Background

The Blue Sky Radiomic trial is a multicenter, observational, retrospective and prospective study started in 2020, with a target sample size of 100 patients with unresectable stage IIIA-C NSCLC treated with the PACIFIC regimen (clinicaltrial.gov identifier: NCT04364776, active, recruiting). We here report an exploratory analysis on PFS-2 after the first progression.

Methods

All patients were deemed unresectable by MTB and had PD-L1 positive (>1%) tumors, with at least stable disease, and receiving one durvalumab dose after CRT; 93/100 pts were evaluable, with 56 recorded events (6 deaths and 50 progressions). PFS2 was calculated for these 50 pts from the date of first to second progression or death (Kaplan-Meier).

Results

At a median follow-up time of 18 months, median PFS of the entire cohort was 23.2 months (2.10-47.63). Median OS was not reached. Among patients experiencing a first PD (n=50), 9 pts (18%) relapsed within the first 3 months from durvalumab start, 10 (20%) between 3 and 6, and 31 (62%) after 6 months. Pattern of relapse was as follows: 16 local recurrences (32%), 17 distant progressions (34%), and 17 both (34%), respectively. Forty-one/50 (82%) patients did receive an active treatment at first progression: 22 pts systemic therapy (53.6%, 9 pts a platinum-based doublet, 11 mono-CT, 1 IO and 1 TKI); 10 RT alone (24.4%); 6 CT plus local treatment (14.6%), and 3 metastasectomy alone (7.4%).

With a median follow-up of 5.3 months (1.07-32.43) from first PD, we recorded 29 deaths. Ten pts are alive without progression, and 11 are alive with progressive disease. Median PFS2 was 7.23 months (1.03-42), and median OS was 15.5 months (1.07-46.17), respectively.

Conclusion

This exploratory analysis suggests that most of progressing patients (80%) can receive a second-line therapy at the time of first progression following CRT plus durvalumab in a real-world setting. The median PFS2 of around 7 months could be used as reference for the design of future trials.


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