

Use of archival versus newly collected tumor samples for assessing PD-L1 expression and overall survival: an updated analysis of KEYNOTE-010 trial

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Abstract

Background: In KEYNOTE-010, pembrolizumab versus docetaxel improved overall survival (OS) in patients with programmed death-1 protein (PD)-L1-positive advanced non-small-cell lung cancer (NSCLC). A prespecified exploratory analysis compared outcomes in patients based on PD-L1 expression in archival versus newly collected tumor samples using recently updated survival data.

Patients and methods: PD-L1 was assessed centrally by immunohistochemistry (22C3 antibody) in archival or newly collected tumor samples. Patients received pembrolizumab 2 or 10 mg/kg Q3W or docetaxel 75 mg/m² Q3W for 24 months or until progression/intolerable toxicity/other reason. Response was assessed by RECIST v1.1 every 9 weeks, survival every 2 months. Primary end points were OS and progression-free survival (PFS) in tumor proportion score (TPS) 50% and 1%; pembrolizumab doses were pooled in this analysis.

Results: At date cut-off of 24 March 2017, median follow-up was 31 months (range 23–41) representing 18 additional months of follow-up from the primary analysis. Pembrolizumab versus docetaxel continued to improve OS in patients with previously treated, PD-L1-expressing advanced NSCLC; hazard ratio (HR) was 0.66 [95% confidence interval (CI): 0.57, 0.77]. Of 1033 patients analyzed, 455(44%) were enrolled based on archival samples and 578 (56%) on newly collected tumor samples. Approximately 40% of archival samples and 45% of newly collected tumor samples were PD-L1 TPS 50%. For TPS 50%, the OS HRs were 0.64 (95% CI: 0.45, 0.91) and 0.40 (95% CI: 0.28, 0.56) for archival and newly collected samples, respectively. In patients with TPS 1%, OS HRs were 0.74 (95% CI: 0.59, 0.93) and 0.59 (95% CI: 0.48, 0.73) for archival and newly collected samples, respectively. In TPS 50%, PFS HRs were similar across archival [0.63 (95% CI: 0.45, 0.89)] and newly collected samples [0.53 (95% CI: 0.38, 0.72)]. In patients with TPS 1%, PFS HRs were similar across archival [0.82 (95% CI: 0.66, 1.02)] and newly collected samples [0.83 (95% CI: 0.68, 1.02)].

Keywords

Pembrolizumab, Tumor samples, PD-L1 expression.