UROTHELIAL CARCINOMA

First line avelumab in PD-L1+ve metastatic or locally advanced urothelial cancer (aUC) patients unfit for cisplatin (cis): The ARIES trial.

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Abstract Disclosures

Abstract

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Background: Avelumab (ave) was approved as maintenance therapy after platinum-based first line (1L) therapy for patients (pts) with aUC based on ph. 3 Javelin Bladder 100 study (NCT02603432), showing significant overall survival (OS) improvement. Here we tested the activity of ave as 1L of therapy in cis-unfit pts with aUC and PD-L1+ve expression. **Methods:** ARIES is a single-arm, multi-site, open-label phase II trial. Enrolled pts had aUC, were cis-unfit (at least one of: ECOG-PS = 2, CrCl < 60 mL/min, grade ≥2 peripheral neuropathy/hearing loss, progression within 6-mos before the end of neo/adj

COMPANION ARTICLES

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chemo), had not previously received chemo for aUC and PD-L1≥5% (SP263) centrally assessed. Pts received ave 10 mg/Kg IV Q2W until progression, unacceptable toxicity and withdrawal, whichever occurred first. The primary endpoint was the 1-year OS. Key secondary endpoints were median-OS, -PFS, ORR and safety. **Results:** A total of 198 eligible cis-unfit pts have been tested for PD-L1 and 71 (35.6%) have been found positive. Among enrolled patients (N = 71), median age was 75 y, 35 (49.3%) had visceral disease, and 22 (31.0%) had ECOG-PS = 2; 50 (70.4%) had CrCl < 60 mL/min and 9 (12.7%) progressed within 6-mos from the end of neo/adj chemo. At the cut-off data (Oct 7, 2021), median follow up was 9.0 mo and 13 patients are still on treatment. The median OS was 10.0 mos (95% CI, 5.7-14.3), and 40.8% of patients were alive at 1-year. The ORR for all patients was 22.5%; complete response, 1.4% (n = 1); partial response, 21.1% (n = 15). Clinical benefit was 43.6% (n = 31). Median PFS was 2.0 mos (95% CI, 1.4-2.6). Among the 56 pts who received at least 3 cycles (29 days) of therapy the median OS was 16.0 vs 1.0 mos. Five (7.0%) grade 3 ave-related adverse events, and no treatment-related death were reported. **Conclusions:** Ave is active and safe in pts with cis-unfit, PD-L1+ve aUC and poor baseline characteristics. Clinical trial information: NCT03891238.

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