

SIMPOSIO SATELITE

INMUNOTERAPIA DEL CÁNCER: INNOVACIÓN Y SOSTENIBILIDAD

Dr. Javier Gardé
Serv. de Oncología Arnau de Vilanova
"Avances en Cáncer de Pulmón"

Patrocina:



Bristol-Myers Squibb

The graphic features a stylized wine glass containing several jars and bottles. The jars are labeled with words related to cancer: 'cancer', 'oncología', 'nódulo', 'metástasis', 'tumor', 'paciente', 'cancer', 'oncología', 'nódulo', 'metástasis', 'tumor', 'paciente', 'cancer', 'oncología', 'nódulo', 'metástasis', 'tumor', 'paciente'. The word 'SVFH' is prominently displayed in large blue letters across the center of the glass. Above the glass, the text 'VII CONGRESO' is written vertically next to a large orange 'VII'. Below the glass, the text 'Jueves 4 de Mayo de 12h. a 13h' is displayed in red, along with the SVFH logo. At the bottom of the graphic, there is a blue bar with the website 'www.svfh.es' and the Twitter handle '@SVFH_'. The entire graphic is set against a background of vertical stripes in shades of grey and white.

VII CONGRESO

SVFH

Jueves
4 de Mayo
de 12h. a 13h

#SVFH17

www.svfh.es @SVFH_

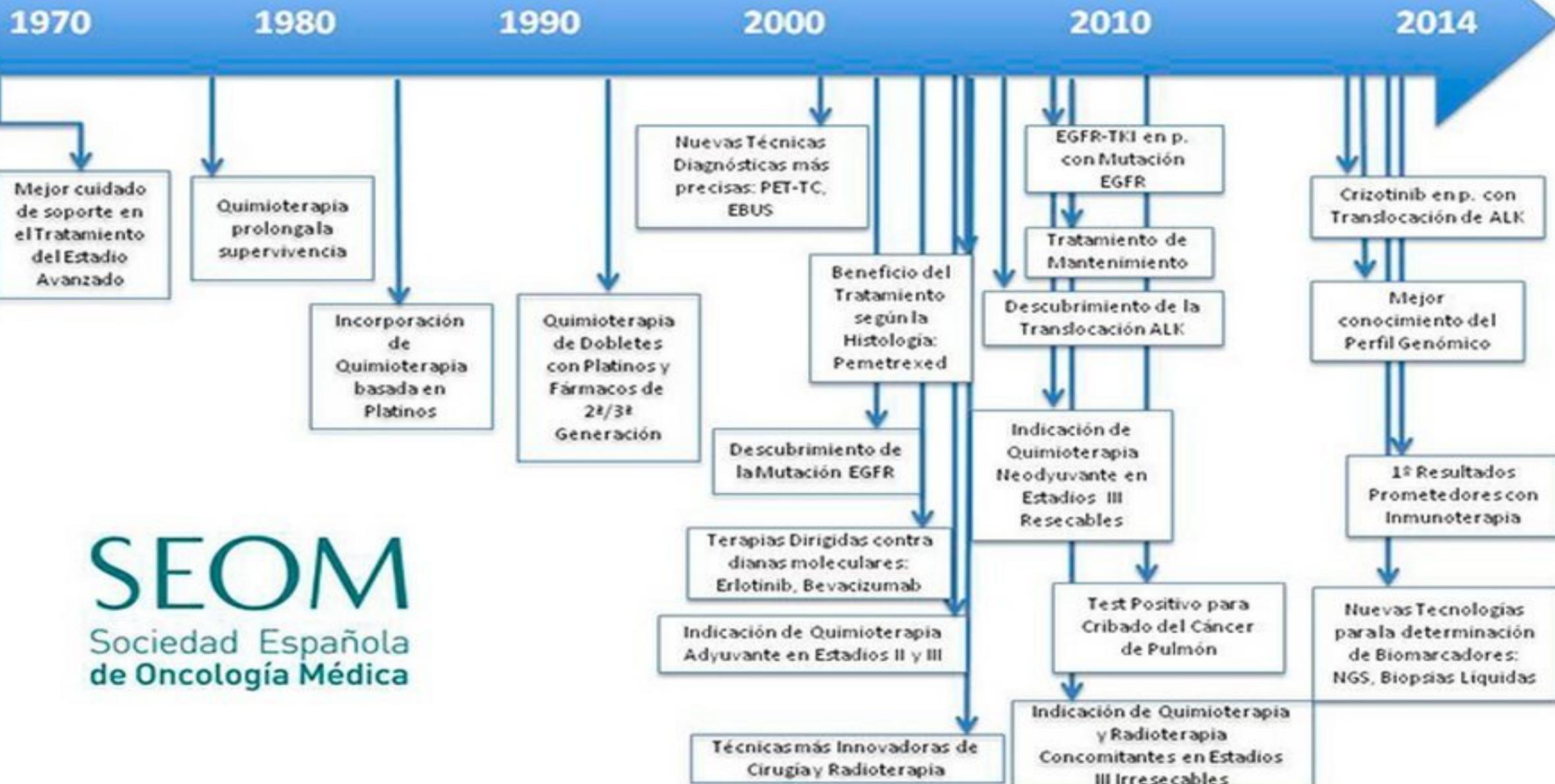
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- TRATAMIENTO DEL CÁNCER DE PULMÓN EN LA **ACTUALIDAD**
- **FUTURO INMINENTE** DEL TRATAMIENTO DEL CÁNCER DE PULMÓN.

... DE DONDE VENIMOS



AVANCES EN CÁNCER DE PULMÓN



AVANCES EN CÁNCER DE PULMÓN

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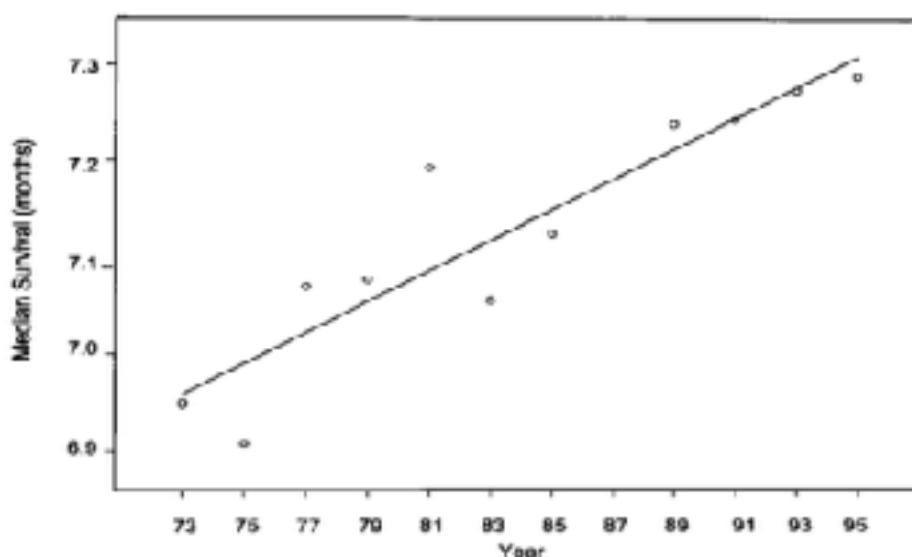
2000

2010

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Twenty-Two Years of Phase III Trials for Patients With Advanced Non-Small-Cell Lung Cancer: Sobering Results

PHASE III TRIALS FOR ADVANCED NON-SMALL-CELL LUNG CANCER



Journal of Clinical Oncology 2001; 19:6, 1734-1742

VII SVFH INMUNOTERAPIA
en Cáncer

Técnicas más Innovadoras de Cirugía y Radioterapia

Nuevas Técnicas
Técnicas más
: PET-TC,
US

Beneficio del
Tratamiento
según la
Histología:
Pemetrexed

Descubrimiento de
Mutación EGFR

Terapias Dirigidas contra
las moléculas:
Crizotinib, Bevacizumab

Indicación de Quimioterapia
Neoadyuvante en
Estadios III
Reseables

Indicación de Quimioterapia
ante en Estadios II y III

EGFR-TKI en p.
con Mutación
EGFR

Tratamiento de
Mantenimiento

Descubrimiento de la
Translocación ALK

Indicación de Quimioterapia
Neoadyuvante en
Estadios III
Reseables

Test Positivo para
Cribado del Cáncer
de Pulmón

Indicación de Quimioterapia
y Radioterapia
Concomitantes en Estadios
III Irresecables

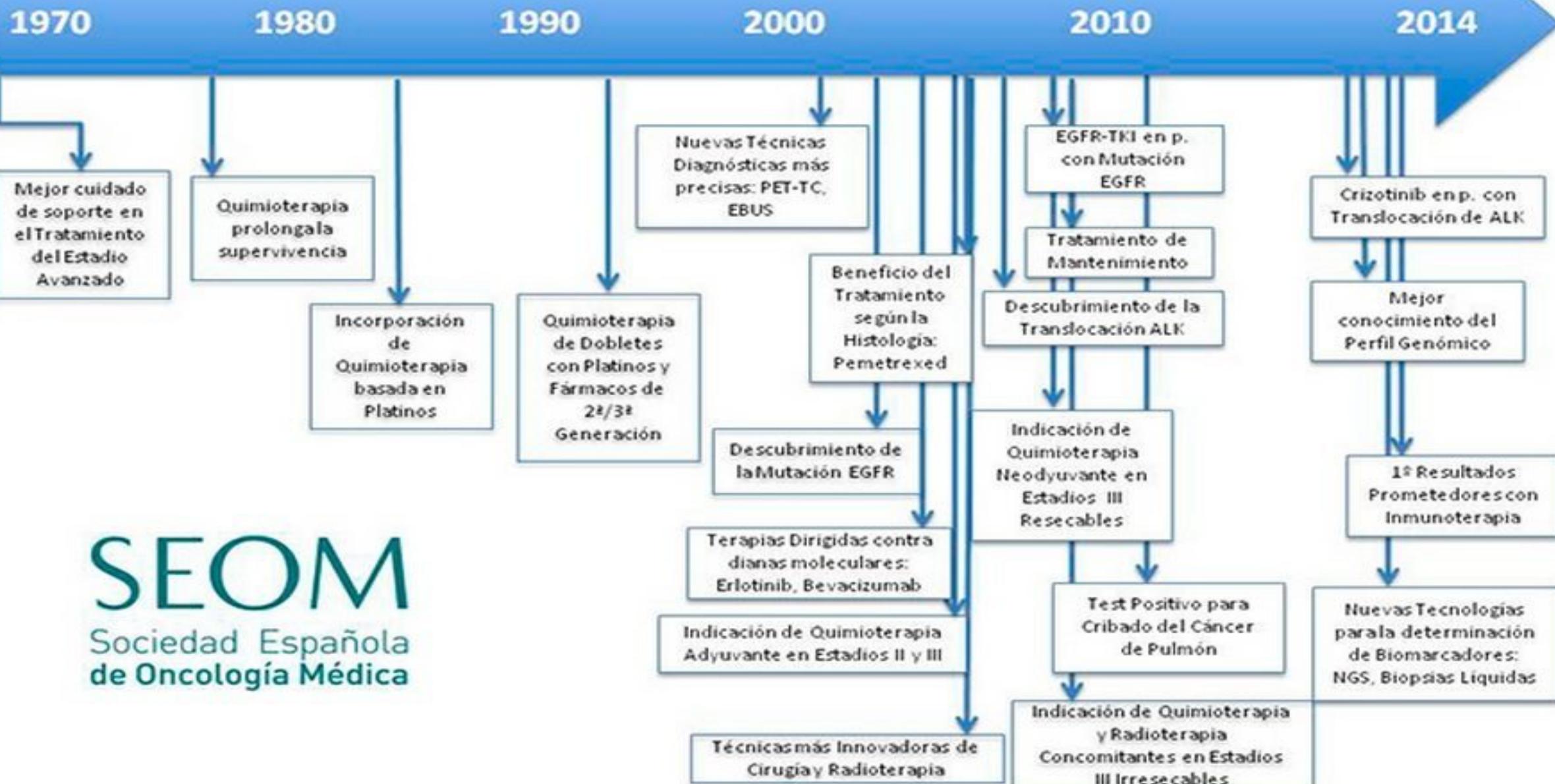
Crizotinib en p.
con Translocación de ALK

Mejor
conocimiento del
Perfil Genómico

1º Resultados
Prometedores con
Inmunoterapia

Nuevas Tecnologías
para la determinación
de Biomarcadores:
NGS, Biopsias Liquidas

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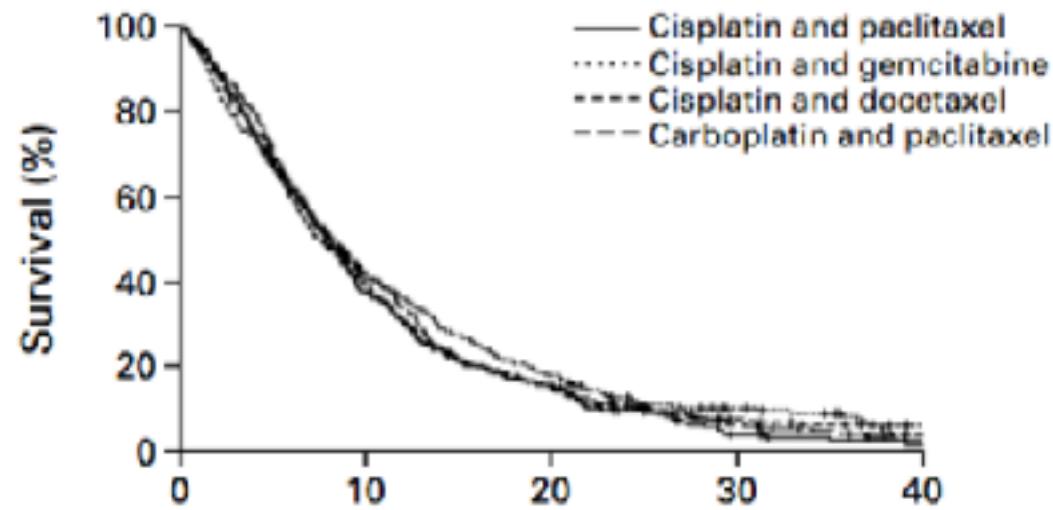
2000

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Mejor cuidado de soporte en el Tratamiento del Estadio Avanzado

COMPARISON OF FOUR CHEMOTHERAPY REGIMENS FOR ADVANCED NON-SMALL-CELL LUNG CANCER



N Engl J Med, Vol. 346, No. 2 • January 10, 2002

Técnicas más Innovadoras de Cirugía y Radioterapia

EGFR-TKI en p. con Mutación EGFR

Tratamiento de Mantenimiento

Descubrimiento de la Translocación ALK

Indicación de Quimioterapia Neoadyuvante en Estadios III Reseables

Test Positivo para Cribado del Cáncer de Pulmón

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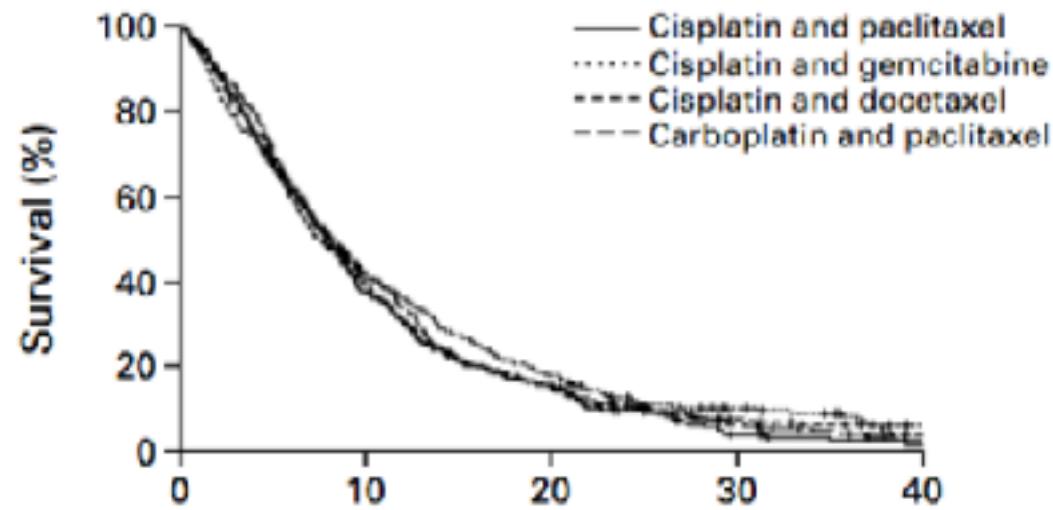
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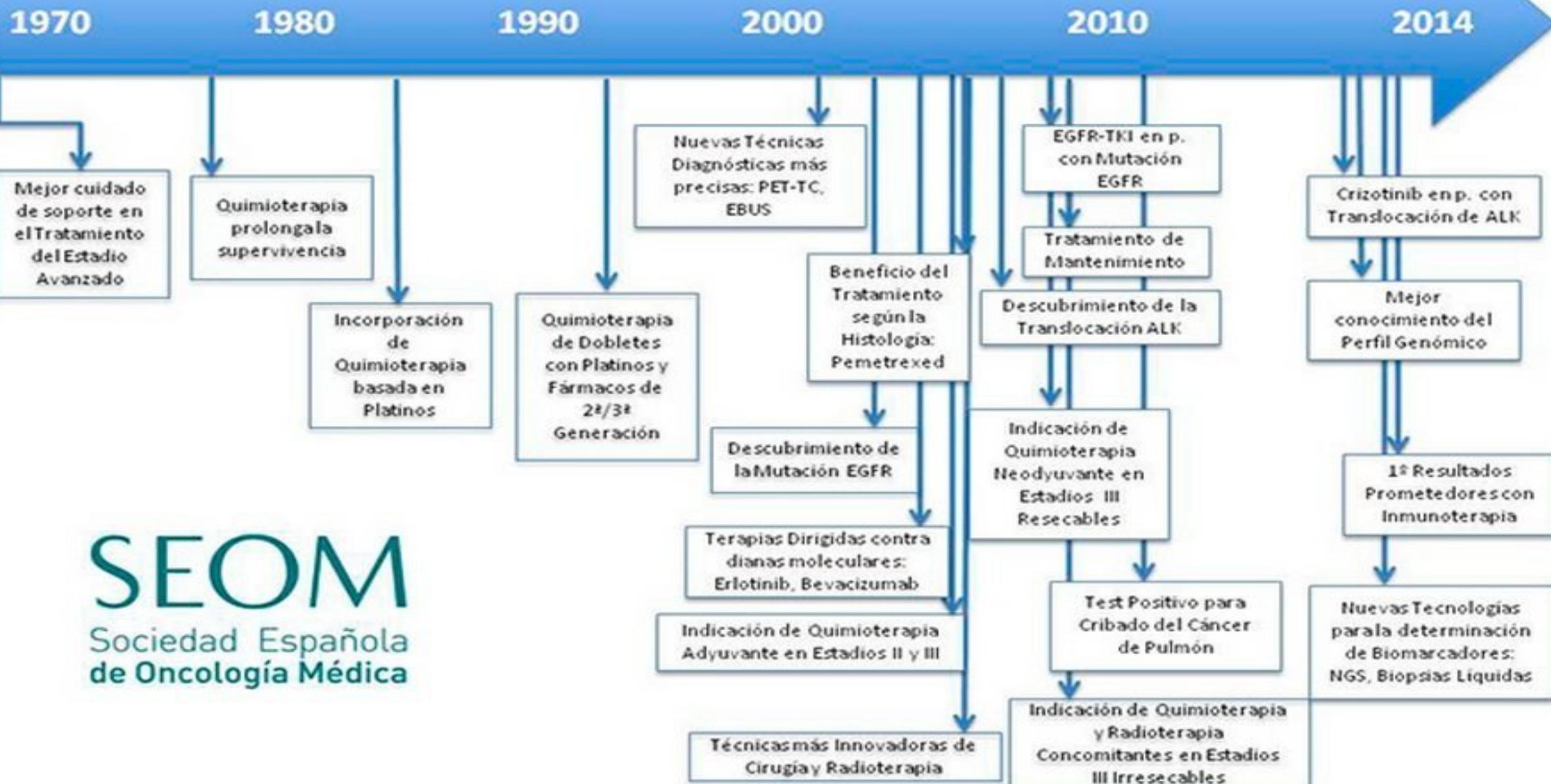
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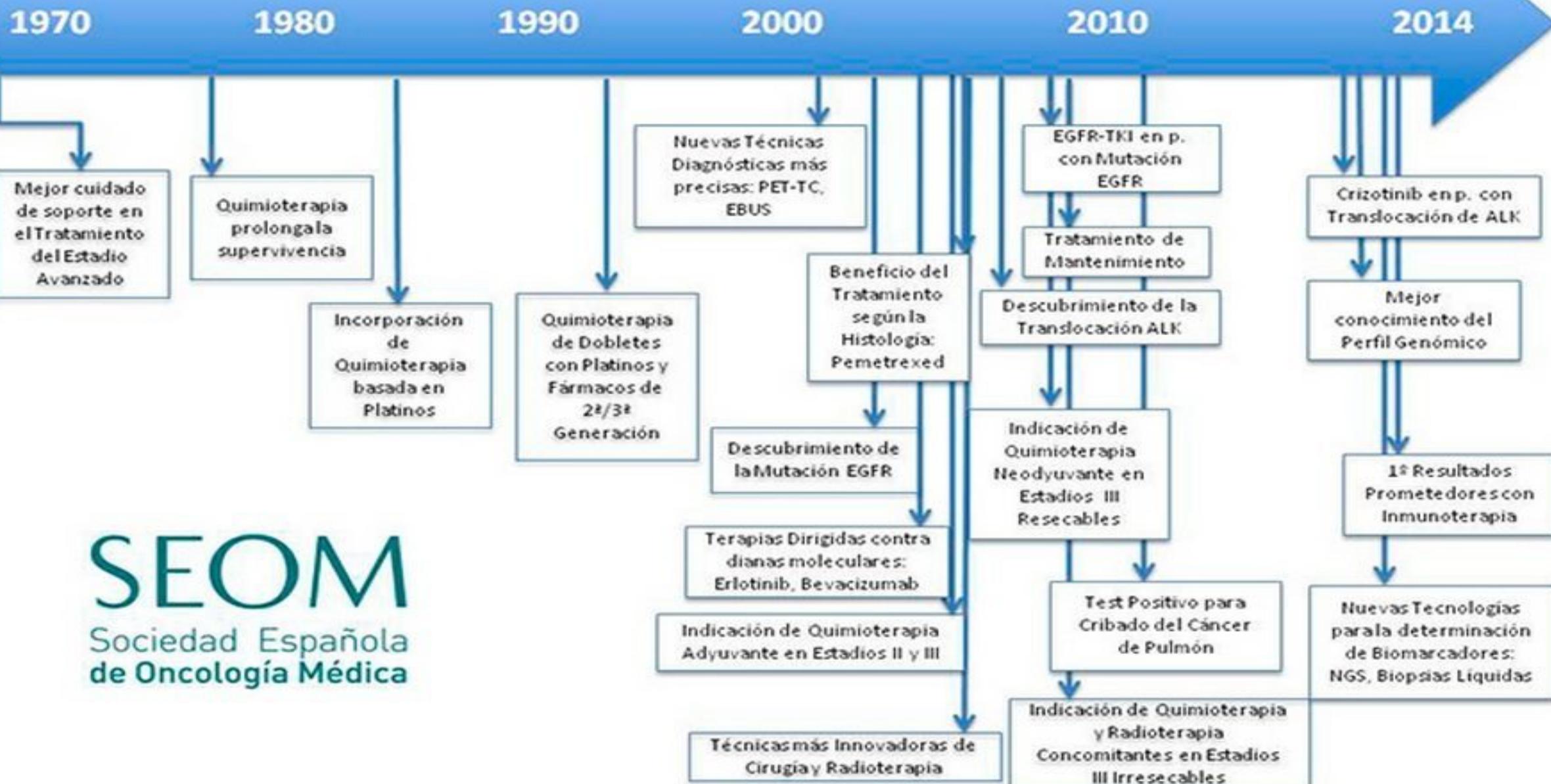
Nuevas Técnicas

Table 4. Summary of Nonhematologic Toxicity

Toxicity	Docetaxel 75 mg/m ² (n = 55)*		Docetaxel 100 mg/m ² (n = 49)*		Best Supportive Care (n = 100)*			
	All grades	Grade 3/4	All grades	Grade 3/4	All grades	Grade 3/4	All grades	Grade 3/4
	No.	%	No.	%	No.	%	No.	%
Asthenia	30	54.5	10	18.2	30	61.2	11	22.4
Cardiac	5	9.1	1	1.8	8	16.3	2	4.1
Diarrhea	20	36.4	1	1.8	15	30.6	2	4.1
Fever, no infection	34	61.8	0	0	18	36.7	0	0
Fluid retention	7	12.7	0	0	5	10.2	0	0
Hypertension	2	3.6	0	0	0	0	0	0
Hypotension	2	3.6	0	0	6	12.2	3	6.1
Infection	17	30.9	3	5.5	18	36.7	7	14.3
Nausea	20	36.4	2	3.6	17	34.7	1	2.0
Neuromotor	8	14.5	1	1.8	8	16.3	2	4.1
Neurosensory	11	20	1	1.8	13	26.5	1	2.0
Pulmonary	21	38.2	11	20.0	26	53.1	18	36.7
Stomatitis	14	25.5	1	1.8	13	26.5	2	4.1
Vomiting	13	23.6	2	3.6	13	26.5	1	2.0

*Total number of patients.

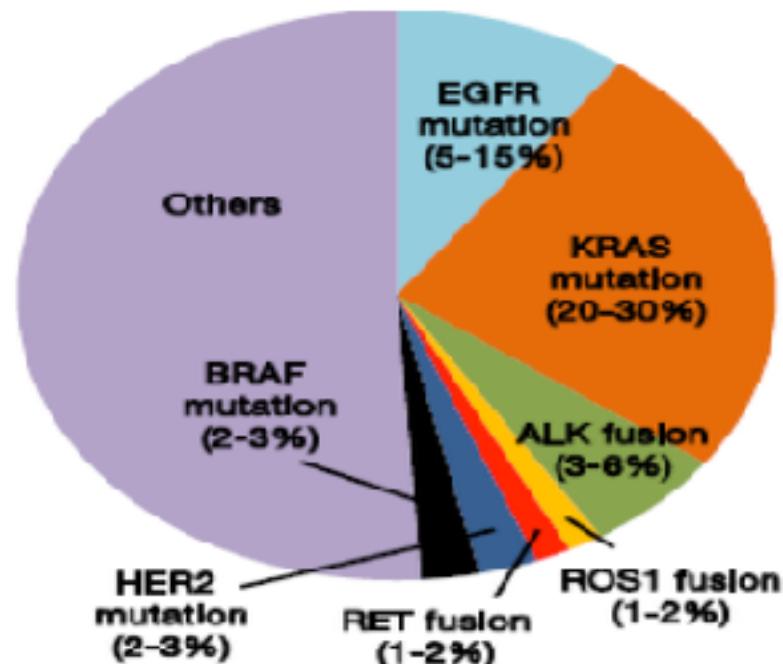
AVANCES EN CÁNCER DE PULMÓN



SEOM
Sociedad Española
de Oncología Médica

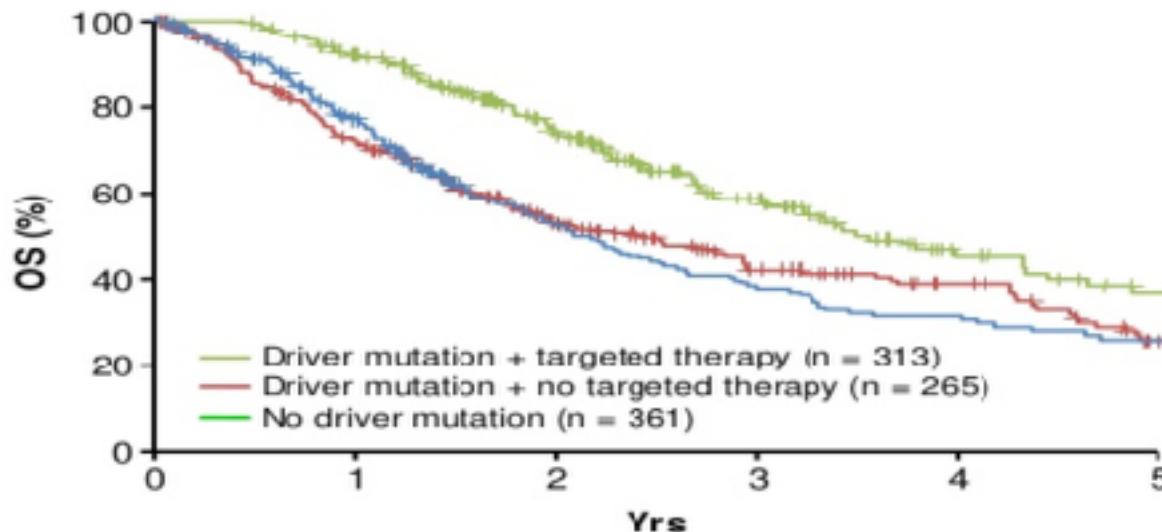
AVANCES EN CÁNCER DE PULMÓN

1970 1980 1990 2000 2010 2014



Nuevas Técnicas

Lung Cancer Mutation Consortium: OS by Mutation and Treatment



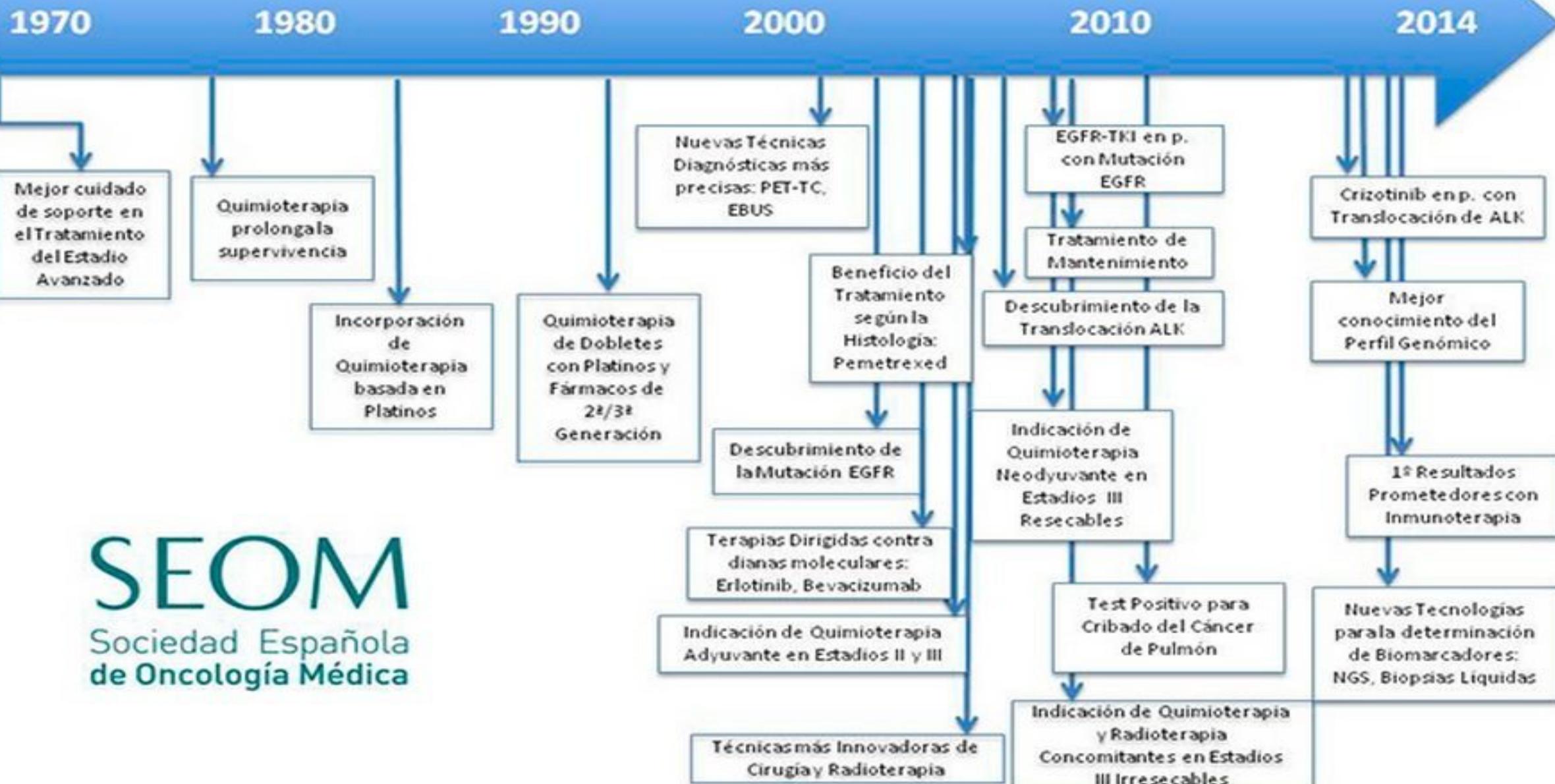
Journal of Thoracic Oncology • Volume 7, Number 11, November 2012

Johnson B, et al. ASCO 2013. Abstract 8019.

Técnicas más Innovadoras de
Cirugía y Radioterapia

Indicación de Quimioterapia
y Radioterapia
Concomitantes en Estadios
III Irresecables

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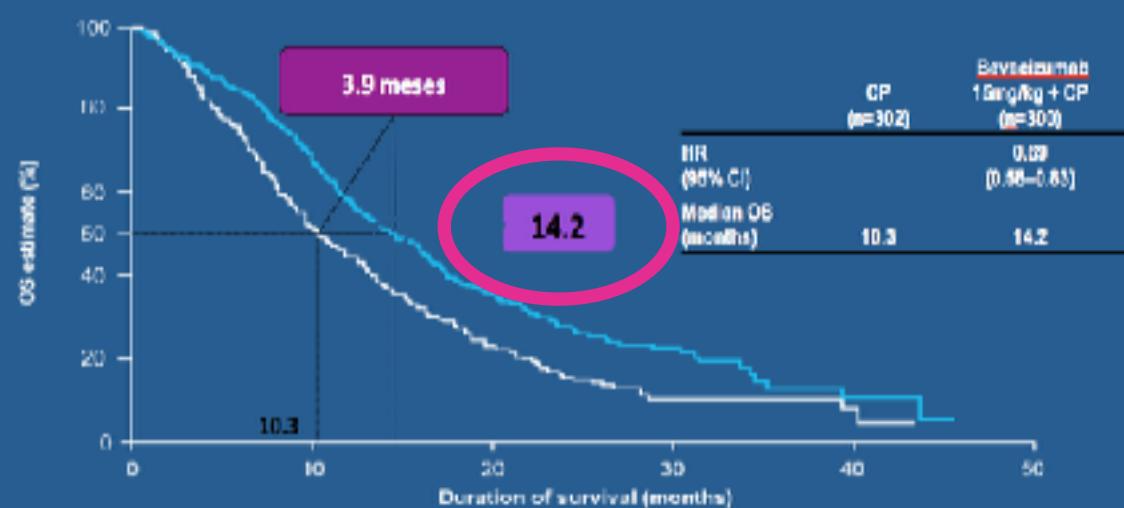
2010

2014

Nuevas Técnicas

E4599 análisis pre-planeado en pacientes con adenocarcinoma

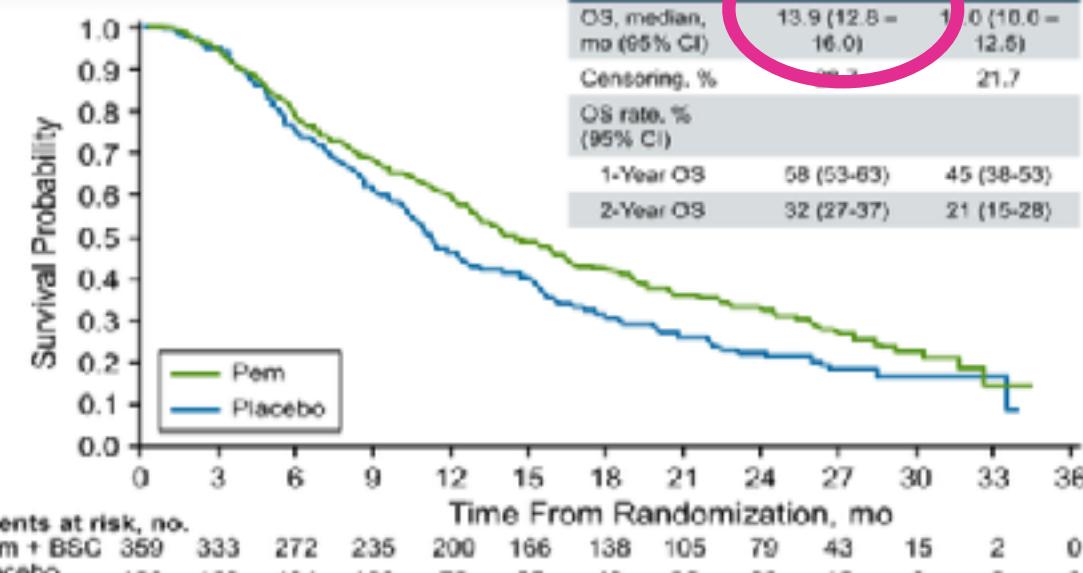
E4599



bevacizumab administrado como progestina en la enfermedad (*)
CP = bevacizumab

Niedel et al. JTO 2012; 55(10):1019-23.

PARAMOUNT: Final OS From Randomization

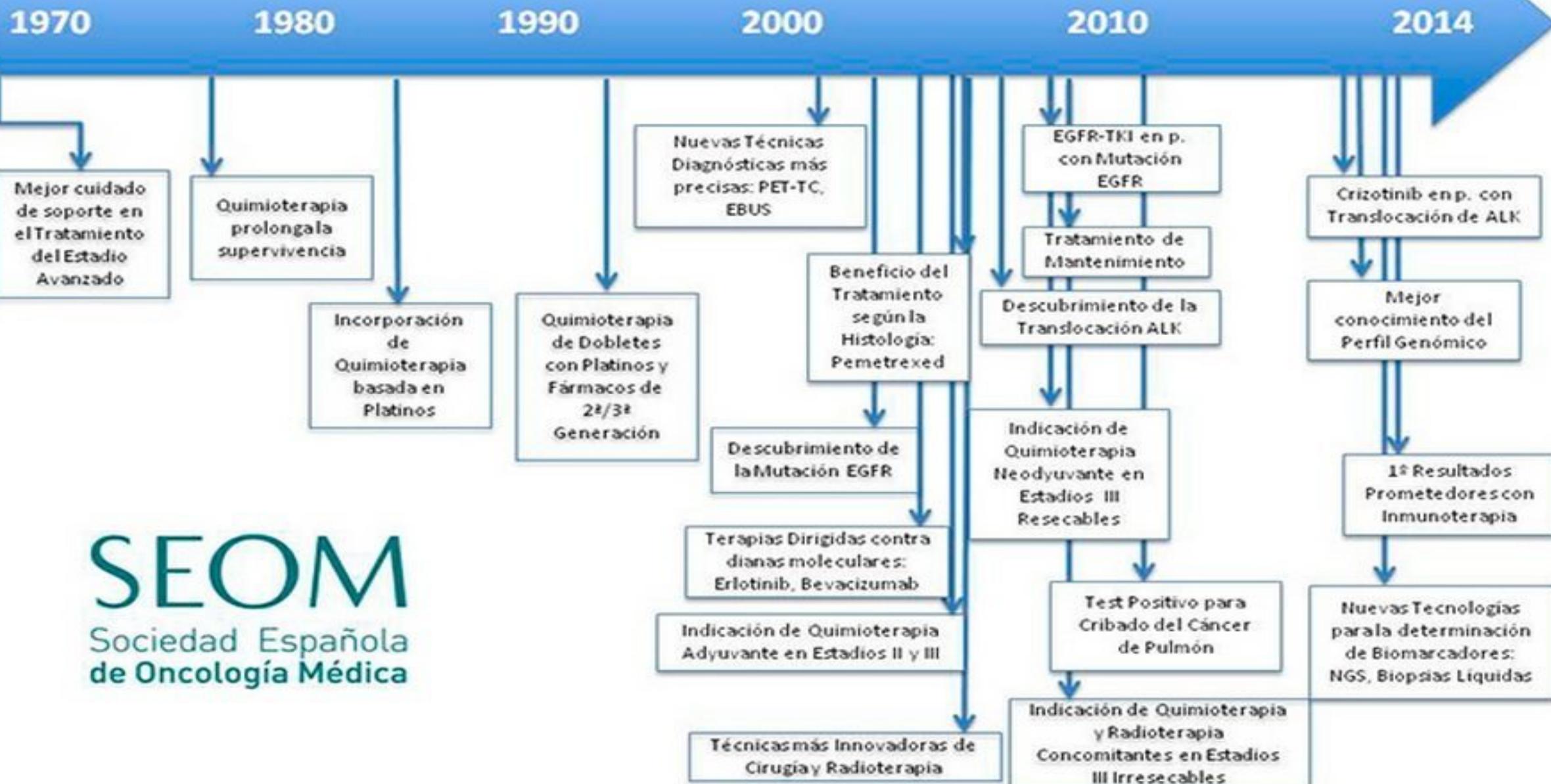


Paz-Ares LG et al. J Clin Oncol. 2012;30:LBA7507.

Técnicas más Innovadoras de Cirugía y Radioterapia

Indicación de Quirúrgica y Radioterapia Concomitantes en Estadios III Irresecables

AVANCES EN CÁNCER DE PULMÓN



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Nuevas Técnicas

Patients with Adenocarcinoma

Patients with AEs, n (%)	Nintedanib + docetaxel (n=320)	Placebo + docetaxel (n=333)
Any AE, all grades	308 (96.3)	314 (94.3)
Drug-related AEs, all grades	260 (81.3)	241 (72.4)
Any AE, grades ≥3	243 (75.9)	228 (68.5)
Drug-related AEs, grades ≥3	176 (55.0)	152 (45.6)
Any AE leading to discontinuation	67 (20.9)	59 (17.7)
Any serious AE	111 (34.7)	107 (32.1)

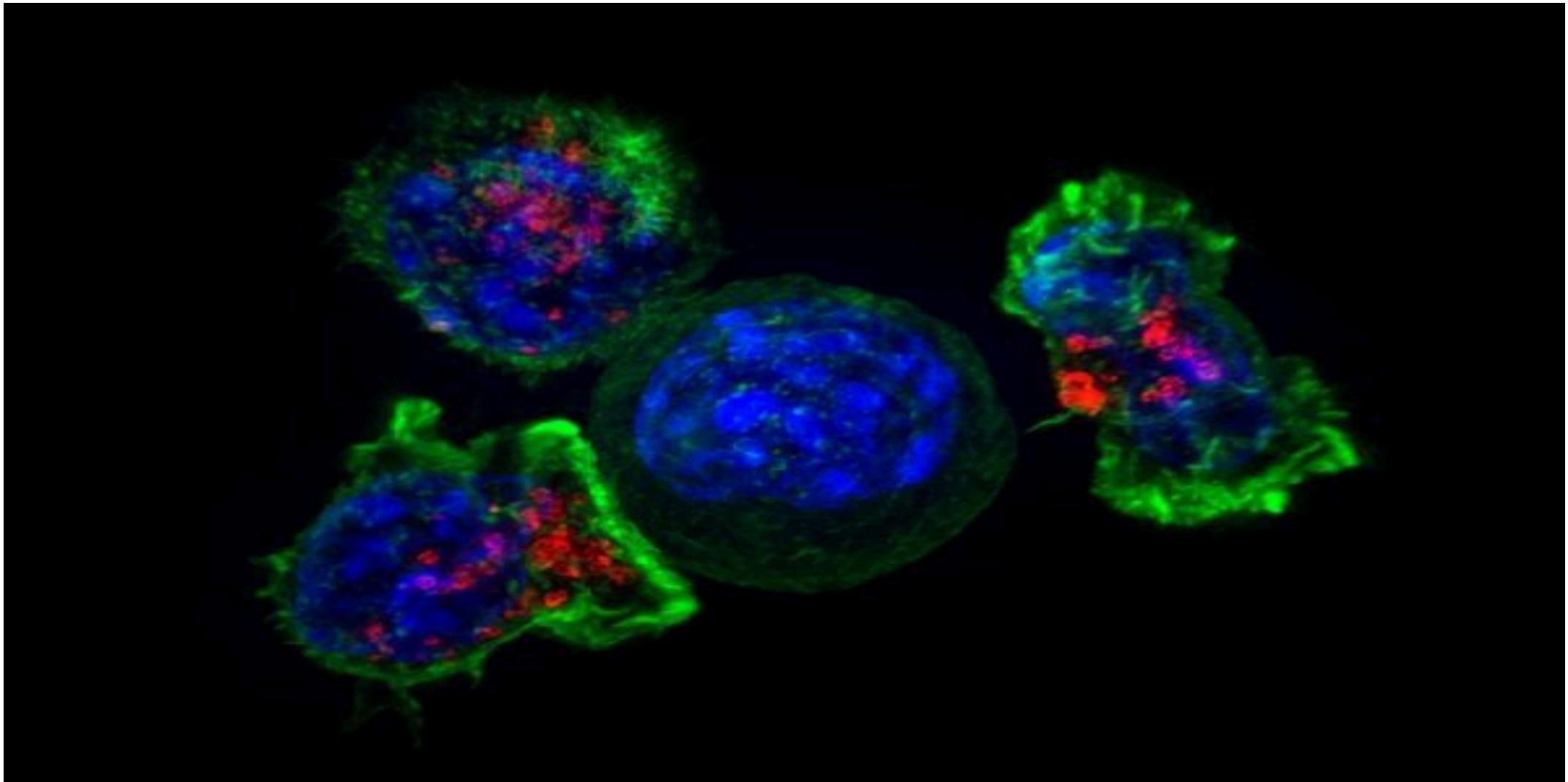
Técnicas más Innovadoras de Cirugía y Radioterapia

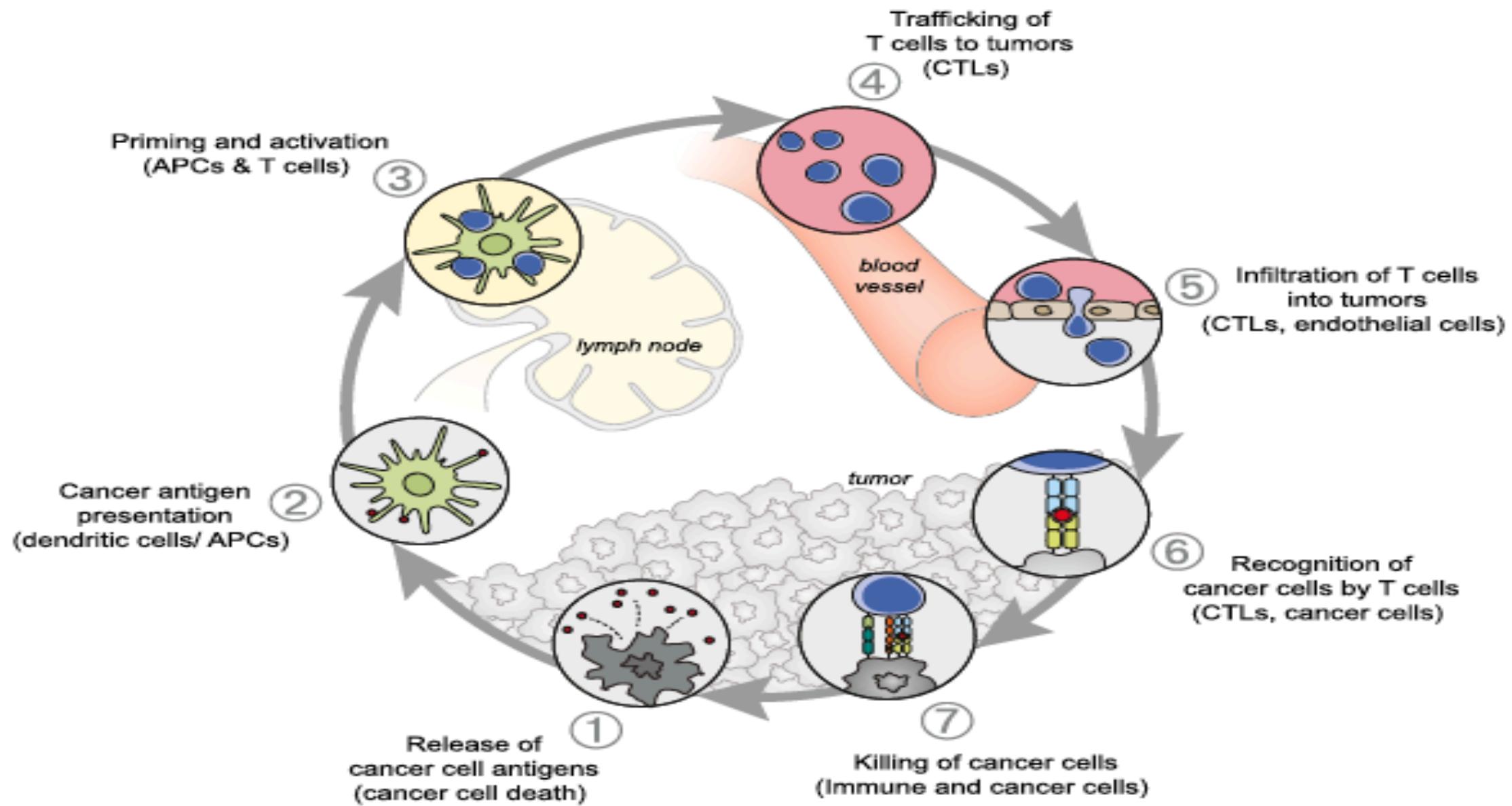
Indicación de Quimioterapia y Radioterapia Concomitantes en Estadios III Irresecables

DONDE ESTAMOS

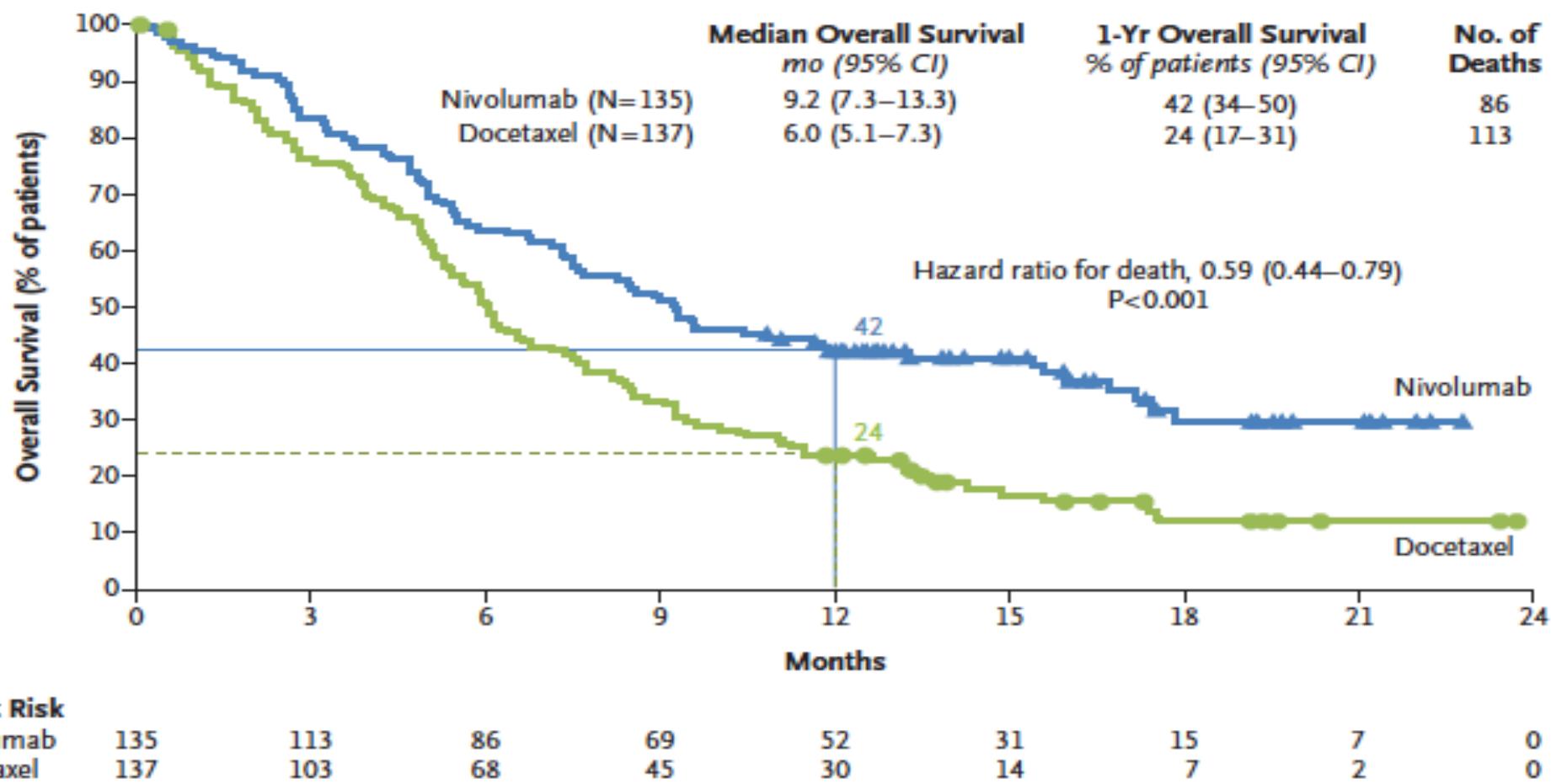


INMUNOTERAPIA

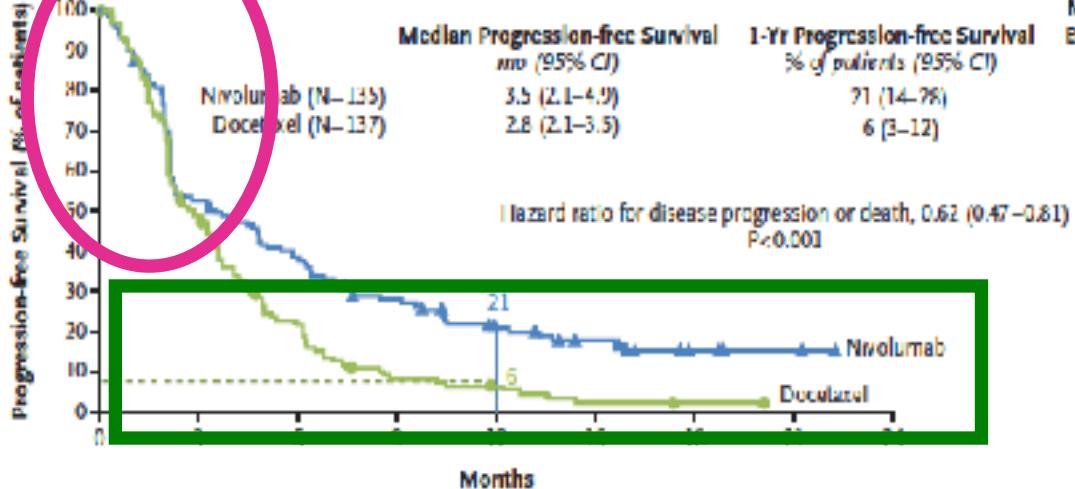




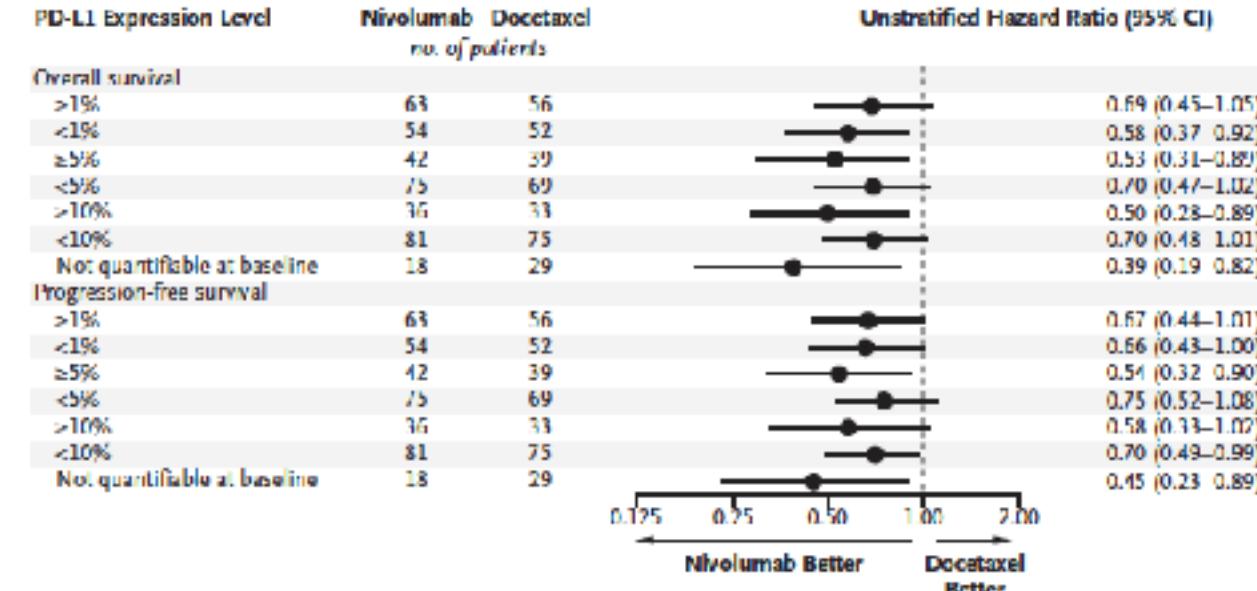
Nivolumab versus Docetaxel in Advanced Squamous-Cell Non-Small-Cell Lung Cancer



B Progression-free Survival

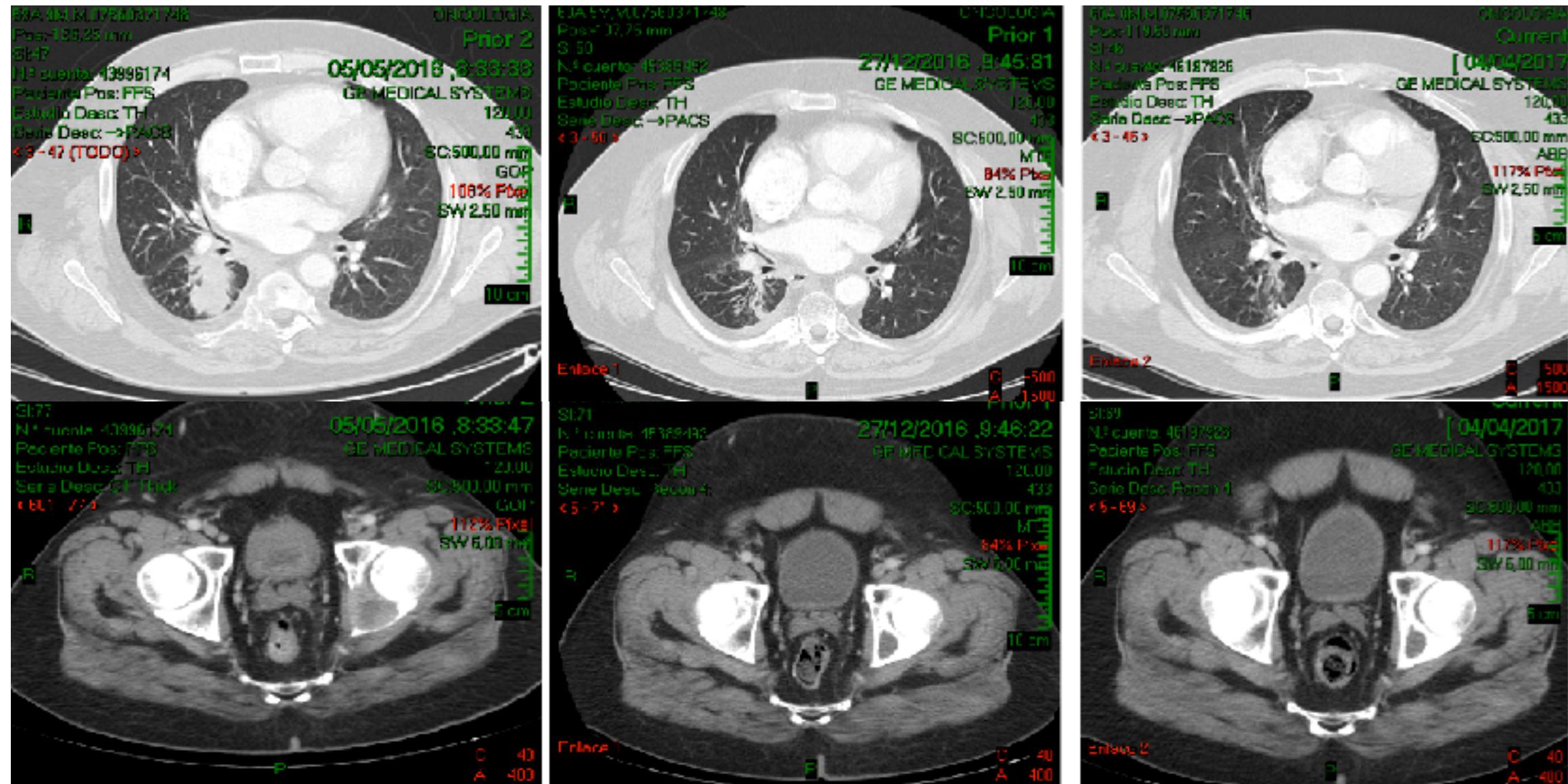


C Overall and Progression-free Survival According to PD-L1 Expression Level

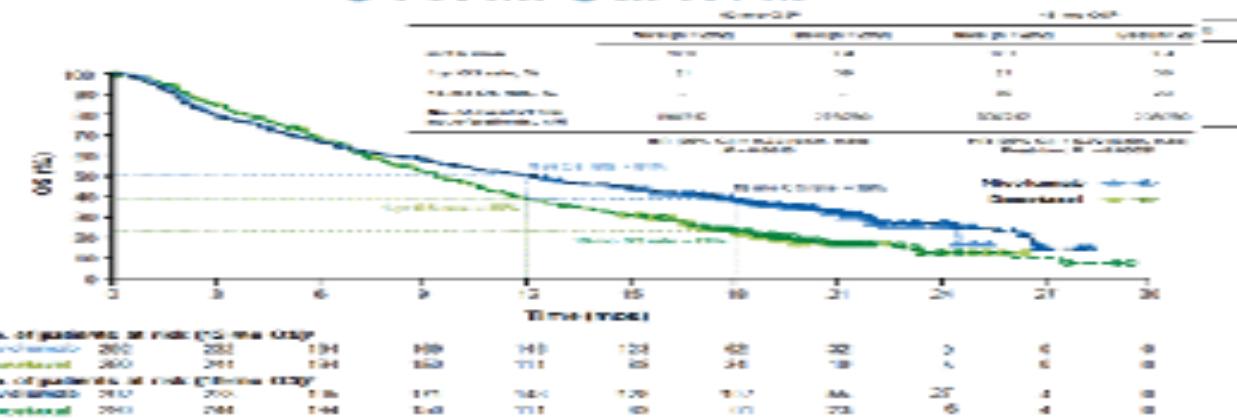


	Nivolumab n=135	Docetaxel n=137
ORR, % (95% CI)	20 (14, 28)	9 (5, 15)
P-value^a	0.0083	
Best overall response, %		
Complete response	10	0
Partial response	19	9
Stable disease	29	34
Progressive disease	41	35
Unable to determine	10	22
Median DCR,^c mos (range)	NR (2.9, 21+)	8.4 (1.4+, 15+)
Median time to response,^c mos (range)	2.2 (1.6, 12)	2.1 (1.8, 9.5)
Ongoing response, % (no. ongoing/total responders)	63 (17/27)	33 (4/12)

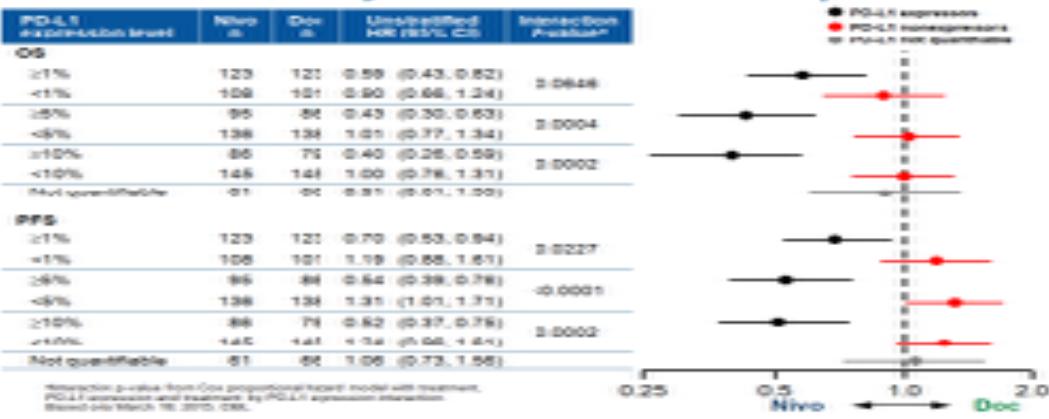
CASO 3. Carcinoma Epidermoide de Pulmón con Metástasis Oseas en tratamiento con Nivolumab



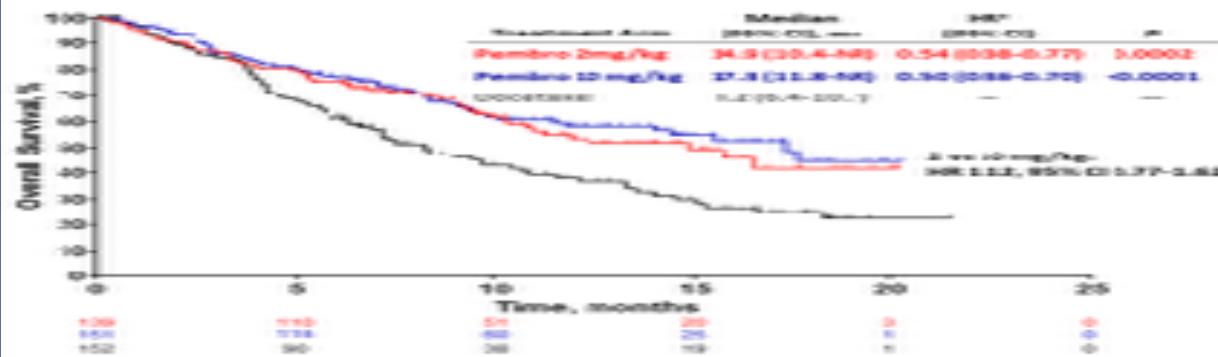
Overall Survival



Survival by Baseline PD-L1 Expression



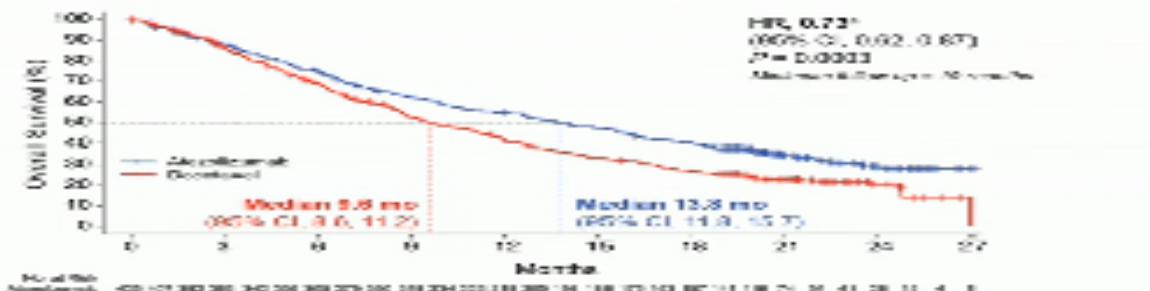
OS, PD-L1 TPS ≥50% Stratum



ORR (RECIST v1.1, Central Review)

PD-L1 TPS ≥50%	Pembro 2 mg/kg n = 130	Pembro 10 mg/kg n = 151	Docetaxel n = 152
ORR, % (95% CI)	30 (23-39) <i>P < 0.0001*</i>	29 (22-37) <i>P < 0.0001*</i>	8 (4-13)
PD-L1 TPS <50%	Pembro 2 mg/kg n = 344	Pembro 10 mg/kg n = 346	Docetaxel n = 343
ORR, % (95% CI)	18 (14-22) <i>P = 0.0005*</i>	18 (14-23) <i>P = 0.0002*</i>	9 (6-13)

OVERALL SURVIVAL, ITT (N = 850)



OS BY PD-L1 EXPRESSION

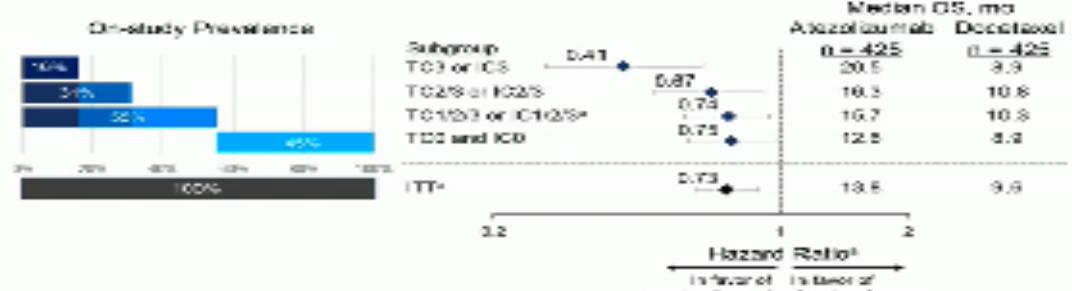
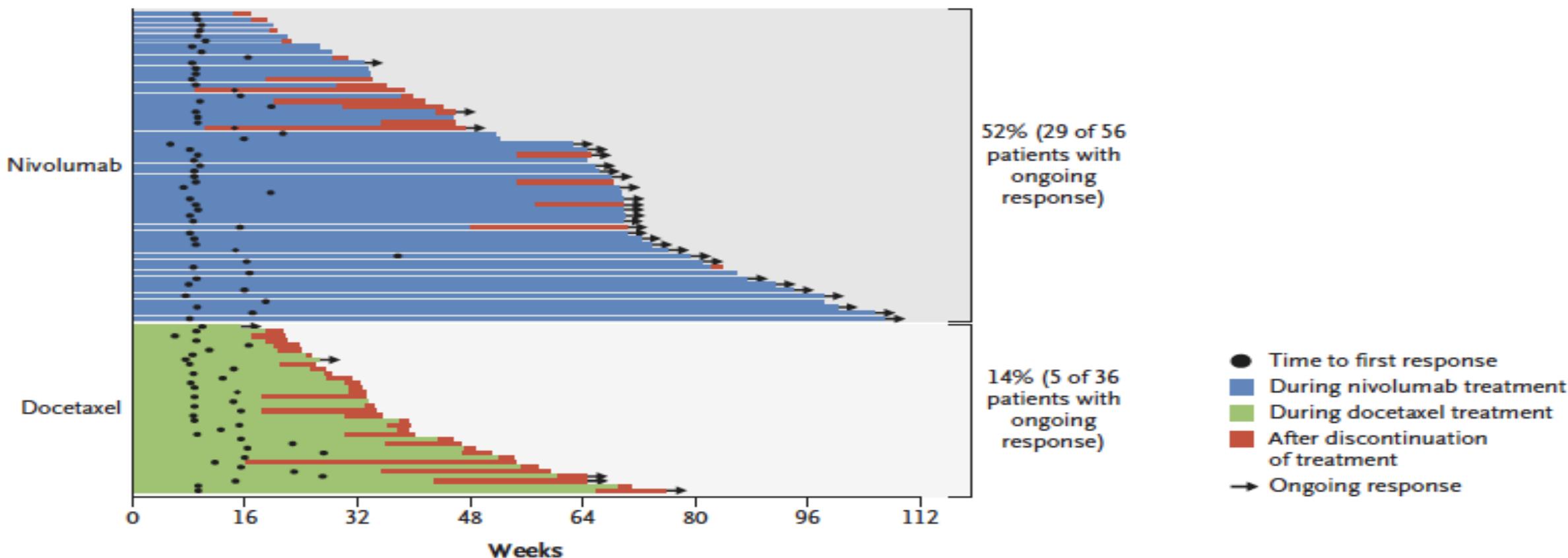


Table 2. Tumor Response with Nivolumab versus Docetaxel in Patients with Advanced Nonsquamous Non-Small-Cell Lung Cancer.*

B Duration of Response



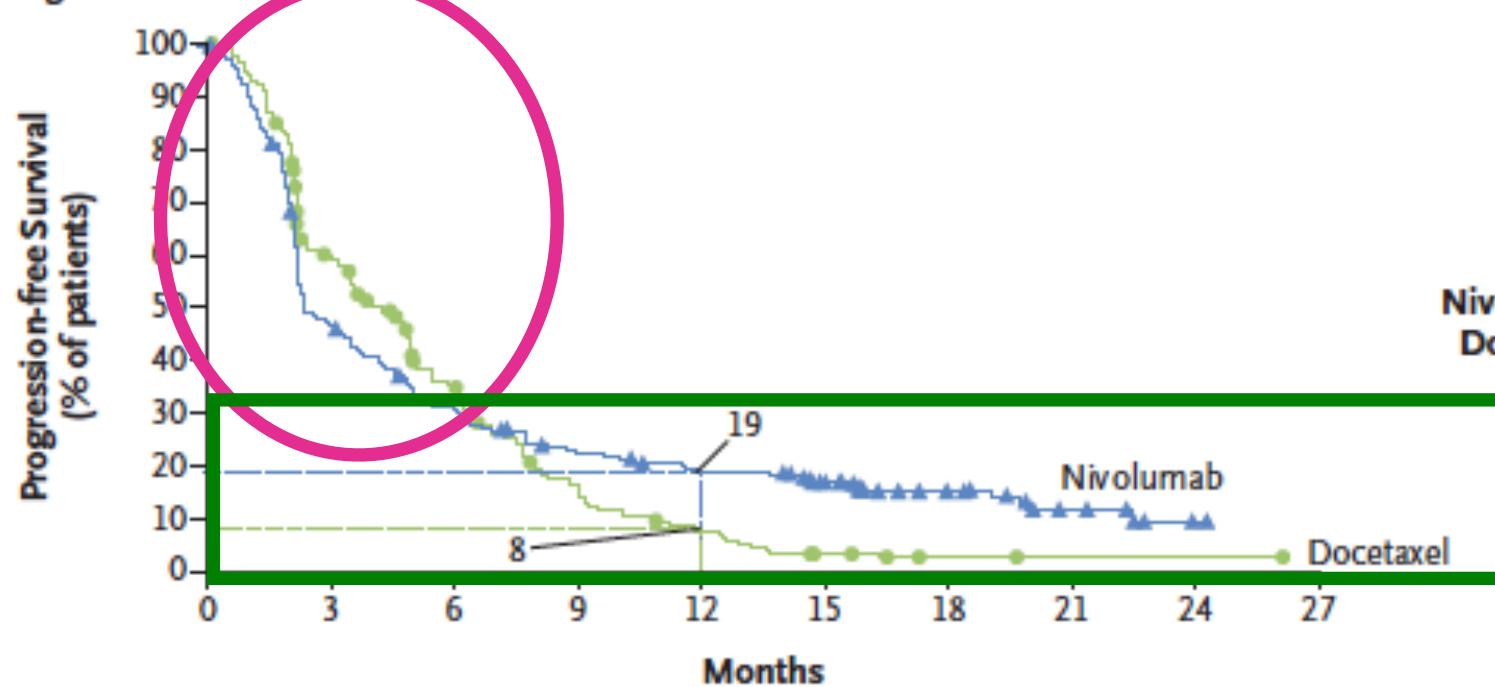
Duration of response — months	1.2–8.6	1.4–6.3
Range	1.2–8.6	1.4–6.3
Median	17.2	5.6
Range	1.8 to 22.6+	1.2+ to 15.2+

	Nivolumab (n = 287)		Docetaxel (n = 268)	
	Any grade	Grade 3–4 ^a	Any grade	Grade 3–4 ^a
	Percentage (%) of patients with an event			
Any event	69	10	88	54
Fatigue	16	1	29	5
Nausea	12	1	26	1
Decreased appetite	10	0	16	1
Asthenia	10	<1	18	2
Diarrhea	8	1	23	1
Peripheral edema	3	0	10	<1
Myalgia	2	<1	11	0
Anemia	2	<1	20	3
Alopecia	<1	0	25	0
Neutropenia	<1	0	31	27
Febrile neutropenia	0	0	10	10
Leukopenia	0	0	10	8

Borghaei, *N Engl J Med*, 2015

Nivolumab versus Docetaxel in Advanced Nonsquamous Non-Small-Cell Lung Cancer

C Progression-free Survival



No. of Events/ Total No. of Patients	Median Progression- free Survival (95% CI) mo	1-Yr Progression- free Survival (95% CI) %
Nivolumab 234/292	2.3 (2.2–3.3)	19 (14–23)
Docetaxel 245/290	4.2 (3.5–4.9)	8 (5–12)

Hazard ratio for disease progression or death,
0.92 (95% CI, 0.77–1.11); P=0.39

No. at Risk

Nivolumab	292	128	82	58	46	35	17	7	2	0
Docetaxel	290	156	87	38	18	6	2	1	1	0

Informe Público Europeo de Evaluación (EPAR) de Nivolumab

Análisis multivariado post-hoc: Pacientes con enfermedad agresiva y PD-L1 Negativo

- ✓ Menos de 3 meses desde el último tratamiento
- ✓ Progresión de enfermedad como mejor respuesta
- ✓ PS= 1

Predictive and Prognostic Clinical and Pathological Factors of Nivolumab Efficacy in Non-Small-Cell Lung Cancer (NSCLC) Patients

Authors:

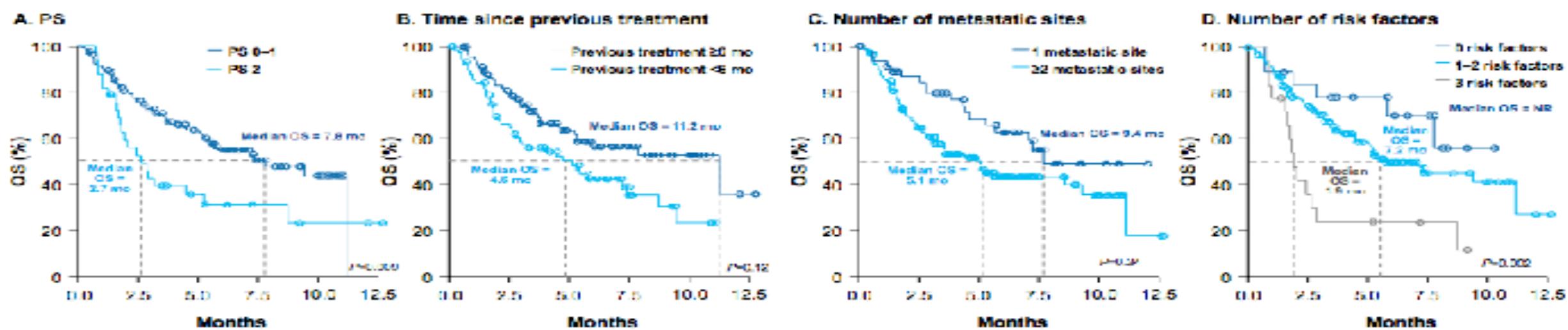
P. Martín Martorell¹, M. De Julián², J Perez Altozano³, C Salvador Coloma⁴, J. García Sánchez⁵, A. Insa Molla¹, M. Martín⁶, X. Mielgo Rubio⁷, S. Marin⁸, A. Blasco Cordellat⁹, S. Blasco Liebana¹⁰, R. Gironés¹¹, D. Marquez¹², F. Aparisi¹³, M. Bas Cerda¹⁴, O. Juan Vidal⁴, S. Macia Escalante¹⁵, J. Garde-Noguera⁵

¹University Hospital Clínic de Valencia, Valencia, Spain; ²Hospital Provincial de Castellón, Castellón, Spain; ³Hospital General de Elche, Elche, Spain; ⁴Hospital Universitari I Politècnic La Fe, Valencia, Spain; ⁵Hospital Arnau de Vilanova, Valencia, Spain; ⁶Hospital Dr Peset, Valencia, Spain; ⁷Hospital Universitario Fundación Alcorcón, Alcorcón, Spain; ⁸Hospital de Manises, Manises, Spain; ⁹Hospital General Universitario de Valencia, Valencia, Spain; ¹⁰Hospital de Sagunto, Sagunto, Spain, ¹¹Hospital Lluis Alcanyís, Xàtiva, Spain; ¹²Hospital Arnau de Vilanova, Lleida/Spain, ¹³Hospital Virgen de los Lirios, Alcoy/Spain, ¹⁴Universidad Politecnica de Valencia, Valencia, Spain; ¹⁵Pivotal CRO, Madrid, Spain.

Journal of Thoracic Oncology Vol. 12 No. 1S:1328

Variable	OS	
	HR (95% CI)	P value*
PS (0–1 vs 2)	0.62 (0.36, 1.04)	0.073
Previous anti-angiogenic therapy (no vs yes)	1.73 (0.86, 3.40)	0.113
Radiotherapy within 30 days (yes vs no)	—	—
Time since previous treatment (<6 vs ≥6 mo)	1.85 (1.16, 2.99)	0.010
Disease stage (III vs IV)	0.50 (0.20, 1.29)	0.151
Number of metastatic sites (1 vs ≥2)	0.56 (0.31, 0.98)	0.044
Lung metastasis (no vs yes)	0.85 (0.48, 1.49)	0.589
Adrenal metastasis (no vs yes)	0.71 (0.41, 1.25)	0.236
Brain metastasis (no vs yes)	1.02 (0.57, 1.83)	0.903
Liver metastasis (no vs yes)	—	—
Bone metastasis (no vs yes)	0.84 (0.51, 1.39)	0.497
Anemia (yes vs no)	—	—
Normal leukocyte count (yes vs no)	—	—

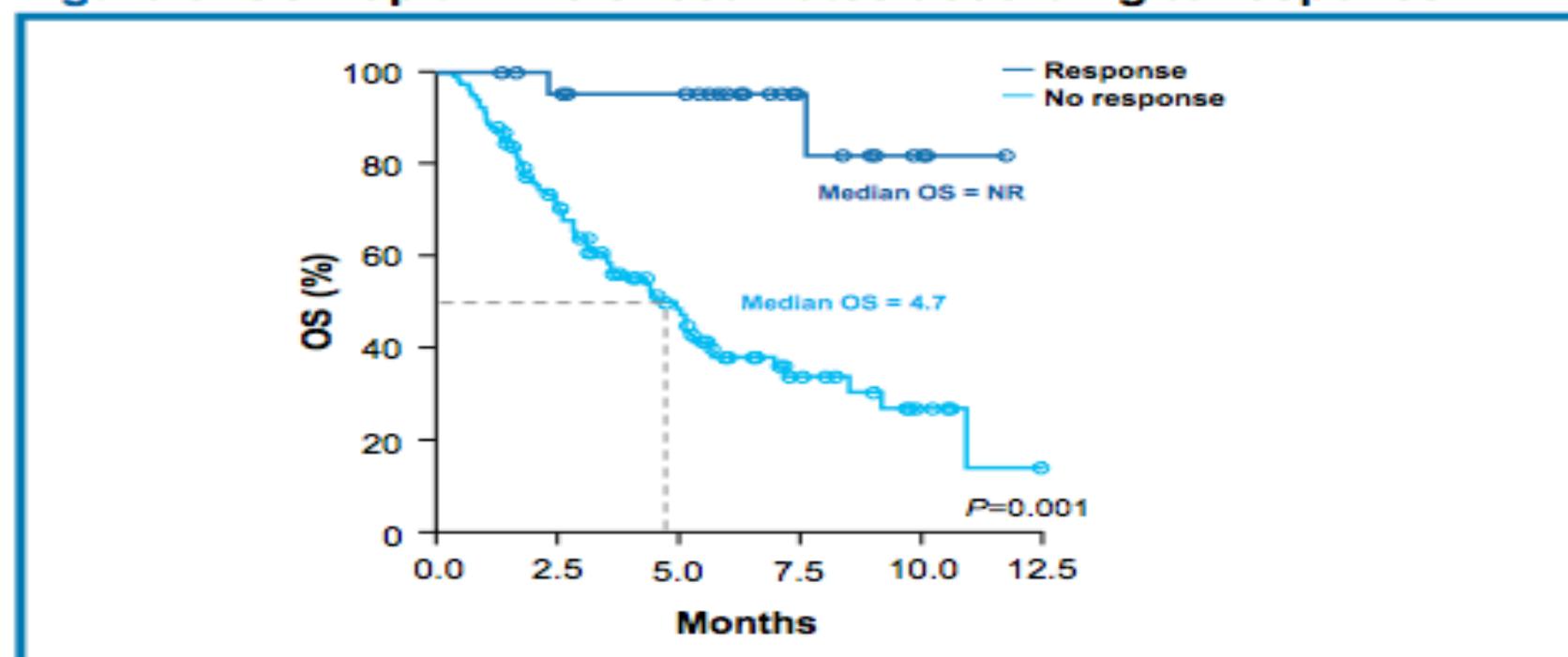
Figure 1. OS Kaplan-Meier estimates according to the independent risk factors in the multivariate analysis



Variable	ORR	
	OR (95% CI)	P value ^a
PS (0–1 vs 2)	—	—
Previous anti-angiogenic therapy (no vs yes)	—	—
Radiotherapy within 30 days (yes vs no)	0.94 (0.44, 2.00)	0.876
Time since previous treatment (<6 vs ≥6 mo)	0.40 (0.61, 1.00)	0.051
Disease stage (III vs IV)	3.57 (1.97, 6.45)	<0.0001
Number of metastatic sites (1 vs ≥2)	1.15 (0.60, 3.50)	0.412
Lung metastasis (no vs yes)	1.44 (0.62, 3.34)	0.402
Adrenal metastasis (no vs yes)	—	—
Brain metastasis (no vs yes)	—	—
Liver metastasis (no vs yes)	1.0 (0.49, 2.10)	0.997
Bone metastasis (no vs yes)	1.40 (0.67, 2.92)	0.376
Anemia (yes vs no)	0.94 (0.42, 2.14)	0.891
Normal leukocyte count (yes vs no)	1.08 (0.45, 2.57)	0.856

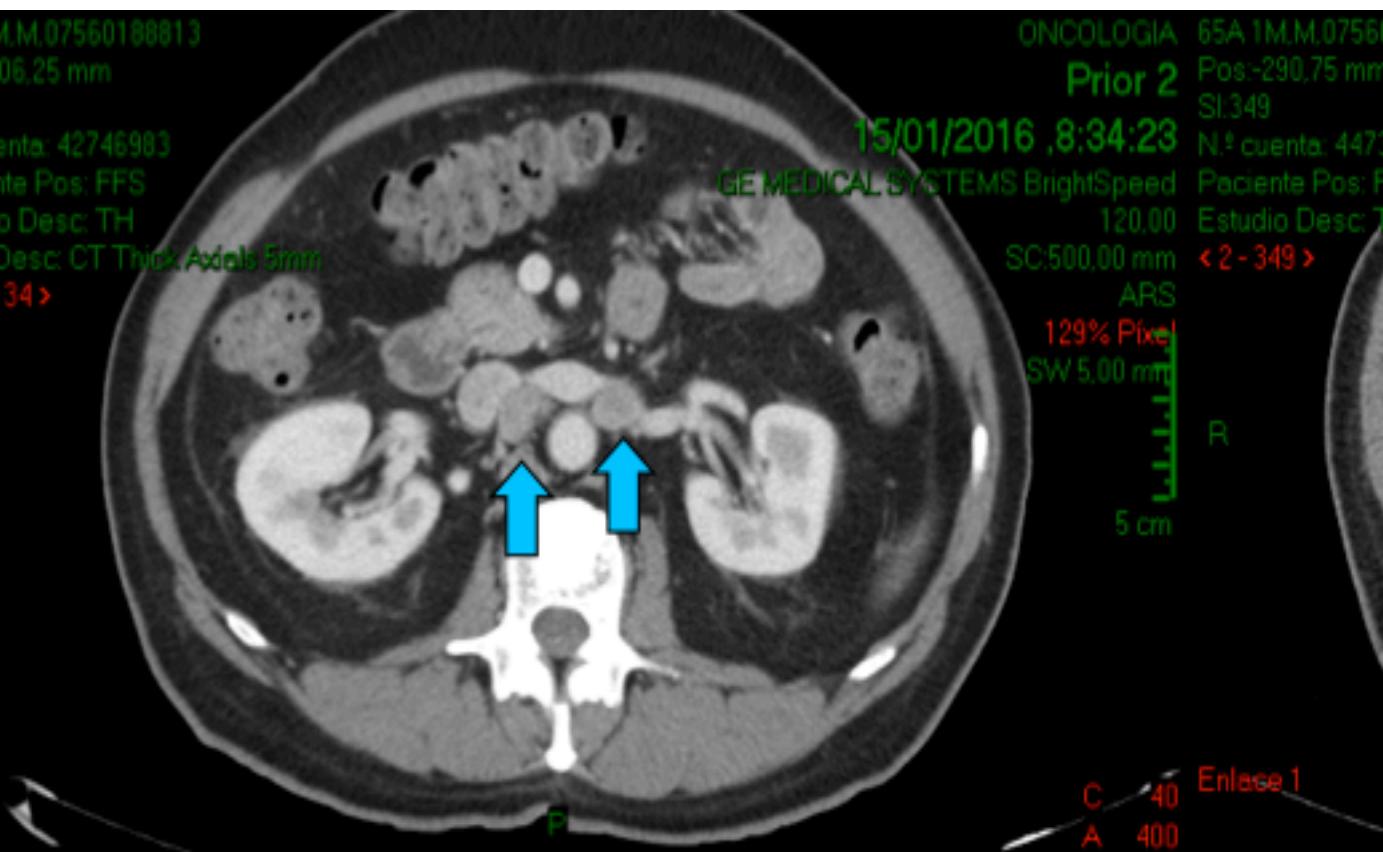
Tasa Respuesta 13.7%

Figure 3. OS Kaplan–Meier estimates according to response



CASO 1. Adenocarcinoma de Pulmón en tratamiento con Nivolumab

64A 6M.M.07560188813
Pos.-306,25 mm
SI:34
N.^o cuenta: 42746983
Paciente Pos: FFS
Estudio Desc: TH
Serie Desc: CT Thick Axials 5mm
<601-34>



ONCOLOGIA 65A 1M.M.07560188813

Prior 2

15/01/2016 ,8:34:23

GE MEDICAL SYSTEMS BrightSpeed

120.00

SC:500.00 mm

ARS

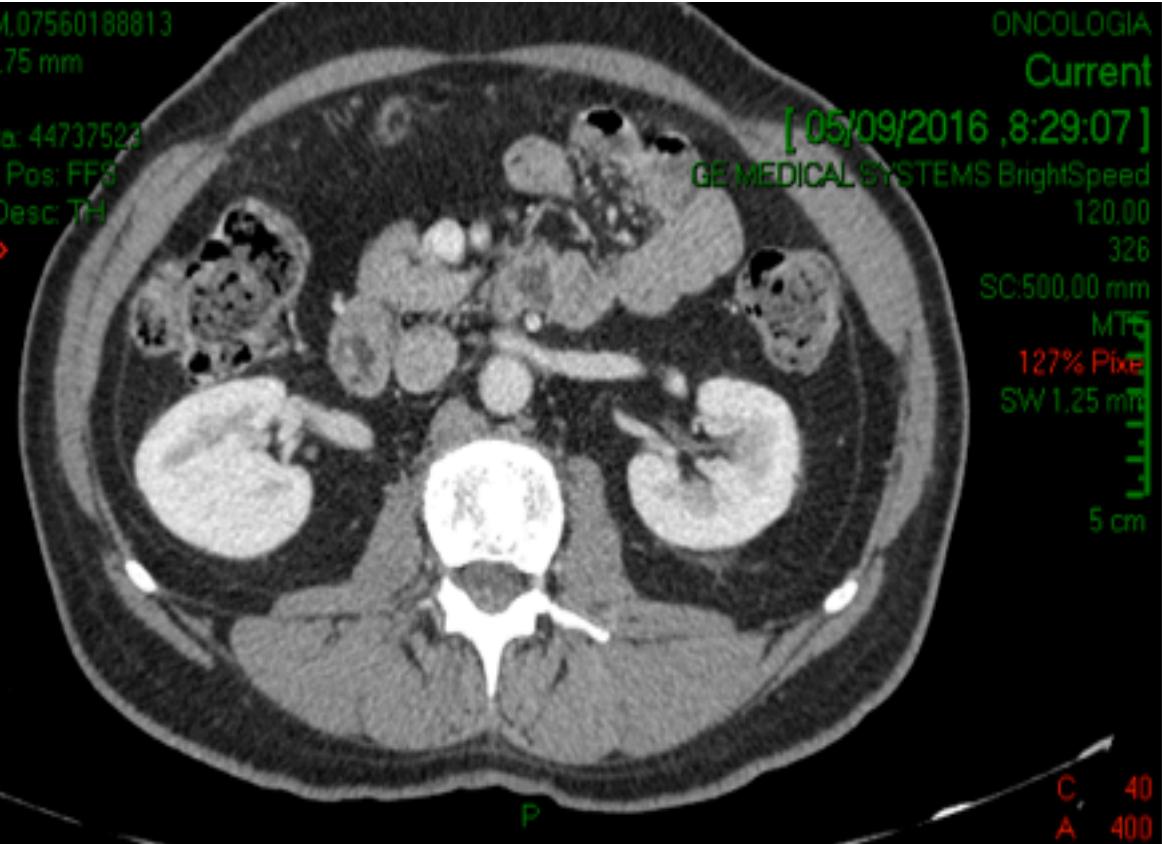
129% Pixel

SW 5.00 mm

R

5 cm

C 40
A 400
Enlace 1



ONCOLOGIA

Current

[05/09/2016 ,8:29:07]

GE MEDICAL SYSTEMS BrightSpeed

120.00

326

SC:500.00 mm

MTF

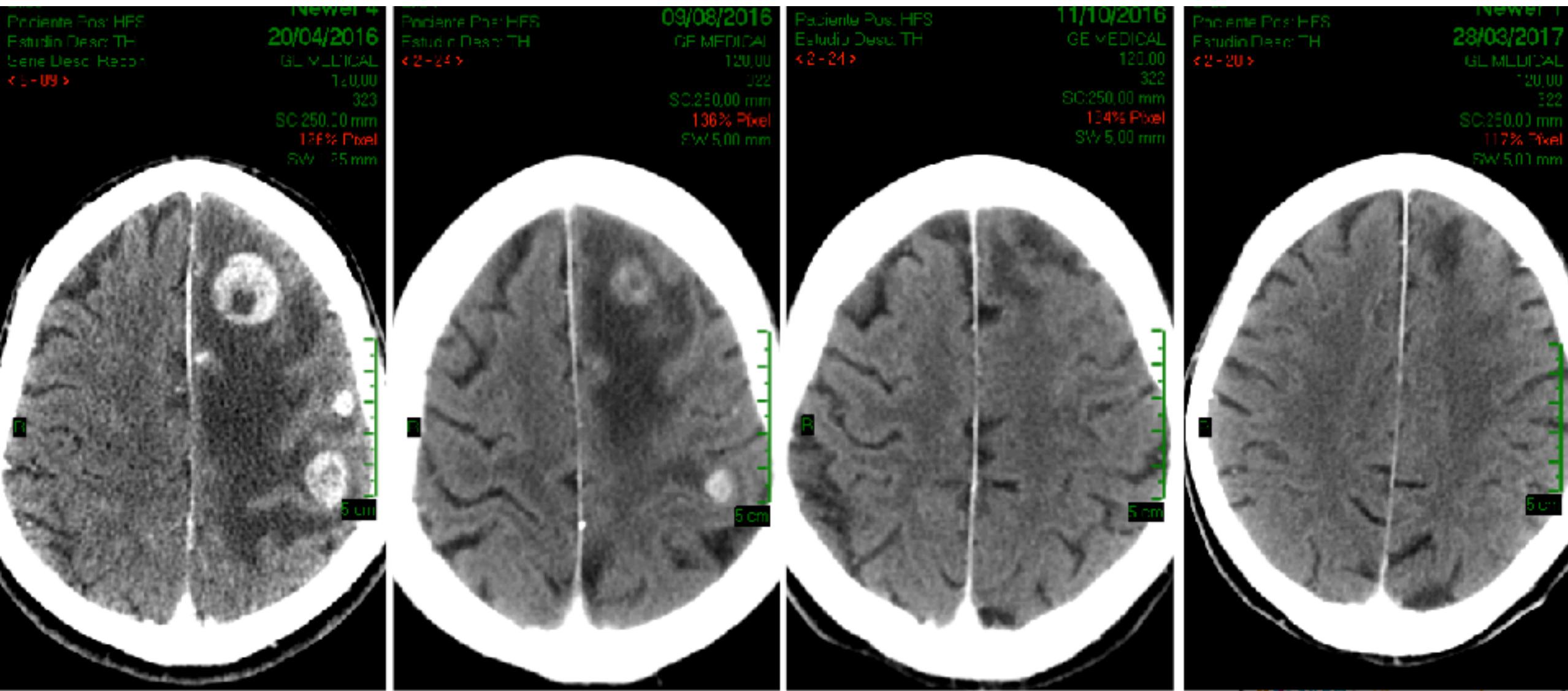
127% Pixel

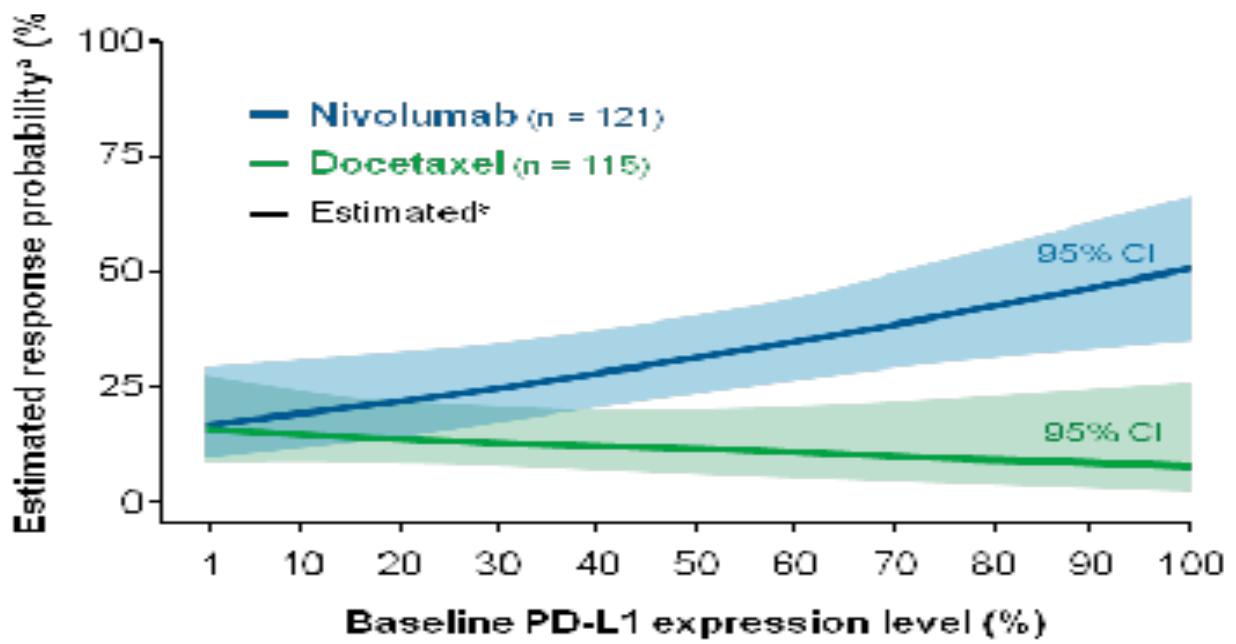
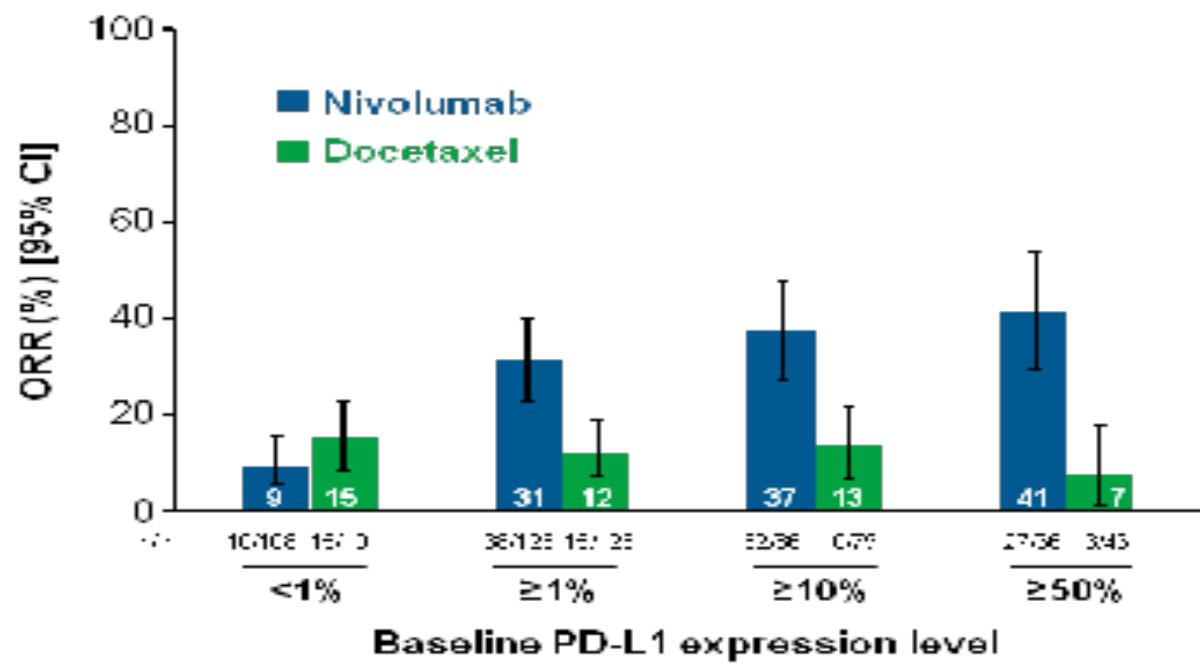
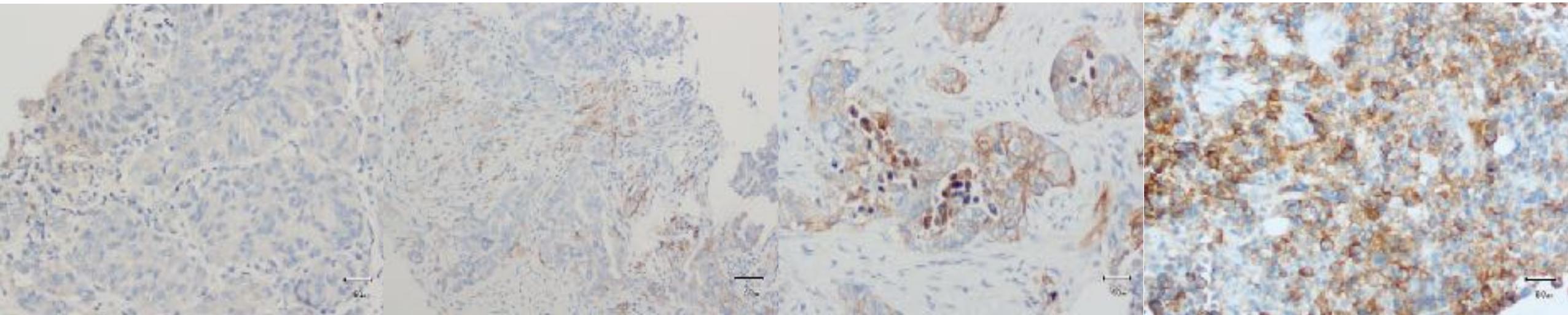
SW 1.25 mm

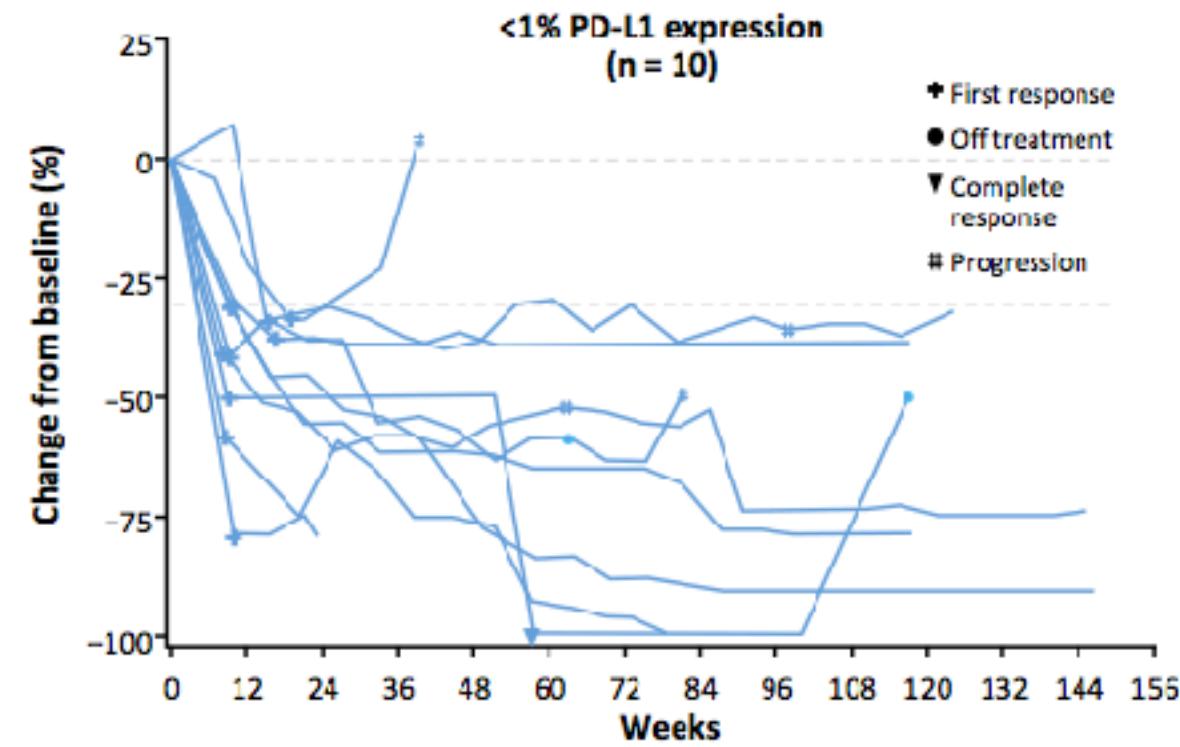
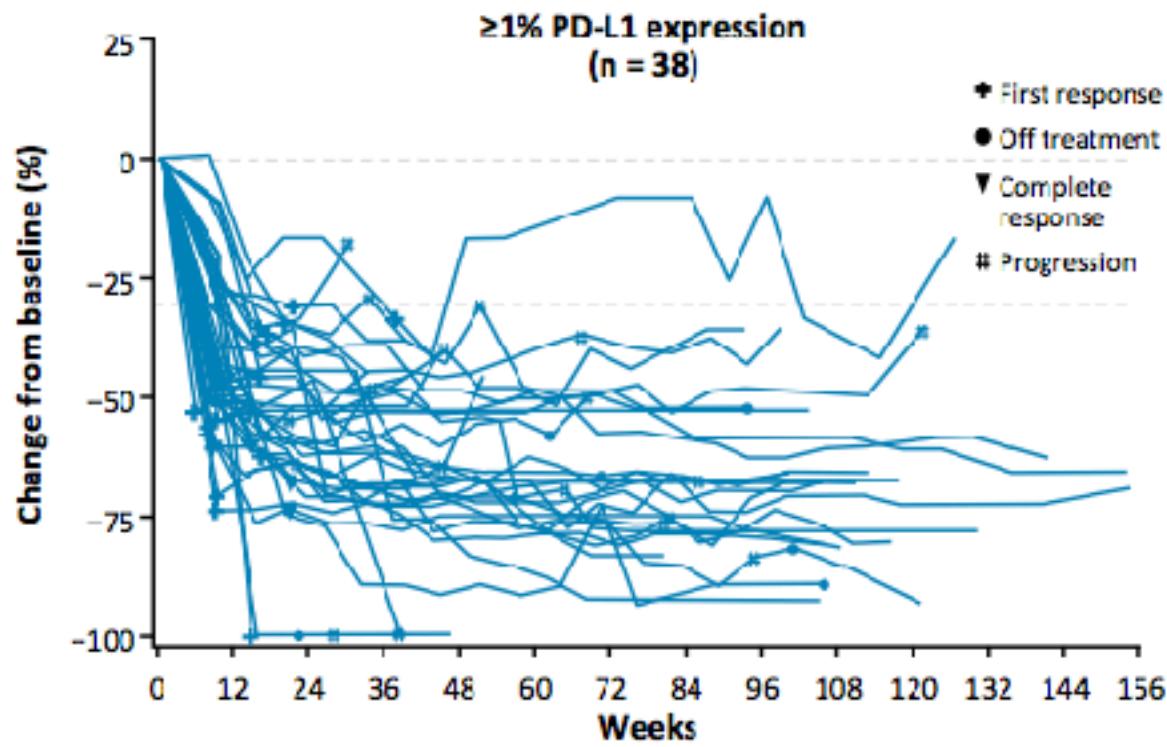
5 cm

C 40
A 400

CASO 2. Adenocarcinoma de Pulmón con Metástasis Cerebrales en tratamiento con Nivolumab





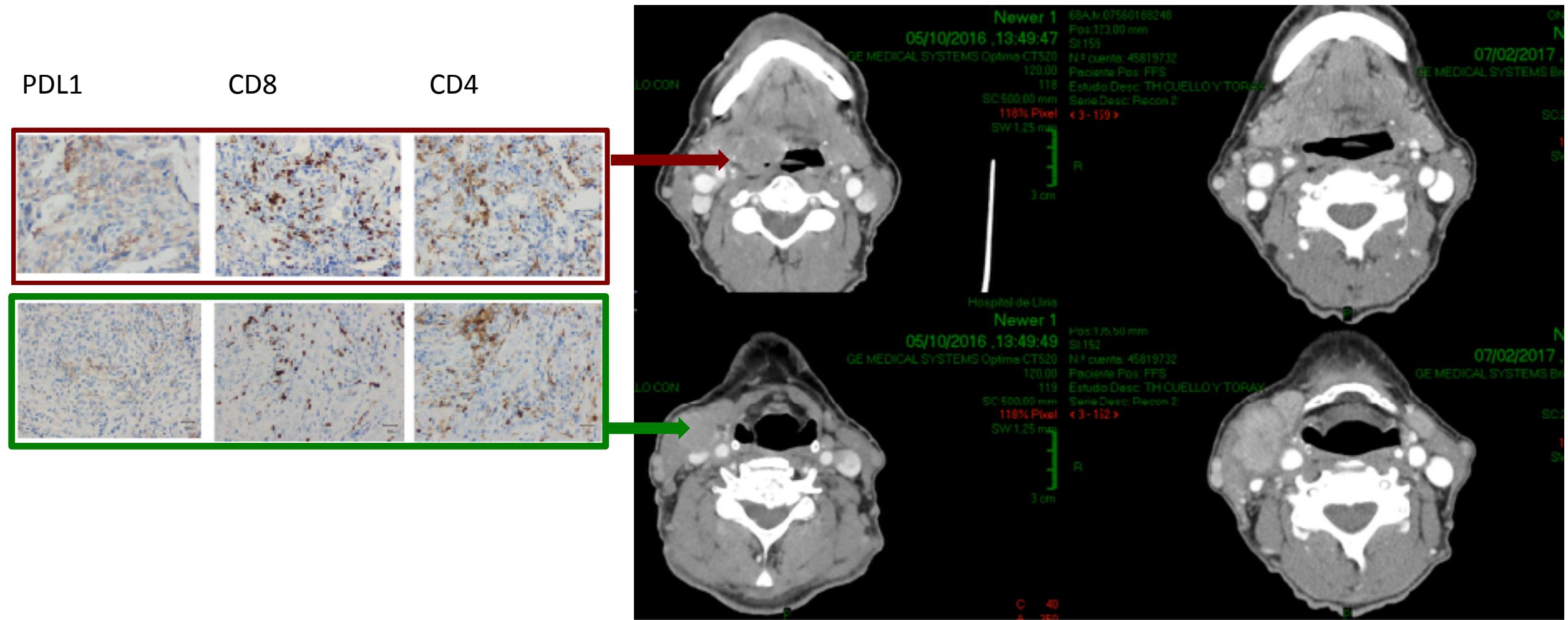


No hubo diferencia en la calidad de la respuesta en función de la expresión de PD-L1

Mediana de duración de la respuesta en $\text{PD-L1} \geq 1\%$: 17.2 m (95% CI, 8.4-NE)

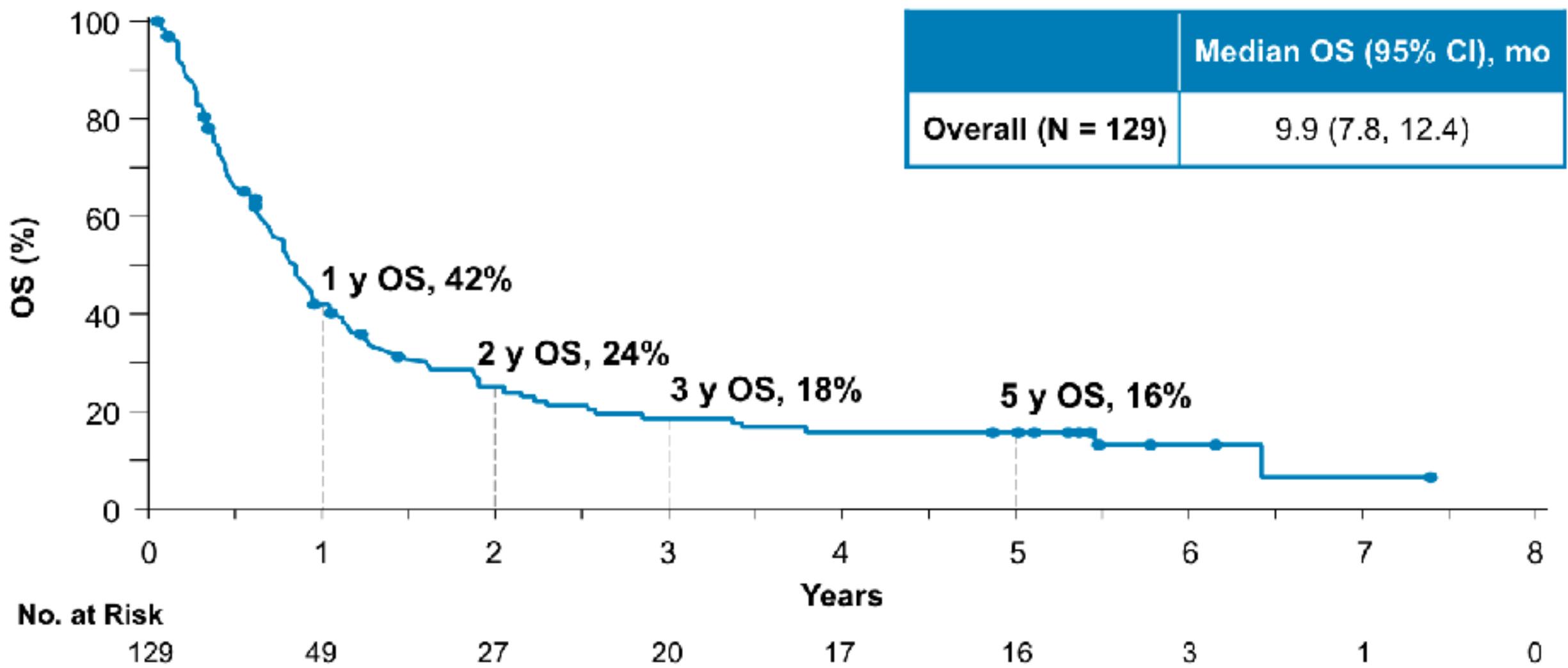
Mediana de duración de la respuesta en $\text{PD-L1} < 1\%$: 18.3 m (95% CI, 5.5-NE)

CASO 4. Adenocarcinoma de Pulmón con Metástasis en Lengua y Ganglionar cerviccal en tratamiento con Nivolumab



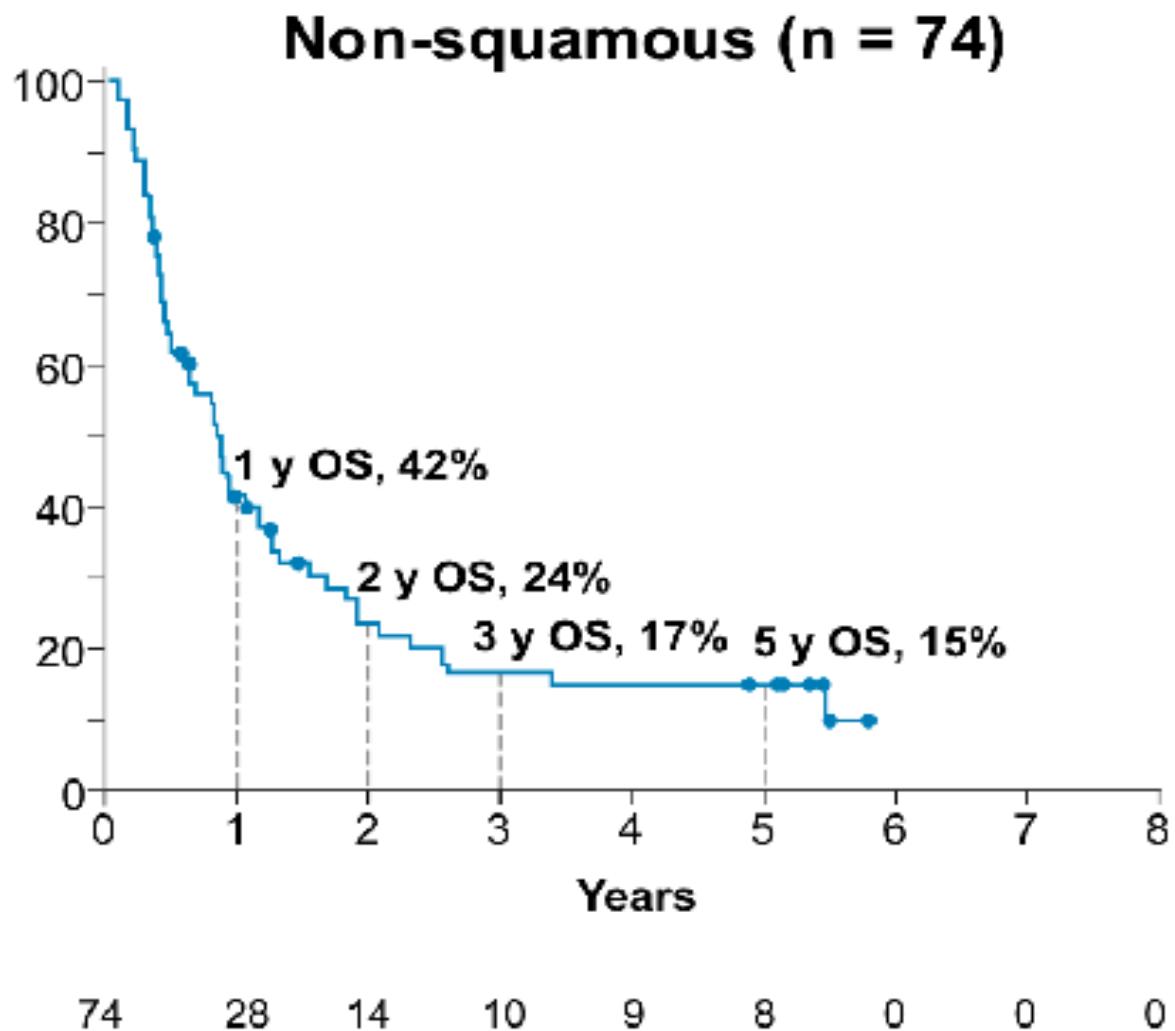
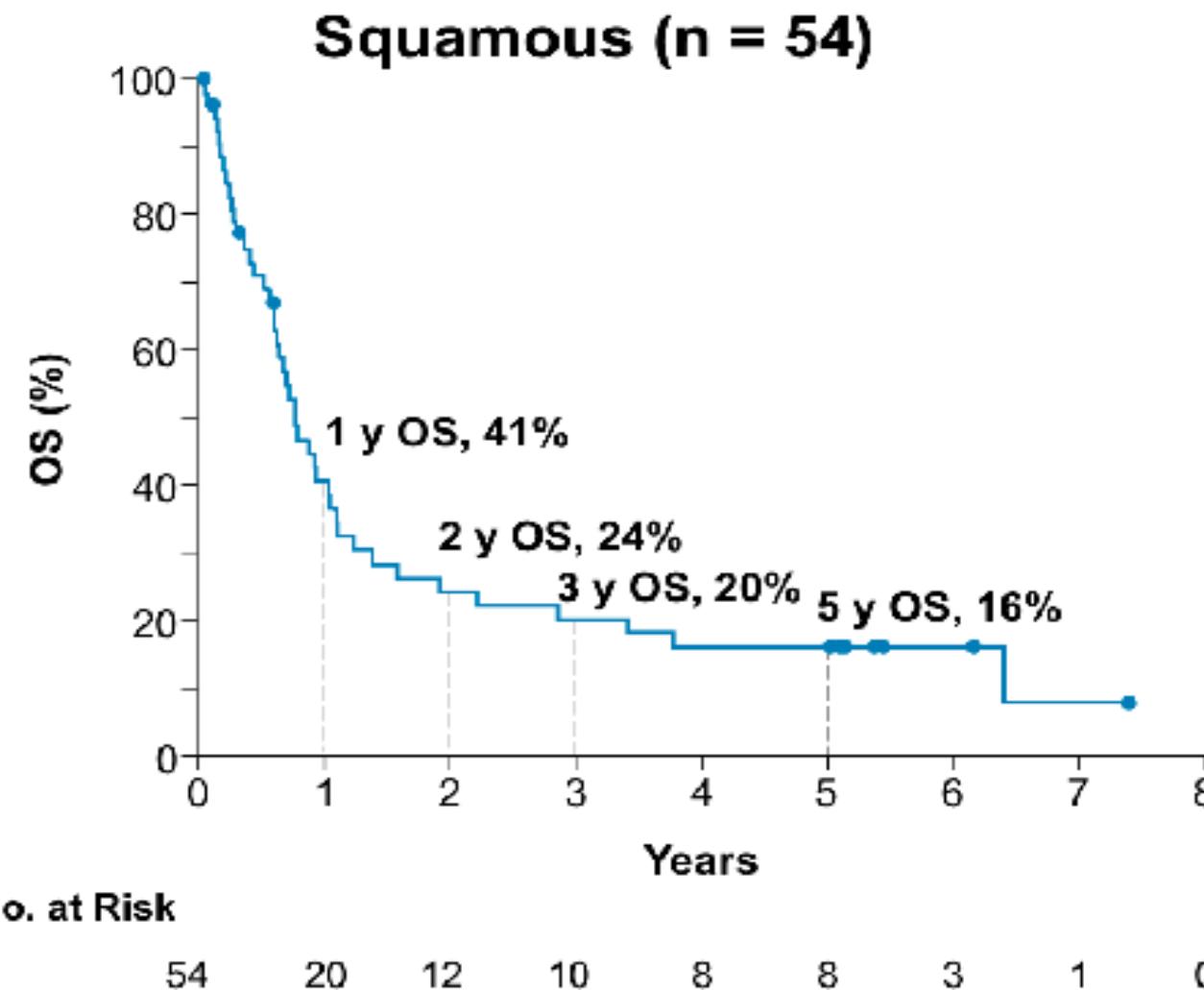
5-Year Estimates of OS^a

CA209-003 5-Year Update: Phase 1 Nivolumab in Advanced NSCLC



5-Year Estimates of OS by Histology

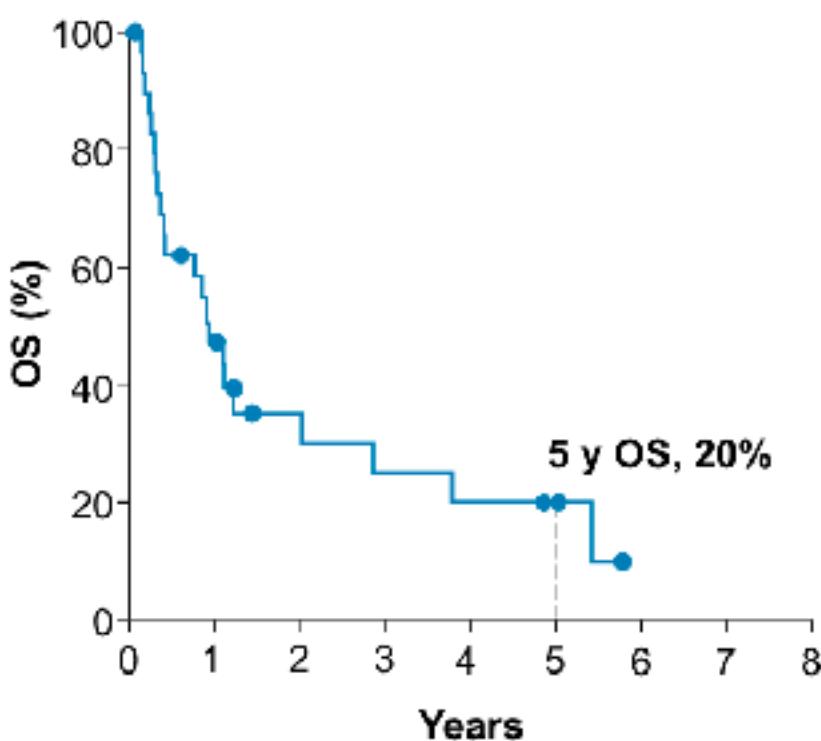
CA209-003 5-Year Update: Phase 1 Nivolumab in Advanced NSCLC



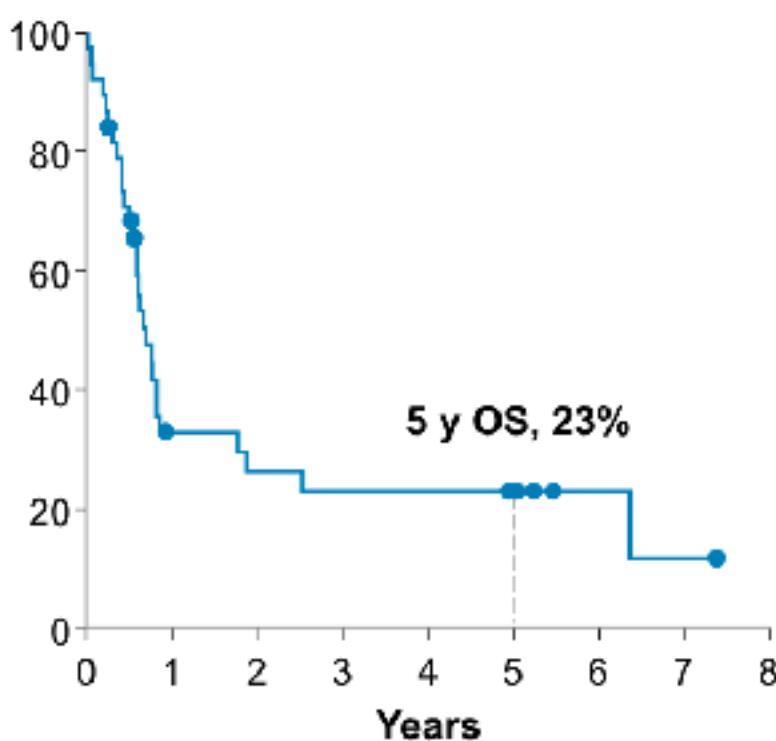
5-Year Estimates of OS by PD-L1 Status^a

CA209-003 5-Year Update: Phase 1 Nivolumab in Advanced NSCLC

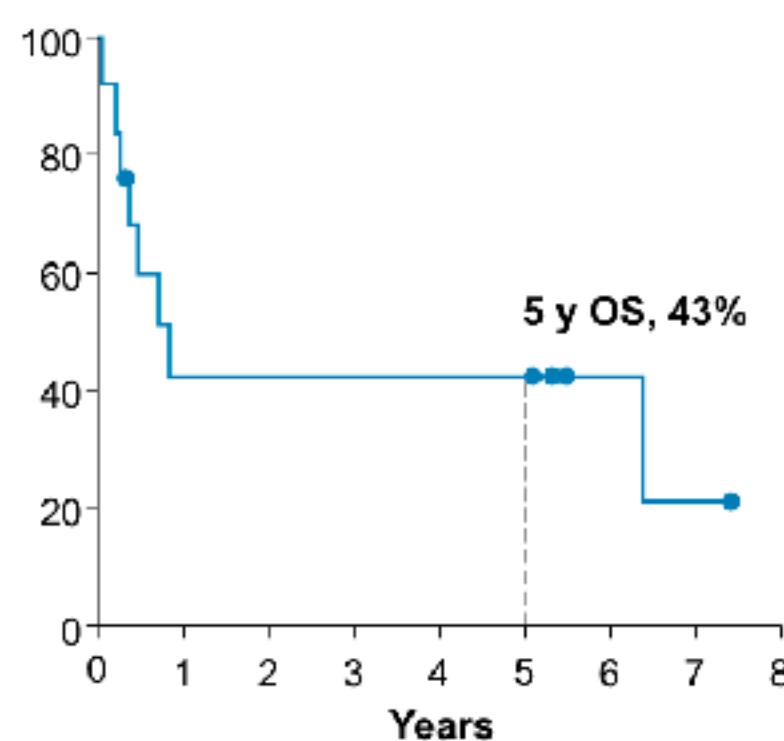
PD-L1 <1% (n = 30)



PD-L1 ≥1% (n = 38)



PD-L1 ≥50% (n = 13)



No. at Risk

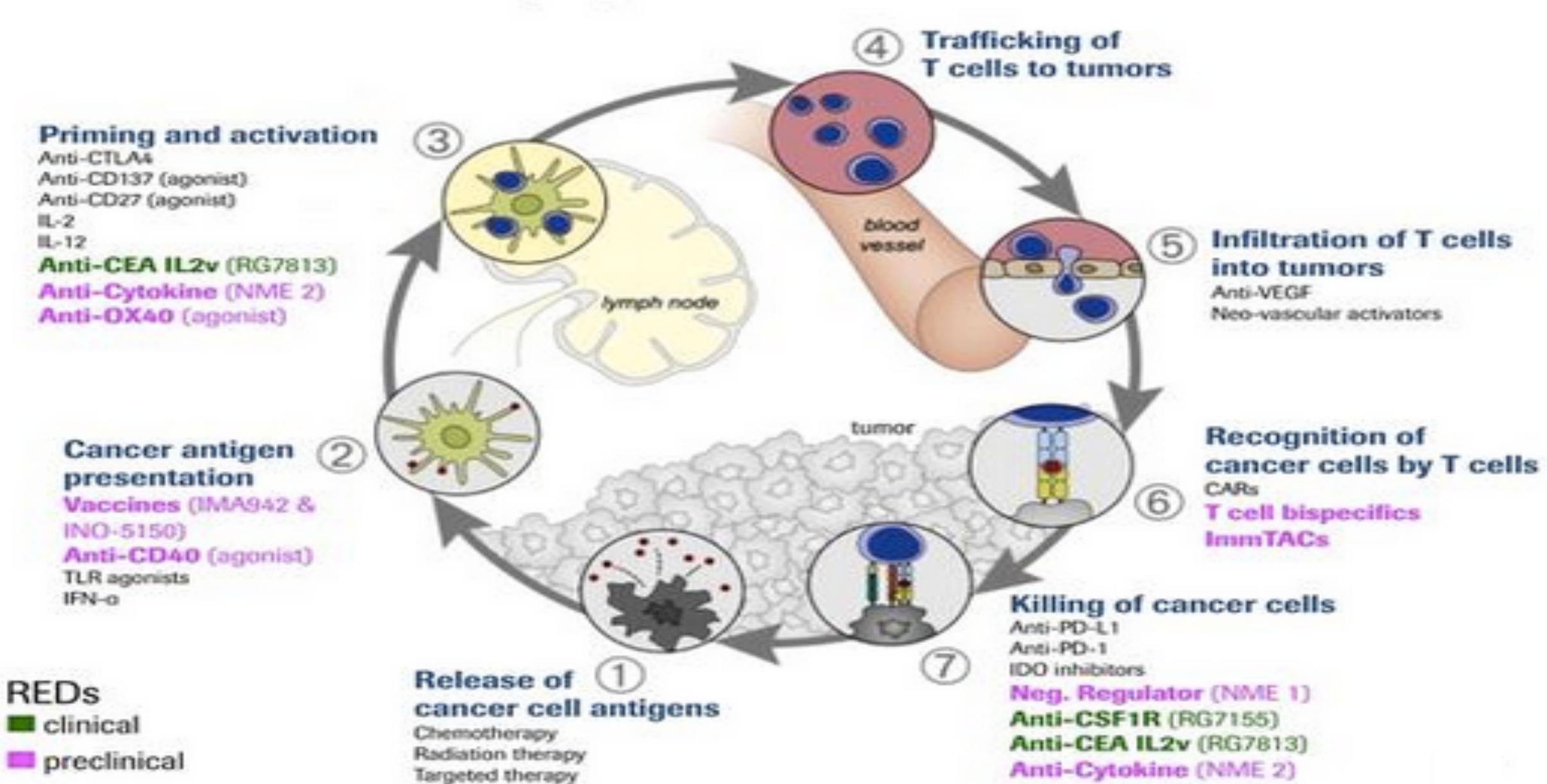
30 13 7 5 4 3 0 0 0

38 10 8 7 7 2 1 0 0

13 5 5 5 2 1 0 0 0

HACIA DONDE VAMOS...

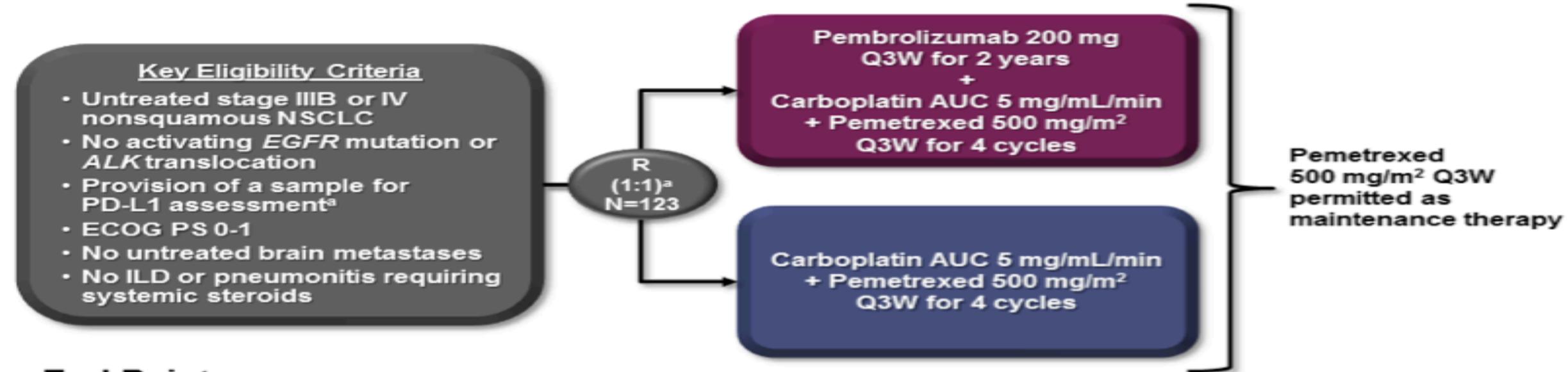




Randomized Phase 2 Study of Carboplatin and Pemetrexed \pm Pembrolizumab as First-Line Therapy for Advanced NSCLC:

CJ Langer. ESMO 2016.

KEYNOTE-021 Cohort G



End Points

Primary: ORR (RECIST v1.1 per blinded, independent central review)

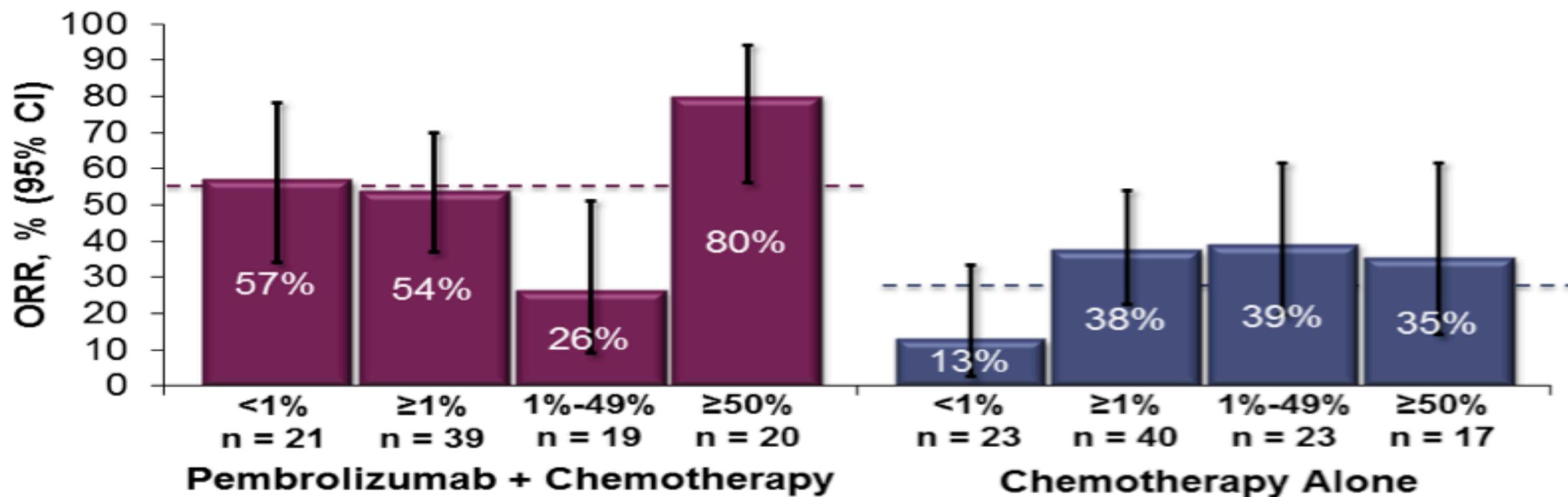
Key secondary: PFS

Other secondary: OS, safety, relationship between antitumor activity and PD-L1 TPS

Confirmed Objective Response Rate (RECIST v1.1 by Blinded, Independent Central Review)

CJ Langer. ESMO 2016.

Objective Response Rate by PD-L1 Status (RECIST v1.1 by Blinded, Independent Central Review)



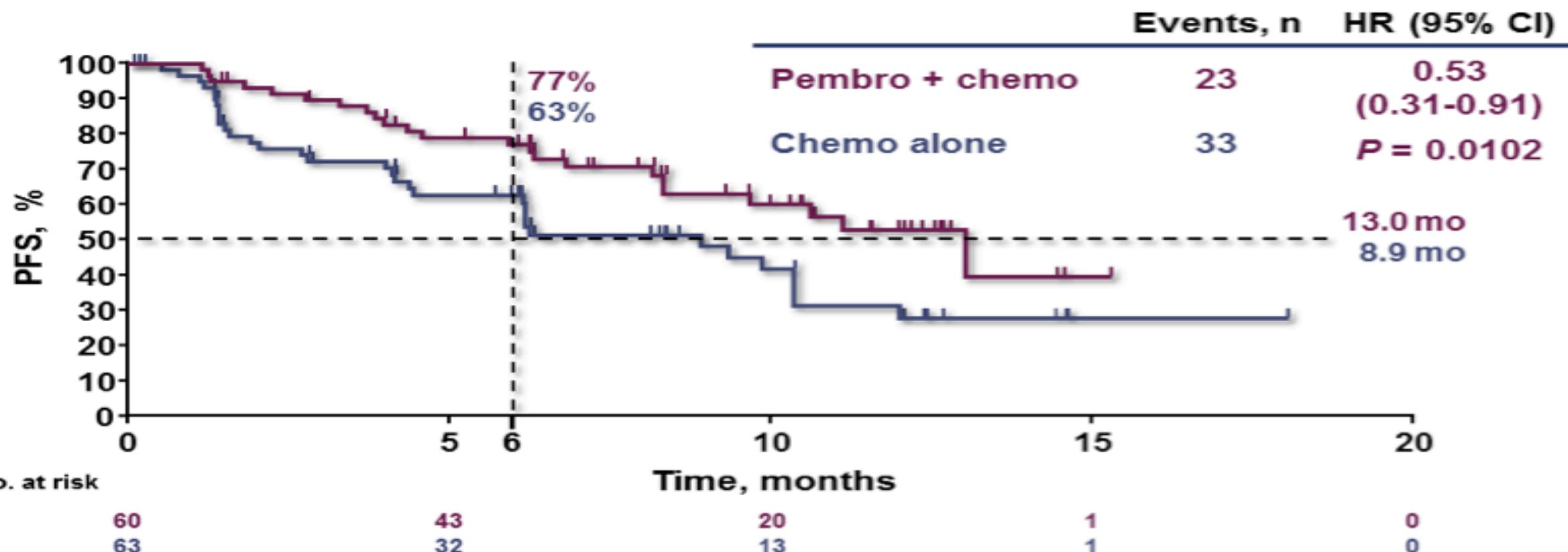
Horizontal dotted lines represent the ORR in the total population.

Data cut-off: August 8, 2016.

COPENHAGEN
2016 congress

Progression-Free Survival

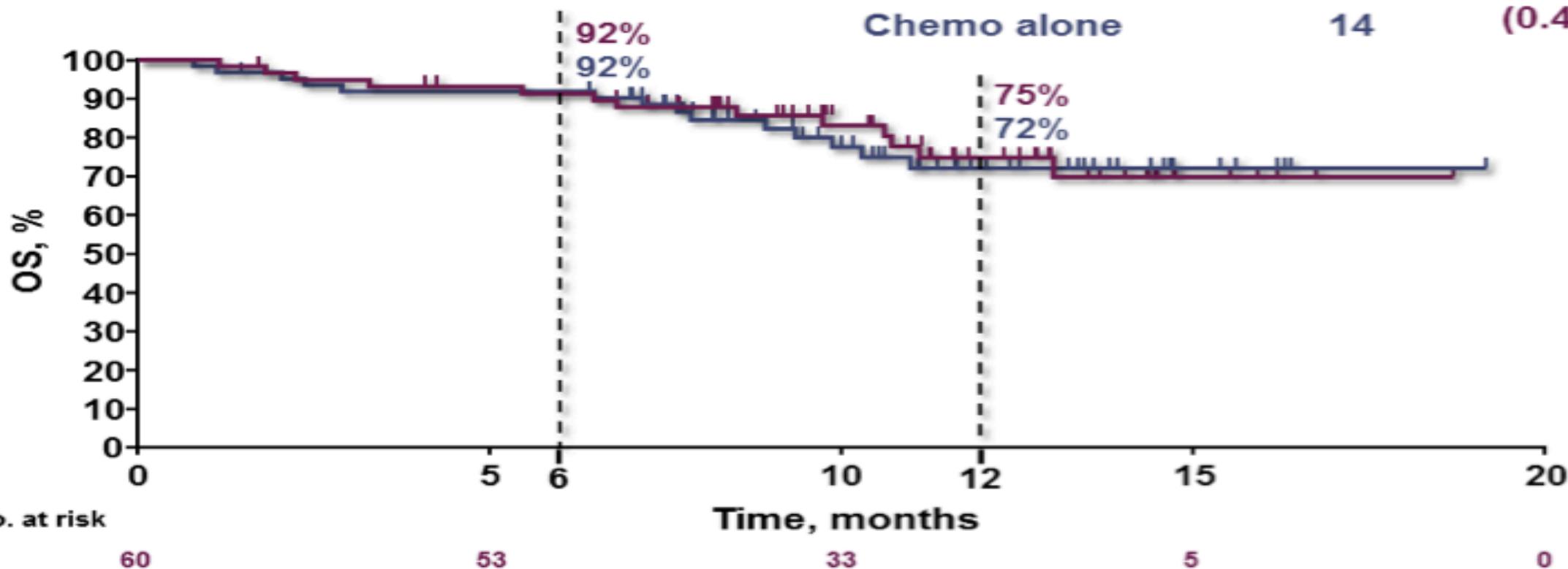
(RECIST v1.1 by Blinded, Independent Central Review)



Data cut-off: August 8, 2016.

COPENHAGEN
2016 ESMO congress

Overall Survival



No. at risk

60

63

53

57

33

31

5

6

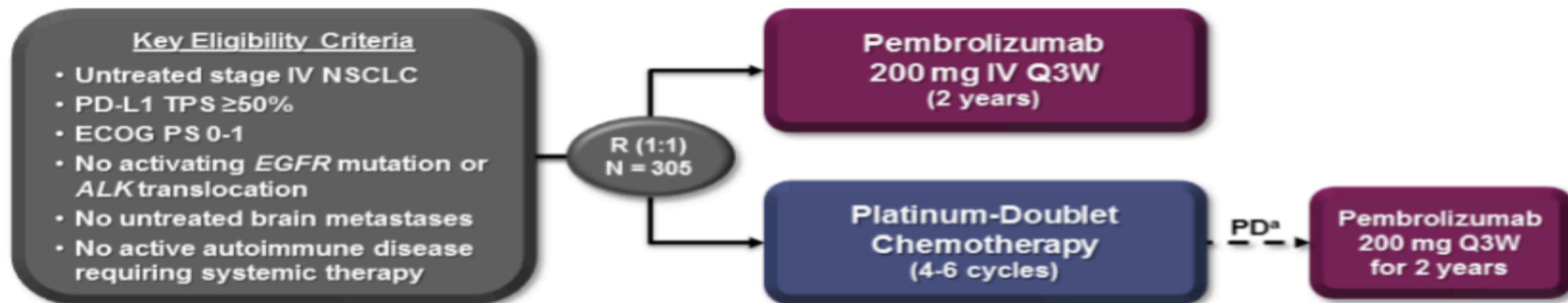
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0

Data cut-off: August 8, 2016.

COPENHAGEN
2016 ESMO congress

KEYNOTE-024 Study Design (NCT02142738)



Key End Points

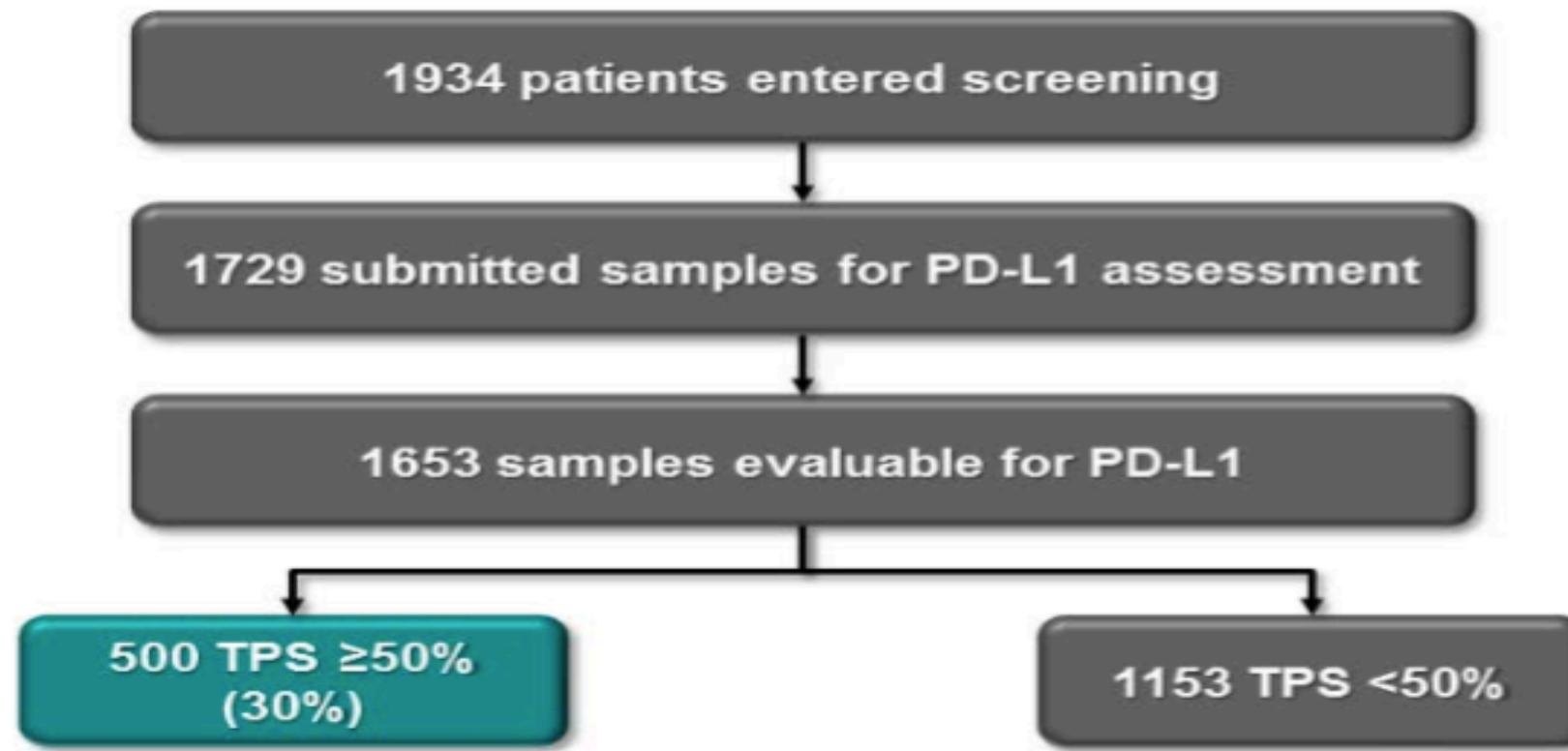
Primary: PFS (RECIST v1.1 per blinded, independent central review)

Secondary: OS, ORR, safety

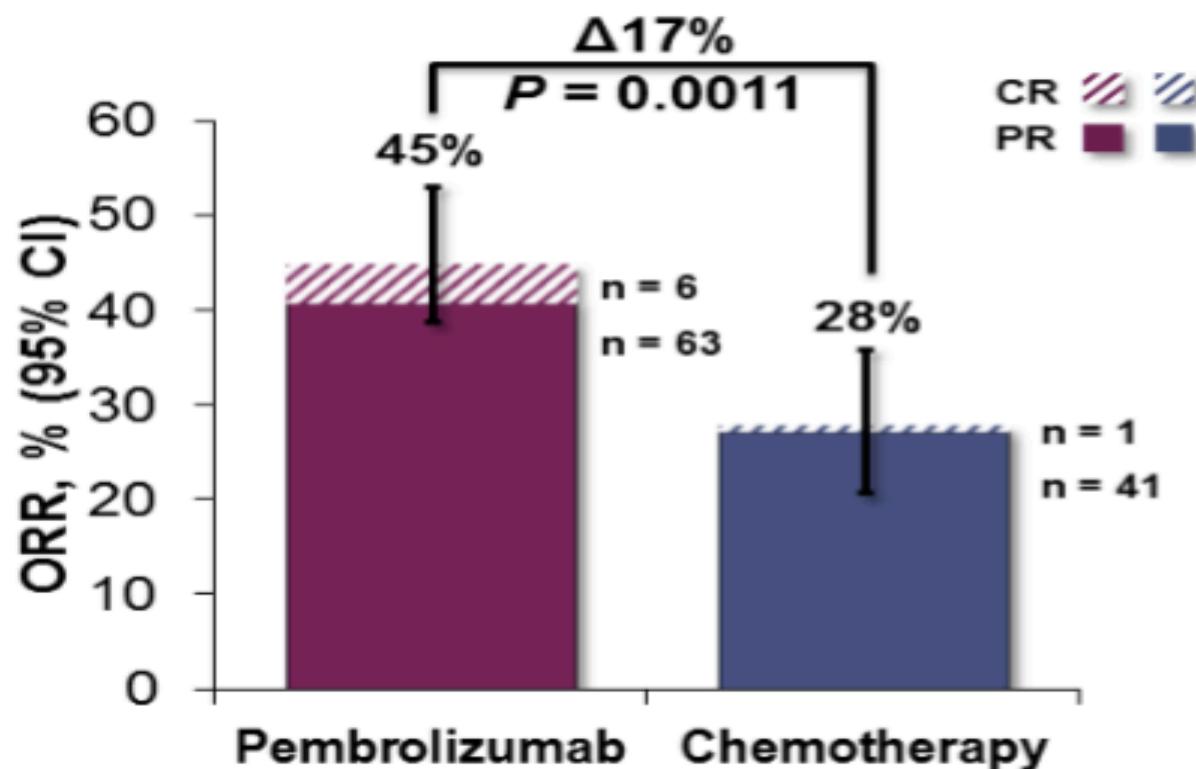
Exploratory: DOR

^aTo be eligible for crossover, progressive disease (PD) had to be confirmed by blinded, independent central radiology review and all safety criteria had to be met.

PD-L1 Screening



Confirmed Objective Response Rate

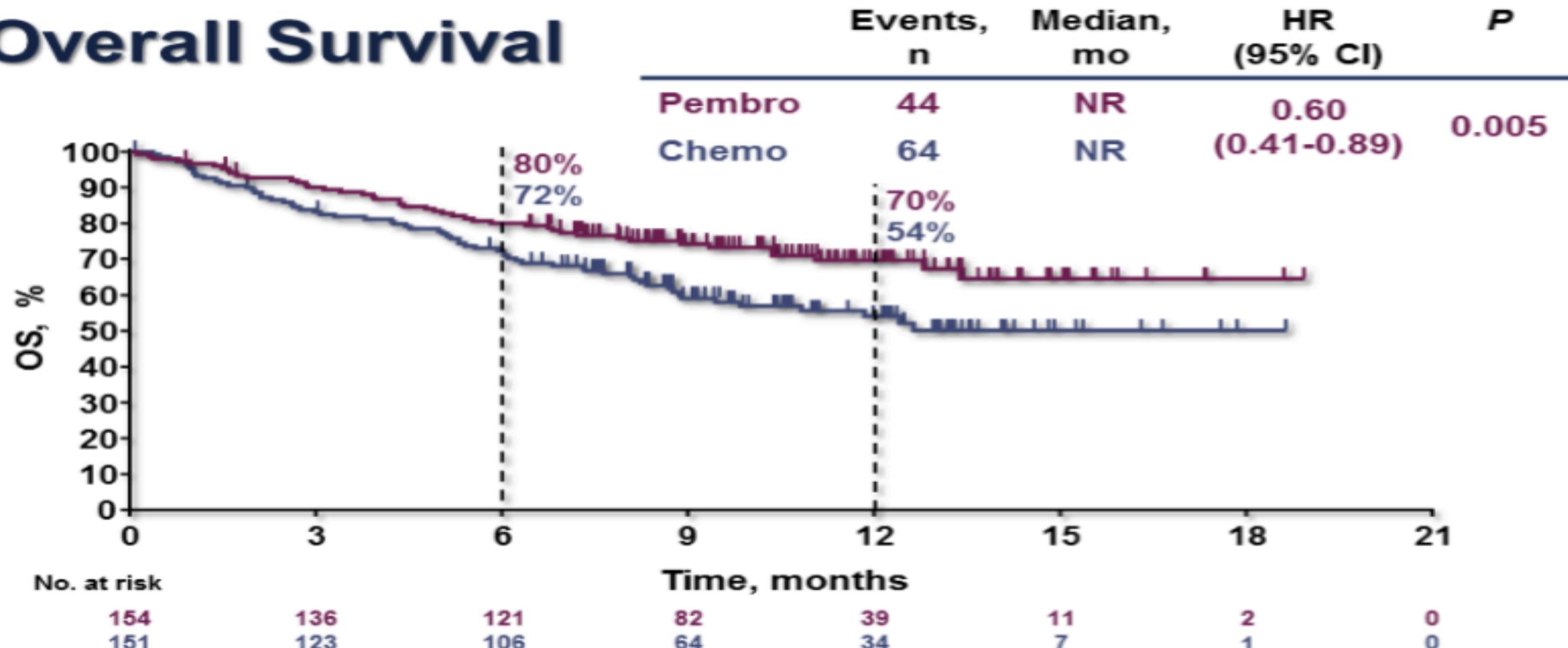


	Pembro Responders n = 69	Chemo Responders n = 42
TTR, mo median (range)	2.2 (1.4-8.2)	2.2 (1.8-12.2)
DOR, mo median (range)	NR (1.9+ to 14.5+)	6.3 (2.1+ to 12.6+)

Assessed per RECIST v1.1 by blinded, independent central review.
Data cut-off: May 9, 2016.

ESMO congress
2016

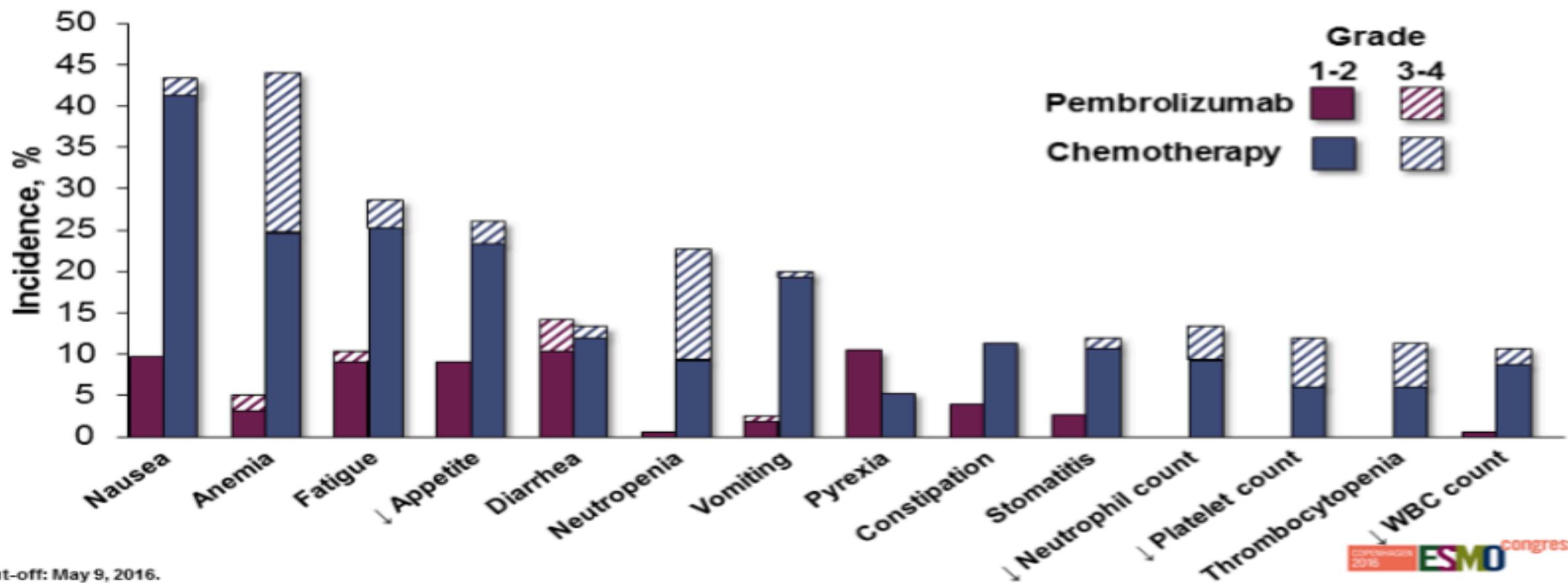
Overall Survival



Data cut-off: May 9, 2016.

ESMO congress
ESMO congress
ESMO congress

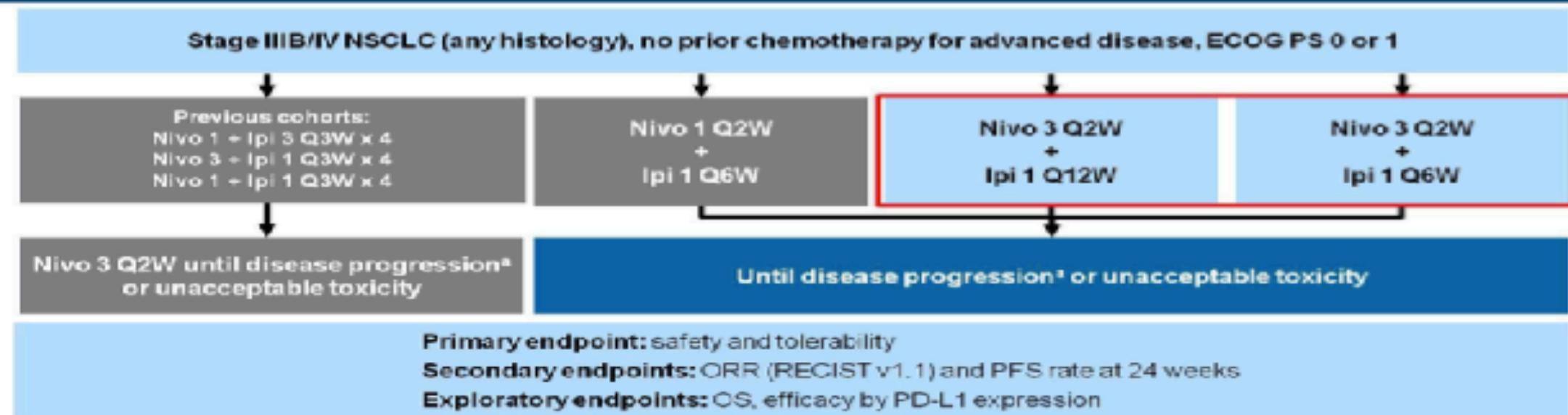
Treatment-Related AEs With Incidence >10%



Data cut-off: May 9, 2016.

ESMO congress
Milano 2016

Phase 1 CheckMate 012 Study Design: Nivolumab Plus Ipilimumab in First-line NSCLC



- The safety and tolerability of the nivolumab-ipilimumab combination was improved with less frequent ipilimumab dosing^a
- Schedules with nivolumab 3 mg/kg also showed increased clinical efficacy in a previous analysis^b
- Here, we report longer follow-up on nivolumab 3 mg/kg plus ipilimumab schedules^b

*Patients tolerating study treatment permitted to continue treatment beyond RECIST v1.1-defined progression if considered to be deriving clinical benefit

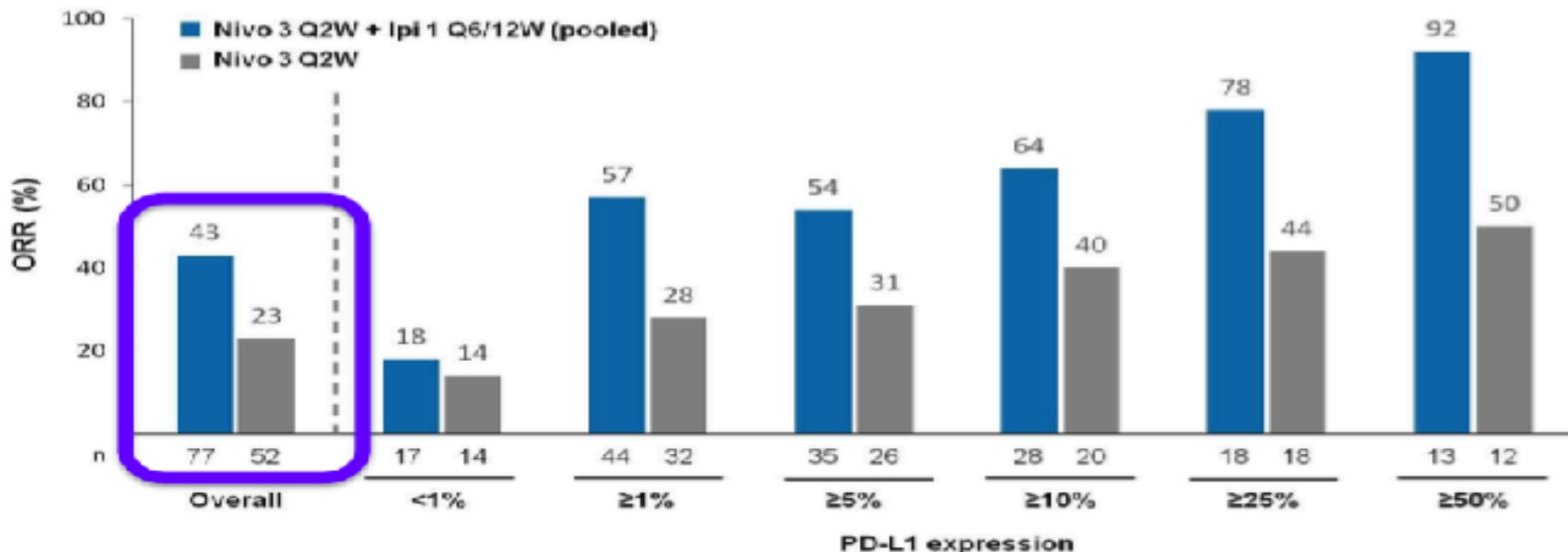
^aFebruary 2016 database lock

^bIpilimumab and nivolumab dosing are shown in mg/kg IV (eg, nivo 1 = nivolumab 1 mg/kg IV)

4

Presented By Matthew Hellmann et 2016 ASCO Annual Meeting

Nivolumab Plus Ipilimumab in First-line NSCLC: Efficacy Across All Tumor PD-L1 Expression Levels



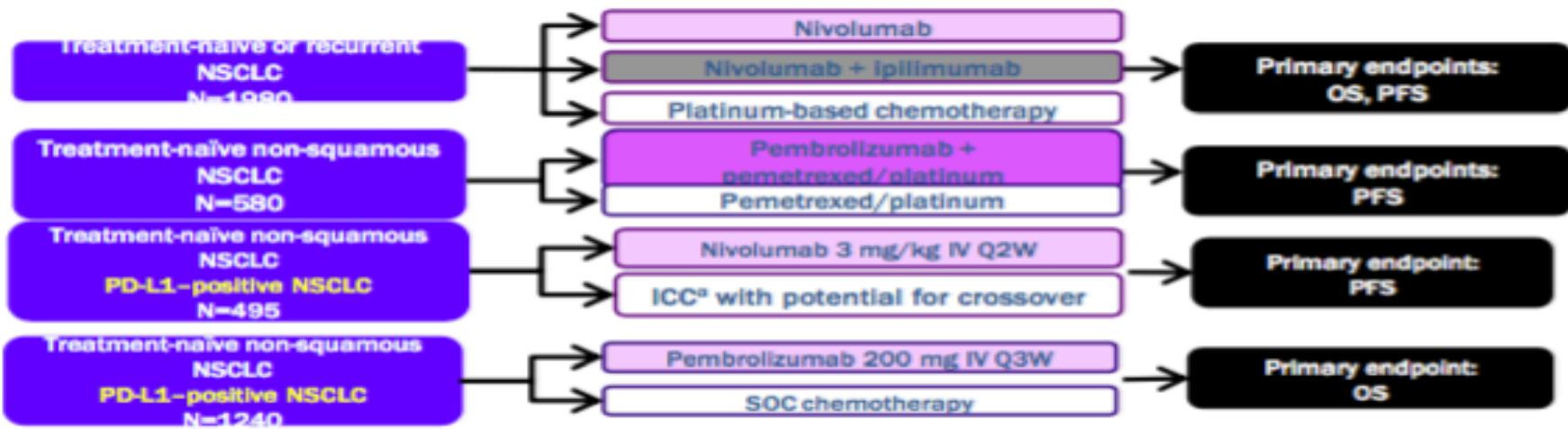
Combination data based on a February 2016 database lock; monotherapy data based on a March 2015 database lock.

11

Presented By Matthew Hellmann at 2016 ASCO Annual Meeting

Anti-PD-1/PD-L1

Nivolumab
CHECKMATE 227



Pembrolizumab
KEYNOTE-189

Nivolumab
CHECKMATE 026

Pembrolizumab
KEYNOTE-042

Durvalumab
MYSTIC

Durvalumab
NEPTUNE

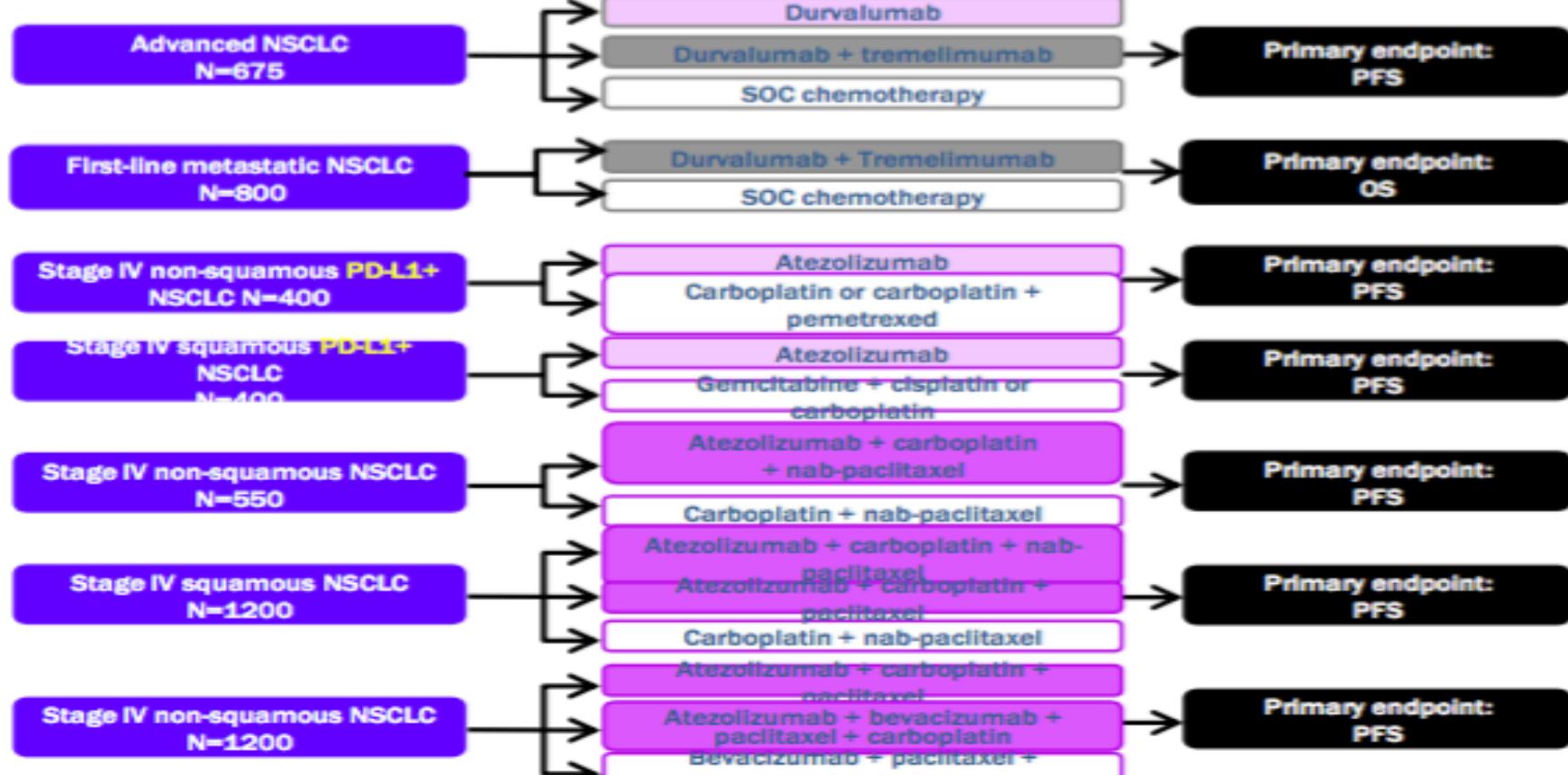
Atezolizumab
Impower 110

Atezolizumab
Impower 111

Atezolizumab
Impower 130

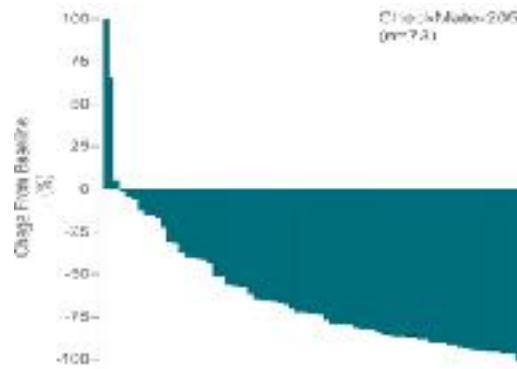
Atezolizumab
Impower 131

Atezolizumab
Impower 150

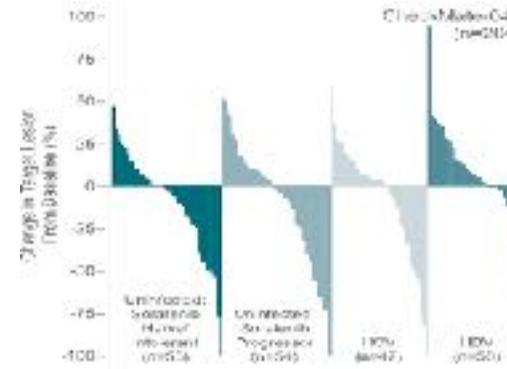


Próximas indicaciones de Anti-PDL1/Anti-PD1

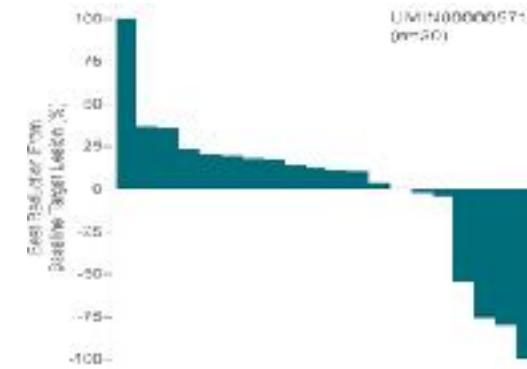
Hodgkin Lymphoma¹



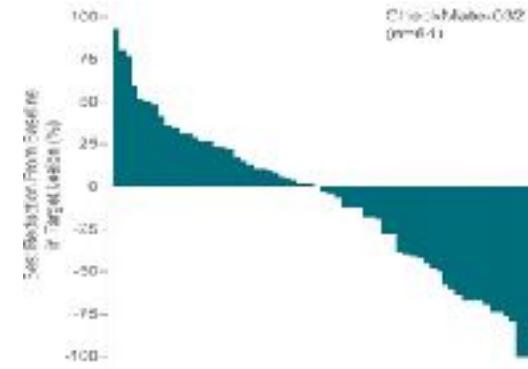
Hepatocellular Carcinoma²



Ovarian Cancer³

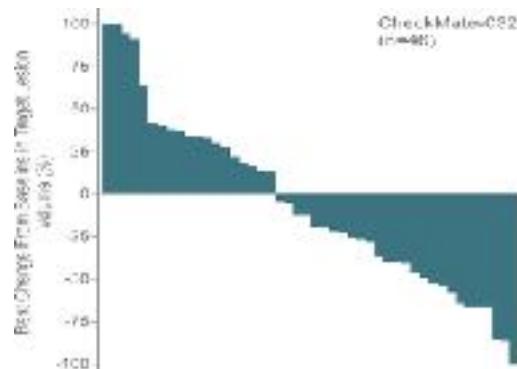


Urothelial Cancer⁴



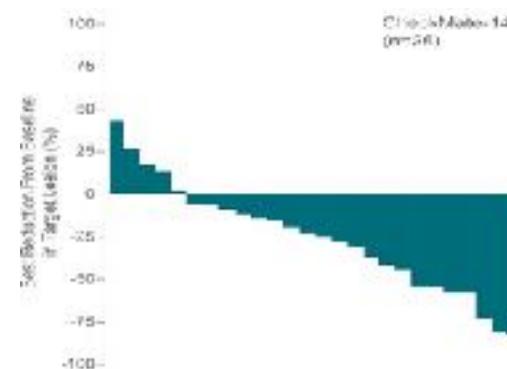
Small Cell Lung Cancer⁵

(Nivolumab 1 mg/kg BW + Ipilimumab 3 mg/kg BW)



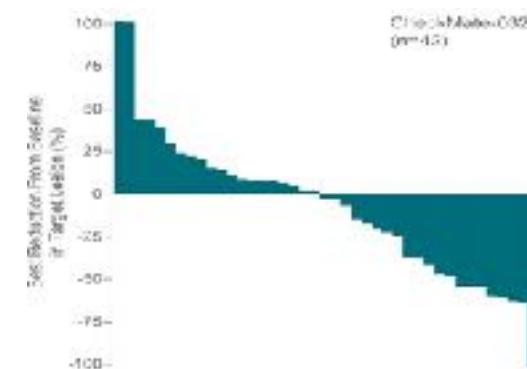
Colorectal Cancer – MSI-H⁶

(Nivolumab 3 mg/kg BW + Ipilimumab 1 mg/kg BW)

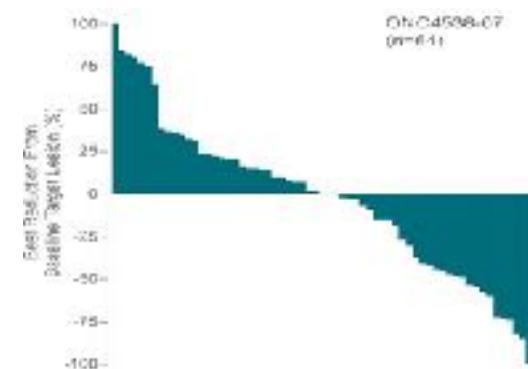


Gastric Cancer⁷

(Nivolumab 1 mg/kg BW + Ipilimumab 3 mg/kg BW)



Esophageal Cancer⁸



MUCHAS GRACIAS