

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

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authors and unedited

SUPPLEMENTARY INFORMATION

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	Ensino e Terapia de Inovacao Clinica AMO	Dybal, Vanessa
	Clinica de Pesquisas e Centro de Estudos em Oncologia Ginecologica e Mamaria Ltda	Hegg, Roberto
	Hospital Araujo Jorge Associacao de Combate ao Cancer de Goias	Freitas Junior, Ruffo de
	ONCOSITE - Centro de Pesquisa Clinica em Oncologia	Franke, Fabio
	Centro de Novos Tratamentos Itajai - Clinica de Neoplasias Litoral	Borges, Giuliano
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	ICESP – Instituto do Câncer do Estado de São Paulo	Linck, Rudinei Diogo Marques
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	Saskatoon Cancer Centre	Haider, Kamal-Uddin/Iqbal, Nayyer
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	Sunnybrook Research Institute	Pezo, Rossanna
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	Guangdong General Hospital	Liao, Ning
	Fudan University Shanghai Cancer Center	Shao, Zhimin
	Renji Hospital Shanghai Jiaotong University School of Medicine	Xu, Shuguang
	Fujian Medical University Union Hospital	Zhang, Jie
	Cancer Hospital Chinese Academy of Medical Sciences	Wang, Jing
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	Zhejiang Cancer Hospital	Yang, Hongjian
	Hubei Cancer Hospital	Wu, Xinhong
	Henan Cancer Hospital	Liu, Zhenzhen
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	Hospital Teresa Herrera - Chuac	Antolin Novoa, Silvia
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	Complejo Hospitalario de Jaen	Sanchez Rovira, Pedro
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	Hospital General Universitario Gregorio Maranon	Martin Jimenez, Miguel
	Hospital Clinico San Cecilio	Blancas, Isabel
	Hospital General Arnau de Vilanova de Valencia	Llombart Cussac, Antonio
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	China Medical University Hospital	Wang, Hwei-Chung
	Linkou Chang Gung Memorial Hospital	Chen, Shin-Cheh
	Koo Foundation Sun Yat-Sen Cancer Center	Chung, Chi-Feng
	National Taiwan University Hospital	Huang, Chiun-Sheng
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	St. Georges University Hospital NHS Foundation Trust	Kyle, Fiona
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	University of Colorado Cancer Center	Diamond, Jennifer
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	Memorial Cancer Institute	Perez, Alejandra
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	UC Davis Comprehensive Cancer Center	Chew, Helen
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	Southeastern Regional Medical Center, Inc.	Hansra, Damien
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	Cedars Sinai Medical Center Samuel Oschin Comp. Cancer Institute	McArthur, Heather
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	Southern Cancer Center, PC	Meshad, Michael
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	MI Odesa Regional Clinical Hospital	Berzoy, Oleksandr
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	Vinnitsya Regional Clinical Oncological Dispensary	Shevnya, Sergii
	Communal nonprofit enterprise "Kherson Regional Oncology Dispensary" of Kherson Regional Council	Sokur, Iryna
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	PP PPC Acinus Medical and Diagnostic Centre	Ursol, Grygorii

	Kyiv City Clinical Oncology Centre	Voitko, Nataliia/Osinsky, Dmytro
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Steering Committee

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David Cescon	Princess Margaret Cancer Centre	Canada
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Heather McArthur	Cedars Sinai Medical Center Samuel Oschin Comp. Cancer Institute	United States
Peter Schmid	Barts Health NHS Trust	United Kingdom
Melinda Telli	Stanford University School of Medicine/Standard Cancer Institute	United States

*At the time of patient enrollment in study

Data Monitoring Committee

Name	Affiliation	Country
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James J. Dignam, PhD	University of Chicago, Department of Public Health Sciences, The University of Chicago	United States
Kevin Kalinsky	Associate Professor, Department of Hematology and Medical Oncology, Emory University School of Medicine	United States

Eligibility Criteria

Inclusion Criteria

An individual is eligible for inclusion in the study if the individual meets all of the following criteria:

Type of Participant and Disease Characteristics

1. Participant has a localized invasive breast ductal adenocarcinoma, confirmed by the local pathologist, that includes either T1c-T2 (tumor size ≥ 2 cm), clinical node stage (cN)1-cN2, or T3-T4, cN0-cN2.

Note: Multifocal tumors defined as the presence of 2 or more foci of cancer within the same quadrant are allowed; at least 1 of the tumors needs to be ≥ 2 cm. ER+/HER2– status needs to be confirmed for each focus.

Note: Inflammatory breast cancer is allowed.

Note: Participants with node negative disease will be capped at 20% of the total population.

2. Has centrally confirmed ER+/HER2–, Grade 3 breast cancer of ductal histology, according to the most recent American Society of Clinical Oncology/College of American Pathologist guidelines.
3. Provides a new or recently obtained core needle biopsy, consisting of multiple cores, taken from the primary breast tumor(s) for central determination of HR status (ER and progesterone receptor), HER2, grade, and PD-L1 status.

Note: Adequacy of the biopsy specimen for the above analyses must be confirmed by the central laboratory. Submission of another tumor specimen may be required, if adequate tumor tissue was not provided the first time.

Note: Sponsor agreement is required for formalin-fixed paraffin-embedded (FFPE) tumor tissue sample or slides that were obtained greater than 60 days prior to the date that the documented informed consent was obtained.

Demographics

4. Is a male or female ≥ 18 years of age on the day of signing informed consent.
5. Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, as assessed within 10 days prior to initiation of study treatment.

Male Participants

6. A male participant must agree to use a contraception during the treatment period and for at least 12 months (for participants who received cyclophosphamide) or 6 months (for participants who did not receive cyclophosphamide) after the last dose of study treatment and refrain from donating sperm during this period.

Female Participants

7. A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies:
 - a. Not a woman of childbearing potential (WOCBP).

OR

- b. A WOCBP who agrees to follow the contraceptive guidance during the treatment period and for at least 12 months (for participants who received cyclophosphamide) or 6 months (for participants who did not receive cyclophosphamide) after the last dose of study treatment with pembrolizumab or placebo.

Informed Consent

8. The participant (or legally acceptable representative if applicable) provides documented informed consent for the study. The participant may also provide consent for future biomedical research. However, the participant may participate in the main study without participating in future biomedical research.

Laboratory Evaluations

9. Has adequate organ function as detailed in the **Table**; all screening laboratory tests should be performed within 10 days prior to initiation of study treatment.

Table. Adequate Organ Function Laboratory Values

System	Laboratory Value
Hematological	
Absolute neutrophil count	$\geq 1,500$ cells/ μ L
Platelets ^a	$\geq 100,000$ cells/ μ L
Hemoglobin ^a	≥ 9 g/dL or ≥ 5.6 mmol/L
Renal	
Creatinine OR Measured or calculated ^b creatinine clearance (GFR can also be used instead of CrCl)	$\leq 1.5 \times \text{ULN}$ OR ≥ 50 mL/min for participants with creatinine levels $\geq 1.5 \times \text{institutional ULN}$
Hepatic	
Total bilirubin	$\leq 1.5 \times \text{ULN}$ OR Direct bilirubin $\leq \text{ULN}$ for participants with total bilirubin levels $\geq 1.5 \times \text{ULN}$
AST (SGOT) and ALT (SGPT)	$\leq 2.5 \times \text{ULN}$
Coagulation	
INR or PT Activated partial thromboplastin time (aPTT) or partial thromboplastin time (PTT)	$\leq 1.5 \times \text{ULN}$ unless participant is receiving anticoagulant therapy as long as PT or aPTT/PTT is within therapeutic range of intended use of anticoagulants
ALT, alanine aminotransferase; AST, aspartate aminotransferase; CrCl, creatinine clearance; GFR, glomerular filtration rate; INR, international normalized ratio; PT, prothrombin time; SGOT, serum glutamic oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase; ULN, upper limit of normal. ^a Platelet and hemoglobin requirements cannot be met by use of recent transfusion or growth factor support (granulocyte colony-stimulating factor [G-CSF], granulocyte-macrophage colony-stimulating factor [GM-CSF], or erythropoietin) within 2 weeks prior to initiation of study treatment. ^b Creatinine clearance should be calculated per institutional standard.	

Exclusion Criteria

An individual must be excluded from the study if the individual meets any of the following criteria:

Medical Conditions

1. Has a history of non-infectious pneumonitis that required treatment with steroids or has current pneumonitis.
2. Has breast cancer with lobular histology.
3. Has bilateral invasive breast cancer.
4. Has metastatic (Stage IV) breast cancer.
5. Has multi-centric breast cancer (presence of more than 1 tumor in different quadrants of the breast).
6. Has any of the following clinical lymph node staging per current AJCC staging criteria for breast cancer staging based on radiological and/or clinical assessment: cN3, cN3a, cN3b, or cN3c.
7. Has ER–, progesterone receptor-positive breast cancer.
8. Participants who have undergone excisional biopsy of the primary tumor and/or axillary lymph nodes or have undergone sentinel lymph node biopsy prior to study treatment.
9. Has a known additional, invasive, malignancy that is progressing or required active treatment in the last 5 years.

Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, breast ductal carcinoma in situ, or cervical carcinoma in situ that has undergone potentially curative therapy are not excluded.

10. Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to the first dose of study treatment.
11. Has an active autoimmune disease that has required systemic treatment in the past 2 years (i.e., with use of disease modifying agents, corticosteroids, or immunosuppressive drugs).

Note: Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment.

12. Has a known history of active tuberculosis (*Bacillus tuberculosis*).
13. Has an active infection requiring systemic therapy.
14. Has a history or current evidence of any condition (e.g., transfusion-dependent anemia or thrombocytopenia), therapy, or laboratory abnormality that is specifically contraindicated per the current locally-approved labeling, that might confound the results of the study, interfere with the participant's involvement for the full duration of the study, or is not in the best interest of the participant to be involved, in the opinion of the treating investigator.
15. Has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the study.
16. Has left ventricular ejection fraction (LVEF) of <50% or below the institution limit of normal, as assessed by echocardiogram (ECHO) or multigated acquisition (MUGA) scan performed at screening.
17. Has other significant cardiac disease, such as:
 - a. History of myocardial infarction, acute coronary syndrome, or coronary angioplasty/stenting/bypass within the last 6 months;

- b. Congestive heart failure (CHF) New York Heart Association (NYHA) Class II-IV or history of CHF NYHA Class III or IV.

18. Has a known history of human immunodeficiency virus (HIV) infection.

Note: No HIV testing is required unless mandated by local health authority.

19. Has a known history of hepatitis B (defined as hepatitis B surface antigen [HbsAg] reactive) or known active hepatitis C virus (defined as HCV RNA [qualitative] is detected) infection.

Note: No testing for hepatitis B or hepatitis C is required unless mandated by local health authority.

20. A WOCBP who has a positive urine pregnancy test within 72 hours before the first dose of study treatment. If the urine test cannot be confirmed as negative, a serum pregnancy test is required. In such cases, the participant must be excluded from participation if the serum pregnancy result is positive.

Prior/Concomitant Therapy

21. Has received prior treatment for breast cancer.

22. Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., CTLA-4, OX 40, CD137).

23. Has received a live vaccine within 30 days prior to the first dose of study treatment.

Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster (chicken pox), yellow fever, rabies, Bacillus Calmette–Guérin (BCG), typhoid, and intranasal influenza vaccines (eg, FluMist®) vaccine.

Note: Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed.

24. Has severe hypersensitivity ($\geq$ Grade 3) to any of the components or excipients used in the study treatments.

Prior/Concurrent Clinical Study Experience

25. Is/was enrolled in a study of an investigational agent and received study therapy, or used an investigational device within 4 weeks (12 months for an investigational agent or device with anticancer or antiproliferative properties) prior to the first dose of study treatment.

Note: Participants who have entered the follow-up phase of an investigational study may participate as long as 4 weeks (12 months, for an investigational agent or device with anticancer or antiproliferative properties) have elapsed since the last dose of the previous investigational agent or last use of investigational device.

Other Exclusions

26. Is pregnant, breastfeeding, or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 12 months (for participants who received cyclophosphamide) or 6 months (for participants who did not receive cyclophosphamide) after the last dose of study treatment.