Patient-reported outcomes (PROs) in recurrent or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN) treated with nivolumab (nivo) or investigator’s choice (IC): CheckMate 141


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Background: Patients (pts) with platinum-refractory R/M SCCHN have median survival ≤6 mo and suffer from their disease and its treatment. Accordingly, maintaining quality of life (QoL) is a key treatment goal. PRO data were collected as exploratory endpoints in CheckMate 141 (NCT02105636), a randomized, open-label, phase 3 trial comparing nivo to IC (methotrexate, docetaxel, or cetuximab) in 361 pts with platinum-refractory R/M SCCHN. We report the first comparative results for PRO for nivo and IC in R/M SCCHN.

Methods: The European Organisation for Research and Treatment of Cancer QoL Questionnaire (EORTC QLQ-C30), EORTC Head and Neck Cancer module (QLQ-H&N35), and EQ-5D were administered at baseline (BL), wk 9, and then at 6-wk intervals during treatment. A clinically relevant score change or difference was regarded as 10 points for the EORTC subscales. Analysis of covariance (ANCOVA) was applied to compare mean score changes between arms. Proportional hazards regression was used to evaluate time to clinically relevant score deterioration (TTD).

Results: BL questionnaire completion rates for nivo and IC were ~80% and ~75%, respectively. Low IC completion rates precluded analysis of mean differences after wk 15. Overall, 129 pts completed a PRO measure at BL and during follow up. Nivo significantly delayed TTD (P < 0.05, 2-tailed) vs IC for global health; physical, role, cognitive, and social functioning; fatigue; dyspnea; and insomnia (EORTC QLQ-C30) as well as pain; sensory problems; and mouth opening problems (QLQ H&N35).

ANCOVA revealed statistically significant, clinically relevant differences favoring nivo at wks 9 and 15 for role and social functioning, fatigue, dyspnea, and appetite loss (EORTC QLQ-C30) as well as pain and sensory problems (QLQ H&N35). Differences in mean values were observed for other PROs at wk 15 only.

Conclusions: Pts treated with nivo had delayed worsening of functioning and symptoms with PRO differences between arms favoring nivo up to ~4 mo of follow up. These results, as assessed through wk 15, suggest that pts receiving nivo maintained functioning for longer and had less pain, fatigue, and dyspnea on treatment as compared with IC.

Clinical trial identification: NCT02105636; Study start date, May 2014

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