659P Avelumab (anti–PD-L1) in Japanese patients with advanced gastric or gastroesophageal junction cancer (GC/GEJC): Updated results from the phase Ib JAVELIN solid tumour JPN trial

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Background: Avelumab, a human anti–PD-L1 IgG1 monoclonal antibody that can induce innate effector function against tumor cells in preclinical models, is an approved treatment for metastatic Merkel cell carcinoma in various countries and platinum-treated advanced urothelial carcinoma in the US and Canada. We report updated results from the dose-expansion part of a phase 1b trial of avelumab in Japanese patients (pts) with advanced GC/GEJC (NCT01943461).

Methods: Pts had stage IV GC/GEJC adenocarcinoma and progression after 1 or 2 prior lines of chemotherapy including a platinum and fluoropyrimidine agent (initially enrolled pts) or progression after platinum/fluoropyrimidine followed by a taxane or irinotecan (later pts). Pts received avelumab 10 mg/kg Q2W by IV infusion until confirmed progression, unacceptable toxicity or withdrawal. PD-L1 expression was assessed using the Dako PD-L1 IHC 73-10 assay ($\geq$1% tumor cell cutoff).

Results: At data cutoff on Aug 10, 2016, 40 pts had received avelumab (median treatment duration 2.7 mo; range 0.5–21.4). 21 pts (52.5%) had received $\geq$3 prior lines of therapy for advanced disease. The objective response rate (ORR) was 10.0% (95% CI 2.8–23.7), including complete response in 1 pt and partial response in 3 pts. 17 pts had stable disease as best response and the disease control rate was 52.5%. Median progression-free survival was 2.5 mo (95% CI 1.4–2.8). Median overall survival (OS) was 9.1 mo (95% CI 7.2–11.2) and the 12-mo OS rate was 31.0% (95% CI 15.6–47.8). In evaluable pts with PD-L1 + (n = 11) or PD-L1 − (n = 27) tumors, ORR was 27.3% and 3.7%, respectively. Treatment-related adverse events (TRAEs) of any grade occurred in 32 pts (80.0%), including infusion-related reaction (27.5%; all grade 1/2), pruritus (15.0%), pyrexia (12.5%) and rash (10.0%) in $\geq$ 10% of pts. Grade 3 TRAEs occurred in 3 pts (7.5%; ALT increase, anemia and hyponatremia); no pt had a grade $\geq$4 TRAE. 5 pts had an immune-related AE (all grade 1/2); the most common were pruritus (n = 3) and maculopapular rash (n = 2).

Conclusions: Avelumab showed acceptable safety and clinical activity in Japanese pts with advanced GC/GEJC progressed after chemotherapy.

Clinical trial identification: EMR 100070-002 (NCT01943461).

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