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Iparomlimab and tucunarlimab (QL1706) plus chemotherapy with or without bevacizumab as first-line treatment for persistent, recurrent, or metastatic cervical cancer (R/M CC): Results from a double-blind, randomized, placebo-controlled phase 3 trial

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Background

QL1706, a bifunctional antibody targeting PD-1 and CTLA-4, has been approved by China's NMPA for patients (pts) with R/M CC who failed prior platinum-based chemotherapy.

Methods

In this multi-center, double-blind, randomized, placebo-controlled phase 3 trial, eligible pts who had not received systemic anti-tumor treatment were randomized 1:1 to receive QL1706 (5 mg/kg) or placebo plus paclitaxel-cisplatin/carboplatin with or without bevacizumab (15 mg/kg) every 3 weeks for six cycles, followed by maintenance therapy every 3 weeks for up to 2 years. Stratification factors were use of bevacizumab (yes or no), previous concurrent chemoradiotherapy (CCRT; yes or no), and PD-L1 CPS (<1, 1≤CPS<10, or ≥10). The primary endpoints were progress-free survival (PFS) per RECIST v1.1 assessed by blinded independent central review and overall survival (OS).

Results

As of Jan 16, 2026, 492 pts were randomized to QL1706 group (n=243) and placebo group (n=249). Majority of pts (80.9%) had CPS of ≥1. Nearly half (48.4%) of pts had received CCRT previously. Bevacizumab was administered in 188 pts (77.4%) and 187 pts (75.1%), respectively. Median PFS was 12.35 months (95% CI: 9.53-15.21) in the QL1706 group and 7.75 months (95% CI: 6.51-8.31) in the placebo group (hazard ratio [HR]=0.64, 95% CI: 0.51-0.81; p=0.0001). Median OS was 30.95 months (95% CI: 24.94-not evaluable (NE)) in the QL1706 group and 21.78 months (95% CI: 18.14-25.69) in the placebo group (HR=0.73, 95% CI: 0.57-0.93; P=0.0101). The PFS and OS benefits favored QL1706 over placebo regardless of age, distant metastasis, prior CCRT, PD-L1 expression, or bevacizumab administration. Treatment-related adverse events (TRAEs) occurred in 98.8% of pts in the QL1706 group and 99.2% in the placebo group, including grade ≥3 TRAEs of 80.6% and 75.9%, respectively.

Conclusions

QL1706 plus chemotherapy with or without bevacizumab demonstrated significantly prolonged PFS and OS in pts with persistent, recurrent, or metastatic cervical cancer. The safety profile of the combination was manageable with no new safety signal.

Clinical trial identification

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Legal entity responsible for the study

The authors.

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Disclosure

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