Lung Cancer UPDATES
IASLC HIGHLIGTHS
06-09 AGOSTO 2022
Viena, Austria

Iniciativa científica de:
GECP
lung cancer research

ESTADIOS INICIALES

Manuel Dómine

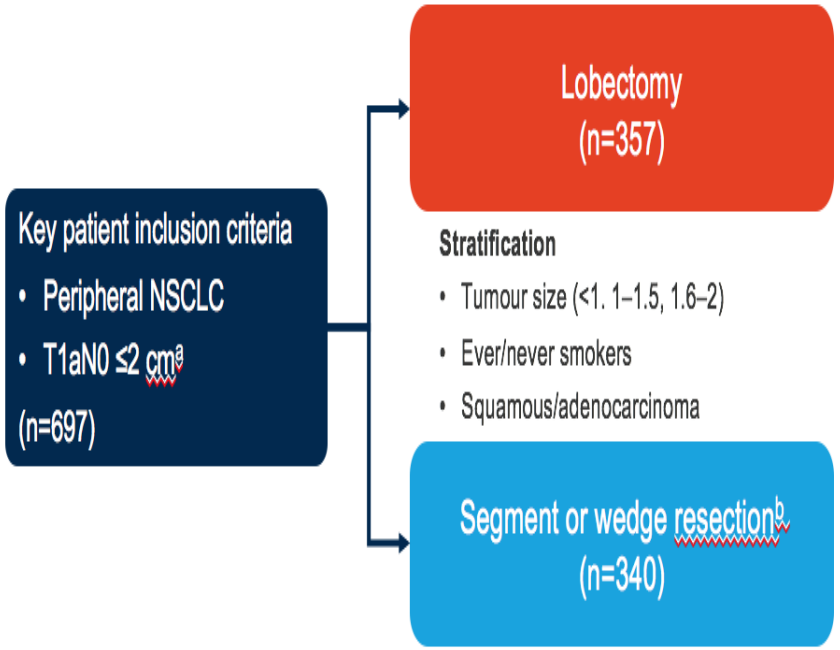
Jefe Asociado Oncología

Fundación Jiménez Díaz IIS-FJD

PL03.06: Lobar or Sub-lobar Resection for Peripheral Clinical Stage IA ≦ 2 cm Non-small Cell Lung Cancer (NSCLC): Results From an International Randomized Phase III Trial (CALGB 140503 [Alliance]) – Altorki NK, et al

- Lobar resection has been the surgical standard of care for cT1N0 NSCLC since 1995.
- Recently JCOG 0802 investigators reported that in fit patients with cT1aN0 NSCLC ≤ 2 cms segmentectomy was not inferior to lobectomy for the primary endpoint of OS.
- ALGB 140503 [Alliance] is a randomized international trial comparing lobar and SLR in patients with clinical cT1aN0 NSCLC ≤ 2 cms.
- (*Ginsberg RJ, Ann.Thorac. Surg. 1995, Saji H; Lancet 2022)*

- **Study objective**
  - To evaluate the efficacy of lobar or sub-lobar resection in patients with peripheral clinical stage IA ≤2 cm NSCLC in the CALGB 140503 study

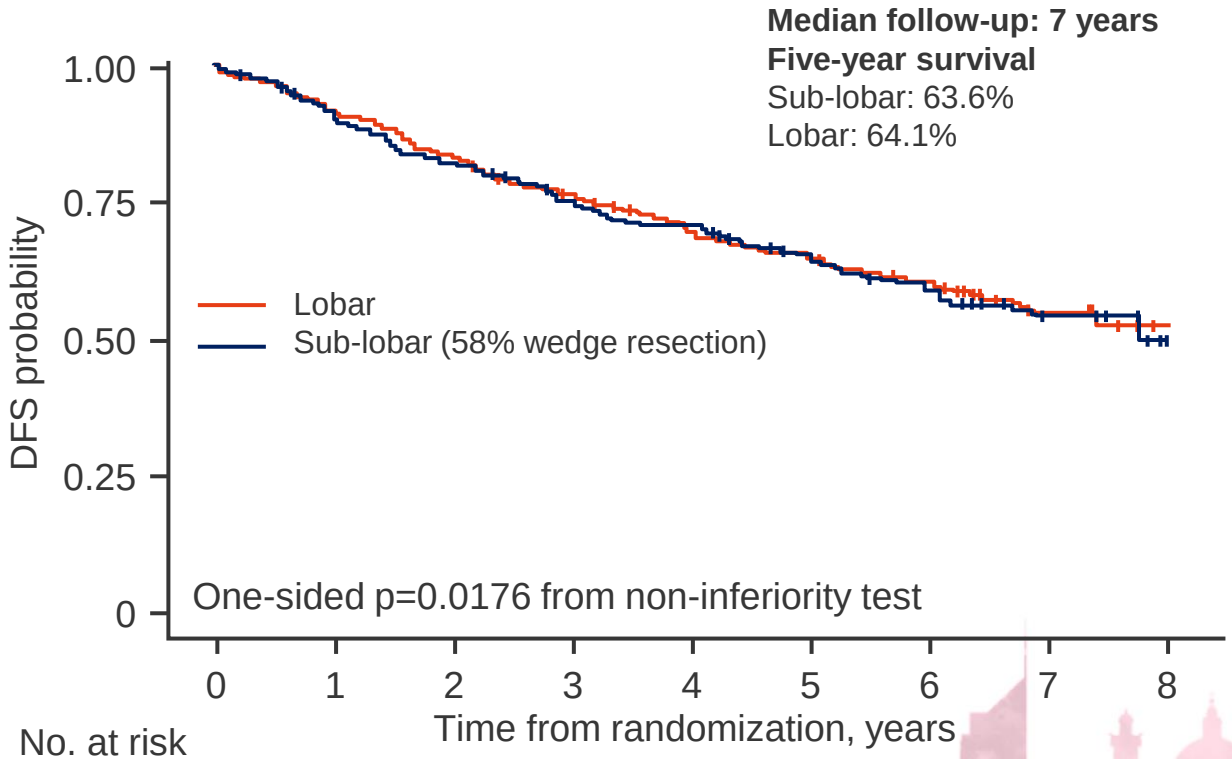


[a]Mediastinal nodal staging was mandatory to confirm lymph nodes status; [b]depending on investigator's choice

Altorki NK, et al. J Thorac Oncol 2022;17(suppl):Abstr PL03.06

DFS and OS

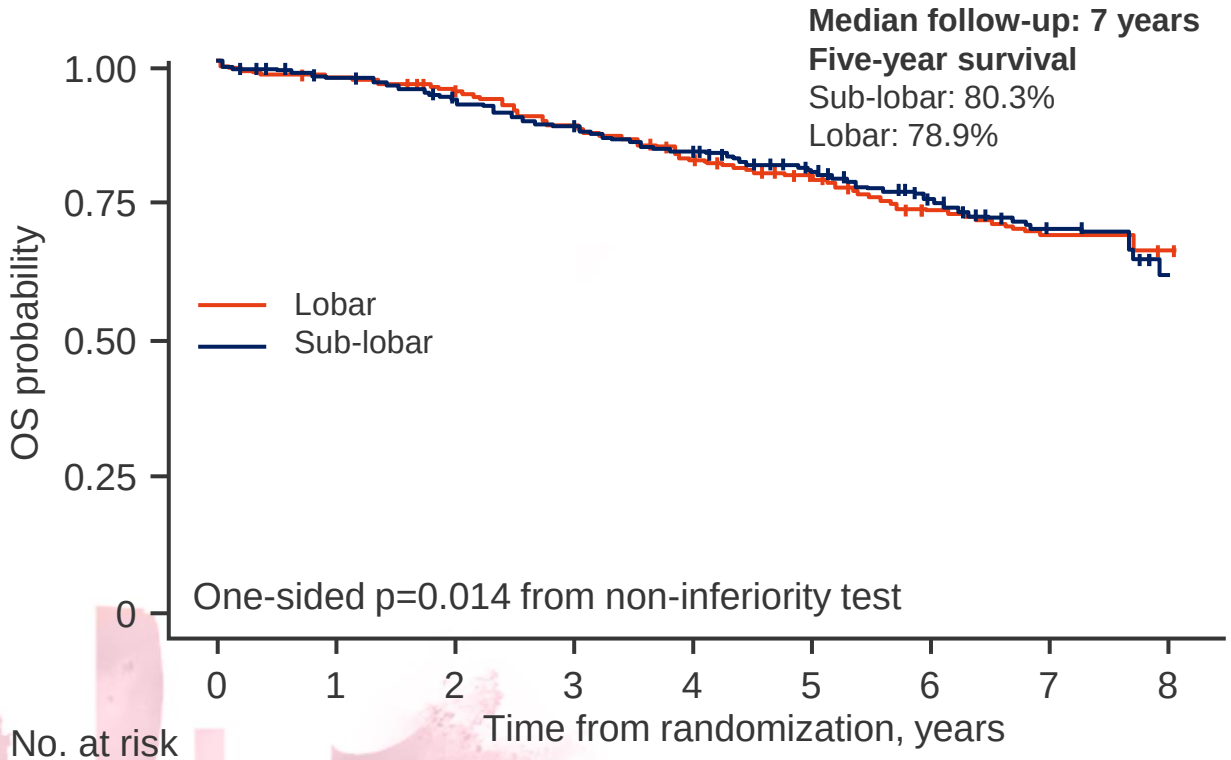
Disease-free survival (primary endpoint)



No. at risk

Lobar	357	310	276	246	209	175	132	80	5
Sub-lobar	340	291	254	222	201	172	123	78	6

Overall survival (secondary endpoint)



No. at risk

Lobar	357	337	322	297	270	240	192	142	14
Sub-lobar	340	320	298	276	258	236	185	127	19

Recurrences and pulmonary funtion

	Lobar	Sub-lobar
Lung cancer-related recurrences/death, n	93	88
HR (95%CI); p-value	0.99 (0.74, 1.33); 0.9521	
Competing deaths, n	45	48
HR (95%CI); p-value	1.12 (0.75, 1.68); 0.5897	

Disease recurrence, n (%)	Lobar	Sub-lobar	p-value
Overall	103 (29.3)	102 (30.4)	0.8364
Locoregional only	35 (10.0)	45 (13.4)	0.2011
Regional only	9 (2.6)	6 (1.8)	0.6623
Any distant	59 (16.8)	51 (15.2)	0.6323

Pulmonary function	Lobar (n=357)	Sub-lobar (n=340)	p-value
FEV1 (% predicted)	n=268	n=252	
Median change from baseline (IQR)	-6.0 (-14.0, -1.0)	-4.0 (-10.0, 2.5)	0.0006
FVC (% predicted)	n=268	n=252	
Median change from baseline (IQR)	-5.0 (-13.0, 3.5)	-3.0 (-11.0, 5.0)	0.0712

- **Conclusions**
  - In patients with peripheral clinical stage IA ≤2 cm NSCLC, sub-lobar resection was not inferior to lobectomy in terms of survival (DFS and OS) and had similar rates of recurrence

Summary of trials

Summary of RCTs in Early Stage NSCLC

	JCOG0802/WJOG4607L	CALGB(Alliance) 140503	NCT02011997
Organization / Country	JCOG & WJOG	CALGB(Alliance)	Guangzhou Med. Univ.
Study design	non-inferiority	non-inferiority	non-inferiority
Primary endpoint	OS	DFS	RFS
Experimental arm	Segmentectomy only	Sublobar resection (segmentectomy / wedge resection)	cVATS segmentectomy
Target	Peripheral NSCLC (tumor diameter ≤2 cm; CTR >0.5)	Peripheral T1aN0M0 NSCLC	Stage IA NSCLC with adenocarcinoma in situ or with microinvasion
Accrual	Completed	Closed due to slow accrual	Not updated
N	1106 pts (lob arm = 554; seg arm = 552)	697 pts (lob arm = 357; seg arm = 340)	Estimated 500 pts
Final result	Lancet 2022	WCLC 2022	Not yet

	CALGB(Alliance)	JCOG/WJOG	Conclusion Sublobar vs. Lobar
Patients Characteristics	Poor PS Higher smoking status More squamous cell ca.		
Endpoints	Lobar vs. Sublobar	Lobar vs. Segmentectomy	
DFS	HR 1.01 non-inferior	HR 0.998 non-inferior	Non-inferior in the both
OS	HR 0.95 non-inferior	HR0.663 superior	Non-inferior in CALGB Superior in JCOG
G3 or higher AE	15.7 vs. 12.7	4.9 vs. 4.5	Similar between the two arms in the both
Loco-regional only recurrence	10.3 vs. 13.4	3.1 vs. 6.9	Difference at 3% between the two arms in the both

Sublobar resection, including wedge resection and segmentecomy, must be considered as a standard care for small-sized peripheral non-small cell lung cancer without lymph node metastasis.

Neoadjuvant Chemo-Inmmunotherapy NADIM II Trial

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NIVOLUMAB + CHEMOTHERAPY vs CHEMOTHERAPY AS NEOADJUVANT TREATMENT FOR RESECTABLE IIIA-B NSCLC

Progression-free survival and overall survival results from the phase 2 NADIM II trial

Dr. Mariano Provencio

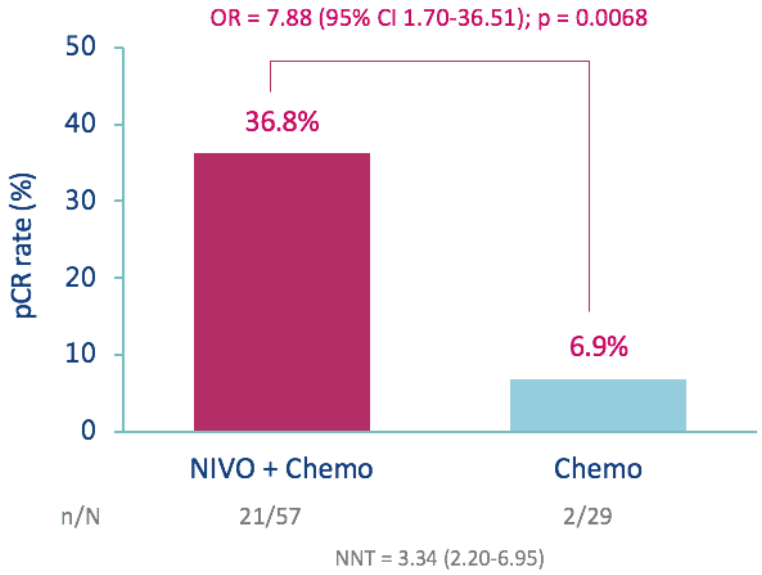
Hospital Universitario Puerta de Hierro-Majadahonda, Madrid

SPAIN

Neoadjuvant Chemo-Inmmunotherapy NADIM II Trial

Background

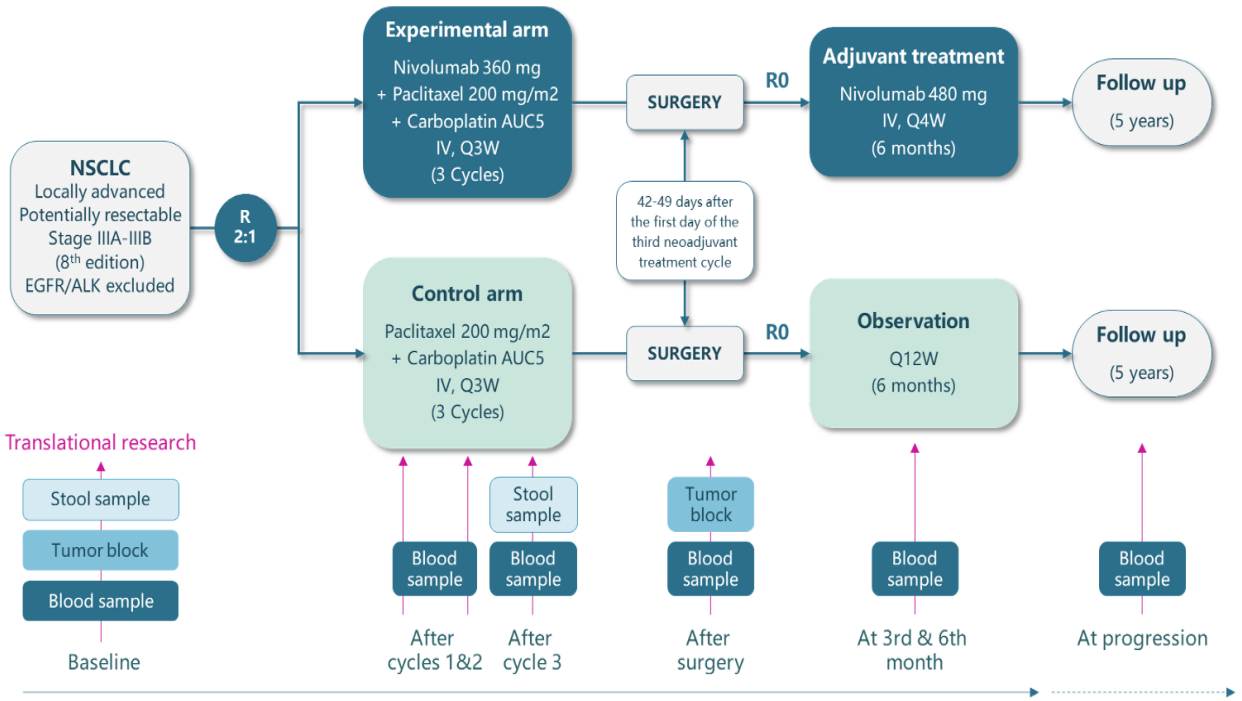
- **Results from the single-arm, phase 2 NADIM trial (NCT03081689), evaluating neoadjuvant nivolumab plus chemotherapy, showed unprecedentedly high survival rates in patients with resectable stage IIIA NSCLC —with an OS almost three times that reported in the historical series —, and improved percentage of patients with pCR[1,2].**
- **In the randomized phase 3 CheckMate 816 trial (NCT02998528), neoadjuvant nivolumab plus CT significantly improved the median event-free survival (HR 0.63 [97.38% CI, 0.43-0.91]; p=0.0052) and the pCR rate (OR 13.94 [99% CI, 3.49-55.75]; p<0.0001) versus CT alone in patients with resectable NSCLC[3].**
- **In the randomized phase 2 NADIM II study, neoadjuvant nivolumab plus chemotherapy significantly improved the primary endpoint of pCR vs Chemo in patients with resectable stage IIIA-B NSCLC (36.8% vs 6.9%, OR 7.88 [95% CI 1.70-36.51]; p = 0.0068)[4].**
- **Here we present the results of the secondary endpoints of PFS and OS rates at 24 months.**



1. Provencio M. et al. Lancet Oncol 2020;21:1413-22; 2. Provencio M, et al. J Clin Oncol 2022; doi: 10.1200/JCO.21.02660; 3. Forde P, et al. Clinical Trial NEJM 2022;386:1973-1985; Provencio M, et al. J Clin Oncol 40, 2022 (suppl 16; abstr 8501)

Neoadjuvant Chemo-Inmmunotherapy NADIM II Trial

STUDY DESIGN



Primary endpoint

- Pathological complete response in the ITT population

Secondary endpoints

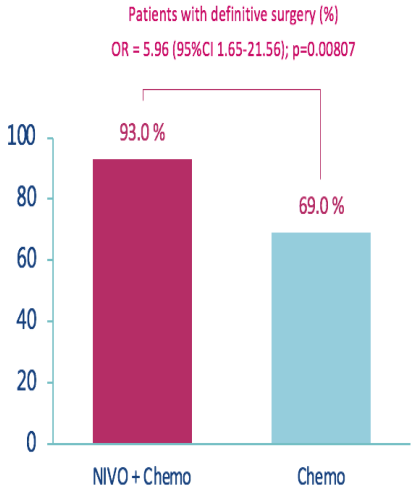
- Major pathological response (MPR)
- Portion of delayed/canceled surgeries, length of hospital stays, surgical approach, incidence of AE/SAE related to surgery
- Safety and tolerability: Adverse events graded according to CTCAE v5.0
- OS at 12, 18 and 24 months
- PFS at 12, 18 and 24 months
- Potential predictive biomarkers (ctDNA, TCR)

NADIM II: Surgery Data

SURGERY SUMMARY

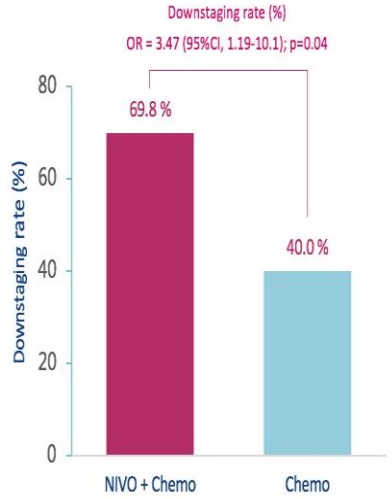
Type of surgery, No. (%)	NIVO + Chemo (n = 53)	Chemo (n = 20)	Total (n = 73)
Pneumonectomy	6 (11.3)	2 (10.0)	8 (11.0)
Lobectomy	40 (75.5)	17 (85.0)	57 (78.1)
Bilobectomy	4 (7.5)	1 (5.0)	5 (6.8)
Segmentectomy	2 (3.8)	0 (0.0)	2 (2.7)
Right Lower Lobectomy + Segmentectomy	1 (1.9)	0 (0.0)	1 (1.4)

Resection degree, No (%)	NIVO + Chemo (n = 57)	Chemo (n = 29)
R0	49 (92.5)	13 (65.0)



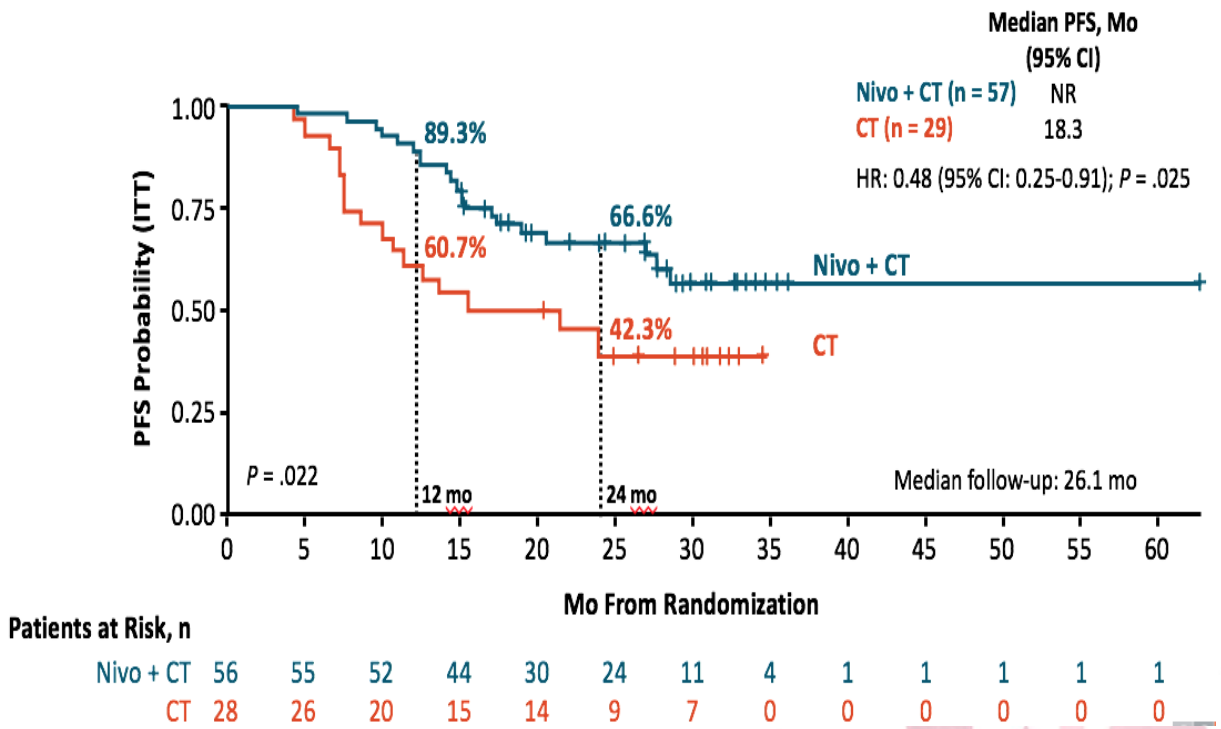
SECONDARY ENDPOINTS – Downstaging

Downstaging, No. (%)	Yes	No	Total
Nivolumab + chemotherapy	37 (69.8)	16 (30.2)	53
Chemotherapy	8 (40.0)	12 (60.0)	20
Total	45 (61.6)	28 (38.4)	73

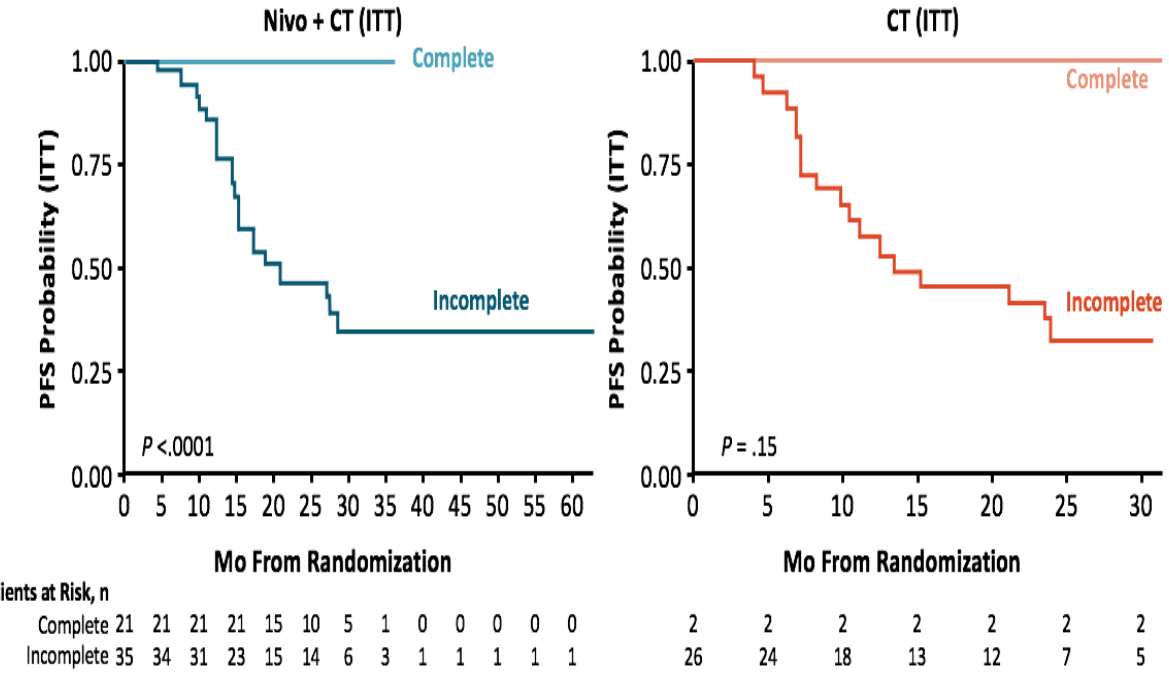


NADIM II: PFS (Secondary Endpoint)

NADIM II: PFS (Secondary Endpoint)

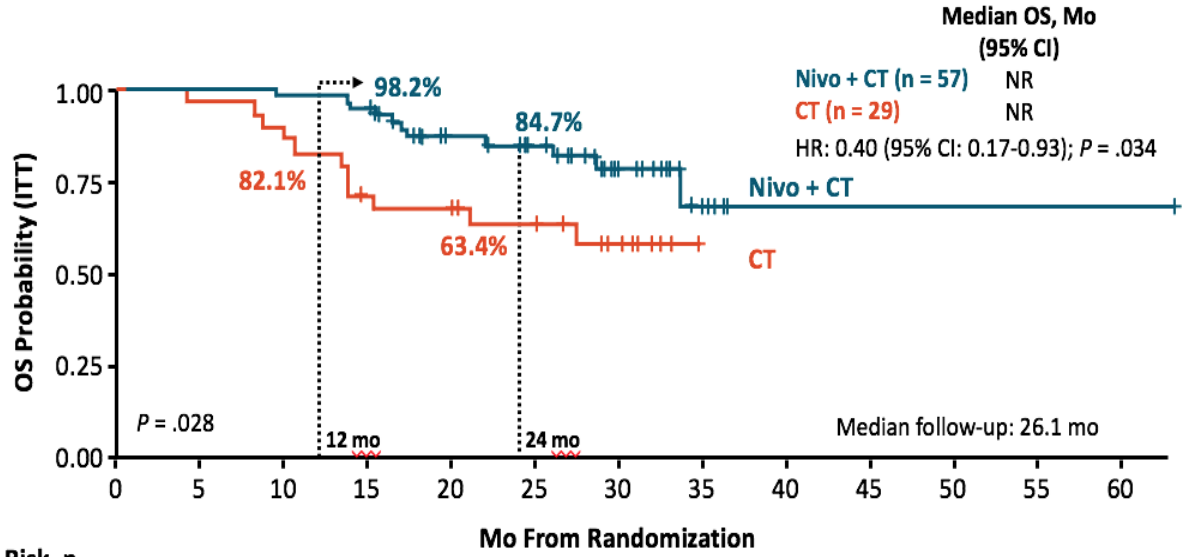


NADIM II: PFS by pCR Status (Secondary Endpoint)



NADIM II: OS (Secondary Endpoint)

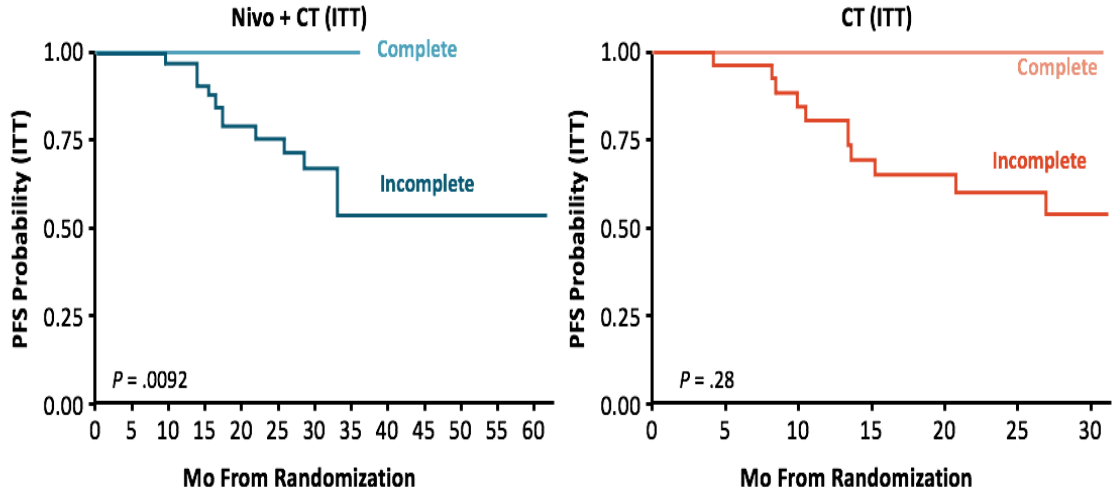
NADIM II: OS (Secondary Endpoint)



Patients at Risk, n

Nivo + CT	56	56	55	53	37	31	15	5	1	1	1	1	1
CT	28	27	25	19	17	13	9	0	0	0	0	0	0

NADIM II: OS by pCR Status (Secondary Endpoint)



Patients at Risk, n

Complete	21	21	21	21	15	10	5	1	0	0	0	0	0
Incomplete	35	35	34	32	22	21	10	4	1	1	1	1	1

2	2	2	2	2	2	2	
26	25	23	17	15	11	7	

NADIM II: Conclusions

- **NADIM II confirms superiority of neoadjuvant nivolumab plus chemotherapy combination in patients with resectable stage IIIA-B NSCLC**
- **The addition of neoadjuvant nivolumab to chemotherapy:**

  → Significantly improved pCR (OR = 7.88 [95% CI 1.70-36.51]) (Chi-squared test: p=0.0068)

  → Significantly improved PFS rate at 12 (89.3% vs 60.7%, p=0.001) and 24 months (66.6% vs 42.3%, p=0.012)

  → Significantly improved OS rate at 12 (98.2% vs 82.1%, p=0.007) and 24 months (84.7% vs 63.4%, p=0.014)

  → Maintained a tolerable safety profile, with a moderate increase in grade 3-4 toxicity

  → Did not impede the feasibility of surgery

- **NADIM II is the first clinical trial with a neoadjuvant immunotherapy-based combination (nivolumab + chemotherapy) for resectable stage IIIA-B NSCLC to show improved OS**

Chemo+ICI is superior to chemo alone in neoadjuvant setting

	Stage for Subjects	ICI	pCR/ MPR	EFS: 1 year/2 year, HR (90 or 95%C.I)	OS 1 year/2 year, HR (90 or 95%C.I)	Median follow-up
NADIM I	IIIA, 7th edition N2: 73.9%	nivolumab		NA, 3 year - 69.6% (ITT), 81.1% (PP)	NA, 3 year – 81.9% (ITT), 91.0% (PP)	38.0 m
SAKK 16/14	IIIA (N2) 7th edition	Sequential durvalumab	18%/62%	73% (63-82), 68% (54-78)	91% (81-96), 83% (71-90)	28.6 m
NADIM II	IIIA/IIIB 8th edition N2: 71.9% (multiple: 36.8%)	nivolumab	36.8%/ 52.6%	89.3%, 66.6% HR:0.48 (95%CI, 0.25-0.91)	98.2%, 84.7% HR: 0.40 (95% CI 0.17-0.93)	26.1 m
CheckMate 816	IB - IIIA 7th edition IIIA: 63.1% PD-L1 >50%: 21.2%	nivolumab	24.0%/ 36.9%	76.1%, 63.8% HR: 0.63 (97.38% CI, 0.43–0.91)	Immature 90.3%, 82.7% HR: 0.57 (99.67% CI, 0.30–1.07)	31.6 m

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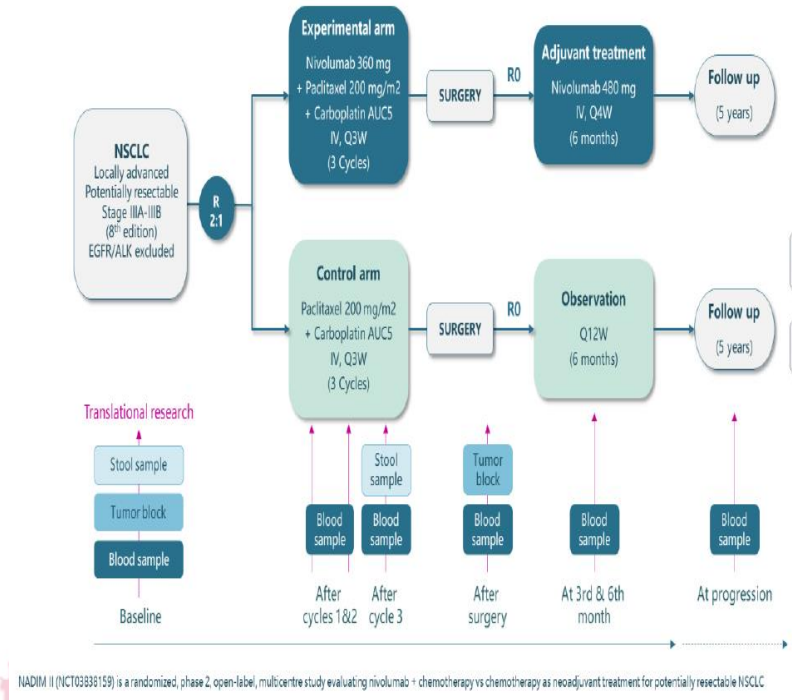
Pre-treatment ctDNA levels significantly predicts of OS and PFS in NADIM 2 trial

Atocha Romero, Roberto Serna-Blasco, E. Nadal, JL Glez Larriba, A. Martinez, R. Bernabé, J.Bosch-Barrera, A. Garrido Fdez, V. Calvo, A. Insa, S Ponce, N. Reguart, J. de Castro, B. Massuti, R. Palmero, C. Aguado de la Rosa, J. Mosquera, M. Cobo, Andrés Aguilar, G. López Vivanco, C.Camps, F. Hernando Trancho, R. Lopez Castro, T. Moran, I. Barneto, D.Rodriguez-Abreu, A. Cruz, Mariano Provencio

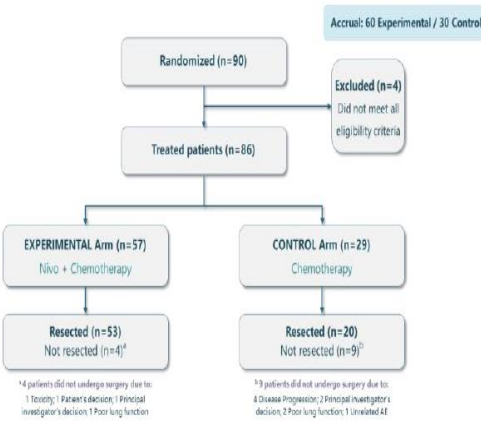
Spanish Lung Cancer Group

STUDY DESIGN



NADIM II (NCT03838159) is a randomized, phase 2, open-label, multicentre study evaluating nivolumab + chemotherapy vs chemotherapy as neoadjuvant treatment for potentially resectable NSCLC

PATIENTS AND METHODS



cfDNA was isolated from 4-6 mL plasma using the QIAamp Circulating Nucleic Acid Kit.

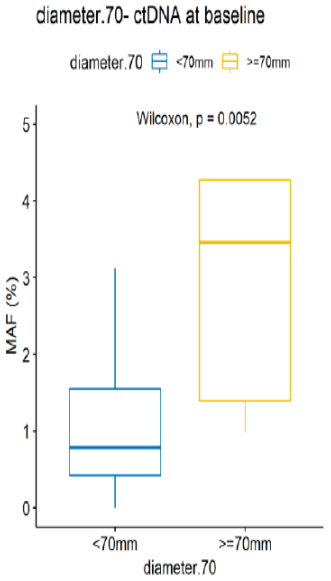
ctDNA (minimum input: 30ng) was analyzed with the TruSight Oncology ctDNA next-generation sequencing (NGS) assay on a NovaSeq .

61 (71%) samples passed filter quality and were considered valid for ctDNA quantification (41 in the experimental arm, 20 in the control arm)

MA 06.03

RESULTS

Pre-treatment ctDNA levels were significantly associated with tumor size (maximum diameter ≥ 70mm)

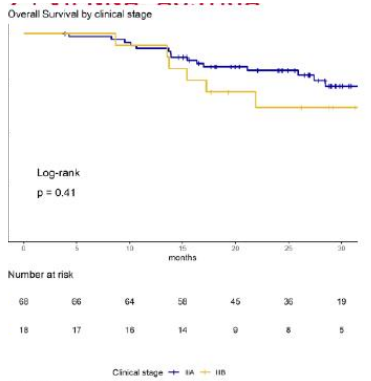


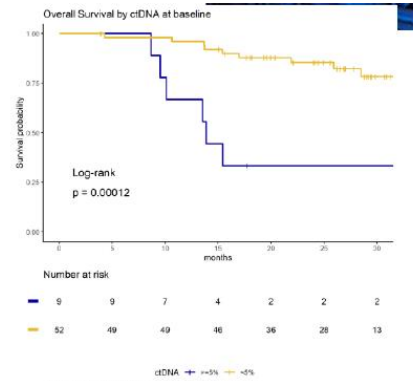
Median follow up time was 26.1 (IQR: 17.6-30.9) months

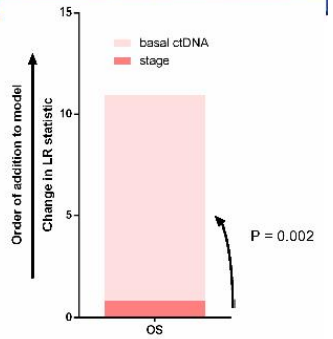
Pre-treatment ctDNA levels were significantly associated with progression free survival (PFS) and overall survival (OS) and regardless of the cutoff used (Table 1).

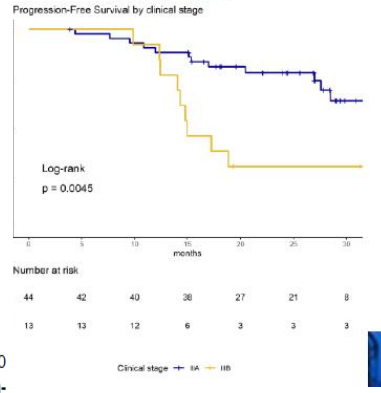
	PFS			OS			
Cut-off	HR (95% CI for HR)	P-value	P-value LogRank	*Cut-off*	HR (95% CI for HR)	P-value	P-value LogRank
MAF 3%	0.43 (0.19-0.96)	0.039	0.033	MAF 3%	0.32 (0.11-0.91)	0.032	0.024
MA F3.5%	0.34 (0.15-0.79)	0.012	0.008	MA F3.5%	0.23 (0.079-0.64)	0.005	0.002
MAF 4%	0.28 (0.12-0.66)	0.003	0.002	MAF 4%	0.19 (0.067-0.55)	0.002	0.001
MAF 4.5%	0.29 (0.12-0.69)	0.005	0.003	MAF 4.5%	0.16 (0.058-0.47)	0.001	<0.001
MAF 5%	0.29 (0.12-0.69)	0.005	0.003	MAF 5%	0.16 (0.058-0.47)	0.001	<0.001
MAF 5.5%	0.35 (0.14-0.87)	0.024	0.018	MAF 5.5%	0.21 (0.071-0.62)	0.005	<0.001
MAF 6%	0.28 (0.11-0.76)	0.012	0.007	MAF 6%	0.21 (0.065-0.67)	0.008	0.004
MAF 6.5%	0.28 (0.11-0.76)	0.012	0.007	MAF 6.5%	0.21 (0.065-0.67)	0.008	0.004
MAF 7%	0.28 (0.11-0.76)	0.012	0.007	MAF 7%	0.21 (0.065-0.67)	0.008	0.004
MAF 7.5%	0.28 (0.11-0.76)	0.012	0.007	MAF 7.5%	0.21 (0.065-0.67)	0.008	0.004
MAF 8%	0.29 (0.1-0.86)	0.025	0.017	MAF 8%	0.16 (0.05-0.52)	0.002	<0.001
MAF 8.5%	0.29 (0.1-0.86)	0.025	0.017	MAF 8.5%	0.16 (0.05-0.52)	0.002	<0.001
MAF 9%	0.29 (0.1-0.86)	0.025	0.017	MAF 9%	0.16 (0.05-0.52)	0.002	<0.001
MAF 9.5%	0.29 (0.1-0.86)	0.025	0.017	MAF 9.5%	0.16 (0.05-0.52)	0.002	<0.001
MAF 10%	0.29 (0.1-0.86)	0.025	0.017	MAF 10%	0.16 (0.05-0.52)	0.002	<0.001
MAF 15%	0.12 (0.024-0.56)	0.007	0.001	MAF 15%	0.084 (0.017-0.41)	0.002	<0.001

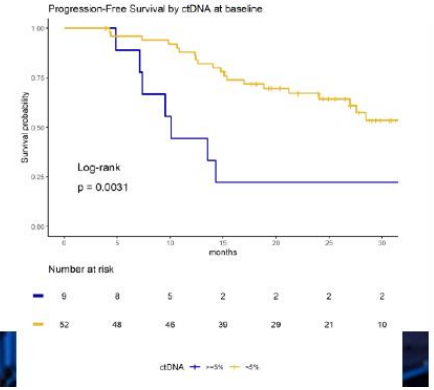
Table 1. Hazard ratio (HR), 95% confidence interval (95%CI), and P-values for PFS and OS according to ctDNA levels at baseline. Abbreviations: MAF, mutant allele fraction; OS, overall survival; PFS, progression-free survival

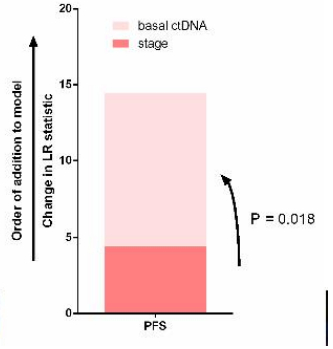












SUMMARY

- Baseline ctDNA levels clearly identified patients at high risk of progression and death.
- •Pre-treatment circulating tumor DNA levels significantly correlated with tumor size.

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IMpower010: Overall survival interim analysis of a phase III study of atezolizumab vs best supportive care in resected NSCLC

Enriqueta Felip,[1] Nasser Altorki,[2] Eric Vallieres,[3] Ihor O. Vynnychenko,[4] Andrey Akopov,[5] Alex Martinez-Marti,[1] Antonio Chella,[6] Igor Bondarenko,[7] Shunichi Sugawara,[8] Yun Fan,[9] Hirotsugu Kenmotsu,[10] Yuh-Min Chen,[11] Yu Deng,[12] Meilin Huang,[12] Virginia McNally,[13] Elizabeth Bennett,[12] Barbara J. Gitlitz,[12] Caicun Zhou,[14] Heather A. Wakelee[15]

Completely resected stage IB-IIIA[a] NSCLC

- Stage IB tumors ≥4 cm
- ECOG 0-1
- Lobectomy
- Tumor tissue for PD-L1 analysis

Cisplatin + pemetrexed, gemcitabine, docetaxel or vinorelbine

1-4 cycles

N=1280

R 1:1

No crossover

Atezolizumab 1200 mg q21d x 16 cycles or 1 year

N = 1005

BSC

Survival follow-up

Stratification factors

- Sex | Stage | Histology | PD-L1 status

Primary endpoint

- Investigator-assessed DFS tested hierarchically

Key secondary endpoints

- OS in ITT | DFS in PD-L1 TC ≥50% | 3-yr and 5-year DFS

Key exploratory endpoints

- OS biomarker analyses

Clinical cutoff: 18 April 2022. Both arms included observation and regular scans for disease recurrence on the same schedule. ECOG, Eastern Cooperative Oncology Group, q21d, every 21 days.

Hierarchical statistical testing of endpoints

DFS in PD-L1 TC ≥1% stage II–IIIA population[b]

If positive:

DFS in all-randomized stage II–IIIA population[b]

If positive:

DFS in ITT population (stage IB-IIIA)[b]

If positive:

OS in ITT population[b]

Endpoint was met at DFS IA

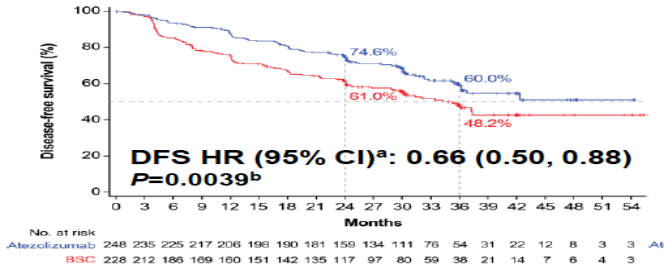
Endpoint was not met at DFS IA and follow up is ongoing

Endpoint was not formally tested

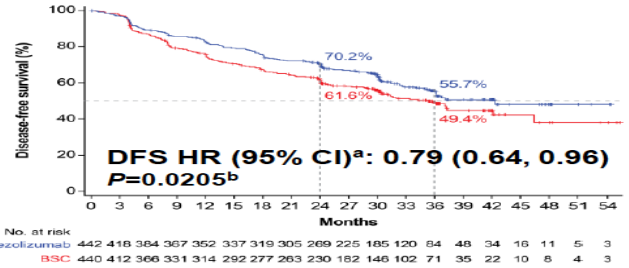
Recap of DFS and OS data from the DFS IA[1,2]

(data cutoff: 21 Jan '21, median follow-up: 32 months)

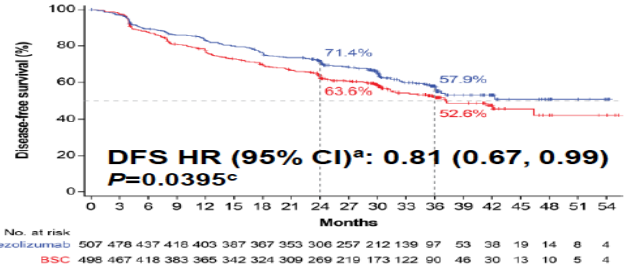
DFS: PD-L1 TC ≥1% stage II-IIIA population



DFS: All-randomised stage II-IIIA population



DFS: ITT (randomised stage IB-IIIA) population



- **OS data** were not mature (event to patient ratio in ITT was 19% in atezolizumab arm, 18% in BSC arm)
  - PD-L1 TC ≥1% stage II-IIIA population: OS HR, 0.77 (95% CI: 0.51, 1.17)[a]
  - All-randomised stage II-IIIA population: OS HR, 0.99 (95% CI: 0.73, 1.33)[a]
  - ITT (randomised stage IB-IIIA) population: OS HR, 1.07 (95% CI: 0.80, 1.42)[a]

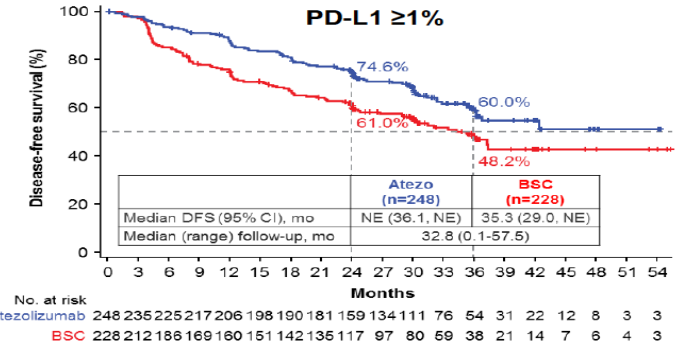
Clinical cutoff: 21 Jan 2021. [a] Stratified. [b] Statistical significance boundary for DFS crossed. [c] Statistical significance boundary for DFS not crossed.
1. Felip, E et al Lancet 2021; 938; 1344-1357; 2. Wakelee. HA et al ASCO 2021; abs #8500.

Summary of previous results : DFS in stage II-IIIA

Population analyzed for DFS[1]	n	HR (95% CI)
PD-L1 TC ≥1%[a] Stage II-IIIA	**476**	**0.66 (0.50, 0.88)[b]**
PD-L1 TC 1-49% Stage II-IIIA[2]	247	0.87 (0.60, 1.26)[c]
PD-L1 TC ≥50% Stage II-IIIA	**229**	**0.43 (0.27, 0.68)[c]**

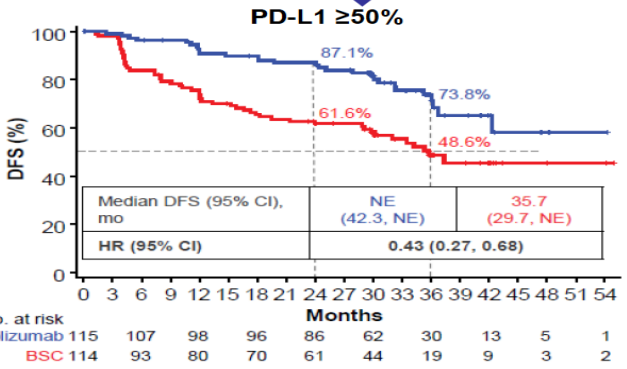
[a]Per SP263 assay. [b]Stratified. [c]Unstratified.

PD-L1 ≥1%



APPROVAL

PD-L1 ≥50%



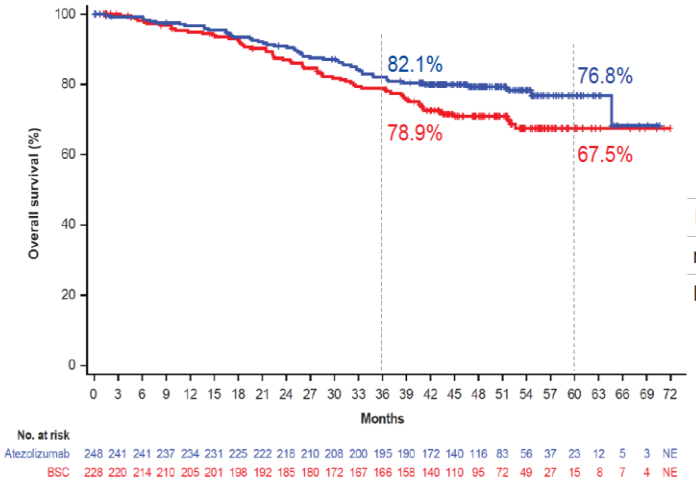
APPROVAL

and other countries

Impower 010 Atezolizumab vs BSC in resected NSCLC: OS Interim Analysis OS

Results of OS IA: PD-L1 TC ≥1%[a] (stage II-IIIA)

(data cutoff: 18 Apr '22, median follow-up: 46 months)

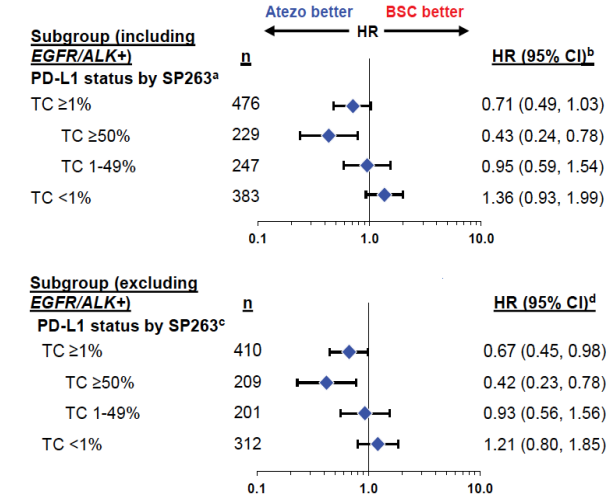


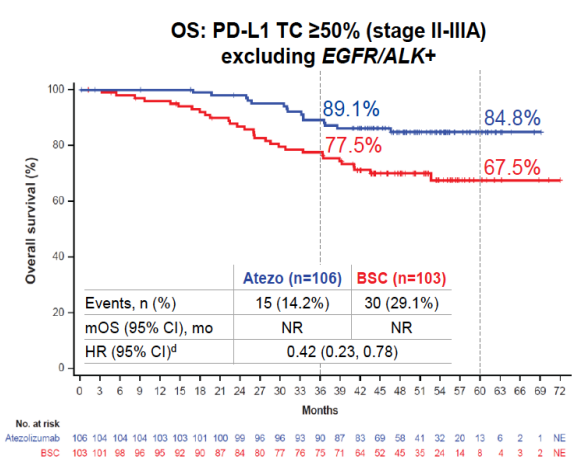
	Atezo (n=248)	BSC (n=228)
Events, n (%)	52 (21.0%)	64 (28.1%)
mOS (95% CI), mo	NR	NR
HR (95% CI)[b]	0.71 (0.49, 1.03)	

mOS, median overall survival; NR, not reached. [a]By SP263 assay. [b]Stratified.

OS by biomarker status (stage II-IIIA)

(data cutoff: 18 Apr '22)





	Atezo (n=106)	BSC (n=103)
Events, n (%)	15 (14.2%)	30 (29.1%)
mOS (95% CI), mo	NR	NR
HR (95% CI)[d]	0.42 (0.23, 0.78)	

[a] 23 patients had unknown PD-L1 status. [b] Stratified for PD-L1 TC ≥1%; unstratified for all other subgroups. [c] 21 patients had unknown PD-L1 status. [d] Unstratified.

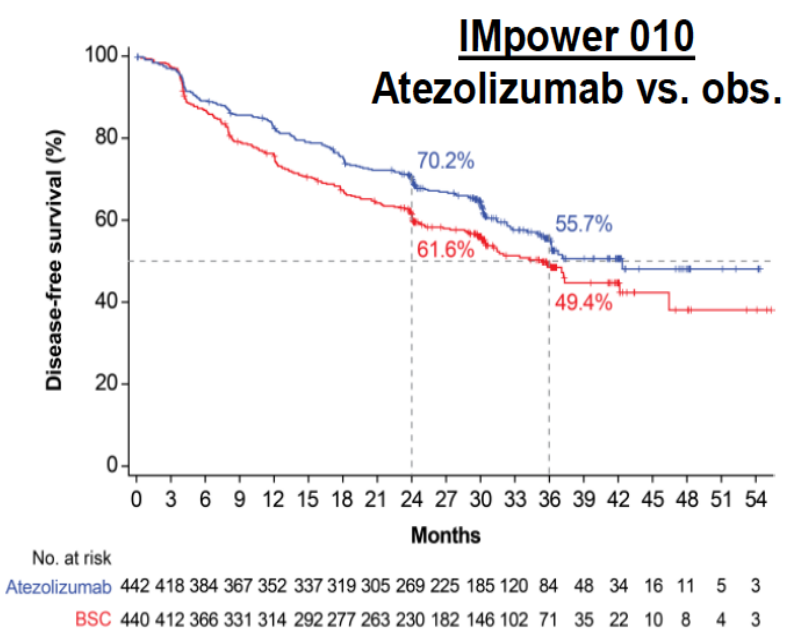
Conclusions

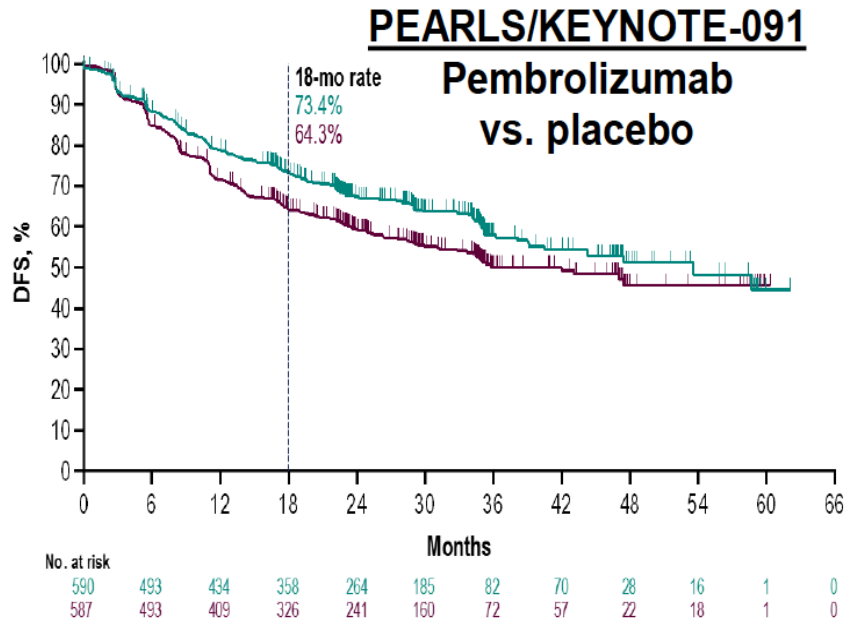
- An OS trend in favor of atezolizumab was seen in the PD-L1 TC ≥1% stage II-IIIA population (OS HR, 0.71 [95% CI: 0.49, 1.03]) at the time of this first pre-specified IA OS analysis
- In the PD-L1 TC ≥50% stage II-IIIA subpopulation, a clinically meaningful OS trend in favor of atezolizumab was observed (OS HR, 0.43 [95% CI: 0.24, 0.78])

Impower 010 Atezolizumab vs BSC in resected NSCLC: OS Interim Analysis OS

Adjuvant study : PRIMARY ENDPOINT !

Stage II and IIIA
PD-L1 ≥ 1%





DFS in PD-L1 TC ≥1% stage II–IIIA
DFS in all-randomized stage II–IIIA

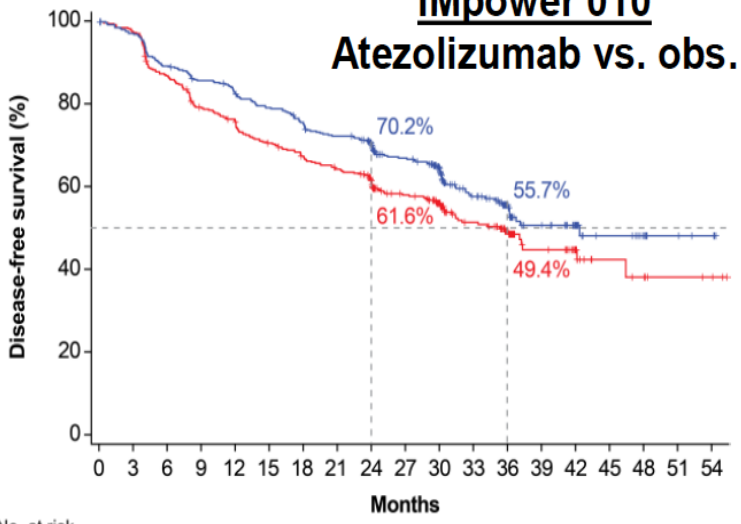
POSITIVE

DFS in the overall population
DFS in the PD-L1 TPS ≥50%

DFS : Effect of PD-L1

Stage II and IIIA
PD-L1 1%

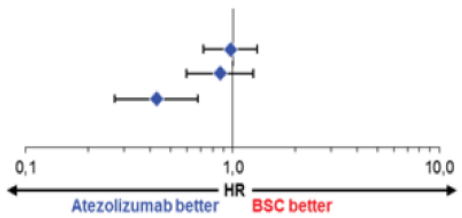
IMpower 010
Atezolizumab vs. obs.



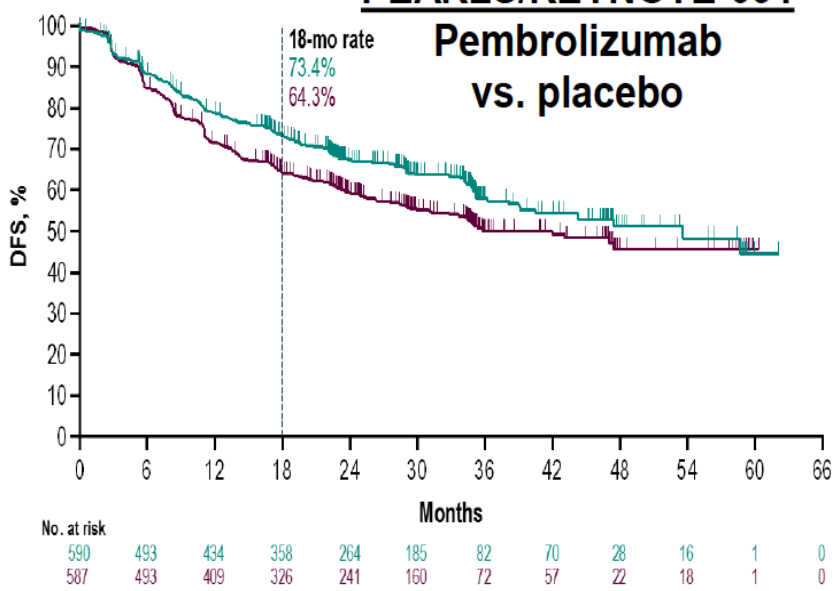
No. at risk

Atezolizumab	442	418	384	367	352	337	319	305	269	225	185	120	84	48	34	16	11	5	3
BSC	440	412	366	331	314	292	277	263	230	182	146	102	71	35	22	10	8	4	3

PD-L1 status by SP263	n	HR (95% CI)[b,c]
TC <1%	383	0.97 (0.72, 1.31)
TC 1-49%	247	0.87 (0.60, 1.26)
TC ≥50%	229	0.43 (0.27, 0.68)



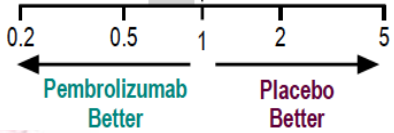
PEARLS/KEYNOTE-091
Pembrolizumab vs. placebo



No. at risk

590	493	434	358	264	185	82	70	28	16	1	0
587	493	409	326	241	160	72	57	22	18	1	0

PD-L1 TPS		
<1%	195/465	0.78 (0.58-1.03)
1-49%	160/379	0.67 (0.48-0.92)
≥50%	117/333	0.82 (0.57-1.18)



Resumen

- En estadios IA < 2 cm periféricos la resección sublobar debe considerarse como tratamiento quirúrgico estandard
- El estudio NADIM 2 confirma la superioridad del tratamiento neoadyuvante con quimio-inmunoterapia en estadios III A-B resecables aumentando significativamente las RC patológicas, SLP, siendo el primer estudio aleatorizado que muestra aumento significativo en supervivencia.
- Los datos del NADIM 2 y CheckMate 816 son consistentes y el tratamiento neoadyuvante con quimioterapia + nivolumab debería ser considerando el tratamiento estándar en estadios II-IIIA resecables seguido de cirugía
- Existe suficientemente evidencia de que el tratamiento adyuvante con inmunoterapia en estadios II-IIIA resecados produce beneficios significativos aunque los datos con los subgrupos de expresión de PD-L1 son inconsistentes

MUCHAS GRACIAS