Sessione BREAST

Nuove prospettive ABC

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Disclosures

Scientific advisory board, meeting, congress:

- ✓Novartis
- ✓Roche
- ✓Pfizer
- ✓Pierre Fabre
- ✓Eisai
- ✓Amgen

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27 SEPT – 1 OCT 2019

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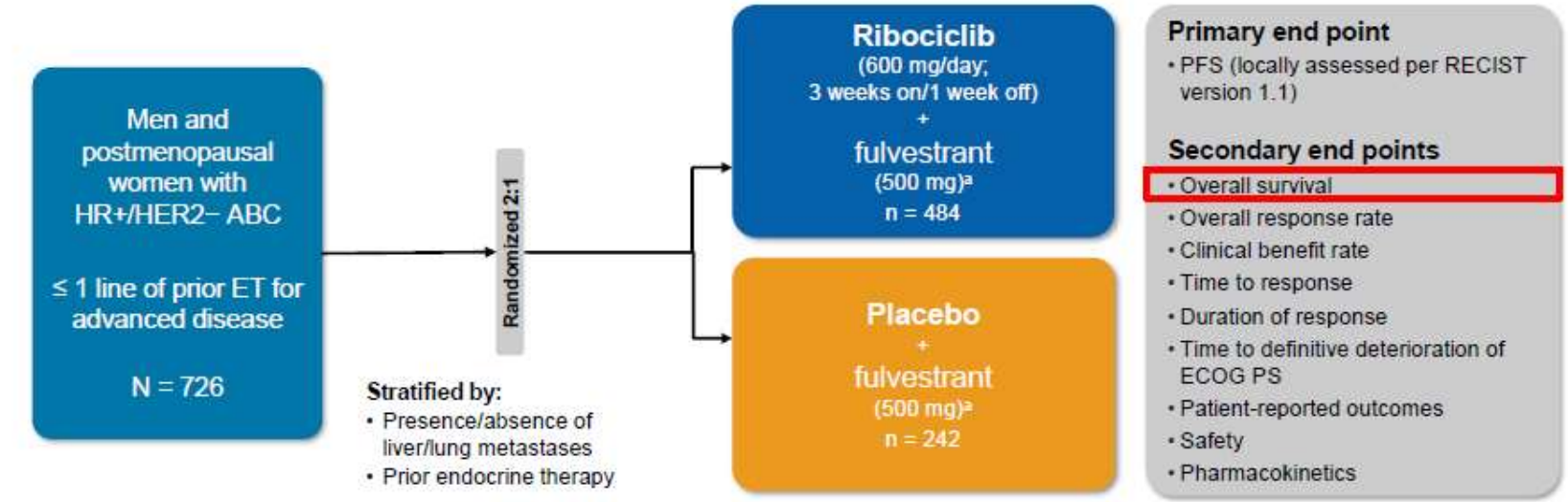
OUTLINE

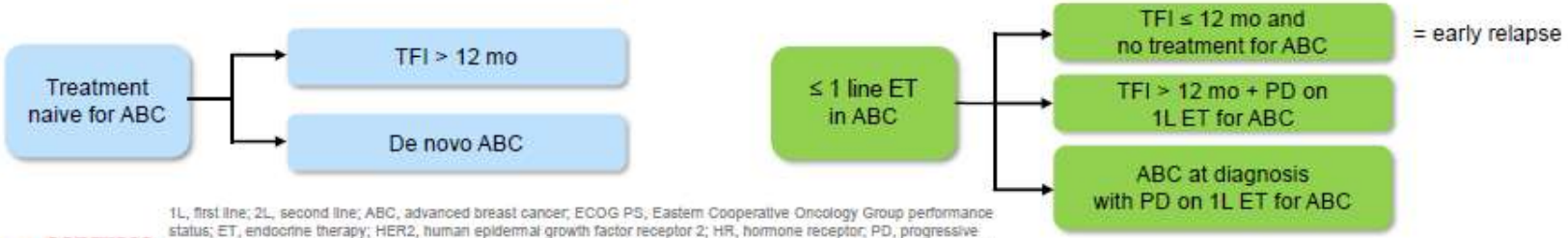
- ✓Monaleesa 3 & Monarch 2
- ✓BROCADE 3
- ✓Keynote-119

MONALEESA 3

MONALEESA-3 Study Design



Patient population definitions



1L, first line; 2L, second line; ABC, advanced breast cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; ET, endocrine therapy; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; PD, progressive disease; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; TFI, treatment-free interval.
[a] Fulvestrant 500 mg intramuscularly every 28 days plus an additional dose on Cycle 1, Day 15.
Slamon DJ, et al. *J Clin Oncol*. 2018;36:2465-247.

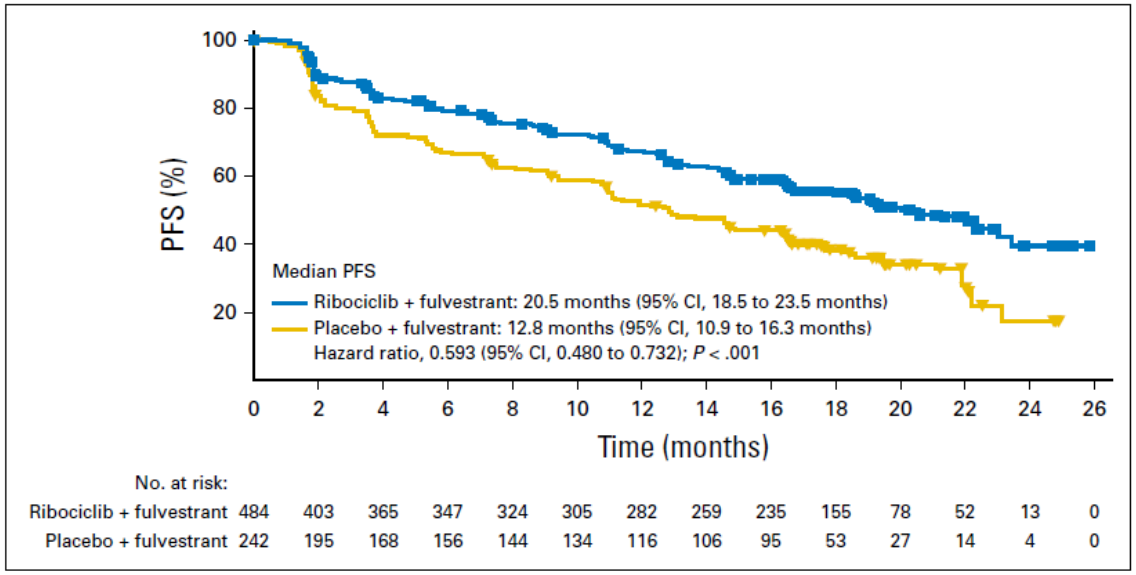
Slamon, ESMO 2019

RIBOCICLIB I-II line: Monaleesa 3

726 pts ER+ HER2- I line ~50%

Prior endocrine therapy setting		
(Neo)adjuvant	289 (59.7)	142 (58.7)
Advanced	110 (22.7)	40 (16.5)

Cut-off 12 mos



PFS 20.5 months vs 12.8 months

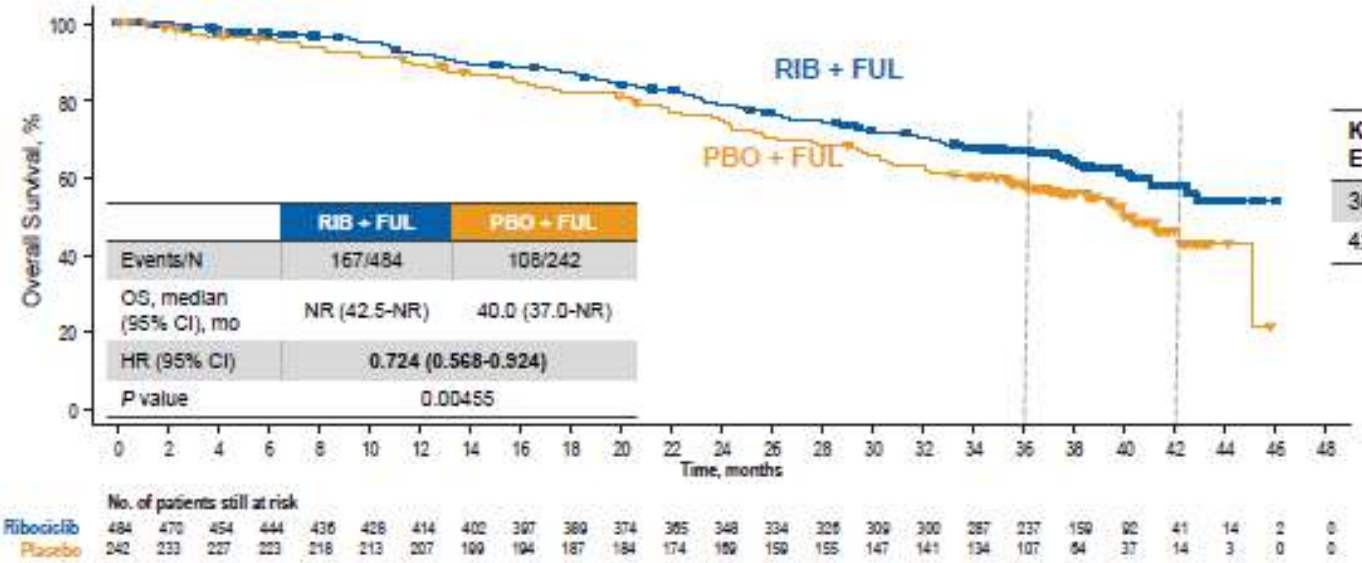
HR 0.59

Slamon, JCO2018

MONALEESA 3

Overall Survival

The reduction in relative risk of death with RIB was 28%



	RIB + FUL	PBO + FUL
Events/N	167/484	108/242
OS, median (95% CI), mo	NR (42.5-NR)	40.0 (37.0-NR)
HR (95% CI)	0.724 (0.568-0.924)	
P value	0.00455	

Landmark Analysis

KM Estimate	RIB + FUL	PBO + FUL
36 months	67.0%	58.2%
42 months	57.8%	45.9%

- The *P* value of 0.00455 crossed the prespecified boundary to claim superior efficacy (*P* <0.01129)

FUL, fulvestrant; HR, hazard ratio; KM, Kaplan-Meier; NR, not reached; OS, overall survival; PBO, placebo; RIB, ribociclib

Slamon, ESMO 2019

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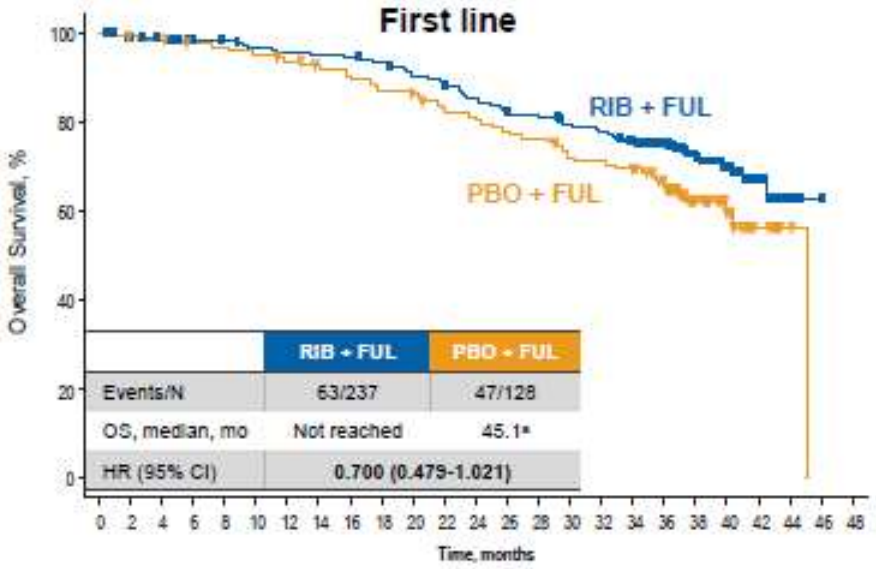
MONALEESA 3

Overall Survival by Line of Therapy

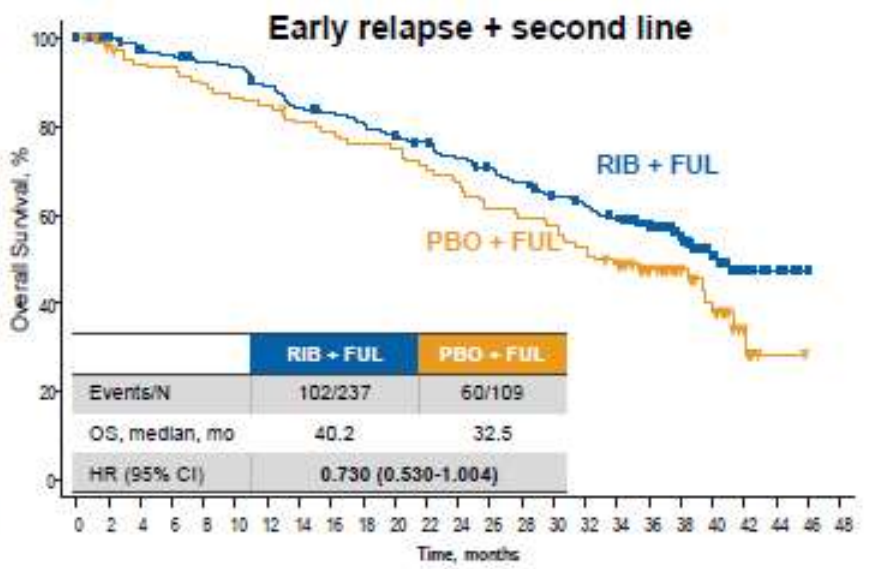
OS by line of therapy was consistent with overall population



	RIB + FUL	PBO + FUL
Events/N	63/237	47/128
OS, median, mo	Not reached	45.1*
HR (95% CI)	0.700 (0.479-1.021)	

No. of patients still at risk

Ribociclib	237	229	222	217	214	210	207	206	205	202	194	190	182	174	173	166	163	157	138	92	54	22	6	1	0
Placebo	128	126	120	122	121	119	116	113	110	106	104	99	97	93	91	85	84	82	70	40	21	8	2	0	0



	RIB + FUL	PBO + FUL
Events/N	102/237	60/109
OS, median, mo	40.2	32.5
HR (95% CI)	0.730 (0.530-1.004)	

No. of patients still at risk

Ribociclib	237	231	222	218	213	210	199	188	184	179	172	167	158	152	145	135	129	122	94	63	36	17	7	1	0
Placebo	109	103	98	97	93	90	88	83	81	78	77	72	69	63	61	59	54	49	35	23	15	6	1	0	0

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FUL, fulvestrant; HR, hazard ratio; OS, overall survival; PBO, placebo; RIB, ribociclib.

* This median value may not be estimated reliably due to the last patient on follow-up, who had an event at 45.1 months.

Slamon, ESMO 2019

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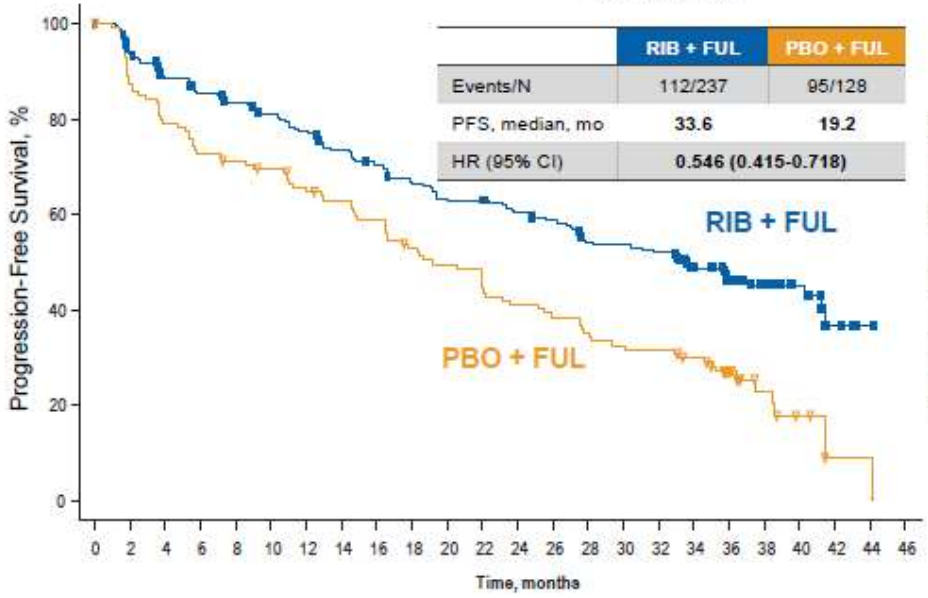
MONALEESA 3

Progression-Free Survival by Line of Therapy

Median PFS for RIB + FUL is now reached in first line (33.6 months)

First line

	RIB + FUL	PBO + FUL
Events/N	112/237	95/128
PFS, median, mo	33.6	19.2
HR (95% CI)	0.546 (0.415-0.718)	

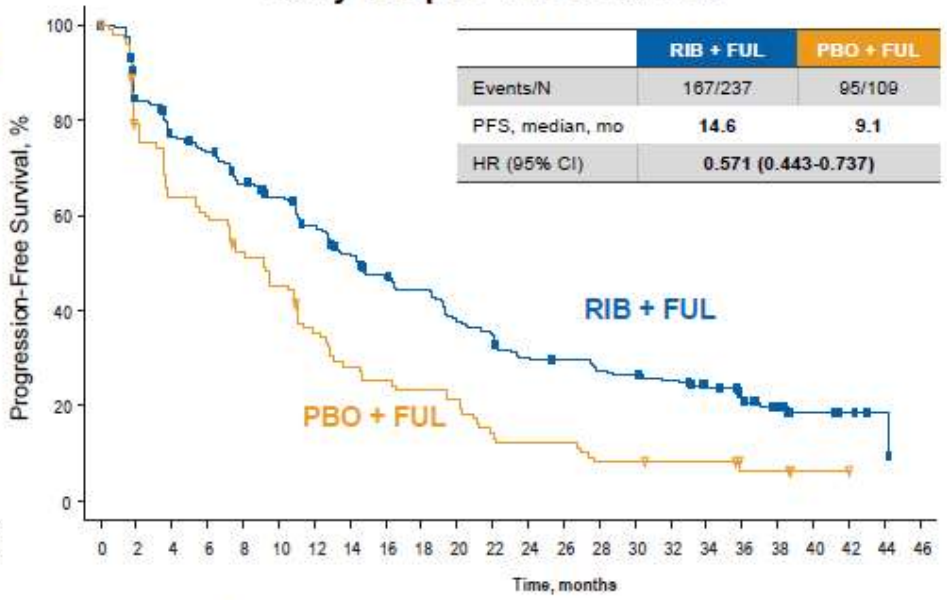


No. of patients still at risk

Ribociclib	237	204	187	178	171	164	157	147	140	132	125	123	117	113	102	101	98	84	63	44	20	7	2	0
Placebo	128	109	99	91	88	85	78	75	70	62	58	52	48	45	41	38	37	33	17	9	5	1	1	0

Early relapse + second line

	RIB + FUL	PBO + FUL
Events/N	167/237	95/109
PFS, median, mo	14.6	9.1
HR (95% CI)	0.571 (0.443-0.737)	



No. of patients still at risk

Ribociclib	237	189	168	160	144	134	119	105	93	87	74	69	58	56	52	50	47	41	27	19	9	4	2	0
Placebo	109	82	66	62	53	46	35	28	25	23	21	14	12	12	8	8	7	7	3	3	1	1	0	0

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FUL, fulvestrant; HR, hazard ratio; PBO, placebo; PFS, progression-free survival; RIB, ribociclib.

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MONARCH 2

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STUDY DESIGN

- HR+, HER2- ABC
- Pre/peri-[a] or postmenopausal
- ET resistant:
  - Relapsed on neoadjuvant or on/within 1 yr of adjuvant ET
  - Progressed on first-line ET for ABC
- No chemo for ABC
- No more than 1 ET for ABC
- ECOG PS ≤ 1

N=669

2:1 Randomization

abemaciclib (n=446): 150 mg[b] BID (continuous schedule)
fulvestrant: 500 mg[c]

placebo (n=223): BID (continuous schedule)
fulvestrant: 500 mg[c]

Primary endpoint:
Investigator-assessed PFS

Secondary endpoint:
Overall survival

Exploratory analysis:
Time to chemotherapy (TTC)

Stratification factors:
- Metastatic site (visceral, bone only, or other)
- ET resistance (primary or secondary)[7,8]

- Data cut-off: 20 June 2019
- Median follow-up: 47.7 months
  - 17% patients (abemaciclib arm) vs 4% (placebo arm) remained on treatment

[a]Required to receive GnRH agonist
[b]Dose reduced by protocol amendment in all new and ongoing patients from 200 mg to 150 mg BID after 178 patients enrolled
[c]Fulvestrant administered per label
Abbreviations: N, number of patients in population; n, number of patients

[7]Cardoso et al. *Breast.* 2017;35:203-217; [8]Cardoso et al. *Ann Oncol.* 2017;28(12):3111

Sledge, ESMO 2019

ABEMACICLIB I & II line: Monarch 2

669 pts ER+ HER2-
17% PREMENOPAUSAL

Primary resistence 25%

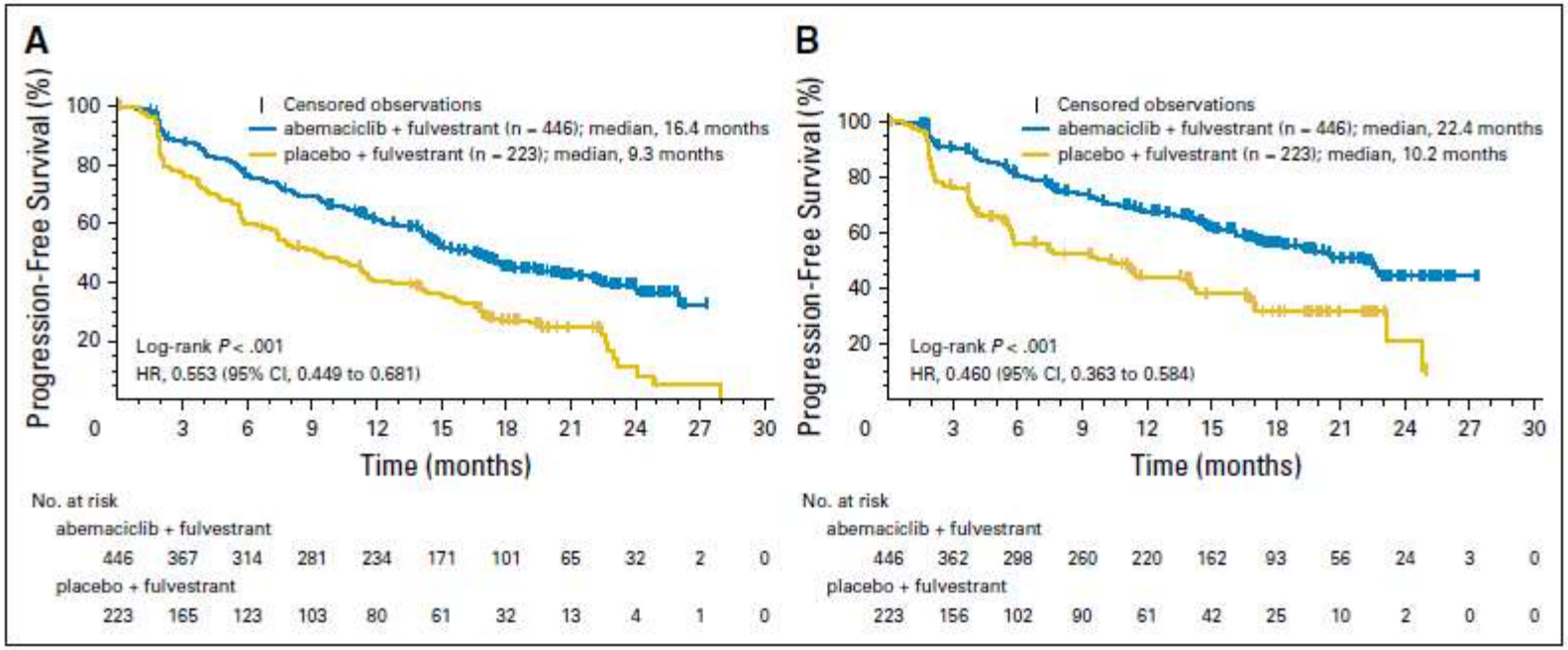

Fig 2. Kaplan-Meier plots of progression-free survival. (A) Investigator-assessed and (B) independent central review of intent-to-treat population. HR, hazard ratio.

PFS 16.4 months vs 9.3 months

HR 0.55

Sledge, JCO 2017

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MONARCH 2

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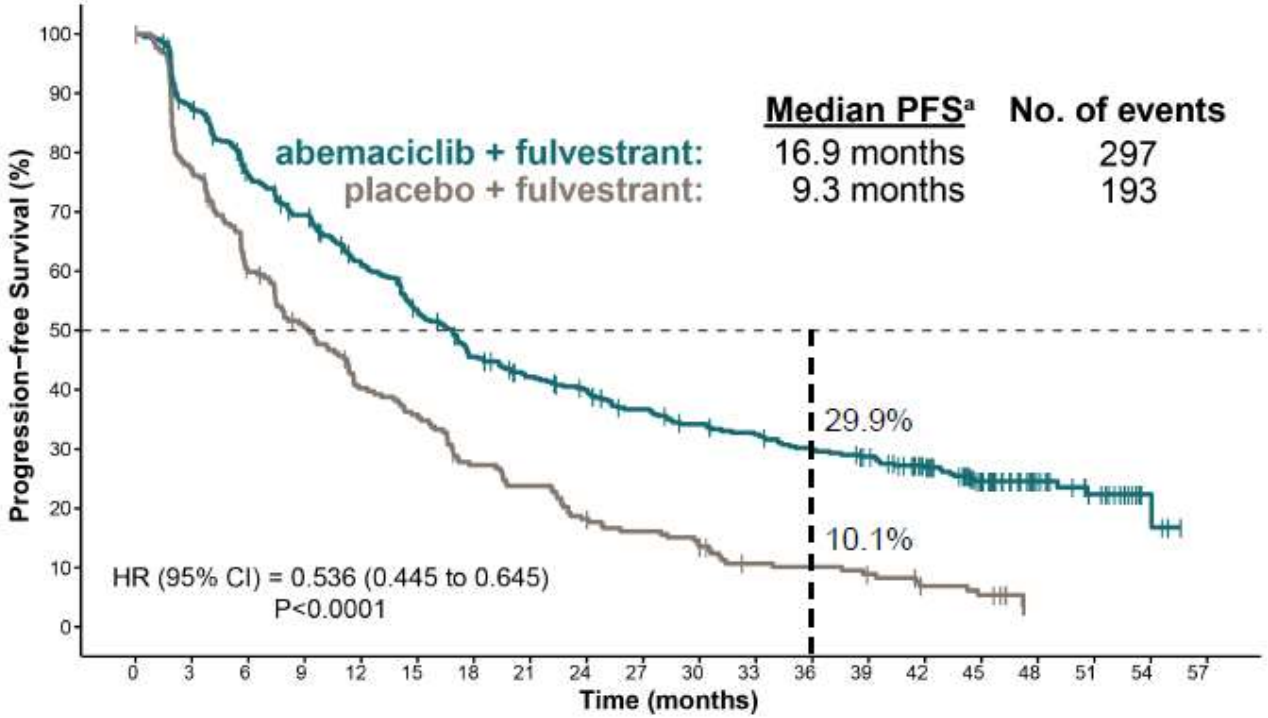
UPDATED PROGRESSION-FREE SURVIVAL



No. at risk

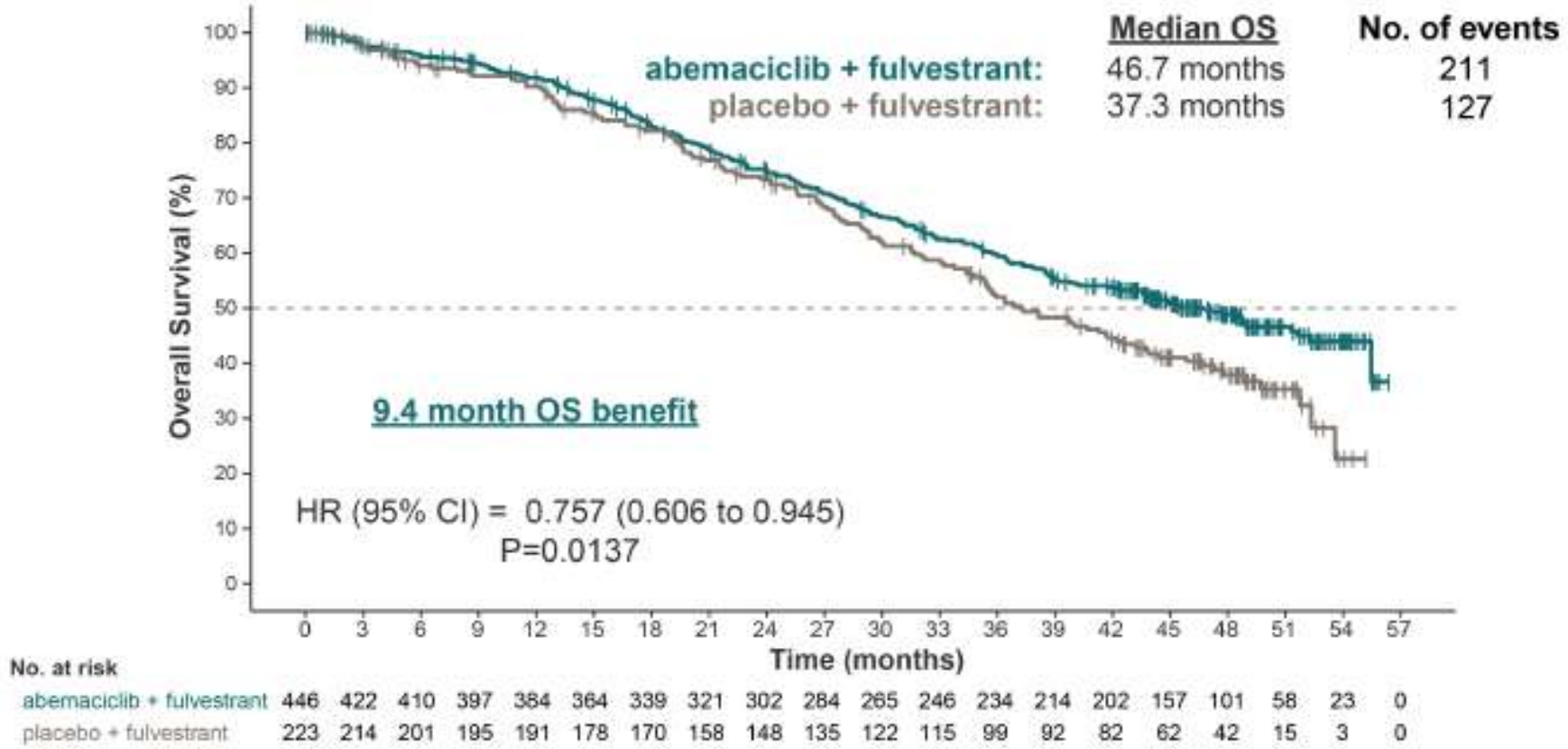
abemaciclib + fulvestrant	446	365	312	280	242	208	176	158	147	132	121	114	104	97	78	53	28	18	4	0
placebo + fulvestrant	223	165	124	103	81	72	54	47	36	31	26	18	17	14	9	7	0	0	0	0

[a]PFS results at primary analysis: Median: 16.4 vs 9.3 months (HR: 0.553; 95% CI: 0.449, 0.681; P<0.001), 222 events abemaciclib arm vs 157 events placebo arm

Sledge, ESMO 2019

MONARCH 2

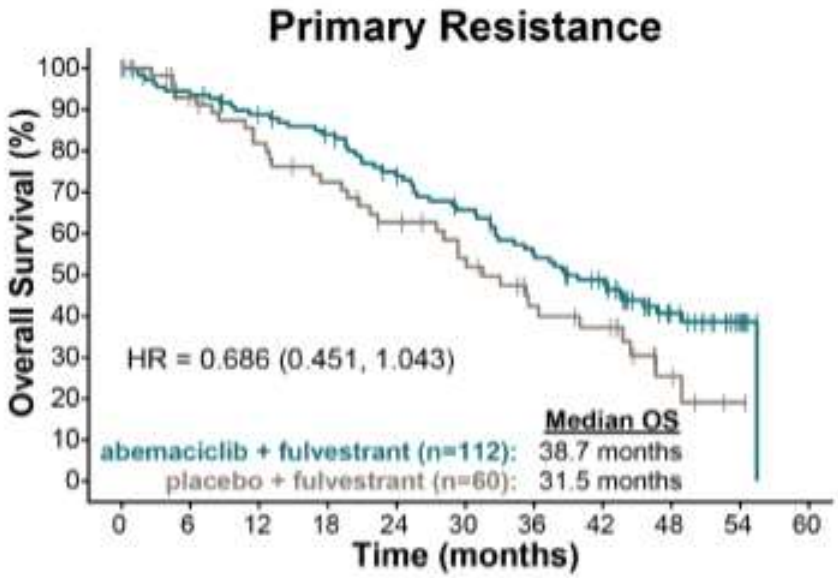
OVERALL SURVIVAL

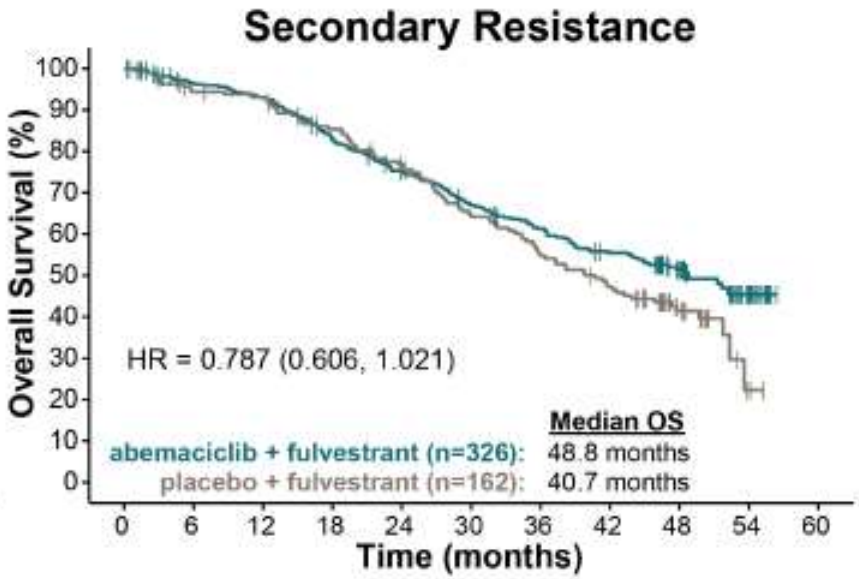


Sledge, ESMO 2019

MONARCH 2

OVERALL SURVIVAL BY RESISTANCE TO ENDOCRINE THERAPY[a]





[a]Interaction P-value: 0.588

Sledge, ESMO 2019

Definitions of endocrine resistance in ER+ MBC

PRIMARY ENDOCRINE RESISTANCE

Relapse while on the first 2 years of adjuvant ET, or PD within first 6 months of 1st line ET for MBC, while on ET

SECONDARY (ACQUIRED) ENDOCRINE RESISTANCE

Relapse while on adjuvant ET but after the first 2 years, or relapse within 12 months of completing adjuvant ET,

or PD ≥ 6 months after initiating ET for MBC, while on ET

Loibl, ESMO 2019

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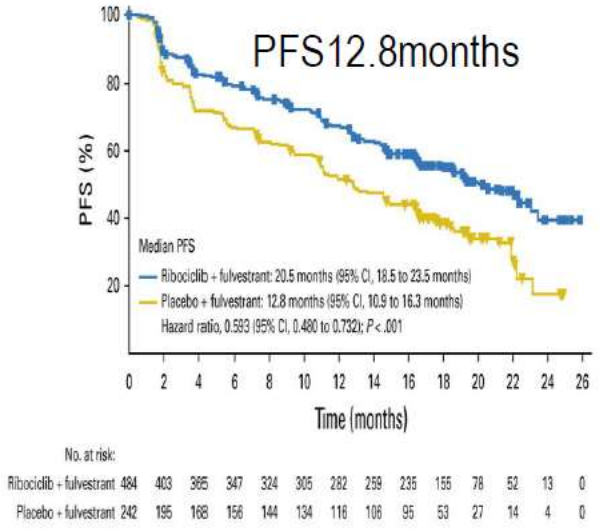
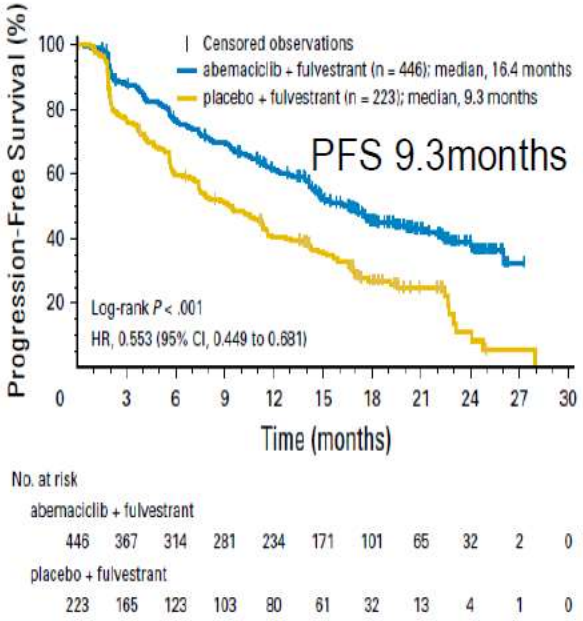
PFS data of fulvestrant + CDK 4/6 inhibitor Phase III trials in ET pretreated

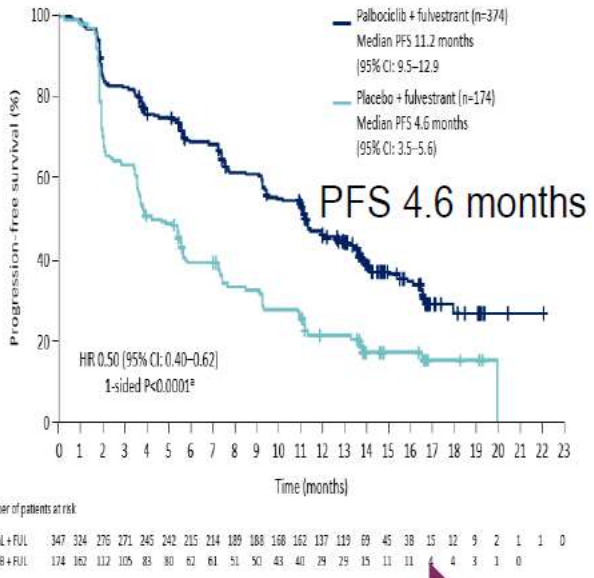
MONALEESA-3[1]



MONARCH-2[2]



PALOMA-3[3]



Level of pretreatment increases and PFS in control arm decreases

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1. Slamon D et al *JCO* 2018;36:2465-72; 2. Sledge GW et al *JCO* 2017;35:2875-84; 3. Turner N et al. New Engl J Med 2016

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Monaleesa 3 e Monarch 2

Subsequent Therapy After Discontinuation

First Subsequent Therapy After Discontinuation by Type, n (%)[a]	RIB + FUL n = 484 n discontinued = 362	PBO + FUL n = 242 n discontinued = 209
Any medication	295 (81.5)	177 (84.7)
Chemotherapy alone	84 (23.2)	42 (20.1)
Chemotherapy + hormone therapy/other[b]	46 (12.7)	33 (15.8)
Hormone therapy alone	94 (26.0)	38 (18.2)
Hormone therapy + other[c]	66 (18.2)	61 (29.2)
Targeted therapy alone	5 (1.4)	3 (1.4)

- CDK4/6 inhibitors as any line of subsequent therapy after discontinuation were received by 11% of patients in the RIB arm and 25% of patients in the PBO arm

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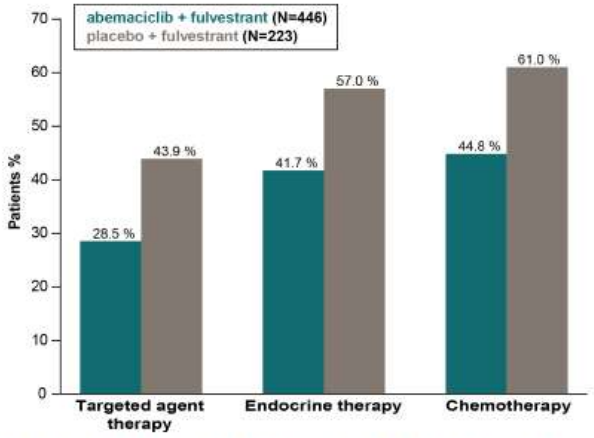
POST DISCONTINUATION THERAPY



Subsequent CDK4 & 6 Inhibitor therapy	
abemaciclib + fulvestrant	5.8%
placebo + fulvestrant	17.0%

At the time of data cutoff, a total of 584 patients in the ITT population had discontinued from study treatment (82.7% (n=369) in abemaciclib arm, 96.4% (n=215) in the placebo arm)

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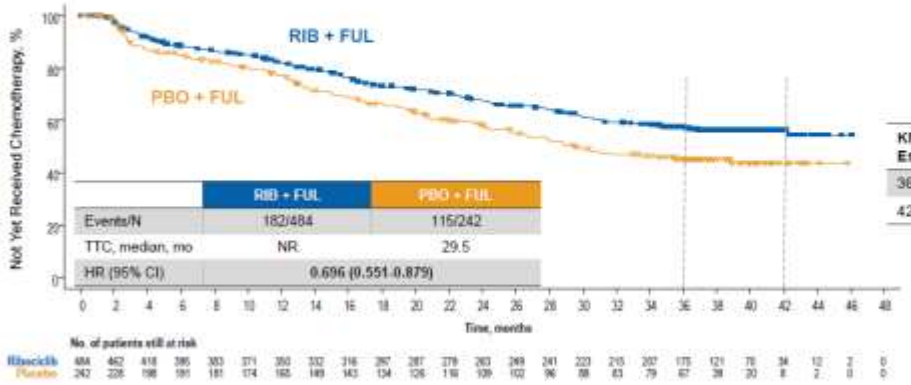
Monaleesa 3 e Monarch2

Time to First Chemotherapy

Time to first chemotherapy was longer with RIB + FUL



	RIB + FUL	PBO + FUL
Events/N	182/484	115/242
TTC, median, mo	NR	29.5
HR (95% CI)	0.696 (0.551-0.879)	

Landmark analysis

KM Estimate	RIB + FUL	PBO + FUL
36 months	57.4%	45.2%
42 months	56.4%	43.7%

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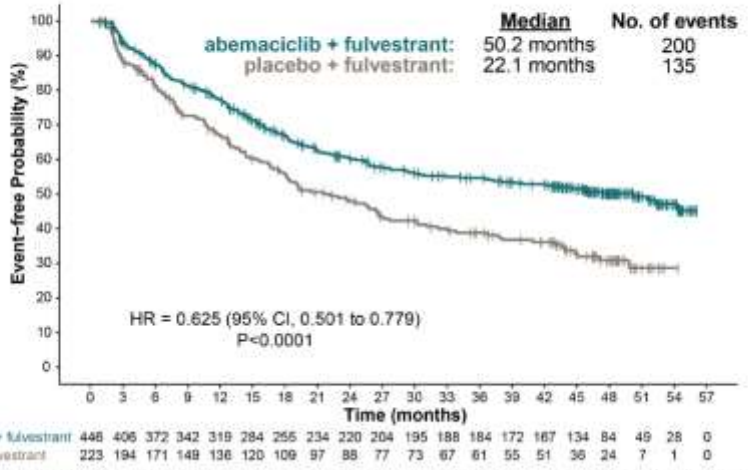
EXPLORATORY ANALYSIS: TIME TO CHEMOTHERAPY[a]



[a]Time to chemotherapy was analyzed from randomization to initiation of first post discontinuation chemotherapy (censoring patients who died prior to initiation of chemotherapy)

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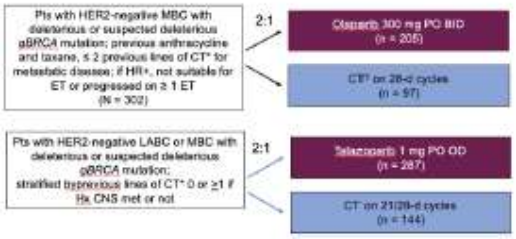
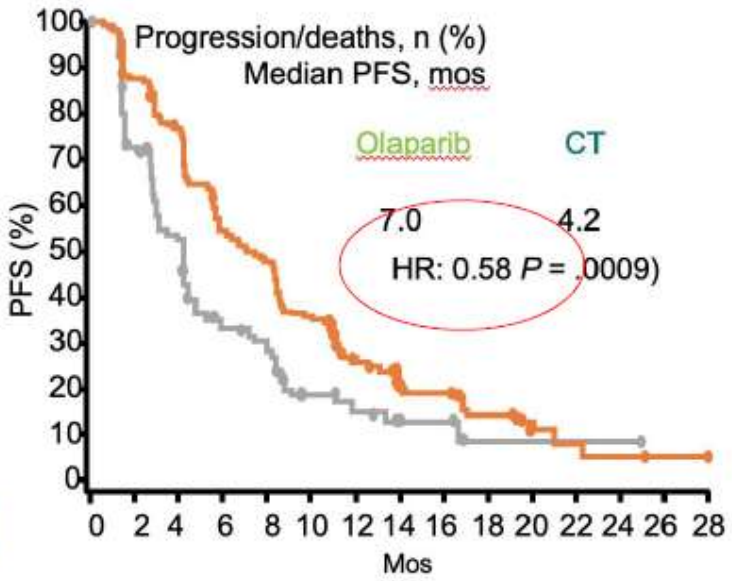
- ✓BROCADE 3
- ✓Keynote-119

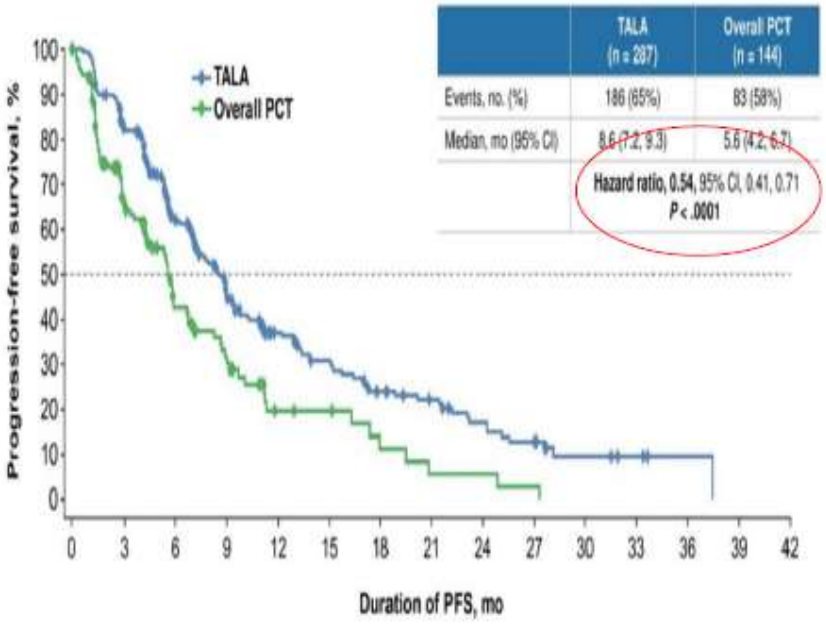
OLYMPIA-D & EMBRACA; Phase III PARPi Trials



OLYMPIAD



EMBRACA



	TALA (n = 287)	Overall PCT (n = 144)
Events, no. (%)	186 (65%)	83 (58%)
Median, mo (95% CI)	8.6 (7.2, 9.3)	5.6 (4.2, 6.7)
	Hazard ratio, 0.54, 95% CI, 0.41, 0.71 P < .0001	

Dent, ESMO 2019

Study Design: BROCADE3 (NCT02163694)

Patient Population

- Advanced HER2-negative breast cancer
- Germline *BRCA1* or *BRCA2* mutation
- ≤2 prior lines cytotoxic therapy for metastatic disease
- ≤1 prior lines of platinum; no progression ≤12 months of completing

Stratification Factors

- Hormone Receptor Expression
- Prior Platinum
- CNS Metastasis

2:1 Randomization
N=513

- **Veliparib + Carboplatin/paclitaxel**
- **Placebo + Carboplatin/paclitaxel**

Treat to progression:
If carboplatin and paclitaxel were discontinued prior to progression, dosing of veliparib/placebo increased to 300mg BID continuous, and then 400mg BID if tolerated

Optional open-label crossover to veliparib

Primary Endpoint:
Investigator-assessed PFS per RECIST 1.1

21-Day Cycles:
- Carboplatin (C): AUC 6 on Day 1
- Paclitaxel (P): 80 mg/m² on Days 1, 8, 15
- Veliparib or Placebo: 120mg BID on Days -2 to 5

Dieras, ESMO 2019

Patient Characteristics (2)

Characteristic, no. (%)	Veliparib + C/P (N = 337)	Placebo + C/P (N = 172)
Hormone Receptor Expression		
ER and/or PgR pos	174 (52)	92 (54)
ER and PgR neg	163 (48)	80 (47)
***BRCA* Mutation Status**		
BRCA1 Mutation	177 (53)	89 (52)
BRCA2 Mutation	167 (50)	86 (50)
Measurable Disease		
Yes	285 (85)	143 (84)
No	52 (15)	28 (16)
ECOG Performance Status		
0	208 (62)	102 (59)
1	121 (36)	63 (37)
2	8 (2)	7 (4)

Characteristic, no. (%)	Veliparib + C/P (N = 337)	Placebo + C/P (N = 172)
Prior Platinum		
Yes	27 (8)	16 (9)
No	310 (92)	156 (91)
Prior (Neo)-Adjuvant Chemotherapy		
Yes	236 (70)	113 (66)
No	101 (30)	59 (34)
Prior Chemotherapy for Metastatic Disease		
Yes	63 (19)	33 (19)
No	274 (81)	139 (81)
History of CNS Metastases		
Yes	16 (5)	10 (6)
No	320 (95)	161 (94)

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C/P: Carboplatin and Paclitaxel

Measurable disease status missing- 1 patient, control arm
History of CNS Metastases missing- 1 patient in each arm

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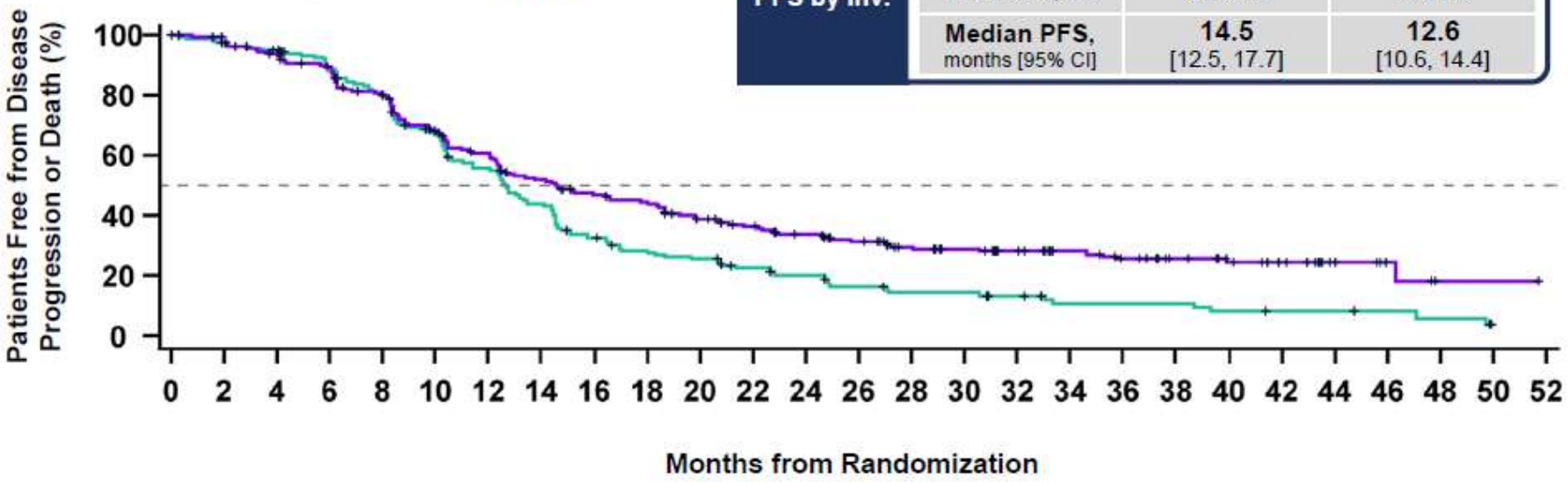
Primary Endpoint: PFS by Investigator Assessment

HR 0.705
[95% CI 0.566-0.877], p = 0.002

PFS by Inv.

	Veliparib + C/P	Placebo + C/P
PFS Events, n/N	217/337	132/172
Median PFS, months [95% CI]	**14.5** [12.5, 17.7]	**12.6** [10.6, 14.4]



No. at Risk

Control	172	160	153	140	123	99	82	64	47	39	35	27	23	18	15	15	12	8	8	8	6	5	5	4	3	0
Veliparib	337	316	301	282	250	207	181	154	137	126	107	92	81	72	60	51	45	38	32	25	20	16	8	4	1	1	0

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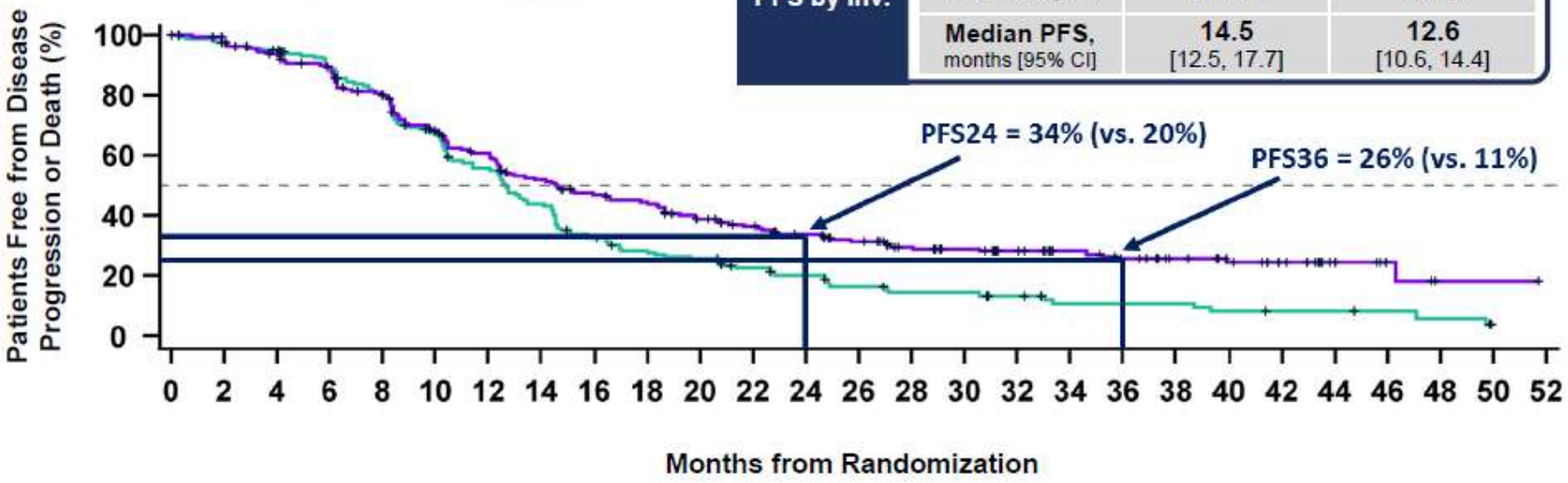
C/P: Carboplatin and Paclitaxel

Dieras, ESMO 2019

Primary Endpoint: PFS by Investigator Assessment

HR 0.705
[95% CI 0.566-0.877], p = 0.002

PFS by Inv.	Veliparib + C/P	Placebo + C/P
PFS Events, n/N	217/337	132/172
Median PFS, months [95% CI]	**14.5** [12.5, 17.7]	**12.6** [10.6, 14.4]



No. at Risk

Control	172	160	153	140	123	99	82	64	47	39	35	27	23	18	15	15	12	8	8	8	6	5	5	4	3	0
Veliparib	337	316	301	282	250	207	181	154	137	126	107	92	81	72	60	51	45	38	32	25	20	16	8	4	1	1	0

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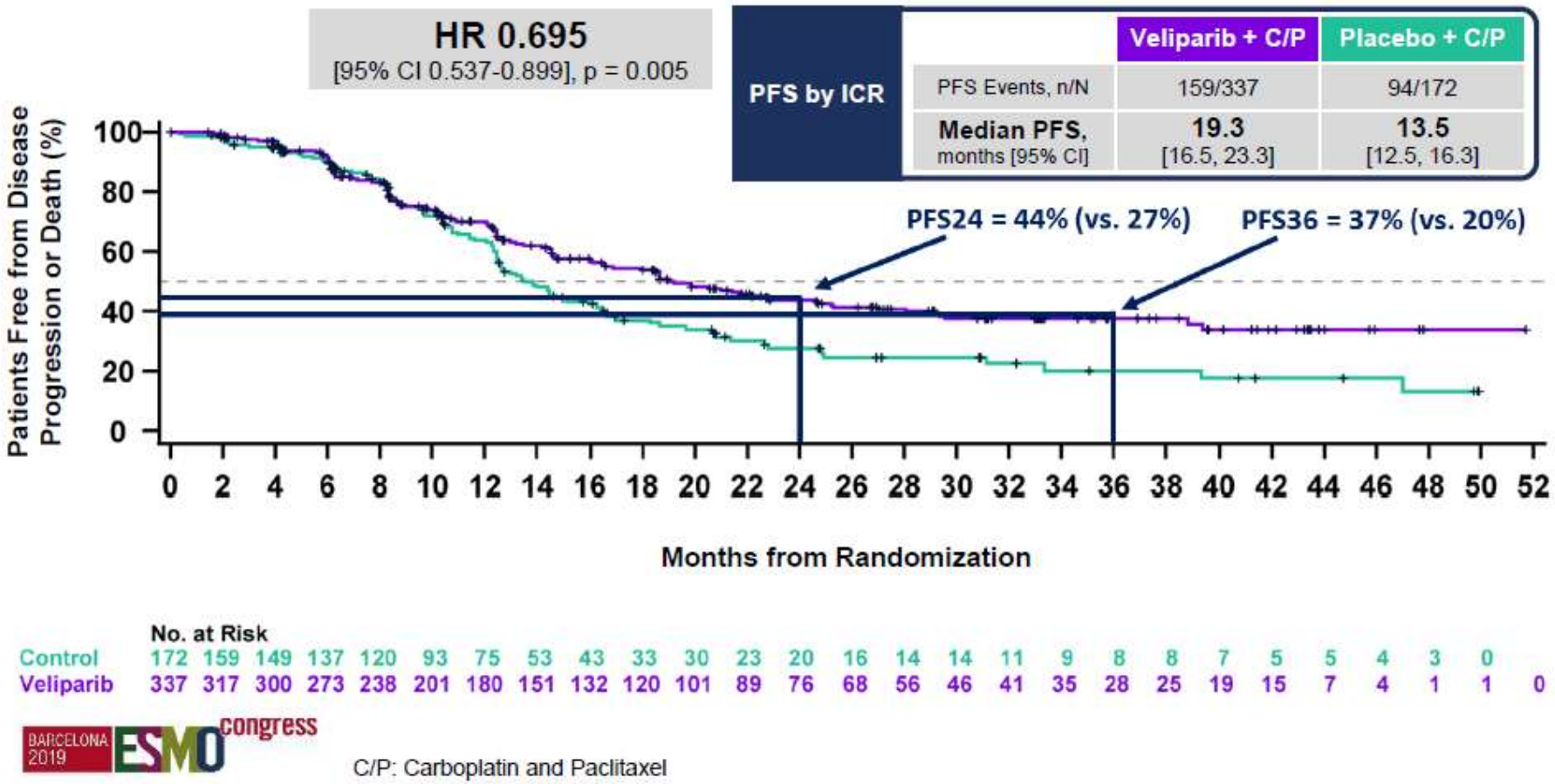
C/P: Carboplatin and Paclitaxel

Dieras, ESMO 2019

Primary Endpoint: PFS by Independent Central Review



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C/P: Carboplatin and Paclitaxel

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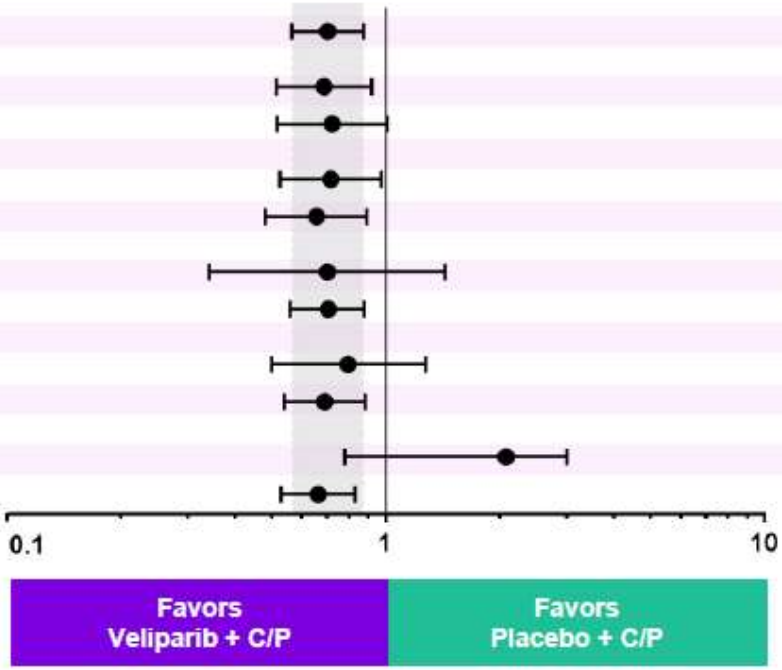
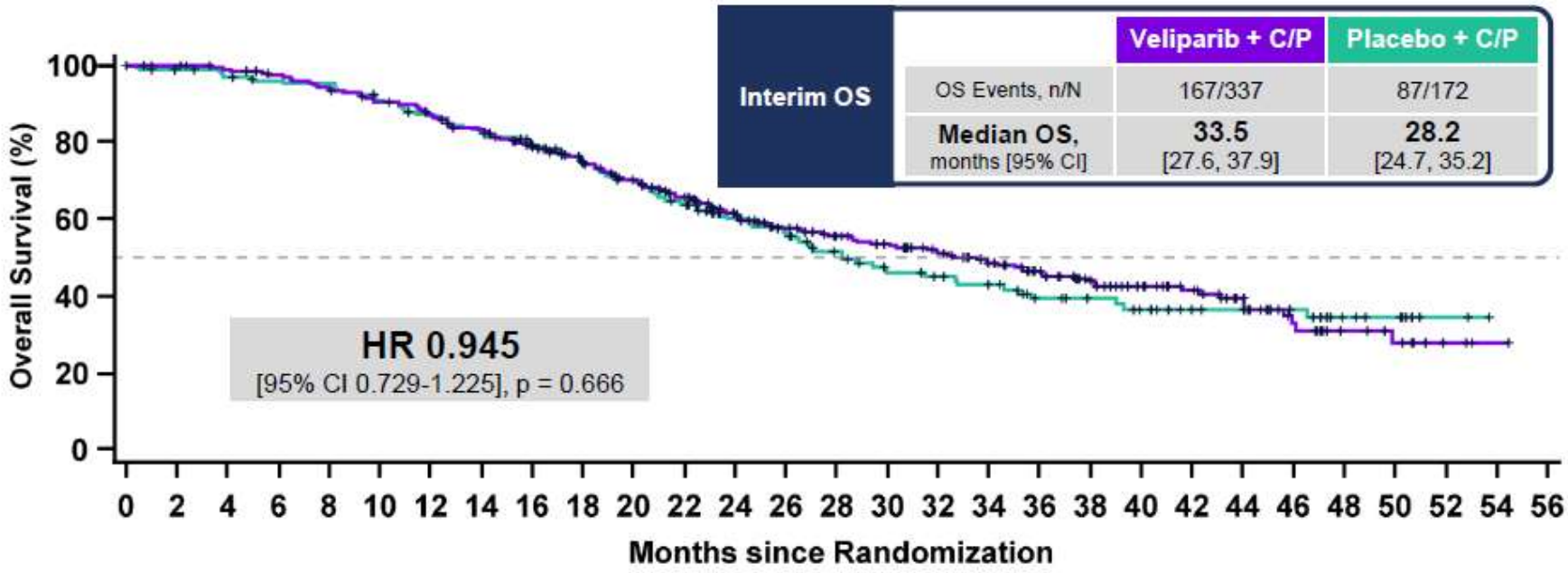
PFS Subgroup Analysis (Investigator-Assessed)

Subgroup	Veliparib+C/P	Placebo+C/P
	No. of patients with events/total	
All patients	217/337	132/172
Hormone receptor status		
ER positive and/or PgR positive	124/174	74/92
ER negative and PgR negative (TNBC)	93/163	58/80
***BRCA* status**		
BRCA1 mutation	113/177	68/89
BRCA2 mutation	106/167	67/86
Prior platinum therapy		
Prior platinum therapy	19/27	14/16
No prior platinum therapy	198/310	118/156
Prior cytotoxic therapy for metastatic disease		
Prior chemotherapy in metastatic setting	46/63	29/33
No prior chemotherapy in metastatic setting	171/274	103/139
History of CNS metastases		
Yes	14/16	8/10
No	203/320	124/161



C/P: Carboplatin and Paclitaxel

Secondary Endpoint: Overall Survival (Interim Analysis)



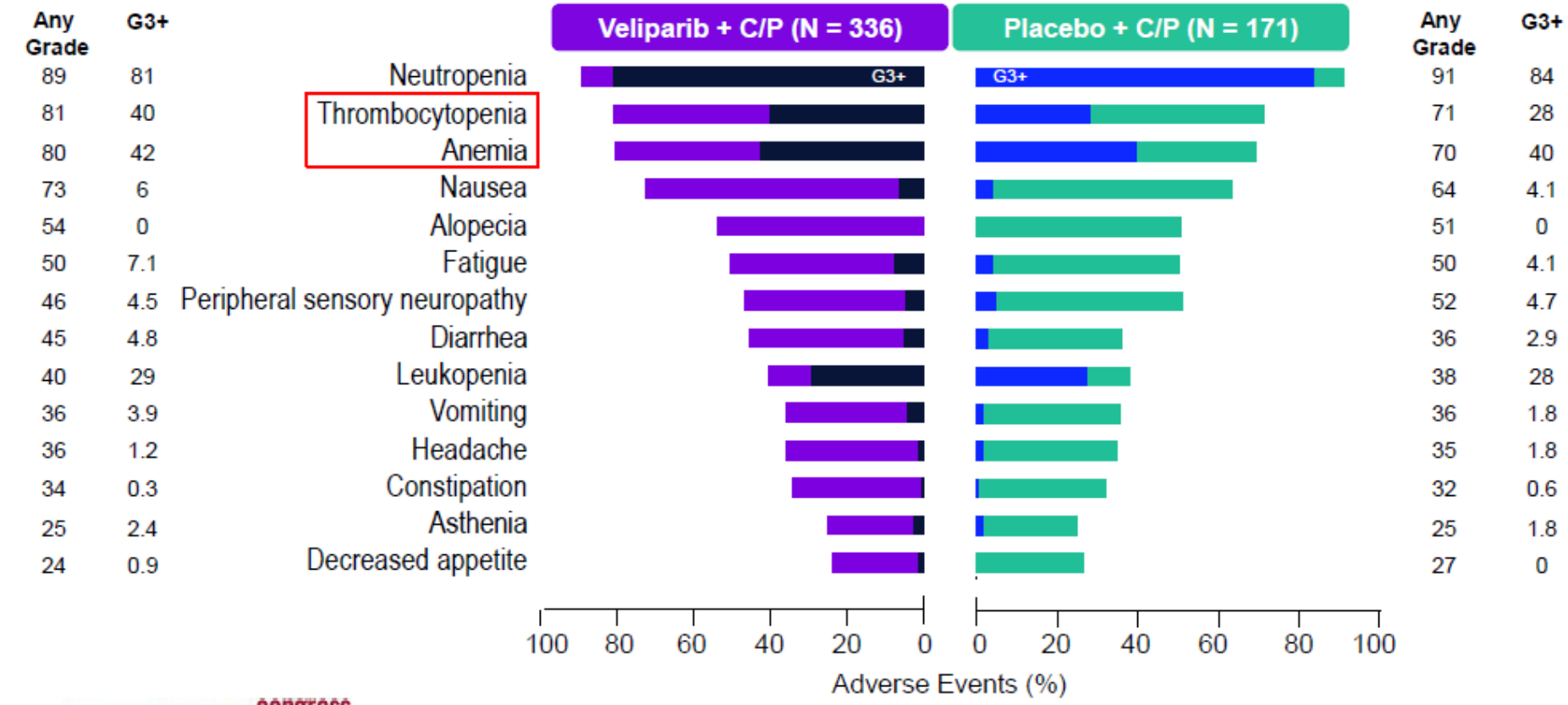
No. at Risk

Control	172	166	162	158	157	149	141	134	125	111	102	90	75	68	57	47	44	40	32	29	25	19	18	15	9	7	2	0	
Veliparib	337	332	326	318	307	294	281	265	247	223	203	185	161	145	132	117	106	90	76	62	50	41	30	18	11	8	3	1	0

C/P: Carboplatin and Paclitaxel

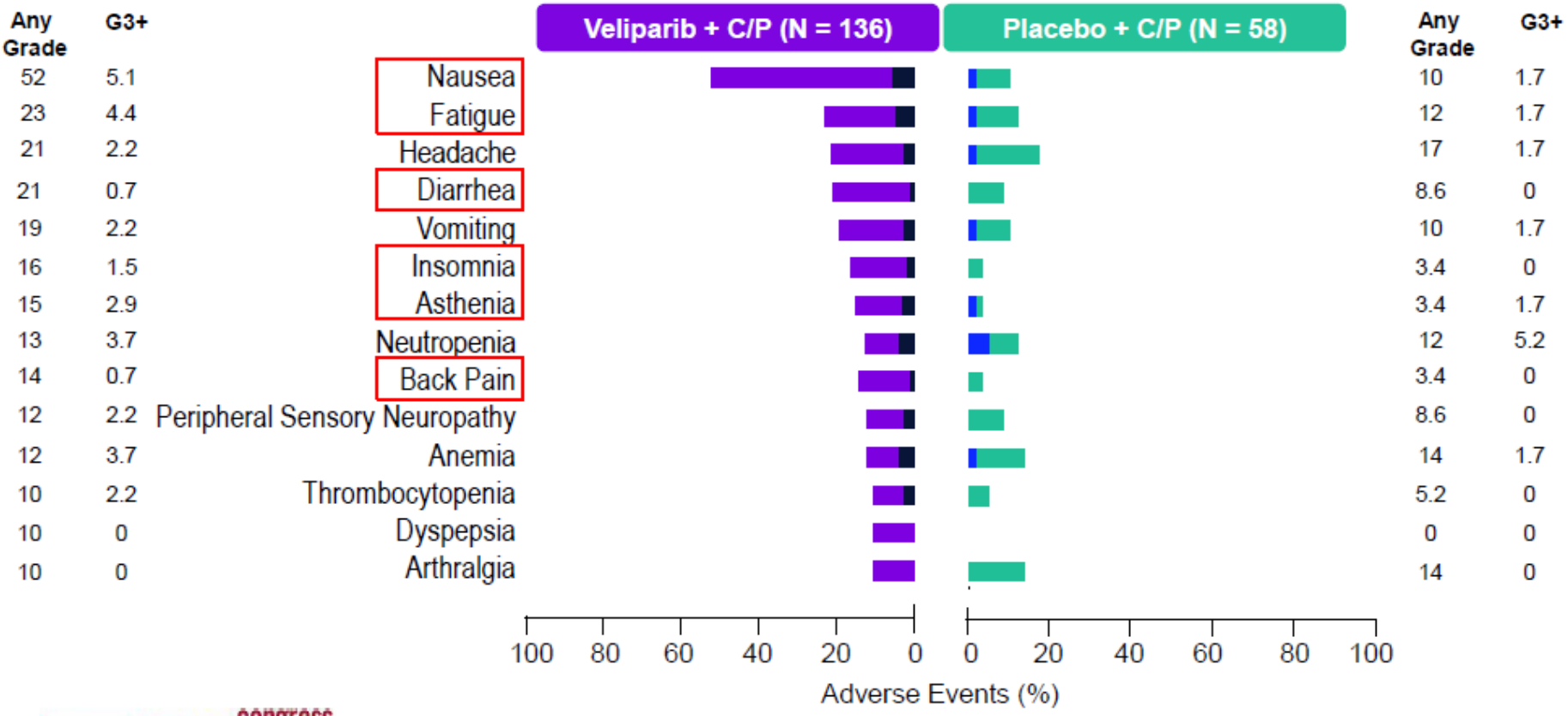
Crossover: 44% of ITT subjects randomized to placebo + C/P elected open-label veliparib as 1st subsequent therapy

Common Adverse Events (Entire Treatment Period)



All-grade AEs in ≥25% of patients. Red boxes indicate differences ≥10% in any grade AEs between arms.
G3+: Grade 3 or Higher. C/P: Carboplatin and Paclitaxel

Common Adverse Events (Blinded Monotherapy)



All-grade AEs in ≥10% of patients. Red boxes indicate differences ≥10% in any grade AEs between arms.
G3+: Grade 3 or Higher. C/P: Carboplatin and Paclitaxel

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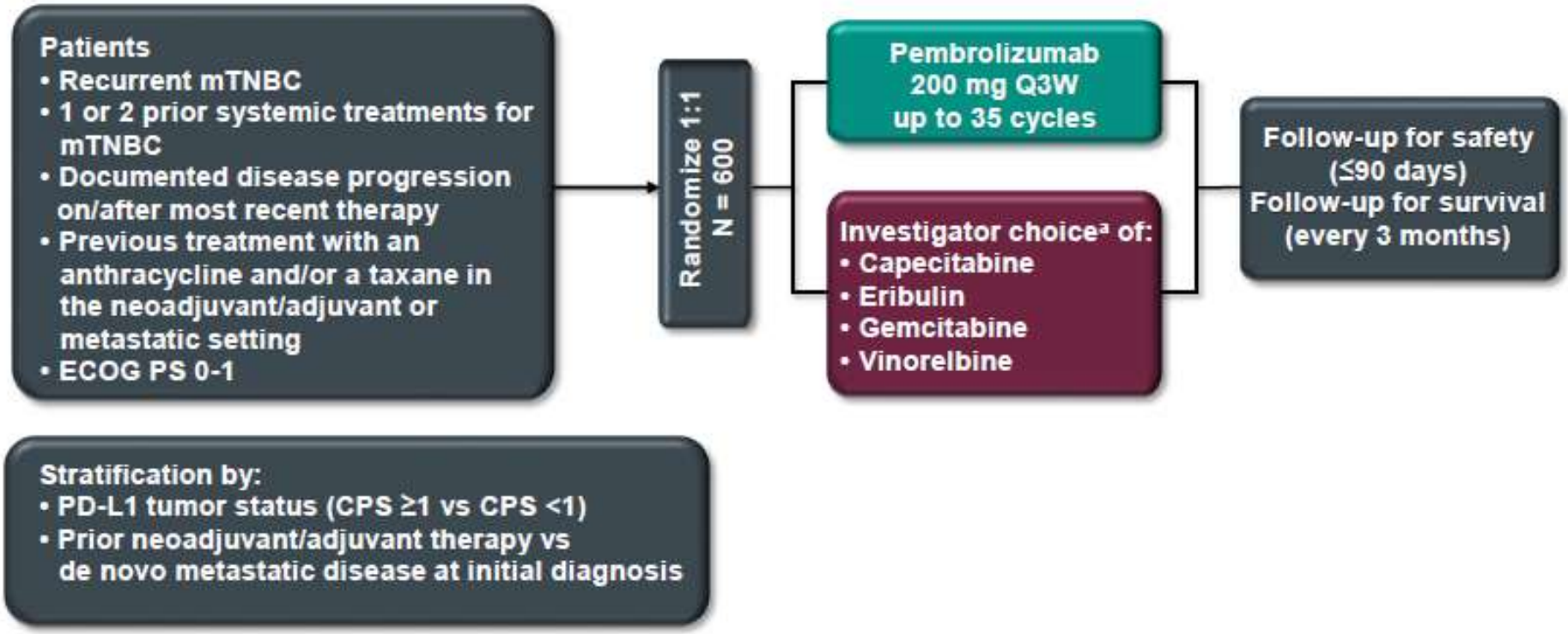
OUTLINE

- ✓Monaleesa 3 & Monarch 2
- ✓BROCADE 3
- ✓Keynote-119

KEYNOTE-119 Study Design (NCT02555657)



ECOG PS = Eastern Cooperative Oncology Group performance status; mTNBC = metastatic triple-negative breast cancer; PD-L1 = programmed death ligand 1; Q3W = every 3 weeks.
[a]Maximum enrollment cap of 60% of total enrollment for each chemotherapy drug.

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Baseline Characteristics

Characteristic, n (%)	Pembro N = 312	Chemo N = 310
Age, median (range), y	50 (28 – 85)	50 (25 – 79)
<65 years	264 (84.6)	260 (83.9)
Post-menopausal	238 (76.3)	239 (77.1)
ECOG PS		
0	169 (54.2)	158 (51.0)
1	141 (45.2)	151 (48.7)
No. prior lines		
1	187 (59.9)	187 (60.3)
2	124 (39.7)	123 (39.7)

Characteristic, n (%)	Pembro N = 312	Chemo N = 310
Prior neoadjuvant/adjuvant	246 (78.8)	246 (79.4)
Time to progression on 1L		
<6 mo	156 (50.0)	151 (48.7)
≥6 mo	156 (50.0)	159 (51.3)
Chemotherapy received		
Eribulin	-	167 (53.9)
Capecitabine	-	85 (27.4)
Vinorelbine	-	43 (13.9)
Gemcitabine	-	15 (4.8)

Data cutoff date: April 11, 2019.

Cortes, ESMO 2019

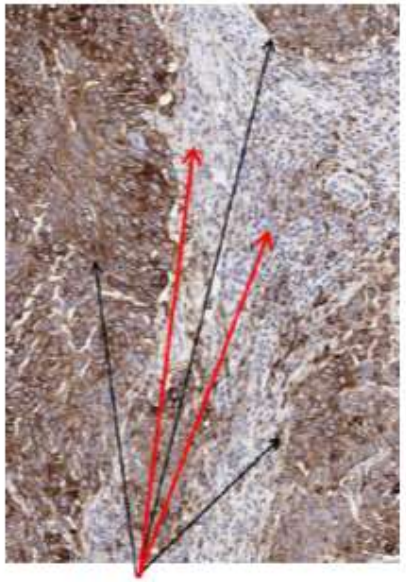
PD-L1 Expression Analysis

- Measure of PD-L1 expression: combined positive score (CPS)

$$\text{CPS} = \frac{\text{\# PD-L1–staining cells (tumor cells, lymphocytes, macrophages)}}{\text{Total \# viable tumor cells}} \times 100$$

- Assessed centrally in newly obtained core or excisional biopsy from metastatic, not previously irradiated, tumor lesion using PD-L1 IHC 22C3 pharmDx (Agilent Technologies)

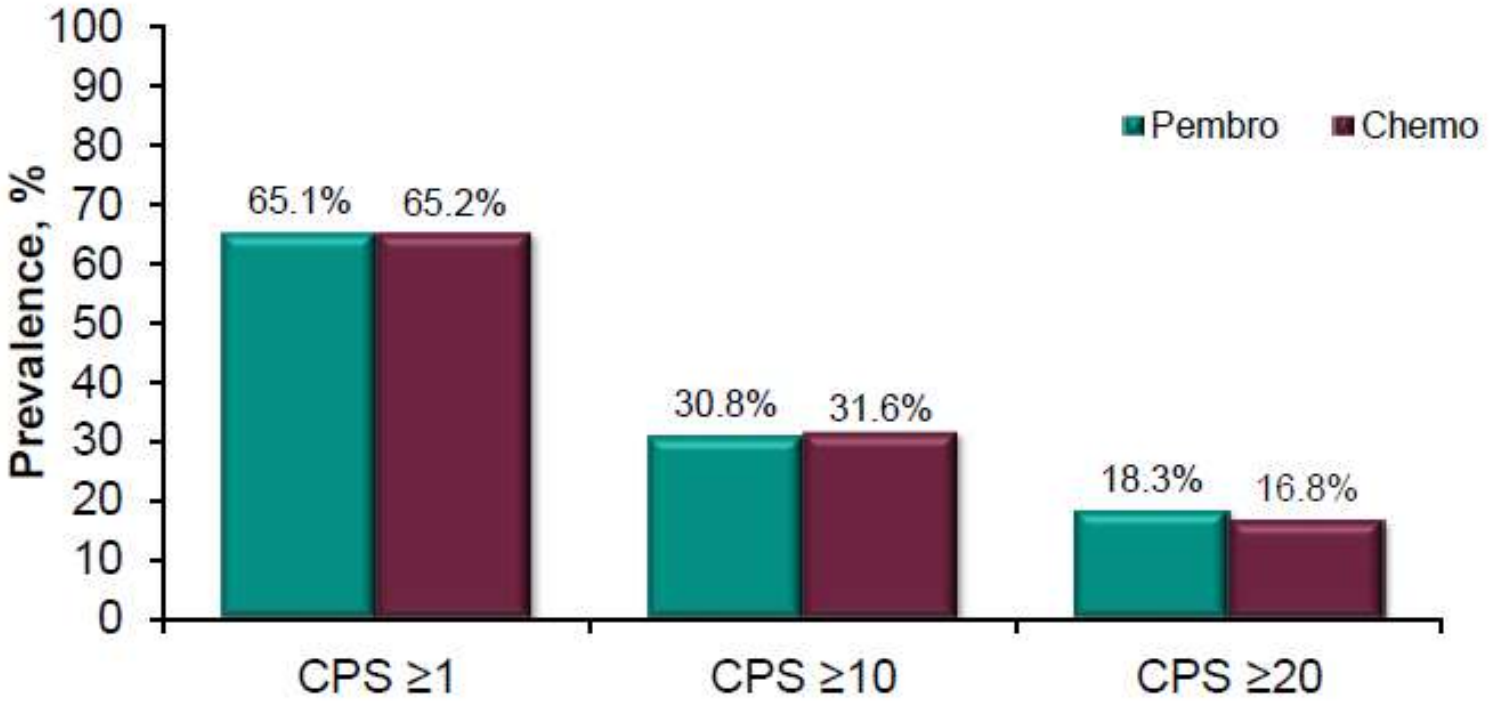
- Positive PD-L1 expression: CPS ≥10 and CPS ≥1



PD-L1 positive cells
(Tumor Cells, Immune Cells)

Balar AV et al. Presented at ESMO 2016; Oct 7-11, 2016; Copenhagen, Denmark. Abstr. LBA32-PR.

Prevalence of PD-L1 CPS Categories



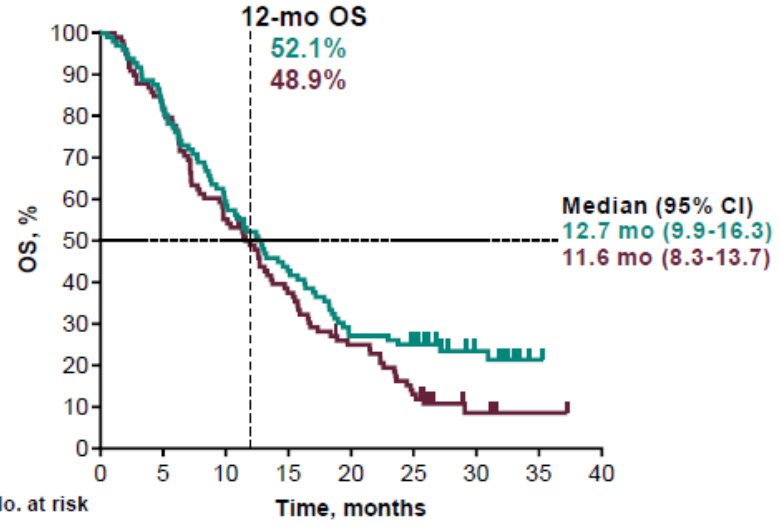
CPS = combined positive score defined as the number of PD-L1–positive cells (tumor cells, lymphocytes, macrophages) divided by total number of tumor cells × 100.
Data cutoff date: April 11, 2019.

Cortes, ESMO 2019

Overall Survival: Primary Endpoints

CPS ≥10

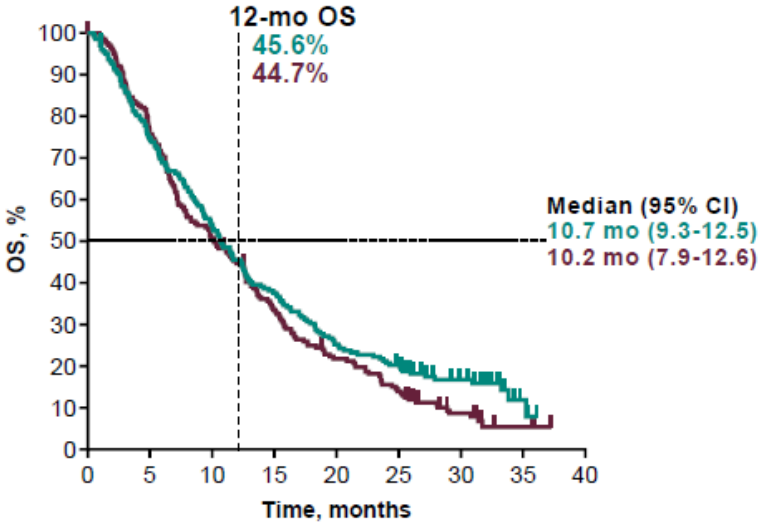
Events	HR (95% CI)	P
77.1%	0.78	0.057
88.8%	(0.57-1.06)	



No. at risk									
Pembro	96	79	57	41	26	23	11	1	0
Chemo	98	80	54	36	23	12	4	1	0

CPS ≥1

Events	HR (95% CI)	P
84.2%	0.86	0.073
90.6%	(0.69-1.06)	



203	151	109	76	51	40	20	3	0
202	152	102	66	42	27	12	3	0

Data cutoff date: April 11, 2019.

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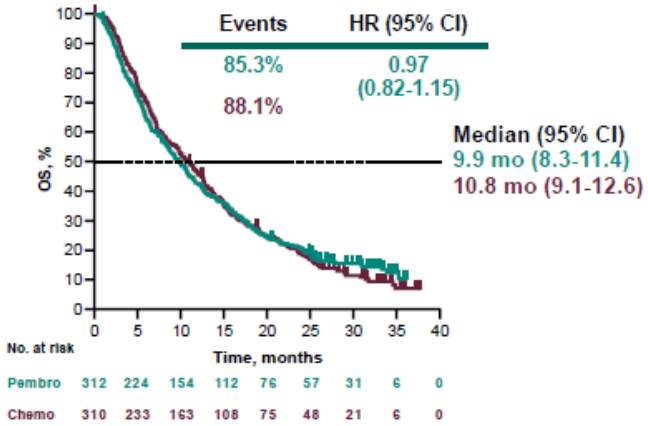
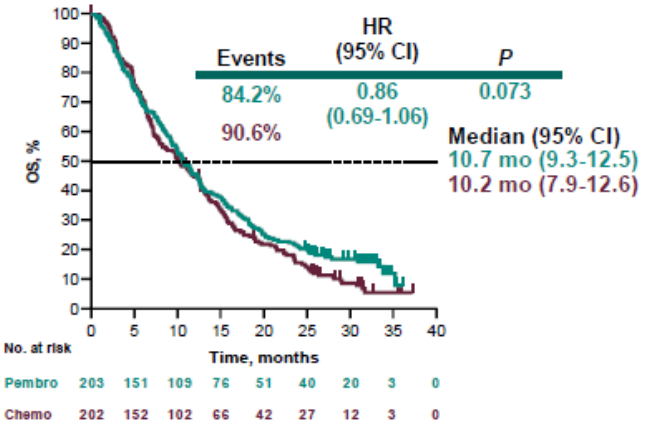
Overall Survival by PD-L1 CPS

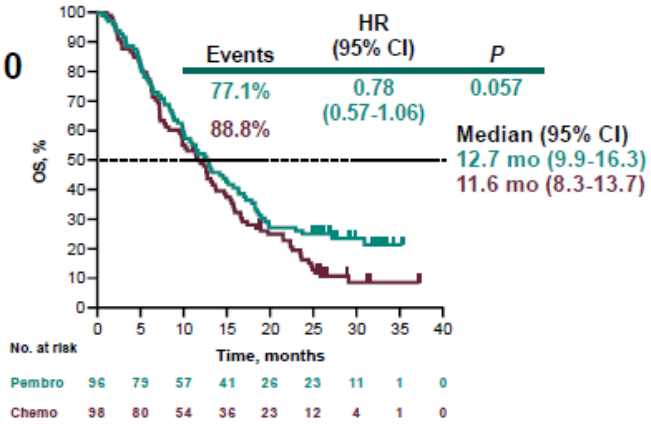
ITT



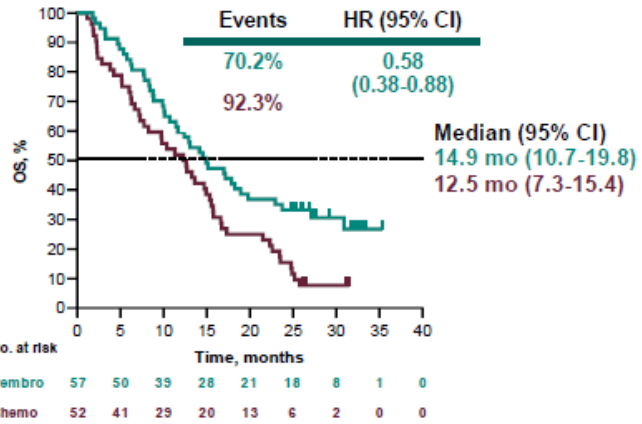
CPS ≥1



CPS ≥10



CPS ≥20



OS in the ITT, CPS ≥1 and CPS ≥10 populations were primary endpoints; OS in the CPS ≥20 population was an exploratory endpoint. Data cutoff date: April 11, 2019

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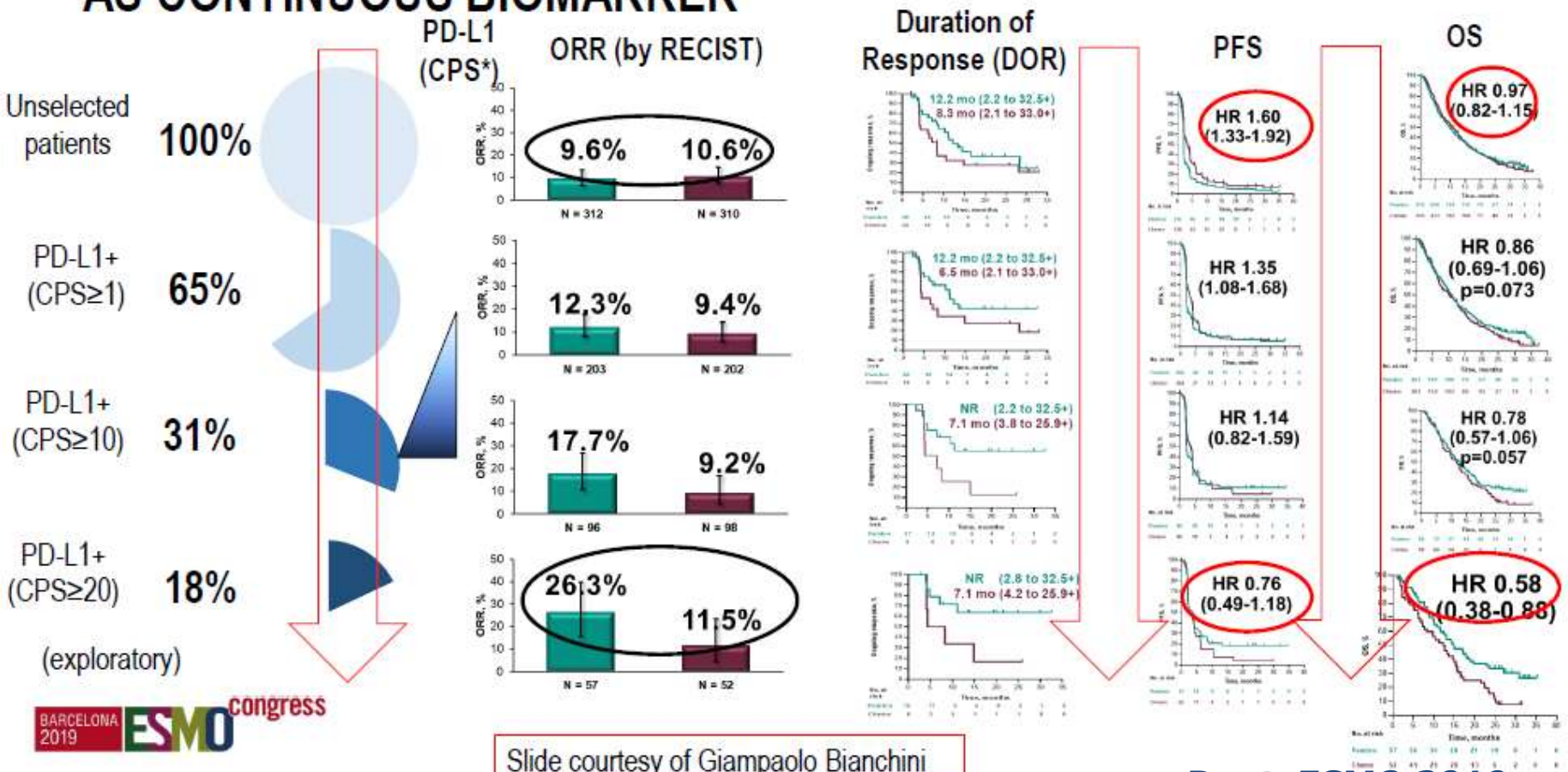
Summary

- Pembrolizumab monotherapy as 2/3L treatment for mTNBC did not significantly improve OS vs chemotherapy in the primary analysis populations
- Pembrolizumab showed a clear trend in improved efficacy with PD-L1 enrichment
  - OS HR: 0.96, 0.86, 0.78, and 0.58 in ITT, CPS ≥1, ≥10, and ≥20, respectively
  - PFS HR: 1.60, 1.35, 1.14, and 0.76, respectively
  - ORR: 9.6% vs 10.6%, 12.3% vs 9.4%, 17.7% vs 9.2%, and 26.3% vs 11.5%, respectively
- Responses to pembrolizumab were more durable than those to chemotherapy
- Pembrolizumab monotherapy was generally well tolerated
  - Lower incidence vs chemotherapy of any-grade and grade 3-5 AEs
  - Lower incidence vs chemotherapy of AEs leading to discontinuation and dose modification
  - Safety profiles as expected for pembrolizumab and chemotherapy

A CLOSER LOOK INTO KEYNOTE-119: PD-L1 (CPS*, USING 22C3) AS CONTINUOUS BIOMARKER



Slide courtesy of Giampaolo Bianchini

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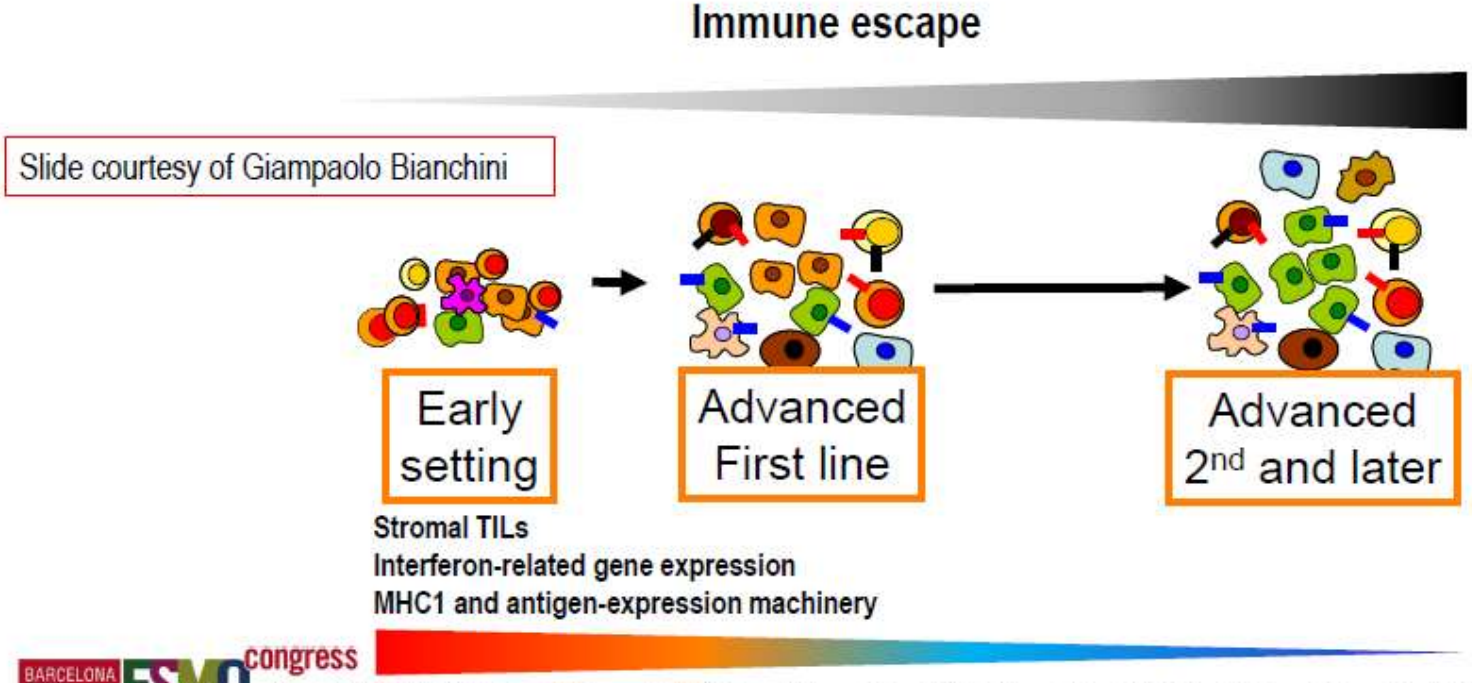
SHOULD WE GIVE IMMUNE CHECKPOINTS INHIBITORS IN FIRST LINE OR SUBSEQUENT LINES OF TREATMENT? YES!

Tumor/immune co-evolution leads to an increasing immuno-editing and immune subversion



Bianchini G SABCS 2015; Ogyia R Cancer Sci 2016; Luen SJ Lancet Oncol 2017; SJ Lancet Oncol 2017; Dieci MV Breast Cancer Res 2018; Szekely B Ann Oncol 2018

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- ✓ Keynote-119 

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Thanks