

6-7 JULIO 2023

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and Development

GUARD SYMPOSIUM

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Adyuvancia en tumores uroteliales

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JULIO 2023

Objetivos

- Flujo de pacientes
- Definir perfil de pacientes: documento de consenso
- Nuevos proyectos
 - RWD
 - Nomogramas
 - Histologías mixtas

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Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

Characteristic	Nivolumab (N=353)	Placebo (N=356)
Age		
Mean (range) — yr	65.3 (30–92)	65.9 (42–88)
<65 yr — no. (%)	155 (43.9)	136 (38.2)
≥65 yr — no. (%)	198 (56.1)	220 (61.8)
Sex — no. (%)		
Male	265 (75.1)	275 (77.2)
Female	88 (24.9)	81 (22.8)
Race or ethnic group — no. (%)†		
White	264 (74.8)	272 (76.4)
Asian	80 (22.7)	75 (21.1)
Black	2 (0.6)	3 (0.8)
American Indian or Alaska Native	1 (0.3)	0
Other	6 (1.7)	5 (1.4)
Not reported	0	1 (0.3)
ECOG performance-status score — no. (%)‡		
0	224 (63.5)	221 (62.1)
1	122 (34.6)	125 (35.1)
2	7 (2.0)	9 (2.5)
Not reported	0	1 (0.3)
Tumor origin at initial diagnosis — no. (%)		
Urinary bladder	279 (79.0)	281 (78.9)
Renal pelvis	44 (12.5)	52 (14.6)

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Characteristic	Nivolumab (N=353)	Placebo (N=356)
Urinary bladder	279 (79.0)	281 (78.9)
Renal pelvis	44 (12.5)	52 (14.6)
Ureter	30 (8.5)	23 (6.5)
Time from initial diagnosis to randomization — no. (%)		
<1 yr	325 (92.1)	324 (91.0)
≥1 yr	28 (7.9)	32 (9.0)
PD-L1 expression level of ≥1% by IVRS — no. (%)	140 (39.7)	142 (39.9)
Previous neoadjuvant cisplatin therapy — no. (%)	153 (43.3)	155 (43.5)
Pathological tumor stage and nodal status at resection — no. (%)§		
pT2N-	25 (7.1)	29 (8.1)
pT3,4N-	158 (44.8)	159 (44.7)
pT0-4N1	71 (20.1)	72 (20.2)
pT0-4N2,3	96 (27.2)	96 (27.0)
pTisN-	1 (0.3)	0
Not reported	2 (0.6)	0
Pathological tumor stage at resection — no. (%)¶		
pTX	5 (1.4)	0
pT0	5 (1.4)	7 (2.0)
pTis	4 (1.1)	3 (0.8)
pT1	13 (3.7)	14 (3.9)
pT2	62 (17.6)	65 (18.3)
pT3	206 (58.4)	204 (57.3)

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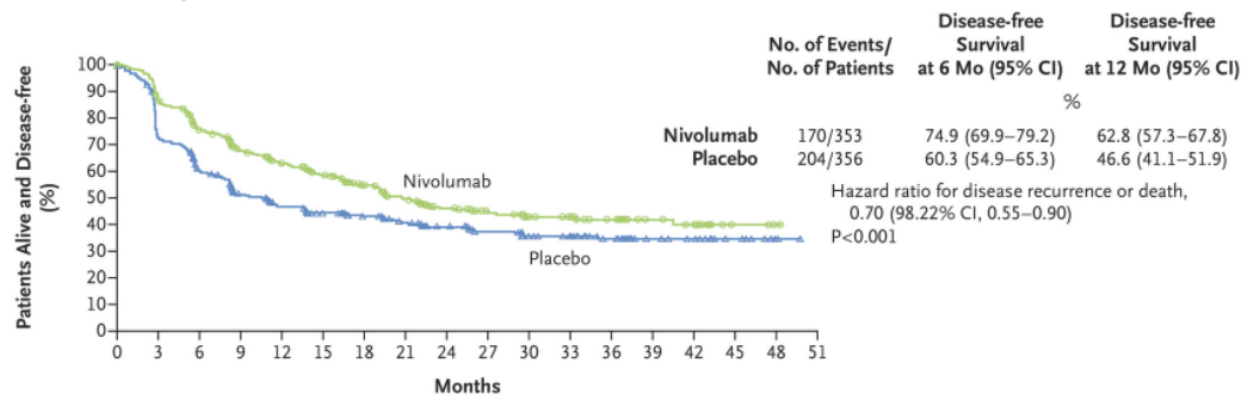
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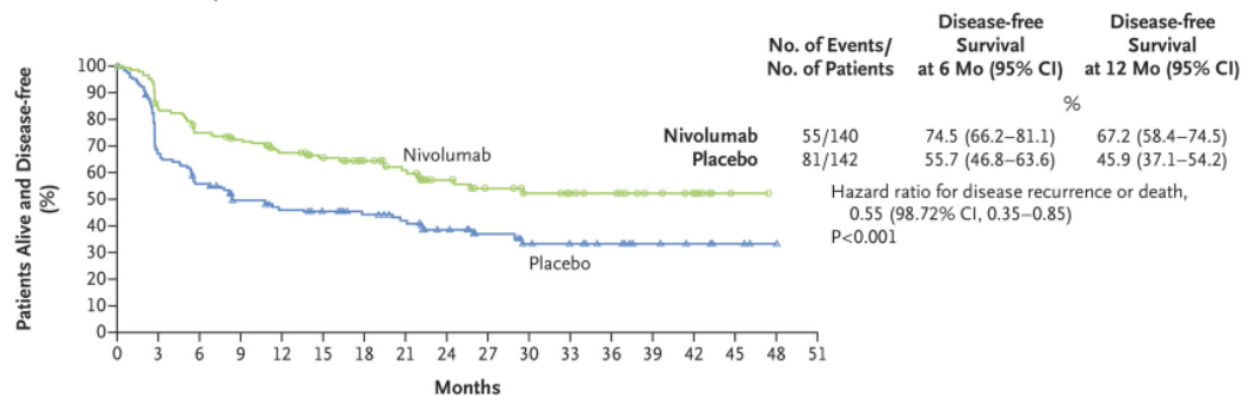
A Intention-to-Treat Population



No. at Risk

Nivolumab	353	296	244	212	178	154	126	106	85	68	57	51	36	23	20	3	1	0
Placebo	356	248	198	157	134	121	105	94	80	65	54	50	37	22	19	10	2	0

B Patients with a PD-L1 Expression Level of $\geq 1\%$



No. at Risk

Nivolumab	140	113	98	91	76	68	58	50	38	31	27	24	21	12	10	1	0	0
Placebo	142	90	73	59	53	49	42	37	28	22	17	16	12	7	5	3	1	0

Casos clinicos

- Mujer 47 años
 - Tumor localizado de vejiga
cT3N0M0
 - Fit para cisplatino
 - Cisplatino-gemcitabinax4 ciclos.
 - TC enfermedad estable
 - Cistectomia :
 - Carcinoma urotelial alto grado
pT3N0M0
 - PDL1 +
- Hombre de 75 años
 - Tumor localizado vejiga
 - Infecciones de repetición
 - Clínica local : polaquiruria cada 30 minutos.
 - Fit para cisplatino
 - Cistoprostatectomia pT3N0

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