

AIGOM
ASSOCIAZIONE ITALIANA
ONCOLOGI MAMMARI

13^a EDIZIONE
Progetto **CANOA**

CARCINOMA MAMMARIO:

QUALI NOVITA' PER IL 2023?

"Saper leggere" uno studio clinico per migliorare la pratica clinica

24-25 Marzo 2023

Ospedaletto di Pescantina (VR)
Centro Congressi Park Hotel Villa Quaranta

Coordinatori scientifici:
Stefania Gori
Giovanni L. Pappagallo



Immunoterapia e carcinoma
mammario:
quali evidenze dalla
letteratura?
Quali indicazioni per la
pratica clinica?

Emilia Montagna
Divisione Senologia Medica
Istituto Europeo di Oncologia
Milano



Declaration of Interests

Emilia Montagna

Institutional financial interests with commercial entities:

- Novartis
- Pierre fabre

- **No personal financial interests with any commercial entity**

Agenda

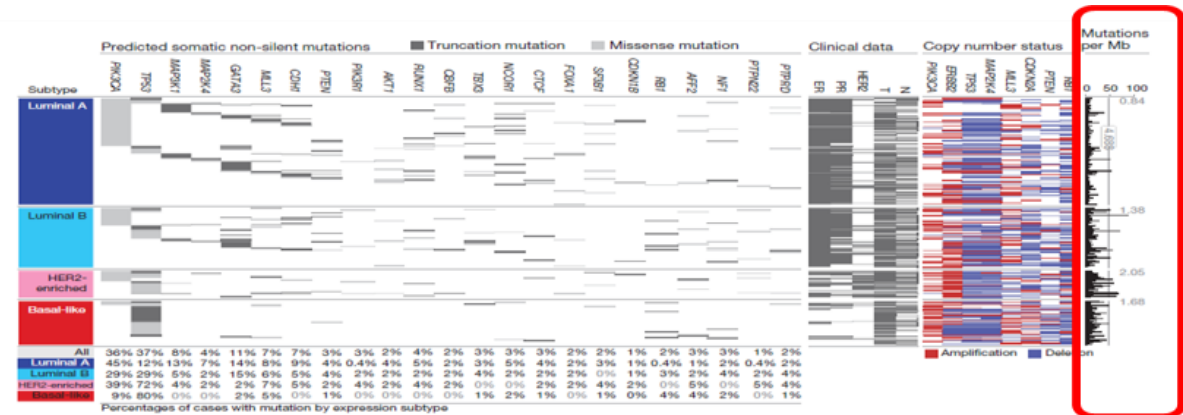
- **Quali evidenze dalla letteratura?**

Prima considerazione

- I dati di letteratura più rilevanti sono relativi alla pazienti con tumore mammario *triplo negativo*
- I dati di applicabilità clinica si riferiscono alle pazienti con tumore mammario *triplo negativo* -> *cambiamento nella pratica clinica*

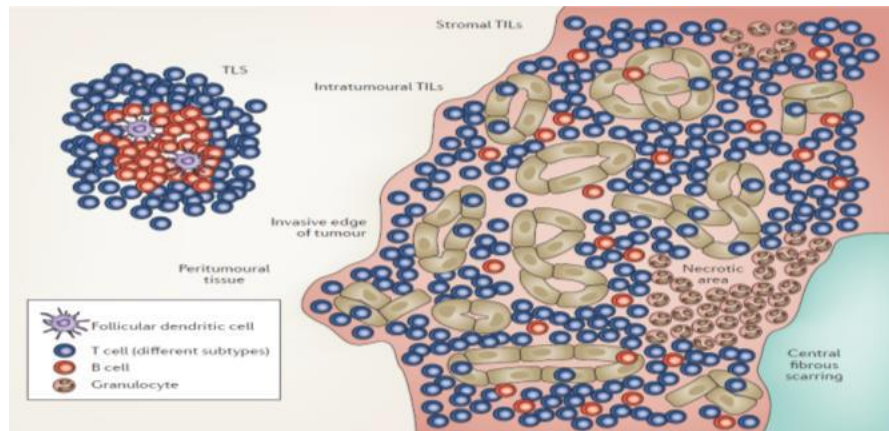
RATIONALE FOR IMMUNOTHERAPY IN TNBC

1) Higher mutational rate



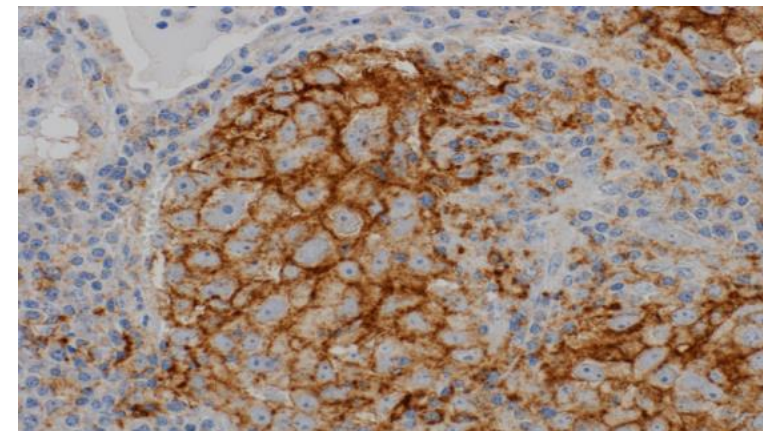
Wang, et al. Nature 2014

2) Higher TILs Agenda



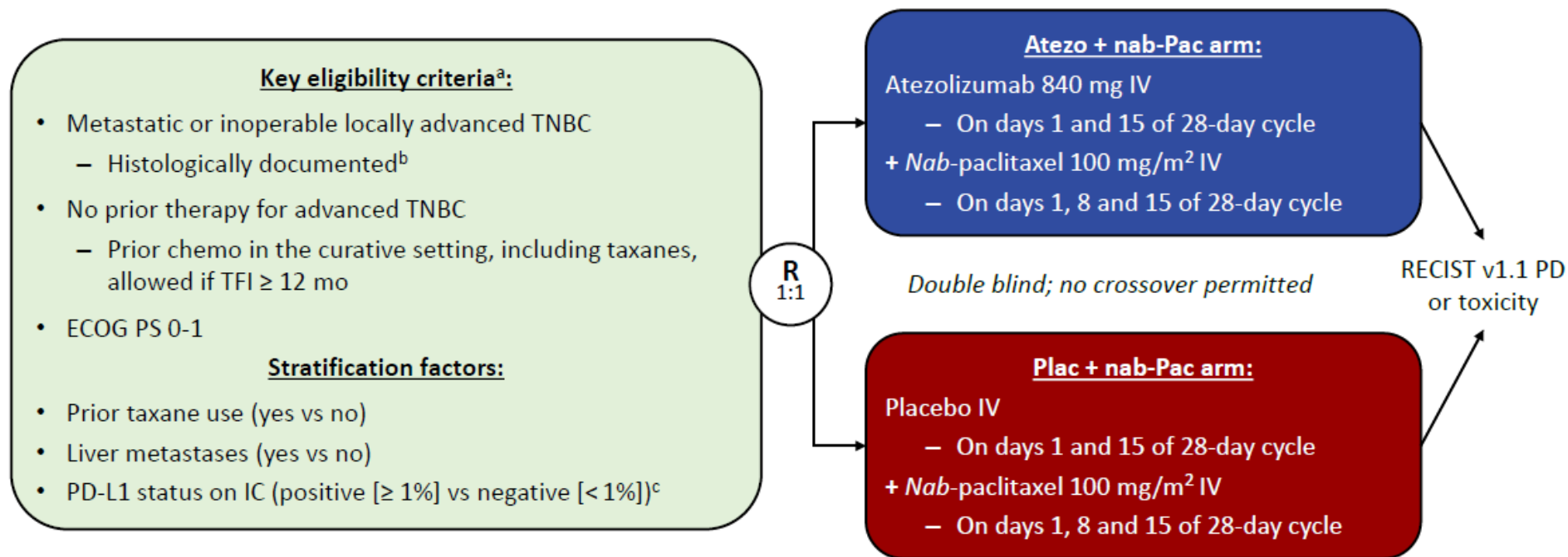
Cimino-Matthews, et al. Hum Pathol 2013

3) Higher PD-L1 expression



Mittendorf, et al. Cancer ImmunolRes 2014;

IMpassion130 (Phase III) – Study Design (TNBC metastatic disease)



- Co-primary endpoints were PFS and OS in the ITT and PD-L1+ populations^d.
- Key secondary efficacy endpoints (ORR and DOR) and safety were also evaluated.

IC, tumour-infiltrating immune cell; TFI, treatment-free interval. ^a ClinicalTrials.gov: NCT02425891. ^b Locally evaluated per ASCO–College of American Pathologists (CAP) guidelines. ^c Centrally evaluated per VENTANA SP142 IHC assay (double blinded for PD-L1 status). ^d Radiological endpoints were investigator assessed (per RECIST v1.1).

IMpassion130 – Study Population

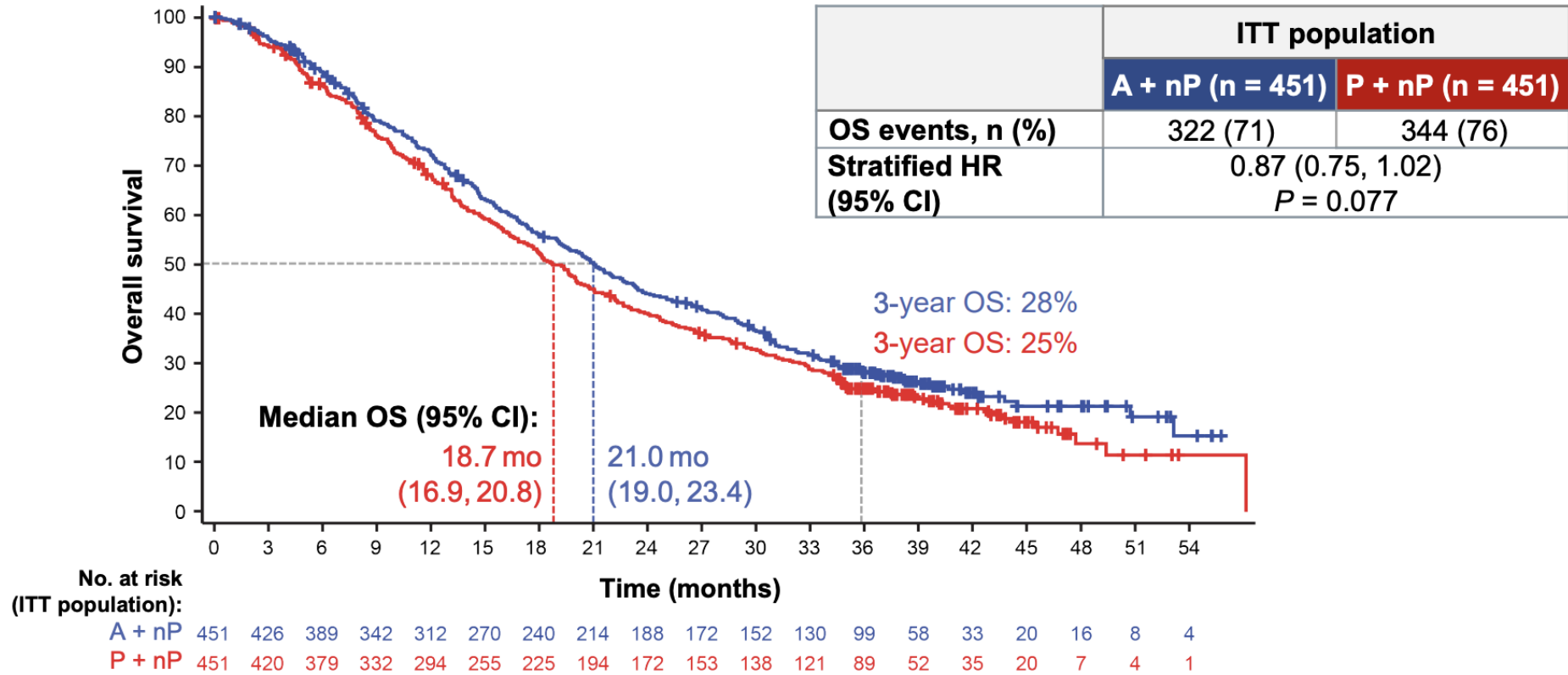
Characteristic	Atezo + nab-Pac (N = 451)	Plac + nab-Pac (N = 451)
Median age (range), y	55 (20-82)	56 (26-86)
Female, n (%)	448 (99%)	450 (100%)
Race, n (%) ^a		
White	308 (68%)	301 (67%)
Asian	85 (19%)	76 (17%)
Black/African American	26 (6%)	33 (7%)
Other/multiple	20 (4%)	26 (6%)
ECOG PS, n (%) ^{b,c}		
0	256 (57%)	270 (60%)
1	193 (43%)	179 (40%)
Prior (neo)adjuvant treatment, n (%)		
Prior taxane	231 (51%)	230 (51%)
Prior anthracycline	243 (54%)	242 (54%)

Characteristic	Atezo + nab-Pac (N = 451)	Plac + nab-Pac (N = 451)
Metastatic disease, n (%)	404 (90%)	408 (91%)
No. of sites, n (%) ^d		
0-3	332 (74%)	341 (76%)
≥ 4	118 (26%)	108 (24%)
Site of metastatic disease, n (%)		
Lung	226 (50%)	242 (54%)
Bone	145 (32%)	141 (31%)
Liver	126 (28%)	118 (26%)
Brain	30 (7%)	31 (7%)
Lymph node only ^d	33 (7%)	23 (5%)
PD-L1+ (IC), n (%)	185 (41%)	184 (41%)

Data cutoff: 17 April 2018. ^a Race was unknown in 12 patients in the Atezo + nab-Pac arm and 15 in the Plac + nab-Pac arm. ^b Of n = 450 in each arm. ^c ECOG PS before start of treatment was 2 in 1 patient per arm. ^d Of n = 450 in the Atezo + nab-Pac arm and n = 449 in the Plac + nab-Pac arm.

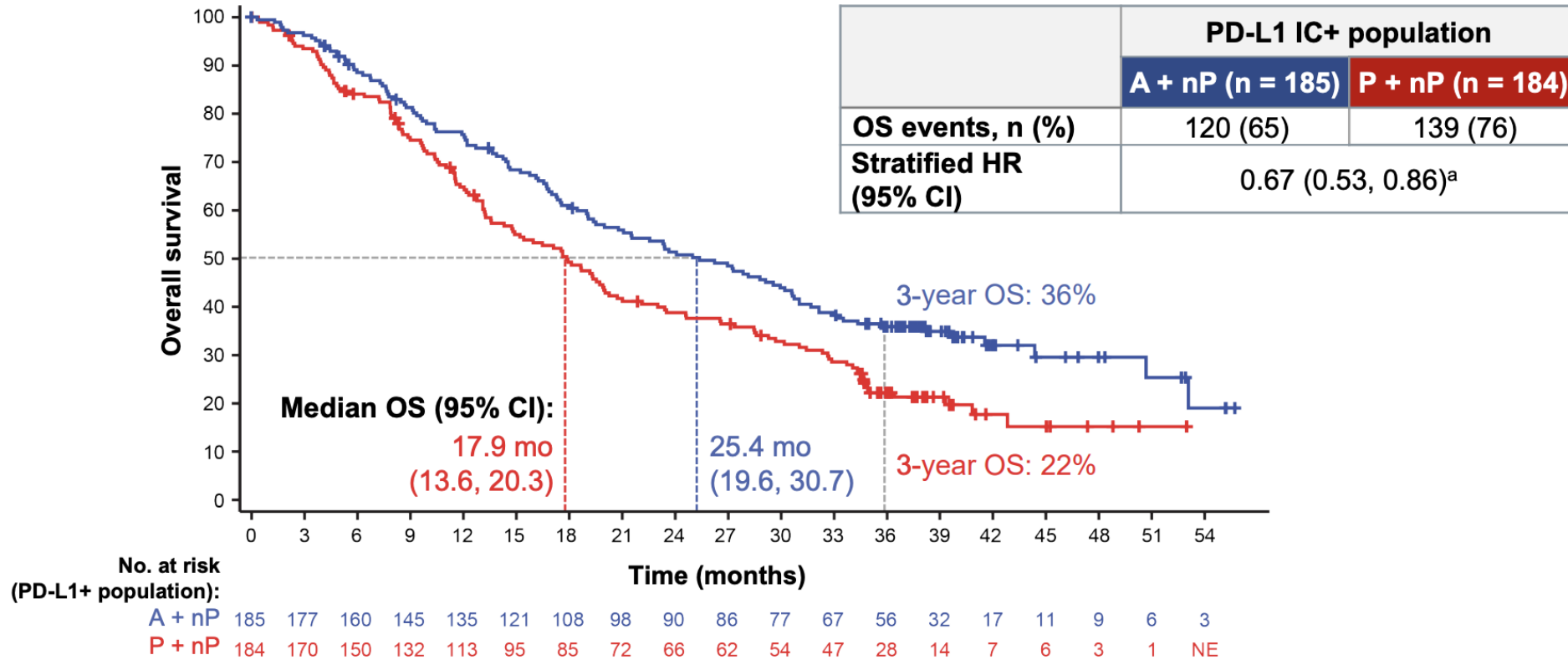
IMpassion130 – Final OS analysis

OS in the ITT population



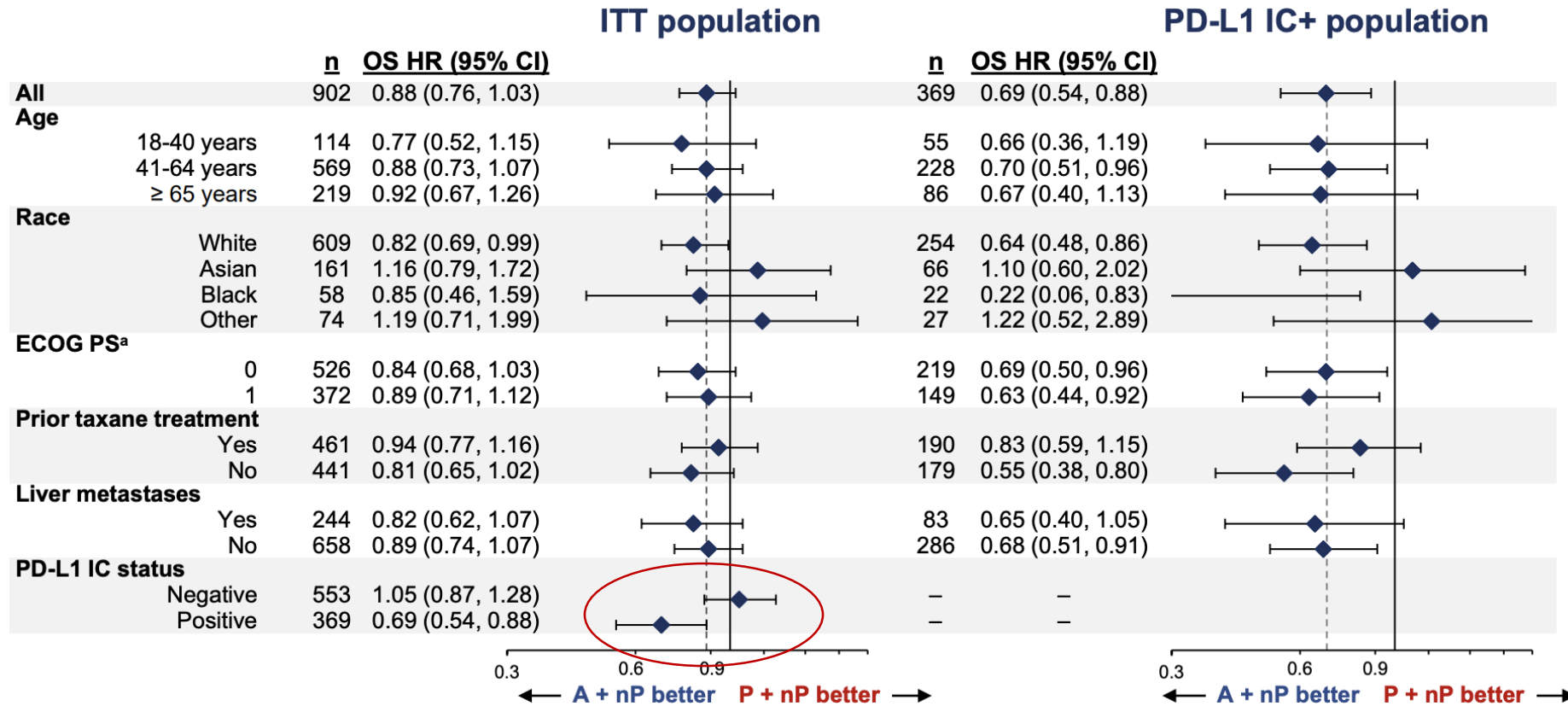
IMpassion130 – Final OS analysis

OS in the PD-L1 IC+ population



+7.5-mo median OS improvement

IMpassion130 – Final OS analysis



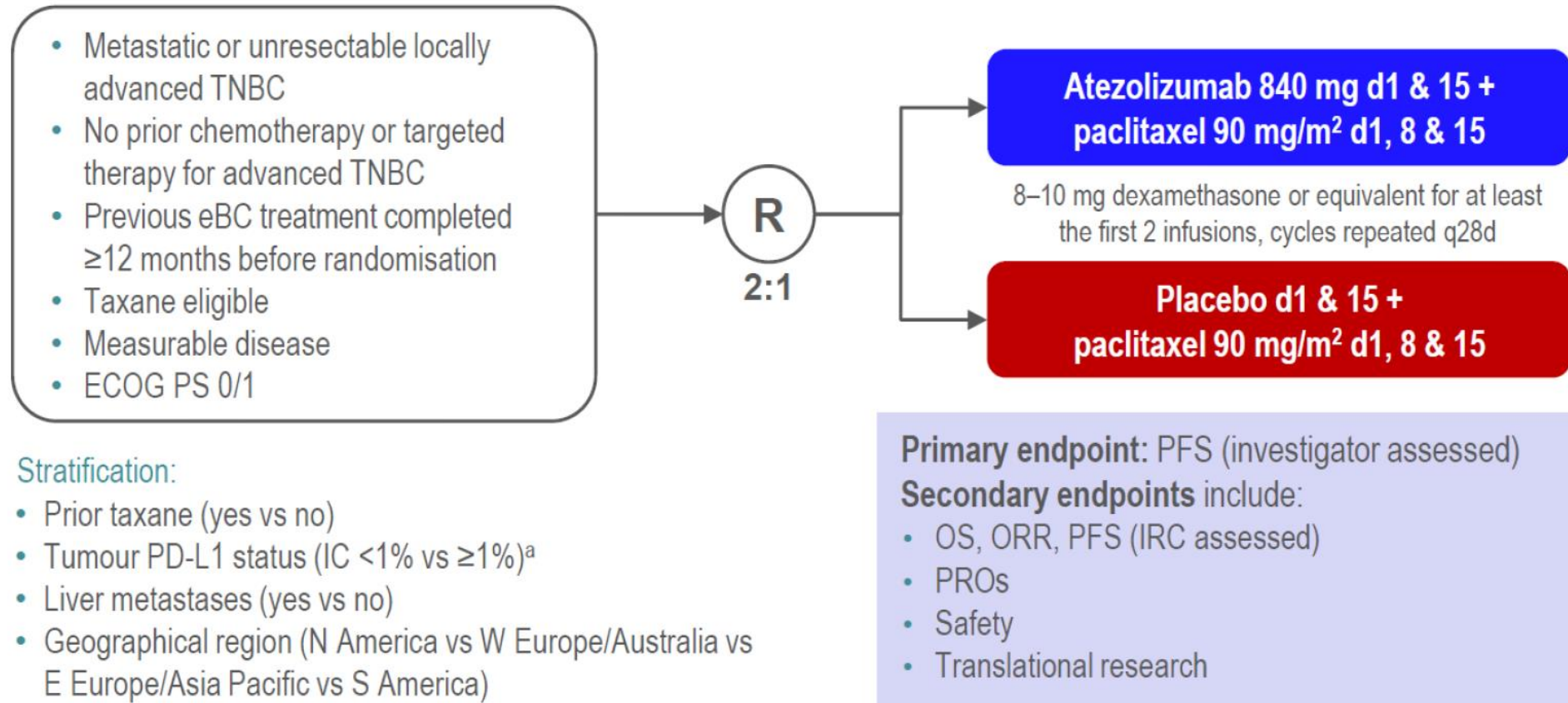
IMpassion130 – Safety

AEI, n (%) ^a	Plac + nab-Pac (n = 438)		Atezo + nab-Pac (n = 452)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
Hepatitis (all)	62 (14.2%)	13 (3.0%)	69 (15.3%)	23 (5.1%)
Hepatitis (diagnosis)	7 (1.6%)	1 (0.2%)	10 (2.2%)	6 (1.3%)
Hepatitis (lab abnormalities)	58 (13.2%)	12 (2.7%)	62 (13.7%)	17 (3.8%)
Hypothyroidism	19 (4.3%)	0	78 (17.3%)	0
Hyperthyroidism	6 (1.4%)	0	20 (4.4%)	1 (0.2%)
Adrenal insufficiency	0	0	4 (0.9%)	1 (0.2%)
Pneumonitis	1 (0.2%)	0	14 (3.1%)	1 (0.2%)
Colitis	3 (0.7%)	1 (0.2%)	5 (1.1%)	1 (0.2%)
Pancreatitis*	0	0	2 (0.4%)	1 (0.2%)
Diabetes mellitus	2 (0.5%)	1 (0.2%)	1 (0.2%)	1 (0.2%)
Other AEI (Rash)	114 (26.0%)	2 (0.5%)	154 (34.1%)	4 (0.9%)

There were no reported events of Guillian-Barre syndrome, Hypophysitis, Myasthenia Gravis or Myocarditis

*Enzyme elevations only

IMpassion131 – Study design (TNBC metastatic disease)



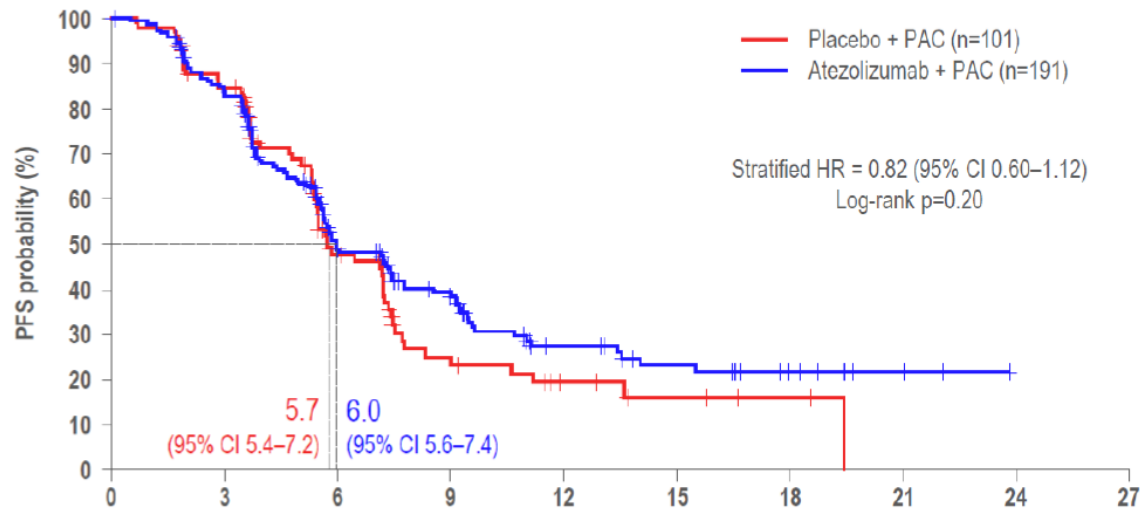
^aPD-L1 IC: area of PD-L1-stained tumour-infiltrating ICs as a percentage of tumour area by VENTANA SP142 immunohistochemistry assay. eBC = early breast cancer; ECOG PS = Eastern Cooperative Oncology Group performance status; IC = immune cell; IRC = independent review committee; ORR = objective response rate; PRO = patient-reported outcome; q28d = every 28 days; R = randomisation

IMpassion131 – Results



Primary analysis: PFS in the PD-L1+ population

Events in 61% of patients (data cut-off: 15 Nov 2019)

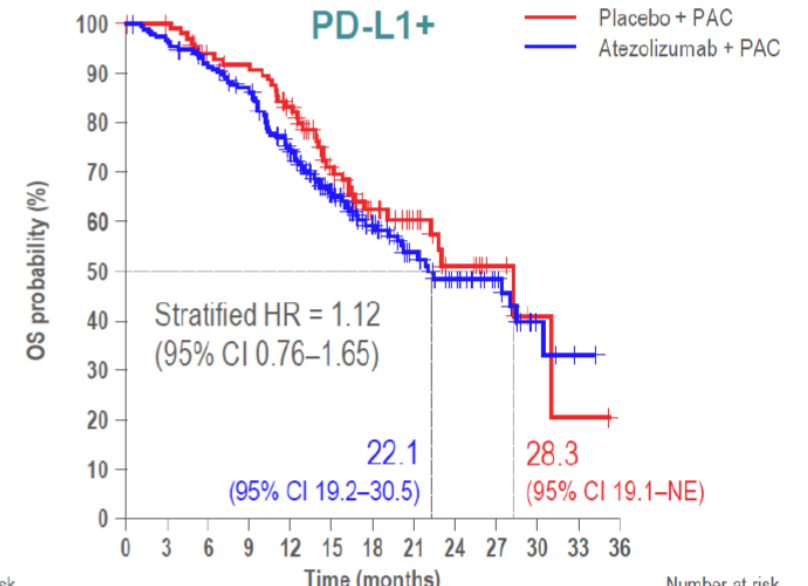


Number at risk	0	3	6	9	12	15	18	21	24	27
Placebo + PAC	101	81	33	14	7	4	2	0	0	0
Atezolizumab + PAC	191	152	69	44	22	15	8	3	0	0

Median duration of follow-up: 8.6 months (placebo + PAC) vs 9.0 months (atezolizumab + PAC). CI = confidence interval

Updated OS

Data cut-off 19 Aug 2020



Number at risk	0	3	6	9	12	15	18	21	24	27	30	33	36
Placebo + PAC	101	99	89	86	75	53	34	25	12	6	2	1	0
Atezolizumab + PAC	191	184	171	160	129	95	60	43	30	19	6	1	0

Median duration of follow-up: 14.5 months (placebo + PAC) vs 14.1 months (atezolizumab + PAC) in the ITT population

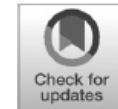
No benefit observed from the addition of Atezolizumab

Possibile impatto degli steroidi sull'efficacia della Immunoterapia

CLINICAL CANCER RESEARCH | TRANSLATIONAL CANCER MECHANISMS AND THERAPY

Concurrent Dexamethasone Limits the Clinical Benefit of Immune Checkpoint Blockade in Glioblastoma

J. Bryan Iorgulescu^{1,2}, Prafulla C. Gokhale³, Maria C. Speranza¹, Benjamin K. Eschle³, Michael J. Poitras³, Margaret K. Wilkens³, Kara M. Soroko³, Chhayheng Chhoeu³, Aine Knott³, Yan Gao¹, Mary Jane Lim-Fat⁴, Gregory J. Baker⁵, Dennis M. Bonal⁶, Quang-Dé Nguyen⁶, Gareth R. L. Grant⁷, Keith L. Ligon^{2,8,9}, Peter K. Sorger⁵, E. Antonio Chiocca¹⁰, Ana C. Anderson^{11,12}, Paul T. Kirschmeier³, Arlene H. Sharpe¹², Gordon J. Freeman¹, and David A. Reardon^{1,4}



KEYNOTE-355 Study Design (NCT02819518)

Key Eligibility Criteria

- Age ≥ 18 years
- Central determination of TNBC and PD-L1 expression
- Previously untreated locally recurrent inoperable or metastatic TNBC
- Completion of treatment with curative intent ≥ 6 months prior to first disease recurrence
- ECOG performance status 0 or 1
- Life expectancy ≥ 12 weeks from randomization
- Adequate organ function
- No systemic steroids
- No active CNS metastases
- No active autoimmune disease



Stratification Factors:

- Chemotherapy on study (taxane vs gemcitabine/carboplatin)
- PD-L1 tumor expression (CPS ≥ 1 vs CPS < 1)
- Prior treatment with same class chemotherapy in the neoadjuvant or adjuvant setting (yes vs no)

^aPembrolizumab 200 mg intravenous (IV) every 3 weeks (Q3W)

^bChemotherapy dosing regimens are as follows:

Nab-paclitaxel 100 mg/m² IV on days 1, 8, and 15 every 28 days

Paclitaxel 90 mg/m² IV on days 1, 8, and 15 every 28 days

Gemcitabine 1000 mg/m²/carboplatin AUC 2 on days 1 and 8 every 21 days

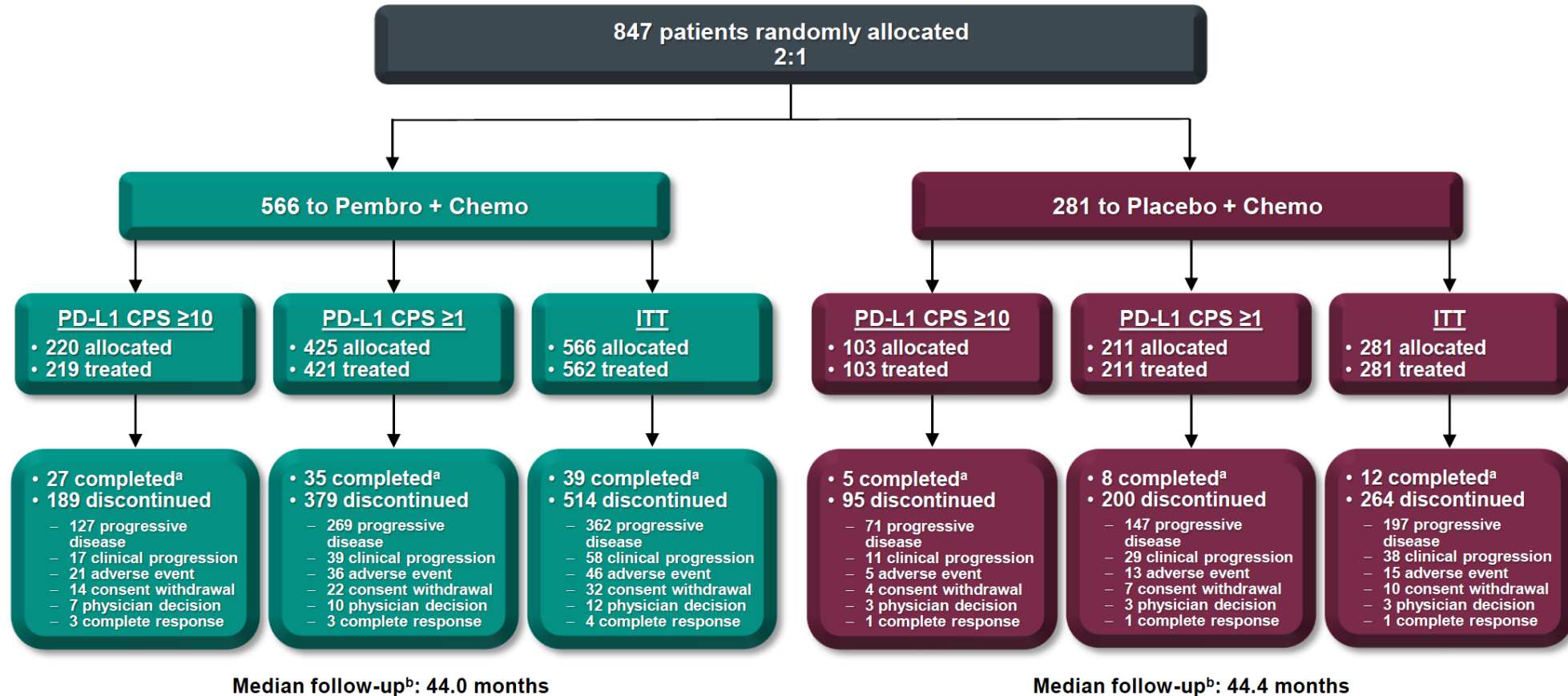
^cNormal saline

^dTreatment may be continued until confirmation of progressive disease

CNS=central nervous system; ECOG=Eastern Cooperative Oncology Group;

PD-L1=programmed death ligand 1; R=randomized; TNBC=triple-negative breast cancer

KEYNOTE 355 – Study Population allocation

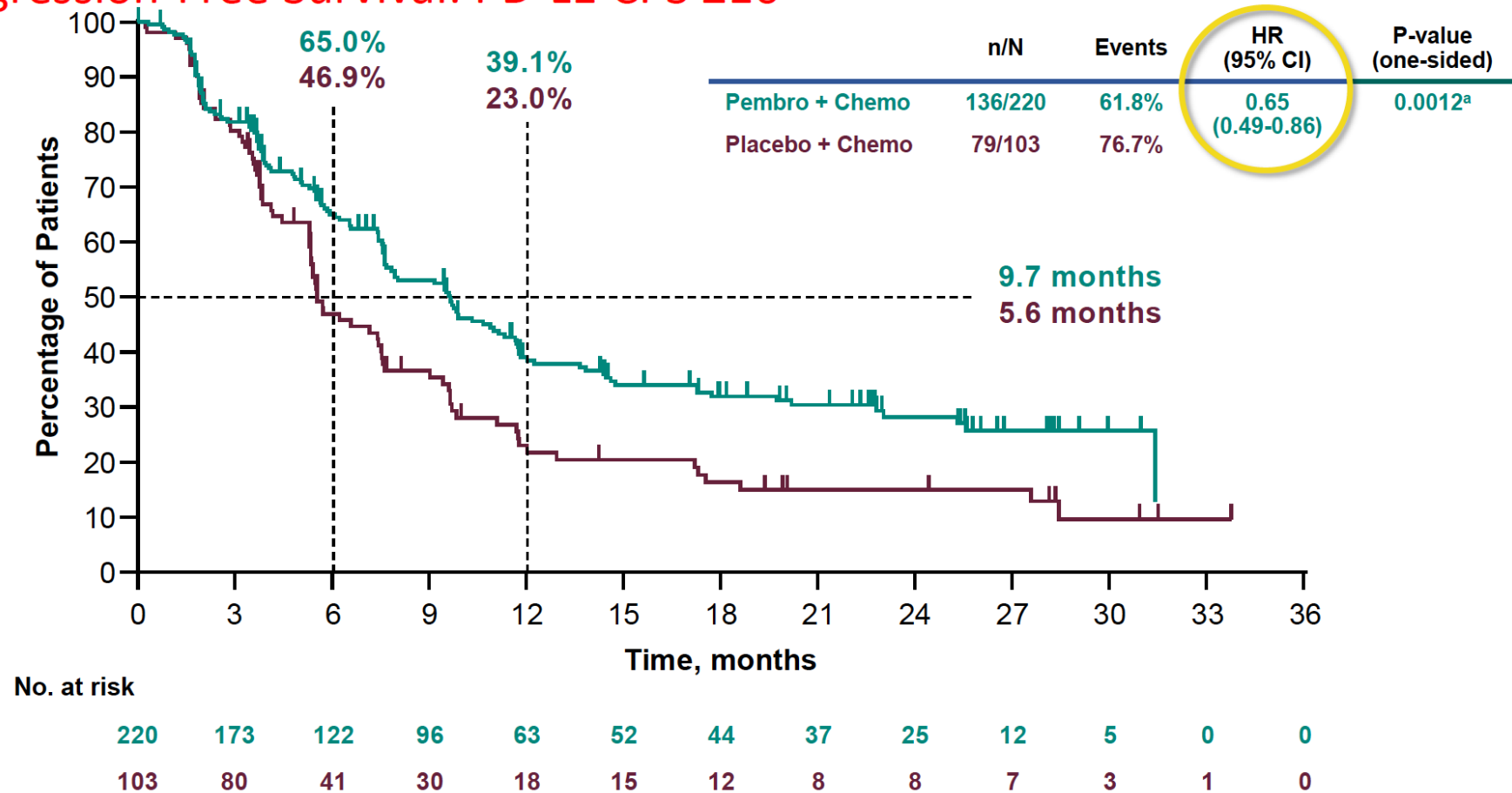


KEYNOTE 355 – Study Population allocation

Characteristic, n (%)	All Subjects, N = 847	
	Pembro + Chemo N = 566	Placebo + Chemo N = 281
Age, median (range), yrs	53 (25-85)	53 (22-77)
ECOG PS 1	232 (41.0)	108 (38.4)
PD-L1–positive CPS ≥1	425 (75.1)	211 (75.1)
PD-L1–positive CPS ≥10	220 (38.9)	103 (36.7)
Chemotherapy on study		
Taxane	255 (45.1)	127 (45.2)
Gemcitabine/Carboplatin	311 (54.9)	154 (54.8)
Prior same-class chemotherapy		
Yes	124 (21.9)	62 (22.1)
No	442 (78.1)	219 (77.9)
Disease-free interval		
de novo metastasis	168 (29.7)	84 (29.9)
<12 months	125 (22.1)	50 (17.8)
≥12 months	270 (47.7)	147 (52.3)

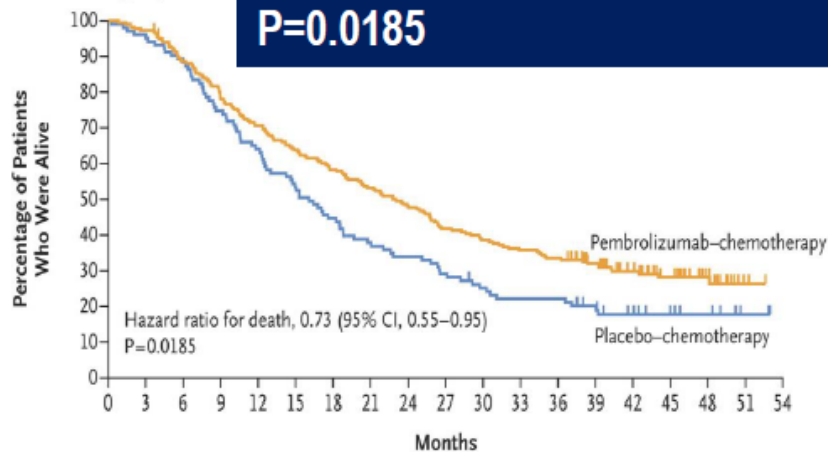
KEYNOTE 355 - Outcomes

Progression-Free Survival: PD-L1 CPS ≥ 10



CPS-10 Subgroup

OS: 23 vs 16.1 months
HR: 0,73 IC 95% [0.55-0.95]
P=0.0185

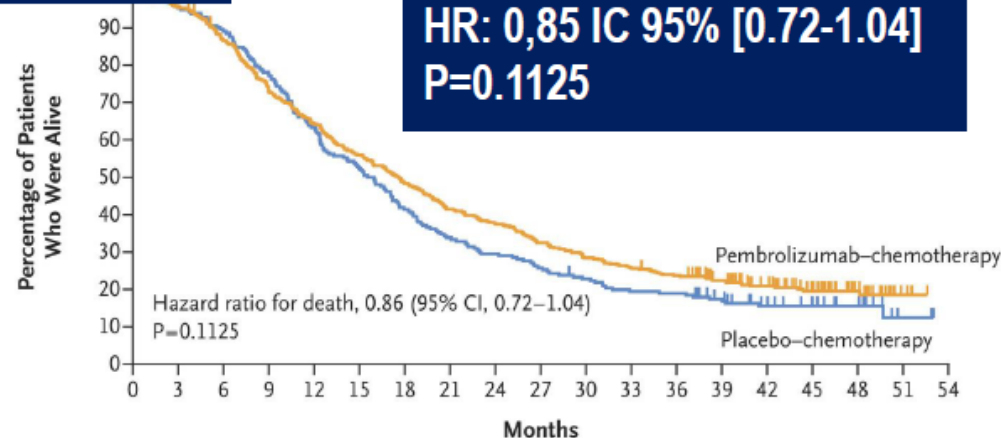


No. at Risk

Pembrolizumab-chemotherapy	220	214	193	171	154	139	127	116	105	91	84	78	73	59	43	31	17	2	0
Placebo-chemotherapy	103	98	91	77	66	55	46	39	35	30	25	22	22	17	12	8	6	2	0

CPS-1 Subgroup

OS: 17.6 vs 16 months
HR: 0,85 IC 95% [0.72-1.04]
P=0.1125

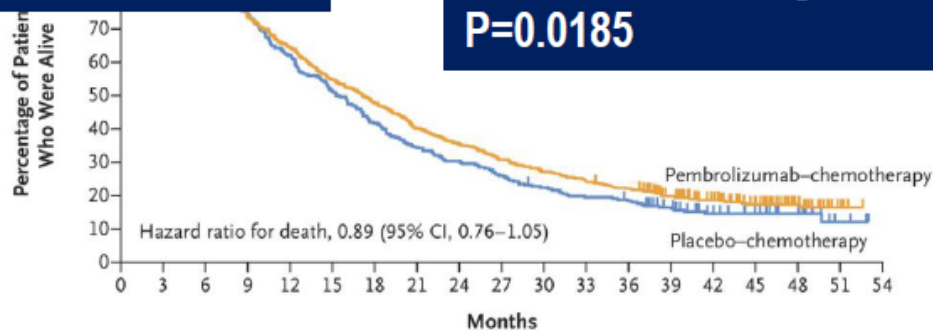


No. at Risk

Pembrolizumab-chemotherapy	425	406	365	308	271	236	204	175	159	137	120	108	99	80	60	38	21	3	0
Placebo-chemotherapy	211	200	187	163	133	110	87	71	62	54	47	40	39	30	21	15	10	2	0

Intention to treat Population

OS: 17.2 vs 15.5 months
HR: 0,789 IC 95% [0.76-1.05]
P=0.0185



No. at Risk

Pembrolizumab-chemotherapy	566	539	486	415	363	309	269	226	200	174	153	137	124	94	69	42	22	4	0
Placebo-chemotherapy	281	267	246	209	174	144	117	97	85	73	62	54	50	38	25	18	12	3	0

[Cortes et al, 2022]

IMMUNOTHERAPY

PEMBROLIZUMAB

KEYNOTE 355
(First line treatment with Pembrolizumab-CT
in advanced and mTNBC)

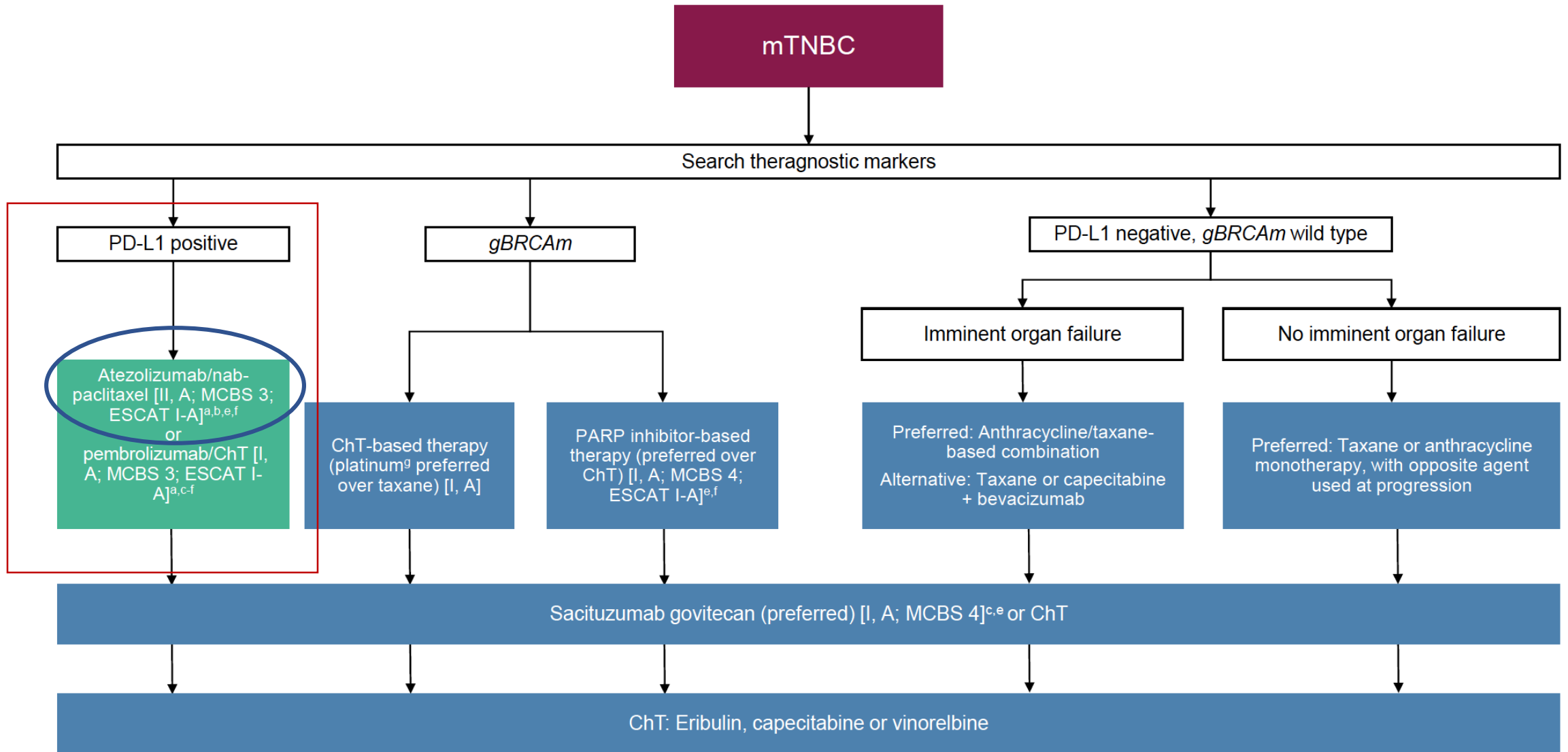
ATEZOLIZUMAB

IM PASSION 130
(First line treatment with Atezoluzimab-Nab
Paclitaxel in mTNBC)

Agenda

- **Quali evidenze dalla letteratura?**
- **Quali indicazioni per la pratica clinica?**

METASTATIC BREAST CANCER - TNBC



Gazzetta ufficiale

Tecentriq in associazione con nab-paclitaxel è indicato per il trattamento di pazienti adulti con TNBC non resecabile localmente avanzato o metastatico, i cui tumori presentano un'espressione di PD-L1 $\geq 1\%$ e che non sono stati sottoposti a precedente chemioterapia per malattia metastatica.



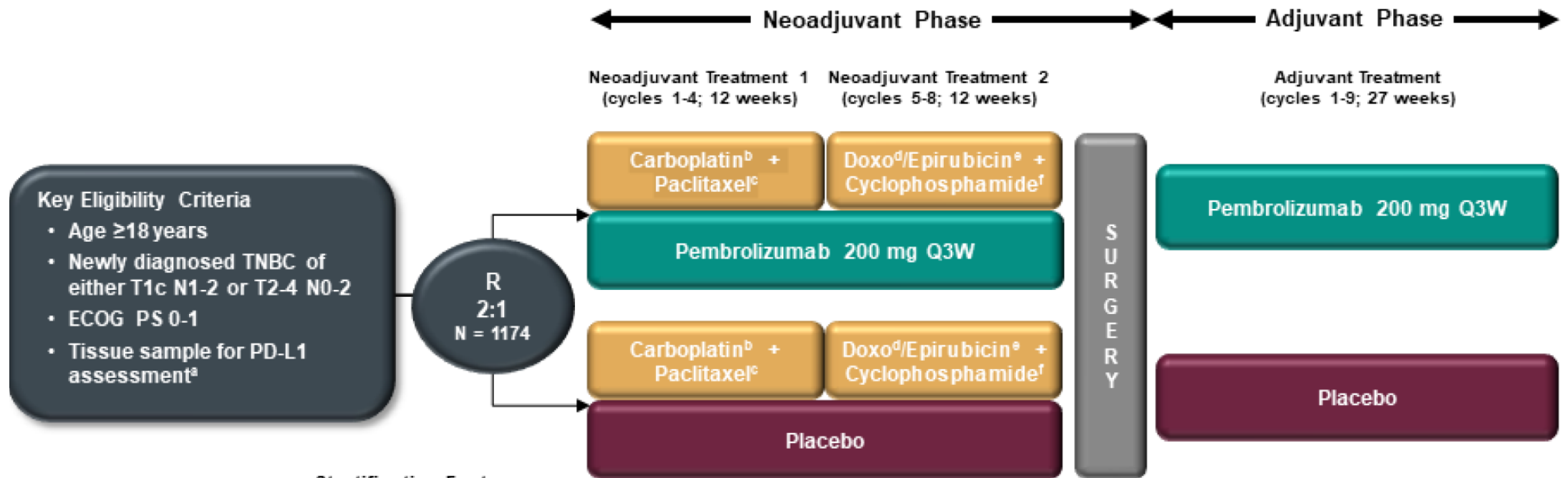
AIFA

AGENZIA ITALIANA DEL FARMACO



- Immunoterapia nel tumore mammario stadio precoce (triplo negativo)

KEYNOTE 522 – Study DESIGN



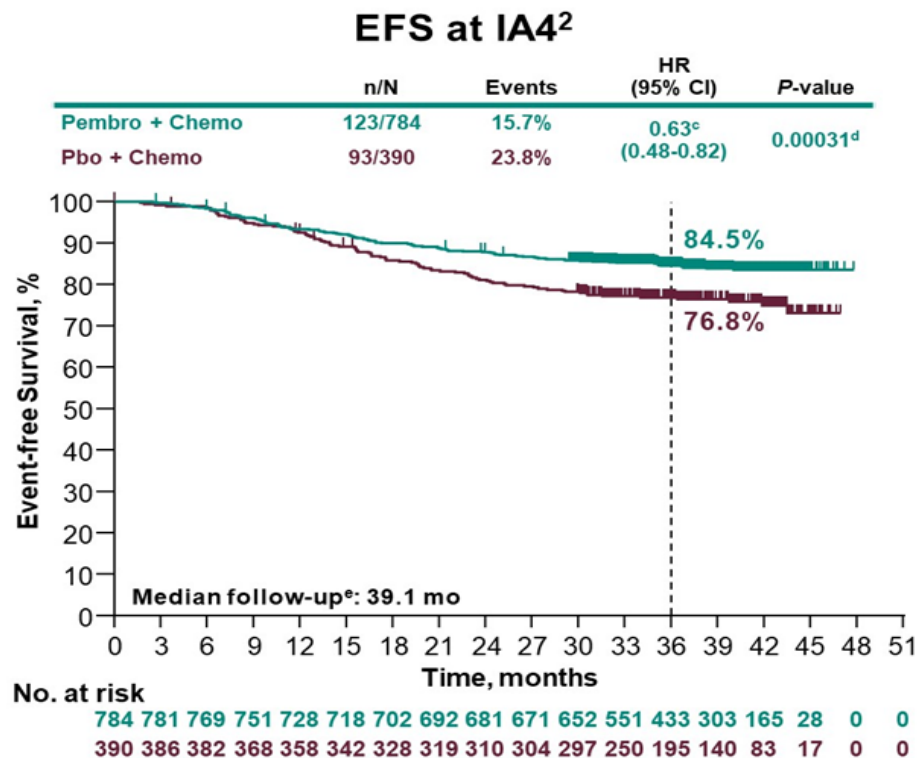
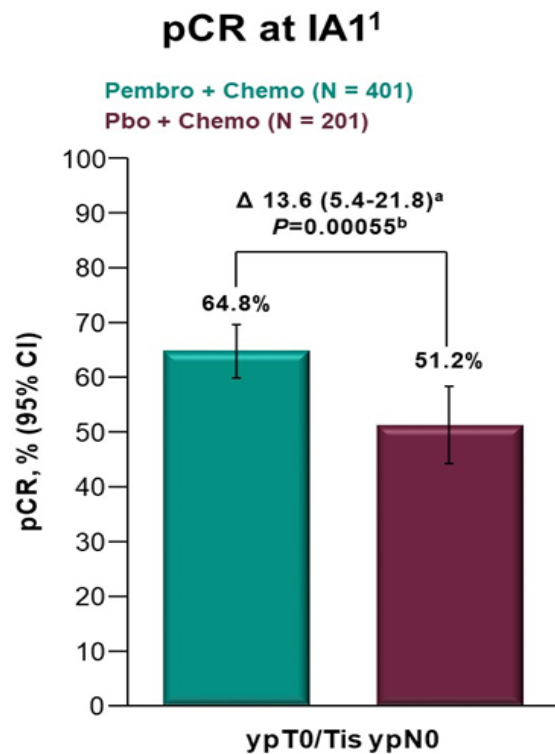
Stratification Factors:

- Nodal status (+ vs -)
- Tumor size (T1/T2 vs T3/T4)
- Carboplatin schedule (QW vs Q3W)

Schmidt, ESMO virtual plenary, 2021

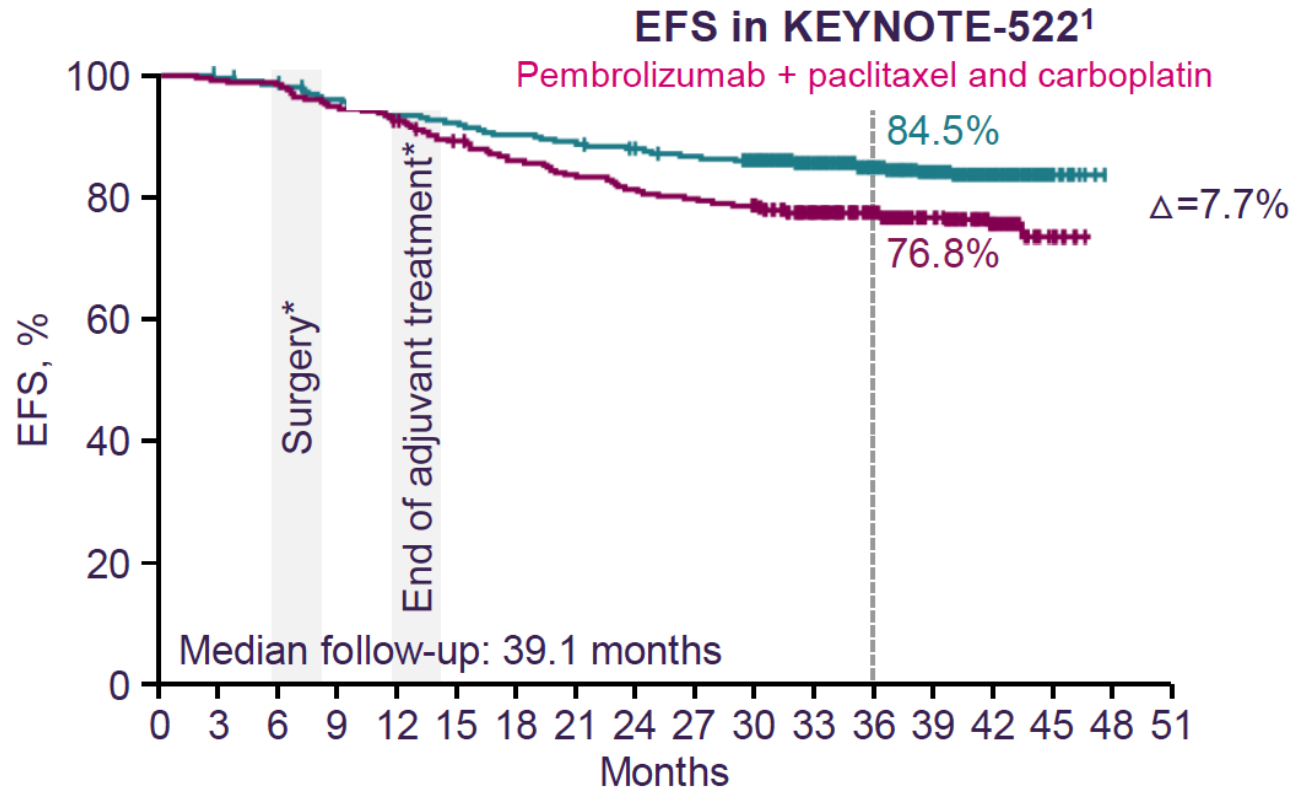
No T1a-T1b; No T1cN0; No T4d (inflammatory)

Primary Analyses of KEYNOTE-522



1. Schmid P, et al. *N Engl J Med* 2020;382:810-21. 2. Schmid P, et al. *N Engl J Med* 2022;386:556-67. ^aEstimated treatment difference based on Miettinen & Nurminen method stratified by randomization stratification factors. ^bPrespecified P -value boundary for significance of 0.003 was crossed; data cutoff date: September 24, 2018. ^cHazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. ^dPrespecified P -value boundary of 0.00517 was crossed. ^eDefined as the time from randomization to the data cutoff date of March 23, 2021.

IO in EARLY TNBC – EFS benefit



No. at risk:

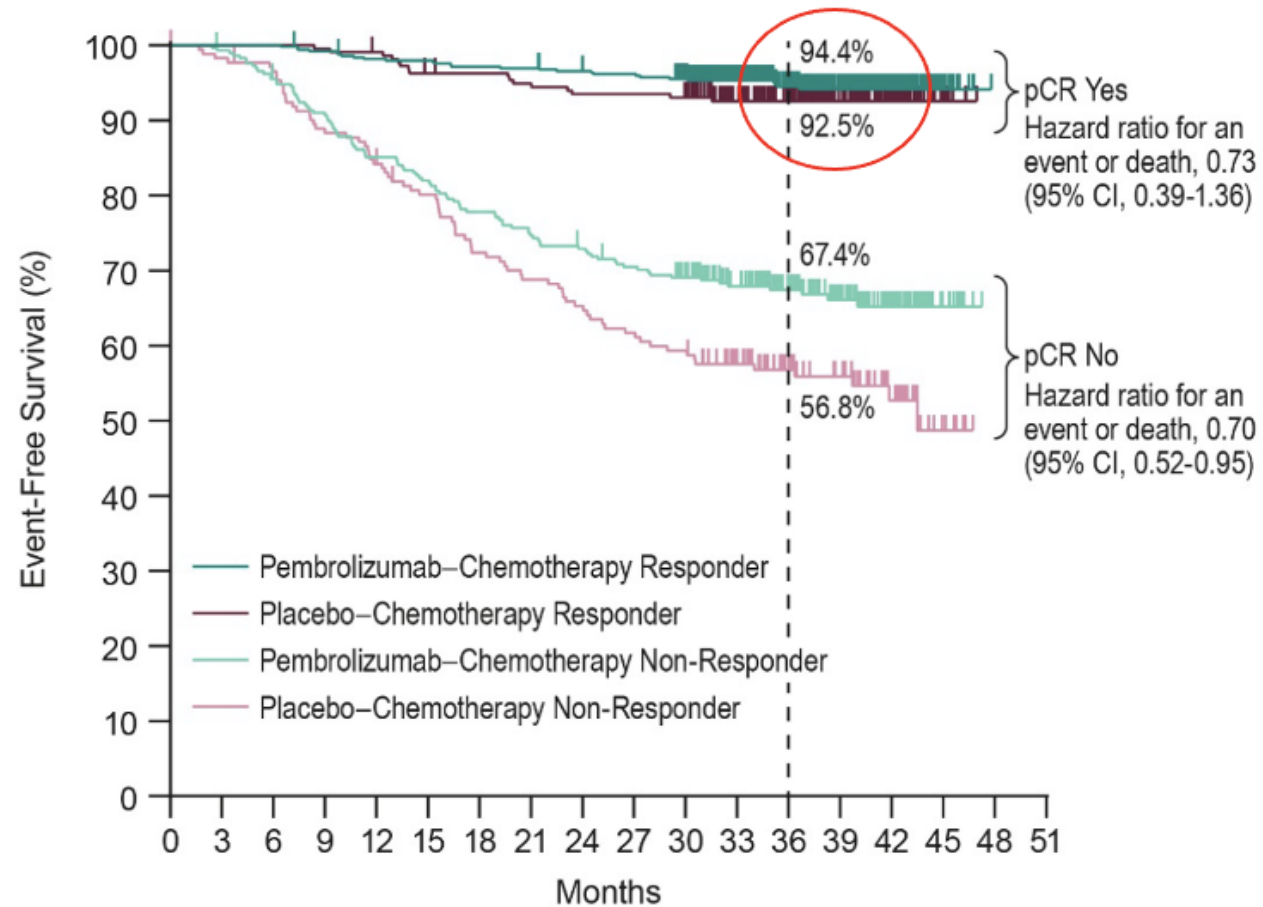
Months	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Pembro+chemo/pembro	784	781	769	751	728	718	702	692	681	671	652	551	433	303	165	28	0	0
Pbo+chemo/pbo	390	386	382	368	358	342	328	319	310	304	297	250	195	140	83	17	0	0

	Pembrolizumab + chemotherapy / pembrolizumab (n=784)	Placebo + chemotherapy / placebo (n=390)
Events	15.7%	23.8%
Hazard ratio 0.63 [†] (95% CI 0.48–0.82) p=0.00031 [‡]		

Schmid et al. N Engl J Med 2022

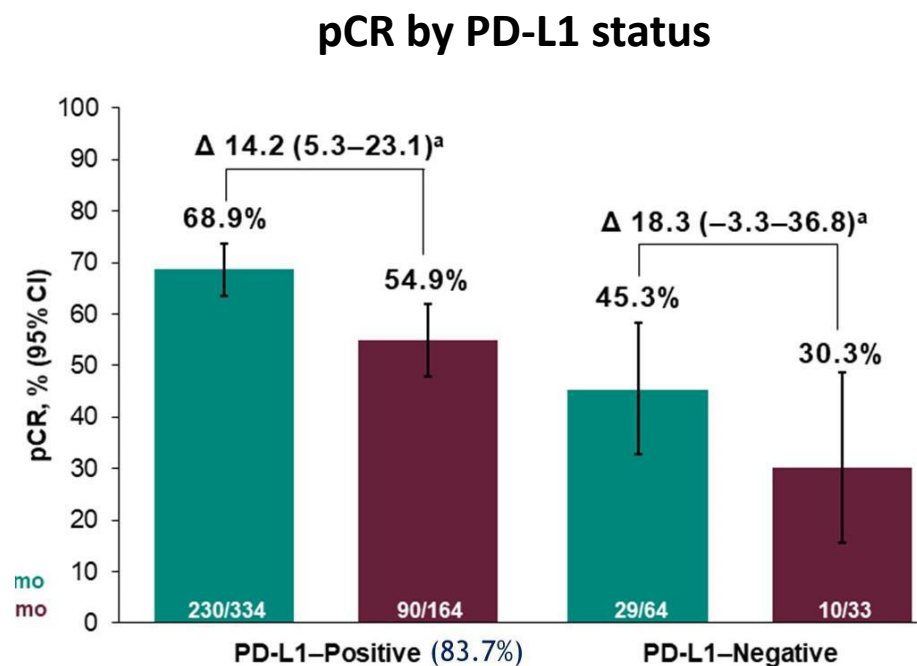
FDA and EMA granted Pembrolizumab approval for high-risk, early-stage TNBC

EFS and pCR



1 - WHO IS A CANDIDATE FOR IMMUNOTHERAPY?

- T stage
- N stage
- PD-L1 status

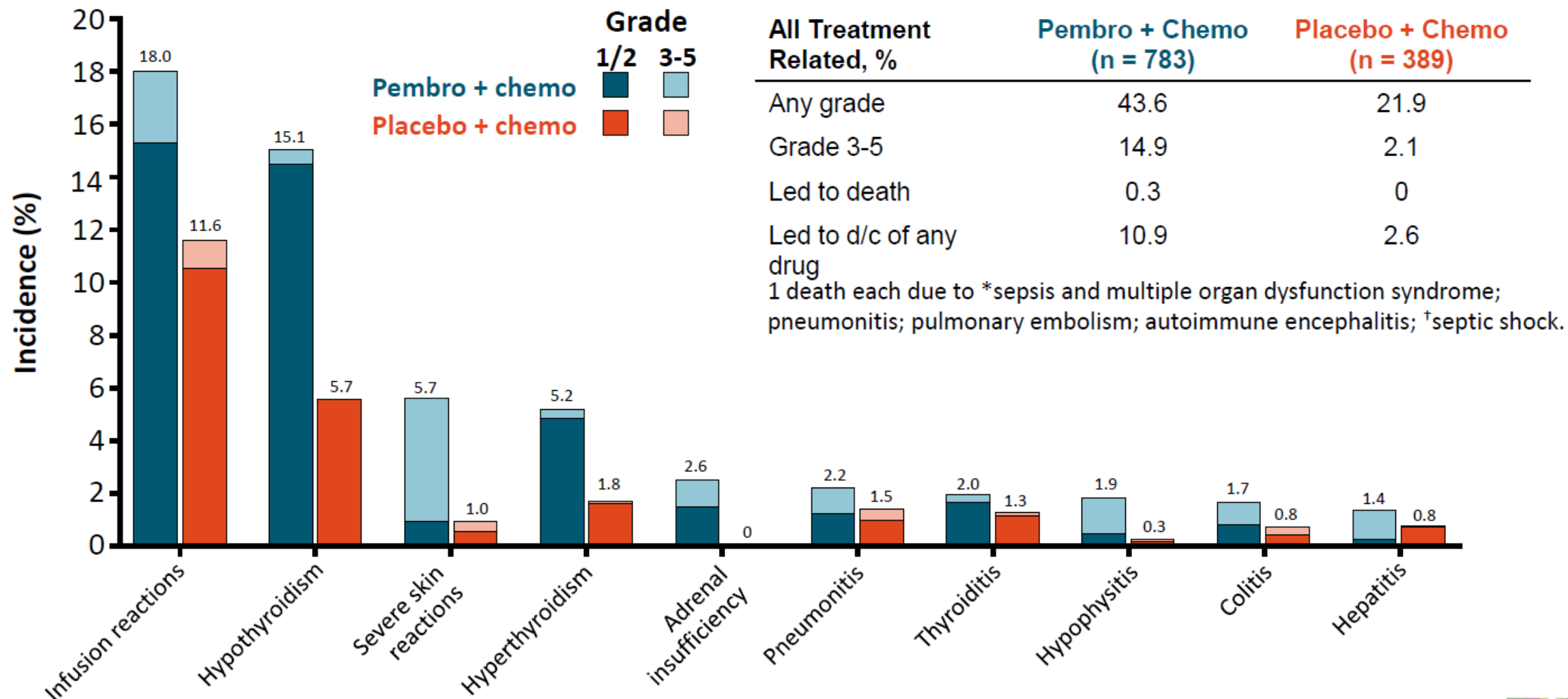


EFS by PD-L1 status

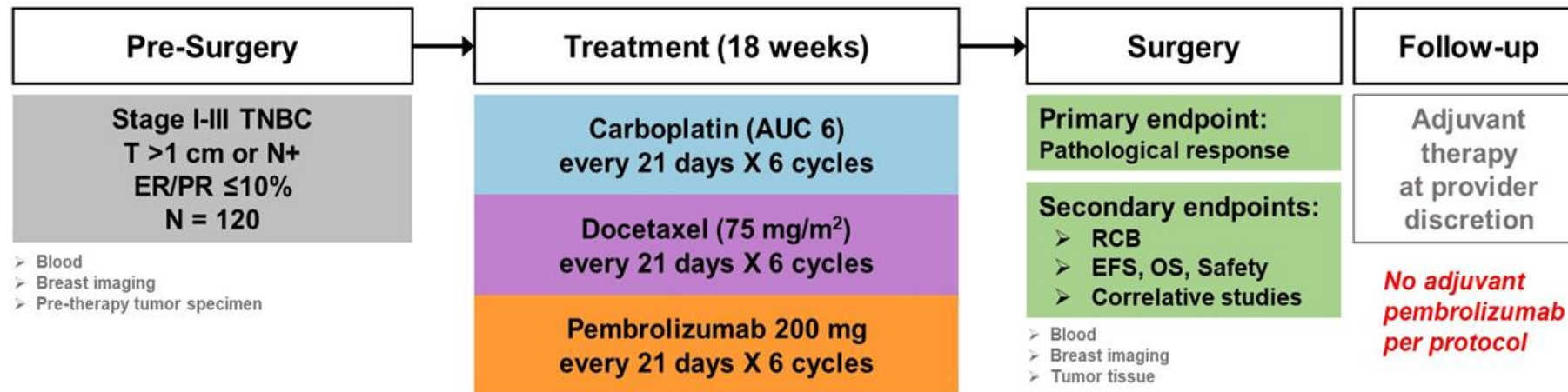
Subgroup	Pembrolizumab- Chemotherapy no. of patients with event/total no. (%)	Placebo- Chemotherapy no. of patients with event/total no. (%)	Hazard Ratio for Event or Death (95% CI)
Overall	123/784 (15.7)	93/390 (23.8)	0.63 (0.48-0.82)
Nodal status			
Positive	80/408 (19.6)	57/196 (29.1)	0.65 (0.46-0.91)
Negative	43/376 (11.4)	36/194 (18.6)	0.58 (0.37-0.91)
Tumor size			
T1 to T2	64/581 (11.0)	59/290 (20.3)	0.51 (0.36-0.73)
T3 to T4	59/203 (29.1)	34/100 (34.0)	0.84 (0.55-1.28)
Carboplatin schedule			
Weekly	71/444 (16.0)	56/220 (25.5)	0.60 (0.42-0.86)
Every 3 wk	50/334 (15.0)	37/167 (22.2)	0.65 (0.42-0.99)
PD-L1 status			
Positive	98/656 (14.9)	68/317 (21.5)	0.67 (0.49-0.92)
Negative	25/128 (19.5)	25/69 (36)	0.48 (0.28-0.85)
Age			
<65 yr	103/700 (14.7)	79/342 (23.1)	0.61 (0.45-0.82)
≥65 yr	20/84 (24)	14/48 (29)	0.79 (0.40-1.56)
ECOG performance-status score			
0	101/678 (14.9)	80/341 (23.5)	0.60 (0.45-0.80)
1	22/106 (20.8)	13/49 (27)	0.81 (0.41-1.62)

PD-L1 status does not predict IO benefit in eTNBC

KEYNOTE-522: Immune-Related Adverse Events



Neoadjuvant Phase II Study of Pembrolizumab and Carboplatin plus Docetaxel in Triple Negative Breast Cancer (NeoPACT)



Sites: University of Kansas and Baylor University Medical Center

THE UNIVERSITY OF KANSAS
CANCER CENTER

2022 ASCO
ANNUAL MEETING

#ASCO22

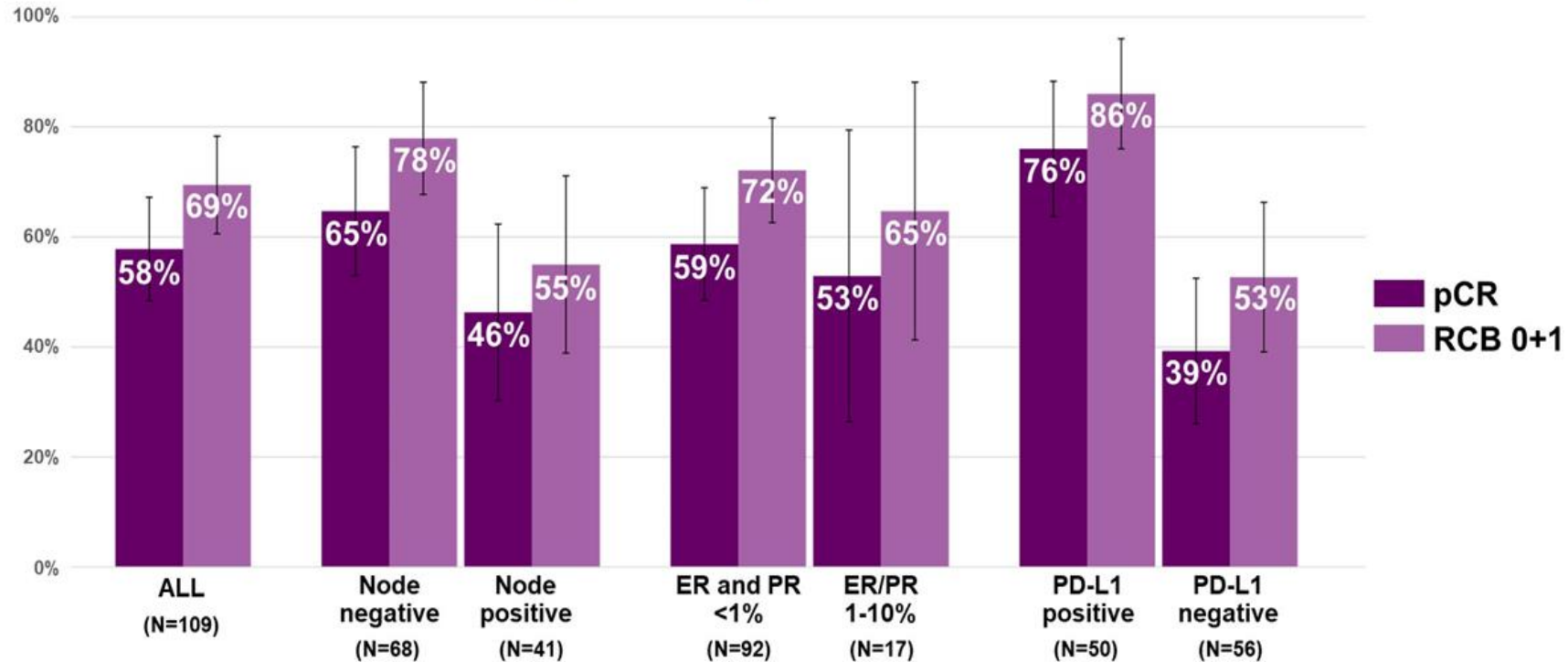
PRESENTED BY:
Priyanka Sharma, M.D.

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KNOWLEDGE CONQUERS CANCER

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RESULTS: Pathologic response



- No patients had disease progression during neoadjuvant treatment.
- Among patients with stage II-III disease and ER & PR IHC <1%, pCR and RCB 0+1 rates were 59% and 69%, respectively.
- pCR in TNM stage I, II, and III disease was 69%, 59%, and 43%, respectively.

Error bars represent 95% binomial confidence intervals

Adverse events (AEs)

Grade 3 or higher treatment-related AEs were observed in 26.9% of patients.

- Most common grade 3 or higher treatment-related AEs were diarrhea (G3=4.3%, G4=0%), anemia (G3=3.5%, G4=0%), and peripheral sensory neuropathy (G3=2.6%, G4=0%).

Treatment discontinuation due to AEs:

- Treatment related AEs led to discontinuation of any trial drug in 12% of patients. Discontinuation of pembrolizumab and chemotherapy due to treatment related AE occurred in 7% and 10% of patients, respectively.

^a Treatment-related AEs that occurred in at least 10% of patients are reported.

^b Grade 1=40.0%, Grade 2=18.3%, Grade 3=4.3%, Grade 4=0%.

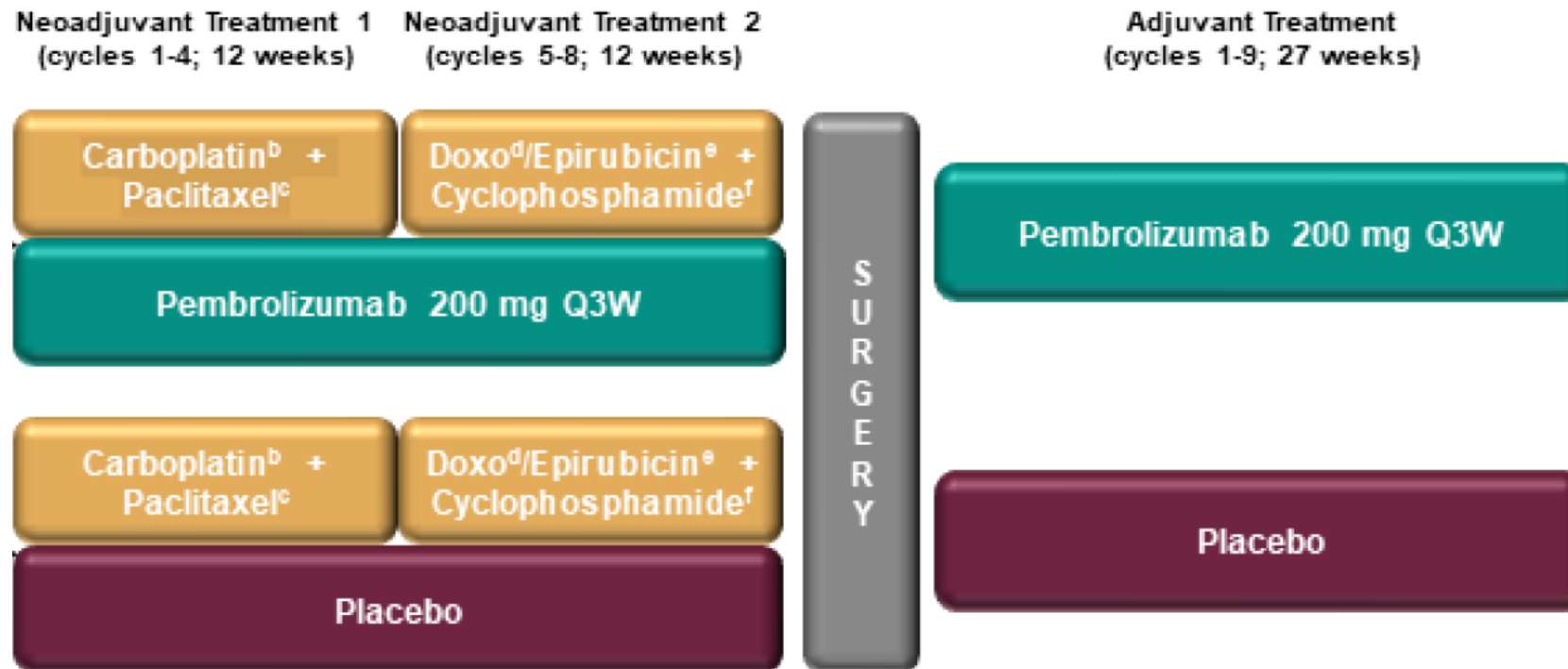
^c Peripheral sensory neuropathy was mainly grade 1 (26.9%), with 10.4% and 2.6% of patients experiencing grade 2 and 3 peripheral neuropathy, respectively (Grade 4=0%).

Treatment-related adverse event ^a	All grades (N=115)	Grade 1-2	Grade 3-4
Any adverse event	115 (100.0%)	84 (73.0%)	31 (26.9%)
Fatigue	87 (75.7%)	86 (74.8%)	1 (0.9%)
Diarrhea ^b	72 (62.6%)	67 (58.3%)	5 (4.3%)
Nausea	68 (59.1%)	66 (57.1%)	2 (1.7%)
Peripheral sensory neuropathy ^c	46 (40.0%)	43 (37.4%)	3 (2.6%)
Constipation	43 (37.4%)	43 (37.4%)	0 (0%)
Dysgeusia	40 (34.8%)	40 (34.8%)	0 (0%)
Alopecia	39 (33.9%)	39 (33.9%)	0 (0%)
Mucositis oral	39 (33.9%)	39 (33.9%)	0 (0%)
Arthralgia	32 (27.8%)	32 (27.8%)	0 (0%)
Watering eyes	27 (23.5%)	27 (23.5%)	0 (0%)
Rash	27 (23.5%)	26 (22.6%)	1 (0.9%)
Edema limbs	26 (22.6%)	26 (22.6%)	0 (0%)
Anorexia	25 (21.7%)	25 (21.7%)	0 (0%)
Myalgia	24 (20.9%)	24 (20.9%)	0 (0%)
Anemia	20 (17.4%)	16 (12.2%)	4 (3.5%)
Bone pain	20 (17.4%)	20 (17.4%)	0 (0%)
Nail discoloration	19 (16.5%)	19 (16.5%)	0 (0%)
Insomnia	18 (15.7%)	18 (15.7%)	0 (0%)
Headache	16 (13.9%)	16 (13.9%)	0 (0%)
Hot flashes	15 (13.0%)	14 (12.2%)	1 (0.9%)
Abdominal pain	14 (12.2%)	14 (12.2%)	0 (0%)
Dyspnea	13 (11.3%)	13 (11.3%)	0 (0%)
Fever	13 (11.3%)	12 (10.4%)	1 (0.9%)
Hypomagnesemia	13 (11.3%)	12 (10.4%)	1 (0.9%)
Dehydration	12 (10.4%)	10 (8.7%)	2 (1.7%)
Vomiting	11 (9.6%)	11 (9.6%)	0 (0%)

Agenda

- **Quali evidenze dalla letteratura?**
- **Quali indicazioni per la pratica clinica?**

TNBC candidato a terapia preoperatoria: applicabilità nella pratica clinica



Richiesta di Pembrolizumab ad uso compassionevole

- ELENCO DOCUMENTI
- 1. Domanda di autorizzazione sottoscritta dal Direttore dell'Unità Operativa e dal Medico Responsabile del trattamento del Paziente;
- 2. Modulo di Assunzione di Responsabilità – Uso compassionevole ;
- 3. Letteratura a supporto
- 4. Protocollo di trattamento, comprensivo delle modalità d'impiego del farmaco (V2_17032022)
- 5. Foglio informativo e consenso informato (versione n°1 del 16.02.2022)
- 6. Lettera informativa per il Medico Curante (versione n°1 del 12.04.2022)
- 7. Dichiarazione della fornitura gratuita del farmaco da parte dell'impresa autorizzata, con l'identificazione della tipologia applicabile, tra quelle previste nel Modello regionale (26/09/2022);
- 8) Relazione clinica del Paziente, con l'indicazione delle motivazioni che hanno portato alla richiesta, e ove URGENTE specificando il motivo del carattere di urgenza;
- 9 Investigator's Brochure del medicinale oggetto della richiesta, nell'ultima versione disponibile (ED 21 02/09/2021);
- 10) Documentazione attestante la produzione del medicinale secondo GMP in accordo alla normativa nazionale e comunitaria;

- E l'immunoterapia nelle altre tipologie di tumore mammario?
- Qualche dato...



PANACEA trial: NCT02129556



Pharma Partner: Merck

Phase Ib/II trial of anti-PD-1 monoclonal ANtibody in AdvanCed, Trastuzumab-resistant, HER2-positive breast cAncer

Advanced HER2+ BC
Trastuzumab resistant

Confirmed PD-L1
status on metastatic
lesion (<1yr)

Trastuzumab+Pembro
until progression

Pembrolizumab + trastuzumab in pretreated patients

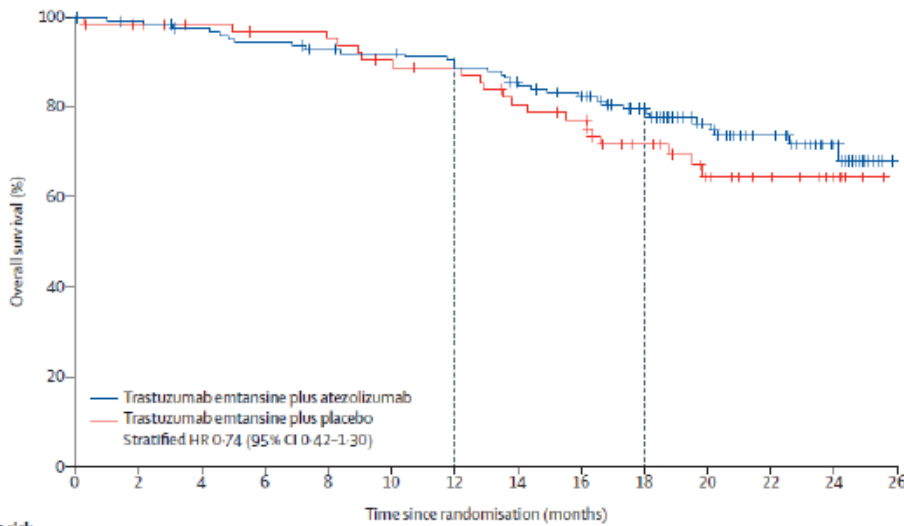
	PD-L1-negative, phase 2 (n=12)	PD-L1-positive, phase 1b (n=6)	PD-L1-positive, phase 2 (n=40)	All PD-L1-positive patients, phase 1b-2 (n=46)
Objective response	0 (0%; 0-18)	1 (17%; 1-58)	6 (15%; 7-29)	7 (15%; 7-27)
Disease control*	0 (0%; 0-18)	1 (17%; 1-58)	10 (25%; 14-39)	11 (24%; 14-36)
Best overall response				
Complete response	0	1 (17%)	1 (3%)	2 (4%)
Partial response	0	0	5 (13%)	5 (11%)
Stable disease	2 (17%)	0	7 (18%)	7 (15%)
Progressive disease	9 (75%)	5 (83%)	25 (63%)	30 (65%)
Not evaluable	1 (8%)	0	2 (5%)	2 (4%)

Data are n (%; 90% CI), or n (%). Objective responses were confirmed by repeat imaging 4-6 weeks later.
 PD-L1=programmed cell death 1 ligand 1. * Includes patients who achieved an objective response or had stable disease as their best response for 24 weeks or more.

Table 3: Best response, by PD-L1 status

Combination with 1st generation ADC (TDM1)

OS

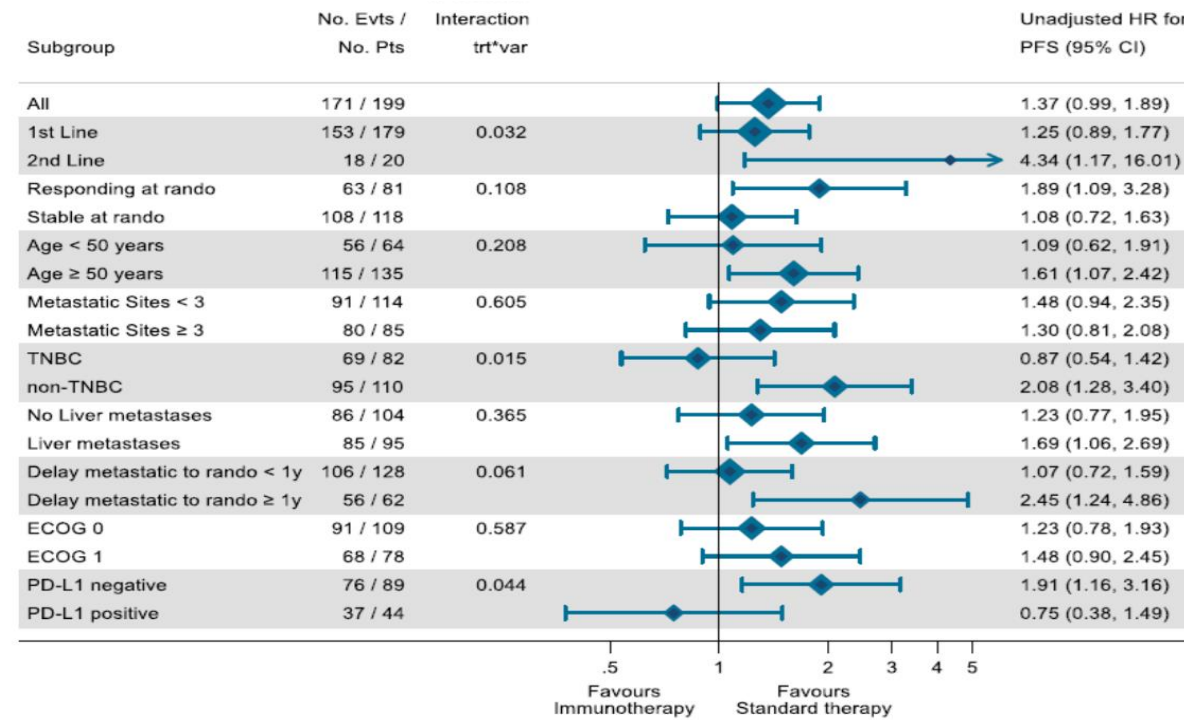


	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Trastuzumab emtansine plus atezolizumab	133 (0)	130 (2)	126 (4)	122 (4)	118 (6)	116 (7)	111 (8)	104 (10)	98 (13)	78 (30)	56 (49)	42 (61)	21 (81)	--
Trastuzumab emtansine plus placebo	69 (0)	66 (2)	63 (5)	61 (6)	60 (6)	55 (7)	54 (8)	48 (9)	45 (10)	35 (17)	23 (26)	14 (35)	8 (41)	--

Addition of atezolizumab to trastuzumab emtansine did not show a clinically meaningful improvement in progression-free survival and was associated with more adverse events.

Trastuzumab emtansine plus atezolizumab versus trastuzumab emtansine plus placebo in previously treated, HER2-positive advanced breast cancer (KATE2): a phase 2, multicentre, randomised, double-blind trial

Durvalumab compared to maintenance chemotherapy in metastatic breast cancer: the randomized phase II SAFIRO2-BREAST IMMUNO trial



Conclusioni

- Immunoterapia non indicata per tutti i tumori mammari
- Vantaggio in sopravvivenza nei pazienti con tumore mammario TN PDL1 positivo
- Aumento della probabilità di pCR e migliore EFS nei tumori mammari TN stadio iniziale indipendentemente dall'espressione di PDL1
- Domande sull'utilizzo dell'immunoterapia in pazienti suscettibili anche ad altre terapia (es capecitabina? Olaparib?)

- GRAZIE MILLE!!!!

AIGOM
ASSOCIAZIONE ITALIANA
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Progetto **CANOA**

CARCINOMA MAMMARIO:

QUALI NOVITA' PER IL 2023?

"Saper leggere" uno studio clinico per migliorare la pratica clinica

24-25 Marzo 2023
Ospedaletto di Pescantina (VR)
Centro Congressi Park Hotel Villa Quaranta

Coordinatori scientifici:
Stefania Gori
Giovanni L. Pappagallo

