Background: Durvalumab gained FDA approval for locally advanced or metastatic UC following failure of platinum-based chemotherapy (CTx) based on the open-label, single arm study 1108. Real-world evidence can be used to enable comparative analyses by matching patients’ baseline characteristics from independent datasets. Overall survival (OS) of patients on durvalumab vs CTx was evaluated by comparing patients in the phase 1/2 study 1108 (NCT01693562) with a real-world dataset.

Methods: Data from patients on durvalumab were compared with data from patients in the Flatiron oncology electronic medical record database treated with physician’s choice of 2nd-line CTx. All patients had progressed following platinum-based CTx. Patients were matched on propensity score to adjust for differences in baseline demographics and disease characteristics. Treatment effect for OS was estimated using Cox proportional hazards models. Prognostic impact of expression of programmed cell death ligand-1 (PD-L1) (>25% of tumour cells [TC]/immune cells [IC] [high] or <25% TC/IC [low/negative]) on OS was also evaluated. As PD-L1 expression was only available for patients in study 1108, PD-L1 subgroups were compared to otherwise-matched CTx patients.

Results: After adjustment for baseline differences between the 2 groups, durvalumab demonstrated a statistically significant improvement in OS vs CTx (n = 158/arm; HR = 0.634, 95% CI 0.479-0.839; median OS 11.2 vs 8.19 months). Treatment effect of durvalumab was greater in the PD-L1 high subgroup (n = 91/arm; HR = 0.434, 95% CI 0.292-0.642; median OS 19.9 vs 7.84 months) vs matched CTx patients. There was no significant difference in OS for the PD-L1 low/negative subgroup for durvalumab vs CTx (n = 77/arm; HR = 0.989, 95% CI 0.679-1.440; median OS 4.86 vs 7.20 months).

Conclusions: This indirect, match-adjusted comparison of durvalumab versus CTx suggests that durvalumab provides a statistically significant improvement in OS vs CTx for patients with locally advanced or metastatic UC who progressed after platinum-based CTx; treatment effect was more pronounced in the PD-L1 high subgroup vs the PD-L1 low/negative subgroup.

Clinical trial identification: CD-ON-MEDI4736-1108 (NCT01693562).

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