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LBA59

First-line nivolumab (NIVO) + ipilimumab (IPI) combined with 2 cycles of platinum-based chemotherapy (chemo) vs 4 cycles of chemo in advanced non-small cell lung cancer (NSCLC): Patient-reported outcomes (PROs) from CheckMate 9LA

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Background

CheckMate 9LA (NCT03215706), a phase III randomized study, met its primary endpoint of improved overall survival with NIVO 360 mg Q3W + IPI 1 mg/kg Q6W + 2 cycles of chemo (n = 361) vs 4 cycles of chemo (n = 358) in patients (pts) with treatment-naive, stage IV/recurrent NSCLC and no known sensitizing *EGFR/ALK* alterations. We present PROs from the study.

Methods

PROs were exploratory endpoints; disease-related symptoms were evaluated using the Lung Cancer Symptom Scale average symptom burden index and 3-item global index (LCSS ASBI/3-IGI); health-related quality of life (HRQoL) was evaluated using EQ-5D-3L visual analog scale and utility index (EQ-5D-3L VAS/UI). Analyses included mean changes from baseline, mixed-effect model repeated measures (MMRM) of longitudinal changes, and time to deterioration.

Results

PRO completion rates were > 80% across arms for most on-treatment assessment time points in which there were ≥ 10 pts (up to week 90 for NIVO + IPI + chemo and week 78 for chemo). A trend for improvement in LCSS ASBI and 3-IGI was seen in both treatment arms, though the minimally important difference was not reached. In both arms, mean EQ-5D-3L VAS scores approached UK population norms after ⊠30 weeks. MMRM analyses showed similar improvement across arms in overall LCSS ASBI when there was a sufficient number of patients in both study arms for assessment (up to week 78). There was a decreased risk of, and delayed time to, definitive deterioration with NIVO + IPI + chemo vs chemo (Table).

Conclusions

Pts with advanced NSCLC treated with NIVO + IPI + chemo (2 cycles) maintained their quality of life as compared with chemo (4 cycles). Pts in the NIVO + IPI + chemo arm had decreased risk of definitive deterioration in HRQoL and symptoms vs chemo.Table: LBA59

Time to deterioration with NIVO + IPI + chemo (2 cycles) vs chemo (4 cycles)

	HR[a] (95% CI)
Time to first deterioration[b]	
LCSS ASBI	1.16 (0.91–1.48)
LCSS 3-IGI	1.10 (0.89–1.36)
EQ-5D-3L VAS	1.07 (0.88–1.30)
EQ-5D-3L UI[d]	0.88 (0.72–1.07)

	HR[a] (95% CI)
Time to definitive deterioration[c]	
LCSS ASBI	0.66 (0.47–0.92)
LCSS 3-IGI	0.66 (0.50–0.88)
EQ-5D-3L VAS	0.73 (0.58–0.93)
EQ-5D-3L UI[d]	0.72 (0.57–0.90)

Includes on-treatment and follow-up. [a]HR < 1 favors NIVO + IPI + chemo over chemo. [b]Time from randomization to when change in PRO score first meets/exceeds deterioration threshold. [c]In addition to initial assessment, all subsequent assessments must meet/exceed the threshold. [d]Based on UK norms.

Clinical trial identification

NCT03215706.

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