#ESMOUPDATES

Iniciativa científica de:

GECP lung cancer research

LUNG CANCER UPDATES

ESMO HIGHLIGHTS

27 SEPTIEMBRE - 1 OCTUBRE 2019

Con la colaboración de:

Bristol-Myers Squibb

illumina

Lilly

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BARCELONA

Mesotelioma inmunoterapia

Dr. Manuel Dómine Gómez

Con la colaboración de:
Bristol-Myers Squibb
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Lilly

PROMISE ETOP 9-15: PHASE III TRIAL COMPARING PEMBROLIZUMAB VS SINGLE AGENT CHEMOTHERAPY FOR ADVANCED PRE-TREATED MPM

LUNG CANCER UPDATES
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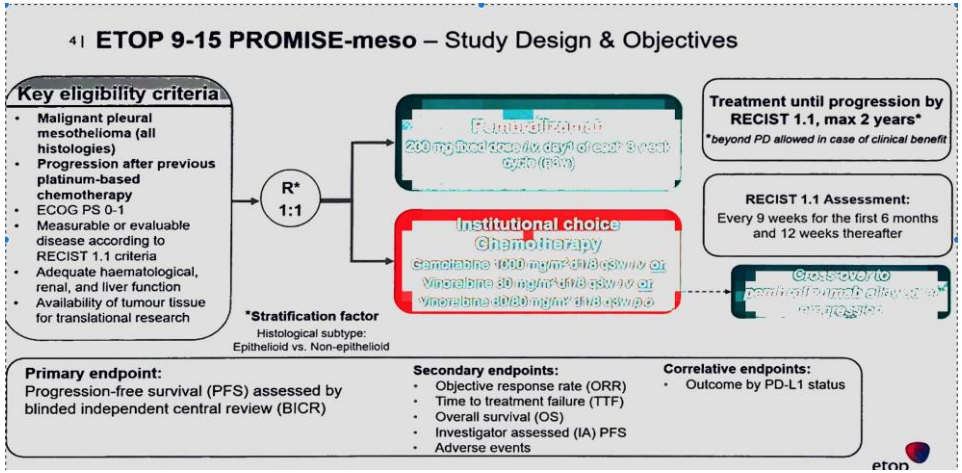

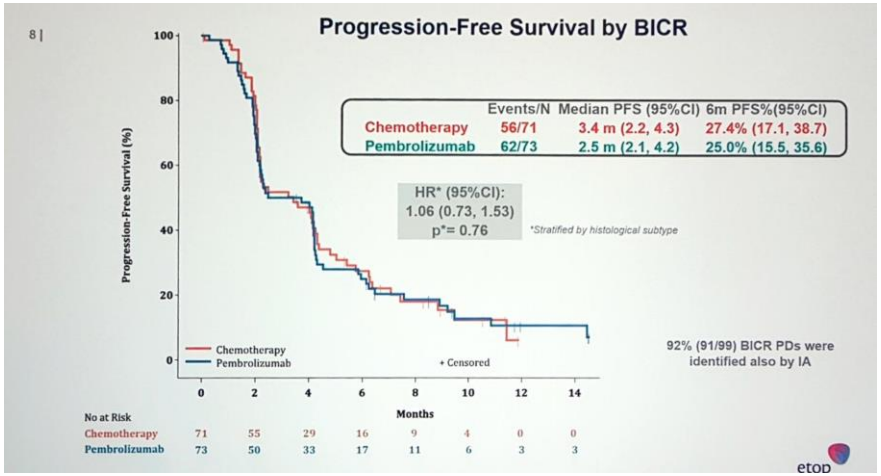

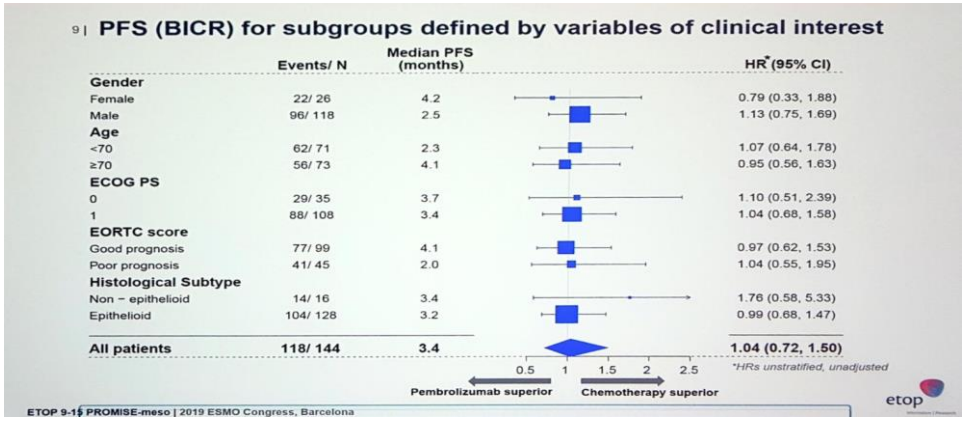

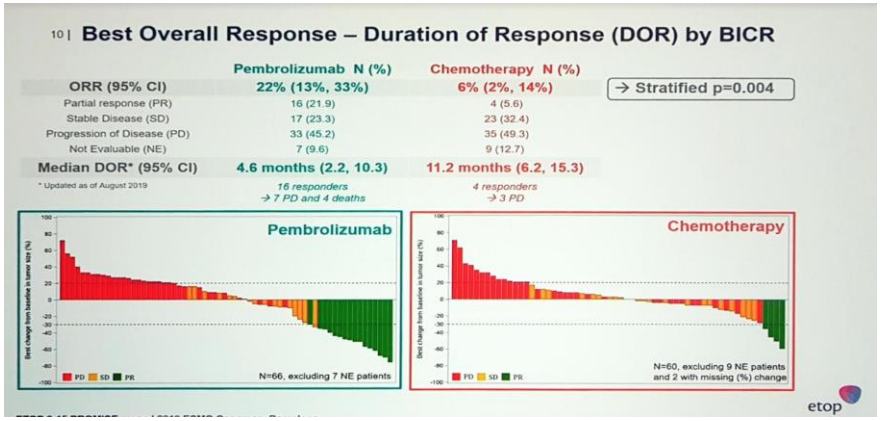

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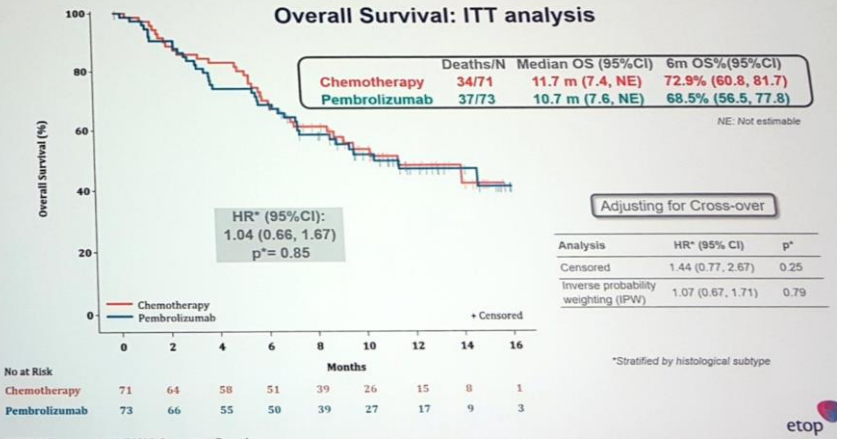
11 | Overall Survival: ITT analysis



	Deaths/N	Median OS (95%CI)	6m OS%(95%CI)
Chemotherapy	34/71	11.7 m (7.4, NE)	72.9% (60.8, 81.7)
Pembrolizumab	37/73	10.7 m (7.6, NE)	68.5% (56.5, 77.8)

NE: Not estimable

HR* (95%CI): 1.04 (0.66, 1.67)
p*= 0.85

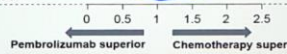
Adjusting for Cross-over

Analysis	HR* (95% CI)	p*
Censored	1.44 (0.77, 2.67)	0.25
Inverse probability weighting (IPW)	1.07 (0.67, 1.71)	0.79

*Stratified by histological subtype

12 | OS (ITT) for subgroups defined by variables of clinical interest

	Deaths/ N	Median OS (months)	HR* (95% CI)
Gender			
Female	12/ 26	9.9	0.67 (0.21, 2.08)
Male	59/ 118	11.7	1.15 (0.69, 1.91)
Age			
<70	35/ 71	14.3	0.99 (0.50, 1.96)
≥70	36/ 73	11.7	1.08 (0.56, 2.09)
ECOG PS			
0	13/ 35	NR	0.94 (0.30, 2.91)
1	57/ 108	9.9	1.12 (0.67, 1.89)
EORTC score			
Good prognosis	40/ 99	15.0	1.02 (0.55, 1.89)
Poor prognosis	31/ 45	7.0	0.82 (0.40, 1.68)
Histological Subtype			
Non – epithelioid	10/ 16	9.1	1.34 (0.38, 4.74)
Epithelioid	61/ 128	14.3	1.01 (0.61, 1.66)
All patients	**71/ 144**	**11.7**	**1.04 (0.65, 1.66)**



*HRs unstratified, unadjusted

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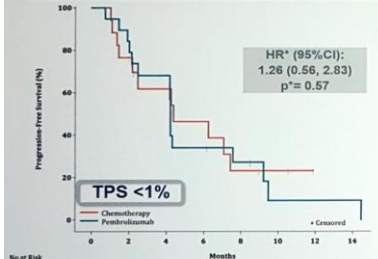
16 | PFS (BICR) by PD-L1 status

	Events/N	Median PFS (95%CI)	6m PFS (95%CI)
Chemo.	11/17	4.4 m (1.4, 7.4)	46.3% (20.2, 69.1)
Pembro.	16/19	4.2 m (2.1, 7.6)	34.0% (14.0, 55.3)

HR* (95%CI): 1.26 (0.56, 2.83)
p*= 0.57

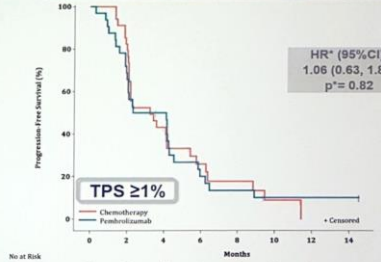
TPS <1%



	Events/N	Median PFS (95%CI)	6m PFS (95%CI)
Chemo.	29/34	3.2 m (2.1, 4.1)	25.8% (12.1, 42.0)
Pembro.	28/32	3.2m (1.9, 4.2)	20.0% (8.2, 35.5)

HR* (95%CI): 1.06 (0.63, 1.80)
p*= 0.82

TPS ≥1%



*Stratified by histological subtype

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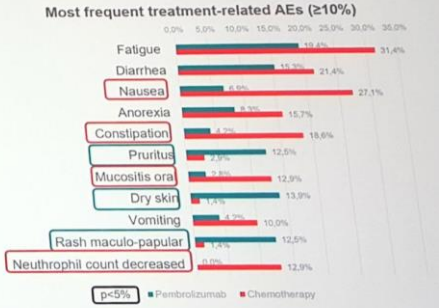
18 | Safety summary (N=142 patients, safety cohort)

	Pembrolizumab N of patients (%)	Chemotherapy N of patients (%)
Safety cohort	72	70
Patients experiencing:		
Any Adverse Event (AE)	70 (97.2)	65 (92.9)
Any Treatment-related AE (TrAE)	50 (69.4)	51 (72.9)
TrAEs of grade 3-5	14 (19.4)	17 (24.3)
TrAEs leading to treatment discontinuation	6 (8.3)	5 (7.1)
TrAEs leading to death	1* (1.4)	1** (1.4)

* Confusion

**Dyspnea, with disease progression being the primary cause of death



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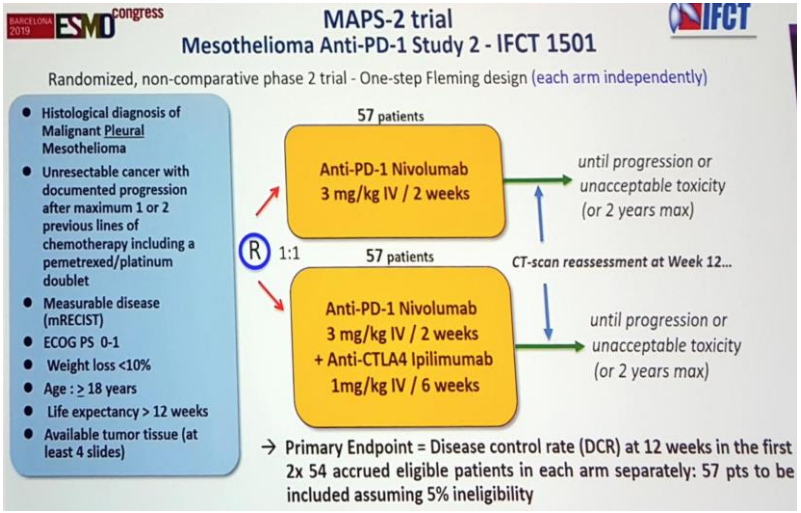
Second or 3rd line Nivolumab vs Nivo + Ipilimumab in MPM patients: Long-term results of the IFCT 1501 MAPS 2 randomized phase II trial with afocus in hyperprogression



Primary Endpoint= Disease Control Rate at 12 weeks assessment in the first 108 evaluable patients : had to be ≥40%

By an independent panel of 3 radiologists blinded to the randomization arm

DCR in **Nivo** arm was : **44.4%** [31.2-57.7%] in 54 patients

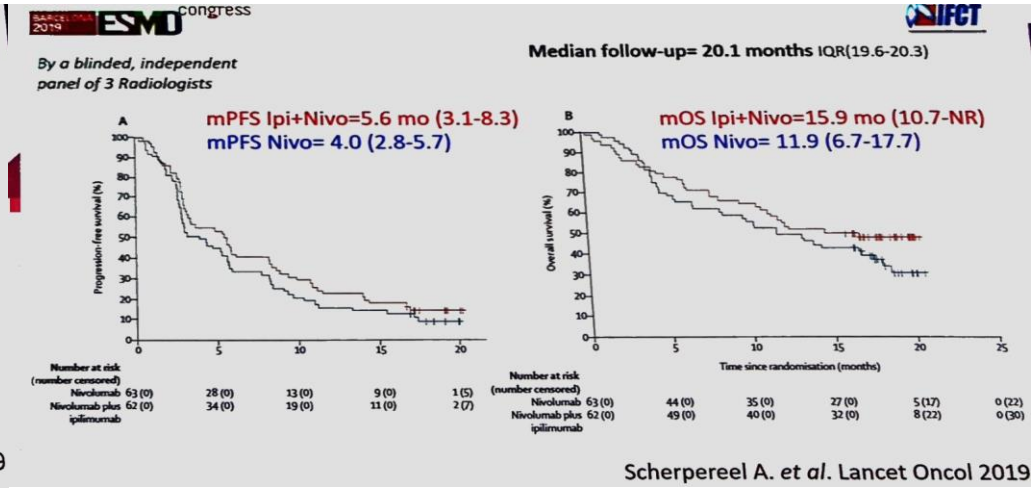
DCR in **Nivo+Ipi** arm was : **50%** [36.7-63.3%] in 54 patients

In the ITT population of 125 patients:

DCR in **Nivo** arm was : **39.7%** [27.6-51.8%] in 63 patients

DCR in **Nivo+Ipi** arm was : **51.6%** [39.2-64.1%] in 62 patients

Scherpereel A. *et al*. Lancet Oncol 2019



Scherpereel A. *et al*. Lancet Oncol 2019

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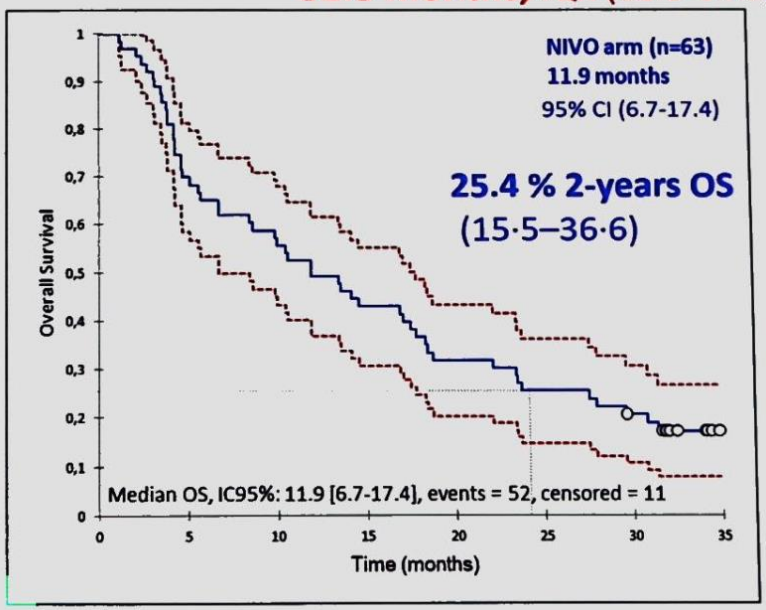
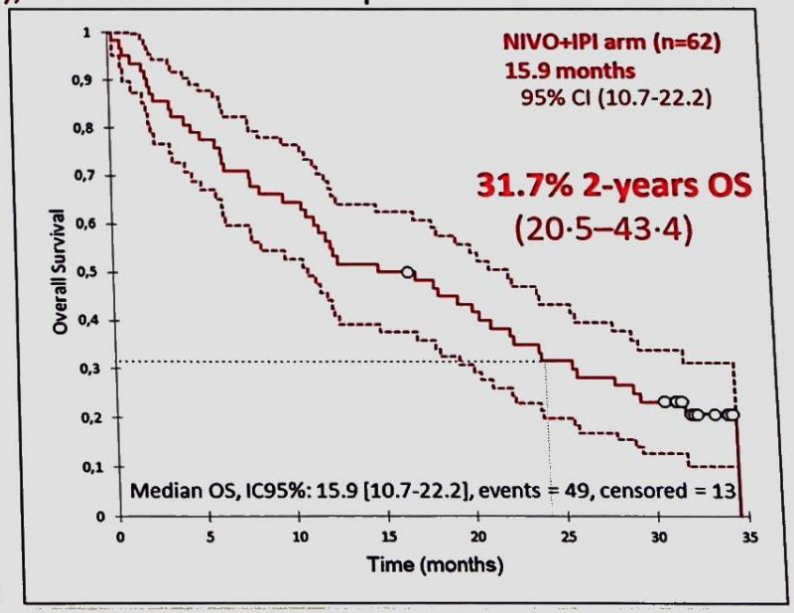
OS updated curves (ITT)

IFCT

data cut-off= 1st March 2019

32.5 months, IQR (31.5-34.0), of median-follow-up

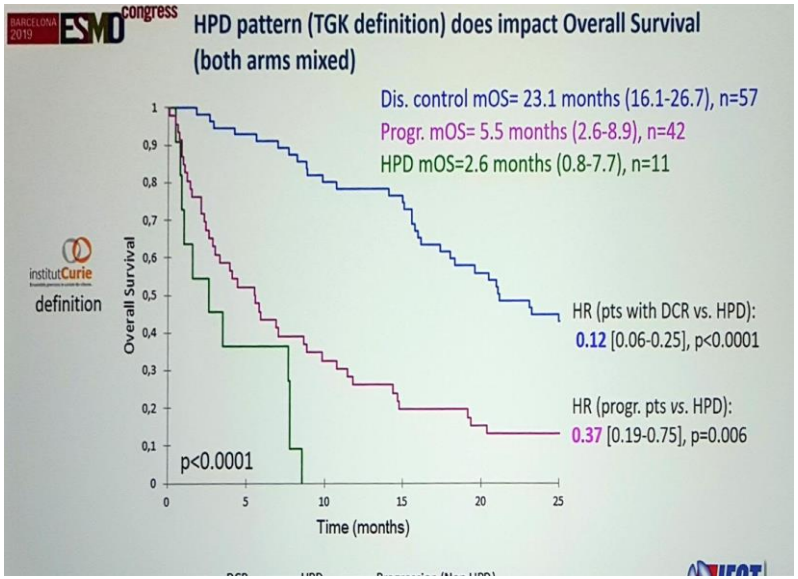


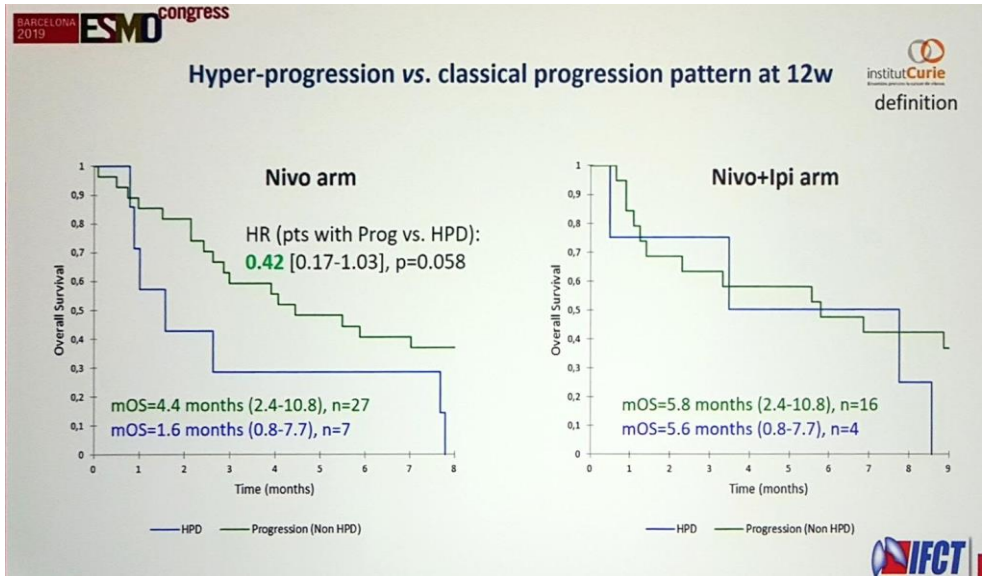


Hyperprogression

Usando los criterios TGR de hiperprogresión del Gustave Roussy (50% de incremento por unidad de tiempo)

- 6 pacientes (4.8%) presentaron HPD: 4 en Nivo , 2 en Nivo-Ipi. Más frecuente en Nivo que Nivo-ipi
- No correlación entre HPD y OS
- HPD en MPM es menos frecuente que NSCLC (13.8%)





Nivo o Nivo ipi son dos regímenes activos en MPM 2ª o 3ª línea mOS 11.9 y 15.9 m comparado con QT (7.7m)