Plenaria II

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Iniciativa científica de:

GECP

Grupo Español de Cáncer de Pulmón
Spanish Lung Cancer Group

PACIFIC: Resultados supervivencia

- Unresectable, Stage III NSCLC without progression after definitive platinum-based cCRT (≥2 cycles)
- 18 years or older
- WHO PS score 0 or 1
- If available, archived pre-cCRT tumor tissue for PD-L1 testing*

All-comers population (i.e. irrespective of PD-L1 status)

N=713 randomized

1–42 days post-cCRT

R

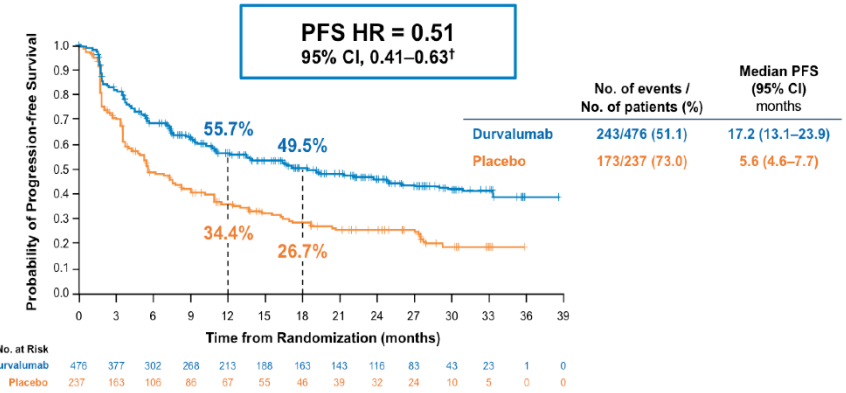
2:1 randomization, stratified by age, sex, and smoking history

Durvalumab 10 mg/kg q2w for up to 12 months N=476

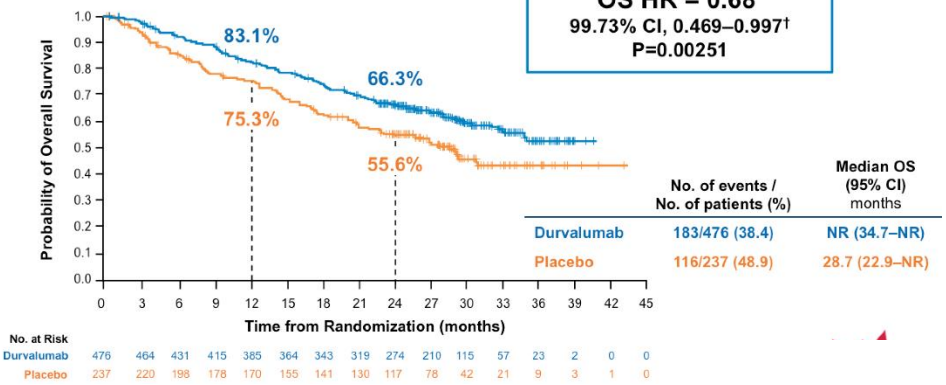
Placebo 10 mg/kg q2w for up to 12 months N=237

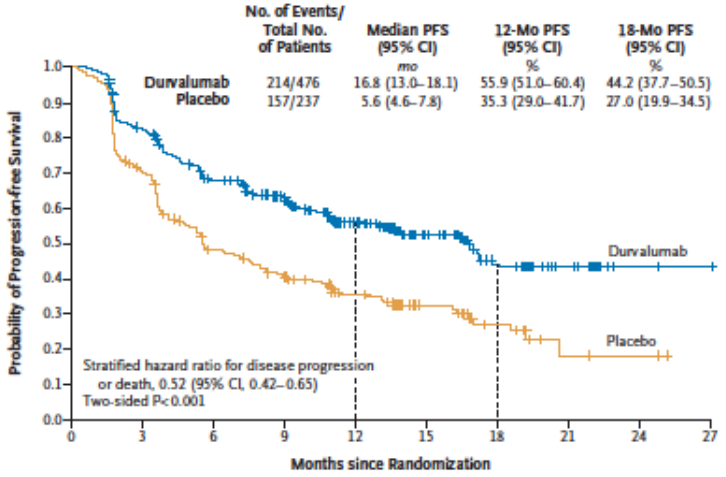
Primary endpoints
- PFS by BICR using RECIST v1.1†
- OS

Key secondary endpoints
- ORR, DoR and TTDM by BICR
- PFS2 by investigator
- Safety
- PROs



Overall Survival* (ITT)





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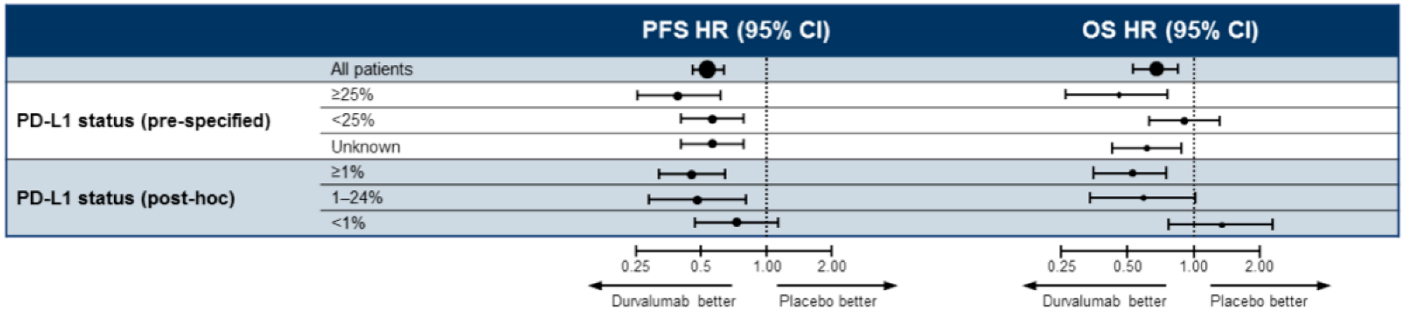
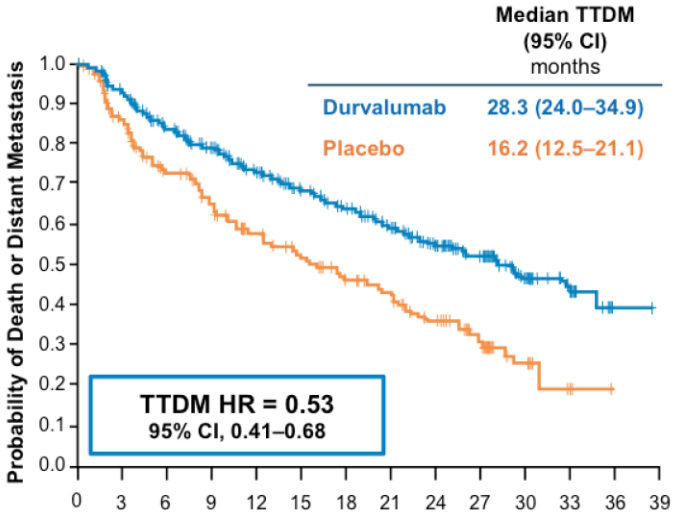


Updated Time to Death or Distant Metastasis (TTDM) by BICR* (ITT)



Updated Incidence of New Lesions by BICR* (ITT)

New Lesion Site†	Durvalumab (N=476)	Placebo (N=237)
Patients with any new lesion, n (%)	107 (22.5)	80 (33.8)
Lung	60 (12.6)	44 (18.6)
Lymph nodes	31 (6.5)	27 (11.4)
Brain	30 (6.3)	28 (11.8)
Liver	9 (1.9)	8 (3.4)
Bone	8 (1.7)	7 (3.0)
Adrenal	3 (0.6)	5 (2.1)
Other	10 (2.1)	5 (2.1)

PACIFIC: resultados supervivencia

	No. of events / No. of patients	Median OS (95% CI) months	12-mo OS (95% CI) %	24-mo OS (95% CI) %
Durvalumab	183/476	NR (34.7–NR)	83.1 (79.4–86.2)	66.3 (61.7–70.4)
Placebo	116/237	28.7 (22.9–NR)	75.3 (69.2–80.4)	55.6 (48.9–61.8)

- Mantenimiento con Durvalumab tras QT/RT nuevo estándar
- Rama control con PFS inferior a la esperable, pero OS dentro de rango
- Neumonitis 34%, (3% G3)
- Si inicia tratamiento Durvalumab < 14 d post-QT/RT HR 0.42 (0.81 si > 14 días)
- Positividad IHQ PD-L1?
- Duración de tratamiento?
- Inicio de tratamiento IT: concurrente?

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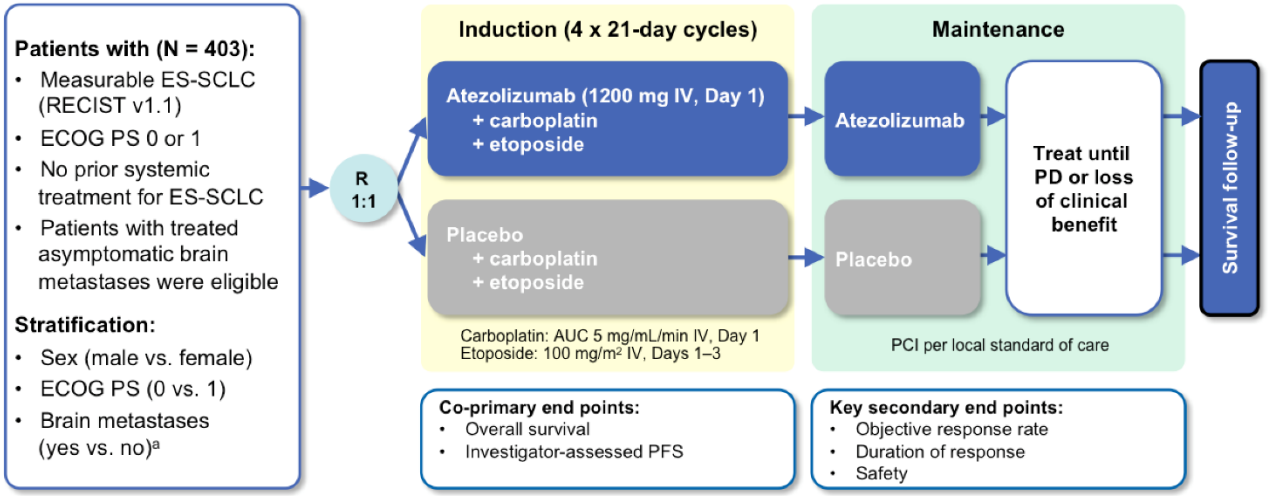
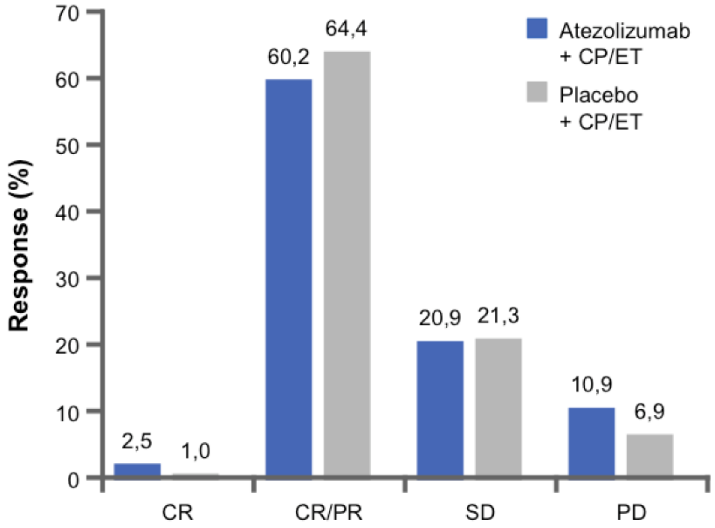
Inmunoterapia microcítico EE: Impower133





Duration of response	Atezolizumab + CP/ET (N = 121)	Placebo + CP/ET (N = 130)
Median duration, months (range)	4.2 (1.4[a] to 19.5)	3.9 (2.0 to 16.1[a])
HR (95% CI)	0.70 (0.53, 0.92)	
6-month event-free rate — %	32.2	17.1
12-month event-free rate — %	14.9	6.2
Patients with ongoing response — no. (%)[b]	18 (14.9)	7 (5.4)

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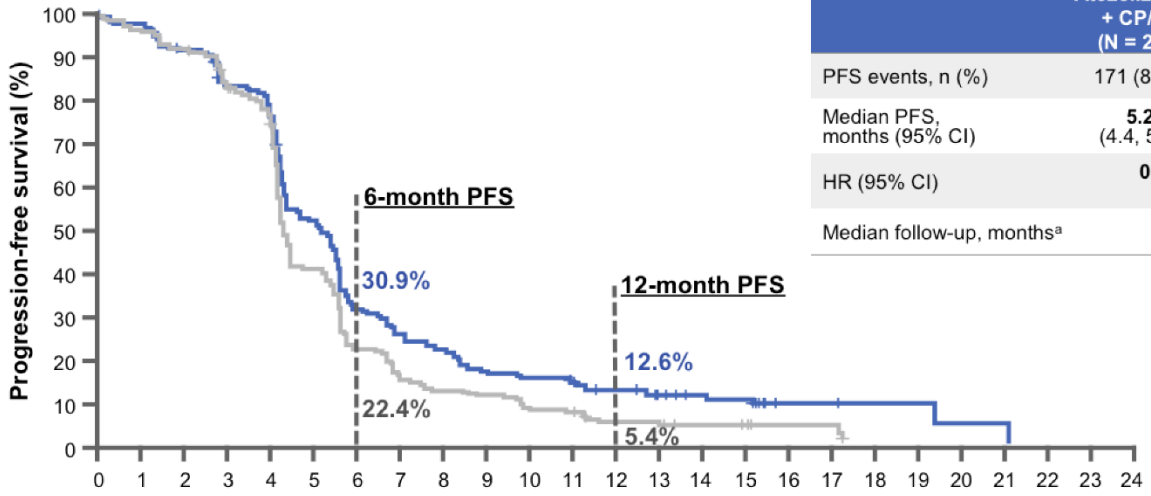
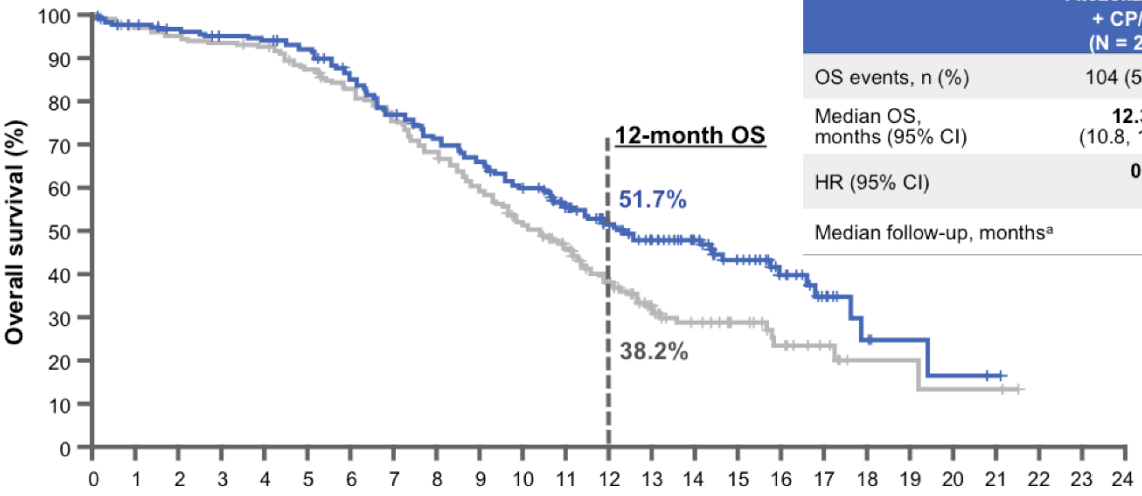
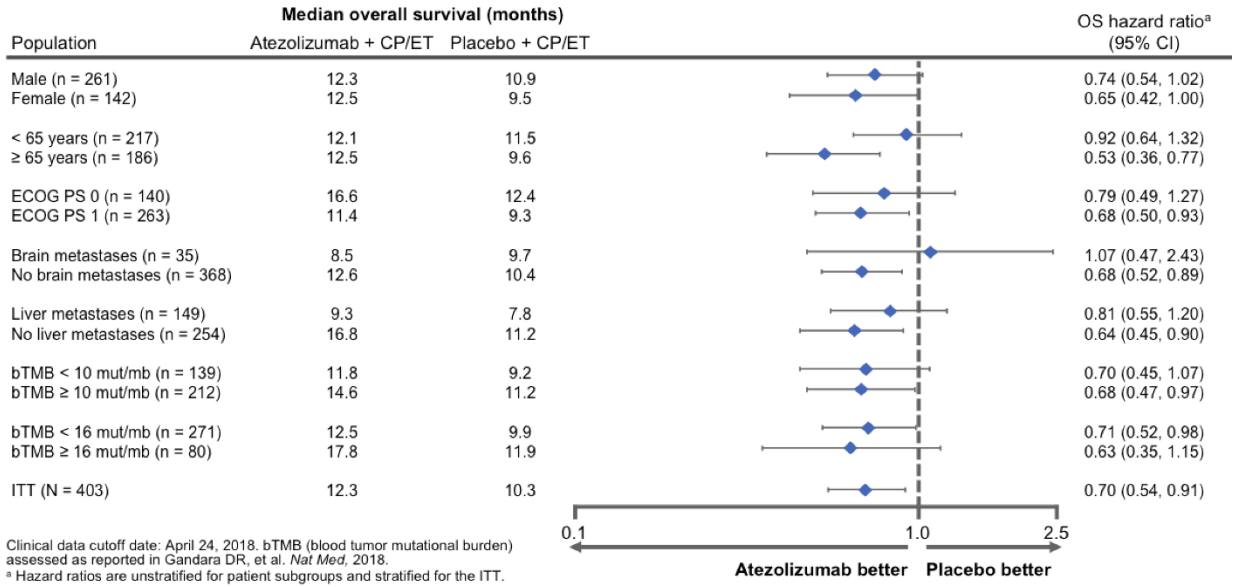


	Atezolizumab + CP/ET (N = 201)	Placebo + CP/ET (N = 202)
PFS events, n (%)	171 (85.1)	189 (93.6)
Median PFS, months (95% CI)	**5.2** (4.4, 5.6)	**4.3** (4.2, 4.5)
HR (95% CI)	**0.77** (0.62, 0.96) p = 0.017	
Median follow-up, months[a]	13.9	



	Atezolizumab + CP/ET (N = 201)	Placebo + CP/ET (N = 202)
OS events, n (%)	104 (51.7)	134 (66.3)
Median OS, months (95% CI)	**12.3** (10.8, 15.9)	**10.3** (9.3, 11.3)
HR (95% CI)	**0.70** (0.54, 0.91) p = 0.0069	
Median follow-up, months[a]	13.9	

Inmunoterapia microcítico EE: Impower133



Clinical data cutoff date: April 24, 2018. bTMB (blood tumor mutational burden) assessed as reported in Gandara DR, et al. *Nat Med*. 2018.
[a] Hazard ratios are unstratified for patient subgroups and stratified for the ITT.

Patients — no. (%)	Atezolizumab Group (N=198)	Placebo Group (N=196)
Patients with ≥1 AE	198 (100)	189 (96.4)
Grade 3–4 AEs	133 (67.2)	125 (63.8)
Grade 5 AEs	4 (2.0)	11 (5.6)
Treatment-related AEs*	188 (94.9)	181 (92.3)
Treatment-related Grade 3–4 AEs	112 (56.6)	110 (56.1)
Treatment-related Grade 5 AEs	3 (1.5)	3 (1.5)
Serious AEs	74 (37.4)	68 (34.7)
Treatment-related serious AEs*	45 (22.7)	37 (18.9)
AEs leading to withdrawal from any treatment*	22 (11.1)	6 (3.1)
AEs leading to withdrawal from carboplatin	5 (2.5)	1 (0.5)
AEs leading to withdrawal from etoposide	8 (4.0)	2 (1.0)