15th CONGRESS on Lung CANCER
MADRID
23&24 November 2023
#15CongressGECP

Fundación GECP lung cancer research

Strategies to improve outcomes of limited stage SCLC

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Disclosures

- No financial disclosures relevant to this presentation

- Other financial relantionships:
  - Advisory Board: Roche, Novartis, Boehringer Ingelheim, Takeda, Sanofi, AstraZeneca
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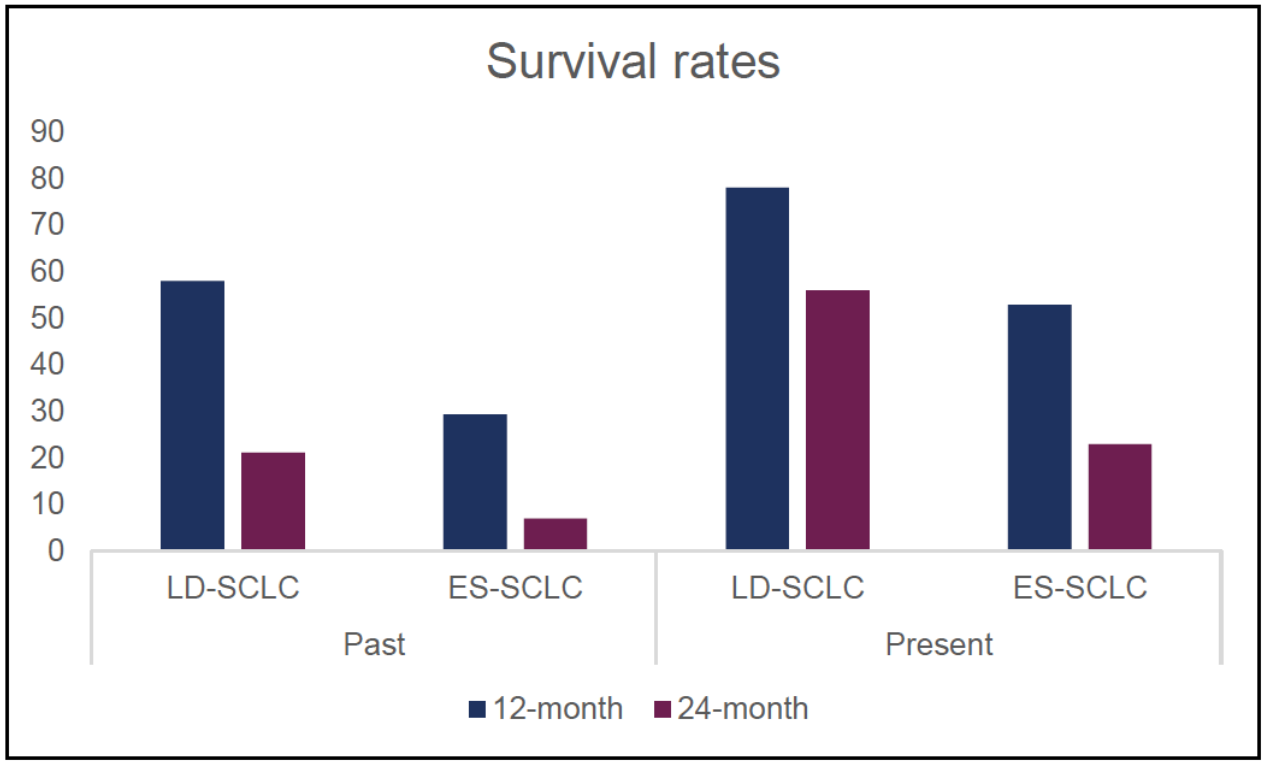
  - Travel Grants: Roche, Takeda, Pfizer, Bristol-Myers Squibb, AstraZeneca, Lilly, Janssen-Cilag

SCLC: expected outcomes

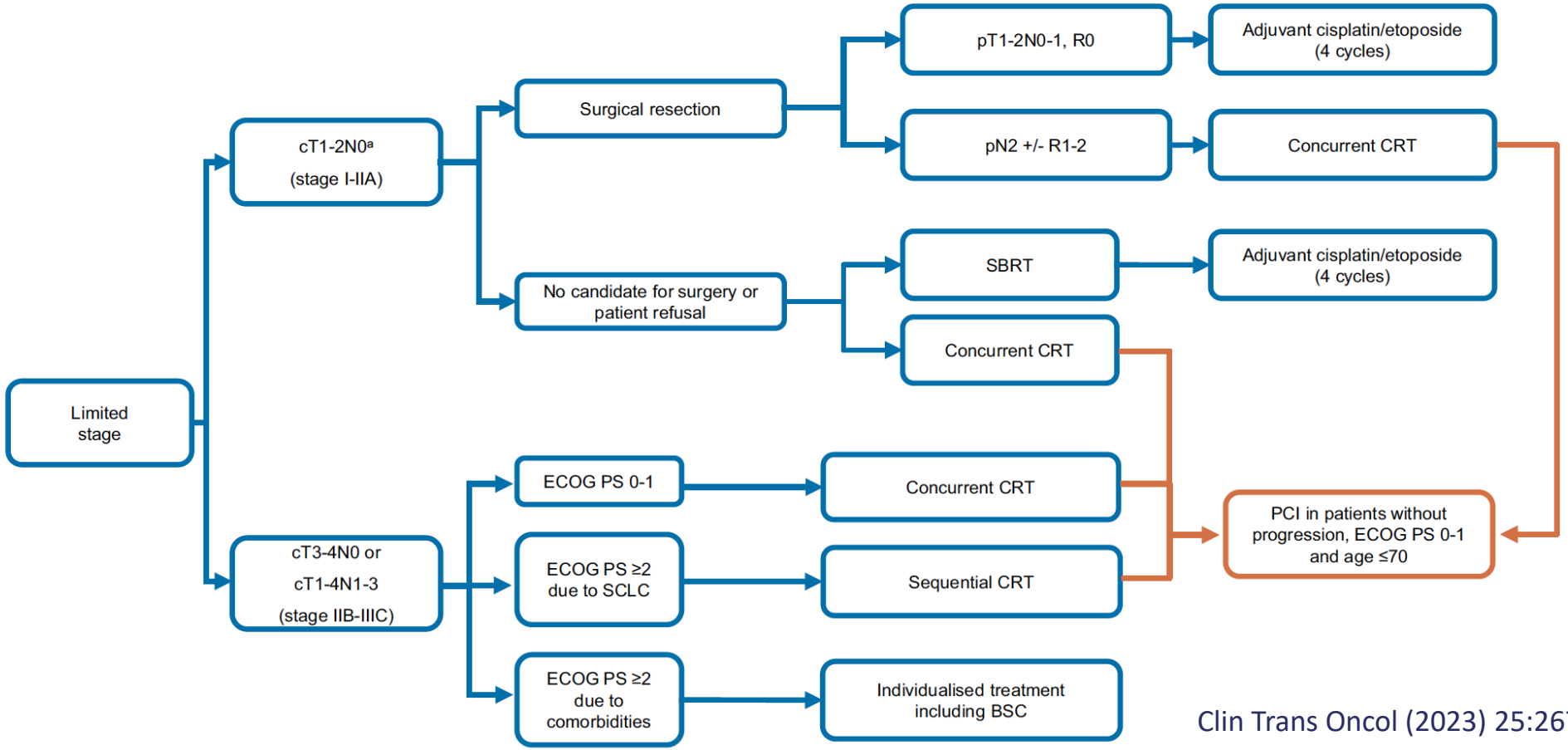
Survival rates @	LD-SCLC: Past vs. present	ED-SCLC Past vs. present
12 months	57.98 vs. 78%	29.37 vs. 52.8%
24 months	21.09 vs. 56%	6.93 vs. 22.9%



Amarasena, et al. Cochrane Database of Systematic Reviews 2015; Pas-Arez et al. ESMO 2022

SEOM-GECP Clinical guidelines for diagnosis, treatment and follow-up of small-cell lung cancer (SCLC) (2022)

Rosario García-Campelo[1] · Ivana Sullivan[2,11] · Edurne Arriola[3] · Amelia Insa[4] · Oscar Juan Vidal[5] · Patricia Cruz-Castellanos[6] · Teresa Morán[7,11] · Noemí Reguart[8] · Jon Zugazagoitia[9] · Manuel Dómine[10]



Clin Trans Oncol (2023) 25:2679–2691

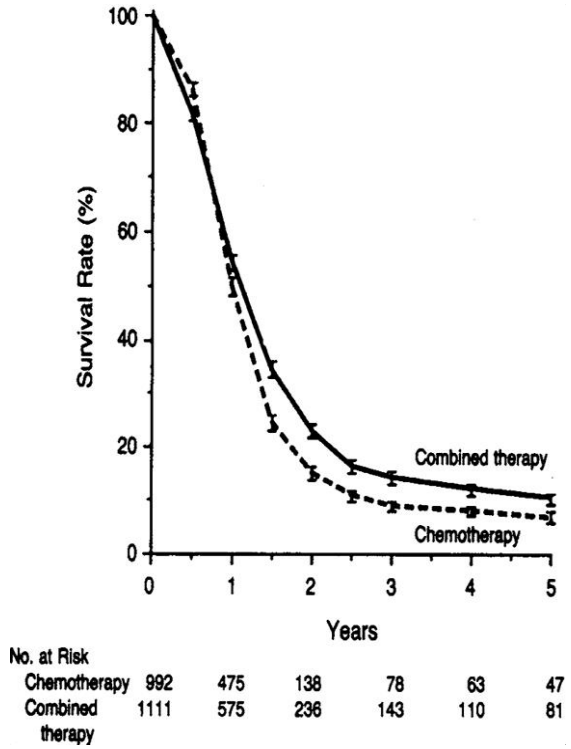
NATIONAL CANCER INSTITUTE
Division of Cancer Prevention

Small Cell Lung Cancer (SCLC) Consortium

Avoidance of the use of tobacco is the only known way to prevent the disease - no screening method has proved effective.

LS-SCLC: ¿where we where?

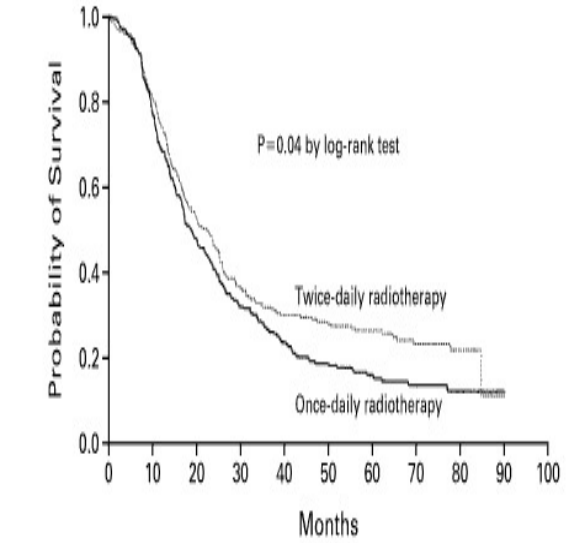
1992



Chemo-RT beats chemo
5-year survival rate 10% vs. 6%

Pignon et al. NEJM

1999



Treatment Group	0–20 Mo	20–40 Mo	40–60 Mo	60–80 Mo	80–100 Mo
	no. of deaths/no. at risk				
Once daily	108/206	48/96	15/47	4/21	0/5
Twice daily	100/211	47/109	7/62	5/42	1/14

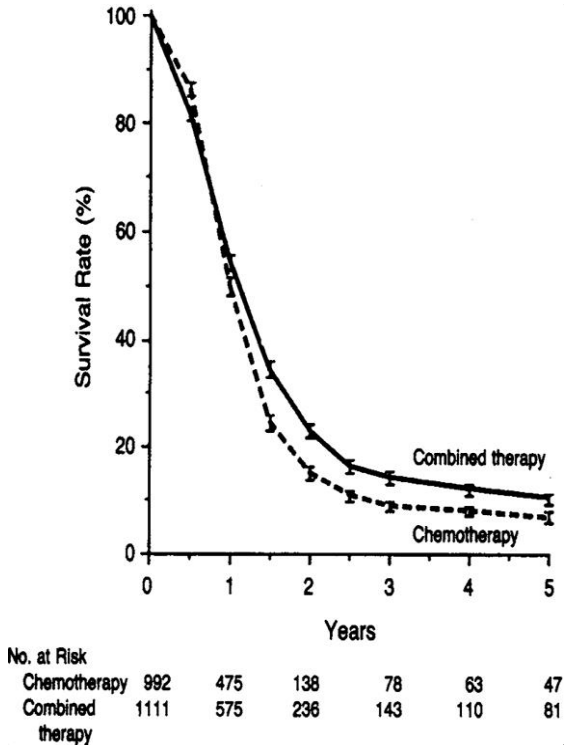
Chemo-RT BID beats daily

Turrisi et al. NEJM

- Compared twice daily (BID) TRT of 45 Gy in 30 fractions vs. once daily (QD) 45 Gy in 25 fractions
- BID TRT:
  - prolonged median OS: 23 vs. 19 months
  - increased 5-year survival: 26% vs. 16%
  - caused more G3-4 esophagitis: 32% vs. 16%

LS-SCLC: ¿where we where? & ¿where we are?

1992



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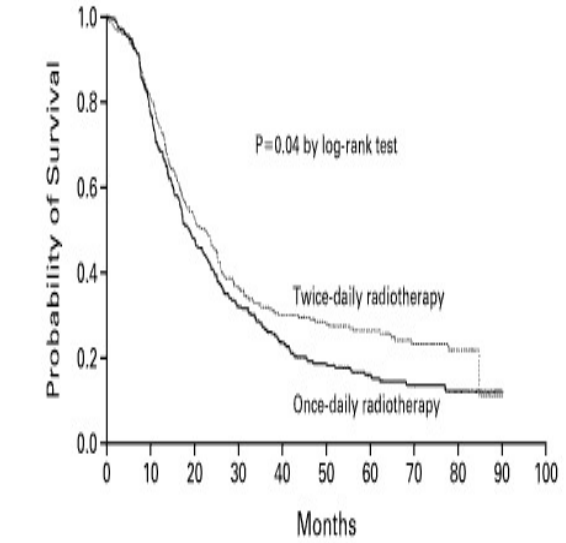

Treatment Group	0–20 Mo	20–40 Mo	40–60 Mo	60–80 Mo	80–100 Mo
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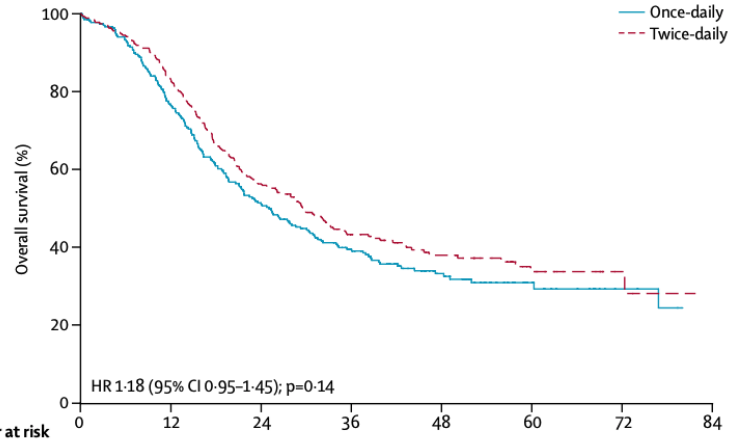
2017



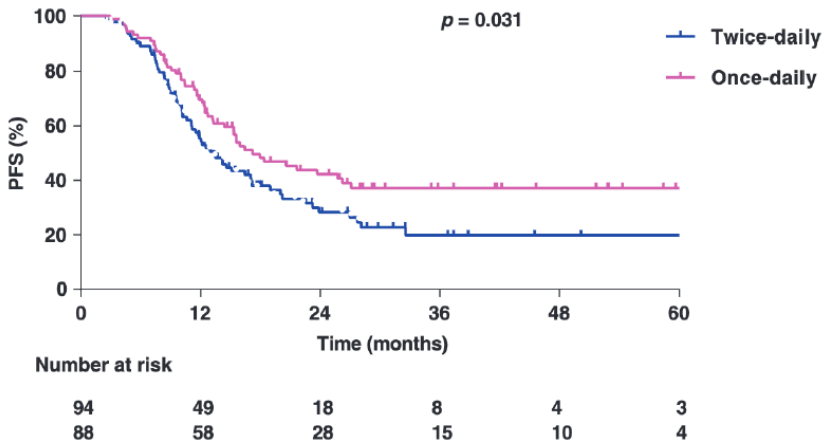
	Median OS	5-year OS
BID 45 Gy	30 months	34%
QD 66 Gy	25 months	31%

Modern chemo-RT (BID v. QD)
5-year survival 34% vs. 31%

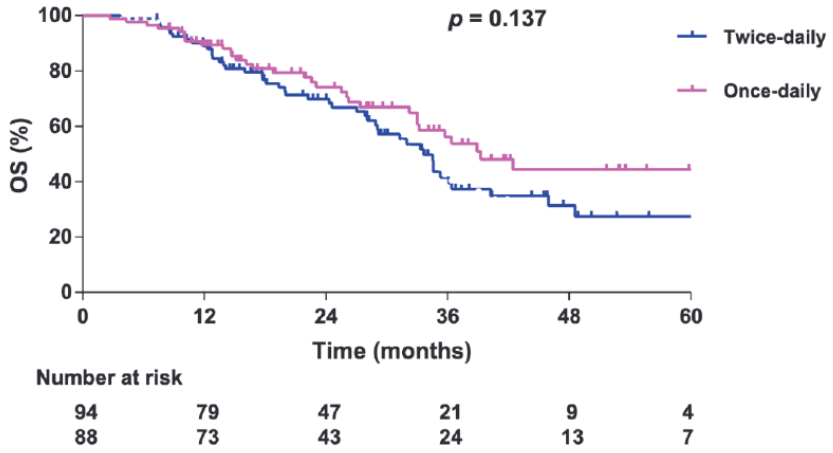
Faivre-Finn et al. Lancet

LS-SCLC: ¿where we where? & ¿where we are?

Hypofractionated accelerated high-dose TRT



	Median PFS	2-year PFS
QD 65 Gy/26 fractions	17.2 months	42.3%
BID 45 Gy	13.4 months	28.4%

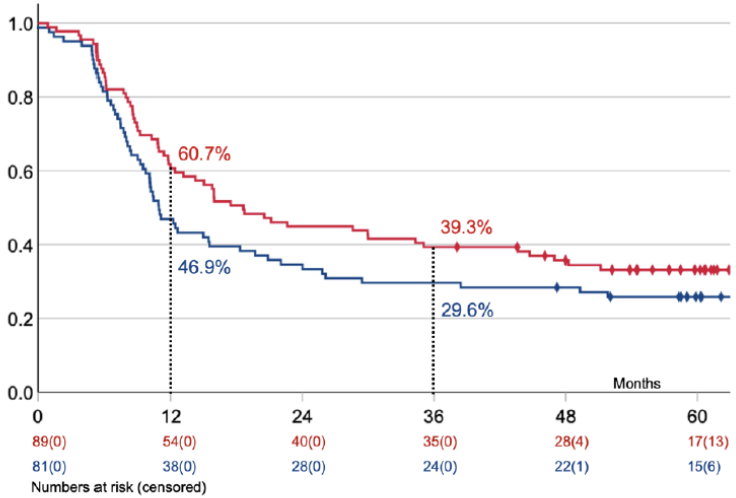


	Median OS	2-year OS
QD 65Gy/26 fractions	39.3 months	74.2%
BID 45 Gy	33.6 months	69.9%

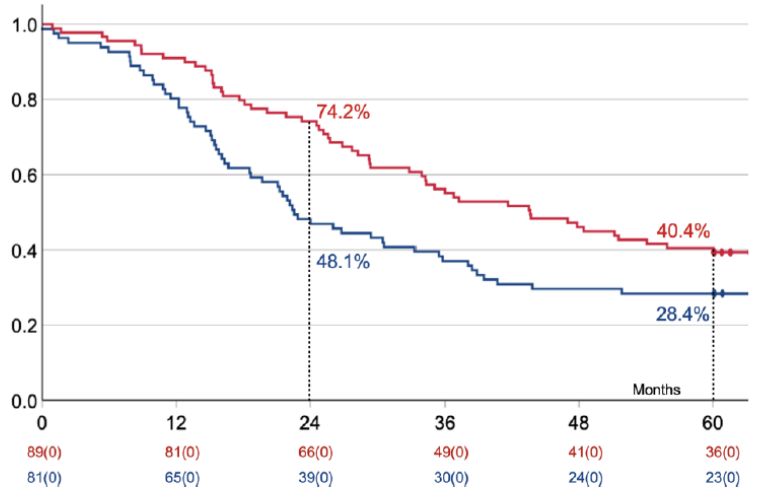
Qiu et al. Moderately Hypofractionated Once daily Compared with BID TRT Concurrently with E/P in LS-SCLC: a Multi-center, Phase II, RCT. Int J Radiat Oncol Biol Phys (2021)

LS-SCLC: ¿where we where? & ¿where we are?

Hyperfractionated accelerated high-dose TRT



	Median PFS	1-year PFS
BID 60 Gy	18.6 months	60.7%
BID 45 Gy	10.9 months	46.9%



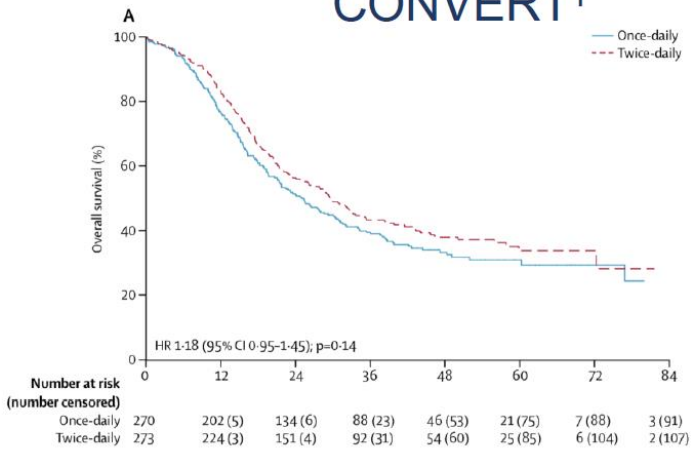
	Median OS	5-year OS
BID 60 Gy	43.6 months	40.4%
BID 45 Gy	22.6 months	28.4%

Grønberg et al. Final survival data from a randomized phase II trial comparing high-dose with standard-dose BID TRT in LS SCLC. J Clin Oncol 23 (suppl16; abstr 8512)

LS-SCLC: ¿where we where? & ¿where we are?

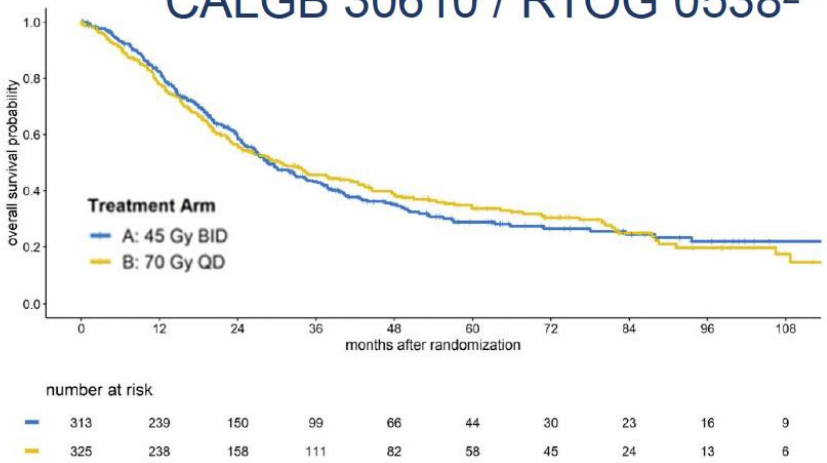
BID 45 Gy vs. High dose QD 66-70 Gy

CONVERT[1]



	Median OS	5-year OS
BID 45 Gy	30 months	34%
QD 66 Gy	25 months	31%

CALGB 30610 / RTOG 0538[2]



	Median OS	5-year OS
BID 45 Gy	28.5 months	29%
QD 70 Gy	30.5 months	34%

1. Faivre-Finn et al. Concurrent once-daily versus twice-daily CRT in patients with LS SCLC (CONVERT): an open-label, phase 3, randomised, superiority trial. Lancet Oncol 2017; 2. Bogart et al. Phase III comparison of high dose once daily TRT with standard twice daily TRT in LS SCLC: CALGB 30610/RTOG 0538. J Clin Oncol 2023

LS-SCLC: ¿where we where? & ¿where we are?

PET-CT implementation

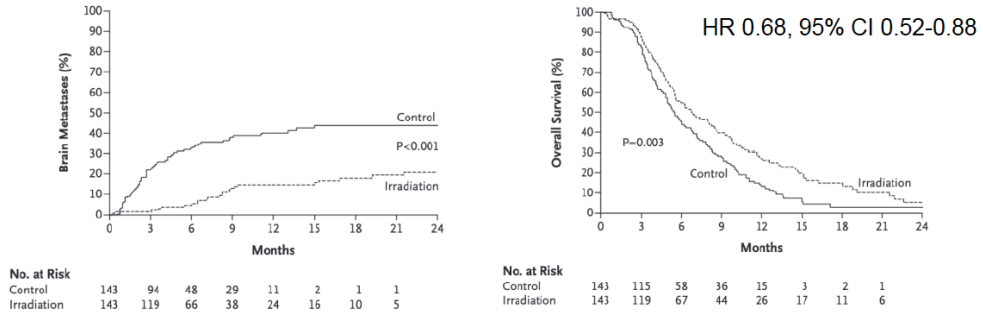
Trial	Schedule	LS definition	Start of TRT	PET CT staging	Target volume	IMRT/VMAT	$EQD2_{10}$	Median OS	G34 esophagitis
1999 Intergroup 0096[1]	45 Gy/30 fr.	VALSG	C1	-	ENI	-	43	23.0	32%
	45 Gy/25 fr.						34	19.0	16%
2002 Takada et al.[2]	45 Gy/30 fr.	VALSG+	C1	-	ENI	-	43	27.2	9%
	45 Gy/30 fr.		C4					19.7	4%
2015 Grønberg et al.[3]	45 Gy/30 fr.	IASLC+	C2	-	ENI	-	43	25.0	33%
	42 Gy/15 fr.						45	19.0	31%
2017 CONVERT [4]	45 Gy/30 fr.	VALSG-	C2	57%	CT or PET CT pos. lesions	17%	43	30.0	19%
	66 Gy/33 fr.						48	25.0	19%
2021 Grønberg et al.[5]	45 Gy/30 fr.	IASCL+	C2	100%	PET CT pos. lesions	33%	43	22.6	18%
	60 Gy/40 fr.						53	43.6	21%
2021 Qiu et al.[6]	45 Gy/30 fr.	VALSG	C1-3		CT/PET CT pos. lesions	100%	43	33.6	17%
	65 Gy/26 fr.						56	39.2	15%
2023 CALGB 36010[7]	45 Gy/30 fr.	VALSG	C1-2	90%	CT/PET CT pos. lesions + ipsilat hilum	60%	43	28.5	17%
	70 Gy/35 fr.						50	30.1	19%

[1]Turrisi et al. Twice-daily compared with once-daily TRT in LS SCLC treated concurrently with cisplatin and etoposide. NEJM 340, 265–271 (1999)
[2]Takada et al. Phase III study of concurrent vs. sequential TRT in combination with cisplatin and etoposide for LS SCLC: Results of the Japan Clinical Oncology Group Study 9104. J Clin Oncol20, 3054–3060 (2002)
[3]Grønberg et al. Randomized phase II trial comparing twice daily hyperfractionated with once daily hypofractionated TRT in LS SCLC. Acta Oncol 55, 591–597 (2016)
[4]Faivre-Finn et al. Concurrent once-daily versus twice-daily CRT in patients with LS SCLC (CONVERT): an open-label, phase 3, randomised, superiority trial. Lancet Oncol 18,1116–1125 (2017)
[5]Grønberg et al. Randomized phase II trial comparing twice daily hyperfractionated with once daily hypofractionated TRT in LS SCLC. Acta Oncol 55, 591–597 (2016)
[6]Qiu et al. Moderately Hypofractionated Once-daily Compared with BID TRT Concurrently with Etoposide and Cisplatin in LS SCLC: a Multi-center, Phase II, RCT. Int J Radiat Oncol Biol Phys (2021)
[7]Bogart et al. Phase III comparison of high dose once daily TRT with standard twice daily TRT in LS SCLC: CALGB 30610 (Alliance) / RTOG 0538. J Clin Oncol 2023 May 1;41(13):2394-2402

LS-SCLC: ¿where we where? & ¿where we are?

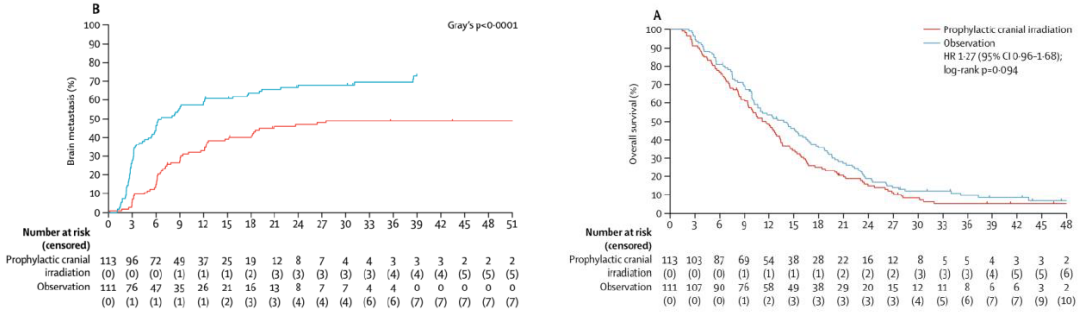
Profylactic cranial irradiation (PCI)

PCI vs. observation in ES-SCLC



Slotman et al. NEJM 2007

PCI vs. MRI surveillance in ES-SCLC



Takahashi et al. Lancet 2017

García-Campelo, Sullivan, et al, CTO 2023

Management of limited-stage IIB–IIIC (T3–4, N0 M0; T1–4, N1–3, M0)	Patients should be treated with concurrent ChT and TRT (I, A) The recommended ChT is the combination of 4 cycles of cisplatin–etoposide (I, A). Carboplatin could replace cisplatin when contraindication (II, A) ChT dose reductions should be avoided, especially during the first two cycles of treatment (II, B) The use of G/GM-CSF is safe, when clinically indicated (II, B) 45 Gy with twice-daily fraction (I, A) or 60–70 Gy (II, A); with once-daily fraction are accepted treatments. Either of them should be administered concomitantly to systemic therapy (II, A) RT should be started as early as with the 1st or 2nd course of ChT (II, A) PCI (25 Gy in ten daily fractions) should be administered after CRT in patients without progression (I, A) Hippocampal avoidance PCI is an alternative option to PCI (II, B)

LS-SCLC: ¿where we will be?

Profylactic cranial irradiation (PCI)

PRIMALUNG - Study design

EORTC
The future of cancer therapy

Stratify:
- Stage (limited vs. extensive)
- Immunotherapy part of first-line regimen (yes vs. no)
- Performance Status (0 or 1 vs. 2)

LS and ES SCLC
Standard of care

No response

Any response
No BM on MRI

R
1:1

PCI: 25 Gy / 10 fx
Hippocampal sparing PCI allowed

no PCI

Max 16 weeks

N=600

Baseline MRI

Follow-up by MRI

MRI Brain, body CT,
and cognitive function
@ 3, 6, 9, 12, 18, 24 months
Clinical Evaluation q3 months

For patients who develop BM on either study arm, treatment with RT is recommended
The techniques used (eg WBRT or SRS) will be determined by the treating team

Hippocampal sparing permitted as per institutional SOC

Primary endpoints
- OS
- QoL

MAVERICK (SWOG 1827)

MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer

Small-cell lung cancer (Limited OR Extensive)

- No prior brain metastases
- No brain metastases on MRI after 1st line therapy

Prophylactic cranial irradiation (PCI) → MRI brain surveillance

Stratify: 1. Limited vs extensive stage
2. Immunotherapy (y/n) 3. Performance Status (0-1 vs 2)

No PCI → MRI brain surveillance

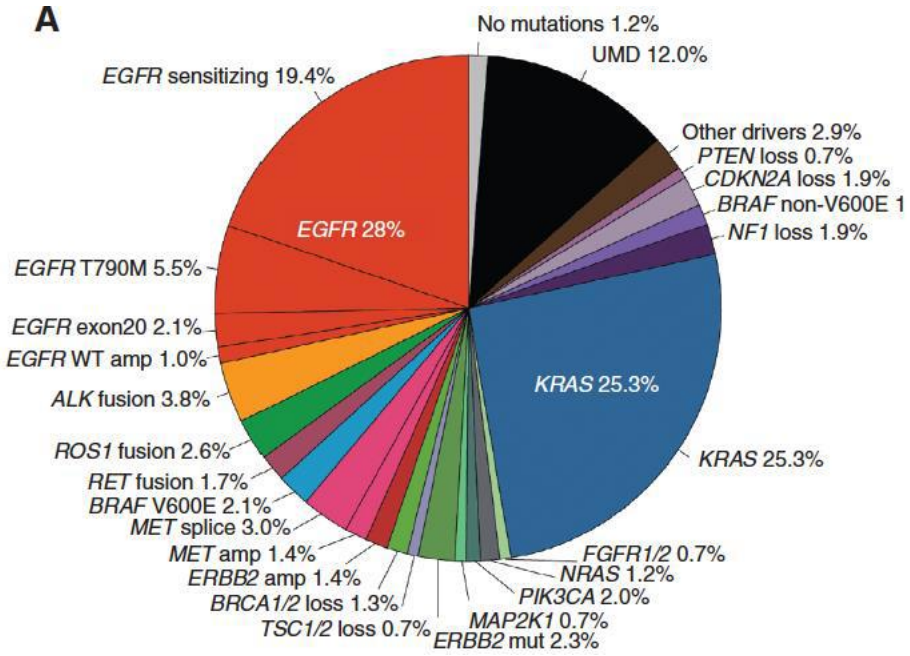
- MRI brain surveillance scheduled at 3, 6, 9, 12, 18, 24 months
- **Hippocampal-avoidance PCI** and WBRT are **allowed**
- Radiation therapy is recommended at the time of brain metastases (WBRT and SRS allowed)
- Patients managed with any/all NCCN-acknowledged first-line treatment strategies are eligible

Primary Endpoint
Overall survival (non-inferiority)

PIs Chad Rusthoven and Paul Brown

SCLC: drivers *versus* ….?

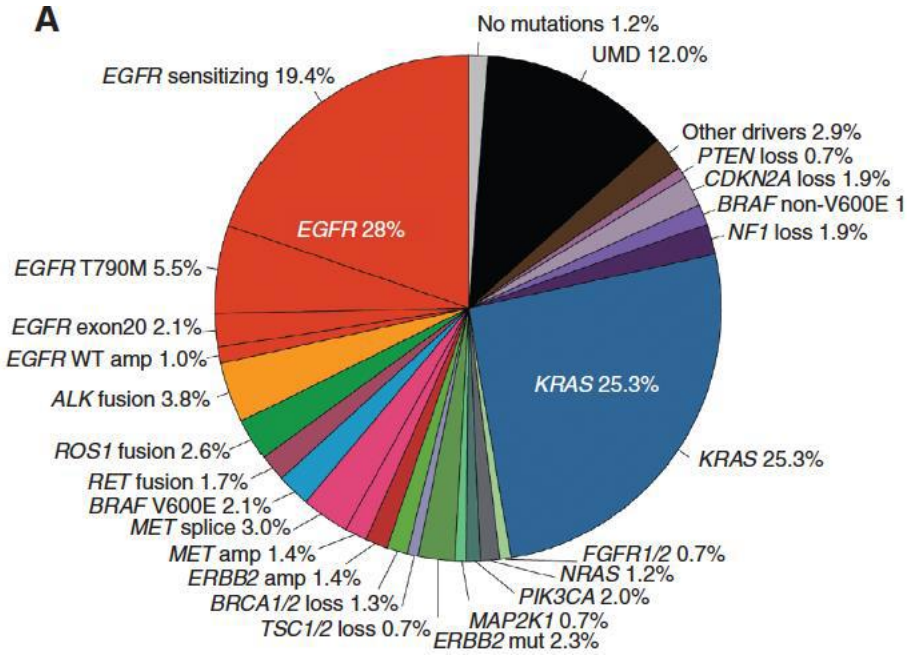
NSCLC (non-squamous)



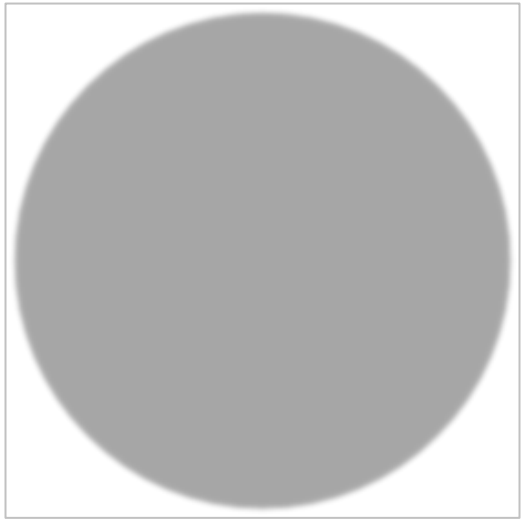
Jordan et al. Cancer Discover 2017

SCLC: drivers *versus* ….?

NSCLC (non-squamous)



SCLC



Jordan et al. Cancer Discover 2017

SCLC: drivers *versus* ….?

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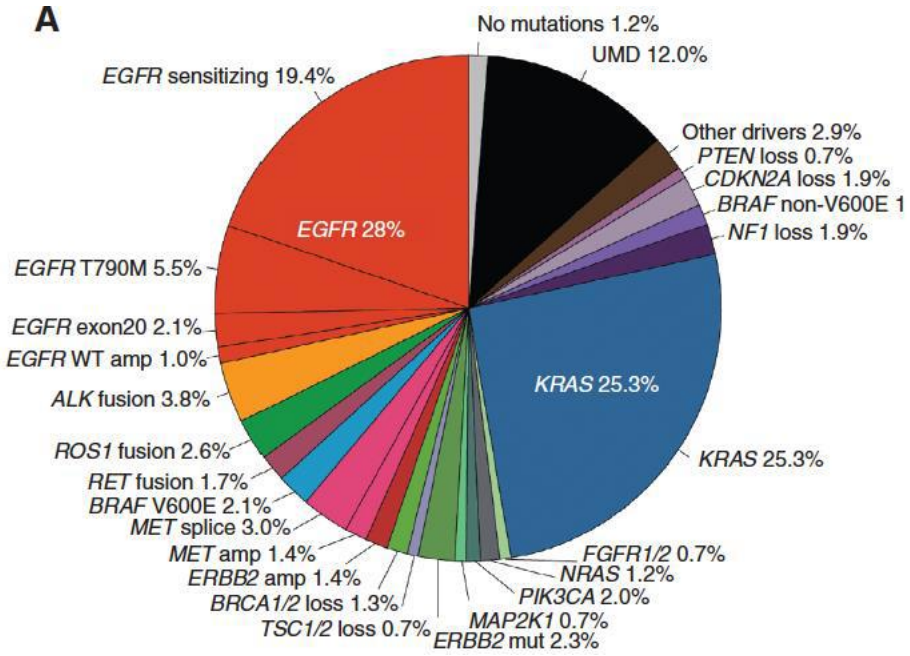

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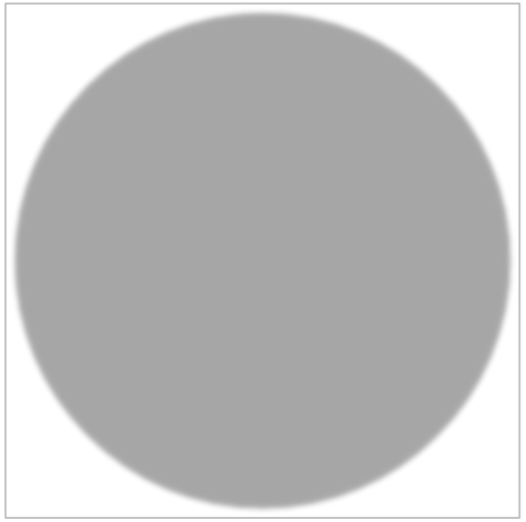


Jordan et al. Cancer Discover 2017

…tumor suppressor genes

…tumor suppressor genes

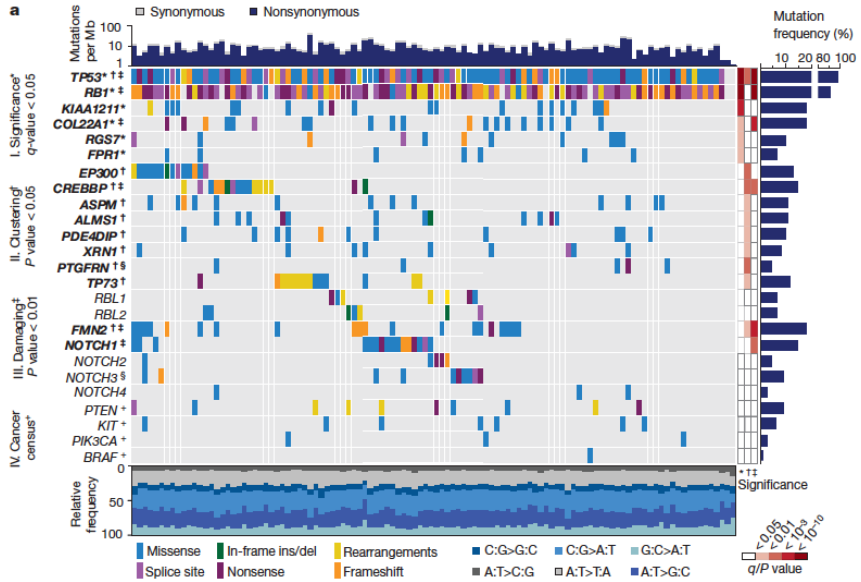
Peifer, Fernández-Cuesta *et al. Nat Genet.*

Rudin *et al. Nat Genet.*

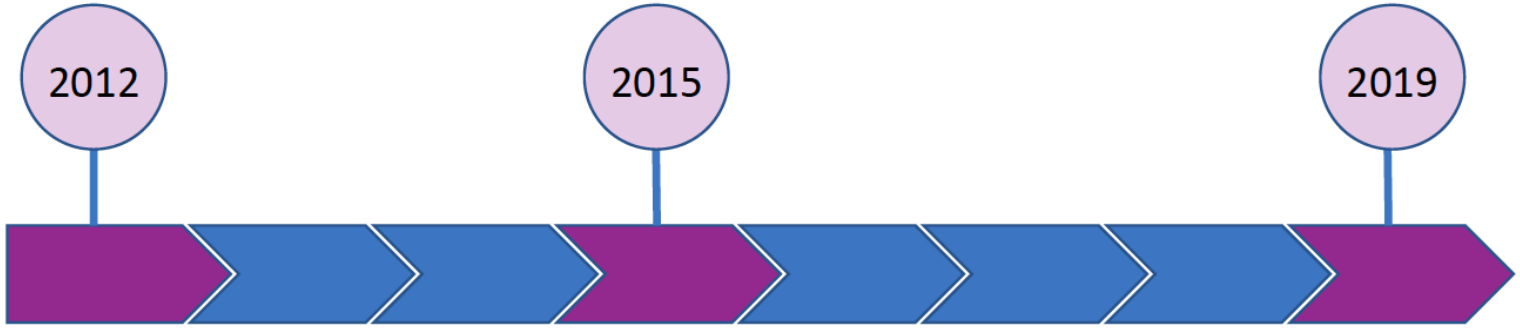
universal inactivation of *TP53* and *RB1*

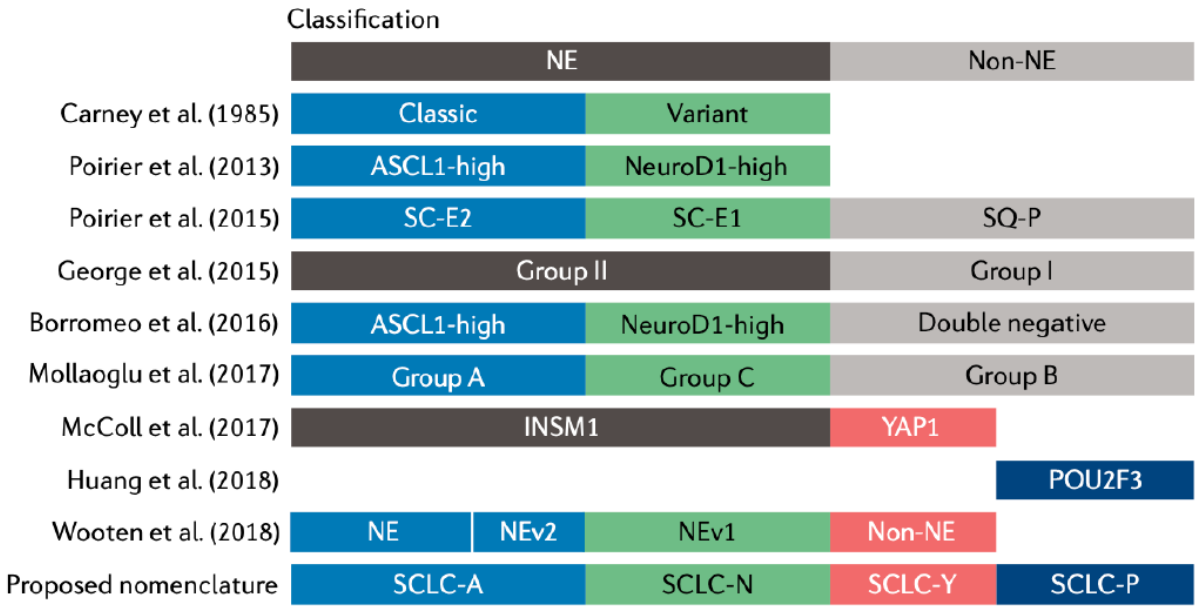
George *et al. Nature*

larger whole-genome sequencing analyses



SCLC - Timeline of key molecular findings





Rudin *et al. Nat Rev Cancer*
molecular subtypes

Randomized trials Concurrent Chemoradiotherapy → Consolidation IO

Courtesy Dr Dómine - modified

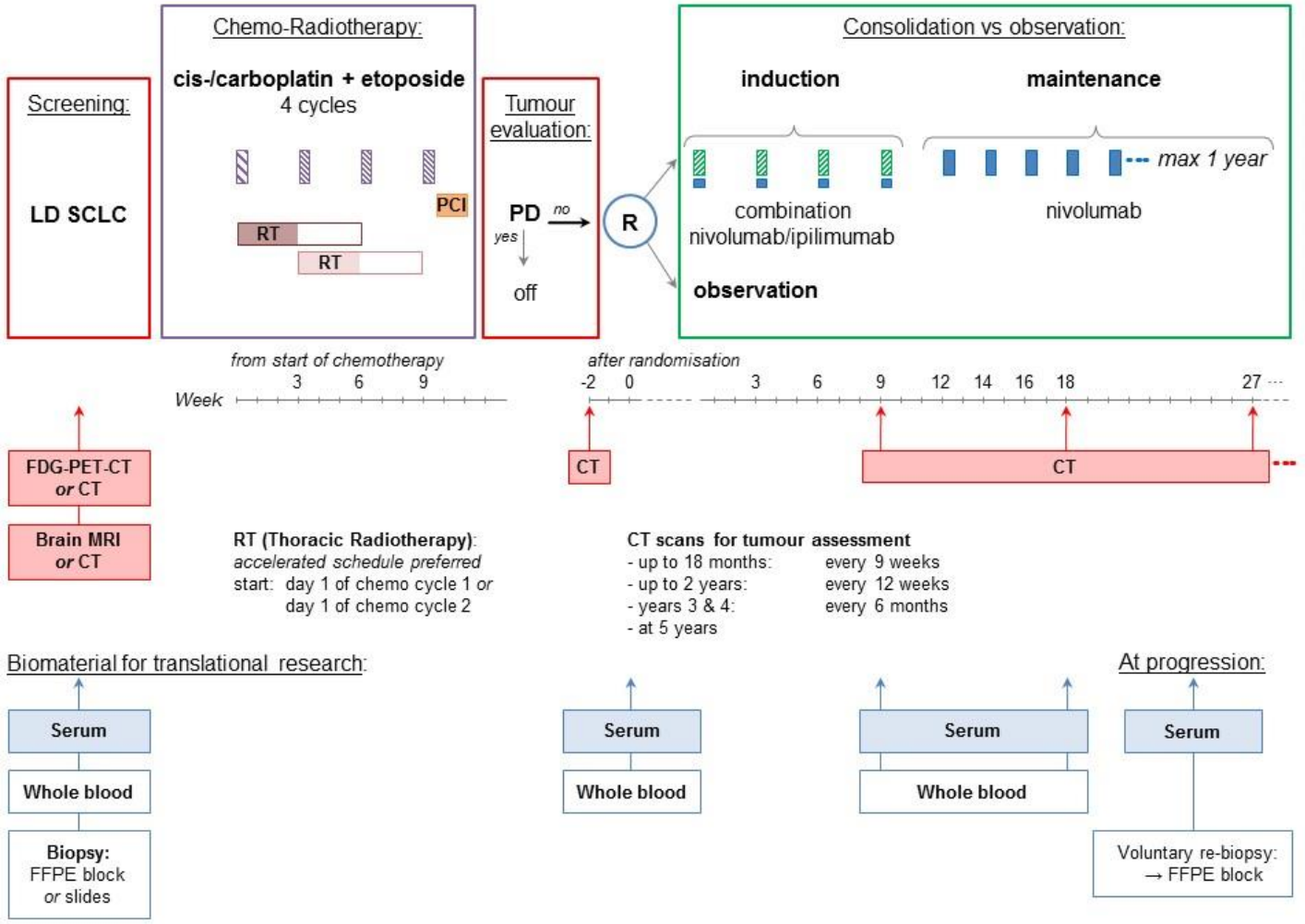
Trial	Treatment regimen	Phase	Patients (n)	Objectives/Recruitment
STIMULI	**ARM1:** Nivolumab-ipilimumab **ARM2**: Observation	II	222	**Primary: PFS** Secondary: OS, TTF, AEs **Negative**
ACHILES	**ARM1:** Atezolizumab **ARM2:** Observation	II	212	**Primary: 2-year OS** Secondary: PFS, Best RR, TRAEs **Recruiting**
ADRIATIC	**ARM1:** Durvalumab **ARM2:** Durvalumab + Tremelimumab **ARM3:** Placebo	III	728	**Primary: PFS and OS** Secondary: ORR, PFS and OS (Arm II), OS/PFS in relation to tumor PD-L1 expression **Recruitment completed**
ML41257	**ARM1:** Atezolizumab + tiragolumab up to 17 cycles **ARM2:** Atezolizumab + placebo up to 17 cycles	II	150	**Primary: PFS** Secondary: OS, ORR, DOR, AEs **Recruiting**
NCT04418648	**ARM1:** Toripalimab (Anti PD-1) for up to 6 months **ARM2:** Observation	II	170	**Primary: PFS** Secondary: OS, ORR, DOR, AEs **Not yet recruiting**

LS-SCLC: how can we improve outcomes?

IMMUNOTHERAPY

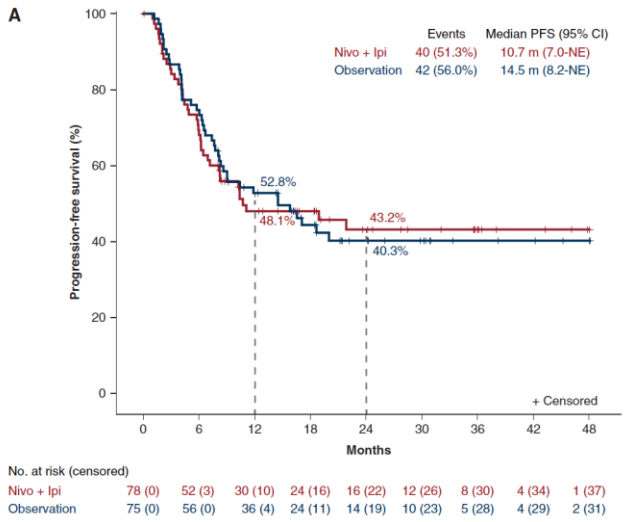
STIMULI

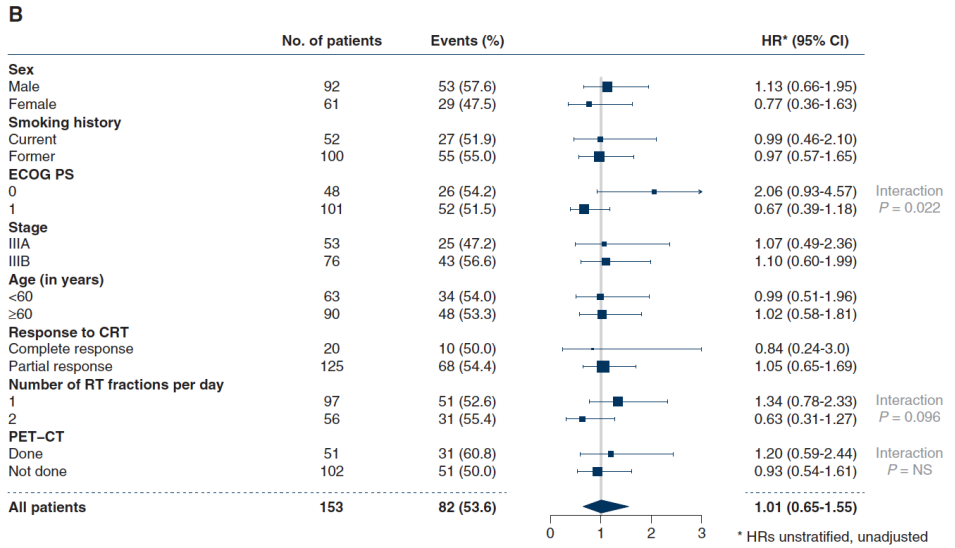
Phase II ETOP/IFCT 4-12



LS-SCLC: STIMULI TRIAL - Efficacy

PFS



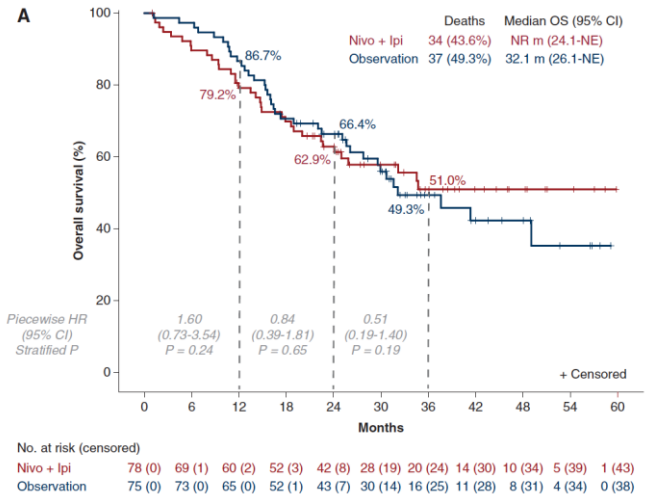


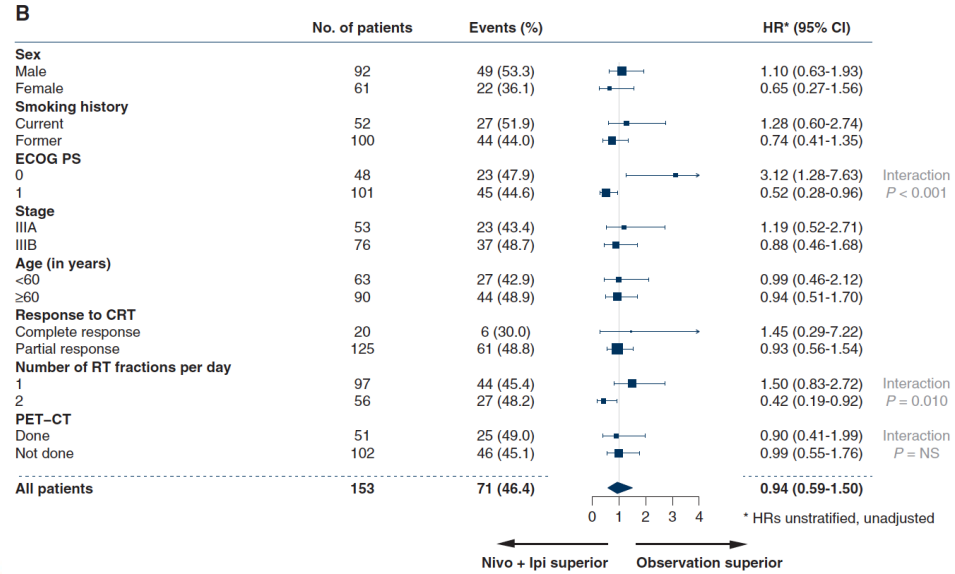
	No. of patients	Events (%)	HR* (95% CI)	
Sex				
Male	92	53 (57.6)	1.13 (0.66-1.95)	
Female	61	29 (47.5)	0.77 (0.36-1.63)	
Smoking history				
Current	52	27 (51.9)	0.99 (0.46-2.10)	
Former	100	55 (55.0)	0.97 (0.57-1.65)	
ECOG PS				
0	48	26 (54.2)	2.06 (0.93-4.57)	Interaction
1	101	52 (51.5)	0.67 (0.39-1.18)	$P = 0.022$
Stage				
IIIA	53	25 (47.2)	1.07 (0.49-2.36)	
IIIB	76	43 (56.6)	1.10 (0.60-1.99)	
Age (in years)				
<60	63	34 (54.0)	0.99 (0.51-1.96)	
≥60	90	48 (53.3)	1.02 (0.58-1.81)	
Response to CRT				
Complete response	20	10 (50.0)	0.84 (0.24-3.0)	
Partial response	125	68 (54.4)	1.05 (0.65-1.69)	
Number of RT fractions per day				
1	97	51 (52.6)	1.34 (0.78-2.33)	Interaction
2	56	31 (55.4)	0.63 (0.31-1.27)	$P = 0.096$
PET–CT				
Done	51	31 (60.8)	1.20 (0.59-2.44)	Interaction
Not done	102	51 (50.0)	0.93 (0.54-1.61)	P = NS
All patients	**153**	**82 (53.6)**	**1.01 (0.65-1.55)**	

0 1 2 3

* HRs unstratified, unadjusted

OS





	No. of patients	Events (%)	HR* (95% CI)	
Sex				
Male	92	49 (53.3)	1.10 (0.63-1.93)	
Female	61	22 (36.1)	0.65 (0.27-1.56)	
Smoking history				
Current	52	27 (51.9)	1.28 (0.60-2.74)	
Former	100	44 (44.0)	0.74 (0.41-1.35)	
ECOG PS				
0	48	23 (47.9)	3.12 (1.28-7.63)	Interaction
1	101	45 (44.6)	0.52 (0.28-0.96)	$P < 0.001$
Stage				
IIIA	53	23 (43.4)	1.19 (0.52-2.71)	
IIIB	76	37 (48.7)	0.88 (0.46-1.68)	
Age (in years)				
<60	63	27 (42.9)	0.99 (0.46-2.12)	
≥60	90	44 (48.9)	0.94 (0.51-1.70)	
Response to CRT				
Complete response	20	6 (30.0)	1.45 (0.29-7.22)	
Partial response	125	61 (48.8)	0.93 (0.56-1.54)	
Number of RT fractions per day				
1	97	44 (45.4)	1.50 (0.83-2.72)	Interaction
2	56	27 (48.2)	0.42 (0.19-0.92)	$P = 0.010$
PET–CT				
Done	51	25 (49.0)	0.90 (0.41-1.99)	Interaction
Not done	102	46 (45.1)	0.99 (0.55-1.76)	P = NS
All patients	**153**	**71 (46.4)**	**0.94 (0.59-1.50)**	

0 1 2 3 4

* HRs unstratified, unadjusted

Nivo + Ipi superior Observation superior

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LS-SCLC: STIMULI TRIAL - Safety

Table 2. Safety information of the as-treated cohort

	Nivo + Ipi (n = 78)		Observation (n = 75)	
	Number of patients (%)			
Any adverse event	77 (98.7)		65 (86.7)	
Treatment related adverse events	75 (96.2)		—	
Adverse events of grade ≥3	48 (61.5)		19 (25.3)	
Adverse events leading to treatment discontinuation	43 (55.1)		—	
Adverse events leading to death	4[a] (5.1)		1[b] (1.3)	
AEs occurring in ≥15% of the patients in either arm	**All grades**	**Grade ≥3**	**All grades**	**Grade ≥3**
Fatigue	38 (48.7)	7 (9.0)	21 (28.0)	—
Anorexia	25 (32.1)	5 (6.4)	12 (16.0)	—
Diarrhoea	22 (28.2)	7 (9.0)	6 (8.0)	—
Vomiting	21(26.9)	1 (1.3)	5 (6.7)	—
Pneumonitis	22 (28.2)	7 (9.0)	4 (5.3)	1 (1.3)
Nausea	19 (24.4)	2 (2.6)	6 (8.0)	—
Cough	20 (25.6)	—	5 (6.7)	—
Hyperthyroidism	22 (28.2)	2 (2.6)	1 (1.3)	1 (1.3)
Anaemia	7 (9.0)	1 (1.3)	13 (17.3)	1 (1.3)
Dyspnoea	13 (16.7)	1 (1.3)	6 (8.0)	1 (1.3)
Pruritus	19 (24.4)	1 (1.3)	—	—
Constipation	15 (19.2)	1 (1.3)	3 (4.0)	—
Hypothyroidism	13 (16.7)	—	—	—

Peters et al. Ann Oncol 2021

LS-SCLC: STIMULI TRIAL - Safety

Table 2. Safety information of

	Observation (n = 75)
	nts (%)
Any adverse event	65 (86.7)
Treatment related adverse event	—
Adverse events of grade ≥3	19 (25.3)
Adverse events leading to treatr	—
Adverse events leading to death	1[b] (1.3)
AEs occurring in ≥15% of the p	**grades** / **Grade ≥3**
Fatigue	28.0) / —
Anorexia	16.0) / —
Diarrhoea	8.0) / —
Vomiting	6.7) / —
Pneumonitis	5.3) / 1 (1.3)
Nausea	8.0) / —
Cough	6.7) / —
Hyperthyroidism	1.3) / 1 (1.3)
Anaemia	17.3) / 1 (1.3)
Dyspnoea	8.0) / 1 (1.3)
Pruritus	— / —
Constipation	4.0) / —
Hypothyroidism	— / —

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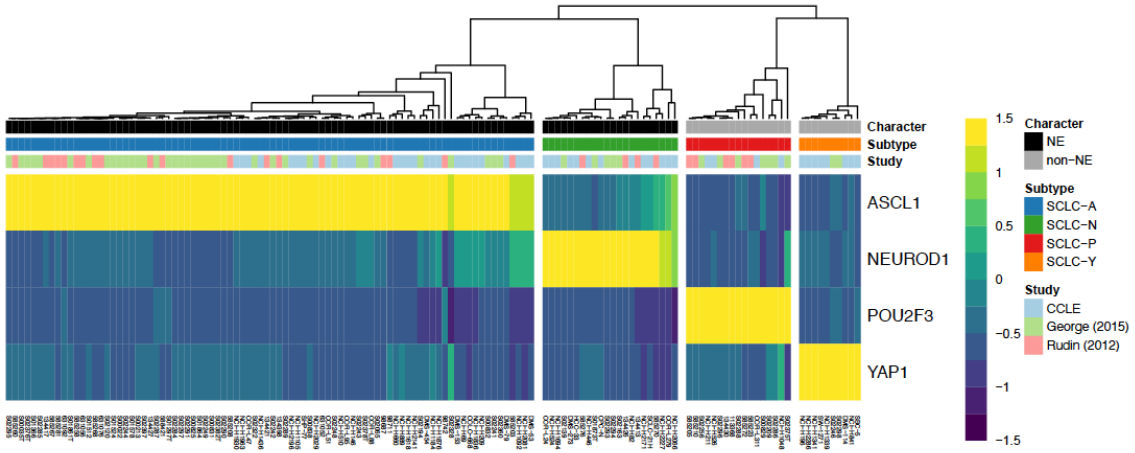
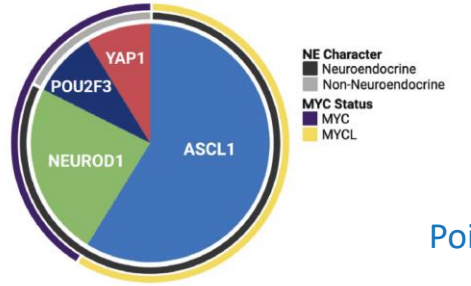
SCLC molecular classification – therapeutic opportunities

SCLC molecular classification: four molecular groups

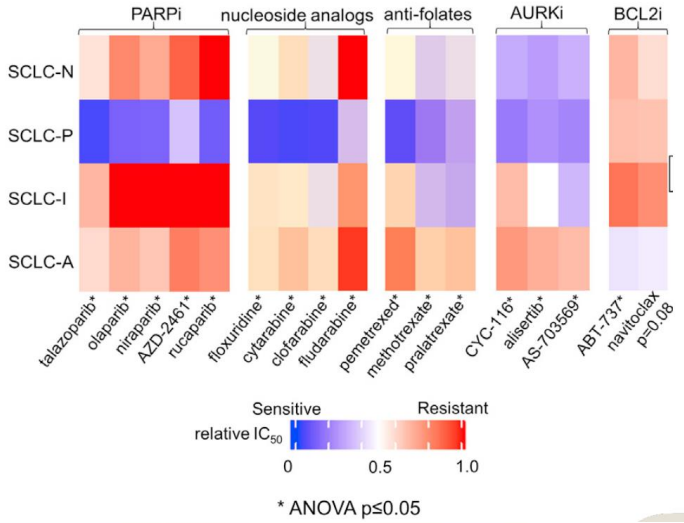


Rudin et al, Nat Rev Cancer 2019

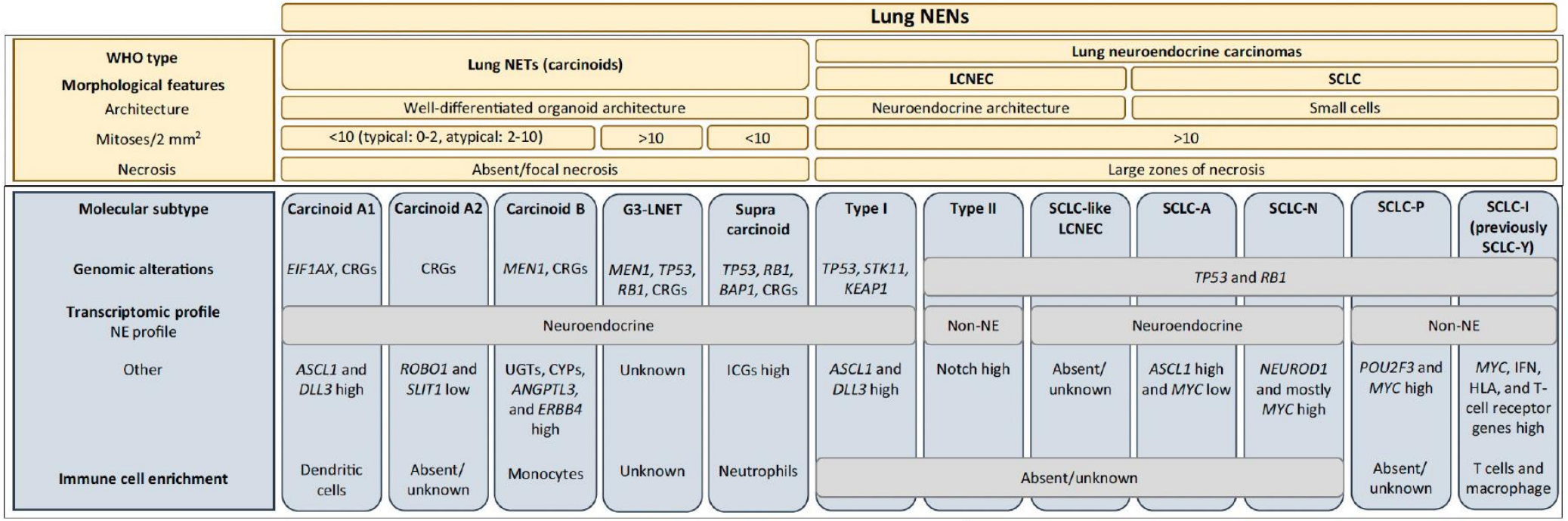


Poirier et al. JTO 2020

ASCL1	NEUROD1	POU2F3	YAP1
BCL2	Arginine Deprivation	Arginine Deprivation	Arginine Deprivation
CREBBP	AURKA/B	AURKA/B	AURKA/B
DLL3	CHK1	CHK1	CHK1
LSD1	IMPDH	IGF-R1	IMPDH
	LSD1	IMPDH	IO



Gay et al. Cancer Cell 2021



	Lung NENs											
WHO type	Lung NETs (carcinoids)					Lung neuroendocrine carcinomas						
Morphological features						LCNEC		SCLC				
Architecture	Well-differentiated organoid architecture					Neuroendocrine architecture		Small cells				
Mitoses/2 mm²	<10 (typical: 0-2, atypical: 2-10)		>10		<10	>10						
Necrosis	Absent/focal necrosis					Large zones of necrosis						
Molecular subtype	**Carcinoid A1**	**Carcinoid A2**	**Carcinoid B**	**G3-LNET**	**Supra carcinoid**	**Type I**	**Type II**	**SCLC-like LCNEC**	**SCLC-A**	**SCLC-N**	**SCLC-P**	**SCLC-I (previously SCLC-Y)**
Genomic alterations	*EIF1AX*, CRGs	CRGs	*MEN1*, CRGs	*MEN1*, *TP53*, *RB1*, CRGs	*TP53*, *RB1*, *BAP1*, CRGs	*TP53*, *STK11*, *KEAP1*	*TP53* and *RB1*					
Transcriptomic profile NE profile	Neuroendocrine						Non-NE	Neuroendocrine			Non-NE	
Other	*ASCL1* and *DLL3* high	*ROBO1* and *SLIT1* low	UGTs, CYPs, *ANGPTL3*, and *ERBB4* high	Unknown	ICGs high	*ASCL1* and *DLL3* high	Notch high	Absent/ unknown	*ASCL1* high and *MYC* low	*NEUROD1* and mostly *MYC* high	*POU2F3* and *MYC* high	*MYC*, IFN, HLA, and T-cell receptor genes high
Immune cell enrichment	Dendritic cells	Absent/ unknown	Monocytes	Unknown	Neutrophils	Absent/unknown					Absent/ unknown	T cells and macrophage

Molecular subtype	**SCLC-A**	**SCLC-N**	**SCLC-P**	**SCLC-I**
Treatment targets	ASCL1 BCL2 CREBBP DLL3 LSD1	Arginine deprivation AURKA/B CHK1 IMPDH LSD1	Arginine deprivation AURKA/B CHK1 IGF-R1 IMPDH	Arginine deprivation AURKA/B CHK1 IMPDH IO

Spotlight on Small-Cell Lung Cancer and Other Lung Neuroendocrine Neoplasms

Lynnette Fernandez-Cuesta, PhD[1]; Alexandra Sexton-Oates, PhD[1]; Leyla Bayat, MD[2]; Matthieu Foll, PhD[1]; Sally C.M. Lau, MD, MPH[2]; and Ticiana Leal, MD[3]

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RECRUITING

A Study to Evaluate the Efficacy and Safety of Serplulimab in Combination With Chemotherapy and Concurrent Radiotherapy in Patients With Limited-Stage Small Cell Lung Cancer

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NCT04624204

Placebo-controlled, Study of Concurrent Chemoradiation Therapy With Pembrolizumab Followed by Pembrolizumab and Olaparib in Newly Diagnosed Treatment-Naïve **Limited-Stage Small Cell Lung Cancer** (LS-**SCLC**) (MK 7339-...

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NOT YET RECRUITING

NCT06095583 NEW

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NOT YET RECRUITING

NCT05443646

A Phase II Study of Consolidation HLX10 (Serplulimab) Following Hypofractionated Radiotherapy With Concurrent Chemotherapy for Patients With Limited Stage **Small Cell Lung Cancer** （ASTRUM-LC01）

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NOT YET RECRUITING

NCT06117774 NEW

Study Evaluating Tarlatamab After Chemoradiotherapy in **Limited-Stage Small-Cell Lung Cancer** (LS-**SCLC**)

TAKE-HOME MESSAGES

DESIGN STUDIES BETTER!!!

Fundación GECP
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Muchas Gracias

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