LIVING BEYOND
BREAST CANCER®

News flash: Updates from the 2026 ASCO Annual Meeting

Highlights from ASCO 2026

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What is the ASCO meeting?

World's Largest Cancer Conference

Largest clinical cancer research conference in the world.

An Overwhelming Firehose of Data

Nearly 3,000–3,400 abstracts at hundreds of sessions — intensely overwhelming!

A Focus on the Human Side of Care

Focuses on supportive and survivorship care for patients.

What Is a Clinical Trial?

A Research Study

Tests new treatments in people, not just a lab.

Rigorously Protected

Independent safety boards monitor every step.

Voluntary & Informed

You can withdraw at any time — consent is ongoing.

Driven by Science

Lab discoveries tested safely in real patients.

Why Participate?

Access Cutting-Edge Treatment 01

Receive therapies years before approval — often at no added cost.

Benefit Future Patients 02

Your data shapes guidelines and saves lives for the next generation.

Close Equity Gaps 03

Diverse enrollment ensures treatments work for all populations.

5-year survival: ~75% (1970s) → 91%+ today — every gain driven by clinical trials

Common Concerns — and the Facts

CONCERN	FACT
"I might just get a placebo."	In cancer trials, you always receive at least standard of care — placebos alone are rarely used.
"Trials are a last resort."	Trials exist at every stage — early, advanced, and metastatic — and may offer newer options sooner.
"I'll lose control of my care."	Informed consent is ongoing. You can withdraw at any time, and all protocol changes must be explained.
"It's too much extra work."	Many trials add no extra visits. Coordinators guide you, and many appointments can be done remotely.

Ask your oncologist about open trials ·

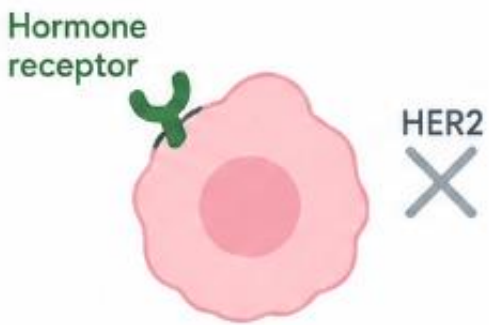
Search ClinicalTrials.gov ·

Ask for a patient navigator

BREAST CANCER SUBTYPES

Three main subtypes, each with different biology and treatment approaches.

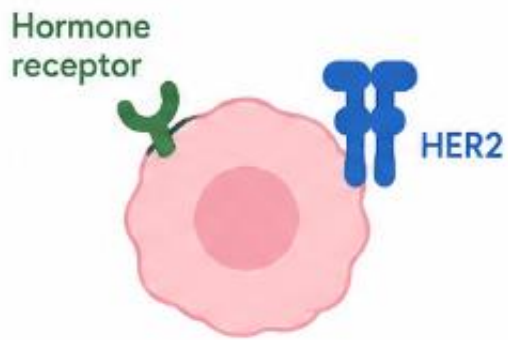
HORMONE RECEPTOR POSITIVE (HR+), HER2 NEGATIVE



70%

OF BREAST CANCERS

HER2 POSITIVE (HR+ OR HR-)



15–20%

OF BREAST CANCERS

TRIPLE NEGATIVE (HR- / HER2-)

15%

OF BREAST CANCERS

Early Stage Breast Cancer

-OPTIMA
-lidERA BC
-KEYNOTE-522

2026 ASCO® ANNUAL MEETING

First results from the OPTIMA phase III randomized non-inferiority trial of test-directed chemotherapy in patients with high clinical risk ER-positive HER2-negative early breast cancer.

a pre-planned time-driven analysis

Robert C. Stein, Andreas Makris, Iain R. Macpherson, Luke Hughes-Davies, Andrea Marshall, Sarah E. Pinder, Abeer Shaaban, Karen J. Taylor, Carmel Conefrey, Mary Rose Falzon, Bjorn Naume, Belinda Emma Kiely, David A. Cameron, Helena Margaret Earl, Daniel William Rea, Peter S. Hall, Adrienne Morgan, Stuart McIntosh, John M.S. Bartlett, Janet Dunn, OPTIMA Investigators and Trial Management Group

OPTIMA is registered as ISRCTN42400492

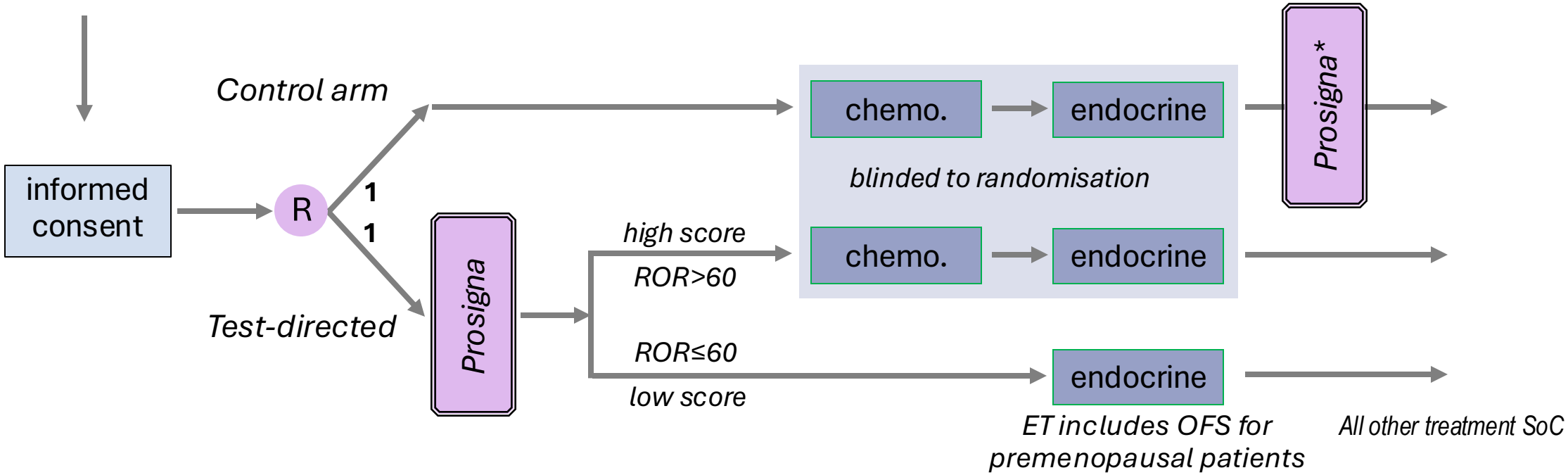
Background

- Tumor gene expression assays are widely used to assist chemotherapy decisions for postmenopausal EBC with up to 3 involved lymph nodes
- Supporting evidence for premenopausal patient use is mixed
- There is no prospective evidence for higher levels of lymph node involvement
- OPTIMA is an international RCT that recruits high clinical risk patients
- The OPTIMA hypothesis is that the number of involved nodes does not affect chemotherapy response for low test-score tumors
- The OPTIMA pilot study selected the 50-gene Prosigna test for the main trial
  - Tumors with a Risk of Recurrence Score >60 are categorized high risk if N0

OPTIMA design

Main eligibility criteria

- Women & men age ≥40 with excised breast cancer
- ER-pos (IHC>10%) & HER2-neg
- Nodes: ▸0-9N+,
  ▸minimum T-size requirement if N0/ N1mi
- Neoadjuvant chemotherapy prohibited



*Control arm Prosigna testing used for analysis only. U.K. control arm testing performed following recruitment completion

OPTIMA: Conclusions

- The OPTIMA trial demonstrates that women and men with ER+ HER2- EBC and ROR score ≤60 tumors can safely avoid chemotherapy.
- The OPTIMA trial provides evidence for the utility of test-directed chemotherapy in premenopausal women treated with OFS and patients with high levels of nodal involvement.

A lay summary of OPTIMA

- The OPTIMA trial was designed to reduce unnecessary chemotherapy use for people with newly diagnosed hormone sensitive breast cancer.
- OPTIMA recruited more than 4400 patients over 9 years from 6 countries.
- The trial compared the number of breast cancer recurrences and deaths in patients treated with standard chemotherapy with those having a chemotherapy decision made using the Prosigna test. Everybody received hormone therapy.
- Prosigna is a 50-gene test performed on cancer tissue removed at surgery.
- OPTIMA showed that at most 2% of patients with low test-score tumors benefit from chemotherapy. Everybody gets chemotherapy side-effects.
- This includes premenopausal women aged 40 or older and patients with more than 3 involved lymph nodes.

2026 ASCO® ANNUAL MEETING

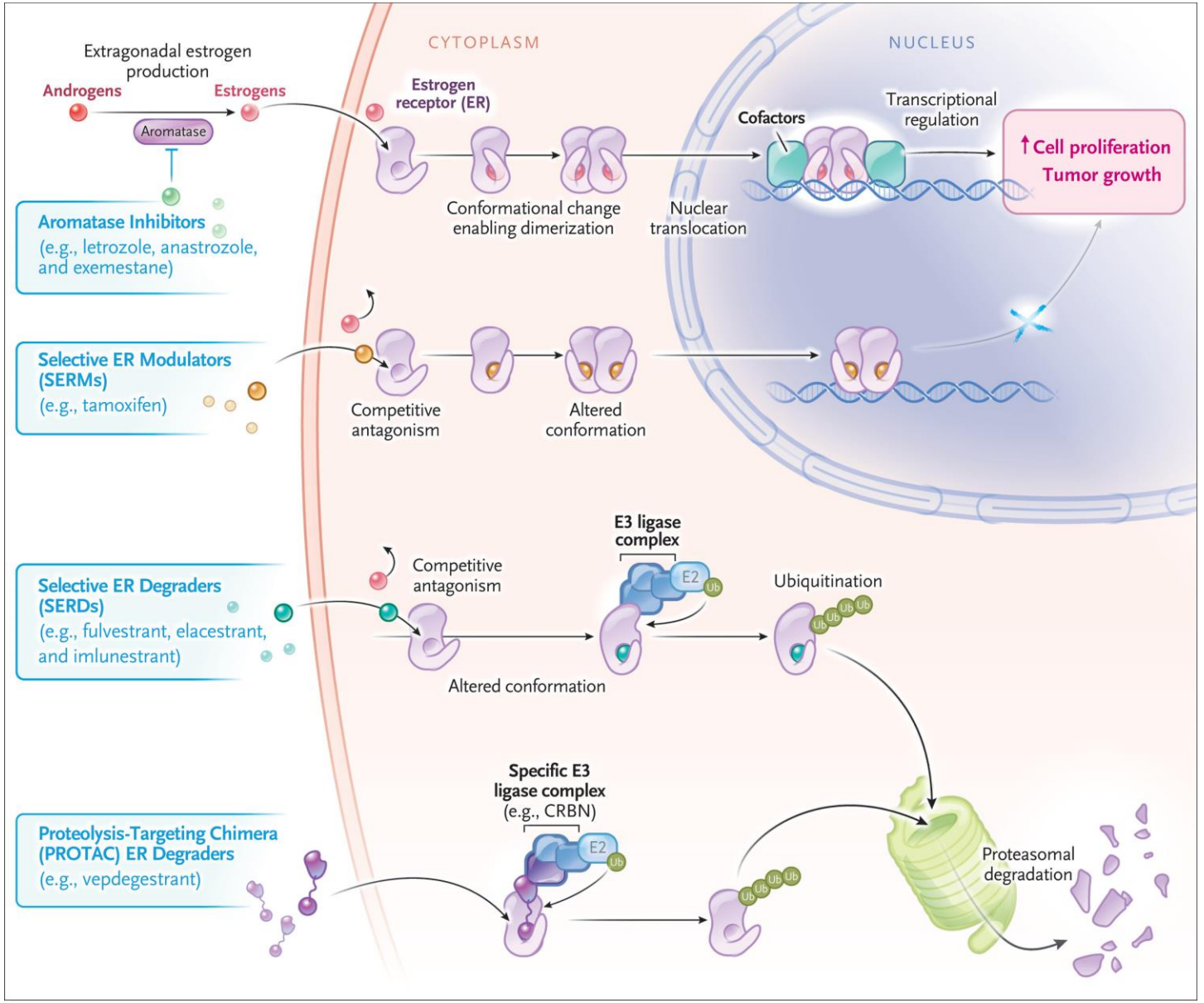
Efficacy and safety of giredestrant (GIRE) in patients (pts) with estrogen receptor-positive, HER2-negative early breast cancer (ER+, HER2– eBC) in the Phase III lidERA BC clinical trial: Results by menopausal status.

Peter Schmid, Charles E. Geyer, Jr., Miguel Martín, Sara A. Hurvitz, Kyung Hae Jung, Mothaffar F. Rimawi, Shigehira Saji, Gustavo Werutsky, Nadia Harbeck, Sherene Loi, Ernesto Pablo Korbenfeld, Isabel Blancas, Chi-Feng Chung, Rena Desai Callahan, Meilin Huang, Miranda Craft, Mona D. Shah, Tanja Badovinac Crnjevic, Pablo Diego Pérez-Moreno, Aditya Bardia

Presenting author: Peter Schmid, MD, PhD, FACP
Queen Mary University of London, London, UK

Strategies to Inhibit Estrogen-Receptor Signaling in Breast Tumors

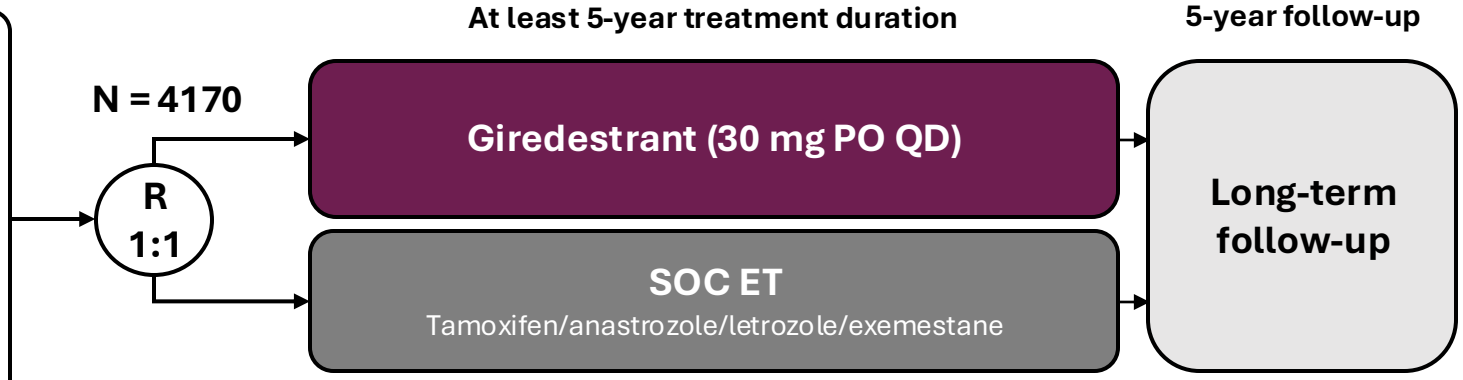
What is giredestrant? Giredestrant is a highly potent, non-steroidal, orally bioavailable selective estrogen receptor antagonist and degrader (SERD) that works through a unique dual mechanism: it both degrades ERα protein and immobilizes the remaining receptor.



McDonnell NEJM 2025

Key eligibility criteria

- Participants with ER+, HER2– eBC
- Stage I–III disease (anatomic)
  - pN0 and pT > 1 cm with Grade 3, or Ki67 ≥ 20%, or high score on genomic assay,* or pT4N0
  - Node-positive
- **Pre- or post-menopausal**
- BC surgery within 12 months
- (Neo)adjuvant chemotherapy if indicated



Stratification factors

- Risk: Medium-[†] vs high-risk[‡] Stage I–III BC
- Region: USA/Canada/Western Europe vs Asia–Pacific vs RoW
- Previous chemotherapy: No vs yes
- Menopausal status[§]: Pre-menopausal vs post-menopausal

Primary endpoint

- IDFS (excluding second primary non-BC)

Key secondary endpoints

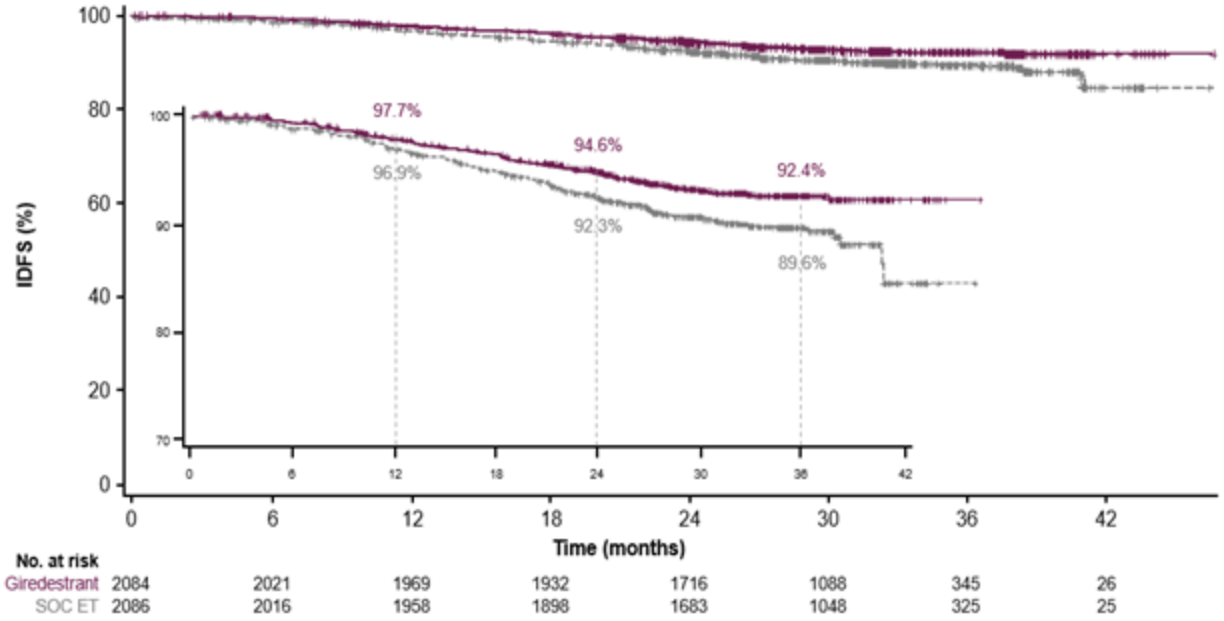
- DFS, DRFI, IDFS (including second primary non-breast invasive cancer, with exception of non-melanoma skin cancers and *in situ* carcinomas of any site), LRRFI, OS, safety

Ovarian function suppression with an approved LHRH agonist was required for all men and pre-menopausal women receiving AIs or giredestrant

ClinicalTrials.gov number, NCT04961996. Adapted from Geyer CE, *et al*. ASCO 2023 (TPS616), with permission. Enrollment: August 2021 to September 2023. Up to 12 weeks of ET ± CDK4/6i were allowed. ER+ was defined as ≥ 1% positive cells by immunohistochemistry. * Oncotype ≥ 26 or high-risk MammaPrint. † Medium risk: pN0 and primary tumor > 1 cm with high-risk biologic features (Grade 3, or Ki67 ≥ 20%, or high score on genomic assay [if available]) and pN1 with low-risk biologic features (Grade 1/2 and Ki67 < 20% and tumor ≤ 5 cm and low score on genomic assay [if available]). ‡ High risk: pT4, or pN2, or pN3 and pN1 with high-risk biologic features (Grade 3, or Ki67 ≥ 20%, or tumor > 5 cm, or high score on genomic assay [if available]). § Defined as: prior bilateral oophorectomy, or age ≥60 years, or <60 years and amenorrheic for 12 months or more.AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; DFS, disease-free survival; DRFI, distant recurrence-free interval; (e)BC, (early) breast cancer; ER+, estrogen receptor-positive; ET, endocrine therapy; HER2–, HER2-negative; IDFS, invasive disease-free survival; LHRH, luteinizing hormone-releasing hormone; LRRFI, locoregional recurrence-free interval; OS, overall survival; PO, orally; QD, once daily; R, randomization; RoW, rest of the world; SOC, standard-of-care.

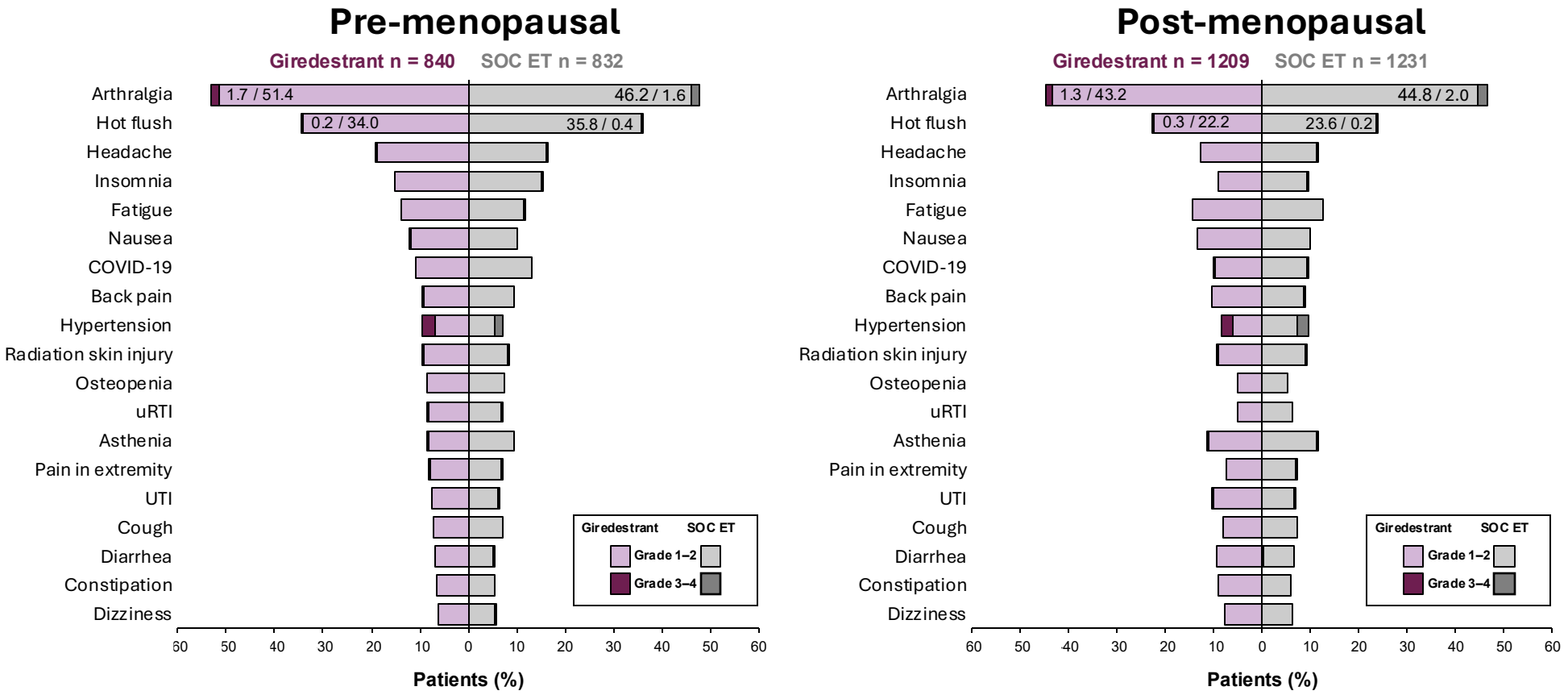
- The lidERA BC trial demonstrated a statistically significant and clinically meaningful IDFS improvement with adjuvant giredestrant over SOC ET
  - HR: 0.70 (95% CI: 0.57, 0.87; p = 0.0014)
  - 3-year IDFS rates: 92.4% vs 89.6%
- DRFI was improved vs SOC ET, with a 31% reduction in risk of developing metastatic disease
- OS trended in favor of the giredestrant arm
- The safety profile was favorable and consistent with the known profile of giredestrant
  - The rate of AEs leading to discontinuation from treatment was lower with giredestrant vs SOC ET

IDFS (primary endpoint)



AE, adverse event; BC, breast cancer; CI, confidence interval; DRFI, distant recurrence-free interval; ET, endocrine therapy; HR, hazard ratio; IDFS, invasive disease-free survival; OS, overall survival; SOC, standard-of-care.

1. Bardia A, *et al*. SABCS 2025 (oral GS1-10).



Independent of menopausal status:

- **Fewer patients** switched to alternative ET in the giredestrant vs. SOC ET arm (5.7 vs 10.1%), mainly due to AEs
- **Fewer patients** discontinued treatment due to AEs in the giredestrant vs. SOC ET arm (5.3 vs 8.2%)

Common AEs were comparable across arms and subgroups at any grade.
Arthralgia and hot flush were the most common AEs regardless of menopausal status

Data cutoff: August 8, 2025.
AE, adverse event; ET, endocrine therapy; SOC, standard-of-care; uRTI, upper respiratory tract infection; UTI, urinary tract infection.

Patients, n (%)	Pre-menopausal n = 1672				Post-menopausal n = 2440			
	Giredestrant n = 840	**SOC ET** n = 832	**AI** n = 563	**TAM** n = 269 + LHRH agonist n = 185 / – LHRH agonist n = 84	**Giredestrant** n = 1209	**SOC ET** n = 1231	**AI** n = 1183	**TAM** n = 48 (not on LHRH agonist)
All grade	488 (58.1)	445 (53.5)	336 (59.7)	109 (40.5) 71 (38.4) / 38 (45.2)	614 (50.8)	660 (53.6)	646 (54.6)	14 (29.2)
Grade 1	332 (39.5)	304 (36.5)	223 (39.6)	81 (30.1) 52 (28.1) / 29 (34.5)	419 (34.7)	423 (34.4)	411 (34.7)	12 (25.0)
Grade 2	141 (16.8)	126 (15.1)	99 (17.6)	27 (10.0) 19 (10.3) / 8 (9.5)	179 (14.8)	210 (17.1)	208 (17.6)	2 (4.2)
Grade 3	15 (1.8)	15 (1.8)	14 (2.5)	1 (0.4) 0 / 1 (1.2)	16 (1.3)	27 (2.2)	27 (2.3)	0
Leading to discontinuation	13 (1.5)	31 (3.7)	28 (5.0)	3 (1.1) 1 (0.5) / 2 (2.4)	20 (1.7)	51 (4.1)	51 (4.3)	0

Fewer discontinuations with giredestrant compared with SOC ET, regardless of menopausal status

Data cutoff: August 8, 2025. * Includes preferred terms of arthralgia, pain in extremity, myalgia, musculoskeletal chest pain, musculoskeletal pain, limb discomfort, and musculoskeletal discomfort.
AI, aromatase inhibitor; ET, endocrine therapy; LHRH, luteinizing hormone-releasing hormone; SOC, standard-of-care; TAM, tamoxifen.

Lay summary

Who does this research impact?

- People with a type of breast cancer called estrogen receptor-positive, HER2-negative early breast cancer

What did this research tell us?

- This study (lidERA Breast Cancer) showed that people lived for longer without an invasive version of their breast cancer coming back after starting treatment with a pill called giredestrant, compared with the current standard endocrine therapy. It did not matter whether they were pre-menopausal or post-menopausal – both groups of people benefitted from giredestrant
- Pre-menopausal and post-menopausal people also lived longer without their cancer coming back in a distant part of their body with giredestrant, compared with the current standard endocrine therapy
- Common side effects were similar in people who received giredestrant and people who received the current standard endocrine therapy, and they were also similar in pre-menopausal and post-menopausal people
- Joint pain and hot flushes were the most common side effects in both pre-menopausal and post-menopausal people
- Fewer people stopped giredestrant treatment overall, and due to side effects to do with pain in their muscles or bones, compared with the current standard endocrine therapy, regardless of whether they were pre-menopausal or post-menopausal

What does this mean for patients right now?

- Giredestrant can help people live for longer without an invasive version of their breast cancer coming back, or their cancer coming back in a distant part of their body, regardless of whether they are pre-menopausal or post-menopausal

Neoadjuvant Pembrolizumab or Placebo plus Chemotherapy Followed by Adjuvant Pembrolizumab or Placebo for High-Risk Early-Stage Triple-Negative Breast Cancer (TNBC): Final Analysis 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] Surui Hou,[16] Usha Malhotra,[16] Francisco Beca,[16] Joyce O'Shaughnessy[17]

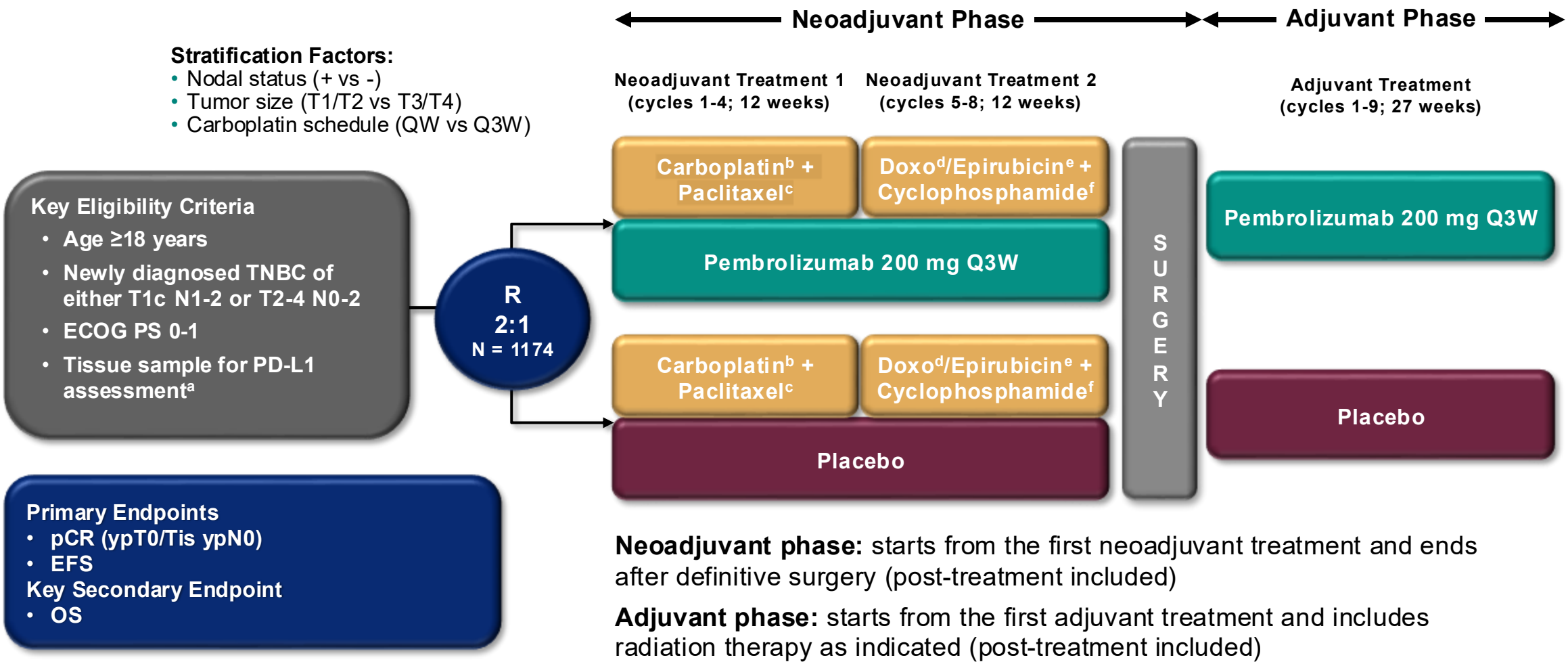
[1]Centre for Experimental Cancer Medicine, Barts Cancer Institute, Queen Mary University London, London, UK; [2]International Breast Cancer Center (IBCC), Pangaea Oncology, Quironsalud Group, Barcelona, Spain; Medical Scientia Innovation Research (MedSIR), Barcelona, Spain; Faculty of Biomedical and Health Sciences, Department of Medicine, Universidad Europea de Madrid, Madrid, Spain; [3]National Cancer Centre Singapore, Duke – National University of Singapore Medical School, Singapore; [4]University of Texas Southwestern Medical Center, Dallas, TX, USA; [5]Yale School of Medicine, Yale Cancer Center, New Haven, CT, USA; [6]Breast Unit, Kliniken Essen-Mitte, Essen, Germany and Charité – Universitätsmedizin Berlin, Department of Gynecology with Breast Center, Berlin, Germany; [7]Institute of Pathology, Philipps-University Marburg and University Hospital Marburg, Marburg, Germany; [8]Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; [9]Westmead Breast Cancer Institute, Westmead Hospital and the University of Sydney, Sydney, NSW, Australia and Centre of Cancer Medicine, School of Clinical Medicine, University of Hong Kong, Hong Kong; [10]Breast Center, Dept. OB&GYN, LMU University Hospital, Munich, Germany; [11]Hokkaido University Hospital, Sapporo, Japan; [12]Seoul National University Hospital, Cancer Research Institute, Seoul National University, Seoul, Republic of Korea; [13]Breast Cancer Center, Helios Klinikum Berlin-Buch, Berlin, Germany; [14]University Hospital Erlangen, Comprehensive Cancer Center Erlangen-EMN, Erlangen, Germany; [15]Department Medical Oncology, Centre Antoine Lacassagne, Nice, France and Advanced Breast Cancer (ABC) Global Alliance; [16]Oncology, Merck & Co., Inc., Rahway, NJ, USA; [17]Baylor University Medical Center, Texas Oncology, Sarah Cannon Research Institute, Dallas, TX, USA

Background

- In KEYNOTE-522, neoadjuvant pembrolizumab (pembro) plus chemotherapy (chemo) followed by adjuvant pembro led to statistically significant and clinically meaningful improvements in pCR, EFS, and OS vs neoadjuvant chemo alone in high-risk, early-stage TNBC
  - First interim analysis: neoadjuvant pembro + chemo significantly increased pCR (ypT0/Tis ypN0) by 13.6 percentage points ($P<0.001$)[1]
  - Fourth interim analysis (median follow-up, ~39 months): neoadjuvant pembro + chemo followed by adjuvant pembro significantly improved EFS (HR, 0.63; $P<0.001$)[2]
  - Seventh interim analysis (median follow-up, ~75 months): the regimen significantly improved OS (HR, 0.66; $P=0.001$)[3]
- Based on this study, regulatory authorities globally have approved pembro with chemo as neoadjuvant therapy and continued as single-agent adjuvant therapy for high-risk, early-stage TNBC, and the regimen is included in standard treatment guidelines[4-6]
- Here, we report the final analysis (FA) results of KEYNOTE-522 after median follow-up of ~94 months

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. 3. Schmid P, et al. *N Engl J Med* 2024;391:1981-91. 4. Cardoso F, et al. *Ann Oncol* 2019;30:1194-1220. 5. Park YH, et al. *Ann Oncol* 2020;31:451-69. 6. Korde LA, et al. *J Clin Oncol* 2022;40:1696-98.

KEYNOTE-522 Study Design (NCT03036488)

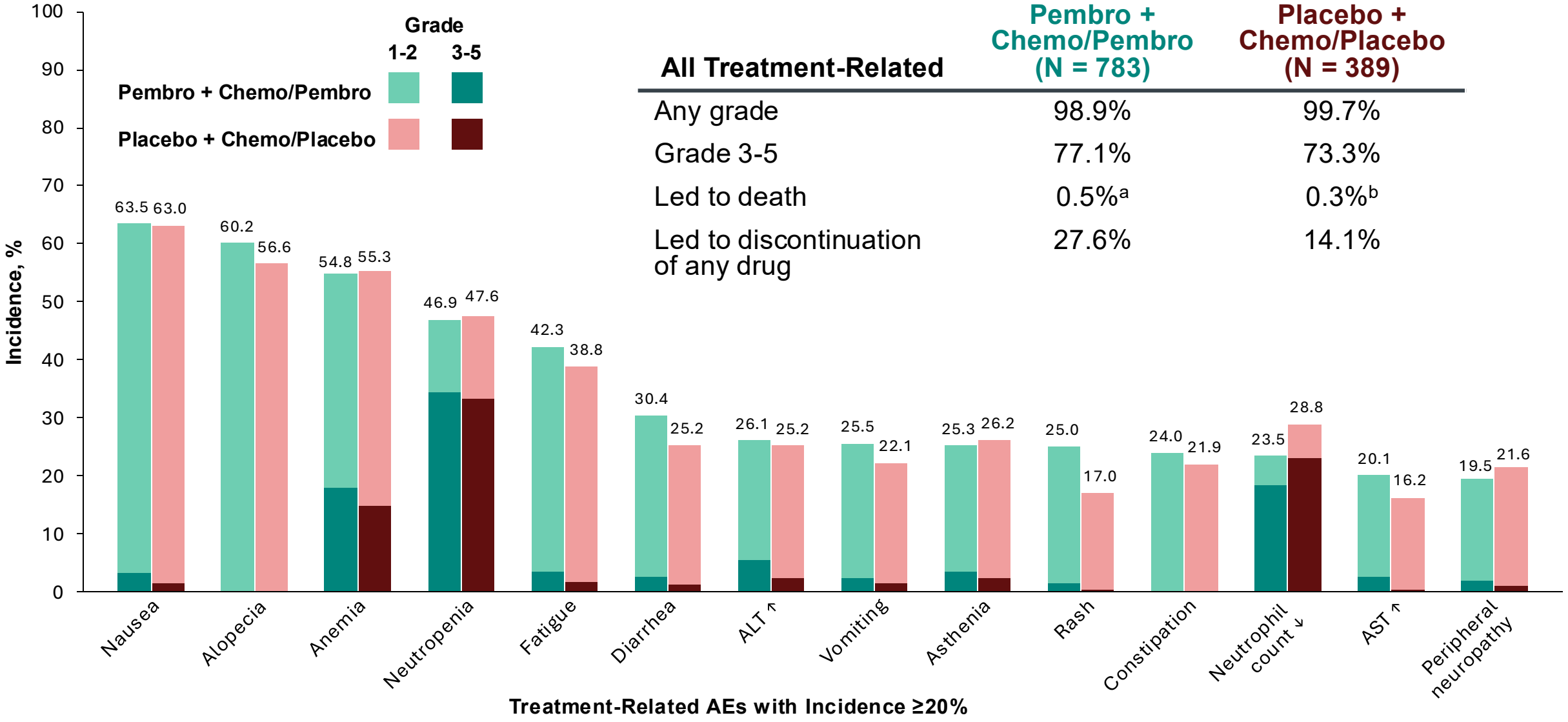


Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post-treatment included)

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

[a]Must consist of at least 2 separate tumor cores from the primary tumor. [b]Carboplatin dose was AUC 5 Q3W or AUC 1.5 QW. [c]Paclitaxel dose was 80 mg/m^2 QW. [d]Doxorubicin dose was 60 mg/m^2 Q3W. [e]Epirubicin dose was 90 mg/m^2 Q3W. [f]Cyclophosphamide dose was 600 mg/m^2 Q3W.

Treatment-Related Adverse Events



All Treatment-Related	Pembro + Chemo/Pembro (N = 783)	Placebo + Chemo/Placebo (N = 389)
Any grade	98.9%	99.7%
Grade 3-5	77.1%	73.3%
Led to death	0.5%[a]	0.3%[b]
Led to discontinuation of any drug	27.6%	14.1%

Listed are adverse events attributed by investigators to trial treatment; participants may have had more than one event. [a]1 participant from sepsis and multiple organ dysfunction syndrome; 1 participant from pneumonitis; 1 participant from pulmonary embolism; 1 participant from autoimmune encephalitis. [b]1 participant from septic shock. Data cutoff date: October 14, 2025.

Summary and Conclusions

- At median follow-up of ~8 years, the protocol-specified final analysis of KEYNOTE-522 shows that adding pembro to platinum-containing neoadjuvant chemo, followed by adjuvant pembro, continued to provide substantial and clinically meaningful survival benefits in participants with high-risk, early-stage TNBC
- The survival benefit with pembro was generally consistent across prespecified subgroups, including PD-L1 status, nodal status, and tumor size, and was observed regardless of pCR status
- The addition of pembro reduced distant recurrence rates, an established predictor of favorable long-term outcomes
- The safety profile remained consistent with prior analyses and the known profiles of pembro and chemo; no new safety signals were identified
- **These long-term results further support neoadjuvant pembro plus platinum-containing chemo, followed by adjuvant pembro, as a standard-of-care treatment option for patients with high-risk, early-stage TNBC**

Plain Language Summary

What was the goal of the study?

- To find out if people with previously untreated, high-risk, early-stage triple-negative breast cancer who receive pembrolizumab plus chemotherapy before surgery and then pembrolizumab after surgery live longer without their cancer growing, spreading, or coming back than those who receive chemotherapy alone before surgery
  - Pembrolizumab is an immunotherapy that allows the immune system to find and kill cancer cells

What were the key results of the study?

- Pembrolizumab plus chemotherapy helped people live longer without their cancer growing, spreading, or coming back compared with chemotherapy alone
  - The percent of people who were alive without their cancer growing, spreading, or coming back after 7 years was higher with pembrolizumab plus chemotherapy (78%) than with chemotherapy alone (70%)
  - The percent of people who were alive after 7 years was higher with pembrolizumab plus chemotherapy (85%) than with chemotherapy alone (77%)

What were the main conclusions of the study?

- People with previously untreated, high-risk, early-stage triple-negative breast cancer who received pembrolizumab plus chemotherapy before surgery and then pembrolizumab after surgery lived longer without their cancer growing, spreading, or coming back than those who received chemotherapy alone before surgery

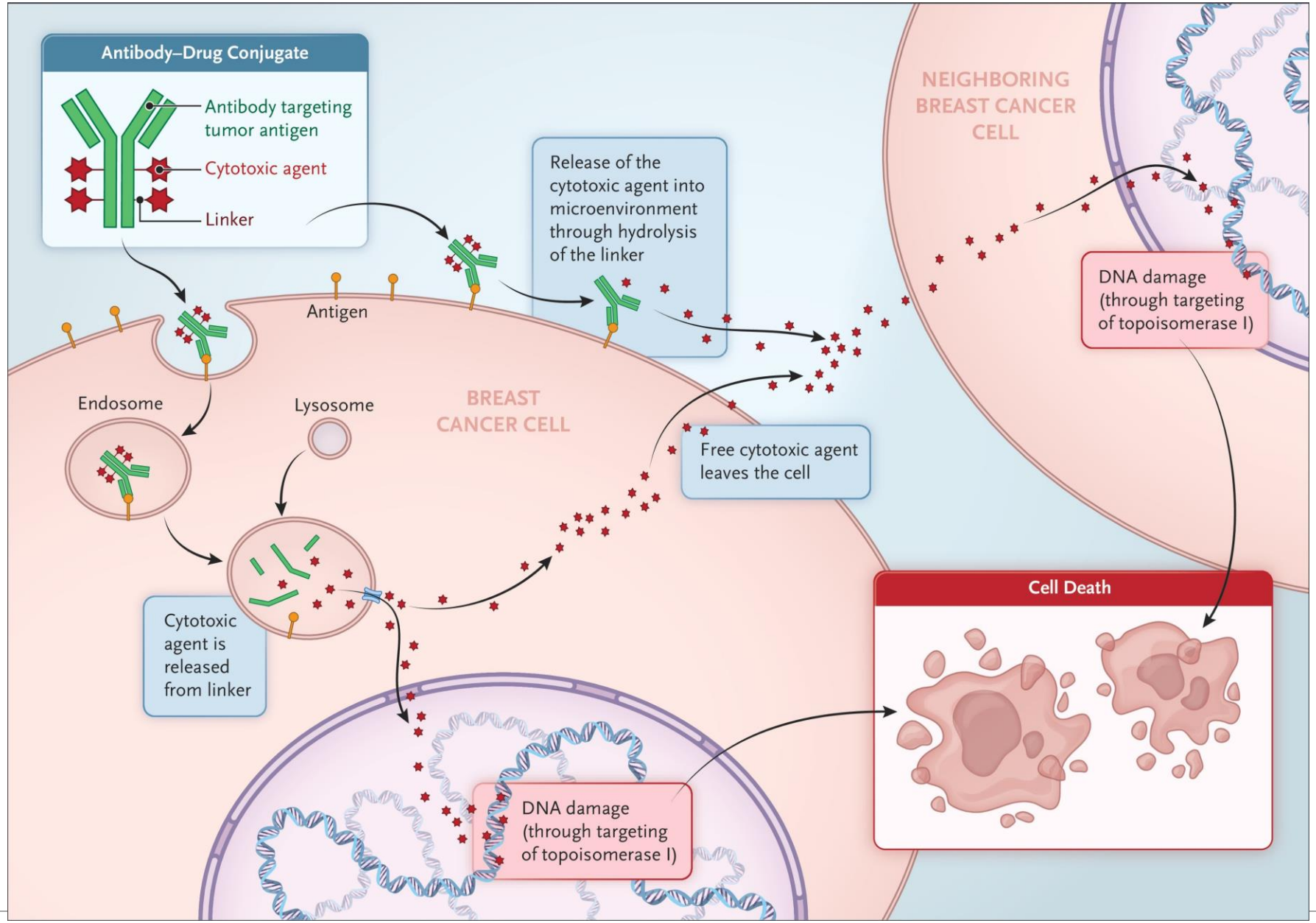
For more information, visit these websites: Clinicaltrialsregister.eu and search with EudraCT number: 2016-004740-11
Clinicaltrials.gov and search with NCT number: NCT03036488

Advanced Breast Cancer

-ASCENT-04 / KEYNOTE-D19

-persevERA BC

Mechanism of Action of Antibody Drug-Conjugates Sacituzumab Govitecan and Trastuzumab Deruxtecan



Trojan Horse

Vidula et al.
NEJM 2024

ASCENT-04: Analysis of Efficacy by Biomarker Subgroups With Sacituzumab Govitecan + Pembrolizumab vs Chemotherapy + Pembrolizumab in Participants With Previously Untreated PD-L1+ Metastatic Triple-Negative Breast Cancer

Sara M Tolaney[1], Peter Schmid[2], Evandro de Azambuja[3], Kevin Kalinsky[4], Sung-Bae Kim[5], Clinton Yam[6], Bernardo Rapoport[7,8], Seock-Ah Im[9], Barbara Pistilli[10], Wassim Mchayleh[11], David W Cescon[12], Junichiro Watanabe[13], Manuel Alejandro Lara Bañuelas[14], Ruffo Freitas-Junior[15], Alain Lortholary[16], Catherine Lai[17], Ann Chen[17], Meghna Das Thakur[17], Yajia Zhang[17], Sherene Loi[18]

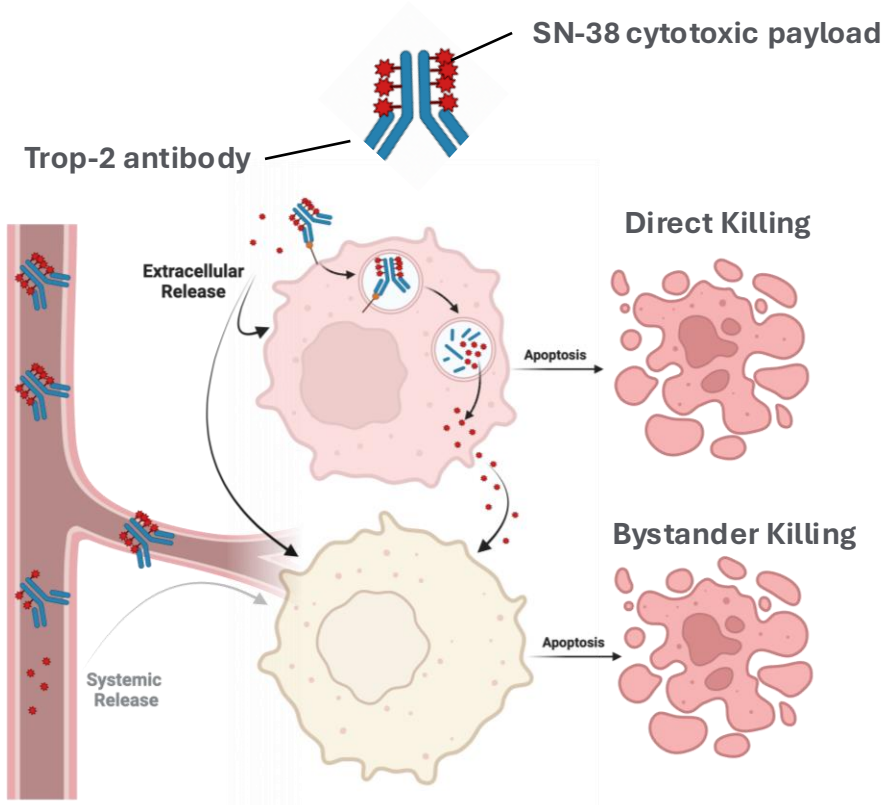
[1]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [2]Centre for Experimental Cancer Medicine, Bart's Cancer Institute, Queen Mary University of London, London, UK; [3]Institut Jules Bordet, Hôpital Universitaire de Bruxelles (H.U.B), Université Libre de Bruxelles (U.L.B.), Brussels, Belgium; [4]Winship Cancer Institute, Emory University, Atlanta, GA, USA; [5]Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea; [6]The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [7]The Medical Oncology Centre of Rosebank, Clinical and Translational Research Unit (CTRU), Saxonworld, South Africa; [8]Department of Immunology, Faculty of Health Sciences, University of Pretoria, Pretoria, South Africa; [9]Seoul National University Hospital, Cancer Research Institute, Seoul National University College of Medicine, Seoul National University, Seoul, Republic of Korea; [10]Gustave Roussy, IHU-National PRecISion Medicine Center in Oncology, Villejuif, France; [11]AdventHealth Cancer Institute, Orlando, FL, USA; [12]Princess Margaret Cancer Centre/UHN, Toronto, ON, Canada; [13]Juntendo University Graduate School of Medicine, Tokyo, Japan; [14]SCIENTIA Investigación Clínica, Chihuahua, Mexico; [15]Advanced Center for Diagnosis of Breast Diseases Federal University of Goiás, Goiás, Brazil; [16]Groupe d'Investigateurs National des Etudes des Cancers Ovariens et du sein (GINECO) and Hôpital Privé du Confluent, Nantes, France; [17]Gilead Sciences, Inc., Foster City, CA, USA; [18]Peter MacCallum Cancer Centre, Melbourne, Australia

Introduction

- The ASCENT-04 study demonstrated significant, clinically meaningful improvement in PFS with SG + pembro vs chemo + pembro (HR, 0.65; 95% CI, 0.51-0.84; *P* < .001) in participants with previously untreated PD-L1–positive advanced TNBC[1]

- SG targets Trop-2, a surface protein overexpressed in many solid tumors, particularly in TNBC[2-4]

- Mutations in *BRCA1* and *BRCA2* and HER2 amplification or overexpression are associated with altered efficacy of some mBC treatments, although the role of these biomarkers is less established in PD-L1–positive TNBC[5-9]



Prespecified retrospective exploratory analyses evaluated the impact of Trop-2, BRCA, and HER2 biomarkers on efficacy of SG + pembro vs chemo + pembro in ASCENT-04

Chemo, *chemotherapy;* **HER2**, *human epidermal growth factor receptor 2;* **HR**, *hazard ratio;* **mBC,** *metastatic breast cancer;* **PD-L1**, *programmed cell death ligand 1;* **pembro**, *pembrolizumab;* **PFS**, *progression-free survival;* **SG**, *sacituzumab govitecan;* **TNBC**, *triple-negative breast cancer.*

1. Tolaney SM, et al. N Engl J Med. 2026;394:354-66. 2. Goldenberg DM, et al. Oncotarget. 2015;6:22496-512. 3. Jacot W, et al. Cancer Med. 2025;14:e70615. 4. Zhao W, et al. Oncol Rep. 2018;40:759-66. 5. Godet I, et al. Integr Cancer Sci Ther. 2017;4:10.15761/ICST.1000228. 6. Stoppa-Lyonnet D. Eur J Hum Genet. 2016;24:S3-S9. 7. Bardia A, et al. Ann Oncol. 2021;32:1148-56. 8. McCann KE, et al. Drugs Context. 2018;7:212540. 9. Chen W, et al. Cancer Discov. 2026;16:235-49.

Methods

- Participants with previously untreated, locally advanced unresectable or metastatic PD-L1–positive (PD-L1 CPS[a] ≥ 10) TNBC were randomized 1:1 to receive SG + pembro or chemo + pembro; the primary end point was PFS by BICR
- This prespecified exploratory analysis was performed using central testing of fresh or archival (formalin-fixed paraffin-embedded) tumor samples; 48% from metastatic sites in the Trop-2 biomarker analysis set
- Biomarker status was analyzed descriptively for association with PFS by BICR
- At the primary data cutoff (March 2025), median follow-up was 14.0 months (range, 0.1-28.6)[1]
- Participants from the ITT population were included in the biomarker analysis set if they had ≥ 1 evaluable biomarker measurement available at baseline

Subgroups Analyzed

Trop-2 Expression

- Characterized by H-score, as determined by IHC[b]
- Participants grouped by Trop-2 expression quartile

tBRCA Status

- Measured by WES as local testing was uncommon
- Participants grouped by t*BRCA* WT or mut status
- Mut indicates mutation in *BRCA1*, *BRCA2*, or both genes

HER2 Expression

- Measured by ISH and IHC
- Participants grouped as HER2 IHC 0 or HER2 low
- HER2 low includes IHC 1+ or IHC 2+/ISH−

[a]Measured per the 22C3 assay. [b]Scoring as follows: 0, negative or no staining of tumor cell; 1, weak or faint staining; 2, moderate staining; 3, strong staining. H-score determined by (% of 1+ tumor cells) + (2x% of 2+ tumor cells) + (3x% of 3+ tumor cells).
BICR, *blinded independent central review;* **chemo**, *chemotherapy;* **CPS**, *combined positive score;* **HER2**, *human epidermal growth factor receptor 2;* **IHC**, *immunohistochemistry;* **ITT**, *intent-to-treat;* **mut**, *mutation;* **PD-L1**, *programmed cell death ligand 1;* **pembro**, *pembrolizumab;* **PFS**, *progression-free survival;* **SG**, *sacituzumab govitecan;* **TNBC**, *triple-negative breast cancer;* **WT**, *wild-type.*
1. Tolaney SM, et al. N Engl J Med. 2026;394:354-66.

ASCENT 04: Conclusion

- Sacituzumab Govitecan + pembro demonstrated longer PFS vs chemo + pembro across all Trop-2, tBRCA, and HER2 subgroups. These analyses strengthen support for the significant, clinically meaningful benefit of SG + pembro as first-line treatment for mTNBC across subgroups.

Conclusions

- Consistent with the results of the primary analysis of ASCENT-04, median PFS was longer across all key participant subgroups with SG + pembro vs chemo + pembro[1]
  - All Trop-2 expression quartiles
  - Participants with both tBRCA WT and tBRCA mut status
  - HER2 IHC 0 and HER 2 low expression subgroups
- The results of these analyses are consistent with results from the ASCENT study, in which participants with metastatic TNBC treated with SG had longer PFS versus chemotherapy across all Trop-2, BRCA, and HER2 categories[2,3]
- Sample sizes in many subgroups were small and the analyses were descriptive, so caution should be used in interpreting these results

The results of this analysis reinforce the significant, clinically meaningful benefit of SG + pembro as a first-line treatment option for patients with previously untreated advanced PD-L1–positive TNBC across key Trop-2, tBRCA, and HER2 biomarker subgroups

Chemo, *chemotherapy;* **HER2**, *human epidermal growth factor receptor 2;* **mut**, *mutant;* **PD-L1**, *programmed cell death ligand 1;* **pembro**, *pembrolizumab;* **PFS**, *progression-free survival;* **SG**, *sacituzumab govitecan;* **tBRCA**, *tumor BRCA;* **TNBC**, *triple-negative breast cancer;* **WT**, *wild-type.*

1. Tolaney SM, et al. N Engl J Med. 2026;394:354-66. 2. Bardia A, et al. J Clin Oncol. 2024;42:1738-44. 3. Bardia A, et al. Ann Oncol. 2021;32:1148-56.

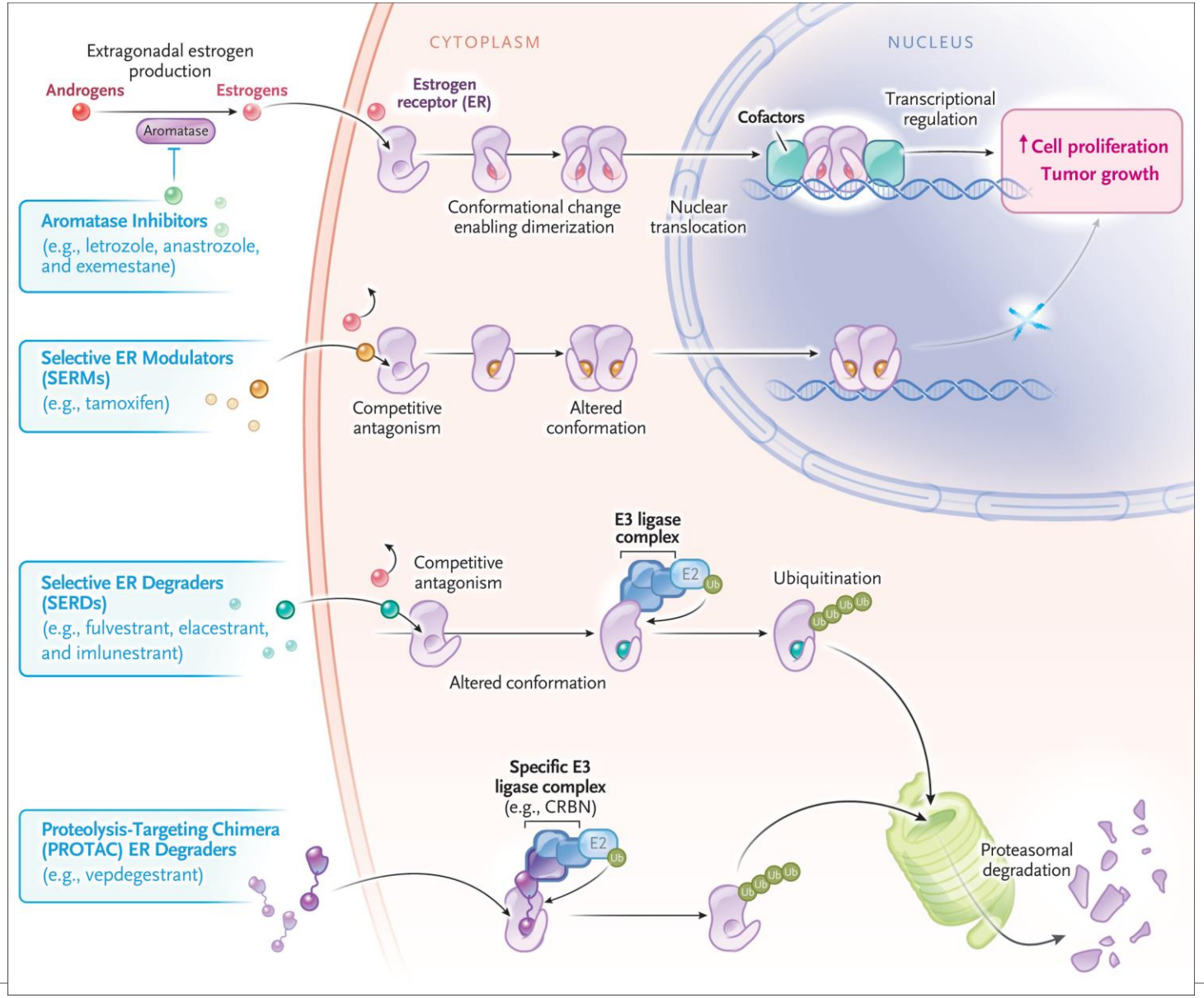
2026 ASCO ANNUAL MEETING

Giredestrant (GIRE) + palbociclib (PALBO) vs letrozole (LET) + PALBO as first-line (1L) therapy in patients (pts) with estrogen receptor-positive, HER2-negative locally advanced or metastatic breast cancer (ER+, HER2– LA/mBC): Primary analysis of the Phase III persevERA BC trial.

Nicholas C. Turner, Komal L. Jhaveri, Aditya Bardia, Naoki Niikura, Meritxell Bellet Ezquerra, Carlos H. Barrios, Véronique Diéras, Seock-Ah Im, Volkmar Müller, Erwei Song, Jorge Luis Martinez Rodriguez, Igor Bondarenko, Mabel Mardones, Ching-Wei Chang, Maria Louka, Miranda Craft, Pablo D. Pérez-Moreno, Monika Patre, Sherene Loi

Presenting author: Nicholas C. Turner, MD, PhD
Royal Marsden Hospital and Institute of Cancer Research, London, UK

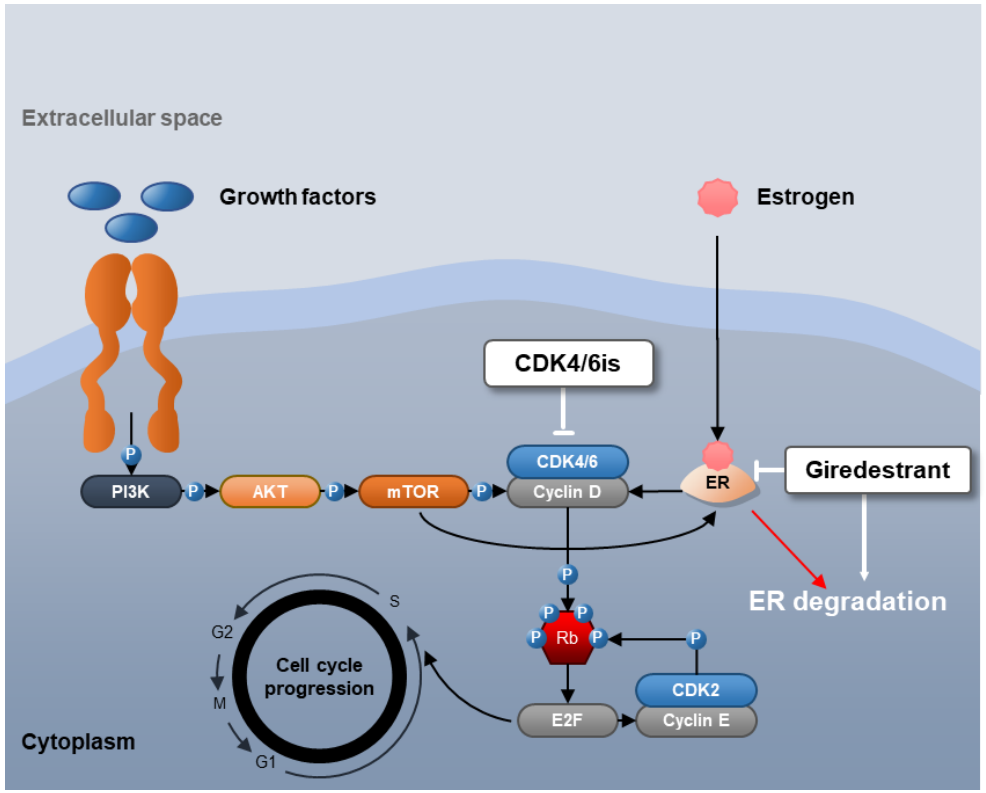
Strategies to Inhibit Estrogen-Receptor Signaling in Breast Tumors



Background

- The combination of ET with a CDK4/6i is the current SOC for the 1L treatment of patients with ER+, HER2− LA/mBC[1]
- Giredestrant is a potent next-generation oral SERD and full ER antagonist, designed to drive deep and sustained inhibition of ER signaling[2]
- In Phase III clinical trials, giredestrant has demonstrated superior efficacy compared with SOC ET
  - As adjuvant monotherapy (lidERA BC)[3]
  - In combination with everolimus post-CDK4/6i for LA/mBC (evERA BC)[4]
- Here we report the primary analysis of persevERA BC, evaluating the efficacy and safety of 1L giredestrant + palbociclib in patients with ER+, HER2– LA/mBC

Giredestrant + CDK4/6i mechanism of action



Adapted from Bardia A, *et al*. SABCS 2025 (GS1-10), with permission

1L, first line; AKT, protein kinase B; CDK2, cyclin-dependent kinase 2; CDK4/6(i), cyclin-dependent kinase 4/6 (inhibitor); ER(+), estrogen receptor(-positive); ET, endocrine therapy; G1/2, gap 1/2 phase; HER2–, HER2-negative; (LA/m)BC, (locally advanced/metastatic) breast cancer; M, mitosis phase; mTOR, mammalian target of rapamycin; P, phosphorylation; PI3K, phosphoinositide 3-kinase; Rb, retinoblastoma; S, synthesis phase; SERD, selective estrogen receptor antagonist and degrader; SOC, standard of care.

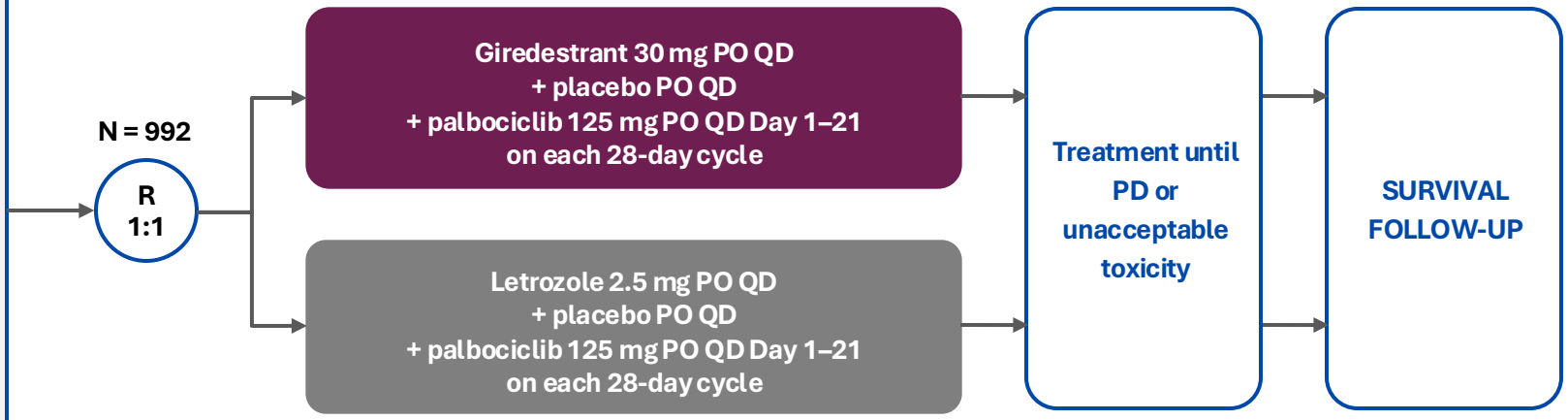
1. Gennari A, *et al. Ann Oncol* 2021; **32:**1475–1496; 2. Liang J, *et al. J Med Chem* 2021; **64:**11841–11856; 3. Bardia A, *et al*. SABCS 2025 (GS1-10); 4. Mayer EL, *et al*. ESMO 2025 (LBA16).

persevERA BC study design

A Phase III, randomized, double-blind, placebo-controlled, multicenter trial in 1L LA/mBC

Key eligibility criteria:

- 1L ER+, HER2– LA/mBC*
- Locally confirmed histologic/cytologic diagnosis
- No prior treatment for advanced disease
- No prior treatment with a SERD
- Disease recurrence > 12 months from completing prior (neo)adjuvant tamoxifen/AI
- Disease recurrence ≤ 12 months for patients receiving (neo)adjuvant tamoxifen (protocol v1)
- No active cardiac disease or history of cardiac dysfunction



* Patients with *de novo* mBC were capped at 20%

Stratification factors:

- Site of disease: Visceral vs non-visceral
- Menopausal status: Post-menopausal vs pre-menopausal/male
- Region: North America vs Western Europe vs Asia–Pacific vs other
- TFI since the end of prior (neo)adjuvant therapy: *De novo* metastatic vs ≤ 12 months vs > 12 months

Primary endpoint:

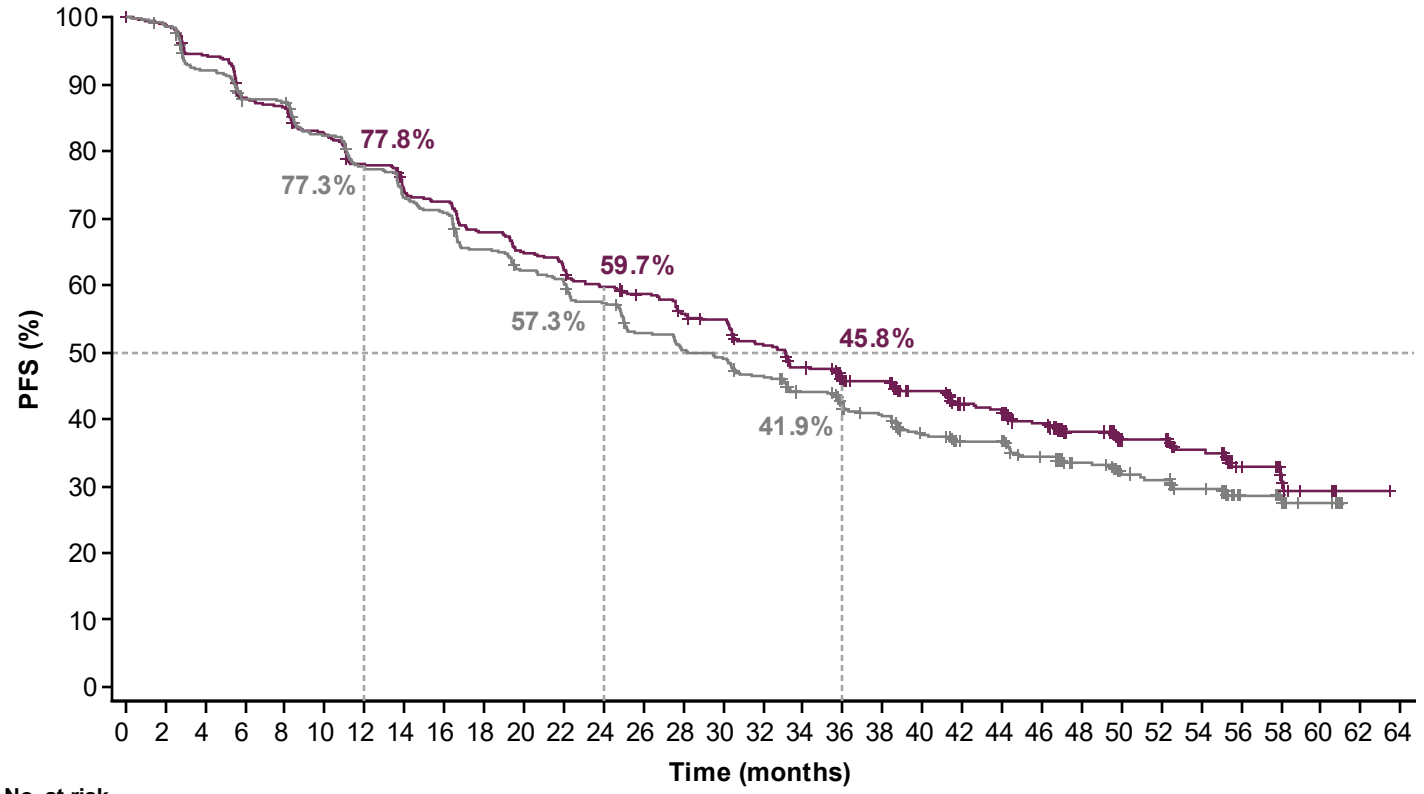
- Investigator-assessed PFS (INV-PFS) per RECIST v1.1

Secondary endpoints:

- OS, ORR, CBR, DoR, safety, PROs (TTD of pain, physical functioning, role functioning, GHS/QoL)

Enrollment: October 9, 2020, to March 27, 2023. ER+ was defined as ≥ 1% positive cells by immunohistochemistry. Pre-menopausal women, and men, also received ovarian function suppression with an approved luteinizing hormone-releasing hormone agonist. 1L, first line; AI, aromatase inhibitor; CBR, clinical benefit rate; DoR, duration of response; ER+, estrogen receptor-positive; GHS/QoL, global health status/quality of life; HER2–, HER2-negative; (LA/m)BC, (locally advanced/metastatic) breast cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PO, orally; PRO, patient-reported outcome; QD, once daily; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumours; SERD, selective estrogen receptor antagonist and degrader; TFI, treatment-free interval; TTD, time to deterioration.
ClinicalTrials.gov number, NCT04546009. Adapted from Turner NC, *et al*. ASCO 2021 (TPS1103), with permission.

Primary endpoint: INV-PFS



No. at risk

Giredestrant + palbociclib	495	484	461	429	422	399	375	353	347	325	310	298	285	276	261	255	236	217	195	190	170	149	142	130	108	88	86	65	42	27	14	1
Letrozole + palbociclib	497	484	449	424	422	394	369	349	338	311	295	286	271	248	236	230	217	200	186	176	156	141	139	119	103	78	75	62	36	27	11	

	Giredestrant + palbociclib n = 495	Letrozole + palbociclib n = 497
Events, n (%)	300 (60.6)	323 (65.0)
Median, months (95% CI)	**33.1** (30.2, 38.3)	**28.2** (25.0, 33.1)
Stratified HR (95% CI)	**0.89** (0.76, 1.05); p = 0.1553	

Median follow-up
Giredestrant arm: 52.2 months (range: 0.4–63.5)
Letrozole arm: 52.1 months (range: 0.3–62.6)

Giredestrant + palbociclib demonstrated a numerical improvement in INV-PFS vs letrozole + palbociclib, despite the lack of statistical significance

Data cutoff: January 30, 2026. The boundary for statistical significance was HR 0.85; 2-sided p < 0.0456.
CI, confidence interval; HR, hazard ratio; (INV-)PFS, (investigator-assessed) progression-free survival.

Key takeaway points/conclusions

1

1L giredestrant + palbociclib resulted in a numerical improvement in INV-PFS vs letrozole + palbociclib in ER+, HER2– LA/mBC, though it did not meet pre-defined statistical significance

2

Giredestrant + palbociclib was well tolerated, with a manageable safety profile and no unexpected findings

3

Further exploration is needed to assess which patients may benefit from giredestrant in the 1L setting

1L, first line; BC, breast cancer; ER+, estrogen receptor-positive; HER2–, HER2-negative; PFS, progression-free survival; LA/mBC, locally advanced/metastatic breast cancer.

Breast Cancer Survivorship

-YOCAS
-DEDiCA study
-OASIS 4 study
-GLP1 studies

2026 ASCO ANNUAL MEETING

CONQUER CANCER® THE ASCO FOUNDATION
MERIT AWARD
Pain and Symptom Management Merit Award

URCC NCORP Research Base

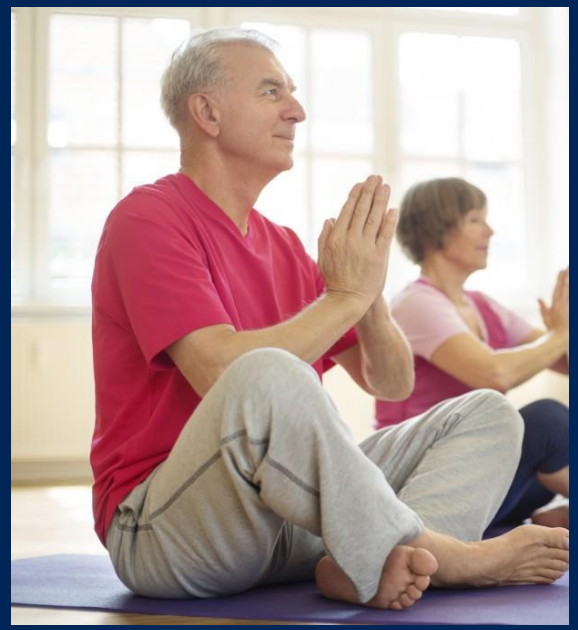
YOCAS©® Yoga, Mood Disturbance, and Insomnia: A URCC NCORP RB Nationwide Phase III Randomized Controlled Trial With Cancer Survivors

Yuri Choi, PhD, RN
Research Assistant Professor
Wilmot Cancer Institute
University of Rochester Medicine
Department of Surgery

NCI Funding: UG1CA189961, UG1CA189860, UG1CA189953, UG1CA189972, T32CA102618, P30CA272302

Background

- Up to 95% of cancer survivors experience mood disturbance, anxiety, fatigue, or insomnia.
- Greater than 50% of survivors experience more than one of these side effects at the same time.
- These side effects increase survivors' morbidity, interfere with resumption of normal daily activities, and reduce QOL.
- Most of the existing evidence on yoga for cancer survivors has been limited to phase I and II trials.



PRESENTED BY: Yuri Choi, PhD, RN

Specific Aims

- To assess the effect of YOCAS©® on **mood disturbance, anxiety,** and **fatigue**

- To assess whether **improvements in mood disturbance**, **anxiety,** and **fatigue** explain **YOCAS©®-associated improvements in insomnia**

YOga for CAncer Survivors (YOCAS©®)

- **Yoga Types**
  - Gentle Hatha
  - Restorative
- **Components**
  - Postures
  - Breathing
  - Mindfulness

- **Prescription**
  - 4 Weeks
  - 2 Sessions/Week (75 Minutes)
  - Home Practice
- **Standardization**
  - Yoga Alliance-Certified Instructors
  - YOCAS©® Kit

PRESENTED BY: Yuri Choi, PhD, RN

Eligibility

❖Participants MUST:

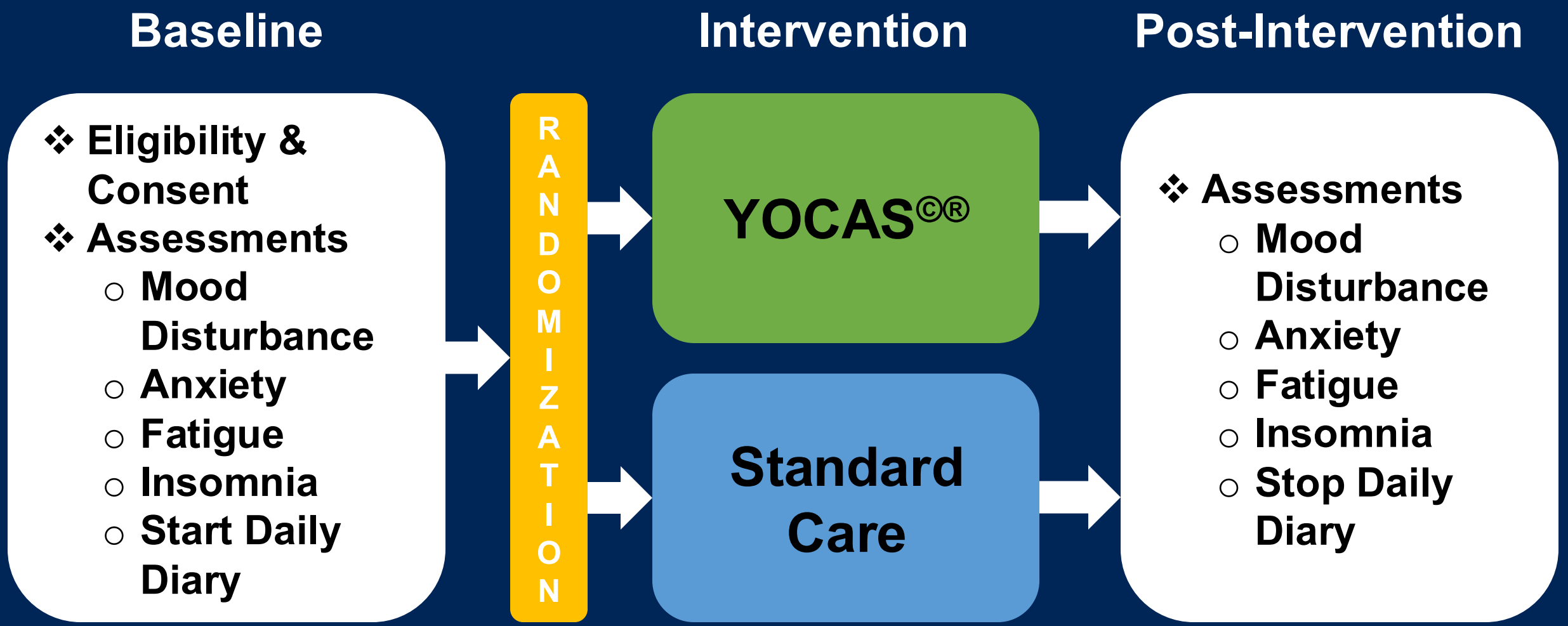
- Have a confirmed diagnosis of cancer
- Have completed treatment 2 to 24 months prior
- Experience persistent moderate to severe sleep disturbance
- Be able to read English
- Be ≥ 21 years of age
- Give written informed consent

❖Participants MUST NOT:

- Have a confirmed diagnosis of sleep apnea
- Have metastatic cancer
- Have regularly practiced yoga in the past 3 months

PRESENTED BY: Yuri Choi, PhD, RN

Clinical Trial Schema



PRESENTED BY: Yuri Choi, PhD, RN

Attendance, Adherence & AEs

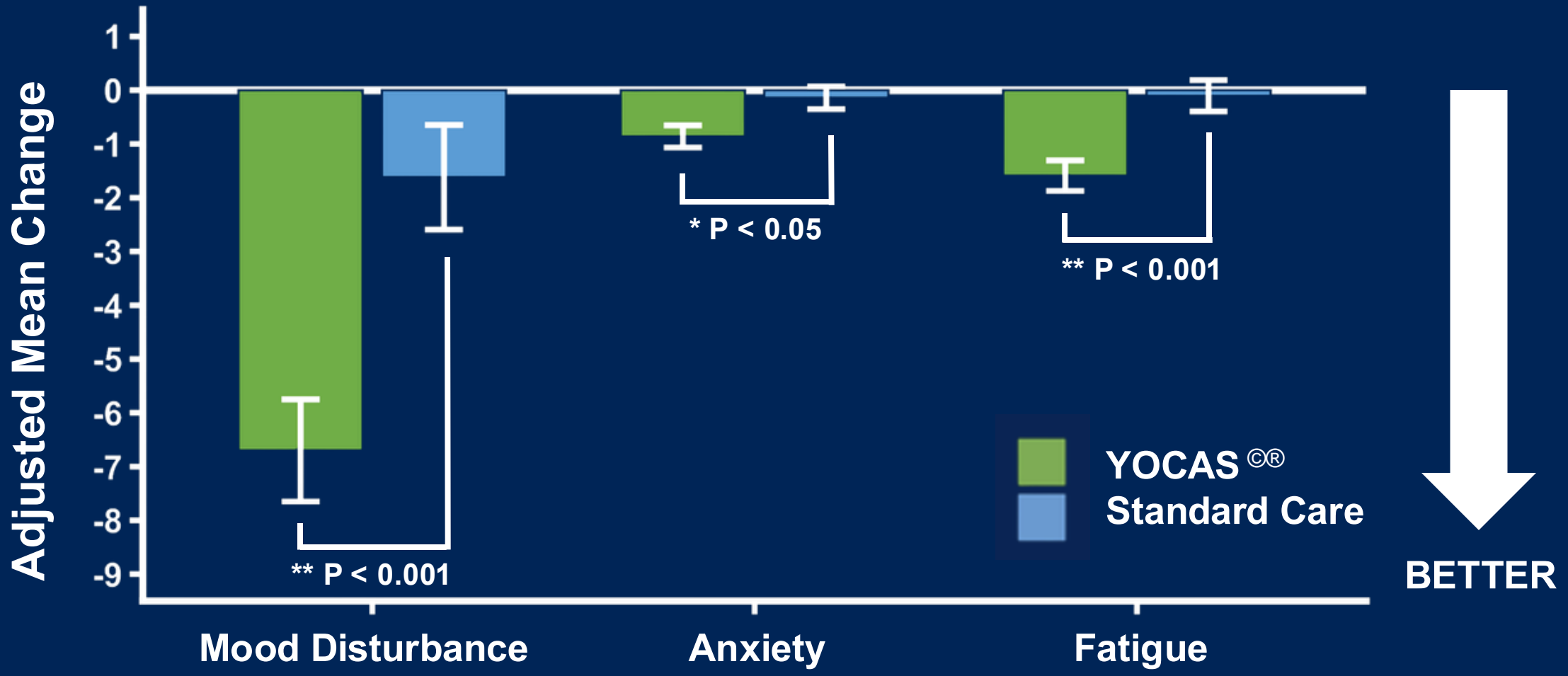
- **Average Attendance of Prescribed Sessions:**
  - 6.5 out of 8 sessions (81%)

- **Total Yoga Dose (FITT):**
  - Frequency: 3x's/week
  - RPE: 3.4
  - Time: 182 minutes/week
  - Type: Gentle Hatha & Restorative yoga

- **Adverse Event:**
  - One serious grade 2 adverse event, unrelated to study procedures or yoga participation

PRESENTED BY: Yuri Choi, PhD, RN

YOCAS©® Improves Mood Disturbance, Anxiety, and Fatigue



ANCOVA model adjusted for baseline values and baseline-by-group interaction

PRESENTED BY: Yuri Choi, PhD, RN

Conclusions & Clinical Implications

- YOCAS©® effectively treats mood disturbance, anxiety, fatigue, and insomnia among cancer survivors.
- YOCAS©® improves insomnia because it reduces mood disturbance and fatigue.
- Clinicians should recommend Gentle Hatha and Restorative Yoga for survivors.
- Clinicians should familiarize themselves with credible yoga resources in their communities for patient referral.

Key Takeaway Points

1

YOCAS©® is effective for treating mood disturbance, anxiety, fatigue, and insomnia among cancer survivors.

2

Part of the reason YOCAS©® improves insomnia is because it reduces mood disturbance and fatigue.

3

Clinicians should recommend Gentle Hatha & Restorative Yoga for survivors experiencing mood disturbance, anxiety, fatigue, or insomnia.

2026 ASCO® ANNUAL MEETING

The effect of Mediterranean diet, physical activity and vitamin D on breast cancer recurrence and cardiometabolic health: a multicenter randomized trial

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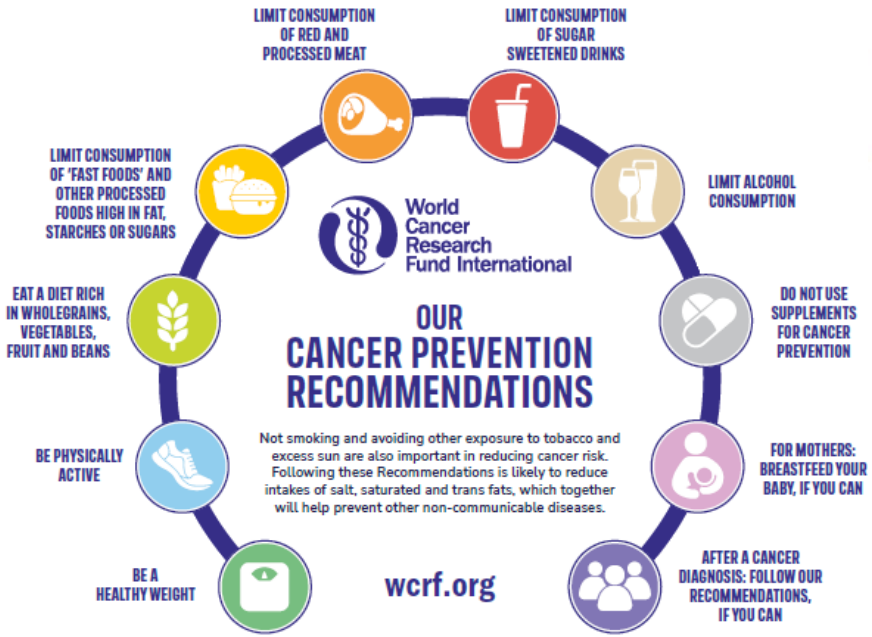
International Lifestyle Recommendations



5yr survival rates for BC in Italy: 88%

Mediterranean lifestyle

LIVING WITH AND BEYOND BREAST CANCER (HEALTH AND HEALTH-RELATED QUALITY OF LIFE OUTCOMES)

2022 — Post diagnosis diet, nutrition and physical activity for breast cancer survivors

		DECREASES RISK		INCREASES RISK	
		EXPOSURE	OUTCOME	EXPOSURE	OUTCOME
STRONG EVIDENCE	CONVINCING				
	PROBABLE	Physical activity interventions	HR quality of life[1]	Body fatness[2]	All mortality BC mortality 2nd BC
LIMITED EVIDENCE	LIMITED–SUGGESTIVE	Healthy dietary patterns[3]	All mortality Non-cancer mortality	Body fatness[4]	Recurrence Non-BC mortality CVD mortality
		Soy foods	All mortality BC mortality Recurrence		
		Dietary fibre	All mortality		
		Vitamin D status[5]	All mortality BC mortality		
		Recreational physical activity	All mortality BC mortality		
	LIMITED–NO CONCLUSION	Post diagnosis BMI change or weight change Low-fat diet, predefined healthy dietary and lifestyle patterns (for breast cancer-specific mortality and cardiovascular disease death), data-driven dietary patterns, high-fat dietary pattern, alcoholic drinks, fruit and vegetables, cruciferous vegetables, dietary fibre (for breast cancer-specific mortality and recurrence), wholegrains, red and processes meats, fish, eggs, milk and dairy products, nutrients (fats, carbohydrate, animal protein, plant protein), supplements (multivitamins, antioxidants, vitamins, carotenoids), vitamin D (blood levels on recurrence)			
STRONG EVIDENCE	SUBSTANTIAL EFFECT ON RISK UNLIKELY				

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DEDiCa study: multicentric RCT in 7 Italian oncologic centres

(Eudract 2015-005247-14; NCT02786875)

Participants: 506 Breast Cancer Survivors (≥30<75y), stages I-III, without metastasis within 12 months from histological diagnosis

253 Low Intensity treatment
4 randomized in error due to presence of exclusion criteria

253 High Intensity treatment
10 randomized in error due to presence of exclusion criteria

249 Low Intensity treatment (ITT)
Traditional Mediterranean diet
Avoidance of sedentary behaviour
Serum 25(OH)D: 30 ng/mL

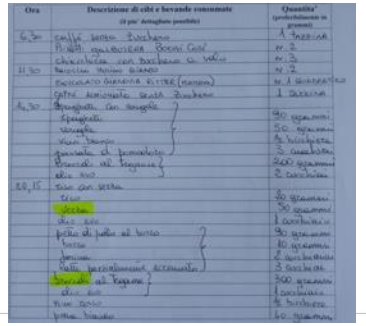
243 High Intensity treatment (ITT)
Traditional Med-diet with low GI carbohydrates (<55)
30 min daily brisk walking
Serum 25(OH)D: 60 ng/mL

After 33 months

Main outcome: Breast cancer recurrence/DFS
Secondary outcomes: cardiometabolic risk factors

Mediterranean diet

5 serve fruit/veg/d
whole grains
20g nuts/d
3 serve/week legumes
3-4 tbs/d extra virgin olive oil
<8%E saturated fatty acids



Low GI foods

EXCLUSION CRITERIA

1. Patients with sarcoidosis or other granulomatous diseases or with hypercalcemia (Ca>11 mg/dL).
2. Patients with any previous or with current concomitant other malignant cancer.
3. Pregnant or lactating women.
4. Patients with AIDS diagnosis
5. Patients with severe renal insufficiency
6. Patients with kidney stones (nephrocalcinosis or nephrolithiasis)
7. Patients participating in other lifestyle clinical trials

Power calculation: Considering a 20% recurrence rate within 3 years for BC cases and a predicted rate of 10% in the high intensity group, with power of 80% and two-sided alpha of 0.05, the subject number required was 506 (n = 253 in each arm).

Statistical Analysis

Within-group changes (baseline to month 12): paired t-test.
Between-group differences: ANCOVA, baseline adjustments.
Main outcome (incidence of recurrences) for intention-to-treat.
Disease-free survival (DFS) between groups: two-sided log-rank test with α = 0.05; HR (95% CI) by Cox models adjusted for recruitment centre and hormonal receptor status.
Observational analysis of recurrence based on treatment adherence changes for the entire cohort (both groups together). Comparisons were made between two categories of adherence (medium-high vs. low) with a log-rank test and subsequently the HR were estimated using a Cox model adjusted for recruitment center, hormonal receptor status and BMI categories.

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Key Takeaway Points/Conclusions

1

- Low quality diets
- Physical inactivity
- Vitamin D deficiency

have been associated with unfavorable breast cancer (BC) outcomes and cardiometabolic conditions (e.g. diabetes, metabolic syndrome, MetS, and obesity)

2

Mediterranean diet (MD), low glycemic index (GI) foods, exercise and vit. D affect metabolism, inflammation and immunity thereby potentially affecting BC prognosis and cardiovascular health

3

A safe and low-cost lifestyle program of low-GI MD + daily brisk walking + oral vitamin D resulted in:

- weight loss
- improved CVD risk factors
- MetS remission
- in women with HR+BC, recurrence risk reduction with higher treatment adherence

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2026 ASCO® ANNUAL MEETING

Effect of elinzanetant on sleep disturbance and aspects of quality of life in women with breast cancer experiencing vasomotor symptoms: OASIS-4 subgroup analysis by type of endocrine therapy

Claudio N. Soares,[1] Kaisa Laapas,[2] Christian Seitz,[3,4] Gilbert Donders,[5,6] Paula Briggs,[7] Shani Paluch-Shimon,[8] Sukhbir S. Singh,[9] Claudia Haberland,[3] Lauren Wahyudi,[10] Fatima Cardoso[11,12] on behalf of the OASIS-4 study investigators

[1]Queen's University School of Medicine, Kingston, Ontario, Canada; [2]Bayer Oy, Espoo, Finland; [3]Bayer AG, Berlin, Germany; [4]Charité – Universitätsmedizin Berlin, Germany; [5]Department of Clinical Research for Women, Femicare VZW, Tienen, Belgium; [6]Department of Obstetrics and Gynecology, University Hospital, University of Antwerp, Antwerp, Belgium; [7]Liverpool Women's Hospital, Liverpool, United Kingdom; [8]Hadassah University Hospital, Jerusalem, Israel; [9]Department of Obstetrics and Gynecology, Faculty of Medicine, University of Ottawa, Ottawa, Canada; [10]Bayer CC AG, Basel, Switzerland; [11]Department Medical Oncology, Centre Antoine Lacassagne, Nice, France; [12]Advanced Breast Cancer (ABC) Global Alliance, Lisbon, Portugal

Introduction

Elinzanetant is the first and only dual neurokinin (NK)-targeted therapy (NK1 and NK3 receptor antagonist) approved in several countries for the non-hormonal treatment of VMS associated with menopause and in the EU for VMS caused by endocrine therapy for breast cancer

In the Phase III OASIS-4 trial, elinzanetant demonstrated rapid, significant, and sustained improvements in VMS, sleep disturbance, and menopause-related quality of life in women taking endocrine therapy for breast cancer

This subgroup analysis evaluated the effect of elinzanetant on sleep disturbance and quality of life by type of endocrine therapy in OASIS-4

EU, European Union; NK, neurokinin; VMS, vasomotor symptoms.

Key takeaways

Elinzanetant demonstrated rapid and sustained improvements in sleep disturbance compared with placebo irrespective of type of background endocrine therapy

Improvements were also seen in vasomotor, psychosocial, physical, and sexual aspects of menopause-related quality of life

Taken with previous data, findings support the efficacy of elinzanetant in reducing VMS frequency and severity, as well as sleep disturbance, and improving menopause-related quality of life independently of the type of endocrine therapy

VMS, vasomotor symptoms.

GLP-1 RA for Primary Prevention of Post-Mastectomy Lymphedema in Breast Cancer patients: A Multi-center real-world analysis

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Abstract Number: 533112

Background

- Post-mastectomy lymphedema (PML) is a common and debilitating complication after breast cancer treatment—especially following axillary lymph node dissection—leading to infections, chronic pain, and reduced quality of life.
- Although weight optimization is central to PML management, the role of GLP-1 receptor agonists in *primary prevention* of PML remains poorly defined, with prior evidence limited to small retrospective studies and case reports. (1)
- This study represents the first large-scale, multi-center, real-world analysis evaluating the effectiveness of GLP-1 receptor agonists for the primary prevention of PML in breast cancer patients.

Methods

- Retrospective cohort study using the TriNetX Global Collaborative Network (150M patients, 108 healthcare organizations; Jan 2000–Jan 2025).
- Breast cancer patients undergoing mastectomy were stratified by GLP-1 receptor agonist exposure vs no exposure; 1:1 propensity score matching balanced demographics, BMI, comorbidities, medications, and labs.
- Over a median 650-day follow-up, PML incidence was evaluated using Kaplan–Meier survival analysis and Cox proportional hazards models to calculate hazard ratios and 95% confidence intervals.

Results

- After 1:1 propensity score matching, 61,630 patients were analyzed (30,815 per cohort); mean age 62.1 ± 10.8 years, 99.2% female, with excellent covariate balance (all standardized mean differences < 0.1)
- GLP-1 RA use was associated with a 63% reduction in incident post-mastectomy lymphedema compared with controls (HR 0.37; 95% CI 0.32–0.43; $p < 0.0001$)
- Absolute PML incidence was 0.88% in the GLP-1 RA cohort vs 2.58% in controls, yielding an absolute risk reduction of 1.7% and a number needed to treat (NNT) of 59.

Cohort	Patients with Outcome*		p-value
	In Numbers	By percentage	< 0.0001
Mastectomy + GLP-1 RA	258/29,259	0.88%	
Mastectomy not on GLP-1 RA	779/30,237	2.58%	

*Outcome: Post-mastectomy Lymphedema

Conclusion

- In a large, real-world cohort, GLP-1 receptor agonist use was associated with a 63% reduction in post-mastectomy lymphedema risk, supporting a strong protective effect.
- Benefits may extend beyond weight loss, potentially involving anti-inflammatory and lymphatic disease-modifying mechanisms, highlighting a novel role in breast cancer survivorship care.
- With a NNT of 59, GLP-1 RAs could meaningfully reduce chronic lymphedema burden in high-risk patients; prospective randomized trials are needed for confirmation.

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GLP-1 therapy and hormone receptor–positive breast cancer risk and survival: A real-world analysis.

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Background

Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are increasingly used for weight management and cardiometabolic risk (CMR) reduction, yet their association with breast cancer (BC) incidence and survival in non-diabetic women with elevated BMI remains unclear. We evaluated the relationship between GLP-1 RA exposure and incident BC, as well as overall survival (OS), in a large real-world (RW) cohort of women without laboratory-defined diabetes.

Methods

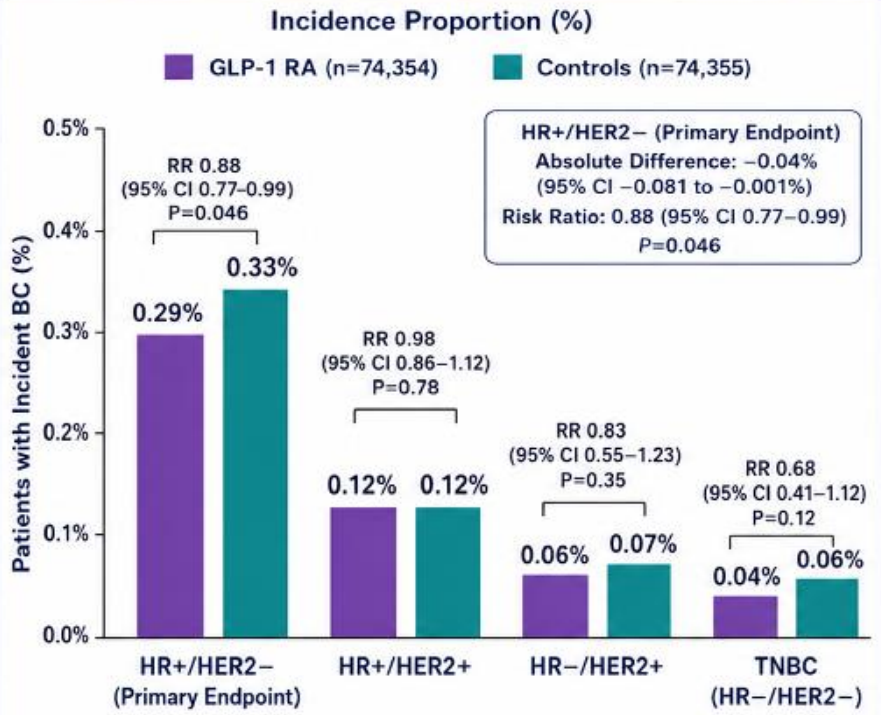
We conducted a retrospective cohort study using the TriNetX US Collaborative Network including female patients (pts) with BMI 25–35 kg/m². Age <50 vs ≥50 years served as proxies for pre- and postmenopausal status, with a ≥50 sensitivity analysis to assess age/menopause confounding. Pts with HbA1c ≥6.5% or prior BC were excluded. Cohorts were propensity score matched (PSM) on age at index, BMI, metformin and statin exposure, BRCA mutation status, hormonal contraceptive use, parity, breastfeeding history, and smoking status. The primary endpoint was incident HR+/HER2− BC, summarized as incidence proportion and risk reduction estimates; secondary analyses evaluated HR+/HER2+, HR−/HER2+, and triple-negative breast cancer (TNBC). OS was evaluated using Kaplan–Meier and Cox regression.

Conclusions

In a large non-diabetic cohort of women with BMI 25–35 kg/m² and no prior BC, GLP-1 RA exposure was associated with a modest reduction in incident HR+/HER2− BC and improved OS. Despite limited follow-up and age-based menopausal proxies, these findings provide RW evidence supporting prospective validation with standardized exposure definitions and longer follow-up. Future studies should clarify whether GLP-1 RAs confer direct antitumor effects or indirect benefits mediated through weight loss and CMR reduction and identify pts most likely to derive BC risk and survival benefit.

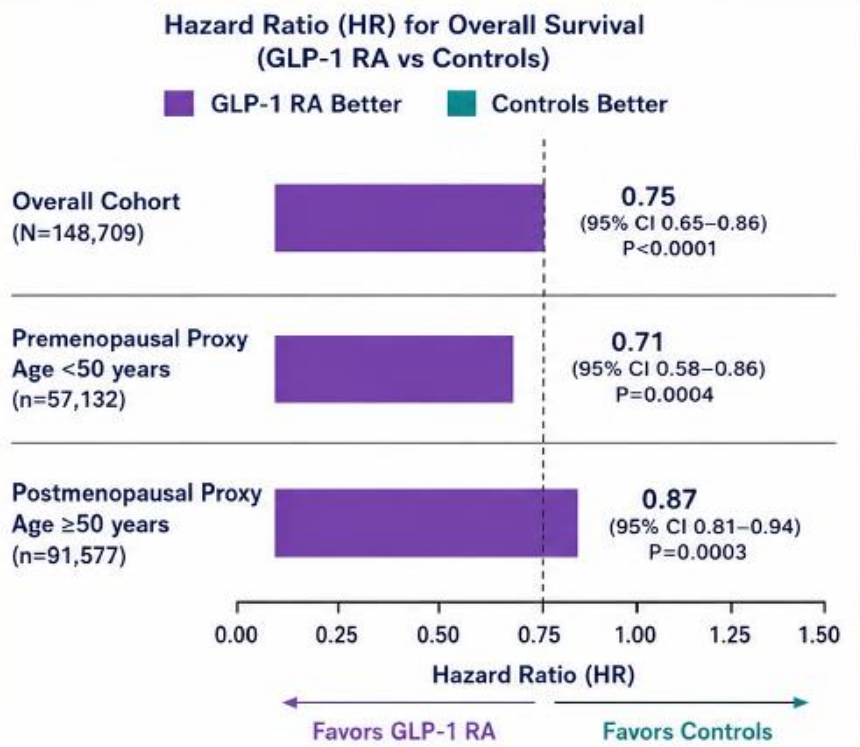
GLP-1 RA EXPOSURE AND BREAST CANCER OUTCOMES IN NON-DIABETIC WOMEN WITH BMI 25–35 kg/m² (REAL-WORLD COHORT)

1. INCIDENT BREAST CANCER (36-MONTH FOLLOW-UP)



PSM on age, BMI, metformin and statin use, BRCA status, hormonal contraceptive use, parity, breastfeeding, and smoking. Excluded HbA1c ≥6.5% or prior BC.

2. OVERALL SURVIVAL



OS analyzed using Kaplan–Meier and Cox regression.
HR <1 favors GLP-1 RA.

Impact of GLP-1 Receptor Agonists in Hormone Receptor-Positive Breast Cancer Patients Receiving CDK4/6 Inhibitors

EMORY HEALTHCARE

EMORY WINSHIP CANCER INSTITUTE

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Background

- Hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer is most common subtype.[1]
- Three cyclin-dependent kinase 4/6 inhibitors (CDK4/6i), abemaciclib, palbociclib, and ribociclib, are FDA-approved as first-line treatment for advanced or metastatic HR+, HER2- breast cancer. Abemaciclib and ribociclib are also approved in the early-stage adjuvant setting.[2-6]
- Obesity and type 2 diabetes, present in ~40% of U.S. adults, are associated with increased breast cancer risk, recurrence, and mortality.[7,8]
- Glucagon-like peptide-1 receptor agonists (GLP-1 RAs), including semaglutide, tirzepatide, dulaglutide, exenatide, and liraglutide, are increasingly prescribed for these comorbidities due to their efficacy in weight reduction, glycemic control, and cardiovascular risk mitigation.[10]
- Beyond metabolic effects, GLP-1 RAs delay gastric emptying, which may affect absorption of oral agents such as CDK4/6i and modulate inflammatory pathways relevant to cancer progression. Both drug classes share gastrointestinal adverse effects (e.g., diarrhea, decreased appetite, nausea/vomiting, abdominal pain), potentially impacting tolerability and clinical outcomes.[8,10]

Objective

The primary objective of this study is to characterize the safety of concomitant GLP-1 RA and CDK4/6i use in patients with HR+, HER2- breast cancer.

Methods

Primary Outcome	Secondary Outcomes
Safety, characterized by: Adverse drug reactions (ADR) Dose reductions Adherence Discontinuations	Overall Survival (OS) Progression-free Survival (PFS)

Inclusion Criteria	Exclusion Criteria
Adults prescribed CDK4/6i (abemaciclib, palbociclib, or ribociclib) for HR+, HER2- breast cancer	Patients treated for non-breast cancer indications, by outside providers, or through clinical trials

Matched criteria (1:1)
- CDK4/6i
- Adjuvant or metastatic setting
- Age (≥65 years, 45-64 years, and <45 years)
- Race

Matched case-control, retrospective chart review from 2/1/14 to 5/31/25

CDK4/6i + GLP-1 RA group (n=41)

CDK4/6i alone group (n=41)

Results

Table 1. Baseline Characteristics

	CDK4/6i + GLP-1 RA (n=41)	CDK4/6i alone (n=41)	P-value
Age, median (IQR), years	54 (46-64)	53 (42-62)	0.625
Female sex, n (%)	41(100)	41 (100)	---
BMI, mean ± SD (kg/m²)	33.7 ± 7.5	27.9 ± 6.9	0.002
Race, n (%) White Black	 23 (56) 13 (31.7)	 25 (61) 12 (29.3)	---
ECOG PS 0-1, n (%)	36 (87.8)	32 (78)	0.002
Metastatic disease, n (%)	20 (48.8)	21 (51.2)	0.825
De novo metastatic breast cancer, n (%)	7 (17)	10 (24.4)	---
Biomarkers, n (%) ER+/PR− ER+/PR-	 32 (78.0) 9 (28.0)	 33 (80.5) 8 (19.5)	0.785
CDK4/6i prescribed, n (%) Abemaciclib Palbociclib Ribociclib	 20 (48.8) 11 (26.8) 10 (24.4)	 21 (51.2) 10 (24.4) 10 (24.4)	0.965
GLP-1 RA therapy, n (%) Semaglutide Tirzepatide Dulaglutide Liraglutide	 22 (53.7) 16 (39) 2 (4.8) 1 (2.4)	---	---
Comorbidities, n (%) Diabetes Prediabetes Obesity Overweight	 17 (41.5) 1 (2.4) 30 (73.2) 6 (14.6)	 3 (7.3) 1 (2.4) 9 (2.2) 15 (21.9)	---

Figure 1. Time to First ADR

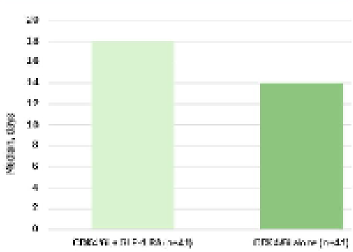


Figure 2. Any CDK4/6i-related ADR

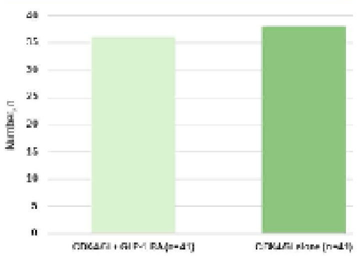
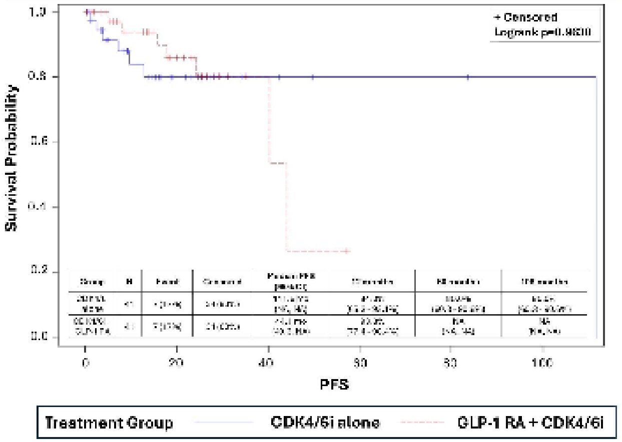


Table 2. Primary Outcome: Safety

	CDK4/6i + GLP-1 RA (n=41)	CDK4/6i alone (n=41)	P-value
Any CDK4/6i-related ADR, n (%)	36 (87.8)	38 (92.7)	0.457
Gastrointestinal ADR, n (%)	19 (44.2)	24 (55.8)	0.269
Hematologic ADR, n (%)	10 (21.4)	11 (26.8)	0.800
Time to first ADR, median (IQR), days	18 (11-36)	14 (8-21)	0.086
CDK4/6i dose reduction, n (%)	15 (44.1)	19 (46.3)	0.476
Therapy interruption, n (%)	11 (26.8)	11 (26.8)	—
Therapy discontinuation, n (%)	1 (2.4)	3 (7.3)	—

Figure 3. Progression-free Survival



Conclusions

- Concurrent GLP-1 RA use was not associated with increased CDK4/6i-related ADRs (e.g., gastrointestinal and hematologic toxicities).
- Patients receiving CDK4/6i alone had earlier and numerically more ADRs, though differences were not statistically significant.
- Dose reductions, interruptions, and discontinuation rates were similar with or without GLP-1 RA therapy.
- PFS outcomes were not compromised by GLP-1 RA use.
- OS will be reported at a later date.
- Larger, multi-center studies are warranted to further characterize the safety and potential pharmacologic interactions between GLP-1 RAs and CDK4/6i.

References

GLP-1 Receptor Agonists for Primary Prevention of Breast Cancer in High-Risk Women with Obesity: A Real-World Analysis of Efficacy and Safety

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BACKGROUND

- Therapeutic options for breast cancer (BC) prevention for high-risk women remain limited.
- Obesity is a known risk factor for postmenopausal BC.
- GLP-1 receptor agonists (GLP-1RA) are used for the management of diabetes and obesity.
- Their role in BC primary prevention (PP) in high-risk women with obesity has not been evaluated.

METHODS

- Retrospective study using TriNetX research network
- De-identified data across 150 million patients from 108 health systems

Study population

- Women 18–90 years with obesity (BMI ≥ 30)
- High risk defined as ≥1 of the following: genetic predisposition to BC, family history of BC, atypical ductal hyperplasia, atypical lobular hyperplasia , lobular carcinoma in situ, dense breasts
- Grouped by GLP-1RA exposure vs. non-use
- Patients with use of endocrine therapy were excluded

Analysis

- Propensity score matching by TriNetX adjusted for demographics, comorbidities, social determinants of health, lifestyle factors, BMI, HbA1c, and prior breast imaging
- Cox proportional hazards models were used to assess outcomes
- Subgroup and sensitivity analyses were performed

Endpoints

- Primary: Breast Cancer incidence
- Secondary: Safety outcomes

RESULTS

STUDY POPULATION

After matching, a total of 80,480 participants were included in the study, with 40,240 assigned to each cohort.

Figure 1. Flow Diagram for Patient Selection

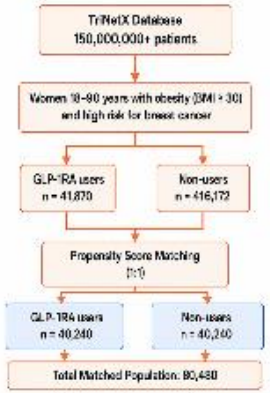


Table 1. Demographics

Baseline Characteristics After Matching

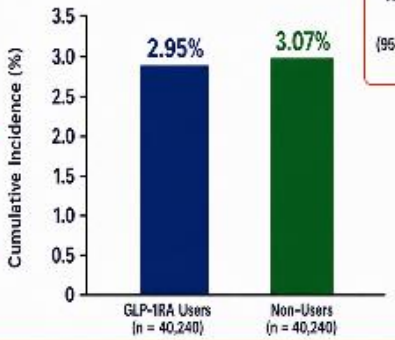
Characteristic	GLP-1RA Users (n = 40,240)	Non-Users (n = 40,240)	Standardized Mean Difference
Age, mean (SD), years	46.4 (12.2)	46.8 (13.0)	0.031
BMI, mean (SD), kg/m²	35.3 (7.7)	29.1 (2.4)	0.042
HbA1c, mean (SD), %	7.1 (1.5)	6.2 (1.2)	0.229
Race / Ethnicity, n (%)			
White	27,353 (68.0)	27,963 (69.5)	<0.021
Black or African American	8,275 (20.6)	8,360 (20.8)	0.006
Other / Unknown	1,571 (3.9)	1,511 (3.8)	0.008
Female sex, n (%)	38,523 (95.7)	38,444 (95.5)	0.010

Figure 2. Breast Cancer Incidence (Primary Endpoint)

Median Follow-up

2,790 days
GLP-1RA Users

2,737 days
Non-Users



Hazard Ratio (HR): 0.844
(95% CI: 0.779–0.915)
p < 0.001

GLP-1RA use was associated with a modest reduction in incident breast cancer.

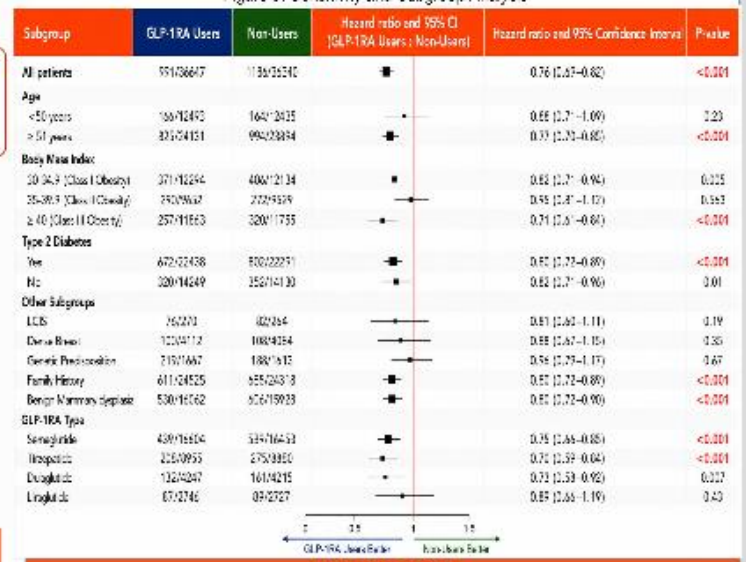
Table 2. Safety Outcomes (Secondary Endpoints)

Adverse Event	GLP-1RA Users (n = 40,240) Cases / Patients	Non-Users (n = 40,240) Cases / Patients	HR (95% CI)	p-value
VTE	301/40,128	228/40,156	1.171 (0.973–1.372)	0.100
Nausea and Vomiting	10,699/37,059	6,916/36,997	1.419 (1.377–1.462)	<0.001
Abdominal Pain	3,506/39,309	2,412/39,295	1.284 (1.219–1.353)	<0.001
Diarrhea	7,769/38,270	4,735/38,472	1.500 (1.446–1.555)	<0.001
Constipation	7,688/38,502	4,872/38,328	1.415 (1.365–1.467)	<0.001

Endometrial Cancer and Osteoporosis: No Significant Association on Sensitivity Analysis

Primary analyses showed nominally higher incidence of endometrial cancer and osteoporosis among GLP-1RA users. However, results were not robust to sensitivity analyses.

Figure 3. Sensitivity and Subgroup Analysis



KEY FINDINGS

- GLP-1RA use was associated with a modest reduction in BC incidence among high-risk women with obesity
- In subgroup analysis, the effect was seen in the postmenopausal, but not premenopausal patients
- Gastrointestinal adverse events were significantly higher in the GLP-1RA cohort. No significant association was observed for VTE
- Additional sensitivity analyses found that endometrial cancer and osteoporosis associations were no longer significant

CONCLUSIONS

- GLP-1RAs may offer a potential strategy to reduce BC risk in high-risk women with obesity, particularly in postmenopausal patients
- Prospective studies are needed to validate these associations

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535490

Real-World Survival Benefit of Glucagon-like Peptide-1 Receptor Agonists (GLP-1 RAs) Concomitant with Cyclin-dependent Kinase 4/6 Inhibitors (CDK4/6i) and Endocrine Therapy in Hormone Receptor-positive (HR+)/HER2− Metastatic Breast Cancer: A Large Propensity-Matched Analysis

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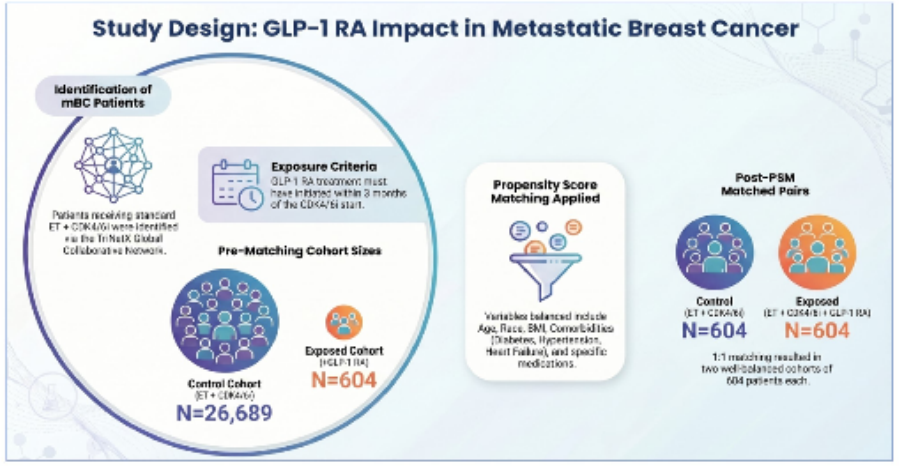
Background

Obesity increases hormone receptor-positive (HR+) breast cancer risk through adipose-derived estrogens and inflammation. In metastatic HR+/HER2- disease, endocrine therapy (ET) combined with cyclin-dependent kinase 4/6 inhibitors (CDK4/6i) is standard first-line therapy, improving survival. The widespread use of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) for diabetes and obesity management induces meaningful weight loss and may enhance ET efficacy by reducing body fat mass, which modulates estrogen levels and cancer-related inflammation, albeit their impact on mBC survival in patients receiving ET plus CDK4/6i remains unclear.

Methods

Using the TriNetX Global Collaborative Network, we retrospectively identified two cohorts of patients with mBC receiving endocrine therapy (ET) plus a CDK4/6i: 26,689 patients treated with ET+CDK4/6i alone and 604 patients who also received a GLP-1 RA initiated within 3 months of CDK4/6i start. Propensity score matching (PSM) was applied to balance cohorts for age, race, body mass index, heart failure, hypertension, diabetes mellitus, fulvestrant use, and type of CDK4/6i. Overall survival (OS) was estimated using the Kaplan–Meier method, and hazard ratios (HRs) were calculated to compare OS between cohorts.



Characteristics	GLP-1 RA naive (N = 604)	GLP-1 RA exposed (N = 604)	*p*-value
Age at Index (Mean ± SD)	61.4 ± 11.3	61.8 ± 11.8	0.534
Body mass index (BMI), kg/m² (Mean ± SD)	33.8 ± 7.5	33.5 ± 8.0	0.494
Lung metastasis (n [%])	58 (9.6%)	96 (15.9%)	0.001
Aromatase inhibitors (n [%])	530 (87.7%)	489 (81.0%)	0.001

Abbreviations: BMI, body mass index; SD, standard deviation

Table 1. Baseline Patient Characteristics After Propensity Score Matching.

Conclusions

This is the largest real-world, propensity-matched analysis demonstrating a significant OS benefit with GLP-1 RAs added to ET+CDK4/6i in HR+/HER2− mBC. These provocative findings warrant prospective validation to elucidate underlying mechanisms—such as metabolic reprogramming or immune modulation—and explore GLP-1 RAs as a novel therapeutic strategy in this setting.

Results

After PSM, 604 matched pairs of ET plus CDK4/6i-treated patients were identified in GLP-1RA-exposed and -naïve groups. Both groups showed well-balanced baseline characteristics, including age (GLP-1 RA-naïve and -exposed mean age +/- standard deviation were 61.4±11.3 and 61.8 ±11.8 years, respectively) (Table 1). Similar median follow-up was documented: 18.8 months (interquartile range, IQR 27.9) in the non-exposed cohort and 15.8 months (IQR 24.5) in the exposed cohort. Patients receiving GLP-1 RA showed longer median OS (67.9 months) compared to GLP-1 RA- naïve cohort (49 months), with HR 0.70 (95% CI, 0.56–0.89; $p = 0.003$) (Figure 1).

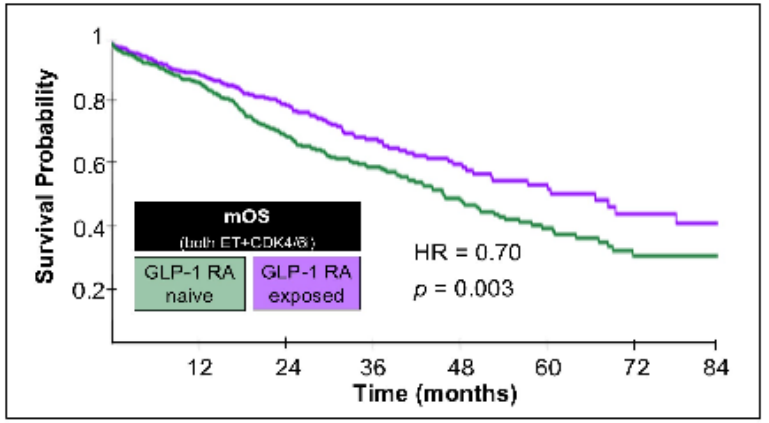


Figure 1. Kaplan-Meier overall survival analysis.

Acknowledgments

The authors would like to acknowledge TriNetX Global Collaborative Network for the valuable support in the development of this study. Its contribution to data analysis and methodological consultation was crucial in completing this work.

GLP1-RA's and Breast Cancer

•These are observational studies, so they show association but not causation. They cannot prove that GLP-1 RAs reduce risk of breast cancer.

•The effects appear consistent across subgroups, suggesting potential broad applicability, but more research is needed to confirm mechanisms and benefits.

•GLP-1 RAs may exert effects beyond glucose control, possibly through anti-inflammatory, immune-modulatory, and metabolic effects that influence tumor progression

Next steps:

•Prospective clinical trials are needed!

•Current guidance is that GLP-1 RAs should be used for approved indications (diabetes, obesity) and not prescribed solely for breast cancer prevention or treatment.

•ASCO 2026 data are promising but preliminary, showing that GLP-1 RA use is associated with lower breast cancer incidence and better survival in some populations.

•While these findings warrant excitement, they also underscore the need for rigorous prospective trials before any preventive recommendations can be made.

Thank you! Please reach out with questions.

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