Zhrnutie sekcie karcinóm prsníka

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Vyhlásenie o konflikte záujmov autora

□ Nemám potenciálny konflikt záujmov

✔ Deklarujem nasledujúci konflikt záujmov

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

Podľa UEMS (upravené v zmysle slovenskej legislatívy)

Prednáška je podporená agentúrou
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Včasný karcinóm prsníka

Abstrakt LBA1

OlympiA: A phase III, multicenter, randomized, placebo-controlled trial of adjuvant olaparib after (neo)adjuvant chemotherapy in patients with germline *BRCA1/2* mutations and high-risk HER2-negative early breast cancer.

Andrew Tutt, Judy Ellen Garber, Bella Kaufman, Giuseppe Viale, Debora Fumagalli, Priya Rastogi, Richard D. Gelber, Evandro de Azambuja, Anitra Fielding, Judith Balmana Gelpi, Karen A. Gelmon, Nigel Baker, Amal Arahmani, Elzbieta Senkus-Konefka, Eleanor Mc Fadden, Vassiliki Karantza, Sunil R. Lakhani, Greg Yothers, Christine Campbell, Charles E. Geyer

J Clin Oncol 39, 2021 (suppl 15; abstr LBA1)

OlympiA: Trial schema

- Local genetic testing or on-study central screening (Myriad Genetics Inc.)
- Germline pathogenic or likely pathogenic *BRCA1/2* mutation
- HER2–negative (hormone receptor–positive or TNBC)
- Stage II-III Breast Cancer or lack of PathCR to NACT

Neoadjuvant Group
- *TNBC:* non-pCR
- *Hormone receptor–positive:* non-pCR and CPS+EG score ≥ 3

≥ 6 cycles Neoadjuvant Chemotherapy → Surgery → +/- Radiotherapy

Adjuvant Group
- *TNBC:* ≥ pT2 or ≥ pN1
- *Hormone receptor–positive:* ≥ 4 positive lymph nodes

Surgery → ≥ 6 cycles Adjuvant Chemotherapy → +/- Radiotherapy

1:1 Randomization N=1836

Olaparib 300 mg twice daily for 1 year

Placebo twice daily for 1 year

Primary End Point
- Invasive disease-free survival (IDFS) by STEEP system[1]

Secondary End Points
- Distant disease-free survival[1] (DDFS)
- Overall survival[1] (OS)
- BRCA1/2 associated cancers
- Symptom / Health related QoL
- Safety

Stratification Factors
- Hormone receptor–positive vs. TNBC
- Neoadjuvant vs. adjuvant
- Prior platinum-based chemotherapy (yes vs. no)

Concurrent Adjuvant Therapy
- Endocrine therapy
- Bisphosphonates
- No 2nd Adjuvant Chemotherapy

Hormone receptor +ve defined as ER and/or PgR positive (IHC staining ≥ 1%)
Triple Negative defined as ER and PgR negative (IHC staining < 1%)
[1]Hudis CA, J Clin Oncol 2007

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OlympiA: Patient characteristics

	Olaparib (N = 921)	Placebo (N = 915)
Hormone receptor status*		
Hormone receptor ≥ 1% / HER2-†	168 (**18.2%**)	157 (**17.2%**)
Triple Negative Breast Cancer‡	751 (**81.5%**)	758 (**82.8%**)
Menopausal status (female only)		
Premenopausal	572/919 (62.2%)	553/911 (60.7%)
Postmenopausal	347/919 (37.8%)	358/911 (39.3%)
Prior chemotherapy		
Adjuvant (ACT)	461 (**50.1%**)	455 (**49.7%**)
Neoadjuvant (NACT)	460 (**49.9%**)	460 (**50.3%**)
Anthracycline and taxane regimen	871 (**94.6%**)	849 (**92.8%**)
Neo(adjuvant) platinum-based therapy	247 (**26.8%**)	239 (**26.1%**)
Concurrent endocrine therapy (HR–positive only)	146/168 (86.9%)	142/157 (90.4%)

*Defined by local test results
†Following a protocol amended in 2015, the first patient with hormone receptor–positive disease was enrolled in December 2015
‡Two patients are excluded from the summary of the triple–negative breast cancer subset because they do not have confirmed HER2–negative status

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OlympiA: Pathological characteristics

CPS+EG score* (Neoadjuvant only)

	Olaparib (n = 460)	Placebo (n = 460)
HR+/HER2-		
CPS+EG score ≤2†	13 (2.8%)	6 (1.3%)
CPS+EG score of 3 or 4	**88 (19.1%)**	**85 (18.5%)**
CPS+EG score of 5 or 6	3 (0.7%)	1 (0.2%)
Not recorded	0 (0.0%)	0 (0.0%)
Triple Negative Breast Cancer		
CPS+EG score ≤2	**151 (32.8%)**	**144 (31.3%)**
CPS+EG score of 3 or 4	**179 (38.8%)**	**197 (42.8%)**
CPS+EG score of 5 or 6	19 (4.1%)	14 (3.0%)
Not recorded	7 (1.5%)	13 (2.8%)

*CPS+EG score is a staging system for disease specific survival in patients with breast cancer treated with neoadjuvant chemotherapy incorporating pretreatment clinical stage, estrogen receptor status, nuclear grade and post-neoadjuvant chemotherapy pathological stage. (Mittendorf EA, J Clin Oncol 2011)
† Reported as protocol deviations

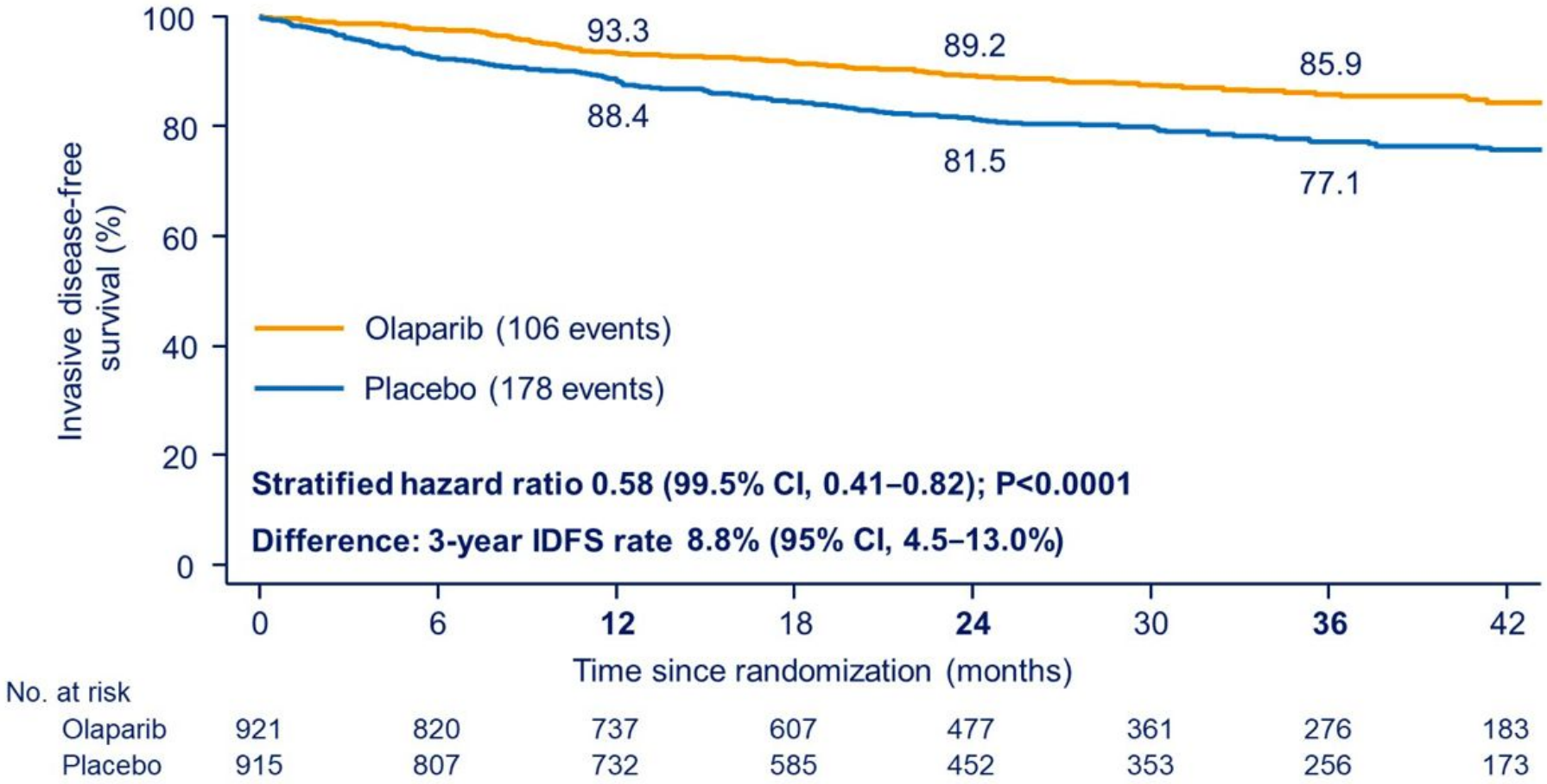
Pathological AJCC stage (Adjuvant only)

	Olaparib (n = 461)	Placebo (n = 455)
0	0 (0.0%)	0 (0.0%)
IA*	5 (1.1%)	2 (0.4%)
IB	15 (3.3%)	11 (2.4%)
IIA	**264 (57.3%)**	**250 (54.9%)**
IIB	**70 (15.2%)**	**75 (16.5%)**
IIIA	73 (15.8%)	70 (15.4%)
IIIB	0 (0.0%)	2 (0.4%)
IIIC	28 (6.1%)	41 (9.0%)
NA†	6 (1.3%)	4 (0.9%)

*Reported as protocol deviations
† These include 2 occult BC (placebo, n = 2), 6 pTx (olaparib, n = 4; placebo, n = 2) and 2 pNx (olaparib, n = 2)

J Clin Oncol 39, 2021 (suppl 15; abstr LBA1)

OlympiA: Invasive disease-free survival (ITT)



J Clin Oncol 39, 2021 (suppl 15; abstr LBA1)

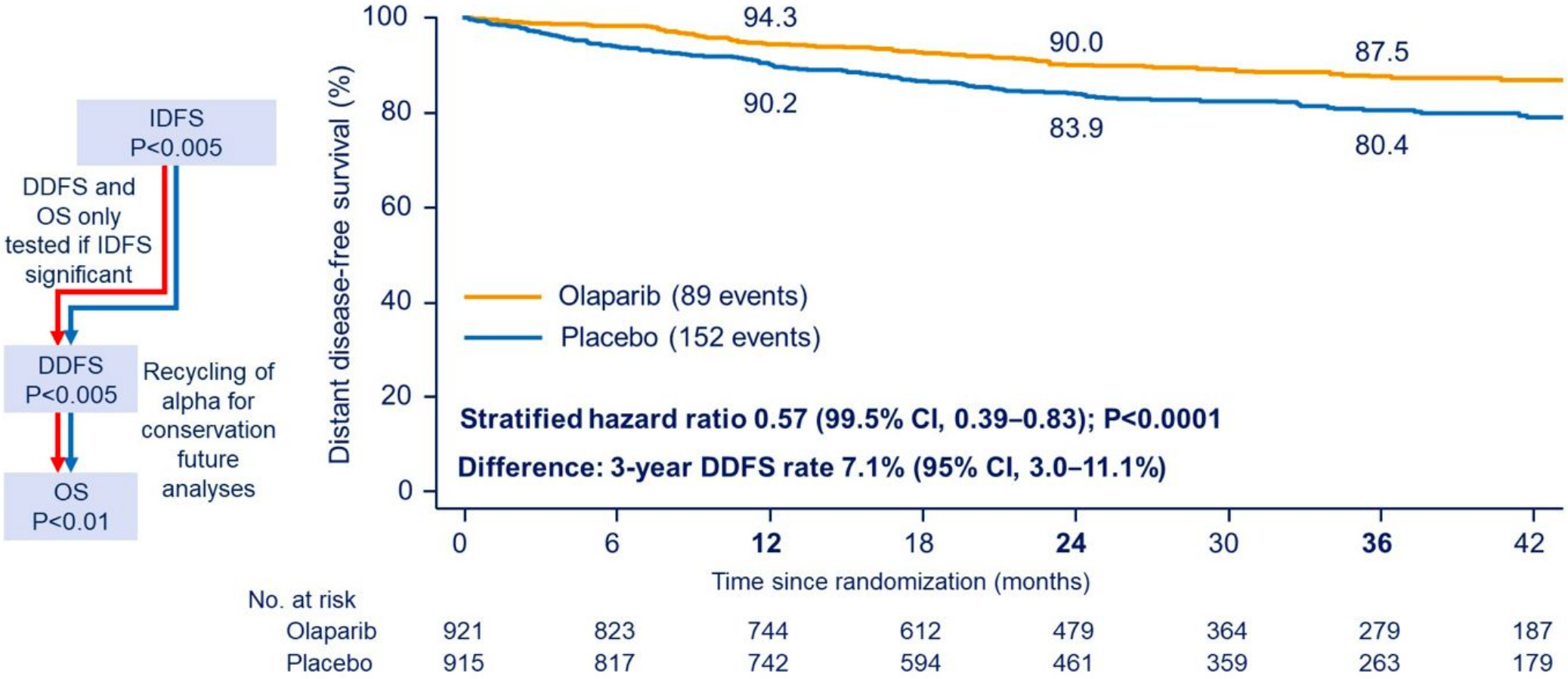
OlympiA: Type of first IDFS event

	Olaparib (N = 921)	Placebo (N = 915)
Number of patients with a first IDFS event	**106 (11.5%)**	**178 (19.5%)**
Distant recurrence	**72 (7.8%)**	**120 (13.1%)**
Distant CNS Recurrence	22 (2.4%)	36 (3.9%)
Distant excluding CNS Recurrence	50 (5.4%)	84 (9.2%)
Regional (Ipsilateral) Recurrence	6 (0.7%)	14 (1.5%)
Local (Ipsilateral) Recurrence	7 (0.8%)	11 (1.2%)
Contralateral invasive breast cancer	8 (0.9%)	12 (1.3%)
Second primary non-breast malignancies	11 (1.2%)	21 (2.3%)
Ovarian	1 (0.1%)	4 (0.4%)
Peritoneal	0 (0.0%)	0 (0.0%)
Fallopian tube	1 (0.1%)	4 (0.4%)
Other	9 (1.0%)	13 (1.4%)
Deaths without a prior IDFS event*	2 (0.2%)	0 (0.0%)

There can only be one first IDFS event per patient
*1 death due to cardiac arrest and 1 patient with unknown cause of death

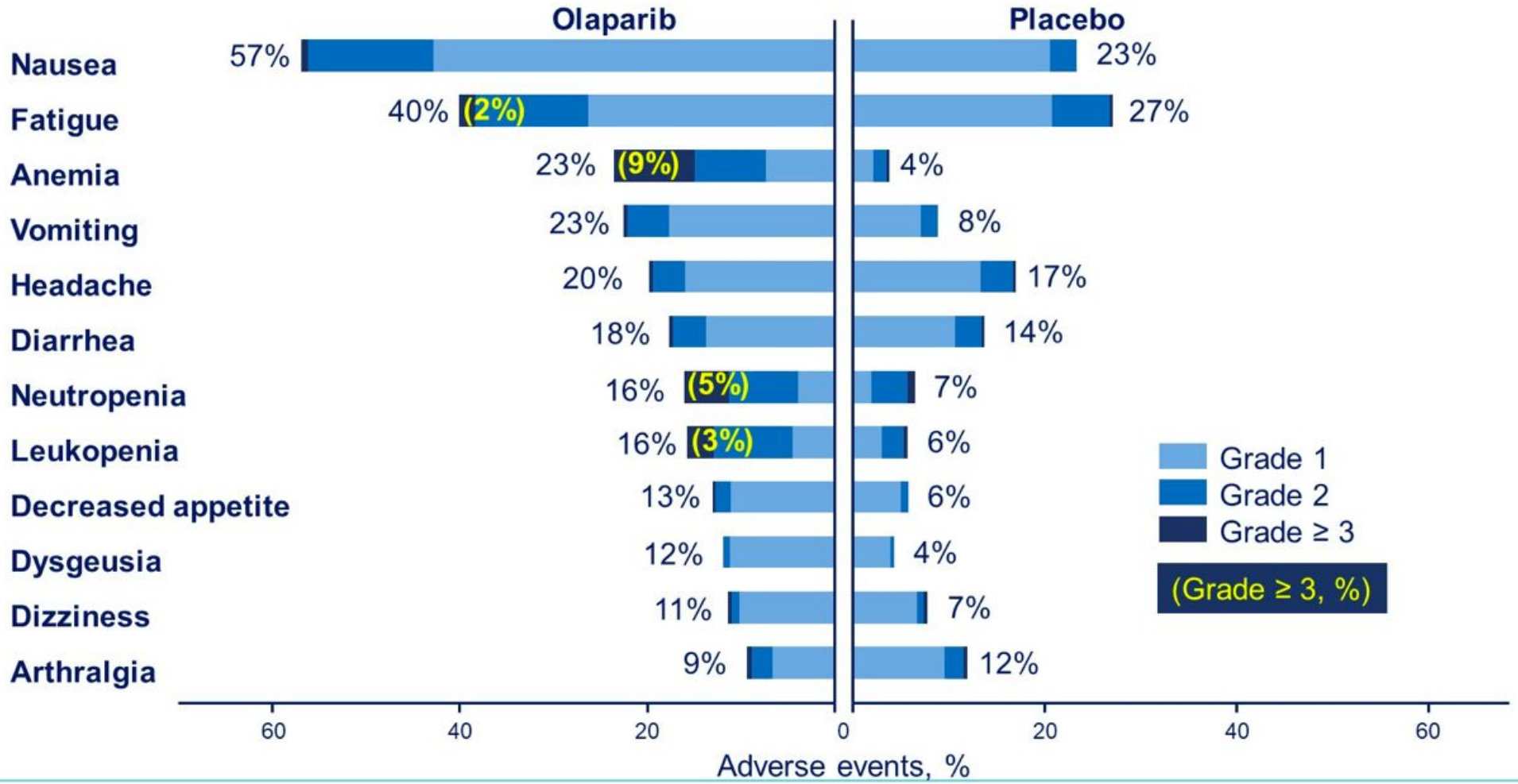
J Clin Oncol 39, 2021 (suppl 15; abstr LBA1)

OlympiA: Distant disease-free survival



J Clin Oncol 39, 2021 (suppl 15; abstr LBA1)

OlympiA: Adverse events of any grade ≥ 10%



J Clin Oncol 39, 2021 (suppl 15; abstr LBA1)

Záver

- Pacientky s vysoko-rizikovým HER2- EBC so zárodočnými mutáciami BRCA1/2 majú signifikantne vyššie riziko relapsu - IDFS, DDFS napriek štandardnej liečbe
- Adjuvantné podanie olaparibu 1rok po ukončení lokálnej liečby a (neo) adjuvantnej chemoterapie signifikantne predlžuje IDFS, DDFS
- Menej úmrtí v ramene s olaparibom, údaje OS zatiaľ bez signifikantného rozdielu po 2,5 ročnom sledovaní, očakávané v budúcnosti

Abstrakt č.: 505

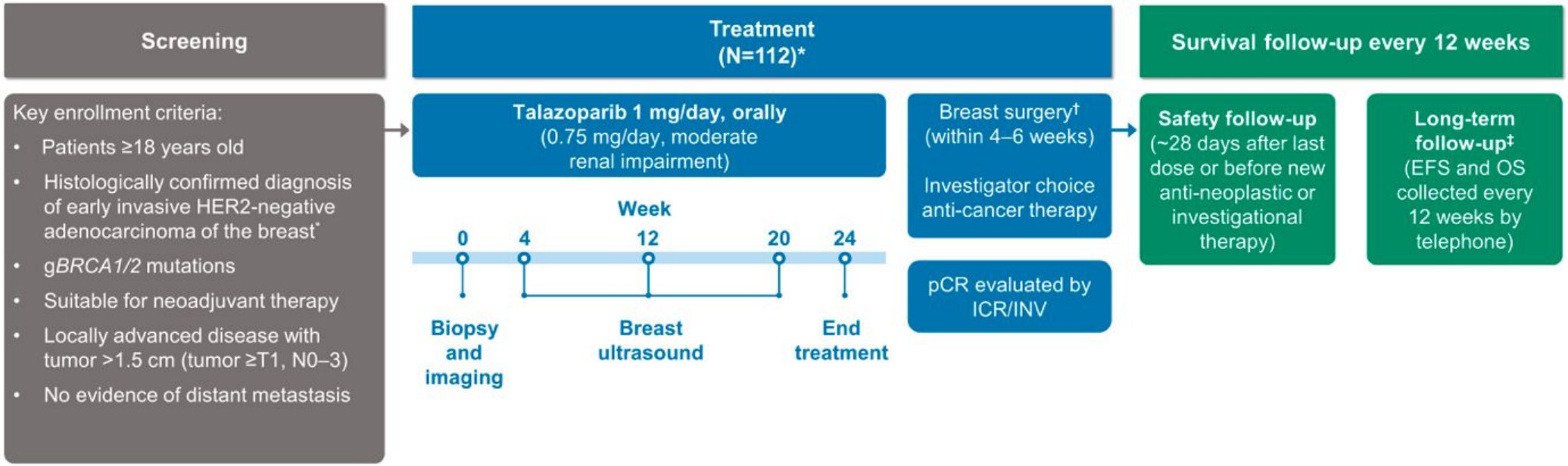
Neoadjuvant talazoparib in patients with germline *BRCA1/2* (g*BRCA1/2*) mutation-positive, early HER2-negative breast cancer (BC): Results of a phase 2 study.

Jennifer Keating Litton, Joseph Thaddeus Beck, Jason M. Jones, Jay Andersen, Joanne Lorraine Blum, Lida A. Mina, Raymond Brig, Michael A. Danso, Yuan Yuan, Antonello Abbattista, Kay Noonan, Jayeta Chakrabarti, Akos Czibere, William Fraser Symmans, Melinda L. Telli

J Clin Oncol 39, 2021 (suppl 15; abstr 505)

Study Design

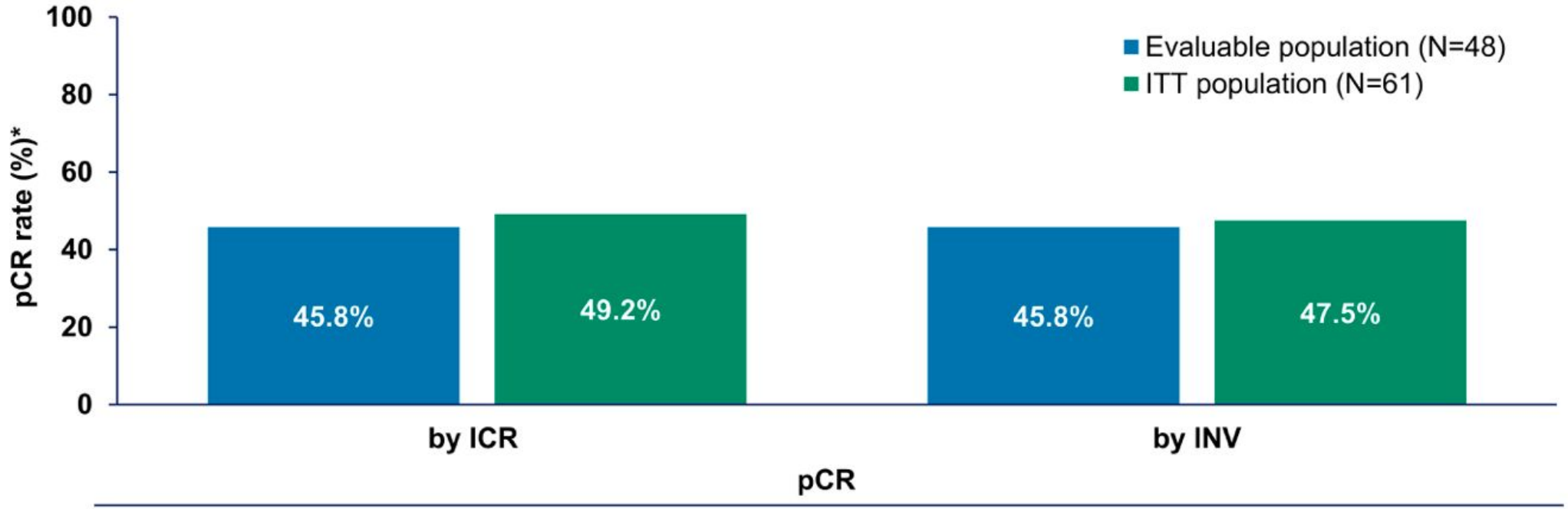
NEOTALA is a non-randomized, open-label, multi-center, single-arm, Phase 2 trial (NCT03499353)



EFS=event-free survival; HR=hormone receptor; ICR=independent central review; INV=investigator; OS=overall survival.
*Study design was amended to include HR-positive, HER2-negative patients with BC and the patient numbers were reduced from 112 to 60 in order to address lower than expected enrollment.
†Breast/axillary tissue must be removed by either lumpectomy or mastectomy with clinically appropriate axillary surgery. Patients may not have had surgery due to progressive disease and initiation of new anti-cancer therapy.
‡Long-term follow-up planned to be at 3 years, starting from the date of surgery for EFS and after the first dose of drug for OS. However, Pfizer decided to make a strategic change in the development program for talazobarib in neoadjuvant BC and decided not to pursue further development in this setting. The study was closed after all patients completed safety follow-up and EFS/OS was not reached.

J Clin Oncol 39, 2021 (suppl 15; abstr 505)

Pathologic Complete Response



95% CI†	(32.0–60.6)	(36.7–61.6)	(32.0–60.6)	(35.0–60.1)
80% CI†	(36.4–55.2)	(41.0–57.4)		
Posterior probability that true pCR rate exceeds 45%	0.55	0.75		

*The denominator is N, the number of patients in the evaluable/ITT analysis set as per ICR/INV.
†The exact CI was calculated using the Blaker's method.

J Clin Oncol 39, 2021 (suppl 15; abstr 505)

Záver

- Pôsobivé výsledky pCR a RCB u BRCA mutovaných pacientok s TNBC pri monoterapii v neoadjuvantnej intencii!
- pCR hodnotiteľná populácia 45,8 %, ITT 49,2 %
- Liečba celkovo dobre tolerovaná s predvídateľnou a manažovateľnou toxicitou

Abstrakt č.: 10510

Clinically sufficient vitamin D levels at breast cancer diagnosis and survival outcomes in a prospective cohort of 3,995 patients after a median follow-up of 10 years.

Song Yao, Haiyang Sheng, Marilyn L. Kwan, Qianqian Zhu, Janise M. Roh, Lia D'addario, Isaac J. Ergas, Emily Schultz, Ting-Yuan David Cheng, Warren Davis, Catherine Thomsen, Scarlett Lin Gomez, Christine B. Ambrosone, Lawrence H. Kushi

J Clin Oncol 39, 2021 (suppl 15; abstr 10510)

Lower Vitamin D Levels linked with Poor Patient Outcomes – Pathways Study (updated, n=3,995, median F/U=115 months)

Outcome	Vitamin D levels	# events/Total	M1: non-clinical factors		M2: M1+ clinical factors		M3: M2 + treatment factors	
			HR (95% CI)	P for trend	HR (95% CI)	P for trend	HR (95% CI)	P for trend
Overall Survival	Deficient	308/1518	1.00	1.1E-06	1.00	0.001	1.00	0.003
	Insufficient	257/1487	0.85 (0.71-1.00)		0.94 (0.78-1.13)		0.97 (0.81-1.17)	
	Sufficient	136/990	0.64 (0.52-0.79)		0.70 (0.56-0.88)		0.73 (0.58-0.91)	
Breast Cancer Specific Survival	Deficient	165/1518	1.00	0.002	1.00	0.18	1.00	0.31
	Insufficient	123/1487	0.83 (0.66-1.06)		1.01 (0.78-1.32)		1.03 (0.79-1.34)	
	Sufficient	56/990	0.60 (0.43-0.82)		0.74 (0.53-1.03)		0.78 (0.56-1.09)	
Recurrence-free Survival	Deficient	374/1518	1.00	1.3E-05	1.00	0.004	1.00	0.014
	Insufficient	319/1487	0.85 (0.73-1.00)		0.93 (0.79-1.10)		0.97 (0.82-1.14)	
	Sufficient	179/990	0.69 (0.57-0.83)		0.77 (0.63-0.93)		0.79 (0.65-0.97)	
Invasive Disease-free Survival	Deficient	405/1518	1 [Ref]	7.5E-05	1.00	0.010	1.00	0.026
	Insufficient	340/1487	0.83 (0.72-0.97)		0.90 (0.77-1.05)		0.93 (0.79-1.09)	
	Sufficient	202/990	0.72 (0.60-0.86)		0.80 (0.66-0.96)		0.82 (0.68-0.99)	

M1: non-clinical factors: age at diagnosis, race/ethnicity, season of blood collection, physical activity, smoking status;
M2: clinical factors: covariates in M1, plus tumor stage, grade, and HR subtype;
M3 treatment factors: covariates in M2, plus surgery, radiation therapy, chemotherapy, endocrine therapy

J Clin Oncol 39, 2021 (suppl 15; abstr 10510)

Včasný karcinóm prsníka ASCO© 2021

HER2 pozitívny karcinóm prsníka

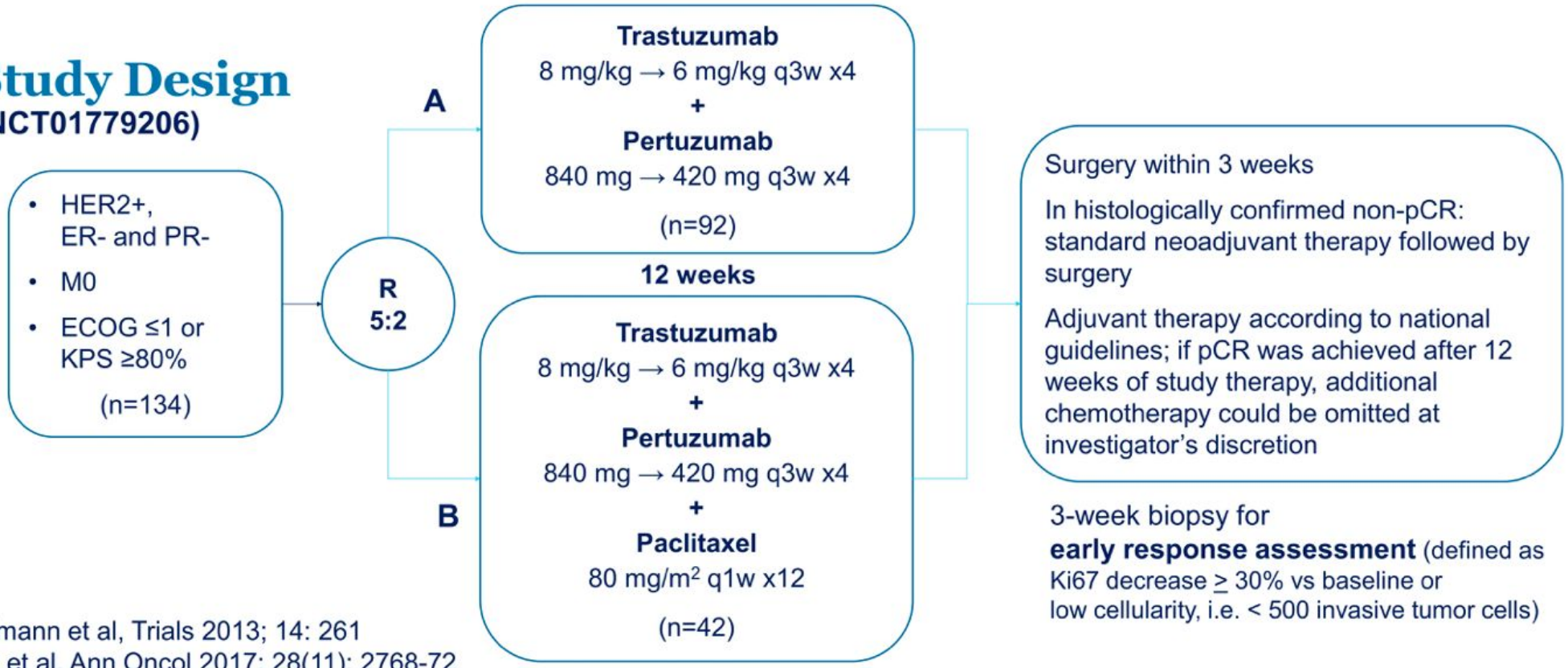
Abstrakt č.: 503

De-escalated neoadjuvant pertuzumab+trastuzumab with or without paclitaxel weekly in HR-/HER2+ early breast cancer: ADAPT-HR-/HER2+ biomarker and survival results

Nadia Harbeck, Oleg Gluz, Matthias Christgen, Sherko Kuemmel, Eva-Maria Grischke, Michael Braun, Jochem Potenberg, Katja Krauss, Claudia Schumacher, Helmut Forstbauer, Toralf Reimer, Andrea Stefek, Hans Holger Fischer, Enrico Pelz, Monika Graeser, Christine zu Eulenburg, Ronald E. Kates, Rachel Wuerstlein, Hans Heinrich Kreipe, Ulrike Nitz
J Clin Oncol 39, 2021 (suppl 15; abstr 503)

WSG-ADAPT HER2+/HR-

Study Design
(NCT01779206)

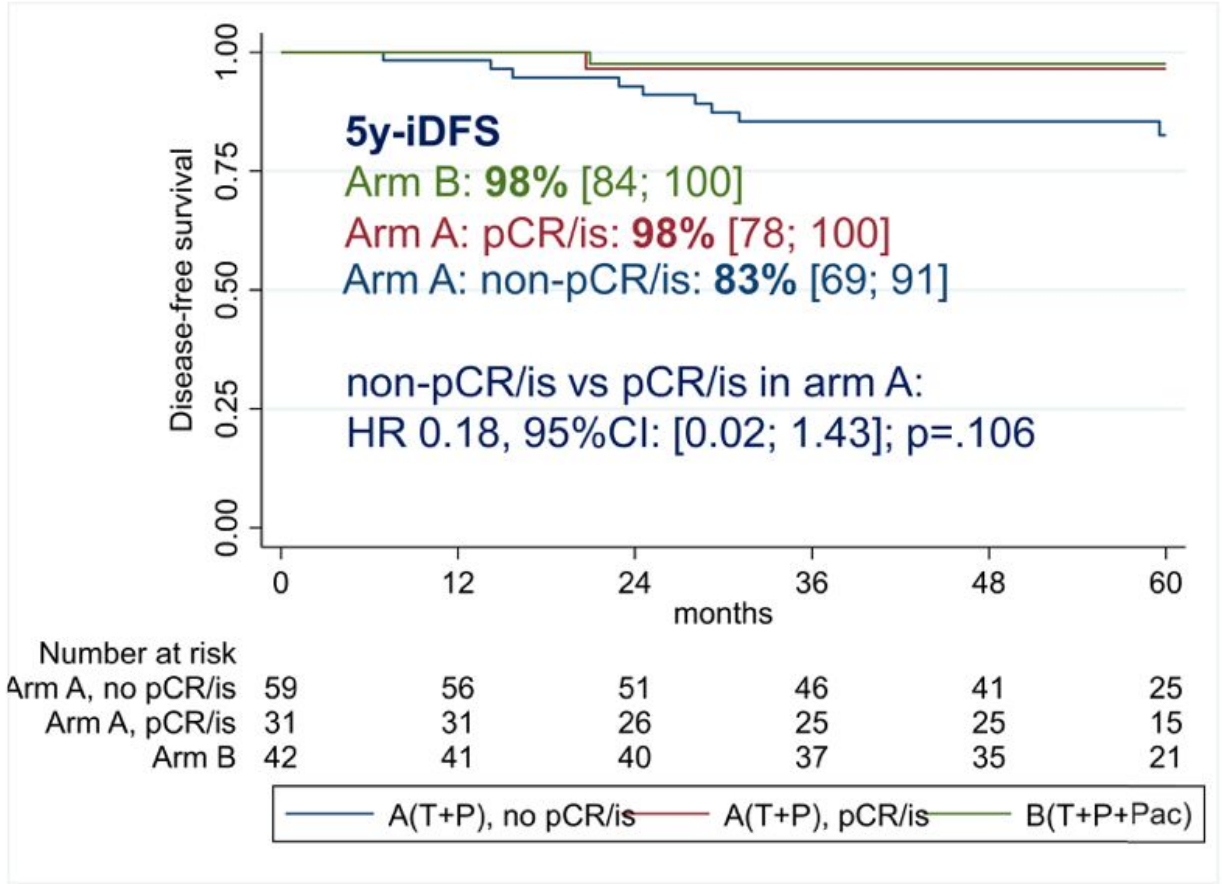


Hofmann et al, Trials 2013; 14: 261
Nitz et al, Ann Oncol 2017; 28(11): 2768-72

J Clin Oncol 39, 2021 (suppl 15; abstr 503)

WSG-ADAPT HER2+/HR-

iDFS Arm A: non-pCR vs pCR



J Clin Oncol 39, 2021 (suppl 15; abstr 503)

Záver

- Optimálne využitie deeskalovaných režimov (prípadne bez chemoterapie) v neoadjuvantnej intencii HER2+ včasného karcinómu prsníka zatiaľ nejasné, limitované údaje
- Režimy bez chemoterapie sa ukazujú ako zaujímavá možnosť pre selektované pacientky, avšak zatiaľ nie sú výsledky celkového prežívania
- Ďalšie prebiehajúce klinické štúdie zaoberajúce sa danou problematikou- CompassHER2 a DeCrescendo

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ER pozitívny karcinóm prsníka

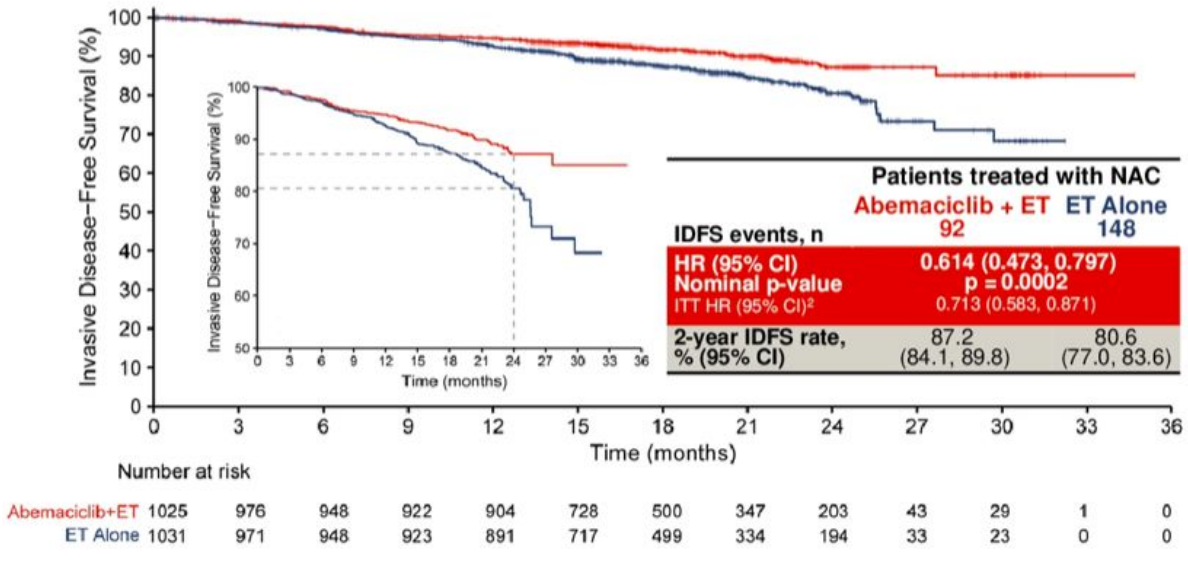
Abstrakt č.: 517

Abemaciclib combined with adjuvant endocrine therapy in patients with high risk early breast cancer who received neoadjuvant chemotherapy (NAC).

Miguel Martin, Roberto Hegg, Sung-Bae Kim, Michael Schenker, Daniela Grecea, José A. García-Sáenz, Konstantinos Papazisis, Quchang Ouyang, Aleksandra Lacko, Berna Oksuzoglu, James Andrew Reeves, Meena Okera, Laura Testa, Chikako Shimizu, Ran Wei, Tammy D Forrester, Maria Munoz, Annamaria H. Zimmermann, Desiree Headley, Stephen R. D. Johnston

J Clin Oncol 39, 2021 (suppl 15; abstr 517)

IDFS IN PATIENTS WHO RECEIVED NAC



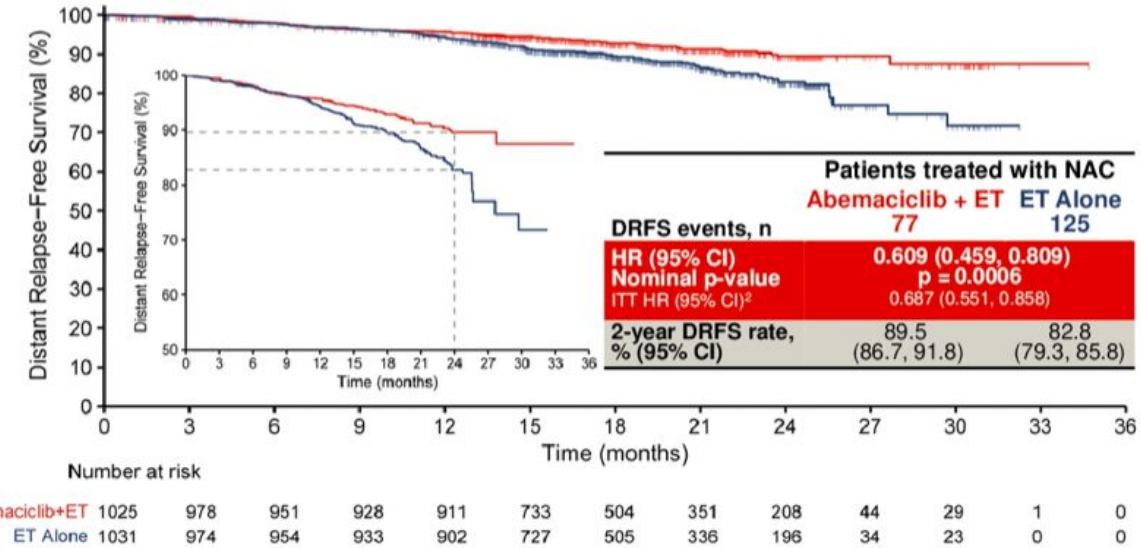
Patients treated with NAC	Abemaciclib + ET	ET Alone
IDFS events, n	92	148
HR (95% CI) Nominal p-value ITT HR (95% CI)[2]	0.614 (0.473, 0.797) p = 0.0002 0.713 (0.583, 0.871)	
2-year IDFS rate, % (95% CI)	87.2 (84.1, 89.8)	80.6 (77.0, 83.6)

Clinically meaningful improvement in IDFS – 38.6% reduction in the risk of developing an IDFS event

Two-year IDFS rates were 87.2% in the abemaciclib + ET arm and 80.6% in the ET arm – 6.6% difference

[2]Rastogi P. et al. SABCS 2020; presentation number GS1-01

DRFS IN PATIENTS WHO RECEIVED NAC



Patients treated with NAC	Abemaciclib + ET	ET Alone
DRFS events, n	77	125
HR (95% CI) Nominal p-value ITT HR (95% CI)[2]	0.609 (0.459, 0.809) p = 0.0006 0.687 (0.551, 0.858)	
2-year DRFS rate, % (95% CI)	89.5 (86.7, 91.8)	82.8 (79.3, 85.8)

Clinically meaningful benefit in DRFS – 39.1% reduction in the risk of developing distant metastases

Two-year DRFS rates were 89.5% in the abemaciclib + ET arm and 82.8% in ET arm – 6.7% difference

[2]Rastogi P. et al. SABCS 2020; presentation number GS1-01

J Clin Oncol 39, 2021 (suppl 15; abstr 517)

Včasný karcinóm prsníka ASCO © 2021

Trojito negatívny karcinóm prsníka

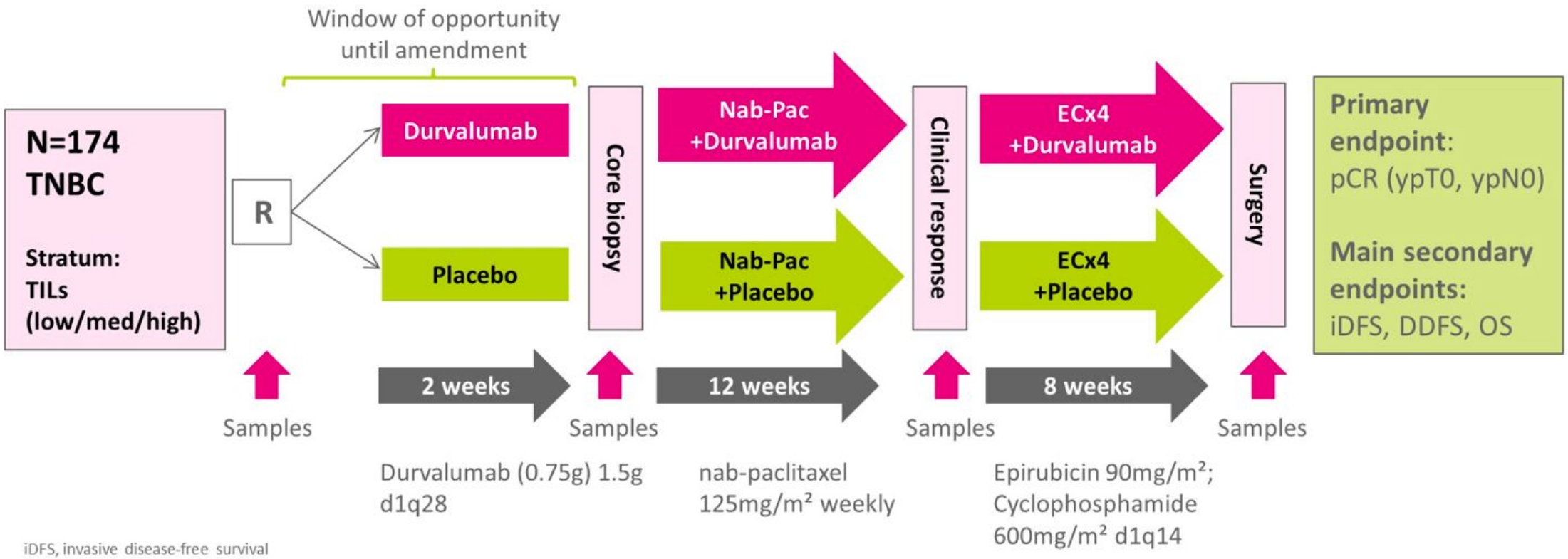
Abstrakt č.: 506

Durvalumab improves long-term outcome in TNBC: results from the phase II randomized GeparNUEVO study investigating neodjuvant durvalumab in addition to an anthracycline/taxane based neoadjuvant chemotherapy in early triple-negative breast cancer (TNBC).

Sibylle Loibl, Andreas Schneeweiss, Jens Bodo Huober, Michael Braun, Julia Rey, Jens U. Blohmer, Jenny Furlanetto, Dirk Michael Zahm, Claus Hanusch, Jörg Thomalla, Christian Jackisch, Peter Staib, Theresa Link, Kerstin Rhiem, Christine Solbach, Peter A. Fasching, Nicole Burchardi, Carsten Denkert, Michael Untch

J Clin Oncol 39, 2021 (suppl 15; abstr 506)

Study Design



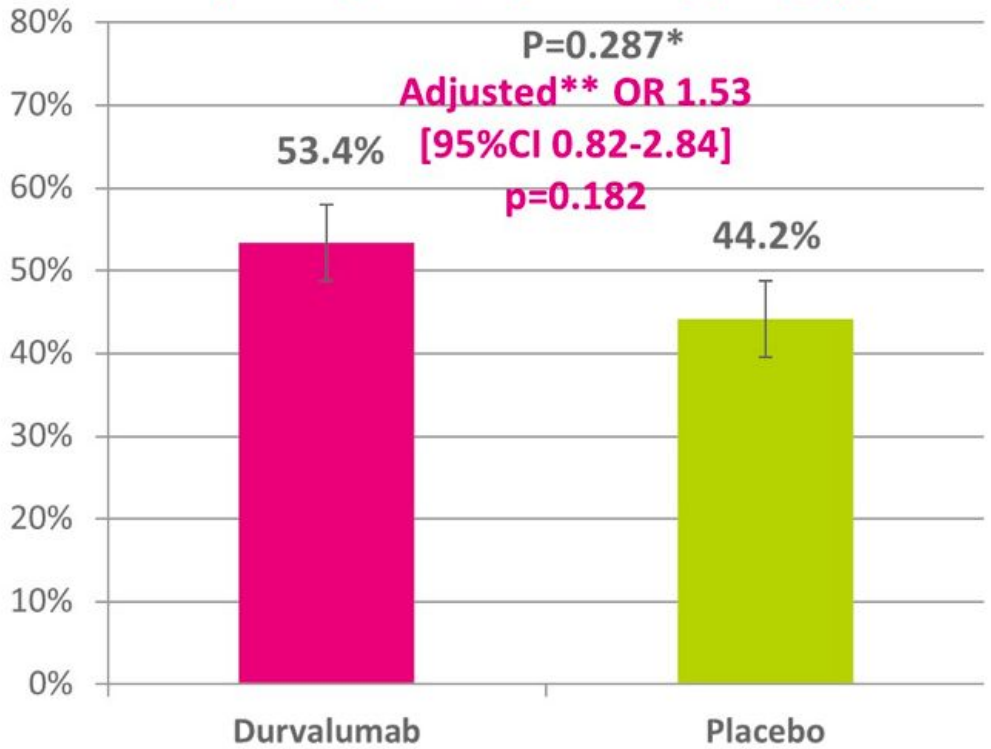
iDFS, invasive disease-free survival
DDFS, distance disease-free survival
OS, overall survival

Loibl S. et al. Ann Oncol 2019

J Clin Oncol 39, 2021 (suppl 15; abstr 506)

Efficacy Endpoints

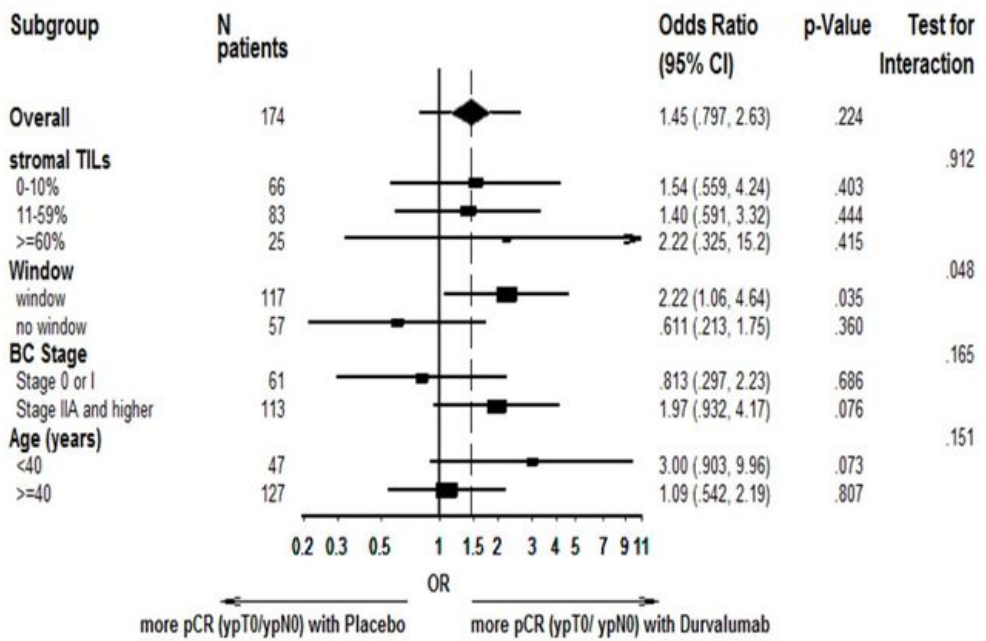
Primary endpoint: pCR – ypT0, ypN0



* Continuous corrected χ^2 test
** For stratification factor (TIL groups)

Loibl S, et al. Ann Oncol 2019

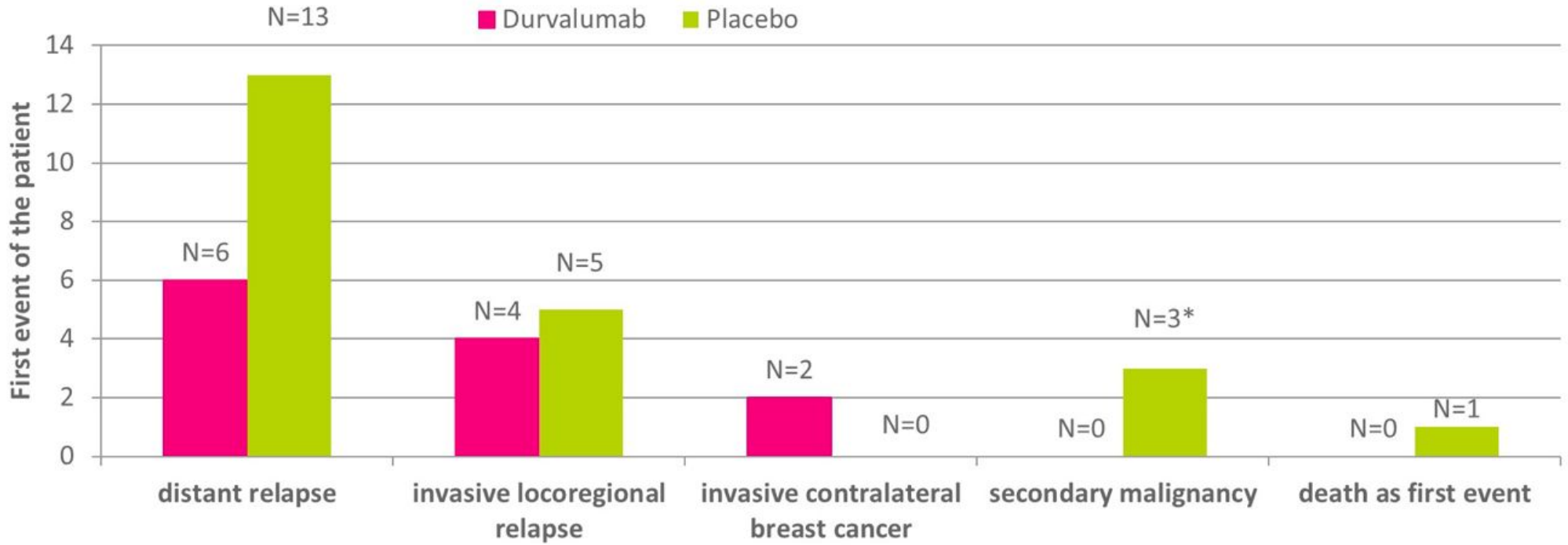
Subgroup Analyses (predefined)



J Clin Oncol 39, 2021 (suppl 15; abstr 506)

Time-To-Event Analysis

After a median follow-up 43.7 (range 4.9-56.1) months 34 iDFS events were reported (12 in the durvalumab arm and 22 in the placebo arm)



* malignant melanoma, cholangiocarcinoma with liver metastases, non-small-cell lung cancer

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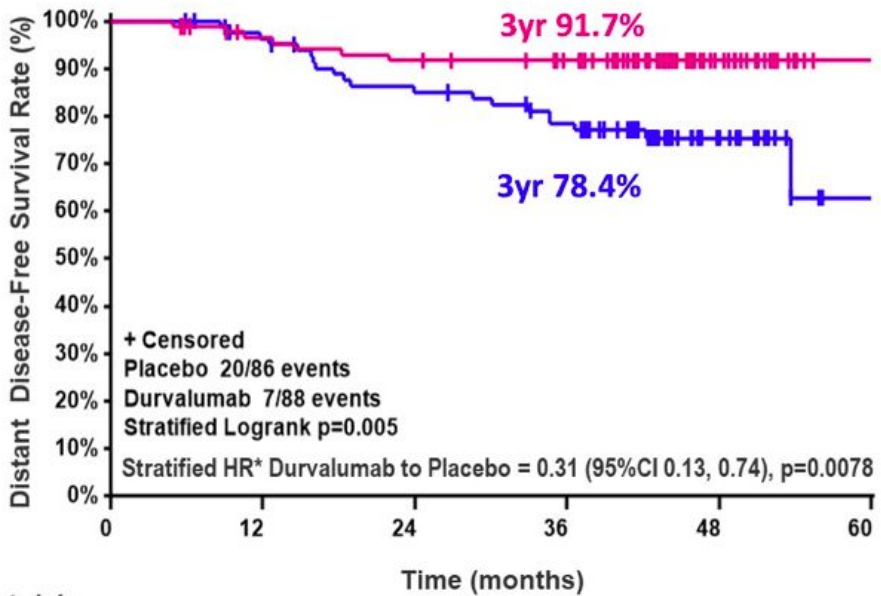
DDFS and OS Between Treatment Arms

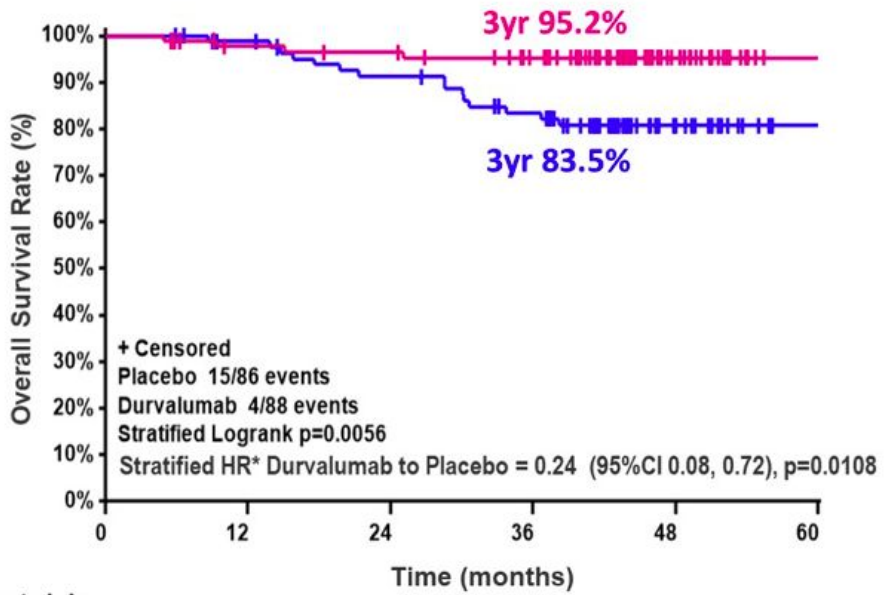
DDFS



Patients at risk:

Placebo	86	78	67	59	16	0
Durvalumab	88	80	76	70	20	0

OS



Patients at risk:

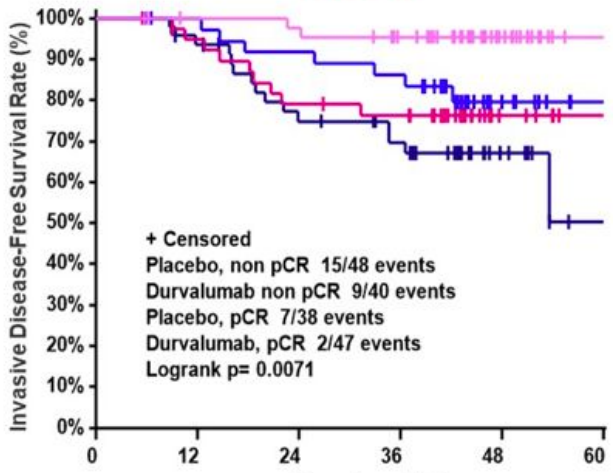
Placebo	86	80	72	63	16	0
Durvalumab	88	81	79	71	20	0

* Stratified by sTILs

J Clin Oncol 39, 2021 (suppl 15; abstr 506)

iDFS, DDFS and OS by pCR and Treatment Arm

iDFS

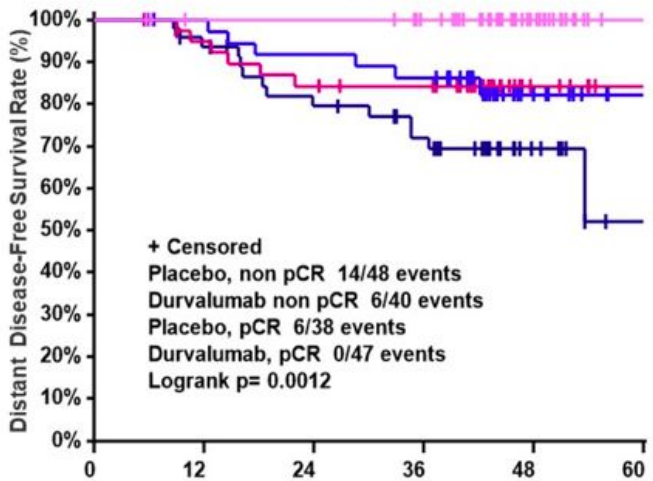


Patients at risk:

Placebo, non pCR	48	42	32	27	8	0
Durvalumab non pCR	40	36	30	28	5	0
Placebo, pCR	38	36	33	31	8	0
Durvalumab, pCR	47	44	43	38	13	0

HR (non pCR vs pCR)=0.34
(95%CI 0.16-0.73)
log-rank p=0.004

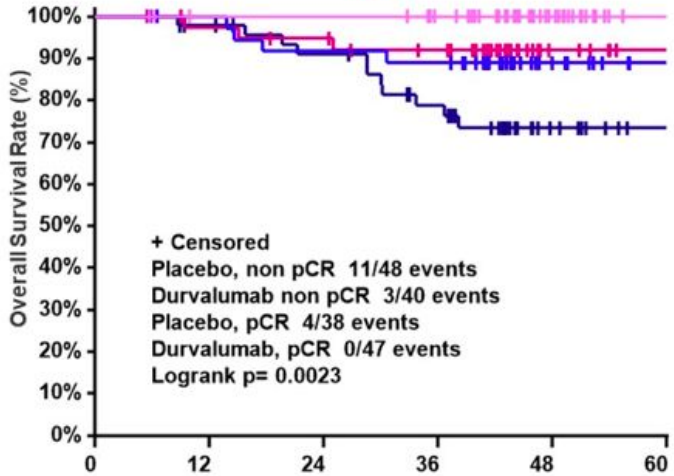
DDFS



	48	42	34	28	8	0
	40	36	32	30	5	0
	38	36	33	31	8	0
	47	44	44	40	15	0

HR (non-pCR vs pCR) 0.28
(95%CI 0.11-0.69)
log-rank p=0.003

OS



	48	44	39	31	8	0
	40	37	35	31	5	0
	38	36	33	32	8	0
	47	44	44	40	15	0

HR (non-pCR vs pCR)=0.27
(95%CI 0.09-0.81)
log-rank p=0.012

J Clin Oncol 39, 2021 (suppl 15; abstr 506)

Záver

- Pridanie durvalumabu k neoadjuvatnej chemoterapii pri TNBC signifikantne zlepšilo prežívanie (iDFS, DDFS, OS)- prvé údaje o dlhšom sledovaní pacientok
- pCR nezávislý prognostický faktor- pacienti s pCR v ramene s durvalumabom mali trend k lepšiemu prežívaniu
- Potrebné ďalšie a konzistentné údaje pre jednoznačné etablovanie checkpoint inhibítorov v neoadjuvantnej intencii, ale prezentované výsledky vyzerajú sľubne
- Chýba stratifikácia pacientok podľa štádia a uzlinového statusu

Abstrakt č.: 605

A randomized phase III post-operative trial of platinum-based chemotherapy (P) versus capecitabine (C) in patients (pts) with residual triple-negative breast cancer (TNBC) following neoadjuvant chemotherapy (NAC): ECOG-ACRIN EA1131

Ingrid A. Mayer, Fengmin Zhao, Carlos L. Arteaga, William Fraser Symmans, Ben Ho Park, Brian Leslie Burnette, Amye Juliet Tevaarwerk, Sofia F. Garcia, Karen L. Smith, Erica L. Mayer, William M. Sikov, Eve T. Rodler, Lynne I. Wagner, Angela DeMichele, Joseph A. Sparano, Antonio C. Wolff, Kathy Miller

J Clin Oncol 39, 2021 (suppl 15; abstr 605)

EA1131

Hypothesis: iDFS with Platinum > iDFS Capecitabine in Basal Subtype TNBC

ECOG-ACRIN cancer research group

Patients with:
- Clinical stage II/III TNBC at diagnosis
- T +/- A NAC
- ≥pT1c in the breast at surgery (any pN)

NCT02445391

SCREENING

Tissue submission PAM50 Analysis (basal vs non-basal subtype)

RANDOMIZE

- Observation
- Carboplatin AUC 6 or Cisplatin 75 mg/m² (treating provider discretion) D1 every 3 weeks x 4 cycles
- (1:1)
- Capecitabine 1000 mg/m2 D1-14 every 3 weeks x 6 cycles

FOLLOW-UP

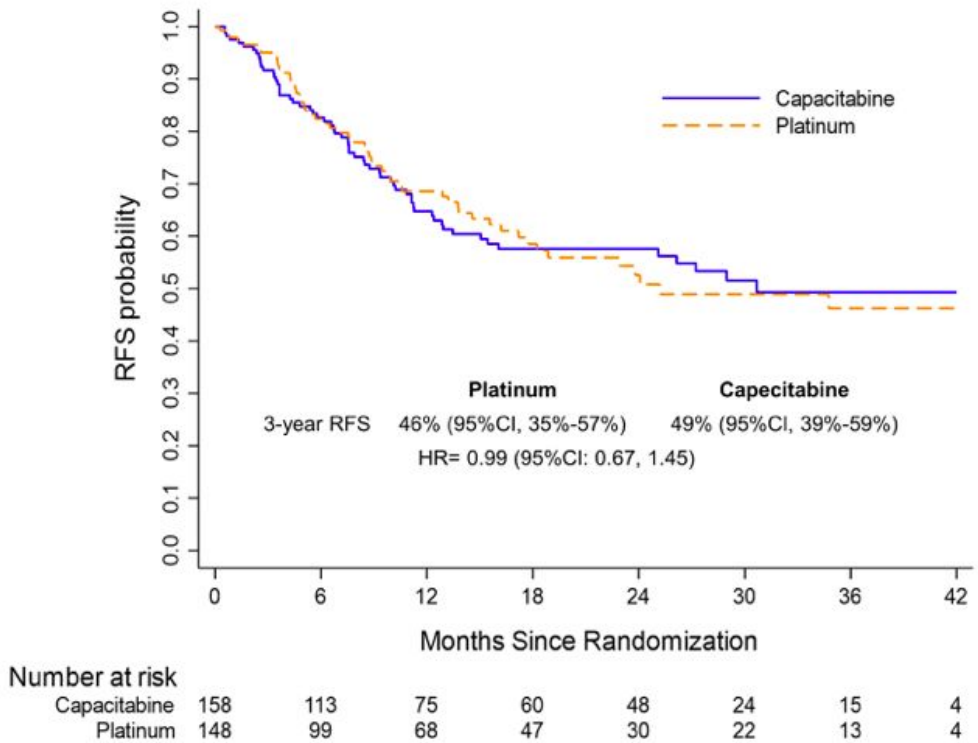
Stratification Factors:
- Clinical stage at diagnosis (II or III)
- Tumor diameter at surgery (1-3 or >3 cm)
- Planned platinum (carboplatin or cisplatin)
- Anthracycline use (yes or no)
- RT at any time (yes or no)

Radiotherapy:
- Prior to or after treatment (treating provider discretion)
- Required for BCS and post-mastectomy if T >5 cm and/or N3

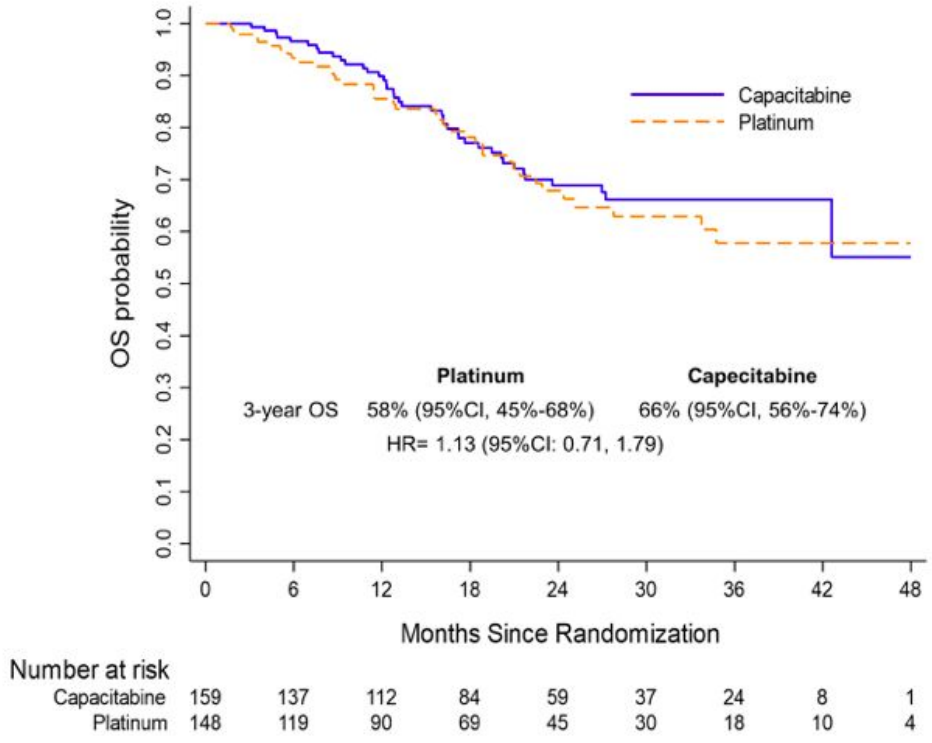
J Clin Oncol 39, 2021 (suppl 15; abstr 605)

3-year RFS and OS in Patients with Basal Subtype TNBC

RFS by Treatment in Basal Subtype



OS by Treatment in Basal Subtype



J Clin Oncol 39, 2021 (suppl 15; abstr 605)

Metastatický karcinóm prsníka ASCO © 2021

Metastatický karcinóm prsníka

Metastatický karcinóm prsníka ASCO © 2021

HER2 pozitívny karcinóm prsníka

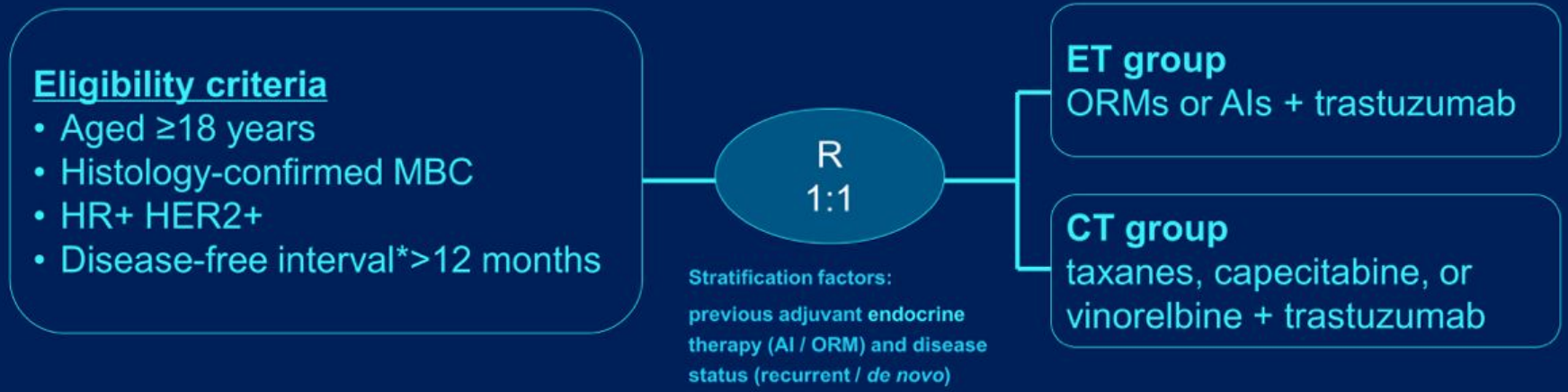
Abstrakt Č.: 1003

Trastuzumab plus endocrine therapy or chemotherapy as first-line treatment for metastatic breast cancer with hormone receptor-positive and HER2-positive: The sysucc-002 randomized clinical trial.

Zhongyu Yuan, Jia-Jia Huang, Xin Hua, Jian-Li Zhao, Ying Lin, Yuan-Qi Zhang, Zhiyong Wu, Lehong Zhang, XiWen Bi, Wen Xia, Yong-yi Zhong, Shu-Sen Wang, Fei Xu, Ruoxi Hong, Kuikui Jiang, Yanxia Shi, Cong Xue, Xin An

J Clin Oncol 39, 2021 (suppl 15; abstr 1003)

Trial Design



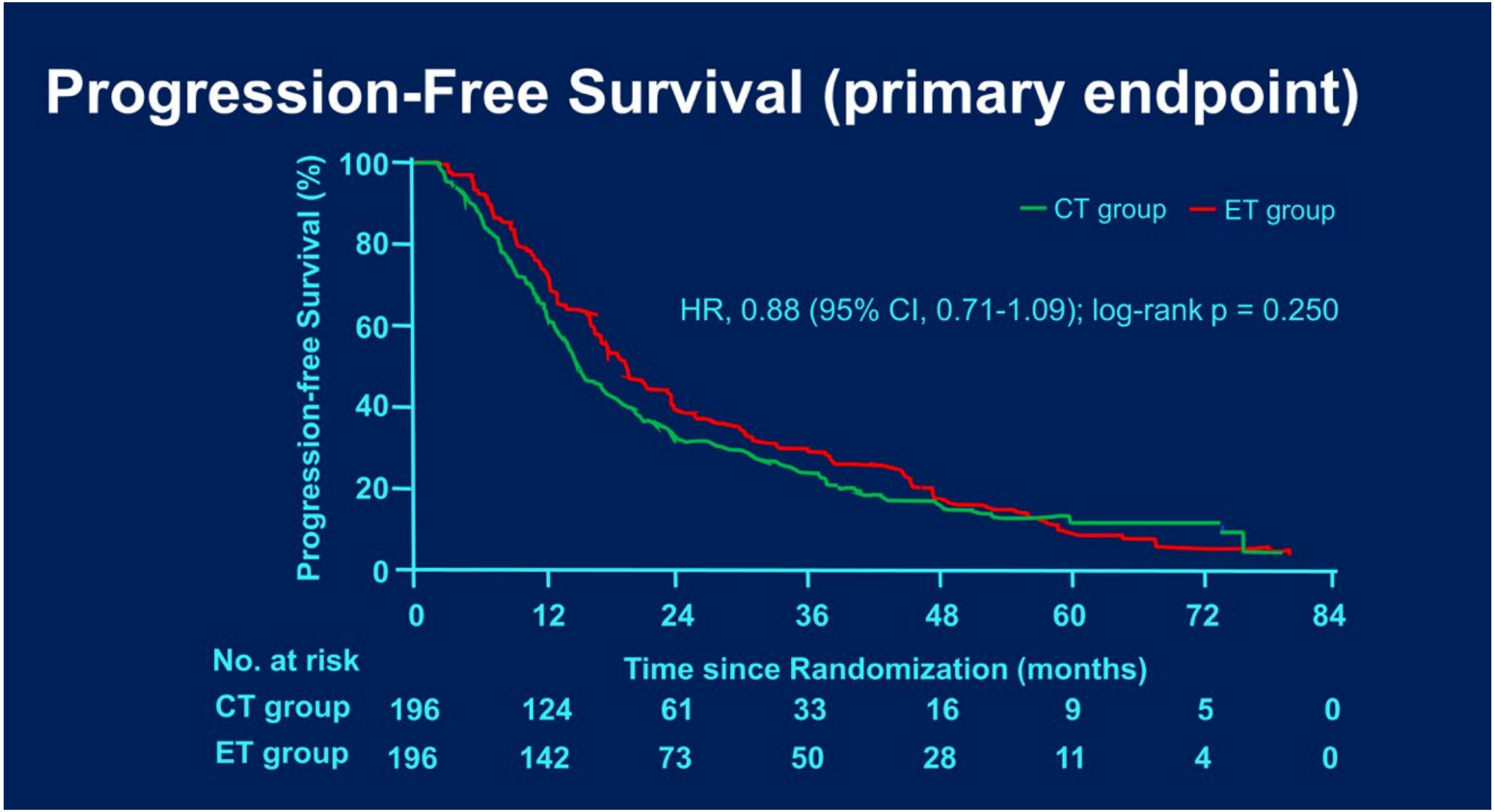
Primary endpoint: Progression-free survival (PFS)

Secondary endpoint: Overall survival (OS), objective response rate (ORR), and Safety

*Disease-free interval defined as the time from the diagnosis of the primary breast cancer to the first recurrence in patients who received (neo)adjuvant therapy) had to be >12 months

J Clin Oncol 39, 2021 (suppl 15; abstr 1003)

Progression-Free Survival (primary endpoint)



J Clin Oncol 39, 2021 (suppl 15; abstr 1003)

Metastatický karcinóm prsníka ASCO © 2021

ER pozitívny karcinóm prsníka

Abstrakt Č.: 1001

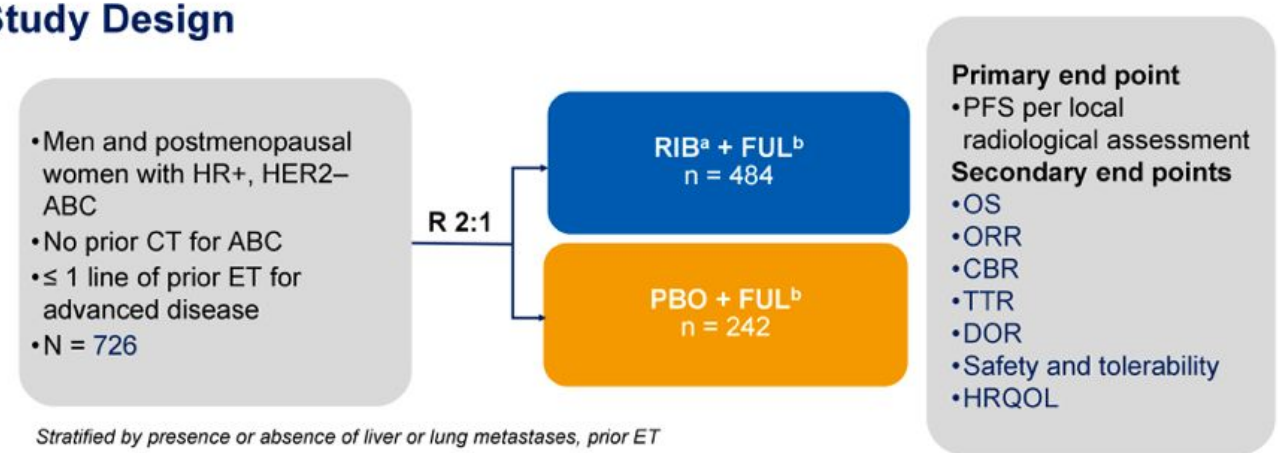
Updated overall survival (OS) results from the phase III MONALEESA-3 trial of postmenopausal patients (pts) with HR+/HER2- advanced breast cancer (ABC) treated with fulvestrant (FUL) ± ribociclib (RIB).

Dennis J. Slamon, Patrick Neven, Stephen K. L. Chia, Guy Heinrich Maria Jerusalem, Michelino De Laurentiis, Seock-Ah Im, Katarina Petrakova, Giulia Valeria Bianchi, Miguel Martin, Arnd Nusch, Gabe S. Sonke, Luis de la Cruz-Merino, J. Thaddeus Beck, Craig Wang, Uday Deore, Arunava Chakravartty, Juan Pablo Zarate, Tetiana Taran, Peter A. Fasching
J Clin Oncol 39, 2021 (suppl 15; abstr 1001)

Background

- The MONALEESA-3 trial evaluating ribociclib + fulvestrant in postmenopausal patients with HR+/HER2– ABC previously demonstrated a significant PFS and OS benefit over fulvestrant alone[1,2]
  - Median OS in the final protocol-specified OS analysis was not reached in the ribociclib arm and was 40.0 months in the placebo arm (hazard ratio, 0.72; 95% CI, 0.57-0.92; *P* = 0.00455)[2]
- **Here we report an exploratory update of OS with longer follow-up (median follow-up, 56.3 months)**

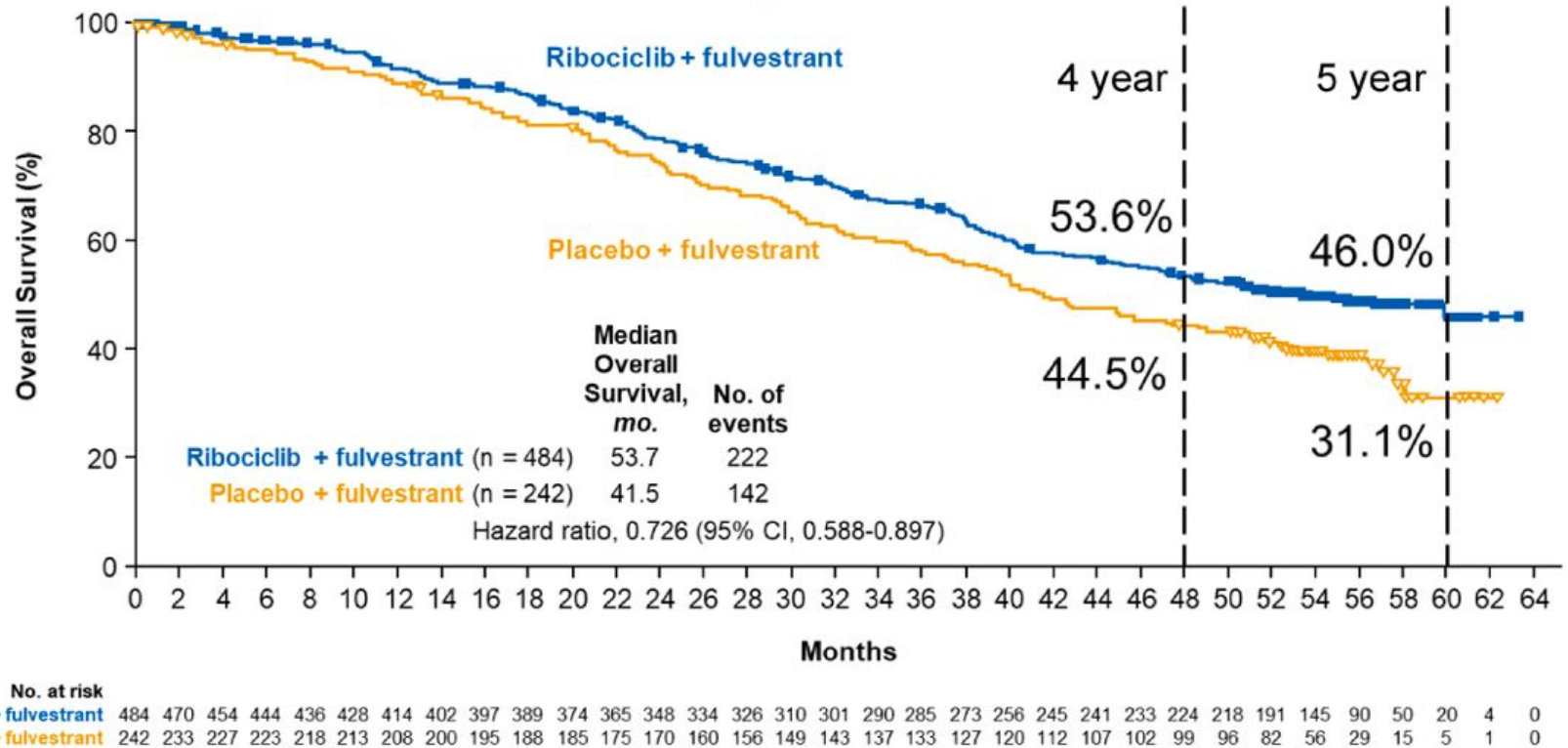
MONALEESA-3 Study Design



ABC, advanced breast cancer; CT, chemotherapy; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; OS, overall survival; PFS, progression-free survival.
[a] 600 mg/day (3 weeks on, 1 week off).
[b] 500 mg/28 days (1 additional dose on cycle 1 day 15).
1. Slamon DJ, et al. *J Clin Oncol*. 2018;24:2465-2472. 2. Slamon DJ, et al. *N Engl J Med*. 2020;382:514-524.

J Clin Oncol 39, 2021 (suppl 15; abstr 1001)

Overall Survival in the Overall Population

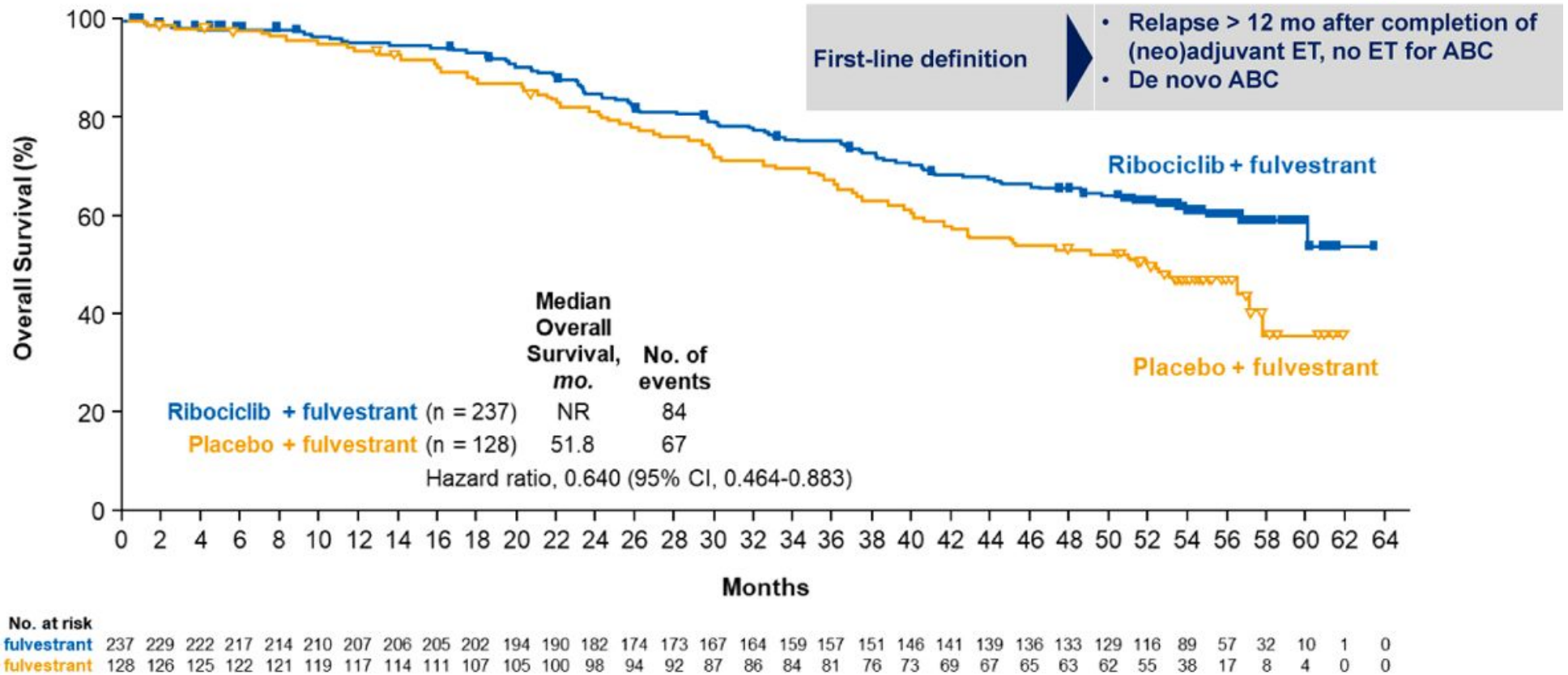


- With an extended follow-up of > 4 years, ribociclib + fulvestrant continued to demonstrate a clinically relevant > 1 year OS benefit compared with placebo + fulvestrant

Data cutoff: October 30, 2020.
OS, overall survival.

J Clin Oncol 39, 2021 (suppl 15; abstr 1001)

Overall Survival in Patients Treated in the First-line Setting

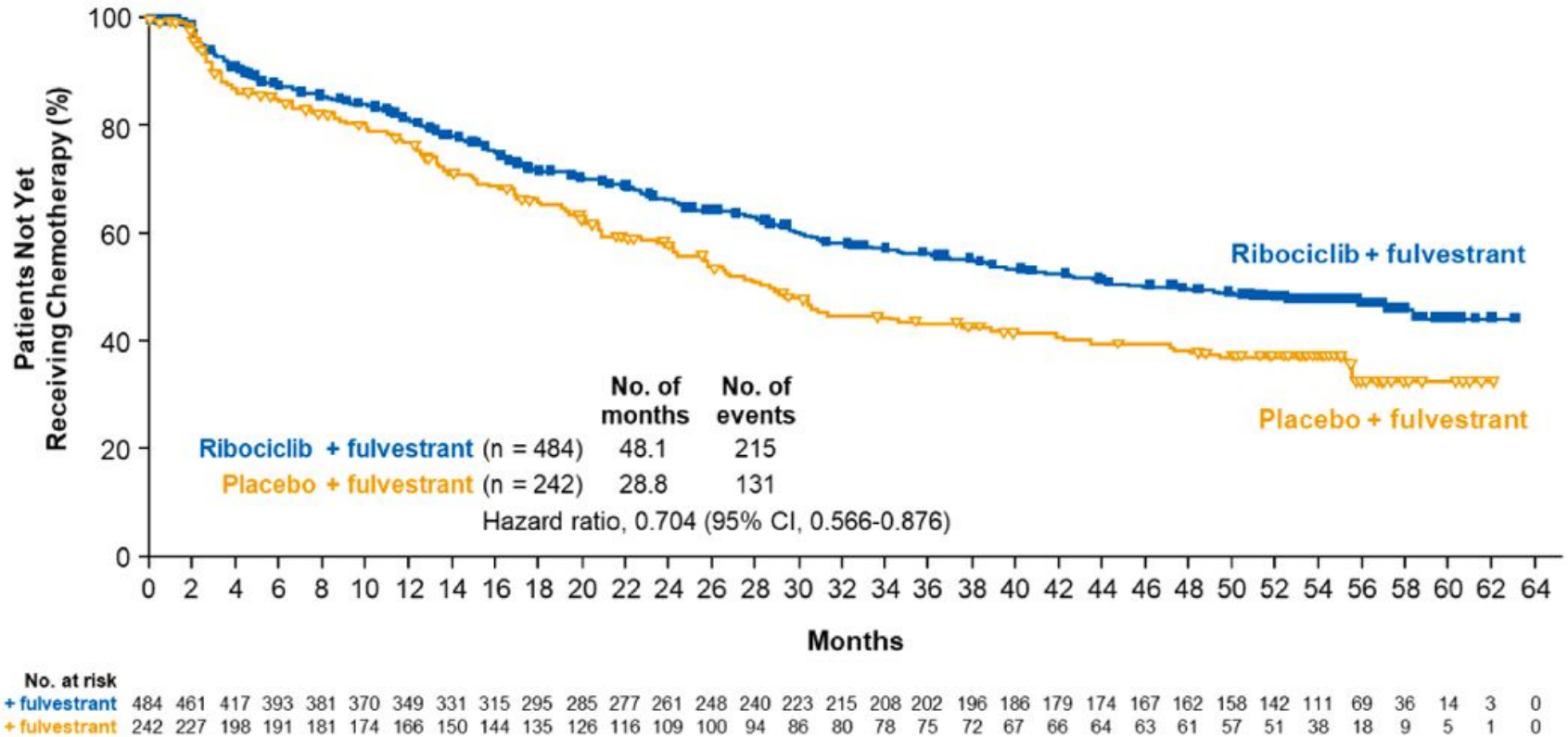


- A larger magnitude of benefit of ribociclib + fulvestrant over placebo + fulvestrant in the first-line setting was observed compared with the prior reported data cutoff for OS (HR, 0.70; 95% CI, 0.48-1.02)[1]

Data cutoff: October 30, 2020.
ET, endocrine therapy; OS, overall survival.
1. Slamon DJ, et al. *N Engl J Med*. 2020:382:514-524.

J Clin Oncol 39, 2021 (suppl 15; abstr 1001)

Time to First Chemotherapy[a]



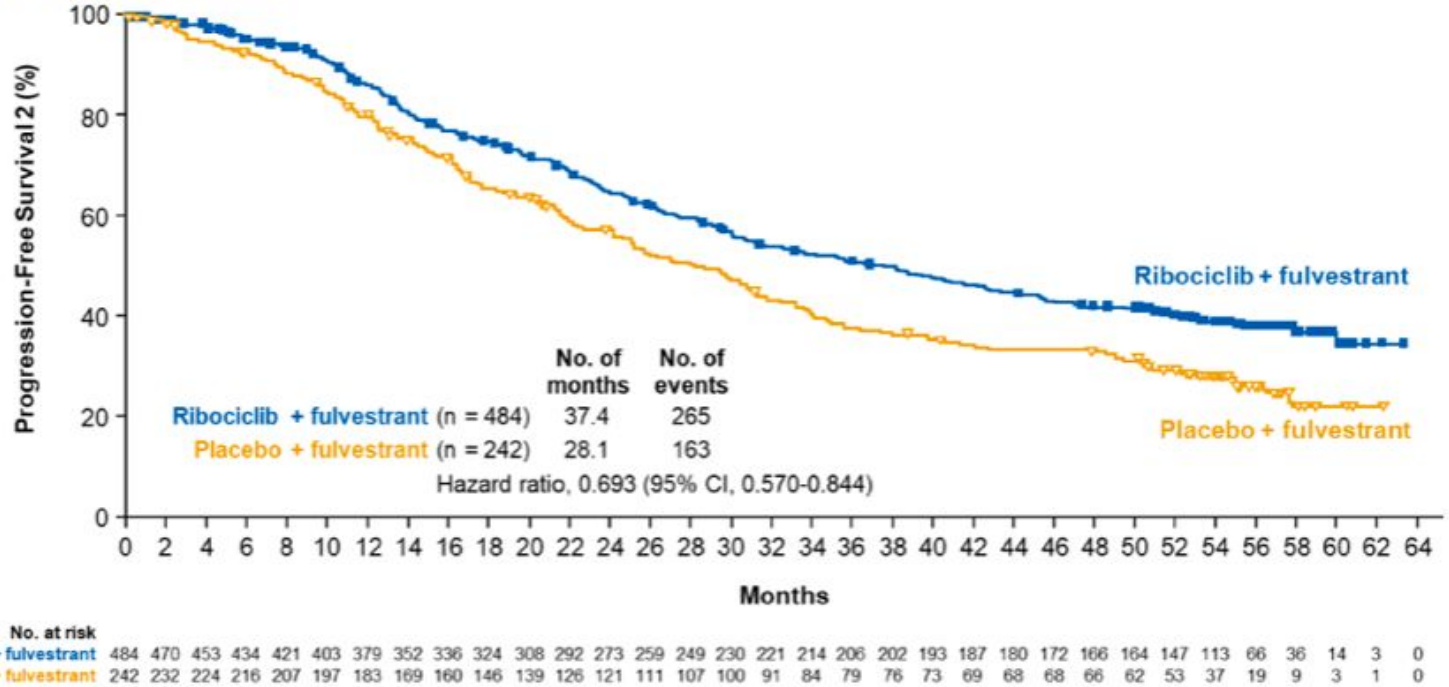
- Ribociclib + fulvestrant was associated with a nearly 20-month delay in first subsequent chemotherapy use over placebo + fulvestrant

Data cutoff: October 30, 2020.

[a] Time to first chemotherapy was defined as the time from randomization to the beginning of the first chemotherapy after discontinuation of the trial regimen, with death being censored.

J Clin Oncol 39, 2021 (suppl 15; abstr 1001)

PFS2[a] in All Patients



- A longer PFS2 was observed for patients receiving ribociclib + fulvestrant vs placebo + fulvestrant, demonstrating that patients had improved benefit beyond disease progression
- This benefit was observed regardless of treatment setting, but was especially notable in the first-line setting (HR, 0.63; 95% CI, 0.47-0.84)

Data cutoff: October 30, 2020.
PFS2, progression-free survival 2.
[a] PFS2 was defined as the time from randomization to the first documented disease progression (physician reported) while the patient was receiving subsequent antineoplastic therapy or death from any cause, whichever occurred first.

J Clin Oncol 39, 2021 (suppl 15; abstr 1001)

Záver

- Predĺžené sledovanie s mediánom 56,3 mesiaca
- Ribociklib + fulvetsrant potvrdenie benefitu v celkovom prežívaní u postmenopauzálnych pacientok HR+/HER2-ABC (OS 53,7 vs. 41,5 mesiaca - HR 0,73; 95 %CI)
- MONALEESA-3 zostáva jediná randomizovaná štúdia s inhibítormi CDK4/6 potvrdzujúca benefit v OS v 1. línii liečby
- Kombinácia ribociklib + fulvestrant oddialila následné podanie CHT a viedla k predĺženiu PFS2
- Z pohľadu bezpečnosti po 4,5 rokoch sledovania bez nových signálov

Abstrakt č.: 1000

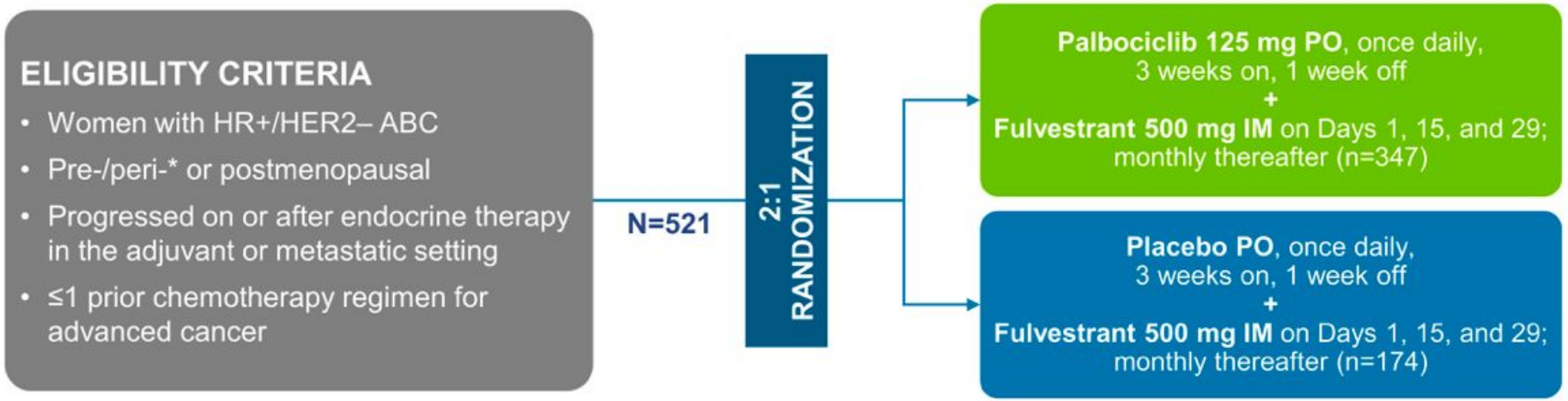
Overall survival (OS) with palbociclib (PAL) + fulvestrant (FUL) in women with hormone receptor–positive (HR+), human epidermal growth factor receptor 2–negative (HER2–) advanced breast cancer (ABC): Updated analyses from PALOMA-3.

Massimo Cristofanilli, Hope S. Rugo, Seock-Ah Im, Dennis J. Slamon, Nadia Harbeck, Igor Bondarenko, Norikazu Masuda, Marco Colleoni, Angela DeMichele, Sherene Loi, Hiroji Iwata, Ben O'Leary, Eustratios Bananis, Yuan Liu, Xin Huang, Sindy Kim, Mariajose Lechuga, Nicholas C. Turner; Robert H.

J Clin Oncol 39, 2021 (suppl 15; abstr 1000)

PALOMA-3 Study Design[1]

- PALOMA-3 was a phase 3, international, multicenter, randomized, double-blind, placebo-controlled, clinical study (NCT01942135).



- Stratification factors
  - Documented sensitivity to prior hormonal therapy
  - Menopausal status at study entry
  - Presence of visceral metastases
- Primary endpoint: investigator-assessed PFS according to RECIST version 1.1
- Secondary endpoints included ORR, OS, DOR, and safety
- ctDNA analysis was performed among patients who consented for this study.

- 34% of patients received prior chemotherapy for ABC, and 35% of patients received ≥2 prior regimens for ABC[2].
- Patients with prior chemotherapy for ABC or ≥2 prior regimens for ABC were excluded from other phase 3 CDK4/6 inhibitor plus fulvestrant trials.

ABC=advanced breast cancer; CDK4/6=cyclin-dependent kinase 4/6; ctDNA=circulating tumor DNA; DOR=duration of response; HR=hormone receptor; HER2=human epidermal growth factor receptor 2; IM=intramuscular; ORR=objective response rate; OS=overall survival; PO=oral; PFS=progression-free survival; RECIST=Response Evaluation Criteria in Solid Tumors.

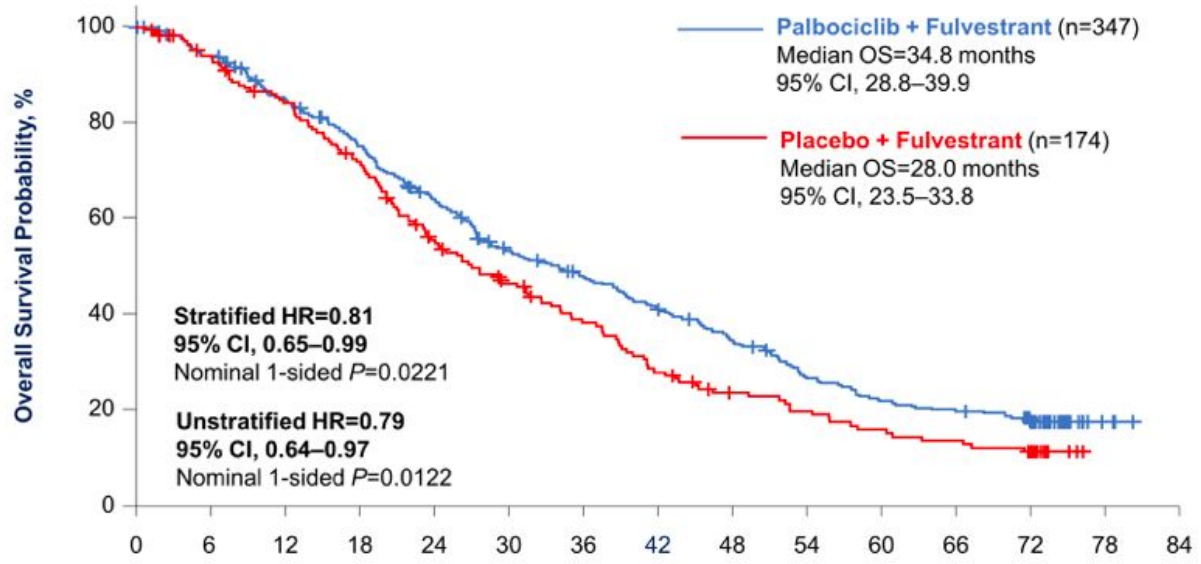
[1]Turner et al. *New Engl J Med*. 2015;373(3):209-19.

[2]Turner et al. *New Engl J Med*. 2018;379(20):1926-1936. *All received concurrent goserelin.

J Clin Oncol 39, 2021 (suppl 15; abstr 1000)

Updated Overall Survival Analysis

Median Follow-up, 73.3 Months



Number of patients at risk

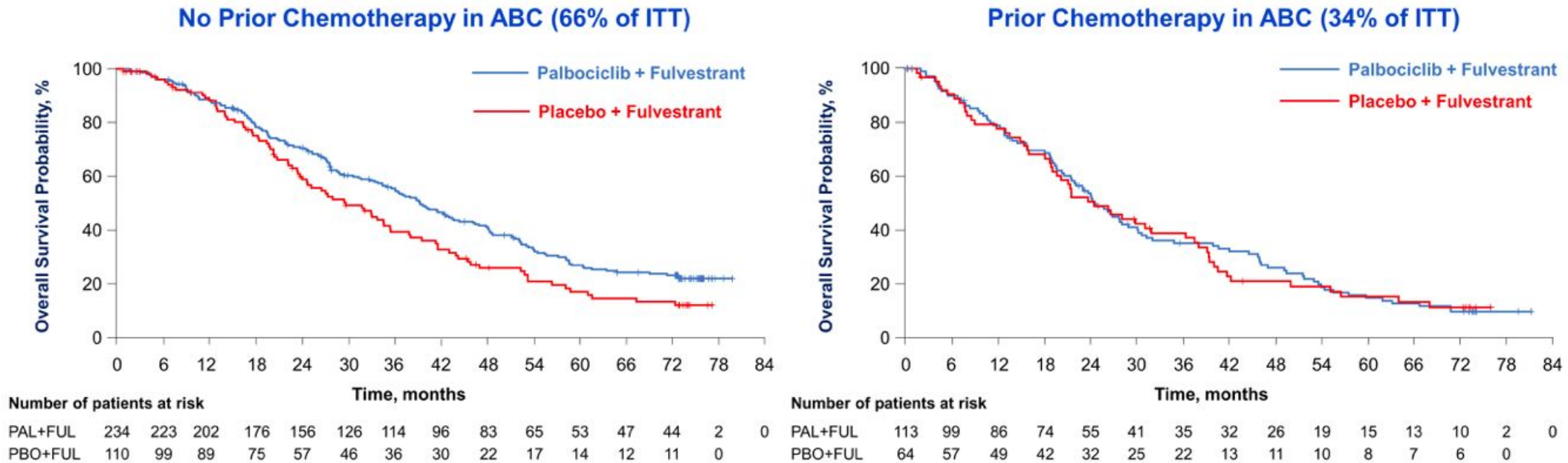
PAL+FUL	347	322	288	250	211	167	149	128	109	84	68	60	54	4	0
PBO+FUL	174	156	138	117	89	71	58	43	33	27	22	19	17	0	

- Median OS was 34.8 months in the palbociclib arm vs 28.0 months in the placebo arm.
- 5-year OS rate (95% CI): 23.3% (18.7–28.2) in the palbociclib arm; 16.8% (11.2–23.3) in the placebo arm.

FUL=fulvestrant; HR=hazard ratio; OS=overall survival; PAL=palbociclib; PBO=placebo.

J Clin Oncol 39, 2021 (suppl 15; abstr 1000)

Overall Survival in Patients With Prior Chemotherapy in ABC



	Palbociclib + Fulvestrant	Placebo + Fulvestrant	Palbociclib + Fulvestrant	Placebo + Fulvestrant
	No Prior Chemotherapy		Prior Chemotherapy	
Patients, n	234	110	113	64
Median OS (95% CI), mo	39.3 (34.5–44.4)	29.7 (23.8–35.5)	24.6 (21.3–30.0)	24.3 (18.9–36.3)
Hazard ratio (95% CI)	0.72 (0.55–0.94)		0.97 (0.69–1.36)	
Nominal P-Value	0.008		0.432	

ABC=advanced breast cancer; FUL=fulvestrant; ITT=intent-to-treat; OS=overall survival; PAL=palbociclib; PBO=placebo.

J Clin Oncol 39, 2021 (suppl 15; abstr 1000)

Záver

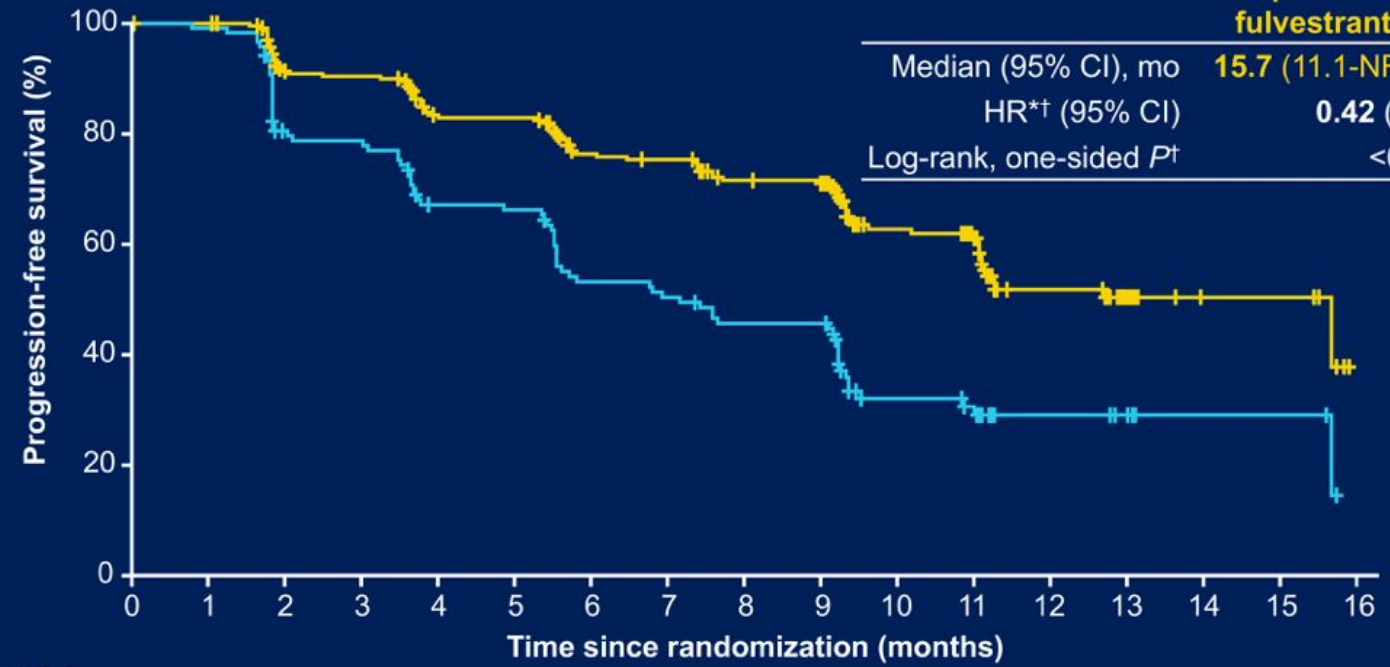
- Zlepšenie celkového prežívania pri kombinovanej liečbe palbociklib plus fulvestrant aj po 6-ročnom sledovaní (bez štat. signifikancie- sekundárny cieľ nedosiahnutý)
- Najlepšie výsledky v zmysle predĺženia OS v skupine pacientok s hormonálne senzitívnym ochorením a tých, ktoré neboli predliečené chemoterapiou pre pokročilé/metastatické ochorenie
- Benefit v celkovom prežívaní vo všetkých podskupinách-nezávisle od mutačného statusu ESR1, PIK3CA a TP53
- Všeobecne dobrá tolerancia liečby so známym profilom toxicity (leukopénia, neutropénia)
- Údaje podporujú doterajšie zistenia v prospech kombinácie palbociklib+ fulvestrant

Abstrakt Č.: 1002

Dalpiciclib versus placebo plus fulvestrant in HR+/HER2- advanced breast cancer that relapsed or progressed on previous endocrine therapy (DAWNA-1): A multicenter, randomized, phase 3 study.

Binghe Xu, Qingyuan Zhang, Pin Zhang, Xichun Hu, Wei Li, Zhongsheng Tong, Tao Sun, Yuee Teng, Xinhong Wu, Quchang Ouyang, Xi Yan, Jing Cheng, Qiang Liu, Jifeng Feng, Xiaojia Wang, Xiaoyu Zhu, Fei Wu, Xiao Zhang, Jianjun Zou
J Clin Oncol 39, 2021 (suppl 15; abstr 1002)

Primary endpoint: PFS per investigator



	Dalpiciclib + fulvestrant	Placebo + fulvestrant
Median (95% CI), mo	**15.7** (11.1-NR)	**7.2** (5.6-9.2)
HR*† (95% CI)	**0.42** (0.31-0.58)	
Log-rank, one-sided *P*†	<0.0001	

No. at risk																	
Dalpiciclib + fulvestrant	241	239	204	200	172	171	146	143	131	130	78	72	39	20	6	6	0
Placebo + fulvestrant	120	119	91	89	73	72	57	54	48	48	23	20	9	7	3	3	0

*Estimated using a stratified Cox proportional hazards model. †Analysis stratified by the randomization strata.

J Clin Oncol 39, 2021 (suppl 15; abstr 1002)

Abstrakt č.: 1004

Results from VERONICA: A randomized, phase II study of second-/third-line venetoclax (VEN) + fulvestrant (F) versus F alone in estrogen receptor (ER)-positive, HER2-negative, locally advanced, or metastatic breast cancer (LA/MBC).

Geoffrey J Lindeman, Rebecca Bowen, Katarzyna Joanna Jerzak, Xinni Song, Thomas Decker, Frances M. Boyle, Steven L. McCune, Anne Armstrong, Catherine M. Shannon, Gianfilippo Bertelli, Tharu M Fernando, Rupal Desai, Kushagra Gupta, Jerry Y. Hsu, Aulde Flechais, Aditya Bardia

J Clin Oncol 39, 2021 (suppl 15; abstr 1004)

VERONICA (NCT03584009): Methods and study design

Primary analysis:*
Aug 5, 2020
Updated OS analysis:
Apr, 2021

A Phase II study of venetoclax + fulvestrant vs. fulvestrant alone in ER+/HER2–, post-CDK4/6i therapy LA/MBC

- Females (≥18 yrs)
- ER+/HER2– LA/MBC
- ≤2 prior lines in the LA/MBC setting without chemotherapy
- Prior-CDK4/6i therapy (≥8 wks)
- Measurable disease only

R 1:1

Stratified

n = 51
Venetoclax
Oral; 800 mg daily
+
Fulvestrant
IM; 500 mg D1/15 of C1; D1 of subsequent 28-D cycles

n = 52
Fulvestrant
IM; 500 mg D1/15 of C1; D1 of subsequent 28-D cycles

Until disease progression, unacceptable toxicity, withdrawal of consent, death, or predefined study end

Long-term FU

Stratification factors
- 1L vs. 2L of prior therapy in the LA/MBC setting
- BCL2 status (high vs. low)

Primary efficacy endpoint
CBR† (CR, PR, SD ≥24 wks)

Secondary endpoints
PFS / OS / ORR (CR/PR) / DOR

Other endpoints
Safety and tolerability
Biomarker analysis / PK / PROs

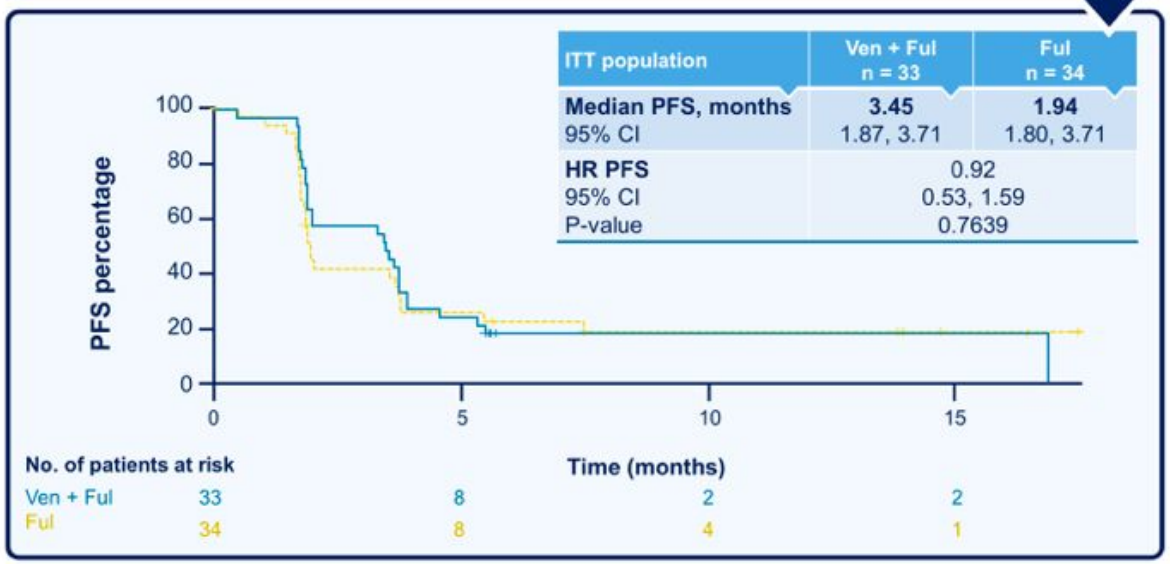
* The primary analysis was conducted when all patients had discontinued study treatment, or 6 months after the last patient had been enrolled, whichever occurred first. † Subgroup analysis in BCL2-high and -low tumors. 1L, first-line; 2L, second-line; BCL2, B-cell lymphoma 2; CBR, clinical benefit rate; CDK4/6(i), cyclin-dependent kinase 4/6 (inhibitors); CR, complete response; CX, Cycle X; DX, Day X; DOR, duration of response; ER, oestrogen receptor; FU, follow-up; IM, intramuscular; LA, locally advanced; MBC, metastatic breast cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; PR, partial response; PROs, patient-reported outcomes; SD, stable disease; wks, weeks; yrs, years.

J Clin Oncol 39, 2021 (suppl 15; abstr 1004)

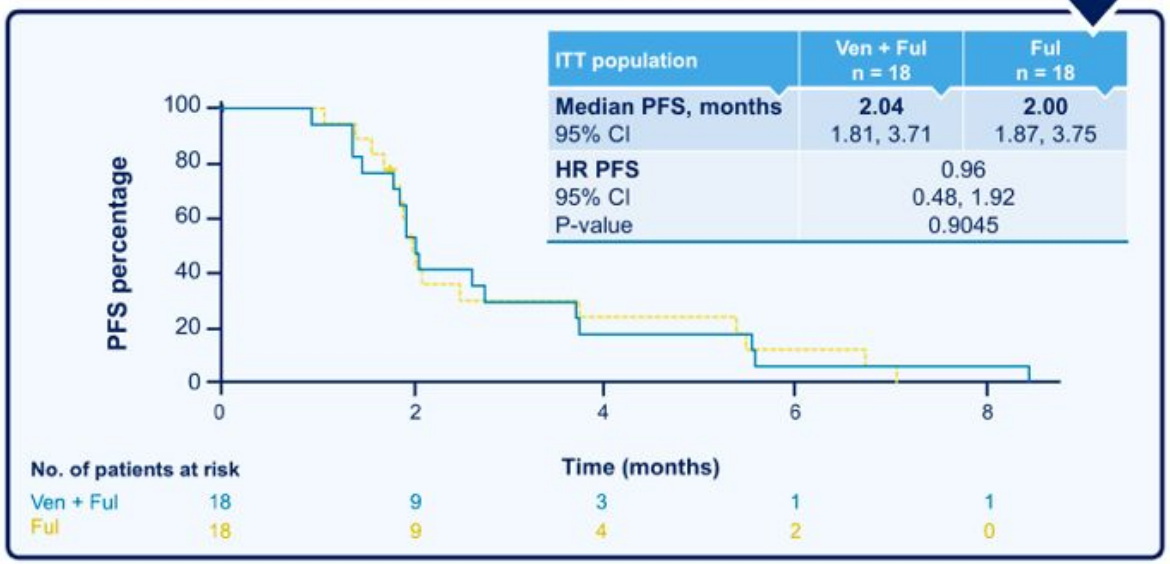
BCL2 subgroups had similar CBR and PFS*

	BCL2-high tumors		BCL2-low tumors	
Baseline measurable disease	**Ven + Ful (n = 33)**	**Ful (n = 33)**	**Ven + Ful (n = 18)**	**Ful (n = 18)**
CBR, n (%)	6 (18.2)	6 (18.2)	0	1 (5.6)
Risk difference, % 95% CI	0 –21.64, 21.64		–5.56 –21.69, 10.58	

PFS: BCL2-high



PFS: BCL2-low



* BCL2 clinical status was determined as "High" if ≥50% of tumor cells expressed BCL2 at 2+ or 3+ staining intensity by immunohistochemistry. Note: 62% of tissue specimens were archival, collected >1 year prior to study start.
BCL2, B-cell lymphoma 2; CBR, clinical benefit rate; CI, confidence interval; Ful, fulvestrant; HR, hazard ratio; ITT, intention-to-treat; PFS, progression-free survival; Ven, venetoclax.

J Clin Oncol 39, 2021 (suppl 15; abstr 1004)

Abstrakt č.: 1054

Long-term (LT) disease control in patients (pts) with hormone receptor-positive (HR+), *PIK3CA*-altered advanced breast cancer (ABC) treated with alpelisib (ALP) + fulvestrant (FUL).

Dejan Juric, Fabrice Andre, Udaiveer Panwar, Filip Janku, Yen-Shen Lu, Howard A. Burris III, Josefina Cruz Jurado, Zsuzsanna Papai, Salomon M. Stemmer, Josep Tabernero, Johan Ahlgren, Marianne Leheurteur, Ines Lorenzo, Dragana Jankovic, Cornelia Quadt, Huilin Hu, Xueying Chen, Hope S. Rugo

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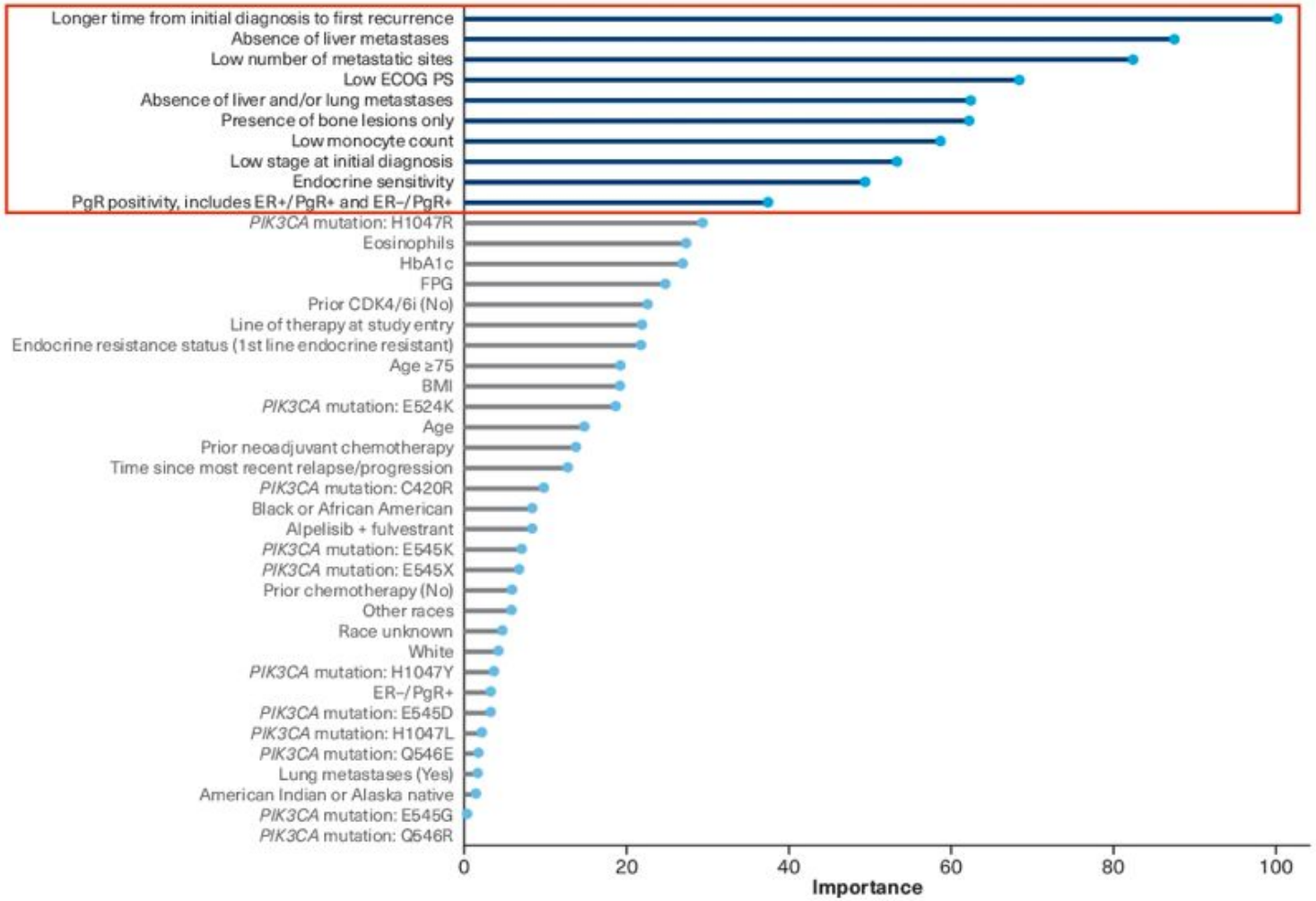
Figure 1. Top baseline predictors of long-term disease control



Analysis of the direction of the predictor effect was only performed for the top 10 variables.
BMI, body mass index; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; ECOG PS, Eastern Cooperative Oncology Group performance status; ER, estrogen receptor; FPG, fasting plasma glucose; HbA1c, hemoglobin A1c; PgR, progesterone receptor; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha

J Clin Oncol 39, 2021 (suppl 15; abstr 1054)

Metastatický karcinóm prsníka ASCO © 2021

Trojito negatívny karcinóm prsníka

Abstrakt Č.: 1007

Combination of famitinib with camrelizumab plus nab-paclitaxel as first-line treatment for patients with immunomodulatory advanced triple-negative breast cancer (FUTURE-C-PLUS): A prospective, single-arm, phase 2 study.

Li Chen, Shao Zhimin, Zhonghua Wang, Wentao Yang, Yizhou Jiang, Jianjun Zou, Jiong Wu, Genhong Di, Guangyu Liu, Keda Yu, Lei Fan, Junjie Li, Yifeng Hou, Zhen Hu, Canming Chen, Xiaoyan Huang, Ayong Cao, Xin Hu, Songyang Wu, Shen Zhao

J Clin Oncol 39, 2021 (suppl 15; abstr 1007)

Results Primary Endpoint: ORR

Efficacy: The ORR is 81.3%, which is the highest ORR in first-line treatment for mTNBC at present

Antitumor Activity	ITT (n=48)	PP (n=46)[Δ]
Objective response (ORR) — no. (%)	**39 (81.3)**	**39 (84.8)**
95% CI	70.2-92.3	74.4-95.2
Best overall response — no. (%)		
Complete response (CR)	5 (10.4)	5 (10.9)
Partial response (PR)	34 (70.8)	34 (73.9)
Stable disease (SD)	5 (10.4)	5 (10.9)
Disease progression (PD)	2 (4.2)	2 (4.3)

[Δ]Two patients without post-baseline efficacy assessments were excluded

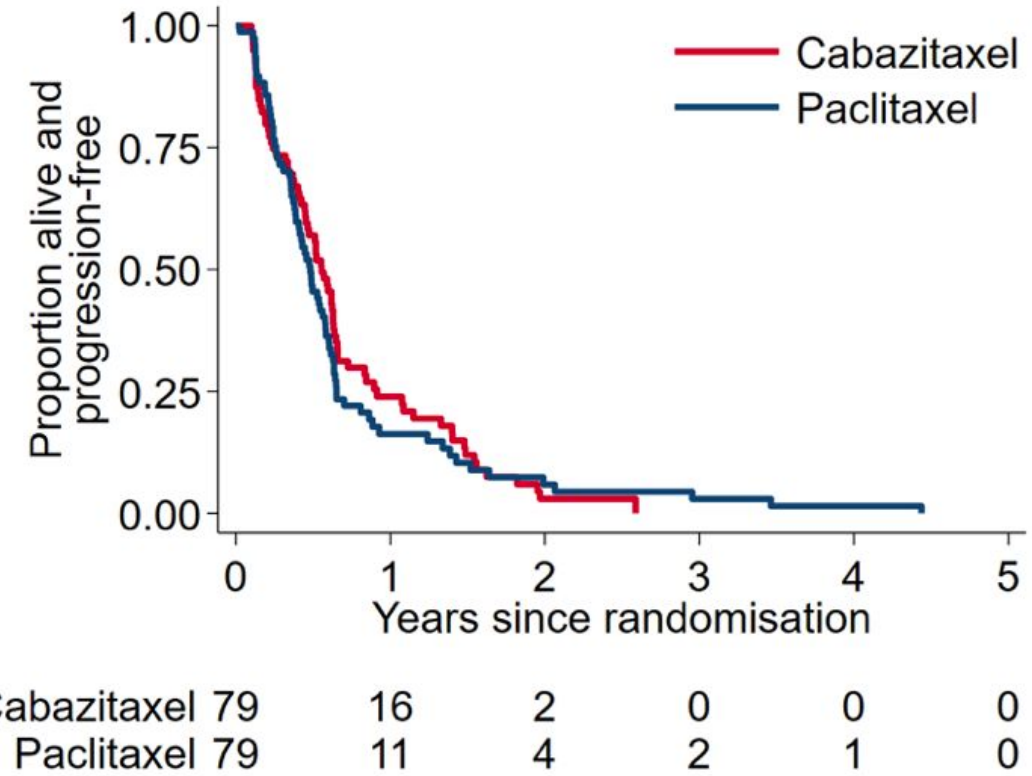
J Clin Oncol 39, 2021 (suppl 15; abstr 1007)

Abstrakt Č.: 1008

Randomized multicenter trial of 3 weekly cabazitaxel versus weekly paclitaxel chemotherapy in the first-line treatment of HER2 negative metastatic breast cancer (MBC).

Leisha A. Emens, Leonard D Goldstein, Peter Schmid, Hope S. Rugo, Sylvia Adams, Carlos H. Barrios, Andreas Schneeweiss, Veronique Dieras, Hiroji Iwata, Ching-Wei Chang, Hartmut Koeppen, Stephen Y. Chui, Sherene Loi, Luciana Molinero
J Clin Oncol 39, 2021 (suppl 15; abstr 1008)

Primary Analysis: PFS



At the time of analysis there had been 149 PFS events

- **Median PFS 6.7 months (95% CI 5.4 – 7.6) in the Cabazitaxel arm vs. median PFS 5.8 months in the Paclitaxel arm (95% CI 4.6 – 6.9)**
- **HR 0.87 (80% CI 0.70 – 1.08, P=0.4)**

Three weekly Cabazitaxel does not significantly improve PFS compared to weekly paclitaxel

J Clin Oncol 39, 2021 (suppl 15; abstr 1008)

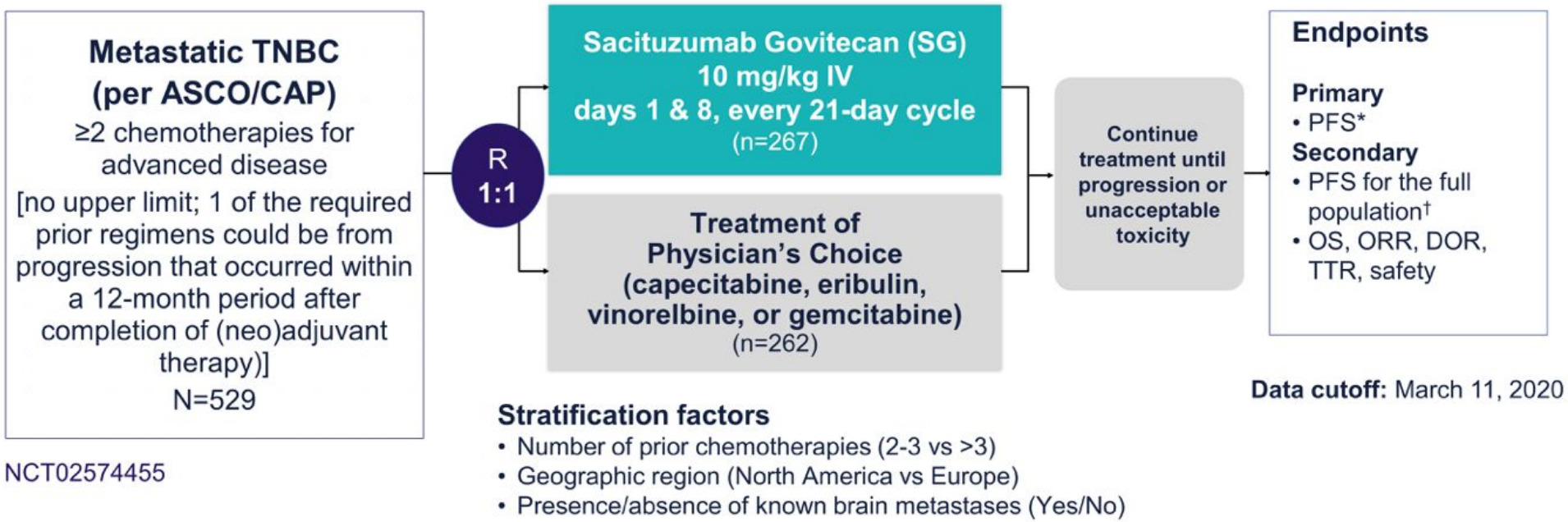
Abstrakt č.: 1011

Outcomes in patients (pts) aged ≥65 years in the phase 3 ASCENT study of sacituzumab govitecan (SG) in metastatic triple-negative breast cancer (mTNBC).

Kevin Kalinsky, Mafalda Oliveira, Tiffany A. Traina, Sara M. Tolaney, Delphine Loirat, Kevin Punie, Sara A. Hurvitz, Filipa Lynce, Erika P. Hamilton, Rita Nanda, Lowell L. Hart, Paul D. Richards, Zulfiqar A. Malik, Hope S. Rugo, Veronique Dieras, Aditya Bardia, Quan Hong, Martin Sebastian Olivo, Loretta Itri, Sibylle Loibl

J Clin Oncol 39, 2021 (suppl 15; abstr 1011)

ASCENT: A Phase 3 Confirmatory Study of Sacituzumab Govitecan in Refractory/Relapsed mTNBC

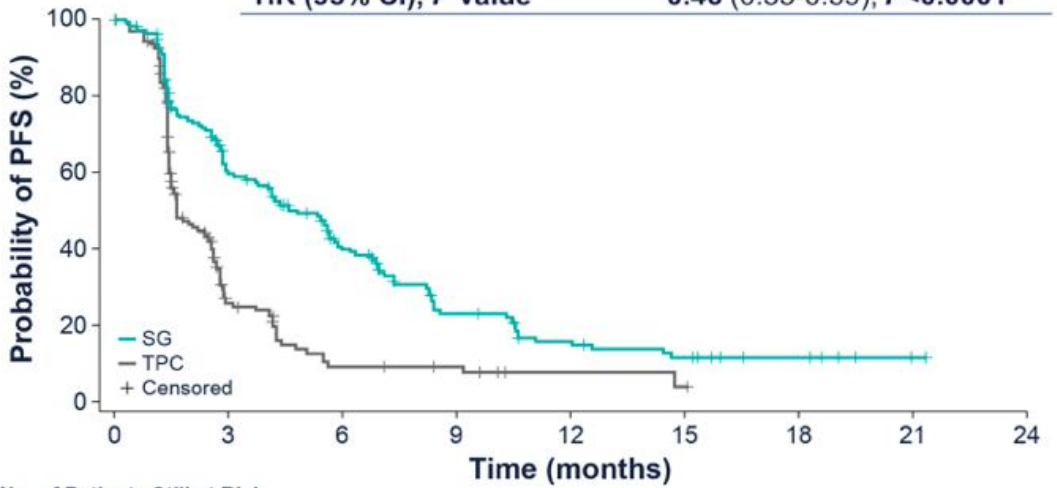


Adapted from *The New England Journal of Medicine*. Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab govitecan in metastatic triple-negative breast cancer. Vol. 384, pp 1529-1541. Copyright ©2021 Massachusetts Medical Society. Reused with permission from Massachusetts Medical Society.
*PFS measured by an independent, centralized, and blinded group of radiology experts who assessed tumor response using RECIST 1.1 criteria in patients without brain metastasis.
†The full population includes all randomized patients (with and without brain metastases). Baseline brain MRI only required for patients with known brain metastasis.
ASCO/CAP, American Society of Clinical Oncology/College of American Pathologists; DOR, duration of response; DSMC, Data Safety Monitoring Committee; IV, intravenous; mTNBC, metastatic triple-negative breast cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R, randomization; RECIST 1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; TTR, time to response.
National Institutes of Health. https://clinicaltrials.gov/ct2/show/NCT02574455.

J Clin Oncol 39, 2021 (suppl 15; abstr 1011)

Survival Outcomes: Progression-Free Survival

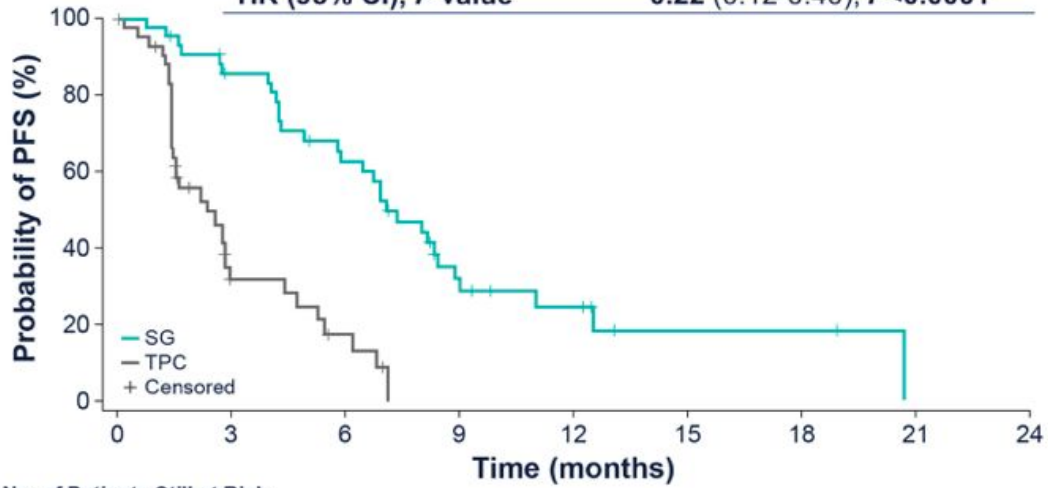
PFS BICR Analysis	<65 y SG (n=191)	<65 y TPC (n=187)
No. of events	136	117
Median PFS—mo (95% CI)	4.6 (3.7-5.7)	1.7 (1.5-2.5)
HR (95% CI), *P* value	**0.46** (0.35-0.59), ***P*<0.0001**	



No. of Patients Still at Risk

SG	191	179	128	100	94	77	57	43	37	27	26	17	16	13	13	11	7	6	6	4	2	1	0
TPC	187	140	59	26	23	12	8	8	7	6	4	2	2	2	2	1	0	0	0	0	0	0	0

PFS BICR Analysis	≥65 y SG (n=44)	≥65 y TPC (n=46)
No. of events	30	33
Median PFS—mo (95% CI)	7.1 (5.8-8.9)	2.4 (1.4-2.9)
HR (95% CI), *P* value	**0.22** (0.12-0.40), ***P*<0.0001**	



No. of Patients Still at Risk

SG	44	43	38	34	33	27	24	20	17	10	7	7	6	3	2	2	2	2	1	1	0	
TPC	46	39	19	9	9	7	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	

- In patients aged ≥65 years, improvement in median PFS with SG vs TPC treatment was comparable with that of the overall population (5.6 vs 1.7 months)[1]

Assessed by independent central review in the brain metastasis-negative population.
BICR, blind independent central review; PFS, progression-free survival; SG, sacituzumab govitecan; TPC, treatment of physician's choice.
1. Bardia A, et al. *N Engl J Med.* 2021;384:1529-1541.

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Responses

	BMNeg Population (n=468)			
	<65 y		≥65 y	
	SG (n=191)	TPC (n=187)	SG (n=44)	TPC (n=46)
ORR—no. (%)	60 (31)	11 (6)	22 (50)	0
CR	7 (4)	2 (1)	3 (7)	0
PR	53 (28)	9 (5)	19 (43)	0
CBR*—no. (%)	78 (41)	16 (9)	27 (61)	4 (9)
Median DOR—mo. (95% CI)	5.8 (5.4-7.9)	3.6 (2.8-NE)	7.1 (4.4-12.3)	NE

- In patients aged ≥75 years, 2 of 7 patients in the SG arm achieved a PR as best response, whereas none of the 11 patients in the TPC arm achieved a PR

Assessed by independent central review in the brain metastasis-negative population.
*CBR is defined as the percentage of patients with a confirmed best overall response of CR or PR and SD ≥6 months.
BMNeg, brain metastases-negative breast cancer; CBR, clinical benefit rate; CR, complete response; DOR, duration of response; NE, not evaluable; ORR, objective response rate; PR, partial response; SG, sacituzumab govitecan; TPC, treatment of physician's choice.

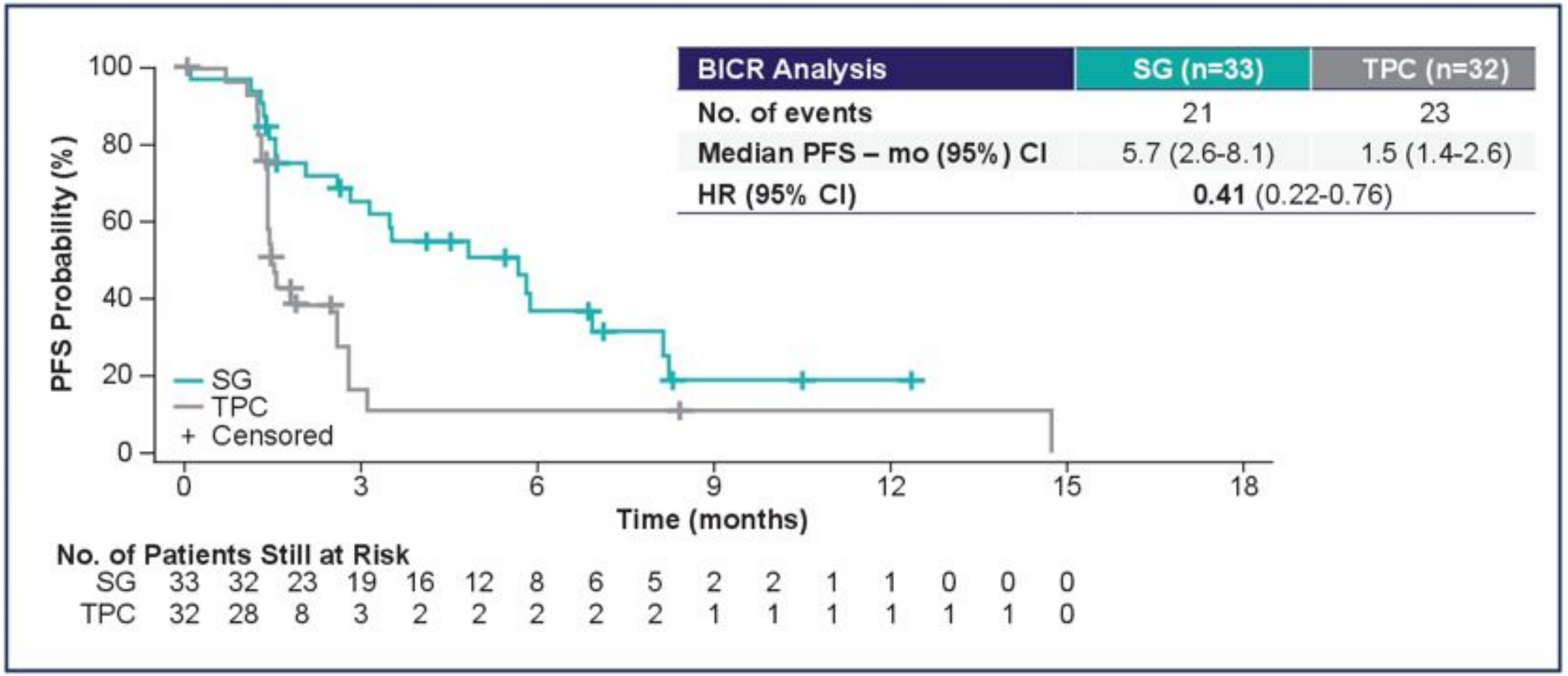
J Clin Oncol 39, 2021 (suppl 15; abstr 1011)

Abstrakt Č.: 1080

Assessment of sacituzumab govitecan (SG) in patients with prior neoadjuvant/adjuvant chemotherapy in the phase 3 ASCENT study in metastatic triple-negative breast cancer (mTNBC).

Lisa A. Carey, Delphine Loirat, Kevin Punie, Aditya Bardia, Veronique Dieras, Florence Dalenc, Jennifer Robinson Diamond, Christel Fontaine, Grace Wang, Hope S. Rugo, Sara A. Hurvitz, Kevin Kalinsky, Joyce O'Shaughnessy, Sibylle Loibl, Luca Gianni, Martine J. Piccart-Gebhart, Quan Hong, Martin Sebastian Olivo, Loretta Itri, Javier Cortes
J Clin Oncol 39, 2021 (suppl 15; abstr 1080)

Figure 3. Progression-Free Survival



BICR Analysis	SG (n=33)	TPC (n=32)
No. of events	21	23
Median PFS – mo (95%) CI	5.7 (2.6-8.1)	1.5 (1.4-2.6)
HR (95% CI)	**0.41** (0.22-0.76)	

Assessed by independent central review in the brain metastasis-negative population who recurred ≤12 months after (neo)adjuvant chemotherapy and received 1 line of therapy in the metastatic setting, prior to study enrollment.
BICR, blind independent central review; PFS, progression-free survival; SG, sacituzumab govitecan; TPC, treatment of physician's choice.

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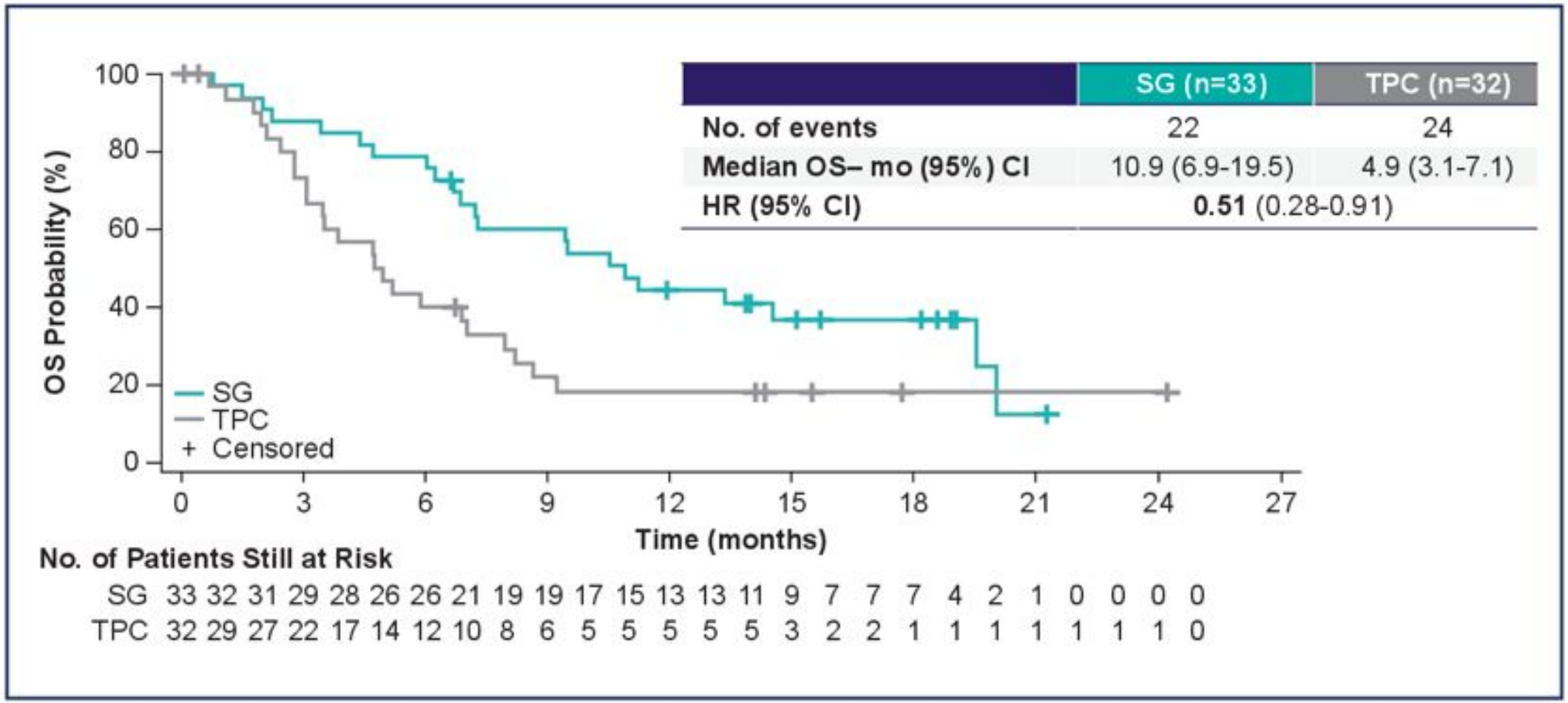
Figure 4. Overall Survival



Assessed in the brain metastasis-negative population who recurred ≤12 months after (neo)adjuvant chemotherapy and received 1 line of therapy in the metastatic setting, prior to study enrollment.
OS, overall survival; SG, sacituzumab govitecan; TPC, treatment of physician's choice.

J Clin Oncol 39, 2021 (suppl 15; abstr 1080)

Ďakujem pekne za pozornosť

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