










Durvalumab in Combination With Neoadjuvant Chemotherapy in Early Triple-Negative Breast Cancer: Long-Term Analysis From the GeparNuevo Trial

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DOI <https://doi.org/10.1200/JCO-25-02311>

ABSTRACT

The phase II GeparNuevo trial investigated whether adding durvalumab to neoadjuvant chemotherapy (NACT) only in patients with early triple-negative breast cancer cT1b-cT4a-d would improve pathologic complete response (pCR) rate and patient survival. Hundred and seventy-four patients were randomly assigned to receive durvalumab or placebo concurrently with nab-paclitaxel once per week and followed by dose-dense epirubicin and cyclophosphamide. With 86.4 months of median follow-up compared with the previously reported 43.7 months, durvalumab showed sustained significant improvements in long-term outcomes as defined by STEEP compared with placebo regarding not only invasive disease-free survival (iDFS; hazard ratio [HR], 0.56 [95% CI, 0.32 to 0.99]; stratified log-rank $P = .0431$), but also distant disease-free survival (DDFS; HR, 0.41 [95% CI, 0.21 to 0.80]; $P = .0069$) and overall survival (OS; HR, 0.33 [95% CI, 0.14 to 0.79]; $P = .0085$). All analyses were stratified by stromal tumor-infiltrating lymphocytes (sTILs) at baseline (low [$\leq 10\%$], intermediate [11%–59%], high [$\geq 60\%$]). In exploratory subgroup analysis, patients with nodal involvement at baseline demonstrated a greater iDFS benefit (HR, 0.33 [95% CI, 0.144 to 0.771]; $P = .01$; $P_{interaction} = 0.045$). sTILs in residual disease (RD) could be assessed in 39/71 patients without pCR. Post hoc analyses by sTILs high ($> 10\%$) versus low ($\leq 10\%$) in RD showed estimated 7-year iDFS rates of 92.3% (95% CI, 56.6 to 98.9) and 51.4% (95% CI, 29.2 to 69.7), respectively. Hence, adding durvalumab to dose-dense NACT without adjuvant continuation of checkpoint inhibition improved long-term survival outcomes, irrespective of the extent of pathologic response. This underscores the necessity to re-evaluate the adjuvant continuation of checkpoint inhibition.

ACCOMPANYING CONTENT

-  [Data Sharing Statement](#)
-  [Data Supplement](#)
-  [Protocol](#)

Accepted February 17, 2026
Published April 20, 2026

J Clin Oncol 00:1-7
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INTRODUCTION

Triple-negative breast cancer (TNBC) is an aggressive breast cancer (BC) subtype with limited treatment options and poor prognosis.¹ It is characterized by elevated PD-L1 expression,² along with high levels of tumor-infiltrating lymphocytes (TILs),³ features linked to improved immunotherapy response.⁴⁻⁶ The clinical efficacy of checkpoint inhibitors (CPI) in metastatic TNBC⁷⁻⁹ as well as other malignancies¹⁰⁻¹² supported their evaluation as part of the neoadjuvant treatment concept. The phase II GeparNuevo trial assessed the benefit of adding durvalumab to anthracycline-/taxane-containing neoadjuvant chemotherapy (NACT) in patients with cT1b-cT4a-d early (e)TNBC. Despite a statistically nonsignificant increase in pathologic complete response (pCR) rate (53.4% [95% CI, 42.5 to 61.4], v 44.2% [95% CI, 33.5 to 55.3]; unadjusted continuity corrected $\chi^2 P = .287$), after a median follow-up of 43.7 months, the addition of durvalumab versus placebo demonstrated a

statistically significant increase in 3-year invasive disease-free survival (iDFS; hazard ratio [HR], 0.48 [95% CI, 0.24 to 0.97]; stratified log-rank $P = .036$), distant disease-free survival (DDFS; HR, 0.31 [95% CI, 0.13 to 0.74]; $P = .005$), and overall survival (OS; HR, 0.24 [95% CI, 0.08 to 0.72]; $P = .006$).^{4,13} To our knowledge, GeparNuevo was the first trial in early triple-negative breast cancer (eTNBC) reporting improved iDFS and OS via the addition of CPI to NACT. Here, we present updated long-term survival data.

METHODS

Study Design

Details of the GeparNuevo (ClinicalTrials.gov identifier: [NCT02685059](#)) study design have been published previously.^{4,6} The study was a randomized, phase II, placebo-controlled trial, and patients were randomly assigned 1:1 to receive either durvalumab or placebo. Before protocol amendment 2

TABLE 1. Baseline Characteristics

Parameter	Durvalumab (n = 88)	Placebo (n = 86)	Overall (N = 174)
Age, years, No. (%)			
<30	5 (5.7)	5 (5.8)	10 (5.7)
30 to <40	21 (23.9)	16 (18.6)	37 (21.3)
40 to <50	18 (20.5)	22 (25.6)	40 (23.0)
50 to <60	32 (36.4)	25 (29.1)	57 (32.8)
60 to <70	11 (12.5)	17 (19.8)	28 (16.1)
≥70	1 (1.1)	1 (1.2)	2 (1.1)
Years, median (range)	49.5 (25.0-74.0)	49.5 (23.0-76.0)	49.5 (23.0-76.0)
Menopausal status, No. (%)			
Premenopausal	53 (60.2)	50 (58.1)	103 (59.2)
Postmenopausal	35 (39.8)	36 (41.9)	71 (40.8)
Tumor stage by sonography, No. (%)			
cT1	40 (45.5)	38 (44.2)	78 (44.8)
cT2	41 (46.6)	45 (52.3)	86 (49.4)
cT3	4 (4.5)	2 (2.3)	6 (3.4)
cT4	3 (3.4)	1 (1.2)	4 (2.3)
Nodal stage by sonography, No. (%)			
cN0	59 (68.6)	59 (68.6)	118 (68.6)
cN1	20 (23.3)	22 (25.6)	42 (24.4)
cN2	5 (5.8)	3 (3.5)	8 (4.7)
cN3	2 (2.3)	2 (2.3)	4 (2.3)
Missing	2	0	2
Breast cancer stage, No. (%)			
<Stage IIA	32 (36.4)	29 (33.7)	61 (35.1)
≥Stage IIA	56 (63.6)	57 (66.3)	113 (64.9)
Sentinel node biopsy, No. (%)			
None	62 (70.5)	67 (77.9)	129 (74.1)
Negative	22 (25.0)	16 (18.6)	38 (21.8)
Positive	4 (4.5)	3 (3.5)	7 (4.0)
Tumor grading, No. (%)			
G1	0 (0.0)	0 (0.0)	0 (0.0)
G2	14 (15.9)	15 (17.4)	29 (16.7)
G3	74 (84.1)	71 (82.6)	145 (83.3)
Histologic tumor type, No. (%)			
Ductal or ductal-lobular invasive	69 (78.4)	71 (82.6)	140 (80.5)
Lobular invasive	1 (1.1)	1 (1.2)	2 (1.1)
Other	18 (20.5)	14 (16.3)	32 (18.4)
Ki-67, %			
<20	5 (5.7)	7 (8.1)	12 (6.9)
>20	83 (94.3)	79 (91.9)	162 (93.1)
Stromal TILs ^a , %, No. (%)			
0-10	34 (38.6)	32 (37.2)	66 (37.9)
11-59	42 (47.7)	41 (47.7)	83 (47.7)
≥60	12 (13.6)	13 (15.1)	25 (14.4)

(continued on following page)

TABLE 1. Baseline Characteristics (continued)

Parameter	Durvalumab (n = 88)	Placebo (n = 86)	Overall (N = 174)
PD-L1, ^b No. (%)			
Negative	9 (11.5)	11 (13.8)	20 (12.7)
Positive	69 (88.5)	69 (86.2)	138 (87.3)
Missing	10	6	16

NOTE. Data are given as No. (valid %) unless otherwise stated.

Abbreviation: TILs, tumor-infiltrating lymphocytes.

^aStratification factor.

^bPD-L1-positive defined as $\geq 1\%$ of positive tumor cells or TILs (Ventana SP263).

(online only), patients received an additional single dose of durvalumab/placebo (window-phase) before the start of NACT. Durvalumab/placebo once every 4 weeks was administered concurrently with nab-paclitaxel 125 mg/m² once per week for 12 weeks and subsequently with epirubicin/cyclophosphamide once every 2 weeks for four cycles. Stratification was based on baseline stromal (s)TILs (low 0%-10% v intermediate 11%-59% v high 60%-100%). Written informed consent was obtained from all patients. Postoperative therapy was provided at the discretion of the treating investigator.

End Points

As previously reported, the primary end point was pCR (ypTo ypNo).⁴ Secondary time-to-event end points included iDFS, DDFS, and OS, and were analyzed in accordance with the definition used for the first analysis of time-to-event outcomes to maintain comparability of results.¹³ These were defined as the duration in months from random assignment to the occurrence of the first event (detailed definitions of events are provided in the Data Supplement). It should be noted that the study was designed before the NeoSTEEP criteria were published and used end point definitions by STEEP.¹⁴ However, since no progressions before surgery precluding surgery were reported, the presented analysis for iDFS is equivalent to the analysis of event-free survival (EFS) as defined by NeoSTEEP.¹⁵

Statistical Analysis

All analyses were performed on the modified intention-to-treat population, defined as patients who were randomly assigned and started treatment. Final analysis of long-term secondary outcomes was changed per SAP addendum from an initial event-driven to a time-driven analysis after a median follow-up of 3.5 years.⁴ This updated analysis fulfills the original assumption of 25% data maturity in iDFS events for the event-driven analysis, as was defined in the initial SAP. The Kaplan-Meier method was used for estimation of survival probabilities together with their 95% CI. Stratified log-rank test was used for group comparison. HR together with its 95% CI are based on univariate Cox regression models stratified by stromal tumor-infiltrating lymphocytes (sTILs; sTILs low 0%-10% v intermediate 11%-59% v high 60%-100%). Multivariate Cox regression models of the time-to-event end points and subgroup analyses were performed as detailed in

the Data Supplement. No adjustment for multiple comparisons was made. The significance level was set to a two-sided $\alpha = .05$ and analysis is of a hypothesis-generating character. Analyses were performed with SAS (Statistical Analysis Software, Cary, NC), version 9.4, with SAS Enterprise Guide version 8.3.

RESULTS

Baseline Demographics and Patient History

Between June 2016 and October 2017, a total of 235 patients were screened, of whom 174 were randomly assigned. Ultimately, 88 patients in the durvalumab arm and 86 patients in the placebo arm started treatment, as shown in the Data Supplement (Fig S1) and as previously reported.⁴ Baseline characteristics are summarized in Table 1.

Updated Analysis of OS, DDFS, and iDFS

The analysis was conducted after a median follow-up of 86.4 months (range, 4.9-103 months). During the follow-up period, only seven deaths in the durvalumab arm compared with 19 deaths in the placebo arm were recorded, corresponding to 7-year OS rates of 91.6% (95% CI, 81.8 to 96.2) versus 74.7% (95% CI, 63.0 to 83.1), respectively. Based on univariate analysis, a statistically significant improvement in OS was observed (HR, 0.33 [95% CI, 0.14 to 0.79]; log-rank $P = .0085$; Fig 1A).

Among the 50 patients with an iDFS event, distant relapse was the most frequently observed first event, occurring in 22 patients (nine in the durvalumab arm v 13 in the placebo arm). A summary of events in both arms is presented in the Data Supplement (Table S1). Thus, a sustained statistically significant improvement in iDFS was observed for durvalumab versus placebo. Estimated 7-year rates were 73.7% (95% CI, 61.4 to 82.6) with durvalumab and 60.7% (95% CI, 48.2 to 71.0) with placebo (HR, 0.56 [95% CI, 0.32 to 0.99]; log-rank $P = .043$; Fig 1B).

Additionally, statistically significant improvements in DDFS were maintained. Seven-year DDFS rates were 81.6% (95% CI, 70.0 to 89.0) with durvalumab and 62.9% (95% CI, 50.3 to 73.1) with placebo (HR, 0.41 [95% CI, 0.21 to 0.8]; log-rank $P = .007$; Fig 1C).

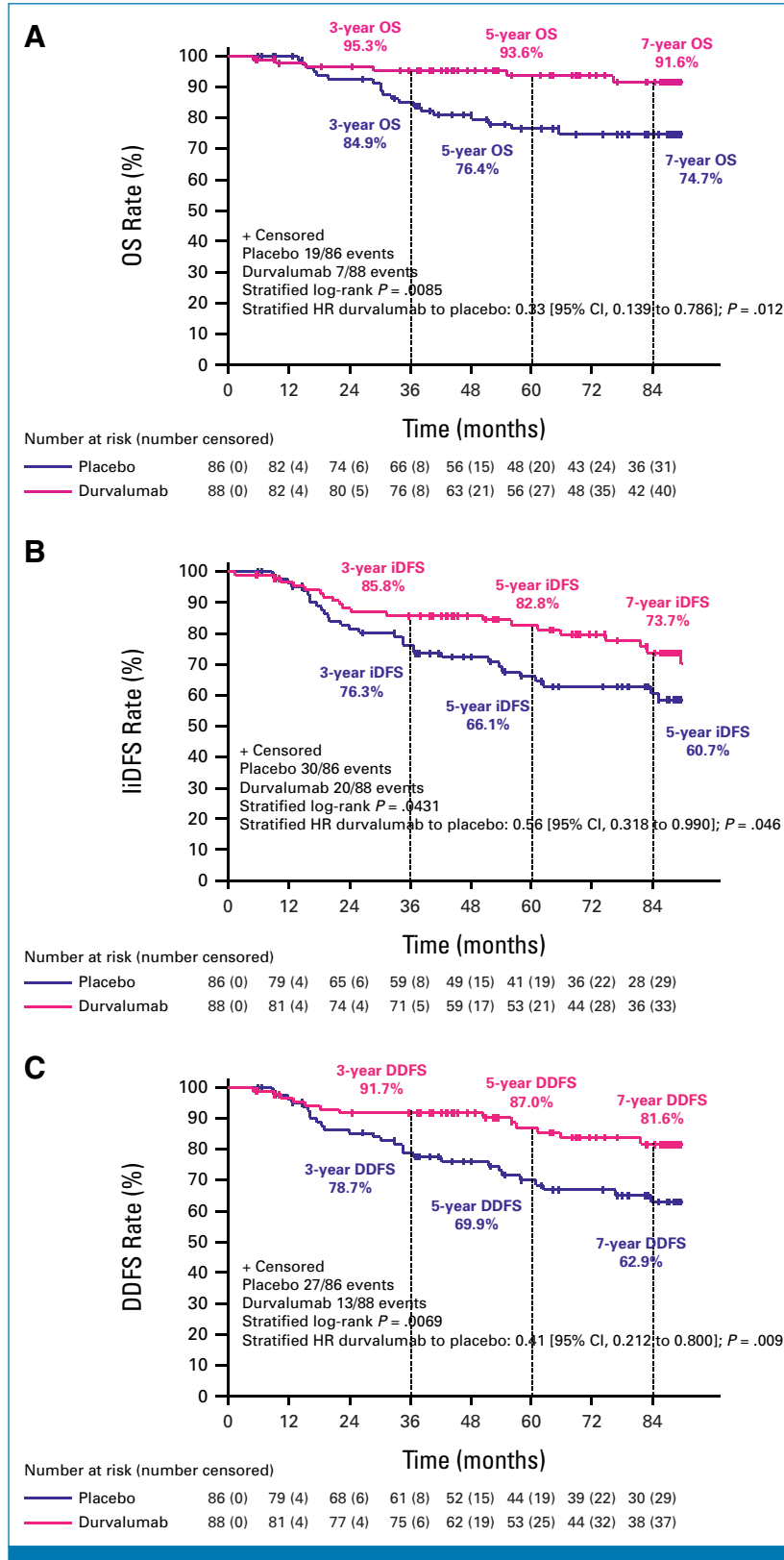


FIG 1. Kaplan-Meier curve for (A) OS, (B) iDFS, and (C) DDFS per treatment arm. DDFS, distant-disease-free survival; HR, hazard ratio; iDFS, invasive disease-free survival; OS, overall survival.

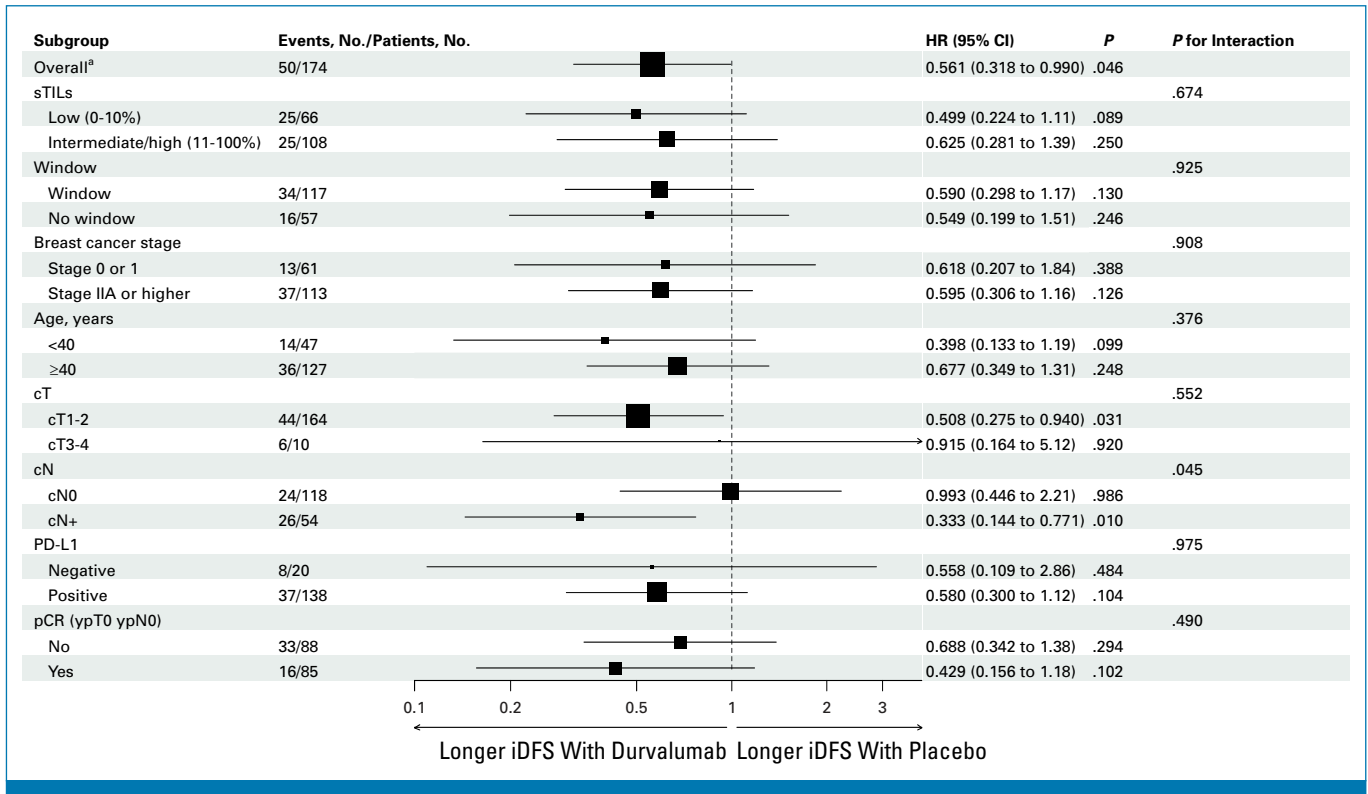


FIG 2. Forest plot of treatment effect on iDFS in subgroups. ^aThe overall HR was stratified by sTILs. Of note, stratification factor sTILs is included as binary parameter in the subgroup analysis because of the only three events reported in the high (60%-100%) sTILs group. HR, hazard ratio; iDFS, invasive disease-free survival; pCR, pathologic complete response; sTILs, stromal tumor-infiltrating lymphocytes.

In multivariate Cox regression analyses adjusting for the stratification factor sTILs, nodal involvement, tumor grade, and with or without pCR status, both DDFS and OS remained significantly improved with durvalumab. Notably, a statistically significant improvement in iDFS was observed only in the model without adjustment for pCR (Data Supplement, Tables S2 and S3).

Among pCR patients, risk for a DDFS event was reduced by 61% compared with non-pCR patients. Within the durvalumab arm, there were less reported DDFS events for pCR as well as non-pCR patients, resulting in 7-year DDFS rates of 90.3% (72.4%-96.8%) for pCR patients versus 71.1% (50.7%-84.2%) for placebo, and 73.2% (54.2%-85.3%) for non-pCR patients versus 55.6% (38.7%-69.6%) for placebo. Moreover, analyses for patients with and without pCR indicated a favorable effect of durvalumab compared with placebo on iDFS and OS irrespective of the extent of pathologic response, with no OS events reported for pCR patients (Data Supplement, Table S4).

Irrespective of the treatment arm, patients with intermediate and high sTILs (11%-100%) at baseline showed significantly improved iDFS compared with those with low sTILs (0%-10%; HR, 0.55 [95% CI, 0.32 to 0.96]; log-rank $P = .033$). In non-pCR patients, sTILs in the residual disease (RD) could be assessed in 39 of 71 patients. Post hoc analyses by sTILs >10% versus ≤10% in the RD showed estimated

7-year iDFS rates of 92.3% (95% CI, 56.6 to 98.9) with high sTILs versus 51.4% (95% CI, 29.2 to 69.7) with low sTILs, with no iDFS event reported in the high sTILs group within the durvalumab arm (Data Supplement, Fig S2).

As shown in Figure 2, exploratory subgroup analysis indicated greater iDFS benefit of durvalumab in patients with nodal involvement at baseline (HR, 0.33 [95% CI, 0.144 to 0.771]; $P = .01$; $P_{interaction} = 0.045$). However, this effect is no longer visible in the subgroup analysis for DDFS and OS (Data Supplement, Fig S3). Regarding the other subgroups of interest as defined in the Data Supplement, the results confirmed those shown for the overall population for iDFS, DDFS, and OS.

DISCUSSION

To our knowledge, the GeparNuevo trial was the first trial to demonstrate an improved overall survival by adding a CPI to NACT for eTNBC. A significant improvement in all long-term survival outcomes with durvalumab compared with placebo was demonstrated among patients with TNBC cT1b-cT4a-d. Most notably, the benefit was achieved without adjuvant continuation of CPI and seen in all relevant subgroups, including stage I patients, and irrespective of the extent of pathologic response.

After a median follow-up of 86.4 months (range, 4.9-103 months), an OS event was reported in only 8.0% patients

who received durvalumab versus 22.1% with placebo. These results demonstrated excellent survival outcomes even in the absence of adjuvant CPI treatment. The exploratory subgroup analysis confirmed the overall results. However, patients with baseline nodal involvement showed a statistically significant improvement in iDFS with durvalumab compared with placebo ($P_{interaction} = 0.045$). This is comparable with data from the NSABP-B59/GeparDouze study, where significant atezolizumab effect was seen in cN+ but not cN0 patients ($P_{interaction} = 0.039$).¹⁶ This trend could not be confirmed for DDFS and OS in our study.

Despite key differences between KEYNOTE-522¹⁷ and GeparNuevo, namely percentage of patients with stage I TNBC (0% v 35%), use of carboplatin (yes v no), application of anthracyclines (once every 3 weeks v once every 2 weeks, ie, dose-dense), type of paclitaxel (solvent-based v albumin-bound), and type of CPI investigated (PD-1 inhibitor v PD-L1 inhibitor), both studies demonstrated sustained OS benefit with CPI-containing therapy, alongside remarkable consistency in 5-year EFS/iDFS. With a comparable median follow-up of 75.1 months (range, 65.9–84.0), KEYNOTE-522 reported an 81.2% EFS and GeparNuevo 82.8% iDFS with CPI, and 72.2% versus 66.1% in the placebo arm, respectively. Moreover, patients with stage I disease, an excluded cohort in KEYNOTE-522, showed excellent survival outcome, with no reported deaths within the durvalumab arm. Additionally, within this subgroup of stage I patients, HRs for iDFS and DDFS were consistent with the overall population, indicating treatment benefit from CPI. This raised the general question whether a CPI as sole treatment in the preoperative setting without the need for adjuvant administration would be sufficient.

The NSABP B-59/GBG-96-GeparDouze trial used a design similar to KEYNOTE-522, but with the PD-L1 inhibitor atezolizumab as neoadjuvant and adjuvant therapy, and demonstrated a small but statistically not significant improvement in EFS (HR, 0.8 [95% CI, 0.62 to 1.03]; log-rank

$P = .08$).¹⁶ One could argue that patients in the NSABP B-59/GBG-96-GeparDouze trial received adequate, for example, dose-dense and platinum-containing NACT, such that the addition of atezolizumab did not contribute to improved survival outcomes. However, all patients in GeparNuevo received dose-dense anthracycline and a potentially superior taxane (nab-paclitaxel).¹⁷ Nevertheless, GeparNuevo demonstrated an improvement in survival outcomes with durvalumab even as neoadjuvant therapy only.

Our study has also indicated that patients with baseline nodal involvement appeared to derive greater iDFS benefit from durvalumab. These findings align with the results from NSABP B-59/GBG-96-GeparDouze trial, which suggested a benefit of atezolizumab over placebo in node-positive patients only.¹⁸ In KEYNOTE-522, the effect was seen regardless of clinical nodal involvement. Whether this is a real effect needs to be investigated in translational studies.

Results from KEYNOTE-522 led to the approval of pembrolizumab in combination with NACT in \geq stage II eTNBC, and, due to the design of the trial, for the adjuvant continuation of pembrolizumab for nine cycles irrespective of the extent of pathologic response.^{19,20} This is currently the standard of care for patients with stage IIA and higher eTNBC.²¹ However, the results of GeparNuevo challenge this standard as, to our knowledge, GeparNuevo is the first randomized trial to demonstrate a survival benefit with neoadjuvant-only CPI. In IMpassion031, a significant improvement in pCR (58% v 41%) did not translate into a statistically significant survival benefit,²² while NeoTRIP suggested potential improvements in EFS in later analyses.²³

Taken together, GeparNuevo stands out as, to our knowledge, the first trial to indicate that durable survival benefit can be achieved without adjuvant continuation of CPI irrespective of the extent of pathologic response, thereby prompting the initiation of trials investigating whether the continuation of CPI after surgery is necessary.

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PRIOR PRESENTATION

Presented in part at the European Society For Medical Oncology 2025 Congress 2025, Berlin, Germany, October 17-21, 2025.

SUPPORT

Supported by AstraZeneca and Celgene (a BMS company).

CLINICAL TRIAL INFORMATION

[NCT02685059](https://clinicaltrials.gov/ct2/show/study/NCT02685059)

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI <https://doi.org/10.1200/JCO-25-02311>.

DATA SHARING STATEMENT

A data sharing statement provided by the authors is available with this article at DOI <https://doi.org/10.1200/JCO-25-02311>.

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Manuscript writing: All authors

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ACKNOWLEDGMENT

The authors thank all patients and their families, the neoadjuvant Subboard of GBG and AGO-B and the IDMC for their continuous support and the team at the GBG Headquarters including data management, monitoring, statistics, project management, and medical writing. The authors thank AstraZeneca and Celgene (BMS company) for drug and financial support.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Durvalumab in Combination With Neoadjuvant Chemotherapy in Early Triple-Negative Breast Cancer: Long-Term Analysis From the GeparNuevo Trial

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No other potential conflicts of interest were reported.