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**Patient-reported outcomes (PROs) from JAVELIN Bladder 100: Avelumab first-line (1L) maintenance + best supportive care (BSC) vs BSC alone for advanced urothelial carcinoma (UC)**

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**Background**

In the phase III JAVELIN Bladder 100 trial (NCT02603432), avelumab (anti-PD-L1) 1L maintenance + BSC significantly prolonged overall survival (primary endpoint) vs BSC alone in patients (pts) with advanced UC without disease progression with 1L induction chemotherapy. Here we report PRO findings.

**Methods**

In JAVELIN Bladder 100, PROs were a secondary endpoint. Pts were assessed at baseline, on day 1 of each 4-week cycle, at the end of treatment/withdrawal visit, and at short-term follow-up visits (up to 90 days post treatment). Two PRO instruments were employed: National Comprehensive Cancer Network – Functional Assessment of Cancer Therapy Bladder Cancer Symptom Index-18 (FBISI-18) and EuroQol 5 Dimensions 5 Levels (EQ-5D-5L). Descriptive, mixed-model, and time-to-deterioration (TTD; ≥3-point decrease from baseline in the FBISI disease-related symptoms–physical subscale for 2 consecutive assessments using the Kaplan-Meier method) analyses were conducted in both primary populations: all randomized pts and pts with PD-L1+ tumors.

**Results**

Among all randomized pts in the avelumab + BSC (n=350) and BSC alone (n=350) arms, completion rates for both PRO instruments were >90% for the majority of the treatment period. Results from the descriptive analysis and mixed models over the treatment period in FBISI-18 and EQ-5D-5L were similar between arms. The hazard ratio for TTD was 1.26 (95% CI, 0.90, 1.77; 1-sided p=0.91); median TTD was not reached (95% CI, 13.9 months, not estimable) with avelumab + BSC and was 13.8 months (95% CI, 12.9 months, not estimable) with BSC alone. However, the TTD results should be interpreted with caution given that death and progression were not included in the event definition, and starting from cycle 2 substantially fewer patients were eligible to complete PROs with BSC alone (n=155) than with avelumab + BSC (n=206). PRO results were consistent in the PD-L1+ population.

**Conclusions**

Adding avelumab 1L maintenance therapy to BSC in pts with advanced UC whose disease had not progressed with 1L platinum-based chemotherapy had no detrimental effect on clinically relevant PROs.

**Clinical trial identification**

NCT02603432.

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## Legal entity responsible for the study

Pfizer.

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