16th CONGRESS Lung ON CANCER

BARCELONA 27 / 28 NOVEMBER 2025

GECP lung cancer research

Changing landscape in SCLC limited disease

Anna Estival MD, PhD

Hospital Universitario Insular de Gran Canaria

Disclousures

- ✓ **Speaker:** GSK, MSD, Roche, Astrazeneca, Pharmamar, BMS, Takeda, Bayer, Deciphera, Pfizer, Lilly.
- ✓ **Conferences and travel expenses:** MSD, Pharmamar, Takeda, Janssen, Deciphera, Amgen.
- ✓ **Advisory role:** GSK, MSD, Roche, Atrazeneca, Deciphera, Janssen

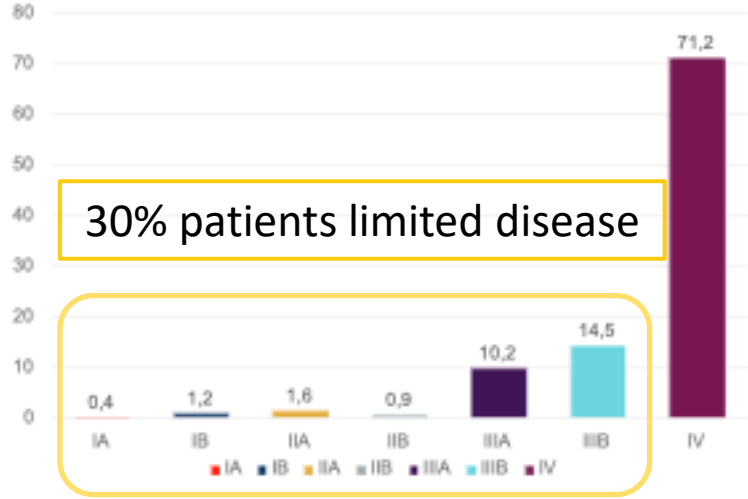
SCLC

The most **aggressive** subtype of lung cancer

Lung cancer most related to tobacco

98% in men, 76% in women

12% of lung cancer in
The Canary Islands



Excellent response to Chemo – radiotherapy but…

↑ Risk of local relapse
↑ Risk of distant spread

mPFS 10.2-15.4m

mOS 25 - 32 m

Few long term survivors

Mortality

150 000/per year US
40.000/per year Europe
3.500/per year Spain

Lopez-Chavez et al. Curr Probl Cancer. 2012 / Turrisi et al. NEJM 1999 / Dayen, C. Et al. *J Clin Oncol* 2013 / Faivre-Finn C, et al. Lancet Oncol. 2017 / Grønberg BH, et al. Acta Oncol. 2016 / Peters S, et al. Ann Oncol. 2022

SCLC Limited disease

Past, present and future

Chemotherapy

Radiotherapy

IO sequencial to Ch-RT

IO concurrent to Ch-RT

Cisplatin etoposide

1985

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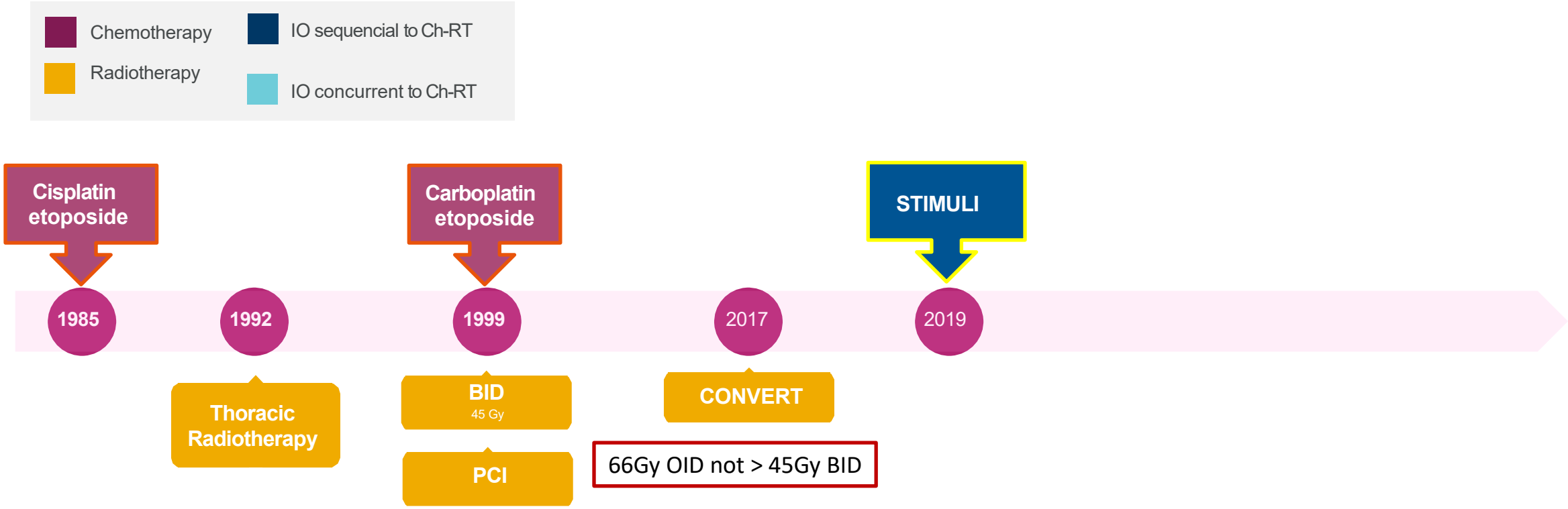
Past, present and future



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SCLC Limited disease

STIMULI

Key eligibility criteria

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

Trial enrolment

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

No PD

R* 1:1

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

Observation
No further treatment

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

RECIST 1.1 Assessment:
Every 9 weeks for the first 16 months, 12 weeks up to year 2 and 6 months up to year 4

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

Measured from randomization

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

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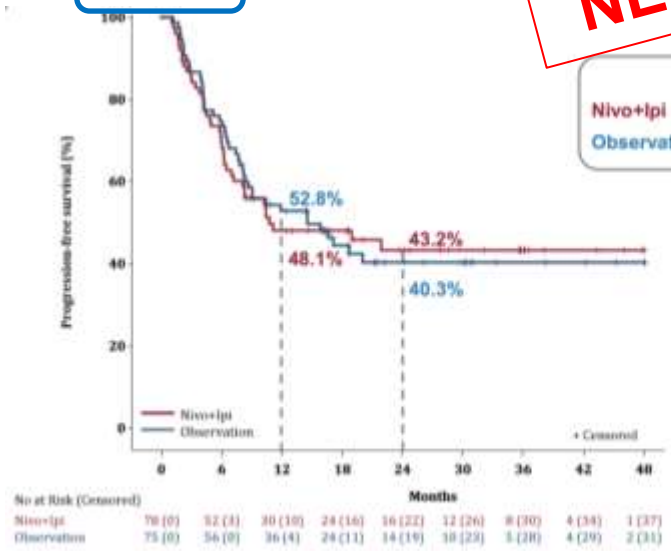
PFS

NEGATIVE



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

NE: Not estimable

Stratified
HR (95%CI): 1.02 (0.66 - 1.58)
p = 0.93
Testing for non-proportionality: p=0.36

Time to Nivo+Ipi discontinuation:
Median: 1.7 months (95%CI: 1.2-2.5)
25.6% on treatment by 6m
15.6% on treatment by 12m

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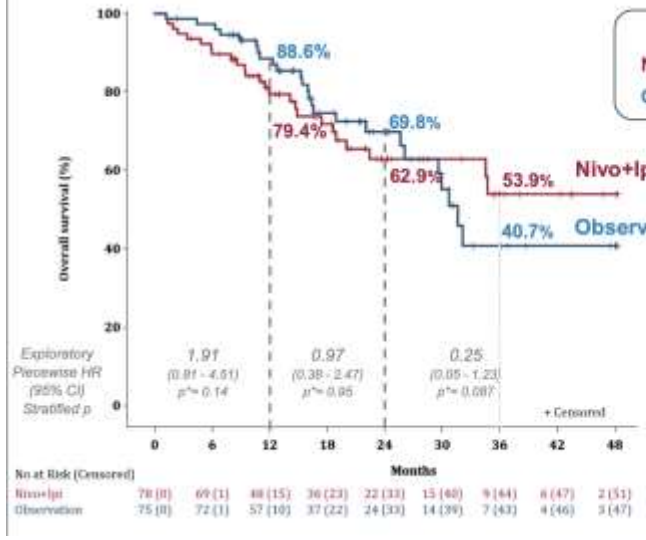
OS



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

NR: Not Reached, NE: Not estimable

Stratified
HR (95%CI): 1.06 (0.61 - 1.86)
p = 0.83
Testing for non-proportionality: p=0.059

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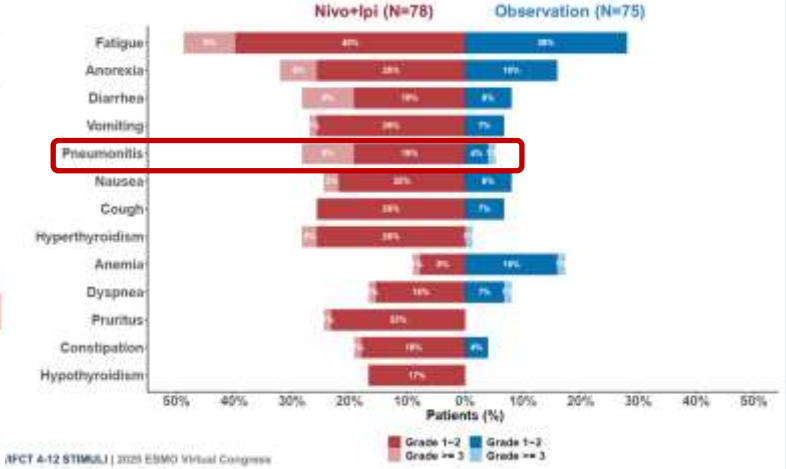
Safety summary (N=153 patients; safety cohort)

	Nivo+Ipi N patients (%)		Observation N patients (%)
Safety cohort	78		75
Patients experiencing:			
Any Adverse Event (AE)	77 (99%)		65 (87%)
Any Treatment-related AE (TrAE)	75 (96%)		-
	Trt-related	*Any cause*	*Any cause*
AEs of grade 3-5	40 (51%)	48 (62%)	19 (25%)
AEs leading to treatment discontinuation	36 (49%)	43 (55%)	-
AEs leading to death	3 (4%)	4 (5%)	1 (1%)



(PCT 4-12 STIMULI | 2020 ESMO Virtual Congress

Peters S. ESMO 2020 / Peters S. Ann Oncol 2022

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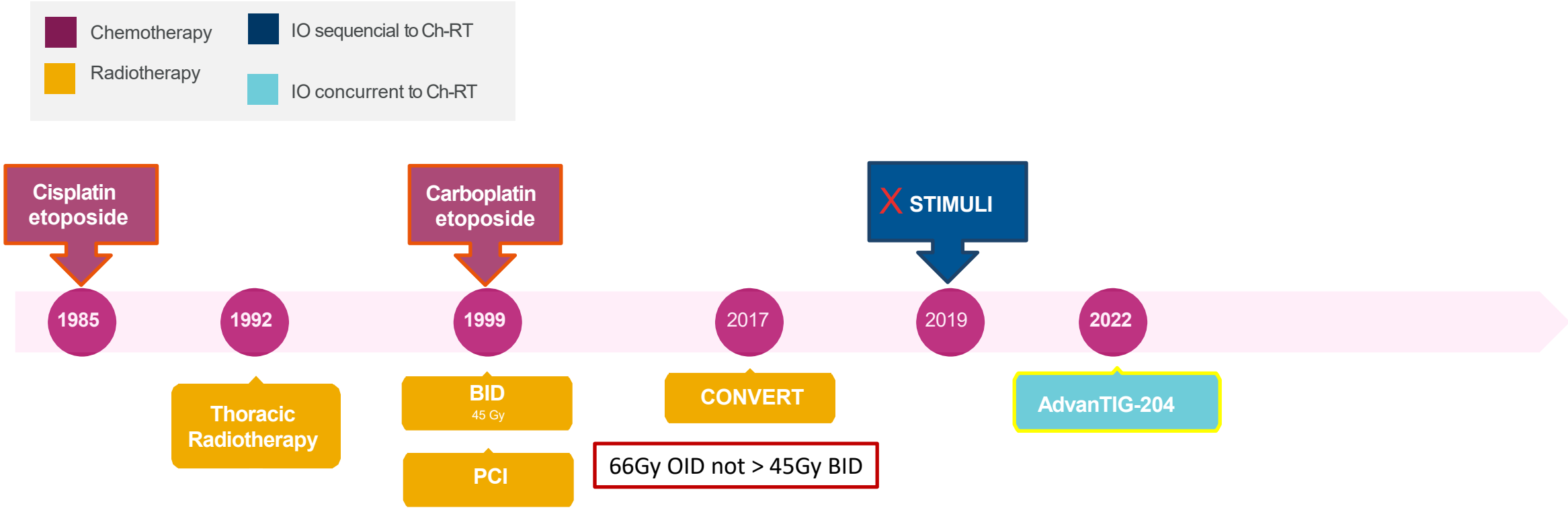
Past, present and future



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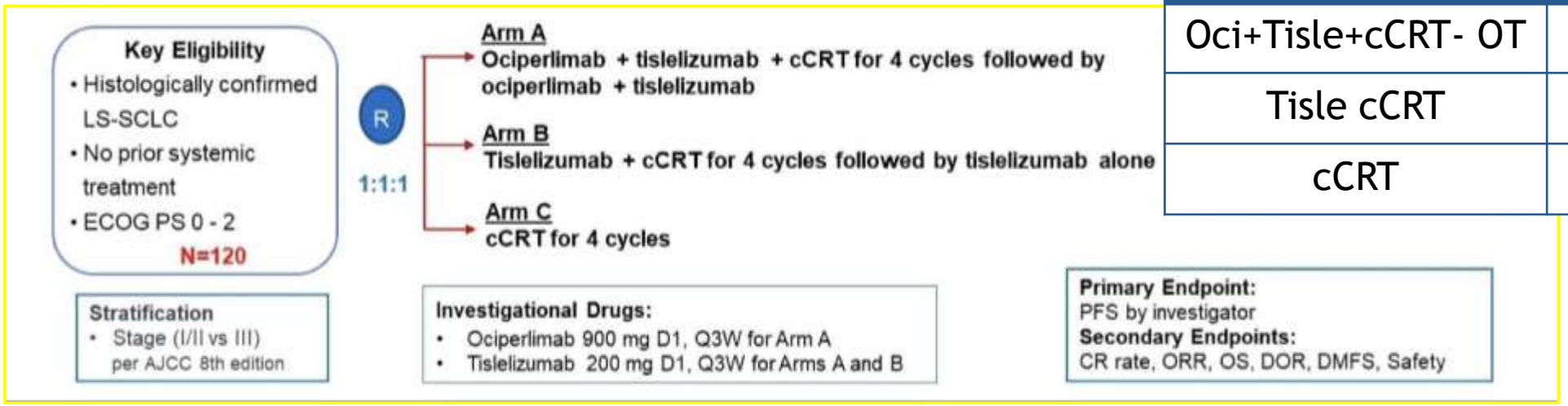
AdvanTIG-204



Outcomes	PFS	ORR
Oci+Tisle+cCRT- OT	12.6m	85.4%
Tisle cCRT	13.2m	88.1%
cCRT	9.5m	76.7%

Tislelizumab + cCRT yielded a **trend** of improvement in PFS and ORR vs cCRT

Ociperlimab did **not** show detectable **improvement**

Gong Y, et al Cancer Research. 2024

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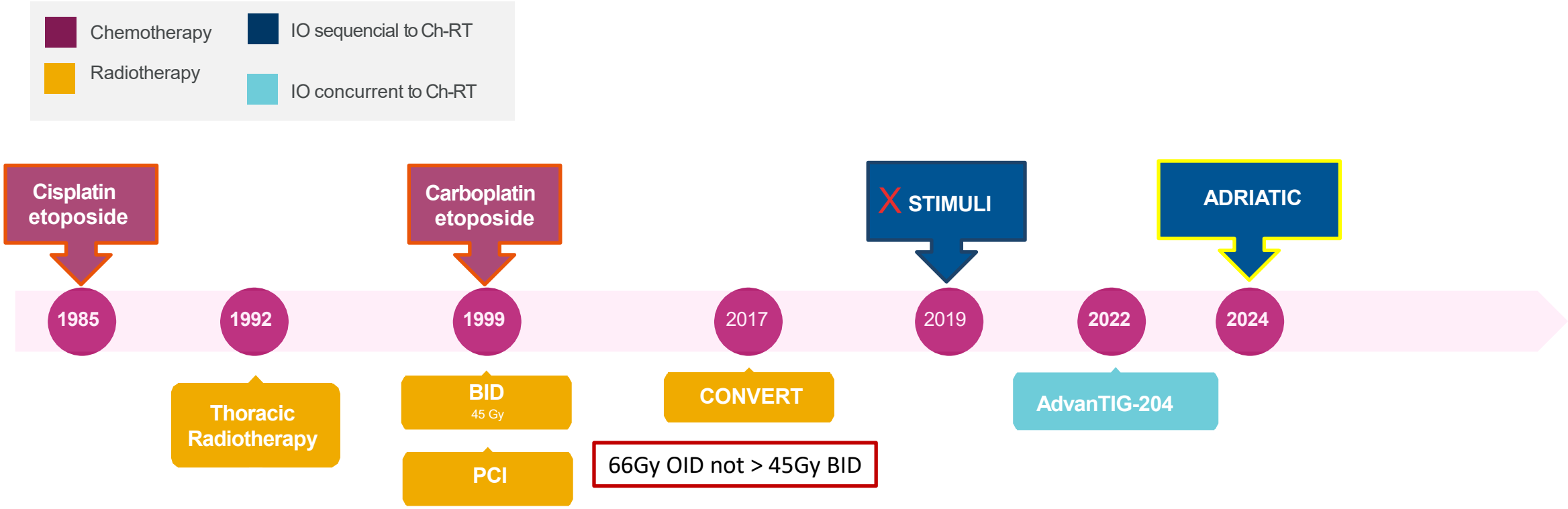
Past, present and future



X EMA negative

Lopez-Chavez et al. Curr Probl Cancer. 2012 / Turrisi et al. NEJM 1999 / Dayen, C. Et al. *J Clin Oncol* 2013 / Faivre-Finn C, et al. Lancet Oncol. 2017 / Grønberg BH, et al. Acta Oncol. 2016 / Peters S, et al. Ann Oncol. 2022 / Gobbini E, et al. ELCC 2024

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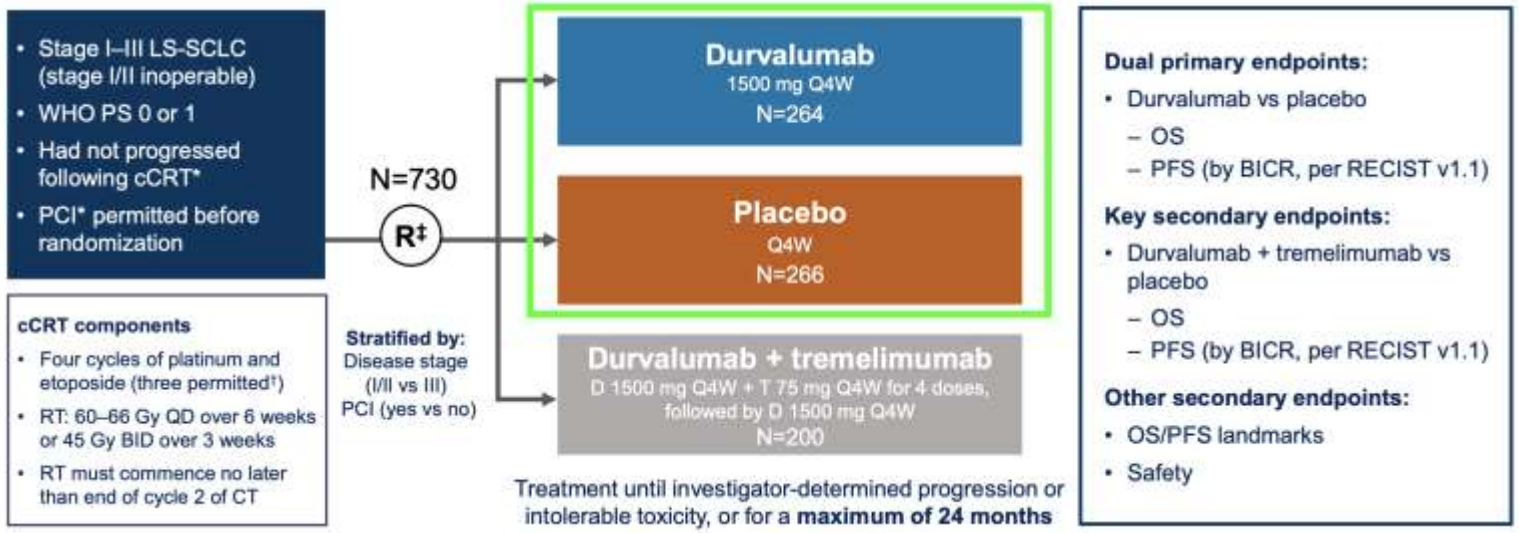
ADRIATIC



cCRT and PCI completed within 1–42 days prior to randomization
The first 600 pts randomized 1:1:1 ratio; subsequent 1:1 to D / P

		Durvalumab (n=264)	Placebo (n=266)
Age, years	Median (range)	62.0 (28–84)	62.0 (28–79)
Sex, %	Male / Female	67.4 / 32.6	70.7 / 29.3
Race, %	White / Asian / Other	49.2 / 49.6 / 1.1	51.5 / 45.5 / 3.0
WHO performance status, %	0 / 1	50.0 / 50.0	47.4 / 52.6
Smoking status, %	Current / Former / Never	23.9 / 67.4 / 8.7	20.7 / 69.5 / 9.8
AJCC disease stage at diagnosis, %	I / II / III	3.0 / 9.5 / 87.5	4.1 / 8.6 / 87.2
Prior chemotherapy regimen, %*	Cisplatin-etoposide / Carboplatin-etoposide	65.5 / 34.5	66.9 / 33.1
Prior radiation schedule, %	Once daily / Twice daily	73.9 / 26.1	70.3 / 29.7
Best response to prior cCRT, %	CR / PR / SD	11.7 / 72.3 / 15.9	12.8 / 75.2 / 12.0
Prior PCI, %	Yes / No	53.8 / 46.2	53.8 / 46.2

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Dual Primary Endopoint

OS

- Median duration of follow up in censored patients: 37.2 months (range 0.1–60.9)

	Durvalumab (n=264)	Placebo (n=266)
Events, n (%)	115 (43.6)	146 (54.9)
mOS, months (95% CI)	**55.9** (37.3–NE)	**33.4** (25.5–39.9)
HR (95% CI)	**0.73** (0.57–0.93)	
p-value	0.0104	

55.9 vs 33.4m

PFS

- Median duration of follow up in censored patients: 27.6 months (range 0.0–55.8)

	Durvalumab (n=264)	Placebo (n=266)
Events, n (%)	139 (52.7)	169 (63.5)
mPFS, months (95% CI)	**16.6** (10.2–28.2)	**9.2** (7.4–12.9)
HR (95% CI)	**0.76** (0.61–0.95)	
p-value	0.0161	

16.6 vs 9.2m

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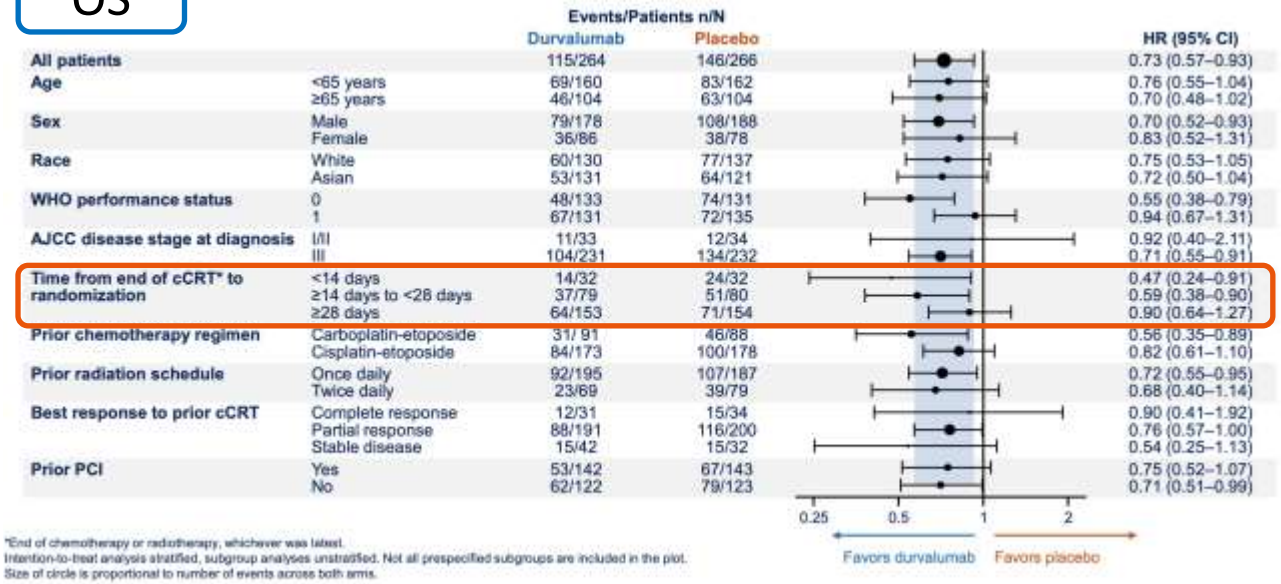
ADRIATIC

Subgrup Analysis

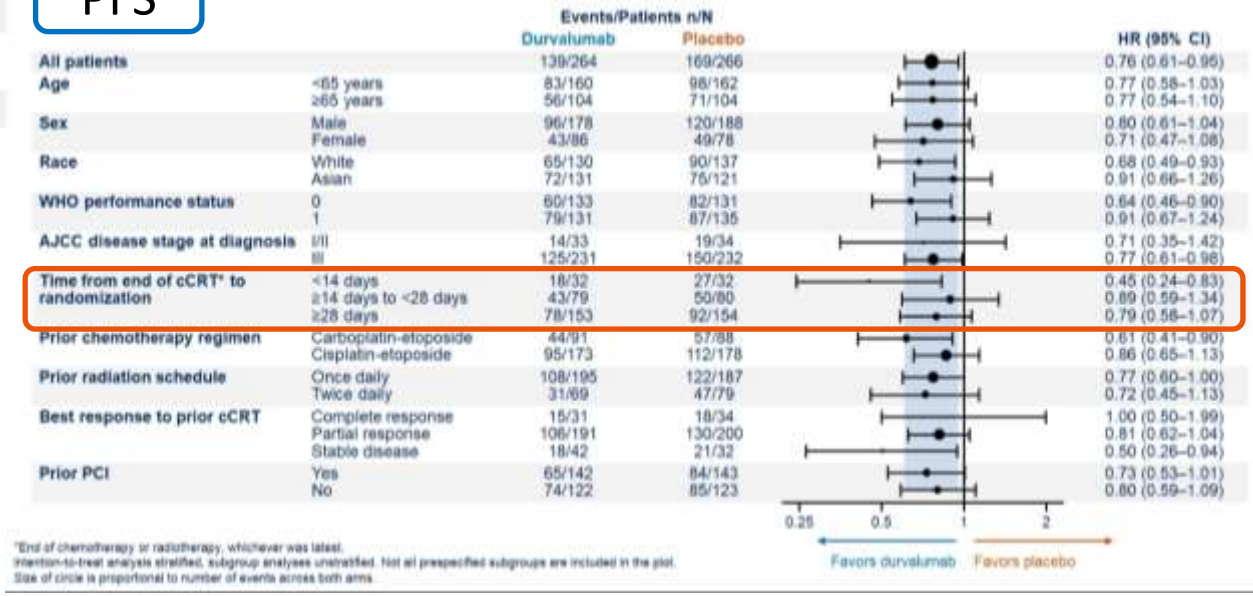
OS



		Events/Patients n/N		HR (95% CI)
		Durvalumab	Placebo	
All patients		115/264	146/266	0.73 (0.57–0.93)
Age	<65 years	69/160	83/162	0.76 (0.55–1.04)
	≥65 years	46/104	63/104	0.70 (0.48–1.02)
Sex	Male	79/178	108/188	0.70 (0.52–0.93)
	Female	36/86	38/78	0.83 (0.52–1.31)
Race	White	60/130	77/137	0.75 (0.53–1.05)
	Asian	53/131	64/121	0.72 (0.50–1.04)
WHO performance status	0	48/133	74/131	0.55 (0.38–0.79)
	1	67/131	72/135	0.94 (0.67–1.31)
AJCC disease stage at diagnosis	I/II	11/33	12/34	0.92 (0.40–2.11)
	III	104/231	134/232	0.71 (0.55–0.91)
Time from end of cCRT* to randomization	<14 days	14/32	24/32	0.47 (0.24–0.91)
	≥14 days to <28 days	37/79	51/80	0.59 (0.38–0.90)
	≥28 days	64/153	71/154	0.90 (0.64–1.27)
Prior chemotherapy regimen	Carboplatin-etoposide	31/ 91	46/88	0.56 (0.35–0.89)
	Cisplatin-etoposide	84/173	100/178	0.82 (0.61–1.10)
Prior radiation schedule	Once daily	92/195	107/187	0.72 (0.55–0.95)
	Twice daily	23/69	39/79	0.68 (0.40–1.14)
Best response to prior cCRT	Complete response	12/31	15/34	0.90 (0.41–1.92)
	Partial response	88/191	116/200	0.76 (0.57–1.00)
	Stable disease	15/42	15/32	0.54 (0.25–1.13)
Prior PCI	Yes	53/142	67/143	0.75 (0.52–1.07)
	No	62/122	79/123	0.71 (0.51–0.99)

*End of chemotherapy or radiotherapy, whichever was latest.
Intention-to-treat analysis stratified, subgroup analyses unstratified. Not all prespecified subgroups are included in the plot.
Size of circle is proportional to number of events across both arms.

PFS



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		Durvalumab	Placebo	
All patients		139/264	169/266	0.76 (0.61–0.95)
Age	<65 years	83/160	98/162	0.77 (0.58–1.03)
	≥65 years	56/104	71/104	0.77 (0.54–1.10)
Sex	Male	96/178	120/188	0.80 (0.61–1.04)
	Female	43/86	49/78	0.71 (0.47–1.08)
Race	White	65/130	90/137	0.68 (0.49–0.93)
	Asian	72/131	76/121	0.91 (0.66–1.26)
WHO performance status	0	60/133	82/131	0.64 (0.46–0.90)
	1	79/131	87/135	0.91 (0.67–1.24)
AJCC disease stage at diagnosis	I/II	14/33	19/34	0.71 (0.35–1.42)
	III	125/231	150/232	0.77 (0.61–0.98)
Time from end of cCRT* to randomization	<14 days	18/32	27/32	0.45 (0.24–0.83)
	≥14 days to <28 days	43/79	50/80	0.89 (0.59–1.34)
	≥28 days	78/153	92/154	0.79 (0.58–1.07)
Prior chemotherapy regimen	Carboplatin-etoposide	44/91	57/88	0.61 (0.41–0.90)
	Cisplatin-etoposide	95/173	112/178	0.86 (0.65–1.13)
Prior radiation schedule	Once daily	108/195	122/187	0.77 (0.60–1.00)
	Twice daily	31/69	47/79	0.72 (0.45–1.13)
Best response to prior cCRT	Complete response	15/31	18/34	1.00 (0.50–1.99)
	Partial response	106/191	130/200	0.81 (0.62–1.04)
	Stable disease	18/42	21/32	0.50 (0.26–0.94)
Prior PCI	Yes	65/142	84/143	0.73 (0.53–1.01)
	No	74/122	85/123	0.80 (0.59–1.09)

*End of chemotherapy or radiotherapy, whichever was latest.
Intention-to-treat analysis stratified, subgroup analyses unstratified. Not all prespecified subgroups are included in the plot.
Size of circle is proportional to number of events across both arms.

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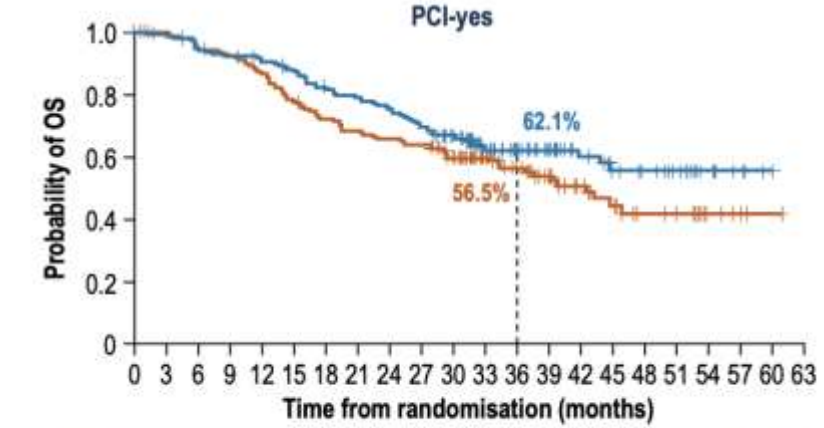
ADRIATIC

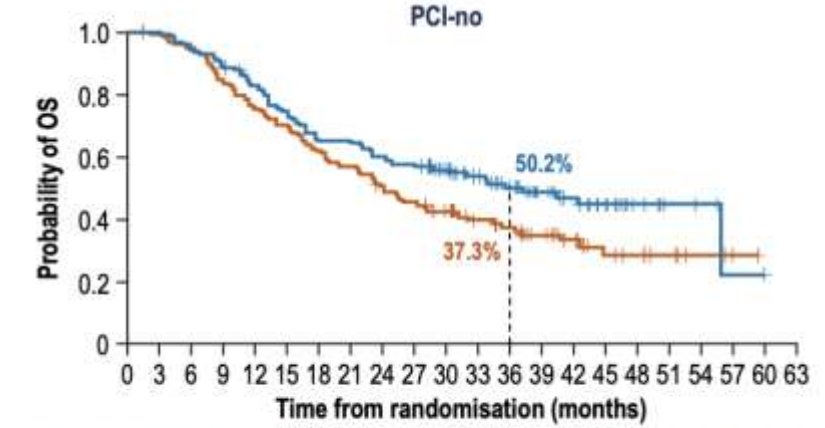
Prespecified Subgrup Analysis

ITT population	Durvalumab (n = 264)	Placebo (n = 266)
Received PCI, %	54	54
Carboplatin / cisplatin CT,§ %	34 / 66	33 / 67
BID / QD thoracic RT, %	26 / 74	30 / 70

Durvalumab arm
3y OS 62.1% PCI and 50.2% non PCI

	PCI-yes		PCI-no		ITT	
	D (n = 142)	P (n = 143)	D (n = 122)	P (n = 123)	D (n = 264)	P (n = 266)
Median OS (95% CI), months	NR (43.9–NE)	42.5 (33.4–NE)	37.3 (24.3–NE)	24.1 (18.8–31.1)	55.9 (37.3–NE)	33.4 (25.5–39.9)
3-year OS, %	62.1	56.5	50.2	37.3	56.5	47.6
HR (95% CI)	0.75 (0.52–1.07)*		0.71 (0.51–0.99)*		0.73 (0.57–0.93)†	
Multivariable HR (95% CI)	0.72 (0.50–1.03)‡		0.73 (0.52–1.02)‡		–	





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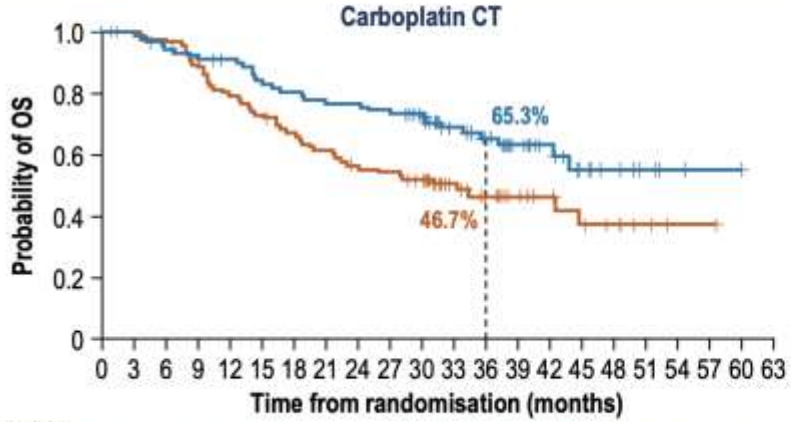
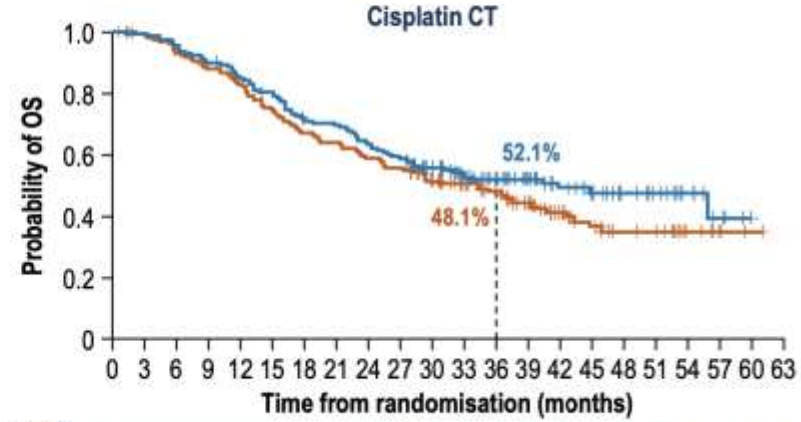
Carboplatin / cisplatin CT,§ %	34 / 66	33 / 67
BID / QD thoracic RT, %	26 / 74	30 / 70

Durvalumab arm
3y OS 65.3% Carbo and 52.1% Cis

	Carboplatin CT		Cisplatin CT		ITT	
	D (n = 91)	P (n = 88)	D (n = 173)	P (n = 178)	D (n = 264)	P (n = 266)
Median OS (95% CI), months	NR (42.5–NE)	33.4 (21.7–NE)	41.9 (27.7–NE)	34.3 (25.4–40.7)	55.9 (37.3–NE)	33.4 (25.5–39.9)
3-year OS, %	65.3	46.7	52.1	48.1	56.5	47.6
HR (95% CI)	0.56 (0.35–0.89)*		0.82 (0.61–1.10)*		0.73 (0.57–0.93)†	
Multivariable HR (95% CI)	0.55 (0.35–0.87)‡		0.81 (0.60–1.08)‡		–	





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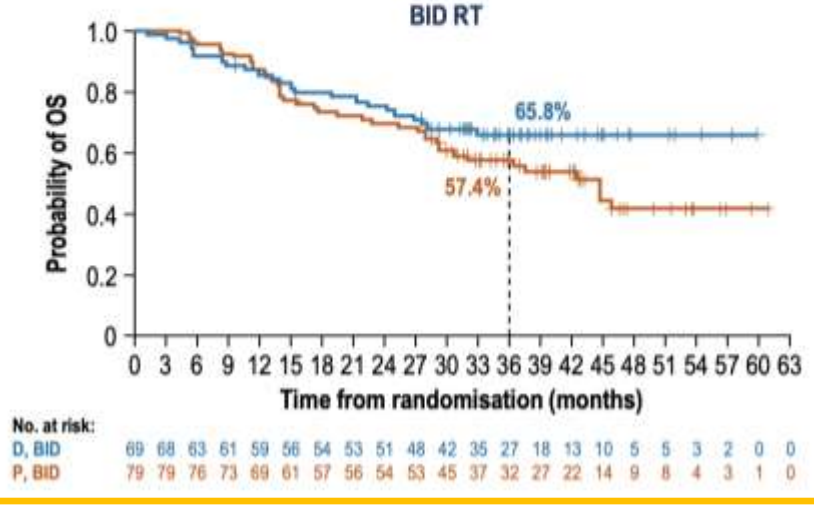
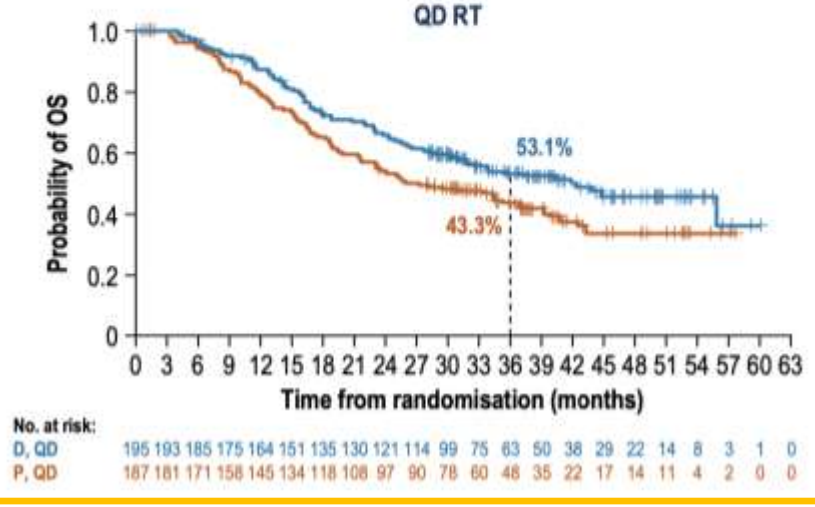
Received PCI, %	54	54
Carboplatin / cisplatin CT,§ %	34 / 66	33 / 67
BID / QD thoracic RT, %	26 / 74	30 / 70

Durvalumab arm
3y OS 65.8% BID and 53.1% QD

	BID RT		QD RT		ITT	
	D (n = 69)	P (n = 79)	D (n = 195)	P (n = 187)	D (n = 264)	P (n = 266)
Median OS (95% CI), months	NR (NE–NE)	44.8 (29.4–NE)	41.9 (32.0–NE)	26.1 (21.7–36.8)	55.9 (37.3–NE)	33.4 (25.5–39.9)
3-year OS, %	65.8	57.4	53.1	43.3	56.5	47.6
HR (95% CI)	0.68 (0.40–1.14)*		0.72 (0.55–0.96)*		0.73 (0.57–0.93)†	
Multivariable HR (95% CI)	0.71 (0.42–1.18)‡		0.73 (0.55–0.96)‡		–	





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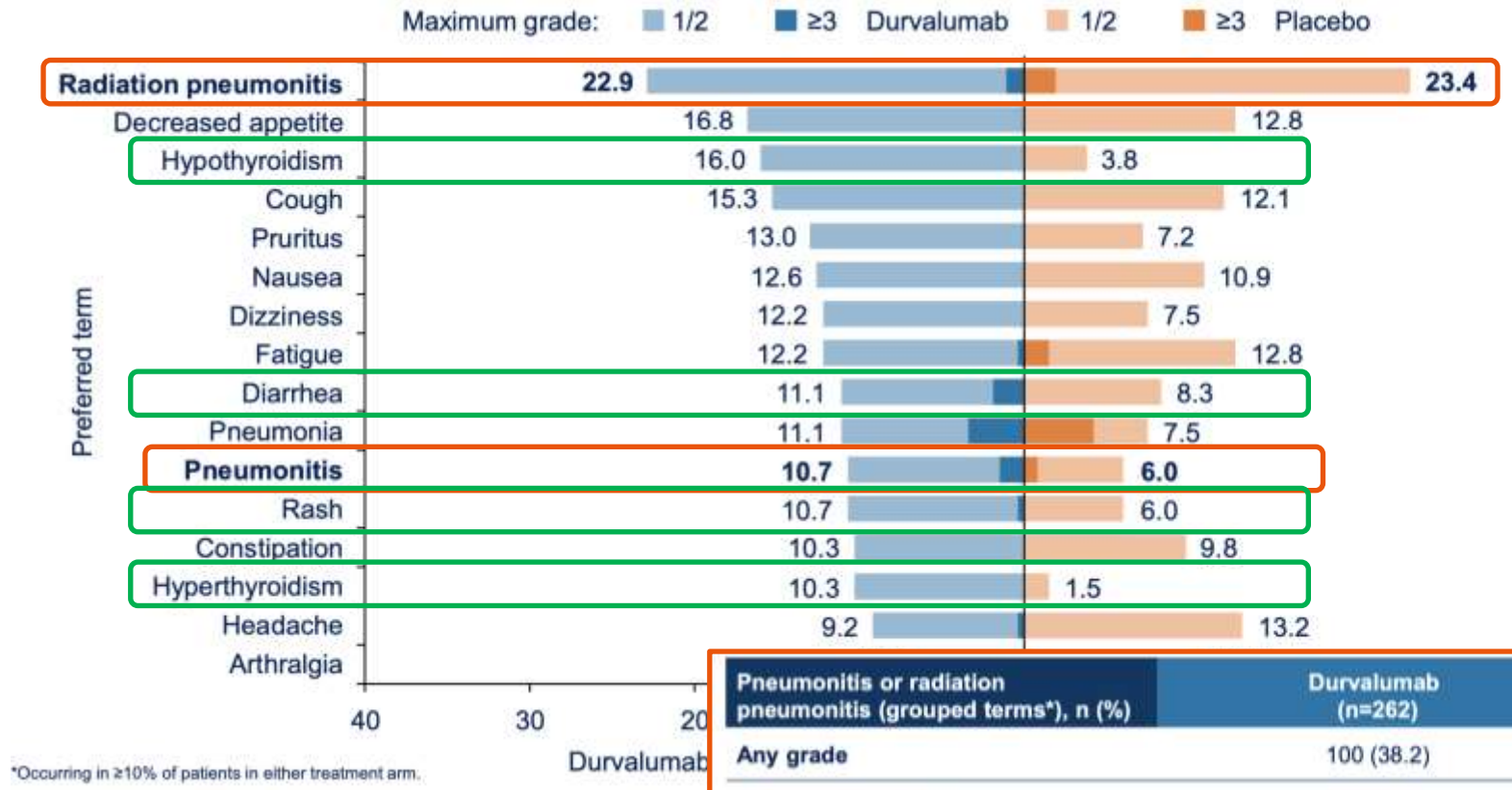
ADRIATIC

Most frequent AEs



Pneumonitis or radiation pneumonitis (grouped terms*), n (%)	Durvalumab (n=262)	Placebo (n=265)
Any grade	100 (38.2)	80 (30.2)
Maximum grade 3/4	8 (3.1)	7 (2.6)
Leading to death	1 (0.4)	0
Leading to treatment discontinuation	23 (8.8)	8 (3.0)

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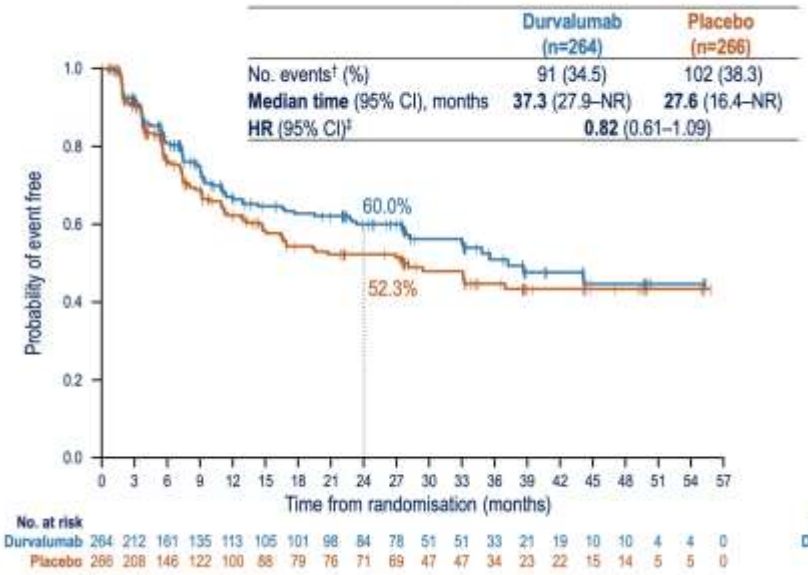
ADRIATIC

Patterns of progession

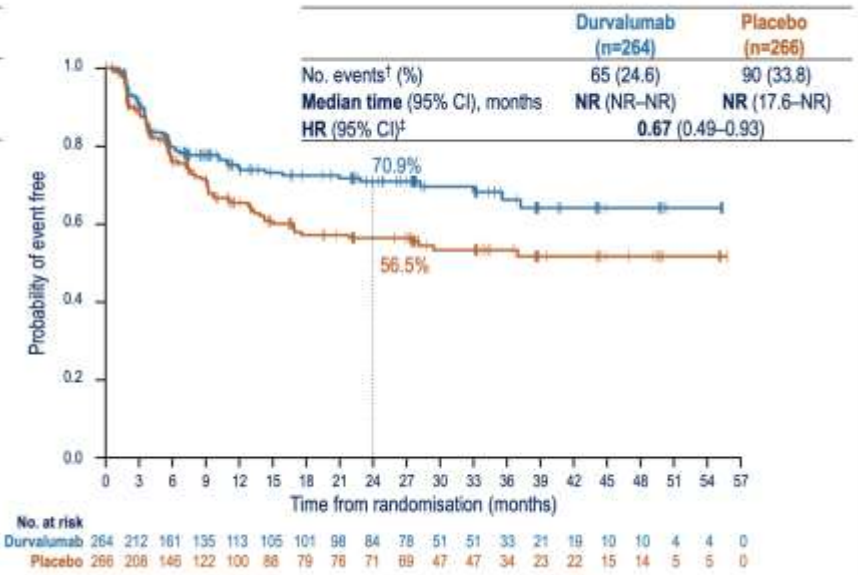
	Durvalumab (n=264)	Placebo (n=266)
First RECIST progression or death, n (%)	139 (52.7)	169 (63.5)
RECIST progression, n (%)	126 (47.7)	158 (59.4)
Intrathoracic only	74 (28.0)	79 (29.7)
Extrathoracic only	48 (18.2)	67 (25.2)
Simultaneous intrathoracic and extrathoracic	4 (1.5)	12 (4.5)
Death in absence of progression, n (%)	13 (4.9)	11 (4.1)

	Durvalumab (n=264)	Placebo (n=266)
Any new extrathoracic lesion*, n (%)	52 (19.7)	79 (29.7)
No. of new organ locations, n (%)		
1	50 (18.9)	76 (28.6)
2	2 (0.8)	3 (1.1)
New lesions by organ location, n (%)		
Brain/CNS	18 (6.8)	33 (12.4)
PCI Yes	4 (2.8)†	9 (6.3)‡
PCI No	14 (11.5)†	24 (19.5)‡
Liver	14 (5.3)	16 (6.0)
Adrenal gland	9 (3.4)	8 (3.0)
Distant lymph node	5 (1.9)	8 (3.0)
Bone	2 (0.8)	6 (2.3)
Other§	6 (2.3)	11 (4.1)

Time to intrathoracic progression* or death



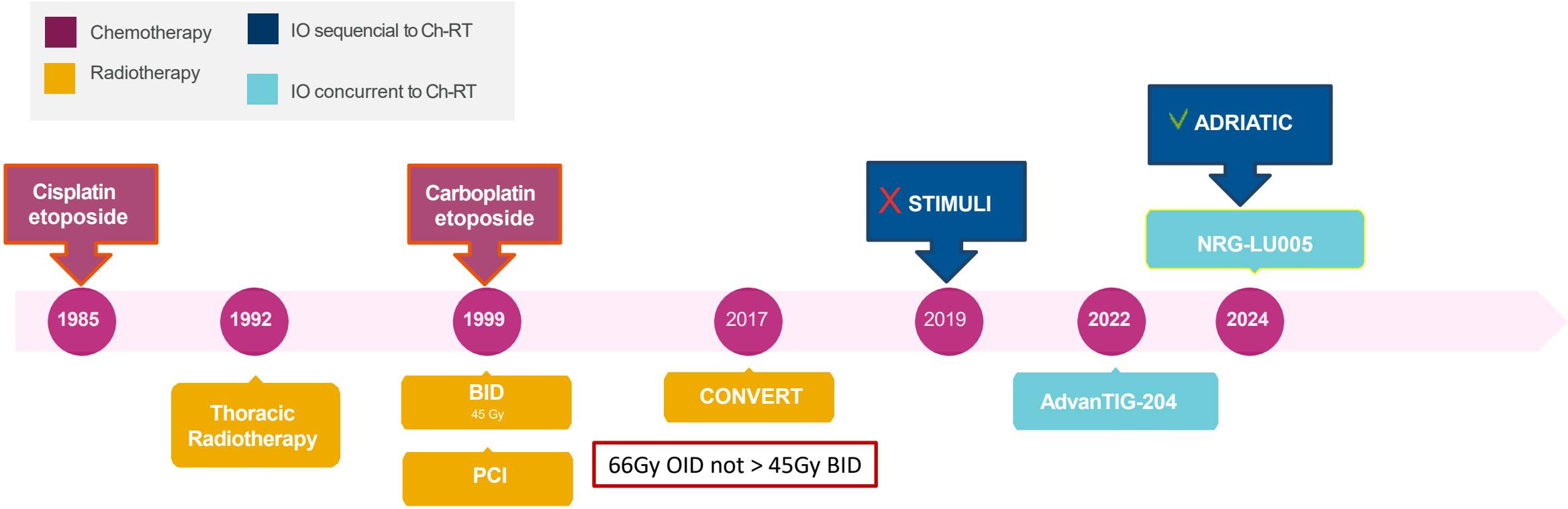
Time to extrathoracic progression* or death



Senan S. ELCC 2025

SCLC Limited disease

Past, present and future



X EMA negative √ Approved

Lopez-Chavez et al. Curr Probl Cancer. 2012 / Turrisi et al. NEJM 1999 / Dayen, C. Et al. *J Clin Oncol* 2013 / Faivre-Finn C, et al. Lancet Oncol. 2017 / Grønberg BH, et al. Acta Oncol. 2016 / Peters S, et al. Ann Oncol. 2022 / Gobbini E, et al. ELCC 2024

SCLC Limited disease

NEGATIVE

NRG-LU005

Phase III (N = 544; US & Japanese sites**)** NCT03811002

Inclusion criteria
- LS-SCLC (Stage Tx, T1–T4, N0–3, M0; AJCC 8th edition)
- PS 0-2
- **One pre-registration cycle of chemotherapy (platinum/etoposide*)**

Stratification factors
- Radiation schedule (BID vs daily)#
- Cisplatin vs carboplatin
- Male vs female
- ECOG PS 0/1 vs 2

1:1 R

From Cycle 2: **Atezolizumab IV** + **Platinum/etoposide*** Q3W for 3 cycles + **Thoracic RT** 45 Gy BID or 66 Gy daily → **Atezolizumab** IV Q3W for up to 1 year (total), until unacceptable toxicity or PD**

From Cycle 2: **Platinum/etoposide*** Q3W for 3 cycles + **Thoracic RT** 45 Gy BID or 66 Gy daily → **Observation****

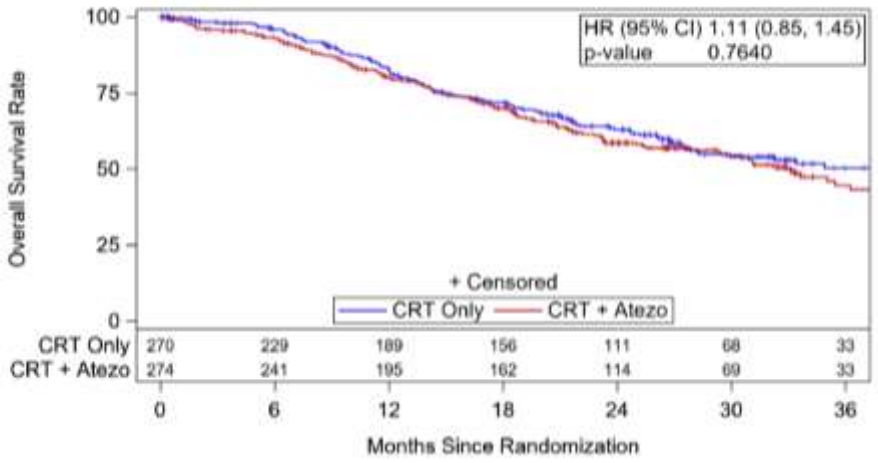
→ Follow-up

Primary endpoints
- OS

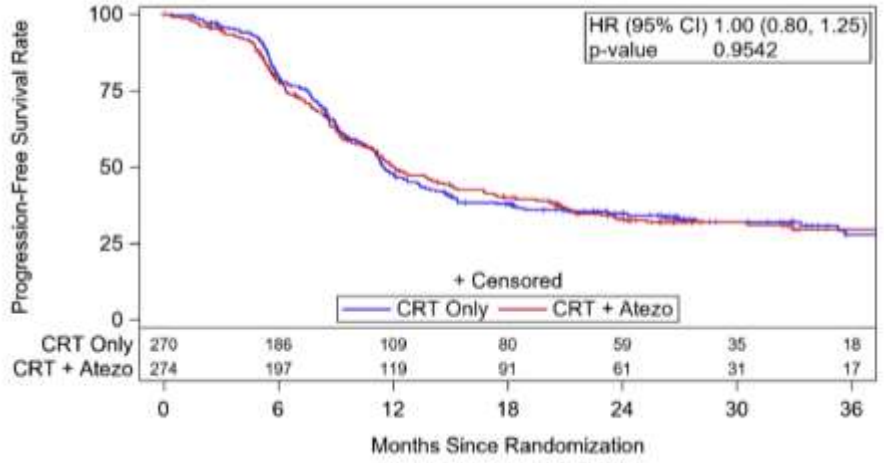
Secondary endpoints
- PFS
- ORR
- Distant metastasis-free survival
- Toxicities (CTCAE v.5.0)
- Patient reported toxicity
- QoL (FACT-TOI)
- Quality-adjusted survival (EQ-5D-5L)
- Fatigue (PROMIS)
- Biomarkers

#Thoracic RT 45 Gy BID (1.5 Gy x 30 fractions ->3 weeks) or 66 Gy daily (2 Gy x 33 fractions ->6.5 weeks) beginning with cycle 2 of chemotherapy; *cisplatin (preferred) or carboplatin; first cycle of chemotherapy given prior to study entry, 3 given on study (for a total of 4 cycles); **All patients with a CR or near CR are strongly recommended to receive prophylactic cranial irradiation (PCI; 25 Gy)

OS



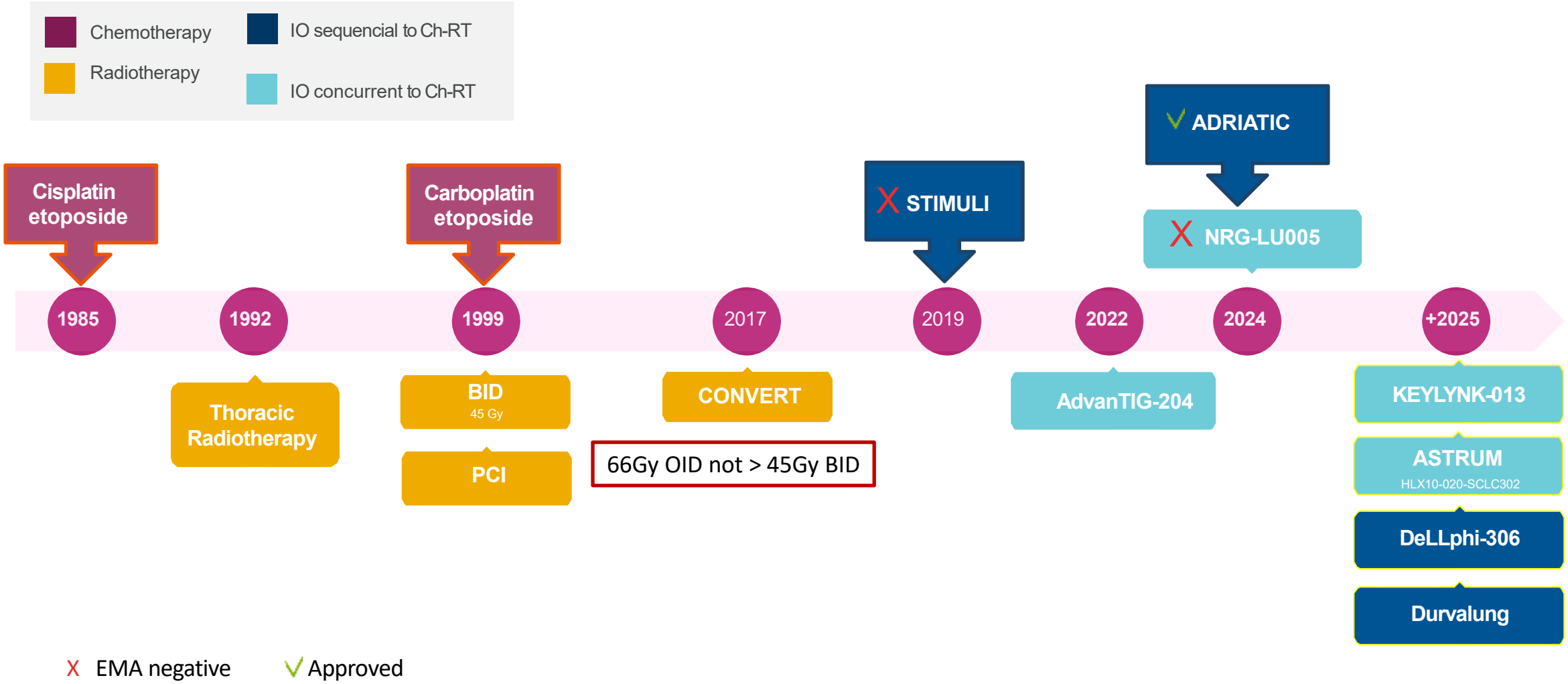
PFS



Higgins KA.et al,ASTRO 24

SCLC Limited disease

Past, present and future

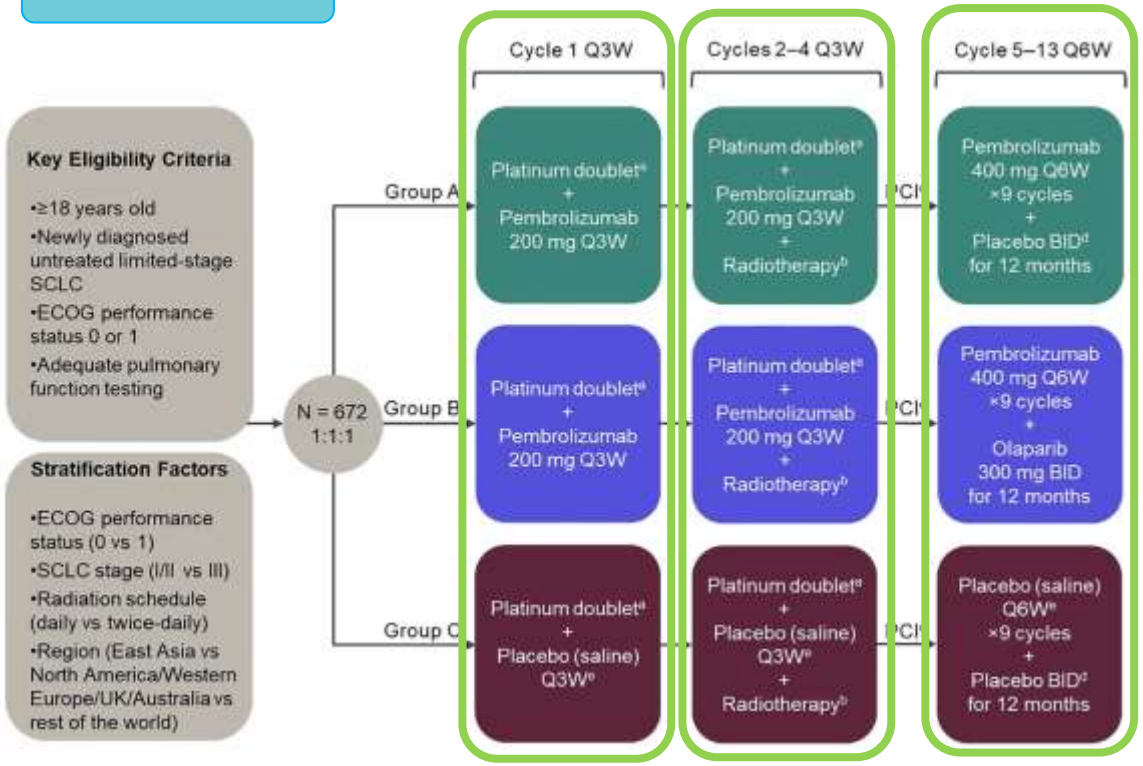


Lopez-Chavez et al. Curr Probl Cancer. 2012 / Turrisi et al. NEJM 1999 / Dayen, C. Et al. *J Clin Oncol* 2013 / Faivre-Finn C, et al. Lancet Oncol. 2017 / Grønberg BH, et al. Acta Oncol. 2016 / Peters S, et al. Ann Oncol. 2022 / Gobbini E, et al. ELCC 2024

SCLC Limited disease

Future

KEYLYNK-013 Study completation 10/2027



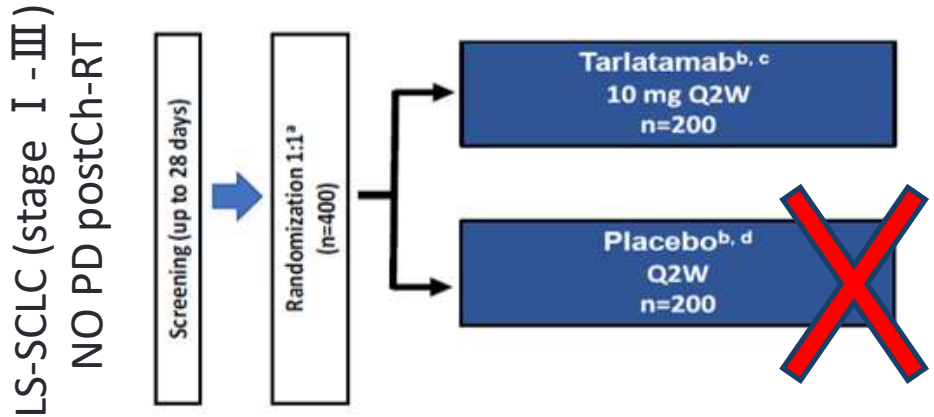
ASTRUM
HLX10-020-SCLC302

Study completation 12/2026

LS-SCLC (stage Ⅰ-Ⅲ)

Serplulimab + Chemotherapy - Radiotherapy

DeLLphi-306 Study completation 3/2026

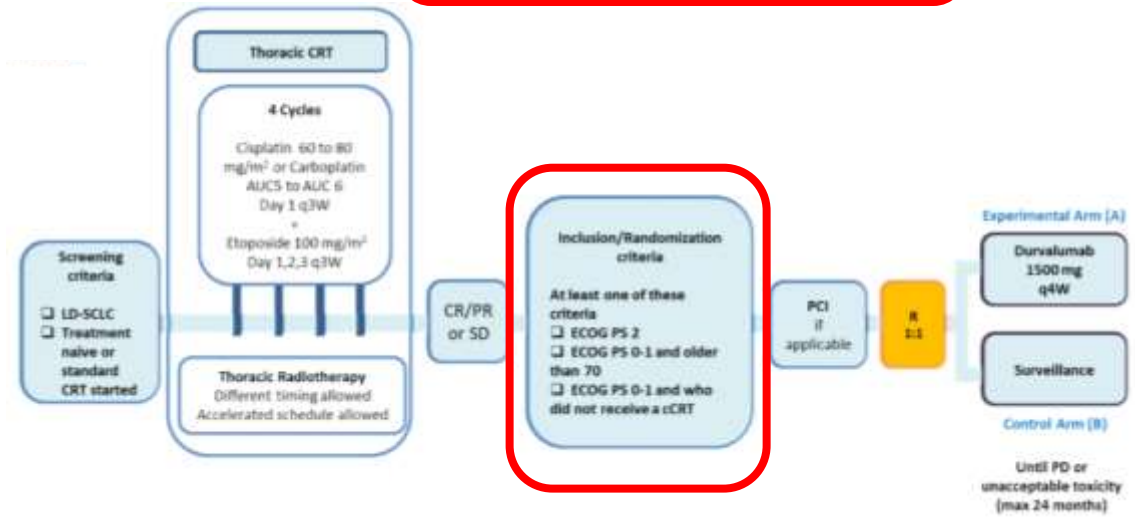


NOT an standar anymore

Durvalung

Frail LD-SCLC patients

- ECOG PS 2
- ECOG PS 0-1 + older than 70
- NO cCRT due to comorbidities



SCLC Limited disease

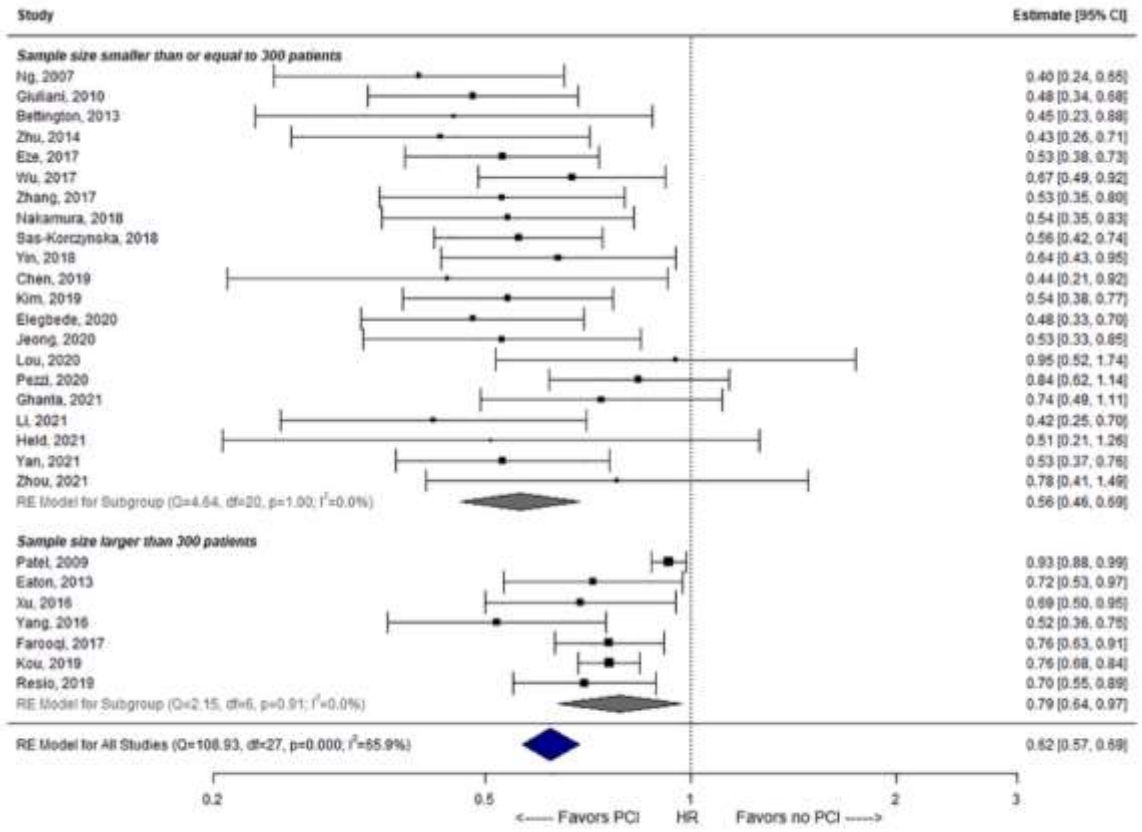
PCI. The eternal question

YES!

But…

Meta- analysis of 28 studies (2007-2021)

38% decreased risk of death



And we can minimize the toxicity!

<u>NRG – CC003 Hippocampus-avoidance PCI</u>

N= 393 patiens (75% LS SCLC)

HA PCI **non inferior** 12 months ICR **intracranial relapse** rate

No differences in **OS**

HA – PCI **reduced risk failure** in any **NCF test**

Tomasson ML. Et al, Clin Trans Rad Oncol 2022 / Gondi V. et al. JCO 2025

SCLC Limited disease

PCI. The eternal question

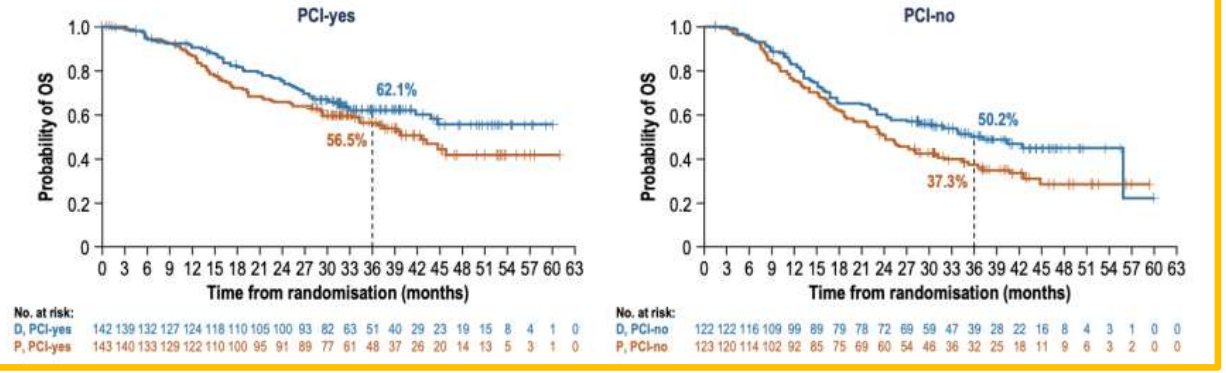
Were those patients similar that the ones in “The IO Era”?

YES!

But…

Who are the ones receiving PCI..?

	PCI-yes		PCI-no		ITT	
	D (n = 142)	P (n = 143)	D (n = 122)	P (n = 123)	D (n = 264)	P (n = 266)
Median OS (95% CI), months	NR (43.9–NE)	42.5 (33.4–NE)	37.3 (24.3–NE)	24.1 (18.8–31.1)	55.9 (37.3–NE)	33.4 (25.5–39.9)
3-year OS, %	62.1	56.5	50.2	37.3	56.5	47.6
HR (95% CI)	0.75 (0.52–1.07)*		0.71 (0.51–0.99)*		0.73 (0.57–0.93)†	
Multivariable HR (95% CI)	0.72 (0.50–1.03)‡		0.73 (0.52–1.02)‡		–	



Which is the risk of CNS progression?

	Durvalumab (n=264)	Placebo (n=266)
Any new extrathoracic lesion*, n (%)	52 (19.7)	79 (29.7)
No. of new organ locations, n (%)		
1	50 (18.9)	76 (28.6)
2	2 (0.8)	3 (1.1)
New lesions by organ location, n (%)		
Brain/CNS	18 (6.8)	33 (12.4)
PCI Yes	4 (2.8)†	9 (6.3)‡
PCI No	14 (11.5)†	24 (19.5)‡

<7%

ESMO

Patients with PS 0-1

Very few **PS >2** after ChRT included in PCI clinical trials but they can be considered

Not well defined in stage I-II and **>70 y**. or frail

OS 11.6m MRI FUP vs 13.7m PCI

Tomasson ML. Et al, Clin Trans Rad Oncol 2022 / Gondi V. et al. JCO 2025 / Takahashi T, et al. Lancet Oncol. 2017

SCLC Limited disease

Take home messages

- ✓ SCLC is a very **agressive** disease. Even when localized an on response to ChRT
- ✓ **BID RT** could be **considered** if feasible and taking into account the toxicities
- ✓ **ADRIATIC** should be the stantard of care in ALL patients with NO PD to Ch-RT
  - ✓ 14 days between end of Ch-RT and Durva could have some impact in the outcomes ?¿
  - ✓ **Carboplatin** WINS! Patients win
- ✓ **PCI** is not the only option. **MRI** FUP should be considered

We can cure patients!!

We should trusth in ourselves

16th CONGRESS Lung ON CANCER

BARCELONA 27 / 28 NOVEMBER 2025

THANK YOU

GECP lung cancer research