

PROMENADE: PembROLizuMab for early ER-low/HER2-breast caNcer, reAlworlD frEnch cohort

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DECLARATION OF INTERESTS

François Cherifi, M.D.

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Registration fees and accommodations : Chugai, AstraZeneca, MSD, Roche, Gilead, Pharmaand

Network membership : ESMO and Oncodistinct

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Background

- ❖ ESMO and ASCO/CAP guidelines recommend a cut-off of ER expression <1% to define TNBC
In France and other countries the cut-off for TNBC is set <10%
- ❖ BC with ER 1%-9% expression, also called “**ER-low BC**”, is a rare subtype
 - Represents less than 10% of TNBC and approximately 5% of ER+
 - Pathological features more similar to ER <1% than ER >10% (e.g. basal like)¹
- ❖ Swedish cohort study² :
 - ER low population had a similar prognosis to the triple negative population
 - Same DFS and OS
- ❖ American cohort study³:
 - Clear benefit for adjuvant endocrine therapy for ER-low BC

ER-low BC are treated like TNBC in France but there is a lack of data concerning this population in the neoadjuvant setting

¹ Y Ke-Da *et al* Cancer Communications V41, I10, 2021

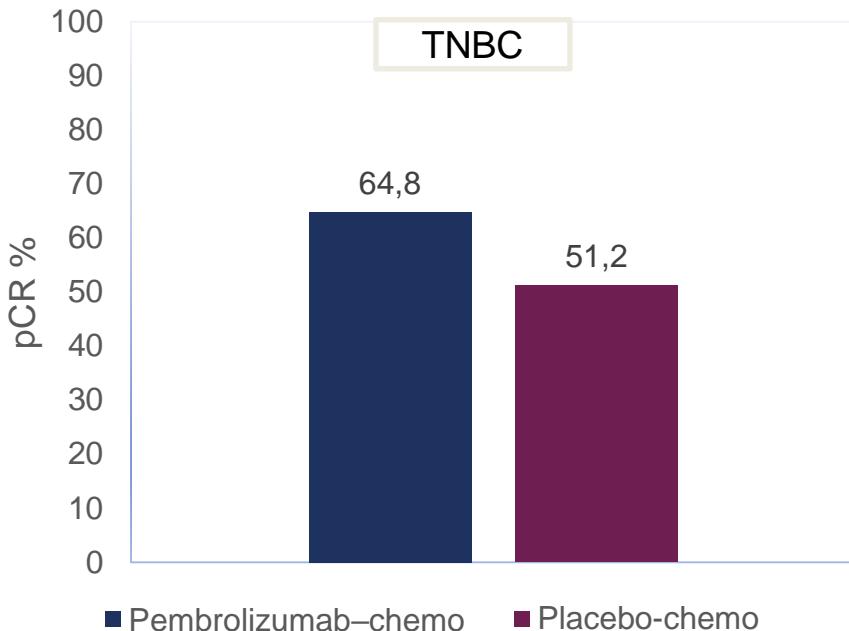
² A Balazs *et al* The Lancet Regional Health-Europe V40, 2024

³ GM Yee Choong *et al* Journal of Clinical Oncology, V42,N16, 2024



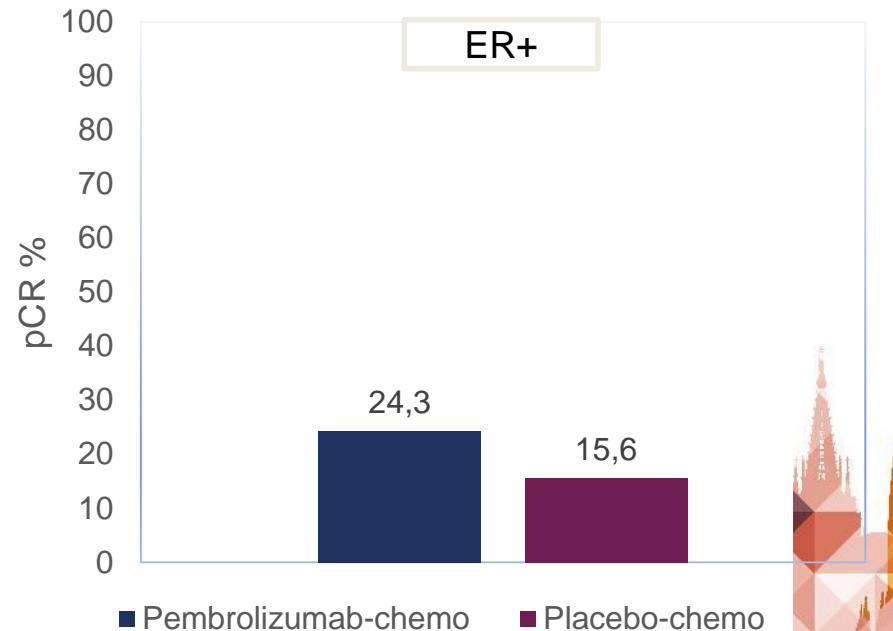
Background

KEYNOTE-522 (NCT03036488)



Standard of Care

KEYNOTE-756 (NCT03725059)



METHODS

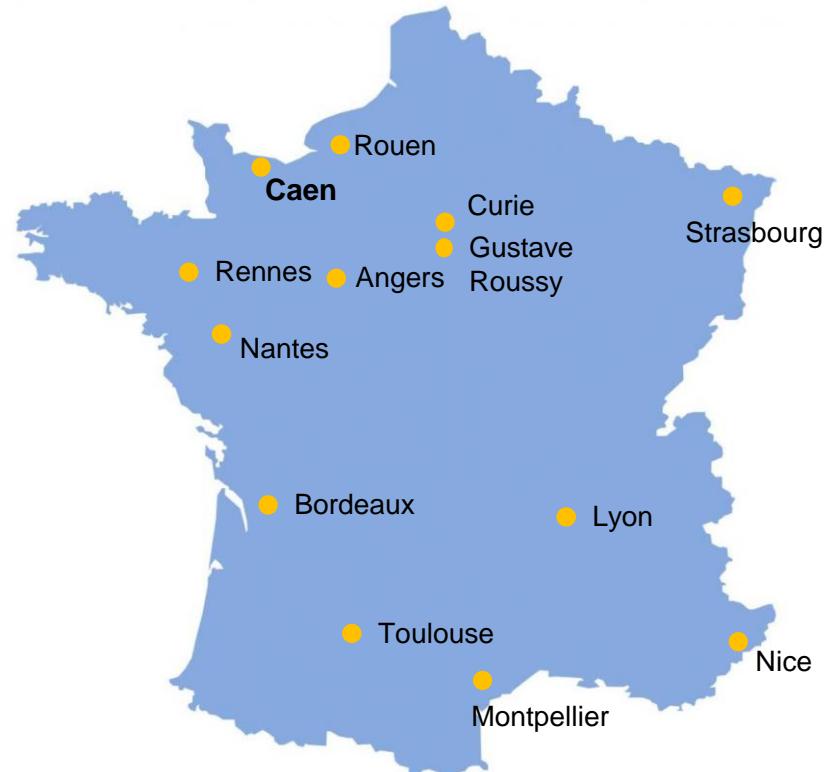
Retrospective real-life study

12 Comprehensive Cancer Centers in 13 cities in France

Inclusion Criteria:

- All patients receiving KEYNOTE 522 regimen
- Since its availability in march 2022
- Estrogen and/or progesterone receptor low (**1-9%**)
- HER2 negative (0, 1+, 2+ ISH neg)

Primary Objective: pCR (ypT0/isN0 or RCB 0) rate



RESULTS

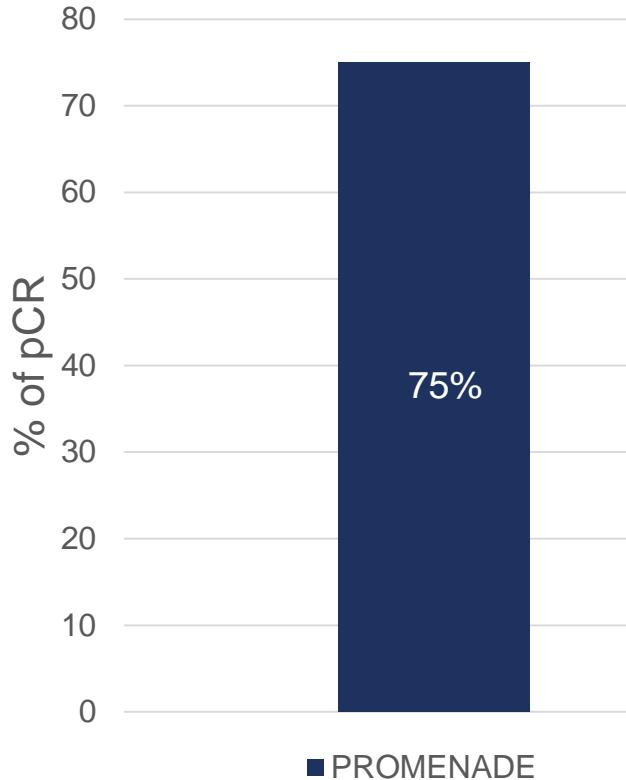
General characteristics		Pathology		Treatment	
Number of patients	114				
Age - Median (min-max)	49 (26-80)				
Missing	2 (1.8%)				
Menopausal status - n (%)					
Pre	64 (57%)				
Post	48 (43%)				
Missing	2 (1.8%)				
Tumor size - n (%)					
<T2	12 (11%)				
≥T2	102 (89%)				
Node - n (%)					
N0	58 (51%)				
N ≥1	56 (49%)				
Histology - n (%)					
Ductal	102 (90%)				
Lobular	2 (2%)				
Other	9 (8%)				
Missing	1 (0.9%)				
SBR grade - n (%)					
II	15 (14%)				
III	95 (86%)				
Missing	4 (3.5%)				
KI67 - Mean (SD)					
	61 (24)				
Missing	15 (13.2%)				
Endocrine receptors - n (%)					
ER-/PR+	37 (32%)				
ER+/PR-	66 (58%)				
ER+/PR+	11 (10%)				
HER2 – n (%)					
0	57 (50%)				
1	35 (31%)				
2 (ISH neg)	22 (19%)				
NACT* completed- n (%)					
Missing	4 (3.5%)				
	83 (75%)				
Surgery - n (%)					
	113 (99%)				
Surgery type - n (%)					
Lumpectomy	62 (54.3%)				
Mastectomy	50 (44%)				
Not done (PD)	1 (0.8%)				
Other	1 (0.8%)				
Nodal intervention - n (%)					
Sentinel lymph node	57 (50%)				
Axillary dissection	54 (47%)				
Not done (PD)	1 (0.8%)				
Other	2 (1.7%)				

RESULTS

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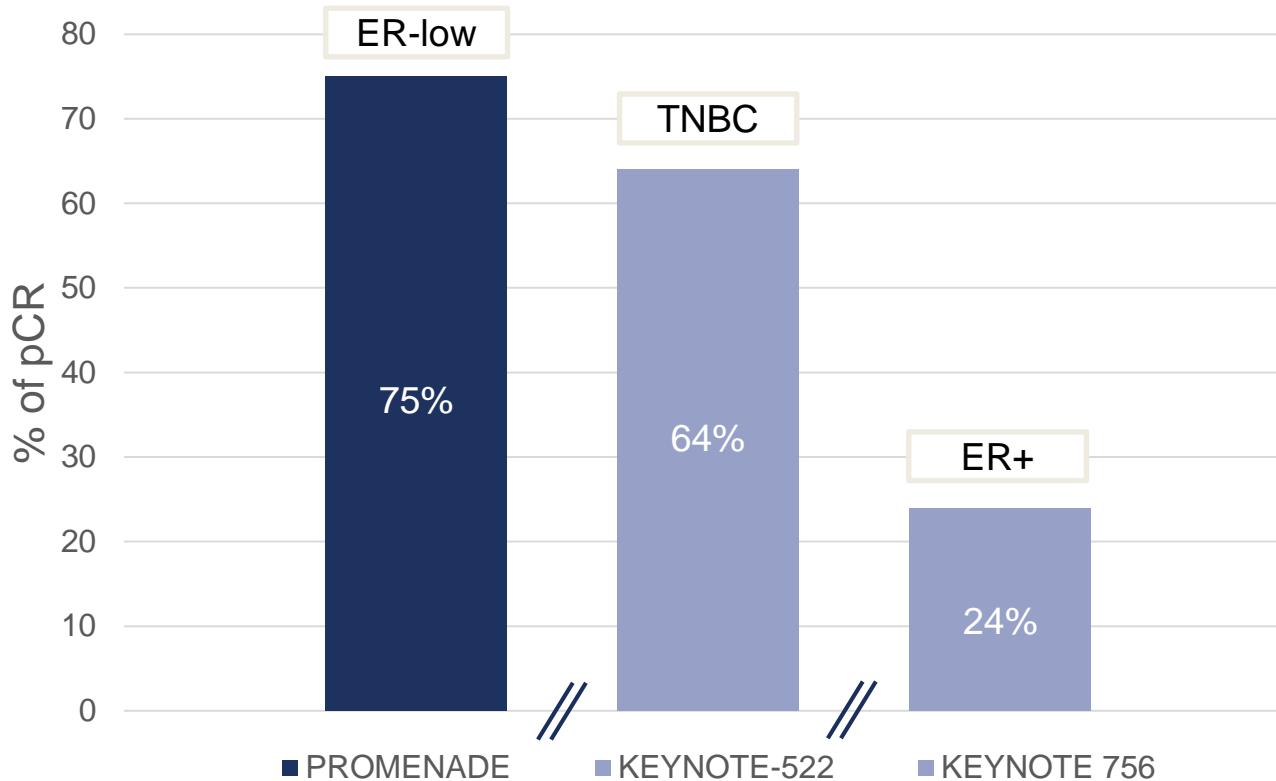
pCR rate with KEYNOTE-522 regimen in ER-low BC



RCB	n (%)
0	85 (75 %)
1	9 (8 %)
2	12 (11 %)
3	7 (6 %)
Progressive disease	1 (1 %)

RESULTS

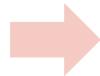
pCR rate with NACT



Data are not intended to be directly comparative

TAKE HOME MESSAGE

- ❖ Tumors with ER-low status have:
 - ❖ A high rate of pCR after KEYNOTE 522 regimen
 - ❖ Respond differently than ER-positive and more like Triple-negative BC
- ❖ KEYNOTE 522 regimen seems to be useful for this population



What is the best treatment in the adjuvant setting ?



Acknowledgements

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- All patients and their families participating in this study
- All investigators and centers
- 2024 ESMO organization committee
- For your attention

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