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Advances in Breast Cancer Treatment and Current Updates

Joyce O'Shaughnessy, MD
Celebrating Women Chair in Breast Cancer Research
Baylor University Medical Center
Texas Oncology
Sarah Cannon Research Institute

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OBJECTIVES

1. Describe which early breast cancer patients benefit from CDK 4/6 inhibitor therapy.
2. Discuss the somatic mutations that are targets for therapy for HR+ HER2- MBC patients.
3. Review recent landmark clinical trial results in HR+ HER2- MBC that support new therapeutic approaches.

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Early Breast Cancer

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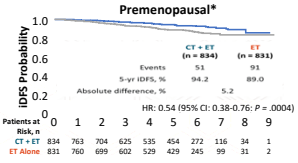
RxPONDER Subset Analysis: iDFS by Menopausal Status

N=5015

- Chemotherapy Followed by ET (n = 2509)
- ET Alone (n = 2506)



*Last menstrual period <6 mo or 6-12 mo and <50 yr.

Premenopausal, HR+ HER2- EBC, 1-3 LN+ (SLND or ALND), Oncotype RS <25, candidate for chemo

- No significant iDFS difference for postmenopausal women
- Assessed benefit chemotherapy in pts <55 yr of age using serum markers of ovarian function/reserve
- Less iDFS benefit in "premenopausal" women ≥50 to 55 yrs of age
- Low serum anti-Müllerian hormone and inhibin B are markers of diminished ovarian reserve and lack of benefit from adjuvant chemotherapy

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BR009: OFSET Trial

Premenopausal; HR+/HER2- BC
pN0 with RS 16-20 (high clinical risk) or RS 21-25
pN1 with RS 0-25

Stratification
Nodal Status (pN0 vs. pN1)
RS (0-15 vs. 16-25)

Randomization

N=3,960

- **Chemotherapy + Ovarian Function Suppression + Aromatase Inhibitor* X 5 Years**
- **Ovarian Function Suppression + Aromatase Inhibitor* X 5 Years**

* Tamoxifen can be used if AI is not tolerated

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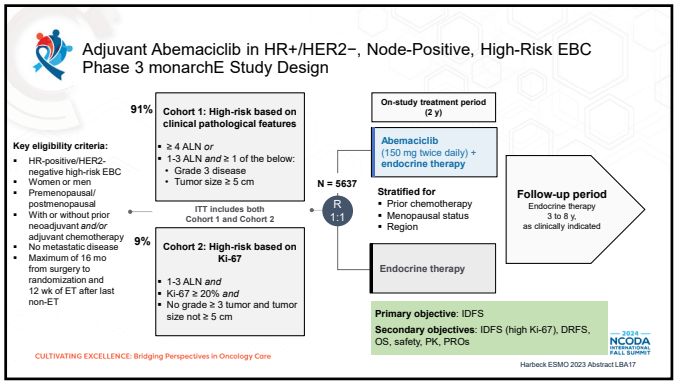
Adjuvant Abemaciclib in HR+/HER2−, Node-Positive, High-Risk EBC
Phase 3 monarchE Study Design
Key eligibility criteria:
HR-positive/HER2-negative high-risk EBC
Women or men
Premenopausal/postmenopausal
With or without prior neoadjuvant and/or adjuvant chemotherapy
No metastatic disease
Maximum of 16 mo from surgery to randomization and 12 wk of ET after last non-ET
91%
Cohort 1: High-risk based on clinical pathological features
≥ 4 ALN or
1-3 ALN and ≥ 1 of the below:
Grade 3 disease
Tumor size ≥ 5 cm
9%
Cohort 2: High-risk based on Ki-67
1-3 ALN and
Ki-67 ≥ 20% and
No grade ≥ 3 tumor and tumor size not ≥ 5 cm
ITT includes both Cohort 1 and Cohort 2
N = 5637
R 1:1
On-study treatment period (2 y)
Abemaciclib (150 mg twice daily) + endocrine therapy
Endocrine therapy
Stratified for
Prior chemotherapy
Menopausal status
Region
Follow-up period
Endocrine therapy 3 to 8 y, as clinically indicated
Primary objective: IDFS
Secondary objectives: IDFS (high Ki-67), DRFS, OS, safety, PK, PROs
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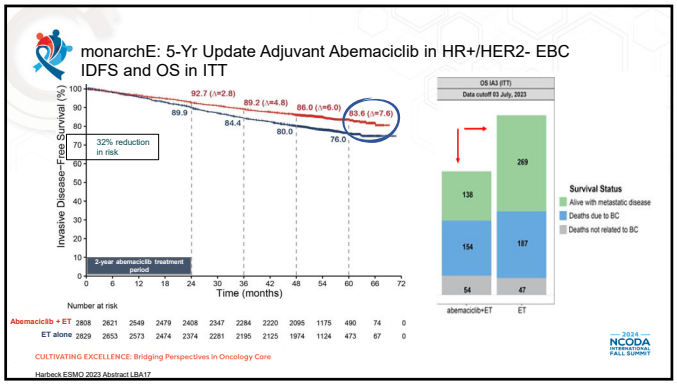
monarchE: 5-Yr Update Adjuvant Abemaciclib in HR+/HER2- EBC
IDFS and OS in ITT
Invasive Disease–Free Survival (%)
92.7 (↓=2.8)
89.9
89.2 (↓=4.8)
84.4
86.0 (↓=6.0)
80.0
83.6 (↓=7.6)
76.0
32% reduction in risk
2-year abemaciclib treatment period
Time (months)
Number at risk
Abemaciclib + ET 2808 2621 2549 2479 2408 2347 2284 2220 2095 1175 490 74 0
ET alone 2829 2653 2573 2474 2374 2281 2195 2125 1974 1124 473 67 0
OS IA3 (ITT)
Data cutoff 03 July, 2023
269
138
154
187
54
47
abemaciclib+ET
ET
Survival Status
Alive with metastatic disease
Deaths due to BC
Deaths not related to BC
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Harbeck ESMO 2023 Abstract LBA17

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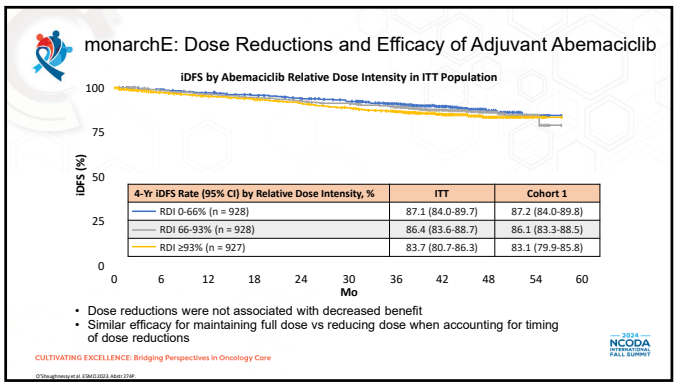
monarchE: Dose Reductions and Efficacy of Adjuvant Abemaciclib
iDFS by Abemaciclib Relative Dose Intensity in ITT Population
iDFS (%)
Mo
4-Yr iDFS Rate (95% CI) by Relative Dose Intensity, %
ITT
Cohort 1
RDI 0-66% (n = 928)
87.1 (84.0-89.7)
87.2 (84.0-89.8)
RDI 66-93% (n = 928)
86.4 (83.6-88.7)
86.1 (83.3-88.5)
RDI ≥93% (n = 927)
83.7 (80.7-86.3)
83.1 (79.9-85.8)
Dose reductions were not associated with decreased benefit
Similar efficacy for maintaining full dose vs reducing dose when accounting for timing of dose reductions
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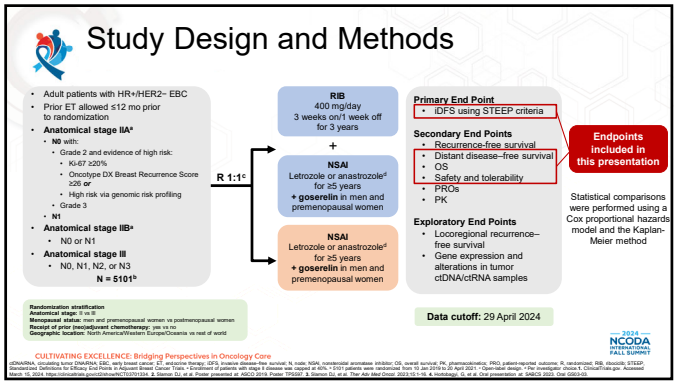
Study Design and Methods
Adult patients with HR+/HER2− EBC
Prior ET allowed ≤12 mo prior to randomization
Anatomical stage IIA[a]
N0 with:
Grade 2 and evidence of high risk:
Ki-67 ≥20%
Oncotype DX Breast Recurrence Score ≥26 or
High risk via genomic risk profiling
Grade 3
N1
Anatomical stage IIB[a]
N0 or N1
Anatomical stage III
N0, N1, N2, or N3
N = 5101[b]
R 1:1[c]
RIB
400 mg/day
3 weeks on/1 week off
for 3 years
+
NSAI
Letrozole or anastrozole[d]
for ≥5 years
+ goserelin in men and premenopausal women
NSAI
Letrozole or anastrozole[d]
for ≥5 years
+ goserelin in men and premenopausal women
Primary End Point
iDFS using STEEP criteria
Secondary End Points
Recurrence-free survival
Distant disease–free survival
OS
Safety and tolerability
PROs
PK
Exploratory End Points
Locoregional recurrence–free survival
Gene expression and alterations in tumor ctDNA/ctRNA samples
Endpoints included in this presentation
Statistical comparisons were performed using a Cox proportional hazards model and the Kaplan-Meier method
Randomization stratification
Anatomical stage: II vs III
Menopausal status: men and premenopausal women vs postmenopausal women
Receipt of prior (neo)adjuvant chemotherapy: yes vs no
Geographic location: North America/Western Europe/Oceania vs rest of world
Data cutoff: 29 April 2024
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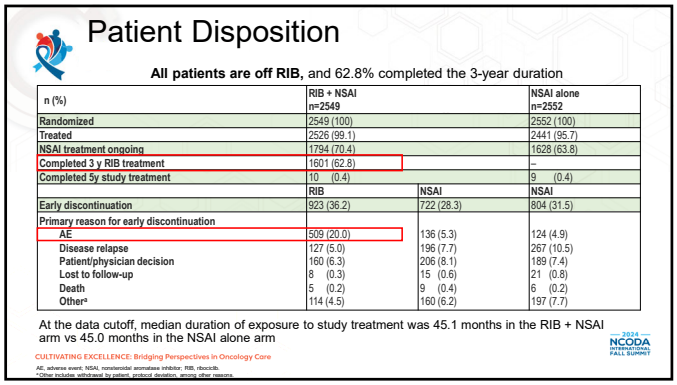
Patient Disposition
All patients are off RIB, and 62.8% completed the 3-year duration
n (%) | RIB + NSAI n=2549 | | NSAI alone n=2552
Randomized | 2549 (100) | | 2552 (100)
Treated | 2526 (99.1) | | 2441 (95.7)
NSAI treatment ongoing | 1794 (70.4) | | 1628 (63.8)
Completed 3 y RIB treatment | 1601 (62.8) | | –
Completed 5y study treatment | 10 (0.4) | | 9 (0.4)
| RIB | NSAI | NSAI
Early discontinuation | 923 (36.2) | 722 (28.3) | 804 (31.5)
Primary reason for early discontinuation
AE | 509 (20.0) | 136 (5.3) | 124 (4.9)
Disease relapse | 127 (5.0) | 196 (7.7) | 267 (10.5)
Patient/physician decision | 160 (6.3) | 206 (8.1) | 189 (7.4)
Lost to follow-up | 8 (0.3) | 15 (0.6) | 21 (0.8)
Death | 5 (0.2) | 9 (0.4) | 6 (0.2)
Other[a] | 114 (4.5) | 160 (6.2) | 197 (7.7)
At the data cutoff, median duration of exposure to study treatment was 45.1 months in the RIB + NSAI arm vs 45.0 months in the NSAI alone arm
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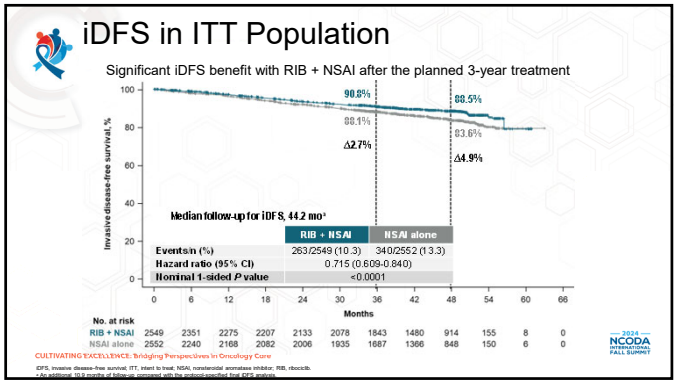
iDFS in ITT Population
Significant iDFS benefit with RIB + NSAI after the planned 3-year treatment
Invasive disease-free survival, %
100
80
60
40
20
0
90.8%
88.1%
Δ2.7%
80.5%
83.6%
Δ4.9%
Median follow-up for iDFS, 44.2 mo[a]
RIB + NSAI | NSAI alone
Events/n (%) | 263/2549 (10.3) | 340/2552 (13.3)
Hazard ratio (95% CI) | 0.715 (0.609-0.840)
Nominal 1-sided P value | <0.0001
0 6 12 18 24 30 36 42 48 54 60 66
Months
No. at risk
RIB + NSAI 2549 2351 2275 2207 2133 2078 1843 1480 914 155 8 0
NSAI alone 2552 2240 2168 2082 2006 1935 1687 1366 848 150 6 0
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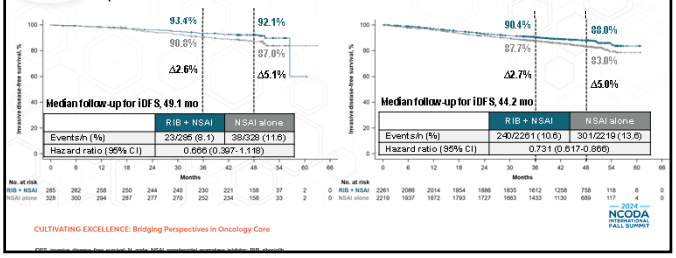
iDFS by Nodal Status

RIB + NSAI showed an increasing magnitude of iDFS benefit over time for patients with N0 or N1-3 disease



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Safety

Incidence of AEs remained stable from prior analyses

	RIB + NSAI n=2526		NSAI alone n=2441	
AESIs, %	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**
Neutropenia[a]	62.8	44.4	4.5	0.9
Febrile neutropenia	0.3	0.3	0	0
Liver-related AEs[b]	26.7	8.6	11.4	1.7
QT interval prolongation[c]	5.4	1.0	1.6	0.7
ECG QT prolonged	4.4	0.2	0.8	<0.1
Interstitial lung disease/pneumonitis[d]	1.6	0	0.9	0.1
Clinically relevant AEs, %				
Arthralgia	38.8	1.0	44.4	1.3
Nausea	23.5	0.2	7.9	<0.1
Headache	22.9	0.4	17.2	0.2
Fatigue	22.8	0.8	13.5	0.2
Diarrhea	14.6	0.6	5.5	0.1
VTE[e]	1.1	0.6	0.5	0.3

- Rates of discontinuation due to AEs (20.0%) remained stable through all of the data cuts, with a <1.0% increase from the previous cutoff[1,2]
- Liver-related AEs were predominantly ALT/AST elevations without concomitant bilirubin increase

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AE, adverse event; AESI, adverse event of special interest; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ECG, electrocardiogram; MedDRA, Medical Dictionary for Regulatory Activities; VTE, venous thromboembolism. [a]Grouped term that combines neutropenia and neutrophil count decreased. [b]Grouped term that includes all preferred terms identified by standardized MedDRA queries for drug-related hepatic disorders. [c]Grouped term. [d]Grouped term that includes all preferred terms identified by standardized MedDRA queries for interstitial lung disease. [e]Grouped term that includes all preferred terms identified by standardized MedDRA queries for venous thromboembolism. 1. Bianchini G, et al. *N Engl J Med* 2024;390(12):1089-1101. 2. Hortobagyi G, et al. Oral presentation at: SABCS 2023; Oral GS2-03.

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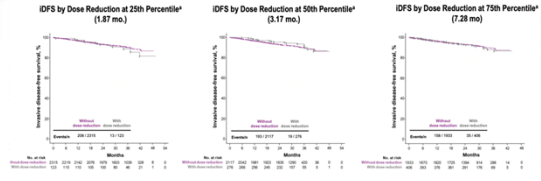
NATALEE: IDFS BY DOSE REDUCTIONS

- Landmark analysis revealed that RIB dose reduction due to AEs did not impact efficacy



[a]Of dose reduction time, calculated from randomization

AE, adverse event; iDFS, invasive disease-free survival; RIB, ribociclib.

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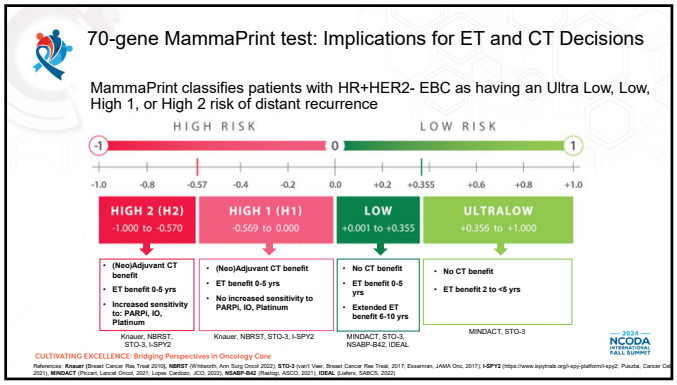
70-gene MammaPrint test: Implications for ET and CT Decisions
MammaPrint classifies patients with HR+HER2- EBC as having an Ultra Low, Low, High 1, or High 2 risk of distant recurrence
HIGH RISK
LOW RISK
-1
0
1
-1.0
-0.8
-0.57
-0.4
-0.2
0.0
+0.2
+0.355
+0.6
+0.8
+1.0
HIGH 2 (H2)
-1.000 to -0.570
HIGH 1 (H1)
-0.569 to 0.000
LOW
+0.001 to +0.355
ULTRALOW
+0.356 to +1.000
(Neo)Adjuvant CT benefit
ET benefit 0-5 yrs
Increased sensitivity to: PARPi, IO, Platinum
Knauer, NBRST, STO-3, I-SPY2
(Neo)Adjuvant CT benefit
ET benefit 0-5 yrs
No increased sensitivity to PARPi, IO, Platinum
Knauer, NBRST, STO-3, I-SPY2
No CT benefit
ET benefit 0-5 yrs
Extended ET benefit 6-10 yrs
MINDACT, STO-3, NSABP-B42, IDEAL
No CT benefit
ET benefit 2 to <5 yrs
MINDACT, STO-3
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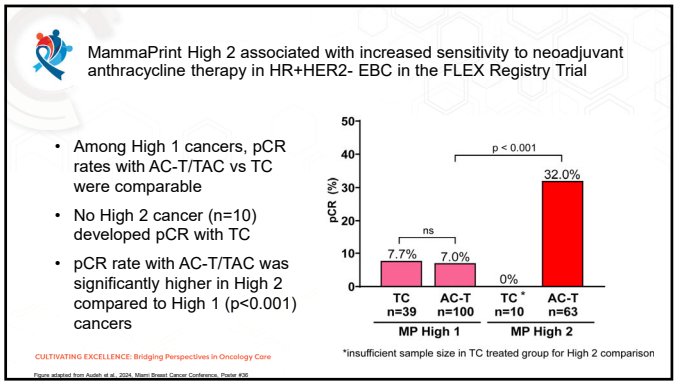
MammaPrint High 2 associated with increased sensitivity to neoadjuvant anthracycline therapy in HR+HER2- EBC in the FLEX Registry Trial
Among High 1 cancers, pCR rates with AC-T/TAC vs TC were comparable
No High 2 cancer (n=10) developed pCR with TC
pCR rate with AC-T/TAC was significantly higher in High 2 compared to High 1 (p<0.001) cancers
pCR (%)
p < 0.001
ns
7.7%
7.0%
0%
32.0%
TC n=39
AC-T n=100
TC * n=10
AC-T n=63
MP High 1
MP High 2
*insufficient sample size in TC treated group for High 2 comparison
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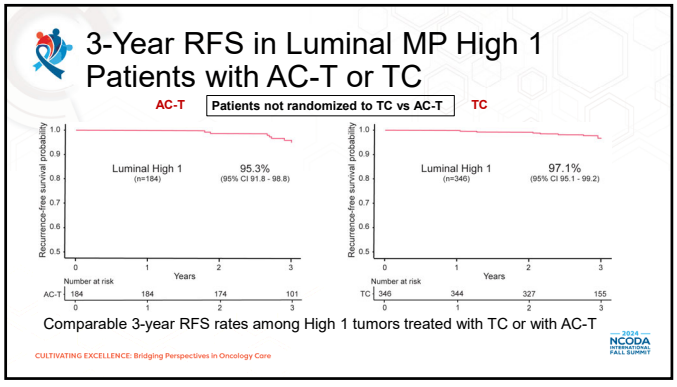
3-Year RFS in Luminal MP High 1 Patients with AC-T or TC
AC-T
Patients not randomized to TC vs AC-T
TC
Recurrence-free survival probability
Luminal High 1
(n=184)
95.3%
(95% CI 91.8 - 98.8)
Luminal High 1
(n=346)
97.1%
(95% CI 95.1 - 99.2)
Years
Number at risk
AC-T 184 184 174 101
TC 346 344 327 155
Comparable 3-year RFS rates among High 1 tumors treated with TC or with AC-T
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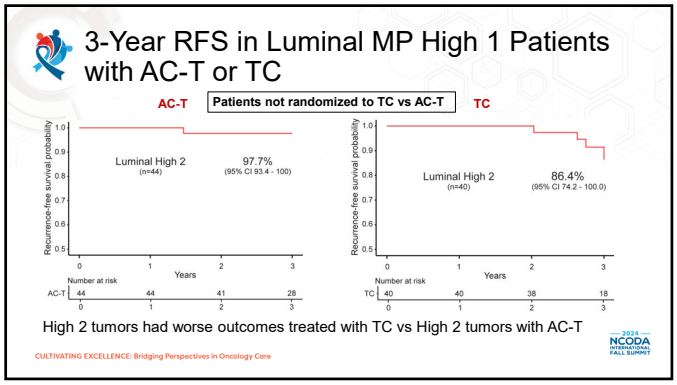
3-Year RFS in Luminal MP High 1 Patients with AC-T or TC
AC-T
Patients not randomized to TC vs AC-T
TC
Recurrence-free survival probability
Luminal High 2
(n=44)
97.7%
(95% CI 93.4 - 100)
Years
Number at risk
AC-T 44 44 41 28
Luminal High 2
(n=40)
86.4%
(95% CI 74.2 - 100.0)
TC 40 40 38 18
High 2 tumors had worse outcomes treated with TC vs High 2 tumors with AC-T
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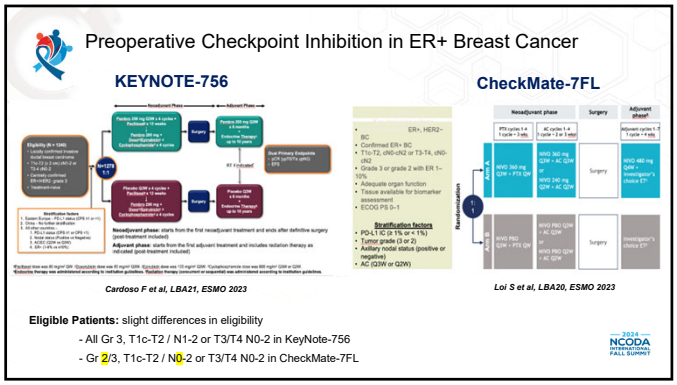
Preoperative Checkpoint Inhibition in ER+ Breast Cancer
KEYNOTE-756
CheckMate-7FL
Cardoso F et al, LBA21, ESMO 2023
Loi S et al, LBA20, ESMO 2023
Eligible Patients: slight differences in eligibility
- All Gr 3, T1c-T2 / N1-2 or T3/T4 N0-2 in KeyNote-756
- Gr 2/3, T1c-T2 / N0-2 or T3/T4 N0-2 in CheckMate-7FL
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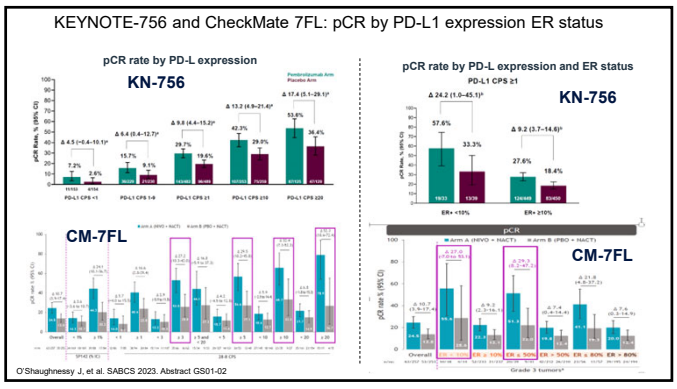
KEYNOTE-756 and CheckMate 7FL: pCR by PD-L1 expression ER status
pCR rate by PD-L expression
KN-756
CM-7FL
pCR rate by PD-L expression and ER status
PD-L1 CPS ≥1
KN-756
CM-7FL
pCR
O'Shaughnessy J, et al. SABCS 2023. Abstract GS01-02

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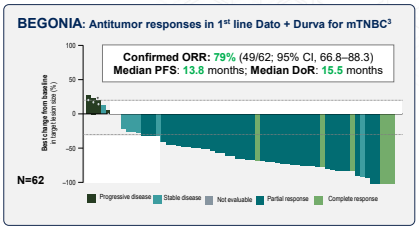
Rationale: Dato + Durva in 1st line mTNBC

- Preclinical data have demonstrated that Topo-I inhibitors can enhance antitumor immune responses and improve the antitumor efficacy of anti-PD-L1 therapy[1,2]
- In the phase 1b/2 BEGONIA study, Dato + Durva had an ORR of 79% in 1st-line mTNBC[3]

BEGONIA: Antitumor responses in 1st line Dato + Durva for mTNBC[3]



Dotted lines indicate thresholds for partial response (–30%) and progressive disease (20%). *If the best percentage change from baseline of target lesions cannot be calculated due to progression, withdrawal, or death, the value is imputed at +20%. ^^ Patients with PD as best overall response. #Unconfirmed response. (a/m)TNBC, (advanced/metastatic) triple-negative breast cancer; ADC, antibody-drug conjugate; CI, confidence interval; CR, complete response; Dato, datopotamab deruxtecan; DoR, duration of response; NC, not calculable; ORR, overall response rate; PD, progressive disease; PD-L1, programmed death ligand-1; PFS, progression-free survival; PR, partial response,; Topo-I, topoisomerase I; TROP2, trophoblast cell surface antigen 2.

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1. McKenzie JA, et al. J Natl Cancer Inst. 2018;110(7):777–86.
2. Hoang KC, et al. Cancers. 2021;13(6):1216.
3. Schmid P, et al. Presented at ESMO 2023. 370MO.

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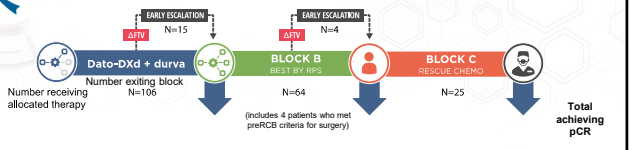
Timing of observed pCR



All patients (N=106)	N achieving pCR	25	22	6	53
	Cumulative % of total observed pCR	**47%** (25/53)	**89%** (47/53)	**100%** (53/53)	**50%** (53/106)
HER2-Immune+ (N=47)	N achieving pCR	20	14	3	37
	Cumulative % of total observed pCR	**54%** (20/37)	**92%** (34/37)	**100%** (37/37)	**79%** (37/47)
HR-HER2-^ (N=63)	N achieving pCR	21	15	3	39
	Cumulative % of total observed pCR	**54%** (21/39)	**92%** (36/39)	**100%** (39/39)	**62%** (39/63)

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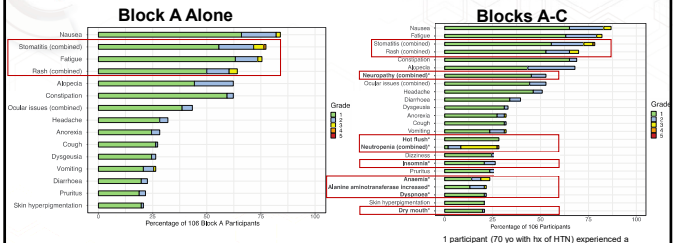
Incidence of most frequent non-immune adverse events



1 participant (70 yo with hx of HTN) experienced a Grade 5 cardiac arrest in Block B

MedDra combined terms

Stomatitis (Combined): Stomatitis, Oropharyngeal pain, Mouth ulceration, Mouth injury, Oral pain, Mouth ulceration, Gingival pain

Rash (Combined): Rash, Rash macular-papular, Dermatitis, Rash pustular, Skin disorder, Dermatitis acneiform, Rash pruritic, Rash erythematous, Eczema, Urticaria, and Rash macular

Ocular issues (Combined): Keratitis, Eye pain, Vision blurred, Eye irritation, Photophobia, Eye pruritus, Dry eye, Photopsia, Conjunctivitis, Eye infection, Eyelid irritation, Corneal ulcer, Uveitis, Corneal opacity, Eye disorder

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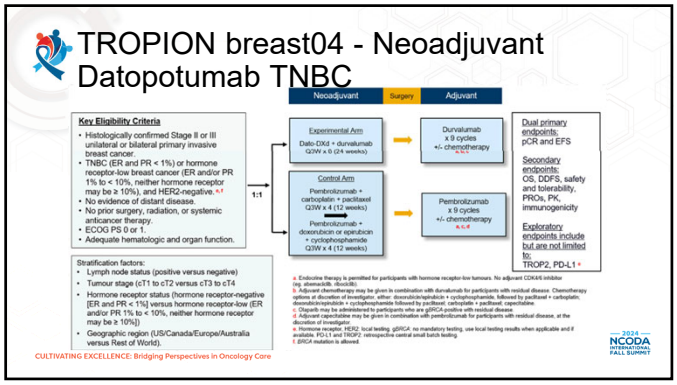
TROPION breast04 - Neoadjuvant Datopotumab TNBC
Neoadjuvant
Surgery
Adjuvant
Key Eligibility Criteria
• Histologically confirmed Stage II or III unilateral or bilateral primary invasive breast cancer.
• TNBC (ER and PR < 1%) or hormone receptor-low breast cancer (ER and/or PR 1% to < 10%, neither hormone receptor may be ≥ 10%), and HER2-negative. a, f
• No evidence of distant disease.
• No prior surgery, radiation, or systemic anticancer therapy.
• ECOG PS 0 or 1.
• Adequate hematologic and organ function.
Stratification factors:
• Lymph node status (positive versus negative)
• Tumour stage (cT1 to cT2 versus cT3 to cT4
• Hormone receptor status (hormone receptor-negative [ER and PR < 1%] versus hormone receptor-low (ER and/or PR 1% to < 10%, neither hormone receptor may be ≥ 10%))
• Geographic region (US/Canada/Europe/Australia versus Rest of World).
1:1
Experimental Arm
Dato-DXd + durvalumab Q3W x 9 (24 weeks)
Control Arm
Pembrolizumab + carboplatin + paclitaxel Q3W x 4 (12 weeks)
Pembrolizumab + doxorubicin or epirubicin + cyclophosphamide Q3W x 4 (12 weeks)
Durvalumab x 9 cycles +/- chemotherapy a, b, c
Pembrolizumab x 9 cycles +/- chemotherapy a, b, c, e
Dual primary endpoints: pCR and EFS
Secondary endpoints: OS, DDFS, safety and tolerability, PROs, PK, immunogenicity
Exploratory endpoints include but are not limited to: TROP2, PD-L1 e
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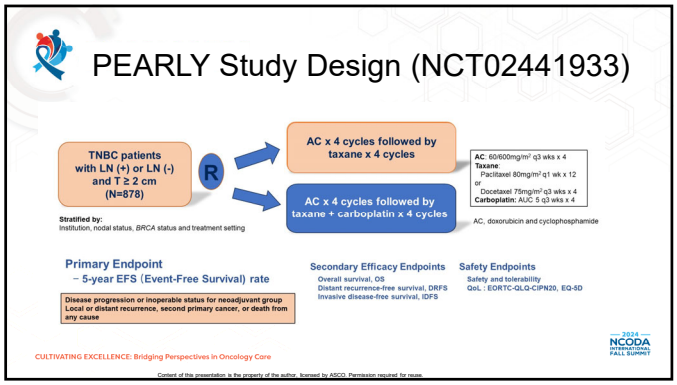
PEARLY Study Design (NCT02441933)
TNBC patients with LN (+) or LN (-) and T ≥ 2 cm (N=878)
R
AC x 4 cycles followed by taxane x 4 cycles
AC x 4 cycles followed by taxane + carboplatin x 4 cycles
AC: 60/600mg/m² q3 wks x 4
Taxane:
Paclitaxel 80mg/m² q1 wk x 12
or
Docetaxel 75mg/m² q3 wks x 4
Carboplatin: AUC 5 q3 wks x 4
AC, doxorubicin and cyclophosphamide
Stratified by:
Institution, nodal status, BRCA status and treatment setting
Primary Endpoint
– 5-year EFS (Event-Free Survival) rate
Disease progression or inoperable status for neoadjuvant group
Local or distant recurrence, second primary cancer, or death from any cause
Secondary Efficacy Endpoints
Overall survival, OS
Distant recurrence-free survival, DRFS
Invasive disease-free survival, IDFS
Safety Endpoints
Safety and tolerability
QoL : EORTC-QLQ-CIPN20, EQ-5D
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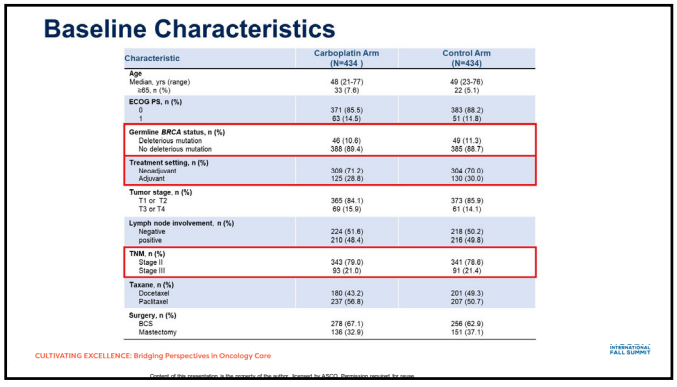
Baseline Characteristics
Characteristic | Carboplatin Arm (N=434) | Control Arm (N=434)
Age
Median, yrs (range) | 48 (21-77) | 49 (23-76)
≥65, n (%) | 33 (7.6) | 22 (5.1)
ECOG PS, n (%)
0 | 371 (85.5) | 383 (88.2)
1 | 63 (14.5) | 51 (11.8)
Germline BRCA status, n (%)
Deleterious mutation | 46 (10.6) | 49 (11.3)
No deleterious mutation | 388 (89.4) | 385 (88.7)
Treatment setting, n (%)
Neoadjuvant | 309 (71.2) | 304 (70.0)
Adjuvant | 125 (28.8) | 130 (30.0)
Tumor stage, n (%)
T1 or T2 | 365 (84.1) | 373 (85.9)
T3 or T4 | 69 (15.9) | 61 (14.1)
Lymph node involvement, n (%)
Negative | 224 (51.6) | 218 (50.2)
positive | 210 (48.4) | 216 (49.8)
TNM, n (%)
Stage II | 343 (79.0) | 341 (78.6)
Stage III | 93 (21.0) | 91 (21.4)
Taxane, n (%)
Docetaxel | 180 (43.2) | 201 (49.3)
Paclitaxel | 237 (56.8) | 207 (50.7)
Surgery, n (%)
BCS | 278 (67.1) | 256 (62.9)
Mastectomy | 136 (32.9) | 151 (37.1)
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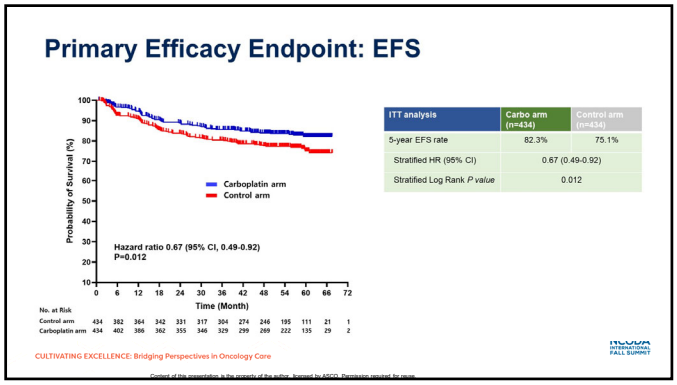
Primary Efficacy Endpoint: EFS
Probability of Survival (%)
Carboplatin arm
Control arm
Hazard ratio 0.67 (95% CI, 0.49-0.92)
P=0.012
Time (Month)
No. at Risk
Control arm 434 382 364 342 331 317 304 274 246 195 111 21 1
Carboplatin arm 434 402 386 362 355 346 329 299 269 222 135 29 2
ITT analysis | Carbo arm (n=434) | Control arm (n=434)
5-year EFS rate | 82.3% | 75.1%
Stratified HR (95% CI) | 0.67 (0.49-0.92)
Stratified Log Rank P value | 0.012
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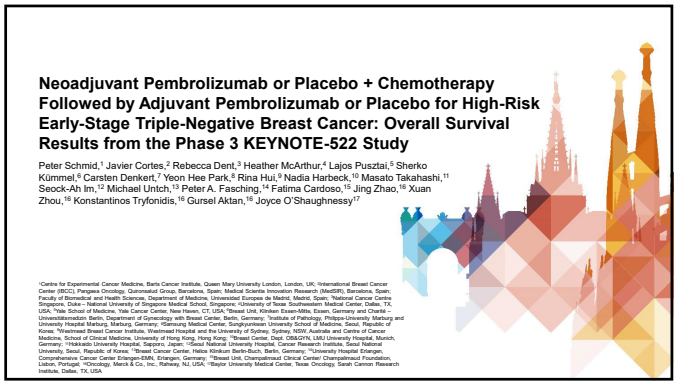
Neoadjuvant Pembrolizumab or Placebo + Chemotherapy Followed by Adjuvant Pembrolizumab or Placebo for High-Risk Early-Stage Triple-Negative Breast Cancer: Overall Survival Results from the Phase 3 KEYNOTE-522 Study
Peter Schmid,[1] Javier Cortes,[2] Rebecca Dent,[3] Heather McArthur,[4] Lajos Pusztai,[5] Sherko Kümmel,[6] Carsten Denkert,[7] Yeon Hee Park,[8] Rina Hui,[9] Nadia Harbeck,[10] Masato Takahashi,[11] Seock-Ah Im,[12] Michael Untch,[13] Peter A. Fasching,[14] Fatima Cardoso,[15] Jing Zhao,[16] Xuan Zhou,[16] Konstantinos Tryfonidis,[16] Gursel Aktan,[16] Joyce O'Shaughnessy[17]

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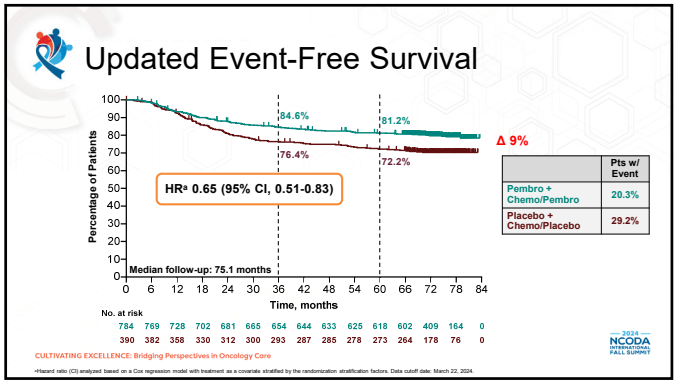
Updated Event-Free Survival
Percentage of Patients
84.6%
76.4%
81.2%
72.2%
Δ 9%
HRa 0.65 (95% CI, 0.51-0.83)
Pts w/ Event
Pembro + Chemo/Pembro 20.3%
Placebo + Chemo/Placebo 29.2%
Median follow-up: 75.1 months
Time, months
No. at risk
784 769 728 702 681 665 654 644 633 625 618 602 409 164 0
390 382 358 330 312 300 293 287 285 278 273 264 178 76 0
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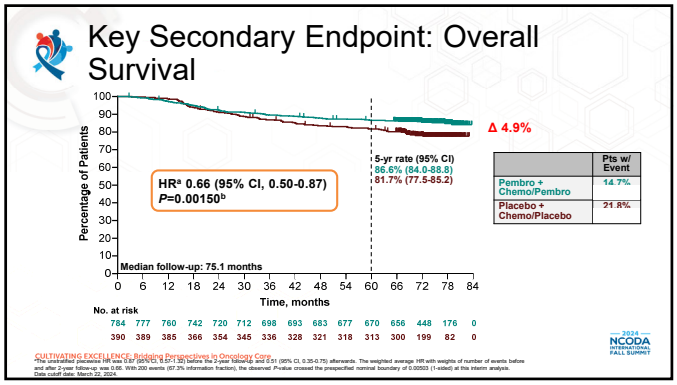
Key Secondary Endpoint: Overall Survival
Percentage of Patients
Δ 4.9%
5-yr rate (95% CI)
86.6% (84.0-88.8)
81.7% (77.5-85.2)
HR[a] 0.66 (95% CI, 0.50-0.87)
P=0.00150[b]
Pts w/ Event
Pembro + Chemo/Pembro 14.7%
Placebo + Chemo/Placebo 21.8%
Median follow-up: 75.1 months
Time, months
No. at risk
784 777 760 742 720 712 698 693 683 677 670 656 448 176 0
390 389 385 366 354 345 336 328 321 318 313 300 199 82 0
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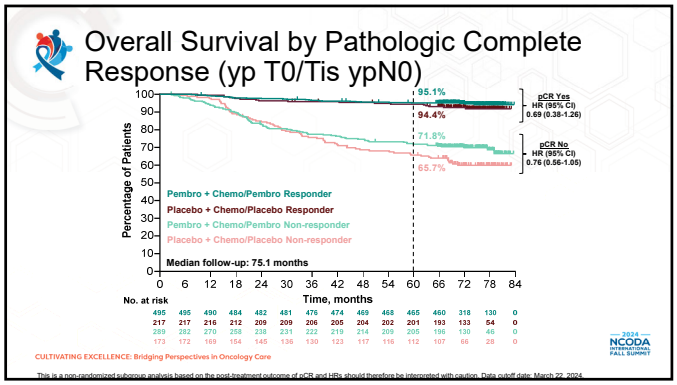
Overall Survival by Pathologic Complete Response (yp T0/Tis ypN0)
Percentage of Patients
95.1%
94.4%
71.8%
65.7%
pCR Yes
HR (95% CI)
0.69 (0.38-1.26)
pCR No
HR (95% CI)
0.76 (0.56-1.05)
Pembro + Chemo/Pembro Responder
Placebo + Chemo/Placebo Responder
Pembro + Chemo/Pembro Non-responder
Placebo + Chemo/Placebo Non-responder
Median follow-up: 75.1 months
Time, months
No. at risk
495 495 490 484 482 481 476 474 469 468 465 460 318 130 0
217 217 216 212 209 209 206 205 204 202 201 193 133 54 0
289 282 270 258 238 231 222 219 214 209 205 196 130 46 0
173 172 169 154 145 136 130 123 117 116 112 107 66 28 0
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This is a non-randomized subgroup analysis based on the post-treatment outcome of pCR and HRs should therefore be interpreted with caution. Data cutoff date: March 22, 2024.
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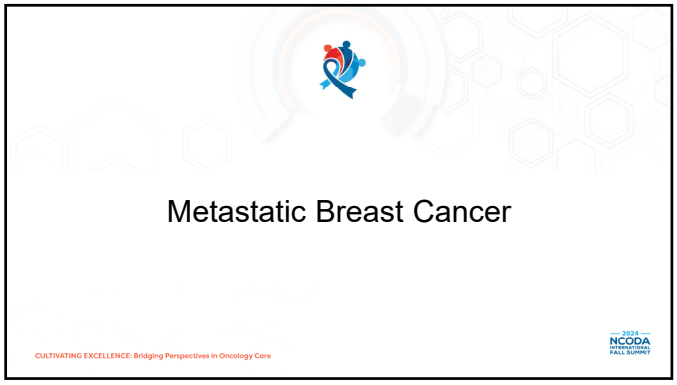
Metastatic Breast Cancer
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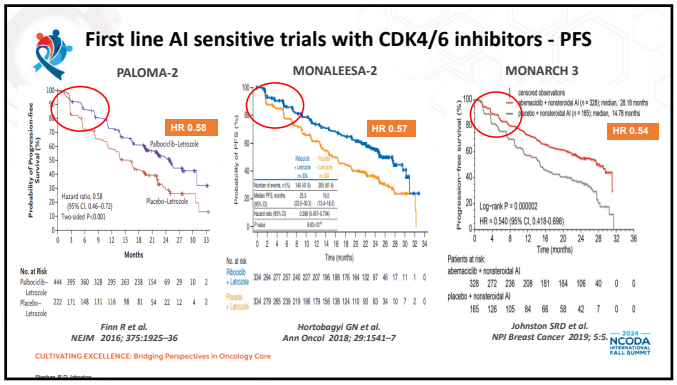
First line AI sensitive trials with CDK4/6 inhibitors - PFS
PALOMA-2
MONALEESA-2
MONARCH 3
HR 0.58
HR 0.57
HR 0.54
Palbociclib–Letrozole
Placebo–Letrozole
Ribociclib + Letrozole
Placebo + Letrozole
abemaciclib + nonsteroidal AI
placebo + nonsteroidal AI
Months
Time (months)
Finn R et al.
NEJM 2016; 375:1925–36
Hortobagyi GN et al.
Ann Oncol 2018; 29:1541–7
Johnston SRD et al.
NPJ Breast Cancer 2019; 5:5
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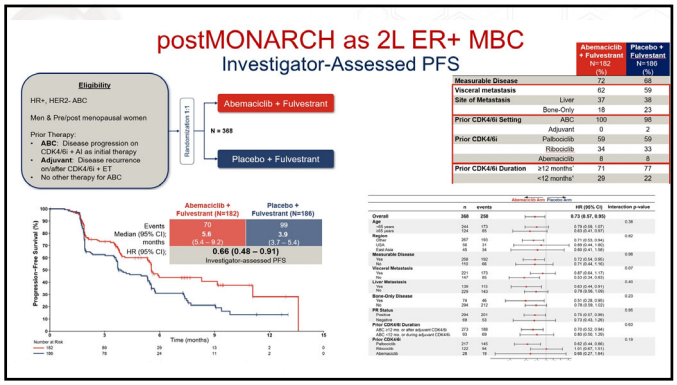
postMONARCH as 2L ER+ MBC
Investigator-Assessed PFS
Eligibility
HR+, HER2- ABC
Men & Pre/post menopausal women
Prior Therapy:
ABC: Disease progression on CDK4/6i + AI as initial therapy
Adjuvant: Disease recurrence on/after CDK4/6i + ET
No other therapy for ABC
Randomization 1:1
N = 368
Abemaciclib + Fulvestrant
Placebo + Fulvestrant
Abemaciclib + Fulvestrant N=182 (%)
Placebo + Fulvestrant N=186 (%)
Measurable Disease 72 68
Visceral metastasis 62 59
Site of Metastasis Liver 37 38
Bone-Only 18 23
Prior CDK4/6i Setting ABC 100 98
Adjuvant 0 2
Prior CDK4/6i Palbociclib 59 59
Ribociclib 34 33
Abemaciclib 8 8
Prior CDK4/6i Duration ≥12 months* 71 77
<12 months* 29 22
Abemaciclib + Fulvestrant (N=182)
Placebo + Fulvestrant (N=186)
Events 70 99
Median (95% CI); months 5.6 (5.4 – 9.2) 3.9 (3.7 – 5.4)
HR (95% CI); 0.66 (0.48 – 0.91)
Investigator-assessed PFS
Progression-Free Survival (%)
Time (months)
Number at Risk

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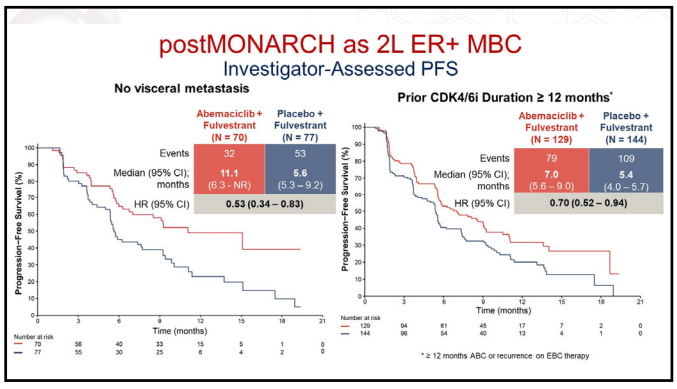
postMONARCH as 2L ER+ MBC
Investigator-Assessed PFS
No visceral metastasis
Abemaciclib + Fulvestrant (N = 70)
Placebo + Fulvestrant (N = 77)
Events 32 53
Median (95% CI); months 11.1 (6.3 - NR) 5.6 (5.3 – 9.2)
HR (95% CI) 0.53 (0.34 – 0.83)
Prior CDK4/6i Duration ≥ 12 months*
Abemaciclib + Fulvestrant (N = 129)
Placebo + Fulvestrant (N = 144)
Events 79 109
Median (95% CI); months 7.0 (5.6 – 9.0) 5.4 (4.0 – 5.7)
HR (95% CI) 0.70 (0.52 – 0.94)
Progression-Free Survival (%)
Time (months)
Number at risk
* ≥ 12 months ABC or recurrence on EBC therapy

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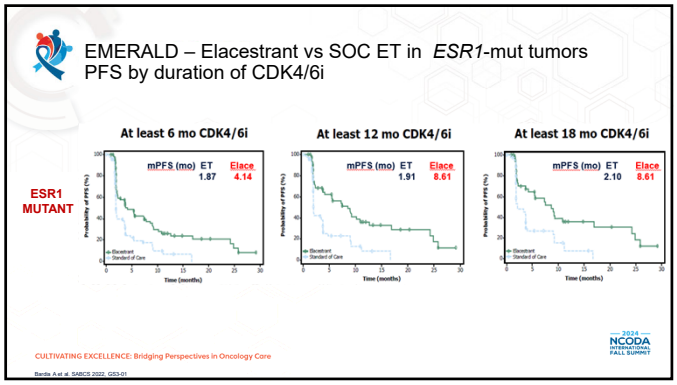
EMERALD – Elacestrant vs SOC ET in ESR1-mut tumors
PFS by duration of CDK4/6i
At least 6 mo CDK4/6i
At least 12 mo CDK4/6i
At least 18 mo CDK4/6i
ESR1 MUTANT
mPFS (mo) ET Elace
1.87 4.14
1.91 8.61
2.10 8.61
Probability of PFS (%)
Time (months)
Elacestrant
Standard of Care
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Bardia A et al. SABCS 2022. GS3-01

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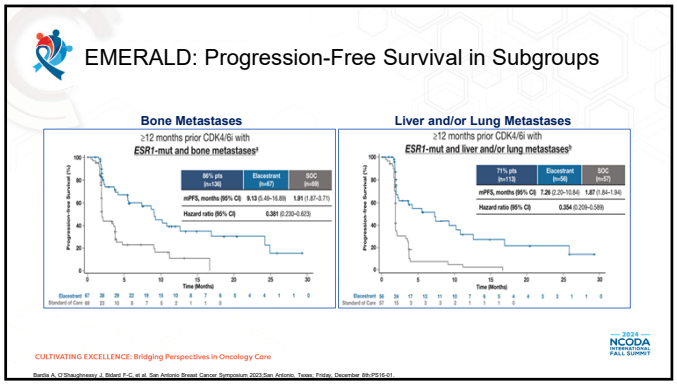
EMERALD: Progression-Free Survival in Subgroups
Bone Metastases
≥12 months prior CDK4/6i with
ESR1-mut and bone metastases
Liver and/or Lung Metastases
≥12 months prior CDK4/6i with
ESR1-mut and liver and/or lung metastases
Progression-free Survival (%)
Time (Months)
Elacestrant
Standard of Care
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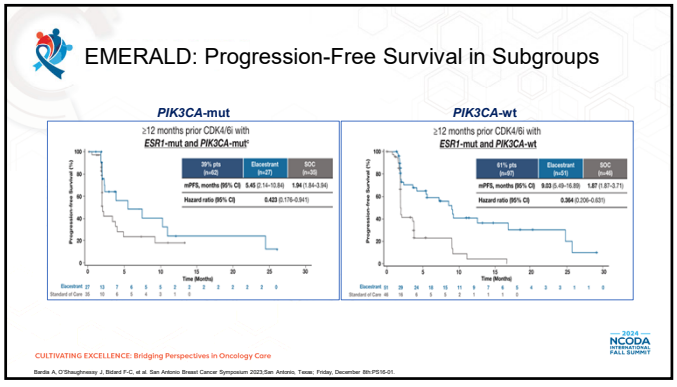
EMERALD: Progression-Free Survival in Subgroups
PIK3CA-mut
≥12 months prior CDK4/6i with
ESR1-mut and PIK3CA-mut
PIK3CA-wt
≥12 months prior CDK4/6i with
ESR1-mut and PIK3CA-wt
Progression-free Survival (%)
Time (Months)
Elacestrant
Standard of Care
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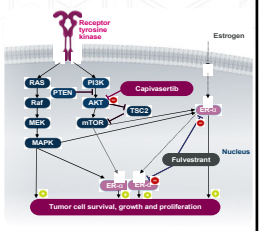
CAPItello-291: Phase 3 trial with capivasertib in ER+ MBC

- HR+ MBC with recurrence while on or within 12 months of adjuvant AI or PD on AI for MBC
- ≤2 lines of ET for MBC
- 0-1 prior chemo for MBC

Capivasertib* + fulvestrant

Placebo + fulvestrant

*400mg BID daily, 4 days on, 3 days off



Patient population

Visceral disease	66-73%
AKT pathway alterations	38-43%
Median priors for MBC	1
Prior CDK 4/6i	67-72%
Prior chemo for MBC	17-19%

Turner NC et al. SABCS 2022, GS3-04

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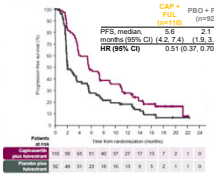
CAPItello-291 (Phase 3, exploratory analysis): Capivasertib and fulvestrant for AI-resistant HR+/HER2− advanced breast cancer

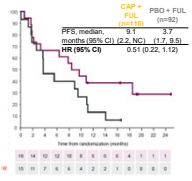
- **Objective:** Explore PFS by tumor PIK3CA/AKT1/PTEN-mutated status among patients from the CAPItell-291 study (including pooled analysis with inclusion of data from the Chinese extension cohort)
- **CAPItell-291 population:** Patients with HR+/HER2− advanced breast cancer after progression during during AI treatment with/without prior CDK4/6i therapy

***PIKCA* alteration only**



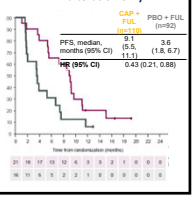
	CAP + FUL (n=119)	PBO + FUL (n=92)
PFS, median, months (95% CI)	5.6 (4.2, 7.4)	2.1 (1.9, 3.6)
HR (95% CI)	0.51 (0.37, 0.70)	

***AKT1* alteration only**



	CAP + FUL (n=119)	PBO + FUL (n=92)
PFS, median, months (95% CI)	9.1 (2.2, NC)	3.7 (1.7, 9.5)
HR (95% CI)	0.51 (0.22, 1.12)	

***PTEN* alteration only**



	CAP + FUL (n=119)	PBO + FUL (n=92)
PFS, median, months (95% CI)	9.1 (5.5, 11.1)	3.6 (1.8, 6.7)
HR (95% CI)	0.43 (0.21, 0.88)	

Howell SJ, et al. SABCS 2023. Abstract PS17-03

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Toxicity with PI3K/AKT Inhibition

	Alpelisib + Fulvestrant		Capivasertib + Fulvestrant	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Hyperglycemia	63.7	36.6	16.3	2.3
Diarrhea	57.7	6.7	72.4	9.3
Nausea	44.7	2.5	34.6	0.8
Vomiting	27.1	0.7	20.6	1.7
Decreased appetite	35.6	0.7	16.6	0.3
Rash	35.6	9.9	38.0	12.1
Stomatitis	24.6	2.5	14.6	2.0
Fatigue	24.3	3.5	20.8	0.6

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Andre F et al. N Engl J Med 2019;380:1929-40; Turner N et al. N Engl J Med 2023;388:2058-70.

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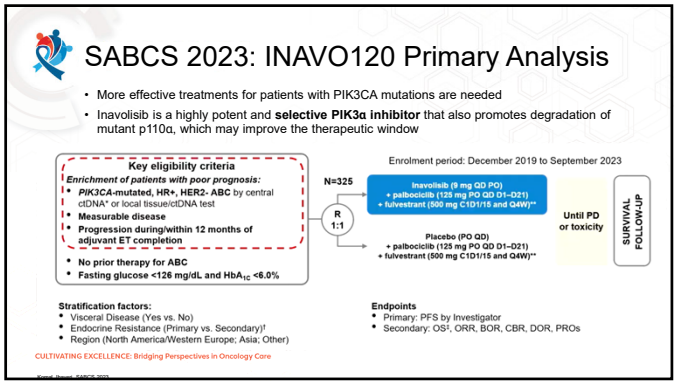
SABCS 2023: INAVO120 Primary Analysis
More effective treatments for patients with PIK3CA mutations are needed
Inavolisib is a highly potent and selective PIK3α inhibitor that also promotes degradation of mutant p110α, which may improve the therapeutic window
Key eligibility criteria
Enrichment of patients with poor prognosis:
PIK3CA-mutated, HR+, HER2- ABC by central ctDNA* or local tissue/ctDNA test
Measurable disease
Progression during/within 12 months of adjuvant ET completion
No prior therapy for ABC
Fasting glucose <126 mg/dL and HbA1c <6.0%
Enrolment period: December 2019 to September 2023
N=325
R 1:1
Inavolisib (9 mg QD PO) + palbociclib (125 mg PO QD D1–D21) + fulvestrant (500 mg C1D1/15 and Q4W)**
Placebo (PO QD) + palbociclib (125 mg PO QD D1–D21) + fulvestrant (500 mg C1D1/15 and Q4W)**
Until PD or toxicity
SURVIVAL FOLLOW-UP
Stratification factors:
Visceral Disease (Yes vs. No)
Endocrine Resistance (Primary vs. Secondary)†
Region (North America/Western Europe; Asia; Other)
Endpoints
Primary: PFS by Investigator
Secondary: OS‡, ORR, BOR, CBR, DOR, PROs
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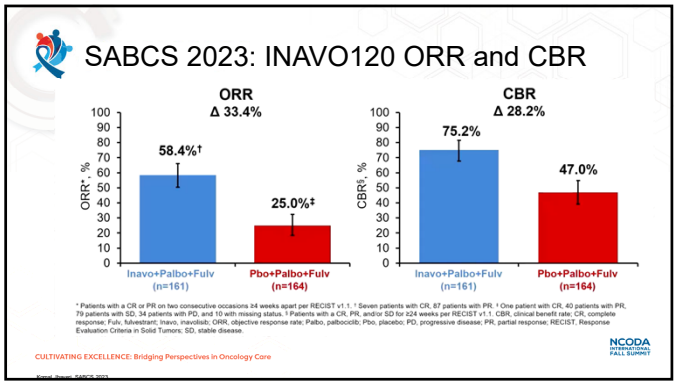
SABCS 2023: INAVO120 ORR and CBR
ORR
Δ 33.4%
ORR*, %
58.4%†
25.0%‡
Inavo+Palbo+Fulv (n=161)
Pbo+Palbo+Fulv (n=164)
CBR
Δ 28.2%
CBR§, %
75.2%
47.0%
* Patients with a CR or PR on two consecutive occasions ≥4 weeks apart per RECIST v1.1. † Seven patients with CR, 87 patients with PR. ‡ One patient with CR, 40 patients with PR, 79 patients with SD, 34 patients with PD, and 10 with missing status. § Patients with a CR, PR, and/or SD for ≥24 weeks per RECIST v1.1. CBR, clinical benefit rate; CR, complete response; Fulv, fulvestrant; Inavo, inavolisib; ORR, objective response rate; Palbo, palbociclib; Pbo, placebo; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.
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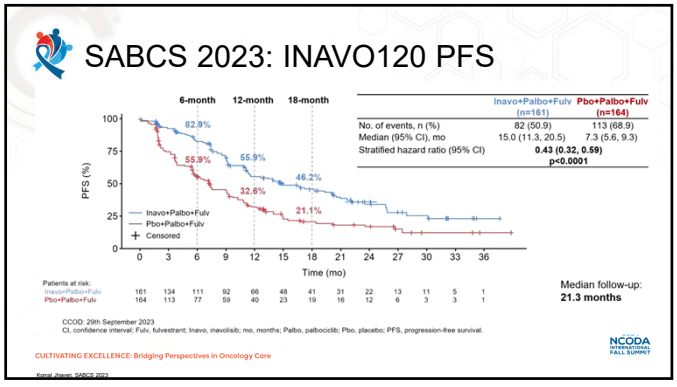
SABCS 2023: INAVO120 PFS
6-month
12-month
18-month
PFS (%)
82.9%
55.9%
55.9%
46.2%
32.6%
21.1%
Inavo+Palbo+Fulv
Pbo+Palbo+Fulv
Censored
Time (mo)
Patients at risk:
Inavo+Palbo+Fulv 161 134 111 92 66 48 41 31 22 13 11 5 1
Pbo+Palbo+Fulv 164 113 77 59 40 23 19 16 12 6 3 3 1
Inavo+Palbo+Fulv (n=161) Pbo+Palbo+Fulv (n=164)
No. of events, n (%) 82 (50.9) 113 (68.9)
Median (95% CI), mo 15.0 (11.3, 20.5) 7.3 (5.6, 9.3)
Stratified hazard ratio (95% CI) 0.43 (0.32, 0.59)
p<0.0001
Median follow-up: 21.3 months
CCOD: 29th September 2023
CI, confidence interval; Fulv, fulvestrant; Inavo, inavolisib; mo, months; Palbo, palbociclib; Pbo, placebo; PFS, progression-free survival.
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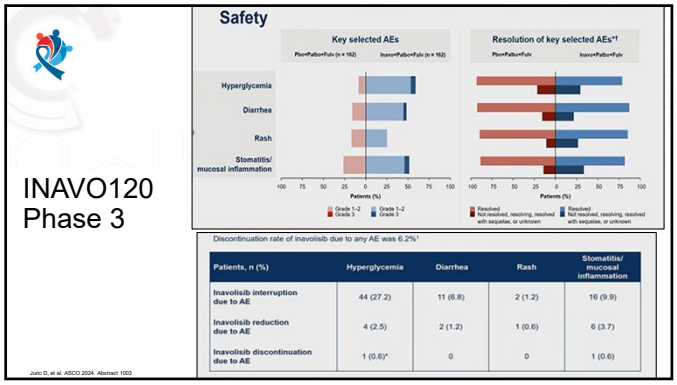
INAVO120
Phase 3
Safety
Key selected AEs
Resolution of key selected AEs*†
Hyperglycemia
Diarrhea
Rash
Stomatitis/ mucosal inflammation
Patients (%)
Discontinuation rate of inavolisib due to any AE was 6.2%†
Patients, n (%)
Hyperglycemia
Diarrhea
Rash
Stomatitis/ mucosal inflammation
Inavolisib interruption due to AE
44 (27.2)
11 (6.8)
2 (1.2)
16 (9.9)
Inavolisib reduction due to AE
4 (2.5)
2 (1.2)
1 (0.6)
6 (3.7)
Inavolisib discontinuation due to AE
1 (0.6)*
0
0
1 (0.6)

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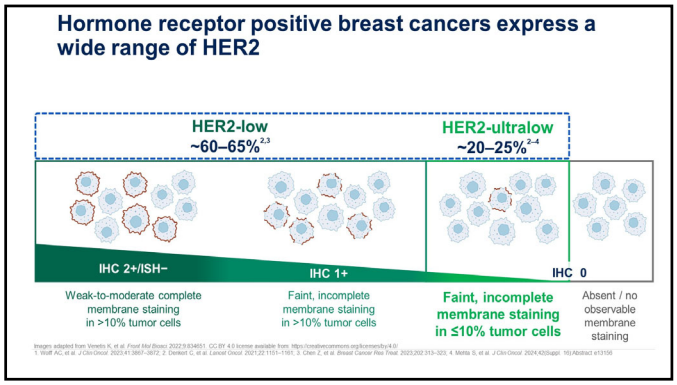
Hormone receptor positive breast cancers express a wide range of HER2
HER2-low
~60–65%2,3
HER2-ultralow
~20–25%2–4
IHC 2+/ISH−
IHC 1+
IHC 0
Weak-to-moderate complete membrane staining in >10% tumor cells
Faint, incomplete membrane staining in >10% tumor cells
Faint, incomplete membrane staining in ≤10% tumor cells
Absent / no observable membrane staining

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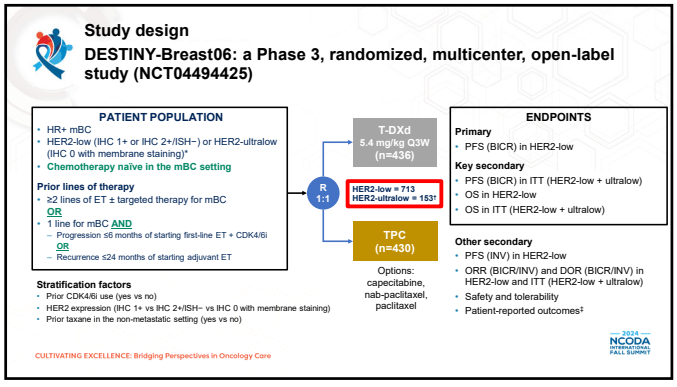
Study design
DESTINY-Breast06: a Phase 3, randomized, multicenter, open-label study (NCT04494425)
PATIENT POPULATION
HR+ mBC
HER2-low (IHC 1+ or IHC 2+/ISH−) or HER2-ultralow (IHC 0 with membrane staining)*
Chemotherapy naïve in the mBC setting
Prior lines of therapy
≥2 lines of ET ± targeted therapy for mBC
OR
1 line for mBC AND
Progression ≤6 months of starting first-line ET + CDK4/6i
OR
Recurrence ≤24 months of starting adjuvant ET
R 1:1
T-DXd 5.4 mg/kg Q3W (n=436)
HER2-low = 713
HER2-ultralow = 153†
TPC (n=430)
Options: capecitabine, nab-paclitaxel, paclitaxel
ENDPOINTS
Primary
PFS (BICR) in HER2-low
Key secondary
PFS (BICR) in ITT (HER2-low + ultralow)
OS in HER2-low
OS in ITT (HER2-low + ultralow)
Other secondary
PFS (INV) in HER2-low
ORR (BICR/INV) and DOR (BICR/INV) in HER2-low and ITT (HER2-low + ultralow)
Safety and tolerability
Patient-reported outcomes‡
Stratification factors
Prior CDK4/6i use (yes vs no)
HER2 expression (IHC 1+ vs IHC 2+/ISH− vs IHC 0 with membrane staining)
Prior taxane in the non-metastatic setting (yes vs no)
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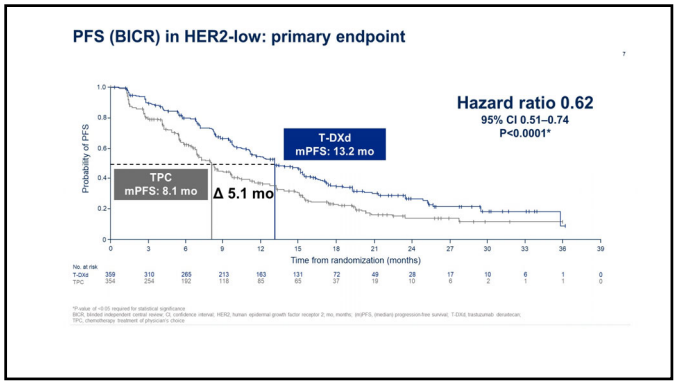
PFS (BICR) in HER2-low: primary endpoint
Hazard ratio 0.62
95% CI 0.51–0.74
P<0.0001*
T-DXd
mPFS: 13.2 mo
TPC
mPFS: 8.1 mo
Δ 5.1 mo
Probability of PFS
Time from randomization (months)
No. at risk
T-DXd 359 310 265 213 163 131 72 49 28 17 10 6 1 0
TPC 354 254 192 118 85 65 37 19 10 6 2 1 1 0

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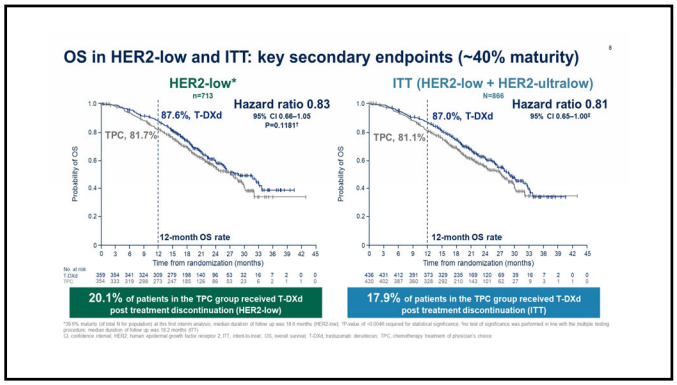
OS in HER2-low and ITT: key secondary endpoints (~40% maturity)
HER2-low*
n=713
Hazard ratio 0.83
95% CI 0.66–1.05
P=0.1181†
87.6%, T-DXd
TPC, 81.7%
12-month OS rate
ITT (HER2-low + HER2-ultralow)
N=866
Hazard ratio 0.81
95% CI 0.65–1.00‡
87.0%, T-DXd
TPC, 81.1%
12-month OS rate
Probability of OS
Time from randomization (months)
20.1% of patients in the TPC group received T-DXd post treatment discontinuation (HER2-low)
17.9% of patients in the TPC group received T-DXd post treatment discontinuation (ITT)

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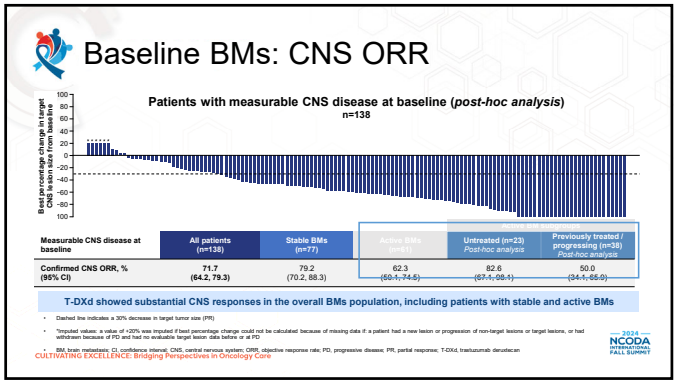
Baseline BMs: CNS ORR
Patients with measurable CNS disease at baseline (post-hoc analysis)
n=138
Best percentage change in target CNS lesion size from baseline
Measurable CNS disease at baseline
All patients (n=138)
Stable BMs (n=77)
Active BMs (n=61)
Untreated (n=23) Post-hoc analysis
Previously treated / progressing (n=38) Post-hoc analysis
Confirmed CNS ORR, % (95% CI)
71.7 (64.2, 79.3)
79.2 (70.2, 88.3)
62.3 (50.1, 74.5)
82.6 (67.1, 98.1)
50.0 (34.1, 65.0)
T-DXd showed substantial CNS responses in the overall BMs population, including patients with stable and active BMs
Dashed line indicates a 30% decrease in target tumor size (PR)
BM, brain metastasis; CI, confidence interval; CNS, central nervous system; ORR, objective response rate; PD, progressive disease; PR, partial response; T-DXd, trastuzumab deruxtecan
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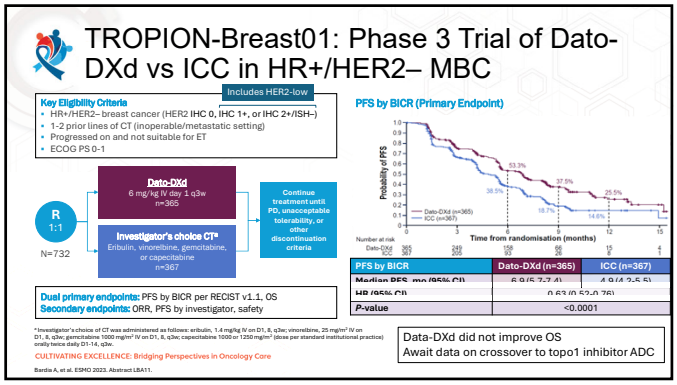

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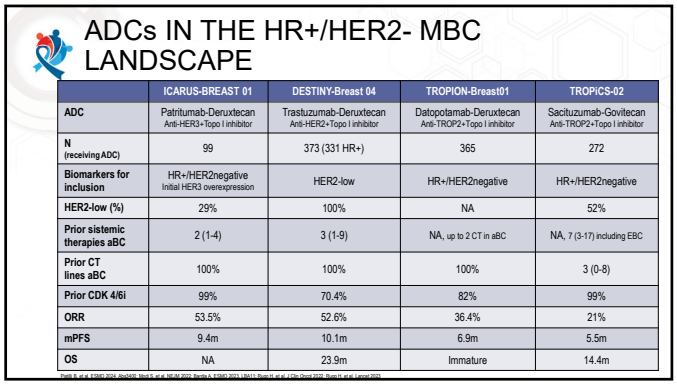

	ICARUS-BREAST 01	DESTINY-Breast 04	TROPION-Breast01	TROPiCS-02
ADC	Patritumab-Deruxtecan Anti-HER3+Topo I inhibitor	Trastuzumab-Deruxtecan Anti-HER2+Topo I inhibitor	Datopotamab-Deruxtecan Anti-TROP2+Topo I inhibitor	Sacituzumab-Govitecan Anti-TROP2+Topo I inhibitor
N (receiving ADC)	99	373 (331 HR+)	365	272
Biomarkers for inclusion	HR+/HER2negative Initial HER3 overexpression	HER2-low	HR+/HER2negative	HR+/HER2negative
HER2-low (%)	29%	100%	NA	52%
Prior sistemic therapies aBC	2 (1-4)	3 (1-9)	NA, up to 2 CT in aBC	NA, 7 (3-17) including EBC
Prior CT lines aBC	100%	100%	100%	3 (0-8)
Prior CDK 4/6i	99%	70.4%	82%	99%
ORR	53.5%	52.6%	36.4%	21%
mPFS	9.4m	10.1m	6.9m	5.5m
OS	NA	23.9m	Immature	14.4m

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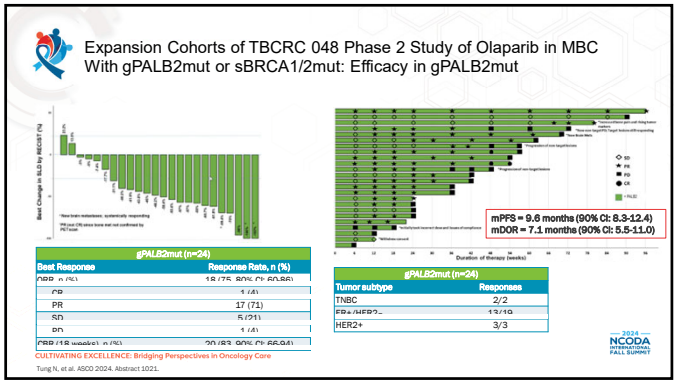

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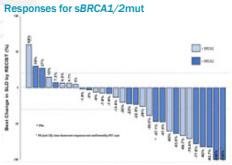
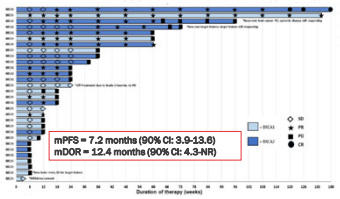
Expansion Cohorts of TBCRC 048 Phase 2 Study of Olaparib in MBC With gPALB2mut or sBRCA1/2mut: Efficacy in sBRCA1/2mut

Responses for *sBRCA1/2*mut



sBRCA1/2mut (n=30)	
Best Response	**Response Rate, n (%)**
ORR, n (%)	11 (37, 80% CI: 25-50)
CR	1 (3)
PR	10 (33)
SD	13 (43)
PD	6 (20)
CBR (18 weeks), n (%)	16 (53, 90% CI: 37-69)

Cohort 2a (*sBRCA1/2*mut): Duration of Therapy



Tung N, et al. ASCO 2024. Abstract 1021.

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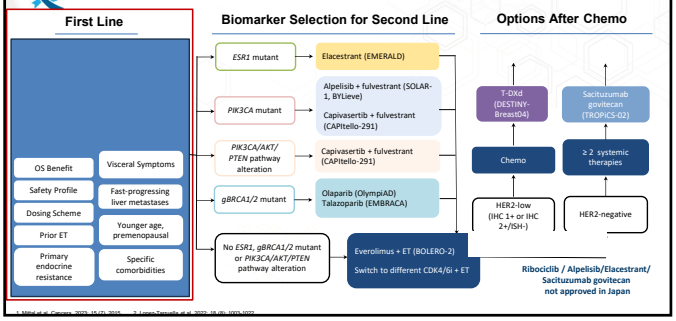
Potential Treatment Algorithm based on Trial Data, not Access: ER+ HER2- Metastatic Breast Cancer [1,2]



1. Mittal et al. Cancers. 2023; 15(7): 2015. 2. Lopez-Tarruella et al. 2022; 18(8): 1003-1022.

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Updates on Endocrine Therapy

- 3 years of ribociclib in high/intermediate risk pts improves iDFS and DRFS
- Adjuvant abemaciclib increasing improvement in IDFS at 5 years
- 1L MBC abemaciclib did not improve OS (13 mo additional OS vs AI alone) – likely due to smaller sample size
- 2L MBC abemaciclib plus fulvestrant had superior PFS than fulvestrant alone – may be an option for 2L therapy after 1L CDK 4/6 inhibitor for patients who are not candidates for mESR1, PIK3CA, AKT or PTEN-directed therapy
- Capivasertib effective in PIK3CA, AKT or PTEN-altered HR+ HER2- MBCs
- Elacestrant effective in CDKi-sensitive ESR1- and PIK3CA- or p53-mutant MBC
- PI3K inhibitor inavolisib + fulvestrant + palbociclib in ET-resistant MBC approved by FDA for ET-resistant 1L pts with PIK3CA-mutant MBC and HgbA1c < 6%
- Topoisomerase-1 inhibitor payload ADCs more effective than chemoRx HR+ MBC

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Summary Triple Negative Breast Cancer

- Addition of carboplatin to AC/T improves outcome in TN EBC pts
- Addition of preop pembrolizumab to chemotherapy improves OS
- SWOG/NCTN: Preop KN-522 vs 6 DCb + pembrolizumab
- Improving outcomes of stage II/III TNBC pts with residual disease s/p KN-522 with phase III trials of ADCs sacituzumab and datopotumab + CPI vs SOC
- SWOG/NCTN SCARLET Trial: Preop KN-522 vs 6 DCb + pembrolizumab
- 1L mTNBC phase III trials sacituzumab and dato-DXd +/- CPI vs chemotherapy +/- pembrolizumab (for CPS > 10 PDL1+)
- Many novel IO combinations, Anti-PD1/PDL1-VEGF bispecific antibod and CAR-T cell therapies

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QUESTION & ANSWERS

Advances in Breast Cancer Treatment and Current Updates

Joyce O'Shaughnessy, MD
Celebrating Women Chair in Breast Cancer Research
Baylor University Medical Center
Texas Oncology
Sarah Cannon Research Institute

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