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A phase II study of avelumab in locally advanced or metastatic penile cancer patients unfit for platinum-based chemotherapy or progressed on or after platinum-based chemotherapy (ALPACA)

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Background

Patients with locally advanced or metastatic penile squamous cell carcinomas (PSCC) have limited treatment options and poor outcomes. Given the success of immune checkpoint inhibitors (ICI) in other HPV-related cancers and frequent PDL-1 expression in PSCC, we evaluated the efficacy and safety of the anti-PDL-1 antibody Avelumab, in this investigator-initiated clinical trial.

Methods

The ALPACA phase II, multicenter, single-arm trial enrolled PSCC patients previously treated with or unfit for platinum-based chemotherapy. Patients received Avelumab 10 mg/kg IV every 2 weeks until progression or limiting toxicity. Primary endpoint was objective response rate (ORR, iRECIST). Secondary endpoints included progression-free survival (PFS), overall survival (OS), safety and tolerability.

Results

Between 08/18–01/25, 25 patients (pts) were enrolled (median age 59 [41–72]; ECOG 0: 20%, 1: 48%, 2: 32%). Nearly all (96%) received prior chemotherapy. Pts completed a median of 3 cycles (range 1-72). Two pts did not complete cycle 1 and were inevaluable for response. Among the 23 evaluable pts, best response was partial response in 4 (17%), stable disease in 1 (4%), and progressive disease in 18 (78%), yielding a clinical benefit rate of 21%. Among responders, median duration of response was 15.9 mos (14.0-16.2). With a median duration of followup of 15 mos, the median PFS was 1.7 mos (95% CI 1.5-1.8) and median OS was 3.9 mos (95% CI 2.6-9.9). Most pts discontinued treatment due to disease progression or death (87%), while 3 (13%) remain on therapy. Avelumab was generally well tolerated; grade ≥3 events were infrequent (4% each) and included infusion reaction, fatigue, rash, anemia, and arthralgia. Preliminary analysis showed no clear correlation with HPV status (updated results pending), whereas a high neutrophil-to-lymphocyte ratio predicted worse outcomes.

Conclusions

Single-agent Avelumab was well-tolerated and demonstrated modest activity with a 21% clinical benefit rate in previously treated advanced PSCC, consistent with prior studies. These findings support further investigation of ICIs and biomarker-driven strategies in this population.

Clinical trial identification

NCT03391479.

Legal entity responsible for the study

University Health Network.

Funding

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Disclosure

S.S. Sridhar: Financial Interests, Personal, Advisory Board: Astellas, AstraZeneca, Bayer, BMS, EMD Serono, Pfizer, Seagen, Gilead, Bicycle

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