1384PD Pembrolizumab in performance status 2 patients with non-small cell lung cancer (NSCLC): Results of the PePS2 trial

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Background: Many patients with advanced NSCLC present with a performance status (PS) of 2. All published immunotherapy data in NSCLC is in PS0-1 patients whilst its safety and activity in this important patient group is unknown.

Methods: Between 4/1/2017 and 13/2/2018 the trial recruited 62 PS2 NSCLC patients. PS was assessed by the registering physician on several occasions prior to trial entry to ensure a bona fide PS2 population. Components of the ECOG PS2 criteria were incorporated into the exclusion/inclusion criteria. Previous therapy and PD-L1 status were recorded at baseline. Co-primary outcomes were: i) durable clinical benefit (DCB) defined as complete or partial response or stable disease at 18 weeks; and ii) toxicity defined as treatment-related dose delay or discontinuation due to adverse event (AE).

Results: Median age 72 yrs (range 43-86), median follow-up 249 days. 60 patients commenced therapy and were evaluable. Co-primary outcomes, objective response rate (ORR) and progression-free survival (PFS) are presented below. 3/18 responders have relapsed, after 67, 201 and 287 days. 23 patients (38%) had grade 3/4 AE by CTCAE v4, 5 (8%) had such an event thought possibly related to pembrolizumab. Of potentially immune-related AEs: 7 patients (12%) reported acneiform/maculopapular rash (6 G1/2; 1 G3); 2 (3%) pruritus (1 each G1 and 2); 1 (2%) G3 vasculitis; 1 (2%) G3 pneumonitis; 1 (2%) G1 colitis; 1 (2%) G1 hyperthroidism; 4 (7%) hypothyroidism (1 G1, 3 G2); 1 (2%) G3 arthralgia. There were no obvious cases of hyperprogression.

Table: 1384PD

	DCB (%)	ORR (%)	Median PFS months	Toxicity (%)
All (n = 60)	20 (33)	18 (30)	4.4	8 (13)
Previous therapy:				
No (n = 9)	1 (11)	0 (0)	1.9	2 (22)
Yes (n = 50)	19 (38)	18 (36)	4.6	6 (12)
Missing (n = 1)	0 (0)	0 (0)		0 (0)
PD-L1 TPS:				
< 1% (n = 27)	6 (22)	5 (19)	3.3	4 (15)
1-49% (n = 15)	5 (33)	5 (33)	6.8	0 (0)
≥ 50% (n = 15)	8 (53)	7 (47)	8.5	3 (20)
Missing (n = 3)	1 (33)	1 (33)		1 (33)

Conclusions: This is the first prospective analysis of pembrolizumab in a rigorously assessed PS2 population. Pembrolizumab can be delivered safely to such patients providing levels of activity at least equivalent to a PS0-1 population. The trial demonstrates that pembrolizumab is a safe, effective therapy for this difficult to treat NSCLC population.

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