the Randomized, Phase 3 Study DESTINY-Breast03

Javier Cortés, MD[a], Sung-Bae Kim, Wei-Pang Chung, Seock-Ah Im, Yeon Hee Park, Roberto Hegg, Min-Hwan Kim, Ling-Ming Tseng, Vanessa Petry, Chi-Feng Chung, Hiroji Iwata, Erika Hamilton, Giuseppe Curigliano, Binghe Xu, Caleb Lee, Yali Liu, Jillian Cathcart, Emarjola Bako, Sunil Verma, Sara Hurvitz
On behalf of the DESTINY-Breast03 investigators

[a]Medical Oncology, International Breast Cancer Center (IBCC), Quironsalud Group, and Vall d'Hebron Institute of Oncology (VHIO), Barcelona, Spain; Universidad Europea de Madrid, Faculty of Biomedical and Health Sciences, Department of Medicine, Madrid, Spain.

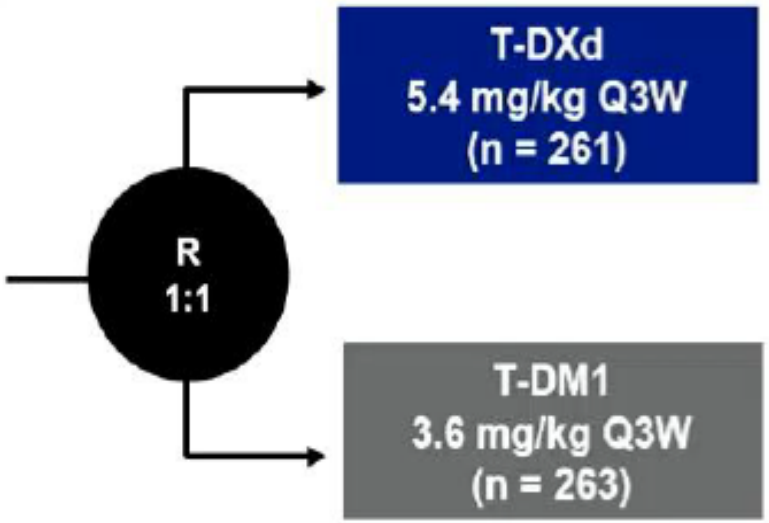
DESTINY-Breast03, první randomizovaná studie fáze III s T-DXd

Patients

- Unresectable or metastatic HER2-positive[a] breast cancer
- Previously treated with trastuzumab and taxane in advanced/metastatic setting[b]
- Could have clinically stable, treated brain metastases

Stratification factors

- Hormone receptor status
- Prior treatment with pertuzumab
- History of visceral disease



Primary endpoint

- PFS (BICR)

Key secondary endpoint

- OS

Secondary endpoints

- ORR (BICR and investigator)
- DOR (BICR)
- PFS (investigator)
- Safety

Interim analysis for PFS (data cutoff: May 21, 2021)

- Efficacy boundary for superiority: $P < 0.000204$ (based on 245 events)
- IDMC recommendation to unblind study (July 30, 2021)

Key secondary endpoint, OS: boundary for efficacy: $P < 0.000265$ (based on 86 events)

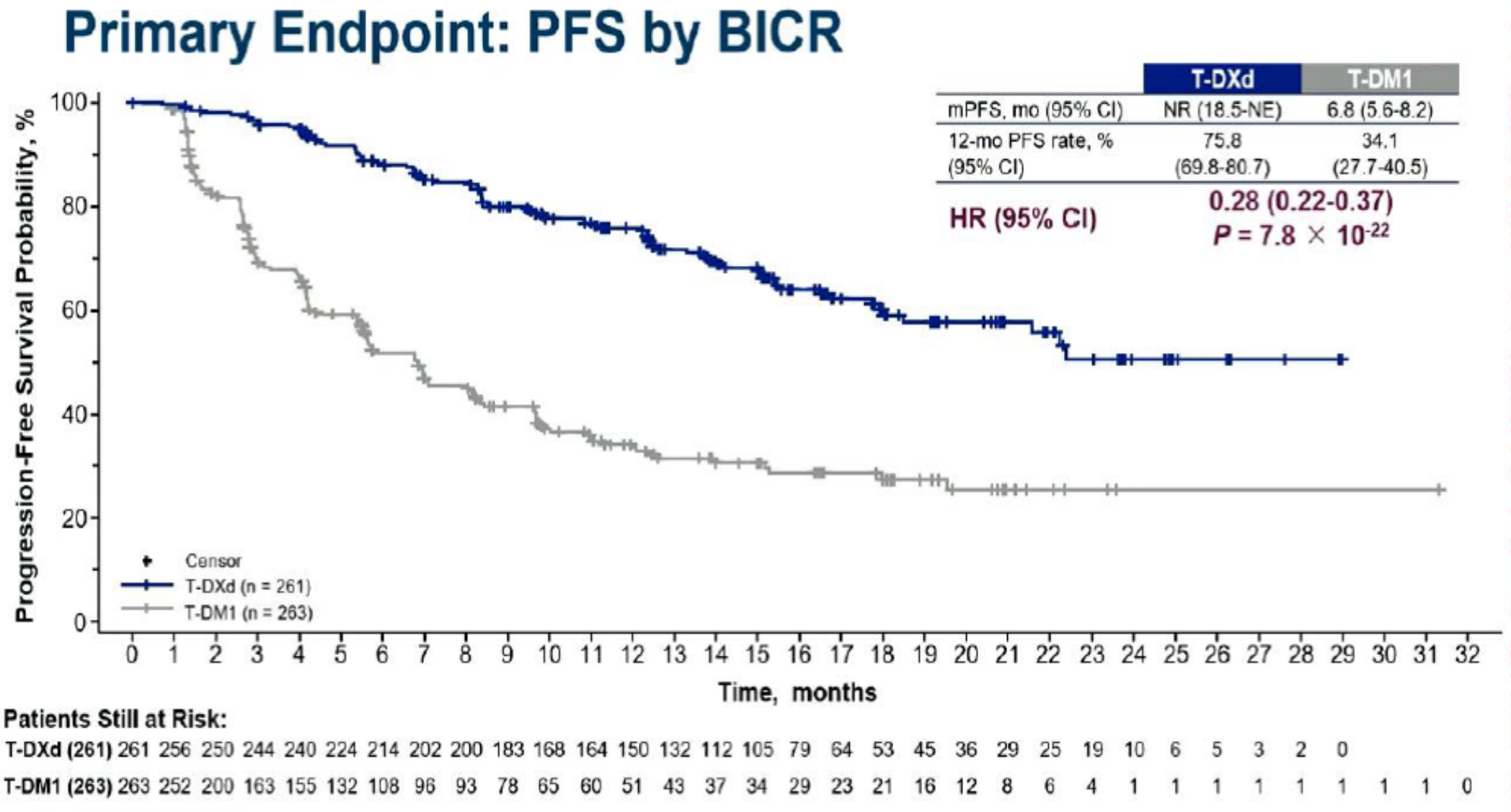
Charakteristika souboru

	T-DXd (n = 261)	T-DM1 (n = 263)
Age, median (range), years	54.3 (27.9-83.1)	54.2 (20.2-83.0)
Female, %	99.6	99.6
Region, %		
Europe	20.7	19.0
Asia	57.1	60.8
North America	6.5	6.5
Rest of world	15.7	13.7
HER2 status (IHC[a], %)		
3+	89.7	88.2
2+ (ISH amplified)	9.6	11.4
1+ | Not Evaluable | Not Examined	0.4 | 0.4 | 0	0 | 0.4 | 0
ECOG PS, %		
0 | 1 | Missing	59.0 | 40.6 | 0.4	66.5 | 33.1 | 0.4
Hormone receptor, %		
Positive | Negative	50.2 | 49.8	51.0 | 49.0
Brain metastases, %		
Yes | No	23.8 | 76.2	19.8 | 80.2
Visceral disease, %		
Yes | No	70.5 | 29.5	70.3 | 29.7

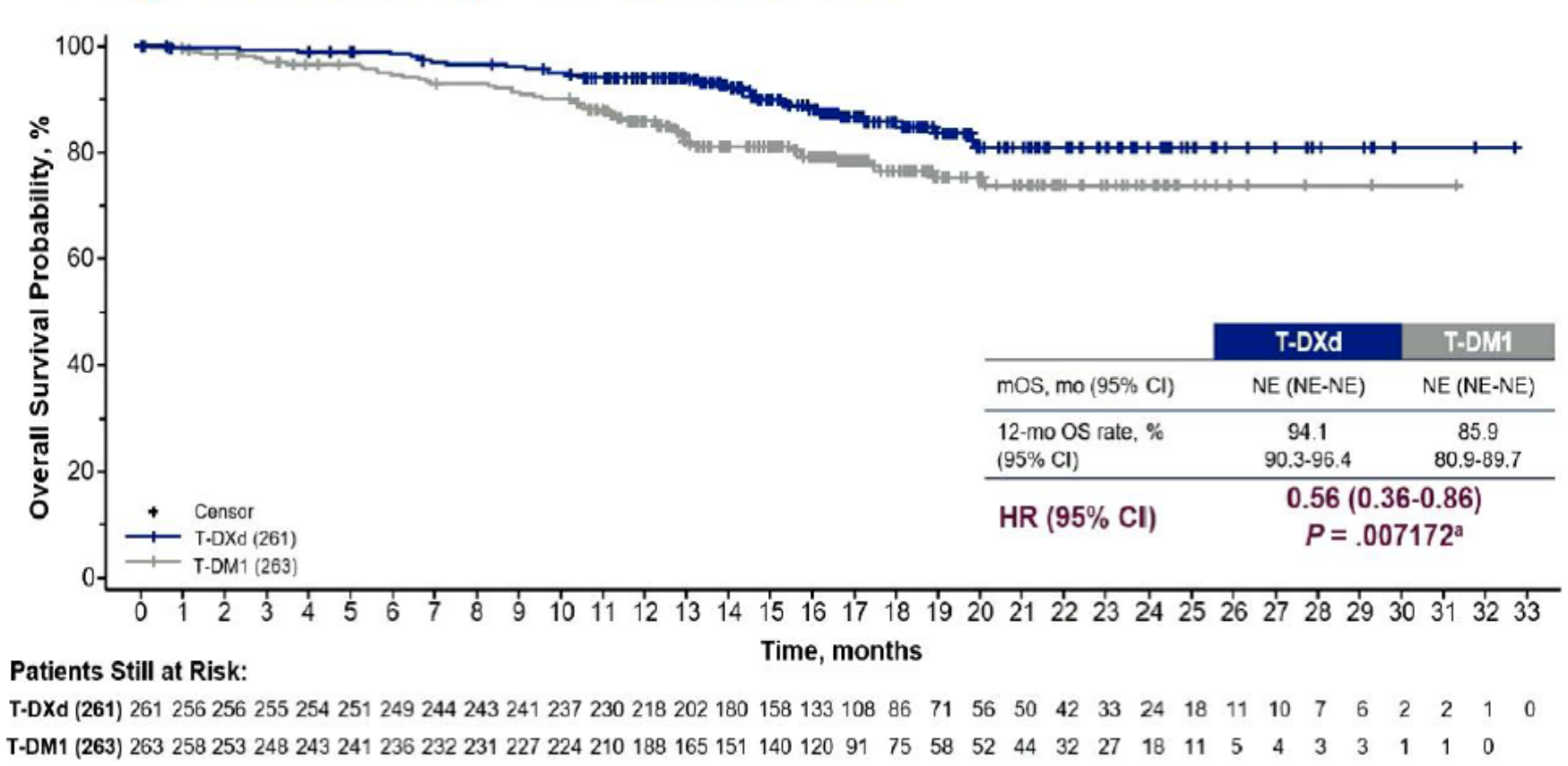
Předchozí léčba

	T-DXd (n = 261)	T-DM1 (n = 263)
Prior Treatment for mBC, n (%)		
No	21 (8.0)	29 (11.0)
Yes	240 (92.0)	234 (89.0)
Prior lines of therapy in the metastatic setting (includes rapid progressors as one line of treatment)[a], n (%)		
0	2 (0.8)	3 (1.1)
1	130 (49.8)	123 (46.8)
2	56 (21.5)	65 (24.7)
3	35 (13.4)	35 (13.3)
4	15 (5.7)	19 (7.2)
≥5	23 (8.8)	18 (6.8)
Prior cancer therapy[b], %		
Trastuzumab	99.6	99.6
Pertuzumab	62.1	60.1
Other anti-HER2		
Anti-HER2 TKI	16.1	13.7
Other anti-HER2 antibody or ADC	0.8	1.1

Primární cíl studie - přežití bez progrese onemocnění (PFS)



Hlavní sekundární cíl studie: celkové přežití (OS)

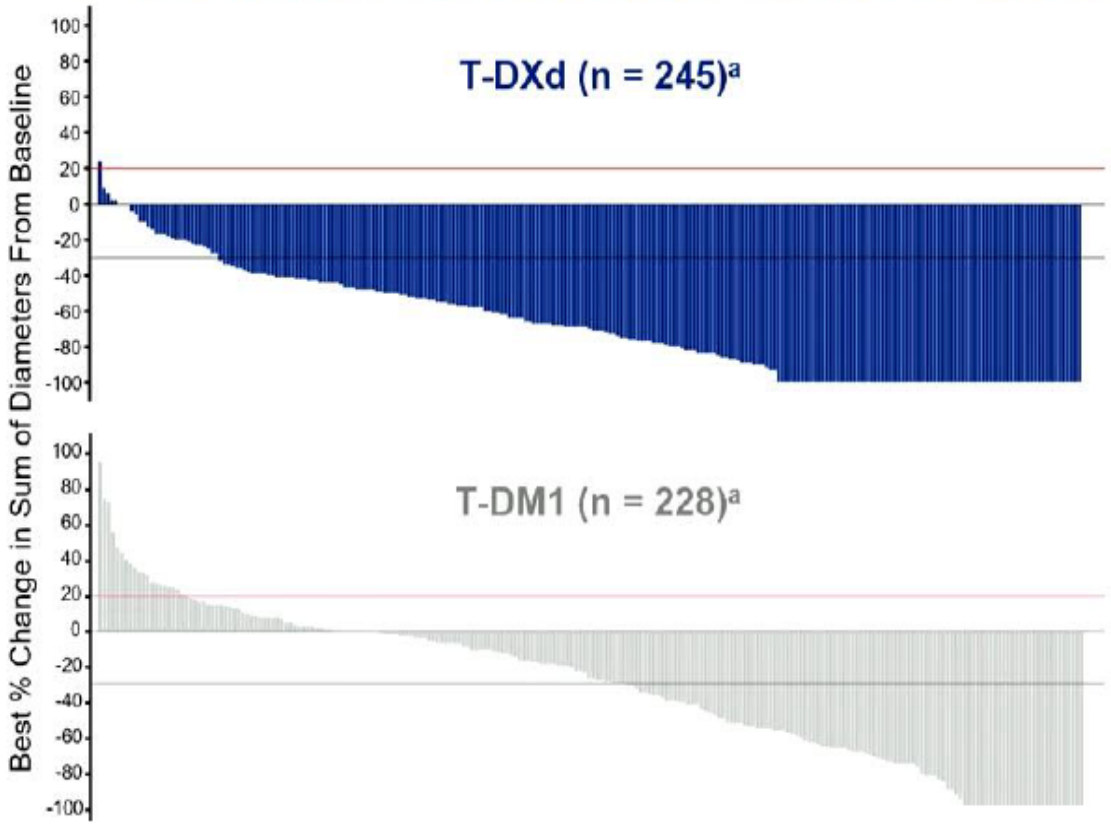


	T-DXd	T-DM1
mOS, mo (95% CI)	NE (NE-NE)	NE (NE-NE)
12-mo OS rate, % (95% CI)	94.1 90.3-96.4	85.9 80.9-89.7
HR (95% CI)	0.56 (0.36-0.86) *P* = .007172[a]	

Early OS data with relatively few events (33 in the T-DXd arm, 53 in the T-DM1 arm)

[a]*P* = .007172, but does not cross pre-specified boundary of *P* < .000265

Nejlepší léčebná odpověď

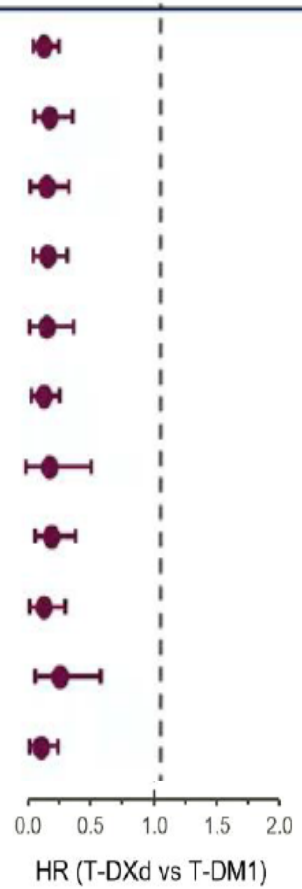


	T-DXd (n = 261)	T-DM1 (n = 263)
Confirmed ORR		
n (%)[b]	208 **(79.7)**	90 **(34.2)**
[95% CI]	[74.3-84.4]	[28.5-40.3]
	P < .0001	
CR	42 **(16.1)**	23 **(8.7)**
PR	166 **(63.6)**	67 **(25.5)**
SD	44 (16.9)	112 (42.6)
PD	3 (1.1)	46 (17.5)
Not evaluable	6 (2.3)	15 (5.7)
CR + PR + SD (DCR)	252 (96.6)	202 (76.8)

CR, complete response; DCR, disease control rate; PD, progressive disease; PR, partial response; SD, stable disease.
[a]Only subjects with measurable disease at baseline and at least one postbaseline target lesion assessment are included. [b]Based on BICR.
Red line at 20% indicates progressive disease; black line at -30% indicates partial response.

PFS – analýza podskupin

		Number of Events		Median PFS (mo, 95% CI)		HR (95% CI)
		T-DXd	T-DM1	T-DXd	T-DM1	
All patients		87/261	158/263	NE (18.5-NE)	6.8 (5.6-8.2)	0.2840 (0.2165-0.3727)
Hormone Receptor Status	Positive (n = 272)	46/133	84/139	22.4 (17.7-NE)	6.9 (4.2-9.8)	0.3191 (0.2217-0.4594)
	Negative (n = 248)	41/126	73/122	NE (18.0-NE)	6.8 (5.4-8.3)	0.2965 (0.2008-0.4378)
Prior Pertuzumab Treatment	Yes (n = 320)	57/162	98/158	NE (18.5-NE)	6.8 (5.4-8.3)	0.3050 (0.2185-0.4257)
	No (n = 204)	30/99	60/105	NE (16.5-NE)	7.0 (4.2-9.7)	0.2999 (0.1924-0.4675)
Visceral Disease	Yes (n = 384)	72/195	123/189	22.2 (16.5-NE)	5.7 (4.2-7.0)	0.2806 (0.2083-0.3779)
	No (n = 140)	15/66	35/74	NE (NE-NE)	11.3 (6.8-NE)	0.3157 (0.1718-0.5804)
Prior Lines of Therapy[a]	0-1 (n = 258)	46/132	75/126	22.4 (17.9-NE)	8.0 (5.7-9.7)	0.3302 (0.2275-0.4794)
	≥2 (n = 266)	41/129	83/137	NE (16.8-NE)	5.6 (4.2-7.1)	0.2828 (0.1933-0.4136)
Brain Metastases	Yes (n = 114)	31/62	31/52	15.0 (12.6-22.2)	5.7 (2.9-7.1)	0.3796 (0.2267-0.6357)
	No (n = 410)	56/199	127/211	NE (22.4-NE)	7.0 (5.5-9.7)	0.2665 (0.1939-0.3665)



Souhrn bezpečnosti léčby

n (%)	T-DXd (n = 257)	T-DM1 (n = 261)
Any drug-related TEAE	252 (98.1)	226 (86.6)
Drug-related TEAE Grade ≥3	116 (45.1)	104 (39.8)
Serious drug-related TEAE	28 (10.9)	16 (6.1)
Drug-related TEAE associated with discontinuation	33 (12.8)	13 (5.0)
Drug-related TEAE associated with dose reduction	55 (21.4)	33 (12.6)
Drug-related TEAE associated with an outcome of death	0 (0.0)	0 (0.0)

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ILD, interstitial lung disease; TEAE, treatment-related adverse event.
Relationship to study drug was determined by the treating investigator.
[a]Interstitial lung disease includes events that were adjudicated as ILD and related to use of T-DXd or T-DM1 (includes cases of potential ILD/pneumonitis, based on MedDRA v23.0 for the narrow ILD SMQ, selected terms from the broad ILD SMQ, and PTs of respiratory failure and acute respiratory failure). [b]This category includes the preferred terms platelet count decreased and thrombocytopenia. [c]This category includes the preferred terms neutrophil count decreased and neutropenia.

- Medián trvání léčby byl 14,3 měsíce (0,7–29,8) pro T-DXd a 6,9 měsíce (0,7–25,1) pro T-DM1
- Nejčastější nežádoucí účinek spojený s ukončením léčby (TEAE) byla ILD/pneumonitida (8,2 %) a pro T-DM1 trombocytopenie (2,7 %)
- Nejčastější důvod redukce T-DXd byla nauzea (6,2 %) a neutropenie (3,5 %) a pro T-DM1 trombocytopenie (4,2 %) a vzestup AST a ALT (2,7 %)

Nežádoucí účinky spojené s léčbou s frekvencí ≥ 20 % pacientů

System Organ Class Preferred term, n (%)	T-DXd (n = 257)		T-DM1 (n = 261)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Blood and lymphatic system disorders				
Neutropenia[a]	110 (42.8)	49 (19.1)	29 (11.1)	8 (3.1)
Anemia[b]	78 (30.4)	15 (5.8)	37 (14.2)	11 (4.2)
Leukopenia[c]	77 (30.0)	17 (6.6)	20 (7.7)	1 (0.4)
Thrombocytopenia[d]	64 (24.9)	18 (7.0)	135 (51.7)	65 (24.9)
Gastrointestinal disorders				
Nausea	187 (72.8)	17 (6.6)	72 (27.6)	1 (0.4)
Vomiting	113 (44.0)	4 (1.6)	15 (5.7)	1 (0.4)
Diarrhea	61 (23.7)	1 (0.4)	10 (3.8)	1 (0.4)
Constipation	58 (22.6)	0	25 (9.6)	0
General disorders				
Fatigue[e]	115 (44.7)	13 (5.1)	77 (29.5)	2 (0.8)
Investigations				
AST increased	60 (23.3)	2 (0.8)	97 (37.2)	13 (5.0)
ALT increased	50 (19.5)	4 (1.6)	71 (27.2)	12 (4.6)
Metabolism and nutrition disorders				
Decreased appetite	67 (26.1)	3 (1.2)	33 (12.6)	0
Skin and subcutaneous tissue disorders				
Alopecia[f]	93 (36.2)	1 (0.4)	6 (2.3)	0

Most drug-related TEAEs were gastrointestinal or hematological in nature

Vybrané nežádoucí účinky

Adjudicated as drug-related ILD/pneumonitis[a], n (%)						
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade
T-DXd (n = 257)	7 (2.7)	18 (7.0)	2 (0.8)	0	0	27 (10.5)
T-DM1 (n = 261)	4 (1.5)	1 (0.4)	0	0	0	5 (1.9)

- There were no grade 4 or 5 adjudicated drug-related ILD/pneumonitis events observed with T-DXd

LVEF decrease, n (%)						
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade
T-DXd (n = 257)	1 (0.4)[b]	6 (2.3)[c]	0	0	0	7 (2.7)
T-DM1 (n = 261)	0	1 (0.4)[c]	0	0	0	1 (0.4)

- In the T-DXd arm, all reported adverse events of LVEF decrease were asymptomatic and no cases of cardiac failure occurred

Závěr autorů

- Prezentované výsledky jsou podkladem, aby se

T-DXd stal standardem 2. linie léčby metastatického HER2 pozitivního karcinomu prsu

Overall Survival Results From the Phase III MONALEESA-2 Trial of Postmenopausal Patients With HR+/HER2– Advanced Breast Cancer Treated With Endocrine Therapy ± Ribociclib

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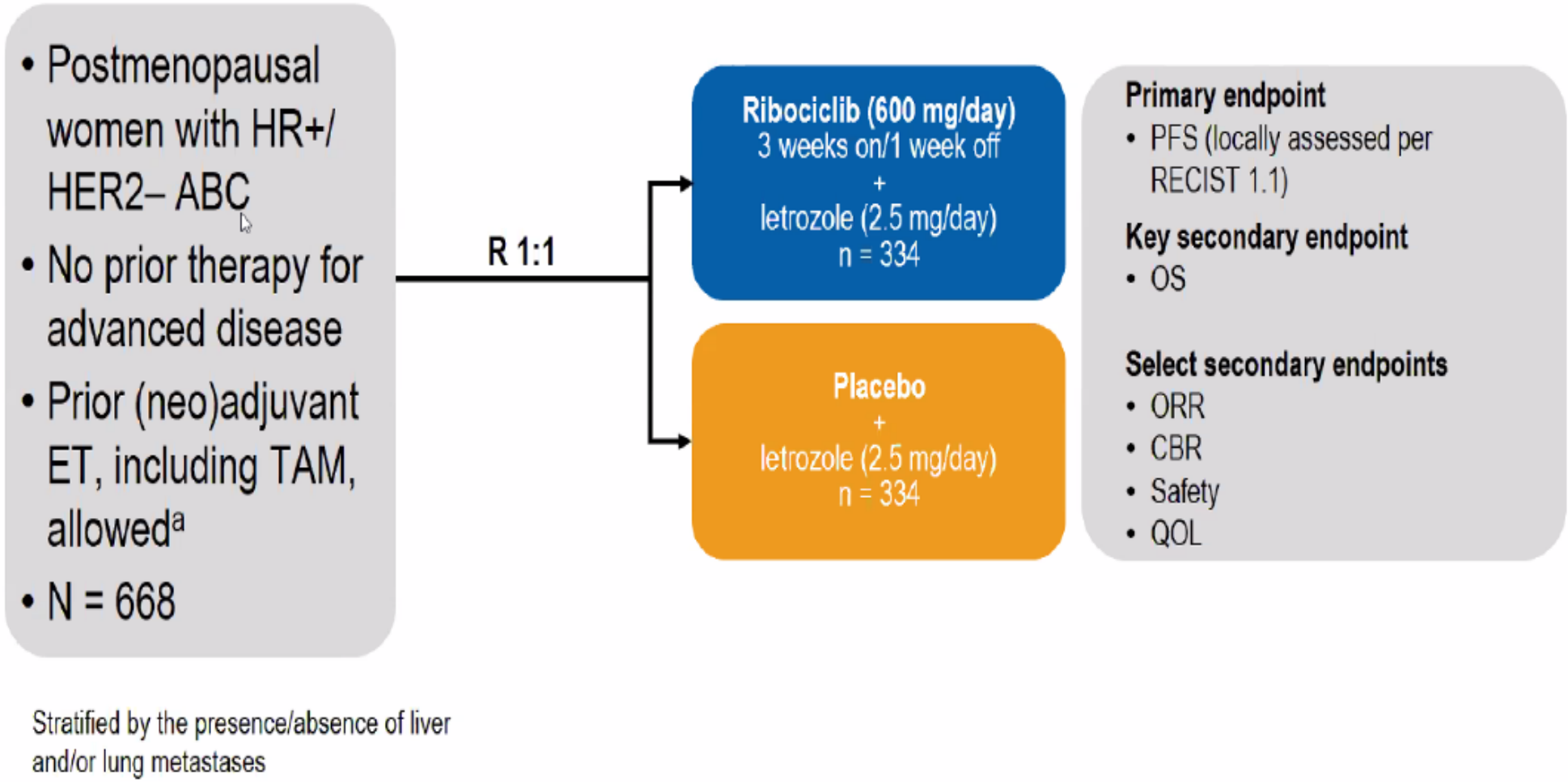
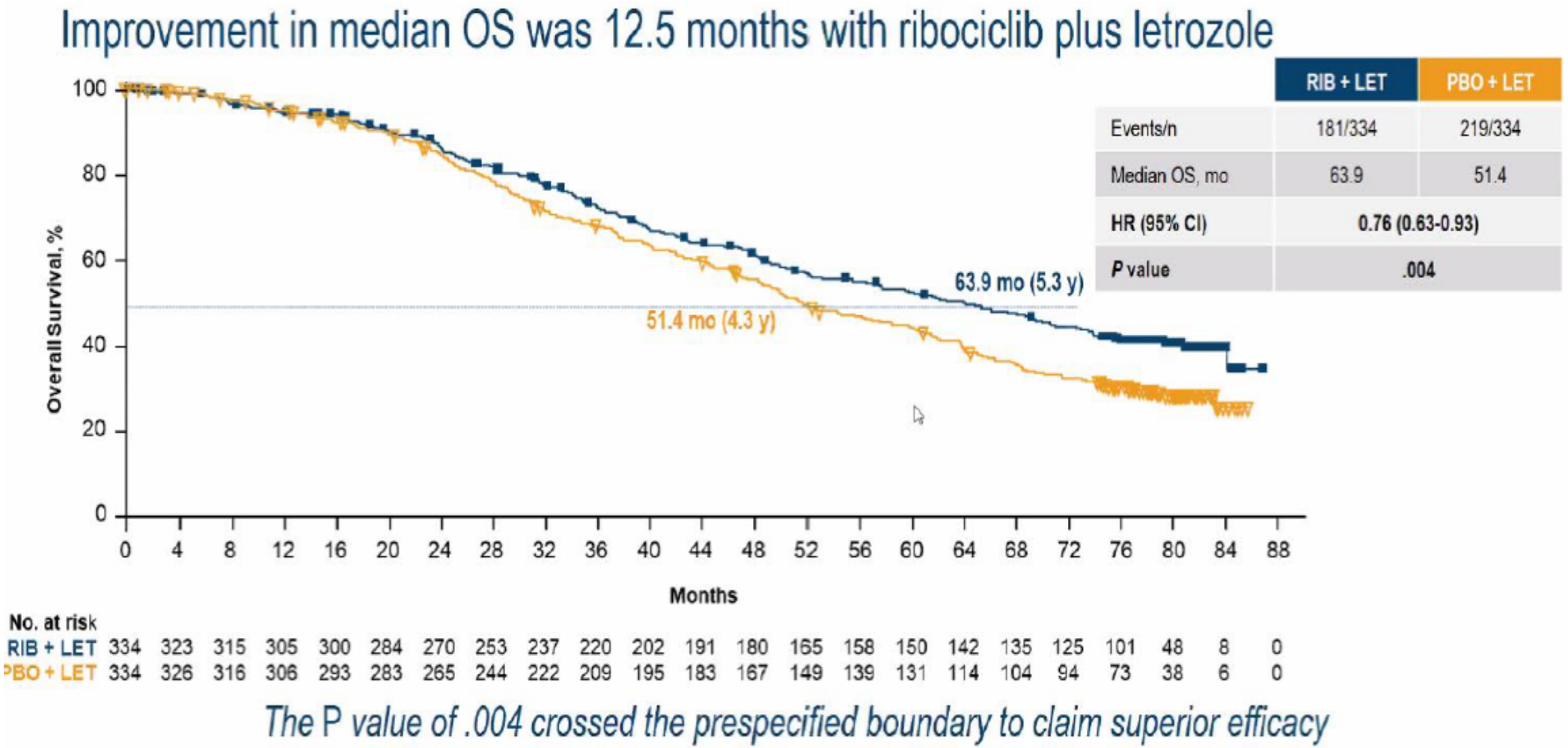
MONALEESA-2 design studie



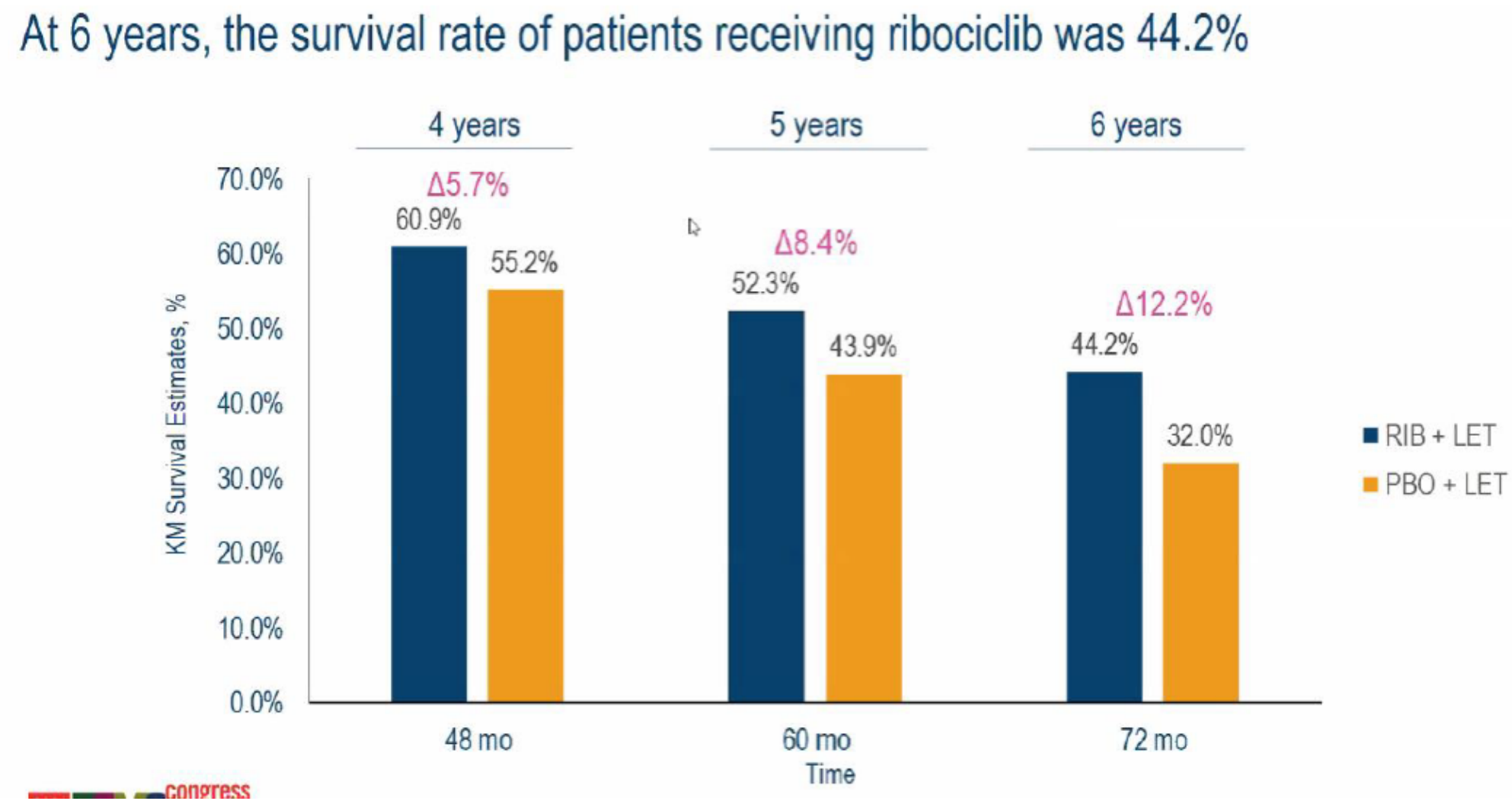
Ribociklib dosáhl statisticky signifikantní rozdíl v OS



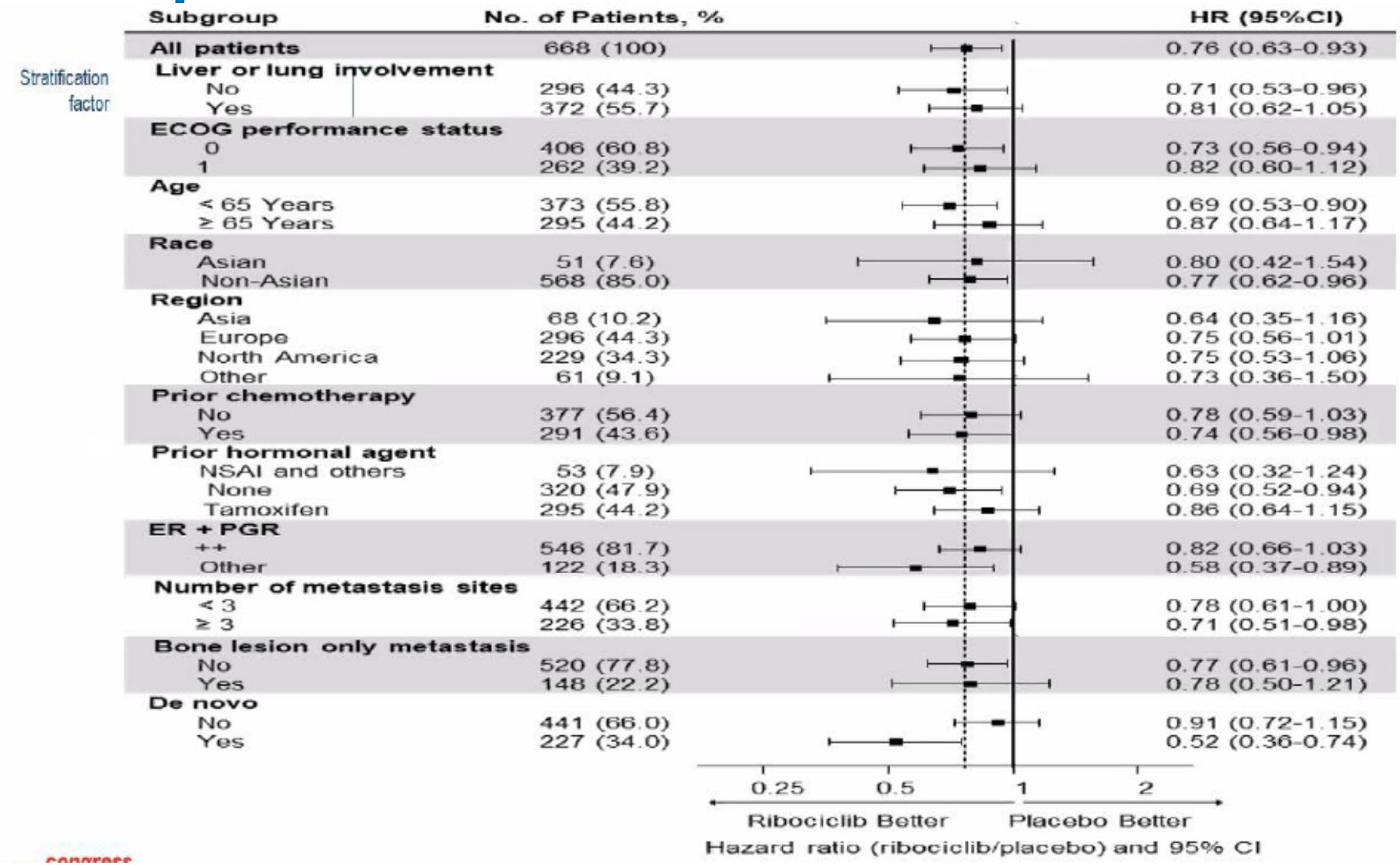
	RIB + LET	PBO + LET
Events/n	181/334	219/334
Median OS, mo	63.9	51.4
HR (95% CI)	0.76 (0.63-0.93)	
P value	.004	

The P value of .004 crossed the prespecified boundary to claim superior efficacy

Rozdíl v OS mezi rameny se časem zvětšuje



Konzistentní přínos v léčbě byl vidět napříč podskupinami

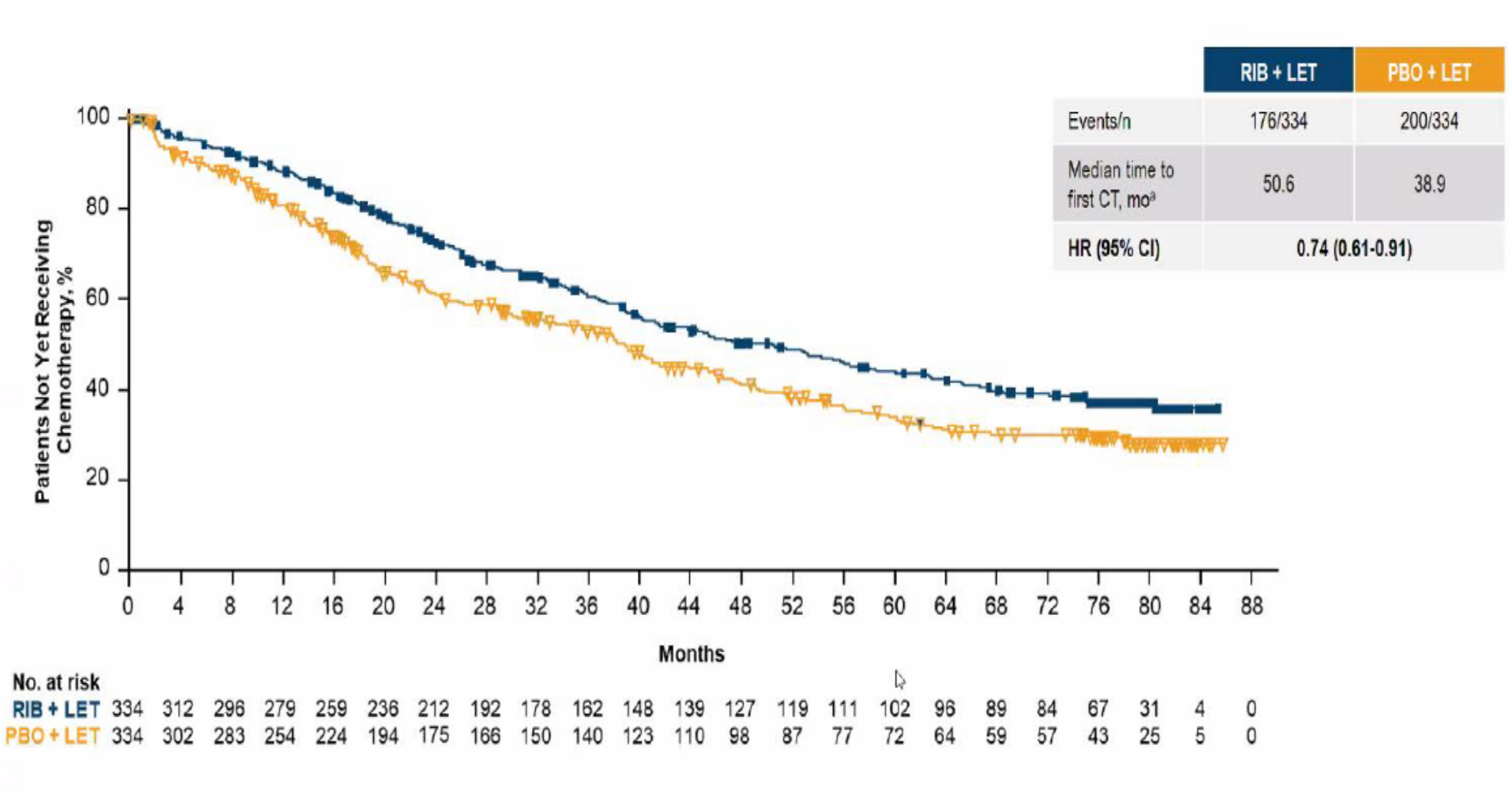


Následná terapie po ukončení léčby

CDK4/6i use was higher in the placebo arm (34.4%) than the ribociclib arm (21.7%)

Parameter, n (%)	RIB + LET n = 334	PBO + LET n = 334
Patients who discontinued study treatment	304 (91.0)	317 (94.9)
Patients who received first subsequent therapy[a,b]	267 (87.8)	286 (90.2)
Hormone therapy alone	100 (32.9)	92 (29.0)
Hormone therapy + other therapy	74 (24.3)	94 (29.7)
Chemotherapy alone	53 (17.4)	61 (19.2)
Chemotherapy + hormone or other therapy	32 (10.5)	33 (10.4)
Patients who received a CDK4/6i in any subsequent line of therapy[a,c]	66 (21.7)	109 (34.4)
Palbociclib	49 (16.1)	100 (31.5)
Ribociclib	14 (4.6)	6 (1.9)
Abemaciclib	8 (2.6)	12 (3.8)

Ribociklib posunul čas k chemoterapii o jeden rok



	RIB + LET	PBO + LET
Events/n	176/334	200/334
Median time to first CT, mo[a]	50.6	38.9
HR (95% CI)	0.74 (0.61-0.91)	

Bezpečnost

- Medián trvání léčby byl 2 roky v rameni s ribociklibem
  a rok v kontrolním rameni
- Po 60 měsících sledování nebyly pozorované nové bezpečnostní signály
- Většina událostí se objevila během prvních 12 měsíců
- Nežádoucí účinky G3/4 byly:

- Neutropenie 63 % vs. 1,2 %
- Hepatobiliarní toxicita 14,4 % vs. 4,8 %
- Prodloužení QT intervalu 4,5 % vs. 2,1 %
- Intersticiální plicní nemoc 0,6 % vs. 0 %

Závěry studie MONALEESA-2

- Zlepšení PFS prokázaly studie s abemaciklibem, ribociklibem i palbociklibem v 1. linii léčby

- Studie MONALEESA-2 je první studií u postmenopauzálních žen s ER pozitivním, HER2 negativním karcinomem prsu, která prokázala statisticky i klinicky významné prodloužení přežití přidáním CDK4/6 inhibitoru


Děkuji za pozornost