Lung Cancer UPDATES
ESMO HIGHLIGTHS
19-21 SEPTIEMBRE 2020

Iniciativa científica de:
GECP lung cancer research

Carcinoma de pulmón de célula pequeña y otras neoplasias torácicas

Rafael López Castro

Hospital Clínico Universitario de Valladolid

Abstracts destacados

Proffered paper non-metastatic NSCLC and other thoracic malignancies

- **#LBA84**: ETOP/IFCT 4-12 STIMULI

Mini oral CPCP

- **#LBA85**: EORTC 1417 REACTION (phase II)
- **#LBA86**: Long-term benefit & TMB in CASPIAN
- **#1781MO**: Long-term survivors in IMPOWER 133
- **#1782MO**: Health Related QoL in Keynote 604

Mini oral MPM

- **#1895MO**: 3y F-U MERIT trial (Nivo 2nd line MPM)
- **#1896MO**: Volumetric PET assessment in MPM with high-dose pembro

#LBA84

Consolidation ipilimumab and nivolumab vs observation in limited stage SCLC after chemo-radiotherapy: Results from the ETOP/IFCT 4-12 STIMULI trial. *Peters S et al.*

etop
Information | Research

Solange Peters, Jean-Louis Pujol, Urania Dafni, Jesús Andrade, Annemarie Becker, Manuel Domine, Alessandra Curioni-Fontecedro, Olivier Molinier, Denis Moro-Sibilot, Kristiaan Nackaerts, Amelia Insa Mollá, Guillermo López Vivanco, Jeannick Madelaine, Sanjay Popat, Martin Reck, Heidi Roschitzki-Voser, Paul Mitchell, Dirk De Ruysscher, Cécile Le Pechoux, Rolf Stahel

5 | ETOP/IFCT 4-12 STIMULI (protocol AM1) – Study Design & Objectives

Key eligibility criteria

- **Small cell lung carcinoma**
- Stage I-IIIB
- **Treatment naïve** (1 chemo cycle before enrolment allowed)
- Age ≥ 18
- ECOG PS 0-1
- Adequate haematological, renal, hepatic and lung function
- Pulmonary function FEV1 of 1.0L or >40% predicted value and DL_{CO} >40% predicted value

Trial enrolment

CRT phase
- Cis/-carboplatin +etoposide: 4 cycles
- Concurrent RT
- PCI after CRT

No PD → R* 1:1

Immunotherapy consolidation
- **Induction**: Nivolumab (1 mg/kg i.v.) & Ipilimumab (3 mg/kg i.v.) Q3W for 4 cycles
- **Maintenance**: Nivolumab (240 mg i.v.) Q2W for max 12 months

Observation
No further treatment

***Stratification factors**
- Twice-daily vs once-daily radiotherapy
- PET CT scan at baseline Y/N

RECIST 1.1 Assessment:
Every 9 weeks for the first 18 months, 12 weeks up to year 2 and 6 months up to year 4

Primary endpoints:
- **Progression-free survival (PFS) according to RECIST 1.1**

Measured from randomization

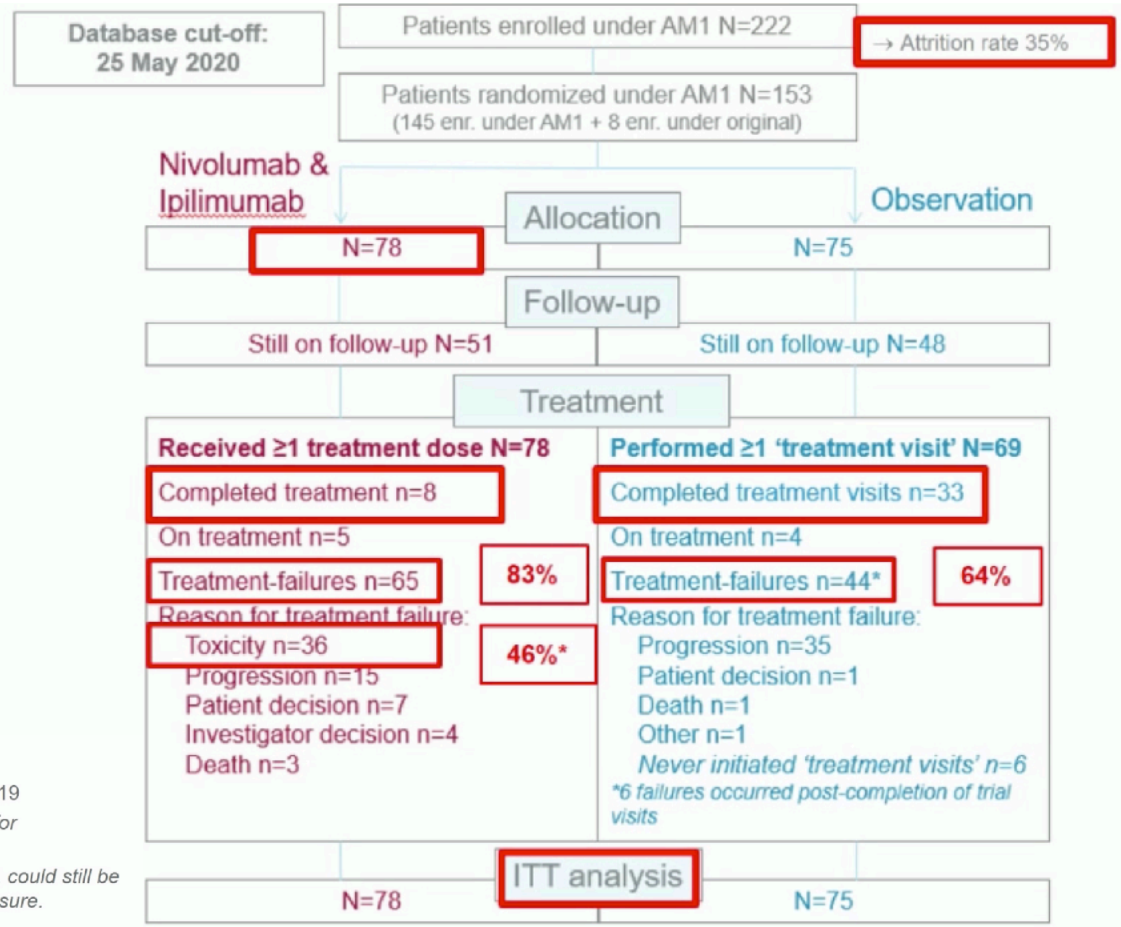
Secondary endpoints:
- Overall survival (OS)
- Time-to-treatment failure (TTF)
- Adverse events (CTCAE V4.0)

- Accrual period:
  23 December 2015 – 30 April 2019
  → *Premature accrual closure (for administrative reasons).*
  → *Patients enrolled by 30 April, could still be randomized after accrual closure.*

- Enrolled patients by country:
  35% France, 28% Spain, 16% Germany, 6% Netherlands, 4% Switzerland, 4% United Kingdom, 4% Belgium, 3% Australia

- **Median Follow-up (post randomization): 22.7 months (IQR: 14.5 - 35.5)**

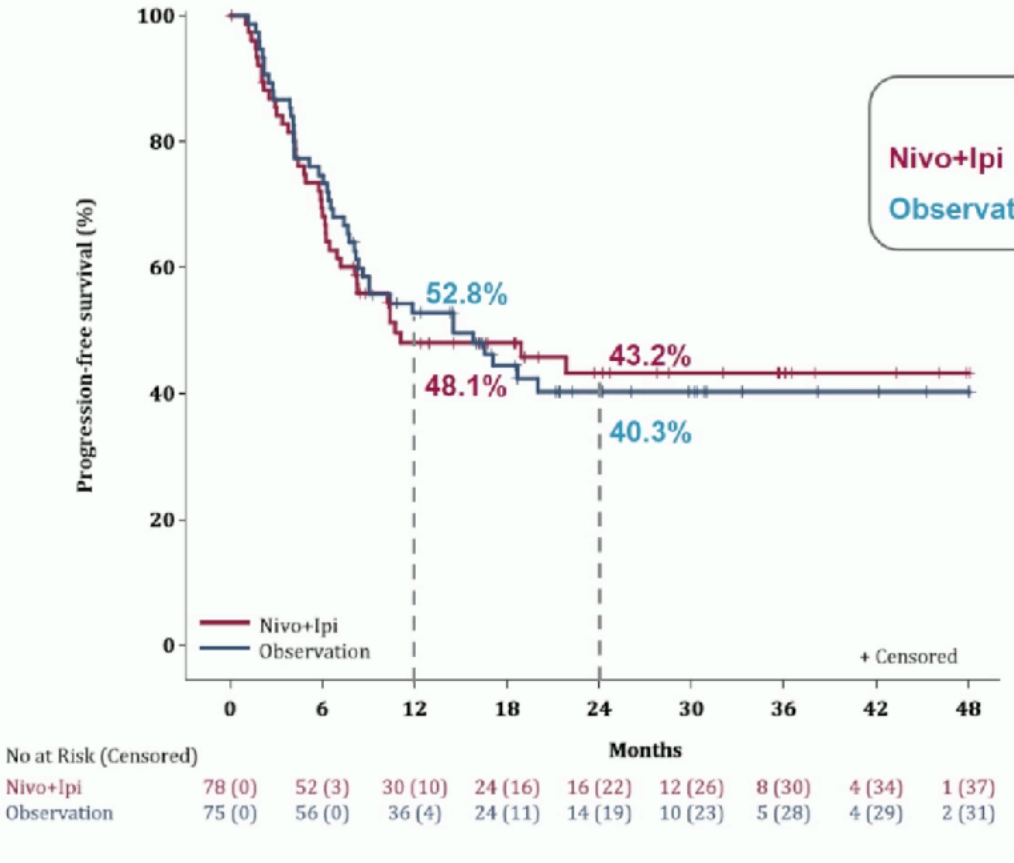
7 | ETOP/IFCT 4-12 STIMULI – Consort Diagram



#LBA84

- Consolidation ipilimumab and nivolumab vs observation in limited stage SCLC after chemo-radiotherapy: Results from the ETOP/IFCT 4-12 STIMULI trial

Progression-Free Survival (N=153; median f-up 22.7 m)



	Events/N	Median PFS (95%CI)
Nivo+Ipi	40/78	10.7 (7.0 - NE)
Observation	42/75	14.5 (8.2 - NE)

NE: Not estimable

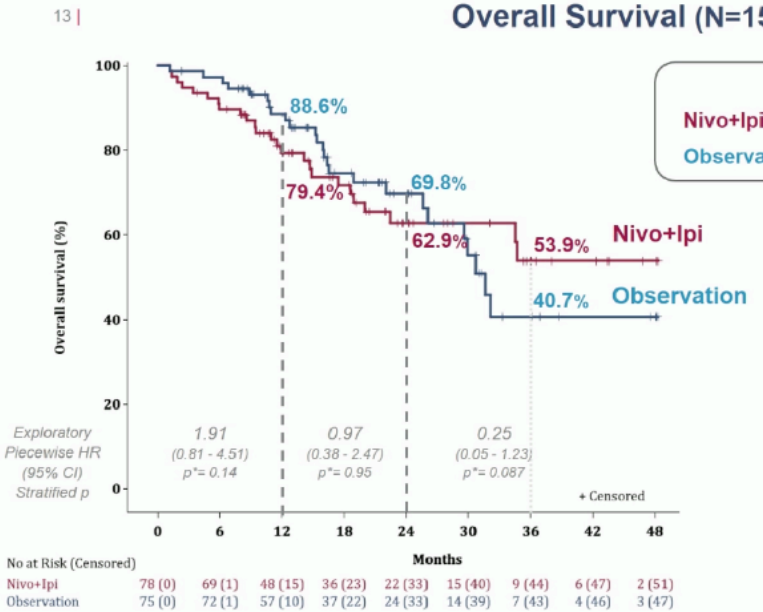
Stratified

HR (95%CI): 1.02 (0.66 - 1.58)
p = 0.93

Testing for non-proportionality: p=0.36

No at Risk (Censored)									
Nivo+Ipi	78 (0)	52 (3)	30 (10)	24 (16)	16 (22)	12 (26)	8 (30)	4 (34)	1 (37)
Observation	75 (0)	56 (0)	36 (4)	24 (11)	14 (19)	10 (23)	5 (28)	4 (29)	2 (31)

Overall Survival (N=153; median f-up 22.7 m)



	Events/N	Median OS (95%CI)
Nivo+Ipi	25/78	NR (22.4 - NE)
Observation	25/75	31.6 (26.1 - NE)

NR: Not Reached, NE: Not estimable

Stratified

HR (95%CI): 1.06 (0.61 - 1.86)
p = 0.83

Testing for non-proportionality: p=0.059

No at Risk (Censored)									
Nivo+Ipi	78 (0)	69 (1)	48 (15)	36 (23)	22 (33)	15 (40)	9 (44)	6 (47)	2 (51)
Observation	75 (0)	72 (1)	57 (10)	37 (22)	24 (33)	14 (39)	7 (43)	4 (46)	3 (47)

#LBA84

- Consolidation ipilimumab and nivolumab vs observation in limited stage SCLC after chemo-radiotherapy: Results from the ETOP/IFCT 4-12 STIMULI trial

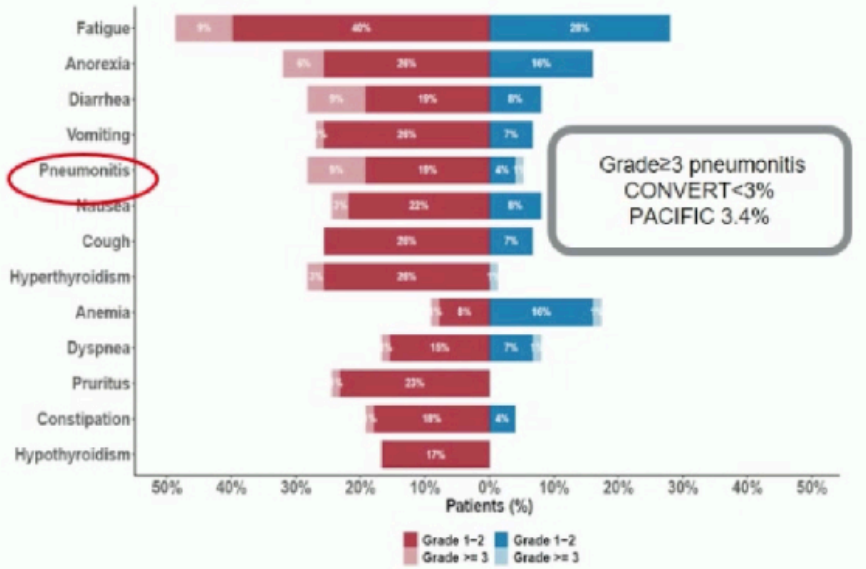
Safety cohort (n=153)

	Nivo+Ipi N patients (%)		Observation N patients (%)
Safety cohort	**78**		**75**
Patients experiencing:			
Any Adverse Event (AE)	77 (99%)		65 (87%)
Any Treatment-related AE	75 (96%)		-
	Trt-related	*Any cause*	*Any cause*
AEs of grade 3-5	40 (51%)	48 (62%)	19 (25%)
AEs leading to treatment discontinuation	38 (49%)	43 (55%)	-
AEs leading to death	3 (4%)	4 (5%)	1 (1%)

* Pneumonitis (2), ileus, Death NOS (not trt-related)

** Lung infection

Most frequent any-cause adverse events (>15%)



- STIMULI trial did not meet its primary endpoint of improving PFS
- Short period of active treatment (toxicity, discontinuation)
- Longer F-U: explore possible late effect on OS with IO
- Greater benefits in: twice daily RT fraction, female, PS1 ($p<0.05$)

#LBA85

REACTION: A phase II study of etoposide and cis/carboplatin with or without pembrolizumab in untreated extensive small cell lung cancer. *Besse B et al.*

EORTC
The future of cancer therapy

EORTC 1417 - REACTION:
A phase II study of etoposide and cis/carboplatin with or without pembrolizumab in untreated extensive small cell lung cancer

Benjamin Besse[1] (benjamin.besse@gustaveroussy.fr), Jessica Menis[2], Paolo Bironzo[3], Radj Gervais[4], Laurent Greillier[5], Isabelle Monnet[6], Lorenzo Livi[7], Robin Young[8], Chantal Decroisette[9], Nicolas Cloarec[10], Gilles Robinet[11], Roland Schott[12], Raffaele Califano[13], Filippo de Marinis[14], Giuseppe L. Banna[15], Murielle Mauer[16], Alessia Pochesci[16], Baktiar Hasan[16], Thierry Berghmans[17], Anne-Marie C. Dingemans[18]

[1]Gustave Roussy, Villejuif, France; [2]University of Padova, Istituto Oncologico Veneto; [3]Universita Di Torino, Italy; [4]Centre Francois Baclesse (CLCC), Caen, France; [5]Aix Marseille Univ, APHM, Marseille, France; [6]Centre Hopitalier Intercommunal De Creteil, France; [7]Radiation Oncology Unit, University of Florence , Italy; [8]Weston Park Hospital, Sheffield, United Kingdom; [9]Centre Hospitalier D'Annecy, Metz-Tessy, France; [10]Centre Hospitalier d'Avignon, Avignon, France; [11]CHU de Brest, Brest, France; [12]Institut de Cancerologie (ICANS), Strasbourg, France; [13]The Christie NHS Foundation Trust,, University of Manchester, Manchester, UK; [14]European Institute of Oncology (IEO), IRCCS, Milan, Italy; [15]Portsmouth Hospitals NHS Trust, Portsmouth, UK; [16]EORTC HQ, Brussels, Belgium; [17]Institut Jules Bordet, Brussels, Belgium; [18]Erasmus MC, Rotterdam, Netherlands

@EORTC

EORTC
The future of cancer therapy

Study design

Open-Label Treatment Period

Untreated Extended disease Small Cell Lung Cancer

2 cycles of etoposide and cis/carboplatin

Partial or complete response

Unselected for PD-L1

Randomization (1:1)

Experimental Arm
4 cycles of
etoposide and cis/carboplatin and pembrolizumab
Then pembrolizumab up to 35 cycles*

Standard Arm
4 cycles of
etoposide and cis/carboplatin

Optional PCI

Optional cross-over**
Up to 6 cycles of
etoposide and carboplatin and pembrolizumab
Then pembrolizumab up to 35 cycles*

Primary endpoint
Progression free survival

Patient Stratification
- Institution
- Platinum agent (cisplatin versus carboplatin)
- Performance status (0 versus 1)
- LDH level (low versus high)

Statistical hypothesis
- With a 1-sided alpha 10%, the study was powered at 90% level to detect a Hazard Ratio (HR) of 0.575 in Progression free survival calculated from randomization

* Patients who have not progressed after 2 years of pembrolizumab are allowed to discontinue pembrolizumab. In case of subsequent progression, patients have the opportunity for a second course re-treatment with pembroliz
** Patients in the control arm that experience disease progression at least 3 months after the last dose of chemotherapy
QD: once daily; Q3W: every three weeks; IV: intravenous; PCI : prophylactic cranial irradiation

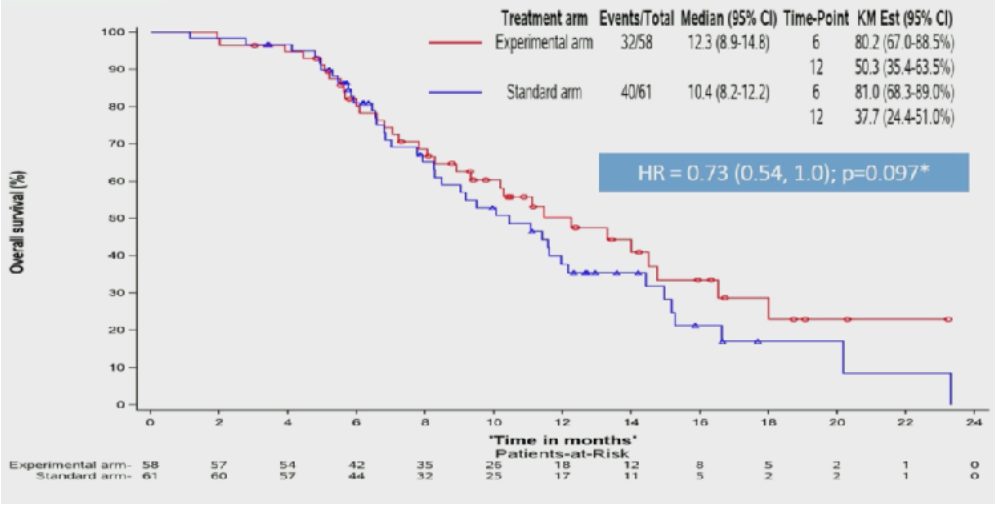
#LBA85

Safety

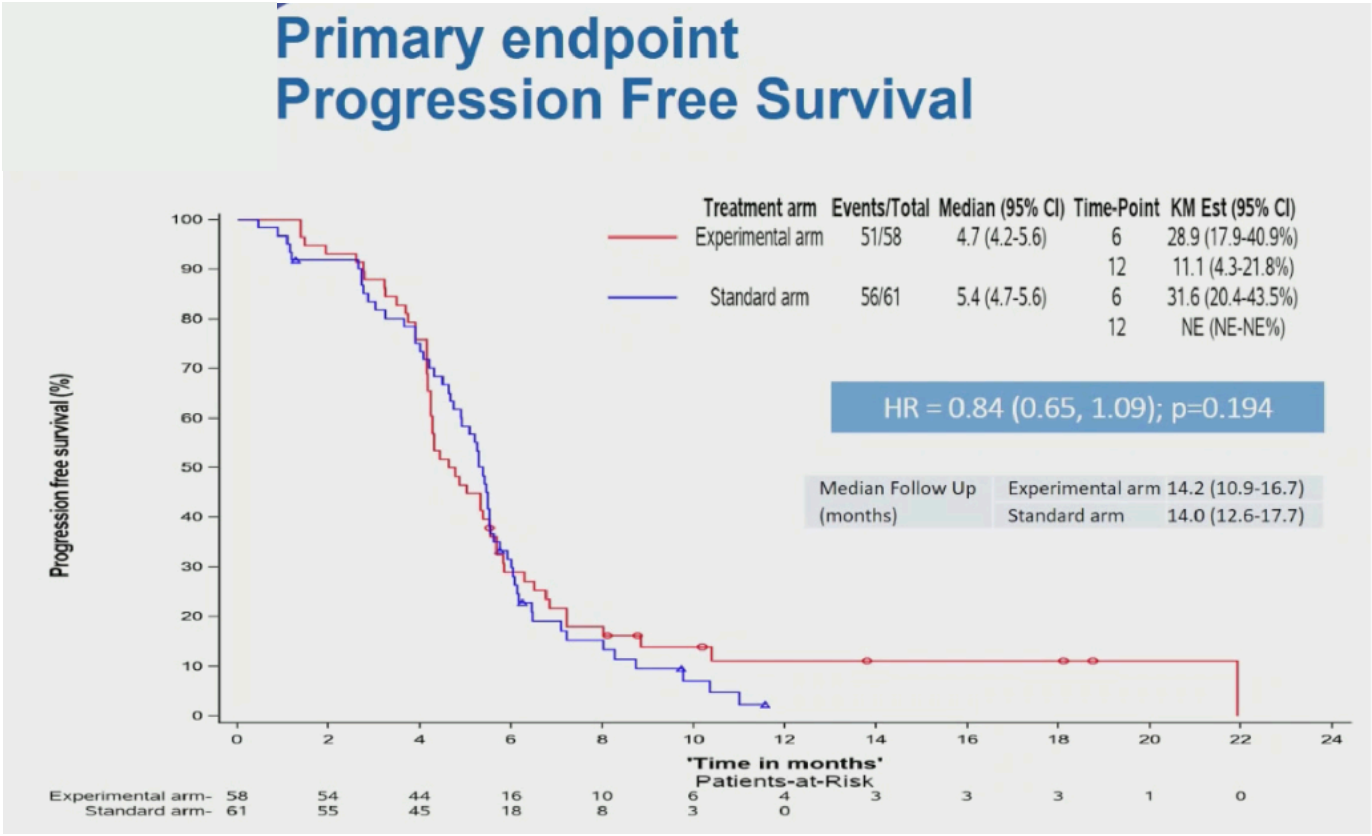
Frequency of Adverse Events*	Standard Arm (N=64)			Experimental Arm (N=60)		
	Grade 3 N (%)	Grade 4 N (%)	Grade 5 N (%)	Grade 3 N (%)	Grade 4 N (%)	Grade 5 N (%)
AEs in ≥5% of the cases	19 (29.7)	3 (4.7)	1 (1.6)**	19 (31.7)	6 (10.0)	1 (1.7) †
Anemia	3 (4.7)			11 (18.3)	1 (1.7)	
Neutrophil Count Decreased	2 (3.1)	1 (1.6)		3 (5)	3 (5)	
Platelet Count Decreased	7 (10.9)			2 (3.3)	2 (3.3)	
Elevated GGT	4 (6.3)			1 (1.7)		
AEs of special interest						
Diarrhea	1 (1.6)			2 (3.3)		
Dyspnea	2 (3.1)	1 (1.6)		2 (3.3)		
All population	19 (29.7)	3 (4.7)	1 (1.6)	19 (31.7)	6 (10.0)	1 (1.7)

*CTCAE version 4.3; **Cardiac Arrest; †deterioration of health status

Overall Survival



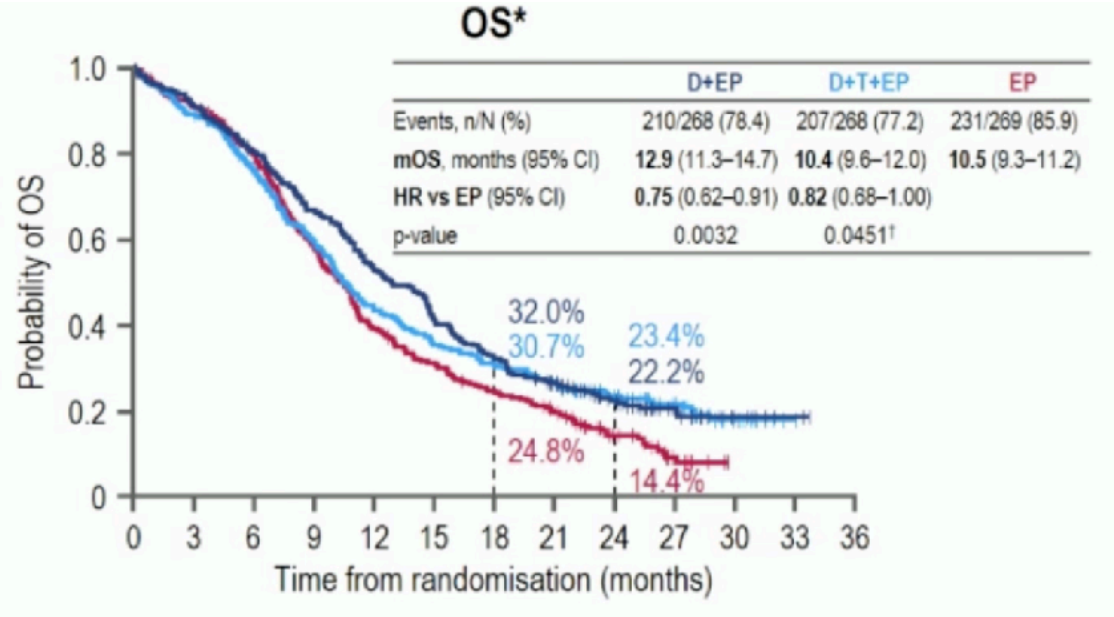
Primary endpoint
Progression Free Survival

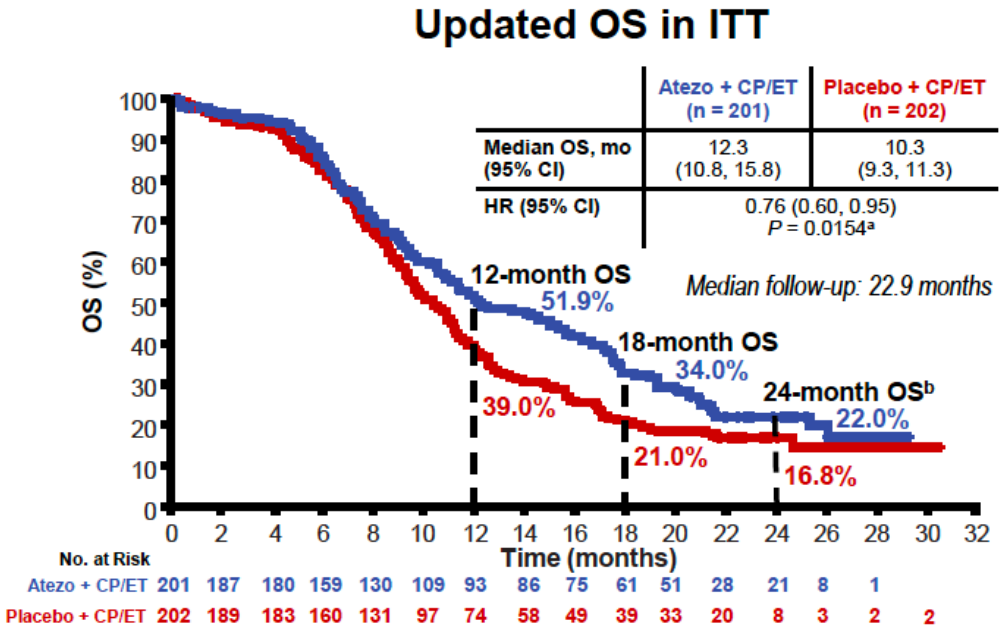


- No benefit in PFS (primary obj); nor OS (secondary)

#LBA86 & #1781MO

- Durvalumab (D) ± tremelimumab (T) + platinum-etoposide (EP) in 1L ES-SCLC: Characterization of long-term clinical benefit and tumour mutational burden (TMB) in CASPIAN. *Goldman JW et al.*
- IMpower133: Characterisation of long-term survivors treated first-line with chemotherapy + atezolizumab in extensive-stage small cell lung cancer. *Liu S et al.*

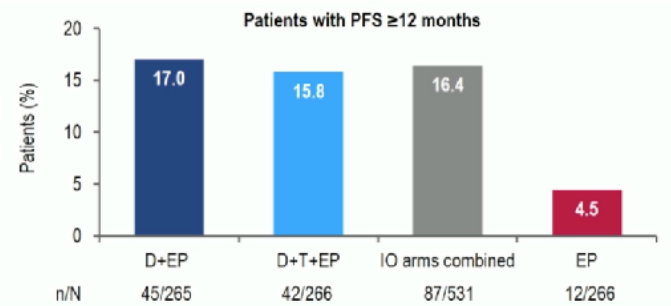




#LBA85 & #LBA86

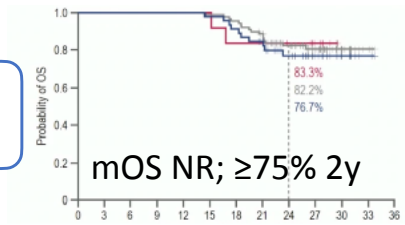
LTS definition

CASPIAN

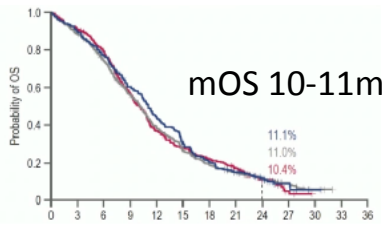


	PFS ≥12 months			PFS <12 months		
	D+EP (n=45)	IO arms combined (n=87)	EP (n=12)	D+EP (n=220)	IO arms combined (n=444)	EP (n=254)
Ongoing durvalumab, n (%)	27 (60)	50 (57)	-	5 (2)	12 (3)	-
Durvalumab cycles, median (range)	**25 (6–37)**	**25 (2–37)**	-	**7 (1–28)**	**6 (1–33)**	-
Received cisplatin, %	22	23	25	25	25	25
Etoposide doses, median (range)	12 (10–18)	12 (6–18)	18 (12–18)	12 (2–24)	12 (1–24)	18 (1–18)
Median age (range), y	60 (47–79)	61 (47–83)	64.5 (47–72)	62 (28–82)	63 (28–88)	63 (35–82)
Male, %	60	63	42	73	75	69
White / Asian / Other, %	98 / 2 / 0	89 / 9 / 2	100 / 0 / 0	83 / 16 / 1	82 / 17 / 2	82 / 16 / 2
Ever / Never smoker, %	91 / 9	91 / 9	100 / 0	92 / 8	93 / 7	94 / 6
WHO PS 0 / 1, %	**47 / 53**	**48 / 52**	**42 / 58**	**35 / 65**	**36 / 64**	**33 / 67**
Brain / Liver metastases, %	**7 / 20**	**3 / 23**	**0 / 17**	**11 / 44**	**14 / 46**	**11 / 40**
tTMB ≥10 mut/Mb, n/N* (%)	11/18 (61)	16/33 (48)	1/1 (100)	46/89 (52)	89/179 (50)	25/70 (36)

OS



mOS NR; ≥75% 2y

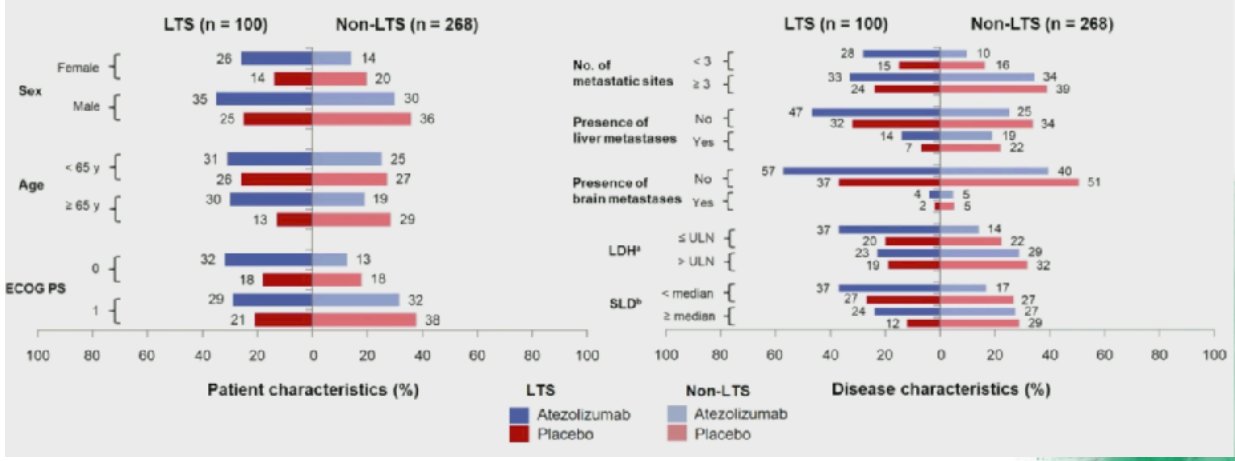


mOS 10-11m

IMP133

- **LTS** are defined as patients who lived ≥ 18 months since randomisation
- **Non-LTS** are defined as patients who died < 18 months post randomisation

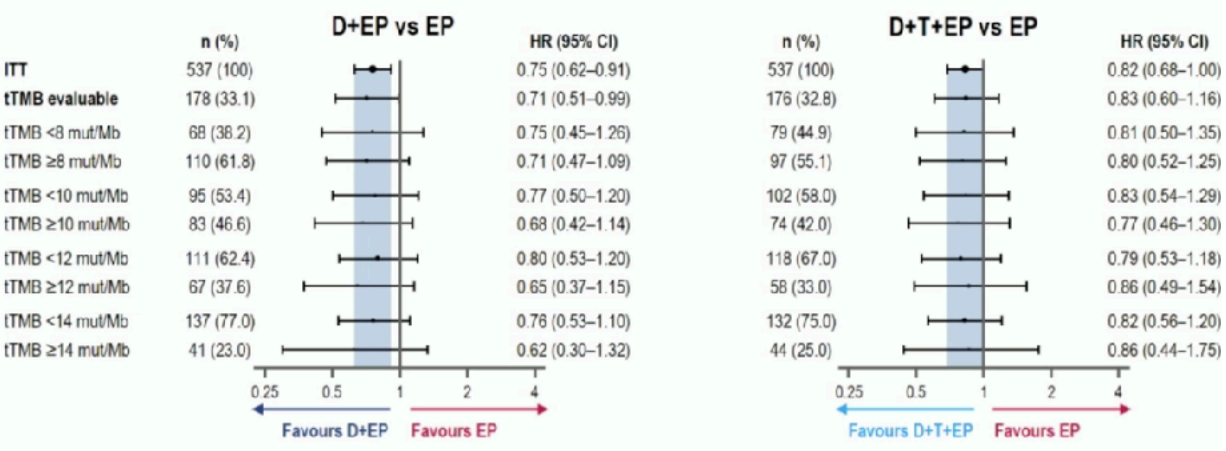
	Atezo + CP/ET (n = 182)	Placebo + CP/ET (n = 191)
LTS, n (%)	61 (33.5)	39 (20.4)
95% CI	(26.7, 40.9)	(14.9, 26.8)
Non-LTS, n (%)	121 (66.5)	152 (79.6)
95% CI	(59.1, 73.3)	(73.2, 85.1)



#LBA85 & #LBA86

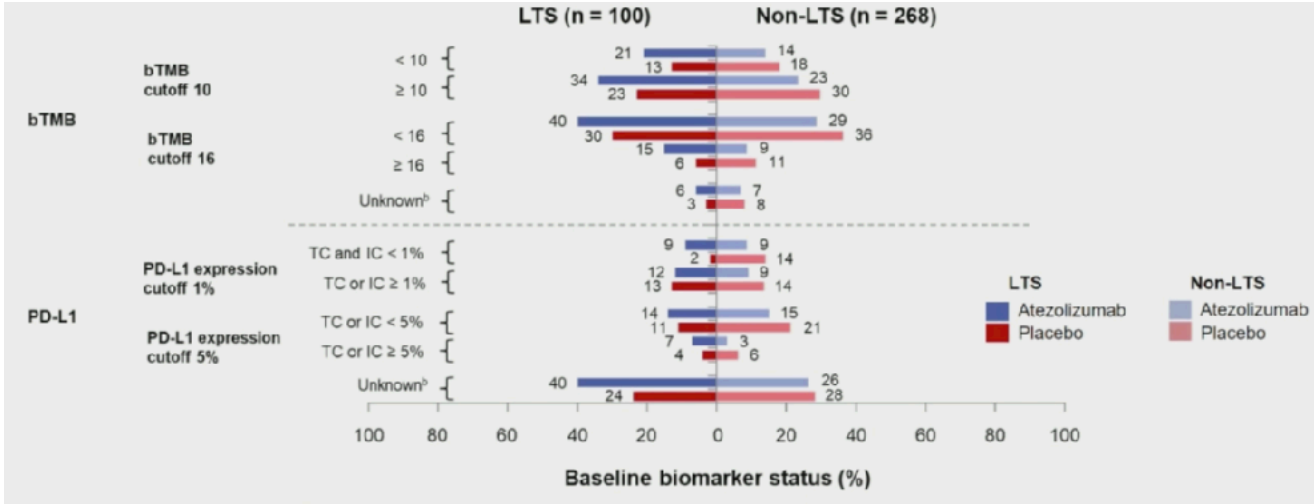
Findings

CASPIAN



	PFS ≥12 months			PFS <12 months		
	D+EP (n=45)	IO arms combined (n=87)	EP (n=12)	D+EP (n=220)	IO arms combined (n=443*)	EP (n=254)
Confirmed ORR, n (%)	43 (96)	82 (94)	12 (100)	139 (63)	256 (58)	144 (57)
Median time to response, days (range)	43 (33–155)	43 (33–196)	42.5 (36–592)	42 (29–92)	42 (29–93)	42 (29–106)
Median DoR, months (95% CI)	NR (18–NE)	NR (24–NE)	20 (12–NE)	4 (3.5–5)	4 (4–5)	5 (5–5)
Patients remaining in response,† %						
At 6 months	100	100	100	20	20	29
At 12 months	93	94	91	0	0	0
At 18 months	67	70	61	0	0	0
At 24 months	54	59	48	0	0	0

IMP133

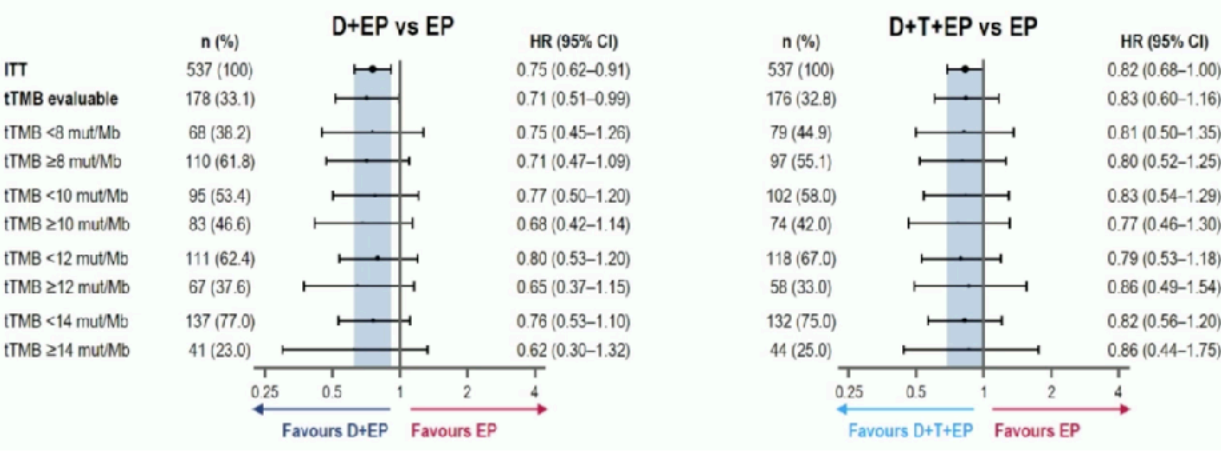


Covariate	Univariate		Multivariate	
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Treatment arm (ref: atezolizumab)	0.76 (0.61, 0.96)	0.02	0.71 (0.56, 0.90)	< 0.01
Sex (ref: male)	1.11 (0.88, 1.41)	0.38	1.21 (0.94, 1.54)	0.13
Age (ref: ≥ 65 y)	1.17 (0.93, 1.47)	0.17	1.18 (0.93, 1.50)	0.17
ECOG PS (ref: 1)	1.64 (1.29, 2.10)	< 0.01	1.43 (1.11, 1.85)	0.01
Metastatic sites (ref: ≥ 3)	1.53 (1.18, 1.97)	< 0.01	1.22 (0.93, 1.61)	0.15
LDH (ref: > ULN)	1.53 (1.21, 1.94)	< 0.01	1.30 (1.01, 1.66)	0.04
SLD (ref: ≥ 111 mm)	1.69 (1.34, 2.12)	< 0.01	1.56 (1.22, 2.00)	< 0.01

#LBA85 & #LBA86

Findings

CASPIAN



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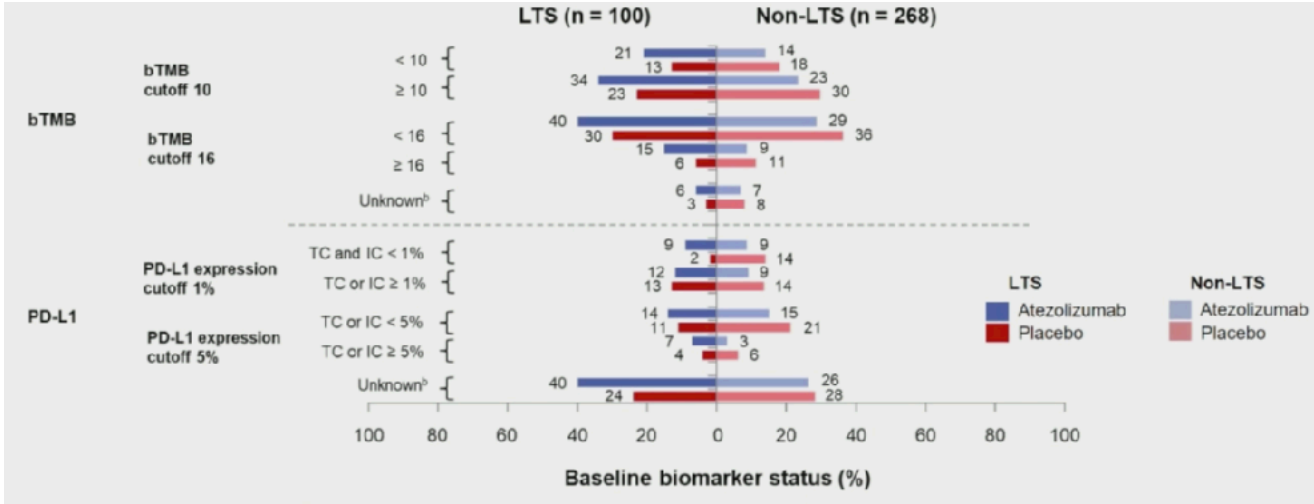
- More LTS in Durva arm (x3)
- Pts with PFS ≥12m had improved ORR, DoR and OS
- Clinical characteristics no predictive of OS
- TMB no predictive of OS

IMP133



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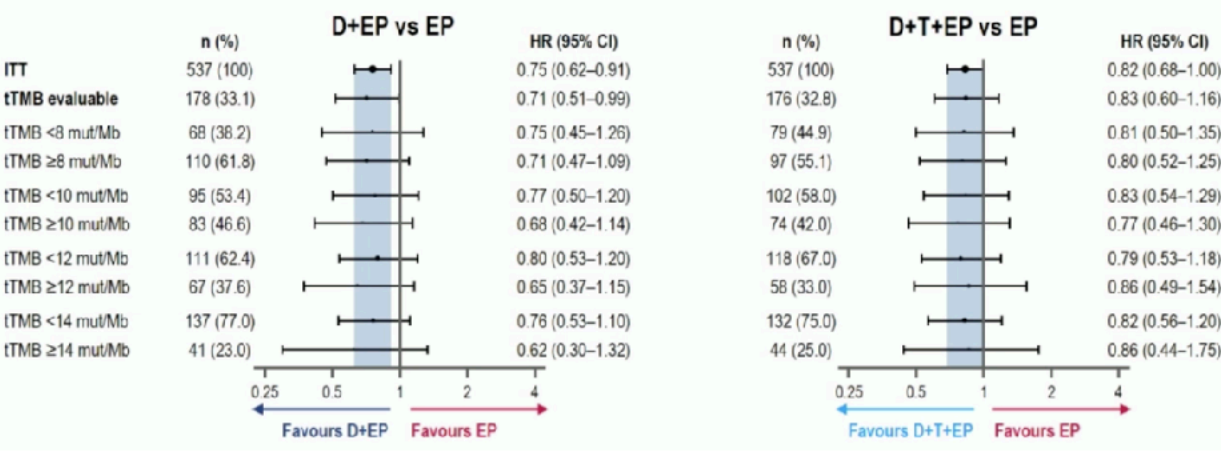
#LBA85 & #LBA86

Findings

CASPIAN



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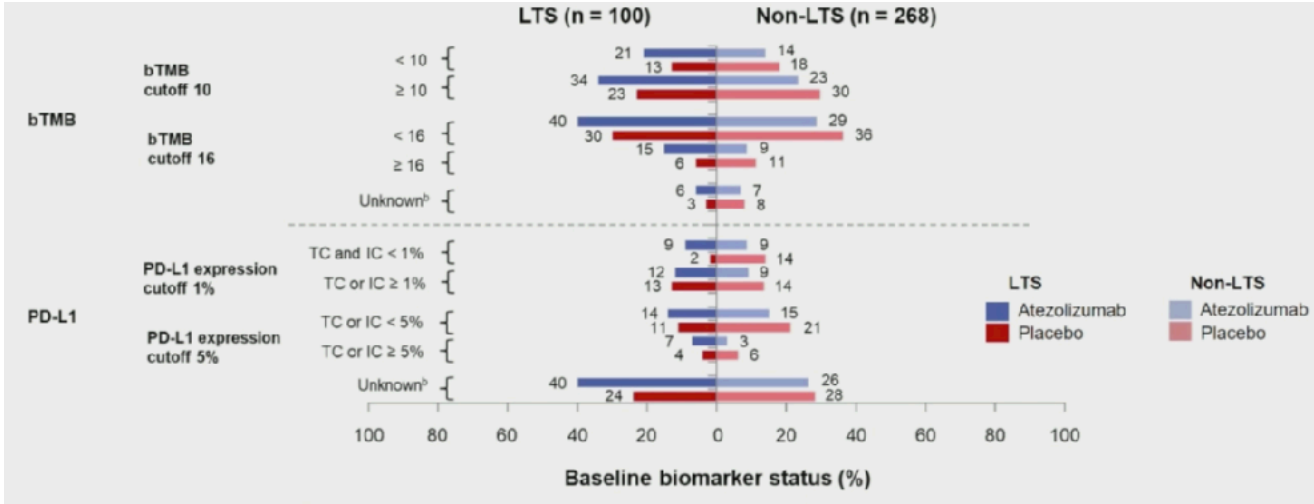

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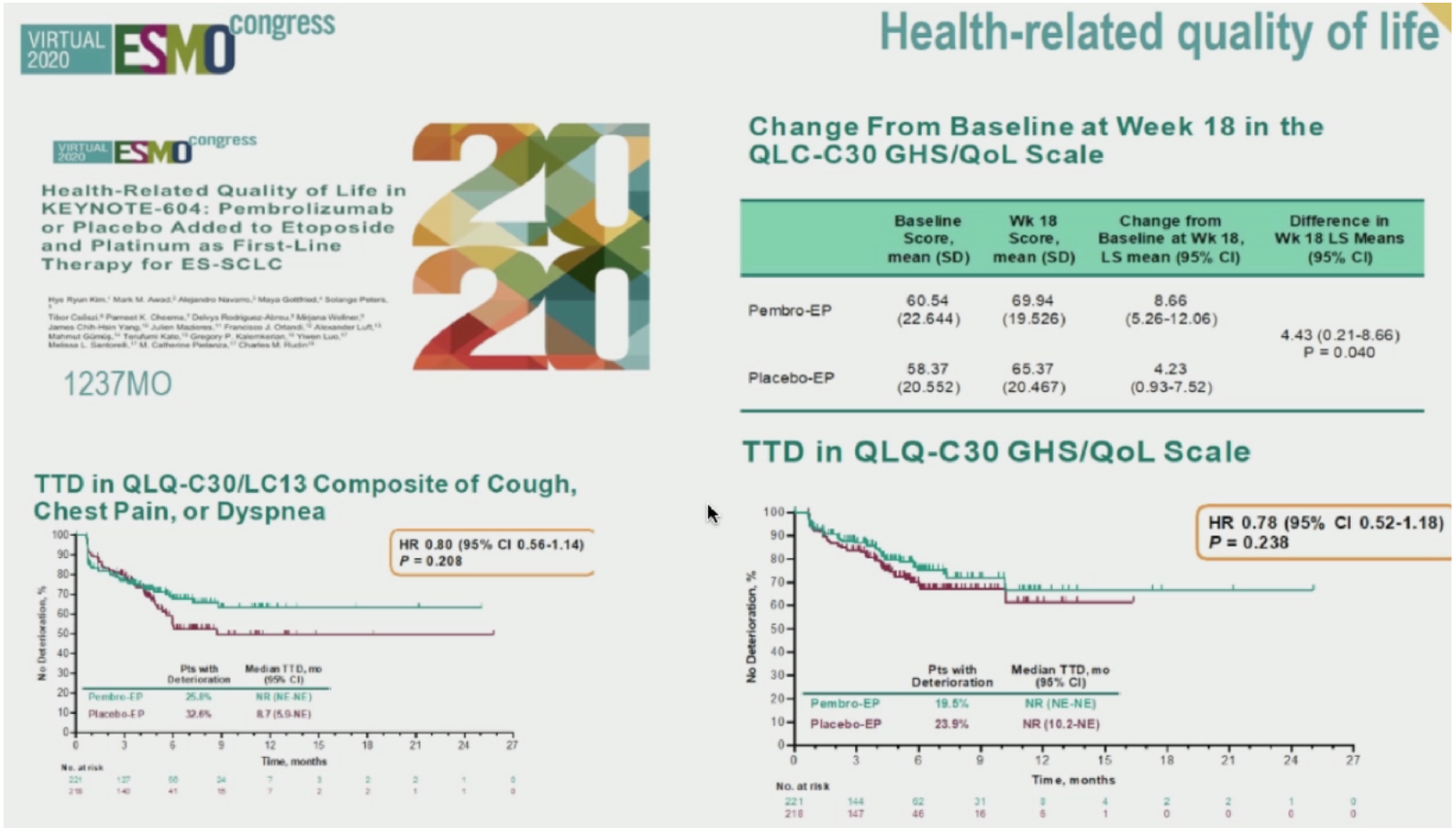
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Treatment arm (ref: atezolizumab)	0.76 (0.61, 0.96)	0.02	0.71 (0.56, 0.90)	< 0.01
Sex (ref: male)	1.11 (0.88, 1.41)	0.38	1.21 (0.94, 1.54)	0.13
Age (ref: ≥ 65 y)	1.17 (0.93, 1.47)	0.17	1.18 (0.93, 1.50)	0.17

- More LTS in Atezo arm
- PS, LDH and SLD impact on survival
- No predictive characteristics identified
- Benefit of Atezo independent of patients or tumor characteristics

#1782MO

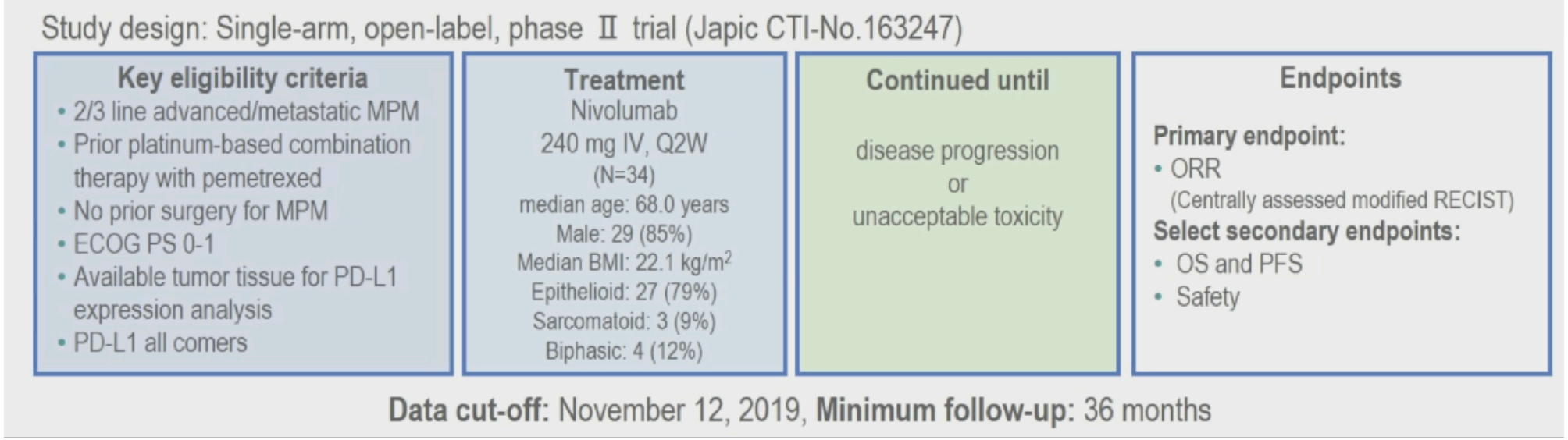
Health-related quality of life (HRQoL) in KEYNOTE-604: Pembrolizumab (pembro) or placebo added to etoposide and platinum (EP) as first-line therapy for ES-SCLC. *Kim HR et al*



- Pembro addition not decrease HRQoL and improves greater at w18

#1895MO

Three-year follow-up results of the MERIT trial: A Japanese phase II study of nivolumab in malignant pleural mesothelioma. *Hayashi et al.*

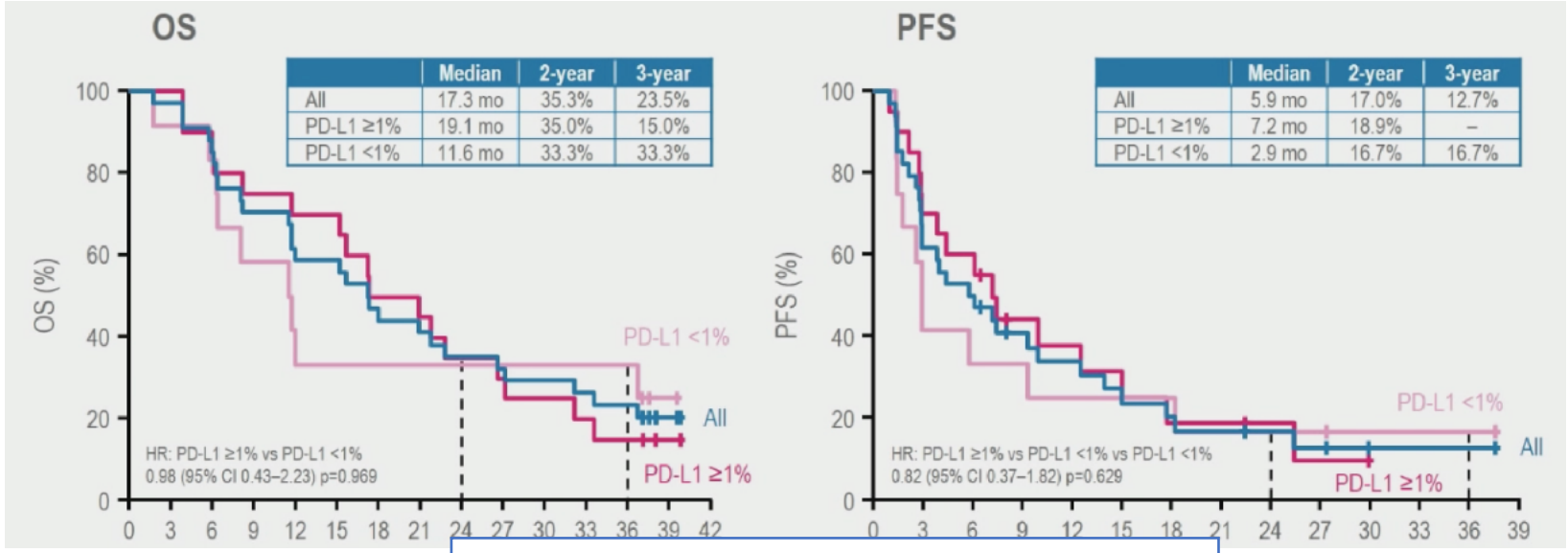


#1895MO Three-year follow-up results of the MERIT trial: A Japanese phase II study of nivolumab in malignant pleural mesothelioma.

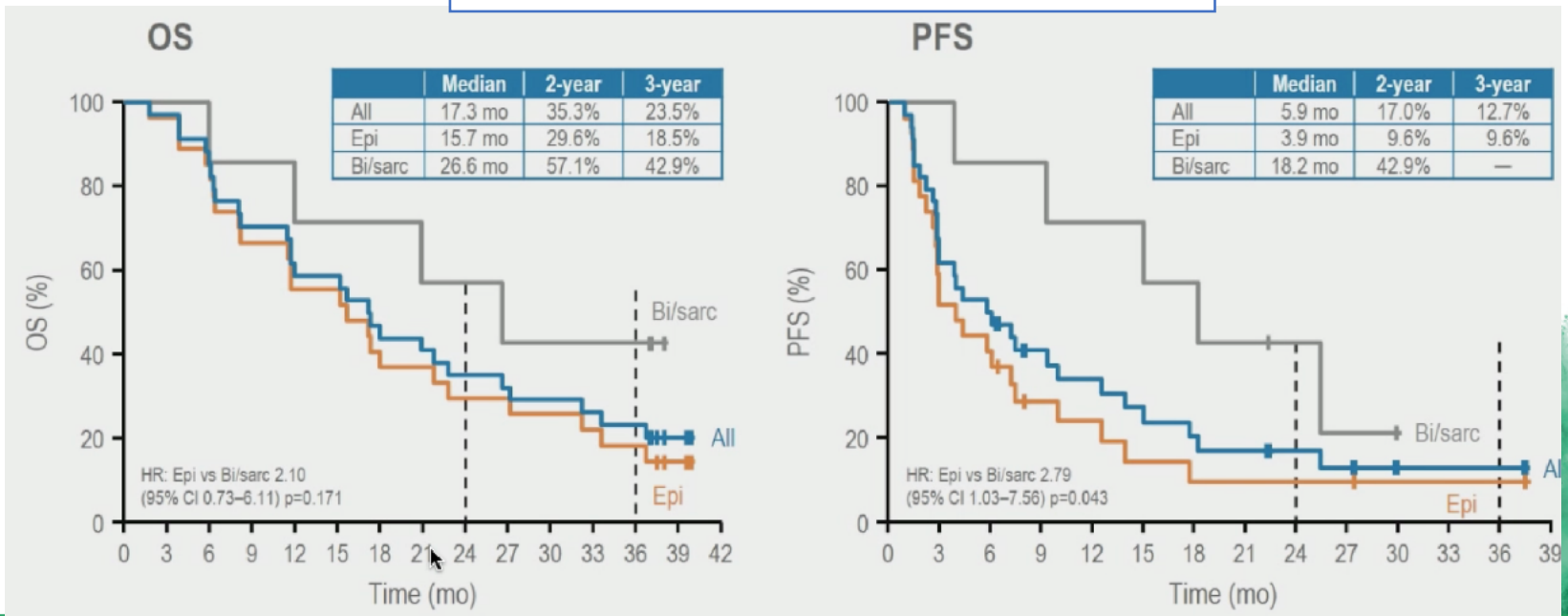
	N = 34
BOR, n (%)	
CR	0 (0.0)
PR	10 (29.4)
SD	13 (38.2)
PD	9 (26.5)
NE	2 (5.9)
ORR, %	29.4
DCR, %	67.6
DOR, median (range), months	11.1 (3.5–28.6+)

subgroup		n/N	ORR, %
Sex	Male	7/29	24.1
	Female	3/5	60.0
Age	<65 years	3/11	27.3
	≥65 years	7/23	30.4
ECOG PS	0	4/13	30.8
	1	6/21	28.6
Histological subtype	Epithelioid	7/27	25.9
	Sarcomatoid	2/3	66.7
	Biphasic	1/4	25.0
Number of prior treatment(s)	1	9/24	37.5
	2	1/10	10.0
PD-L1 expression	≥1%	8/20	40.0
	<1%	1/12	8.3
	NE	1/2	50.0

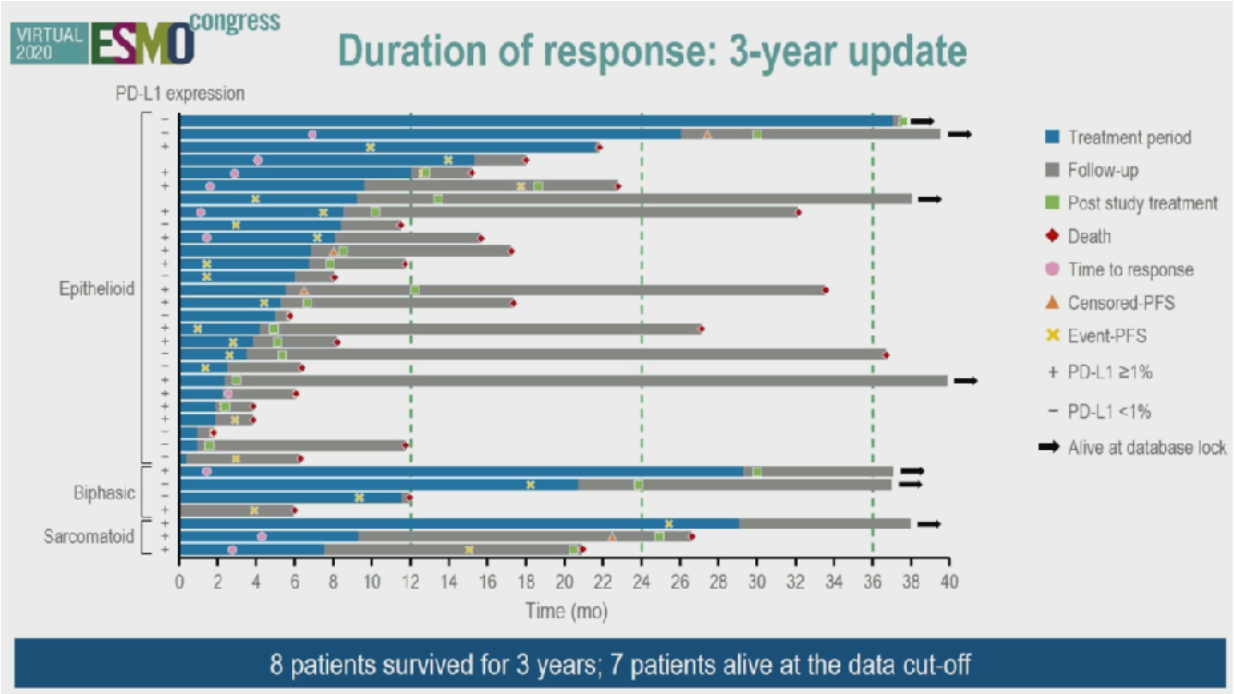
Pts with 2 prior Tx or PD-L1 <1%: lower ORR



3Y OS: 23.5%; 3Y PFS 12.7%



#1895MO Three-year follow-up results of the MERIT trial: A Japanese phase II study of nivolumab in malignant pleural mesothelioma.



- Long-term benefit: 3y OS 23.5% and 3y PFS 12.7%
- ORR higher when PD-L1 >1% but no relation between PD-L1 status and OS/PFS
- Efficacy regardless of histological subtype
- Nivo tolerable and safe

in ≥2 patients by preferred term

n (%)	Any grade N = 34	Grade 3–4 N = 34
Any TRAE	26 (76.5)	11 (32.4)
Rash	6 (17.6)	1 (2.9)
Lipase increased	5 (14.7)	4 (11.8)
Diarrhoea	4 (11.8)	2 (5.9)
Amylase increased	4 (11.8)	2 (5.9)
Stomatitis	3 (8.8)	1 (2.9)
Weight decreased	3 (8.8)	1 (2.9)
Decreased appetite	3 (8.8)	1 (2.9)
Fatigue	3 (8.8)	0
Malaise	3 (8.8)	0
Arthralgia	3 (8.8)	0

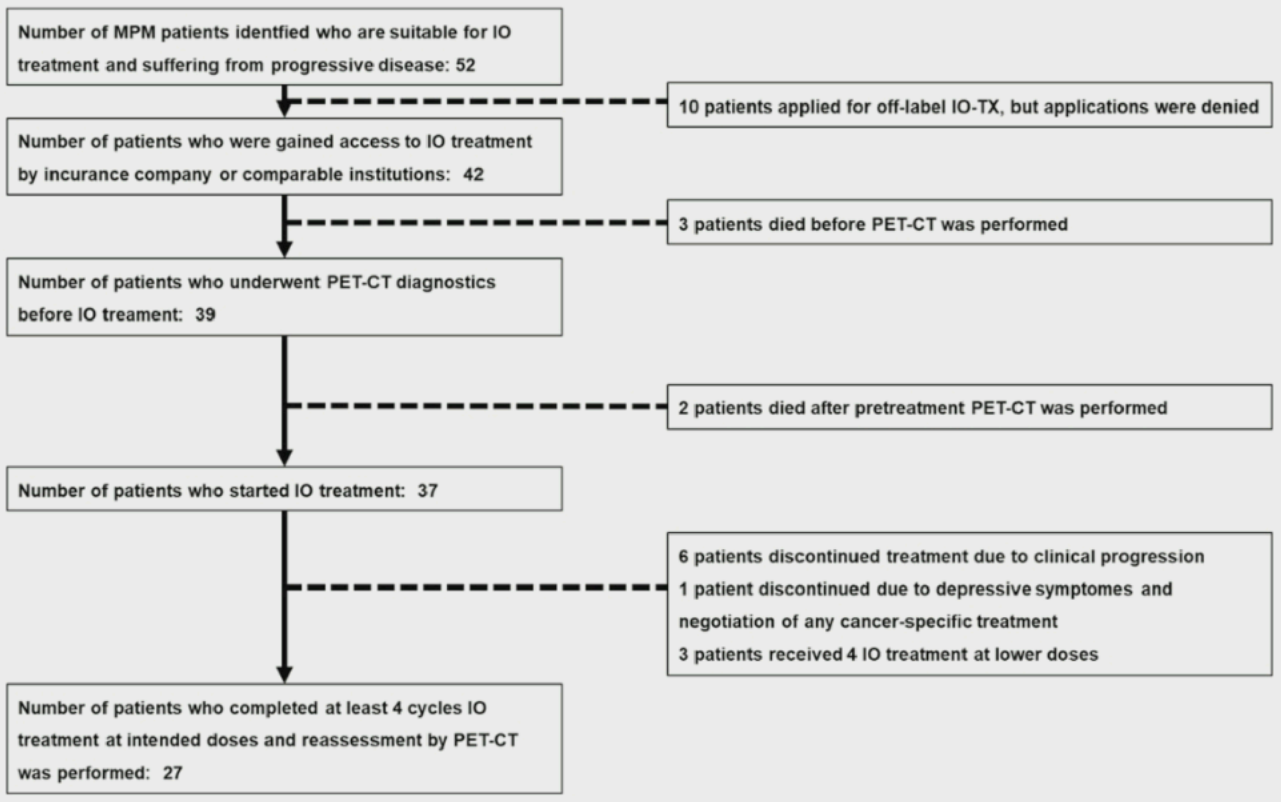
n (%)	Any grade N = 34	Grade 3–4 N = 34
Pneumonitis	2 (5.9)	2 (5.9)
Interstitial lung disease	2 (5.9)	1 (2.9)
Hypothyroidism	2 (5.9)	0
Nausea	2 (5.9)	0
Vomiting	2 (5.9)	0
Mucosal inflammation	2 (5.9)	0
Pyrexia	2 (5.9)	0
Lymphocyte count decreased	2 (5.9)	0
Rash maculopapular	2 (5.9)	0

MedDRA ver. 20.0J, CTCAE ver. 4.0 JCOG version (Japanese translation)

#1896MO

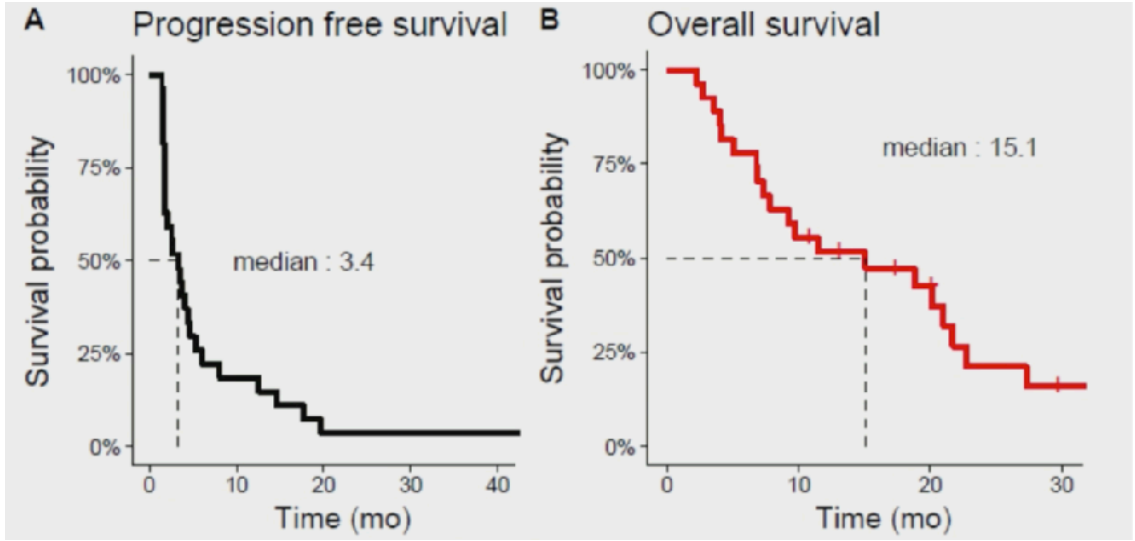
Volumetric PET response assessment outperforms conventional criteria in patients receiving high-dose pembrolizumab for malignant mesothelioma. *Christoph DC et al*

#1895MO Volumetric PET response assessment outperforms conventional criteria in patients receiving high-dose pembrolizumab for malignant mesothelioma.



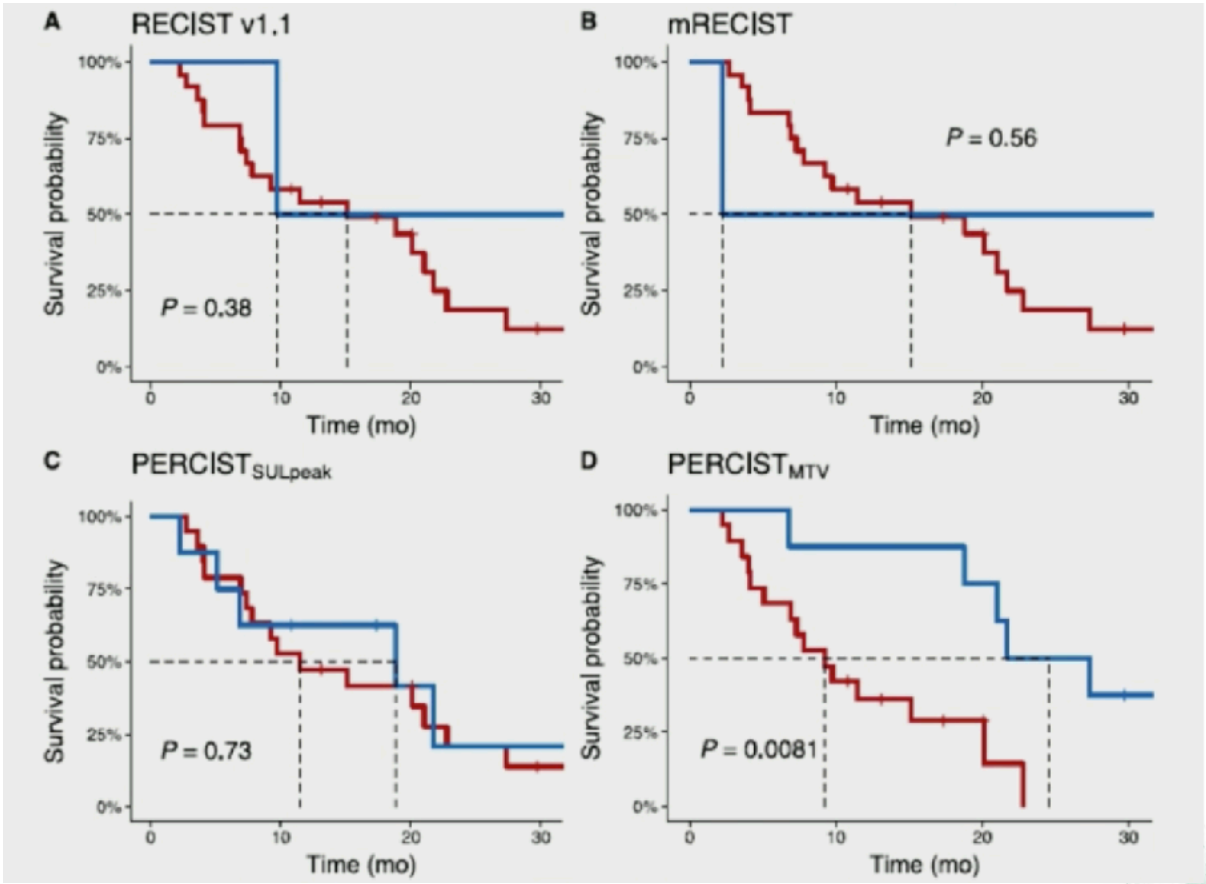
Patient characteristics (n = 27)	
Gender	
Male	23 (85.2%)
Female	4 (14.8%)
Median age at diagnosis, y (range)	68 (51-82)
IMIG / IASLC stadium (if applicable)	
2	3 (11.1%)
3	8 (29.6%)
4	16 (59.3%)
Histological subtype	
Epitheloid	21 (77.8%)
Sarcomatoid	3 (11.1%)
Biphasic	2 (7.4%)
Desmoplastic	1 (3.7%)
Prior lines of chemotherapy	
2	13 (48.1%)
3	8 (29.6%)
≥ 4	6 (22.2%)
PD-L1 expression	
0 %	12 (44.4%)
1 – 49%	11 (40.7%)
50 -100 %	3 (11.1%)
Missing	1 (3.7%)

#1895MO Volumetric PET response assessment outperforms conventional criteria in patients receiving high-dose pembrolizumab for malignant mesothelioma.



Response Criteria	OR	CR/CMR	PR/PMR	SD/SMD	PD/PMD
RECIST v1.1*	2 (7.4%)	0 (0%)	2 (7.4%)	12 (44.4%)	12 (44.4%)
mRECIST*	2 (7.4%)	0 (0%)	2 (7.4%)	11 (40.7%)	13 (48.1%)
$PERCIST_{SULpeak}$	8 (29.6%)	1 (3.7%)	7 (25.9%)	10 (37.0%)	9 (33.3%)
$PERCIST_{MTV}$	8 (29.6%)	0 (0%)	8 (29.6%)	6 (22.2%)	13 (48.1%)

*1 patient with no measurable target lesion at baseline. *OR=Objective response*



- PET better defines responders to pembro high dose than CT, impacting definition on OS assessment