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Patient-reported outcomes (PROs) from IMvigor130: A global, randomised, partially blinded phase III study of atezolizumab (atezo) + platinum-based chemotherapy (PBC) vs placebo (PBO) + PBC in previously untreated locally advanced or metastatic urothelial carcinoma (mUC)

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Background

IMvigor130 met its co-primary endpoint of PFS (HR, 0.82 [95% CI: 0.70, 0.96]) for Arm A (atezo + PBC) vs C (PBO + PBC; Grande ESMO 2019; Galsky *Lancet* 2020). Atezo + PBC was well tolerated. Here we present PROs (Arm A vs C) to better evaluate the overall treatment (tx) benefit of adding atezo to PBC.

Methods

1213 eligible patients (pts) were randomized to Arm A, B (atezo monotherapy) or C. Atezo or PBO was given 1200 mg IV on day (D) 1 of each 3-wk tx cycle; PBC included gemcitabine 1000 mg/m² IV on D1 and 8 + carboplatin AUC 4.5 or cisplatin 70 mg/m² IV on D1. EORTC QLQ-C30 was completed q3w during tx, at tx discontinuation and ≈ q3 mo during survival follow-up. Descriptive analyses of scale scores (range, 0-100) included change from baseline (BL) summaries and time to deterioration (TTD) in all-comers in Arm A (n = 451) and C (n = 400).

Results

Completion rates were 86% at BL and > 70% until wk 66 in both arms; BL PRO scores were comparable. TTD was similar for most function/quality of life (QOL; Table) and symptom scales. HRs for symptom scales (nausea/vomiting, insomnia, appetite loss, diarrhoea, pain, constipation, fatigue, dyspnoea) ranged from 0.74 (95% CI: 0.57, 0.96; nausea/vomiting) to 1.16 (95% CI: 0.89, 1.51; dyspnoea). 12-mo deterioration-free rates favoured Arm A for nausea/vomiting, appetite loss, role function and social function. Change from BL summaries suggested similar changes (stable or marginal improvement) for both arms in most symptom, function and QOL domains through wk 51 (23% pts eligible for PRO assessments). Arm A pts sustained improved QOL above BL until wk 117 (wk 69 in Arm C). Table: 6980

IMvigor130 Arms A vs C TTD

Scale	Stratified HR 95% CI	
Role function	0.82	0.66, 1.02
QOL	0.87	0.68, 1.11
Social function	0.88	0.70, 1.10
Emotional function	0.95	0.70, 1.28

Scale	Stratified HR 95% CI	
Cognitive function	0.97	0.76, 1.25
Physical function	1.05	0.84, 1.33

Stratification factors: PD-L1 status, Bajorin risk factors and/or liver metastases, investigator-specified PBC, enrolment stage. TTD refers to first \geq 10-point score deterioration from BL.

Conclusions

Atezo + PBC improved PFS vs PBO + PBC without compromising pt function or QOL. Collectively, prolonged PFS, a satisfactory safety profile and these PROs reinforce atezo + PBC as an important new 1L mUC tx option.

Clinical trial identification

NCT02807636.

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