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LUNG CANCER

Nivolumab—an effective second-line treatment for NSCLC

Docetaxel is the standard-of-care agent for the treatment of patients with nonsquamous non-small-cell lung cancer (NSCLC) who are refractory to platinum-based first-line chemotherapy regimens. The results of the international phase III CheckMate 057 clinical trial now show that nivolumab has significant benefits over docetaxel.

> “Nivolumab was associated with a significant survival benefit over docetaxel...”

Nivolumab, an antibody that blocks the immune-checkpoint inhibitor programmed cell-death protein 1 (PD-1), has shown promising results in phase I clinical trials for all NSCLC subtypes. The CheckMate 057 trial evaluated the efficacy of this agent in patients with advanced-stage (stage IIIB, IV or recurrent) nonsquamous NSCLC that relapsed after first-line chemotherapy. Among the 582 patients enrolled in this trial, 292 were treated with nivolumab and 290 received docetaxel. The primary end point of the trial was overall survival; secondary end points included the objective response rate, progression-free survival (PFS), efficacy according to tumour PD-L1 expression level, and patient-reported outcomes.

Nivolumab was associated with a significant survival benefit over docetaxel, with a median overall survival of 12.2 months versus 9.4 months. The survival benefit was observed at different time points, with overall survival rates of 51% for nivolumab versus 39% for docetaxel at 1 year, and 39% versus 23%, respectively, at 18 months.

The objective response rate was also significantly higher for patients treated with nivolumab (19%) compared with those in the docetaxel group (12%). Interestingly, the median PFS duration was 2.3 months with nivolumab and 4.2 months with docetaxel, but a clear benefit in the 1-year PFS rate was demonstrated favouring nivolumab (19% versus 8%).

Patients were enrolled in this trial regardless of tumour PD-L1 expression; however, a correlation was observed between PD-L1 expression and benefit from nivolumab treatment. Finally, fewer treatment-related adverse events of grade 3 or 4 were reported in the nivolumab group (10% versus 54%).

This study has demonstrated the greater efficacy of nivolumab over docetaxel as a second-line treatment for advanced-stage NSCLC. In addition to its superiority across several defined end points, nivolumab seems to be a safer treatment option because it was associated with fewer severe adverse events.

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Original article Borghaei, H. *et al.* Nivolumab versus docetaxel in advanced nonsquamous non–small-cell lung cancer. *N. Engl. J. Med.* doi:10.1056/NEJMoa1507643