Oncology Today with Dr Neil Love: Novel Agents and Strategies in Lung Cancer

A CME/MOC-Accredited Live Webinar

Thursday, July 11, 2024
5:00 PM – 6:00 PM ET

Faculty

Melissa Johnson, MD
Ticiana Leal, MD
Manish Patel, MD

Moderator

Neil Love, MD

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Faculty

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Sarah Cannon Research Institute
Associate Director of Drug Development
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Nashville, Tennessee

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Director of Drug Development
Florida Cancer Specialists & Research Institute
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Director, Thoracic Oncology
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MODERATOR
Neil Love, MD
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Miami, Florida

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Leadership	iON Pharma USA
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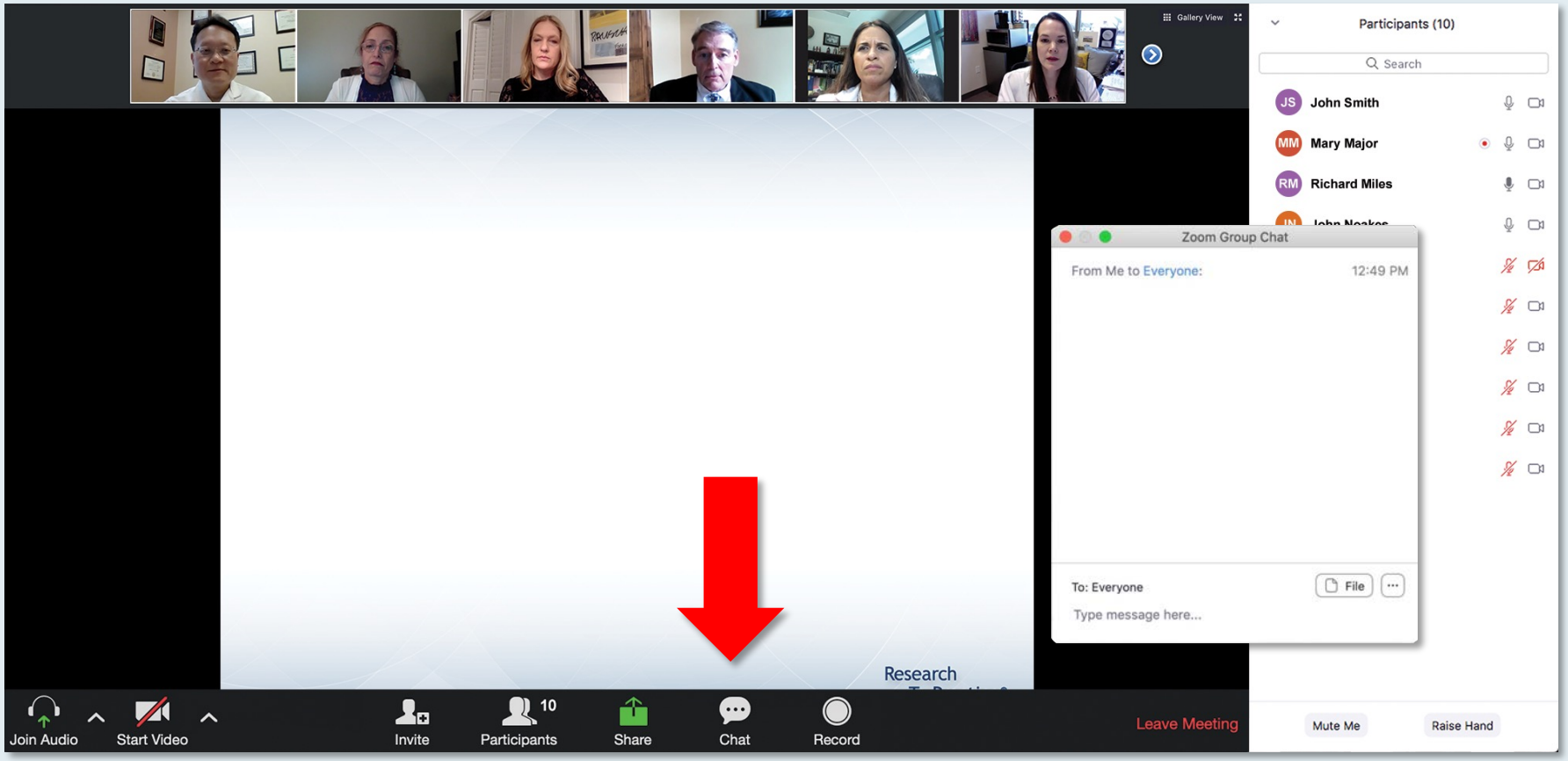

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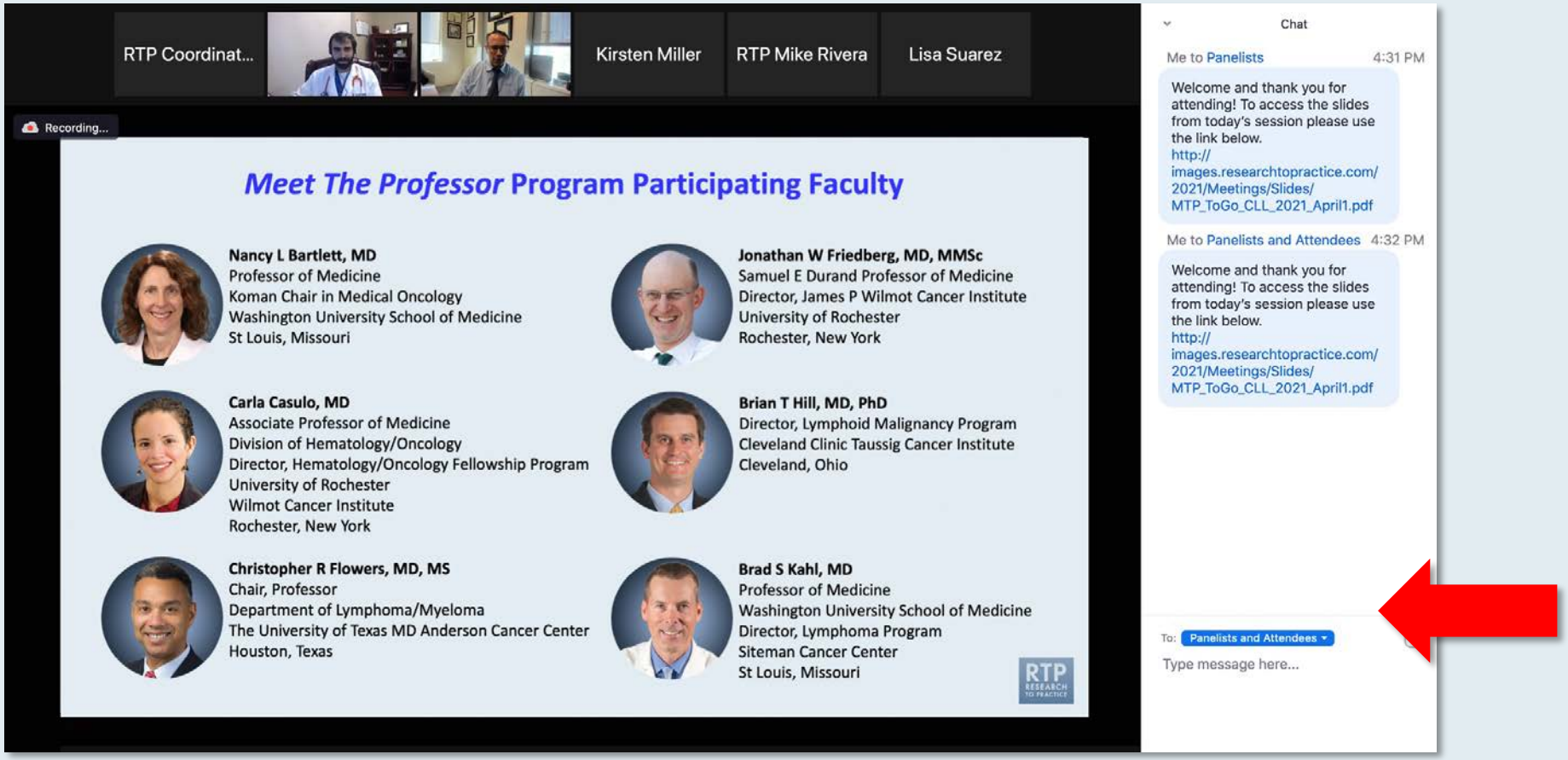

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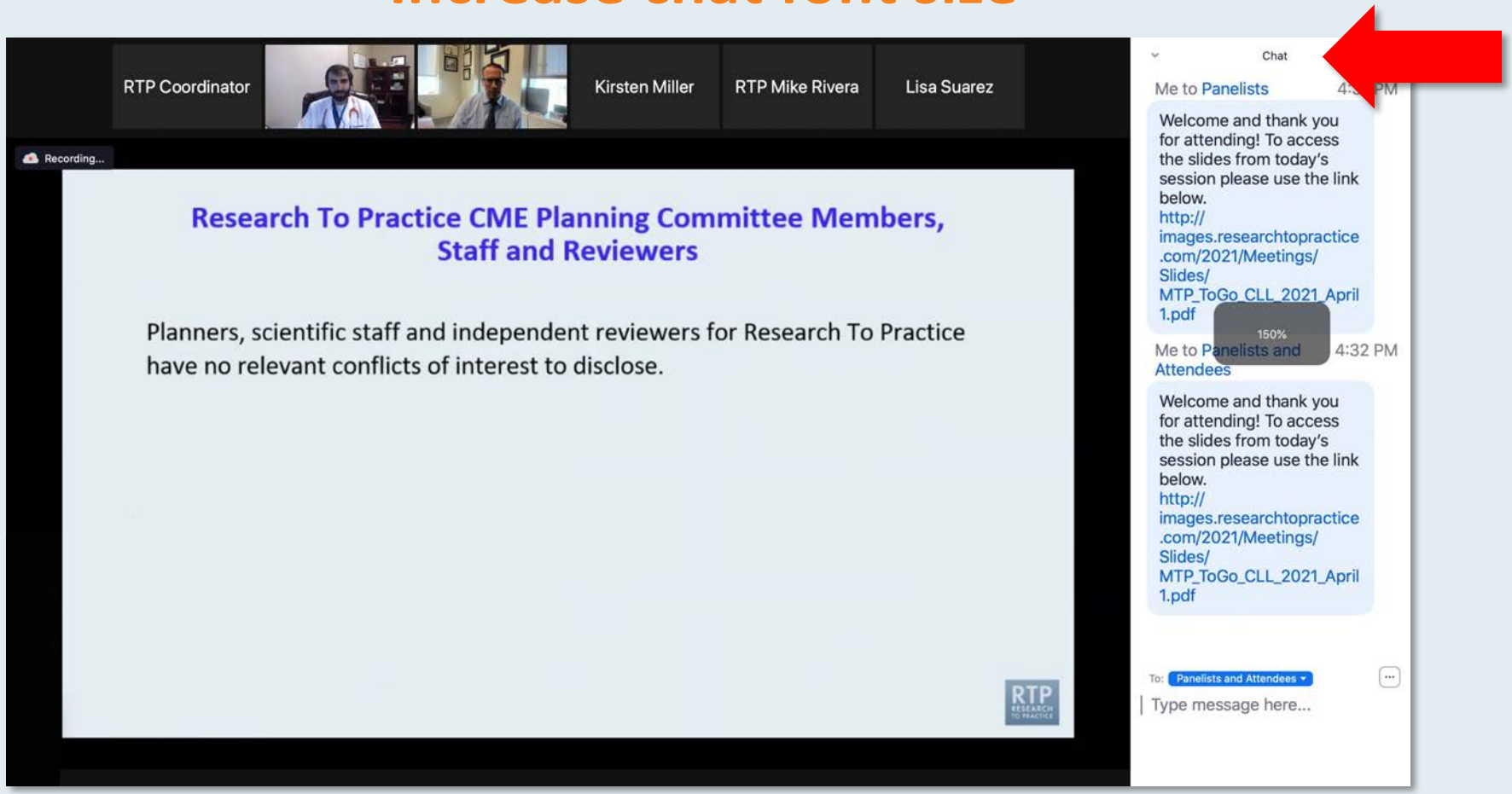

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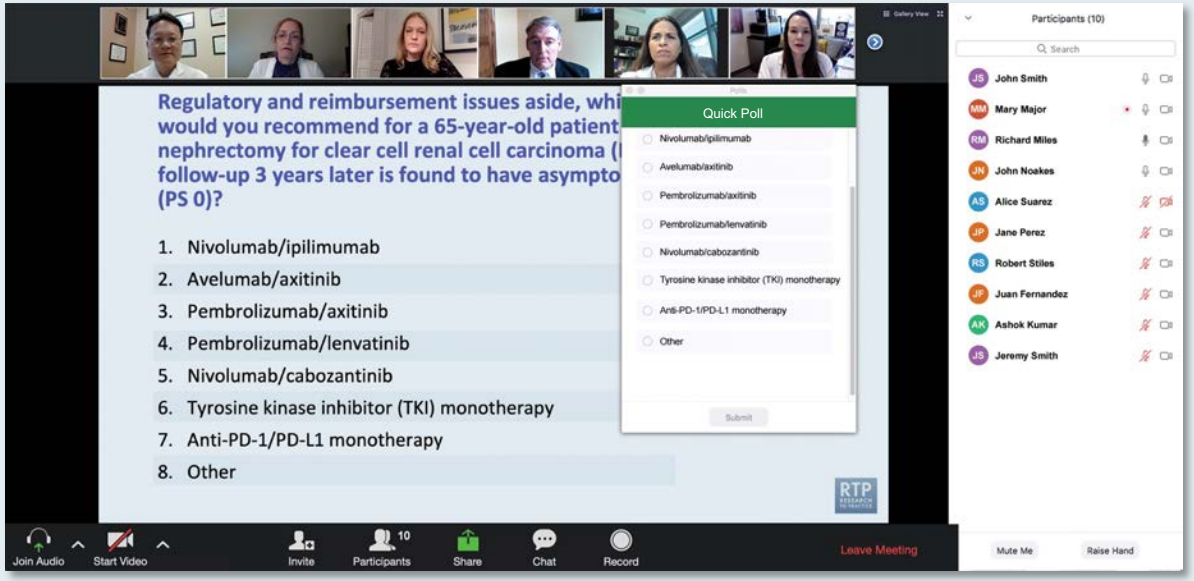

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WITH DR NEIL LOVE

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Targeted Therapy for Non-Small Cell Lung Cancer

DR JUSTIN F GAINOR
MASSACHUSETTS GENERAL HOSPITAL

DR KAREN RECKAMP
CEDARS-SINAI CANCER

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Inside the Issue: Integrating Antibody-Drug Conjugates into the Management of HR-Positive and Triple-Negative Metastatic Breast Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, July 17, 2024
5:00 PM – 6:00 PM ET

Faculty

Professor Peter Schmid, FRCP, MD, PhD
Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

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Inside the Issue: Integrating ALK-Targeted Therapy into the Management of Localized Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Thursday, July 18, 2024
5:00 PM – 6:00 PM ET

Faculty

Professor Solange Peters, MD, PhD
Professor Ben Solomon, MBBS, PhD

Moderator

Neil Love, MD

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Inside the Issue: Integrating HER2-Targeted Strategies into the Management of Gastrointestinal Cancers

A CME/MOC-Accredited Live Webinar

Wednesday, August 21, 2024
5:00 PM – 6:00 PM ET

Faculty

Tanios Bekaii-Saab, MD
John Strickler, MD

Moderator

Neil Love, MD

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Inside the Issue: Optimizing the Diagnosis and Treatment of Neuroendocrine Tumors

A CME/MOC-Accredited Live Webinar

Thursday, August 29, 2024
5:00 PM – 6:00 PM ET

Faculty

Pamela Kunz, MD
Simron Singh, MD, MPH

Moderator

Neil Love, MD

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CME and MOC credit information will be emailed to each participant within 5 business days.

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Ticiana Leal, MD
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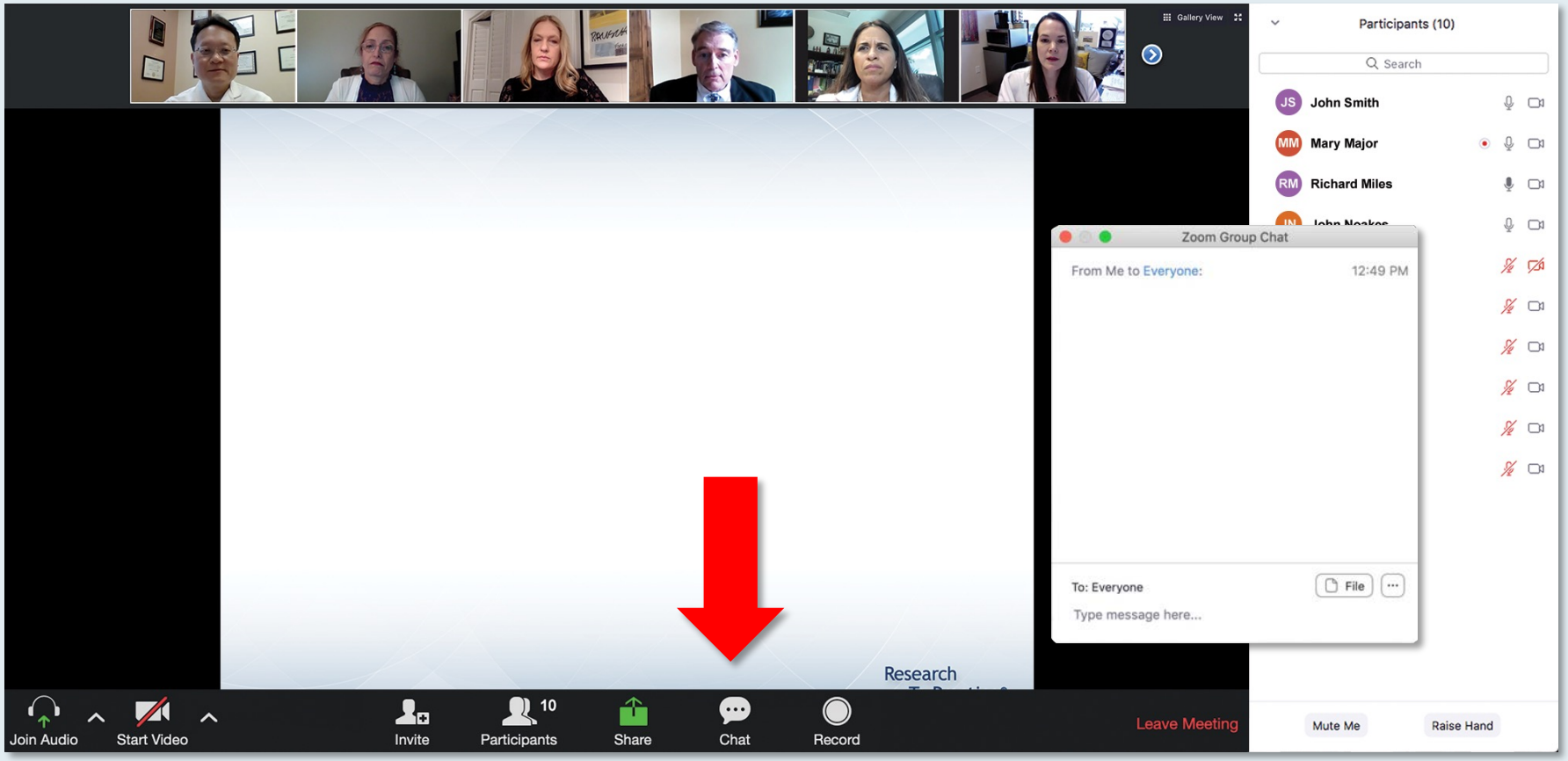

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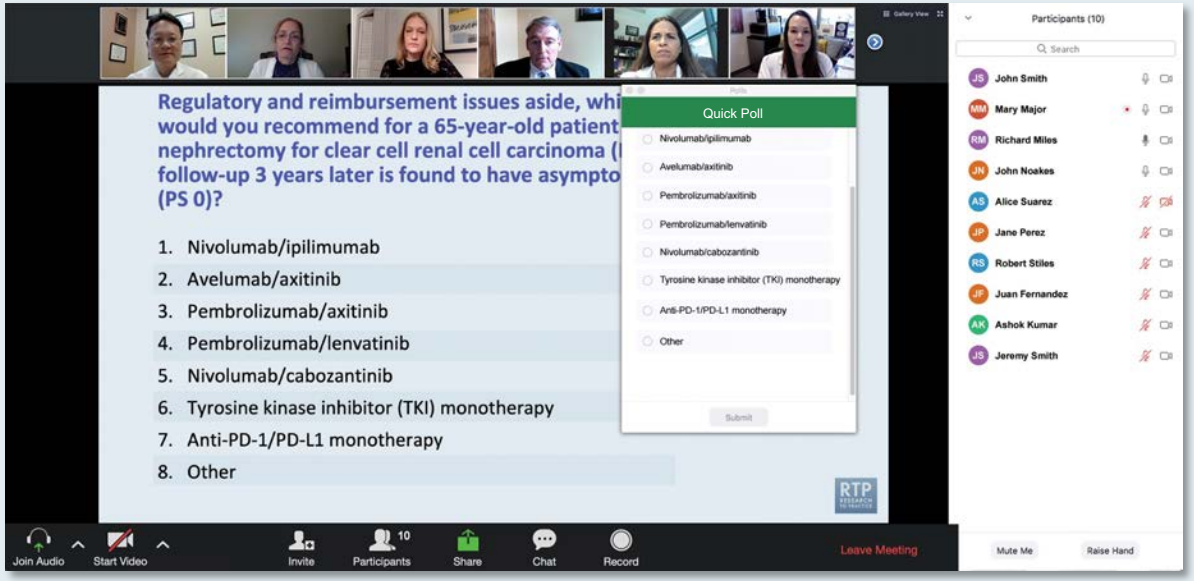

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Introduction: 2 Faces of Lung Cancer Research

Module 1: B7-H3-Targeted Antibody-Drug Conjugates for Lung Cancer — Dr Patel

Module 2: Potential Role of Tumor Treating Fields in the Management of Metastatic NSCLC — Dr Leal

Module 3: Emerging Role of Bispecific T-cell Engaging Immunotherapy in Small Cell Lung Cancer — Dr Johnson

Agenda

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2024 ASCO ANNUAL MEETING

Abstract LBA5

Comparative Effectiveness Trial of Early Palliative Care Delivered via Telehealth versus In Person among Patients with Advanced Lung Cancer: The REACH PC Trial

Joseph A. Greer PhD & Jennifer S. Temel MD on behalf of:

Chardria Trotter MPH MBA, Vicki A. Jackson MD MPH, Simone Rinaldi APN-BC, Mihir Kamdar MD, Areej El-Jawahri MD, Nora Horick MS, Kedie Pintro MS, Dustin Rabideau PhD, Josephine Feliciano MD, Isaac Chua MD MPH, Konstantinos Leventakos MD, Stacy Fischer MD, Toby C. Campbell MD, Michael W. Rabow MD, Finly Zachariah MD, Laura C. Hanson MD, Sara F. Martin MD, Maria Silveira MD, and the REACH PC Investigators

FDA Grants Accelerated Approval to Trastuzumab Deruxtecan for Unresectable or Metastatic HER2-Positive Solid Tumors

Press Release – April 5, 2024

"…the Food and Drug Administration granted accelerated approval to fam-trastuzumab deruxtecan-nxki for adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.

Efficacy was evaluated in 192 adult patients with previously treated unresectable or metastatic HER2-positive (IHC 3+) solid tumors who were enrolled in one of three multicenter trials: DESTINY-PanTumor02 (NCT04482309), DESTINY-Lung01 (NCT03505710), and DESTINY-CRC02 (NCT04744831).

The major efficacy outcome measure in all three trials was confirmed objective response rate (ORR), and an additional efficacy outcome was duration of response (DOR). All outcomes were assessed by independent central review (ICR) based on RECIST v1.1. In DESTINY-PanTumor02, ORR was 51.4% (95% CI: 41.7, 61.0) and median DOR was 19.4 months (range 1.3, 27.9+). In DESTINY-Lung01, ORR was 52.9% (95% CI: 27.8, 77.0) and median DOR was 6.9 months (range 4.0, 11.7+). In DESTINY-CRC02, ORR was 46.9% (95% CI: 34.3, 59.8), and DOR was 5.5 months (range 1.3+, 9.7+)."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2

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Comparative Effectiveness Trial of Early Palliative Care Delivered via Telehealth versus In Person among Patients with Advanced Lung Cancer: The REACH PC Trial

Joseph A. Greer PhD & Jennifer S. Temel MD on behalf of:

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REACH PC: Main Study Findings

- Palliative care led to equivalent benefits for patient-reported quality of life whether delivered via video or in-person visits among adults with advanced lung cancer.
- Findings underscore the potential to increase access to evidence-based early palliative care through telehealth delivery.

Greer JA et al. ASCO 2024;Abstract LBA3.

RTP RESEARCH TO PRACTICE

FDA Grants Accelerated Approval to Trastuzumab Deruxtecan for Unresectable or Metastatic HER2-Positive Solid Tumors

Press Release – April 5, 2024

"…the Food and Drug Administration granted accelerated approval to fam-trastuzumab deruxtecan-nxki for adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.

Efficacy was evaluated in 192 adult patients with previously treated unresectable or metastatic HER2-positive (IHC 3+) solid tumors who were enrolled in one of three multicenter trials: DESTINY-PanTumor02 (NCT04482309), DESTINY-Lung01 (NCT03505710), and DESTINY-CRC02 (NCT04744831).

The major efficacy outcome measure in all three trials was confirmed objective response rate (ORR), and an additional efficacy outcome was duration of response (DOR). All outcomes were assessed by independent central review (ICR) based on RECIST v1.1. In DESTINY-PanTumor02, ORR was 51.4% (95% CI: 41.7, 61.0) and median DOR was 19.4 months (range 1.3, 27.9+). In DESTINY-Lung01, ORR was 52.9% (95% CI: 27.8, 77.0) and median DOR was 6.9 months (range 4.0, 11.7+). In DESTINY-CRC02, ORR was 46.9% (95% CI: 34.3, 59.8), and DOR was 5.5 months (range 1.3+, 9.7+)."

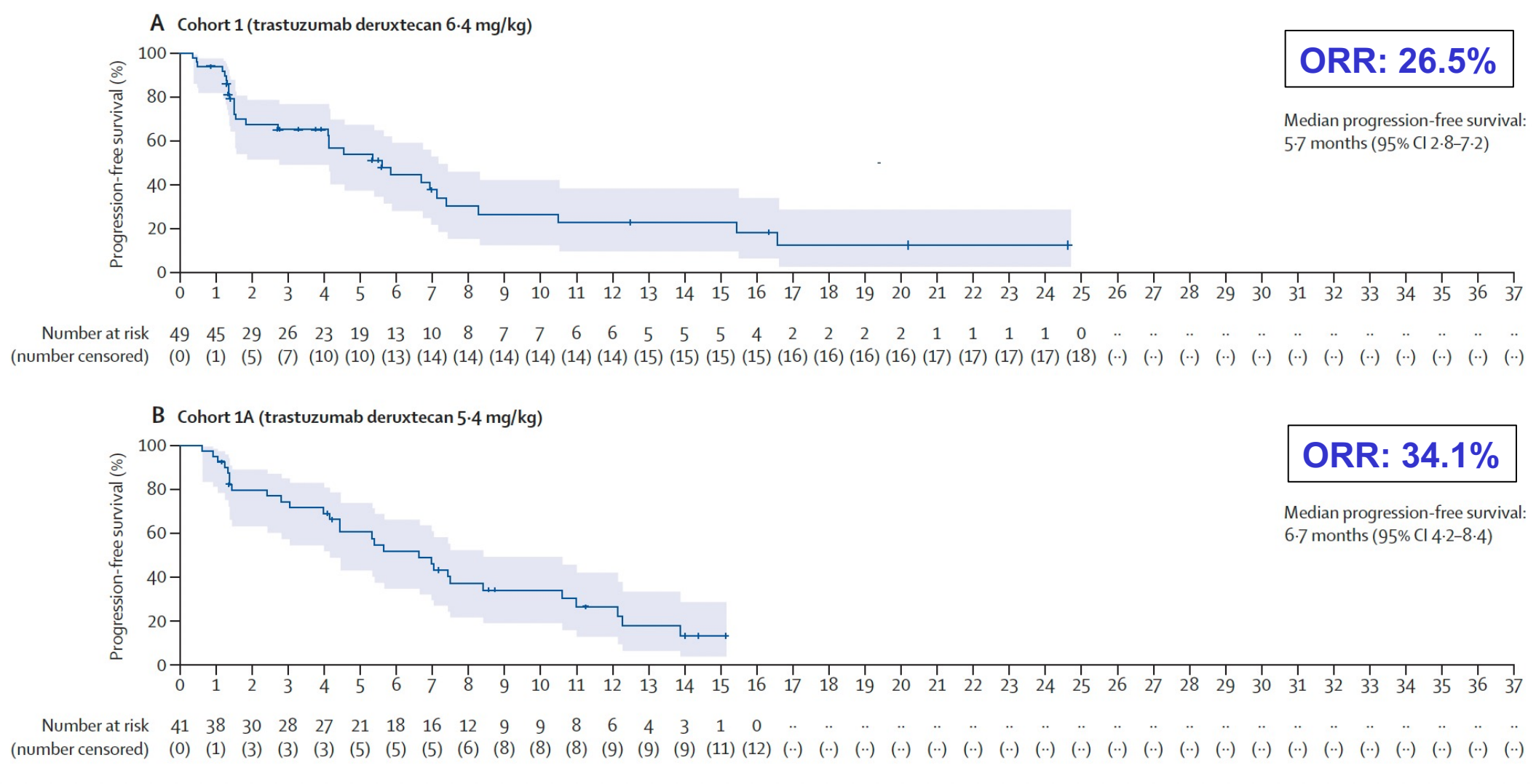
https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2

Trastuzumab deruxtecan in patients with metastatic non-small-cell lung cancer (DESTINY-Lung01): primary results of the HER2-overexpressing cohorts from a single-arm, phase 2 trial

Egbert F Smit, Enriqueta Felip, Dipesh Uprety, Misako Nagasaka, Kazuhiko Nakagawa, Luis Paz-Ares Rodríguez, Jose M Pacheco, Bob T Li, David Planchard, Christina Baik, Yasushi Goto, Haruyasu Murakami, Andreas Saltos, Kaline Pereira, Ayumi Taguchi, Yingkai Cheng, Qi Yan, Wenqin Feng, Zenta Tsuchihashi, Pasi A Jänne

***Lancet Oncol* 2024;25:439-54**

DESTINY-Lung01: PFS by T-DXd Dose — HER2 Overexpression Cohort Data



ORR = objective response rate

Smit EF et al. *Lancet Oncol* 2024;25:439-54.

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DESTINY-Lung01: Most Common Adverse Events — HER2 Overexpression Cohort Data

	Cohort 1 (6·4 mg/kg); N=49				Cohort 1A (5·4 mg/kg); N=41			
	Grades 1–2	Grade 3	Grade 4	Grade 5	Grade 1–2	Grade 3	Grade 4	Grade 5
Nausea	26 (53%)	3 (6%)	0	0	28 (68%)	2 (5%)	0	0
Fatigue	23 (47%)	6 (12%)	0	0	26 (63%)	3 (7%)	0	0
Decreased appetite	20 (41%)	2 (4%)	0	0	19 (46%)	0	0	0
Constipation	15 (31%)	0	0	0	10 (24%)	0	0	0
Vomiting	13 (27%)	2 (4%)	0	0	12 (29%)	1 (2%)	0	0
Diarrhoea	12 (24%)	2 (4%)	0	0	13 (32%)	2 (5%)	0	0
Weight decreased	12 (24%)	0	0	0	7 (17%)	1 (2%)	0	0
Anaemia	10 (20%)	3 (6%)	1 (2%)	0	8 (20%)	3 (7%)	0	0
Alopecia	10 (20%)	0	0	0	5 (12%)	0	0	0
Dyspnoea	8 (16%)	5 (10%)	0	0	10 (24%)	1 (2%)	0	1 (2%)
Dizziness	8 (16%)	2 (4%)	0	0	3 (7%)	0	0	0
Thrombocytopenia	7 (14%)	1 (2%)	1 (2%)	0	3 (7%)	0	0	0
Hypokalaemia	6 (12%)	2 (4%)	0	0	1 (2%)	2 (5%)	0	0
Stomatitis	6 (12%)	0	0	0	2 (5%)	0	0	0
Cough	6 (12%)	0	0	0	12 (29%)	0	0	0
Pneumonitis	5 (10%)	1 (2%)	1 (2%)	1 (2%)†	2 (5%)	0	0	0
Blood creatinine increased	5 (10%)	0	0	0	3 (7%)	0	0	0
Upper respiratory tract infection	5 (10%)	0	0	0	1 (2%)	0	0	0

Smit EF et al. *Lancet Oncol* 2024;25:439-54.

Trastuzumab Deruxtecan in Patients With *HER2*-Mutant Metastatic Non–Small-Cell Lung Cancer: Primary Results From the Randomized, Phase II DESTINY-Lung02 Trial

Koichi Goto, MD, PhD[1]; Yasushi Goto, MD, PhD[2]; Toshio Kubo, MD, PhD[3]; Kiichiro Ninomiya, MD, PhD[4]; Sang-We Kim, MD, PhD[5]; David Planchard, MD, PhD[6]; Myung-Ju Ahn, MD, PhD[7]; Egbert F. Smit, MD, PhD[8]; Adrianus Johannes de Langen, MD, PhD[9]; Maurice Pérol, MD[10]; Elvire Pons-Tostivint, MD, PhD[11]; Silvia Novello, MD, PhD[12]; Hidetoshi Hayashi, MD, PhD[13]; Junichi Shimizu, MD, PhD[14]; Dong-Wan Kim, MD, PhD[15]; Chih-Hsi Kuo, MD, PhD[16]; James Chih-Hsin Yang, MD, PhD[17]; Kaline Pereira, MD, PhD[18]; Fu-Chih Cheng, PhD[18]; Ayumi Taguchi, PharmD[19]; Yingkai Cheng, MD, PhD[18]; Wenqin Feng, PhD[18]; Zenta Tsuchihashi, PhD[18]; and Pasi A. Jänne, MD, PhD[20]

J Clin Oncol **2023 November 1;41(31):4852-63.**

2024 ASCO ANNUAL MEETING

Abstract 8543

Trastuzumab Deruxtecan in Patients With *HER2*-Mutant Metastatic Non–Small Cell Lung Cancer: Final Analysis Results of DESTINY-Lung02

Pasi A. Jänne,[1] Yasushi Goto, Toshio Kubo, Kiichiro Ninomiya, Sang-We Kim, David Planchard, Myung-Ju Ahn, Egbert Smit, Adrianus Johannes de Langen, Maurice Pérol, Elvire Pons-Tostivint, Silvia Novello, Hidetoshi Hayashi, Junichi Shimizu, Dong-Wan Kim, Kaline Pereira, Fu-Chih Cheng, Ayumi Taguchi, Yingkai Cheng, Kyle Dunton, Ahmed Ali, and Koichi Goto

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DESTINY-Lung02: Final Analysis Results

Efficacy summary		
	T-DXd 5.4 mg/kg (n = 102)	**T-DXd 6.4 mg/kg (n = 50)**
cORR,[a] % (95% CI)	50.0 (39.9-60.1)	56.0 (41.3-70.0)
Median DoR, mo (95% CI)	12.6 (6.4-NE)	12.2 (7.0-NE)
Median PFS, mo (95% CI)	10.0 (7.7-15.2)	12.9 (7.2-16.7)
Median OS, mo (95% CI)	19.0 (14.7-NE)	17.3 (13.8-NE)

Adjudicated drug-related interstitial lung disease (ILD)/pneumonitis was reported in 14.9% (15/101) and 32.0% (16/50) of patients in the T-DXd 5.4 and 6.4 mg/kg arms, respectively; most events were grade 1 or 2 (1 grade 5 event in each arm).

Janne PA et al. ASCO 2024;Abstract 8543.

DESTINY-Lung02: Common TRAEs

	T-DXd 5.4 mg/kg Once Every 3 Weeks (n = 101),[a] No. (%)		T-DXd 6.4 mg/kg Once Every 3 Weeks (n = 50),[a] No. (%)	
Preferred Term	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3
Nausea	68 (67.3)	4 (4.0)	41 (82.0)	3 (6.0)
Neutropenia[b]	43 (42.6)	19 (18.8)	28 (56.0)	18 (36.0)
Fatigue[b]	45 (44.6)	8 (7.9)	25 (50.0)	5 (10.0)
Decreased appetite	40 (39.6)	2 (2.0)	25 (50.0)	2 (4.0)
Anemia[b]	37 (36.6)	11 (10.9)	26 (52.0)	8 (16.0)
Vomiting	32 (31.7)	3 (3.0)	22 (44.0)	1 (2.0)
Constipation	37 (36.6)	1 (1.0)	16 (32.0)	0
Leukopenia[b]	29 (28.7)	5 (5.0)	17 (34.0)	8 (16.0)
Thrombocytopenia[b]	28 (27.7)	6 (5.9)	14 (28.0)	5 (10.0)
Diarrhea	23 (22.8)	1 (1.0)	18 (36.0)	2 (4.0)
Alopecia	22 (21.8)	0	17 (34.0)	0
Transaminases increased[b]	22 (21.8)	3 (3.0)	10 (20.0)	0

Goto K et al. *J Clin Oncol* 2023 November 1;41(31):4852-63.

DESTINY-Lung02: Adjudicated Drug-Related ILD

Adjudicated Drug-Related ILD in Patients With Prior Anti–PD-(L)1 Therapy	T-DXd 5.4 mg/kg Once Every 3 Weeks (n = 74), No. (%)	T-DXd 6.4 mg/kg Once Every 3 Weeks (n = 39), No. (%)
Grade 1	4 (5.4)	2 (5.1)
Grade 2	5 (6.8)	9 (23.1)
Grade 3	1 (1.4)	0
Grade 4	0	0
Grade 5	1 (1.4)	0
Total	11 (14.9)	11 (28.2)

Adjudicated Drug-Related ILD in Patients Without Prior Anti–PD-(L)1 Therapy	T-DXd 5.4 mg/kg Once Every 3 Weeks (n = 27), No. (%)	T-DXd 6.4 mg/kg Once Every 3 Weeks (n = 11), No. (%)
Grade 1	0	2 (18.2)
Grade 2	2 (7.4)	0
Grade 3	0	0
Grade 4	0	0
Grade 5	0	1 (9.1)
Total	2 (7.4)	3 (27.3)

*Two of the three patients with grade 1 ILD in the 6.4 mg/kg arm were retreated with T-DXd, both with negative rechallenge (no recurrence of ILD/pneumonitis after retreatment with T-DXd).

Goto K et al. *J Clin Oncol* 2023 November 1;41(31):4852-63.

Agenda

Introduction: 2 Faces of Lung Cancer Research

Module 1: B7-H3-Targeted Antibody-Drug Conjugates for Lung Cancer — Dr Patel

Module 2: Potential Role of Tumor Treating Fields in the Management of Metastatic NSCLC — Dr Leal

Module 3: Emerging Role of Bispecific T-cell Engaging Immunotherapy in Small Cell Lung Cancer — Dr Johnson

B7-H3-Targeted Antibody-Drug Conjugates in Lung Cancer

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Florida Cancer Specialists & Research Institute
Associate Director of Drug Development
Sarah Cannon Research Institute
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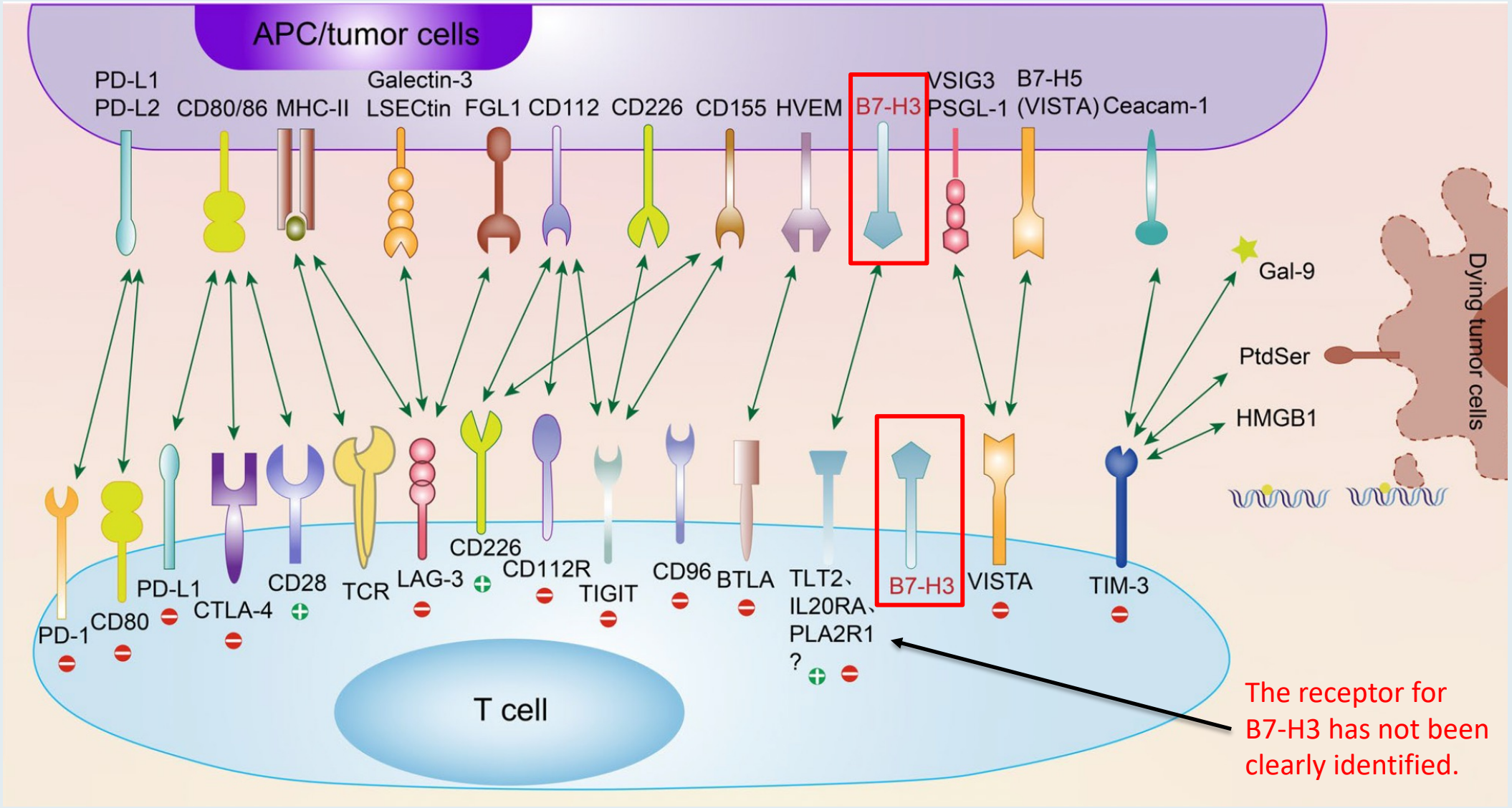
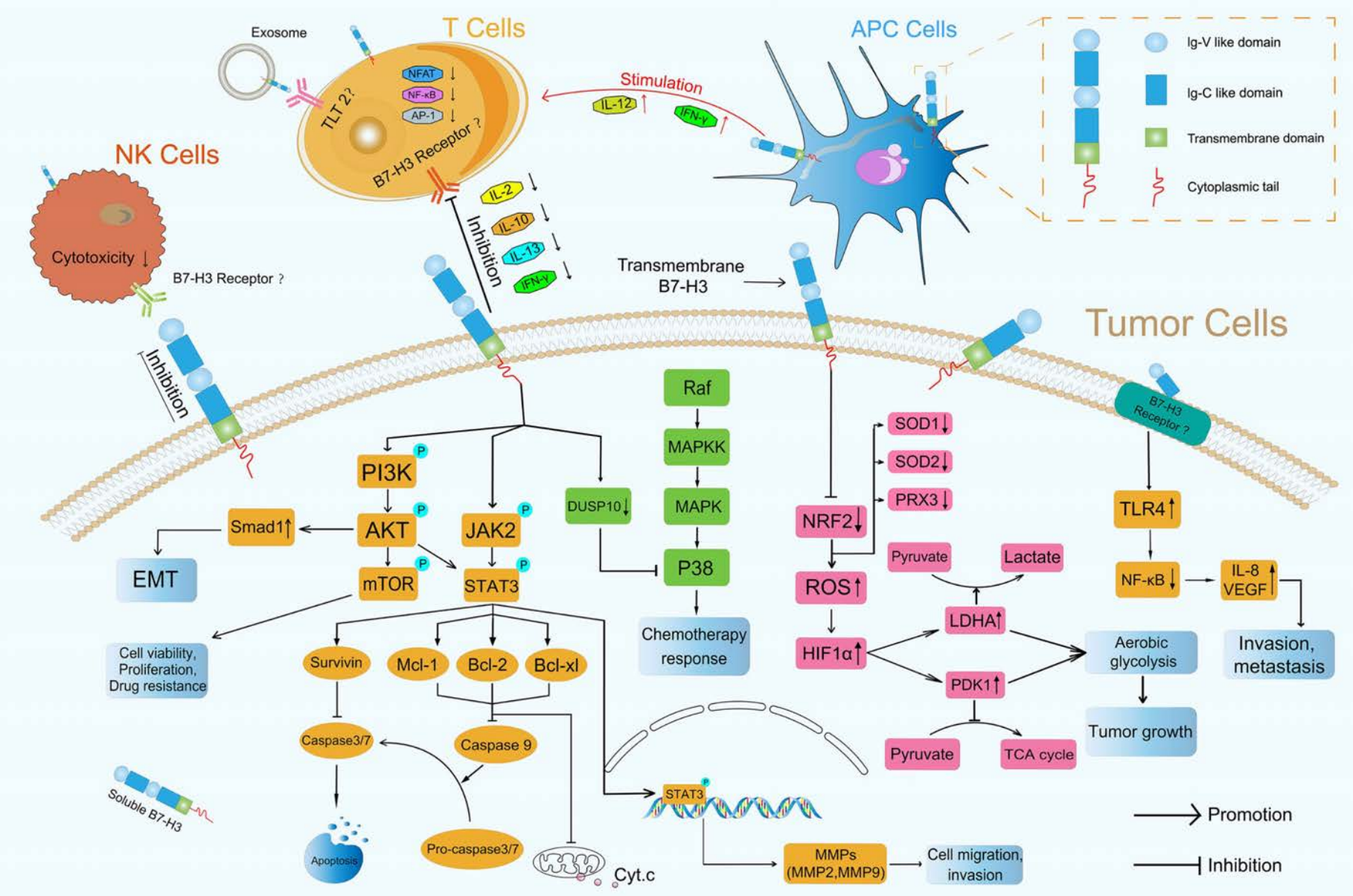
Current Immune Checkpoint Receptors and Their Ligands



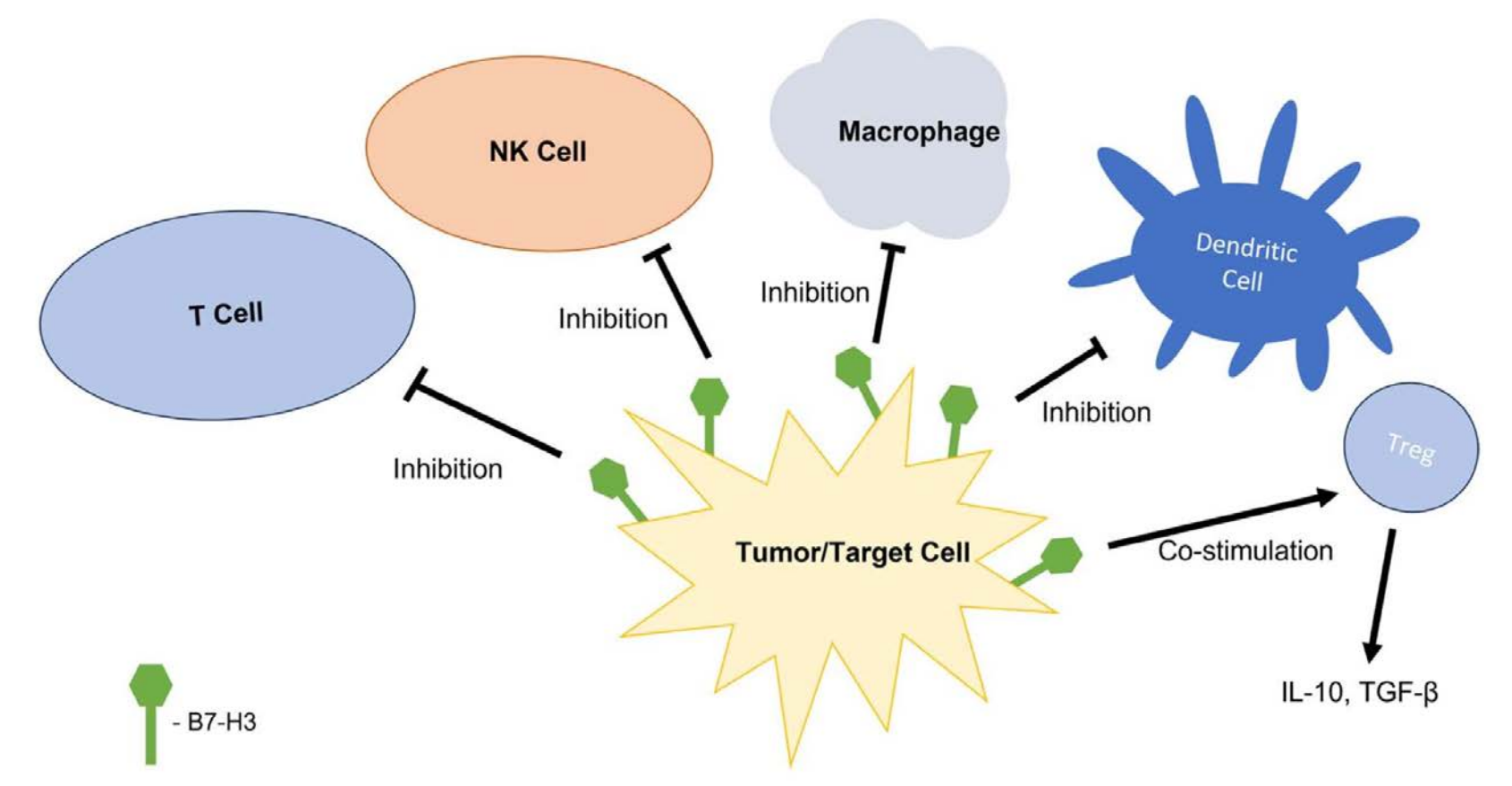
Zhao B et al. *J Hematol Oncol* 2022;15(1):153.

Molecular Pathways Involved with B7-H3



Zhou WT et al. *Front Immunol* 2021;12:701006.

Function of B7-H3 Ligand in Immune Cells



Normal function: B7-H3 downregulates numerous cytokines (eg, IL-2, interferon-c, perforin, granzyme B).

Normal function: B7-H3 inhibits T-cell proliferation along with downregulation of NK cells, macrophages, dendritic cells and neutrophils.

Tumor function: B7-H3 is upregulated and overexpressed in tumor cells, resulting in promotion of cancer survival.

Feustel K et al. *J Immunother Precis Oncol* 2024;7(1):53-66.

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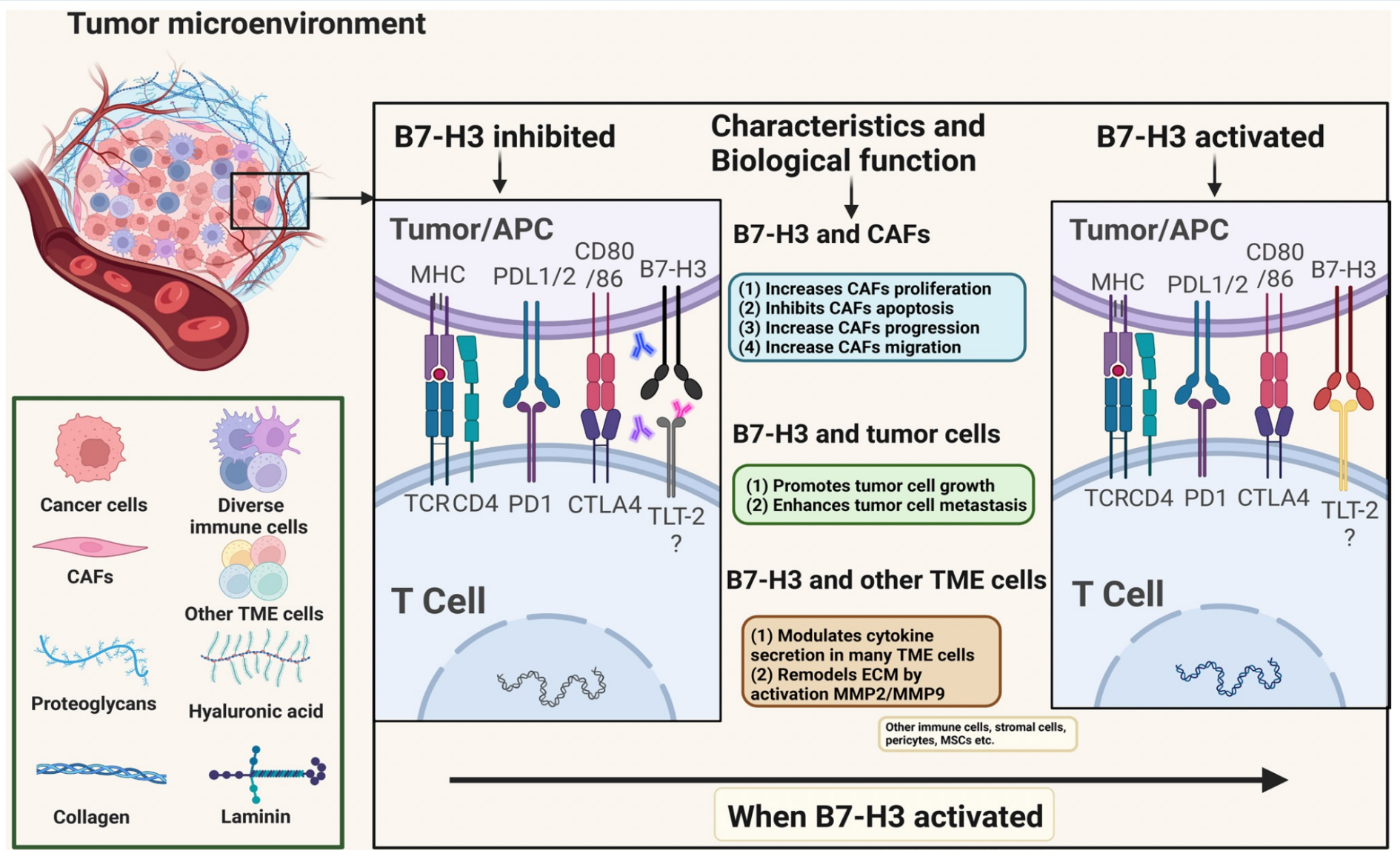
B7-H3 Ligand Interaction with Tumor Microenvironment



CAFs = cancer-associated fibroblasts; TME = tumor microenvironment; ECM = extracellular matrix; MSCs = mesenchymal stromal cells

Zhao B et al. *J Hematol Oncol* 2022;15(1):153.

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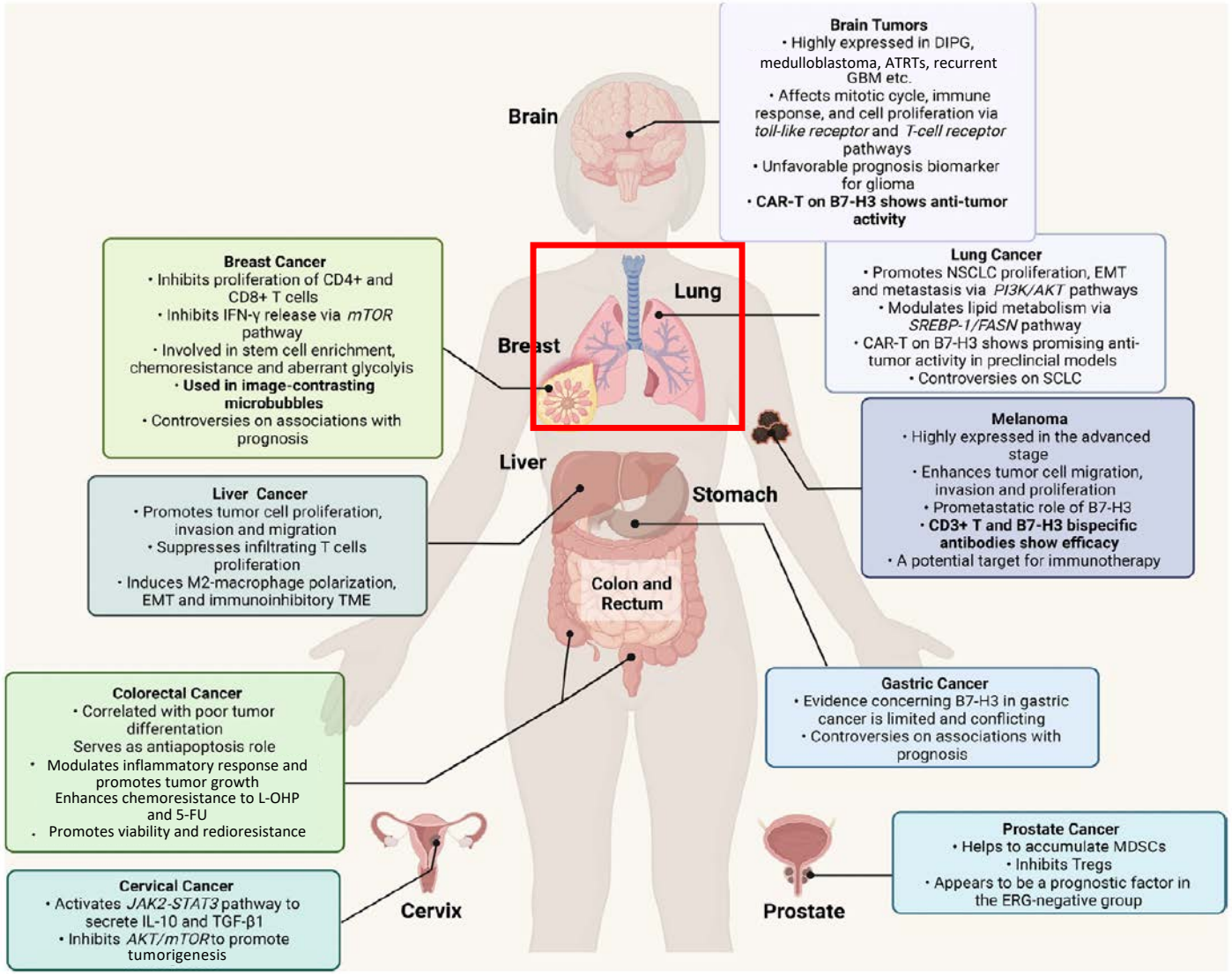
B7-H3 Ligand Is Overexpressed in Lung Cancer

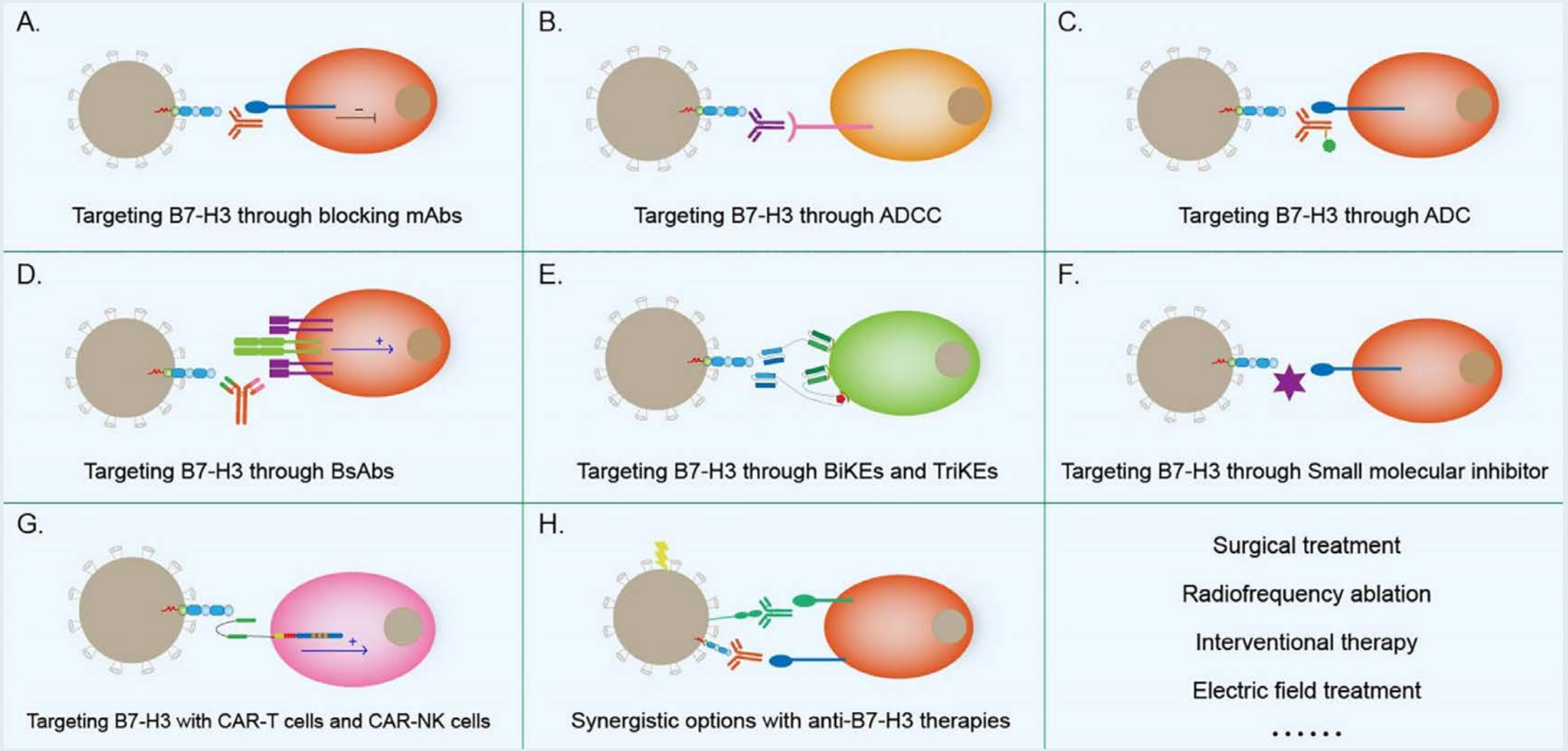


DIPG = diffuse intrinsic pontine glioma; ATRTs = atypical teratoid/rhabdoid tumors; EMT = epithelial–mesenchymal transformation; NSCLC = non-small cell lung cancer; SCLC = small cell lung cancer; MDSCs = myeloid-derived suppressor cells

Zhao B et al. *J Hematol Oncol* 2022;15(1):153.

Courtesy of Manish Patel, MD

Innovative Approaches to Targeting B7-H3



Zhou WT et al. *Front Immunol* 2021;12:701006.

Innovative Therapies Targeting B7-H3

Pharmaceutical agent	Pharmacologic class	Targeted disease state	Trial phase and NCT identifier
Ifinatamab deruxtecan (I-DXd)	Antibody-drug conjugate	Relapsed small-cell lung cancer (SCLC)	Phase III (IDeate-Lung02) NCT06203210
Vobramitamab duocarmazine	Antibody-drug conjugate	Metastatic castration resistant prostate cancer (mCRPC)	Phase II (TAMARACK) NCT05551117
HS-20093	Antibody-drug conjugate	Treatment-naïve extensive-stage SCLC	Phase II (ARTEMIS-007) NCT06052423
Enoblituzumab	Antibody-dependent cellular cytotoxicity (ADCC)-mediated monoclonal antibody	Operable intermediate/high-risk localized prostate cancer	Phase II NCT02923180
^{131}I-Omburtamab	Radiolabeled monoclonal antibody	Pediatric neuroblastoma	Phase II/III NCT03275402

Feustel K et al. *J Immunother Precis Oncol* 2024;7(1):53-66.

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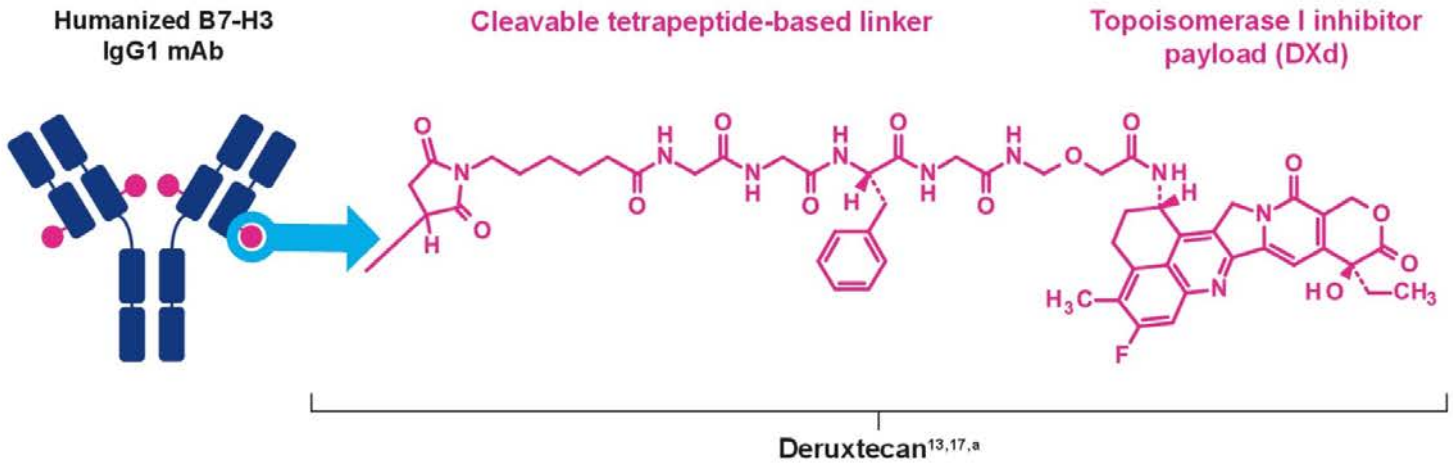
Ifinatamab Deruxtecan (I-DXd; DS-7300) Components

Figure 1. I-DXd was designed with 7 key attributes



The **mAb** directs the DXd ADC to the tumor cell

1. Optimized drug-to-antibody ratio ~4[13,16,b,c]

The **linker** binds the mAb to the payload

2. Plasma-stable linker–payload[13,16,b]
3. Tumor-selective cleavable linker[13,16,b]

The **payload** induces cell death when delivered to the tumor

4. Topoisomerase I inhibitor[13,16,17,b]
5. High potency[13,16,b]
6. Short systemic half-life[13,16,b,c]
7. Bystander antitumor effect[16,17,18,b]

Owonikoko TK et al. ASCO 2024;Abstract TPS8126.

Courtesy of Manish Patel, MD

I-DXd: DS7300-A-J101 Phase I/II Study Design

Patients with advanced/ unresectable or metastatic solid tumors (unselected for B7-H3 expression) N≈205

Part 1: dose-escalation
- I-DXd IV Q3W monotherapy for advanced solid tumors[a]

16.0 mg/kg
12.0 mg/kg
8.0 mg/kg
6.4 mg/kg
4.8 mg/kg
3.2 mg/kg
1.6 mg/kg
0.8 mg/kg

RDE

Part 2: dose-expansion (12.0 mg/kg)
- I-DXd IV Q3W monotherapy for selected advanced solid tumors

Cohort 1: ESCC
(planned n≈40)

Cohort 2: mCRPC
(planned n=40)

Cohort 3: sqNSCLC
(planned n≈40)

Key primary endpoints
- Dose escalation: DLTs, SAEs, TEAEs, AESI
- Dose expansion: ORR, DOR, DCR, PFS, OS

Key secondary endpoints
- PK
- Immunogenicity

[a]Tumor types included advanced/unresectable or metastatic HNSCC, ESCC, mCRPC, sqNSCLC, SCLC, bladder cancer, sarcoma, endometrial cancer, melanoma, and breast cancer.

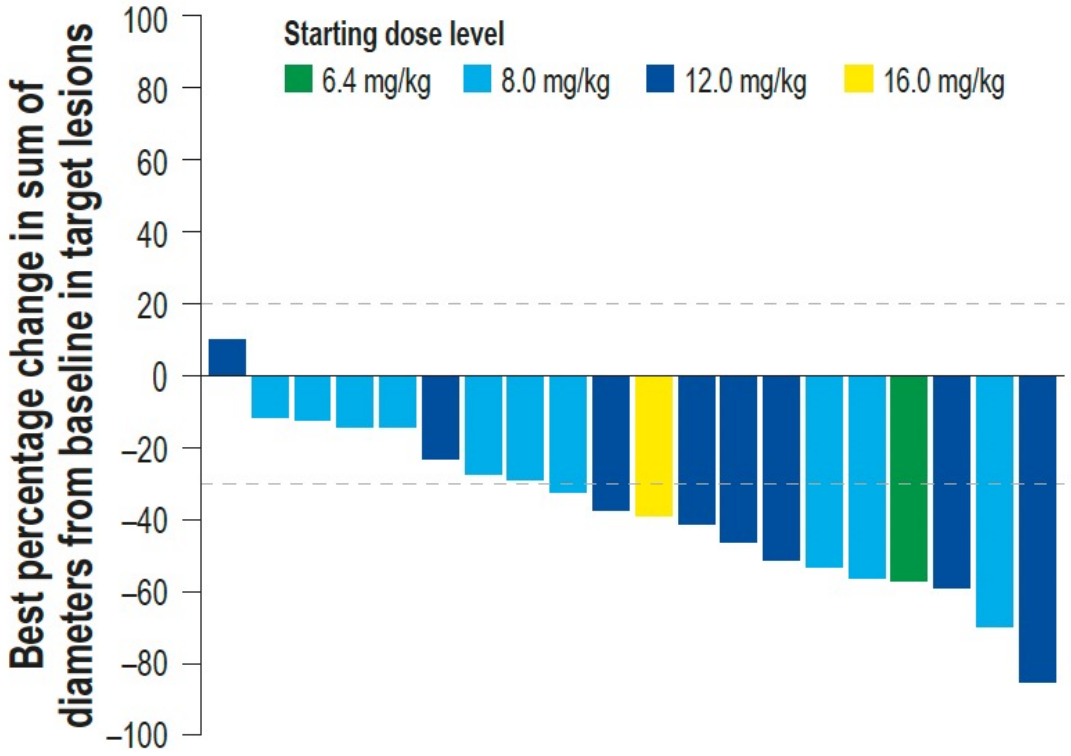
ESCC = esophageal squamous cell carcinoma; mCRPC = metastatic castration-resistant prostate cancer; sqNSCLC = squamous non-small cell lung cancer; DLTs = dose-limiting toxicities; SAEs = serious adverse events; TEAEs = treatment-emergent adverse events; AESI = adverse event of special interest; ORR = objective response rate; DOR = duration of response; DCR = disease control rate; PFS = progression-free survival; OS = overall survival; PK = pharmacokinetics

Patel M et al. ESMO 2023;Abstract 690P.

Courtesy of Manish Patel, MD

I-DXd: Efficacy Results in SCLC

A) SCLC[3]



	SCLC
Efficacy population (≥4.8 mg/kg)	**n=21**
Confirmed ORR, n (%; 95% CI)	11 (52.4; 29.8–74.3)
Confirmed CR, n (%)	1 (4.8)
Confirmed PR, n (%)	10 (47.6)
TTR, median (95% CI), months	1.2 (1.2–1.4)
DOR, median (95% CI), months	5.9 (2.8–7.5)
Median PFS, months (95% CI)	5.6 (3.9–8.1)
Median OS, months (95% CI)	12.2 (6.4–NE)
Follow-up, median (95% CI), months	11.7 (4.6–12.9)
Safety population (all doses)	**n=22**
Number of prior systemic regimens, median (range)	2 (1–7)
Platinum-based chemotherapy, n (%)	22 (100)
Immunotherapy, n (%)	18 (81.8)
Irinotecan or topotecan, n (%)	5 (22.7)[a]
Topotecan, n (%)	3 (13.6)

[a]One patient received both.
Change from baseline in target lesions was assessed per RECIST v1.1. All 21 patients were evaluable at baseline, but one did not have any post-baseline tumor assessments, and so was not included in the waterfall plot.

CR = complete response; PR = partial response; TTR = time to response

Patel M et al. ESMO 2023;Abstract 690P.

Courtesy of Manish Patel, MD

I-DXd: Safety Profile in SCLC

	SCLC (n=22)
Treatment duration, median (range), weeks	17.1 (0.1–54.1)
Any TEAEs[b], n (%)	22 (100)
TEAE of CTCAE Grade ≥3, n (%)	8 (36.4)
TEAE associated with drug discontinuation, n (%)	5 (22.7)
TEAE associated with dose interruption, n (%)	3 (13.6)
TEAE associated with dose reduction, n (%)	3 (13.6)
Treatment-related TEAE associated with death[c], n (%)	0

[a]Includes patients with SCLC, ESCC, mCRPC, sqNSCLC and other tumor type
[c]One patient with endometrial cancer who received I-DXd at 16.0 mg/kg experi

System organ class preferred term, n (%)[a]	SCLC (n=22)	
	All grades	Grade ≥3
Nausea[c]	13 (59.1)	1 (4.5)
Anemia	6 (27.3)	1 (4.5)
IRR[c,d]	3 (13.6)	0
Decreased appetite	5 (22.7)	1 (4.5)
Fatigue	11 (50.0)	0
Vomiting[c]	6 (27.3)	0
Diarrhea	3 (13.6)	0
Pyrexia	4 (18.2)	0
Constipation	4 (18.2)	1 (4.5)

Patel M et al. ESMO 2023;Abstract 690P.

Courtesy of Manish Patel, MD

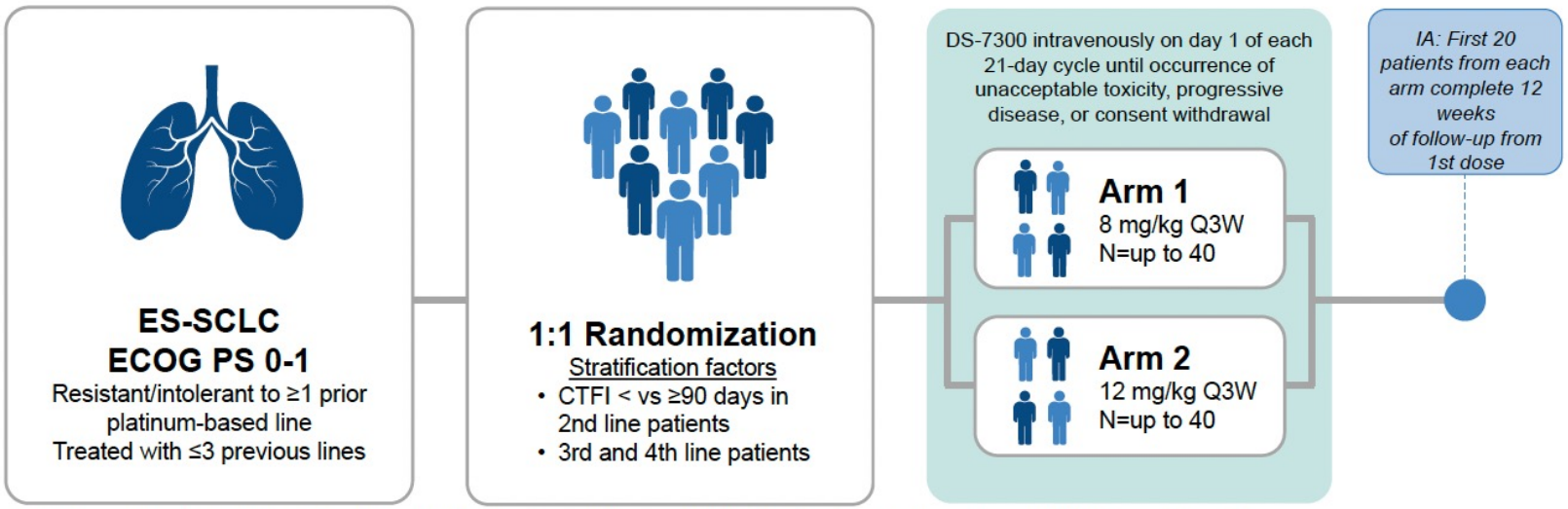
IDeate-Lung01: Phase II Study of I-DXd in Pretreated ES-SCLC

Key Inclusion Criteria
• ≥1 lesion, not previously irradiated, amenable to core biopsy
• Histologically or cytologically documented ES-SCLC
• ECOG PS of 0 or 1
• ≥1 measurable lesion according to RECIST v1.1[19] as assessed by the investigator
• Prior therapy with ≥1 platinum-based line with a maximum of 3 total lines as systemic therapy for extensive-stage disease
• Documentation of radiological disease progression on or after most recent systemic therapy

Key Exclusion Criteria
• Prior treatment with orlotamab, enoblituzumab, or other B7-H3–targeted agents
• Prior treatment with an ADC that consists of an exatecan derivative
• Clinically active brain metastases, spinal cord compression, or leptomeningeal carcinomatosis
• Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses
• History of ILD/pneumonitis that required corticosteroids; current or suspected ILD/pneumonitis
• Active, known, or suspected autoimmune disease

Primary
• Objective response rate[b]
Secondary
• Overall Safety
• Progression-free survival
• Duration of response
• Overall survival
• Time to response
• Objective response rate[c]
• Disease control rate
• Pharmacokinetic parameters
• Treatment-emergent antidrug antibodies

Global, multicenter phase 2 study of patients with histologically or cytologically confirmed, pre-treated ES-SCLC



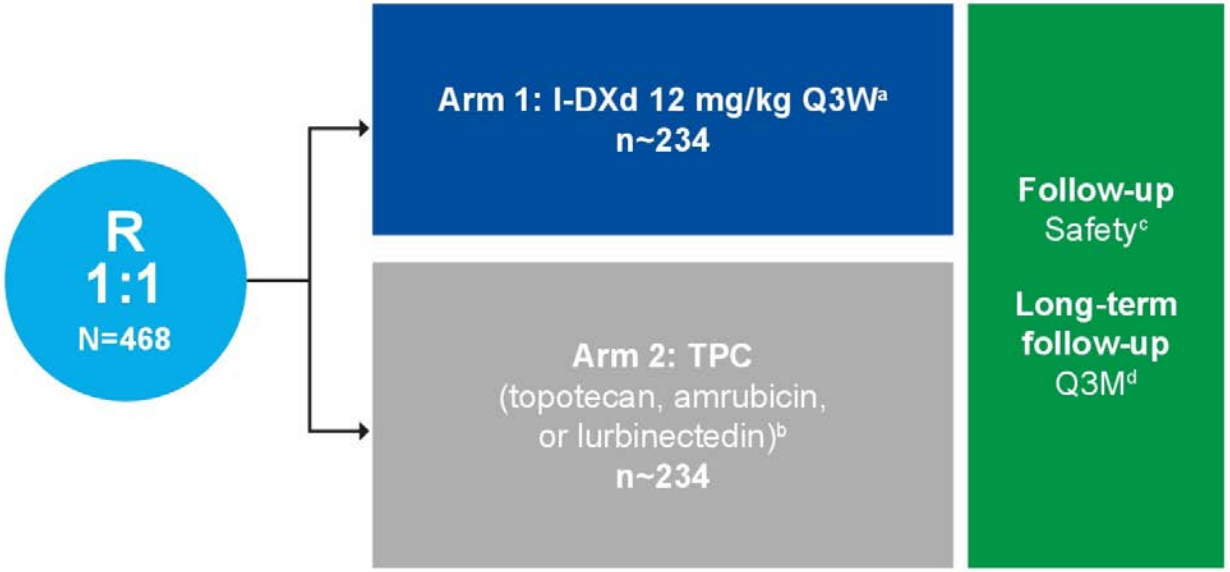
BICR, blinded independent central review; CTFI, chemotherapy-free interval; ES-SCLC, extensive-stage small cell lung cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; IA, interim analysis; Q3W, every 3 weeks.

Paz-Ares L et al. ESMO 2022;Abstract 1550TiP. NCT05280470.

Courtesy of Manish Patel, MD

IDeate-Lung02: Phase III, Randomized, Open-Label Study of I-DXd vs Treatment of Physician's Choice in Relapsed SCLC

Key inclusion criteria	Key exclusion criteria
Histologically or cytologically documented SCLC	Prior treatment with orlotamab, enoblituzumab, or other B7-H3–targeted agents, including I-DXd
Age ≥18 years or minimal legal adult age (whichever is greater)	Prior discontinuation of an ADC that consists of an exatecan derivative (eg, trastuzumab deruxtecan) due to treatment-related toxicities
Received only 1 prior line of platinum-based therapy	Prior treatment with any of the comparators or a topoisomerase I inhibitor
≥1 measurable lesion per RECIST 1.1	Clinically active brain metastasis, spinal cord compression, or leptomeningeal carcinomatosis
Radiologically documented PD on or after platinum-based therapy	Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses
ECOG PS 0–1	History of ILD/pneumonitis that required corticosteroids; current or suspected ILD/pneumonitis
Must provide adequate baseline tumor samples of sufficient quantity and quality	Uncontrolled or significant cardiovascular disease
Patients with asymptomatic brain metastases (untreated or previously treated) are eligible	Known, uncontrolled HIV infection; active or uncontrolled HBV or HCV infection; uncontrolled systemic bacterial, fungal, or viral infection; or active, known, or suspected autoimmune disease



Stratification

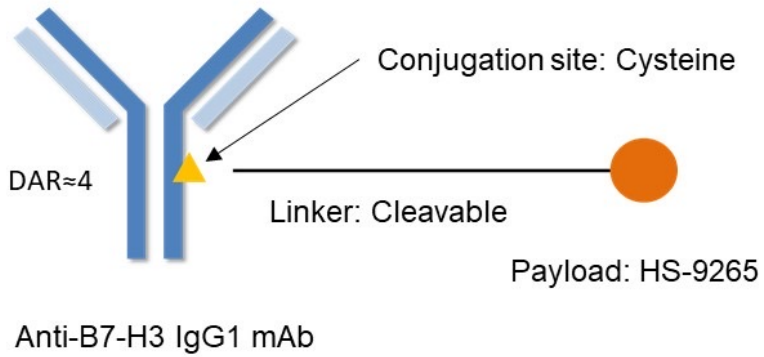
Chemotherapy-free interval following 1L therapy (<90 vs ≥90 days)
TPC (topotecan vs amrubicin vs lurbinectedin)
Treatment with prior PD-(L)1 inhibitors (yes vs no)
Presence or history of asymptomatic brain metastases (yes vs no)

Owonikoko TK et al. ASCO 2024;Abstract TPS8126. NCT06203210.

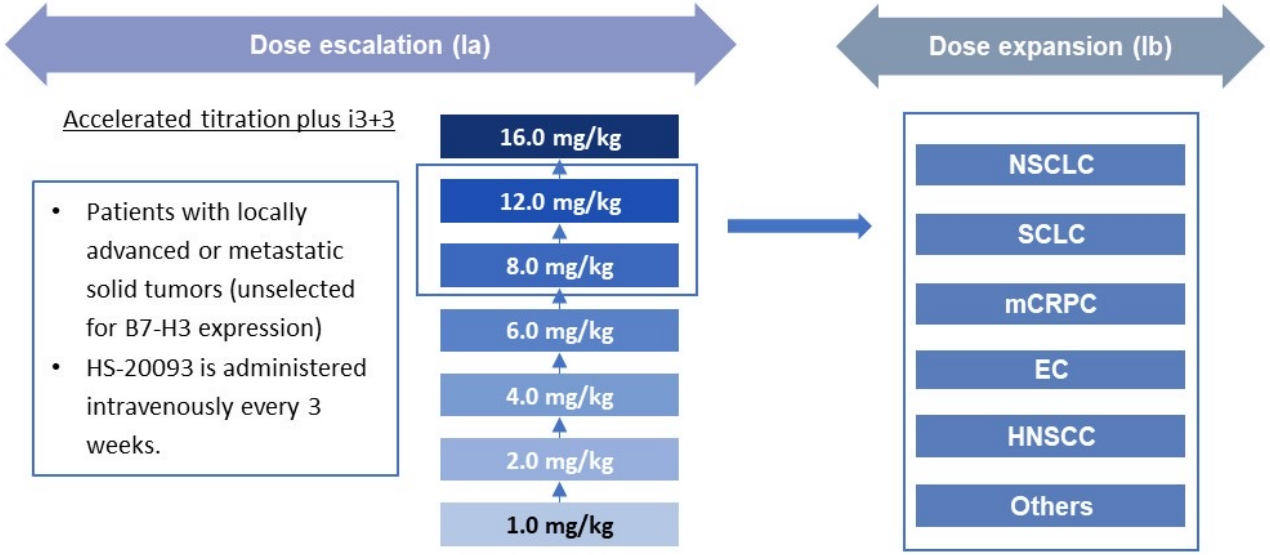
Courtesy of Manish Patel, MD

HS-20093: ADC Components and Phase I Design

Structure of HS-20093



ADC: antibody-drug conjugate, DAR: drug-antibody ratio, NSCLC: non small cell lung cancer, SCLC: small cell lung cancer, mCRPC: metastatic castration-resistant prostate cancer, EC: esophageal carcinoma, HNSCC: head and neck squamous cell carcinoma, MTD: maximum tolerated dose. MAD: maximum applicable dose.



Primary Endpoint (Ia):
- MTD/MAD

Primary Endpoint (Ib):
- ORR by RECIST 1.1

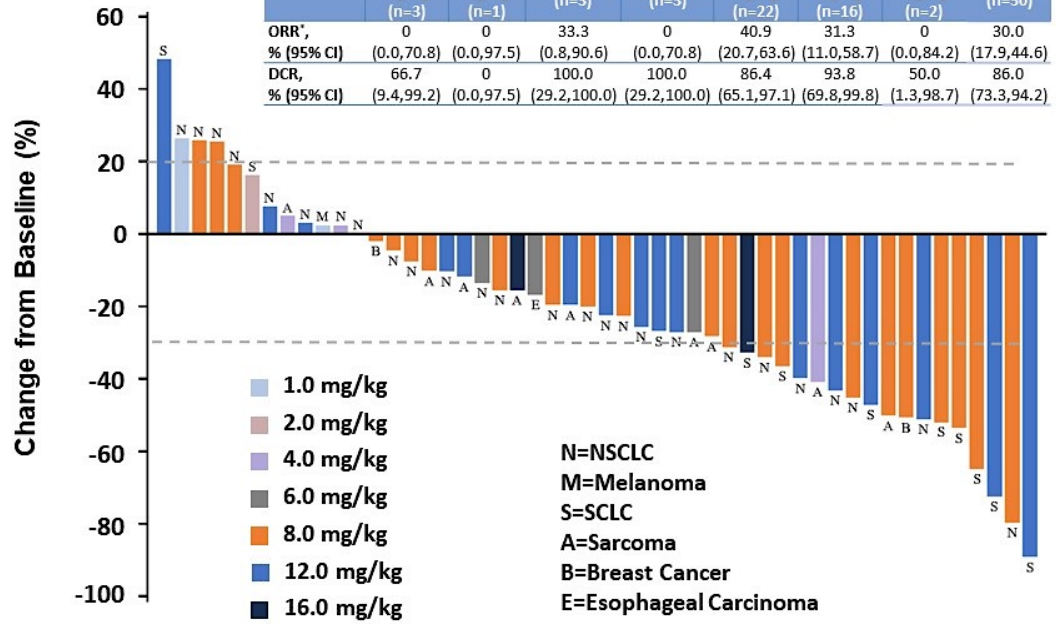
Wang J et al. ASCO 2023;Abstract 3017.

Courtesy of Manish Patel, MD

HS-20093: Initial Efficacy Results in SCLC (Dose Escalation)

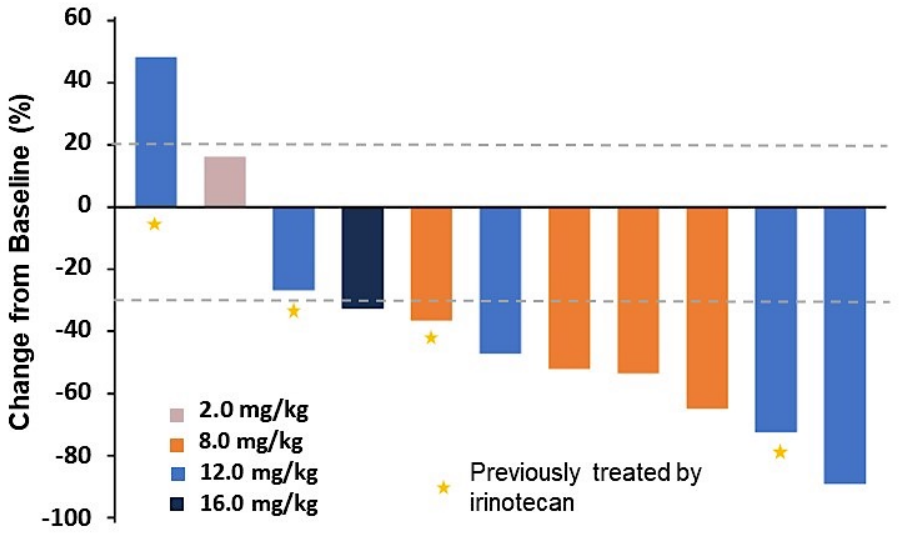
Figure 2. Best Percent Change of Target Lesions in Evaluable Population

	1.0 mg/kg (n=3)	2.0 mg/kg (n=1)	4.0 mg/kg (n=3)	6.0 mg/kg (n=3)	8.0 mg/kg (n=22)	12.0 mg/kg (n=16)	16.0 mg/kg (n=2)	Total (n=50)
ORR*, % (95% CI)	0 (0.0,70.8)	0 (0.0,97.5)	33.3 (0.8,90.6)	0 (0.0,70.8)	40.9 (20.7,63.6)	31.3 (11.0,58.7)	0 (0.0,84.2)	30.0 (17.9,44.6)
DCR, % (95% CI)	66.7 (9.4,99.2)	0 (0.0,97.5)	100.0 (29.2,100.0)	100.0 (29.2,100.0)	86.4 (65.1,97.1)	93.8 (69.8,99.8)	50.0 (1.3,98.7)	86.0 (73.3,94.2)



*Assessed according to RECIST 1.1 by investigators.

Figure 3. Best Percent Change of Target Lesions in SCLC



ORR: Objective response rate
DCR: Disease control rate
PFS:. Progression free survival

	SCLC (n=11)
ORR*, % (95% CI)	63.6 (30.8,89.1)
DCR, % (95% CI)	81.8 (48.2,97.7)
mPFS, mo (95% CI)	4.7 (1.4, NA)
3-mo PFS rate, % (95% CI)	72.7 (37.1, 90.3)

Wang J et al. ASCO 2023;Abstract 3017.

Courtesy of Manish Patel, MD

HS-20093: Updated Efficacy in SCLC (Dose Expansion)

	8.0 mg/kg Q3W (n=31)	10.0 mg/kg Q3W (n=21)
ORR, n (%), (95% CI)	18 (58.1%)* (39.1, 75.5)	12 (57.1%)# (34.0, 78.2)
DCR, n (%), (95% CI)	25 (80.6%) (62.5, 92.5)	20 (95.2%) (76.2, 99.9)
Median DOR, month, (95% CI)	4.3 (3.3, NA)	NA (3.1, NA)
Median PFS, month, (95% CI)	5.6 (3.4, NA)	NA (4.4, NA)
Median follow-up time, month, (95% CI)	4.8 (3.6, 5.6)	4.9 (4.1, 5.6)

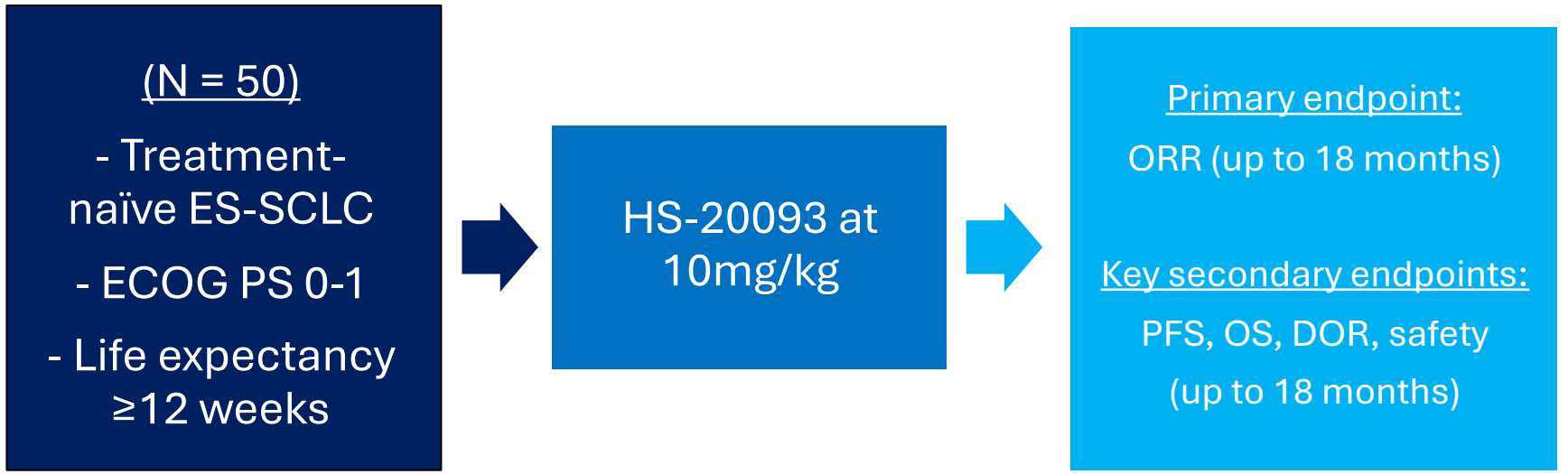
*Fifteen pts were confirmed PRs, 3 pts are awaiting confirmation.

#Ten pts were confirmed PRs, 2 pts are awaiting confirmation. ORR: objective response rate, DCR: disease control rate, DOR: duration of response; PFS: progression free survival, CI: confidence interval, PR: partial response.

Wang J et al. ASCO 2024;Abstract 8093.

Courtesy of Manish Patel, MD

HS-20093: Phase II ARTEMIS-007 in ES-SCLC (Withdrawn)



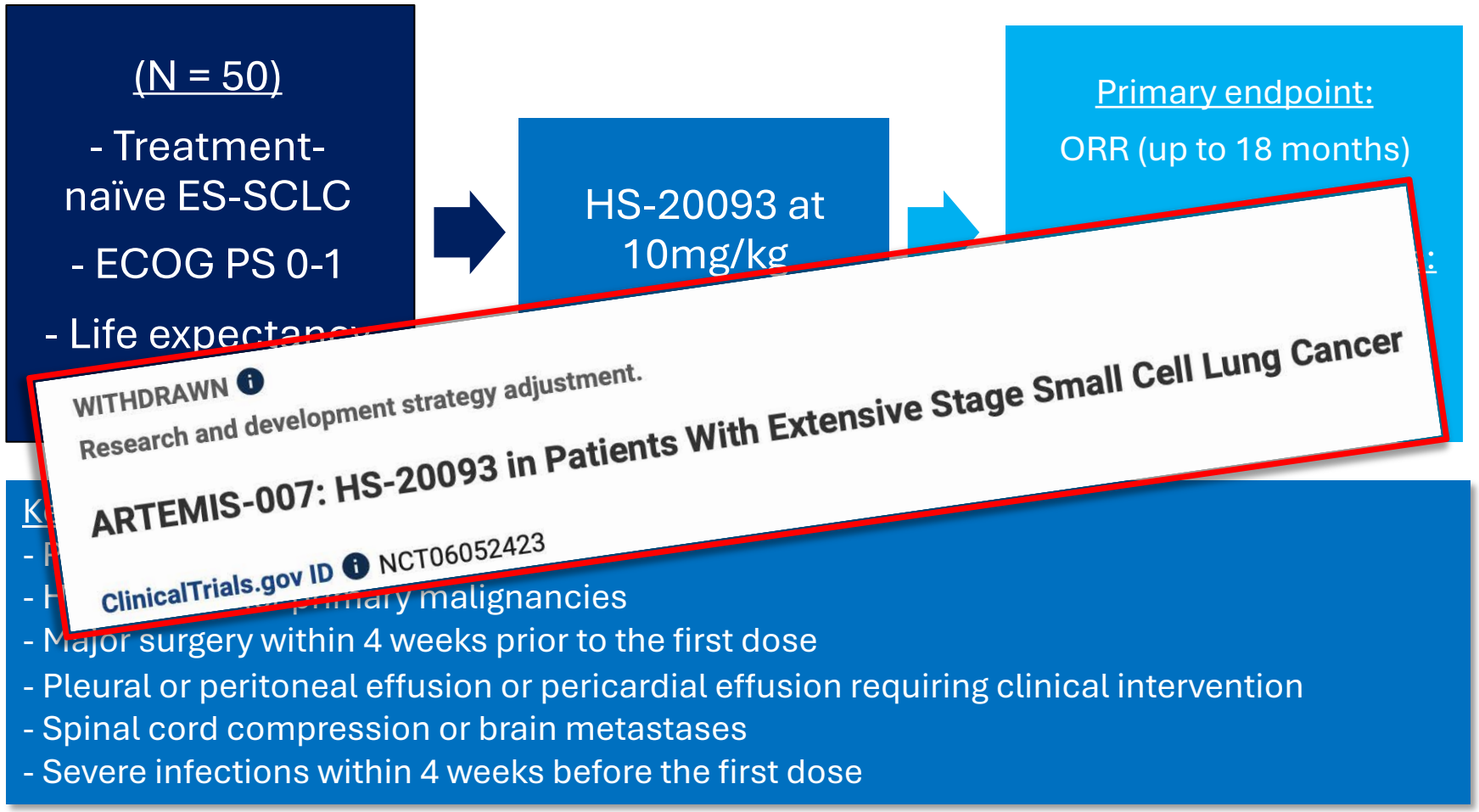
Key exclusion criteria:
- Prior B7-H3 targeted therapy
- History of other primary malignancies
- Major surgery within 4 weeks prior to the first dose
- Pleural or peritoneal effusion or pericardial effusion requiring clinical intervention
- Spinal cord compression or brain metastases
- Severe infections within 4 weeks before the first dose

ORR = overall response rate

www.clinicaltrials.gov. NCT06052423. Accessed July 2024 – Last Updated Posted 2024-03-04.

Courtesy of Manish Patel, MD

HS-20093: Phase II ARTEMIS-007 in ES-SCLC (Withdrawn)



ORR = overall response rate

www.clinicaltrials.gov. NCT06052423. Accessed July 2024 – Last Updated Posted 2024-03-04.

Courtesy of Manish Patel, MD

Agenda

Introduction: 2 Faces of Lung Cancer Research

Module 1: B7-H3-Targeted Antibody-Drug Conjugates for Lung Cancer — Dr Patel

Module 2: Potential Role of Tumor Treating Fields in the Management of Metastatic NSCLC — Dr Leal

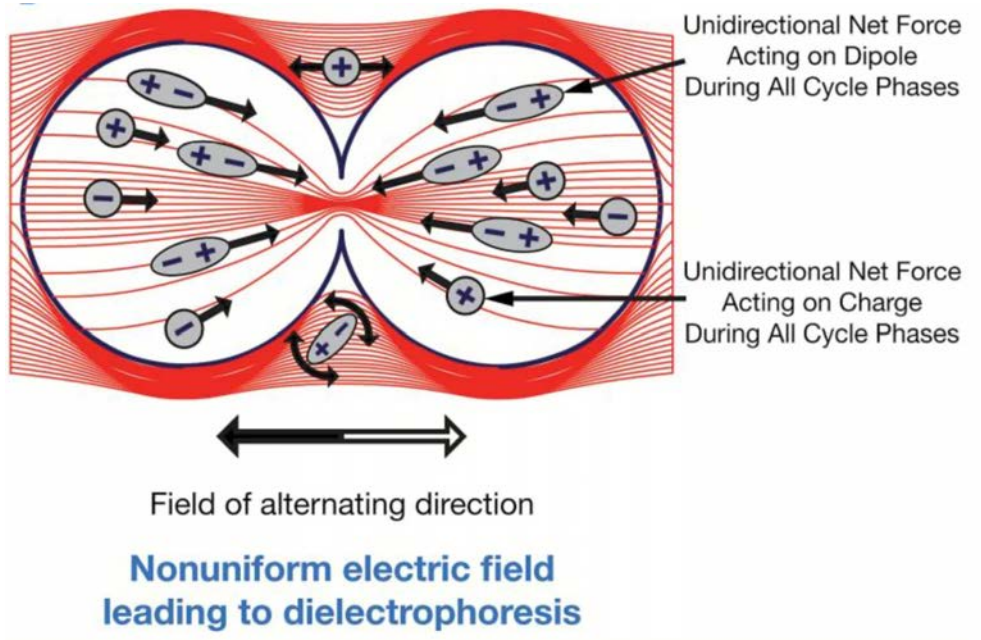
Module 3: Emerging Role of Bispecific T-cell Engaging Immunotherapy in Small Cell Lung Cancer — Dr Johnson

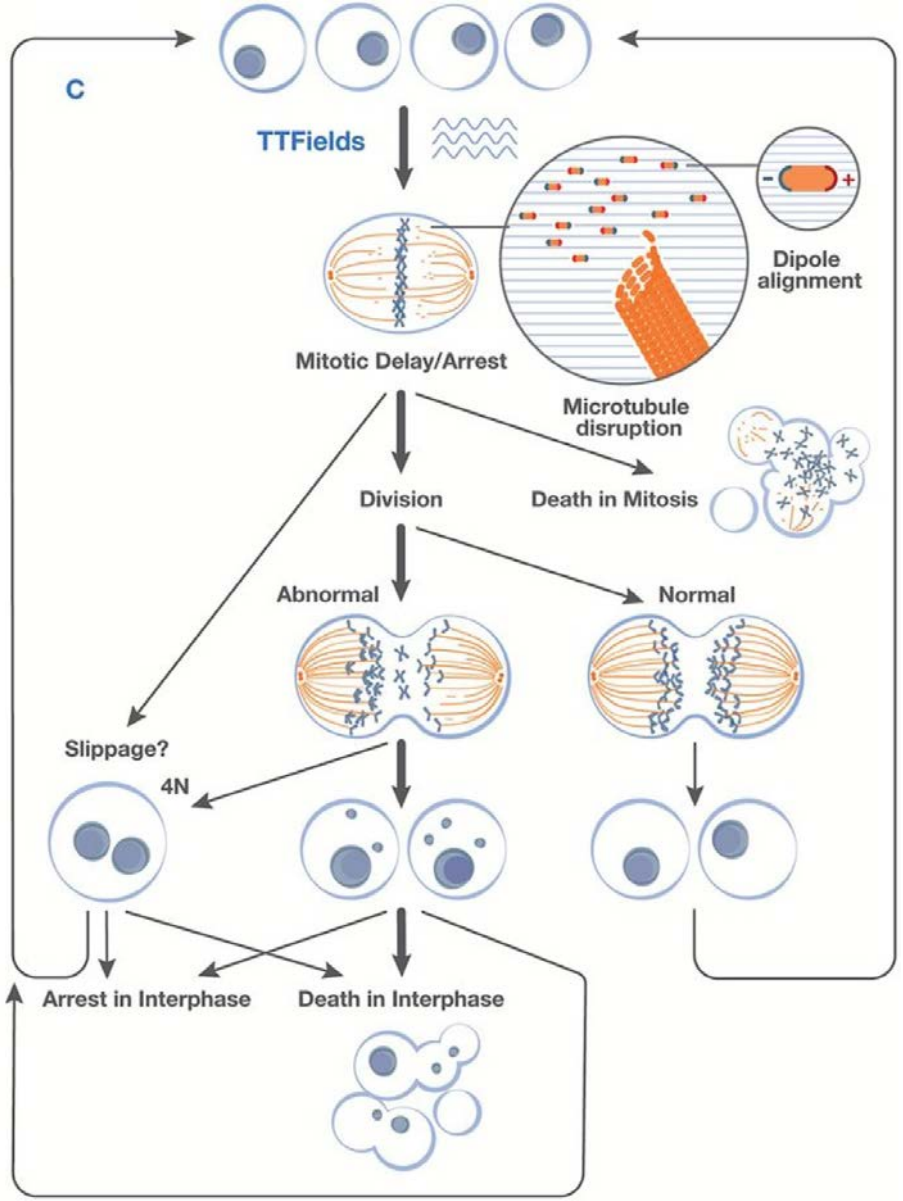
Potential Role of Tumor Treating Fields in the Management of Metastatic Non-Small Cell Lung Cancer

Ticiana Leal, MD

Associate Professor
Department of Hematology and Oncology
Director, Thoracic Oncology
Winship Cancer Institute
Emory University
Atlanta, Georgia

Tumor Treating Fields (TTFields): Mechanism of Action

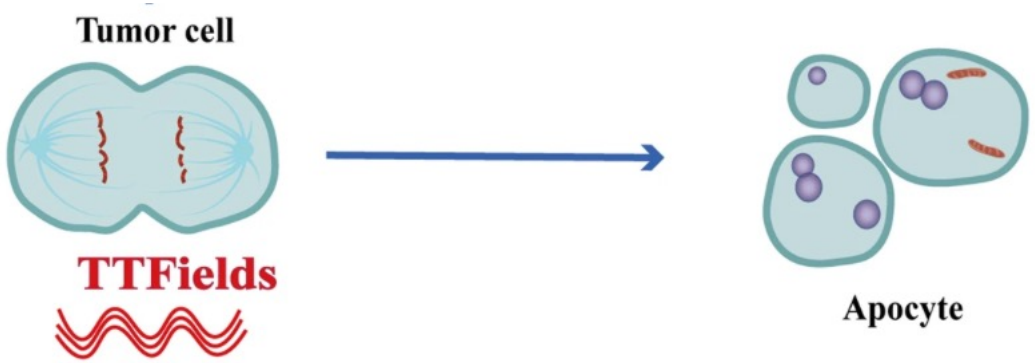


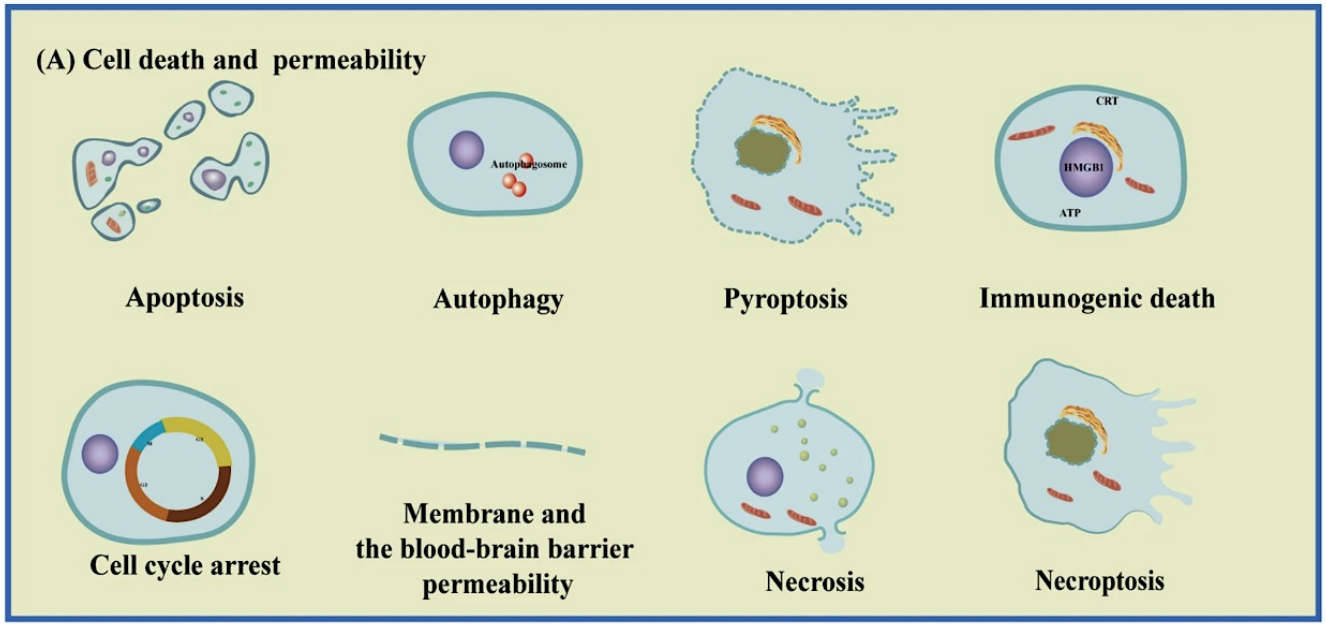


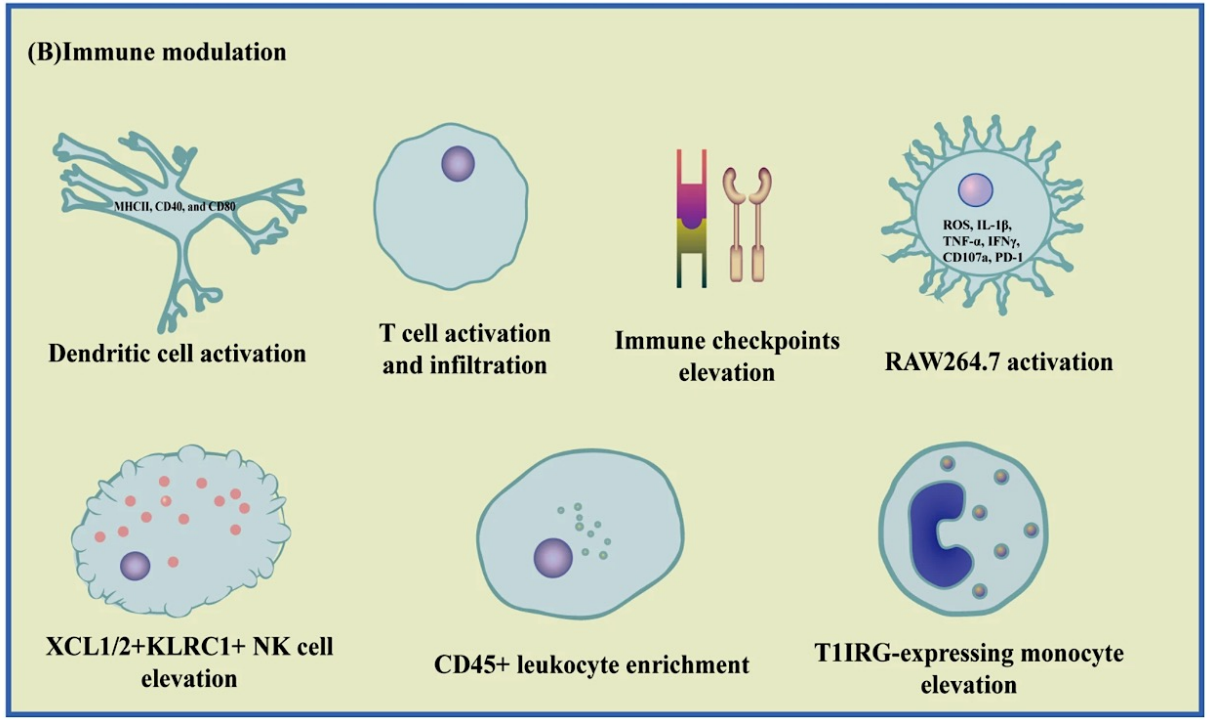
Hottinger AF et al. *Neuro Oncol* 2016;18(10):1338-49.

Courtesy of Ticiana Leal, MD

TTFields Induces Cell Death, Permeability and Immune Modulation



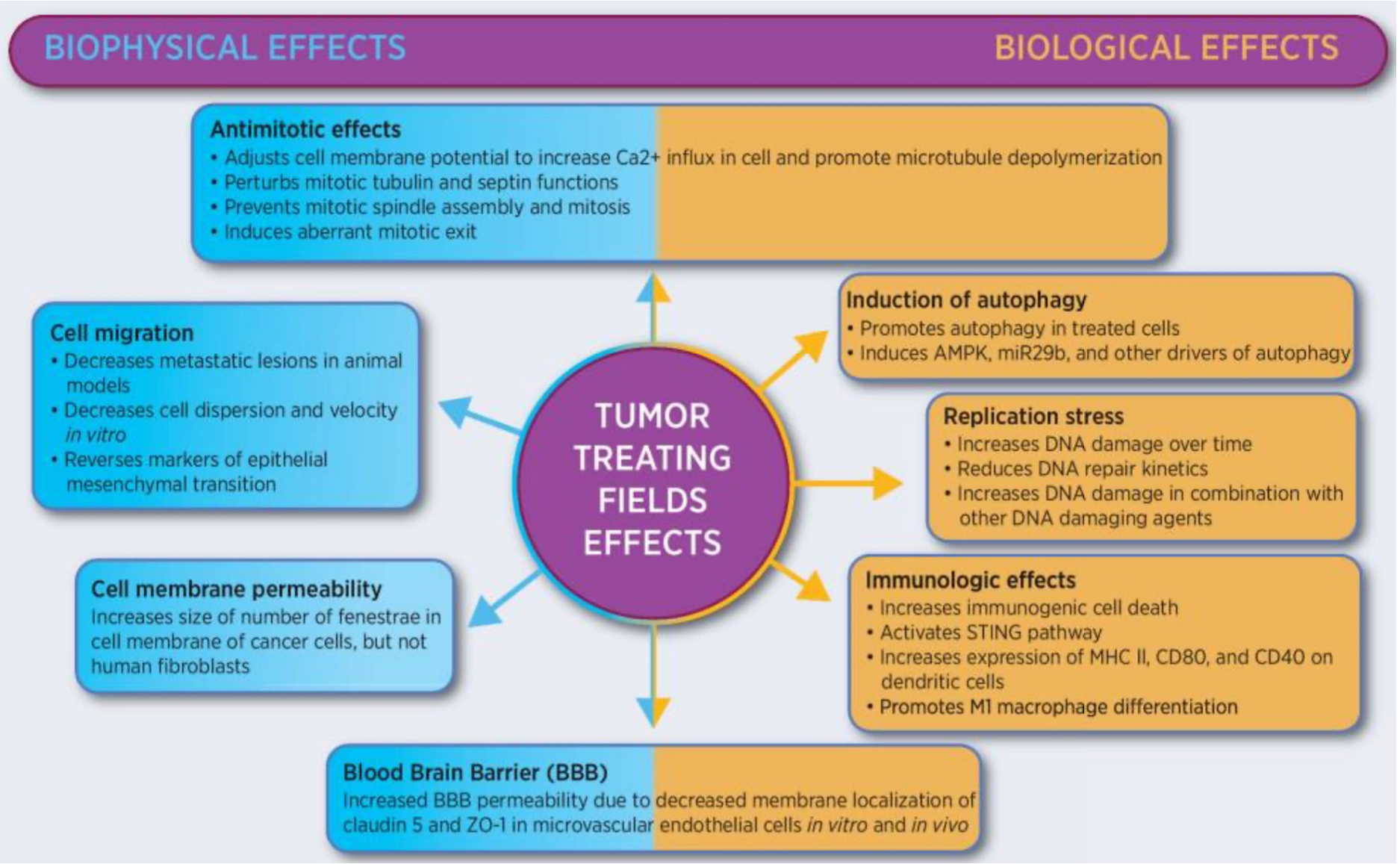




Tanzhu G et al. *Cell Death Discov* 2022;8(1):416.

Courtesy of Ticiana Leal, MD

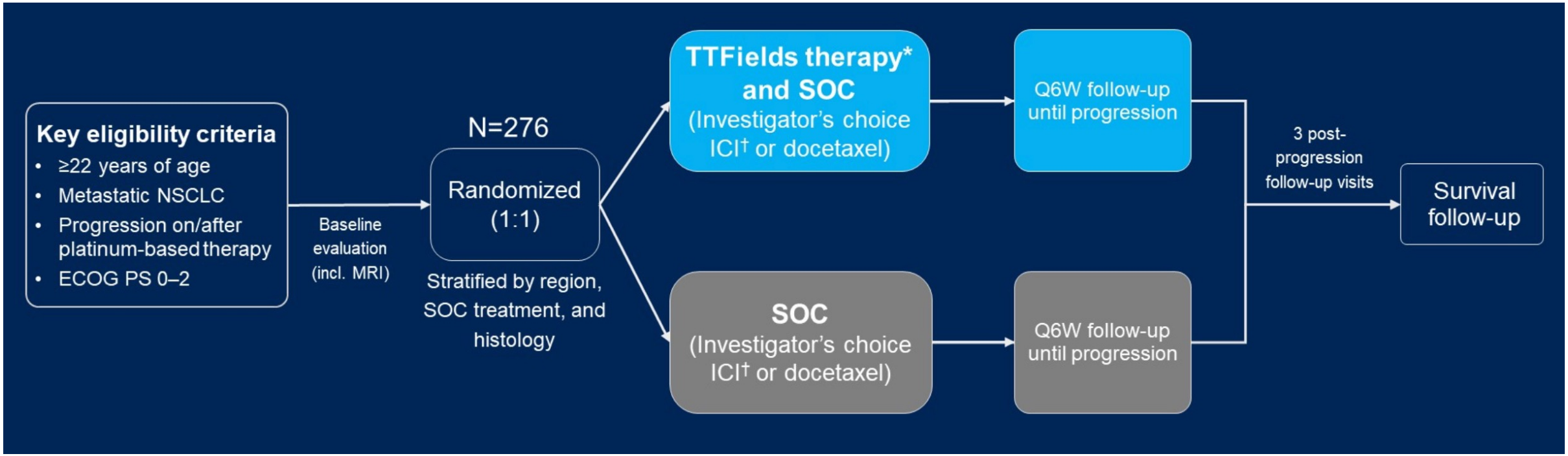
Biophysical and Biological Effects of TTFields



Moser JC et al. *Cancer Res* 2022;82(20):3650-3658.

Courtesy of Ticiana Leal, MD

LUNAR: A Phase III Study of TTFields for Metastatic Non-Small Cell Lung Cancer (mNSCLC) Progressing on Platinum



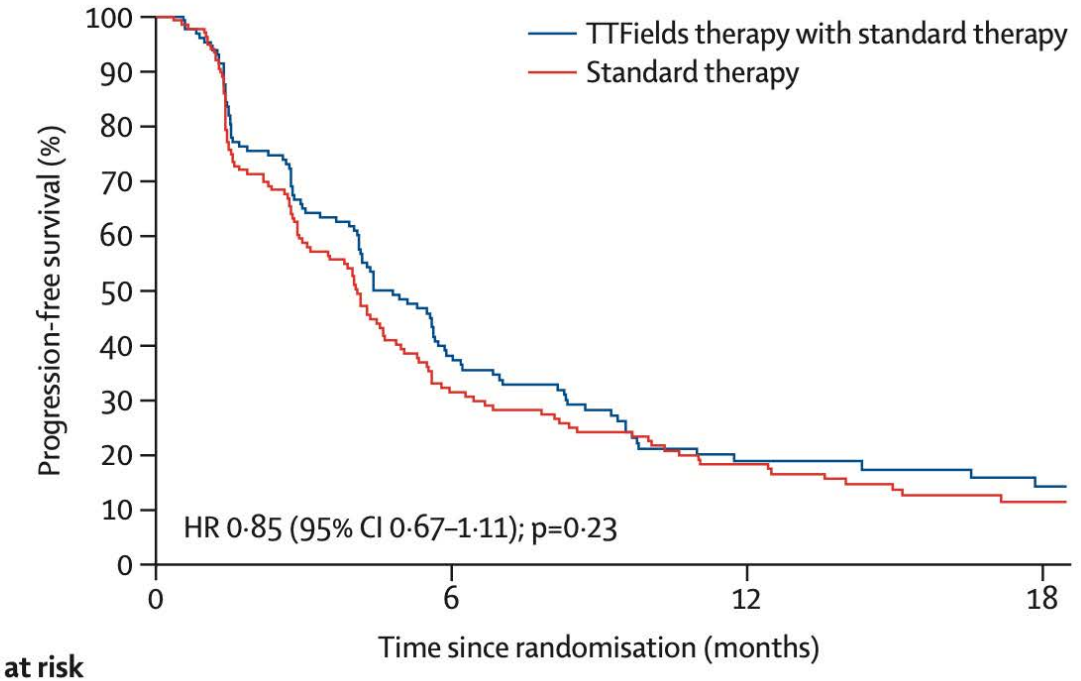
SOC = standard of care; ICI = immune checkpoint inhibitor

Leal T et al. ASCO 2023;Abstract LBA9005. Leal T et al. *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR: Response and Progression-Free Survival Outcomes

	TTFields therapy with standard therapy group (n=137)	Standard therapy group (n=139)
Patients with at least one post-baseline scan, n	122	127
Overall response, n (%; 95% CI)	28 (20·4%; 14·0–28·2)	24 (17·3%; 11·4–24·6)
Best overall response, n (%)		
Complete response	4 (3%)	1 (1%)
Partial response	24 (18%)	23 (17%)
Stable disease	67 (49%)	65 (47%)
Progressive disease	24 (18%)	36 (26%)
Not evaluable	3 (2%)	2 (1%)

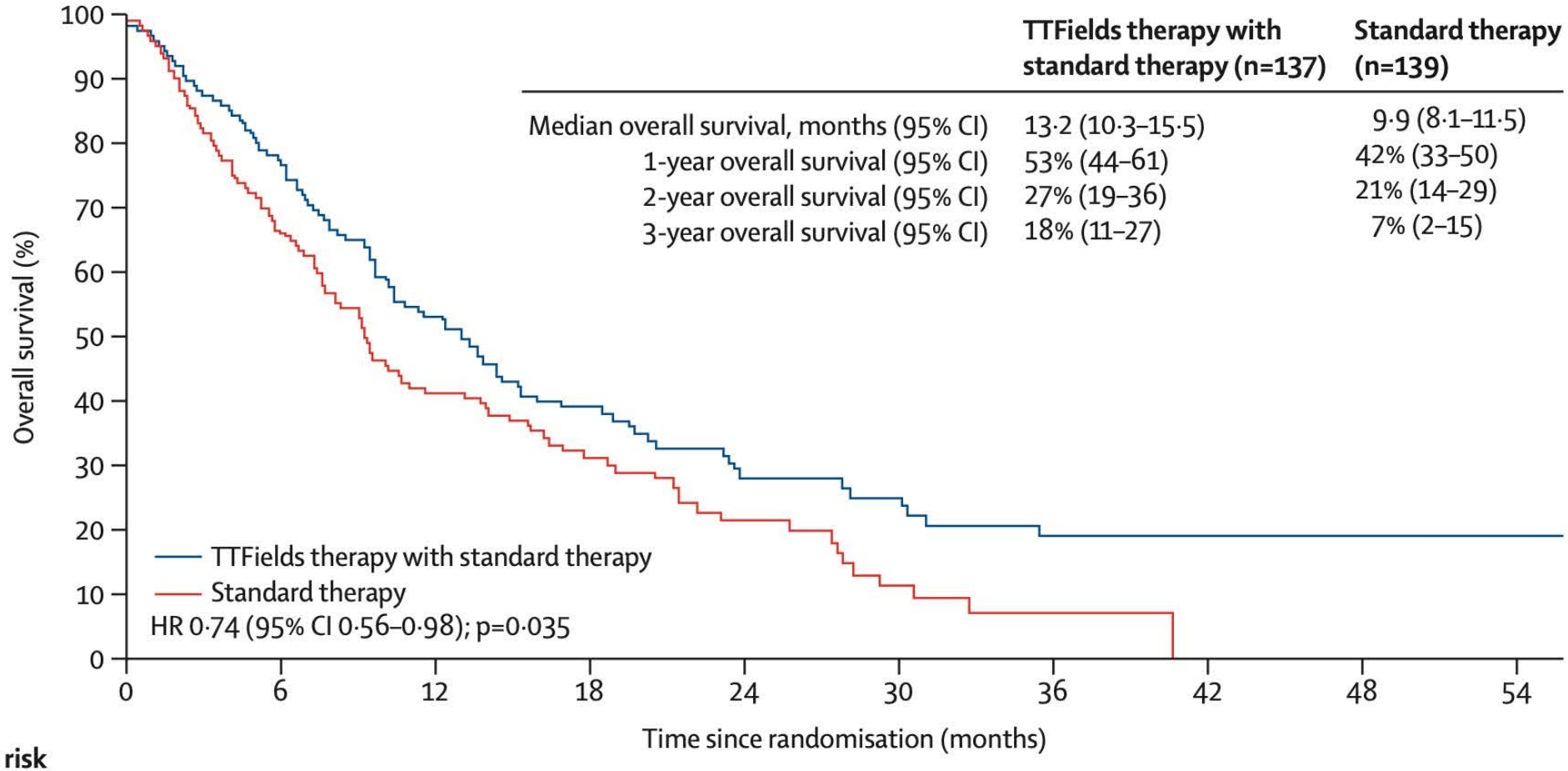


Number at risk (number censored)				
TTFields therapy with standard therapy	137 (0)	44 (17)	17 (24)	9 (29)
Standard therapy	139 (0)	40 (8)	21 (11)	9 (16)

Leal T et al. ASCO 2023;Abstract LBA9005. Leal T et al. *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR: Overall Survival Outcomes in the Intention-to-Treat Population



	TTFields therapy with standard therapy (n=137)	Standard therapy (n=139)
Median overall survival, months (95% CI)	13·2 (10·3–15·5)	9·9 (8·1–11·5)
1-year overall survival (95% CI)	53% (44–61)	42% (33–50)
2-year overall survival (95% CI)	27% (19–36)	21% (14–29)
3-year overall survival (95% CI)	18% (11–27)	7% (2–15)

Number at risk (number censored)										
TTFields therapy with standard therapy	137 (0)	100 (9)	62 (15)	36 (26)	22 (30)	16 (34)	11 (35)	9 (37)	5 (41)	3 (43)
Standard therapy	139 (0)	96 (2)	54 (5)	32 (16)	16 (23)	7 (27)	3 (28)	0 (30)	0 (30)	0 (30)

Leal T et al. ASCO 2023;Abstract LBA9005; *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR: Safety Outcomes

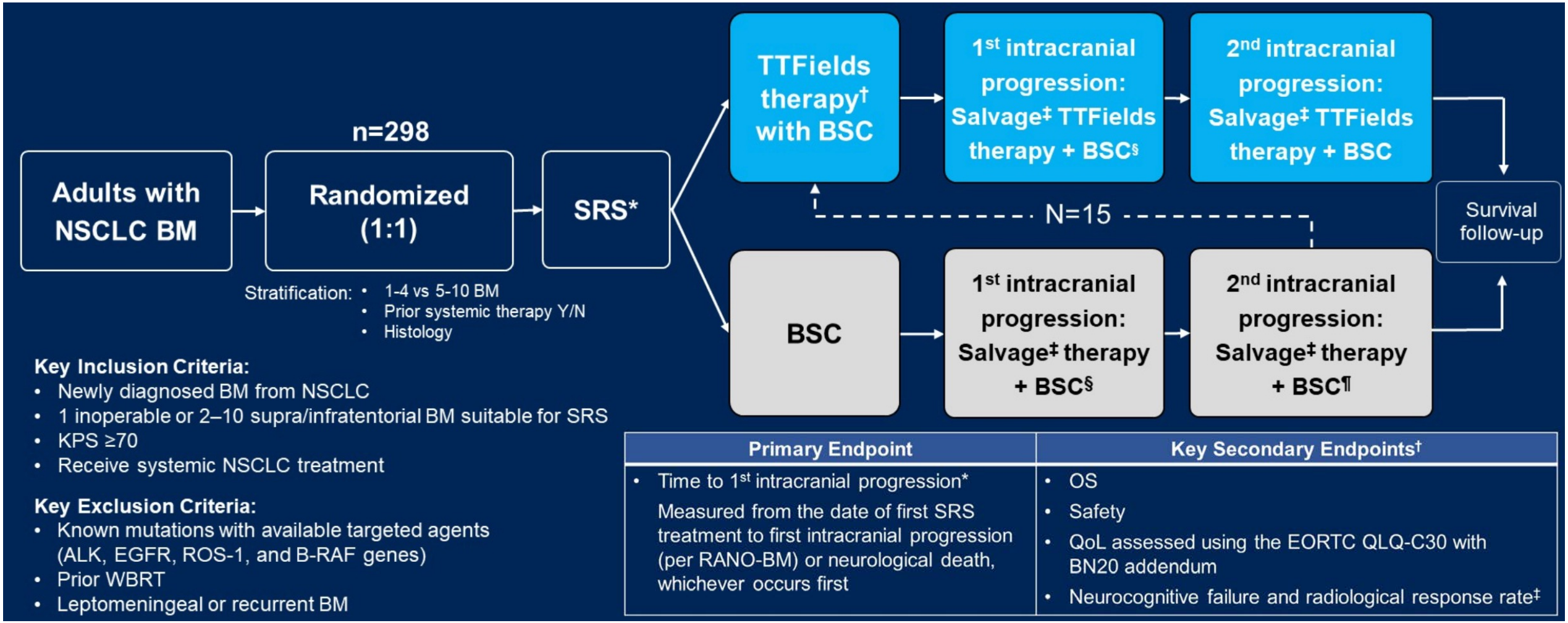
	TTFields + SOC (n=133)		SOC (n=134)	
	All grades	Grade ≥3	All grades	Grade ≥3
Any AE*	97%	59%	91%	56%
Most frequent AEs				
Dermatitis	**43%**	**2%**	**2%**	**0%**
Fatigue	28%	4%	37%	8%
Musculoskeletal pain	36%	3%	27%	4%
Dyspnea	20%	7%	25%	3%
Anemia	23%	8%	22%	8%
Diarrhea	19%	2%	19%	0%
Cough	18%	0%	19%	1%
Nausea	19%	0%	16%	1%
Leukopenia	17%	14%	18%	14%
Pneumonia	15%	11%	17%	11%
Alopecia	10%	0%	17%	1%
Respiratory tract infection	15%	3%	16%	0%
Localized edema	15%	1%	16%	2%
Any serious AE	53%		38%	
Any AE leading to discontinuation	36%		20%	
Any AE leading to death	10%		8%	

AE = adverse event

Leal T et al. ASCO 2023;Abstract LBA9005; *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

METIS: An International, Multicenter Phase III Randomized Study of TTFields for NSCLC with Brain Metastases

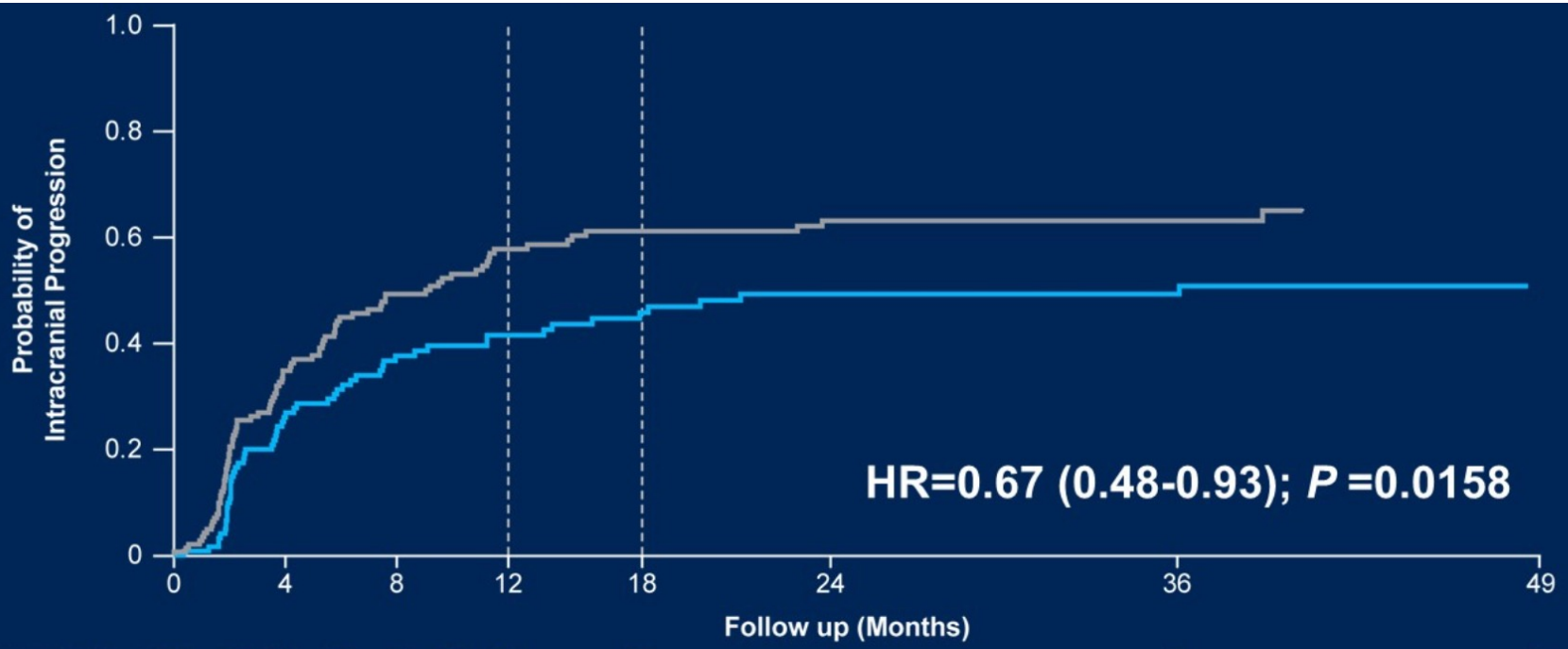


SRS = stereotactic radiosurgery; BSC = best supportive care; BM = brain metastases; WBRT = whole brain radiotherapy; QoL = quality of life

Mehta MP et al. ASCO 2024;Abstract 2008.

Courtesy of Ticiana Leal, MD

METIS: Primary Endpoint of Time to First Intracranial Progression or Neurologic Death



TTFields therapy with BSC	149	95	65	52	36	29	24	12	7	3	1
BSC	149	101	71	50	41	33	23	11	7	3	0

	TTFields + BSC (n=149)	BSC (n=149)	*P*-value
Median Time to Intracranial Progression* (95% CI), months	21.9 (8.3–NE)	11.3 (7.6–NE)	0.0158
Progression rate at 12 months (95% CI)	41.6% (32.4–50.5)	57.8% (49.0–65.7)	0.005
Progression rate at 18 months (95% CI)	46.9% (37.3–56.0)	61.2% (52.3–68.9)	0.0132

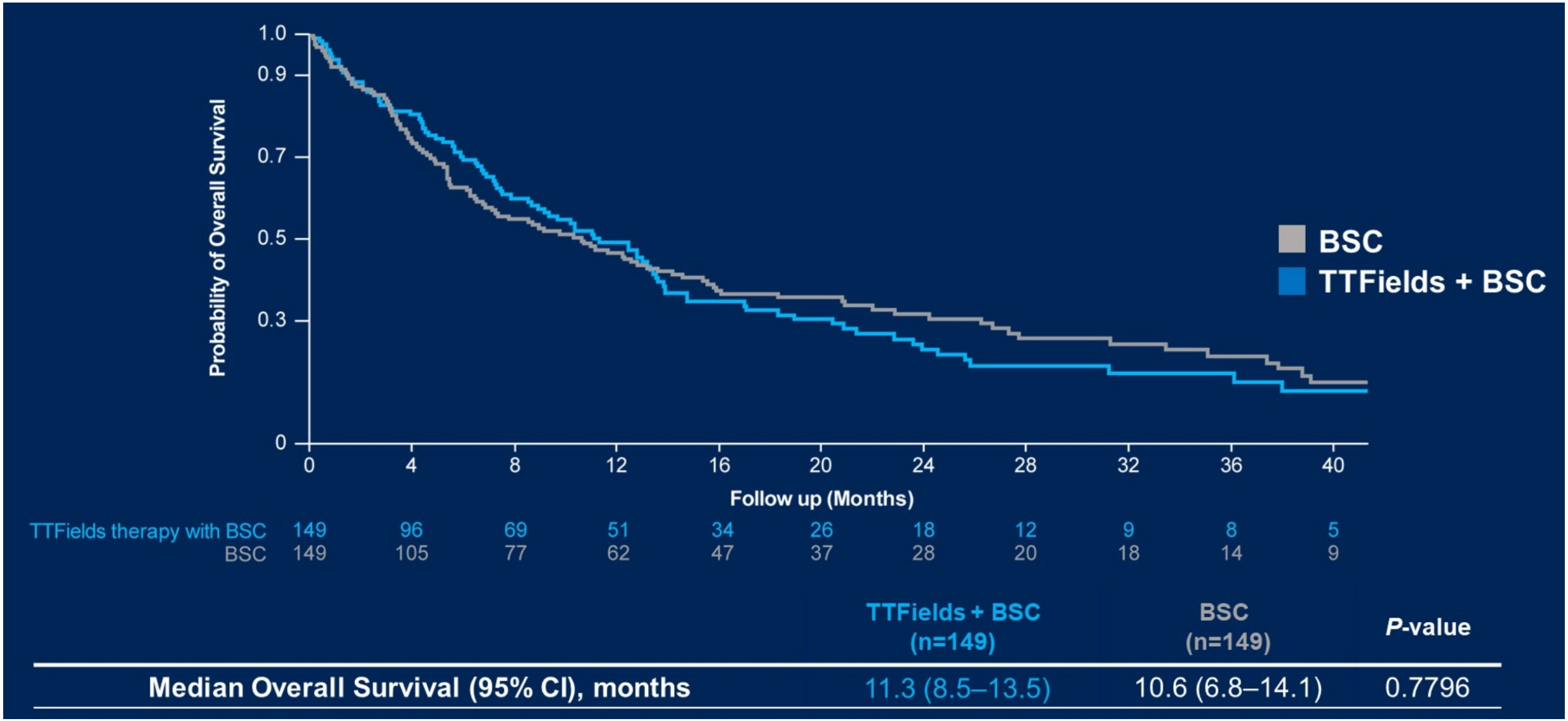
*Primary endpoint measured as per RANO-BM over course of study based on independent radiology review.
BSC, best supportive care, patients in both arms could receive systemic NSCLC treatment; CI, confidence interval; HR, hazard ratio; NE, not evaluable; TTFields, Tumor Treating Fields.

	TTFields + BSC (n=149)	BSC (n=149)
Neurologic deaths, n	9	10
Deaths from other reasons, n	53	44

Mehta MP et al. ASCO 2024;Abstract 2008.

Courtesy of Ticiana Leal, MD

METIS: Overall Survival Outcomes

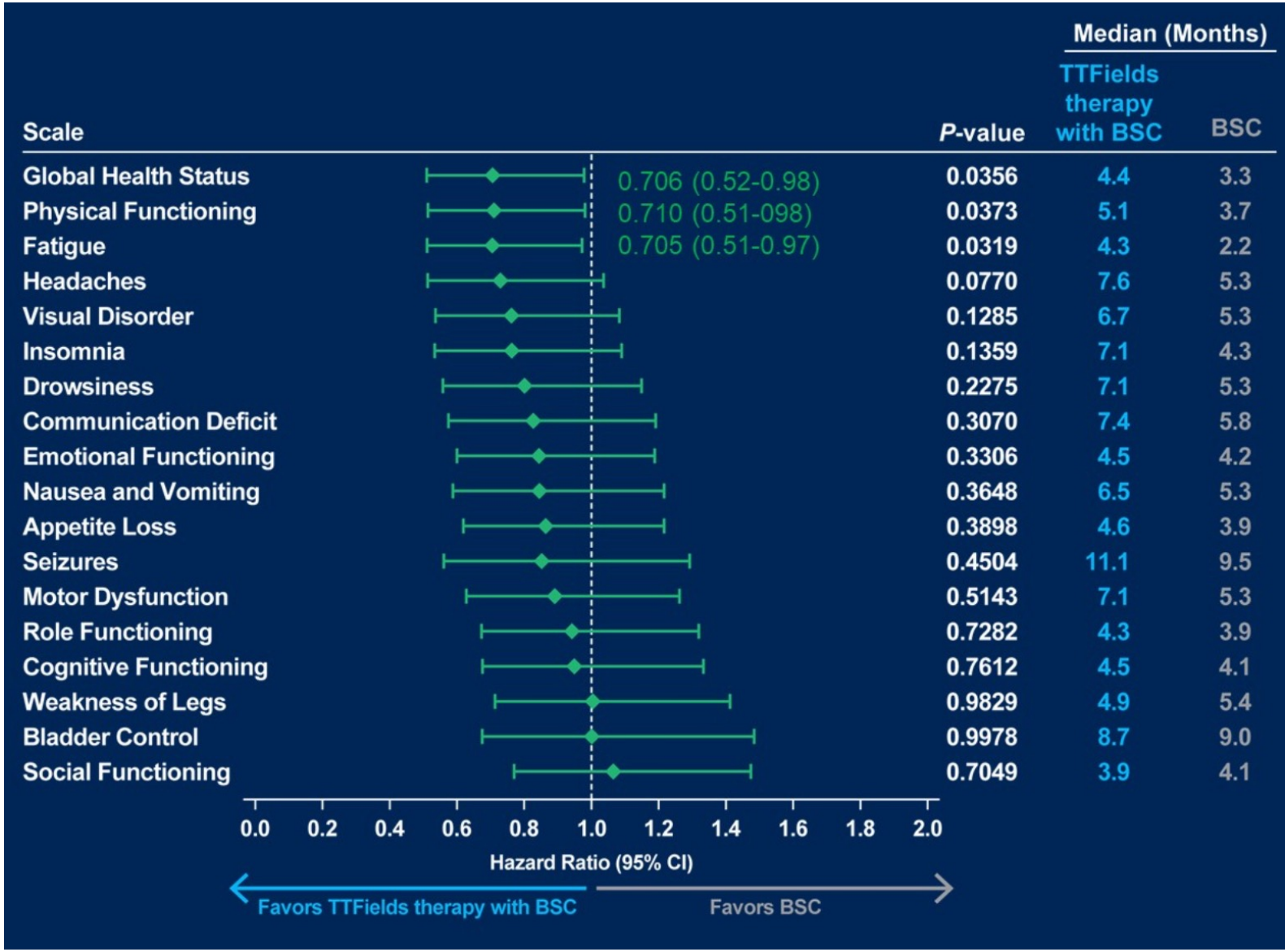


	TTFields + BSC (n=149)	BSC (n=149)	*P*-value
Median Overall Survival (95% CI), months	11.3 (8.5–13.5)	10.6 (6.8–14.1)	0.7796

Mehta MP et al. ASCO 2024;Abstract 2008.

Courtesy of Ticiana Leal, MD

METIS: Quality of Life



- Overall positive trend in most of the 18 scales and items assessed by EORTC QLQ-C30 and -BN20*
- Improvement of global health status, physical functioning, and fatigue
- Similar time to neurocognitive failure in both arms (low number of subjects at risk in both arms beyond 3 months), subset analysis pending

*Evaluable patients as per deterioration-free survival analysis

BN, brain neoplasm; BSC, best supportive care, patients in both arms could receive systemic NSCLC treatment; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Core Quality of Life questionnaire; TTFields, Tumor Treating Fields.

Mehta MP et al. ASCO 2024;Abstract 2008.

Courtesy of Ticiana Leal, MD

METIS: Safety Profile

	TTFields + BSC (n=127)		BSC (n=160)	
	All grades	Grade ≥3	All grades	Grade ≥3
Any AE (BSC +- TTFields)*	95%	60%	88%	64%
Most frequent AEs (≥10%)	89%	60%	81%	64%
Anaemia	26%	7%	24%	10%
Headache	24%	1%	19%	3%
Fatigue	22%	3%	20%	4%
Oedema peripheral	22%	1%	14%	1%
Nausea	20%	2%	18%	3%
Constipation	17%	1%	16%	1%
Decreased appetite	16%	0%	13%	2%
Pneumonia	14%	9%	13%	10%
Skin irritation	**13%**	**0%**	**1%**	**0%**
Pruritus	**13%**	**1%**	**4%**	**0%**
Muscular weakness	13%	2%	9%	1%
Cough	13%	0%	11%	1%
Metastases to central nervous system	13%	10%	10%	9%
Dyspnoea	13%	2%	13%	3%
Dermatitis	**12%**	**0%**	**2%**	**0%**
Pyrexia	12%	0%	8%	0%
Dizziness	12%	0%	9%	1%
Hypokalaemia	11%	2%	8%	1%
Diarrhoea	10%	0%	8%	3%
White blood cell count decreased	10%	2%	6%	2%
Alanine aminotransferase increased	10%	1%	4%	0%
Insomnia	9%	0%	11%	1%
Any serious AE	51%		59%	
Any AE leading to discontinuation	17%		4%	
Any AE leading to death	15%		24%	

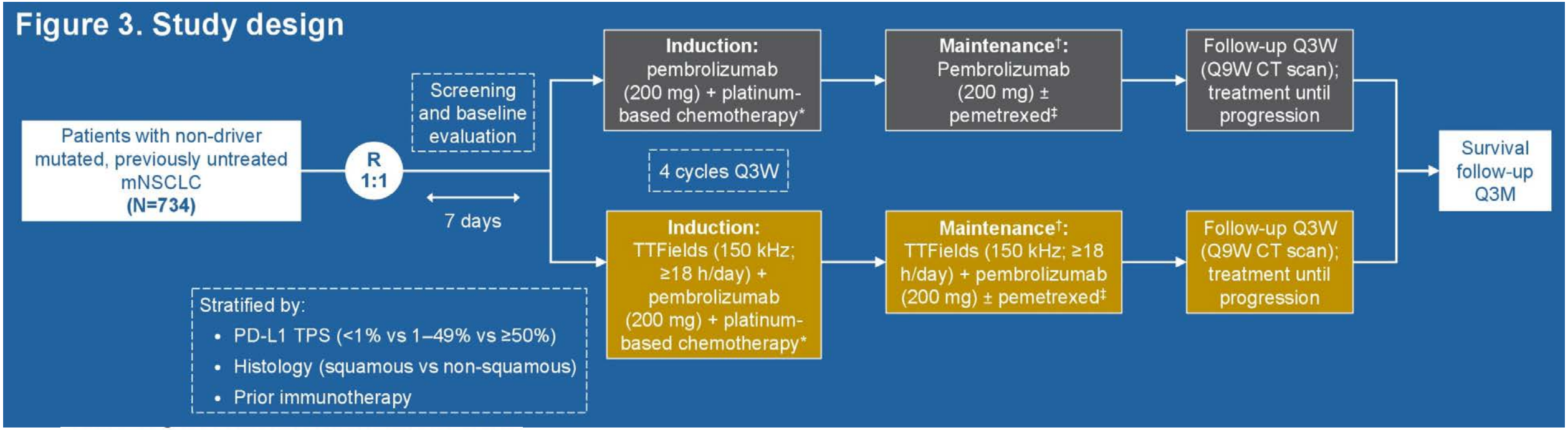
- 66 (52%) TTFields patients developed device-related AE (any grade, mostly G1/2 skin), of which only 3 (2.4%) were Grade ≥3 (1 was G5, ascribed to seizures/tumor progression and scored as device-related by the investigator)
- Of the 15 cross over patients, one device related Grade 3 (headache) was reported
- Comparable incidence of Grade ≥3 SAEs between arms (TTFields + BSC [n=63], 49.6%; BSC [n=87], 54.4%)

AE, adverse event; BSC, best supportive care, patients in both arms could receive systemic NSCLC treatment; G, grade; SAE, serious adverse event; TTFields, Tumor Treating Fields.

Mehta MP et al. ASCO 2024;Abstract 2008.

Courtesy of Ticiana Leal, MD

LUNAR-2: Front-Line TTFields with ICI and Chemotherapy for mNSCLC



Inclusion criteria

- Histologically/cytologically confirmed stage IV NSCLC
- No prior systemic treatment for mNSCLC
- Evaluable (measurable or non-measurable) disease in the thorax per RECIST v1.1
- ≥18 years old (≥22 years in the US)
- ECOG PS 0–1

Endpoints	
Primary*	• OS and PFS per RECIST v1.1 as assessed by a BICR
Secondary	• OS and PFS (by histology and PD-L1 TPS) per RECIST v1.1 as assessed by BICR • ORR, DoR, and DCR (all per RECIST v1.1 as assessed by BICR and by investigator) • PFS rates at 6, 12, 24 and 36 months per RECIST v1.1 as assessed by BICR • 1-, 2-, and 3-year survival rates • Safety profile
Exploratory	• PFS and OS according to in-field or out-of-field location of the disease

TPS = tumor proportion score; OS = overall survival; PFS = progression-free survival; BICR = blinded independent central review; ORR = objective response rate; DoR = duration of response; DCR = disease control rate

Eaton M et al. ASCO 2024;Abstract TPS8665.

Courtesy of Ticiana Leal, MD

Agenda

Introduction: 2 Faces of Lung Cancer Research

Module 1: B7-H3-Targeted Antibody-Drug Conjugates for Lung Cancer — Dr Patel

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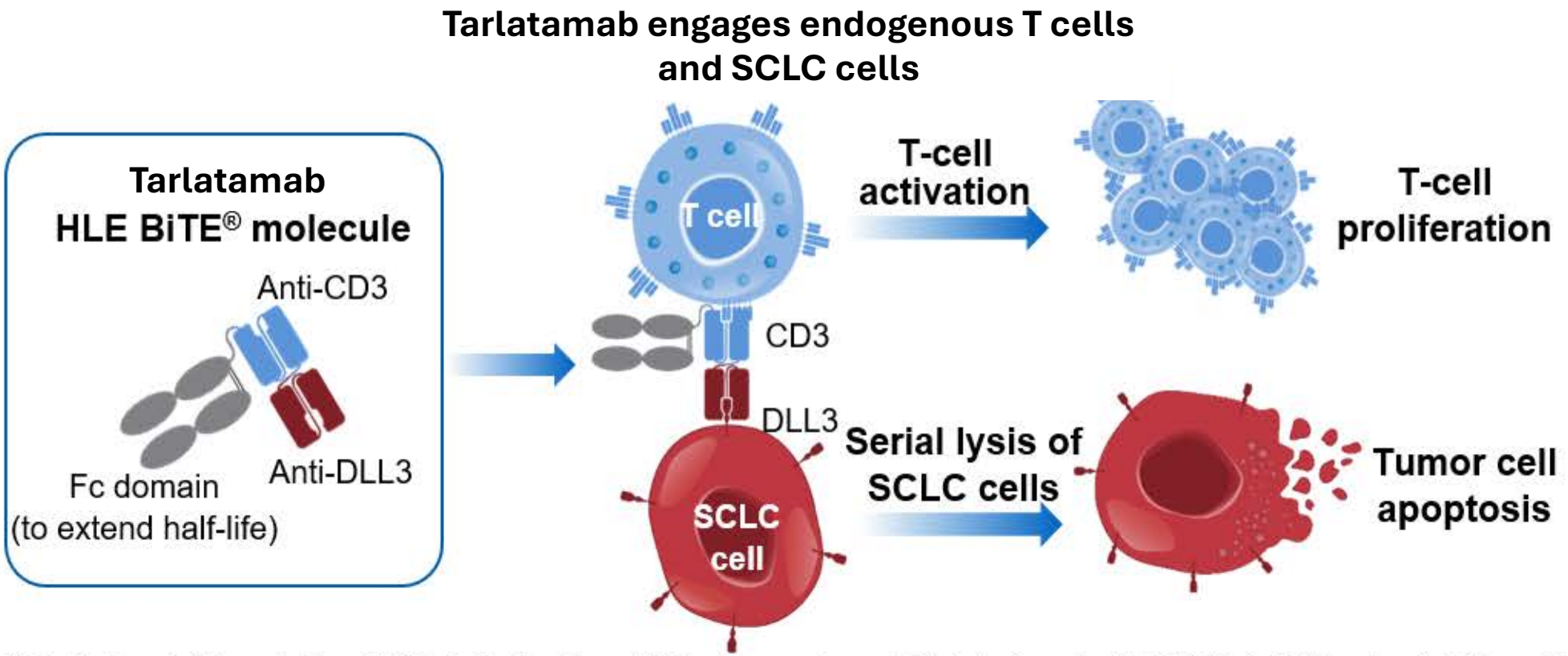
Emerging Role of Bispecific T-cell Engaging Immunotherapy in Small Cell Lung Cancer

Melissa Johnson, MD
Director, Lung Cancer Research Program
Sarah Cannon Research Institute
Associate Director of Drug Development for the
Drug Development Unit in Nashville
SCRI Oncology Partners
Nashville, Tennessee

Tarlatamab: A Half-life Extended BiTE® (bispecific T-cell engager) Immuno-oncology Therapy Targeting DLL3 for SCLC



CD, cluster of differentiation; DLL3, delta-like ligand 3; Fc, fragment crystallizable domain; HLE BiTE, half-life extended bispecific T-cell engager; SCLC, small cell lung cancer.

- The inhibitory notch ligand delta-like ligand 3 (DLL3) is aberrantly expressed on the surface of up to 85% of SCLC cells and minimally expressed in normal tissues.
- *In vitro* SCLC models have indicated a role for DLL3 in promoting tumor growth, migration, and invasion.

Stieglmaier J, et al. *Expert Opin Biol Ther*. 2015;15:1093-1099. Einsele H, et al. *Cancer.* 2020;126:3192-3201. Paz-Ares L, Champiat S, Lai WV, et al. *J Clin Oncol*. 2023;41(16):2893-2903.

Courtesy of Luis Paz-Ares, MD, PhD

FDA Grants Accelerated Approval to Tarlatamab-Dlle for Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

Press Release: May 16, 2024

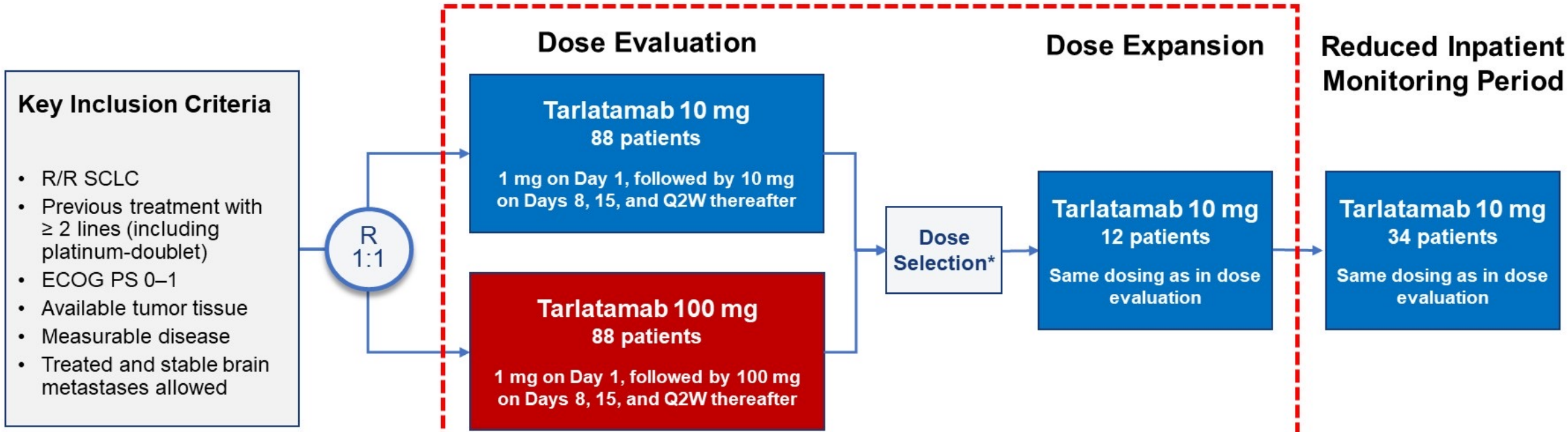
“On May 16, 2024, the Food and Drug Administration granted accelerated approval to tarlatamab-dlle for ES-SCLC with disease progression on or after platinum-based chemotherapy.

Efficacy was evaluated in 99 patients with relapsed/refractory ES-SCLC with disease progression following platinum-based chemotherapy enrolled in DeLLphi-301 [NCT05060016], an open-label, multicenter, multi-cohort study. Patients with symptomatic brain metastases, interstitial lung disease or non-infectious pneumonitis, and active immunodeficiency were excluded. Patients received tarlatamab until disease progression or unacceptable toxicity.

The major efficacy outcome measures were overall response rate (ORR) per RECIST 1.1 and duration of response (DOR), as assessed by blinded independent central review. ORR was 40% (95% CI: 31, 51) and median DOR was 9.7 months (range 2.7, 20.7+). Of the 69 patients with available data regarding platinum sensitivity status, the ORR was 52% (95% CI 32, 71) in 27 patients with platinum-resistant SCLC (defined as progression < 90 days after last dose of platinum therapy) and 31% (95% CI 18, 47) in 42 patients with platinum-sensitive SCLC (defined as progression ≥ 90 days after last dose of platinum therapy).”

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tarlatamab-dlle-extensive-stage-small-cell-lung-cancer

Phase 2 DeLLphi-301 Study Design



Primary Endpoint: ORR per RECIST v1.1 by BICR, TEAEs, tarlatamab serum concentrations
Secondary Endpoints: DOR, DCR, PFS per RECIST v1.1 by BICR, OS

Subgroup Analysis: Efficacy by BICR and safety, by presence or absence of baseline brain metastases
Post-hoc Analysis: Intracranial activity

NCT05060016. Post-enrollment, brain imaging was performed if clinically indicated. *Once 30 patients per dose level had the opportunity to confirm an objective response after the first post-treatment scan or up to 13 weeks of follow-up, whichever occurred first. **BICR**, blinded independent central review; **DCR**, disease control rate; **DOR**, duration of response; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **ORR**, objective response rate; **OS**, overall survival; **PFS**, progression-free survival; **Q2W**, every 2 weeks; **R**, randomization; **RECIST**, Response Evaluation Criteria in Solid Tumors; **R/R SCLC**, relapsed/refractory small cell lung cancer; **TEAE**, treatment-emergent adverse event.
Ahn MJ, et al. *N Engl J Med*. 2023;389:2063-2075.

Dingemans AC et al. ASCO 2024;Abstract 8015.

Courtesy of Melissa Johnson, MD

DeLLphi-301: Tarlatamab Anti-Tumor Activity

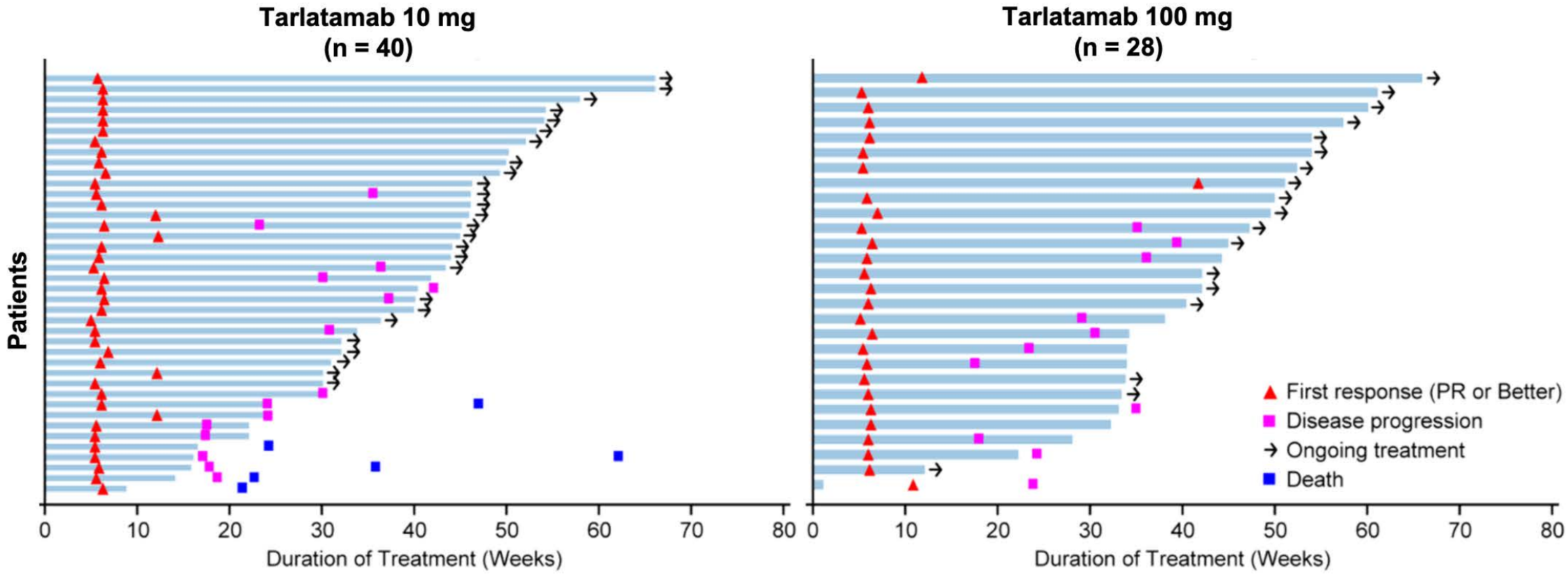
Outcome	Tarlatamab 10 mg (n = 100)	Tarlatamab 100 mg (n = 88)
Objective response rate, n (%) (97.5% CI)	40 (40) (29, 52)	28 (32) (21, 44)
Complete response	1 (1)	7 (8)
Partial response	39 (39)	21 (24)
Stable disease	30 (30)	27 (31)
Progressive disease	20 (20)	13 (15)
Not evaluable / no post-baseline scan*	10 (10)	20 (23)
Observed duration of response ≥ 6 months, n/N (%)	23/40 (58)	17/28 (61)
Disease control rate, n (%) (95% CI)	70 (70) (60, 79)	55 (63) (52, 73)

Tarlatamab 10 mg demonstrated anti-tumor activity in heavily pre-treated SCLC with an objective response rate of 40%

Paz-Ares L et al. ESMO 2023;Abstract LBA92.

Courtesy of Melissa Johnson, MD

DeLLphi-301: Duration of Response and Treatment



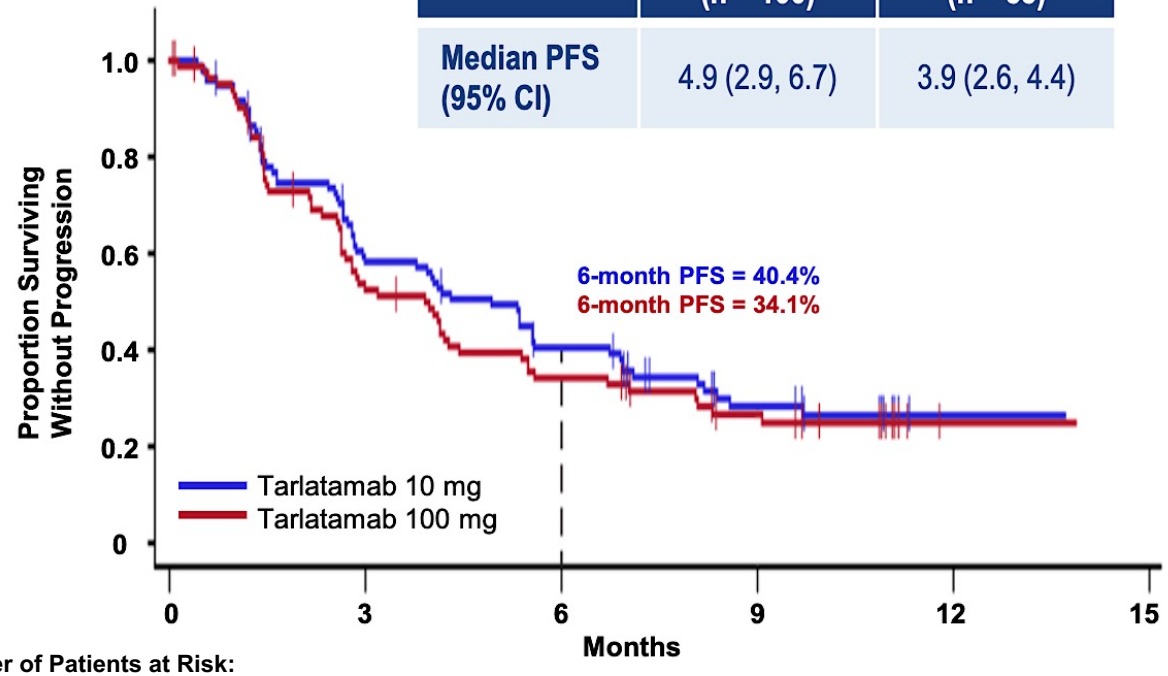
- Median TTR was 1.4 months (range, 1.1–9.6 months), and median DOR was not reached
- Of the 68 responders, the DOR was ≥ 6 months in 40 patients (59%)
- 56% of the responses were ongoing at data cutoff

Paz-Ares L et al. ESMO 2023;Abstract LBA92.

Courtesy of Melissa Johnson, MD

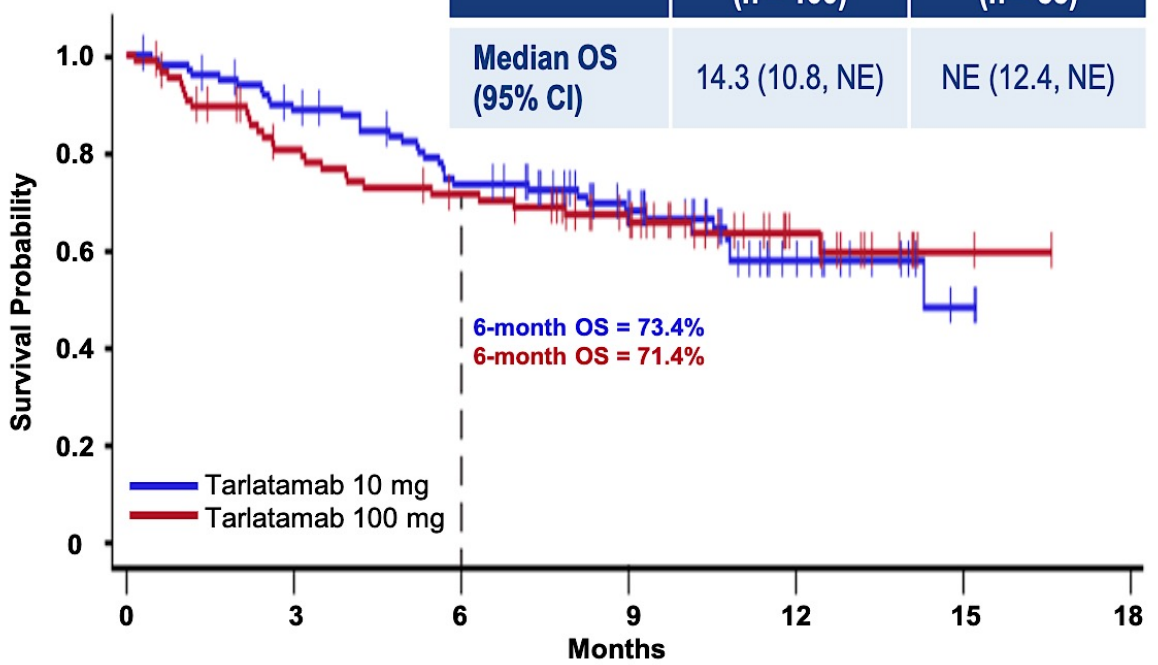
DeLLphi-301: PFS and OS

Outcome	Tarlatamab 10 mg (n = 100)	Tarlatamab 100 mg (n = 88)
Median PFS (95% CI)	4.9 (2.9, 6.7)	3.9 (2.6, 4.4)



Number of Patients at Risk:						
Tarlatamab 10 mg	100	53	35	18	2	0
Tarlatamab 100 mg	88	41	26	15	3	0

Outcome	Tarlatamab 10 mg (n = 100)	Tarlatamab 100 mg (n = 88)
Median OS (95% CI)	14.3 (10.8, NE)	NE (12.4, NE)



Tarlatamab 10 mg	100	84	67	44	17	3	0
Tarlatamab 100 mg	88	62	53	39	16	2	0

OS data is not yet mature; at the last follow-up, 57% of patients in the tarlatamab 10 mg group and 51% of patients in the tarlatamab 100 mg group were still alive

Paz-Ares L et al. ESMO 2023;Abstract LBA92.

Courtesy of Melissa Johnson, MD

DeLLphi-301: Efficacy by Presence of Brain Metastases

Baseline brain metastases:	Tarlatamab 10 mg Q2W* (n = 100)†	
	Yes (n = 23)	No (n = 77)
ORR, % (95% CI)	52 (31–73)	38 (27–49)
Median DOR, months (range)	NE (3–12+)	NE (2–12+)
DOR probability at 12 months, KM estimate, % (95% CI)	55 (22–78)	50 (29–68)
Median PFS, months (95% CI)	6.7 (3–NE)	4.0 (3–6)
Median OS‡, months (95% CI)	14.3 (14–NE)	NE (9–NE)

Tarlatamab demonstrated durable response with promising survival regardless of the presence of treated, stable brain metastases at baseline

Data cutoff, June 27, 2023. Median follow-up: 10.6 months. *Given as 1 mg on Day 1, followed by 10 mg on Days 8, 15, and Q2W thereafter. For 100 mg data, scan QR code or see https://meetings.asco.org/abstracts-presentations/232383. †The intention-to-treat analysis set consists of all patients who were randomized and enrolled according to assigned treatment dose levels. ‡OS data yet to mature. **CI,** confidence interval; **DOR**, duration of response; **KM**, Kaplan-Meier; **NE**, not estimable; **ORR**, objective response rate; **OS**, overall survival; **PFS**, progression-free survival; **Q2W**, every 2 weeks.

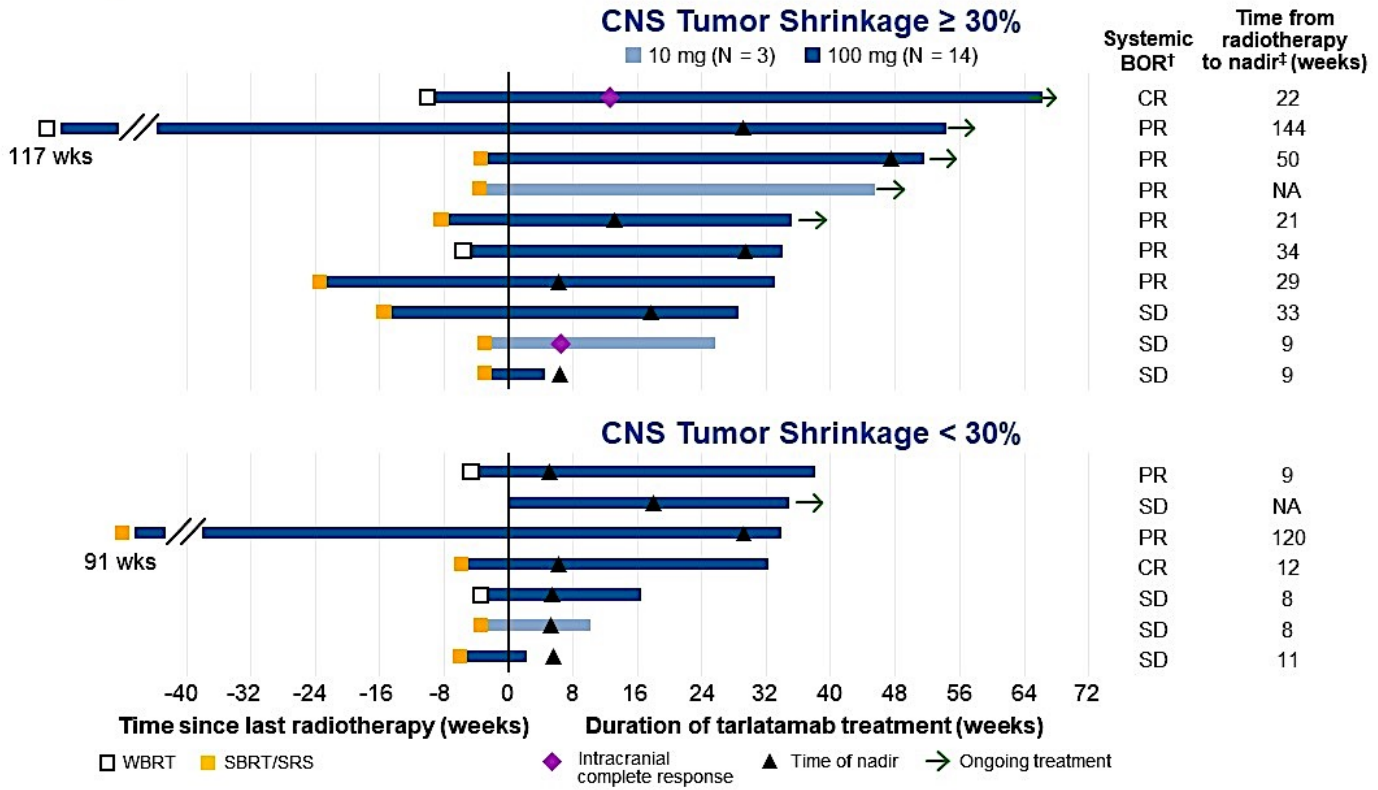
Dingemans AC et al. ASCO 2024;Abstract 8015.

Courtesy of Melissa Johnson, MD

DeLLphi-301: Intracranial Activity*

Tarlatamab 10 mg (n = 3) or 100 mg (n = 14) Q2W with baseline CNS lesion ≥ 10 mm

- **mRANO BM§ analyses (N = 17)**
  - CNS tumor shrinkage ≥ 30% in 10 of 17 patients (59%)
  - Intracranial disease control in 94% (16 of 17) patients (95% CI, 71.3–99.9)
  - Median duration of intracranial disease control was NE (range, 2.6–13.9+ months)
  - CNS disease progression per modified RANO-BM occurred in 3 of 17 patients (18%)



CNS tumor shrinkage was observed in patients with previously treated brain metastases

*The CNS measurable analysis set included patients who had ≥ 2 brain scans (baseline and post-baseline) and were identified per modified RANO-BM by BICR as having ≥ 1 brain lesion ≥ 10 mm at baseline. †Systemic BOR was determined using RECIST v1.1 by BICR. ‡Minimum percentage change from baseline (smallest SLD) before disease progression. Median follow-up: 11.8 months. §mRANO BM represents RANO BM criteria with the following modifications: (1) corticosteroid data and clinical status were not incorporated into imaging reads; (2) diffusion weighted imaging MRI sequences were not required but were made available to the independent reviewer if received. **BICR**, blinded independent central review; **BOR**, best overall response; **CNS**, central nervous system; **CR**, complete response; **mRANO BM**, modified response assessment in neuro-oncology criteria for brain metastases; **MRI**, magnetic resonance imaging; **NA**, not available; **NE**, not estimable; **PR**, partial response; **RECIST**, Response Evaluation Criteria in Solid Tumors; **RT**, radiotherapy; **SBRT**, stereotactic body radiation therapy; **SD**, stable disease; **SLD**, sum of longest diameter; **SRS**, stereotactic radiosurgery; **WBRT**, whole brain radiation therapy.

Dingemans AC et al. ASCO 2024;Abstract 8015.

Courtesy of Melissa Johnson, MD

DeLLphi-301: Safety

TEAEs, n (%)	Part 1 + 2 Tarlatamab 10 mg (n = 99)	Part 1 Tarlatamab 100 mg (n = 87)	Part 3 Tarlatamab 10 mg (n = 34)
Any grade	96 (97)	87 (100)	34 (100)
≥ Grade 3	57 (58)	56 (64)	22 (65)
Related to tarlatamab, any grade	89 (90)	81 (93)	29 (85)
≥ Grade 3	29 (29)	29 (33)	5 (15)
Fatal	0	0	1 (3)†
Leading to dose interruption/reduction	14 (14)	25 (29)	3 (9)
Leading to discontinuation	4 (4)	3 (3)	0

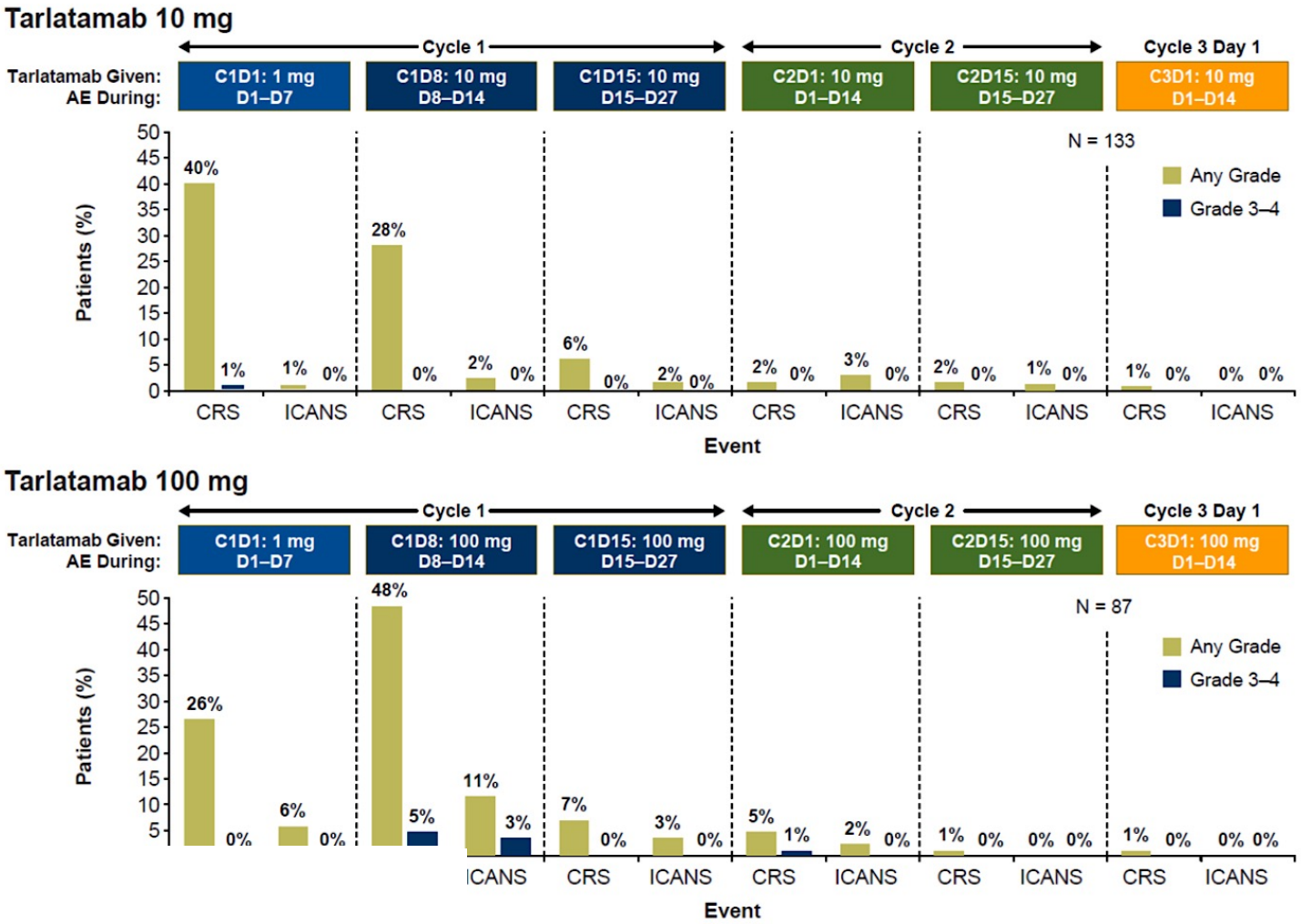
Most Common TEAEs in ≥ 20% of Patients, n (%)	Part 1 + 2 Tarlatamab 10 mg (n = 99)	Part 1 Tarlatamab 100 mg (n = 87)	Part 3 Tarlatamab 10 mg (n = 34)
CRS	49 (49)	53 (61)	19 (56)
Grade 1–2	49 (49)	48 (55)	18 (53)
≥ Grade 3	0	5 (6)	1 (3)
Decreased appetite	25 (25)	38 (44)	13 (38)
Pyrexia	38 (38)	29 (33)	8 (24)
Constipation	28 (28)	22 (25)	8 (24)
Anemia	26 (26)	22 (25)	9 (26)
Asthenia	20 (20)	21 (24)	10 (29)
Dysgeusia	24 (24)	12 (14)	14 (41)
Fatigue	21 (21)	17 (20)	9 (26)

- **Tarlatamab demonstrated a favorable safety profile, with a low rate of discontinuations due to treatment-related adverse events (TRAEs)**
- **Shorter inpatient monitoring (Part 3) did not alter the safety profile**

Paz-Ares L et al. ESMO 2023;Abstract LBA92.

Courtesy of Melissa Johnson, MD

DeLLphi-301: CRS and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)*



- CRS was largely confined to the first or second dose, primarily grade 1–2
- ICANS* occurred infrequently overall and was predominantly observed with tarlatamab 100 mg

Additional Interventions for CRS:

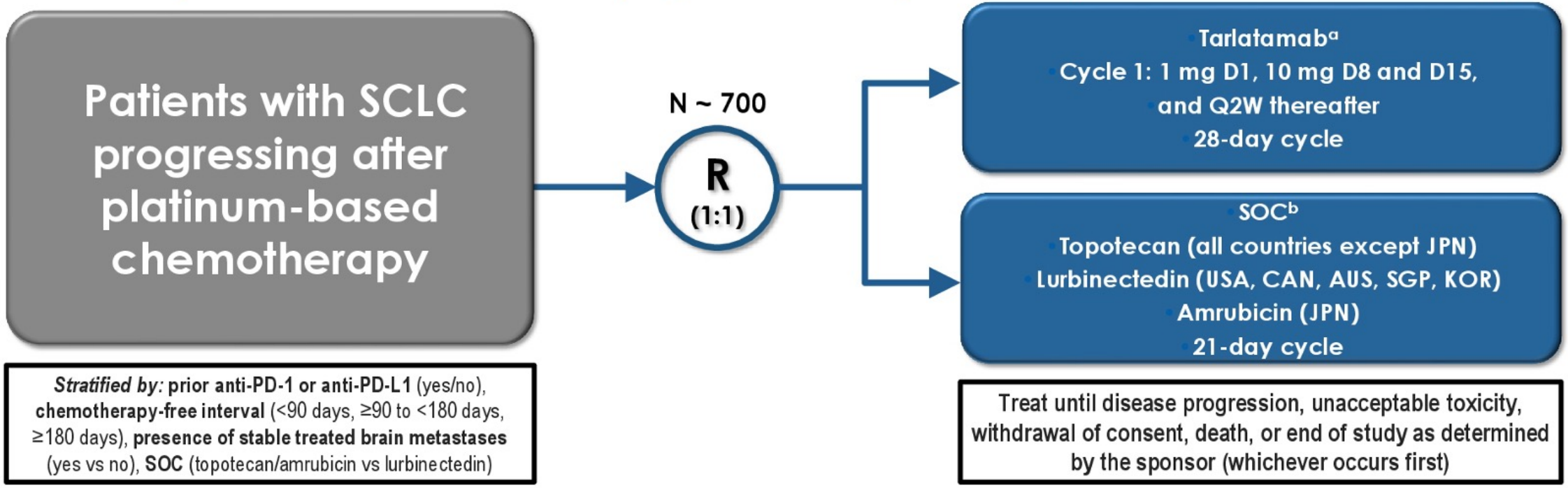
Patients receiving tarlatamab, n (%)	10 mg (n = 133)	100 mg (n = 87)
Tocilizumab	7 (5)	9 (10)
Supplemental oxygen	11 (8)	8 (9)
Vasopressor support	1 (1)	1 (1)

Paz-Ares L et al. ESMO 2023;Abstract LBA92.

Courtesy of Melissa Johnson, MD

DeLLphi-304

Phase 3, open-label, randomized, multi-center study evaluating efficacy and safety of tarlatamab compared with SOC in patients with SCLC who have progressed after 1 prior line of platinum-based chemotherapy



Pre- and post-infusion medication requirements include dexamethasone administered within 1 hour prior to cycle 1 tarlatamab infusion on D1 and D8 and IV hydration following cycle 1 tarlatamab doses on D1, D8, and D15

[a]Tarlatamab will be administered as a 60-minute IV infusion

[b]Standard of care (21-day cycle): Lurbinectedin (USA, Canada, Australia, Singapore, and Korea) will be administered as 3.2 mg/m^2 IV on day 1 every 3 weeks. Topotecan (all countries, except Japan and China) will be administered as IV at 1.5 mg/m^2 or oral at 2.3 mg/m^2/day on days 1, 2, 3, 4, and 5 every 3 weeks. Topotecan (China) will be administered as IV at 1.25 mg/m^2 or oral at 2.3 mg/m^2/day on days 1, 2, 3, 4, and 5 every 3 weeks. Amrubicin (Japan) will be administered as 40 mg/m^2 IV on days 1 to 3 every 3 weeks.

PD-1, programmed cell death protein 1; PD-L1, programmed cell death ligand 1; SCLC, small cell lung cancer; SOC, standard of care.

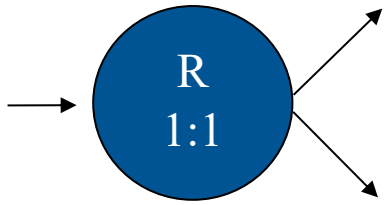
Paz-Ares LG et al. ASCO 2023;Abstract TPS8611.

Courtesy of Melissa Johnson, MD

DeLLphi-305

- A Phase 3, open-label, multicenter, randomized study of tarlatamab in combination with durvalumab vs durvalumab alone in subjects with ES-SCLC following platinum, etoposide and durvalumab

Patients who completed 3-4 cycles of platinum-etoposide chemotherapy with concurrent durvalumab as first-line treatment of extensive-stage ES-SCLC prior to enrollment, without disease progression



Tarlatamab + durvalumab
Participants will receive tarlatamab once every 2 weeks (q2wk) and durvalumab once every 4 weeks (q4wk).

Durvalumab
Participants will receive durvalumab q4wk alone.

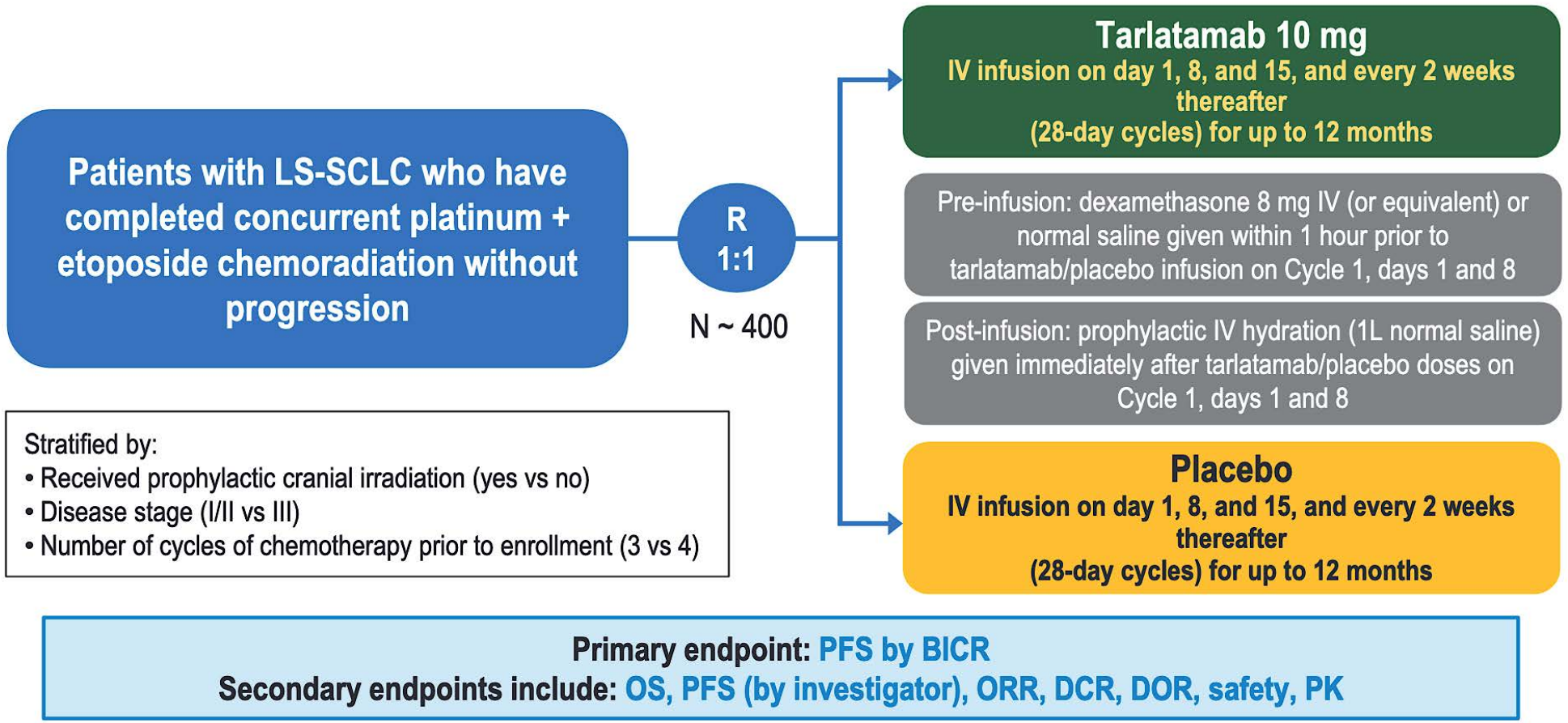
Primary endpoint: OS
Key secondary endpoints: PFS, OR, DCR, DoR

www.clinicaltrials.gov. NCT06211036. Accessed July 2024.

Courtesy of Melissa Johnson, MD

DeLLphi-306

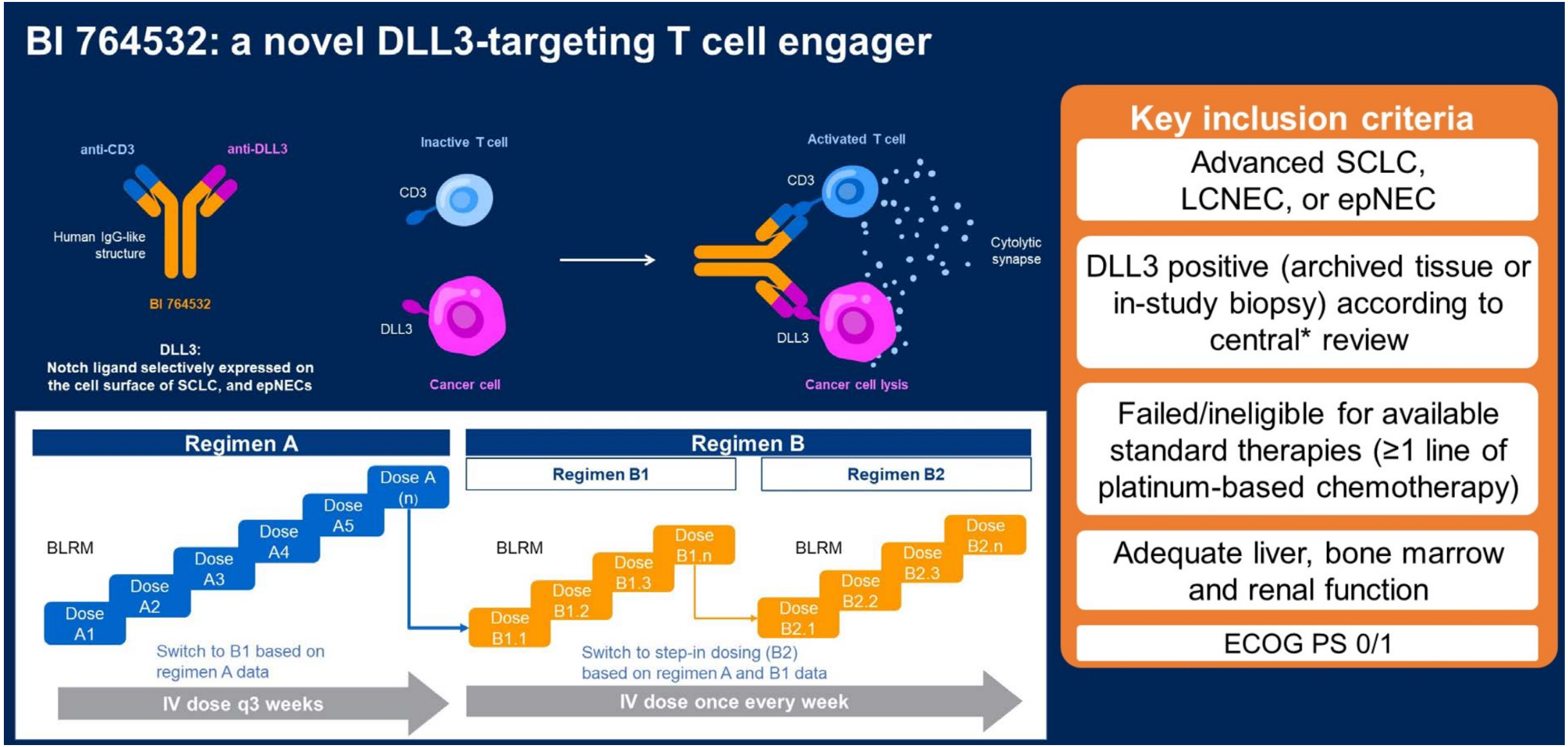
- A Phase 3, randomized, double-blind, placebo-controlled, multicenter study of tarlatamab therapy in subjects with limited-stage small cell lung cancer (LS-SCLC) who have not progressed following concurrent chemoradiation therapy



Hummel H et al. European Lung Cancer Congress 2024;Abstract 214TiP.

Courtesy of Melissa Johnson, MD

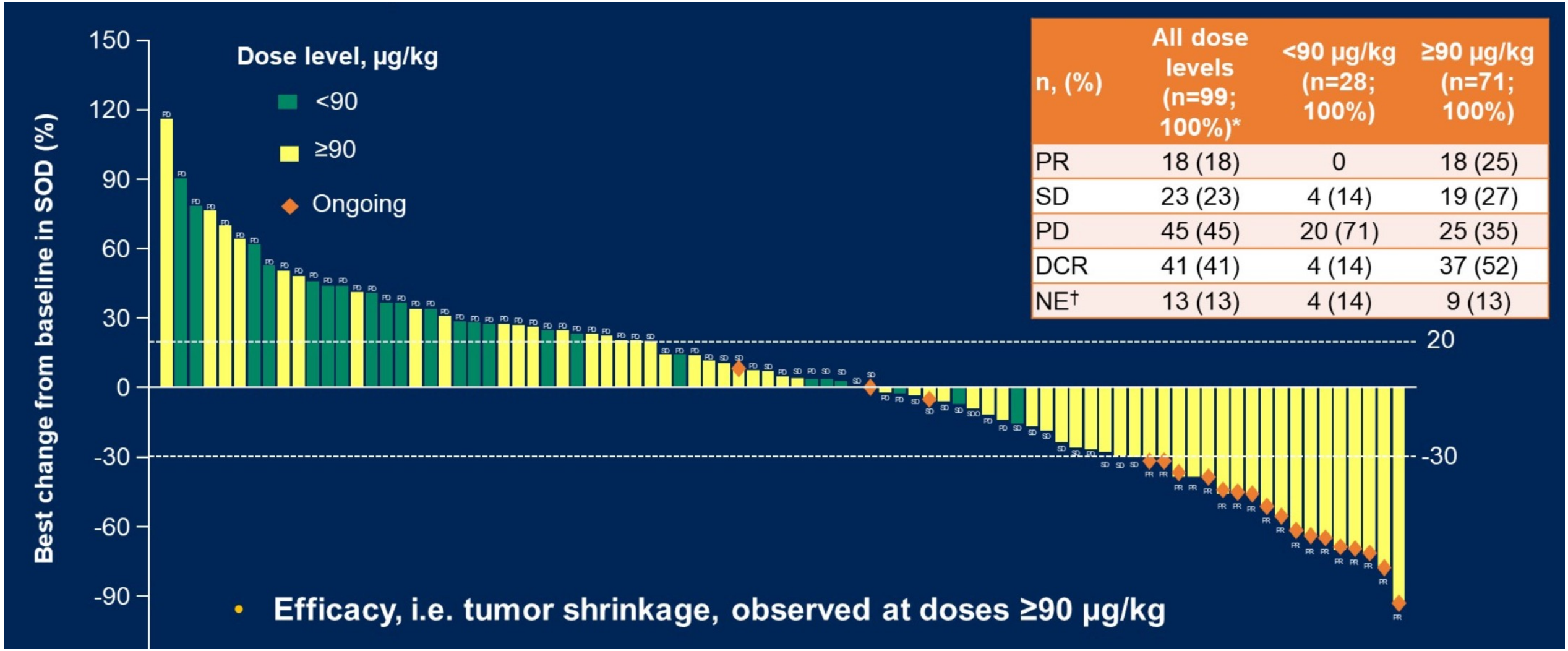
BI 764532: Mechanism and Dose-Escalation Trial



Wermke M et al. ASCO 2023;Abstract 8502.

Courtesy of Melissa Johnson, MD

BI 764532: Overall Efficacy

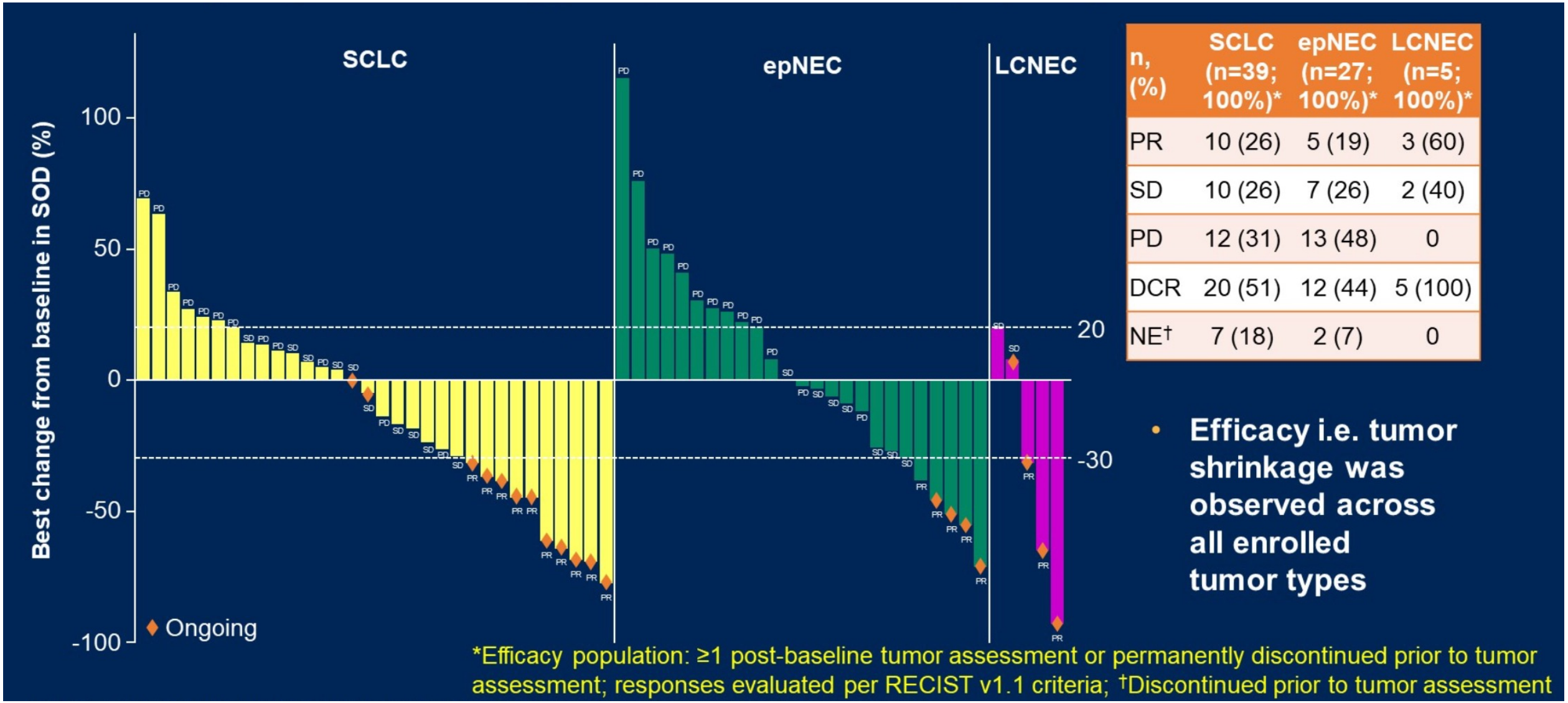


n, (%)	All dose levels (n=99; 100%)*	<90 µg/kg (n=28; 100%)	≥90 µg/kg (n=71; 100%)
PR	18 (18)	0	18 (25)
SD	23 (23)	4 (14)	19 (27)
PD	45 (45)	20 (71)	25 (35)
DCR	41 (41)	4 (14)	37 (52)
NE†	13 (13)	4 (14)	9 (13)

Wermke M et al. ASCO 2023;Abstract 8502.

Courtesy of Melissa Johnson, MD

BI 764532: Efficacy by Tumor Type (Doses ≥90 µg/kg)



n, (%)	SCLC (n=39; 100%)*	epNEC (n=27; 100%)*	LCNEC (n=5; 100%)*
PR	10 (26)	5 (19)	3 (60)
SD	10 (26)	7 (26)	2 (40)
PD	12 (31)	13 (48)	0
DCR	20 (51)	12 (44)	5 (100)
NE†	7 (18)	2 (7)	0

- **Efficacy i.e. tumor shrinkage was observed across all enrolled tumor types**

*Efficacy population: ≥1 post-baseline tumor assessment or permanently discontinued prior to tumor assessment; responses evaluated per RECIST v1.1 criteria; †Discontinued prior to tumor assessment

Wermke M et al. ASCO 2023;Abstract 8502.

Courtesy of Melissa Johnson, MD

BI 764532: Safety Profile

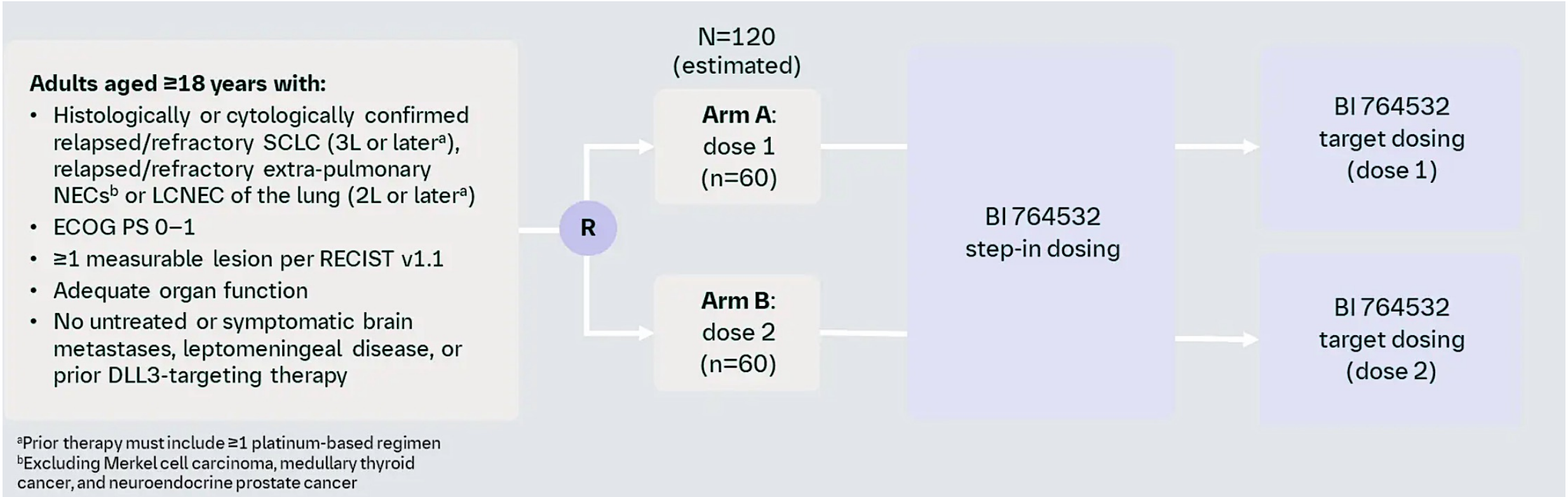
TRAE, n (%)	Total (N=107; 100%)* All grade	Grade 1–2	Grade 3–5
Number of pts with ≥1 TRAE	**92 (86)**	**63 (59)**	**29 (27)**
CRS	63 (59)	61 (57)	2 (2)
Lymphocyte count decreased	21 (20)	4 (4)	17 (16)
Dysgeusia	21 (20)	21 (20)	0
Asthenia	20 (19)	19 (18)	1 (<1)
Pyrexia	19 (18)	19 (18)	0
AST increased	15 (14)	13 (12)	2 (2)
Fatigue	15 (14)	14 (13)	1 (<1)
Nausea	13 (12)	13 (12)	0

AEs, n	Total (N=107*)
DLTs†	**5**
CRS grade 3–4	2
Confusional state grade 3	1
Infusion-related reaction grade 2	1
Nervous system disorder grade 3	1

Wermke M et al. ASCO 2023;Abstract 8502.

Courtesy of Melissa Johnson, MD

DAREON-5: A Phase II, Open-Label Dose-Selection Study of BI 764532 Relapsed/Refractory SCLC and Other NECs



[a]Prior therapy must include ≥1 platinum-based regimen
[b]Excluding Merkel cell carcinoma, medullary thyroid cancer, and neuroendocrine prostate cancer

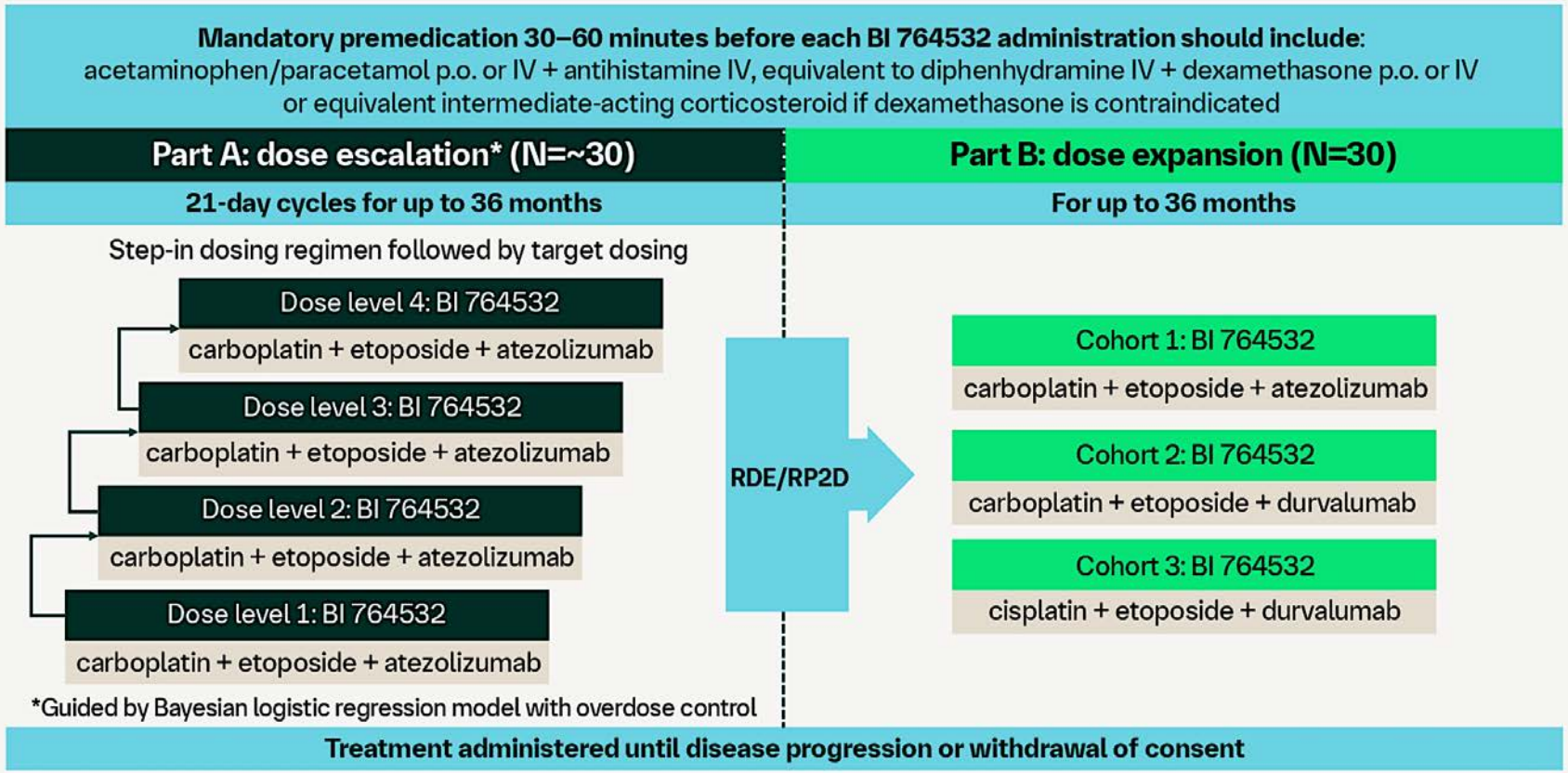
Endpoints		Start date	Status
Primary:	**OR, TEAEs during the on-treatment period**	March 2024	Recruiting
Secondary:	DOR, PFS, DC, OS, PROs, TEAEs leading to discontinuation		Estimated completion: July 2025

www.clinicaltrials.gov. NCT05882058. Accessed July 2024.

Courtesy of Melissa Johnson, MD

DAREON-8: A Phase I, Open-label, Dose Escalation/Expansion Trial of BI 764532 Combined with 1L Standard-of-Care in ES-SCLC

Inclusion
Histologically or cytologically confirmed ES-SCLC
Eligible to receive carboplatin + etoposide + atezolizumab (Part A) or to receive etoposide; carboplatin or cisplatin; and atezolizumab or durvalumab (Part B)
No prior systemic treatment for ES-SCLC
Prior systemic treatment for limited-stage SCLC ≥6 months prior to the diagnosis of ES-SCLC
ECOG performance score of 0/1
Adequate organ function



Peters S et al. ASCO 2024;Abstract TPS8127.

Courtesy of Melissa Johnson, MD

Additional Discussion Topic: ASCO 2024

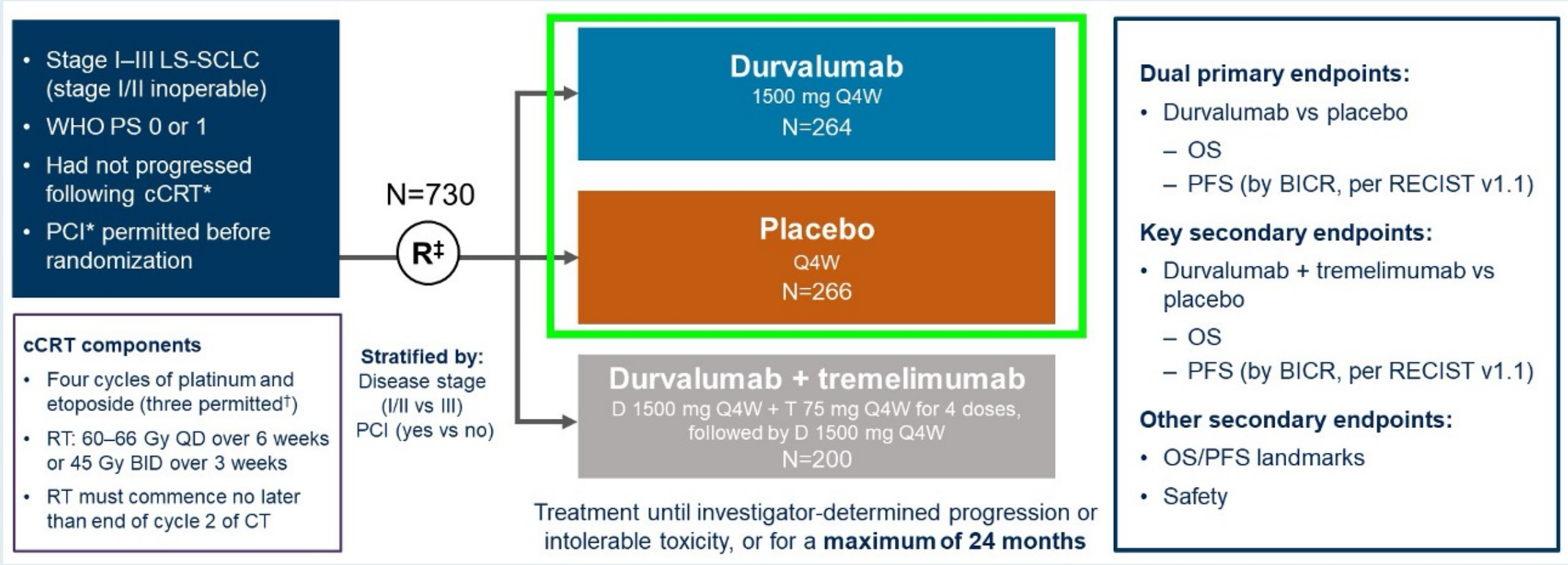
2024 ASCO ANNUAL MEETING

Abstract LBA5

ADRIATIC: durvalumab as consolidation treatment for patients with limited-stage small-cell lung cancer (LS-SCLC)

David R. Spigel, Ying Cheng, Byoung Chul Cho, Konstantin Laktionov, Jian Fang, Yuanbin Chen, Yoshitaka Zenke, Ki Hyeong Lee, Qiming Wang, Alejandro Navarro, Reyes Bernabe, Eva Buchmeier, John Wen-Cheng Chang, Isamu Okamoto, Sema Sezgin Goksu, Andrzej Badzio, Bethany Gill, Hema Gowda, Haiyi Jiang, Suresh Senan

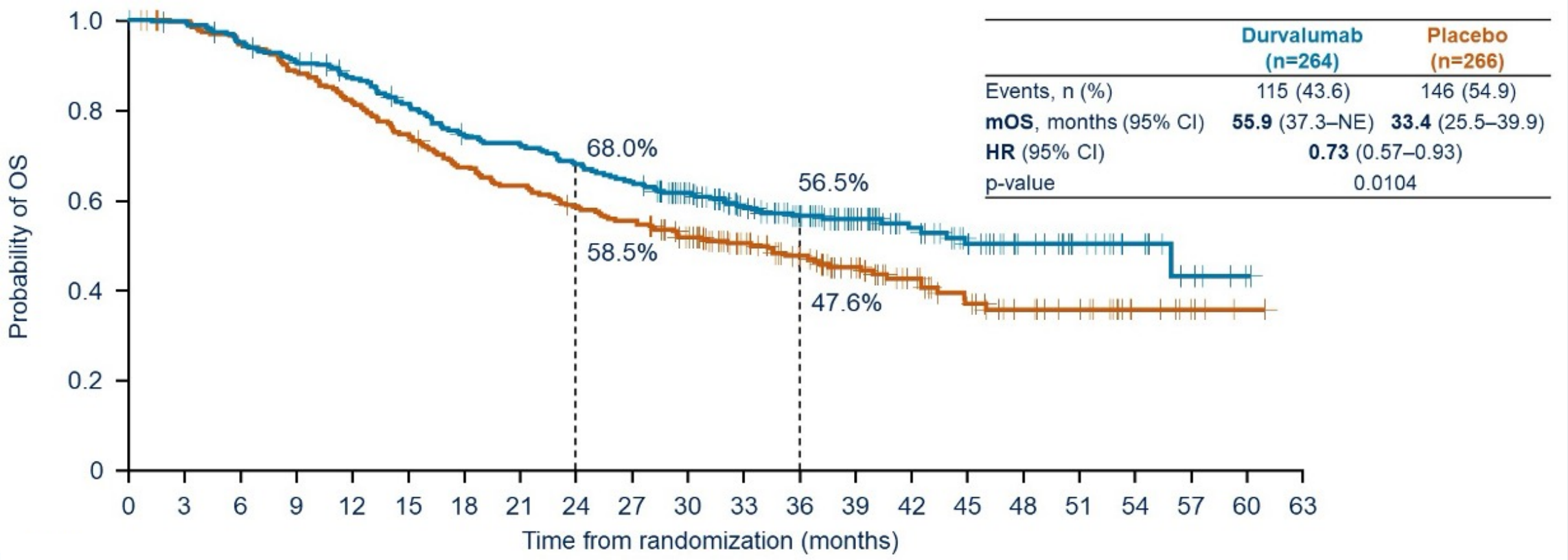
ADRIATIC: Phase III Study Design



cCRT = concurrent chemoradiation therapy; PCI = prophylactic cranial irradiation; RT = radiation therapy

Spigel DR et al. ASCO 2024;Abstract LBA5.

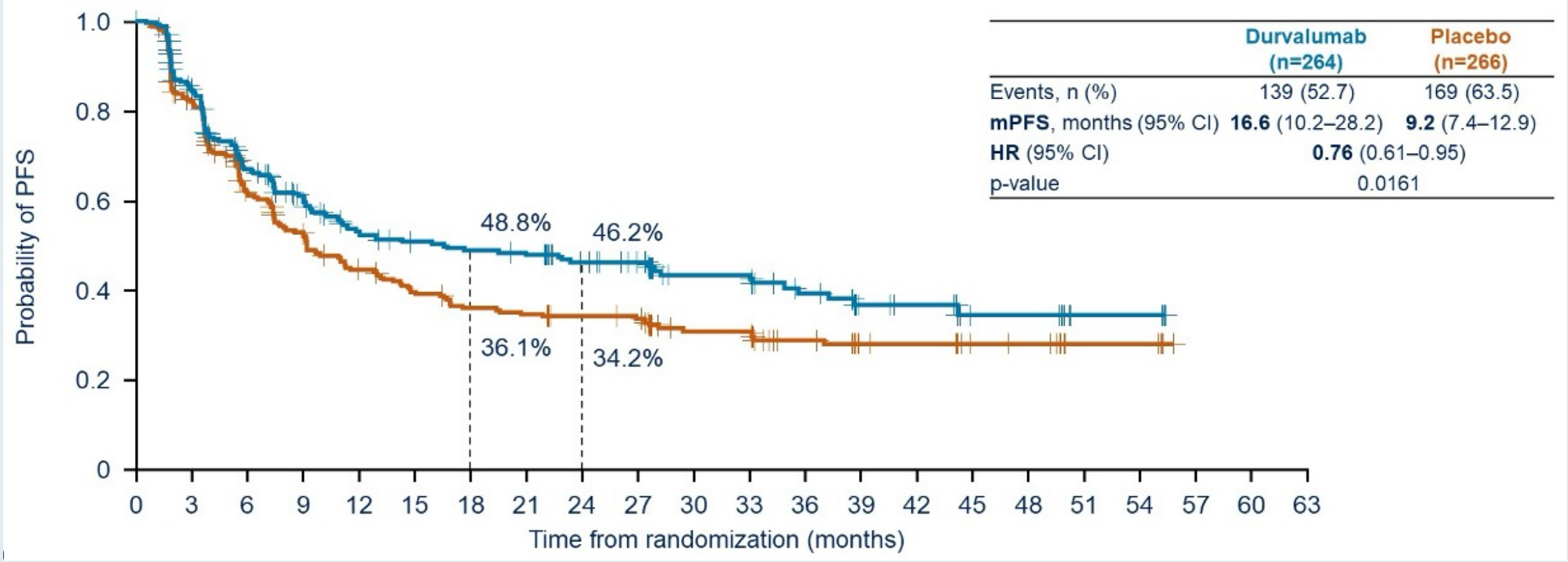
ADRIATIC: Overall Survival (Dual Primary Endpoint)



mOS = median overall survival

Spigel DR et al. ASCO 2024;Abstract LBA5.

ADRIATIC: Progression-Free Survival (Dual Primary Endpoint)



	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	

mPFS = median progression-free survival

Spigel DR et al. ASCO 2024;Abstract LBA5.

RTP RESEARCH TO PRACTICE

ADRIATIC: Author Conclusions

- **Durvalumab as consolidation treatment after cCRT demonstrated statistically significant and clinically meaningful improvement in OS and PFS compared with placebo in patients with LS-SCLC**
  - **OS HR 0.73** (95% CI 0.57–0.93), p=0.0104; mOS 55.9 (95% CI 37.3–NE) vs 33.4 (95% CI 25.5–39.9) months
  - **PFS HR 0.76** (95% CI 0.61–0.95), p=0.0161; mPFS 16.6 (95% CI 10.2–28.2) vs 9.2 (95% CI 7.4–12.9) months
  - Treatment benefit was generally consistent across predefined patient subgroups for both OS and PFS
- **Durvalumab consolidation treatment for up to 2 years was well tolerated, and safety findings were consistent with the known safety profile of durvalumab monotherapy in the post-cCRT setting**

Consolidation durvalumab will become the new standard of care for patients with LS-SCLC who have not progressed after cCRT

Spigel DR et al. ASCO 2024;Abstract LBA5.

ASCO 2024 Highlights of the Day: Metastatic NSCLC

Solomon BJ et al. Lorlatinib vs crizotinib in treatment-naïve patients with advanced ALK+ non-small cell lung cancer: 5-year progression-free survival and safety from the CROWN study. ASCO 2024;Abstract LBA8503.

Leighl NB et al. Subcutaneous amivantamab vs intravenous amivantamab, both in combination with lazertinib, in refractory EGFR-mutated, advanced non-small cell lung cancer (NSCLC): Primary results, including overall survival (OS), from the global, phase 3, randomized controlled PALOMA-3 trial. ASCO 2024;Abstract LBA8505.

Iyengar P et al. NRG-LU002: Randomized phase II/III trial of maintenance systemic therapy versus local consolidative therapy (LCT) plus maintenance systemic therapy for limited metastatic non-small cell lung cancer (NSCLC). ASCO 2024;Abstract 8506.

Paz-Ares LG et al. Sacituzumab govitecan (SG) vs docetaxel (doc) in patients (pts) with metastatic non-small cell lung cancer (mNSCLC) previously treated with platinum (PT)-based chemotherapy (chemo) and PD(L)-1inhibitors (IO): Primary results from the phase 3 EVOKE-01 study. ASCO 2024;Abstract LBA8500.

Inside the Issue: Integrating Antibody-Drug Conjugates into the Management of HR-Positive and Triple-Negative Metastatic Breast Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, July 17, 2024
5:00 PM – 6:00 PM ET

Faculty

Professor Peter Schmid, FRCP, MD, PhD
Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

CME and MOC credit information will be emailed to each participant within 5 business days.

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