III JORNADA DE ACTUALIZACIÓN EN
URO-ONCOLOGÍA:
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IMvigor011: a Phase 3 trial of circulating tumour (ct)DNA-guided adjuvant atezolizumab vs placebo in muscle-invasive bladder cancer

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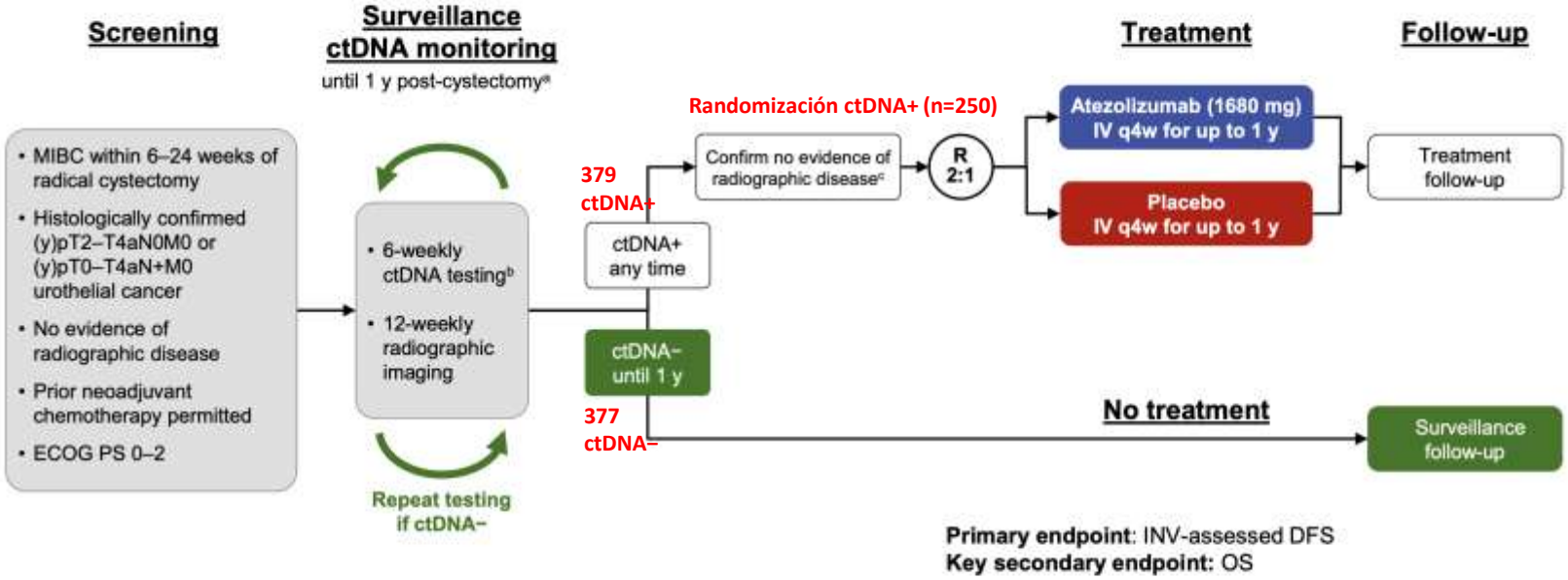
- Tras cistectomía (± neoadyuvancia), **~50%** de MIBC **recaen** → peor pronóstico.
- Adyuvancia: recomendada, pero **sin beneficio claro en supervivencia** en no seleccionados.
- **ctDNA/MRD** post-cistectomía: **fuertemente pronóstico** → permite **estratificar riesgo**.
- Tratar **solo ctDNA+** podría **enriquecer beneficio** y **evitar sobretratamiento** en ctDNA−; IMvigor010 sugiere señal en ctDNA+.

Stein JP, et al. J Clin Oncol 2001;19:666-75. Bajorin DF, et al. N Engl J Med 2021;384:2102-14. Christensen E, et al. J Clin Oncol 2019;37:1547-57. Powles T, et al. Nature 2021;595:432-7. Powles T, et al. J Clin Oncol 2025;43:4503.

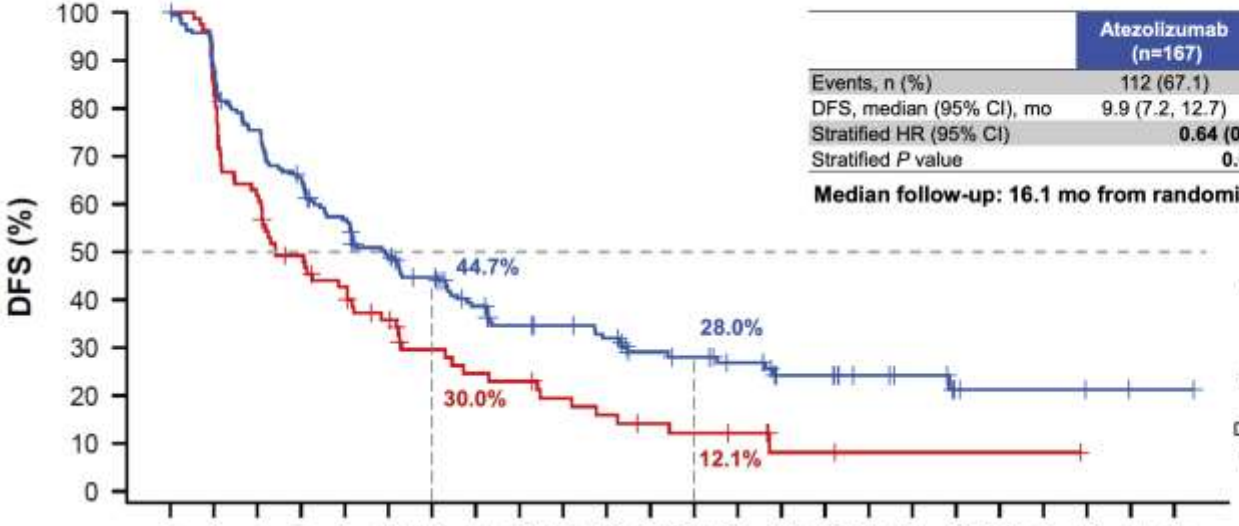
IMvigor011 study design



ClinicalTrials.gov number, NCT04660344. Stratification factors were nodal status (positive vs negative), tumour stage at cystectomy (≤pT2 vs pT3/pT4), PD-L1 status (IC0/1 [<5%] vs IC2/3 [≥5%] by VENTANA SP142 immunohistochemistry assay) and time from cystectomy to first ctDNA+ sample (≤20 weeks vs >20 weeks). [a] Early versions of the protocol included a 21-mo surveillance ctDNA monitoring period. [b] ctDNA status was determined by the Natera Signatera™ MRD test (outside of mainland China) and by the BGI MRD test (in mainland China). [c] By INV and IRF assessment. ECOG PS, Eastern Cooperative Oncology Group performance status; IC, immune cells; INV, investigator; IRF, independent review facility; IV, intravenous; mo, month; PD-L1, programmed death-ligand 1; R, randomised; y, year.
Adapted from Powles T, et al. ESMO 2021 (Abstract 3716) with permission.

Presented by: Thomas Powles, MBBS, MRCP, MD

INV-assessed DFS in patients who tested ctDNA+



	Atezolizumab (n=167)	Placebo (n=83)
Events, n (%)	112 (67.1)	66 (79.5)
DFS, median (95% CI), mo	9.9 (7.2, 12.7)	4.8 (4.1, 8.3)
Stratified HR (95% CI)	**0.64 (0.47, 0.87)**	
Stratified *P* value	**0.0047**	

Median follow-up: 16.1 mo from randomisation

Consistent benefit in relevant secondary endpoints:

DFS per IRF:
HR, 0.66 (95% CI: 0.48, 0.91)

Distant-metastasis free survival:
HR, 0.66 (95% CI: 0.47, 0.94)

No. at risk

Atezolizumab	167	145	122	105	89	73	63	50	42	40	36	28	26	22	16	16	11	9	4	3	3	2	1	1
Placebo	83	69	50	38	32	25	18	15	14	11	9	7	6	5	2	2	1	1	1	1	1			

Clinical cutoff: 15 June 2025. CI, confidence interval.

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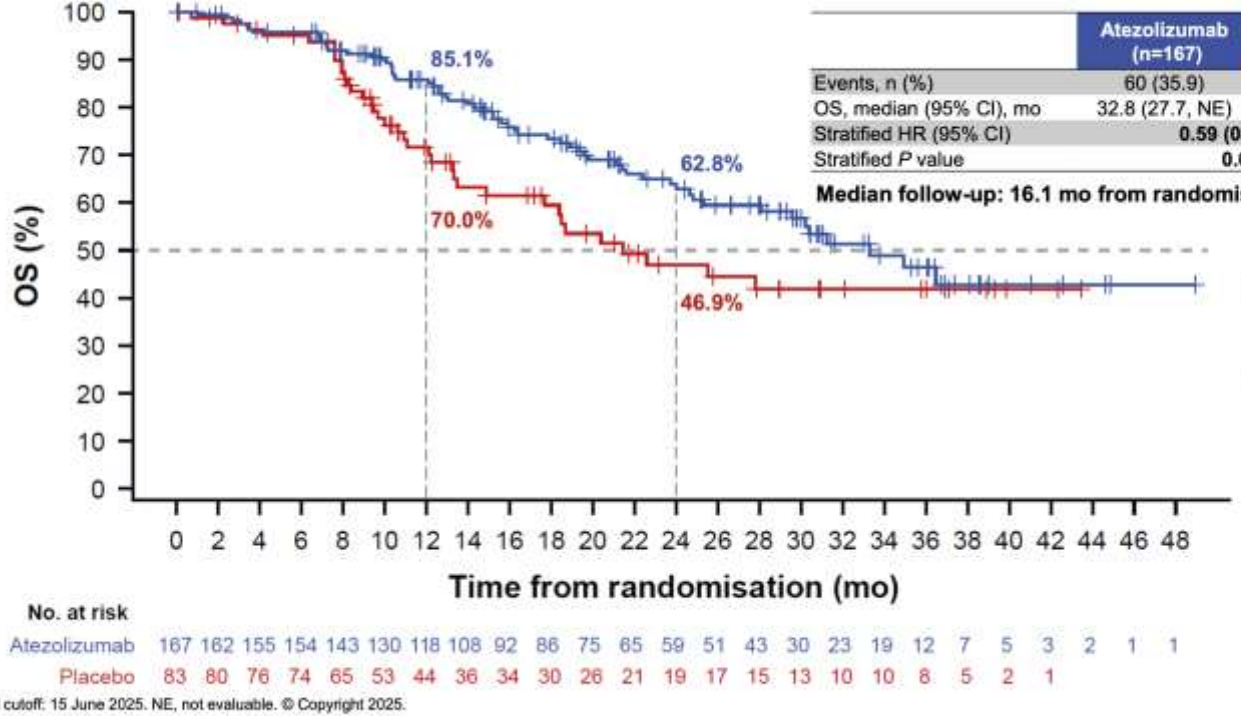
OS in patients who tested ctDNA+



	Atezolizumab (n=167)	Placebo (n=83)
Events, n (%)	60 (35.9)	36 (43.4)
OS, median (95% CI), mo	32.8 (27.7, NE)	21.1 (14.7,NE)
Stratified HR (95% CI)	**0.59 (0.39, 0.90)**	
Stratified *P* value	**0.0131**	

Median follow-up: 16.1 mo from randomisation

Consistent benefit in relevant secondary endpoints:

Disease-specific survival:
HR, 0.64 (95% CI: 0.40, 1.05)

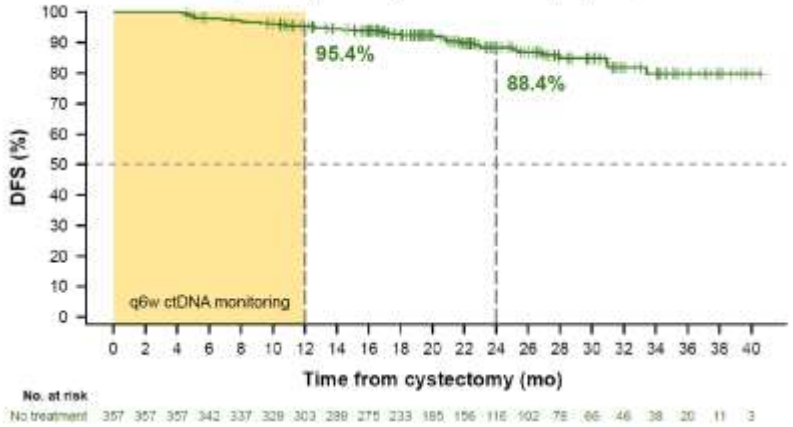
Clinical cutoff: 15 June 2025. NE, not evaluable.

Presented by: Thomas Powles, MBBS, MRCP, MD

DFS and OS in patients who persistently tested ctDNA−

INV-assessed DFS

	No treatment (n=357)
Events, n (%)	39 (10.9)
DFS, median (95% CI), mo	NE (NE)

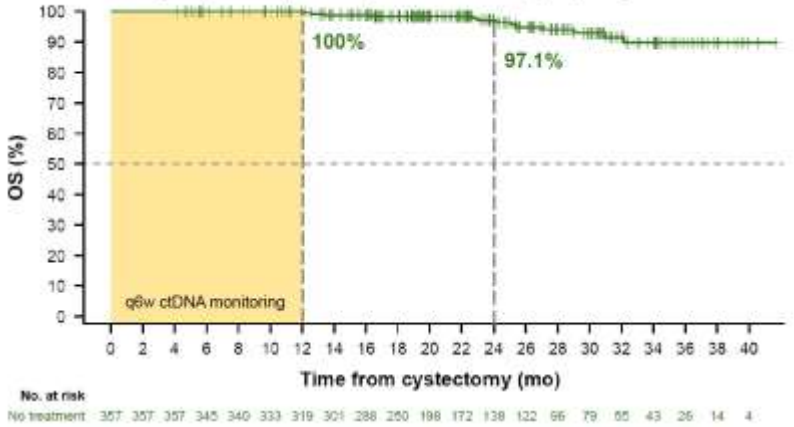


8 DFS events were deaths not clearly attributed to disease recurrence

Median follow-up:
21.8 mo from cystectomy

OS

	No treatment (n=357)
Events, n (%)	14 (3.9)
OS, median (95% CI), mo	NE (NE)



15 patients (4.2%) who experienced disease recurrence during the ctDNA monitoring period were discontinued from the study and censored for OS

Clinical cutoff: 15 June 2025. To be included in the ctDNA− efficacy-evaluable population, patients must have ≥1 negative test result and no positive test result, had ≥1 post-baseline clinical outcome assessment and completed 1 y of surveillance or discontinued from surveillance without a ctDNA+ result. q6w, every 6 weeks

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- En **ctDNA+**, atezolizumab adyuvante **↑DFS y ↑OS** vs placebo.
- Beneficio consistente (incl. **pT2N0**) → ctDNA añade riesgo más allá del estadio.
- Eficacia similar: **ctDNA+ basal** (60%) y **conversión** a ctDNA+ (40%) en seguimiento.
- **ctDNA– persistente (50%)**: bajo riesgo (**DFS 10.9%**, **OS 3.9%**; medianas **NE**)

La monitorización seriada de ctDNA puede identificar a los pacientes con MIBC que se benefician del atezolizumab adyuvante.

¿Es aplicable a la práctica clínica actual?