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.

Conclusion: Durvalumab demonstrated clinical benefit and had a well-tolerated, manageable safety profile irrespective of PD-L1 status obtained from archival tumor samples prior to cCRT. **Keywords:** durvalumab, PACIFIC, PD-L1

	PD-L1 TC<25%		PD-L1 TC≥25%	
	Durvalumab (n=187)	Placebo (n=105)	Durvalumab (n=115)	Placebo (n=44)
Completed 12 months treatment, n (%)	74 (39.6)	35 (33.3)	55 (47.8)	13 (29.5)
PFS*				
Median (95% CI), months	16.9 (11.0–NR)	6.9 (5.0–11.0)	17.8 (11.1–NR)	3.7 (2.0–13.2)
HR (95% CI)	0.59	(0.43–0.82)	0.41	(0.26–0.65)
ORR†	n=170	n=96	n=108	n=40
n (%) [95% CI]	50 (29.4) [22.7–36.9]	19 (19.8) [12.36–29.17]	31 (28.7) [20.4–38.2]	6 (15.0) [5.71–29.84]

*In the overall ITT population, median PFS was 16.8 months (95% CI, 13.0–18.1) with durvalumab (n=476) vs. 5.6 months (95% CI, 4.6–7.8) with placebo (n=237), with an HR of 0.52 (95% CI, 0.42–0.65; P<0.001) (stratified log-rank); PD-L1 assessment was not required in the study; in PD-L1 unknown patients, median PFS was 14.0 months (95% CI, 9.2–NR) with durvalumab (n=174) vs. 6.4 months (95% CI, 3.8–9.0) with placebo (n=88), with an HR of 0.59 (95% CI, 0.42–0.83) (unstratified Cox proportional hazards model); †ORR for n evaluable patients included unconfirmed responses. ITT, intention-to-treat; NR, not reached; ORR, objective response rate; PFS, progression-free survival.

P1.16-07
Cost-Effectiveness of Pembrolizumab as 1st Line Treatment for Metastatic NSCLC Patients with High PD-L1 Expression in Singapore

W.L. Tan,[1] M. Huang,[2] S. Chandwani,[3] T. Hsu,[4] S.C. Tan,[5] D. Tan[6]
[1]National Cancer Centre Singapore, Singapore/SG, [2]Merck and Co., Inc., Center for Observational and Real World Evidence, Rahway/US, [3]Merck and Co., Inc., Center for Observational and Real World Evidence, Rahway, NJ/US, [4]Medical Affairs, Msd Pharma (Singapore) Pte. Ltd., Singapore/SG, [5]Merck Sharp and Dohme (Asia Pacific), Singapore, Singapore/SG, [6]Medical Oncology, National Cancer Centre, Singapore, Singapore/SG

Background: Pembrolizumab, an immune checkpoint inhibitor, has been approved as monotherapy for 1st line treatment of metastatic NSCLC with PD-L1 tumor proportion score (TPS) ≥50% based on the pivotal Keynote (KN)-024 study. This study aims to evaluate the cost-effectiveness of pembrolizumab compared with standard-of-care (SoC) platinum-based chemotherapy in patients with TPS≥50% from a societal perspective in Singapore based on results from KN024. **Method:** A known partitioned-survival model was adapted to estimate progression-free survival, overall survival, costs of treatments, adverse events and disease management, and health utilities over a time horizon of 20 years. The maximum treatment duration of 2 years was applied for pembrolizumab. Clinical and resource utilization inputs were based on data from KN024 study and input from local oncologists. Unit costs captured both patients' payments and government subsidies. Utility scores in different health states were based on EQ-5D data from KN024 with weighting indices suggested by a local quality-of-life study. An annual discount rate of 3% was applied and a series of sensitivity and scenario analyses were conducted to address uncertainty. **Result:** For 1st line treatment for NSCLC patients with TPS≥50%, pembrolizumab monotherapy is estimated to result in 0.91 quality-adjusted-life-years (QALY) gained. The projected incremental cost for pembrolizumab is S$141,979 compared to SoC, leading to an incremental cost-effectiveness ratio (ICER) of S$155,630 per QALY gained. A similar ICER of S$156,862 is observed in a scenario analysis whereby all patients are tested for PD-L1 and those with high PD-L1 expression are treated with pembrolizumab. With a Pembrolizumab Patient Access Program (PAP), the ICER is estimated to be S$95,279 per QALY. In another scenario analysis where government subsidies and claim limits of Medishield / Medisave are considered, the estimated ICER is S$46,308 per QALY from the Ministry of Health (MOH) perspective. **Conclusion:** For NSCLC patients with TPS≥50%, the ICER in the base-case for pembrolizumab as 1st-line treatment is $155,630 — which is between 2-3x gross domestic product (GDP) per capita of Singapore (S$73,167) in 2016, whereas the estimated ICER with Pembrolizumab PAP is 1-2x GDP per capita. Depending on threshold boundaries adopted, 1st line pembrolizumab for patients with similar profile (TPS ≥50%) as those in KN024, would be a cost-effective treatment compared to SoC in Singapore. **Keywords:** pembrolizumab, NSCLC, Cost-effectiveness

P1.16-08
Weekly Nab-Paclitaxel Plus Carboplatin as Neoadjuvant Therapy for IIIA-N2 Lung Squamous Cell Carcinoma: A Prospective Phase II Study

Y. Zhang, J.Q. Zhu, D. Yue, X. Zhao, Q. Zhang, H. Chen, C. Wang
Tianjin Medical University Cancer Institute and Hospital, Tianjin/CN

Background: To evaluate the safety and antitumor activity of weekly nab-paclitaxel combined with carboplatin in patients with advanced stage IIIA-N2 NSCLC patients with squamous histology **Method:** From April 2015 to August 2017, 36 treatment-naive, pathologically diagnosed IIIA-N2 lung squamous cell carcinoma patients were enrolled and given two cycles of weekly nab-paclitaxel (100mg/m^2, day1,8,15 of a 21-day cycle) plus Carboplatin (AUC = 5 at day 1, q3w) as neoadjuvant therapy. Then resectability was assessed and surgery was performed for resectable lesions. Post-operative adjuvant chemotherapy regimens is the combination of Nab-paclitaxel (100mg/m^2, qw x 6) and carboplatin (AUC 5, Q3W x 2) for patients with PD, adjuvant chemotherapy regimen will be changed. The primary objective is the safety and efficacy, and the secondary objectives are quality of life and the role of prognostic biomarker SPARC. **Result:** Of 36 patients, 3 stopped treatment due to patient decision. 33 were finally evaluated and 1 is still on treatment. Significant tumor volume shrinkage was seen in some patients after the neoadjuvant therapy. 66.7% patients achieved partial response (PR), 21.2% patients achieved stable disease (SD). Disease control (PR +SD) rate was 87.9%. Finally, 23 patients underwent surgical resection, the respectability rate was 69.7%. 12.1% occurred disease progress and failed to achieve resection, including 3 with local progress and 1 with pulmonary metastatic nodule; Among 22 PR pts, 4 failed to achieve resection, in which 1 was due to heart function, the other 3 due to personal unwillingness. 2 of 7 with stable disease failed to achieve resection; the pathological improvement in T stage and N stage before and after treatment was 81.8% (18/22) and 50% (11/22) respectively. The major adverse event was neutropenia (grade I and II) and no serious AE was found. **Conclusion:** Nab-paclitaxel in combination with Carboplatin showed promising ORR rate and resection rate in of IIIA-N2 lung squamous cell carcinoma. The regimen could be a new chemo option as the neoadjuvant treatment. PFS and OS data will be reported after follow up completing. **Keywords:** nab-paclitaxel, neoadjuvant therapy, Lung Squamous cell carcinoma

P1.16-09
Surgical Result of Pathologic Stage III a Non Small Cell Lung Cancer: Have We Improved?

C. Wu *Division of Thoracic and Cardiovascular Surgery, Department of Surgery, Chang Gung Memorial Hospital, Linkou, Taoyuan County/TW*