

**1282P Responder analysis based on patient-reported outcomes (PROs) and clinical endpoints (CEPs) in patients (pts) with metastatic Merkel cell carcinoma (mMCC) treated with avelumab**

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**Background:** To better understand the impact of the anti-PD-L1 antibody avelumab, clinical outcomes and PROs in chemotherapy-refractory pts with mMCC enrolled in a single-arm, international phase 2 trial (NCT02155647) were analysed. Here we explore the proportion of pts categorised as responders based on these outcome measures.

**Methods:** PROs were assessed at baseline (BL), at week 7, thereafter Q6W until disease progression, and at end of treatment using EQ-5D, a generic health-related quality of life (HRQoL) tool, and FACT-M, a cancer-specific HRQoL tool. Pts were categorised as meaningfully improved/stable or as meaningfully worsened. HRQoL deterioration-free survival (QFS) was defined as the time from BL to either a meaningful worsening from BL with no further improvement in HRQoL or death. QFS rates of PRO endpoints were computed at specific time points. Responders based on PRO meaningfully improved/stable and QFS analyses were described along with the best overall response (BOR) and progression-free survival (PFS) analyses assessed by IERC per RECIST v1.1.

**Results:** As of Sept 26, 2017, 88 pts had been followed for a minimum of 24 months (mo; median, 29.2 [range, 24.8-38.1]). The table presents responders based on PROs and CEPs at 6, 12, 18, and 24 mo. In addition, PRO-based, 2-year rates of improved/stable endpoints tended to be higher than the BOR rate of 33%, ranging from 41% for FACT-M physical well-being to 58% for FACT-M melanoma surgery scale.

**Table: 1282P**

		6 mo	12 mo	18 mo	24 mo
CEPs					
PFS rate, %		40	29	29	26
PRO endpoints					
QFS rate, %	EQ-5D VAS	52	52	49	38
	FACT-M total	45	40	36	32
	FACT-M physical well-being	44	37	33	33
	FACT-M social/family well-being	40	40	31	26
	FACT-M emotional well-being	45	40	33	33
	FACT-M functional well-being	41	34	31	27
	FACT-M melanoma subscale	53	42	39	39
	FACT-M melanoma surgery scale	46	43	38	38
	FACT-G total	41	39	35	31

**Conclusions:** The findings show similarity in the proportion of responders based on clinical and PRO endpoints, reiterating the potential association of both outcome measures in this mMCC population. This confirms the interest in using PROs in trials to contribute to the interpretation of objective CEPs.

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