Between-treatment endpoint comparisons were performed for patients <70 and ≥70 years. **Result:** As of Feb 13, 2017, 713 patients were randomized; 78% and 22% were <70 and ≥70 years, respectively. Baseline patient and tumor characteristics were generally well balanced across subgroups. However, patients ≥70 were more likely to be male, have PS 1, and, within the placebo arm, to be Asian. Older patients more commonly received carboplatin-based CT than younger patients. Durvalumab demonstrated PFS benefit compared with placebo, regardless if patients were <70 years (median 16.9 vs 5.6 months, HR=0.53, 95% CI: 0.42−0.67) or ≥70 years (median 12.3 vs 6.1 months, HR=0.62, 95% CI: 0.41−0.95). Durvalumab improved TTDM (<70 years: HR=0.53, 95% CI: 0.39−0.71; ≥70 years: HR=0.66, 95% CI: 0.39−1.13) and ORR (<70 years: 27.6% vs 15.4%; ≥70 years: 31.9% vs 17.6%) regardless of age. Younger patients on durvalumab received treatment longer (median total duration 45.5 vs 36.0 weeks). Regardless of treatment, older patients discontinued more due to AEs (durvalumab: 22.0% vs 13.7%; placebo: 16.1% vs 7.8%) and had more grade 5 AEs (durvalumab: 10.9% vs 2.7%; placebo: 9.1% vs. 4.5%). Among patients receiving durvalumab, older patients experienced more all-cause SAEs (42.6% vs 24.9%) and grade 3/4 AEs (41.6% vs 29.4%) but fewer AESIs (56.4% vs 67.9%) than younger patients. **Conclusion:** Patients achieved clinical benefit with durvalumab regardless of age. Increased AEs/SAEs observed in older patients across treatments may reflect age/cCRT related morbidity. **Keywords:** elderly, PACIFIC, durvalumab

P1.16-05
Effect of Induction Chemotherapy in the PACIFIC Study

D. Spigel,[1] J. Vansteenkiste,[2] M. Reck,[3] H. Wakelee,[4] M. Özgüroğlu,[5] D. Daniel,[6] A. Villegas,[7] D. Vicente,[8] R. Hui,[9] S. Murakami,[10] L. Paz-Ares,[11] L. Poole,[12] C. Wadsworth,[13] P. Dennis,[14] S. Antonia[15]
[1]Sarah Cannon Research Institute, Nashville/TN/US, [2]University Hospitals Ku Leuven, Leuven/BE, [3]German Centre for Lung Research (DZL), Grosshansdorf/DE, [4]Stanford University School of Medicine, Stanford/US, [5]Istanbul University Cerrahpaşa School of Medicine, Istanbul/TR, [6]Tennessee Oncology and Sarah Cannon Research Institute, Nashville, TN/US, [7]Cancer Specialists of North Florida, Jacksonville, FL/US, [8]Hospital Universitario Virgen Macarena, Seville/ES, [9]Westmead Hospital and the University of Sydney, Sydney/AU, [10]Kanagawa Cancer Center, Yokohama/JP, [11]Hospital Universitario 12 de Octubre, Ciberonc, Universidad Complutense and Cnio, Madrid/ES, [12]Astrazeneca, Cambridge/GB, [13]Astrazeneca, Alderley Park/GB, [14]Astrazeneca, Gaithersburg/MD/US, [15]H. Lee Moffitt Cancer Center and Research Institute, Tampa/FL/US

Background: The Phase 3 PACIFIC study of patients with stage III, unresectable NSCLC without progression after concurrent chemoradiotherapy (cCRT) demonstrated significantly longer PFS with durvalumab versus placebo (stratified HR 0.52; 95% CI 0.42−0.65; P<0.0001). Overall, 26% and 29% in the durvalumab and placebo groups, respectively, received induction chemotherapy (ICT) before cCRT. Here, we report exploratory analyses of baseline characteristics, disposition, and outcomes from this study based on the presence or absence of prior ICT. **Method:** PACIFIC (NCT02125461) was a Phase 3, randomized, double-blind study of patients with WHO PS 0/1 and any tumor PD-L1 status without progression after ≥2 cycles of platinum-based cCRT. Patients were stratified by age, sex and smoking history and randomized (2:1) to durvalumab 10 mg/kg IV Q2W or placebo up to 12 months. Co-primary endpoints were PFS (blinded independent central review, RECIST v1.1) and overall survival (not available). We investigated associations between the presence/absence of ICT and disposition, baseline characteristics, and efficacy and safety endpoints. **Result:** As of February 13, 2017, 713 patients were randomized; 27% had prior ICT. Baseline characteristics were similar between treatment arms; however, patients with ICT were generally younger, less frequently Asian, had lower incidence of squamous histology, and more often had stage IIIB disease. There were no differences between groups in terms of prior RT dose. PFS benefit with durvalumab was demonstrated irrespective of ICT use (ICT: HR=0.61, 95% CI, 0.41−0.88; no ICT: HR=0.54, 95% CI, 0.42−0.69). Similarly, ORR with durvalumab was numerically higher than with placebo irrespective of ICT use (ICT: 16.1% vs 13.1%; no ICT: 32.9% vs 17.1%). ICT did not affect treatment duration for durvalumab or placebo. Between-treatment safety differences were minimal across subgroups; however, patients with ICT experienced fewer SAEs, treatment-related SAEs and pneumonitis/radiation pneumonitis regardless of treatment arm. **Conclusion:** Durvalumab demonstrated clinical benefit irrespective of ICT. The safety profile of durvalumab was consistent in patients with or without ICT. A lower rate of toxicity was observed in patients with ICT regardless of treatment arm. **Keywords:** induction chemotherapy, PACIFIC, durvalumab

P1.16-06
Expanded Efficacy and Safety Analysis of PACIFIC Based on a PD-L1 Cutpoint of 25%

A. Spira,[1] D. Planchard,[2] B.C. Cho,[3] M. Özgüroğlu,[4] D. Daniel,[5] A. Villegas,[6] D. Vicente,[7] R. Hui,[8] S. Murakami,[9] L. Paz-Ares,[10] A. Boothman,[11] L. Poole,[11] C. Wadsworth,[12] P. Dennis,[13] S. Antonia[14]
[1]Virginia Cancer Specialists, Fairfax, VA/US, [2]Institut Gustave Roussy, Villejuif/FR, [3]Yonsei Cancer Center, Yonsei University College of Medicine, Seoul/KR, [4]Istanbul University, Cerrahpaşa School of Medicine, Istanbul/TR, [5]Tennessee Oncology and Sarah Cannon Research Institute, Nashville, TN/US, [6]Cancer Specialists of North Florida, Jacksonville, FL/US, [7]Hospital Universitario Virgen Macarena, Seville/ES, [8]Westmead Hospital and the University of Sydney, Sydney/AU, [9]Kanagawa Cancer Center, Yokohama/JP, [10]Hospital Universitario 12 de Octubre, Ciberonc, Universidad Complutense and Cnio, Madrid/ES, [11]Astrazeneca, Cambridge/GB, [12]Astrazeneca, Alderley Park/GB, [13]Astrazeneca, Gaithersburg, MD/US, [14]H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL/US

Background: In the Phase 3 PACIFIC study of patients with stage III, unresectable NSCLC without progression after concurrent chemoradiotherapy (cCRT), PFS was significantly longer with durvalumab versus placebo (stratified HR 0.52; 95% CI 0.42−0.65; P<0.0001). We report exploratory analyses of PACIFIC outcomes by PD-L1 expression assessed in tumor samples collected prior to cCRT. **Method:** PACIFIC (NCT02125461) was a Phase 3, randomized, double-blind study of patients with WHO PS 0/1 without progression after ≥2 cycles of platinum-based cCRT. Eligibility was irrespective of PD-L1 expression; archived samples were optional for testing (VENTANA PD-L1 [SP263] assay). No samples were obtained after cCRT, prior to infusion with durvalumab or placebo. Patients were randomized (2:1) to durvalumab 10 mg/kg IV Q2W or placebo up to 12 months, stratified by age, sex and smoking history. Co-primary endpoints were PFS (blinded independent central review, RECIST v1.1) and OS (not available). Secondary endpoints included ORR and safety. We investigated associations between subgroups of patients with PD-L1 expression on tumor cells (TC) of <25% or ≥25% and efficacy. **Result:** As of February 13, 2017, 713 patients were randomized; 451 (63.3%) had known PD-L1 status (TC<25%, 64.7%; TC≥25%, 35.3%; **Table**). Baseline characteristics and prior therapy (including best response to prior therapy) were generally well balanced between arms across both PD-L1 subgroups. PFS benefit with durvalumab was demonstrated irrespective of PD-L1 status (HR 0.59; 95% CI, 0.43−0.82 for TC<25% and HR 0.41; 95% CI, 0.26−0.65 for TC≥25%) (**Table**). ORR was greater with durvalumab compared to placebo regardless of PD-L1 status (**Table**). The overall safety profile of durvalumab in each PD-L1 subgroup was consistent with the ITT population treated with durvalumab.