

http://dx.doi.org/10.1136/jitc-2020-SITC2020.0621

622 PD-L1 IS A POTENTIAL PREDICTIVE BIOMARKER FOR RESPONSE TO RM-1929 TREATMENT IN RECURRENT HEAD AND NECK SQUAMOUS CELL CARCINOMA PATIENTS

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Background RM-1929 is an antibody-drug conjugate comprised of cetuximab covalently linked to the photoactivable dye, IRDye®-700DX (IR700). After systemic infusion of RM-1929, illumination of the tumor with 690 nm non-thermal red light activates the drug and results in targeted and rapid tumor necrosis. Previous preclinical data have shown that RM-1929 treatment triggers immunogenic cell death and activates the innate and adaptive immune response. A retrospective analysis of PD-L1 expression from the phase I/IIa clinical trial in patients with recurrent head and neck squamous cell carcinoma (rHNSCC) (NCT02422979) was conducted. The analysis explored correlations of PD-L1 expression, including combined proportion score (CPS) and tumor proportion score (TPS), with clinical outcomes such as response rate and overall survival.

Methods PD-L1 expression prior to RM-1929 treatment was assessed by immunohistochemistry in 18 out of 30 patients enrolled in Part II of the trial, based on sample availability. PD-L1 expression was evaluated using TPS and CPS. Responders were defined as patients that achieved complete response or partial response, and non-responders had either stable disease or progressive disease. Overall survival (OS) was analyzed using the Kaplan-Meier method.

Results Responders (n=10) had a TPS of 4.3±2.4 (mean ±SEM), which was substantially lower than in non-responders (n=8) with a TPS of 39.4±11.8. Similarly, CPS was lower in responders (8.6±3.6) compared to non-responders (50.0±13.5). The best target response rate for all patients included in this analysis was 56%. Patients with CPS=40 had a response rate of 76.9% (n=13) compared to 0% in patients with CPS>40 (n=5). This suggests that a CPS cut-off of =40 led to enrichment of the best target response rate. The median OS of patients with CPS=40 (13.0±0.8 months) was also higher than in patients with CPS>40 (3.1±0.8 months) and in all patients (12.0±2.9 months).

Conclusions These results suggest that rHNSCC patients with lower PD-L1 expression levels may be more responsive to RM-1929 treatment and CPS/TPS could potentially be predictive biomarkers in identifying patients with a higher probability of benefiting from this treatment. Given the limited number of patients in this analysis, additional clinical trials will be needed to validate PD-L1 expression as an effective predictive biomarker for RM-1929 treatment.

Acknowledgements The authors would like to thank all patients and their families for their participation in this trial. The authors would also like to thank the following investigators for the contribution of samples included in this trial analysis: Dr. David Cognetti (Thomas Jefferson University Hospital), Dr. Ann M Gillenwater (University of Texas MD Anderson Cancer Center), Dr. Mary Jo Fidler (Rush University Medical Center), Dr. Samith K. Kochuparambil (Virginia Piper Cancer Institute ), Dr. John Campana (University of Colorado Head and Neck Specialists), and Dr. Niles R. Vasan (University of Oklahoma Health Sciences Center).