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Research Article

Pembrolizumab in Combination with Paclitaxel for Platinum-Resistant Epithelial Ovarian, Fallopian Tube, and Primary Peritoneal Carcinoma: Clinical Evidence, Regulatory Approval and Therapeutic Implications

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Abstract

Background: Primary peritoneal carcinoma, fallopian tube cancer, and platinum-resistant epithelial ovarian cancer are aggressive cancers with few treatment choices and a dismal prognosis. In a variety of solid malignancies, immune checkpoint medications that target the programmed death receptor-1 (PD-1) have demonstrated encouraging activity.

Objectives: To examine the clinical effectiveness, safety, and therapeutic implications of pembrolizumab in combination with paclitaxel, with or without bevacizumab, for platinum-resistant ovarian cancers that express programmed death-ligand 1 (PD-L1). This approval was recently made by the US Food and Drug Administration (FDA).

Methods: Reviewed KEYNOTE-B96 (NCT05116189) clinical trial data, prescription information, and regulatory announcements. Progress-free survival (PFS) and overall survival (OS), as determined by the RECIST v1.1 criteria, were key effectiveness goals.

Results: PFS was 8.3 months in the pembrolizumab arm and 7.2 months in the placebo arm for patients with PD-L1 combination positive score (CPS) ≥1 (HR 0.72; $p = 0.0014$). 18.2 months and 14.0 months, respectively, were the median OS (HR 0.76; $p = 0.0053$). The safety profile aligned with immune-related side effects linked to PD-1 inhibitors that have been documented before.

Conclusion: The treatment of platinum-resistant ovarian tumors has advanced clinically with the approval of pembrolizumab in combination therapy. PD-L1 CPS-based biomarker-driven patient selection improves precision oncology methods and could lead to better survival rates in this high-risk group.

Abbreviations (Alphabetical)

CPS: Combined Positive Score; FDA: Food and Drug Administration; OS: Overall Survival; PD-1: Programmed Death Receptor-1; PD-L1: Programmed Death-Ligand 1; PFS: Progression-Free Survival; RECIST: Response Evaluation Criteria in Solid Tumors

Introduction

When platinum-based chemotherapy is finished, the illness progresses within six months, which is known as platinum-resistant epithelial ovarian cancer. A poor prognosis and a limited response to further therapy are linked to these cancers. With only small survival improvements, non-platinum cytotoxic medicines, including topotecan, liposomal

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doxorubicin, and paclitaxel, are typically used as standard therapy alternatives.

The treatment of several cancers has changed as a result of immune checkpoint suppression that targets the programmed death receptor-1 (PD-1). By preventing PD-1 from interacting with its ligands PD-L1 and PD-L2, pembrolizumab, a humanized monoclonal antibody against PD-1, improves T-cell-mediated anticancer immune responses.

For adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma expressing PD-L1 (CPS ≥1), the FDA approved pembrolizumab, including its subcutaneous formulation with berahyaluronidase alfa-pmph, using paclitaxel with or without bevacizumab on February 10, 2026. The regulatory implications and supporting clinical evidence are covered in this review.

Materials and methods

This article is presented as a narrative, regulatory and clinical evidence review evaluating the approval of pembrolizumab in combination with paclitaxel for platinum-resistant ovarian cancers.

A literature search was conducted using the electronic databases PubMed, Google Scholar, ClinicalTrials.gov, and FDA regulatory announcements between January 2018 and February 2026. The search strategy included the keywords:

pembrolizumab, *paclitaxel*, *ovarian cancer*, *PD-1 inhibitor*, *PD-L1*, *immune checkpoint inhibitors*, *platinum-resistant ovarian cancer*, and *KEYNOTE-B96*.

Articles were included if they:

- Reported clinical trials involving pembrolizumab or PD-1 inhibitors.
- Evaluated immunotherapy in ovarian cancer.
- Provided regulatory or clinical evidence related to the KEYNOTE-B96 trial.

Regulatory documents from the U.S. Food and Drug Administration (FDA) and clinical trial registry data from ClinicalTrials.gov were also reviewed. Relevant clinical outcomes, including progression-free survival (PFS) and overall survival (OS), were extracted and summarized.

Results

Clinical trial design

643 patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who had undergone one or two previous systemic treatments were enrolled in the multicenter, randomized, double-blind, placebo-controlled phase III trial known as KEYNOTE-B96.

Patients were assigned at random 1:1 to:

- Paclitaxel + bevacizumab + pembrolizumab

OR

- Paclitaxel + placebo ± bevacizumab

Efficacy Outcomes (PD-L1 CPS ≥1; *n* = 466)

- Median PFS:

8.3 months (95% CI: 7.0 – 9.4) *vs.* 7.2 months

HR 0.72 (95% CI: 0.58 – 0.89), $p = 0.0014$

- Median OS:

18.2 months *vs.* 14.0 months

- HR 0.76 (95% CI: 0.61 – 0.94), $p = 0.0053$

These results show that both PFS and OS have improved statistically significantly.

Trial	Population	Treatment Arms	Median PFS	Median OS	Hazard Ratio
KEYNOTE-B96	Platinum-resistant ovarian cancer (PD-L1 CPS ≥1)	Paclitaxel + Pembrolizumab ± Bevacizumab	8.3 months	18.2 months	HR 0.72 (PFS)
Control	Same population	Paclitaxel + Placebo ± Bevacizumab	7.2 months	14.0 months	HR 0.76 (OS)

Trial design considerations and limitations

The KEYNOTE-B96 study was a randomized, double-blind, placebo-controlled phase III trial that enrolled 643 patients with platinum-resistant ovarian, fallopian tube, or primary peritoneal carcinoma. Patients received paclitaxel-based chemotherapy with or without pembrolizumab and optional bevacizumab.

Although the study demonstrated statistically significant improvements in progression-free survival and overall survival, several limitations should be acknowledged. Patient heterogeneity in terms of prior treatments and tumor biology may influence treatment outcomes. Additionally, the trial population was limited to patients with PD-L1 CPS ≥1, which may limit generalizability to broader ovarian cancer populations.

Comparison with earlier immunotherapy trials, such as KEYNOTE-100 and JAVELIN Ovarian 200, suggests that checkpoint inhibitors demonstrate modest activity as monotherapy, highlighting the importance of combination treatment strategies [1-5].

Discussion

Pembrolizumab offers a clinically significant survival benefit when combined with paclitaxel-based treatment for platinum-resistant ovarian cancers that express PD-L1. Longer survival and better disease control are indicated by the decreases in the hazard ratios in both PFS and OS.

Crucially, the need for PD-L1 CPS ≥1 guarantees biomarker-

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guided patient selection, which is consistent with precision oncology tactics. Therapeutic targeting is strengthened by the companion diagnostic approval of PD-L1 IHC 22C3.

The safety profile aligned with known immune-mediated side effects linked to PD-1 inhibitors, such as pneumonitis, immune-mediated endocrinopathies, and responses related to infusion.

This Project Orbis approval is indicative of growing international regulatory cooperation in the assessment of cancer drugs.

PD-1/PD-L1 immune checkpoint pathway

The programmed death receptor-1 (PD-1) is an inhibitory receptor expressed on activated T lymphocytes. Interaction of PD-1 with its ligands PD-L1 and PD-L2, which are frequently overexpressed on tumor cells and tumor-infiltrating immune cells, leads to suppression of T-cell activation and promotes immune tolerance within the tumor microenvironment.

Cancer cells exploit this pathway as a mechanism of immune evasion, allowing tumors to escape immune-mediated destruction. PD-1 inhibitors such as pembrolizumab block this interaction, restoring cytotoxic T-cell function and enhancing anti-tumor immune responses.

The combined positive score (CPS) is a clinically validated biomarker used to quantify PD-L1 expression. CPS reflects PD-L1 expression on both tumor cells and immune cells within the tumor microenvironment and is calculated as the number of PD-L1-positive cells divided by the total number of viable tumor cells. Higher CPS values have been associated with improved response rates to PD-1 blockade therapies in several malignancies.

Clinical relevance of hazard ratios

While the improvements in PFS and OS were modest in absolute terms, the hazard ratios indicate a meaningful reduction in the risk of disease progression and death. In the context of platinum-resistant ovarian cancer, where therapeutic options remain limited and survival outcomes are generally poor, even incremental improvements in survival may represent clinically relevant benefits. However, further long-term follow-up and real-world studies are necessary to determine whether PD-L1 CPS ≥1 represents the optimal biomarker threshold for treatment selection.

Conclusion

An important therapeutic development for platinum-resistant ovarian tumors that express PD-L1 is the combination of pembrolizumab and paclitaxel. Its inclusion in treatment recommendations for qualified patients is supported by the shown increases in progression-free and overall survival.

Recent advances in ovarian cancer research highlight the importance of genomic biomarkers in predicting immunotherapy response. Tumor mutation burden (TMB), BRCA1/BRCA2 mutations, and homologous recombination deficiency (HRD) have been investigated as potential predictors of response to immune checkpoint inhibitors.

BRCA-mutated tumors often exhibit increased genomic instability and neoantigen formation, which may enhance immune recognition and improve response to immunotherapy. In addition, genomic profiling approaches that integrate PD-L1 expression, TMB, and DNA repair gene alterations may help optimize biomarker-driven patient selection strategies in ovarian cancer treatment.

Authors' contributions

SN was responsible for the manuscript's conception, literature review, clinical data analysis, and final manuscript drafting. The author attests that no AI-assisted techniques were employed in data analysis or scientific interpretation. The final version was approved by the author.

Data availability statement

This published article contains all of the data that was analyzed during the investigation.

Ethical approval

Not relevant. Data from clinical trials and publicly accessible regulations served as the basis for this investigation.

Consent to publication

The author attests that this work is unique, hasn't been published before, and isn't being considered by anyone else.

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