Abstract 1279

Long Term Overall Survival Follow-up of Toripalimab versus Placebo in Combination with Gemcitabine and Cisplatin as First-line Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma

Type: Abstract

Topic: Head and neck cancer, excluding thyroid

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Background

Toripalimab plus Gemcitabine-Cisplatin (GP) as a first-line treatment for recurrent or metastatic (RM) NPC has been approved in more than forty countries based on the results of the JUPITER-02 study (NCT03581786), in which significant overall survival benefits were demonstrated with the addition of toripalimab to chemotherapy. Here we present the long-term overall survival results, as well as a sensitivity analysis evaluating the impact of post-progression immunotherapy on survival.

Methods

RM-NPC patients were randomized to receive toripalimab 240 mg (n=146) or placebo (n=143) in combination with GP once every 3 weeks (Q3W) for up to 6 cycles, followed by toripalimab or placebo Q3W until disease progression, intolerable toxicity, or maximum of 2-year of treatment. Stratification factors were ECOG performance (0 *vs.* 1) and disease status (recurrent *vs.* primary metastatic). The primary endpoint was PFS by an independent review committee and OS was a key secondary endpoint.

Results

As of June 24, 2025, 68 months after the last enrollment, 156 deaths have occurred. The median OS was 64.8 months in the toripalimab arm and 33.7 months in the placebo arm. The hazard ratio (HR) was 0.62 (95% CI: 0.45-0.85), nominal p=0.0027. For patients who experienced disease progression, 43% received later-line immunotherapy. Sensitivity analyses were conducted to further assess the impact of post-progression immunotherapy on survival. Among the intent-to-treat population, after adjusting for post-progression anti-PD-

(L)1 therapy, the HR was 0.52 (95% CI: 0.38-0.72), median OS 61.0 vs. 25.1 months in the toripalimab and placebo arms respectively. The improved HR of the sensitivity analysis over the unadjusted analysis suggests that post-progression immunotherapy had more favorable effect on survival in the placebo arm.

Conclusions

Toripalimab plus GP chemotherapy demonstrated significant survival benefits over GP alone as a first-line treatment for RM-NPC. The median OS reached 64.8 months in the toripalimab arm, with a 31-month improvement over GP alone. Toripalimab plus GP chemotherapy represents the new standard care for patients with RM-NPC.

Clinical trial identification

NCT03581786

Editorial acknowledgement

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