Atezolizumab in locally advanced or metastatic urothelial cancer (mUC): Pooled analysis from the Spanish patients of the IMvigor 210 and 211 studies.

Ignacio Durán[1], Daniel Castellano[2], Teresa Alonso[3], Jose Ángel Arranz[4], Pablo Borrega[5], Cristina Caballero[6], Isabel Chirivella[7], Pablo Gajate[3], Enrique Gallardo[8], Xavier García-del-Muro[9], Jorge García[10], Aránzazu González-del-Alba[11], Nuria Laínez[12], Marta Lopez-Brea[1], Pablo Maroto[13], Begoña Mellado[14], Maria José Méndez-Vidal[15], Álvaro Montesa[16], Rafael Morales[17], Jose Luis Pérez[18], Javier Puente[19]

[1]Marqués de Valdecilla University Hospital, Santander; [2]Doce de Octubre University Hospital, Madrid; [3]Ramon y Cajal University Hospital, Madrid; [4]Gregorio Marañón University Hospital, Madrid; Cáceres University Hospital, Cáceres; [6]Valencia General University Hospital, Valencia; [7]Valencia Clinic University Hospital, Valencia; [8]Parc Taulí University Hospital, Sabadell; [9]Catalan Institute for Oncology, Barcelona; [10]Santiago de Compostela Clinic University Hospital, Santiago de Compostela; [11]Puerta de Hierro University Hospital, Majadahonda; [12]Navarra Hospital Complex, Pamplona; [13]Santa Creu i Sant Pau Hospital, Barcelona; [14]Clinic Hospital, Barcelona; [15]Reina Sofía University Hospital, Córdoba; [16]Regional and Virgen de la Victoria University Hospitals, Málaga; [17]Vall d'Hebron University Hospital, Barcelona; [18]Navarra University Clinic, Pamplona; [19]San Carlos Clinic Hospital, Madrid).

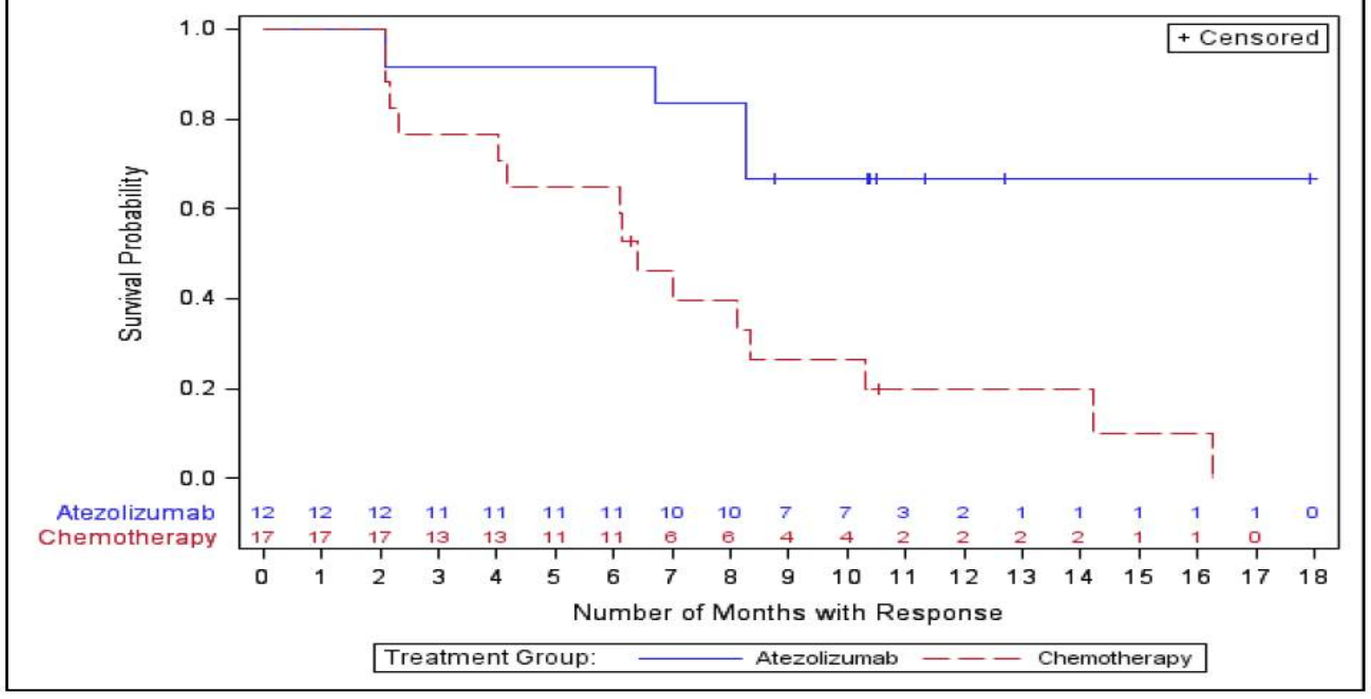
Introduction & Objectives.

Atezolizumab (ATZ) is a PD-L1 inhibitor licensed in mUC patients (pts) after platinum-based chemotherapy or in 1st line in platinum-unfit pts and with PDL1 expression ≥5% and pts who are ineligible for any platinum, irrespective of PD-L1 status (US only). We report here data from a pooled analysis of efficacy and safety of ATZ in Spanish pts that participated in the IMvigor210 cohort 2 and IMvigor211 studies.

Methods.

Overall response rate (ORR), duration of response (DoR), median PFS and OS in the ITT population and according to PDL1 expression (Ventana PD-L1 SP142 assay) on tumor-infiltrating immune cells were assessed.

Duration of response in months. ITT population



Results.

Seventy-four patients received ATZ and 53 patients received chemotherapy (CTX). The ORR for ATZ was 16 % and 32% for CTX. Median PFS was 5.3 months in pts receiving CTX vs 2.1 months in pts receiving ATZ. However, median OS was numerically higher in pts receiving ATZ than in pts receiving CTX (9.2 vs 7.7months) (HR 0.86, 95%CI: 0.57-1.29). When stratified by PDL1 expression, median OS in IC0/1 pts (n=98) was 9.2 vs 6.4 months (p=0.16) for ATZ and CTX respectively, and 10.9 and 12.0 months (p=0.225) for the IC2/3 pts (n= 33).

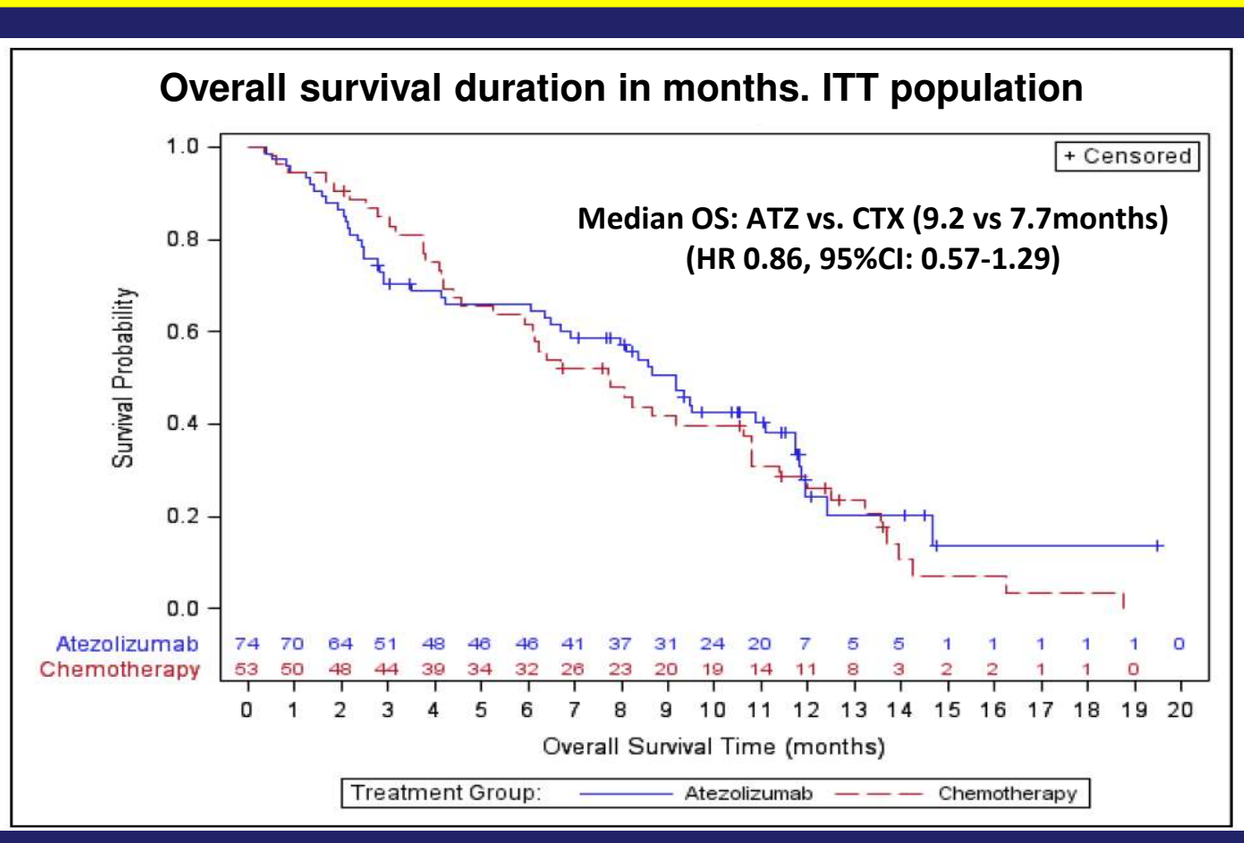
Among the pts who responded, 6 and 12-month survival rates were 92 and 67% with ATZ vs 65 and 20% with CTX. Median OS was not reached for ATZ vs 6.4 months for CTX (HR 0.24, 95%CI: 0.07-0.66). For the IC0/1 and the IC2/3 pts the 12-month survival rate was 57 vs 20%, and 80 vs 20% for ATZ vs. CTX, respectively.

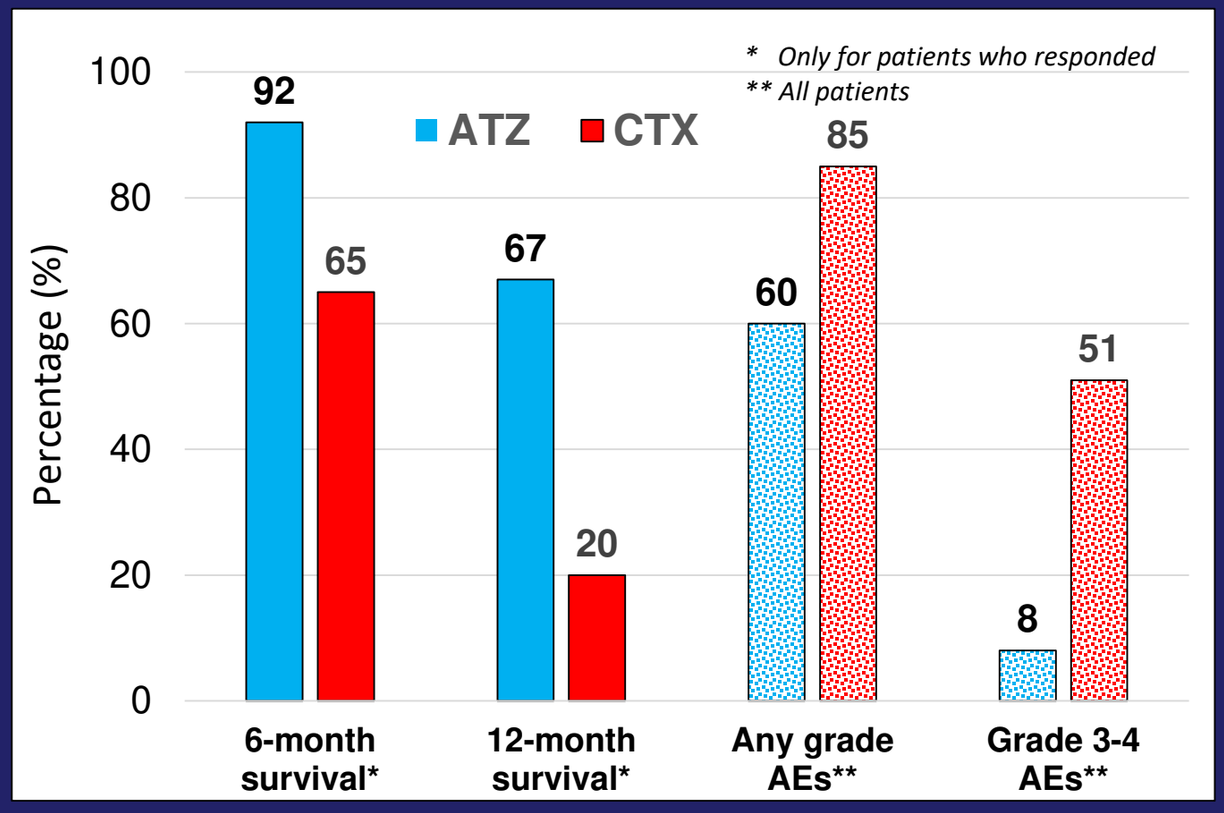
Any grade adverse events (AEs) occurred in 44/74 (60%) ATZ pts vs 45/53 (85%) of those with CTX. Grade 3-4 AEs were documented in 6 out of 74 (8%) ATZ vs 27 out of 53 (51%) CTX patients. Among patients treated with CTX, grade 3-4 AEs occurred in 22/36 (61%) of pts treated with vinflunine and 5/17 (29%) of patients treated with taxanes. The most frequent AEs (≥10% of pts) were asthenia (including 4% of Grade 3-4), pruritus and diarrhea in pts treated with ATZ and asthenia, neutropenia, constipation, alopecia, abdominal pain, anemia, nausea, diarrhea, mucositis, decreased appetite and vomiting in pts treated by CTX. More common grade 3-4 AEs in this group were neutropenia (36%), asthenia (11%), constipation (9%), anemia (8%) and abdominal pain (6%).

Conclusion.

Patients who responded to ATZ presented numerically a longer duration of response and 12-month survival rates than CTX responders. Moreover, ATZ presented a distinct and more manageable safety and tolerability profile than CTX both in quantitative terms, regarding less all grade and grade 3-4 AEs, and in qualitative terms as a distinct toxicity profile.

Overall survival duration in months. ITT population





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Ignacio Durán - ignacioduranmartinez@gmail.com