PLENARY SESSIONS

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Overall Survival with Durvalumab Versus Placebo After Chemoradiotherapy in Stage III NSCLC: Updated Results from PACIFIC

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Background: In the global, Phase 3 PACIFIC study (Antonia 2017; NCT02125461), durvalumab significantly improved progression-free survival (PFS) versus placebo in Stage III, unresectable NSCLC patients without progression after chemoradiotherapy (CRT) (stratified HR, 0.52; 95% CI, 0.42−0.65; P<0.001). This was the first major advance in this disease setting for many years. Here we report the second primary endpoint overall survival (OS) for PACIFIC. **Method:** Patients with WHO PS 0/1 (any PD-L1 tumor status) who received ≥2 cycles of platinum-based CRT were randomized (2:1) 1−42 days post-CRT to durvalumab 10 mg/kg IV Q2W or placebo up to 12 months, stratified by age, sex, and smoking history. Primary endpoints were PFS from randomization (blinded independent central review; RECIST v1.1) and OS (interim analysis reported). Secondary endpoints included time to death or distant metastasis (TTDM) and PFS2 (time to second progression) from randomization and safety. Time to first/second subsequent therapy or death (TFST/TSST) were supportive assessments for PFS/PFS2. **Result:** Between May 2014 and April 2016, 713 patients were randomized of whom 709 received treatment (durvalumab, n=473; placebo, n=236). As of March 22, 2018 (data cutoff), median follow-up duration was 25.2 months (range, 0.2−43.1). After discontinuation, 41.0% and 54.0% in the durvalumab and placebo groups received subsequent anticancer therapy; overall, 8.0% and 22.4% received additional immunotherapy. Durvalumab significantly improved OS versus placebo (stratified HR 0.68, 99.73% CI, 0.469−0.997; P=0.00251), with the median not reached (NR; 95% CI, 34.7 months−NR) and 28.7 months (95% CI, 22.9−NR), respectively. Durvalumab improved OS in all pre-specified subgroups. Updated PFS remained similar (stratified HR 0.51, 95% CI, 0.41−0.63), with medians of 17.2 and 5.6 months with durvalumab and placebo, respectively. Durvalumab improved the updated TTDM (stratified HR 0.53, 95% CI, 0.41−0.68), as well as PFS2 (stratified HR 0.58, 95% CI, 0.46−0.73), TFST (stratified HR 0.58, 95% CI, 0.47−0.72) and TSST (stratified HR 0.63, 95% CI, 0.50−0.79). Within the durvalumab and placebo groups, 30.5% and 26.1% had grade 3/4 any-causality AEs, 15.4% and 9.8% discontinued due to AEs, and no new safety signals were identified. **Conclusion:** Durvalumab demonstrated statistically significant and clinically meaningful improvement in OS compared with placebo, supported by secondary endpoints such as PFS2. PACIFIC is the first study to show a survival advantage following CRT in this population, providing compelling evidence for the unprecedented benefit of durvalumab treatment as the standard of care. **Keywords:** NSCLC, durvalumab, PACIFIC

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Brigatinib vs Crizotinib in Patients With ALK Inhibitor-Naive Advanced ALK+ NSCLC: First Report of a Phase 3 Trial (ALTA-1L)

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Background: Brigatinib has robust efficacy in crizotinib-resistant ALK+ NSCLC, exhibiting median progression-free survival (mPFS) of 16.7 months. We report results of the first interim analysis from the ALTA-