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Title: Tislelizumab Plus Standard Chemotherapy for Treatment of Advanced Squamous Non-Small Cell Lung Cancer: Patients' Health Related Quality of Life

Introduction

Squamous non-small cell lung cancer (SQ NSCLC) accounts for 20% to 30% of lung cancer. SQ NSCLC patients treated with chemotherapy experience substantial reductions in health-related quality of life (HRQoL). The objective of the current study was to assess whether the addition of tislelizumab to first-line standard-of care chemotherapy could improve HRQoL of patients with advanced and metastatic squamous NSCLC.

Methods

Patients in this open-label, randomized, multicenter Phase 3 study conducted in China were randomized to 3 arms: tislelizumab combined with carboplatin and paclitaxel (Arm A), tislelizumab combined with carboplatin and *nab*-paclitaxel (Arm B), or paclitaxel plus carboplatin alone (Arm C). The primary endpoint was progression-free survival (PFS) by IRC in the comparisons of Arms A vs C and B vs C. HRQoL was also evaluated using the EORTC QLQ-C30 and EORTC QLQ-LC13 at baseline and while on treatment (i.e. at every other cycle through Cycle 13, then every 4 cycles thereafter, and at the end of treatment). HRQoL data were collected in all three arms at baseline, cycles 3 and 5 while Arms A and B also completed HRQoL questionnaires up to cycle 17 in this data cut (12/6/2019). The analyses for this report are focused on baseline through cycle 5 for which, all the three arms completed the HRQoL questionnaires.

Results

A total of 360 patients diagnosed with squamous NSCLC were randomized (n=120, Arm A; n=119, Arm B; n=121, Arm C). Patients were 91.7% male with a median age of 62 years (range 34, 74). Demographics and baseline characteristics were comparable across the 3 treatment arms and were representative of the target patient population. The global health status/QoL scores of the QLQ-30 improved for both Arms A [mean change=2.8 (SD=23.2)] and B [mean change=3.9 (SD=18.00)] by cycle 5, whereas it declined in Arm C [mean change=-1.3 (SD=19.4)]. For the symptoms measured by QLQ-LC13, Arm A [mean change = -20.1 (SD =

29.2)] and B [mean change = -12.7 (SD = 33.8)] both experienced a larger reduction in coughing symptoms at cycle 5 compared to Arm C [mean change = -7.3 (23.2)]. For dyspnea, change from baseline at cycle 5, both Arms A [mean -1.9 (SD = 18.1) and B [(mean change = -1.8 (SD = 15.2)] experienced a reduction in dyspnea while Arm C [mean change = 2.4 (SD = 15.2)] experienced more symptoms relative to baseline. Finally, all three Arms experienced a reduction in hemoptysis at cycle 5 with the larger reductions observed for Arms A [mean change = -9.4 (19.8)] and B [mean change = -9.4 (SD = 26.8)] compare to C [mean change = -2.3 (SD = 19.4)]. No clinical differences were observed between the three arms in pain items, all three reported reduction in pain symptoms.

Conclusion

The addition of tislelizumab to platinum-based chemotherapy is associated with clinically meaningful improvements in SQ NSCLC patients' HRQoL, especially in general health status/ QoL and most importantly in the lung cancer specific symptoms including coughing, dyspnea and hemoptysis.