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6980 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
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 ≥ 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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6990 Avelumab first-line (1L) maintenance + best supportive care (BSC) vs BSC alone for advanced urothelial carcinoma (UC): Association between clinical outcomes and exploratory biomarkers

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Background: In the phase 3 JAVELIN Bladder 100 trial (NCT02603432), avelumab (anti-PD-L1 IgG1 antibody) 1L maintenance + BSC significantly prolonged overall survival (OS) vs BSC alone in patients (pts) with advanced UC without disease progression with 1L induction chemotherapy in all randomized pts and pts with PD-L1+ tumors. We report exploratory biomarker analyses.

Methods: Tumor biopsies were collected prior to randomization. Tumor analyses included PD-L1 (Ventana SP263 assay) and CD8 immunohistochemistry, whole-exome sequencing (including *FCGR2A* and *FCGR3A* genotypes), whole-transcriptome

sequencing, and T-cell receptor (TCR) sequencing. Analyses of peripheral blood included baseline C-reactive protein (CRP) level and neutrophil:lymphocyte ratio (NLR) as well as TCR sequencing before and on treatment. Associations between OS or progression-free survival and biomarkers were evaluated using the Cox proportional hazards model. Hazard ratios and nominal p values were reported, and no multiplicity adjustments were made (5% level for statistical significance).

Results: Increased OS benefit with avelumab 1L maintenance + BSC vs BSC alone was positively associated with CD8⁺ T cells in the invasive margin or tumor center, high tumor mutation burden, and tumor gene expression signatures of innate and adaptive immune response. Increased OS benefit was also positively associated with the number of *FCGR2A/FCGR3A* alleles encoding high-affinity Fcγ receptors for IgG1. OS benefit with avelumab was negatively associated with tumor epithelial cell gene signatures, mutations affecting fibroblast growth factor receptor signaling, CRP, and NLR. In pts with elevated immune gene expression signatures, lower TGFβ expression was associated with greater OS benefit with avelumab. Further analyses will be presented, including outcomes by exploratory PD-L1 cutoffs in tumor vs immune cells.

Conclusions: OS benefits of avelumab 1L maintenance in pts with advanced UC are positively associated with biomarkers of immune activity and negatively associated with biomarkers of tumor homeostasis and chronic inflammation.

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Petrylak: Advisory/Consultancy, Research grant/Funding (institution): Ada Cap (Advanced Accelerator Applications); Advisory/Consultancy: Amgen; Advisory/Consultancy, Research grant/Funding (institution): Astellas; Advisory/Consultancy, Research grant/Funding (institution): AstraZeneca; Advisory/Consultancy, Research grant/Funding (institution): Bayer; Advisory/Consultancy: Bicycle Therapeutics; Advisory/Consultancy: Boehringer Ingelheim; Advisory/Consultancy, Research grant/Funding (institution): Bristol-Myers Squibb; Advisory/Consultancy, Research grant/Funding (institution): Clovis; Advisory/Consultancy, Research grant/Funding (institution): Eli Lilly; Advisory/Consultancy: Exelixis; Research grant/Funding (institution): Endocyte; Advisory/Consultancy: Incyte; Advisory/Consultancy: Janssen; Research grant/Funding (institution): Genetech; Research grant/Funding (institution): Inocin; Research grant/Funding (institution): MedImmune; Research grant/Funding (institution): Merck; Research grant/Funding (institution): Novartis; Advisory/Consultancy, Research grant/Funding (institution): Pfizer; Advisory/Consultancy: Pharmacocycles; Research grant/Funding (institution): Progenies; Advisory/Consultancy, Research grant/Funding (institution): Roche Laboratories; Advisory/Consultancy, Research grant/Funding (institution): Seattle Genetics; Research grant/Funding (institution): Sanofi Aventis; Advisory/Consultancy: Urogen; Shareholder/Stockholder/Stock options, Ownership Interest/Investment: Bellicum; Shareholder/Stockholder/Stock options, Ownership Interest/Investment (Sold 10/2019): Tyme. L.M. Dourthe: Honoraria (self), Advisory/Consultancy: Astellas; Honoraria (self), Advisory/Consultancy: Bayer; Travel/Accommodation/Expenses: Janssen; Advisory/Consultancy, Travel/Accommodation/Expenses: Pfizer. C. Alvarez-Fernandez: Advisory/Consultancy: Ipsen; Advisory/Consultancy: Boehringer Ingelheim; Travel/Accommodation/Expenses: Roche; Travel/Accommodation/Expenses: Pfizer; Travel/Accommodation/Expenses: Astellas. X.J. Mu: Research grant/Funding (self), Shareholder/Stockholder/Stock options, Full/Part-time employment: Pfizer. K.A. Ching: Research grant/Funding (self), Research grant/Funding (institution), Travel/Accommodation/Expenses, Shareholder/Stockholder/Stock options, Licensing/Royalties, Full/Part-time employment: Pfizer. J. Pu: Travel/Accommodation/Expenses, Full/Part-time employment: Roche; Full/Part-time employment: Pfizer. S. Roychoudhury: Full/Part-time employment: Pfizer. C.B. Davis: Shareholder/