RATIONALE-309: Effects of Tislelizumab on Health-Related Quality of Life (HRQoL) in Patients with Recurrent or Metastatic Nasopharyngeal Cancer (R/M NPC)

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Background

In RATIONALE-309 (NCT03924986), tislelizumab with gemcitabine and cisplatin (GP) improved progression-free survival, objective response rate, and duration of response compared to placebo +GP in patients receiving first-line treatment for R/M NPC. This study evaluated HRQoL in the intent-to-treat (ITT) population and post-hoc analysis examined HRQoL in patients with liver metastases (LM) subgroup, a negative prognostic factor of overall and cancer-specific survival in patients with NPC.

Methods

Eligible patients in this double-blind, Phase 3 study were randomized 1:1 to tislelizumab +GP (Arm A) or placebo +GP (Arm B). HRQoL was evaluated using EORTC QLQ-C30 and QLQ Head and Neck Cancer module (H&N35). Mean changes from baseline to cycles 4 and 8 were estimated based on linear mixed effects model for repeated measures. Time to deterioration (TTD) was compared between treatment arms using a stratified Cox proportional hazard model. Nominal p-values are reported for descriptive purposes.

Results

All 263 randomized patients (Arm A n=131, Arm B n=132) comprised the ITT population; 43% of them (Arm A n=56; Arm B n=57) were diagnosed with LM. No differences in change from baseline to cycle 4 between the arms were observed for the ITT patients or LM subgroup. Greater reduction from baseline to cycle 8 were observed in Arm A vs Arm B in QLQ-H&N35 pain score (-2.82 vs -0.45, p=0.0117 for ITT population; -3.85 vs -0.05, p=0.0092 for LM subgroup) and sense score (-2.86 vs -0.01 for ITT population; -6.16 vs 1.03, p=0.0338 for LM subgroup). Greater improvement at cycle 8 in Arm A in QLQ-H&N35 symptoms index score (-3.62 vs -1.40, p=0.0580) and restrictions in speech (-2.43 vs 0.41, p=0.0694) for LM subgroup were observed. Differences in TTD were not observed.

Discussion

Patients treated with tislelizumab +GP had greater improvements in symptoms than patients treated with placebo +GP. LM patients experienced a greater reduction in overall symptoms, pain, and problems associated with senses. These results, along with improved survival and an acceptable safety profile, suggest tislelizumab +GP represents a potential first-line treatment option for patients with R/M NPC.

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