

ASKLEPIOS
tumorzentrum hamburg
Klinikum Harburg Pneumologie

CLAAS WESSELER, NBA, HAMBURG 23.6.17

AKTUELLES ZUM KLEINZELLIGEN LUNGENKARZINOM

INTERESSENKONFLIKTE

ASKLEPIOS tumorzentrum hamburg

Studien, Vorträge, Reisekosten, Advisory-Board



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AKTUELLES ZUM KLEINZELLIGEN LUNGENKARZINOM



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ZUSAMMENFASSUNG…

KLEINZELLIGES LUNGENKARZINOM

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- Als Erstbeschreibung des kleinzelligen Lungenkarzinoms gelten die Beobachtungen bei Arbeitern der Schneeberger Gruben im Erzgebirge
- 12-15% der Lungenkarzinome
- Die Inzidenz des kleinzelligen Lungenkarzinoms beträgt bei Männern ca. 15/100.000, bei Frauen ca. 7/100.000 (Insgesamt eher rückläufig)
- mittleres Alter von 70 J
- In Deutschland jährlich ca. 7000-8000 Patienten

- Härting FH, Hesse W: Der Lungenkrebs, die Bergkrankheit in den Schneeberger Gruben. Vierteljahresschrift Gerichtliche Medizin und Öffentliches Sanitätswesen, 1879
-Interdisziplinäre S3-Leitlinie: Prävention, Diagnostik, Therapie und Nachsorge des Lungenkarzinoms, 020-007, 2010
-Gesellschaft der epidemiologischen Krebsregister in Deutschland / Robert - Koch Institut

KLEINZELLIGES LUNGENKARZINOM

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- Das Vermeiden von Rauchen ist die entscheidende Präventionsmaßnahme (WHO Framework Convention on Tobacco Control)

http://www.who.int/fctc/en/

STAGING 2017

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Die überarbeitete Stadieneinteilung erfolgt auf der Basis der TNM und der UICC 8 Kriterien. Zwischen der Stadieneinteilung beim SCLC und NSCLC ist aufgrund der Analysender IASLC ein minimaler Unterschied zu konstatieren:

so wird aktuell beim SCLC noch die alte Einteilung aus UICC 7 in M1a und M1b beibehalten.

Für eine bereits jetzt durchzuführende Unterscheidung in IVA und IVB waren die Daten aufgrund zu kleiner Patientenzahlen in den Subgruppen noch nicht aussagekräftig genug.

Very Limited Disease

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Tabelle 6: Zuordnung von TNM Merkmalen zur Klassifikation der Veterans Administration Lung Study [9]

Stadien der Veterans Administration Lung Study	Zuordnung zur TNM Klassifikation
Very Limited Disease	T1-2 N0-1
Limited Disease	T3-4 und / oder N2-3
Extensive Disease	M1

- Very LD ca. 5% der Patienten
  - 5 JÜ nach adjuvanter Therapie 52%
  - 5 JÜ nach adjuvanter Therapie + PCI 70%
  - Zusätzliche mediastinale Radiatio keinen weiteren Überlebensvorteil.
- In Fallserien und Phase II Studien wurde für eine neoadjuvante Therapiestrategie bei Patienten mit N0 5-Jahres-Überlebensraten von 50-70% und für Patienten mit N1 zwischen 35-40% beobachtet.

Oncopedia /SCLC
Yang Cf et al .: Role of Adjuvant Therapy in a Population-Based Cohort of Patients With Early-Stage Small-Cell Lung Cancer. J Clin Oncol 34:1057-1064, 2016.

LIMITED DISEASE

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- LD ca. 30% der Patienten
  - 5 JÜ nach Radiochemotherapie 20-30% (4-6x Cis/Eto + Radiatio (2x15 Gy bis 45Gy oder 2Gy ED bis 60Gy - CONVERT-Studie)
  - Simultane Gabe (spätestens ab 3.tem Zyklus) erhöht die 5JÜ um ca. 10%
  - PCI reduziert das Auftreten von Hirnfilia von 40% auf 10% + 5JÜ um 5%

Oncopedia /SCLC
Früh M, De Ruysscher D, Popat S et al.: Small-cell lung cancer: ESMO Clinical Practical Guidelines for diagnosis, treatment and follow-up. Ann Oncol 2013

Extensive Disease

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- Ca 60-70 % der Patienten bei Erstdiagnose
- Medianes Überleben mit Therapie 9-12 Monate, 2JÜ 5-10%
- Platinhaltige Therapieschemata erreichen signifikant höhere komplette Remissionsraten als nicht-platinhaltige Kombinationstherapien

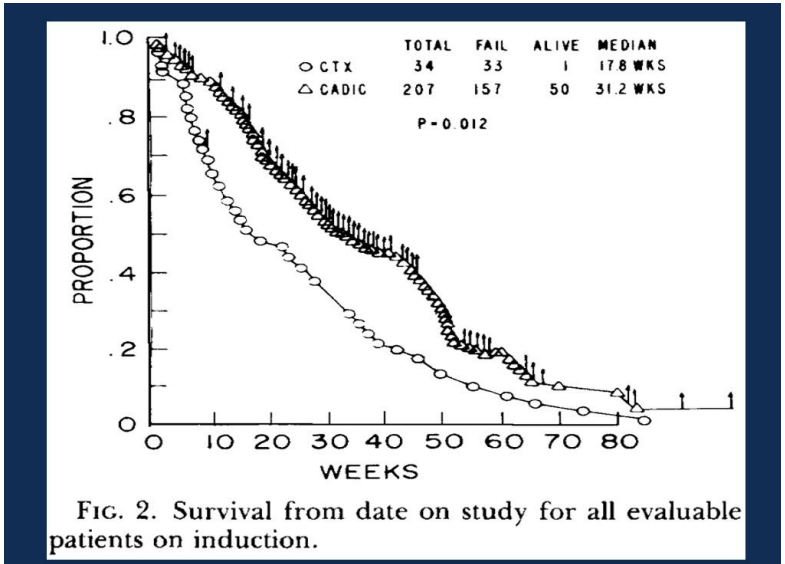


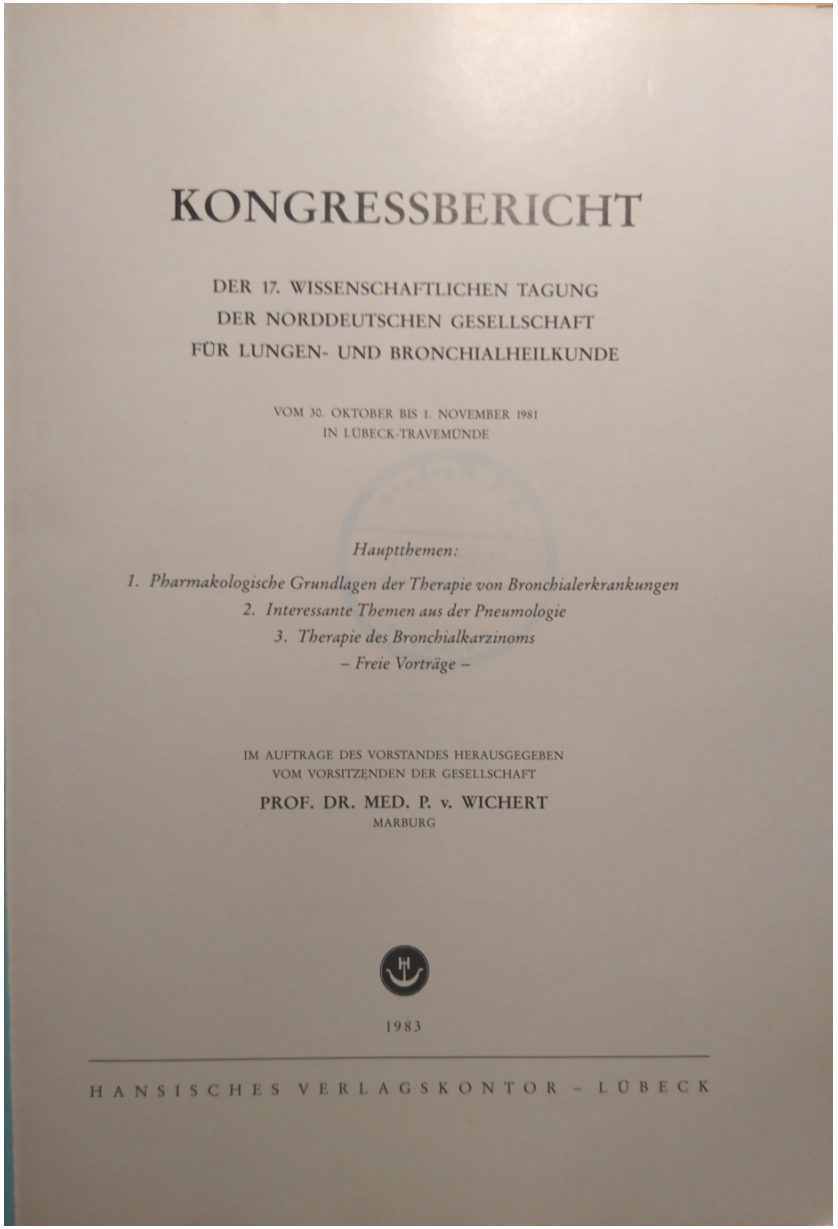
FIG. 2. Survival from date on study for all evaluable patients on induction.

Lowenbraun S, et al. Cancer 1979;1;44(2):406-13.

Oncopedia /SCLC

Rossi A, Garassino MC, Cinquini M et al.: Maintenance or consolidation therapy in smallcell lung cancer: review and meta-analysis. Lung Cancer 2010

Slotman BJ, van Tinteren H, Praag JO et al.: Use of thoracic radiotherapy for extensivestage small-cell lung cancer: a phase 3 randomised controlled trial. Lancet 2015



KONGRESSBERICHT

DER 17. WISSENSCHAFTLICHEN TAGUNG
DER NORDDEUTSCHEN GESELLSCHAFT
FÜR LUNGEN- UND BRONCHIALHEILKUNDE

VOM 30. OKTOBER BIS 1. NOVEMBER 1981
IN LÜBECK-TRAVEMÜNDE

Hauptthemen:

1. Pharmakologische Grundlagen der Therapie von Bronchialerkrankungen
2. Interessante Themen aus der Pneumologie
3. Therapie des Bronchialkarzinoms
– Freie Vorträge –

IM AUFTRAGE DES VORSTANDES HERAUSGEGEBEN
VOM VORSITZENDEN DER GESELLSCHAFT
PROF. DR. MED. P. v. WICHERT
MARBURG

1983

HANSISCHES VERLAGSKONTOR – LÜBECK

Extensive Disease

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- Ca 60-70 % der Patienten bei Erstdiagnose
- Medianes Überleben mit Therapie 9-12 Monate, 2JÜ 5-10%
- Platinhaltige Therapieschemata erreichen signifikant höhere komplette Remissionsraten als nicht-platinhaltige Kombinationstherapien
- Remission 60-70% (Erhaltungstherapie ohne Verlängerung des Überlebens)
- Negativer Prognosefaktor ist die LDH
- Thorakale Radiatio (ohne Progress nach 1-line verlängert nicht das Gesamtüberleben, aber die 2JÜ von 3 auf 13%)

Oncopedia /SCLC
Rossi A, Garassino MC, Cinquini M et al.: Maintenance or consolidation therapy in smallcell lung cancer: review and meta-analysis. Lung Cancer 2010
Slotman BJ, van Tinteren H, Praag JO et al.: Use of thoracic radiotherapy for extensivestage small-cell lung cancer: a phase 3 randomised controlled trial. Lancet 2015

PARANEOPLASTISCHE SYNDROM

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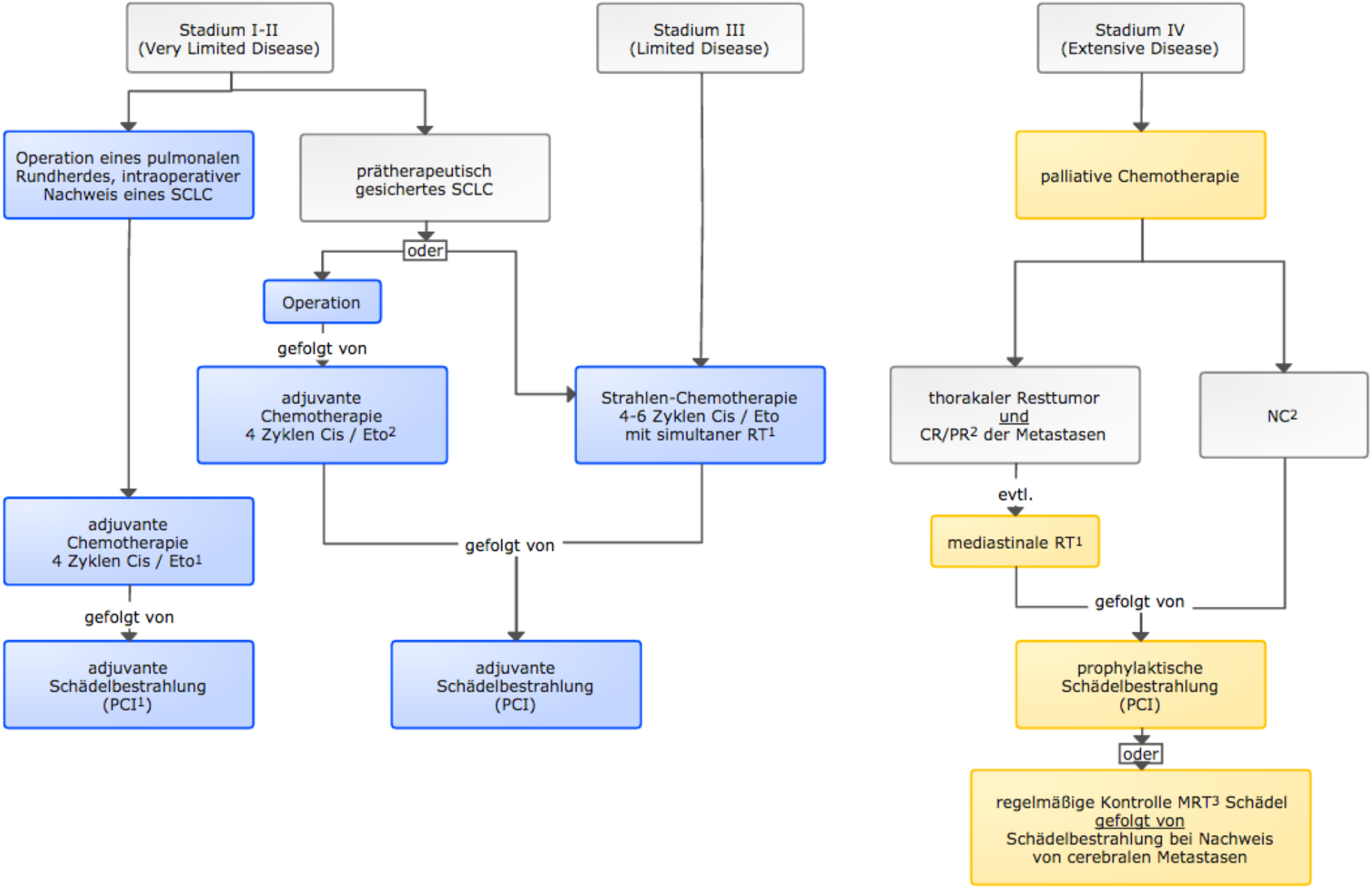
Syndrom	SCLC (% der Patienten)	NSCLC (% der Patienten)
SIADH	10	< 0,1
Cushing (ACTH)	2-4	< 0,1
Lambert Eaton	1	<0,1
andere Neuropathien	bis 5	< 0,1
Trommelschlegelfinger	< 1	5
Osteoarthropathie	< 1	5
Hyperkalzämie	< 1	bis 10

Van Meerbeeck JP, Fennell DA, de Ruysscher DKM: Small-cell lung cancer. Lancet 378:1741-1755, 2011.

Abbildung 2: Therapiestruktur für das kleinzellige Lungenkarzinom (SCLC)



ESMO

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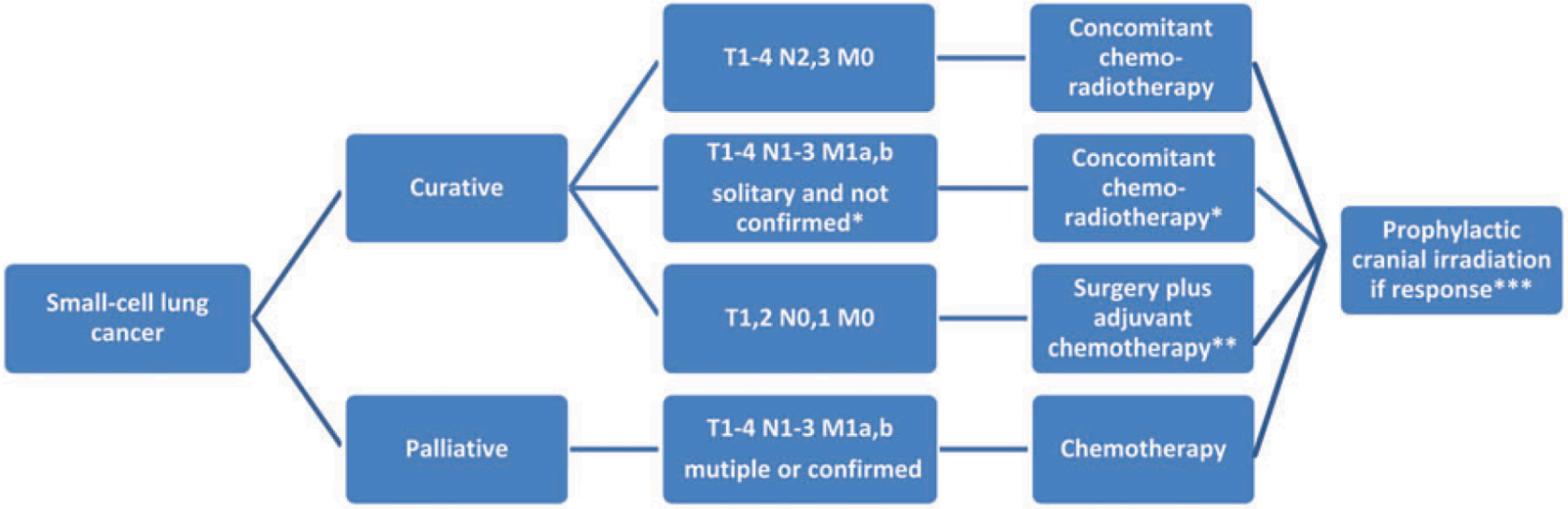

***if no confirmation of solitary metastasis is obtained, radiotherapy may be added after first response evaluation and is omitted in case of obvious metastatic involvement**
**** concomitant chemoradiotherapy as an alternative option**
***** or stable disease in case of localised disease**

Figure 1. Small-cell lung cancer (SCLC) treatment algorithm.

Früh et al, Small-cell lung cancer (SCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up
Ann Oncol 2013; 24 (Suppl 6): vi99-vi105.



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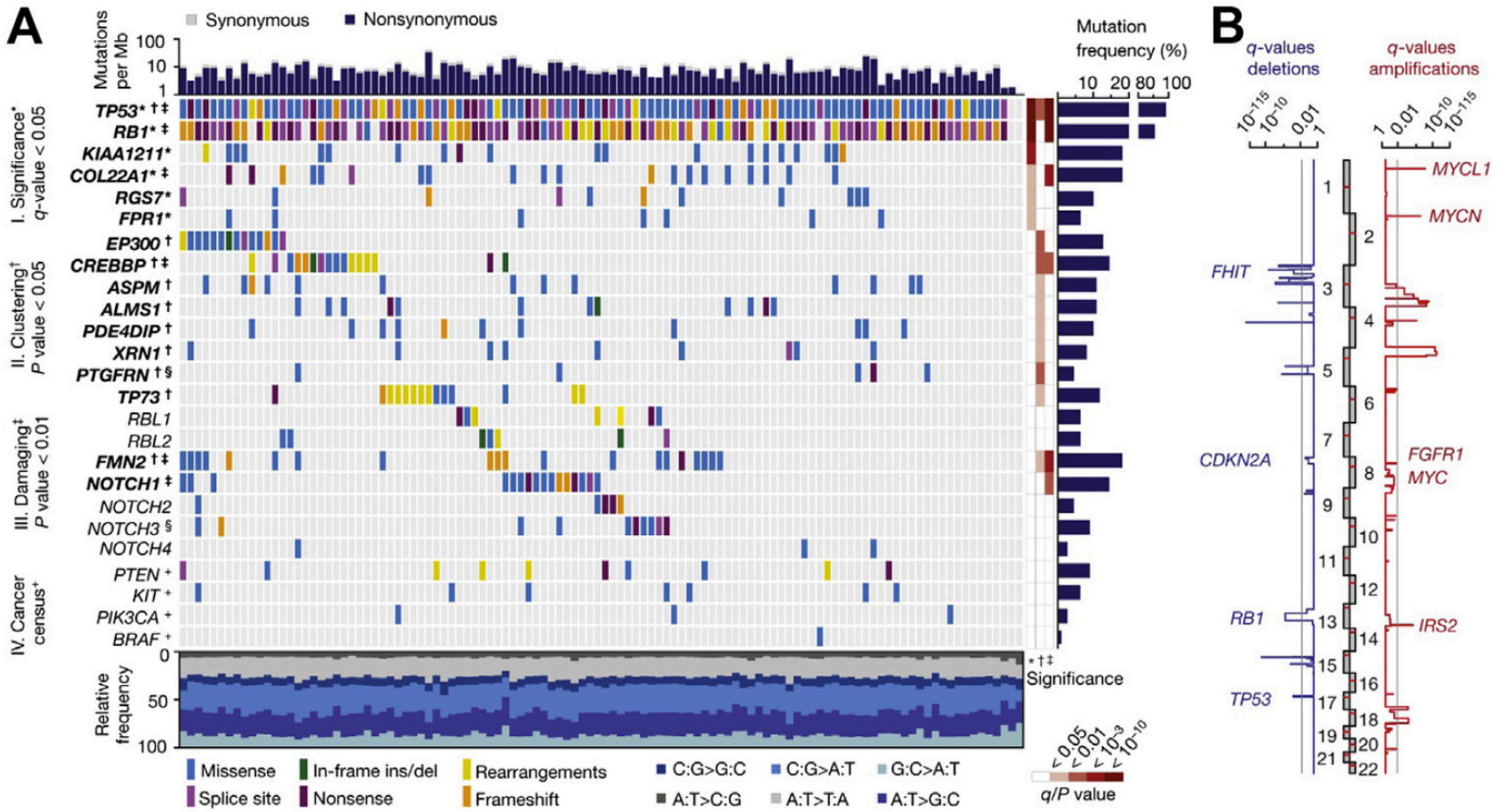
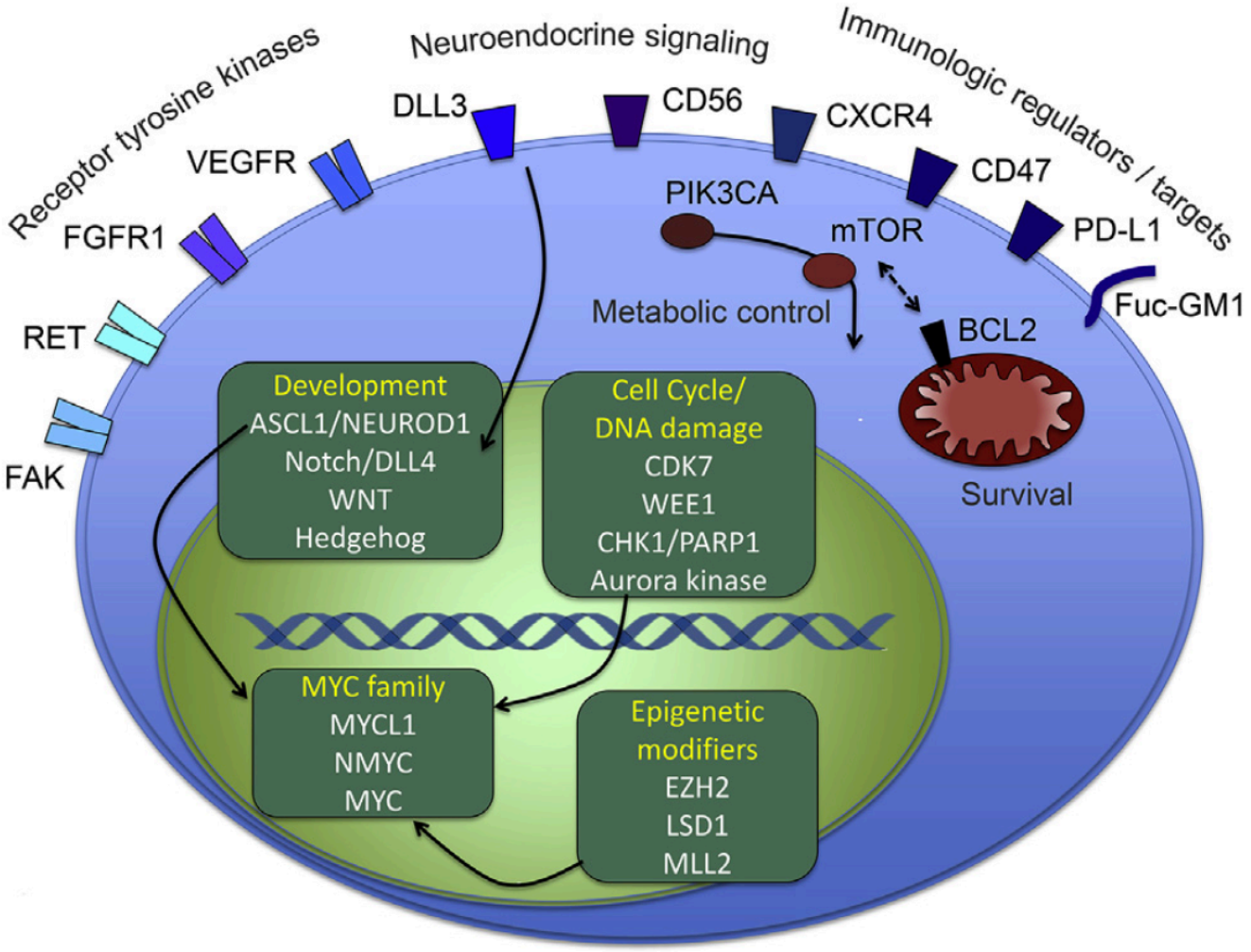
NEUES

Bunn et al *Journal of Thoracic Oncology*



Bunn et al, J Thorac Oncol. 2016 Apr;11(4):453-74. doi: 10.1016/j.jtho.2016.01.012. Epub 2016 Jan 30

Journal of Thoracic Oncology Vol. 11 No. 4



Bunn et al, J Thorac Oncol. 2016 Apr;11(4):453-74. doi: 10.1016/j.jtho.2016.01.012. Epub 2016 Jan 30

Table 1. Therapeutic Agents and Targets in Small Cell Lung Cancer

Agent	Target	Trial Phase
Erismodegib, sonidegib (LDE225)	Smoothened (hedgehog antagonist)	Preclinical, I
Vismodegib (GDC-0449)	Smoothened (hedgehog antagonist)	Preclinical, I, II
ABT-737	Bcl-2, Bcl-xL	Preclinical
Navitoclax (ABT-263)	Bcl-2, Bcl-xL, Bcl-w	Preclinical, I, II[a]
Silvestrol	EIF4E	Preclinical
PHA-680632	Aurora kinases	Preclinical
Alisertib (MLN8237)	Aurora A kinase	Preclinical, I, II
Barasertib (AZD1152)	Aurora B kinase	Preclinical, I[a]
MEDI0639	DLL4	Preclinical, I
Tarextumab (OMP-59R5)	Notch 2/3	Preclinical, I, II
Demcizumab (OMP-21M18)	DLL4	Preclinical, I, II (NSCLC)
Ponatinib (AP24534)	FGFR1, PDGFRa, VEGFR2	Preclinical, I, II
Lucitanib (E-3810)	FGFR1-3, PDGFRα/β, VEGFR1-3	Preclinical, I, II
VS-5584	mTOR/PI3K	Preclinical, I
AZD8055	mTOR	Preclinical, I[a]
Ponatinib, vandetinib, alectinib, cabozaninib	RET	Preclinical, I, II
THZ1	CDK7	Preclinical
Ruxolitinib (INCB1824)	JAK1/2	Preclinical, I, II (NSCLC)
Tofacitinib (CP-690550)	JAK3	Preclinical
AZD1480	JAK2	Preclinical, I[a]
Amrubicin	Topoisomerase II	Preclinical, I, II, III, Marketed
Palifosfamide	Alkylation	Preclinical, I, II, III
Aldoxorubicin	Anthracycline	Preclinical, I, II
Defactinib (VS 6063)	FAK	Preclinical, I, II (NSCLC, Meso
LY2510924	CXCR4	Preclinical, I, II
Olaparib (AZD2281)	PARP1/2	Preclinical, I, II
Rucaparib (AG-014699,PF-01367338)	PARP1	Preclinical, I, II
Talazoparib (BMN-673)	PARP1/2	Preclinical, I, II
Veliparib (ABT-888)	PARP1/2	Preclinical, I, II
Lorvotuzumab mertansine	CD56	Preclinical, I, II[a]
Rovalpituzumab tesirine (SC16LD6.5)	DLL3	Preclinical, I, II
GSK126	EZH2	Preclinical
Sorafenib	RAF1, BRAF, PDGFRβ, VEGFR2	Preclinical, I, II[a]
Bevacizumab	VEGF	Preclinical, I, II, III[a]
Thalidomide	Angiogenesis	Preclinical, I, II, III
Cediranib (AZD2171)	VEGFR1-3, FLT1/4, cKit, PDGFRβ, FGFR1	Preclinical, I, II[a]
Vandetanib	VEGFR2	Preclinical, I, II
Aflibercept	VEGF trap	Preclinical, I, II
Sunitinib	VEGFR1-3, PDGFRβ, c-KIT, FLT3, RET	Preclinical, I, II
Imatinib	PDGFR, c-Kit	Preclinical, I, II[a]
Rilotumumab (AMG 102)	HGF	Preclinical, I, II[a]
Ganitumab (AMG 479)	IGF-1R	Preclinical, I, II
Everolimus	mTOR	Preclinical, I, II
Temsirolimus	mTOR	Preclinical, I, II
AZD1775 (MK-1775)	WEE1	Preclinical, I, II
Ipilimumab	CTLA-4	Preclinical, I, II, III
Nivolumab	PD-1	Preclinical, I, II, III
Pembrolizumab	PD-1	Preclinical, I, II
BMS-986012	Fucosyl-GM1	Preclinical, I, II
CAR T cells	CD56	Preclinical
Anti CD47 antibodies	CD47	Preclinical, I



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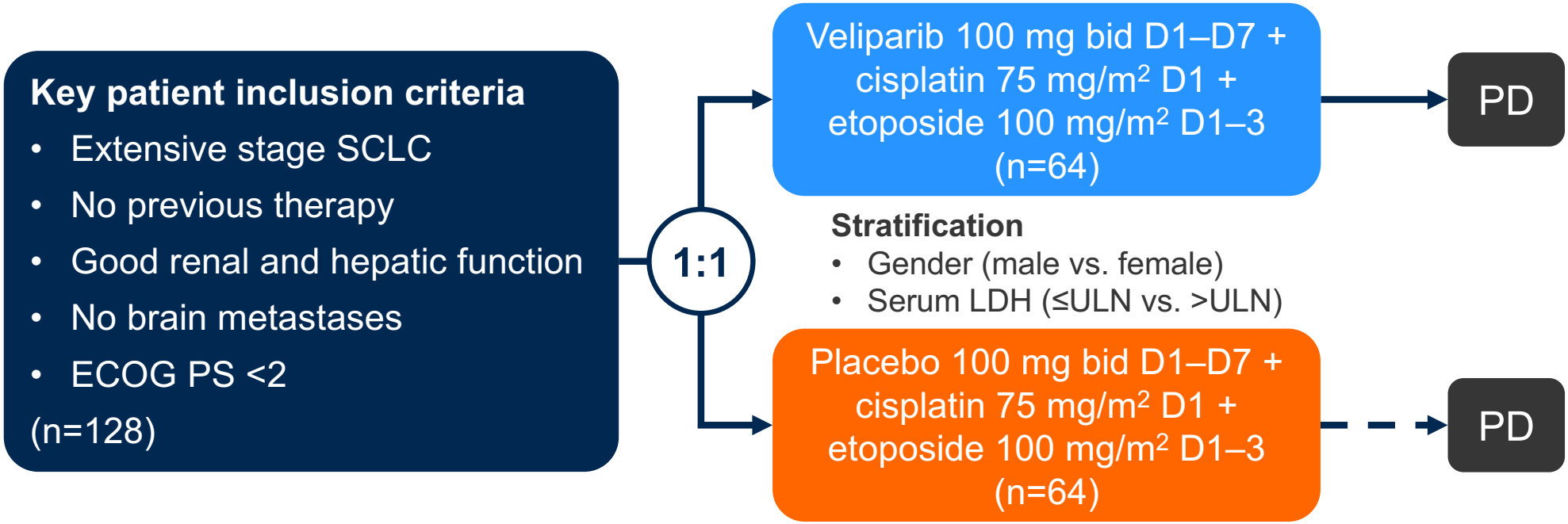
AUSSICHTEN

8505: Randomized Trial of Cisplatin and Etoposide in Combination with Veliparib or Placebo for Extensive Stage Small Cell Lung Cancer: ECOG-ACRIN 2511 Study – Owonikoko TK, et al

- **Study objective**
  - To investigate the efficacy and safety of the polyribose polymerase enzyme inhibitor, veliparib, combined with cisplatin/etoposide doublet over the doublet alone as first-line treatment of extensive stage SCLC



Primary endpoint

- PFS

Secondary endpoints

- OS, ORR, safety

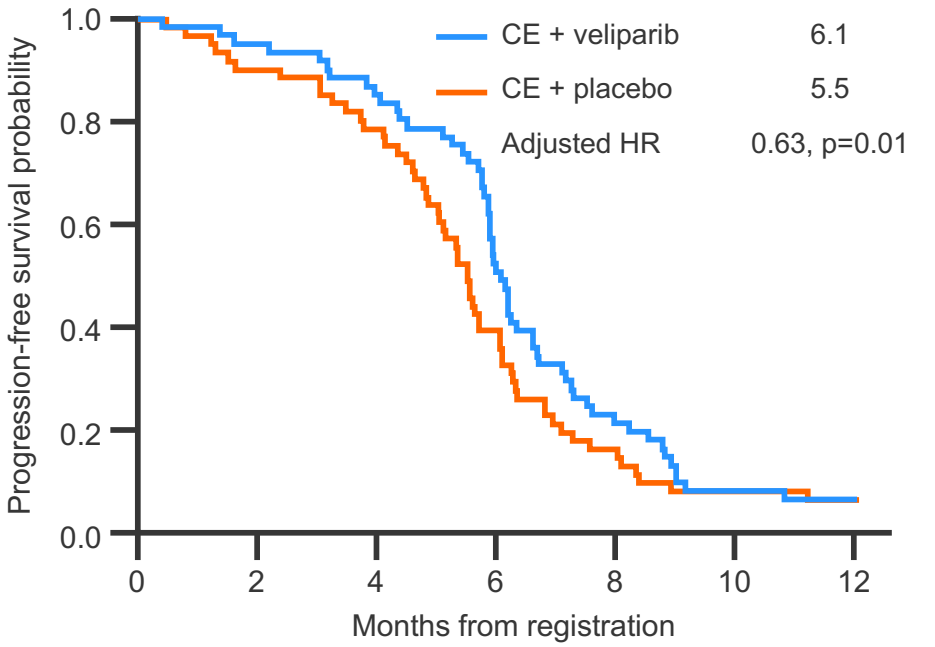
Patients received a maximum of 4 cycles of therapy

Owonikoko TK et al. J Clin Oncol 2017;35(suppl):Abstr 8505

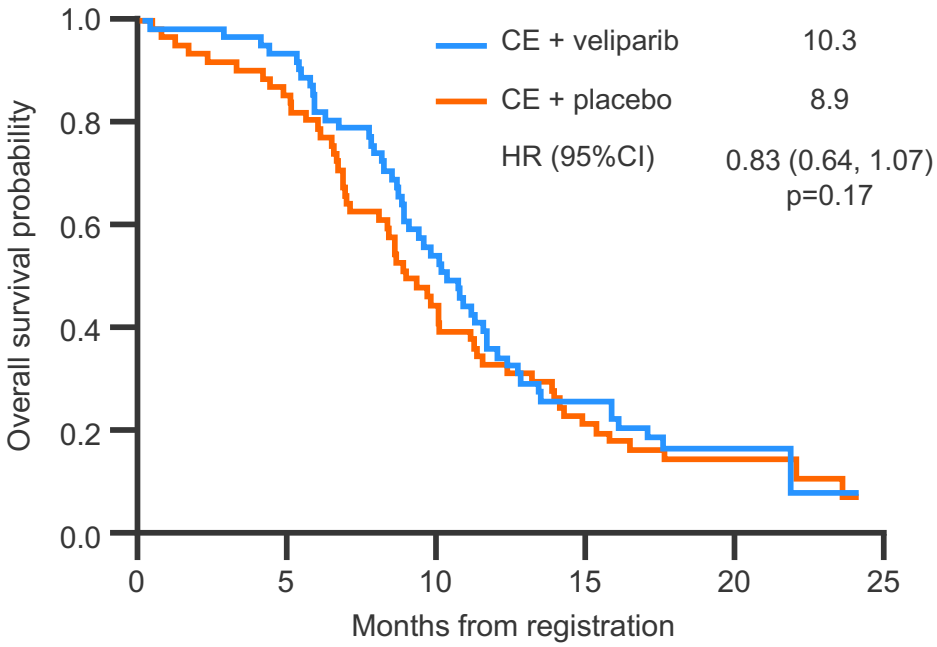
8505: Randomized Trial of Cisplatin and Etoposide in Combination with Veliparib or Placebo for Extensive Stage Small Cell Lung Cancer: ECOG-ACRIN 2511 Study – Owonikoko TK, et al

- **Key results**
  - Addition of veliparib significantly improved PFS but not OS

PFS



OS



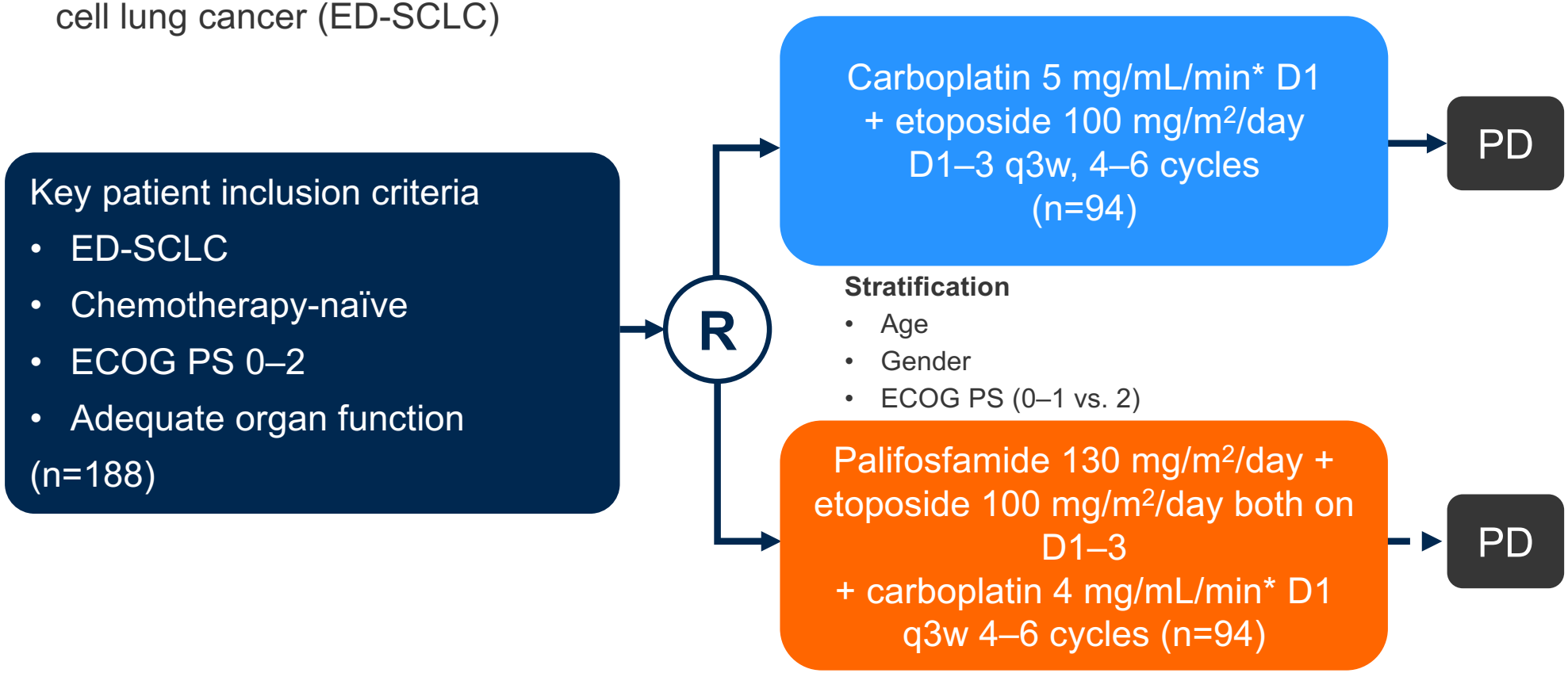
  - Veliparib increased haematological toxicity, including neutropenia, leucopenia and anaemia
- **Conclusion**
  - Adding veliparib to doublet chemotherapy led to an improvement in PFS among patients with extensive stage SCLC

Owonikoko TK et al. J Clin Oncol 2017;35(suppl):Abstr 8505

7504: Results from a randomized study of carboplatin and etoposide (CE) with or without palifosfamide (Pa) in extensive stage small cell lung cancer (ES-SCLC): The MATISSE study – Jalal SI et al

Study objective

- To assess the efficacy and safety of carboplatin and etoposide, the standard first-line regimen, alone or in combination with palifosfamide in patients with extensive-disease small cell lung cancer (ED-SCLC)



Primary endpoint

- OS

Amended secondary endpoints

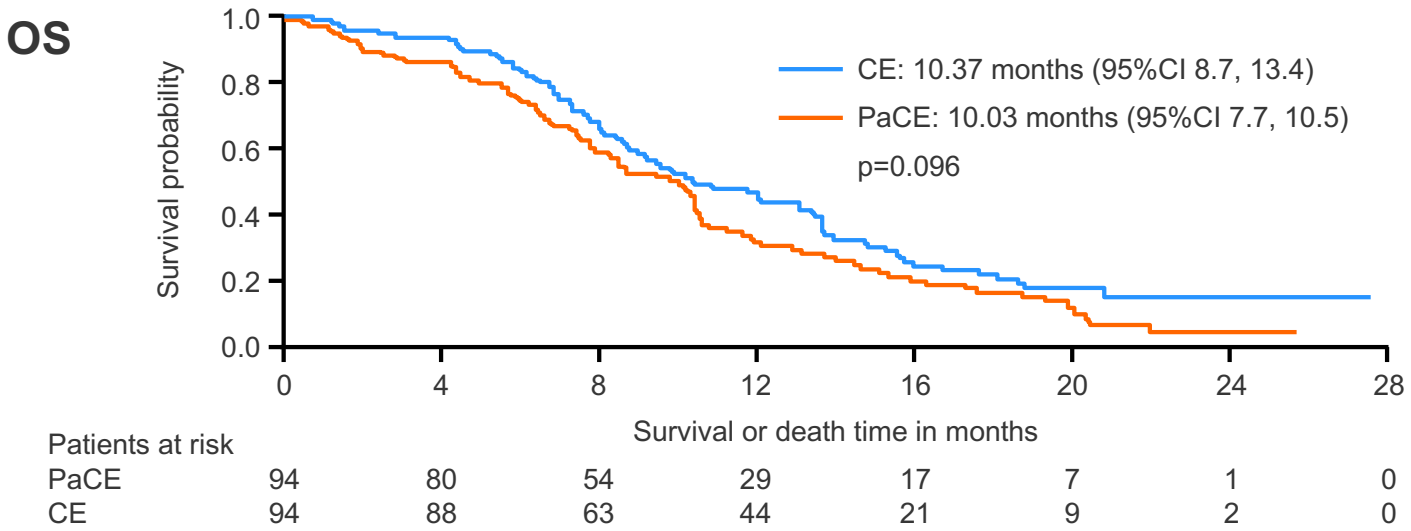
- Serious AEs

*Dose by area under the curve

Jalal et al. J Clin Oncol 2015; 33 (suppl): abstr 7504

7504: Results from a randomized study of carboplatin and etoposide (CE) with or without palifosfamide (Pa) in extensive stage small cell lung cancer (ES-SCLC): The MATISSE study – Jalal SI et al

- **Key results**
  - The MATISSE trial was ended prematurely as a result of the negative phase 3 trial evaluating the addition of palifosfamide to doxorubicin in sarcoma (PICASSO)
  - OS was not significantly improved by adjuvant palifosfamide

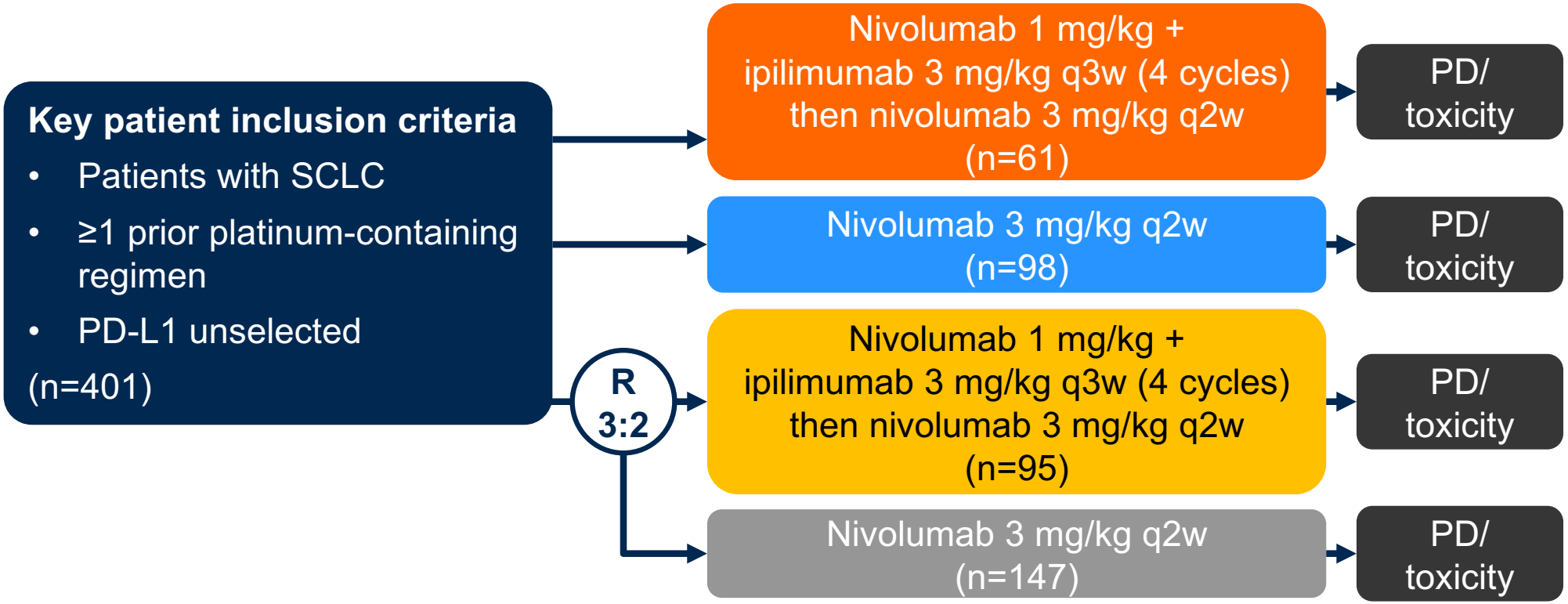


  - Toxicity was similar between the two treatment arms; serious treatment-related AEs were observed in 28.3% of patients receiving carboplatin/etoposide+palifosfamide and 25.5% of those receiving carboplatin/etoposide alone
- **Conclusions**
  - The addition of palifosfamide to carboplatin/etoposide failed to improve survival in patients with ED-SCLC

Jalal et al. J Clin Oncol 2015; 33 (suppl): abstr 7504

8503: Nivolumab (nivo) ± Ipilimumab (ipi) in Advanced Small-cell Lung Cancer (SCLC): First Report of a Randomized Expansion Cohort from CheckMate 032 – Hellmann MD, et al

- **Study objective**
  - To assess the efficacy and tolerability of nivolumab + ipilimumab in advanced SCLC – updated results of CheckMate 032 + randomized expansion cohort



Primary endpoint

- ORR per RECIST v1.1

Secondary endpoints

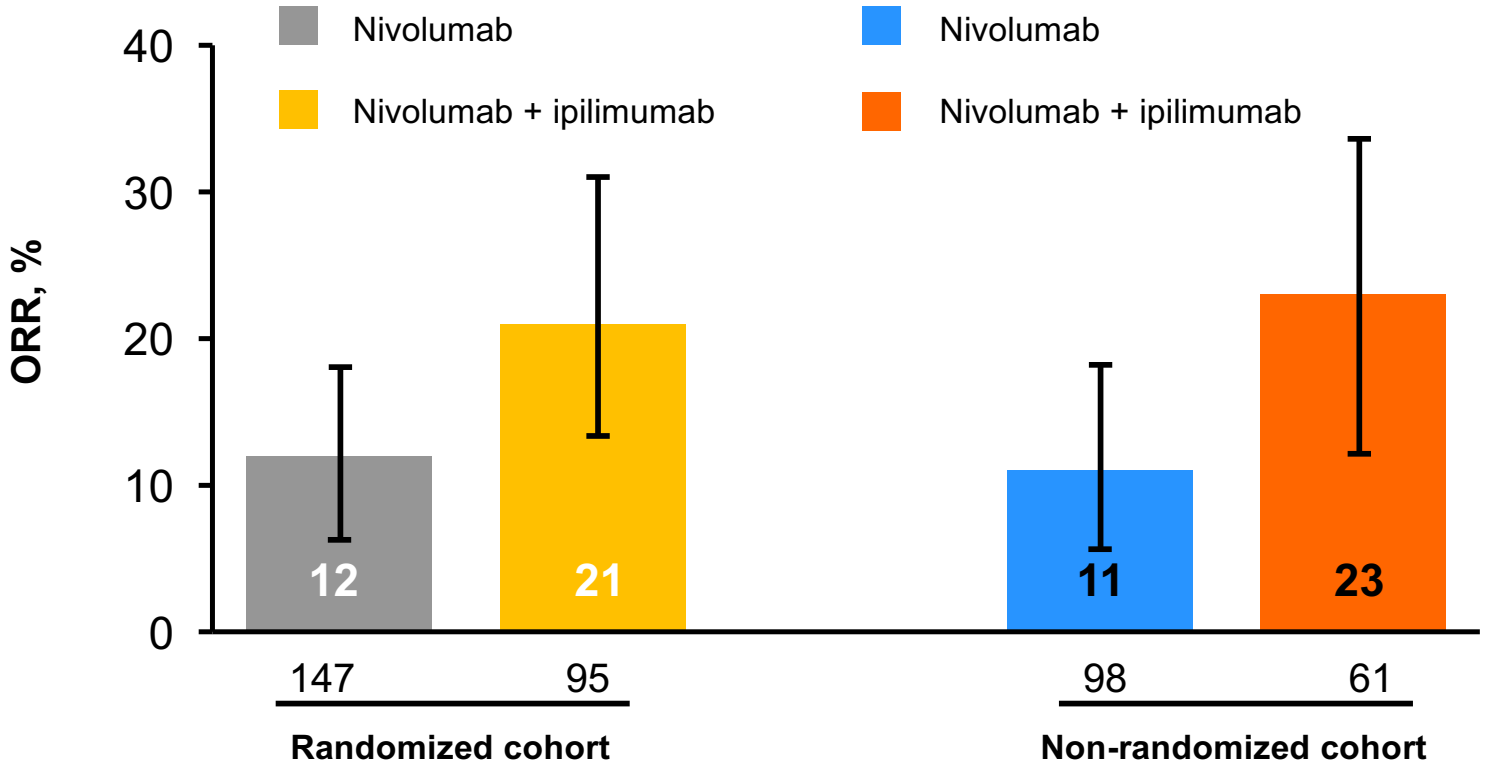
- DCR, DoR, OS, safety

Hellmann MD et al. J Clin Oncol 2017;35(suppl):Abstr 8503

8503: Nivolumab (nivo) ± Ipilimumab (ipi) in Advanced Small-cell Lung Cancer (SCLC): First Report of a Randomized Expansion Cohort from CheckMate 032 – Hellmann MD, et al

- **Key results**
  - In the randomized cohort, ORR was 21% with nivolumab + ipilimumab vs. 12% with nivolumab alone, which was consistent with results observed in the non-randomized cohort with longer follow-up

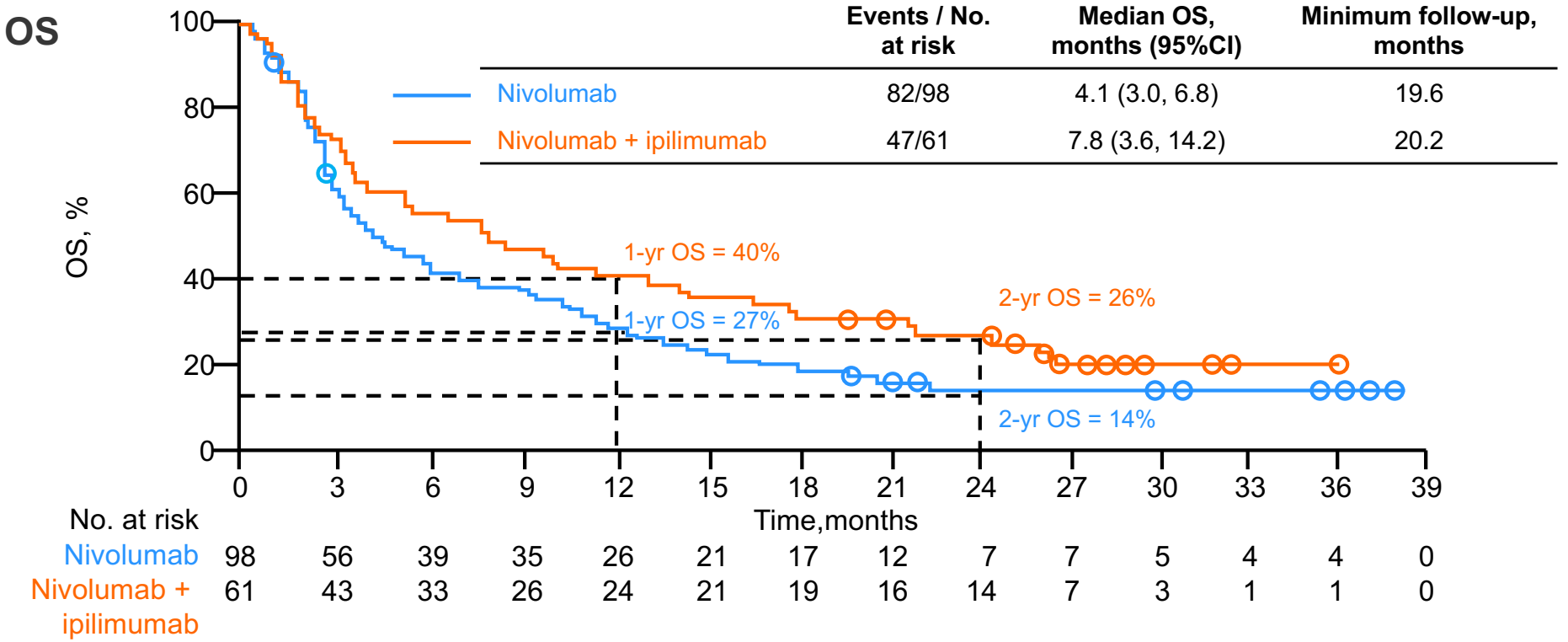
Summary of response by BICR



Hellmann MD et al. J Clin Oncol 2017;35(suppl):Abstr 8503

8503: Nivolumab (nivo) ± Ipilimumab (ipi) in Advanced Small-cell Lung Cancer (SCLC): First Report of a Randomized Expansion Cohort from CheckMate 032 – Hellmann MD, et al

- **Key results (cont.)**
  - Survival rate at 2 years was 14% and 26% with nivolumab alone and in combination with ipilimumab



	Events / No. at risk	Median OS, months (95%CI)	Minimum follow-up, months
Nivolumab	82/98	4.1 (3.0, 6.8)	19.6
Nivolumab + ipilimumab	47/61	7.8 (3.6, 14.2)	20.2

- **Conclusion**
  - Responses to nivolumab with or without ipilimumab were durable in patients with previously treated SCLC

Hellmann MD et al. J Clin Oncol 2017;35(suppl):Abstr 8503

NCCN Guidelines for Nivolumab Plus Ipilimumab in SCLC

PRINCIPLES OF SYSTEMIC THERAPY* (1 of 3)

Systemic therapy as primary or adjuvant therapy:

- Limited stage (maximum of 4–6 cycles):
  - Cisplatin 60 mg/m² day 1 and etoposide 120 mg/m² days 1, 2, 3[1]
  - Cisplatin 80 mg/m² day 1 and etoposide 100 mg/m² days 1, 2, 3[2]
  - Carboplatin AUC 5–6 day 1 and etoposide 100 mg/m² days 1, 2, 3[3]
  - During systemic therapy + RT, cisplatin/etoposide is recommended (category 1).
  - The use of myeloid growth factors is not recommended during concurrent systemic therapy plus radiotherapy (category 1 for not using GM-CSF).**
- Extensive stage (maximum of 4–6 cycles):
  - Carboplatin AUC 5–6 day 1 and etoposide 100 mg/m² days 1, 2, 3[4]
  - Cisplatin 75 mg/m² day 1 and etoposide 100 mg/m² days 1, 2, 3[5]
  - Cisplatin 80 mg/m² day 1 and etoposide 80 mg/m² days 1, 2, 3[6]
  - Cisplatin 25 mg/m² days 1, 2, 3 and etoposide 100 mg/m² days 1, 2, 3[7]
  - Carboplatin AUC 5 day 1 and irinotecan 50 mg/m² days 1, 8, 15[8]
  - Cisplatin 60 mg/m² day 1 and irinotecan 60 mg/m² days 1, 8, 15[9]
  - Cisplatin 30 mg/m² and irinotecan 65 mg/m² days 1, 8[10]

Subsequent systemic therapy:

- Clinical trial preferred.
- Relapse ≤6 mo, PS 0-2:
  - topotecan PO or IV[11-13]
  - irinotecan[14]
  - paclitaxel[15,16]
  - docetaxel[17]
  - temozolomide[18,19]
  - nivolumab ± ipilimumab[20]
  - vinorelbine[21,22]
  - oral etoposide[23,24]
  - gemcitabine[25,26]
  - cyclophosphamide/doxorubicin/vincristine (CAV)[11]
  - bendamustine (category 2B)[27]
- Relapse >6 mo: original regimen[28,29]

Consider dose reduction or growth factor support for patients with PS 2

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Safety and efficacy of single agent rovalpituzumab tesirine (SC16LD6.5), a delta-like protein 3 (DLL3)-targeted antibody-drug conjugate (ADC) in recurrent or refractory small cell lung cancer (SCLC)

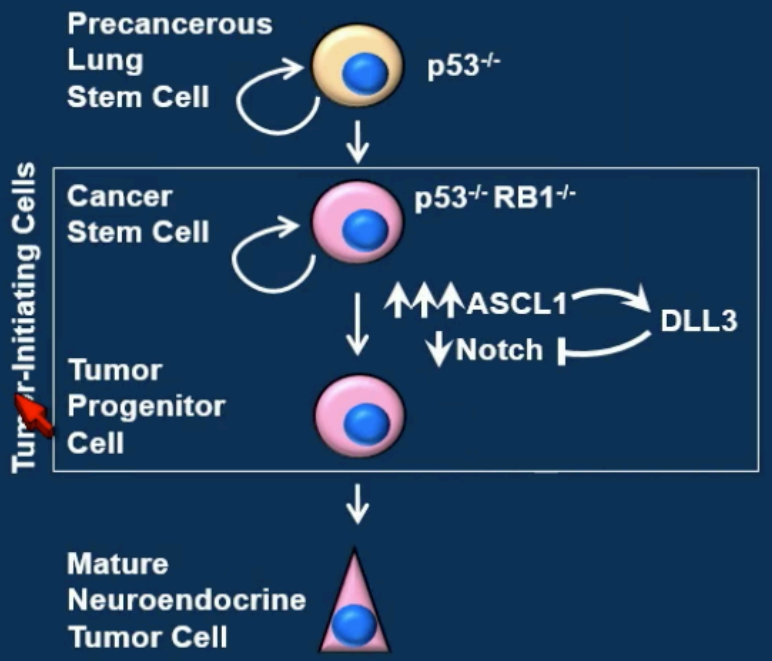
Rudin CM[1], Pietanza MC[1], Bauer TM[2,3], Spigel DR[2,3], Ready N[4], Morgensztern D[5], Glisson BS[6], Byers LA[6], Johnson ML[2,3], Burris HA III[2,3], Robert F[7], Strickland DK[3], Zayed H[8], Govindan R[5], Dylla SJ[8], Peng SL[8]

[1]Memorial Sloan Kettering Cancer Center, New York, NY; [2]Tennessee Oncology, PLLC., Nashville, TN; [3]Medical Oncology, Sarah Cannon Research Institute, Nashville, TN; [4]Duke University Medical Center, Durham, NC; [5]Washington University School of Medicine in St. Louis, St. Louis, MO; [6]The University of Texas MD Anderson Cancer Center, Houston, TX; [7]The University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, AL; [8]AbbVie Stemcentrx LLC, South San Francisco, CA

PRESENTED AT: ASCO ANNUAL MEETING '16

Delta-like Protein 3 (DLL3): a novel target in neuroendocrine tumors

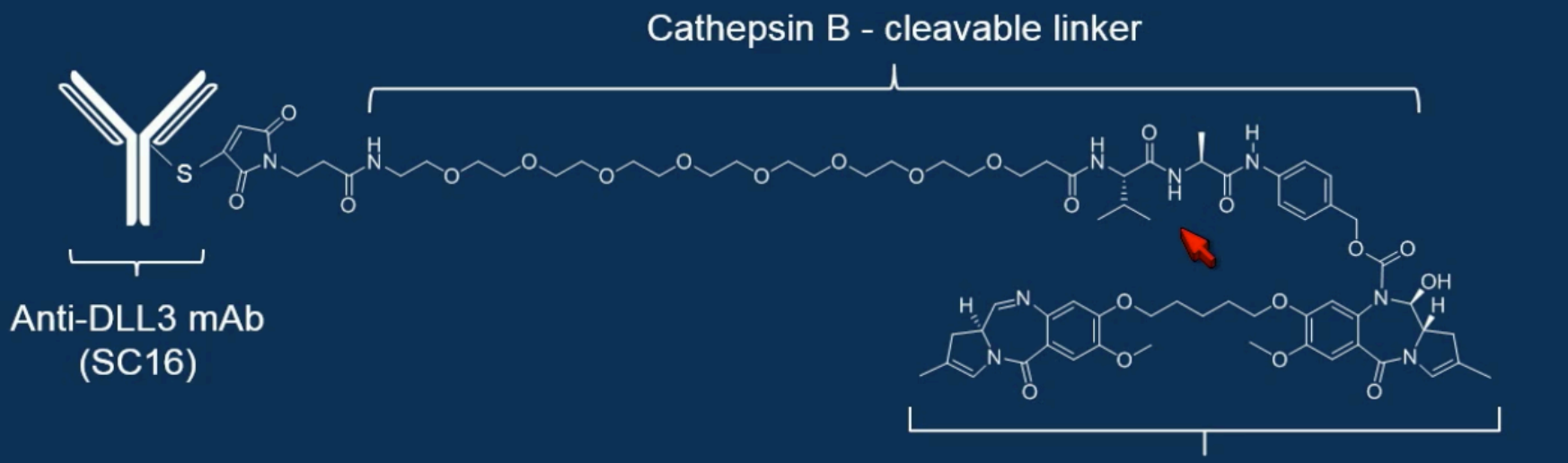
- An atypical inhibitory Notch ligand
- Induced by the key neuroendocrine transcription factor, ASCL1
- Aberrant cell surface expression in >80% of small cell lung and large cell neuroendocrine cancers
  - On both cancer stem and tumor cells but not normal adult tissues
- Not prognostic, and does not predict response to chemotherapy



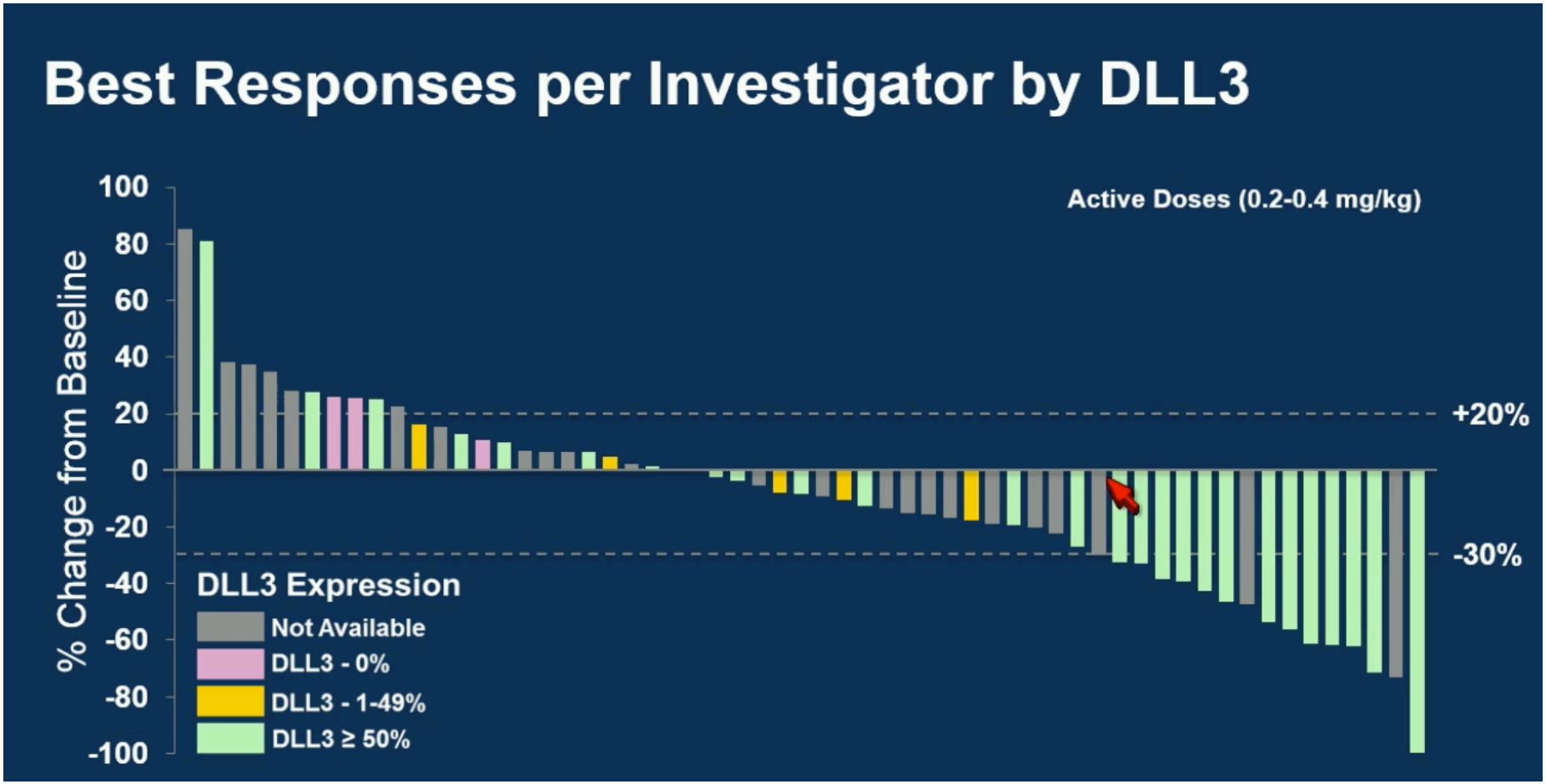
Saunders et al., *Sci Transl Med* 2015

Rovalpituzumab Tesirine (Rova-T™, SC16LD6.5)

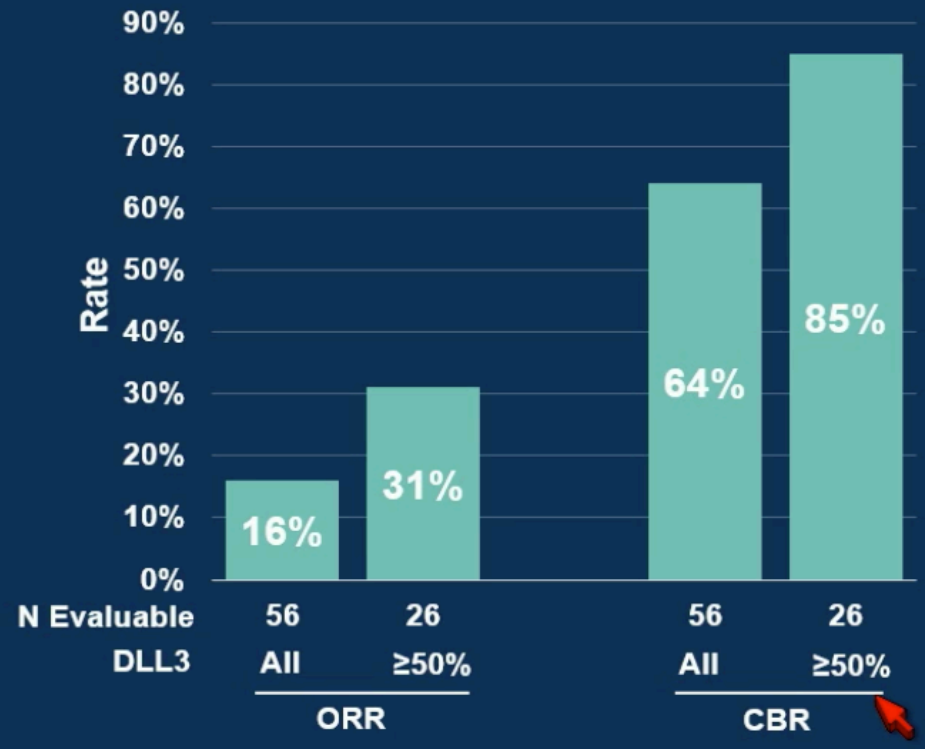
A delta-like protein 3 (DLL3)-targeted antibody-drug conjugate (ADC)



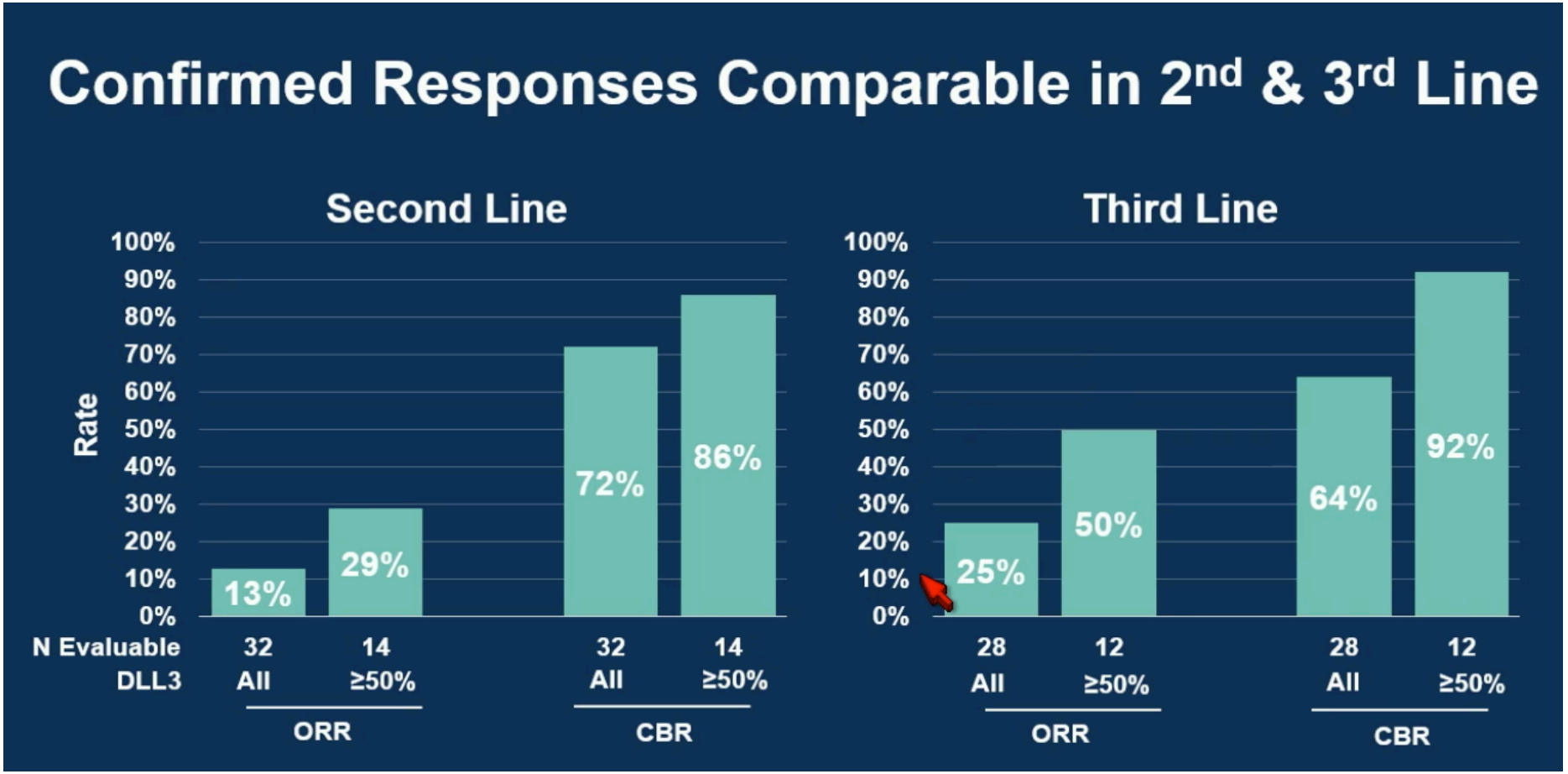
Drug-to-antibody ratio = 2


Best Responses per Investigator by DLL3
Active Doses (0.2-0.4 mg/kg)
% Change from Baseline
100
80
60
40
20
0
-20
-40
-60
-80
-100
+20%
-30%
DLL3 Expression
Not Available
DLL3 - 0%
DLL3 - 1-49%
DLL3 ≥ 50%

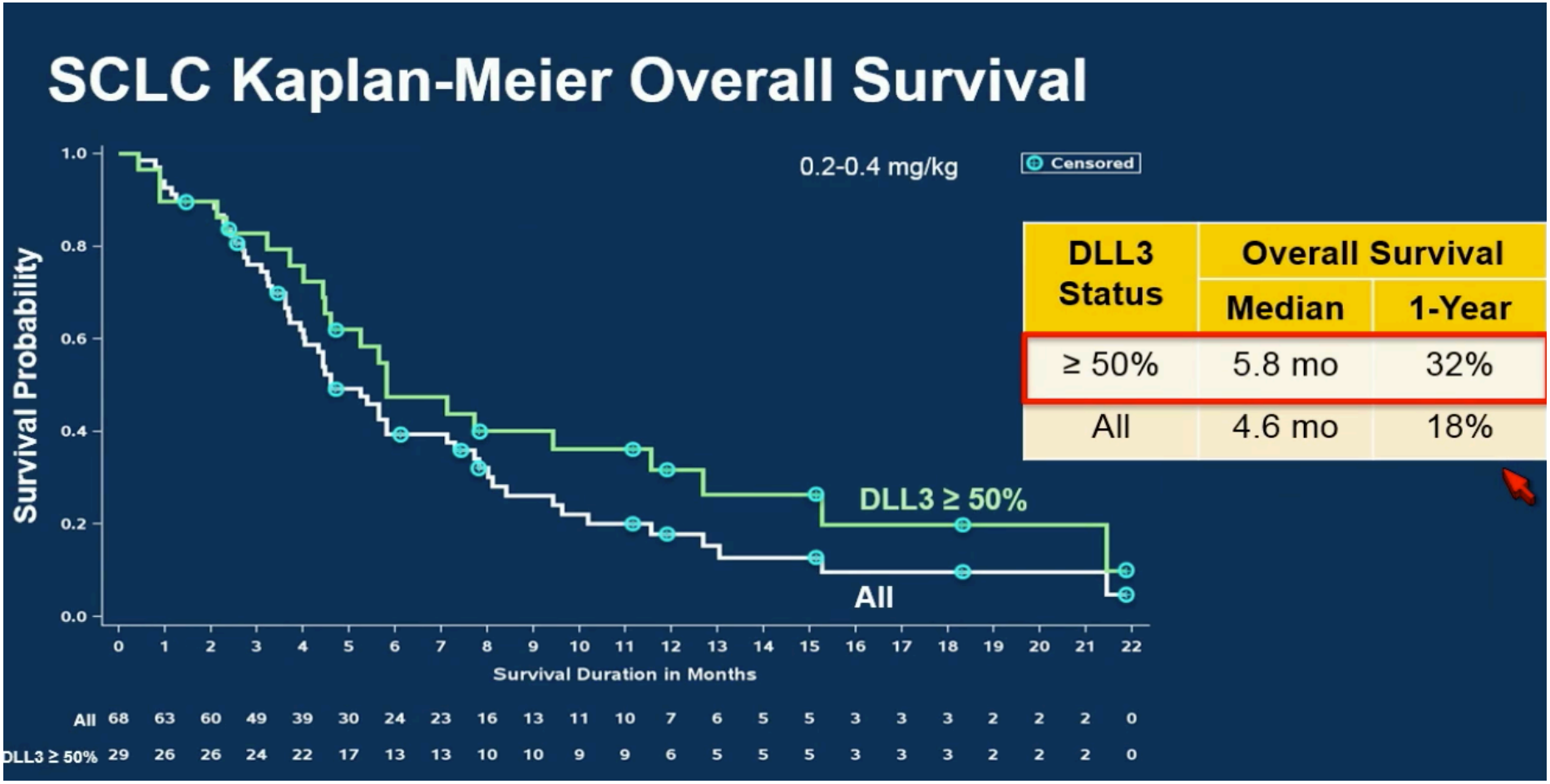
Central Review Validates Confirmed Responses



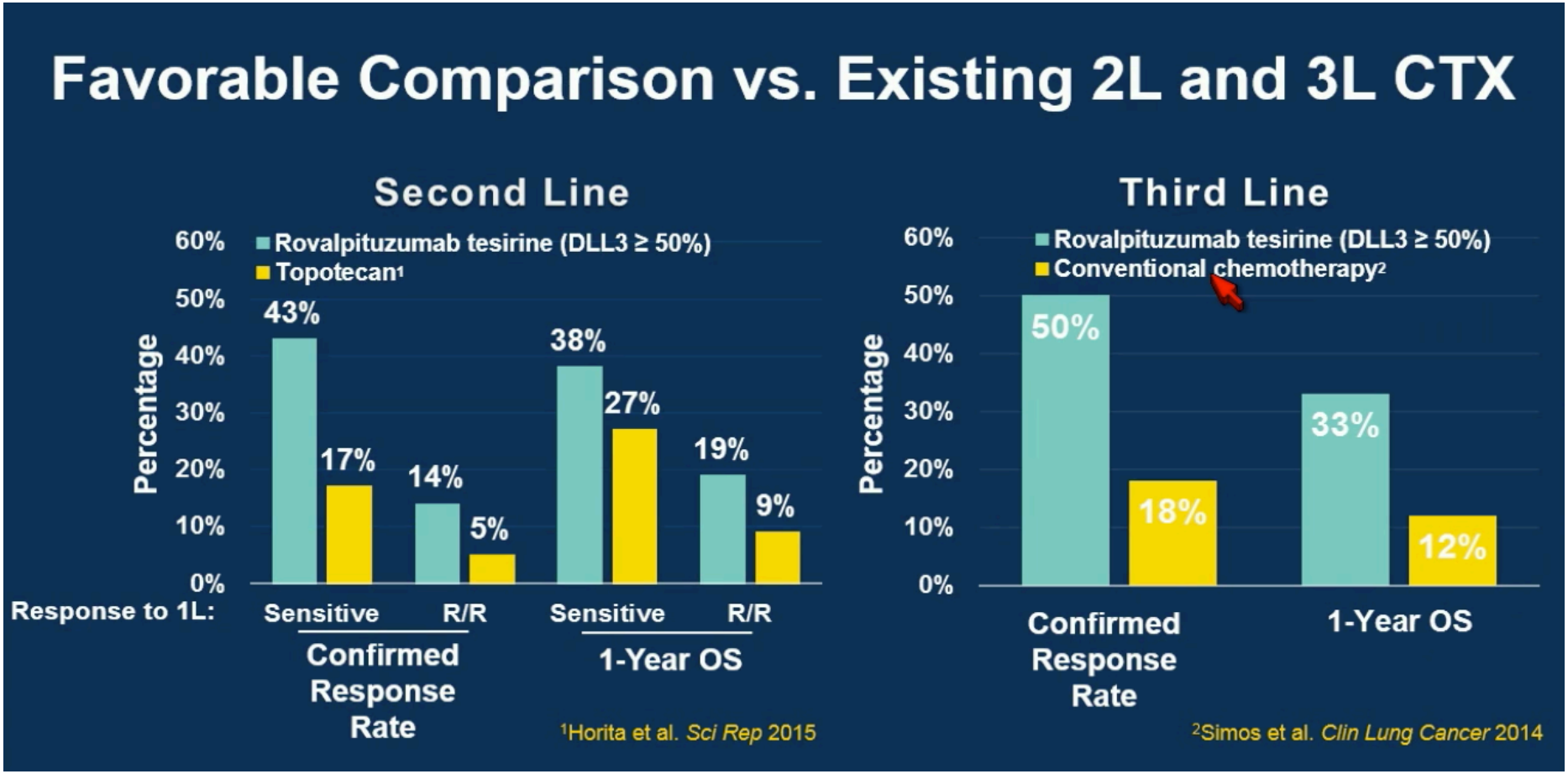
Response-Evaluable Subjects
Available Scans Only
Active Doses (0.2-0.4 mg/kg)


Confirmed Responses Comparable in 2nd & 3rd Line
Second Line
Third Line
Rate
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
13%
29%
72%
86%
25%
50%
64%
92%
N Evaluable
DLL3
32
All
14
≥50%
28
12
ORR
CBR

SCLC Kaplan-Meier Overall Survival



DLL3 Status	Overall Survival	
	Median	1-Year
≥ 50%	5.8 mo	32%
All	4.6 mo	18%


Favorable Comparison vs. Existing 2L and 3L CTX
Second Line
Rovalpituzumab tesirine (DLL3 ≥ 50%)
Topotecan[1]
Percentage
60%
50%
40%
30%
20%
10%
0%
43%
17%
14%
5%
38%
27%
19%
9%
Response to 1L:
Sensitive
R/R
Sensitive
R/R
Confirmed Response Rate
1-Year OS
[1]Horita et al. Sci Rep 2015
Third Line
Rovalpituzumab tesirine (DLL3 ≥ 50%)
Conventional chemotherapy[2]
Percentage
50%
18%
33%
12%
Confirmed Response Rate
1-Year OS
[2]Simos et al. Clin Lung Cancer 2014



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STATE OF THE ART: CONCISE REVIEW

Small Cell Lung Cancer: Can Recent Advances in Biology and Molecular Biology Be Translated into Improved Outcomes?

Paul A. Bunn Jr., MD,[a] John D. Minna, MD,[b] Alexander Augustyn, PhD,[b]

Summary

Despite the paucity of therapeutic advances in SCLC, considerable progress in understanding its biology, molecular biology, model systems, and potential therapeutic targets has been made (Fig. 4 and Table 1).

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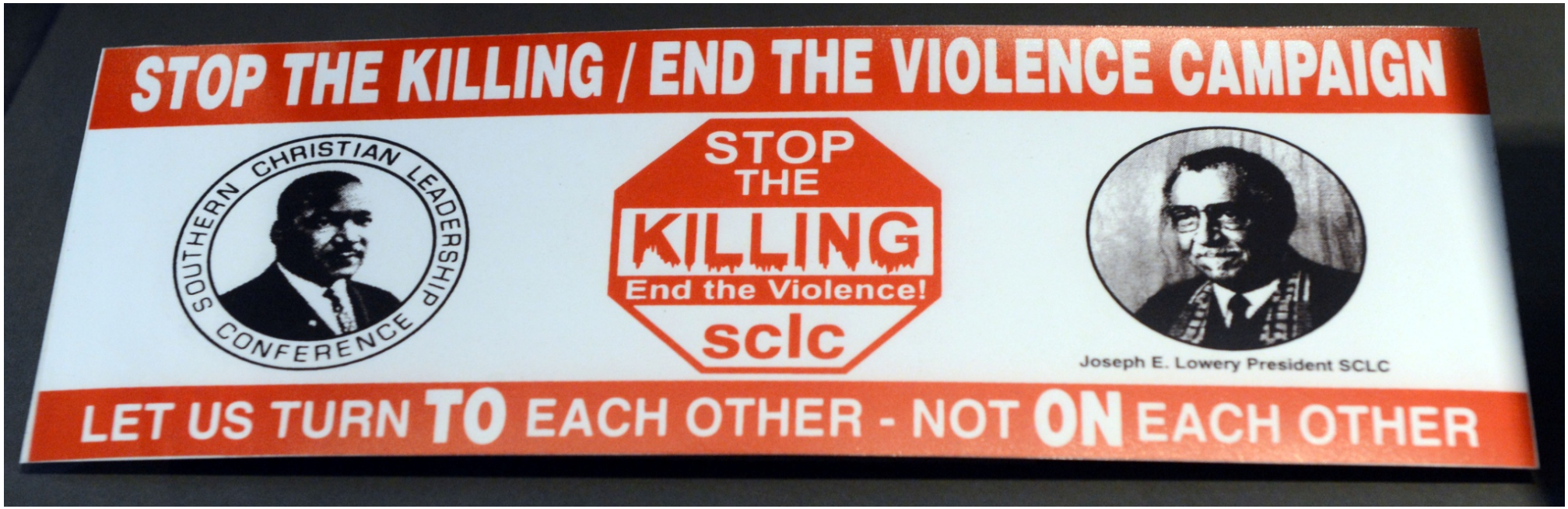
- Staging nun nach UICC
- Immuntherapie mit vielversprechender Responserate (PFS? OS?)
- Ggf Zielgerichtete Therapie möglich
- Insgesamt status idem mit etwas abnehmender Inzidenz

SCLC


sclc
Southern Christian Leadership Conference
SAVE OUR
CHILDREN


SCLC
FREEDOM
NOW!
MARTIN LUTHER KING, JR.
PRESIDENT

SCLC – STOP THE KILLING



SEIT MITTWOCH…..

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