101TiP PACIFIC-R: First real-world study of patients with unresectable, stage III NSCLC treated with durvalumab after chemoradiotherapy

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Background: Approximately 30% of patients (pts) with non-small-cell lung cancer (NSCLC) are diagnosed with Stage III disease, which is often unresectable. Historically, the standard of care (SoC) has been platinum-based chemoradiotherapy (CRT), but outcomes have been poor. Durvalumab is a selective high-affinity, human IgG1 monoclonal antibody that blocks PD-L1 binding to PD-1 and CD80. In the phase 3 PACIFIC trial of durvalumab versus placebo in pts with unresectable, Stage III NSCLC without progression after concurrent CRT (cCRT), both primary endpoints progression-free survival (PFS) and overall survival (OS) were met and significantly improved with durvalumab (HR for PFS, 0.52; 95% CI 0.42–0.65; $P < 0.001$; HR for OS, 0.68; 99.73% CI 0.47–0.997; $P = 0.0025$) with similar safety between treatments (Antonia et al, NEJM 2017; 2018). Based on these findings, the PACIFIC regimen (durvalumab following CRT) is becoming the SoC. PACIFIC-Real World (PACIFIC-R) will assess if durvalumab treatment after cCRT shows similar efficacy and safety in a large, real-world population.

Trial design: PACIFIC-R is an international, observational study that will enroll ~1200 NSCLC pts who have received durvalumab as part of early access programs (EAPs) between Sept 2017 and Dec 2018. In the EAP, eligible pts are adults with histologically or cytologically documented unresectable, Stage III NSCLC, regardless of tumor PD-L1 expression, who have not progressed after definitive CRT. Pts received durvalumab (10 mg/kg intravenously) every two weeks. Pts will be enrolled in the PACIFIC-R study after discontinuation of the EAP in participating countries. Data will be abstracted from pts' medical records at several time points within the 5 year study period. Primary endpoints are PFS (investigator assessed) and OS. Secondary endpoints include PFS and OS in pt subgroups; time to distant metastases; sites of disease progression; adverse events of special interest leading to treatment interruption, discontinuation or medical intervention; and descriptive analyses of demographic and clinical characteristics of pts treated with durvalumab in a real-world setting. Recruitment for this study is ongoing.

Clinical trial identification: NCT03798535.

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