Urothelial carcinoma

• Fully human anti-PD-L1 IgG1 monoclonal antibody
• Approximately half of patients who receive 1st-line therapy go on to 2nd-line therapy with cisplatin-based regimens achieves a median survival of 20.9 months in patients without visceral metastasis

Clinical activity associated with PD-L1 expression level:
- ORR: 36.4% in PD-L1+ vs 20.9% in patients without visceral metastasis
- DCR: 59.1% in PD-L1+ vs 46.8% in patients without visceral metastasis

Avelumab (MSB0010718C) efficacy was assessed on the basis of PD-L1 expression by different cut-off levels in patients whose tumors were evaluable for PD-L1 expression.

Safety

- Nineteen patients (43.2%) had grade ≥3 TEAEs; only 1 (2.3%) was related TEAEs, treatment-emergent adverse reactions (grade 3 asthenia; treatment-related)
- Median duration of TEAE: 6 weeks
- Most frequent TEAE were asthenia, nausea, and fatigue

CONCLUSIONS

- Treatment with avelumab was associated with an acceptable safety profile
- Avelumab showed clinical activity, including 1 CR, 69.9% ORR, 38.6% DCR, 60.5% mPFS, with an overall survival benefit of 14.6 months
- Responses were reported in patients with visceral metastases, a population specifically identified as having a high burden of disease

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