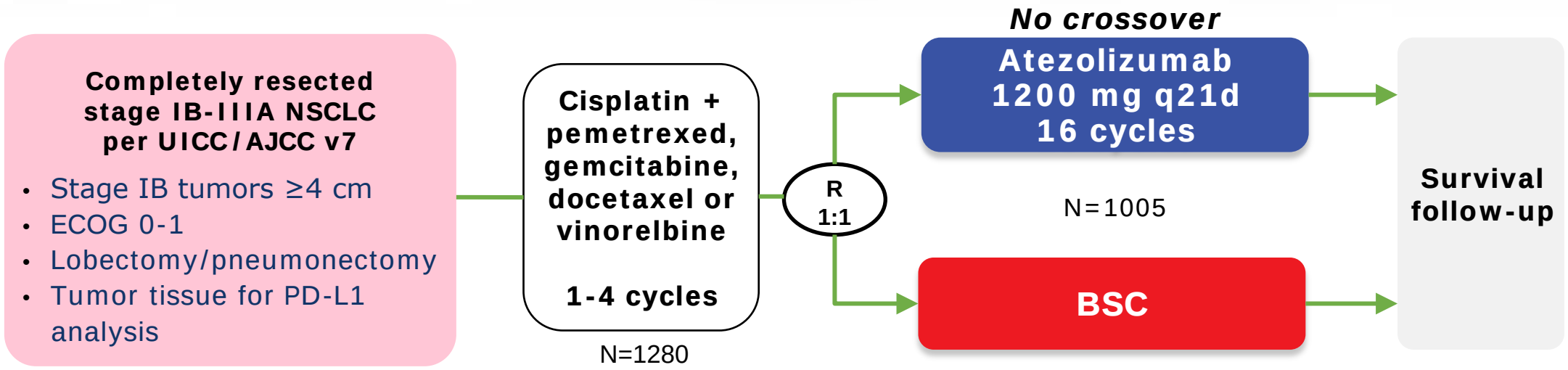
IMpower010: Adjuvant Atezolizumab after adjuvant chemotherapy in resected stage IB - IIIA non-small cell lung cancer

IMpower010 Phase III, multicentre, open-label, randomised study



Stratification factors

- Male/female
- Stage (IB vs II vs IIIA)
- Histology
- PD-L1 tumor expression status[a]: TC2/3 and any IC vs TC0/1 and IC2/3 vs TC0/1 and IC0/1

Primary endpoints

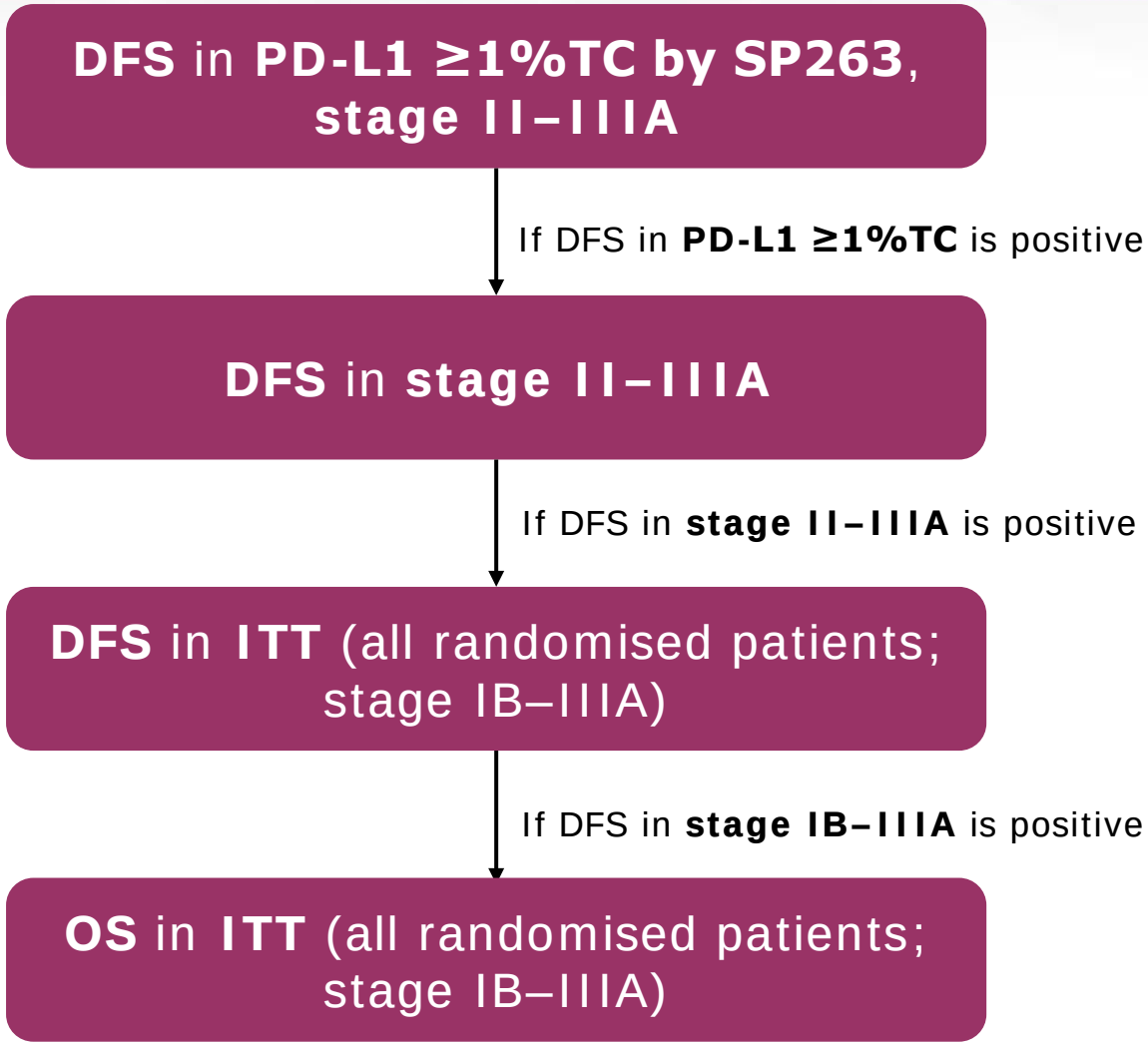
- Investigator-assessed DFS tested hierarchically:
  - PD-L1 TC ≥1% (per SP263) stage II-IIIA population
  - All-randomized stage II-IIIA population
  - ITT population (stage IB-IIIA)

Key secondary endpoints

- OS in ITT population
- DFS in PD-L1 TC ≥50% (per SP263) stage II-IIIA population
- 3-y and 5-y DFS in all 3 populations

Both arms included observation and regular scans for disease recurrence on the same schedule.
ECOG, Eastern Cooperative Oncology Group; IC, tumor-infiltrating immune cells; ITT, intent to treat; TC, tumor cells. [a] Per SP142 assay.

IMpower010 statistical analysis plan



The primary DFS endpoint was tested hierarchically in 3 primary analysis populations

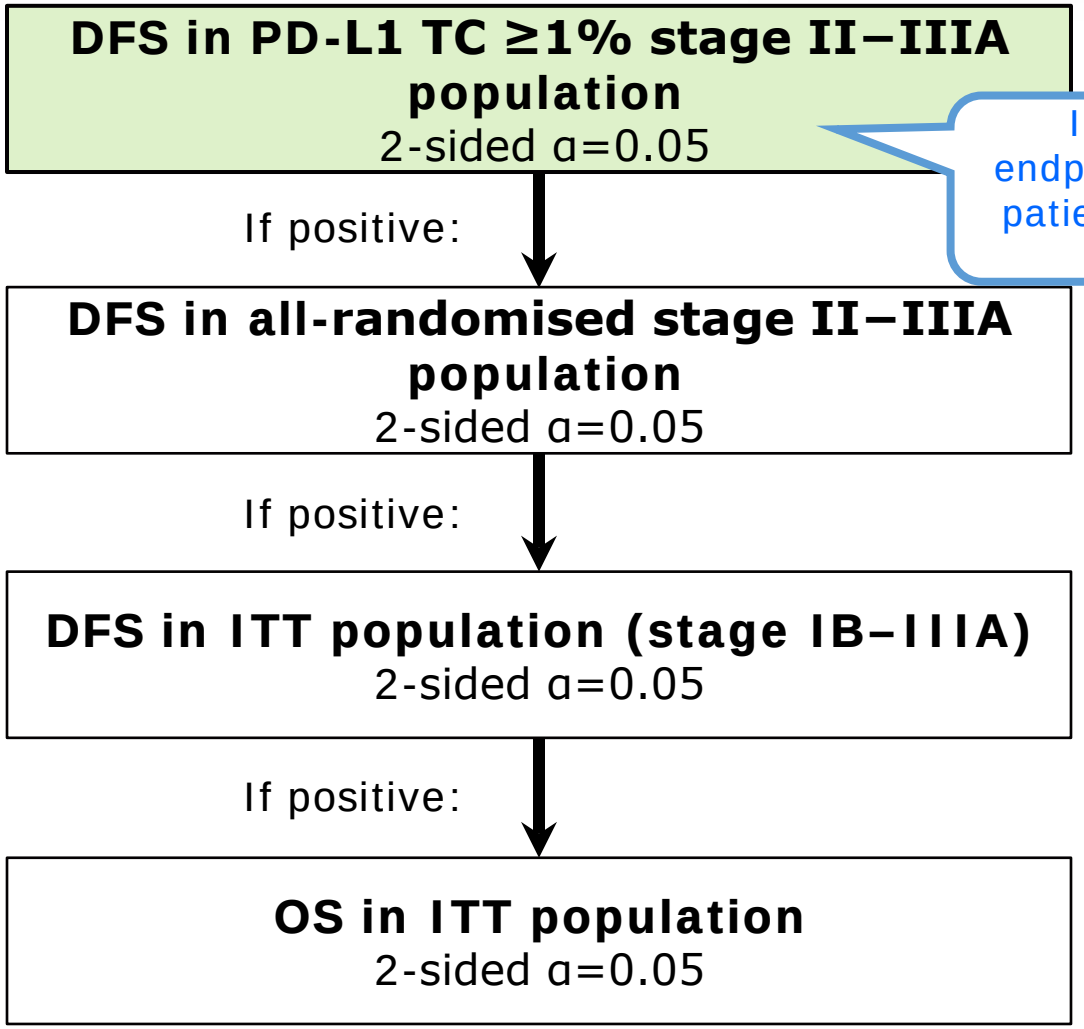
IMpower010 study protocol, version 8 (11 February 2020)
IMpower010 statistical analysis plan (30 June 2020)

IMpower010- baseline characteristics

Characteristic	All patients (N=1005)	PD-L1 TC ≥1% (SP263) (stage II-IIIA)		All randomized (stage II-IIIA)		ITT (stage IB-IIIA)	
		Atezolizumab (n=248)	BSC (n=228)	Atezolizumab (n=442)	BSC (n=440)	Atezolizumab (n=507)	BSC (n=498)
Median (range) age, y	**62 (26-84)**	61 (34–82)	62 (26–84)	62 (33–82)	62 (26–84)	62 (33–83)	62 (26–84)
Age ≥65 y, n (%)	**382 (38.0)**	92 (37.1)	97 (42.5)	161 (36.4)	177 (40.2)	184 (36.3)	198 (39.8)
Sex, male, n (%)	**672 (66.9)**	171 (69.0)	147 (64.5)	295 (66.7)	294 (66.8)	337 (66.5)	335 (67.3)
Race, n (%)							
White	**738 (73.4)**	162 (65.3)	166 (72.8)	307 (69.5)	324 (73.6)	362 (71.4)	376 (75.5)
Asian	**242 (24.1)**	78 (31.5)	56 (24.6)	121 (27.4)	106 (24.1)	130 (25.6)	112 (22.5)
Other	**25 (2.5)**	8 (3.2)	6 (2.6)	14 (3.2)	10 (2.3)	15 (3.0)	10 (2.0)
ECOG PS, n (%)							
0	**556 (55.3)**	140 (56.5)	125 (54.8)	239 (54.1)	252 (57.3)	273 (53.8)	283 (56.8)
1	**446 (44.4)**	107 (43.1)	102 (44.7)	201 (45.5)	187 (42.5)	232 (45.8)	214 (43.0)
Histology, non-squamous, n (%)	**659 (65.6)**	152 (61.3)	143 (62.7)	292 (66.1)	296 (67.3)	328 (64.7)	331 (66.5)
Stage, n (%)							
IB	**123 (12.2)**	–	–	–	–	65 (12.8)	58 (11.6)
IIA	**295 (29.4)**	85 (34.3)	76 (33.3)	147 (33.3)	148 (33.6)	147 (29.0)	148 (29.7)
IIB	**174 (17.3)**	46 (18.5)	37 (16.2)	90 (20.4)	84 (19.1)	90 (17.8)	84 (16.9)
IIIA	**413 (41.1)**	117 (47.2)	115 (50.4)	205 (46.4)	208 (47.3)	205 (40.4)	208 (41.8)
Tobacco use history, n (%)							
Never	**222 (22.1)**	51 (20.6)	41 (18.0)	100 (22.6)	96 (21.8)	114 (22.5)	108 (21.7)
Current/previous	**783 (77.9)**	197 (79.4)	187 (82.0)	342 (77.4)	344 (78.2)	393 (77.5)	390 (78.3)
PD-L1 by SP263, TC≥1%, n (%)[a]	**535 (54.6)**	248 (100)	228 (100)	248 (57.8)	228 (53.0)	283 (57.4)	252 (51.9)
EGFR mutation status, n (%)[b]							
Positive	**117 (11.6)**	23 (9.3)	20 (8.8)	49 (11.1)	60 (13.6)	53 (10.5)	64 (12.9)
Negative	**527 (52.4)**	123 (49.6)	125 (54.8)	229 (51.8)	234 (53.2)	261 (51.5)	266 (53.4)
Unknown[c]	**361 (35.9)**	102 (41.1)	83 (36.4)	164 (37.1)	146 (33.2)	193 (38.1)	168 (33.7)
ALK rearrangement status, n (%)[b]							
Positive	**33 (3.3)**	12 (4.8)	11 (4.8)	14 (3.2)	17 (3.9)	15 (3.0)	18 (3.6)
Negative	**574 (57.1)**	133 (53.6)	121 (53.1)	251 (56.8)	256 (58.2)	280 (55.2)	294 (59.0)
Unknown[c]	**398 (39.6)**	103 (41.5)	96 (42.1)	177 (40.0)	167 (38.0)	212 (41.8)	186 (37.3)

Clinical cutoff: January 21, 2021. [a] 26 patients in the ITT population had unknown PD-L1 status as assessed by SP263. [b] For patients with non-squamous NSCLC, *EGFR/ALK* status was assessed locally or centrally. [c] 89.2% of patients with unknown *EGFR* status and 80.7% of patients with unknown *ALK* status in the ITT population had squamous NSCLC and were not required to undergo local or central testing.

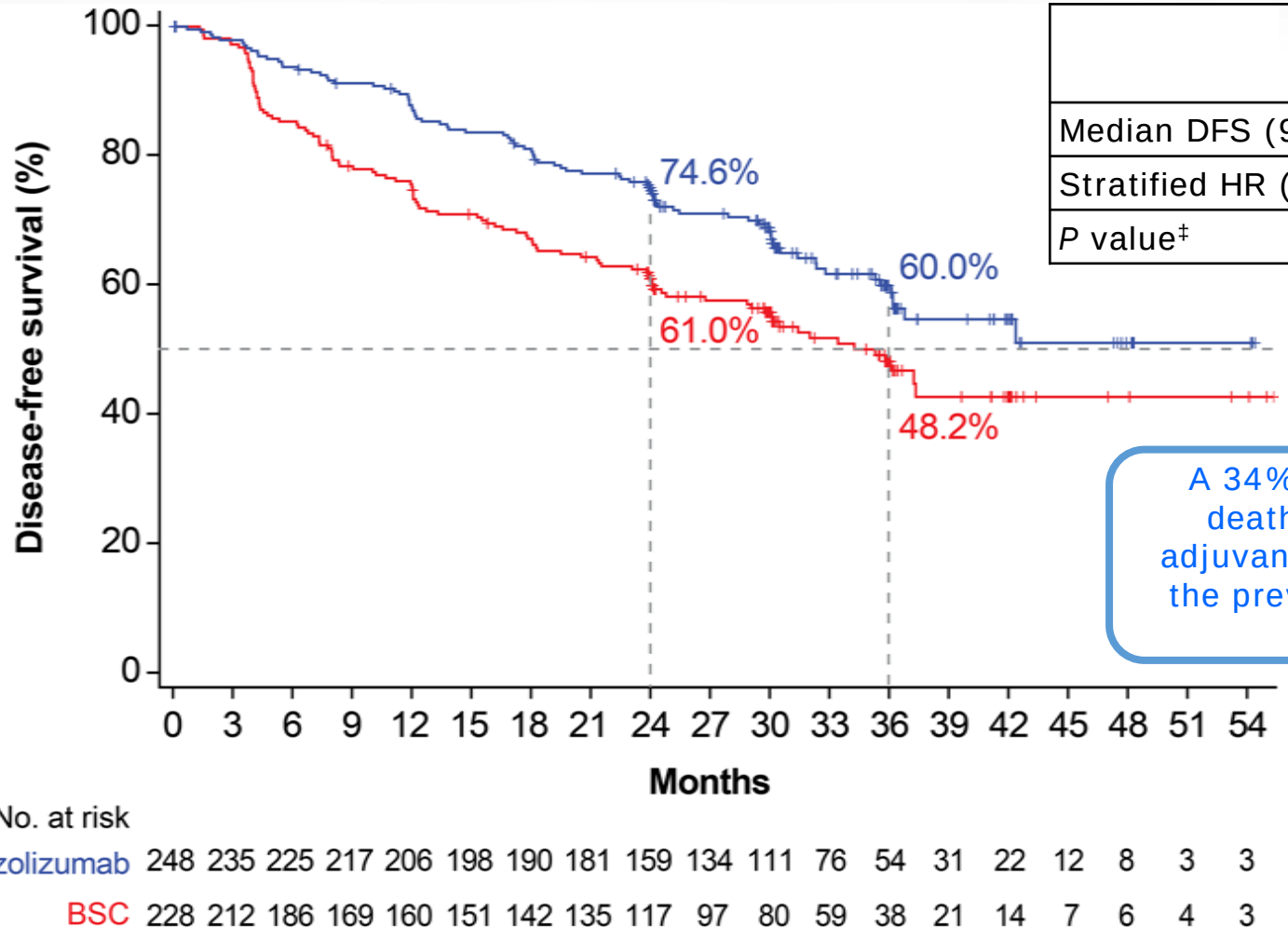
First, the primary DFS endpoint was tested in the PD-L1 TC ≥1% stage II–IIIA population



IMpower010 met its primary endpoint of improved DFS vs BSC in patients with PD-L1 TC ≥1%, stage II–IIIA NSCLC

Wakelee, et al. ASCO 2021 (Abs 8500); Felip, et al. Lancet 2021

A DFS benefit was observed in the PD-L1 TC ≥1%* stage II–IIIA population (primary endpoint)



	Atezolizumab (n=248)	BSC (n=228)
Median DFS (95% CI), mo	NE (36.1, NE)	35.3 (29.0, NE)
Stratified HR (95% CI)	0.66 (0.50, 0.88)	
P value‡	0.004§	

Median follow-up: 32.8 mo (range, 0.1–57.5)

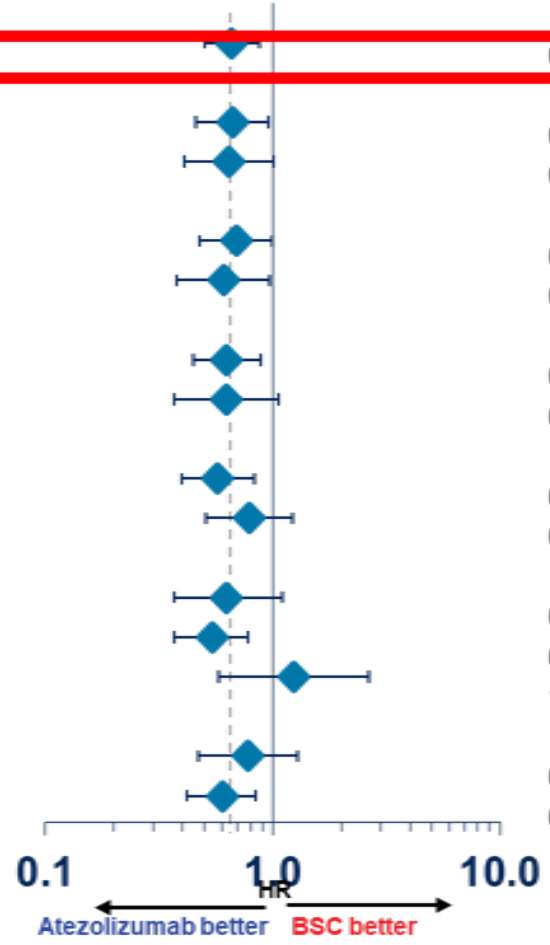
A 34% reduction in risk of disease recurrence or death was observed in patients randomised to adjuvant atezolizumab. This benefit is *in addition* to the previously established benefit achieved by SoC chemotherapy alone

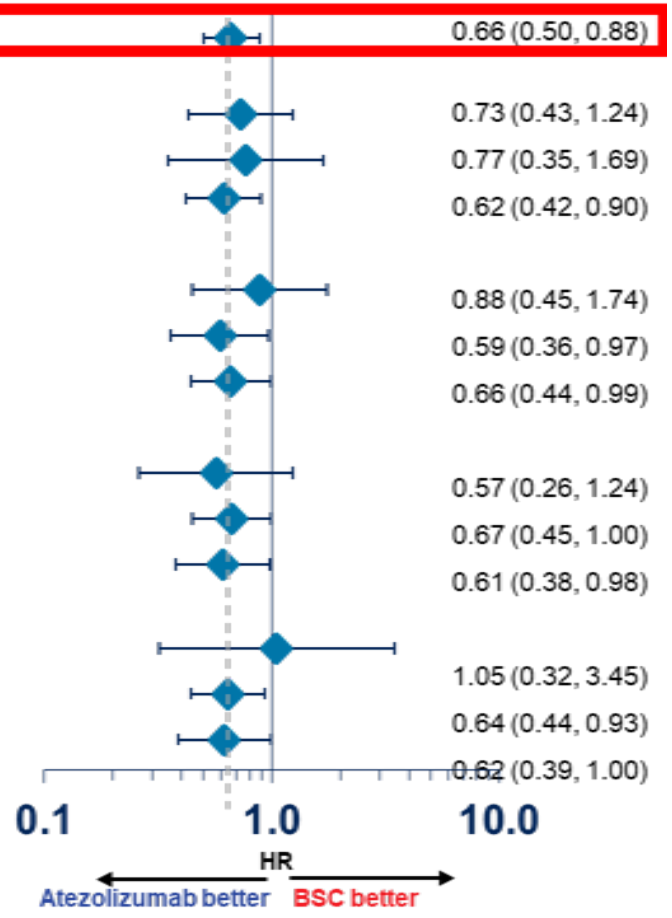
Clinical cut-off: 21 January 2021. NE, not evaluable. *Per SP263 assay.
‡Stratified log-rank. §Crossed the significance boundary for DFS

Wakelee, et al. ASCO 2021 (Abs 8500);
Felip, et al. Lancet 2021

A DFS benefit was consistently observed across in key subgroups of the PD-L1 TC ≥1%* stage II–IIIA population

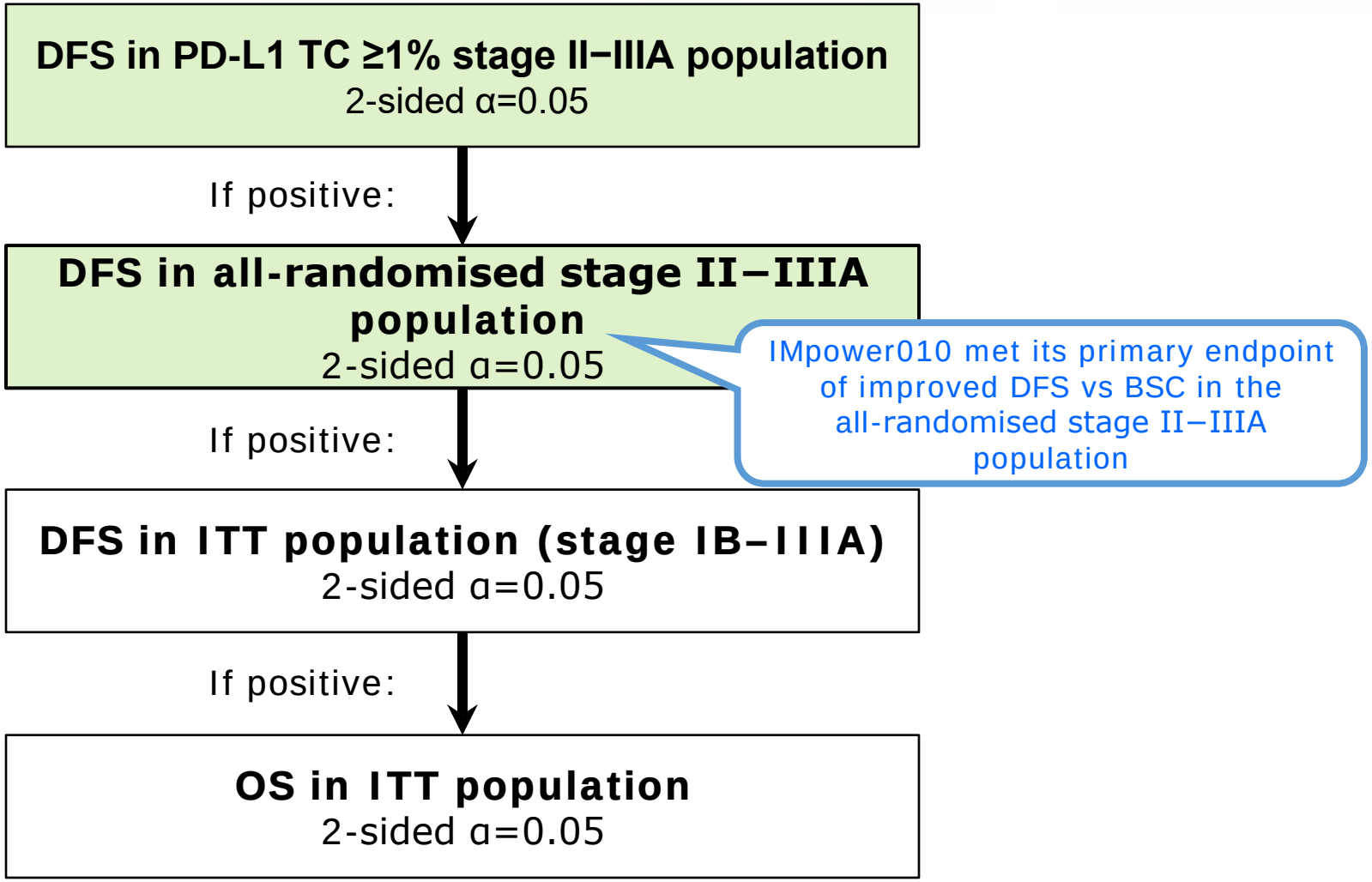
Subgroup	N	HR (95% CI)[b]
All patients	476	0.66 (0.50, 0.88)
Age		
<65 y	287	0.67 (0.46, 0.96)
≥65 y	189	0.64 (0.41, 1.01)
Sex		
Male	318	0.69 (0.48, 0.99)
Female	158	0.61 (0.38, 0.97)
Race		
White	328	0.63 (0.45, 0.89)
Asian	134	0.63 (0.37, 1.06)
ECOG PS		
0	265	0.57 (0.40, 0.83)
1	209	0.79 (0.51, 1.23)
Tobacco use history		
Never	92	0.63 (0.37, 1.10)
Previous	309	0.54 (0.37, 0.78)
Current	75	1.24 (0.58, 2.64)
Histology		
Squamous	181	0.78 (0.47, 1.29)
Non-squamous	295	0.60 (0.42, 0.84)
All patients	476	0.66 (0.50, 0.88)
Stage		
IIA	161	0.73 (0.43, 1.24)
IIB	83	0.77 (0.35, 1.69)
IIIA	232	0.62 (0.42, 0.90)
Regional lymph node stage (pN)		
N0	106	0.88 (0.45, 1.74)
N1	194	0.59 (0.36, 0.97)
N2	176	0.66 (0.44, 0.99)
***EGFR* mutation status**		
Yes	43	0.57 (0.26, 1.24)
No	248	0.67 (0.45, 1.00)
Unknown[c]	185	0.61 (0.38, 0.98)
***ALK* rearrangement status**		
Yes	23	1.05 (0.32, 3.45)
No	254	0.64 (0.44, 0.93)
Unknown[c]	199	0.62 (0.39, 1.00)





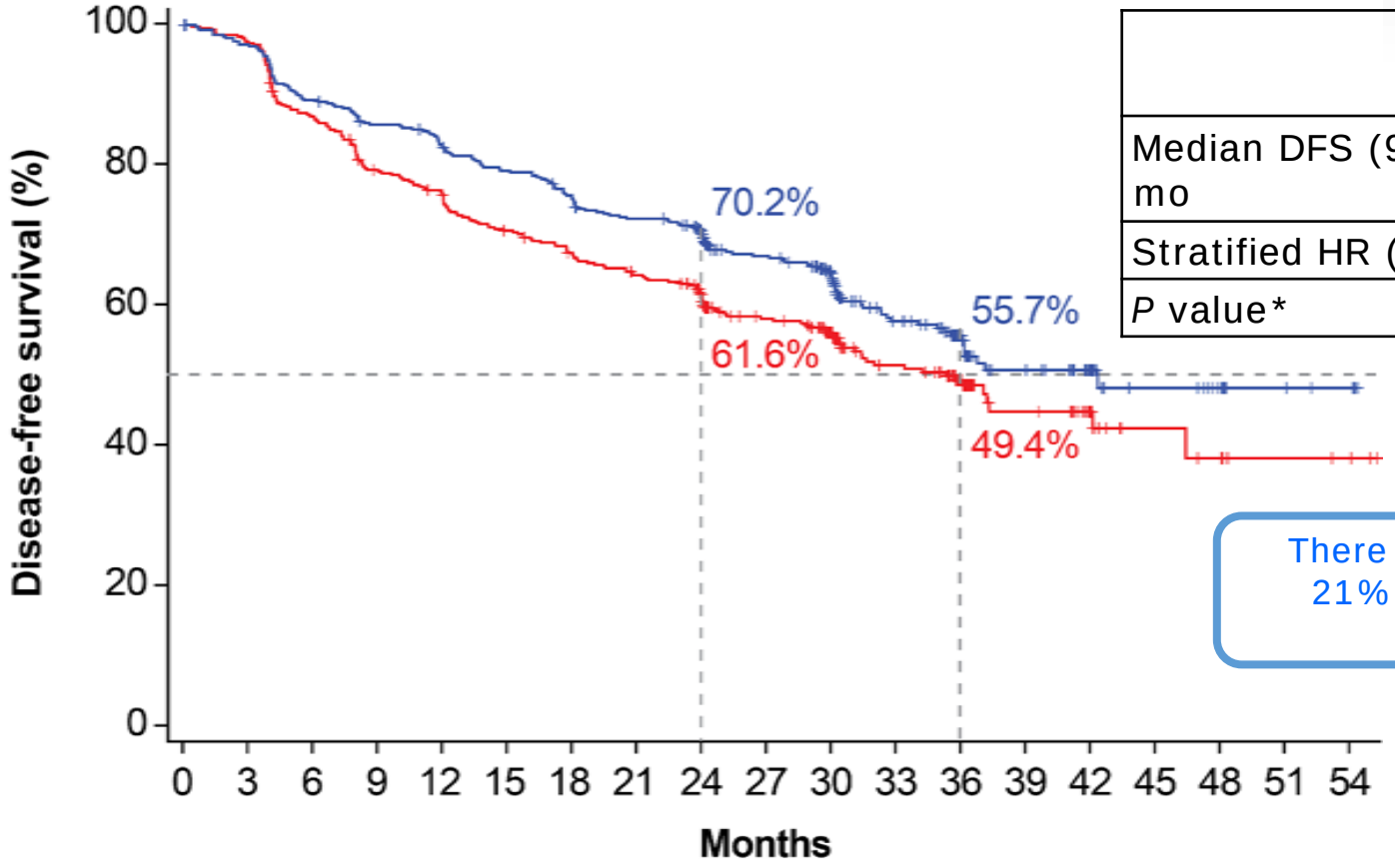
Clinical cutoff: January 21, 2021. [a] Per SP263 assay. [b] Stratified for all patients; unstratified for all other subgroups.
[c] 89.2% and 80.7% of patients in the ITT population with unknown *EGFR* or *ALK* status, respectively, had squamous NSCLC and were not required to undergo local or central testing.

Second, the primary DFS endpoint was tested in the all-randomised stage II–IIIA population



Wakelee, et al. ASCO 2021 (Abs 8500);
Felip, et al. Lancet 2021

A DFS benefit was also seen in the all-randomised stage II–IIIA population (primary endpoint)



	Atezolizumab (n=442)	BSC (n=440)
Median DFS (95% CI), mo	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‡	

Median follow-up: 32.2 mo (range, 0–57.5)

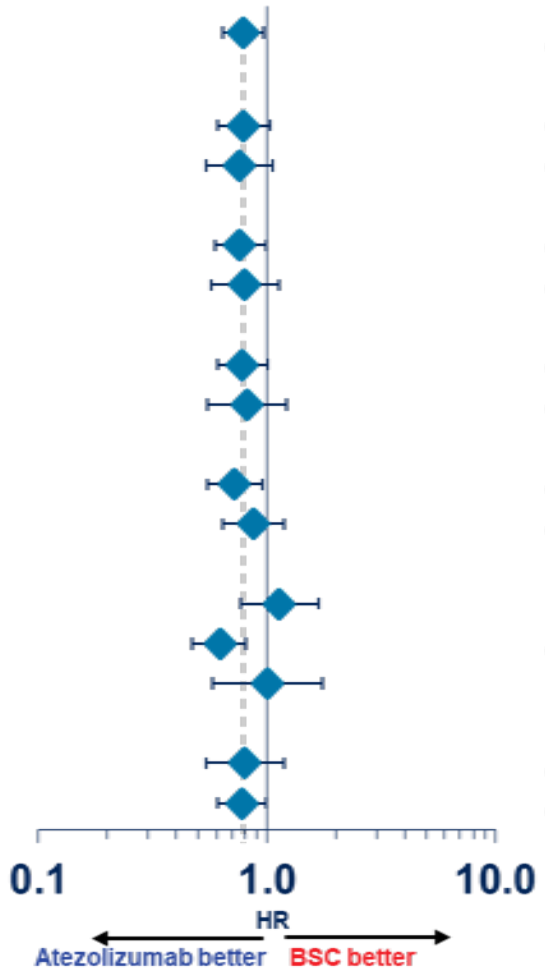
There was a statistically significant 21% reduction in risk of disease recurrence

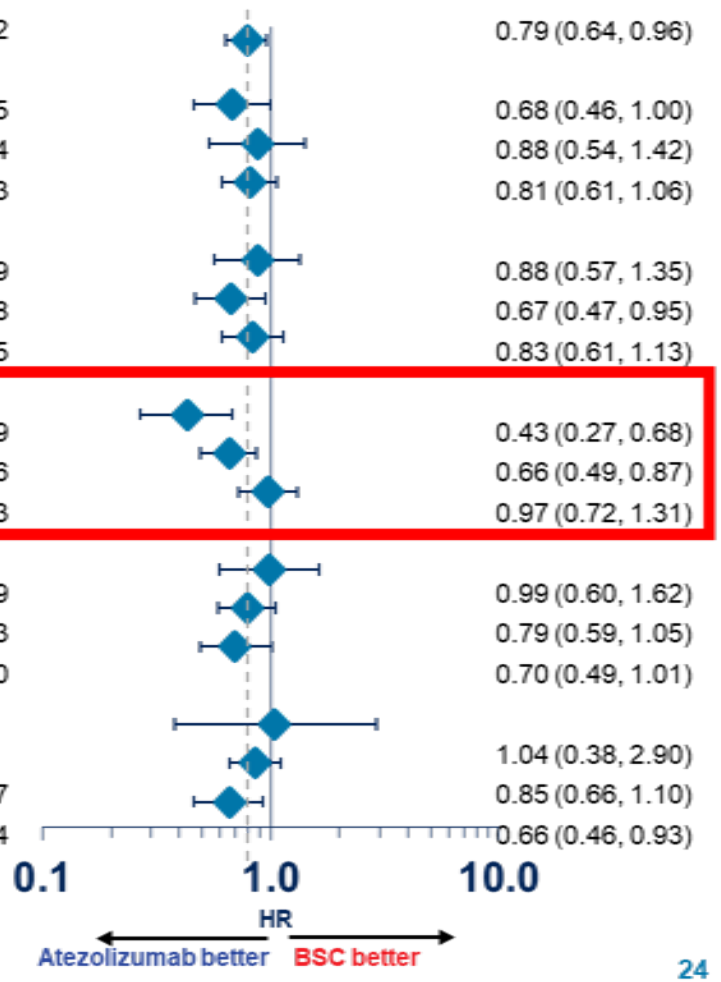
Clinical cut-off: 21 January 2021. *Stratified log-rank. ‡Crossed the significance boundary for DFS

Wakelee, et al. ASCO 2021 (Abs 8500); Felip, et al. Lancet 2021

DFS in key subgroups of the all-randomized stage II-IIIA population

Subgroup	N	HR (95% CI)[a]
All patients	882	0.79 (0.64, 0.96)
Age		
<65 y	544	0.79 (0.61, 1.03)
≥65 y	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)
Non-squamous	588	0.78 (0.61, 0.99)
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* rearrangement 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)





Clinical cutoff: January 21, 2021. [a] Stratified for all patients; unstratified for all other subgroups.

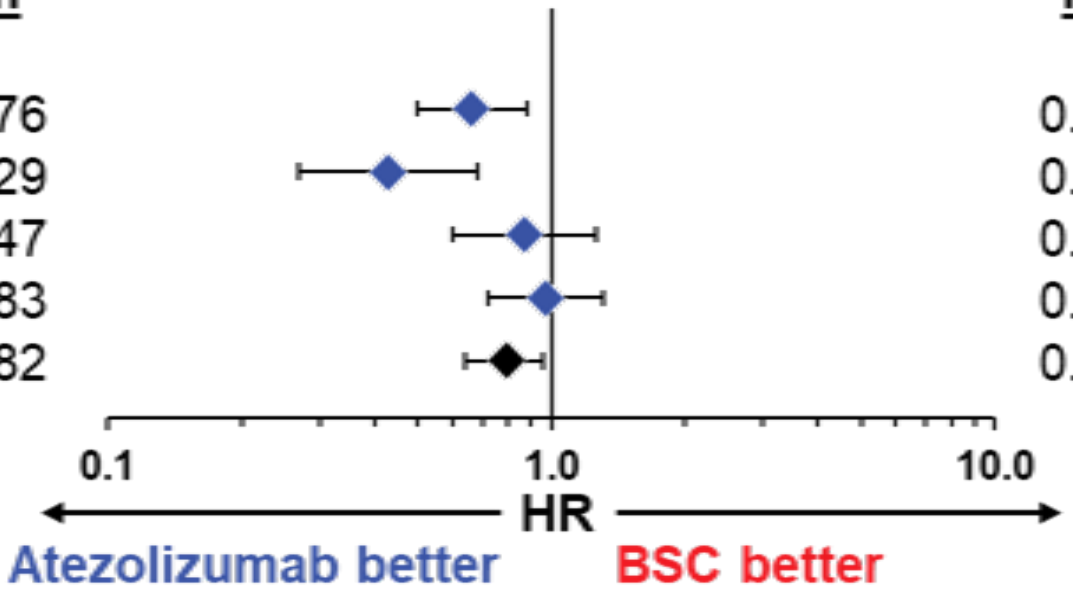
In the all-randomised, stage II–IIIA population, an enriched clinical benefit was observed in patients whose tumours express PD-L1*

A clear benefit was seen in the pre-specified PD-L1 TC ≥1% subgroup

The clinical benefit was further enriched in patients with higher PD-L1 expression. This is consistent with observations for CIT monotherapy in other NSCLC settings

No clear benefit was seen in the PD-L1 negative patients at the DFS interim analysis

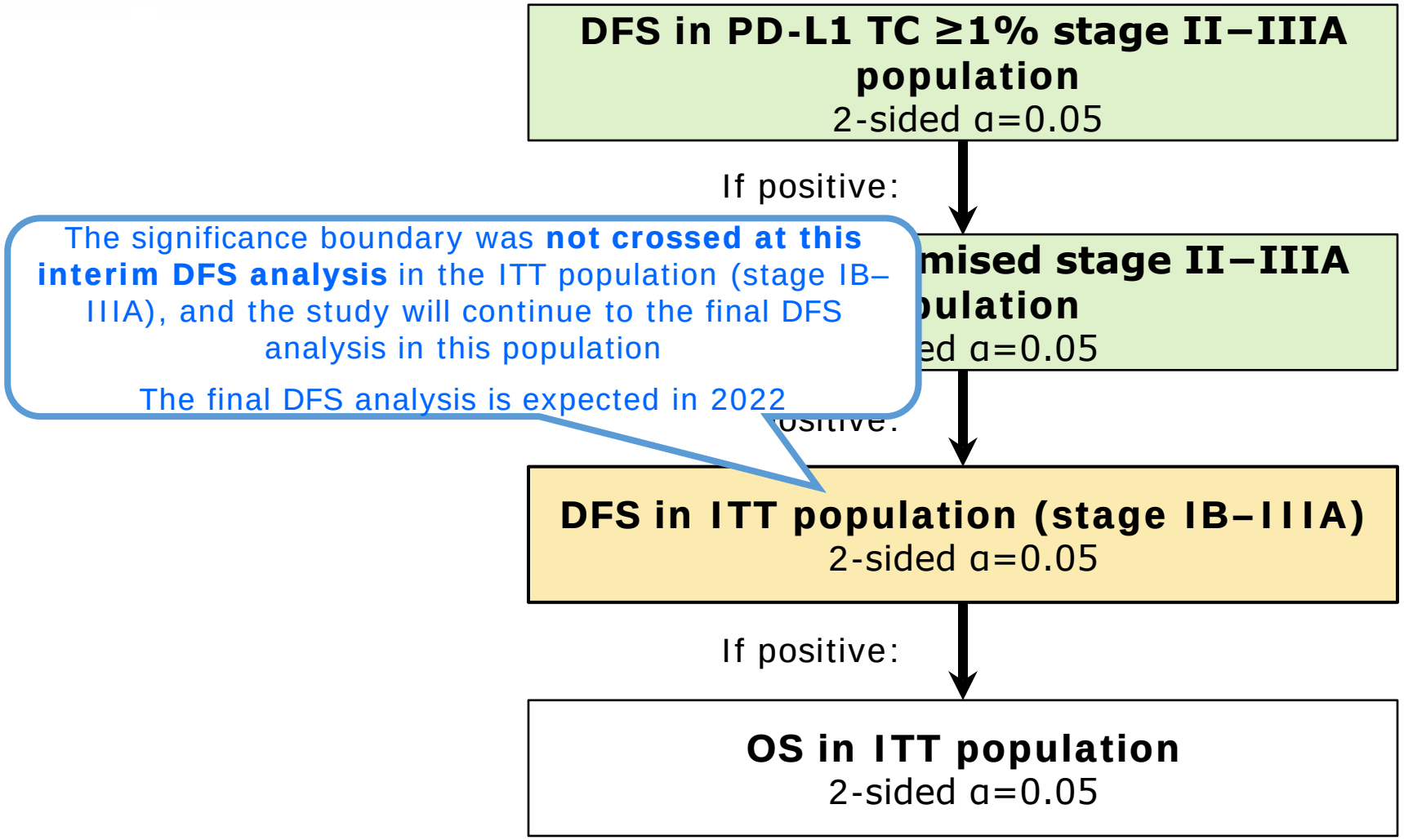
All-randomised stage II–IIIA population	n	HR (95% CI)‡§
PD-L1 status by SP263		
TC ≥1%	476	0.66 (0.50, 0.88)
TC ≥50%	229	0.43 (0.27, 0.68)
TC 1–49%	247	0.87 (0.60, 1.26)
TC <1%	383	0.97 (0.72, 1.31)
All patients¶	882	0.79 (0.64, 0.96)



Clinical cut-off: 21 January 2021
*Per SP263 assay; ‡Stratified for all patients and PD-L1 TC ≥1%; unstratified for all other subgroups; §DFS analyses in the PD-L1 TC <1% and TC 1–49% subgroups were exploratory; ¶23 patients had unknown PD-L1 status as assessed by SP263

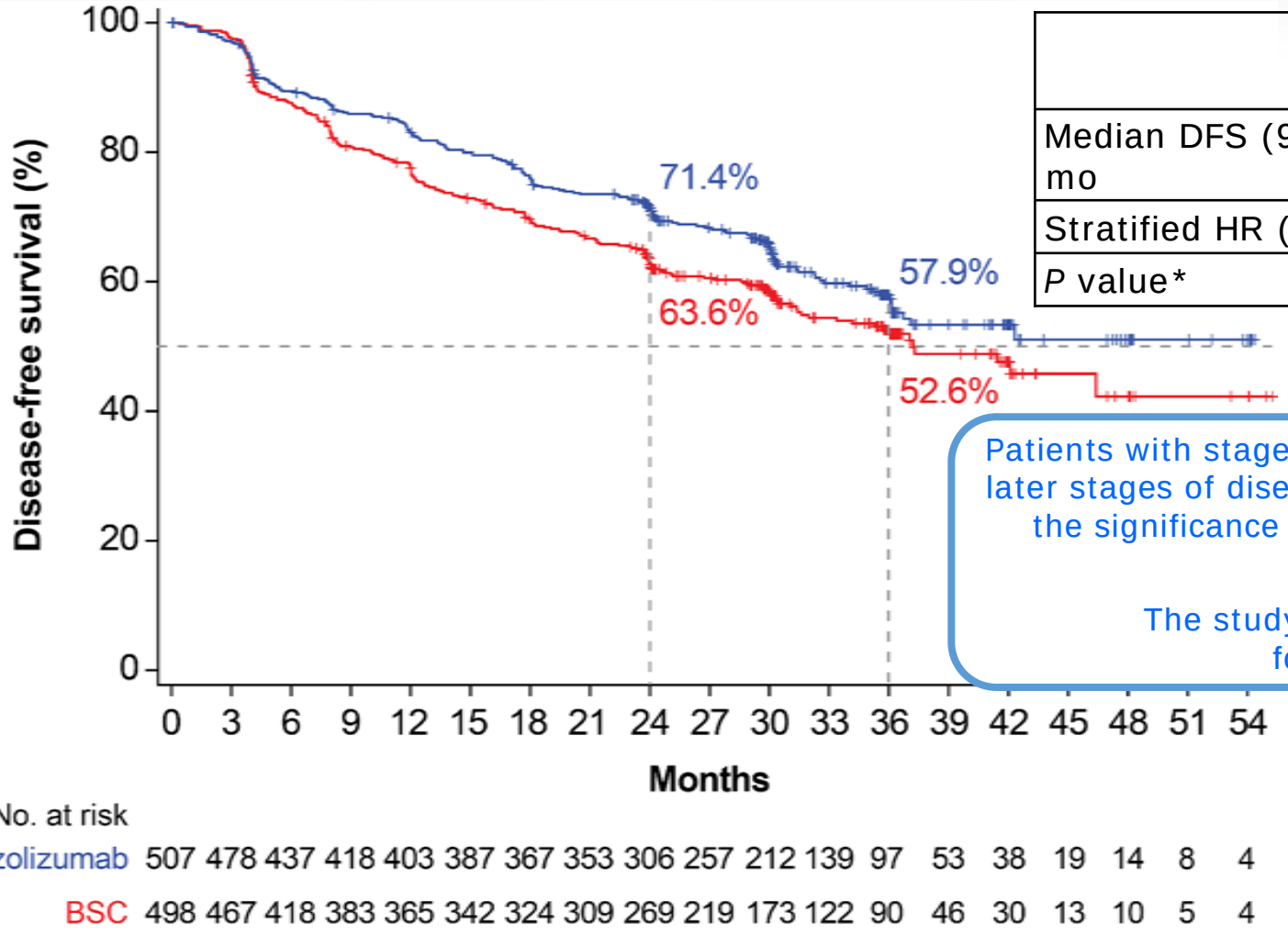
Felip, et al. ESMO 2021 (Abs LBA9)

Third, the primary DFS endpoint was tested in the in the ITT population (stage IB–IIIA)



Wakelee, et al. ASCO 2021 (Abs 8500);
Felip, et al. Lancet 2021

DFS in the ITT population (stage IB–IIIA; primary endpoint)



	Atezolizumab (n=507)	BSC (n=498)
Median DFS (95% CI), mo	NE (36.1, NE)	37.2 (31.6, NE)
Stratified HR (95% CI)	0.81 (0.67, 0.99)	
P value*	0.04‡	

Median follow-up: 32.2 mo (range, 0–58.8)

Patients with stage IB NSCLC typically relapse later than those with later stages of disease, and this may explain why DFS did not cross the significance boundary in the ITT population at this interim analysis

The study will continue to the final DFS analysis for this wider patient population

Clinical cut-off: 21 January 2021. *Stratified log-rank. ‡The statistical significance boundary for DFS was not crossed

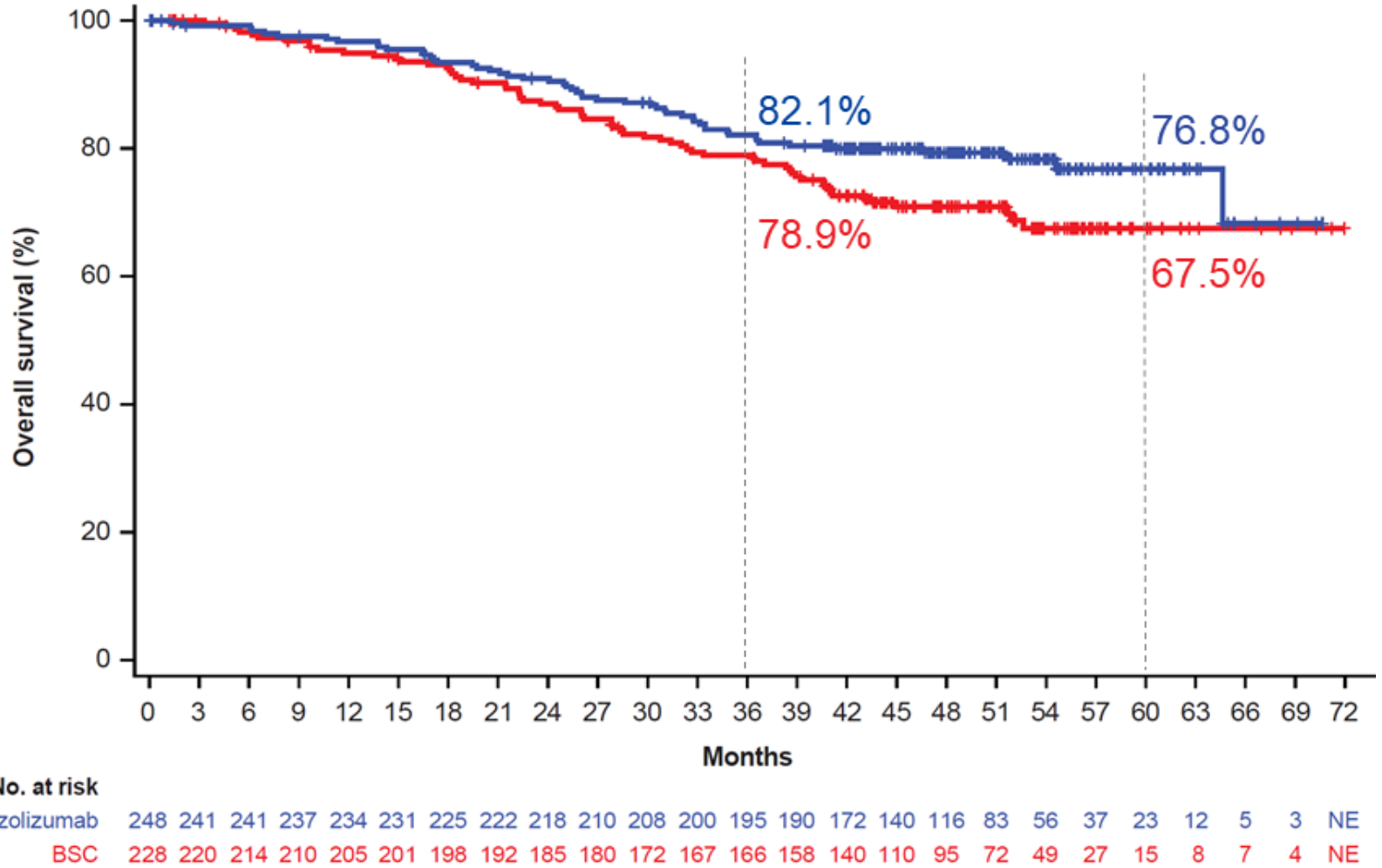
Wakelee, et al. ASCO 2021 (Abs 8500); Felip, et al. Lancet 2021

Overview of planned OS analyses

- There are five formal OS analyses planned in the ITT population.
- Based on the statistical analysis plan and current event projections, the first formal OS interim analysis is planned when approximately 254 events are reached in the ITT population (estimated 25% event-to-patient ratio corresponding to 45% of the information), Data was presented at WCLC 2022
- The subsequent analysis will be conducted approximately one year after the previous one.

IMpower010: Overall survival interim analysis

PD-L1 TC ≥1% (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)**	

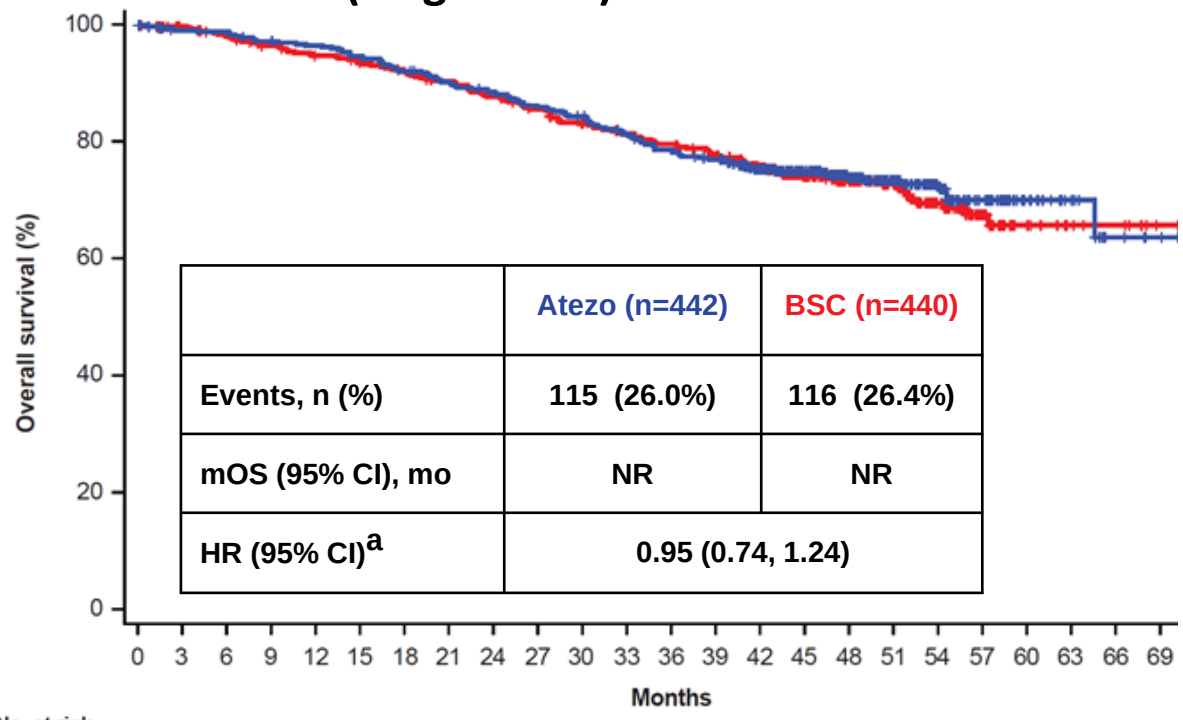
mOS, median overall survival; NR, not reached.
b Stratified.

Enriqueta Felip at WCLC Aug 2022

IMpower010: Overall survival interim analysis

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

All randomised (stage II-IIIA)

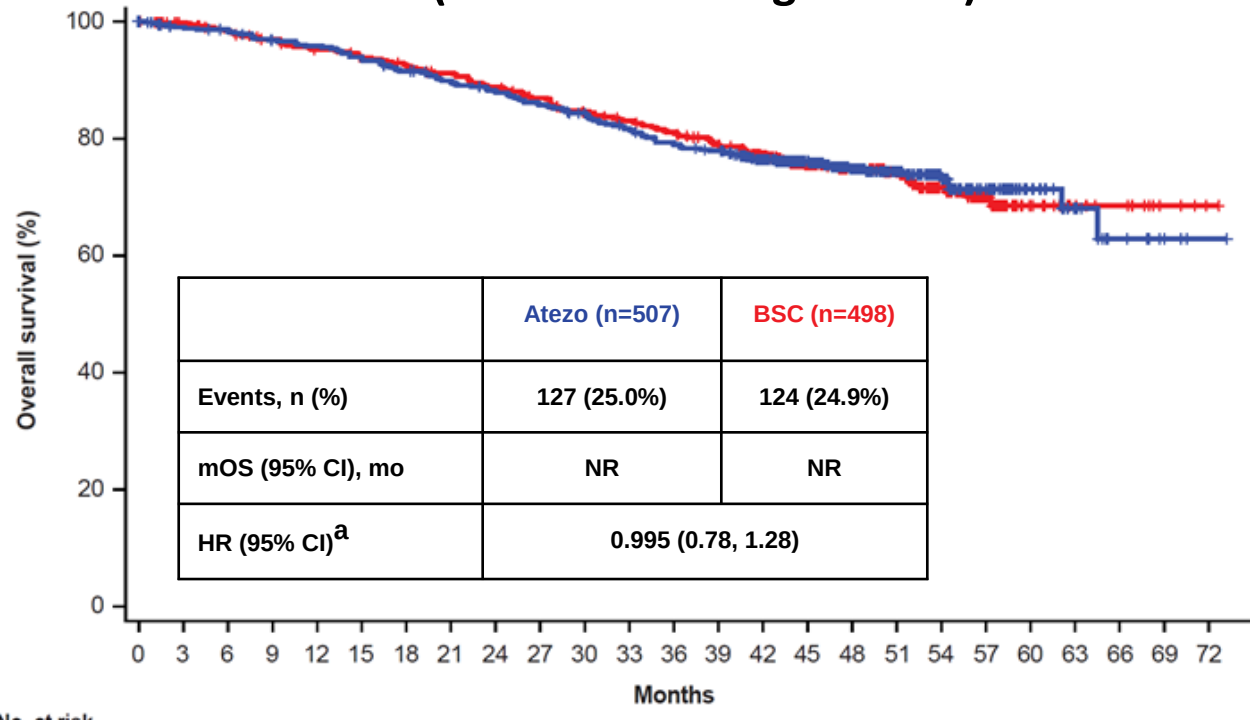


	Atezo (n=442)	BSC (n=440)
Events, n (%)	115 (26.0%)	116 (26.4%)
mOS (95% CI), mo	NR	NR
HR (95% CI)[a]	0.95 (0.74, 1.24)	

No. at risk

Atezolizumab	442	429	428	420	416	408	396	386	378	367	359	344	332	323	287	228	179	128	85	56	27	15	6	3
BSC	440	426	416	405	396	389	382	373	362	350	337	328	320	310	279	215	178	125	81	42	20	11	9	4

ITT (randomised stage IB-IIIA)



	Atezo (n=507)	BSC (n=498)
Events, n (%)	127 (25.0%)	124 (24.9%)
mOS (95% CI), mo	NR	NR
HR (95% CI)[a]	0.995 (0.78, 1.28)	

No. at risk

Atezolizumab	507	492	488	478	472	463	450	439	430	419	408	393	381	372	328	262	203	144	96	61	30	17	8	4	1
BSC	498	484	473	462	452	444	437	428	417	405	391	381	371	357	325	253	207	148	101	57	25	14	11	5	1

Clinical cutoff: 18 April 2022. [a] Stratified. [b] No formal testing until statistical significance observed for DFS in the ITT population due to the prespecified testing hierarchy. [c] Descriptive purposes only.

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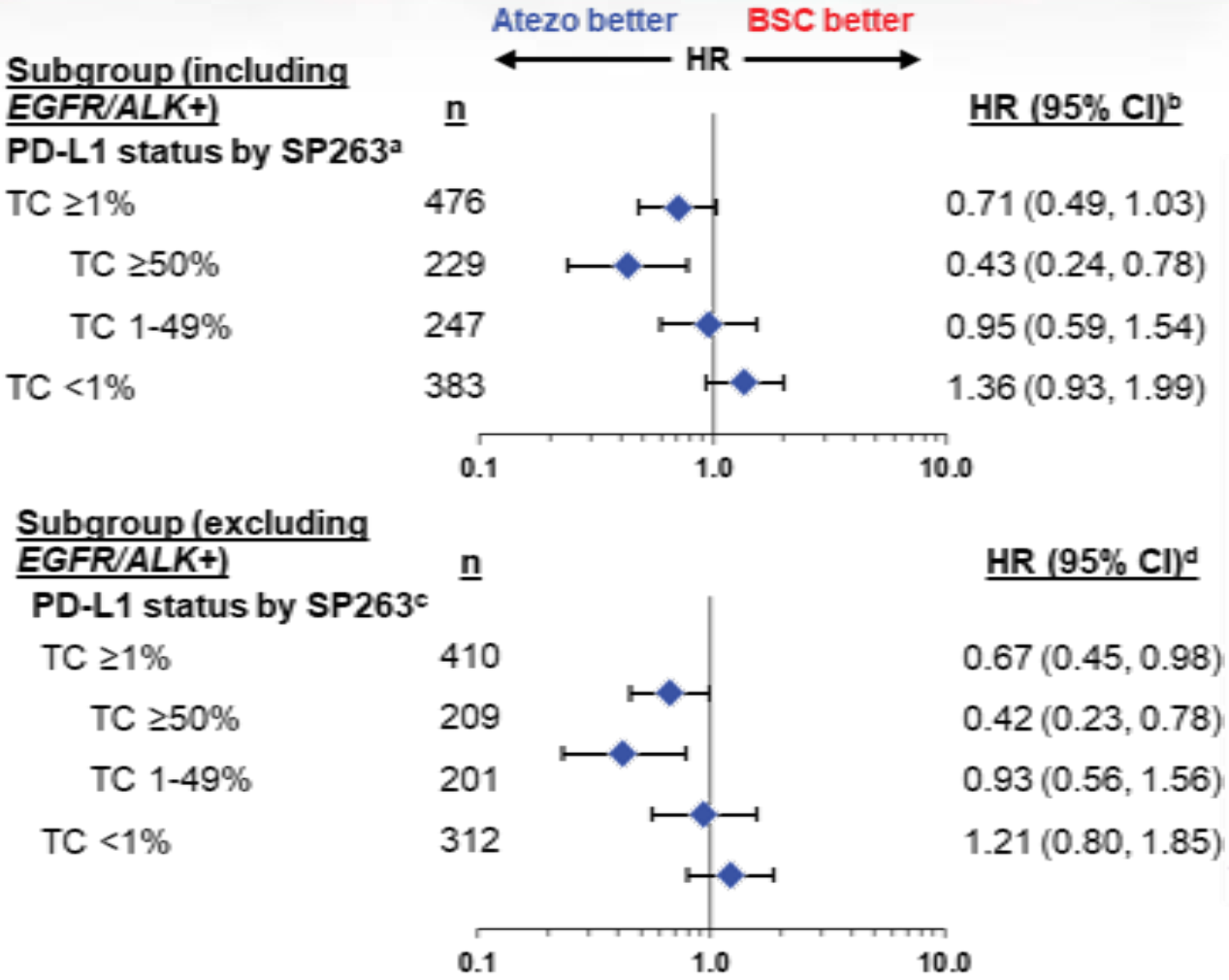
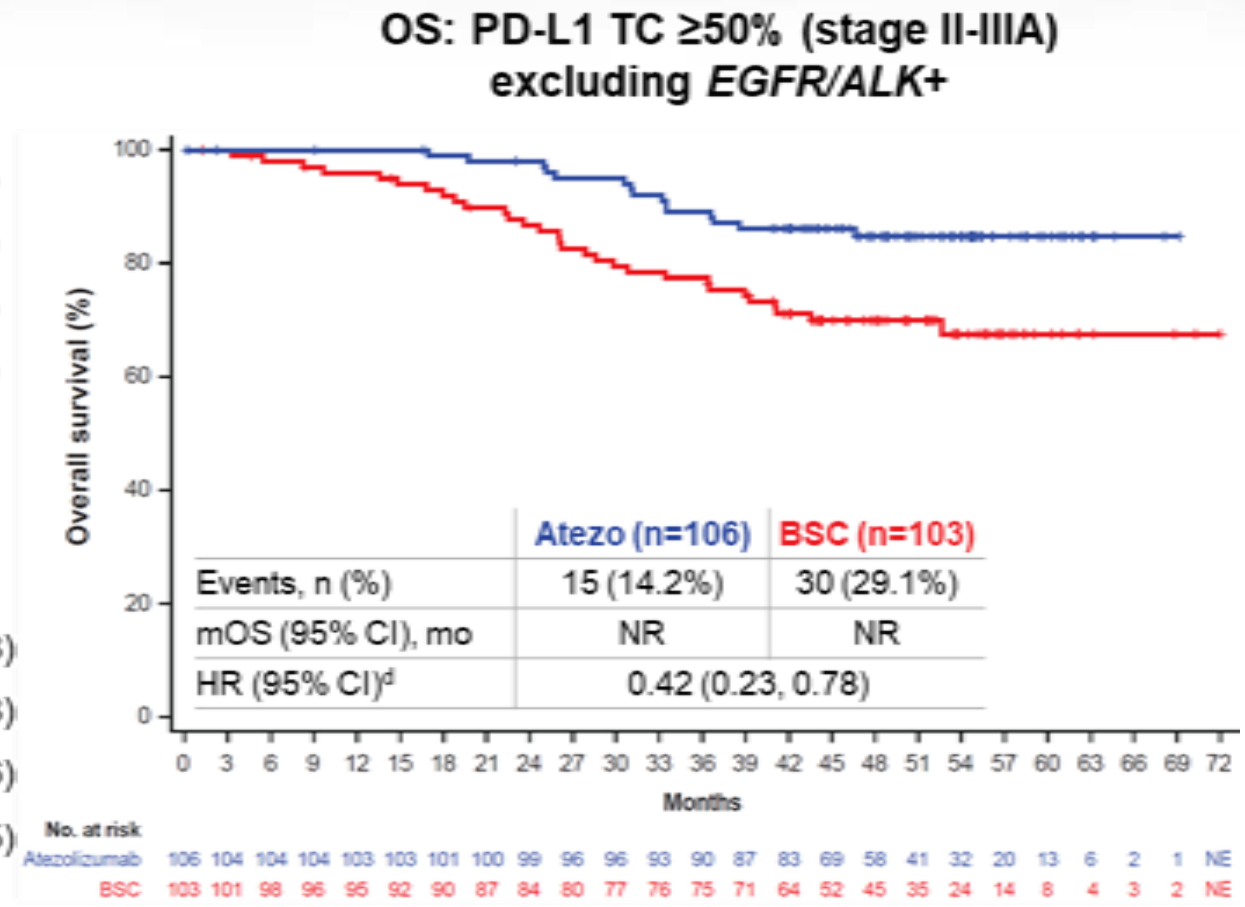
OS by biomarker status (stage II-IIIA) (data cutoff: 18 Apr '22)





[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.

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Safety: Atezolizumab exposure

	IMpower010 Atezo (N=495)
Median Treatment Duration (months)	10.4
Median Dose Intensity (%)	100.0
Number of Doses/Cycles Received (median, range)	16.0 (1.0-16.0)
Number of Doses/Cycles	
≥16	323 (65.3%)
≥8 and <16	47 (9.5%)
0 to <8	125 (25.3%)

Overall safety profile (safety-evaluable population)

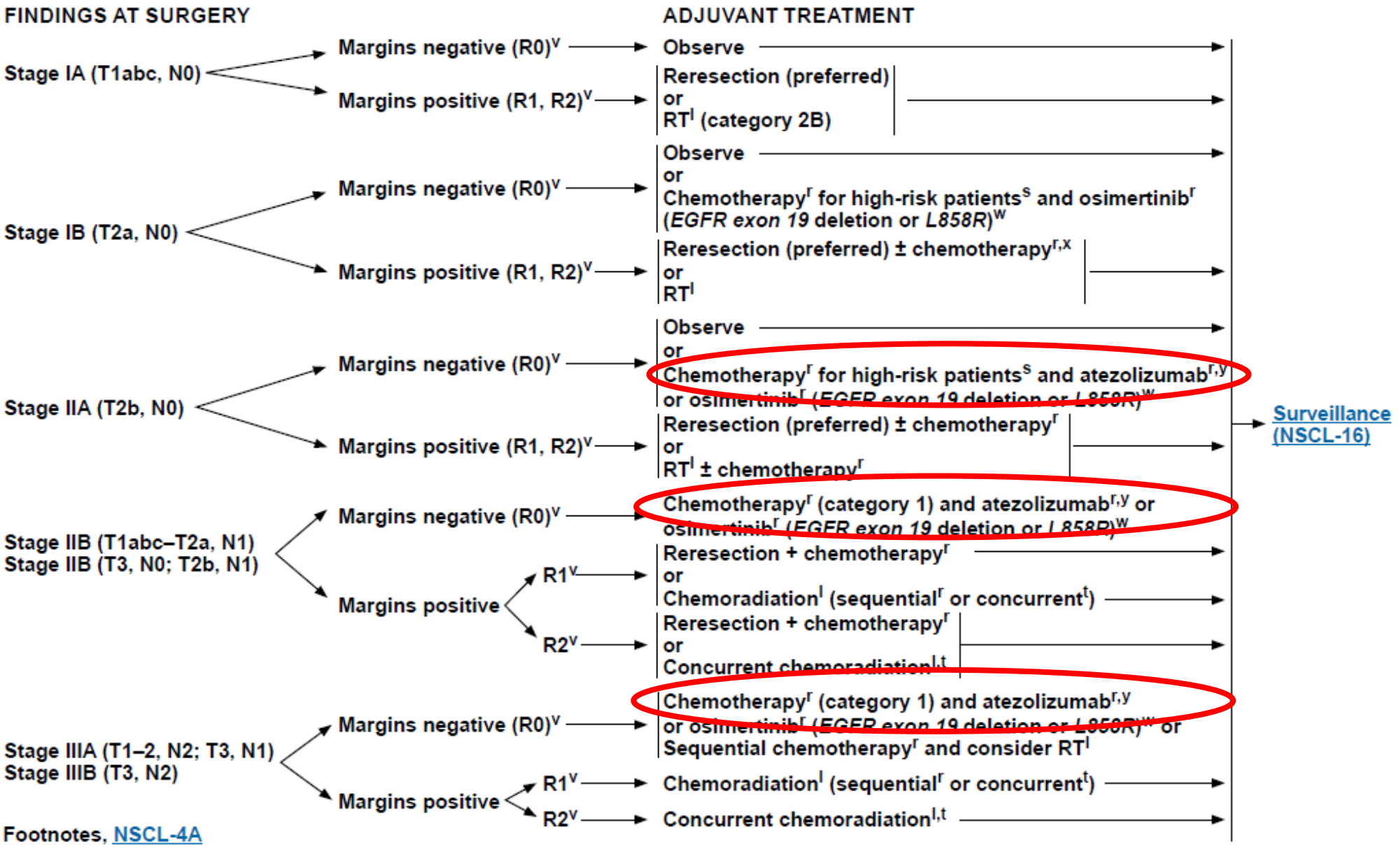
All treated patients	IMpower010		Atezo Mono Pool**
	BSC (N=495)	**Atezo (N=495)**	**(N=3178)**
All Grade AE, any cause	350 (70.7%)	459 (92.7%)	3051 (96.0%)
Treatment-related AE*	-	335 (67.7%)	2168 (68.2%)
Grade 3-4 AE	57 (11.5%)	108 (21.8%)	1482 (46.6%)
Treatment-related Grade 3-4 AE*	-	53 (10.7%)	496 (15.6%)
Serious Adverse Event	42 (8.5%)	87 (17.6%)	1309 (41.2%)
Treatment-Related SAE*	-	37 (7.5%)	353 (11.1%)
Grade 5 AE	3 (0.6%)	8 (1.6%)	119 (3.7%)
Treatment-related Grade 5 AE*	-	4 (0.8%)	11 (0.3%)
AE leading to dose interruption of atezolizumab	-	142 (28.7%)	882 (27.8%)
AE leading to Atezolizumab discontinuation	-	90 (18.2%)	226 (7.1%)
Atezo AESI			
All Grade Atezo AESI	47 (9.5%)	256 (51.7%)	1098 (34.6%)
Grade 3-4 Atezo AESI	3 (0.6%)	39 (7.9%)	248 (7.8%)
All Grade Atezo AESI requiring use of systemic corticosteroids	4 (0.8%)	60 (12.1%)	247 (7.8%)

* Related to Atezolizumab
** Atezo Mono Pool included eight atezolizumab monotherapy studies across multiple tumor types (OAK, POPLAR, FIR, BIRCH, PCD4989g [All Cohorts], IMmotion150, IMvigor210 and IMvigor211)

IMpower010: conclusions

- IMpower010 is the first Phase III study of cancer immunotherapy to demonstrate DFS improvement in the adjuvant NSCLC setting after platinum-based chemotherapy.
- Adjuvant atezolizumab following complete resection and adjuvant chemotherapy showed statistically significant DFS benefit in the PD-L1 TC ≥1% stage II-IIIA (HR, 0.66; 95% CI: 0.50, 0.88) and all-randomized stage II-IIIA (HR, 0.79; 95% CI: 0.64, 0.96) populations, with enriched clinical benefit in patients whose tumors express PD-L1.
- DFS in the ITT population, including patients with stage IB disease, did not cross the significance boundary at this interim DFS analysis.
- 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
- The safety profile of atezolizumab was consistent with prior experience of atezolizumab monotherapy across indications and lines of therapy

NCCN Guidelines Version 5.2022
Non-Small Cell Lung Cancer



Footnotes, NSCL-4A

Abbreviations

- NSCLC- Non-small cell lung cancer
- WT- Wild-type
- ITT- Intent-to-treat
- CIT- Cellular immunotherapy
- ECOG- Eastern Cooperative Oncology Group
- PD-L1- programmed death ligand 1
- BSC- Best supportive care
- PD- Progressive disease
- SCLC- Small cell lung cancer
- ORR- Overall response ate
- EGFR- Epidermal growth factor receptor
- ALK- Anaplastic lymphoma kinase
- ROS1- ROS Proto-Oncogene 1
- OS- overall survival
- SoC- Standard of Care
- TC- Tumour cell
- IC- Immune cell
- HR- Hazard ratio
- mPFS- median progression-free survival
- NE- not estimable
- AE- adverse event

IHC- Immunohistochemistry

VEGF- Vascular endothelial growth factor

TKI- Tyrosine kinase inhibitor

CR- Complete response

KM- Kaplan Meier

SLD- Sum of the longest diameters of target lesions

SD- Stable Disease

PR- Partial Response

T_{eff}- T effector

NCCN- National Comprehensive Cancer Network

WARNING: To be sold by retail on the prescription of a "Registered Oncologist Only"

ABRIDGED PRESCRIBING INFORMATION (Tecentriq®) SUMMARY OF PRESCRIBING INFORMATION: Generic Name: Atezolizumab Injection Brand Name: Tecentriq® Composition: *Active ingredient:* Atezolizumab. Tecentriq is supplied as a single-use vial containing preservative-free, colorless to slightly yellow solution, at an active ingredient concentration of 60 mg/mL as follows: • 14 mL vial containing a total of 840 mg atezolizumab • 20 mL vial containing a total of 1200 mg atezolizumab **Indications:** Tecentriq® is indicated for- ***Urothelial carcinoma (UC)*** Atezolizumab is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who: are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area), as approved test or are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status ***Non-small cell lung cancer*** 1.Tecentriq is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. 2. Tecentriq in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies. 3. Atezolizumab in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. 4. Atezolizumab as monotherapy for the first line treatment of patients of metastatic NSCLC whose tumors have a PD L1 expression > 50% tumor cells or > 10% tumor infiltrating immune cells and who do not have EGFR or ALK genomic tumor aberrations. 5. Atezolizumab, as a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells 2 ***Small cell lung cancer*** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). ***Triple-negative breast cancer*** Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease. ***Hepatocellular carcinoma*** Atezolizumab, in combination with Bevacizumab, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. **Type of dosage form:** Tecentriq® is available in single use vials as Concentrate for solution for infusion. **Dosage and Administration:** Tecentriq must be administered as an intravenous infusion under the supervision of a qualified healthcare professional. Do not administer as an IV push or bolus. The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated all subsequent infusions may be administered over 30 minutes. The recommended dose of Tecentriq in monotherapy or combination therapy: • 840 mg administered by IV infusion every 2 weeks, or • 1200 mg administered by IV infusion every 3 weeks **Tecentriq monotherapy** 2L NSCLC, 1L NSCLC, *early stage NSCLC*, 1L UC in Cisplatin ineligible patients **Tecentriq combination therapy** *1L UC* Tecentriq in combination with gemcitabine and cisplatin or carboplatin. Tecentriq is administered according to its dosing schedules by intravenous (IV) infusion. For each 21-day cycle, gemcitabine is administered on days 1 and 8; cisplatin or carboplatin is administered on day 1. *1L non-squamous NSCLC:* Tecentriq in combination with bevacizumab, paclitaxel, and carboplatin: During the induction phase, Tecentriq is administered according to its dosing schedules by IV infusion and bevacizumab, paclitaxel and carboplatin are administered every 3 weeks for four or six cycles. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion and bevacizumab is administered every 3 weeks. 3 *Tecentriq in combination with nab-paclitaxel and carboplatin:* During the induction phase, the recommended dose of Tecentriq is 1200 mg administered by IV infusion, followed by nab-paclitaxel and carboplatin every 3 weeks for four or six cycles. For each 21-day cycle, Tecentriq, nab-paclitaxel and carboplatin is administered on day 1. In addition, nab-paclitaxel is administered on days 8 and 15. The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq is administered by IV infusion every 3 weeks. *1L ES-SCLC:* Tecentriq in combination with carboplatin and etoposide During the induction phase, Tecentriq is administered according to its dosing schedules by IV infusion and carboplatin and etoposide are administered by IV infusion every three weeks for four cycles. Carboplatin and etoposide are administered on day 1 of each cycle, and etoposide is also administered on days 2 and 3. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion. *1L TNBC:* Tecentriq in combination with nab-paclitaxel The recommended dose of Tecentriq is 840 mg administered by IV infusion, followed by 100 mg/m2 nab-paclitaxel. For each 28-day cycle Tecentriq is administered on days 1 and 15, and nab-paclitaxel is administered on days 1, 8 and 15. *HCC:* Tecentriq in combination with bevacizumab Tecentriq is administered according to its dosing schedules by IV infusion, and bevacizumab 15 mg/kg is administered every 3 weeks. *Duration of Treatment:* Patients are treated with Tecentriq until loss of clinical benefit in NSCLC, ES-SCLC, HCC and patients are treated until disease progression or unacceptable toxicity in 1L TNBC and 1L UC. In Early stage NSCLC, patients are treated with Tecentriq for 1 year unless there is disease recurrence or unacceptable toxicity. **Contraindications:** Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. **Warnings and Precautions**: *Immune-mediated pneumonitis:* Cases of pneumonitis, including fatal cases, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 pneumonitis. *Immune-mediated hepatitis:* Cases of hepatitis, some leading to fatal outcomes, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or Grade 4 events. *Immune-mediated colitis:* Cases of diarrhea or colitis have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 4 diarrhea or colitis. *Immune-mediated endocrinopathies:* Hypothyroidism, hyperthyroidism, adrenal insufficiency and type 1 diabetes mellitus, including diabetic ketoacidosis, have been observed in clinical trials with Tecentriq. For Grade 4 Hypophysitis, treatment with Tecentriq should be permanently discontinued. 4 *Immune-mediated meningoencephalitis:* Meningoencephalitis has been observed in clinical trials with Tecentriq. Permanently discontinue for all grades of meningoencephalitis. *Immune-mediated neuropathies:* Myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome, which may be life threatening, were observed in patients receiving Tecentriq. Permanently discontinue Tecentriq for all grades of immune mediated neuropathies. *Immune-mediated pancreatitis:* Pancreatitis, including increases in serum amylase and lipase levels, has been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 4, or any grade of recurrent pancreatitis. *Immune-mediated myocarditis:* Myocarditis has been observed in clinical trials with Tecentriq. Tecentriq should permanently discontinued for Grade 2 or above myocarditis. Myocarditis may also be a clinical manifestation of myositis and should be managed accordingly. *Immune-mediated myositis:* Cases of myositis, including fatal cases, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 recurrent myositis or Grade 4 events. Patients with possible myositis should be monitored for signs of myocarditis. *Immune-mediated nephritis:* Nephritis has been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 nephritis. *Infusion related reactions:* Infusion related reactions (IRRs) have been observed in clinical trials with Tecentriq. Tecentriq should be permanently discontinued in patients with Grade 3 or 4 infusion related reactions. *Immune-mediated severe cutaneous adverse reactions:* Immune-mediated severe cutaneous adverse reactions (SCARs), including cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients receiving Tecentriq. Patients should be monitored for suspected severe skin reactions and other causes should be excluded. Tecentriq should be permanently discontinued for Grade 4 skin reactions, and corticosteroids should be administered. For confirmed SJS or TEN, Tecentriq should be permanently discontinued. *Immune-mediated pericardial disorders:* Pericardial disorders, including pericarditis, pericardial effusion and cardiac tamponade, some leading to fatal outcomes, have been observed in clinical trials with Tecentriq. Patients should be monitored for clinical signs and symptoms of pericardial disorders. Tecentriq should be permanently discontinued in patients with Grade 2 or above. *Special populations:* Patients with autoimmune disease were excluded from clinical trials with Tecentriq. In the absence of data,

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Thank you

Doing what patients need next