Novedades y Claves en Cáncer de Pulmón 2021

Early & locally advanced NSCLC 2021

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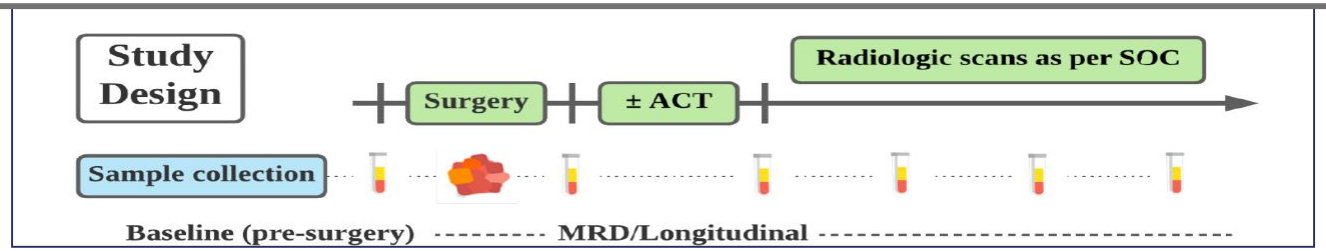
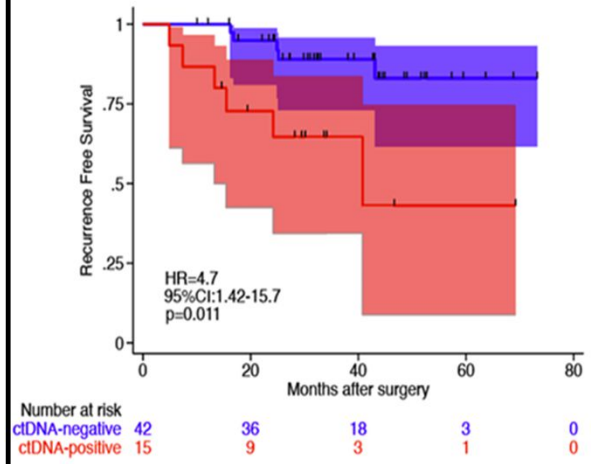
Organizado por:

GECP lung cancer research

Circulating tumor DNA



ctDNA detection pre-surgery associated with shorter RFS



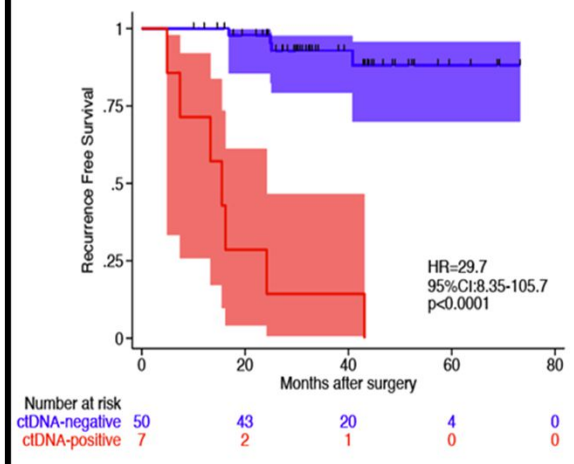
ctDNA status prior to surgery

ctDNA positivity pre-surgery also correlated with

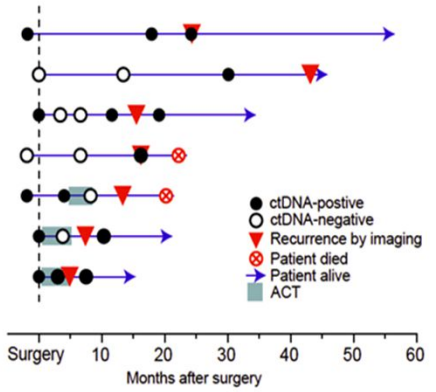
- Higher stage (p<0.0001)
- Lymph node positivity (p<0.0001)

Pre-surgery ctDNA+ (N=15)	N (%)
Stage	
I	7 (47)
II	2 (13)
III	6 (40)
Relapsed	7 (47)
No adjuvant therapy	3 out of 7

Longitudinal ctDNA+ preceded radiological recurrence



Longitudinal ctDNA monitoring



- Median lead time: 3.9 mths
- Longitudinal ctDNA negativity associated with favourable outcomes with NPV of 94% (45/49)

In resected early-stage patients:

- baseline ctDNA positivity associated with early relapse
- ctDNA detection preceded radiological recurrence

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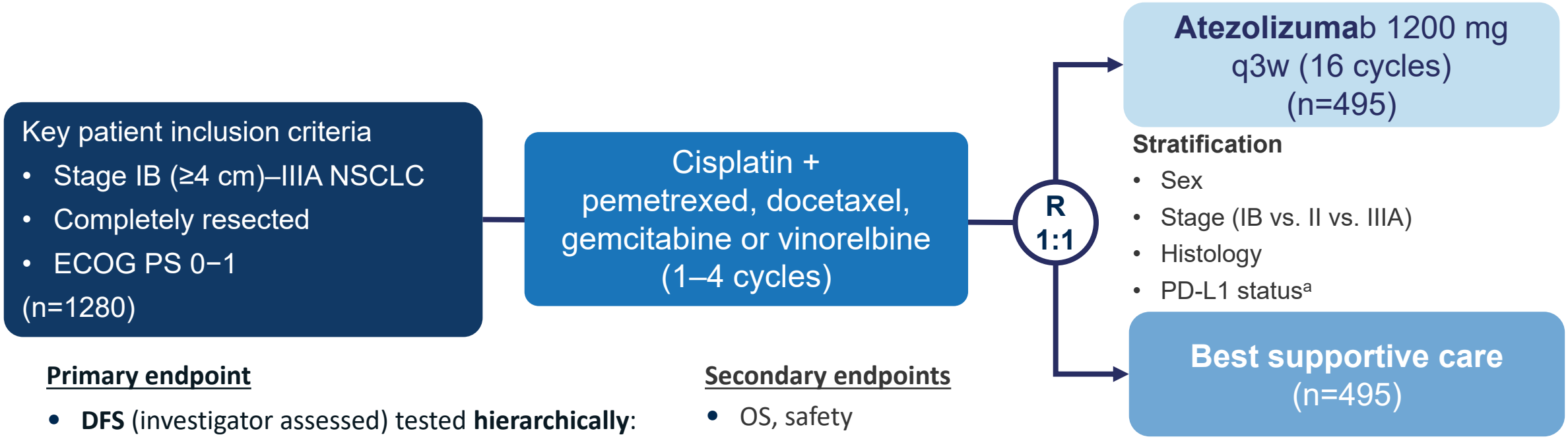
Tan A, et al. Abstract MA 07.06.- IASLC 2021

IMpower010: Phase III global study of atezolizumab versus BSC after adjuvant CT in resected stage IB-IIIA NSCLC (interim analysis)

- **Study objective:** To evaluate the efficacy and safety of atezolizumab after adjuvant chemotherapy in patients with early stage resected NSCLC in IMpower010



Primary endpoint

- **DFS** (investigator assessed) tested **hierarchically**:

  1º Stage II-III PD-L1 ≥1%
  2º Stage II-III
  3º ITT, stage IB-IIA
  4º OS ITT

Secondary endpoints

- OS, safety

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[a]TC2/3 and any IC vs. TC0/1 and IC2/3 vs. TC0/1 and IC0/1

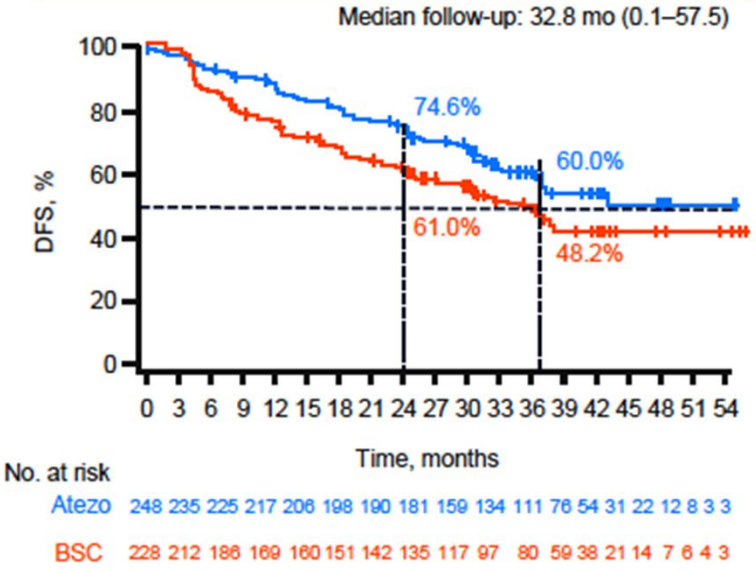
Wakelee HA, et al. J Clin Oncol 2021;39(suppl):Abstr 8500 – ASCO 2021

IMpower010: Phase III global study of atezolizumab versus BSC after adjuvant CT in resected stage IB-IIIA NSCLC (interim analysis)

Disease-free survival

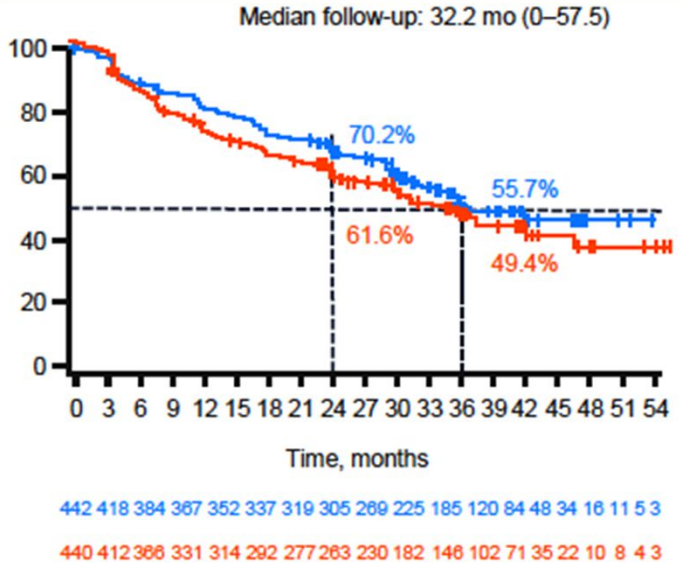
PD-L1 ≥1% stage II–IIIA population

	Atezolizumab (n=248)	BSC (n=228)
mDFS, mo (95%CI)	NE (36.1, NE)	35.3 (29.0, NE)
Stratified HR (95%CI)	0.66 (0.50, 0.88)	
p-value	0.004	



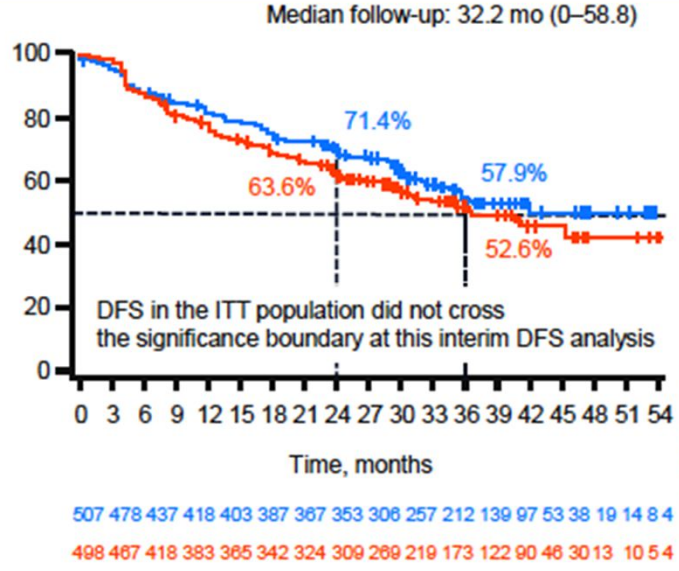
All-randomized stage II–IIIA population

	Atezolizumab (n=442)	BSC (n=440)
mDFS, mo (95%CI)	42.3 (36.0, NE)	35.3 (30.4, 46.4)
Stratified HR (95%CI)	0.79 (0.64, 0.96)	
p-value	0.02	



ITT population stage IB–IIIA population

	Atezolizumab (n=507)	BSC (n=498)
mDFS, mo (95%CI)	NE (36.1, NE)	37.2 (31.6, NE)
Stratified HR (95%CI)	0.81 (0.67, 0.99)	
p-value	0.04	



Cut-off date: Jan 21, 2021. Log-rank test

Wakelee HA, et al. J Clin Oncol 2021;39(suppl):Abstr 8500 – ASCO 2021

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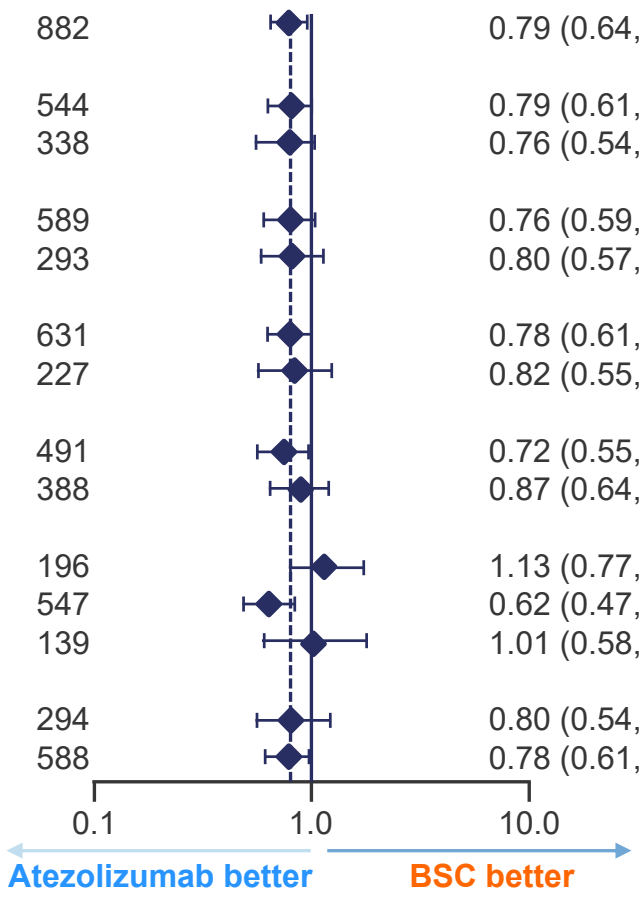
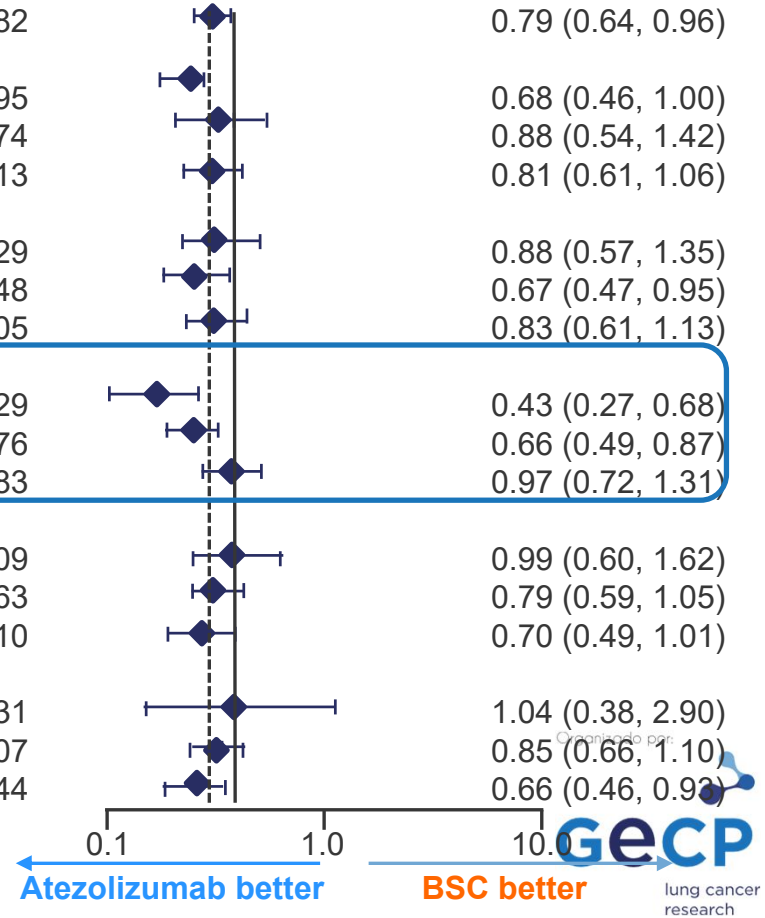
IMpower010: Phase III global study of atezolizumab versus BSC after adjuvant CT in resected stage IB-IIIA NSCLC (interim analysis)

Disease-free survival in all-randomized stage II–IIIA population subgroups

Subgroup	N	HR (95%CI)*
All patients	882	0.79 (0.64, 0.96)
Age, years		
<65	544	0.79 (0.61, 1.03)
≥65	338	0.76 (0.54, 1.05)
Sex		
Male	589	0.76 (0.59, 0.99)
Female	293	0.80 (0.57, 1.13)
Race		
White	631	0.78 (0.61, 1.00)
Asian	227	0.82 (0.55, 1.22)
ECOG PS		
0	491	0.72 (0.55, 0.95)
1	388	0.87 (0.64, 1.18)
Tobacco use history		
Never	196	1.13 (0.77, 1.67)
Previous	547	0.62 (0.47, 0.81)
Current	139	1.01 (0.58, 1.75)
Histology		
Squamous	294	0.80 (0.54, 1.18)
Nonsquamous	588	0.78 (0.61, 0.99)
All patients	882	0.79 (0.64, 0.96)
Stage		
IIA	295	0.68 (0.46, 1.00)
IIB	174	0.88 (0.54, 1.42)
IIIA	413	0.81 (0.61, 1.06)
Regional lymph node stage (pN)		
N0	229	0.88 (0.57, 1.35)
N1	348	0.67 (0.47, 0.95)
N2	305	0.83 (0.61, 1.13)
SP263 PD-L1 status		
TC ≥50%	229	0.43 (0.27, 0.68)
TC ≥1%	476	0.66 (0.49, 0.87)
TC <1%	383	0.97 (0.72, 1.31)
EGFR mutation status		
Yes	109	0.99 (0.60, 1.62)
No	463	0.79 (0.59, 1.05)
Unknown	310	0.70 (0.49, 1.01)
ALK re-arrangement status		
Yes	31	1.04 (0.38, 2.90)
No	507	0.85 (0.66, 1.10)
Unknown	344	0.66 (0.46, 0.93)

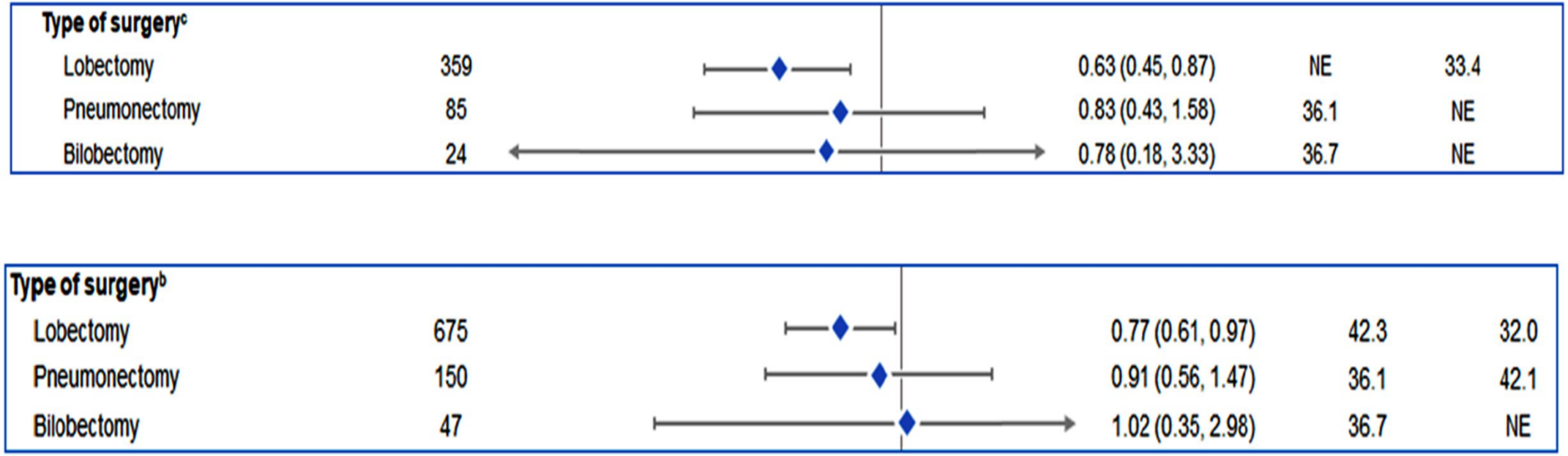




Cut-off date: Jan 21, 2021. *Stratified for all patients, unstratified for all other subgroups

Wakelee HA, et al. J Clin Oncol 2021;39(suppl):Abstr 8500 – ASCO 2021

IMpower010: Phase III global study of atezolizumab versus BSC after adjuvant CT in resected stage IB-IIIA NSCLC (interim analysis)



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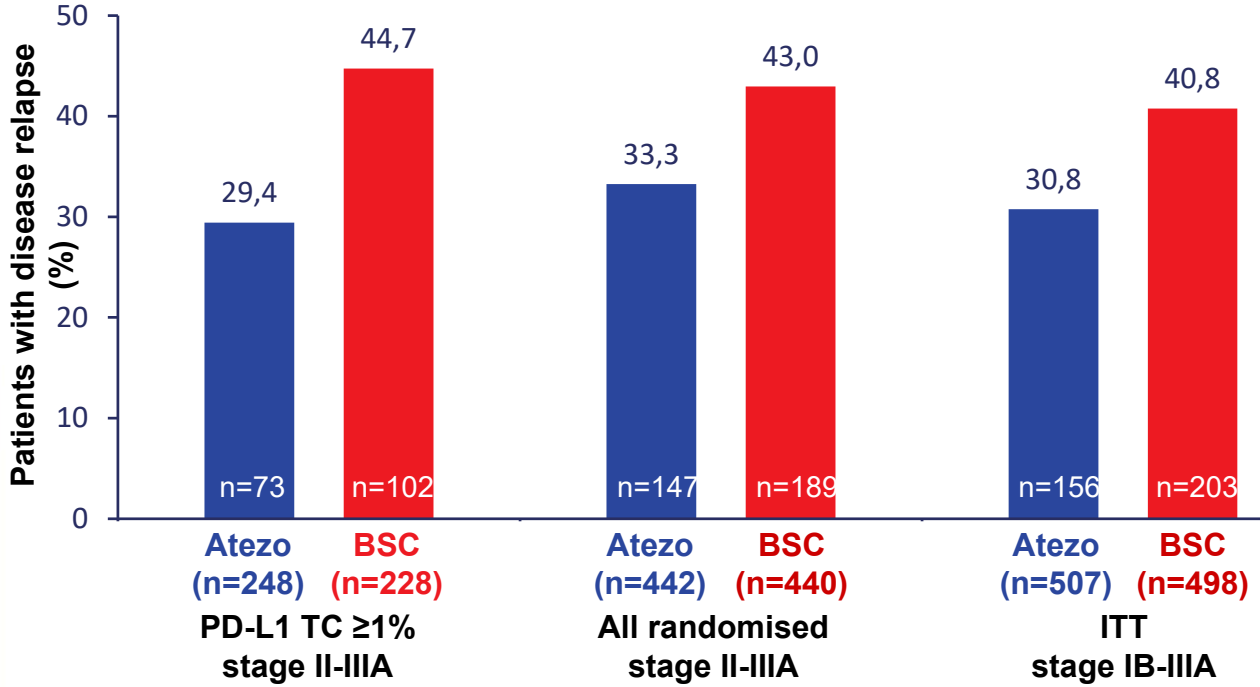
Altorki N, et al. J Thorac Oncol 2021;16(suppl):Abstr PL02.05; Felip E, et al. Ann Oncol 2021;32(suppl):Abstr LBA9 – ESMO 2021

IMpower010: Relapse patterns



Site of relapse, n (%)	Atezolizumab (n=156)	BSC (n=203)
Locoregional only[a]	**59 (37.8)**	**75 (36.9)**
Distant only[b]	**67 (42.9)**	**82 (40.4)**
CNS	16 (10.3)	29 (14.3)
Bone/bone marrow	14 (9.0)	14 (6.9)
Contralateral lung	10 (6.4)	16 (7.9)
Liver	10 (6.4)	8 (3.9)
Lymph node	8 (5.1)	11 (5.4)
Ipsilateral lung	6 (3.8)	8 (3.9)
Subcutaneous tissue	1 (0.6)	2 (1.0)
Other	16 (10.3)	15 (7.4)
Locoregional and distant	**27 (17.3)**	**38 (18.7)**
Bone/bone marrow	11 (7.1)	8 (3.9%)
Contralateral lung	7 (4.5)	10 (4.9)
Liver	6 (3.8)	4 (2.0)
Lymph node	5 (3.2)	9 (4.4)
Ipsilateral lung	5 (3.2)	1 (0.5)
CNS	3 (1.9)	6 (3.0)
Subcutaneous tissue	1 (0.6)	0
Other	6 (3.8)	13 (6.4)

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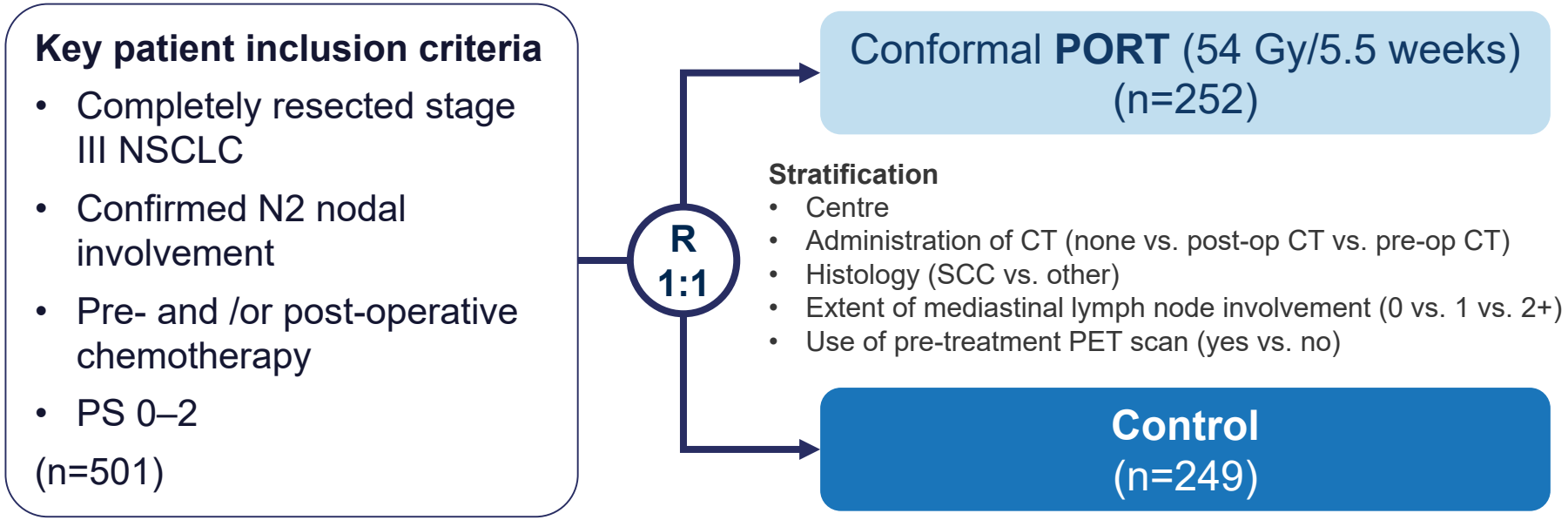
GECP lung cancer research

Felip E, et al. Ann Oncol 2021;32(suppl):Abstr LBA9 – ESMO 2021

Lung ART: Phase 3 randomized trial, comparing post-operative conformal radiotherapy (PORT) to no PORT, in patients with completely resected NSCLC and mediastinal N2 involvement

- **Study objective:** To investigate the survival benefit of post-operative radiotherapy in patients with mediastinal lymph node-positive NSCLC in the Lung ART study



Primary endpoint: DFS

Secondary endpoints

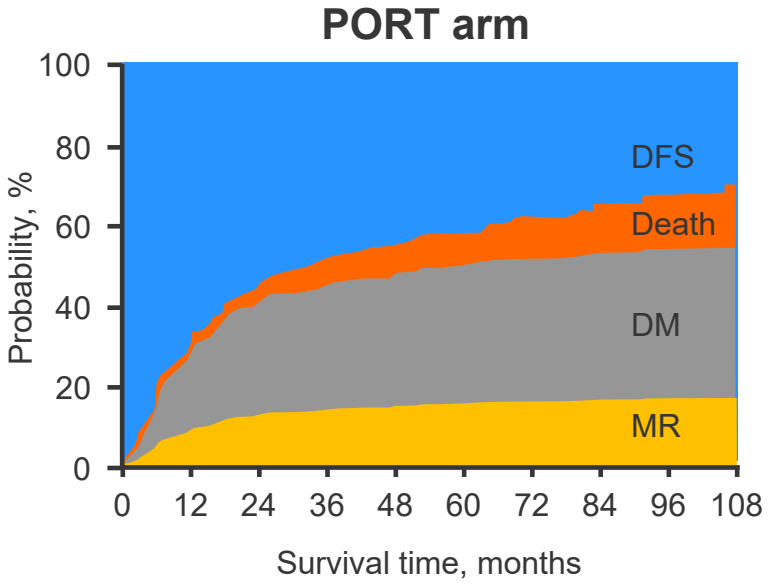
OS, patterns of relapse, local failure, second cancers, safety

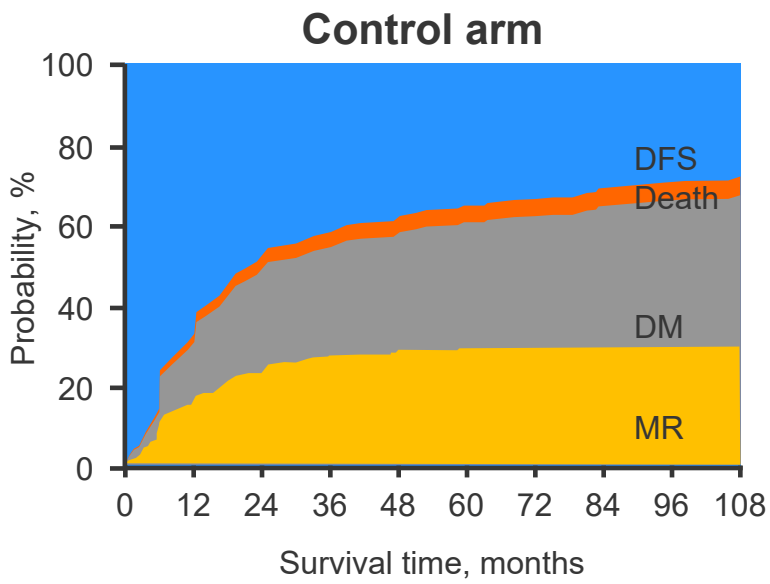
Organizado por: GECP lung cancer research

Le Pechoux C, et al. Ann Oncol 2021;32(suppl):Abstr 1170O – ESMO 2021

Lung ART: Phase 3 randomized trial, comparing post-operative conformal radiotherapy (PORT) to no PORT, in patients with completely resected NSCLC and mediastinal N2 involvement

Primary analysis





3-year DFS:
47.1% vs 43.8%, HR 0.86

Grade 3-4 AEs:
23.7% vs 15.0%

Event, n (%)	PORT (n=144)	Control (n=152)	Total (n=296)	HR (95%CI)[a]
Mediastinal relapse (MR)	36 (**25**)	70 (**46**)	106 (36)	**0.45** (0.30, 0.69)
All distant metastases (DM)	87 (60)	74 (49)	161 (54)	1.17 (0.86, 1.60)
Including brain metastases (BM)	34 (24)	27 (18)	61 (21)	1.33 (0.78, 2.26)
Death	21 (15)	8 (5)	29 (10)	2.63 (1.18, 5.84)

[a]Fine-Gray sub-distribution hazard model

Le Pechoux C, et al. Ann Oncol 2021;32(suppl):Abstr 1170O – ESMO 2021

Lung ART: An international randomized trial, comparing post-operative conformal radiotherapy (PORT) to no PORT, in patients with completely resected NSCLC and mediastinal N2 involvement

Prognostic factors for DFS	HR	p-value
Treatment arm radiotherapy (vs. control)	0.89	0.33
Gender female (vs. male)	0.73	0.02
Histology squamous cell carcinoma (vs. other)	0.71	0.03
N2 involvement with N1 involvement (left or right) (vs. without)	1.50	<0.01
Number of mediastinal nodes stations involved (vs. 1)		0.01
None	0.99	
≥2	1.46	
Quality of resection (vs. R0)		<0.001
R (uncertain)	1.29	
R1 (extra-capsular extension)	1.31	
R2[a]	1.95	

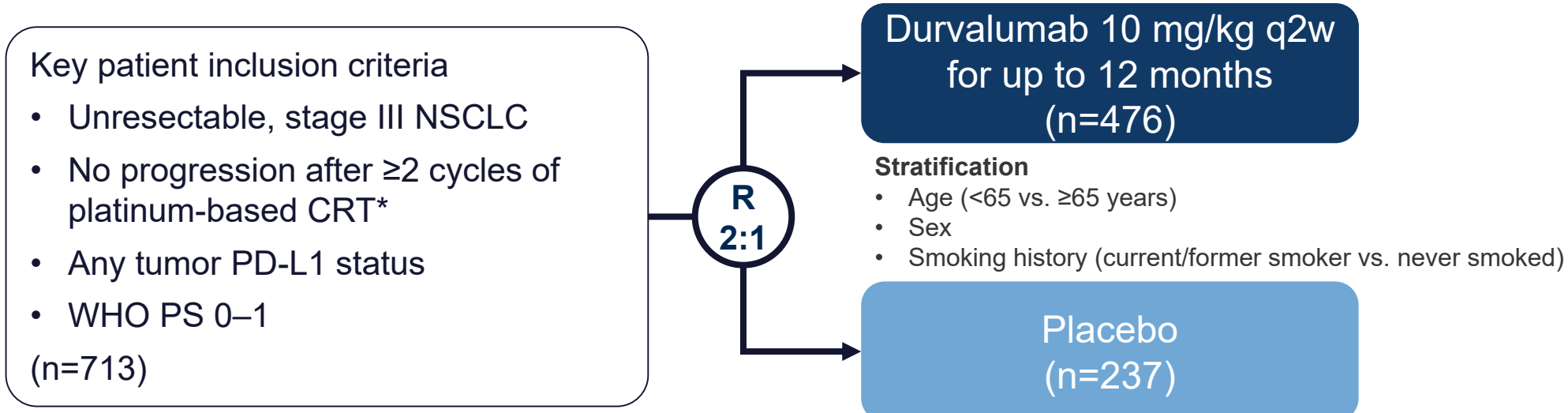
- In patients with completely resected NSCLC and mediastinal N2 involvement, use of post-operative radiotherapy reduced the risk of mediastinal recurrence, but had no significant impact on survival rate
- Prognostic factors associated with different DFS included quality of resection, extent of mediastinal involvement and lymph node ratio (involved/explored)

[b]Two patients should not have been included

Le Pechoux C, et al. Ann Oncol 2021;32(suppl):Abstr 1170O – ESMO 2021

Five-year survival outcomes with durvalumab after chemoradiotherapy in unresectable stage III NSCLC: An update from the PACIFIC trial

- **Study objective:** To evaluate the longer term efficacy and safety of durvalumab in patients with unresectable stage III NSCLC in PACFIC



Primary endpoints

- OS, PFS (RECIST v1.1, BICR)

Secondary endpoints

- ORR, DoR and TTDM (BICR), safety, PROs

*60–66 Gy in 30–33 fractions

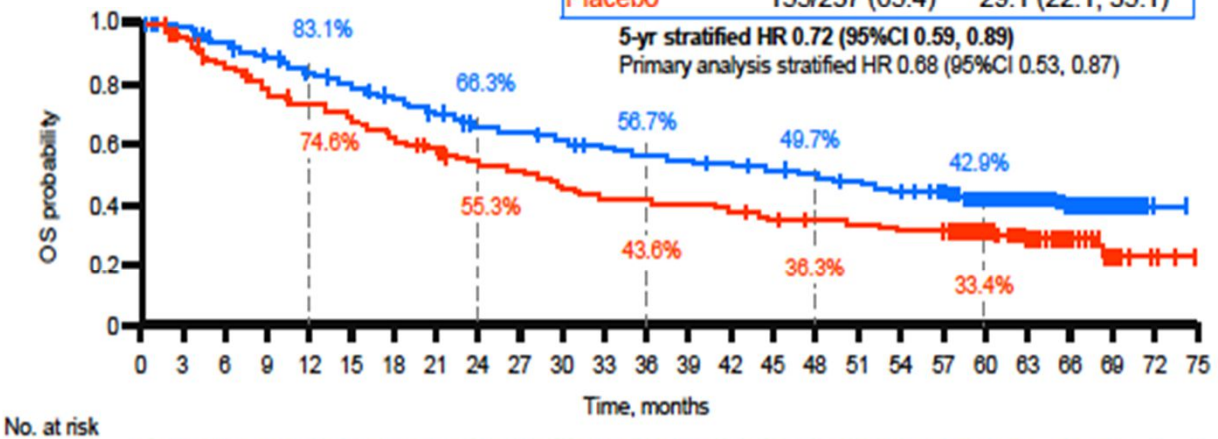
Spigel Dr, et al. J Clin Oncol 2021;39(suppl):Abstr 8511 – ASCO 2021

Five-year survival outcomes with durvalumab after chemoradiotherapy in unresectable stage III NSCLC: An update from the PACIFIC trial

Overall survival

	No. events/total patients, %	mOS, mo (95%CI)
Durvalumab	264/476 (55.5)	47.5 (38.1, 52.9)
Placebo	155/237 (65.4)	29.1 (22.1, 35.1)

5-yr stratified HR 0.72 (95%CI 0.59, 0.89)
Primary analysis stratified HR 0.68 (95%CI 0.53, 0.87)



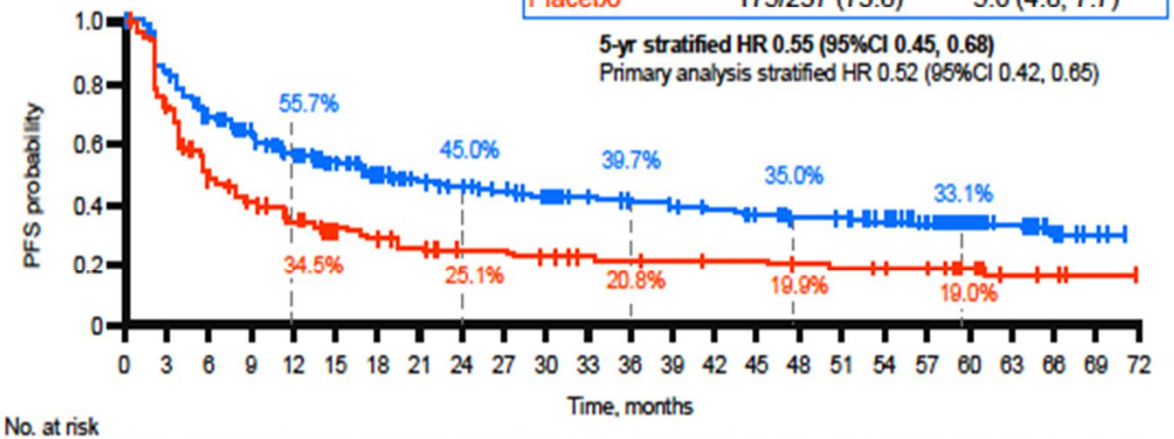
No. at risk

Durvalumab	476	464	431	414	385	364	343	319	298	289	273	264	252	241	236	227	218	207	196	183	134	91	40	18	2	0
Placebo	237	220	199	179	171	156	143	133	123	116	107	99	97	93	91	83	78	77	74	72	56	33	16	7	2	0

Progression-free survival

	No. events/total patients, %	mPFS mo (95%CI)
Durvalumab	268/476 (56.3)	16.9 (13.0, 23.9)
Placebo	175/237 (73.8)	5.6 (4.8, 7.7)

5-yr stratified HR 0.55 (95%CI 0.45, 0.68)
Primary analysis stratified HR 0.52 (95%CI 0.42, 0.65)



No. at risk

Durvalumab	476	377	301	267	215	190	165	147	137	128	119	110	103	97	92	85	81	78	67	57	34	22	11	5	0	
Placebo	237	164	105	87	68	56	48	41	37	36	30	27	26	25	24	24	22	21	19	19	14	6	4	1	0	

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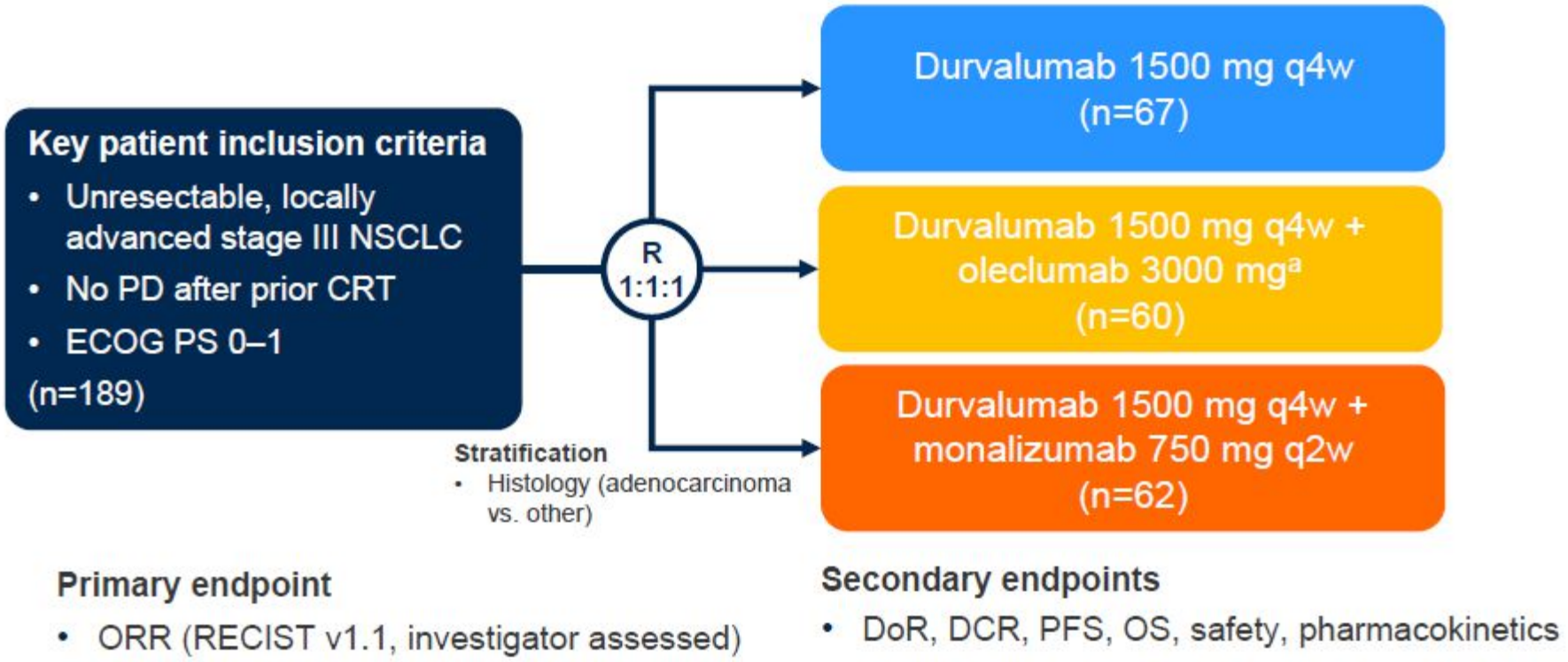
Spigel Dr, et al. J Clin Oncol 2021;39(suppl):Abstr 8511 – ASCO 2021

COAST: an open-label, randomised, phase 2 platform study of durvalumab alone or in combination with novel agents in patients with locally advanced, unresectable, stage III NSCLC



[a]Oleclumab q2w for cycle 1 or 2, then q4w starting cycle 3

Martinez-Marti A, et al. Ann Oncol 2021;32(suppl):Abstr LBA42 – ESMO 2021

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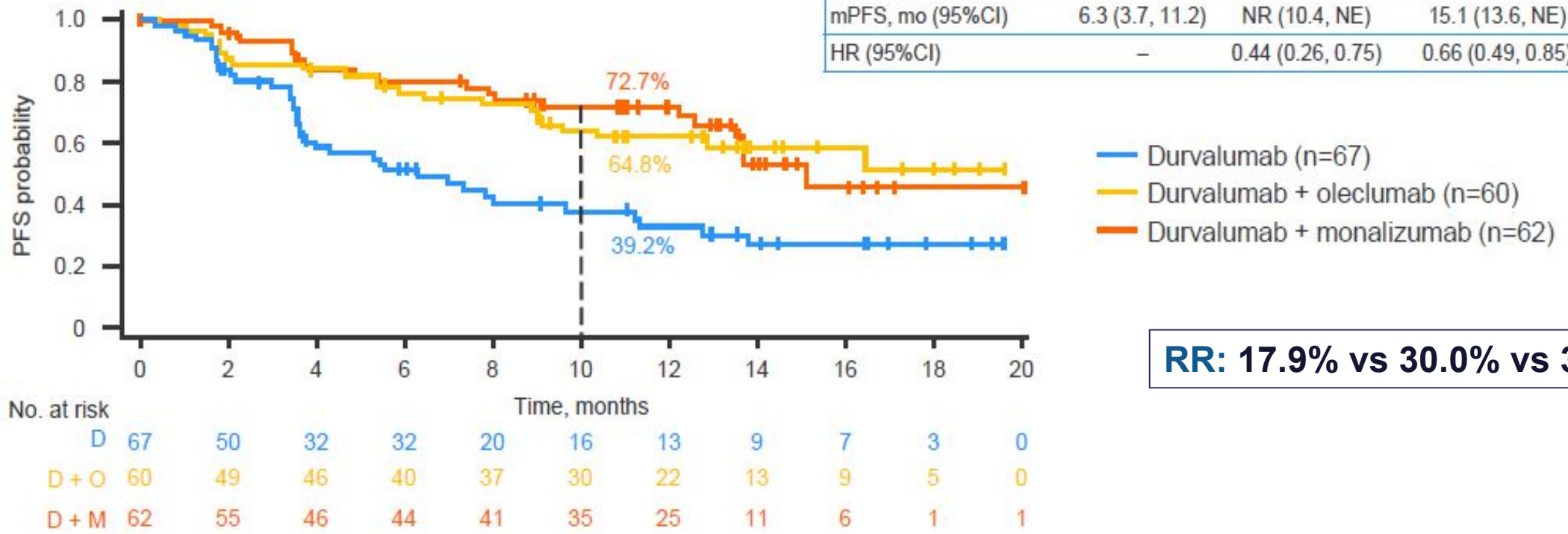
COAST: an open-label, randomised, phase 2 platform study of durvalumab alone or in combination with novel agents in patients with locally advanced, unresectable, stage III NSCLC

(Interim analysis; ITT population)

PFS by investigator assessment

	Durvalumab	Durvalumab + oleclumab	Durvalumab + monalizumab
Events/patients, n	38/67	22/60	21/62
mPFS, mo (95%CI)	6.3 (3.7, 11.2)	NR (10.4, NE)	15.1 (13.6, NE)
HR (95%CI)	–	0.44 (0.26, 0.75)	0.66 (0.49, 0.85)

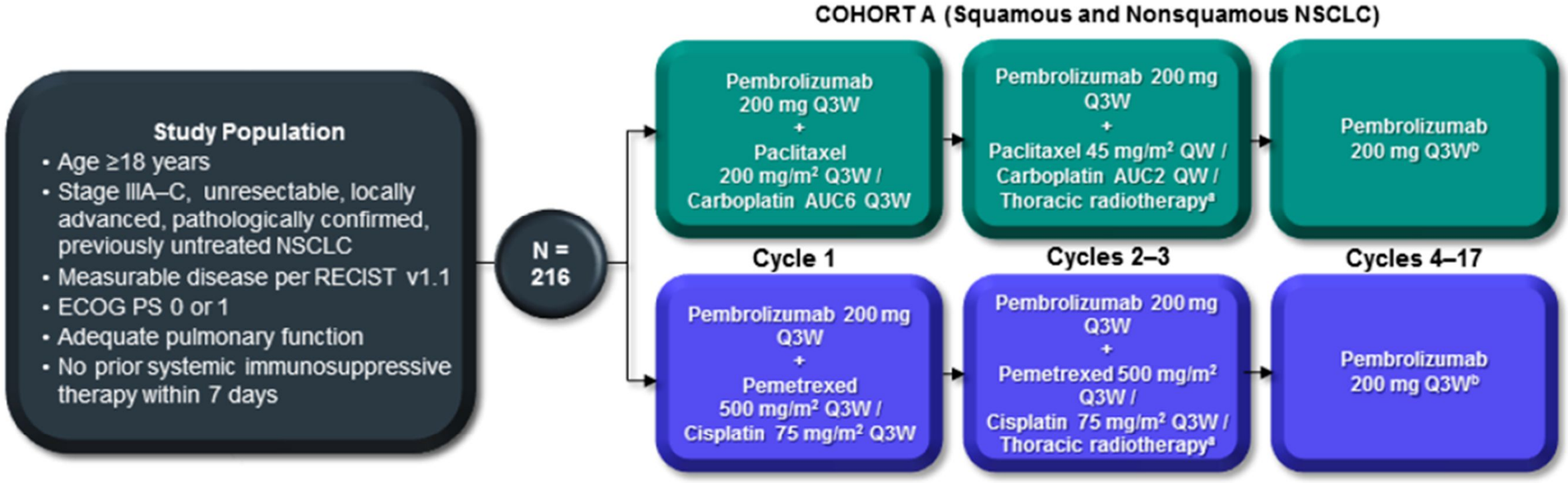


RR: 17.9% vs 30.0% vs 35.5%

In patients with stage III NSCLC, combined immunomodulation therapy including durvalumab provided additional ORR and PFS benefit over durvalumab monotherapy, with no new safety signals reported

Martinez-Marti A, et al. Ann Oncol 2021;32(suppl):Abstr LBA42 – ESMO 2021

KEYNOTE-799: Phase 2 trial, nonrandomized, open-label of Pembrolizumab plus platinum CT and RT for unresectable, LA, stage III NSCLC



Primary Objectives
- ORR per RECIST v1.1 by BICR
- Patients who develop grade ≥3 pneumonitis

Secondary Objectives
- PFS per RECIST v1.1 by BICR, OS, safety

Statistical Analysis Details
- Efficacy and safety assessed in all patients as-treated

NCT03631784

Jabbour SK, et al. ASCO 2021; Jabbour SK, et al. JAMA Oncol 2021

GECP lung cancer research

KEYNOTE-799: Phase 2 trial, nonrandomized, open-label of Pembrolizumab plus platinum CT and RT for unresectable, LA stage III NSCLC

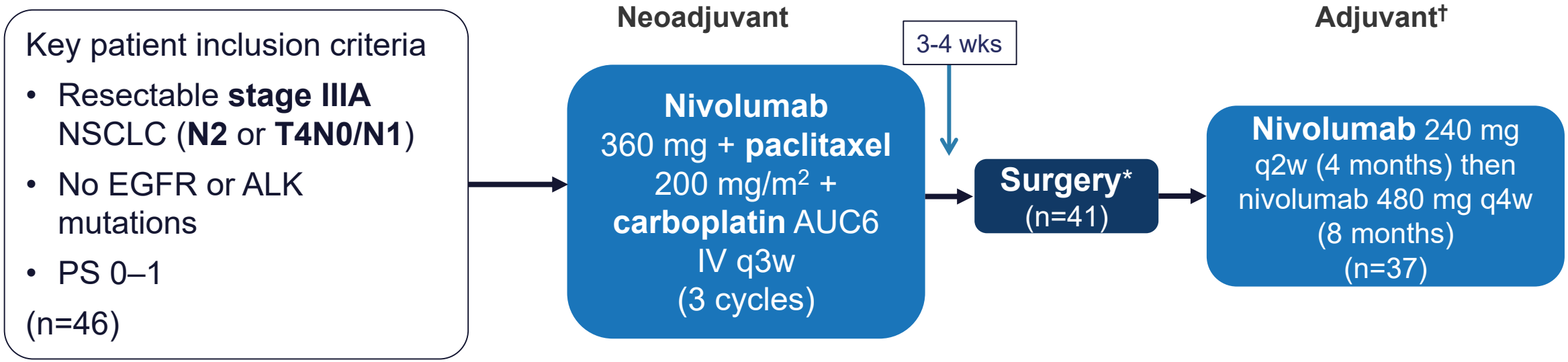
Total Population	Cohort A (Squamous and Nonsquamous) n = 112		Cohort B (Nonsquamous) n = 102	
ORR, % (95% CI)	**70.5 (61.2–78.8)**		**70.6 (60.7–79.2)**	
CR	4 (3.6)		5 (4.9)	
PR	75 (67.0)		67 (65.7)	
SD	20 (17.9)		23 (22.5)	
PD	1 (0.9)		0	
Not evaluable[a]/No assessment[b]	2 (1.8) / 10 (8.9)		0 / 7 (6.9)	
DOR, median (range),[c] mo	NR (1.7+ to 19.7+)		NR (1.8+ to 21.4+)	
DOR ≥12 mo,[c] %	79.7		75.6	
PFS,[c] median (95% CI), mo	NR (16.6–NR)		NR (NR–NR)	
12-mo PFS rate, %	67.1		71.6	
OS,[c] median (95% CI), mo	NR (NR–NR)		NR (21.9–NR)	
12-mo OS rate, %	81.3		87.0	
PD-L1 Status	**TPS <1% (n = 21)**	**TPS ≥1% (n = 66)**	**TPS <1% (n = 28)**	**TPS ≥1% (n = 40)**
ORR, n (%)	14 (66.7)	50 (75.8)	20 (71.4)	29 (72.5)
Histology	**Nonsquamous (n = 39)**	**Squamous (n = 73)**	**Nonsquamous (n = 102)**	**Squamous (n = 0)**
ORR, n (%)	27 (69.2)	52 (71.2)	72 (70.6)	NA

Jabbour SK, et al. ASCO 2021; Jabbour SK, et al. JAMA Oncol 2021

GECP lung cancer research

Phase 2 NADIM Study: Neoadjuvant Nivolumab + CT

- **Study objective:** To investigate the **efficacy** and **safety** of neoadjuvant nivolumab + paclitaxel-carboplatin followed by adjuvant nivolumab in patients with stage **IIIA** NSCLC



Primary endpoint

- 24-month PFS

Secondary endpoints

- OS, ORR, OS, TTP, cPR, MPR, dowstaging rate, safety

Exploratory endpoints

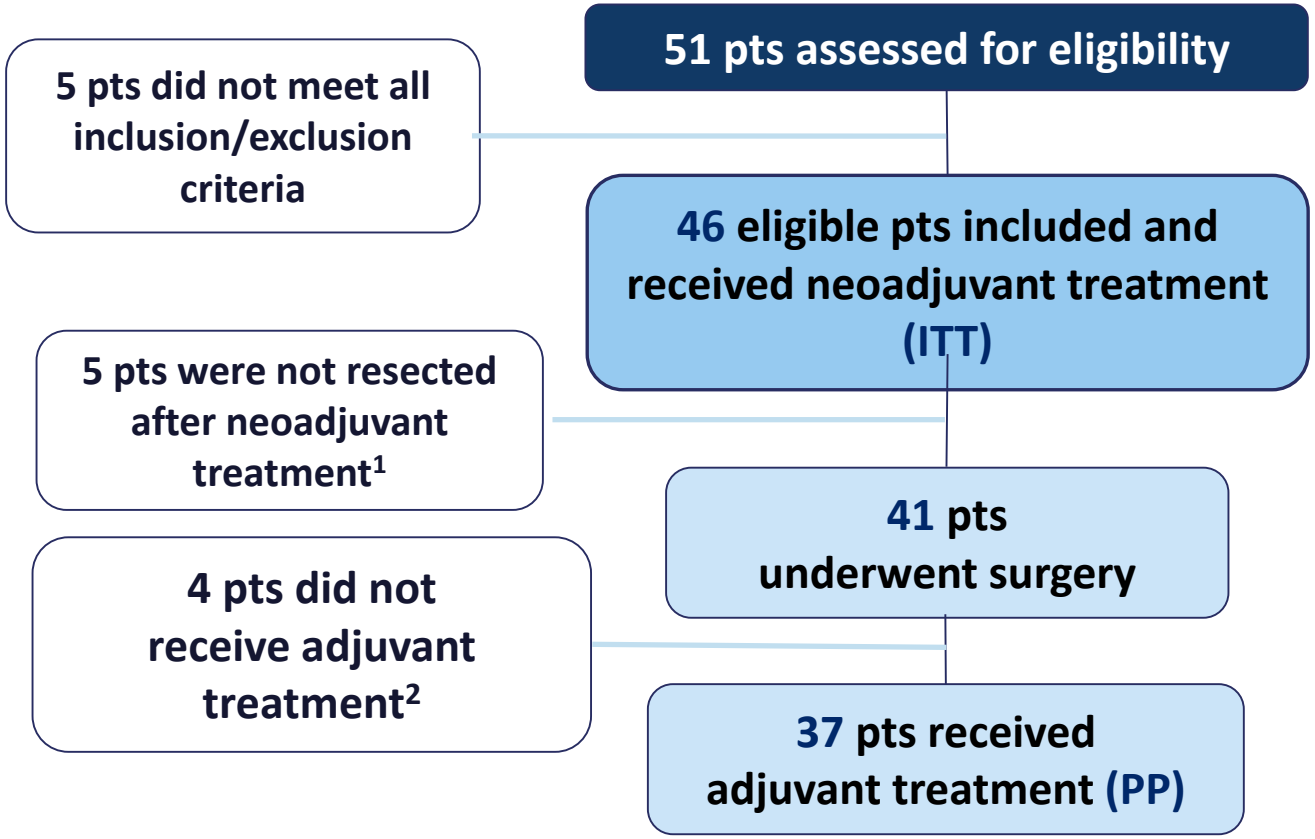
- Translational biomarkers, PD-L1, TMB, TILs, ctDNA

*In weeks 3 or 4 from D21 of cycle 3;
†within 3–8 weeks after surgical resection

Provencio M, et al. *Lancet Oncol* 2020; Provencio M, et al. *WCLC* 2021

Phase 2 NADIM Study

Patient Disposition



Patient baseline characteristics	N=46 (ITT)
Age (median, range)	63(41-77)
Male, N (%)	34 (74 %)
ECOG PS 0 N (%) 1 N (%)	 25 (54%) 21 (46%)
Smoking status, N (%) Former/current	 46 (100%)
Adenocarcinoma, N (%)	28 (61)
Co-morbidities, N (%)	43 (93,5)
N2	33 (89.2)
Multiple station	25 (75.8)

[1] Two patients were not resected due to their own decision, 3 patients did not fulfill resectability criteria according to the surgeons' opinion

[2] Three patients did not receive adjuvant treatment due to toxicity, 1 patient exceeded the time per protocol to start adjuvant treatment

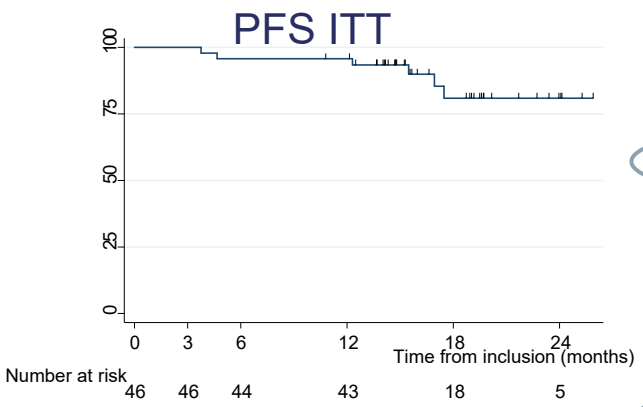
Provencio M, et al. *Lancet Oncol* 2020; Provencio M, et al. *WCLC* 2021

Organizado por GECP lung cancer research

Phase 2 NADIM Study: Results

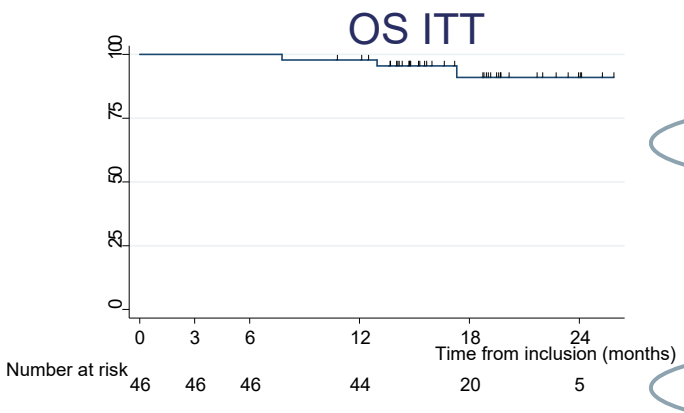
Response	n=41 (89%)
ORR, n (%)	35 (**76**)
CR	2 (**4**)
PR	33 (**72**)
SD	11 (**24**)
Pathological response, n (%) [95%CI]	
MPR	34 (**83**) [68, 93]
CR	24 (**63**) [62, 91]
>10% residual viable tumour	7 (**17**) [7, 32]

Surgery	N=41 (%)
Lobectomy	38 (92.7)
Pneumonectomy	3 (7.3)
R0 resection	41 (100)



PFS ITT population:
12-month PFS: 96%
24-month PFS: 77%
36-month PFS: 69.6%

PFS PP population:
PFS at 12 mo.: 100%
PFS at 24 mo.: 87.9%
PFS at 36 mo.: 81.1%



OS ITT population
12-month OS: 98%
24-month OS: 89.9%
36-month OS: 81.9%

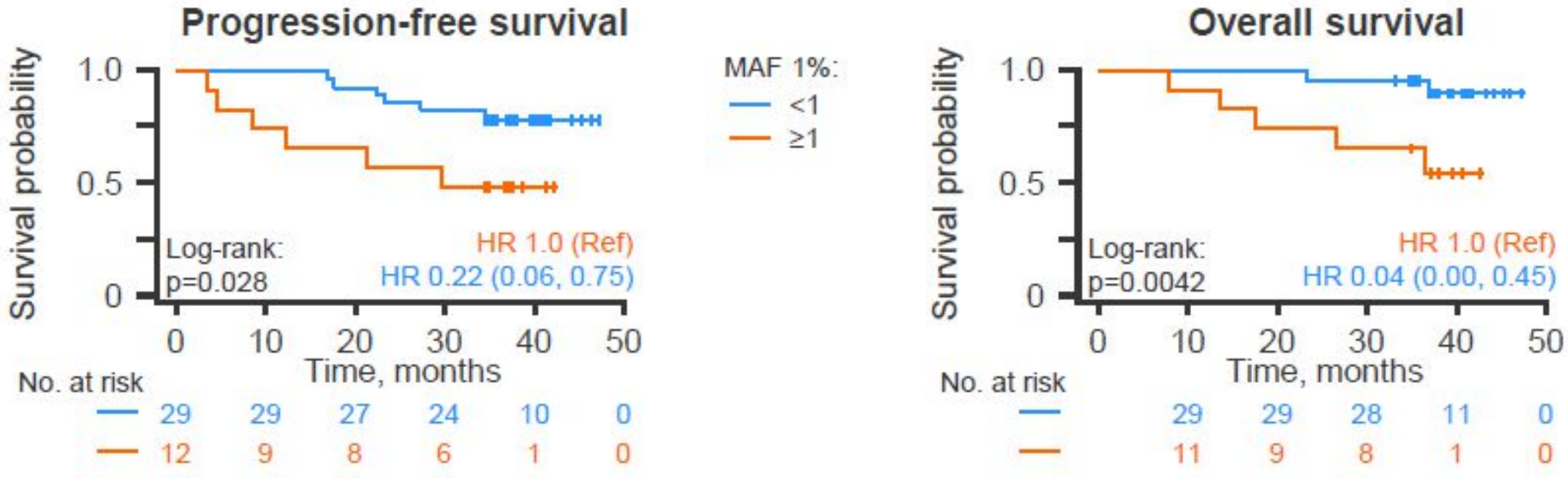
OS PP population:
OS at 12 mo.: 100%
OS at 24 mo.: 97.3%
OS at 36 mo.: 91.0%

lung cancer research

Provencio M, et al. *Lancet Oncol* 2020; Provencio M, et al. *WCLC* 2021

Pre-treatment levels of DNA for long-term survival prediction in stage IIIA NSCLC treated with neoadjuvant chemo-immunotherapy (NADIM)

Pre-treatment ctCNA levels



- Pre-treatment ctDNA analysis appears to be able to determine which patients are likely to be at a higher risk of progression
- Neither tumor cell PD-L1 nor TMB assessment were associated with survival outcome

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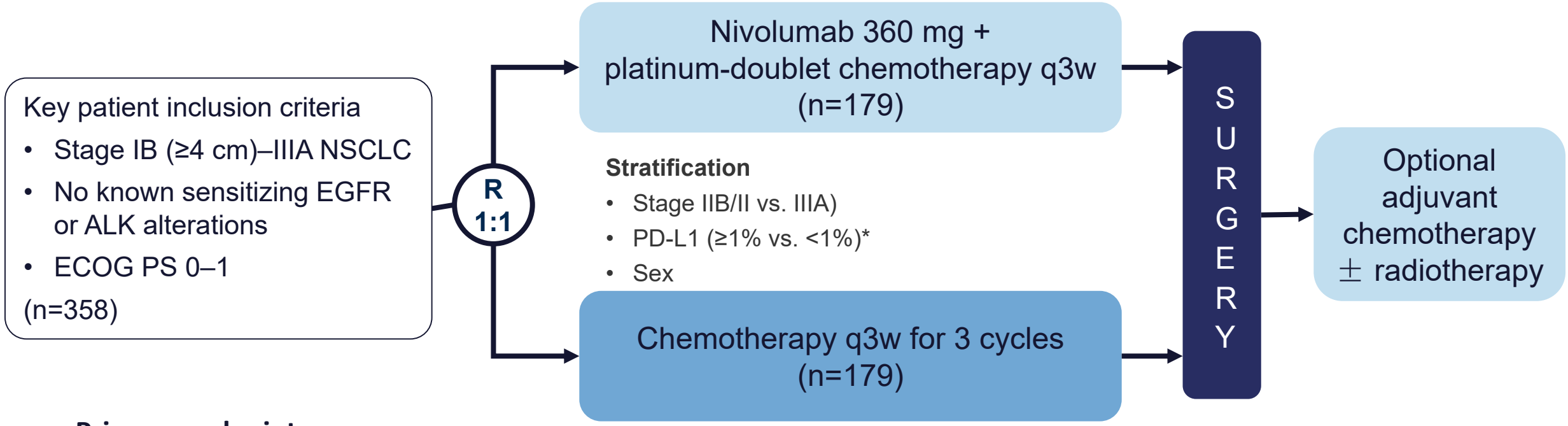
Romero A, et al. J Thorac Oncol 2021;16(suppl):Abstr OA20.02 – IASLC 2021

Phase 3 CheckMate 816 trial: Nivolumab + platinum-doublet CT vs CT alone as neoadjuvant treatment for patients with resectable NSCLC



Primary endpoints

- pCR (0% viable tumor cells in lung and lymph nodes),
- EFS by BICR

Secondary endpoints

- MPR, OS, Time To Death or distant metastases, safety

Exploratory endpoints

- ORR by BICR
- Predictive biomarkers (PD-L1, TMB, ctDNA)

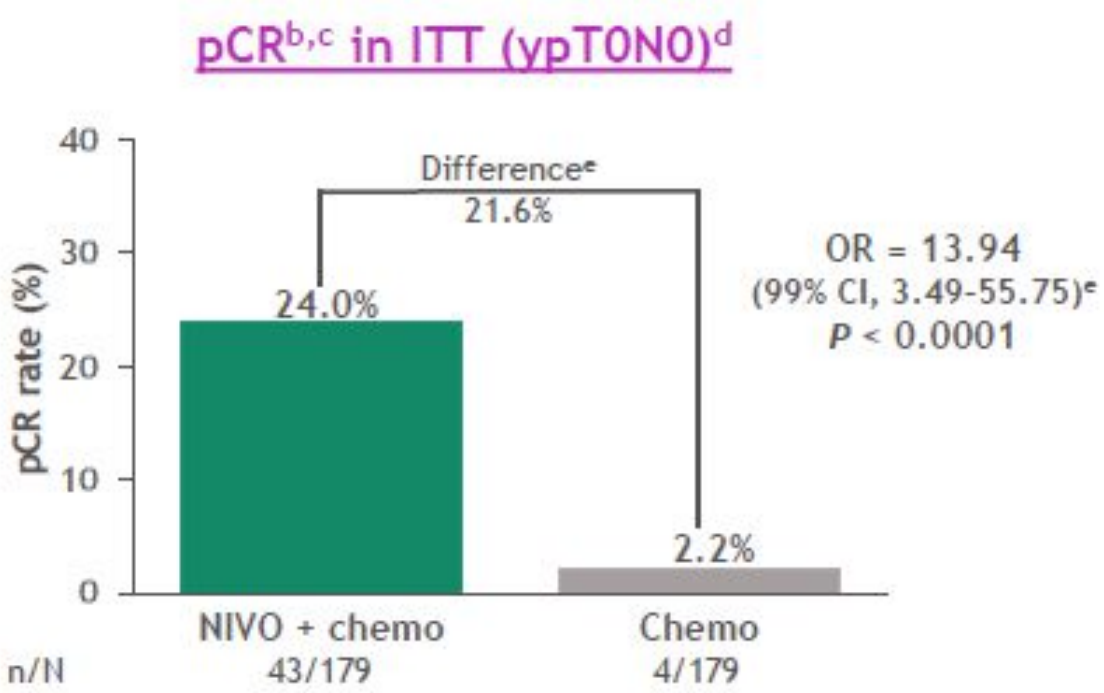
*Determined using IHC 28-8 pharmDx assay

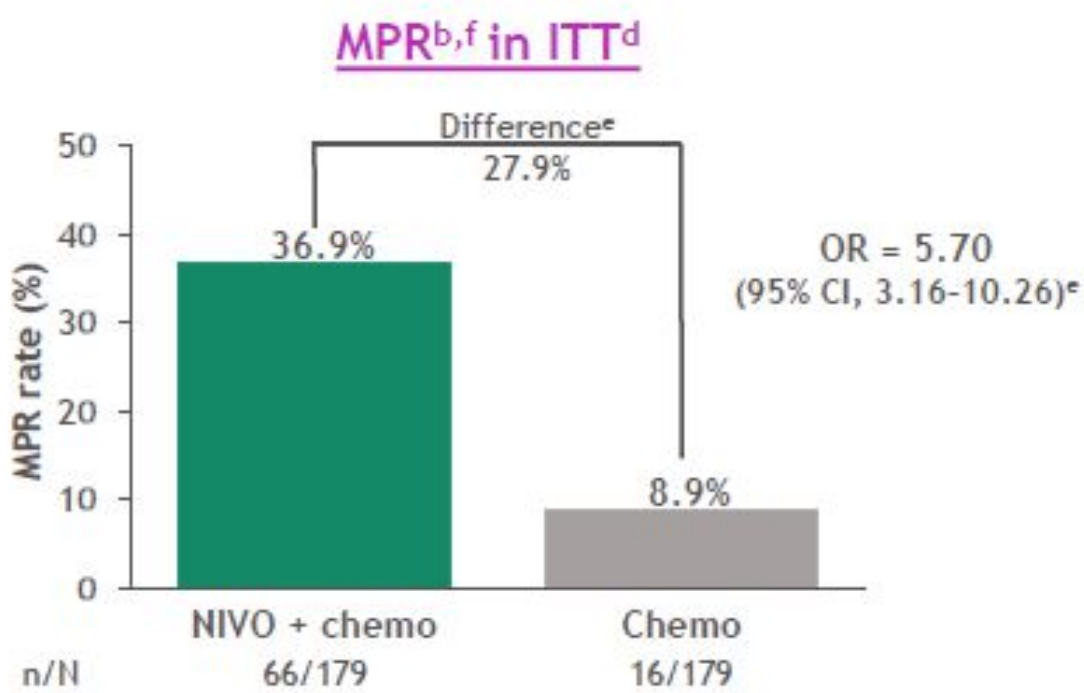
Forde PM, et al. AACR 2021; Spicer J, et al. J Clin Oncol 2021;39(suppl):Abstr 8503 – ASCO 2021

Organizado por: GECP lung cancer research

CheckMate 816:

pCR (primary endpoint) and **MPR** with neoadjuvant Nivo + CT vs CT





pCR in patients with resection: 30.5% vs. 3.2%

MPR in patients with resection: 46.8% vs. 12.7%

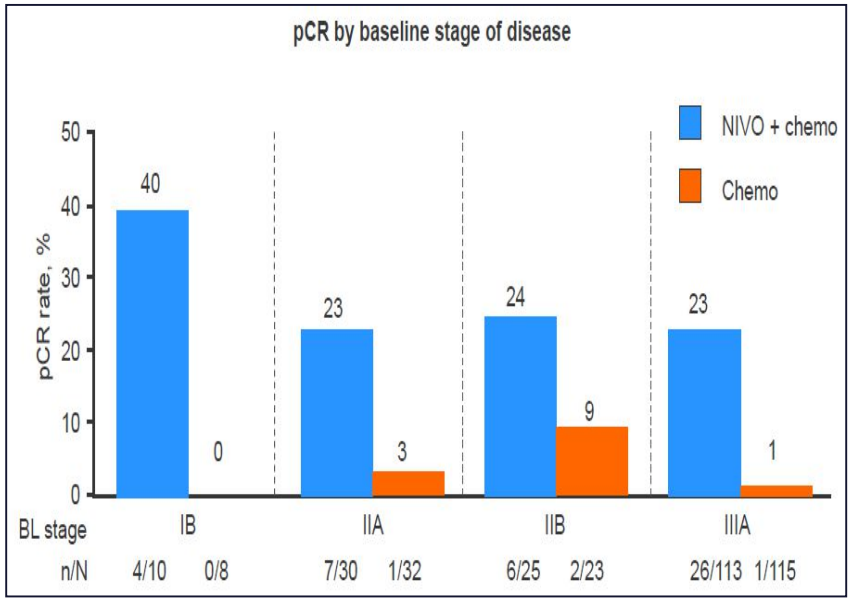
Median viable tumor cells:10% vs. 74%

Organizado por:

GECP lung cancer research

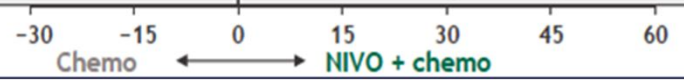
Forde PM, et al. AACR 2021; Spicer J, et al. J Clin Oncol 2021;39(suppl):Abstr 8503 – ASCO 2021

Phase 3 CheckMate 816 trial: Nivolumab + platinum-doublet CT vs CT alone as neoadjuvant treatment for patients with resectable NSCLC



pCR subgroup analysis

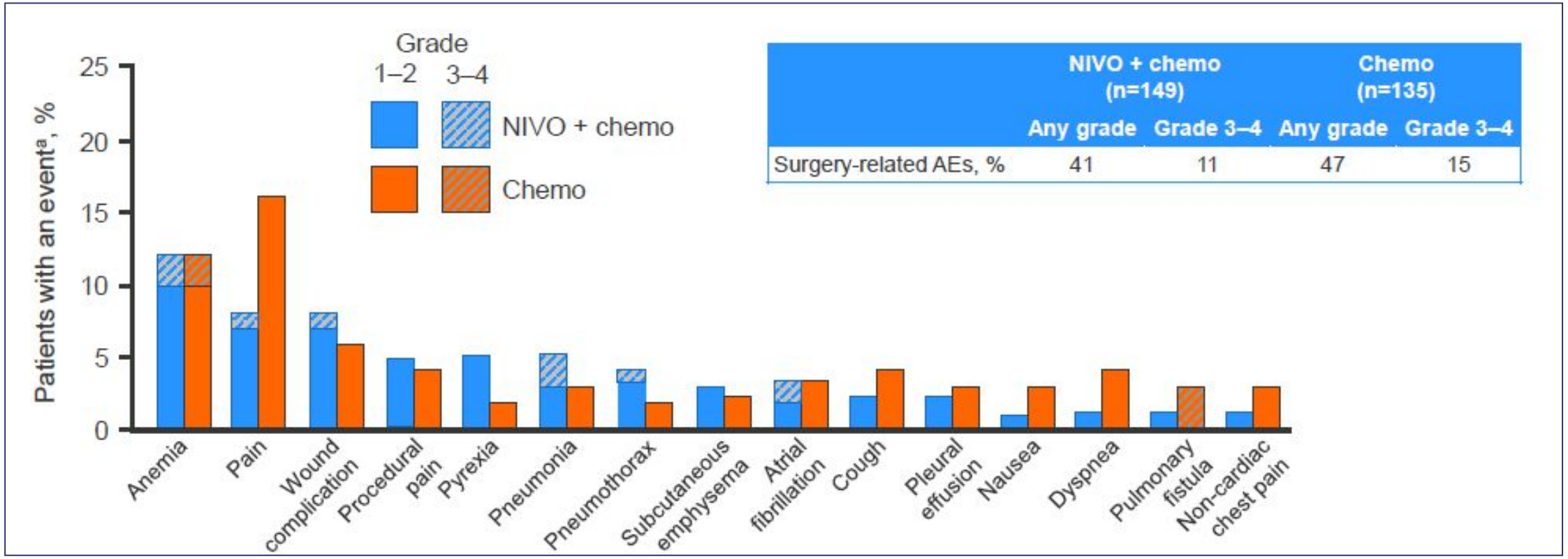
	pCR[a] rate, %		Unweighted pCR difference, % (95% CI)	Unweighted pCR difference, %
	NIVO + chemo (n = 179)	Chemo (n = 179)		
Overall (N = 358)	24	2		22
< 65 years (n = 176)	27	0		27
≥ 65 years (n = 182)	21	4		17
Male (n = 255)	23	2		20
Female (n = 103)	28	2		26
North America (n = 91)	22	2		20
Europe (n = 66)	24	0		24
Asia (n = 177)	28	3		25
Stage IB-II (n = 128)	**26**	**5**		**21**
Stage IIIA (n = 228)	**23**	**1**		**22**
Squamous (n = 182)	**25**	**4**		**21**
Non-squamous (n = 176)	**23**	**0**		**23**
Current/former smoker (n = 318)	26	2		23
Never smoker (n = 39)	10	0		10
PD-L1 < 1% (n = 155)	**17**	**3**		**14**
PD-L1 ≥ 1% (n = 178)	**33**	**2**		**30**
PD-L1 1-49% (n = 98)	24	0		24
PD-L1 ≥ 50% (n = 80)	45	5		40
TMB < 12.3 mut/Mb (n = 102)	22	2		21
TMB ≥ 12.3 mut/Mb (n = 76)	31	3		28
Cisplatin (n = 258)	22	2		20
Carboplatin (n = 72)	31	0		31



[a]Per BIPR in ITT.

Forde PM, et al. AACR 2021; Spicer J, et al. J Clin Oncol 2021;39(suppl):Abstr 8503 – ASCO 2021

Phase 3 CheckMate 816 trial: Nivolumab + platinum-doublet CT vs CT alone as neoadjuvant treatment for patients with resectable NSCLC



	NIVO + chemo (n=149)		Chemo (n=135)	
	Any grade	Grade 3–4	Any grade	Grade 3–4
Surgery-related AEs, %	41	11	47	15

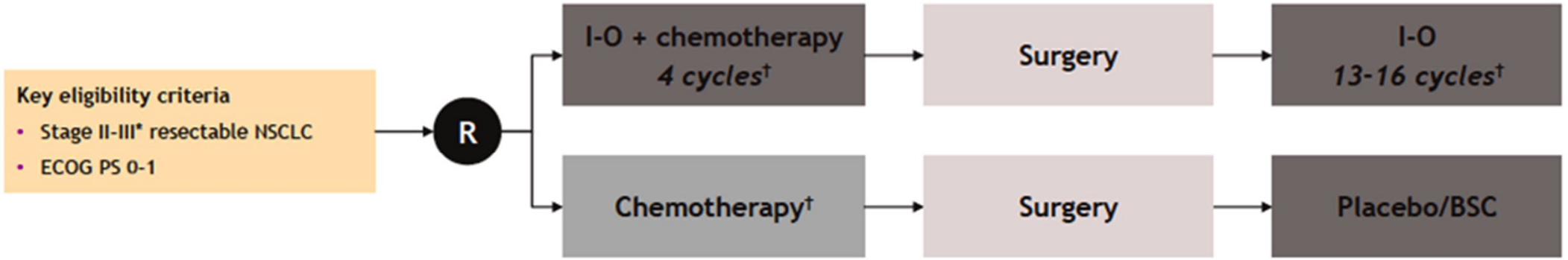
In patients with resectable NSCLC, neoadjuvant nivolumab + chemotherapy showed a significant improvement in pCR rates and depth of pathological response compared with chemotherapy alone and was generally well-tolerated with no increase in postoperative complications

Organizado por: GECP lung cancer research

Forde PM, et al. AACR 2021; Spicer J, et al. J Clin Oncol 2021;39(suppl):Abstr 8503 – ASCO 2021

Ongoing phase 3 perioperative studies with I-O in resectable NSCLC

Checkmate 77T, KEYNOTE-671, IMpower030, AEGEAN[1-5]



	Checkmate 77T[1]	KEYNOTE-671[2]	IMpower030[3]	AEGEAN[4,5]
I-O agent	Nivolumab	Pembrolizumab	Atezolizumab	Durvalumab
Primary endpoint(s)	EFS	EFS, OS	MPR, EFS	MPR, EFS
Primary completion date	December 2023	January 2024	November 2024	January 2024
Stages	IIA-IIIB‡	II-IIIB‡	II-IIIB‡	IIA-IIIB‡
Target enrollment	452	786	450	300

Cross-trial comparisons are not intended.
*Stages included differ between trials. †Dosage, timing, duration, and chemotherapy backbones differ between trials; information not available for Checkmate 77T or AEGEAN.
‡Includes stages IIIB patients with N2 disease that is considered resectable.
1. Clinicaltrials.gov. NCT04025879. Accessed December 10, 2020. 2. Clinicaltrials.gov. NCT03425643. Accessed December 10, 2020. 3. Clinicaltrials.gov. NCT03456063. Accessed December 10, 2020. 4. Clinicaltrials.gov. NCT03800134. Accessed December 10, 2020. 5. Heymach JV et al. Poster presentation at WCLC 2019. Abstract P1.18-02.