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Nivolumab versus gemcitabine or pegylated liposomal doxorubicin for patients with platinum-resistant (advanced or recurrent) ovarian cancer: Open-label, randomized trial in Japan (NINJA trial)

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Background

Nivolumab, a human anti-programmed death-1 (PD-1) receptor monoclonal antibody, is effective against some cancers. A phase II trial has supported the efficacy of nivolumab in platinum-resistant ovarian cancer, but a randomized trial is required to confirm its efficacy. This multicenter, open-label, randomized, phase III study investigated the efficacy and safety of nivolumab vs gemcitabine or pegylated liposomal doxorubicin (GEM/PLD) in platinum-resistant ovarian cancer.

Methods

Patients aged ≥20 years with platinum-resistant (advanced or recurrent) ovarian cancer and no prior GEM/PLD treatment were randomized (1:1) to nivolumab (240 mg intravenously [IV], every 2 weeks) or GEM/PLD (GEM 1000 mg/m^2 IV for 30 minutes on days 1, 8, and 15, then every 4 weeks; or PLD 50 mg/m^2 IV every 4 weeks) after stratifying for histological type (clear cell carcinoma vs others) and number of prior chemotherapy regimens after diagnosis of resistance (0 or 1). Treatment continued until disease progression or unacceptable toxicity. Tumor was assessed every 8 weeks through week 48, then every 12 weeks. Primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS) and safety.

Results

Of 316 patients randomized, 77.8% had ≥2 prior chemotherapies and 14.2% had ECOG PS score of 1. Median OS was 10.12 (95% confidence interval [CI], 8.34-14.09) months with nivolumab (n=157) and 12.09 (95% CI, 9.26-15.34) months with GEM/PLD (n=159), with no statistically significant difference between the groups (hazard ratio [HR] 1.03, 95% CI, 0.80-1.32; *P*=0.808). Median PFS was 2.04 (95% CI, 1.91-2.20) months with nivolumab and 3.84 (95% CI, 3.58-4.17) months with GEM/PLD (HR 1.46; 95% CI, 1.15-1.85; *P*=0.002). The rate of treatment-related grade 3/4 adverse events (AEs) was 22.4% with nivolumab and 68.4% with GEM/PLD; the major AEs (all grades) with nivolumab were diarrhea (15.4%), nausea, pruritus and rash (12.2% each). There was no difference in the toxicity profile of nivolumab from that previously reported.

Conclusions

Nivolumab did not improve OS compared with GEM/PLD in patients with platinum-resistant ovarian cancer.

Clinical trial identification

JapicCTI-153004.

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