

**2385P**  
**Long-term survival upon anti-PD-(L)1 monotherapy in metastatic urothelial cancer (mUC): A multicenter retrospective study**

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**Background**

Agents targeting programmed cell death (ligand) 1 (α-PD-(L)1) are approved as first- and second-line (1L, 2L) treatment options for mUC. Durable responses have been reported, but clinical trials were often closed before long-term follow-up (FU) could be assessed. C-reactive protein (CRP) and antibiotic (AB) use at start of α-PD-(L)1 have been suggested to be associated with progression. Here, we show 'real-world' long-term survival upon α-PD-(L)1 monotherapy for mUC and correlate outcome to several baseline clinical and laboratory parameters. We expect patients (pts) requiring AB around α-PD-(L)1 start to have poor survival outcomes.

**Methods**

This is a retrospective, multicenter study, in which data were collected for mUC pts treated with α-PD-(L)1 monotherapy as 1L-4L between 2014-2023. Overall- and progression-free survival (OS, PFS) were estimated with the Kaplan-Meier method. Uni- and multivariate regression models were used to identify independent factors associated with progression, death, PFS and OS.

**Results**

We included 375 pts (median age 67 years (yr) (59-75); 75% male; 68% visceral metastasis; 43% 1L α-PD-(L)1). After a median FU of 55 months (mo), median OS and PFS for all lines combined were 9 (7.448-10.552) and 3 mo (2.525-3.475) respectively. OS and PFS were comparable between treatment lines. For pts who did not progress within 2 yr after α-PD-(L)1 start, PFS and OS were 53.2% and 62.4% respectively at 5 yr after treatment start. Results from the regression analyses are depicted in the table. Table: 2385P

Regression analyses

	OS		PFS		Death		Progression	
	Univariate (U)	Multivariate (M)	U	M	U	M	U	M
Lymph node metastasis	0.000	0.038	0.000	0.122	0.000	0.776	0.000	0.179
Visceral metastasis	0.000	0.000	0.000	0.001				
gamma-glutamyltransferase >ULN	<0.001	0.198	<0.001	0.113	0.018	0.883	0.004	0.386
Lactate dehydrogenase >ULN	0.004	0.429	0.039	0.016	0.241	0.527	0.107	0.502
CRP>75 percentile	<0.001	0.264	0.010	0.919	0.274	0.985	0.499	0.237
AB use	0.094	0.004	0.618	0.002	0.324	0.290	0.945	0.182
Steroid use	0.111	0.178	0.338	0.199	0.512	0.787	0.415	0.477
Platinum fitness	0.676	0.242	0.719	0.147	0.694	0.498	0.087	0.120
Metastasis at cancer diagnosis	0.182	0.070	0.824	0.020	0.630	0.157	0.865	0.998

**Conclusions**

Median OS and PFS observed in our cohort is in line with data from clinical trials. Our data suggest that of the patients without progression at 24 mo, half will still be progression-free and alive at 5 yr from treatment start. Our data indicate that AB use around start of α-PD-(L)1 is associated with inferior PFS and OS. We recognize the retrospective nature of our cohort as a limitation. More data will be available and presented at ESMO2023.

## Legal entity responsible for the study

The Netherlands Cancer Institute.

## Funding

Has not received any funding.

## Disclosure

B. Perez Valderrama: Financial Interests, Personal, Advisory Board: Pfizer, Astellas Pharma, Bristol Myers Squibb, Ipsen, EUSA Pharma, Merck, MSD, AstraZeneca, AAA; Financial Interests, Personal, Invited Speaker: Bristol Myers Squibb, Roche, Bayer, EUSA Pharma, MSD, Merck, Pfizer, Janssen, Astellas Pharma, AAA. C. Vulsteke: Financial Interests, Personal, Advisory Board: MSD, Janssen-Cilag, GSK, Astellas Pharma, BMS, Leo Pharma, Bayer, AstraZeneca, Pfizer, Merck; Financial Interests, Institutional, Research Grant, Funding for research project on immune related toxicities: MSD. R. Morales Barrera: Financial Interests, Personal, Advisory Board: AstraZeneca, Astellas, Pfizer; Financial Interests, Personal, Invited Speaker: Pfizer, Astellas; Financial Interests, Personal, Other, Congress registration: Bayer, BMS; Financial Interests, Institutional, Other, Institutional: AB Science, Aragon Pharmaceuticals, Bayer, Aveo Pharmaceuticals INC, Astellas, AstraZeneca, Blueprint Medicines Corporation, BN Immunotherapeutics INC, Boehringer Ingelheim, Clovis Oncology, Deciphera Pharmaceuticals Llc, Exelixis, Roche, Genentech, GSK, Incyte Corporation, Karyopharm Therapeutics INC, Laboratoires Leurquin Mediolanum, Lilly, MedImmune, Millennium Pharmaceuticals, Nanobiotix, Novartis, Pfizer, Sanofi-Aventis, SFJ Pharma LTD, Teva Pharma; Financial Interests, Principal Investigator: AstraZeneca, Gilead, Roche, BMS, AstraZeneca, Pfizer, Astellas, MSD, Janssen, Clovis Oncology, GSK, Incyte Corporation. J. Carles Galceran: Financial Interests, Personal, Advisory Board: Astellas Pharma, AstraZeneca, Bayer, Johnson & Johnson, MSD Oncology, Novartis (AAA), Roche, Sanofi; Financial Interests, Institutional, Local PI: Janssen-Cilag International NV, Lilly, S.A, MedImmune, Novartis Farmacéutica, S.A, Sanofi-Aventis, S.A; Other, Member of the Comission: Catalan Program of Ambulatory Medication Comission (CAHMDA). P. Giannatempo: Financial Interests, Personal, Other, Personal fee: Merck, Janssen; Financial Interests, Institutional, Research Grant: AstraZeneca, Ipsen. P. Grivas: Financial Interests, Personal, Advisory Board: AstraZeneca, MSD, Bristol Myers Squibb, Asieris Pharmaceuticals, Merck KGaA, Seattle Genetics, Aadi Bioscience, Pfizer, Janssen, Boston Gene, Mirati Therapeutics, Exelixis, Genentech/Roche, Gilead Sciences, CG Oncology, Dyania Health, Infinity Pharmaceuticals, QED Therapeutics, 4D Pharma PLC, ImmunityBio, Lucence Health, G1 Therapeutics, Fresenius Kabi, Guardant Health, PureTech, Regeneron Pharmaceuticals, Strata Oncology, Urogen, Silverback Therapeutics, Astellas Pharma; Financial Interests, Institutional, Local PI: Pfizer, Clovis Oncology, Bavarian Nordic, Gilead Sciences, Bristol Myers Squibb, Debiopharm Group, MSD, QED Therapeutics, GSK, Mirati Therapeutics, G1 Therapeutics, Merck KGaA. M.S. van der Heijden: Financial Interests, Institutional, Advisory Board: AstraZeneca, BMS, Janssen, MSD, Seagen, Pfizer; Financial Interests, Institutional, Funding, Investigator-initiated trial: BMS, Roche, AstraZeneca, 4SC; Financial Interests, Institutional, Steering Committee Member, Local PI + SSC member: BMS, AstraZeneca, MSD, Seagen; Financial Interests, Institutional, Steering Committee Member, Local PI + study co-PI: Janssen; Financial Interests, Institutional, Local PI: GSK. All other authors have declared no conflicts of interest.

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