PROGETTO CANOA – QUALI NOVITA' PER IL 2025?

Immunoterapia nel Carcinoma Mammario ER-Positivo: Quali novità?

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OUTLINE

- **Background**
- **Checkmate-7FL**
- **Keynote-756**
- **Neo-CheckRay**
- **Discussion**

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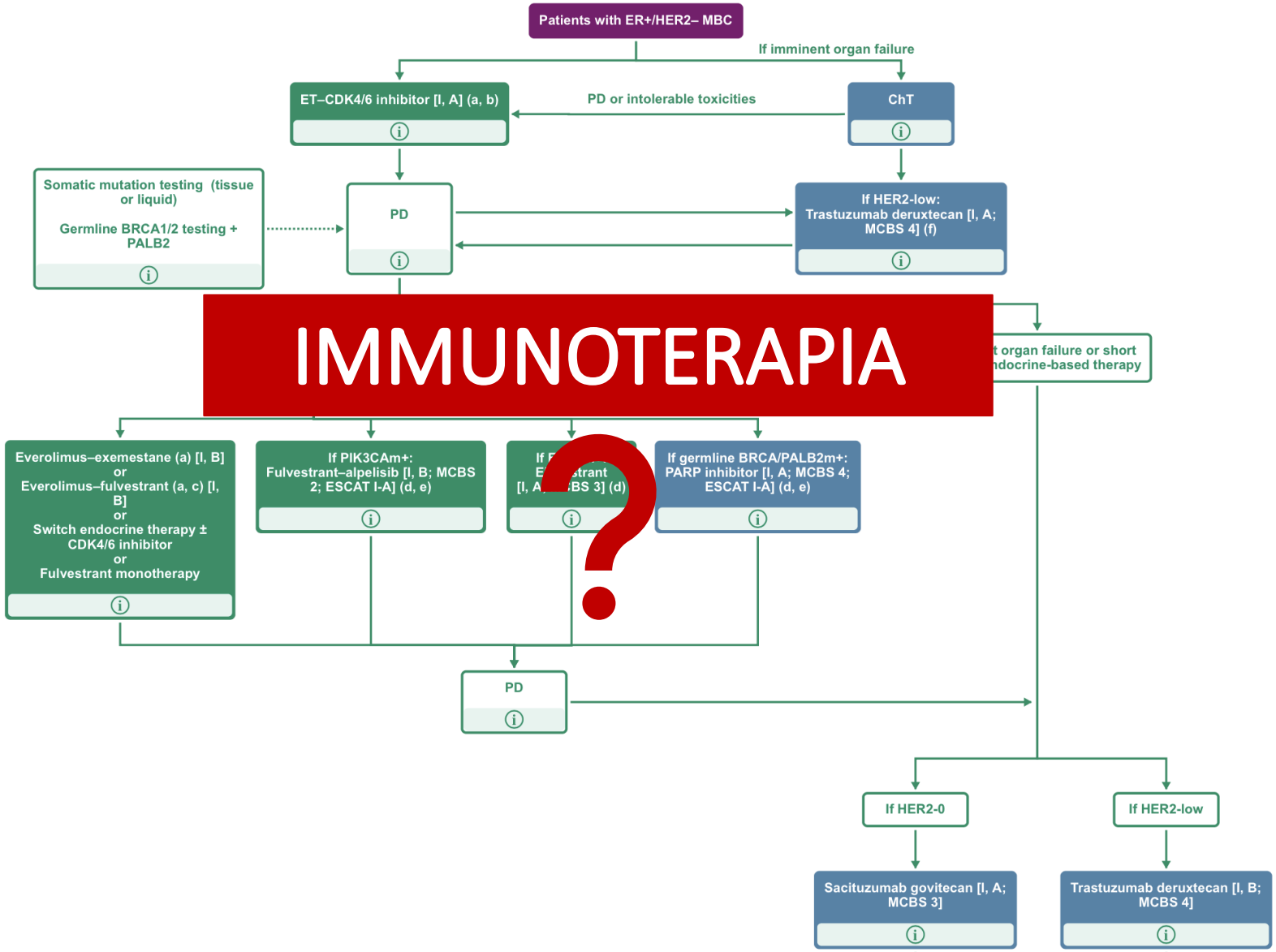
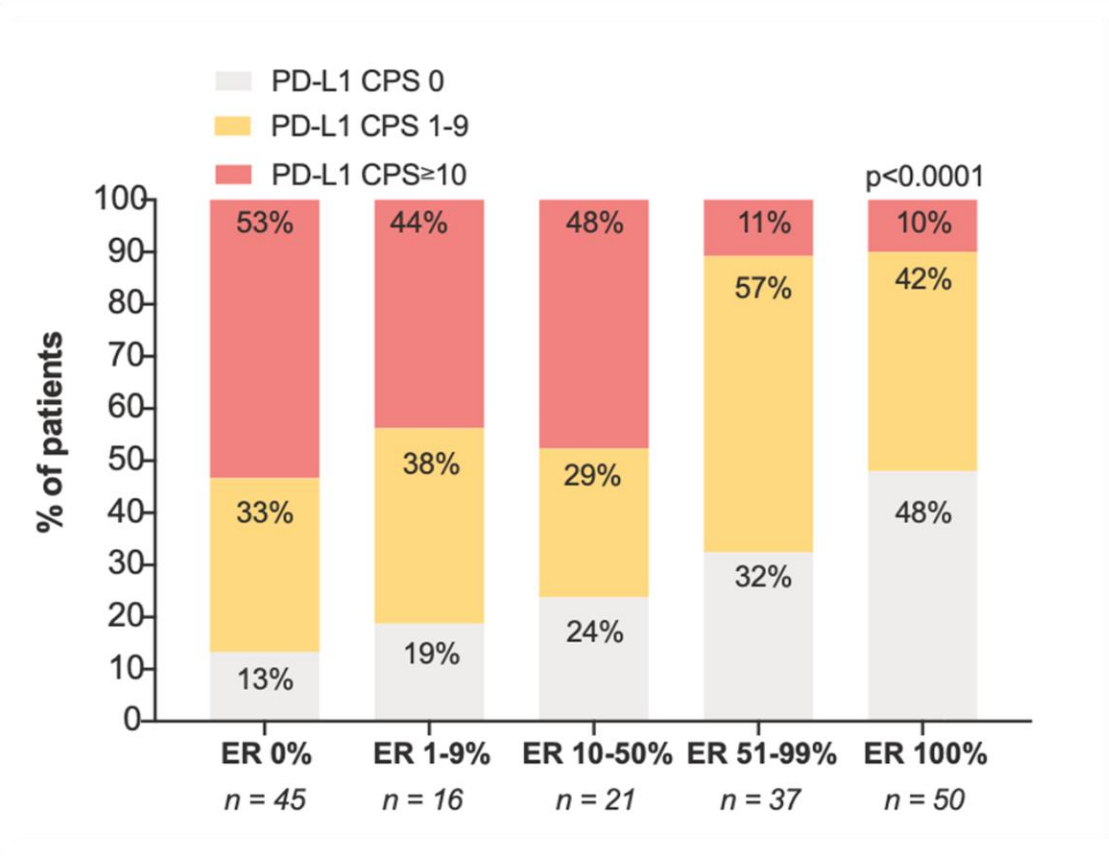
LUMINAL-LIKE BREAST CANCER

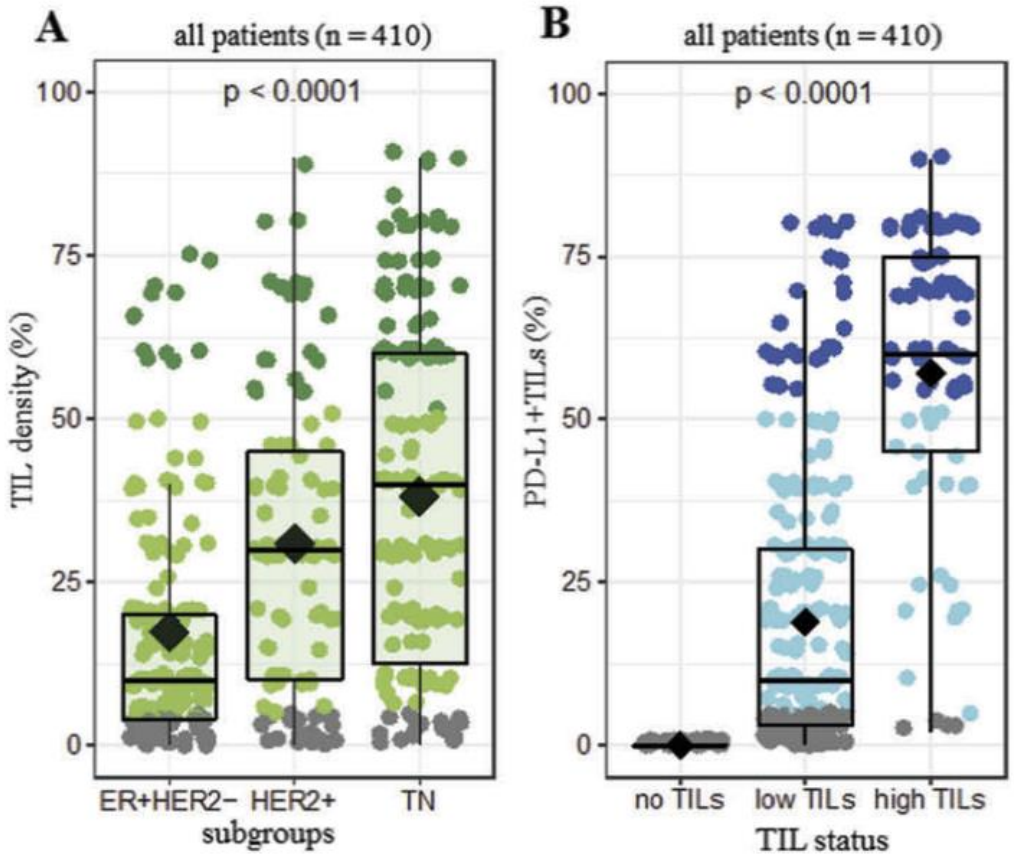


ER-POSITIVE BC NON E' UN'UNICA ENTITA'

ESPRESSIONE DI PD-L1 IN BASE AD ESPRESISONE RECETTORI ESTROGENICI



ESPRESSIONE TILS E PD-L1 IN BASE A SOTTOTIPO INTRINSECO

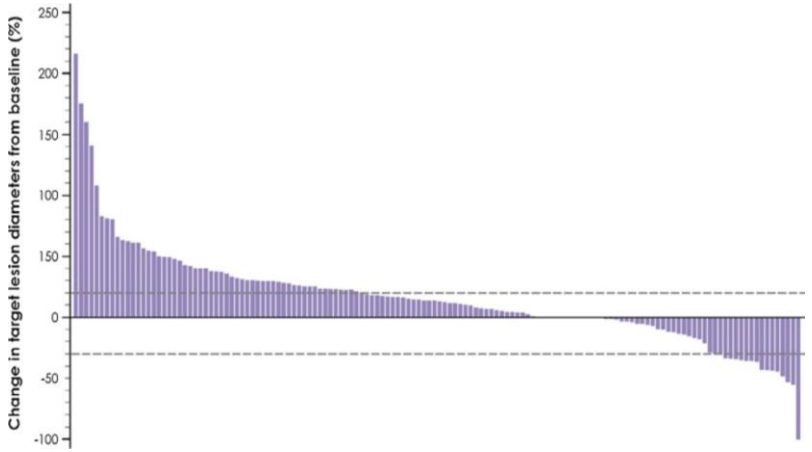


Sobral-Leite et al. Oncoimmunology 2018 | Voorwerk et al. NPJ Breast Cancer 2023

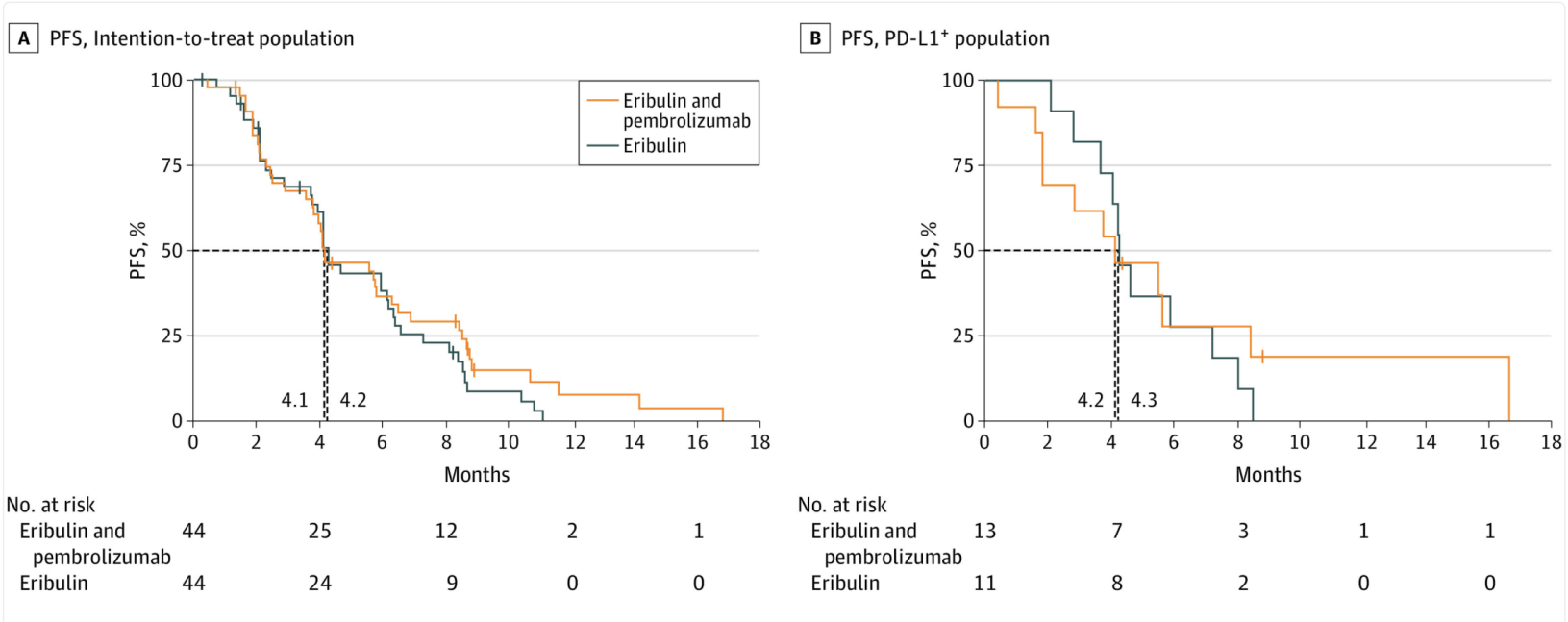
RAZIONALE PER L'IMMUNOTERAPIA NELL'ER+ BC?

- ER+ BC è un tumore "freddo" dal punto di vista immunitario (a differenza del TNBC): ↓TILs e ↓PD-L1
- L'immunoterapia <u>non ha dimostrato efficacia</u> in setting avanzato di malattia ER+

JAVELIN Solid Tumors (Avelumab)



Eribulin ±Pembrolizumab



Dirix LY et sl., Breast Cancer Res Treat. 2018 | Rugo HS, et al., Clin Cancer Res. 2018 | Tolaney SM, JAMA Oncol. 2020

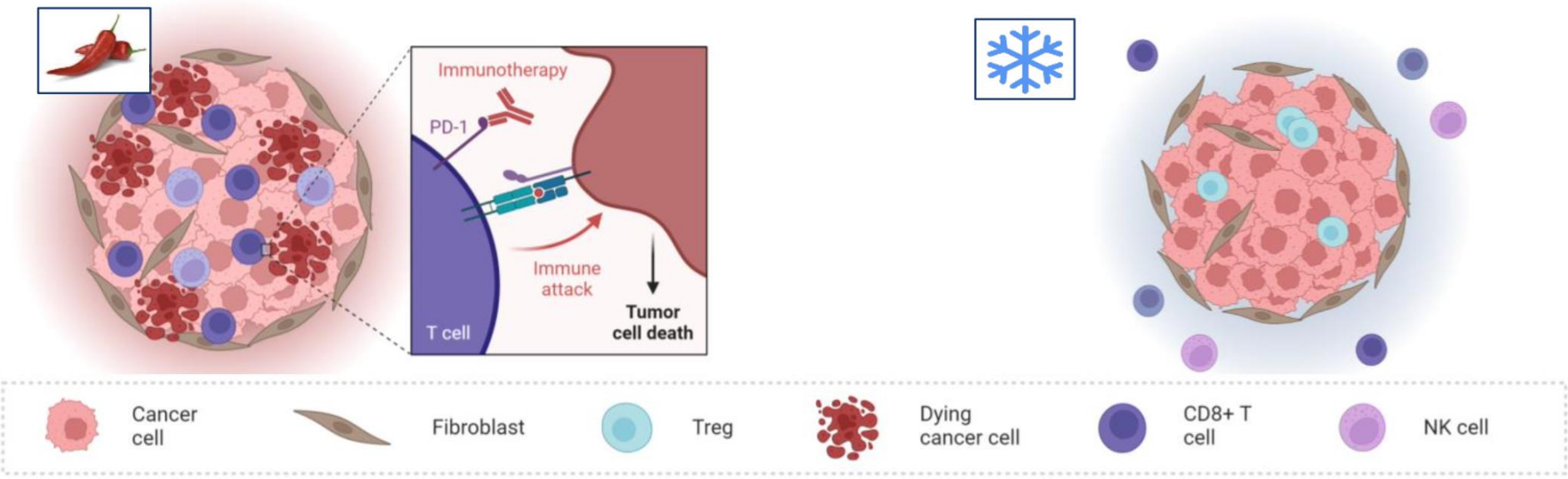
RAZIONALE PER L'IMMUNOTERAPIA NELL'ER+ BC?

- Sappiamo che i tumori primitivi sono spesso meno immunosoppressi rispetto ai tumori pretrattati
- Inoltre, la combinazione di ICIs con agenti citotossici può suscitare maggiori risposte immunitarie antitumorali

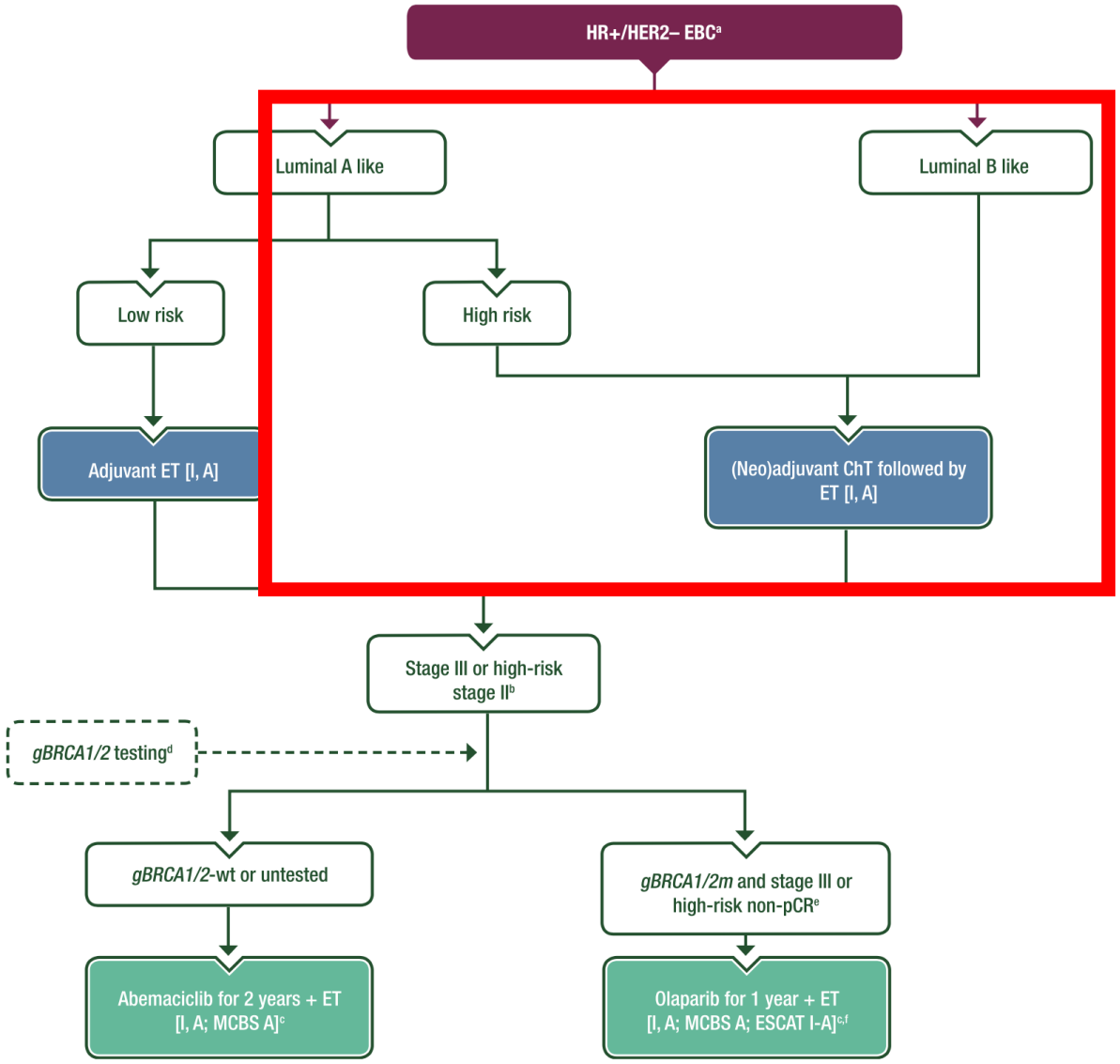
TNBC ⇔ **ER+**

→ neo-adj immuno-chemo is standard of care

→ neo-adj immuno-chemo is NOT standard of care



RAZIONALE PER L'IMMUNOTERAPIA NELL'ER+ EBC



RAZIONALE PER L'IMMUNOTERAPIA NELL'ER+ EBC?

H.U.B HÔPITAL UNIVERSITAIRE DE BRUXELLES ACADEMISCH ZIEKENHUIS BRUSSEL | Clinical Trials Center

Neoadjuvant Chemotherapy and Immunotherapy in Luminal B-like Breast Cancer: Results of the Phase II GIADA Trial

Maria Vittoria Dieci[1,2], Valentina Guarneri[1,2], Anna Tosi[1], Giancarlo Bisagni[3], Antonino Musolino[4,5], Simon Spazzapan[6], Gabriella Moretti[3], Grazia Maria Vernaci[1,2], Gaia Griguolo[1,2], Tommaso Giarratano[2], Loredana Urso[1], Francesca Schiavi[7], Claudia Pinato[7], Giovanna Magni[8], Marcello Lo Mele[9], Gian Luca De Salvo[8], Antonio Rosato[1,10], and Pierfranco Conte[1,2]

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO ANNALS OF ONCOLOGY DRIVING INNOVATION IN ONCOLOGY

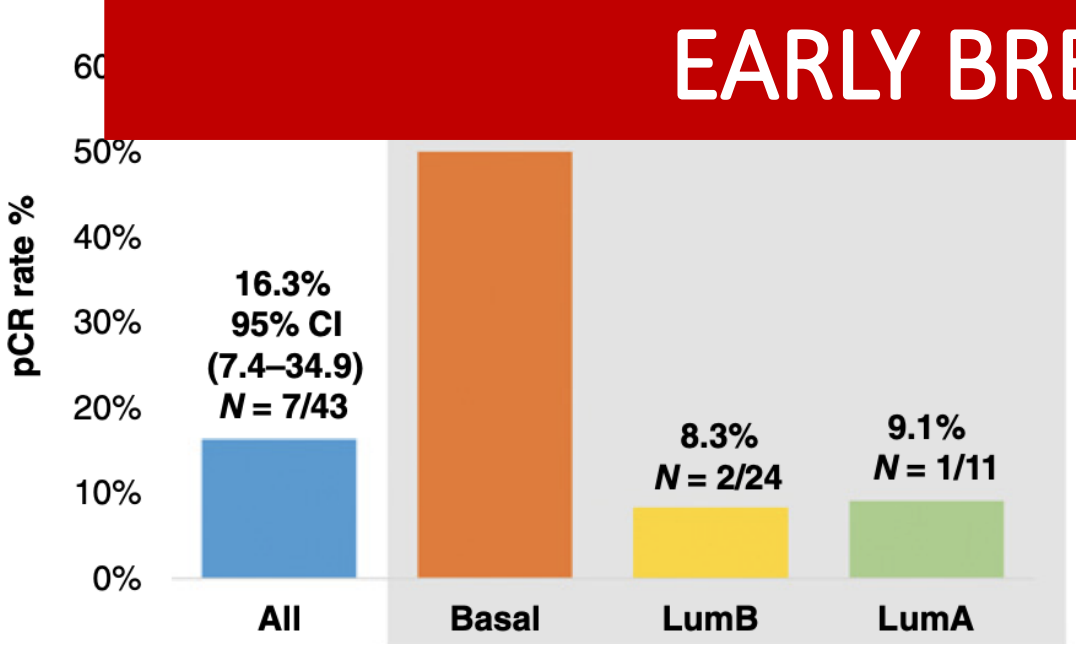
ORIGINAL ARTICLE

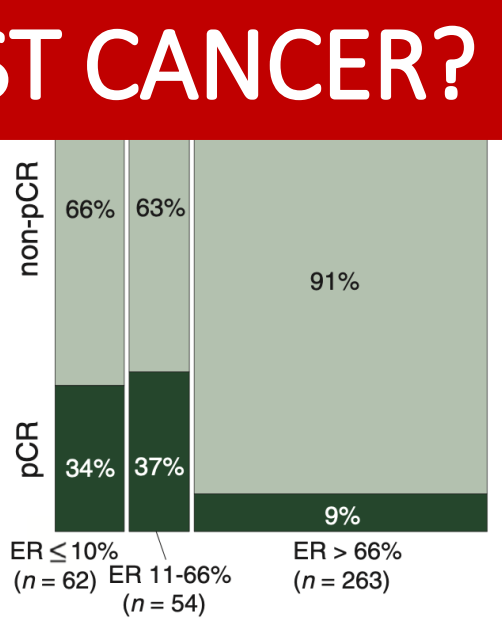
Pathologic complete response (pCR) rates for patients with HR+/HER2− high-risk, early-stage breast cancer (EBC) by clinical and molecular features in the phase II I-SPY2 clinical trial

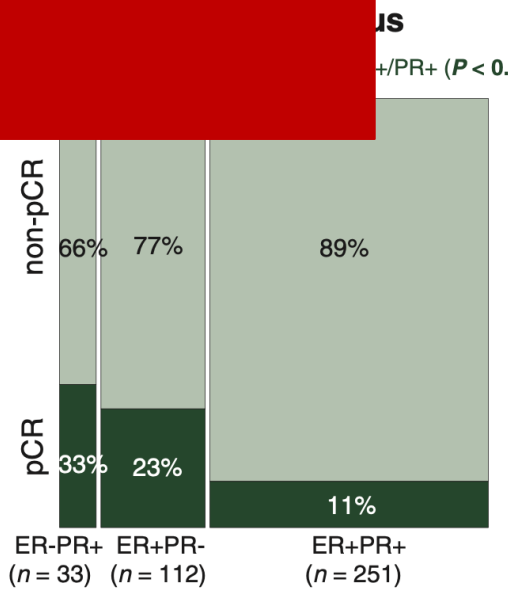
L. A. Huppert[1*], D. Wolf[2], C. Yau[3], L. Brown-Swigart[2], G. L. Hirst[3], C. Isaacs[4], L. Pusztai[5], P. R. Pohlmann[6], A. DeMichele[7],

SPAZIO PER IMMUNOTERAPIA IN ER+ EARLY BREAST CANCER?

A







pCR rates: 13% → >30% in 40 patients with ER+/HER2− MammaPrint-high BC

OUTLINE

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- Discussion

STUDY DESIGN

nature medicine

Article https://doi.org/10.1038/s41591-024-03414-8

Neoadjuvant nivolumab and chemotherapy in early estrogen receptor-positive breast cancer: a randomized phase 3 trial

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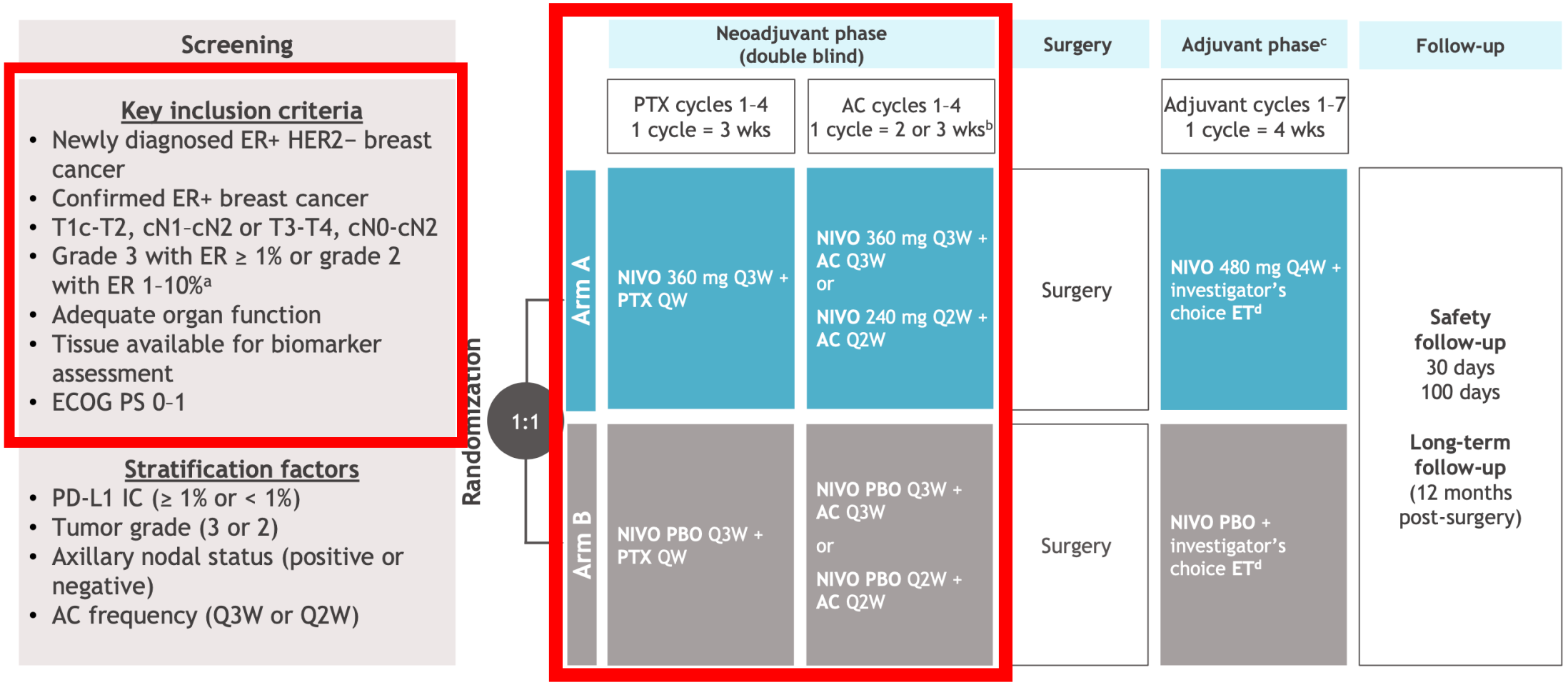
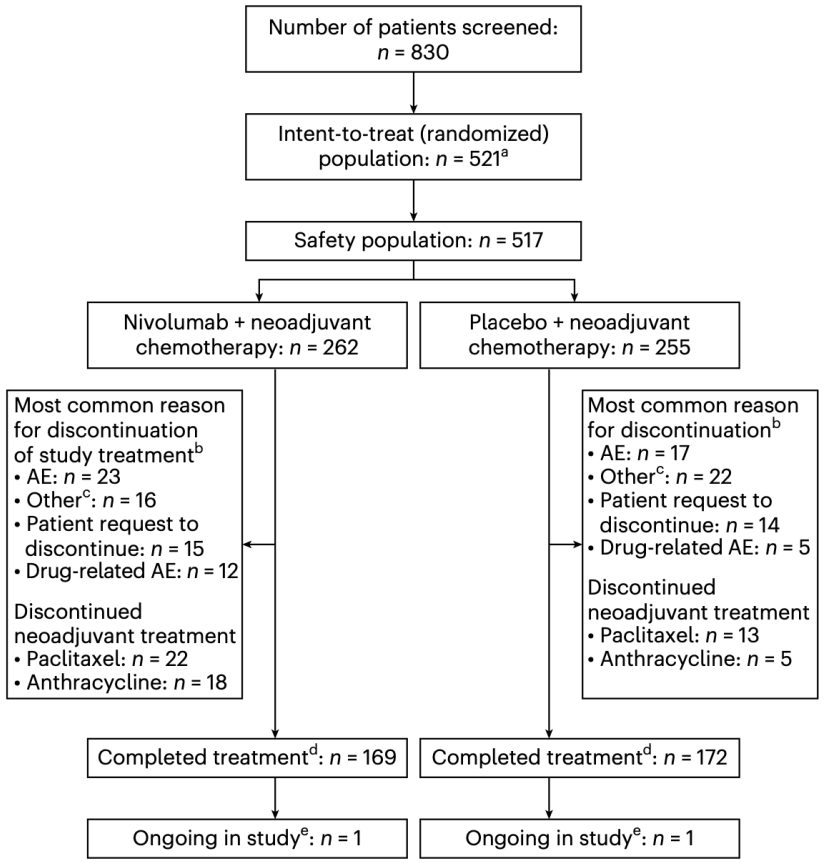


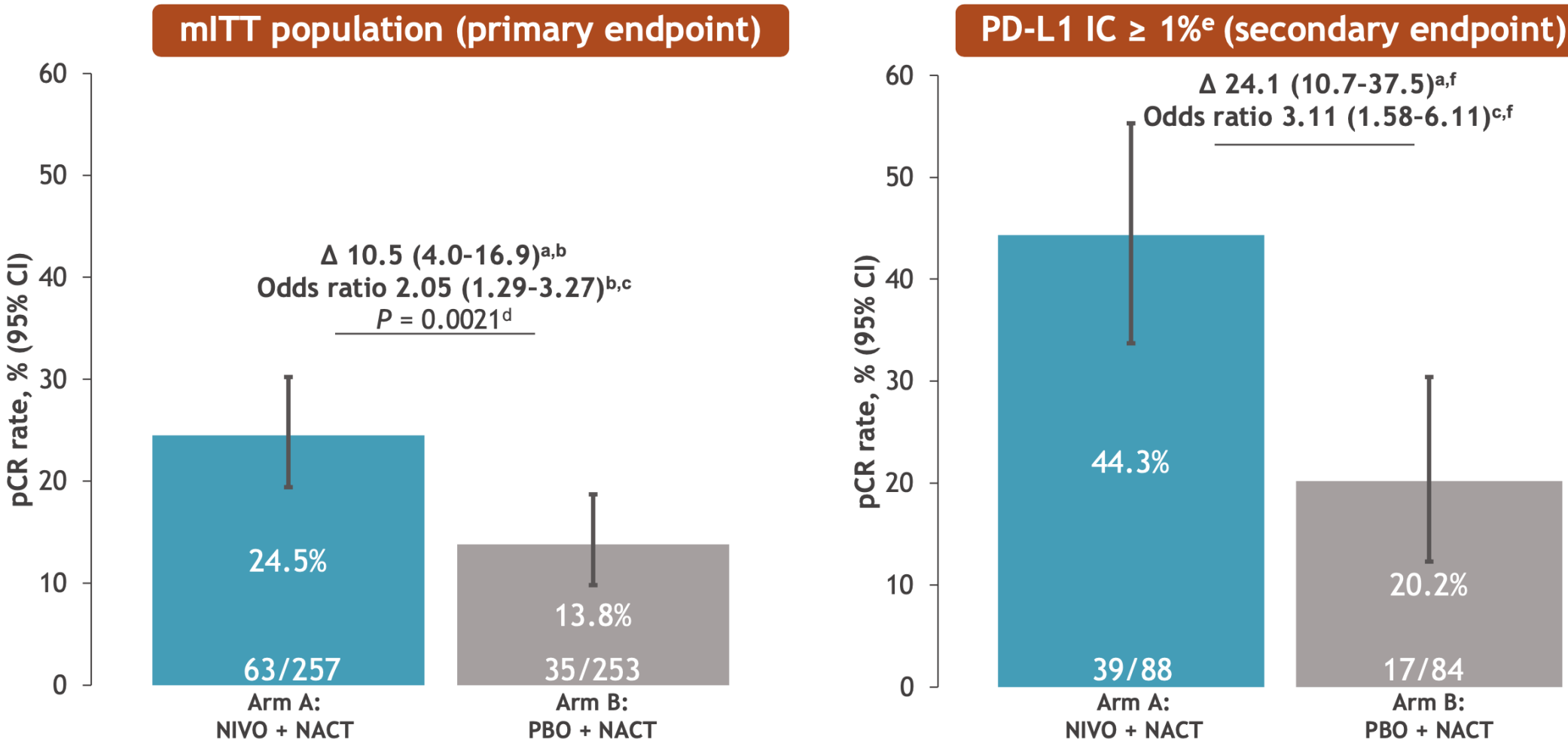
VENTANA PD-L1 SP142 in immunoistochimica (cutoff 1%)

POPOLAZIONE



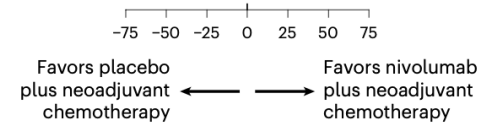
Demographic/characteristic	Nivolumab plus neoadjuvant CT			Placebo plus neoadjuvant CT		
	mITT population (*n*=257)	SP142 PD-L1– (*n*=169)[a]	SP142 PD-L1+ (*n*=88)[a]	mITT population (*n*=253)	SP142 PD-L1– (*n*=169)[a]	SP142 PD-L1+ (*n*=84)[a]
Female	257 (100)	169 (100)	88 (100)	252 (99.6)	168 (99.4)	84 (100)
Median age, years (range)	50 (24–78)	51 (24–77)	49 (28–78)	51 (23–79)	51 (23–79)	51 (27–78)
ECOG PS						
0	221 (86)	144 (85)	77 (88)	222 (88)	146 (86)	76 (91)
1	36 (14)	25 (15)	11 (13)	31 (12)	23 (14)	8 (10)
Tumor grade[b]						
Grade 2	6 (2)	2 (1)	4 (5)	1 (<1)	1 (1)	0 (0)
Grade 3	251 (98)	167 (99)	84 (96)	252 (>99)	168 (99)	84 (100)
Stage[c] (cTNM classification[d])						
Stage II	135 (53)	88 (52)	47 (53)	138 (55)	94 (56)	44 (52)
Stage III	118 (46)	77 (46)	41 (47)	105 (42)	67 (40)	38 (45)
Not assigned/reported	4 (2)	4 (2)	0 (0)	7 (3)	6 (4)	1 (1)
PD-L1[b]						
<1%	169 (66)	–	–	169 (67)	–	–
≥1%	88 (34)			84 (33)		
Axillary nodal status						
Positive	205 (80)	135 (80)	70 (80)	201 (79)	134 (79)	67 (80)
Negative	52 (20)	34 (20)	18 (21)	52 (21)	35 (21)	17 (20)
AC dose-frequency CT regimen[e]						
Q2W	132 (51)	85 (50)	47 (53)	134 (53)	88 (52)	46 (55)
Q3W	125 (49)	84 (50)	41 (47)	119 (47)	81 (48)	38 (45)

PCR RATES


mITT population (primary endpoint)
pCR rate, % (95% CI)
60
50
40
30
20
10
0
Δ 10.5 (4.0-16.9)a,b
Odds ratio 2.05 (1.29-3.27)b,c
P = 0.0021d
24.5%
63/257
13.8%
35/253
Arm A:
NIVO + NACT
Arm B:
PBO + NACT
PD-L1 IC ≥ 1%e (secondary endpoint)
Δ 24.1 (10.7-37.5)a,f
Odds ratio 3.11 (1.58-6.11)c,f
44.3%
39/88
20.2%
17/84
Arm A:
NIVO + NACT
Arm B:
PBO + NACT

RESULTS

		pCR rate, % (95% CI)		Unweighted pCR difference
	n	Nivolumab plus neoadjuvant chemotherapy	Placebo plus neoadjuvant chemotherapy	% (95% CI)
Overall	510	24.5 (19.4 to 30.2)	13.8 (9.8 to 18.7)	10.7 (3.9 to 17.4)
PD-L1 on ICs by SP142 (IRT)				
< 1%	338	14.2 (9.3 to 20.4)	10.7 (6.4 to 16.3)	3.6 (−3.6 to 10.7)
≥ 1%	172	44.3 (33.7 to 55.3)	20.2 (12.3 to 30.4)	24.1 (10.1 to 36.7)
Axillary nodal status (IRT)				
Positive	406	24.4 (18.7 to 30.9)	11.9 (7.8 to 17.2)	12.4 (5.0 to 19.8)
Negative	104	25.0 (14.0 to 38.9)	21.2 (11.1 to 34.7)	3.8 (−12.3 to 19.8)
Baseline anatomical stage defined by TNM classification				
Stage I	1	NA, 0/0	0.0 (0.0 to 97.5)	
Stage II	273	23.0 (16.2 to 31.0)	16.7 (10.9 to 24.0)	6.3 (−3.2 to 15.7)
Stage III	223	26.3 (18.6 to 35.2)	10.5 (5.3 to 18.0)	15.8 (5.6 to 25.5)
Stage IV[a]	2	NA	0.0 (0.0 to 84.2)	
Not assigned	9	25.0 (0.6 to 80.6)	20.0 (0.5 to 71.6)	
Not reported	2	NA	0.0 (0.0 to 84.2)	
Age				
< 50	241	23.0 (15.8 to 31.4)	12.6 (7.2 to 19.9)	10.3 (0.6 to 19.9)
≥ 50	269	25.9 (18.8 to 34.2)	14.9 (9.4 to 22.1)	11.0 (1.3 to 20.4)
Ethnic background				
White	384	25.5 (19.6 to 32.2)	12.2 (7.9 to 17.8)	13.3 (5.5 to 20.9)
Black or African American	14	16.7 (0.4 to 64.1)	12.5 (0.3 to 52.7)	
Asian	42	8.3 (1.0 to 27.0)	5.6 (0.1 to 27.3)	2.8 (−18.3 to 20.9)
American Indian or Alaska Native	35	33.3 (13.3 to 59.0)	29.4 (10.3 to 56.0)	3.9 (−25.3 to 31.9)
Native Hawaiian or Other Pacific Islander	5	0.0 (0.0–84.2)	33.3 (0.8 to 90.6)	
Other	29	36.4 (10.9 to 69.2)	22.2 (6.4 to 47.6)	14.1 (−17.1 to 45.3)
Not reported	1	NA	0.0 (0.0 to 97.5)	
AC dose-frequency chemotherapy regimen (IRT)				
Q2W	266	23.5 (16.5 to 31.6)	14.2 (8.8 to 21.3)	9.3 (−0.1 to 18.6)
Q3W	244	25.6 (18.2 to 34.2)	13.4 (7.9 to 20.9)	12.2 (2.2 to 21.8)



OUTLINE

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- Checkmate-7FL
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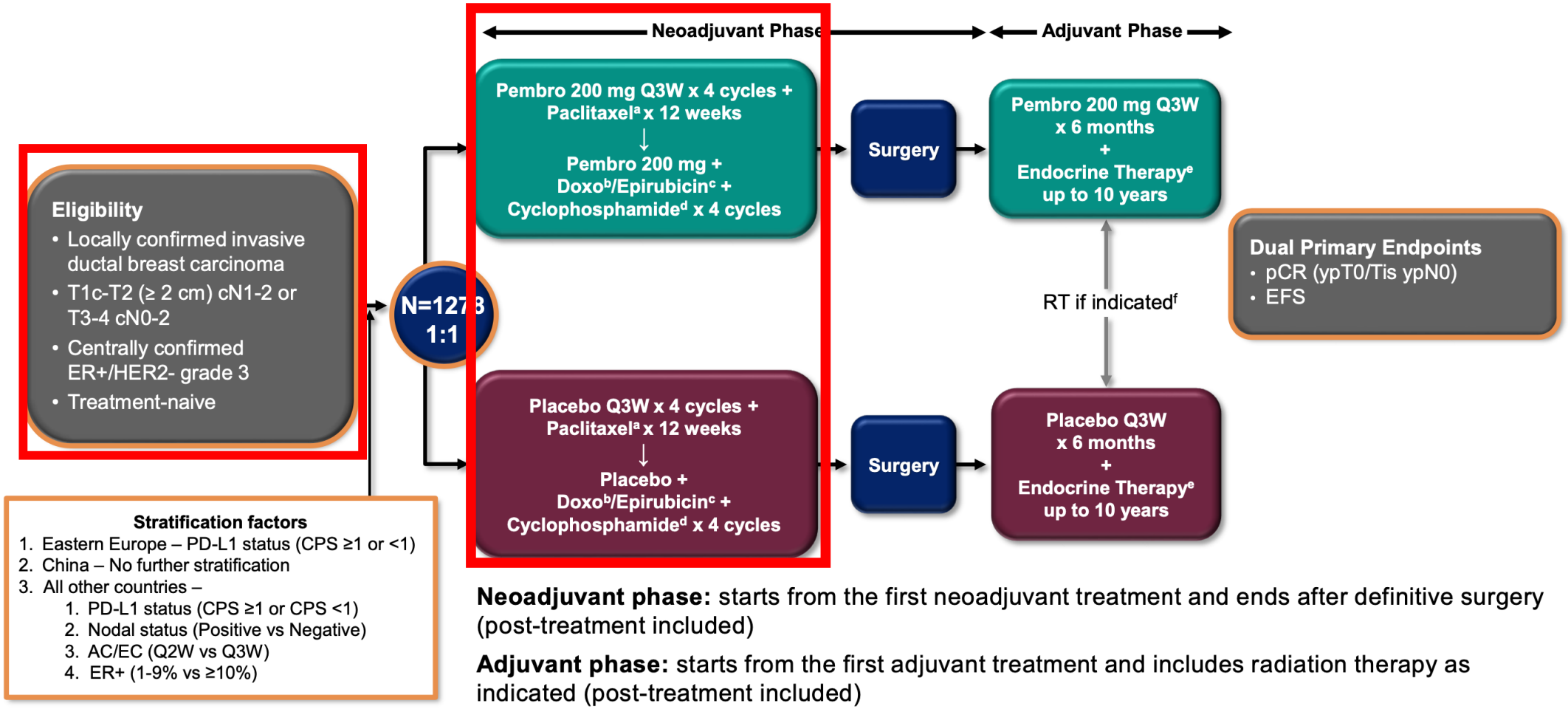
- Discussion

STUDY DESIGN

nature medicine

Article https://doi.org/10.1038/s41591-024-03415-7

Pembrolizumab and chemotherapy in high-risk, early-stage, ER$^+$/HER2$^-$ breast cancer: a randomized phase 3 trial

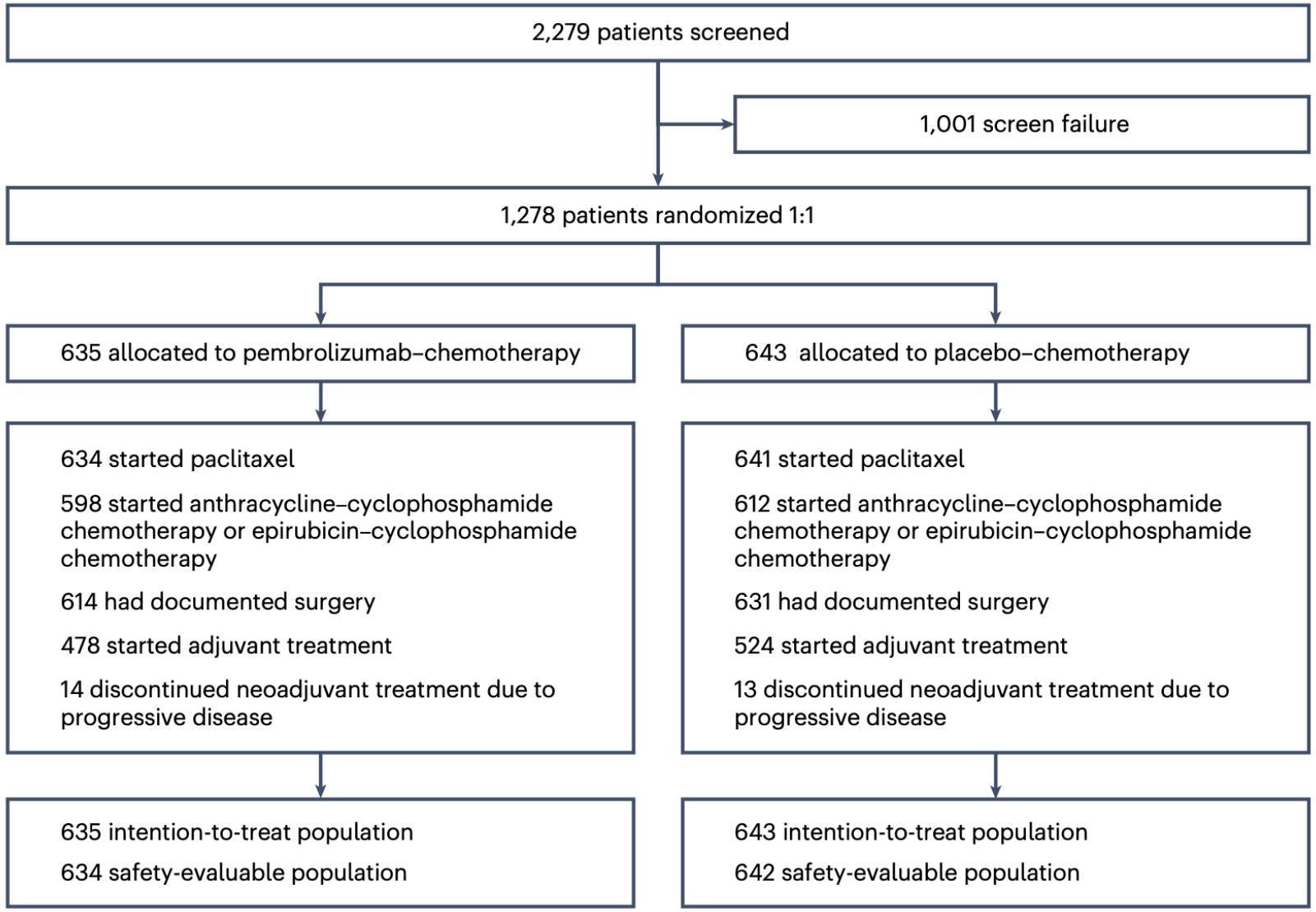


Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post-treatment included)

Adjuvant phase: starts from the first adjuvant treatment and includes radiation therapy as indicated (post-treatment included)

PD-L1 CPS ≥ 1 tumor

RESULTS

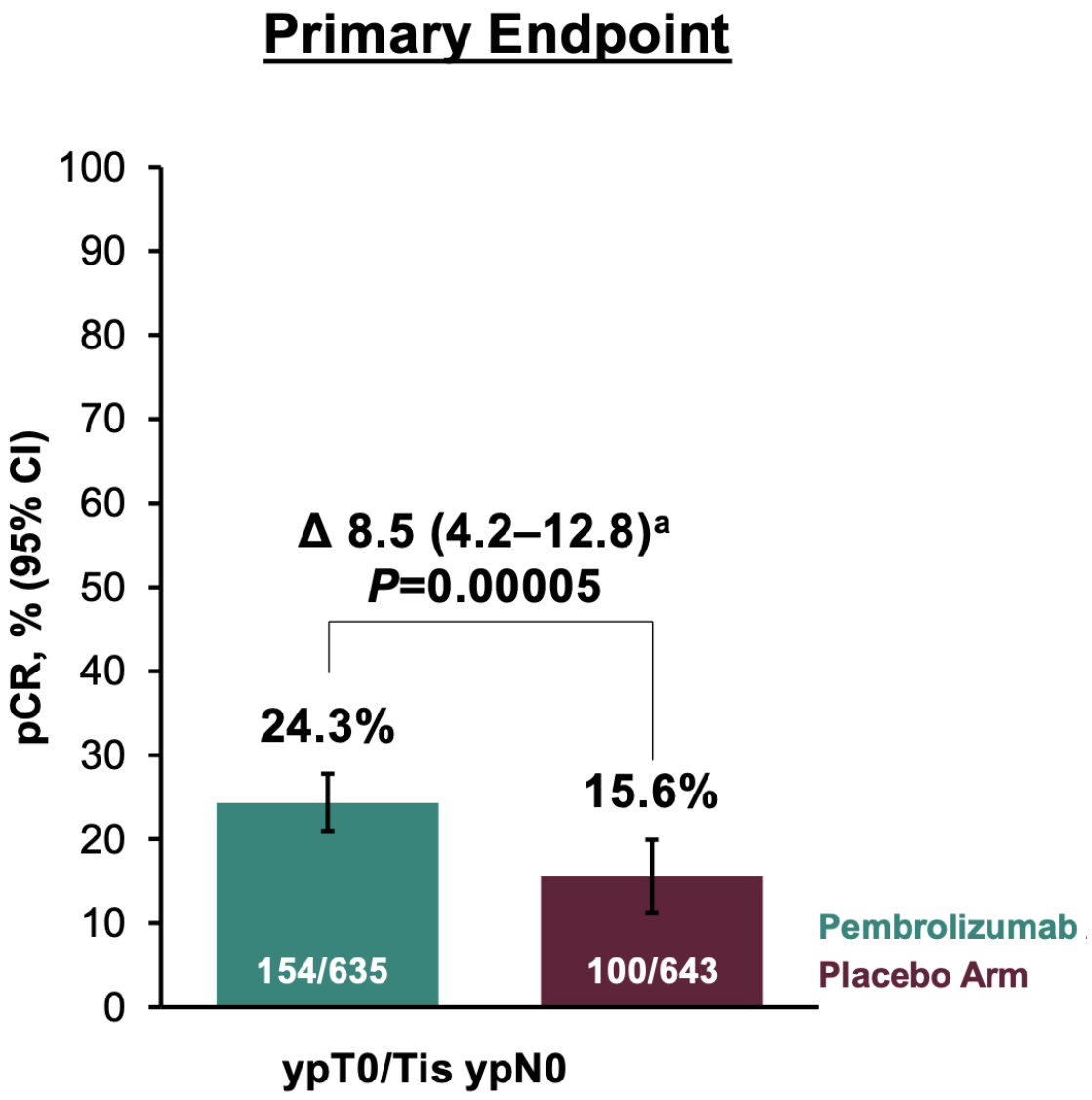


Cardoso F. et al., Nat Med. 2025

BASELINE CHARACTERISTICS

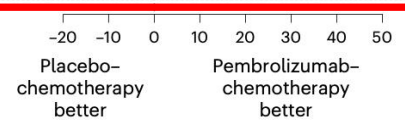
Characteristic	Pembrolizumab–chemotherapy (*n*=635)	Placebo–chemotherapy (*n*=643)
Age (year)		
Median (range)	49 (24–82)	49 (19–78)
≥65—no. (%)	89 (14.0)	76 (11.8)
Country/region—no. (%)		
China	88 (13.9)	91 (14.2)
Eastern Europe	139 (21.9)	130 (20.2)
Other	408 (64.3)	422 (65.6)
PD-L1 CPS—no. (%)[b]		
<1	153 (24.1)	154 (24.0)
≥1	482 (75.9)	489 (76.0)
≥10	253 (39.8)	259 (40.3)
≥20	125 (19.7)	129 (20.1)
ECOG performance status—no. (%)[c]		
0	570 (89.8)	588 (91.4)
1	65 (10.2)	55 (8.6)
Anthracycline schedule—no. (%)		
Every 3 weeks	415 (65.4)	425 (66.1)
Every 2 weeks	183 (28.8)	187 (29.1)
Not started	37 (5.8)	31 (4.8)
Tumor classification—no. (%)		
T1–T2	402 (63.3)	413 (64.2)
T3–T4	233 (36.7)	230 (35.8)
Nodal involvement—no. (%)		
Positive	570 (89.8)	582 (90.5)
Negative	65 (10.2)	61 (9.5)
Overall disease stage—no. (%)		
Stage II	399 (62.8)	408 (63.5)
Stage III	236 (37.2)	235 (36.5)
Tumor grade—no. (%)		
Grade 3	635 (100)	642 (99.8)
Grade 2	0	1 (0.2)[d]
ER positivity—no. (%)		
≥10%	601 (94.6)	600 (93.3)
<10%	34 (5.4)	43 (6.7)
Menopausal status—no. (%)		
Premenopausal	354 (55.7)	353 (54.9)
Postmenopausal	278 (43.8)	287 (44.6)
Not applicable	3 (0.5)	3 (0.5)

RESULTS


Primary Endpoint
100
90
80
70
60
50
40
30
20
10
0
pCR, % (95% CI)
Δ 8.5 (4.2–12.8)a
P=0.00005
24.3%
15.6%
154/635
100/643
Pembrolizumab
Placebo Arm
ypT0/Tis ypN0

RESULTS

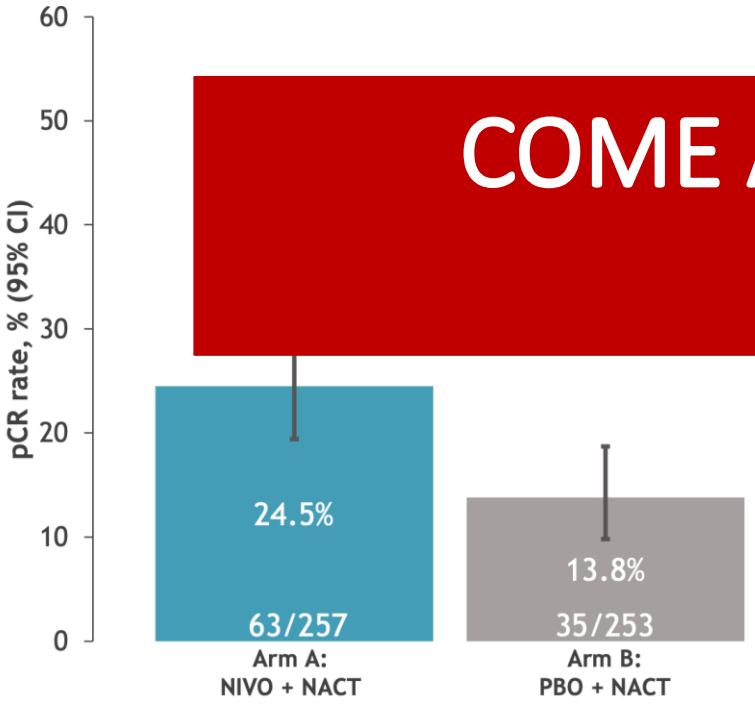
	Pembrolizumab–chemotherapy	Placebo–chemotherapy	Difference in pathological complete response (95% CI)
	No. of patients with response/no. of patients (%)		Percentage points
Overall	154/635 (24.3)	100/643 (15.6)	8.5 (4.2 to 12.8)
Disease stage			
Stage II	103/399 (25.8)	68/408 (16.7)	9.1 (3.5 to 14.8)
Stage III	51/236 (21.6)	32/235 (13.6)	8.0 (1.1 to 14.9)
Nodal status			
Positive	143/570 (25.1)	92/582 (15.8)	9.3 (4.6 to 13.9)
Negative	11/65 (16.9)	8/61 (13.1)	3.8 (–9.2 to 16.7)
Tumor size			
T1–T2	111/402 (27.6)	71/413 (17.2)	10.4 (4.7 to 16.1)
T3–T4	43/233 (18.5)	29/230 (12.6)	5.8 (–0.8 to 12.5)
Anthracycline schedule			
Every 3 week	97/415 (23.4)	55/425 (12.9)	10.4 (5.3 to 15.7)
Every 2 week	54/183 (29.5)	44/187 (23.5)	6.0 (–3.0 to 15.0)
Not started	3/37 (8.1)	1/31 (3.2)	4.9 (–9.2 to 18.8)
PD-L1 CPS			
<1	11/153 (7.2)	4/154 (2.6)	4.5 (–0.4 to 10.1)
≥1	143/482 (29.7)	96/489 (19.6)	9.8 (4.4 to 15.2)
≥10	107/253 (42.3)	75/259 (29.0)	13.2 (4.9 to 21.4)
≥20[a]	67/125 (53.6)	47/129 (36.4)	17.4 (5.1 to 29.1)
ER positivity			
≥10	135/601 (22.5)	87/600 (14.5)	8.0 (3.6 to 12.4)
<10	19/34 (55.9)	13/43 (30.2)	25.6 (3.3 to 45.8)
Age			
<65 yr	135/546 (24.7)	89/567 (15.7)	9.0 (4.3 to 13.7)
≥65 yr	19/89 (21.3)	11/76 (14.5)	6.9 (–5.2 to 18.6)
ECOG performance status			
0	142/570 (24.9)	91/588 (15.5)	9.4 (4.8 to 14.1)
1	12/65 (18.5)	9/55 (16.4)	2.1 (–12.2 to 15.8)
Geographic region			
China	11/88 (12.5)	9/91 (9.9)	2.6 (–7.0 to 12.5)
Eastern Europe	41/139 (29.5)	21/130 (16.2)	13.3 (3.3 to 23.2)
Other	102/408 (25.0)	70/422 (16.6)	8.4 (2.9 to 13.9)
Menopausal status			
Premenopausal	83/354 (23.4)	57/353 (16.1)	7.3 (1.4 to 13.2)
Postmenopausal	69/278 (24.8)	42/287 (14.6)	10.2 (3.7 to 16.8)



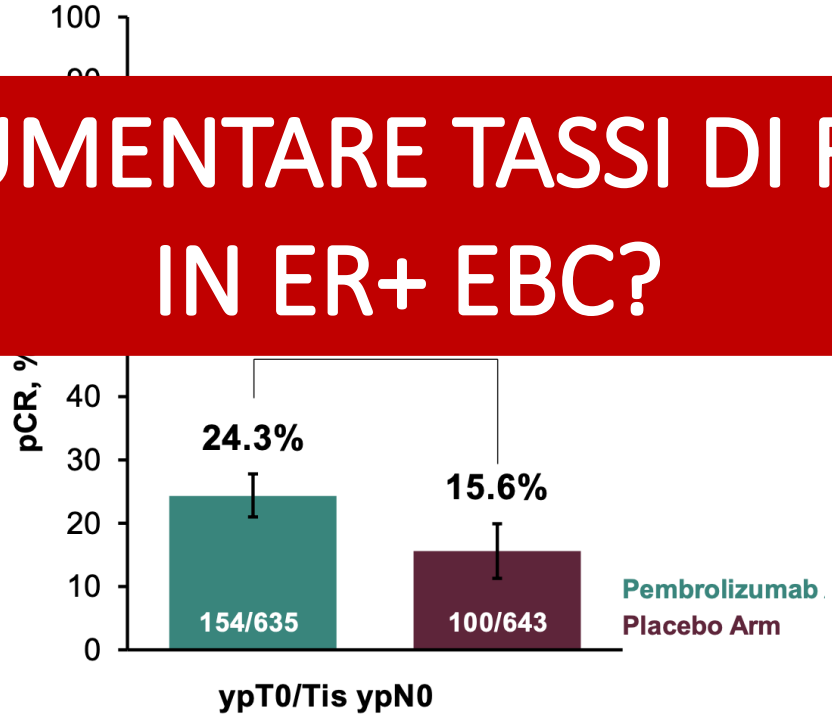
Cardoso F. et al., Nat Med. 2025

CONFRONTO IN TASSI DI PCR

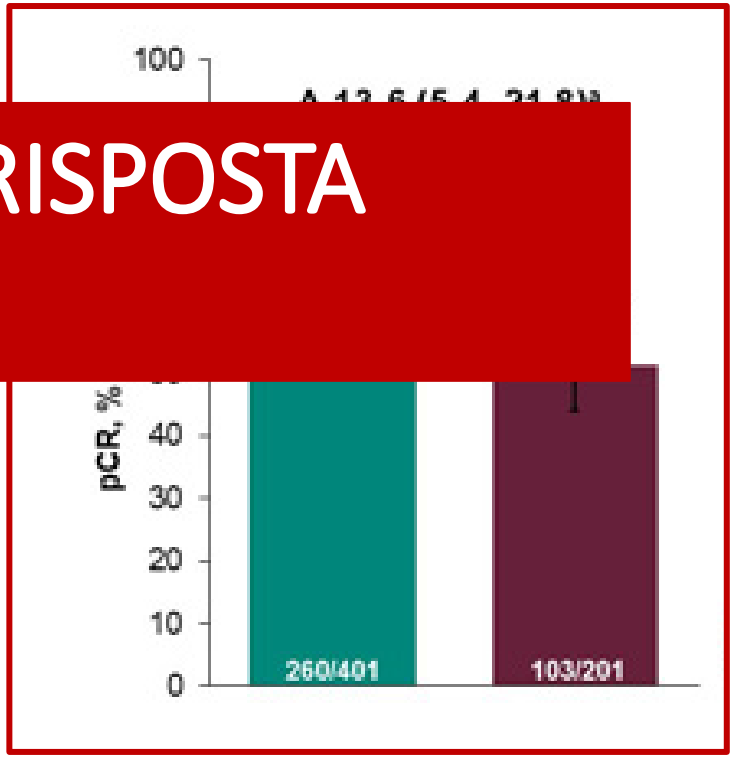
CHECKMATE-7FL



KEYNOTE-756



KEYNOTE-522

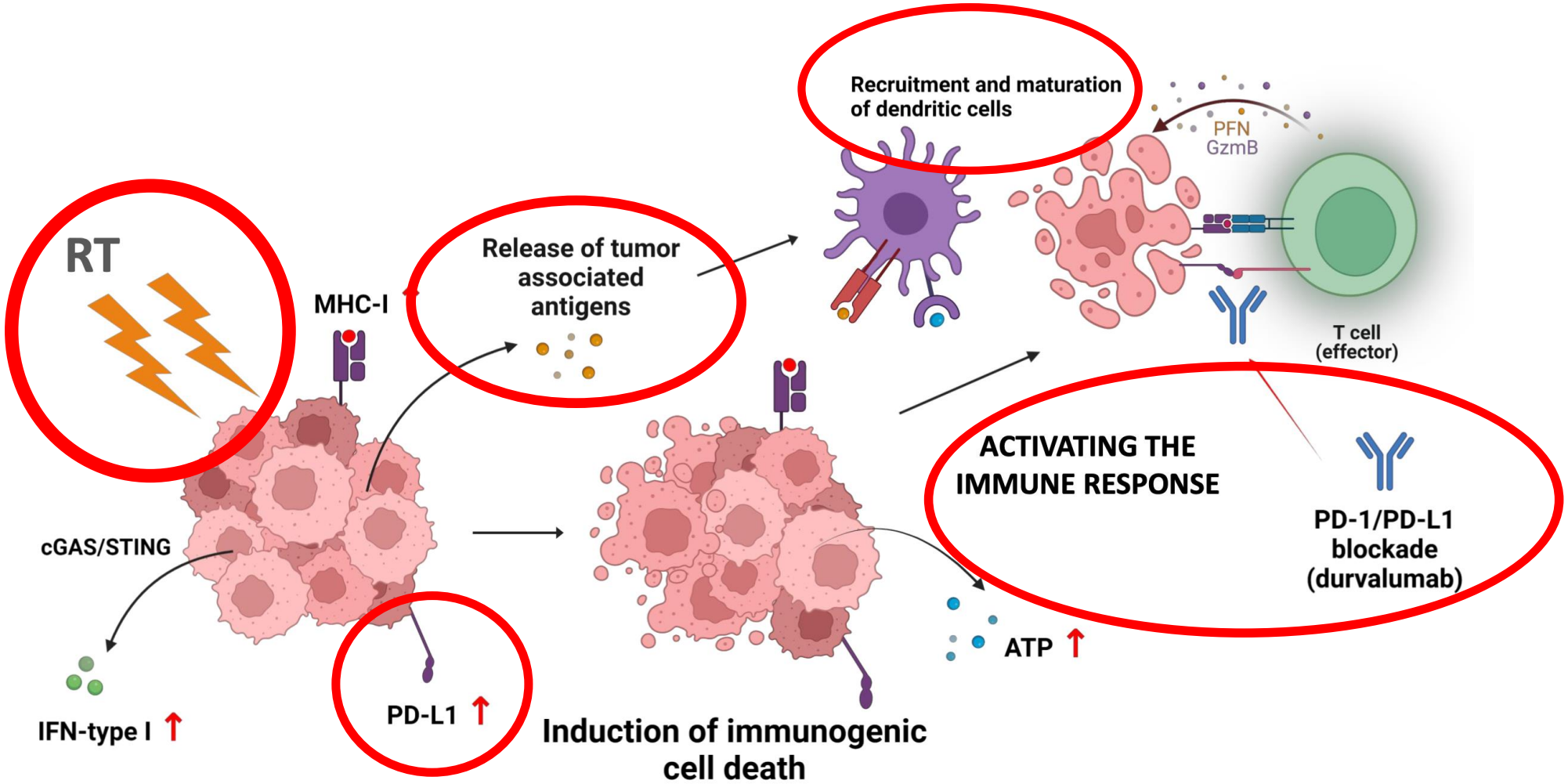


COME AUMENTARE TASSI DI RISPOSTA IN ER+ EBC?

Cardoso F. et al., Nat Med. 2025 | Loi S. et al., Nat Med. 2025 |Schmid P. et al., ESMO 2020

COME AUMENTARE L'ATTIVAZIONE IMMUNITARIA?

LA RADIOTERAPIA PUÒ STIMOLARE LA RISPOSTA IMMUNITARIA

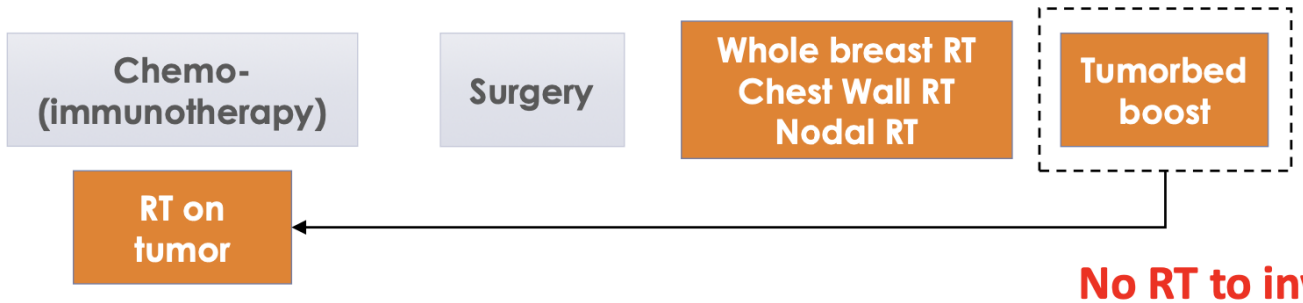


OUTLINE

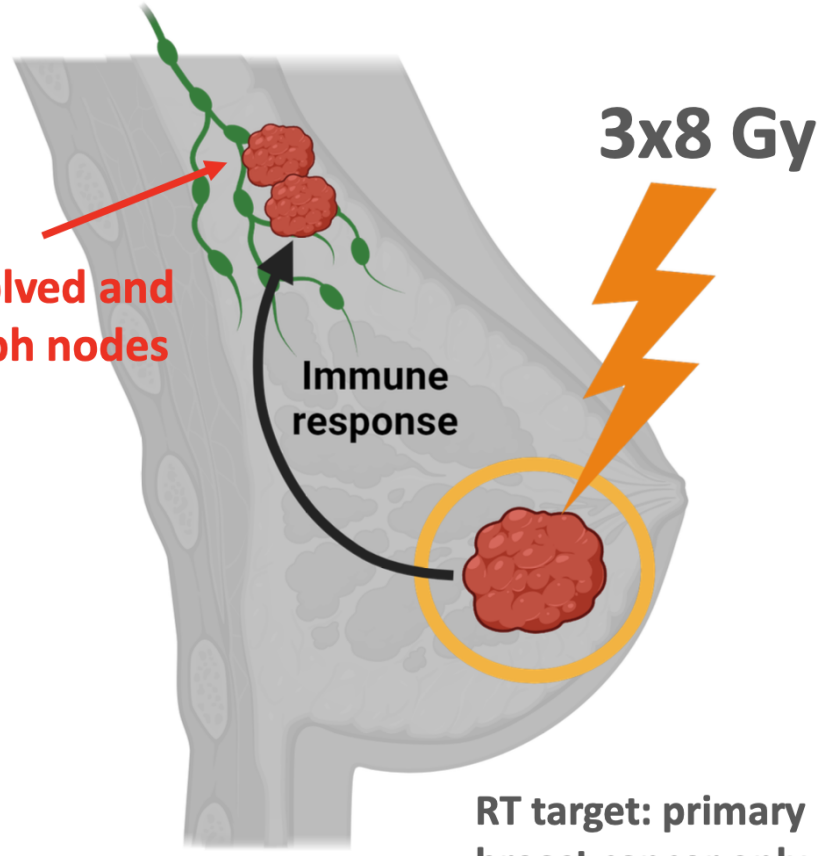
- Background
- Checkmate-7FL
- Keynote-756
- **Neo-CheckRay**
- Discussion

RADIOTERAPIA IN ER+ BC?

COME SPOSTARE LA RADIOTERAPIA NEL SETTING NEO-ADIUVANTE?



No RT to involved and draining lymph nodes



RT target: primary breast cancer only

What radiation dose?

Immune modulating SBRT = iSBRT	
RT Intent	**Immunomodulation** Non-ablative intent of RT
RT dose	3 daily fraction of 8 Gy
When?	Shortly <u>before</u> the second cycle of durvalumab

STUDY DESIGN

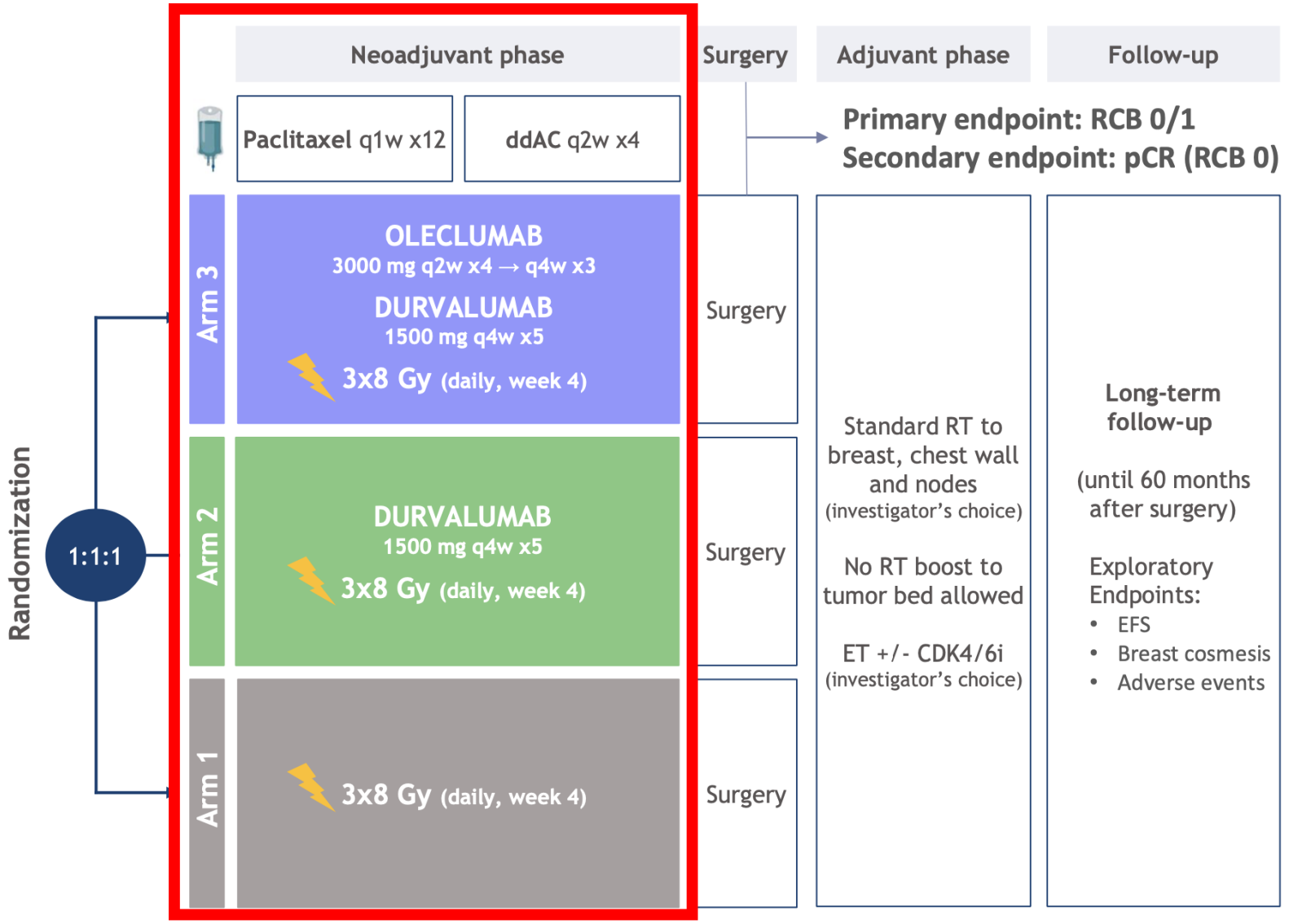
Screening

Key inclusion criteria

- **Newly diagnosed early ER+ HER2− breast cancer**
- Grade 3 or grade 2 with Ki67≥15%
- **MammaPrint® high risk**
- cT1c-3 (≥ 2 cm) cN0 *or* cT1c-3 (≥ 1.5 cm) cN1-3
- ECOG PS 0-1
- Adequate organ function
- Tissue available for PD-L1 assessment (central lab)

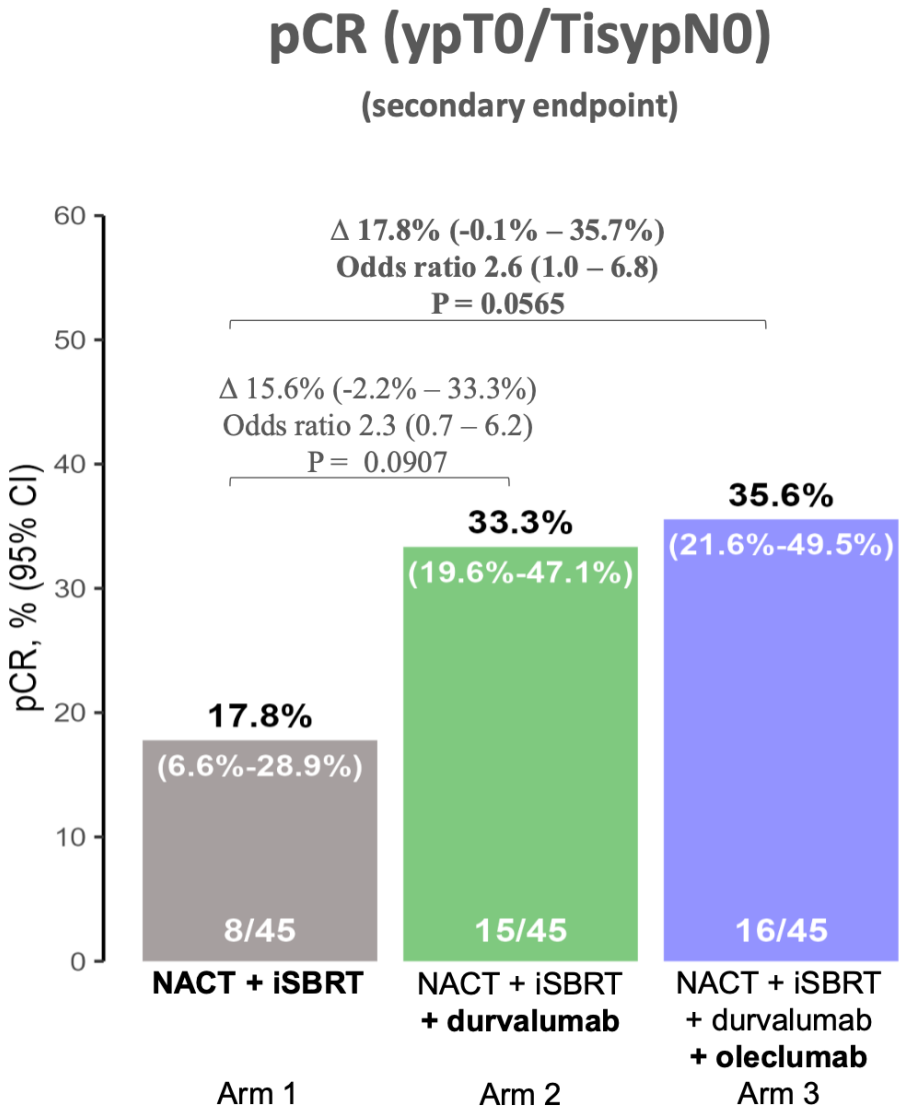
Stratification factors

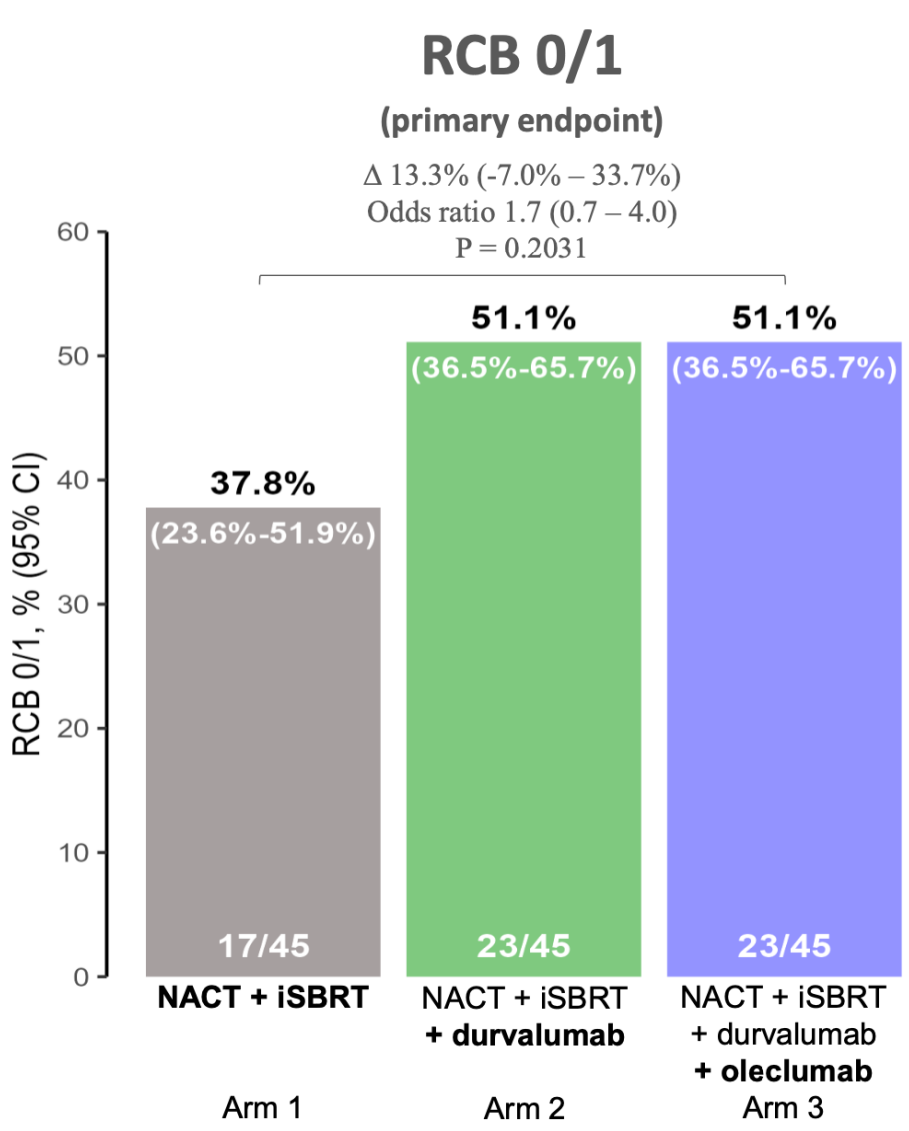
- PD-L1 IC (≥ 1% or < 1%) by SP263
- Nodal status (positive or negative)
- cT1/cT2 or cT3



The Immune Cell score (IC score) is defined as the % of tumor area occupied by PD-L1 stained immune cells. RCB, residual cancer burden; RCB-0: no residual disease; RCB-1: minimal residual disease.

RESULTS


pCR (ypT0/TisypN0)
(secondary endpoint)
Δ 17.8% (-0.1% – 35.7%)
Odds ratio 2.6 (1.0 – 6.8)
P = 0.0565
Δ 15.6% (-2.2% – 33.3%)
Odds ratio 2.3 (0.7 – 6.2)
P = 0.0907
pCR, % (95% CI)
60
50
40
30
20
10
0
17.8%
(6.6%-28.9%)
8/45
33.3%
(19.6%-47.1%)
15/45
35.6%
(21.6%-49.5%)
16/45
NACT + iSBRT
NACT + iSBRT + durvalumab
NACT + iSBRT + durvalumab + oleclumab
Arm 1
Arm 2
Arm 3


RCB 0/1
(primary endpoint)
Δ 13.3% (-7.0% – 33.7%)
Odds ratio 1.7 (0.7 – 4.0)
P = 0.2031
RCB 0/1, % (95% CI)
60
50
40
30
20
10
0
37.8%
(23.6%-51.9%)
17/45
51.1%
(36.5%-65.7%)
23/45
51.1%
(36.5%-65.7%)
23/45
NACT + iSBRT
NACT + iSBRT + durvalumab
NACT + iSBRT + durvalumab + oleclumab
Arm 1
Arm 2
Arm 3

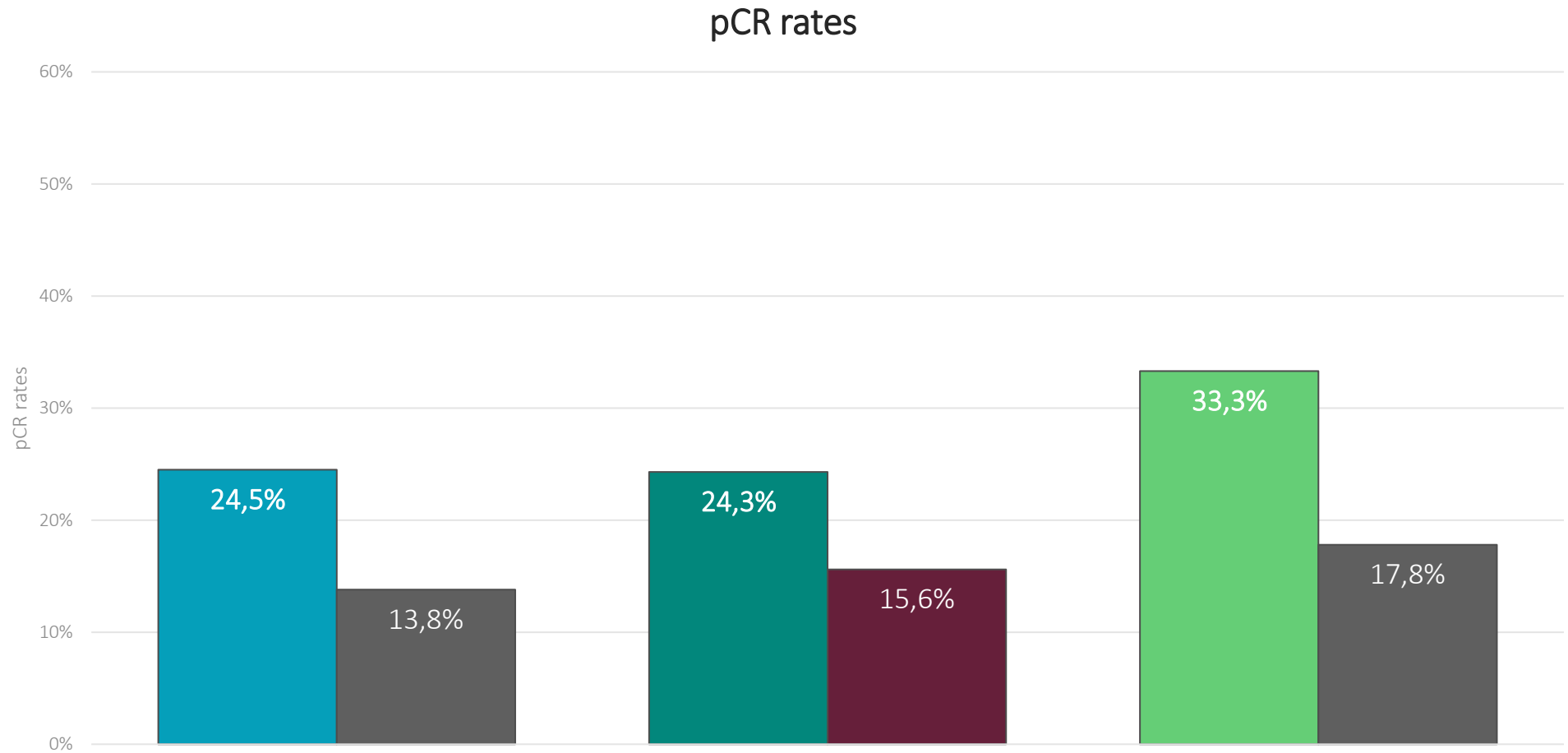
OUTLINE

- Background
- Checkmate-7FL
- Keynote-756
- Neo-CheckRay
- **Discussion**

DISEGNO DEGLI STUDI

Study	CheckMate-7FL	CheckMate-7A8	GIADA	KEYNOTE-756	Neo-CheckRay	I-SPY2
Phase and design	III RCT (1:1)	Ib/II RT noncomparative	II single arm, open label	III RCT (1:1)	Ib/II RT (1:1:1)	II adaptively randomized platform trial
Stage	T1c or T2 N1-2 T3-T4 N0-2	≥T1c	T0-1 N1-N2 T2 N0-2 T3 N0-2	T1c or T2 N1-2 T3-T4 N0-2	T1c (≥15 mm) N1-3 T1c (=20 mm) N0-3 T2-T3-T4 N0-3	T2 (≥25 mm) N0-3 T3-T4 N0-3
ICI agent	Nivolumab (PD-1)	Nivolumab	Nivolumab	Pembrolizumab (PD-1)	Durvalumab (PD-L1) ± Oleclumab	Pembrolizumab and Durvalumab
Key biological inclusion criteria (ER+, PD-L1, other)	G3 and ER ≥1% (+/- PR positive) G2 and ER 1-10% (+/-PR positive) Ductal histology Men allowed	Postmenopausal ER-positive Men allowed	Premenopausal ER ≥ 10% and/or PgR ≥10% G3 and/or Ki67 >20% Men not allowed	ER ≥1% (+/-PR positive) G3 Ductal histology Men allowed	ER ≥1% (+/-PR positive) G3 or G2 and Ki67 ≥ 15% MP high risk OR MP NA at time of randomization if Ki67 ≥ 20% or G3 and Age<50 yo+cN0 OR Age ≥ 50 yo + cN+ Men not allowed	MP high risk any ER/HER2 status MP low and ER <5%, any HER2 status MP Low, ER and HER2 positive Men allowed
Key biological exclusion criteria	HER2-positive	Inflammatory BC (T4d) HER2-positive	Inflammatory BC (T4d) HER2-positive	HER2-positive	Inflammatory BC (T4d) HER2-positive	
Stratification factors	PD-L1 Grading Nodal status Dose frequency of anthracycline	NR	NR	PD-L1 ER (≥10% vs < 10%) Nodal pathological status Dose frequency of anthracycline	PD-L1 T size Nodal status	NR
Adjuvant regimen (sperimental arm)	Nivolumab 480 mg q4w with ET by IC	Not planned	Not planned	Pembrolizumab 200 mg q3w for 9 cycles with ET by IC	Not planned	Not planned
Primary Endpoint	pCR (ypT0/is, ypN0)	DLTs within 4 weeks of treatment initiation	pCR (ypT0, ypN0)	pCR rate (ypT0/Tis ypN0) and EFS.	RCB 0-1 rates	pCR (ypT0/is, ypN0)

RISULTATI A CONFRONTO: PCR

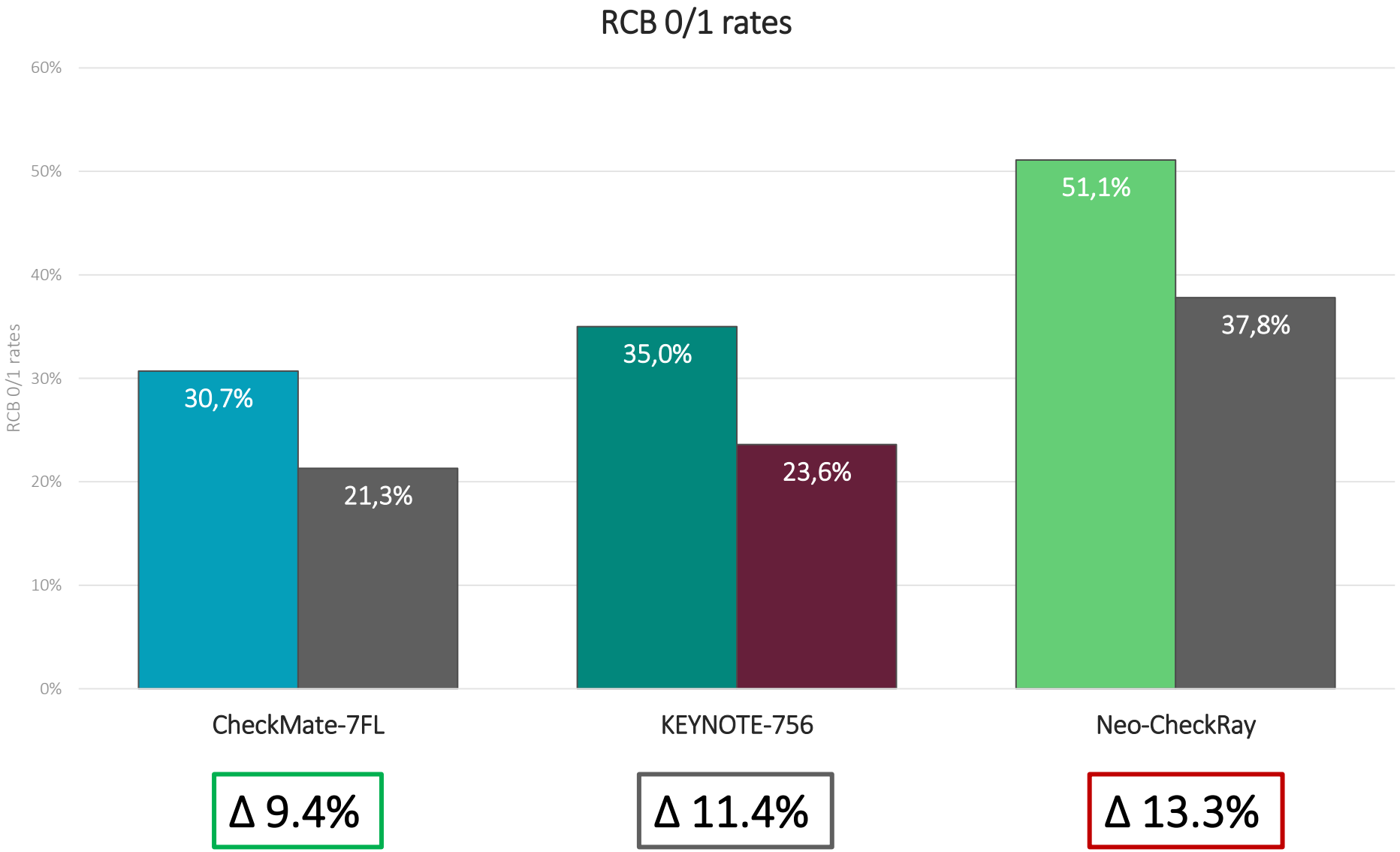


Δ 10.7%

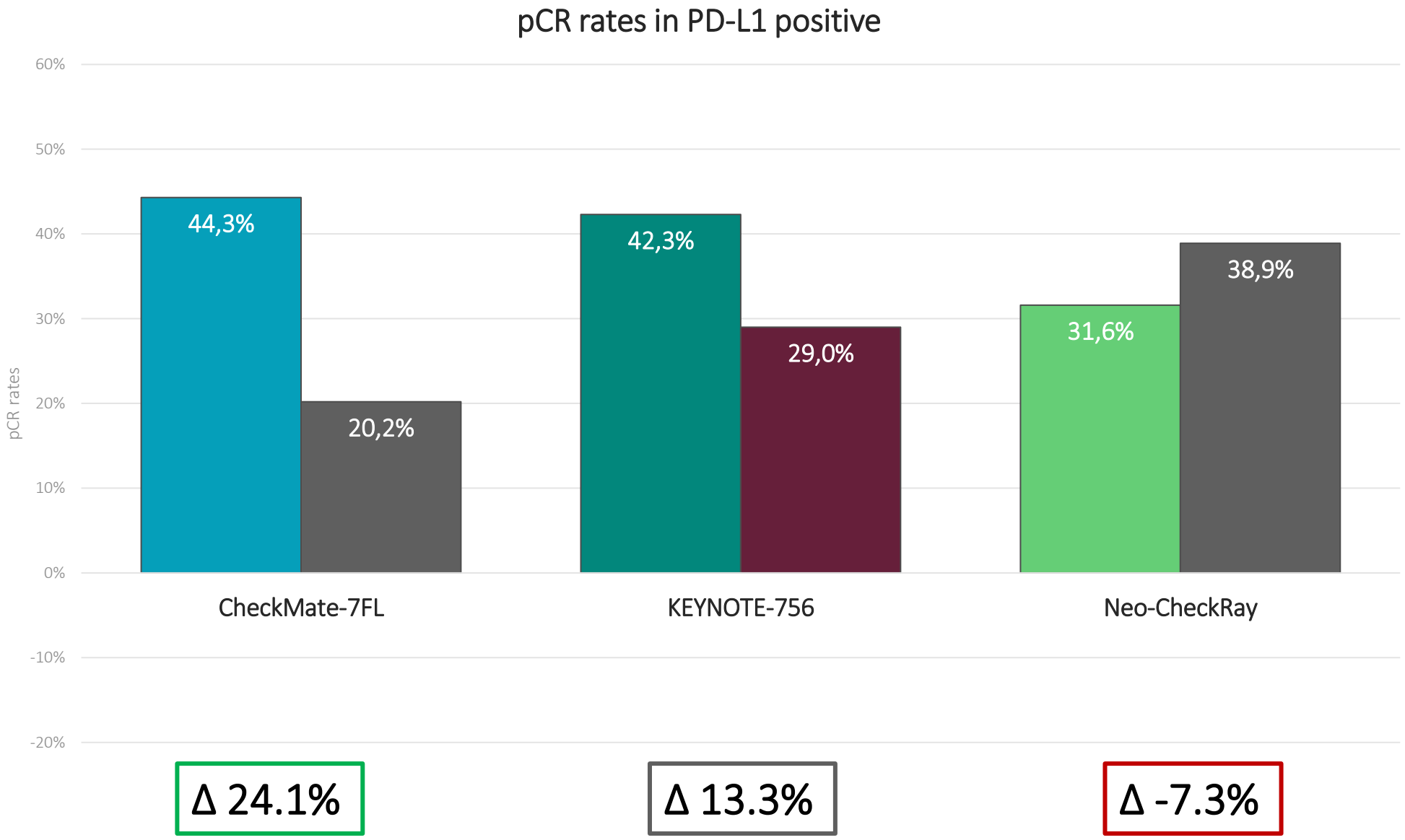
Δ 8.7%

Δ 15.5%

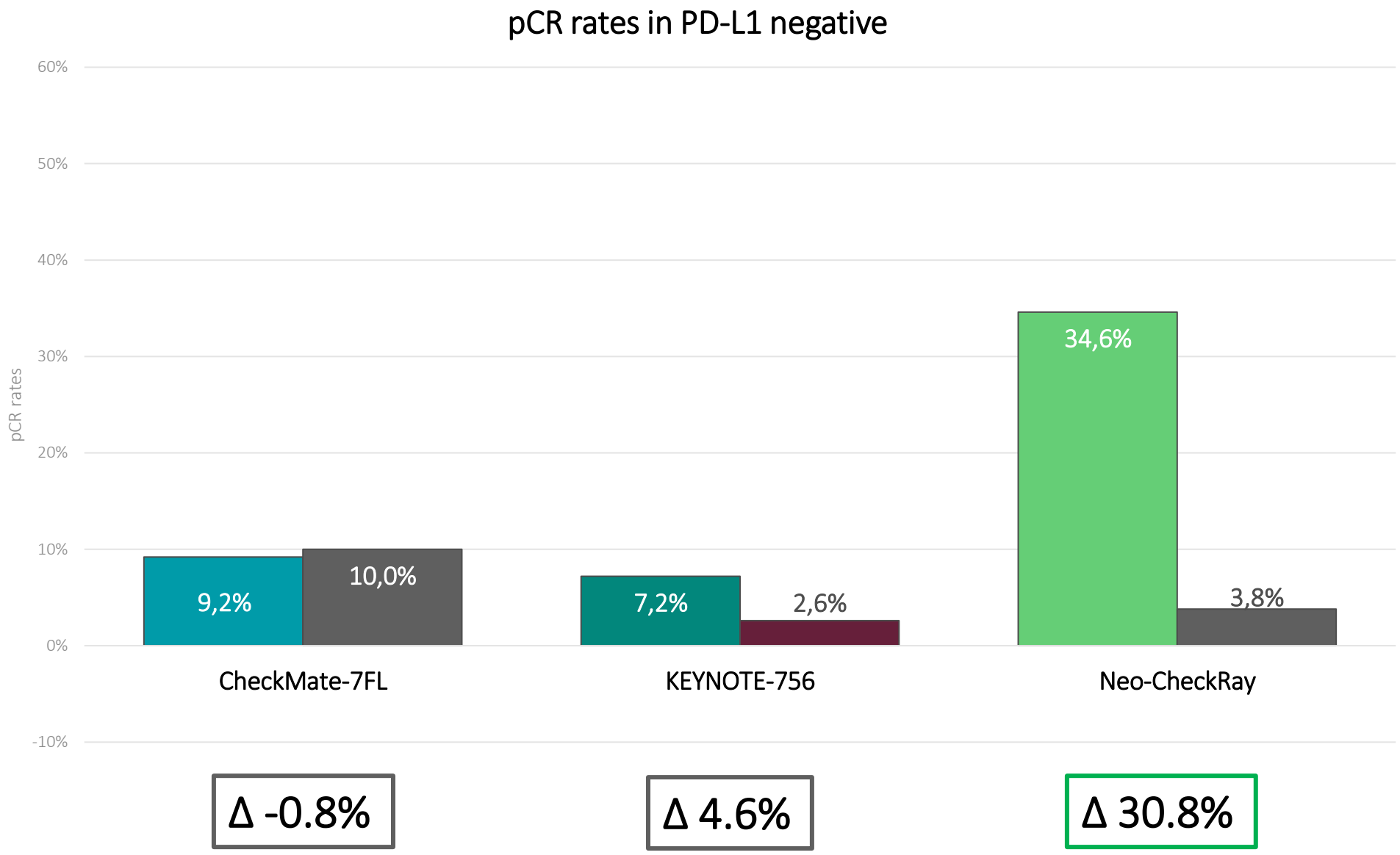
RISULTATI A CONFRONTO: RCB



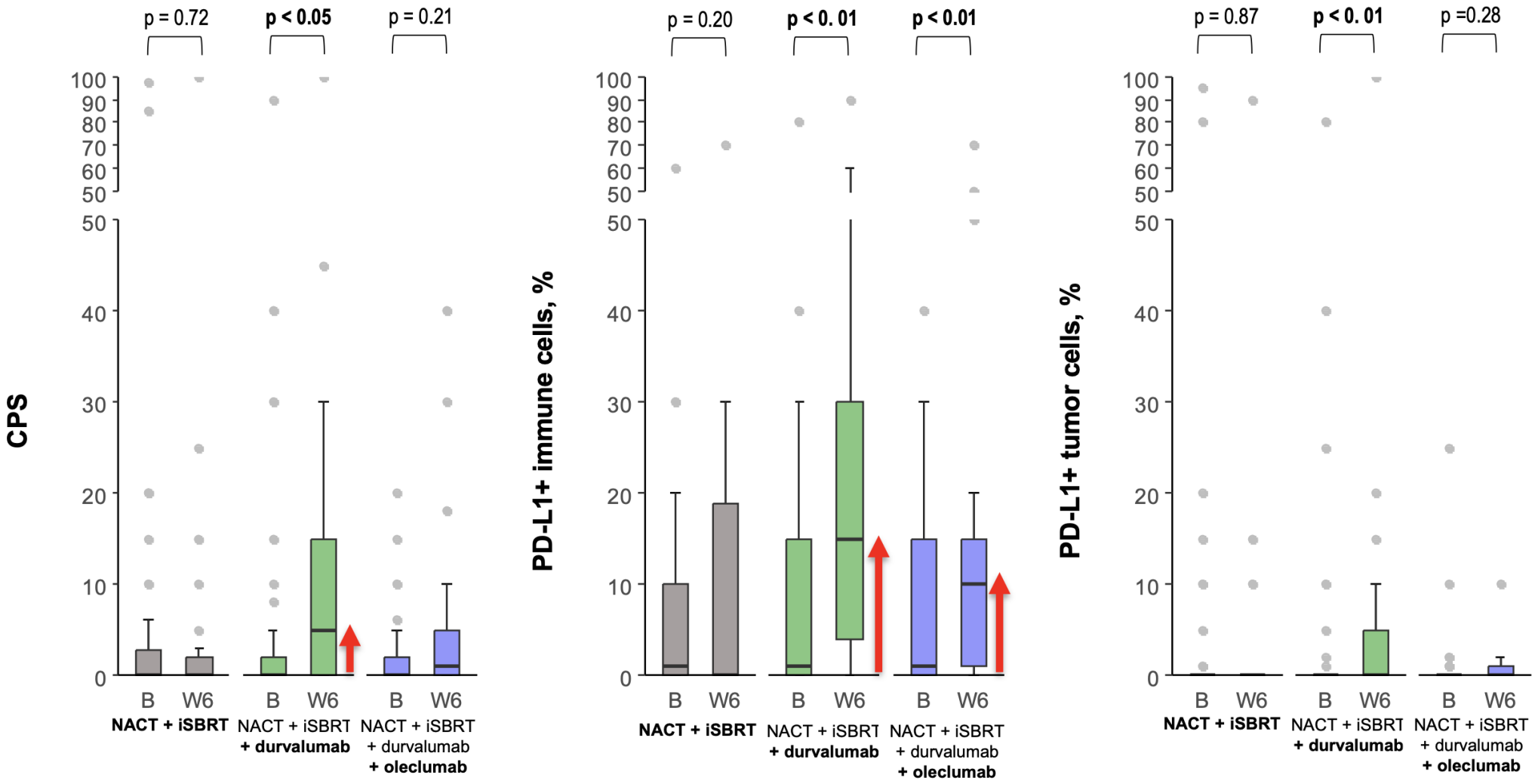
RISULTATI IN BASE ALL'ESPRESSIONE DI PDL1



RISULTATI IN BASE ALL'ESPRESSIONE DI PDL1



ANDAMENTO PD-L1: BASELINE VS WEEK 6



CONCLUSIONI

- Il ruolo dell'immunoterapia sta diventando sempre più importante nel trattamento neoadiuvante dell'eBC

- Gli ICIs hanno dimostrato efficacia in pazienti con malattia luminal-like ad alto rischio di recidiva, ma questo si tradurrà in un beneficio in sopravvivenza?

- Il beneficio ad oggi sembra essere pronunciato in particolari sottogruppi:
  - PD-L1 positivi
  - Rischio clinicamente più elevato (node-positive, stadio più elevato)

- Altre strategie possono aumentare la risposta all'immunoterapia, rendendo i tumori più "caldi" e aumentare ulteriormente i tassi di risposta

- Ruolo dell'immunoterapia adiuvante? Beneficio nelle pazienti candidate a CDK4/6i?

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GRAZIE PER L'ATTENZIONE!

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