850 Prevalence of programmed death ligand-1 (PD-L1) by demographic, disease and sample characteristics in unresectable, stage III NSCLC (PACIFIC)

D. Planchard[1], M.C. Garassino[2], L. Paz-Ares[3], C. Faivre-Finn[4], A. Spira[5], Y. Gu[6], C. Wadsworth[7], J. Whiteley[8], M. Scott[8], A-M. Boothman[8], M. Ratcliffe[8], J. Walker[8], P.A. Dennis[6], S.J. Antonia[9]

[1]Department of Medical Oncology, Thoracic Group, Institut Gustave Roussy, Villejuif, France, [2]Thoracic Unit, Fondazione IRCCS - Istituto Nazionale dei Tumori, Milan, Italy, [3]CiberOnc, Universidad Complutense and CNIO, University Hospital 12 de Octubre, Madrid, Spain, [4]Clinical Oncology, The University of Manchester and The Christie NHS Foundation Trust, Manchester, UK, [5]Virginia Cancer Specialists Research Institute, Fairfax, VA, USA, [6]AstraZeneca, Gaithersburg, MD, USA, [7]AstraZeneca, Alderley Park, UK, [8]Precision Medicine and Genomics, IMED Biotech Unit, AstraZeneca, Cambridge, UK, [9]Thoracic Oncology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL, USA

Background: PACIFIC (NCT02125461) was a randomised, placebo-controlled, phase 3 trial evaluating the immune checkpoint inhibitor durvalumab in patients (pts) with unresectable, Stage III non-small cell lung cancer (NSCLC) who did not have disease progression after concurrent chemoradiotherapy (cCRT). Both primary endpoints of progression-free survival and overall survival were met and significantly improved with durvalumab, with similar safety, versus placebo (Antonia et al, NEJM 2017; 2018). We report exploratory analyses of the prevalence of tumour PD-L1 expression by baseline pt, disease and sample characteristics and by response to prior treatment for pts in PACIFIC.

Methods: If available (provision of formalin-fixed paraffin-embedded tumour resection or biopsy samples was optional), archived pre-cCRT tumour tissue was tested retrospectively for PD-L1 tumour cell (TC) expression using the VENTANA PD-L1 (SP263) immunohistochemistry assay and scored at validated pre-specified ($\geq$25%) and post-hoc ($\geq$1%) cutoffs. Overall PD-L1 prevalence (regardless of treatment arm) was summarised by pt subgroups defined by various characteristics, and assessed using a Pearson's chi-squared test for between-group differences.

Results: Of 713 randomized pts, 451 (63.2%) were evaluable for PD-L1 status. Among PD-L1-evaluable pts, 67.2% (303/451) had TC $\geq$ 1% and 35.3% (159/451) had TC $\geq$ 25% (similar to previous reports in metastatic NSCLC). PD-L1 prevalence by various characteristics at the TC $\geq$ 1% cut-off are reported in the table.

Conclusions: There were no important differences noted in PD-L1 prevalence between relevant subgroups at the TC $\geq$ 1% or TC $\geq$ 25% cut-offs (latter data to be presented). PD-L1 status was unaffected by sample type or age or biopsy location, suggesting expression is stable from pre-cCRT diagnostic biopsies, and supports the use of either primary tumour or lymph node biopsies for PD-L1 testing.

Clinical trial identification: NCT02125461.

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Table: 85O

Patient/disease/sample characteristic	Subgroup	Prevalence of PD-L1 TC ≥1%, % (n/N)	P value
Race	White	67.5 (206/305)	0.5882
	Black or African American	81.8 (9/11)	
	Asian	66.4 (85/128)	
	Other	50.0 (3/6)	
Region	Asia	64.3 (74/115)	0.2642
	Europe	64.9 (124/191)	
	North America and South America	72.4 (105/145)	
Patient age (years)	<65	66.5 (167/251)	0.7418
	≥65	68.0 (136/200)	
Smoking status	Smoker	66.8 (276/413)	0.5956
	Non-smoker	71.1 (27/38)	
Sex	Male	65.3 (209/320)	0.1858
	Female	71.8 (94/131)	
Histology	Squamous	64.9 (150/231)	0.2973
	Non-squamous	69.5 (153/220)	
Disease stage	IIIA	69.2 (166/240)	0.5029
	IIIB	66.2 (131/198)	
ECOG/WHO performance status	Normal activity (0)	65.8 (150/228)	0.5236
	Restricted activity (1)	68.6 (153/223)	
EGFR status	Positive	67.7 (21/31)	0.1176
	Negative	68.6 (264/385)	
	Unknown	51.4 (18/35)	
Best response to prior therapy	Complete response	41.7 (5/12)	0.1611
	Partial response	67.7 (151/223)	
	Stable disease	68.1 (143/210)	
Biopsy sample location	Lung	67.0 (209/312)	0.8045
	Lymph node(s)	65.6 (63/96)	
Specimen type	Formalin-fixed paraffin-embedded block	69.2 (126/182)	0.4461
	Unstained slides	65.8 (175/266)	
Collection method	Biopsy	68.2 (279/409)	0.5879
	Resection	63.6 (21/33)	
Age of biopsy sample	≤90 days	73.3 (88/120)	0.0902