Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

Immunotherapy and Other Nontargeted Approaches for Lung Cancer

Thursday, April 13, 2023
5:00 PM – 6:00 PM ET

Faculty

Luis Paz-Ares, MD, PhD

Heather Wakelee, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

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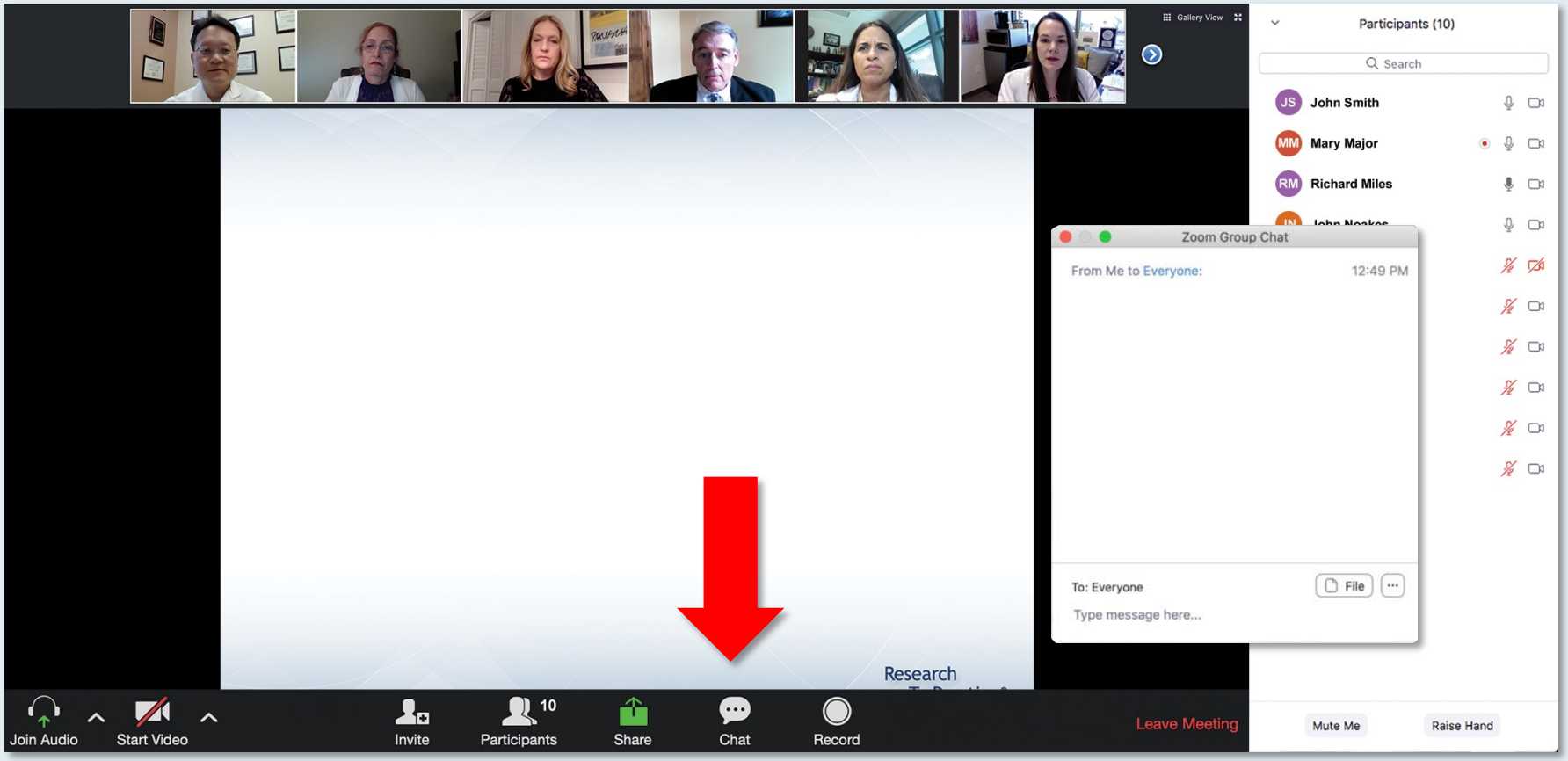
Chair of the Medical Oncology Department at the Hospital Universitario 12 de Octubre
Associate Professor at the Universidad Complutense
Head of the Lung Cancer Unit at the National Oncology Research Center
Madrid, Spain

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Heather Wakelee, MD
Professor of Medicine
Chief, Division of Oncology
Deputy Director, Stanford Cancer Institute
President, International Association for the Study of Lung Cancer (IASLC)
Stanford, California

We Encourage Clinicians in Practice to Submit Questions



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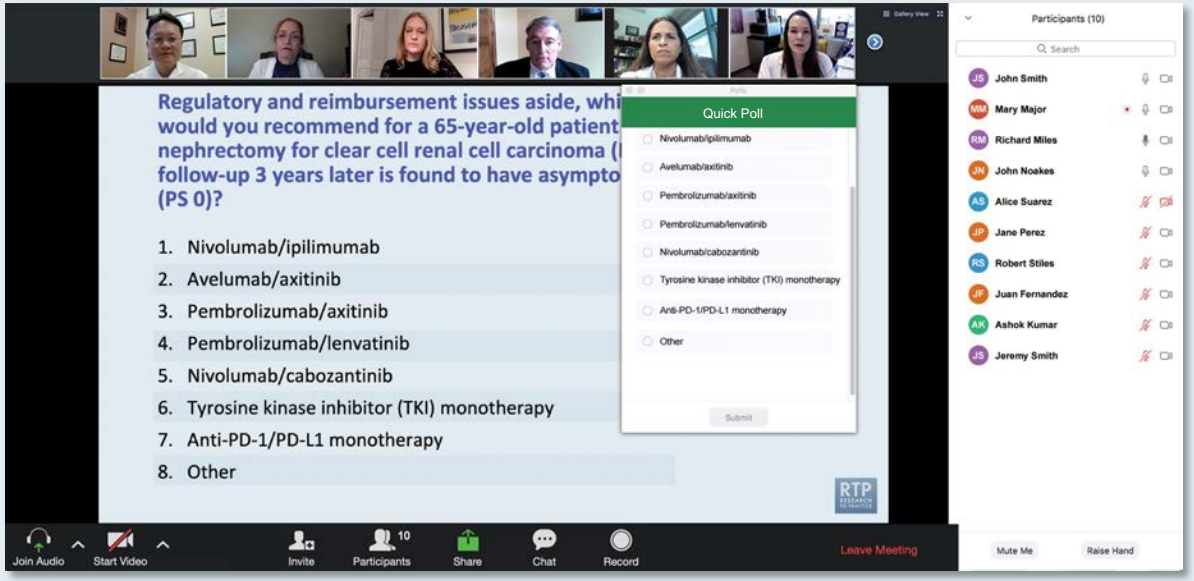

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What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

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Beyond The Guidelines: Urologic Oncology Investigators Provide Perspectives on the Optimal Management of Urothelial Bladder Cancer

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Arlene Siefker-Radtke, MD

RTP RESEARCH TO PRACTICE

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Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma Corp, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Corporation, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab US Inc, Gilead Sciences Inc, Grail Inc, GSK, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Kronos Bio Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc, and Zymeworks Inc.

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Dr Paz-Ares — Disclosures

Advisory Committee	AbbVie Inc, Amgen Inc, AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Eisai Inc, EMD Serono Inc, Genentech, a member of the Roche Group, GSK, Guardant Health, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Lilly, Merck Sharp & Dohme LLC, Novartis, Pfizer Inc, PharmaMar, Regeneron Pharmaceuticals Inc, Sanofi, Takeda Pharmaceuticals USA Inc
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Agenda

Introduction: Looking Back at Immuno-oncology Therapies (IOs)

MODULE 1: Metastatic Disease

MODULE 2: Localized Non-Small Cell Lung Cancer (NSCLC)

MODULE 3: Small Cell Lung Cancer (SCLC)

MODULE 4: Appendix

Thank you for joining us!

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

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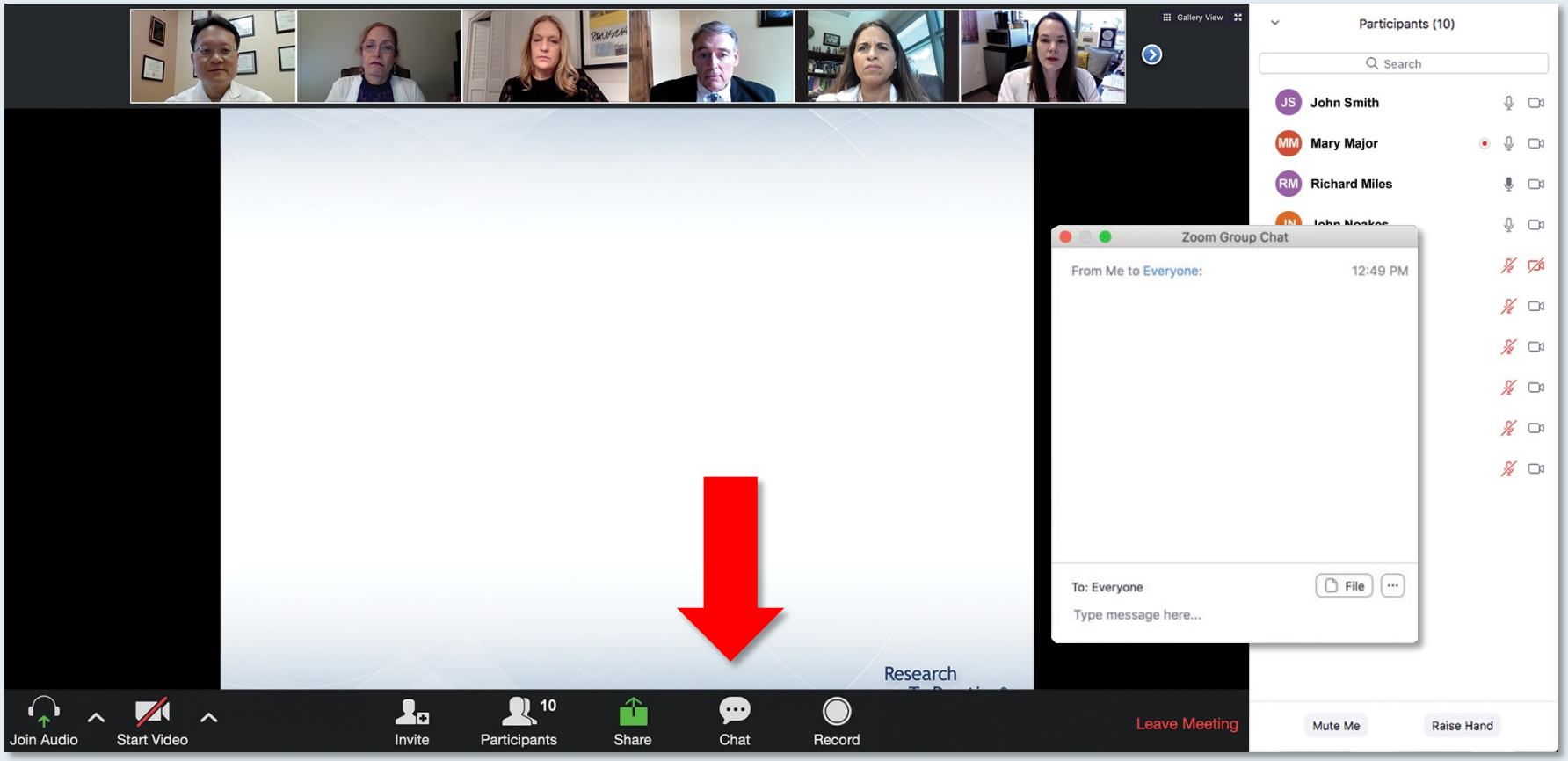

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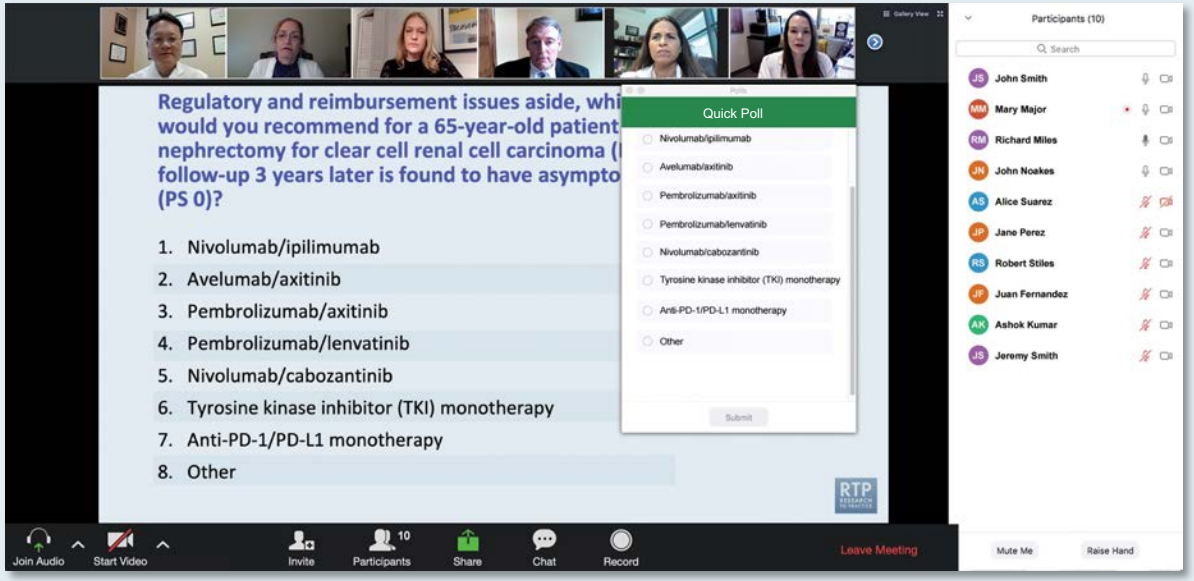

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Year in Review: Webinar
Non-Targeted Lung Cancer

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Chief, Division of Medical Oncology
Interim Medical Director, Stanford Cancer Center
Stanford University School of Medicine
Deputy Director, Stanford Cancer Institute
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i+12 Instituto de Investigación Hospital 12 de Octubre

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Year in Review — Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology: Immunotherapy and other Non-Targeted Approaches for Lung Cancer Edition

Luis Paz-Ares
Hospital Universitario 12 de Octubre

RTP Year in Review 2023

Key Data Sets

Heather Wakelee, MD

- Castro G Jr et al. Five-year outcomes with **pembrolizumab** versus chemotherapy as **first-line** therapy in patients with non-small-cell lung cancer and programmed death ligand-1 **tumor proportion score ≥ 1%** in the **KEYNOTE-042** study. *J Clin Oncol* 2022;[Online ahead of print].
- Özgüroğlu M et al. **Three years** survival outcome and continued **cemiplimab (CEMI) beyond progression** with the addition of chemotherapy (chemo) for patients (pts) with advanced non-small cell lung cancer (NSCLC): The **EMPOWER-Lung 1** trial. ESMO 2022;Abstract LBA54.
- Burotto Pichun M et al. **IMscin001** (**Part 2**: Randomized **Phase III**): Pharmacokinetics (PK), efficacy and safety of **atezolizumab (atezo) subcutaneous** (SC) vs intravenous (IV) in previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC). ESMO Immuno-Oncology Congress 2022;Abstract 61MO.
- Garassino MC et al. **Pembrolizumab** plus **pemetrexed** and **platinum** in **nonsquamous** non-small-cell lung cancer: **5-year** outcomes from the Phase 3 **KEYNOTE-189** study. *J Clin Oncol* 2023;[Online ahead of print].

Key Data Sets

Heather Wakelee, MD (continued)

- Novello S et al. **Pembrolizumab** plus **chemotherapy** in **squamous** non-small-cell lung cancer: **5-year** update of the Phase III **KEYNOTE-407** study. *J Clin Oncol* 2023;[Online ahead of print].
- Gogishvili M et al. **Cemiplimab plus chemotherapy** versus **chemotherapy** alone in non-small cell lung cancer: A randomized, controlled, double-blind phase 3 trial. *Nat Med* 2022;28(11):2374-80.
- Brahmer JR et al. **Five-year** survival outcomes with **nivolumab plus ipilimumab** versus chemotherapy as **first-line** treatment for metastatic non-small-cell lung cancer in **CheckMate 227**. *J Clin Oncol* 2023;41(6):1200-12.
- Paz-Ares LG et al. **First-line** (1L) **nivolumab (NIVO) + ipilimumab (IPI)** + **2 cycles** of **chemotherapy** (chemo) versus **chemo alone (4 cycles)** in patients (pts) with metastatic non–small cell lung cancer (NSCLC): **3-year** update from **CheckMate 9LA**. ASCO 2022;Abstract LBA9026.
- Johnson ML et al. **Durvalumab** with or without **tremelimumab** in combination with **chemotherapy** as **first-line** therapy for metastatic non-small-cell lung cancer: The **Phase III POSEIDON** study. *J Clin Oncol* 2023;41(6):1213-27.

Key Data Sets

Heather Wakelee, MD (continued)

- Johnson ML et al. **Durvalumab (D) ± tremelimumab (T)** + chemotherapy (CT) in **1L** metastatic (m) NSCLC: Overall survival (OS) update from **POSEIDON** after median follow-up (mFU) of approximately **4 years** (y). ESMO 2022;Abstract LBA59.
- Levy B et al. **TROPION-Lung02**: Initial results for **datopotamab deruxtecan** plus pembrolizumab and platinum chemotherapy in advanced NSCLC. WCLC 2022;Abstract MA13.07.
- Ricordel C et al. Safety and efficacy of **tusamitamab ravtansine** (SAR408701) in long-term treated patients with **nonsquamous** non–small cell lung cancer (NSQ NSCLC) expressing carcinoembryonic antigen-related cell adhesion molecule 5 (**CEACAM5**). ASCO 2022;Abstract 9039.
- Besse B et al. **HUDSON**: An open-label, **multi-drug**, **biomarker-directed**, Phase II platform study in patients with NSCLC, who progressed on anti-PD(L)1 therapy. WCLC 2022;Abstract OA15.05
- Kotecha R et al. **KEYNOTE B36**: A pilot study of **first-line tumor treating fields** (150 kHz) plus **pembrolizumab** for advanced or metastatic NSCLC. WCLC 2022;Abstract EP08.01-076.

Key Data Sets

Luis Paz-Ares, MD, PhD

- Forde PM et al. **Neoadjuvant nivolumab** plus chemotherapy in **resectable** lung cancer. *N Engl J Med* 2022;386(21):1973-85.
- Wakelee H et al. **IMpower010**: Overall survival interim analysis of a Phase III study of **atezolizumab** vs best supportive care in **resected** NSCLC. WCLC 2022;Abstract PL03.09.
- O'Brien M et al. **Pembrolizumab** versus placebo as **adjuvant** therapy for **completely resected** stage IB-IIIA non-small-cell lung cancer (**PEARLS/KEYNOTE-091**): An interim analysis of a randomised, triple-blind, phase 3 trial. *Lancet Oncol* 2022;23(10):1274-86.
- Spigel DR et al. **Five-year** survival outcomes from the **PACIFIC** trial: **Durvalumab** after chemoradiotherapy in **Stage III** non-small-cell lung cancer. *J Clin Oncol* 2022;40(12):1301-11.
- Senan S et al. Outcomes with **durvalumab** after chemoradiotherapy in **stage IIIA-N2** non-small-cell lung cancer: An **exploratory** analysis from the **PACIFIC** trial. *ESMO Open* 2022;7(2):100410.
- Girard N et al. **Real-world** overall survival (OS) with **durvalumab** (D) after chemoradiotherapy (CRT) in patients (pts) with unresectable Stage III non-small-cell lung cancer (NSCLC): Interim analysis from the **PACIFIC-R** study. ESMO Immuno-Oncology Congress 2022;Abstract 58O.

Key Data Sets

Luis Paz-Ares, MD, PhD (continued)

- Garassino MC et al. **Durvalumab** after sequential chemoradiotherapy in **Stage III, unresectable** NSCLC: The Phase 2 **PACIFIC-6** trial. *J Thorac Oncol* 2022;17(12):1415-27.
- Herbst RS et al. **COAST**: An open-label, Phase II, multidrug platform study of **durvalumab** alone or in combination with **oleclumab or monalizumab** in patients with **unresectable, Stage III** non-small-cell lung cancer. *J Clin Oncol* 2022;40(29):3383-93.
- Reck M et al. Brief report: Exploratory analysis of maintenance therapy in patients with **extensive-stage SCLC** treated **first line** with **atezolizumab** plus **carboplatin and etoposide**. *J Thorac Oncol* 2022;17(9):1122-9.
- Paz-Ares L et al. **Durvalumab**, with or without **tremelimumab**, plus platinum-etoposide in **first-line** treatment of extensive-stage small-cell lung cancer: **3-year** overall survival update from **CASPIAN**. *ESMO Open* 2022;7(2):100408.

Key Data Sets

Luis Paz-Ares, MD, PhD (continued)

- Aix SP et al. Combination **lurbinectedin** and doxorubicin versus physician's choice of chemotherapy in patients with **relapsed** small-cell lung cancer (**ATLANTIS**): A multicentre, randomised, open-label, **phase 3** trial. *Lancet Respir Med* 2023;11(1):74-86.
- Calles A et al. A phase 1/2 trial of **lurbinectedin** (L) in combination with **pembrolizumab** (P) in **relapsed** small cell lung cancer (SCLC): The **LUPER** study. ASCO 2022;Abstract 8581.
- Paz-Ares L et al. **Tarlatamab**, a first-in-class **DLL3-targeted bispecific T-cell engager**, in **recurrent** small cell lung cancer: An open-label, Phase I study. *J Clin Oncol* 2023;[Online ahead of print].
- Doi T et al. **DS-7300 (B7-H3 DXd** antibody-drug conjugate [**ADC**]) shows durable antitumor activity in advanced solid tumors: Extended follow-up of a phase I/II study. ESMO 2022;Abstract 453O.

Agenda

Introduction: Looking Back at Immuno-oncology Therapies (IOs)

MODULE 1: Metastatic Disease

MODULE 2: Localized Non-Small Cell Lung Cancer (NSCLC)

MODULE 3: Small Cell Lung Cancer (SCLC)

MODULE 4: Appendix

Agenda

Introduction: Looking Back at IOs

MODULE 1: Metastatic Disease

MODULE 2: Localized NSCLC

MODULE 3: SCLC

MODULE 4: Appendix

Agenda

Introduction: Looking Back at IOs

MODULE 1: Metastatic Disease

- Long-term data/perspective
  - IO monotherapy
  - IOs with chemotherapy
  - IO/CTLA-4 combinations
- Antibody-drug conjugates: Datopotamab deruxtecan (Dato-DXd), tusamitamab ravtansine
- Novel “basket” trials
- Tumor treating fields

MODULE 2: Localized NSCLC

MODULE 3: SCLC

MODULE 4: Appendix

Year in Review: Webinar Non-Targeted Lung Cancer

Heather Wakelee, MD, FASCO
Professor of Medicine, Oncology
Chief, Division of Medical Oncology
Interim Medical Director, Stanford Cancer Center
Stanford University School of Medicine
Deputy Director, Stanford Cancer Institute
President, International Association for the Study of Lung Cancer (IASLC)

IO Monotherapy

- Castro G Jr et al. Five-year outcomes with **pembrolizumab** versus chemotherapy as **first-line** therapy in patients with non-small-cell lung cancer and programmed death ligand-1 **tumor proportion score ≥ 1%** in the **KEYNOTE-042** study. *J Clin Oncol* 2022;[Online ahead of print].
- Özgüroğlu M et al. **Three years** survival outcome and continued **cemiplimab (CEMI) beyond progression** with the addition of chemotherapy (chemo) for patients (pts) with advanced non-small cell lung cancer (NSCLC): The **EMPOWER-Lung 1** trial. ESMO 2022;Abstract LBA54.
- Burotto Pichun M et al. **IMscin001** (**Part 2**: Randomized **Phase III**): Pharmacokinetics (PK), efficacy and safety of **atezolizumab (atezo) subcutaneous** (SC) vs intravenous (IV) in previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC). ESMO Immuno-Oncology Congress 2022;Abstract 61MO.
- Garassino MC et al. **Pembrolizumab** plus **pemetrexed** and **platinum** in **nonsquamous** non-small-cell lung cancer: **5-year** outcomes from the Phase 3 **KEYNOTE-189** study. *J Clin Oncol* 2023;[Online ahead of print].

IOs with Chemotherapy

- Novello S et al. **Pembrolizumab** plus **chemotherapy** in **squamous** non-small-cell lung cancer: **5-year** update of the Phase III **KEYNOTE-407** study. *J Clin Oncol* 2023;[Online ahead of print].
- Gogishvili M et al. **Cemiplimab plus chemotherapy** versus **chemotherapy** alone in non-small cell lung cancer: A randomized, controlled, double-blind phase 3 trial. *Nat Med* 2022;28(11):2374-80.

IO/CTLA-4 Combinations

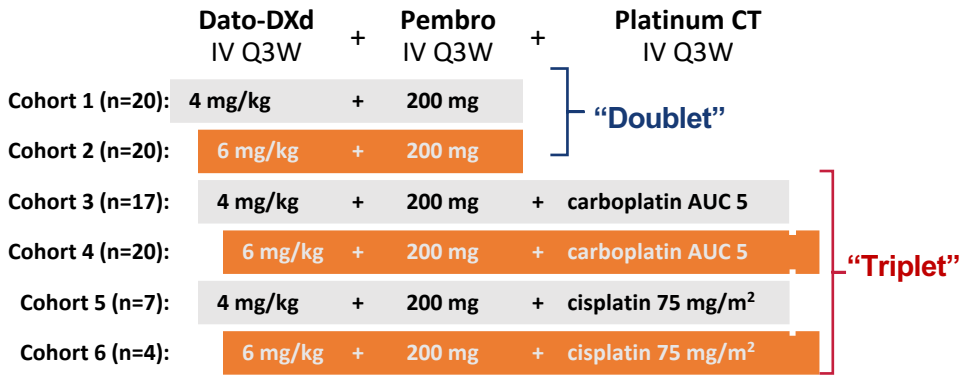
- Brahmer JR et al. **Five-year** survival outcomes with **nivolumab plus ipilimumab** versus chemotherapy as **first-line** treatment for metastatic non-small-cell lung cancer in **CheckMate 227**. *J Clin Oncol* 2023;41(6):1200-12.
- Paz-Ares LG et al. **First-line** (1L) **nivolumab (NIVO) + ipilimumab (IPI)** + **2 cycles** of **chemotherapy** (chemo) versus **chemo alone (4 cycles)** in patients (pts) with metastatic non–small cell lung cancer (NSCLC): **3-year** update from **CheckMate 9LA**. ASCO 2022;Abstract LBA9026.
- Johnson ML et al. **Durvalumab** with or without **tremelimumab** in combination with **chemotherapy** as **first-line** therapy for metastatic non-small-cell lung cancer: The **Phase III POSEIDON** study. *J Clin Oncol* 2023;41(6):1213-27.
- Johnson ML et al. **Durvalumab (D) ± tremelimumab (T)** + chemotherapy (CT) in **1L** metastatic (m) NSCLC: Overall survival (OS) update from **POSEIDON** after median follow-up (mFU) of approximately **4 years** (y). ESMO 2022;Abstract LBA59.

Antibody-Drug Conjugates: Dato-DXd, Tusamitamab Ravtansine

- Levy B et al. **TROPION-Lung02**: Initial results for **datopotamab deruxtecan** plus pembrolizumab and platinum chemotherapy in advanced NSCLC. WCLC 2022;Abstract MA13.07.
- Ricordel C et al. Safety and efficacy of **tusamitamab ravtansine** (SAR408701) in long-term treated patients with **nonsquamous** non–small cell lung cancer (NSQ NSCLC) expressing carcinoembryonic antigen-related cell adhesion molecule 5 (**CEACAM5**). ASCO 2022;Abstract 9039.
- Besse B et al. **HUDSON**: An open-label, **multi-drug**, **biomarker-directed**, Phase II platform study in patients with NSCLC, who progressed on anti-PD(L)1 therapy. WCLC 2022;Abstract OA15.05.

Levy B et al. TROPION-Lung02: Initial results for datopotamab deruxtecan plus pembrolizumab and platinum chemotherapy in advanced NSCLC. WCLC 2022;Abstract MA13.07

- **Dato-DXd ADC:** humanized TROP2 IgG1 mAb covalently linked to topoisomerase I inhibitor payload; via stable tetrapeptide-based cleavable linker
- **Study approach:** safety of Dato-DXd + pembro "doublets" was established prior to evaluation of platinum-containing "triplets"
  - Safety of Dato-DXd 4-mg/kg combinations was established prior to evaluation of 6-mg/kg combinations



Primary endpoint:
- Safety & tolerability

Secondary endpoints:
- Efficacy, pharmacokinetics, anti-drug antibodies

Patient baseline characteristics

Characteristic		Doublet (n=40)	Triplet (n=48)
Age, median (range), years		68 (44–77)	64 (33–84)
Male, n (%)		28 (70)	33 (69)
Histology, n (%)	Non-squamous	28 (70)	41 (85)
	Squamous	11 (28)	7 (15)
History of brain metastases, n (%)		8 (20)	10 (21)
PD-L1 expression, n (%)	<1%	13 (33)	21 (44)
	1–49%	13 (33)	14 (29)
	≥50%	12 (30)	11 (23)
Prior lines of therapy, median[c]		1	0
Previous systemic treatment, n (%)	Immunotherapy	12 (30)	18 (38%)
	Platinum CT	24 (60)	17 (35)
Dato-DXd combination line of therapy, n (%)	1L	13 (33)[d]	30 (63)[d]
	2L+	27 (68)[d]	18 (38)[d]

Courtesy of Heather Wakelee, MD

Levy B et al. TROPION-Lung02: Initial results for datopotamab deruxtecan plus pembrolizumab and platinum chemotherapy in advanced NSCLC. WCLC 2022;Abstract MA13.07

Antitumor activity

In the overall population:
ORRs (confirmed + pending):
- Double (n=38): 37%
- Triplet (n=37): 41%
- Both groups had 84% DCR

Best overall response with 1L therapy for advanced NSCLC[a,b]

Response, n (%)	Doublet (n=13)	Triplet (n=20)
ORR (confirmed + pending)	8 (62)	10 (50)
CR	0	0
PR (confirmed)	8 (62)	7 (35)
PR (pending)	0	3 (15)
SD	5 (39)	8 (40)
DCR	13 (100)	18 (90)

- As 2L+ therapy, respective ORRs (confirmed + pending) were 24% and 29%

Safety

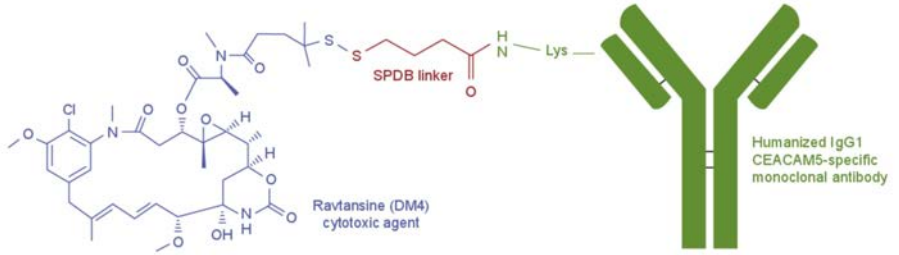
Events, n (%)	Doublet (n=40)	Triplet (n=48)
TEAEs	37 (93)	47 (98)
Study treatment-related[a]	33 (83)	46 (96)
Grade ≥3 TEAEs	16 (40)	29 (60)
Study treatment-related[a]	14 (35)	26 (54)
Serious TEAEs	9 (23)	13 (27)
Study treatment-related	4 (10)	7 (15)
TEAEs associated with		
Death[b]	2 (5)	1 (2)
Discontinuation due to any drug	9 (22)	9 (19)
Discontinuation due to Dato-DXd	6 (15)	5 (10)
ILD adjudicated as drug related		
Grade 1/2	2 (5)	0
Grade 3	1 (3)	1 (2)

- The Phase 3 TROPION-Lung08 trial (NCT05215340) is evaluating Dato-DXd + pembro vs pembro alone as 1L therapy in advanced/metastatic NSCLC with PD-L1 TPS >50%

Courtesy of Heather Wakelee, MD

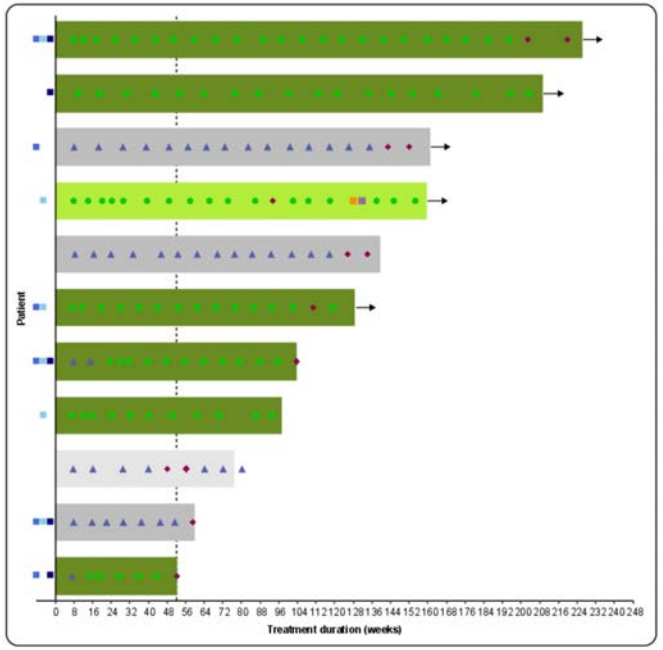
Ricordel C et al. Safety and efficacy of tusamitamab ravtansine (SAR408701) in long-term treated patients with nonsquamous non–small cell lung cancer (NSQ NSCLC) expressing carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5). ASCO 2022;Abstract 9039

Figure 1. Structure of tusamitamab ravtansine



Drug-to-antibody ratio is 3.8.[3]
CEACAM5, carcinoembryonic antigen-related cell adhesion molecule 5; DM4, ravtansine; IgG1, immunoglobulin G1; SPDB, N-succinimidyl 4-(2-pyridyldithio)butyrate.

- In previously reported results from an open-label Phase 1/2 study (NCT02187848), tusamitamab ravtansine showed promising antitumor activity in patients with heavily pretreated NSQ NSCLC[4]
  - Among 64 patients with high CEACAM5 expression, 13 (20.3%) had a confirmed partial response (PR) and 28 (43.8%) had stable disease (SD)
  - Of 28 moderate expressors of CEACAM5, 2 (7.1%) had confirmed PR and 15 (53.6%) had SD
- Herein we report results for patients with NSQ NSCLC and high or moderate CEACAM5 expression who were treated with tusamitamab ravtansine for ≥ 12 months as of April 14, 2022



Best overall response

- Non-responder / Moderate CEACAM5 expressor
- Non-responder / High CEACAM5 expressor
- Responder / Moderate CEACAM5 expressor
- Responder / High CEACAM5 expressor

11/92 patients had long responses

Courtesy of Heather Wakelee, MD

Besse B et al. HUDSON: An open-label, multi-drug, biomarker-directed, Phase II platform study in patients with NSCLC, who progressed on anti-PD(L)1 therapy. WCLC 2022;Abstract OA15.05

- Multidrug, nonrandomized umbrella phase II study (data cutoff April 14, 2021)
- **Primary endpoint:** ORR
- **Secondary endpoints:** DCR, PFS, OS, safety

HUDSON is an ongoing, modular phase II trial evaluating several treatment options
for patients with biomarker matched or nonmatched locally advanced/metastatic NSCLC after receipt of a platinum doublet and failure of anti–PD-1/PD-L1 immunotherapy
Current analysis reports results from cohorts of durvalumab in combination
with either ceralasertib (ATR inhibitor), danvatirsen (STAT3 inhibitor),
olaparib (PARP inhibitor), or oleclumab (anti-CD73 mAb)

Locally advanced or metastatic NSCLC; previous platinum-doublet chemotherapy and PD-1/PD-L1 targeted therapy; no *EGFR, ALK, ROS1, BRAF, MET,* or *RET* targetable mutations
(N = 225)

Group A: Biomarker Matched (n = 86)

- HRRm: durvalumab + olaparib (n = 21)
- LKB1: durvalumab + olaparib (n = 21)
- ATM: durvalumab + ceralasertib* (n = 21)
- ATM: ceralasertib*
- CD73h: durvalumab + oleclumab (n = 23)
- HER2e/m: durvalumab + trastuzumab deruxtecan†

Group B: Biomarker Nonmatched (n = 169)

Primary Resistance (PD‡ ≤24 Wk)

- Durvalumab + olaparib (n = 22)
- Durvalumab + danvatirsen (n = 23)
- Durvalumab + ceralasertib (n = 20)
- Durvalumab + oleclumab (n = 9)

Acquired Resistance (PD‡ >24 Wk)

- Durvalumab + olaparib (n = 23)
- Durvalumab + danvatirsen (n = 22)
- Durvalumab + ceralasertib (n = 25)
- Durvalumab + oleclumab (n = 25)
- Durvalumab + cediranib†

Courtesy of Heather Wakelee, MD

Besse B et al. HUDSON: An open-label, multi-drug, biomarker-directed, Phase II platform study in patients with NSCLC, who progressed on anti-PD(L)1 therapy. WCLC 2022;Abstract OA15.05 — PFS/OS by Treatment

Efficacy Parameter	Durvalumab + Ceralasertib (n = 66)	Durvalumab + Olaparib (n = 87)	Durvalumab + Danvatirsen (n = 45)	Durvalumab + Oleclumab (n = 57)
ORR (primary endpoint), %	16.7	4.6	0	1.8
Median PFS, mo (80% CI)	6.0 (4.6-7.5)	2.7 (1.6-3.0)	2.9 (1.7-3.1)	1.8 (1.6-2.7)
6-mo PFS, % (80% CI)	46.3 (37.9-54.2)	18.7 (13.5-24.5)	18.8 (11.5-27.6)	16.6 (10.8-23.6)

OS Parameter	Durvalumab + Ceralasertib (n = 66)	Other Regimens* (n = 189)	Durvalumab + Olaparib (n = 87)	Durvalumab + Danvatirsen (n = 45)	Durvalumab + Oleclumab (n = 57)
Median OS, mo (80% CI)	15.9 (14.1-20.3)	9.4 (7.5-10.6)	9.4 (6.9-10.8)	7.9 (6.0-10.6)	11.0 (7.6-13.5)
12-mo OS, % (80% CI)	61.6 (53.4-68.8)	39.7 (35.1-44.3)	40.8 (34.0-47.5)	28.8 (20.2-38.0)	46.2 (37.5-54.5)

*Pooled internal control of durvalumab + olaparib, durvalumab + danvatirsen, and durvalumab + oleclumab.

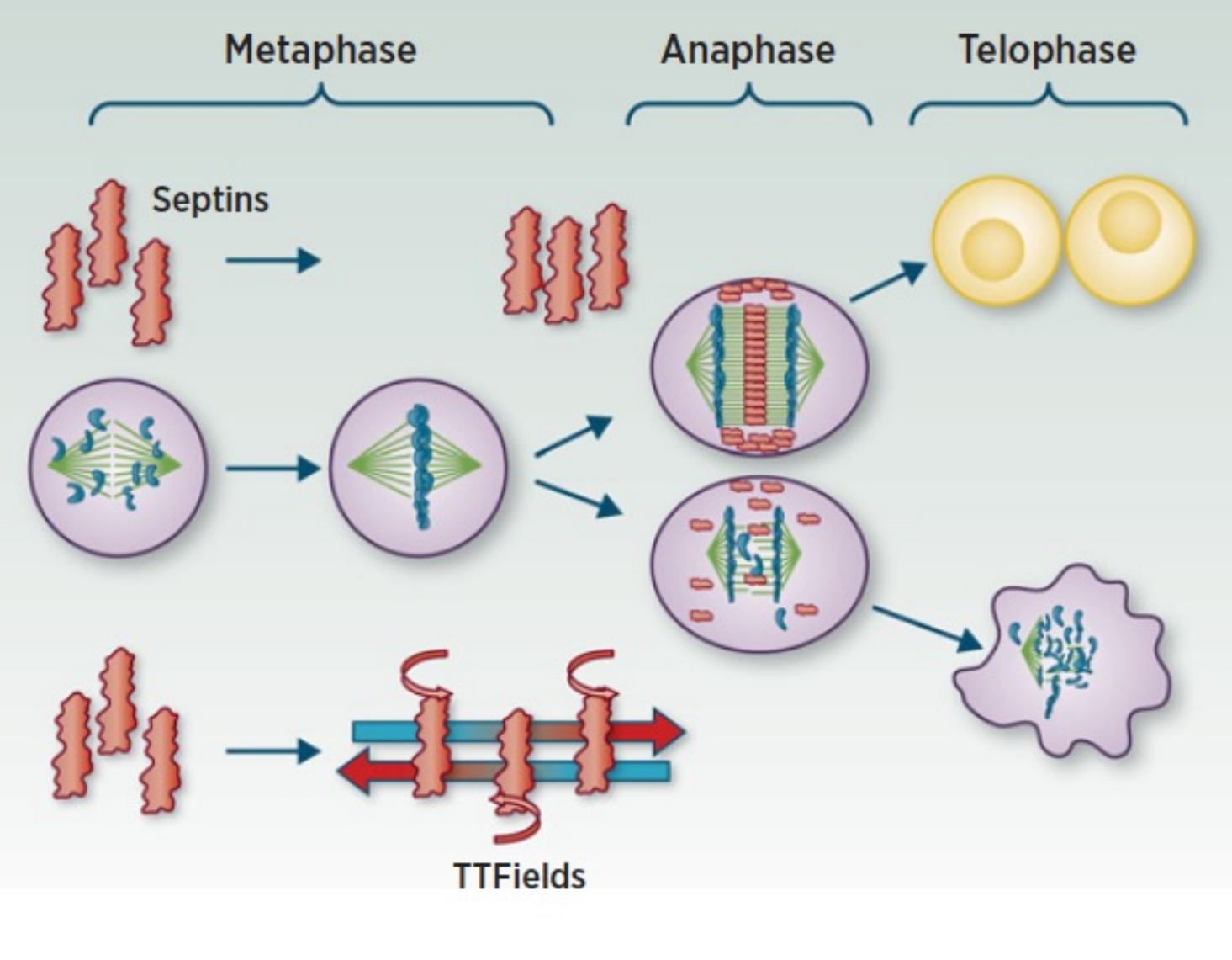
In this umbrella phase II study, durvalumab + ceralasertib showed promising activity HUDSON remains ongoing,

Courtesy of Heather Wakelee, MD

Tumor Treating Fields

- Kotecha R et al. **KEYNOTE B36**: A pilot study of **first-line tumor treating fields** (150 kHz) plus **pembrolizumab** for advanced or metastatic NSCLC. WCLC 2022;Abstract EP08.01-076.

Model for Tumor Treating Fields (TTFields) Leading to Mitotic Disruption



- Successful mitosis requires precise spatial and temporal alignment of polarizable or charged structures, notably tubulin and septin, at various stages of cell division
- TTFields are able to inhibit the propagation of lattice formation by disrupting the ability of individual fibers to bind each other.
- In the absence of proper septin function, contractile elements of the cytokinetic furrow are not restrained within the equatorial midline of the cell resulting in ectopic furrow malfunction that leads to violent membrane contractions at the onset of anaphase followed by aberrant mitotic exit.

Mun EJ et al. *Clin Cancer Res* 2018;24(2):266-75.

TTFields Application in the Clinic: Apparatus

Second-generation Optune® device

The complete system consists of

A. Electric field generator

B. Rechargeable battery pack

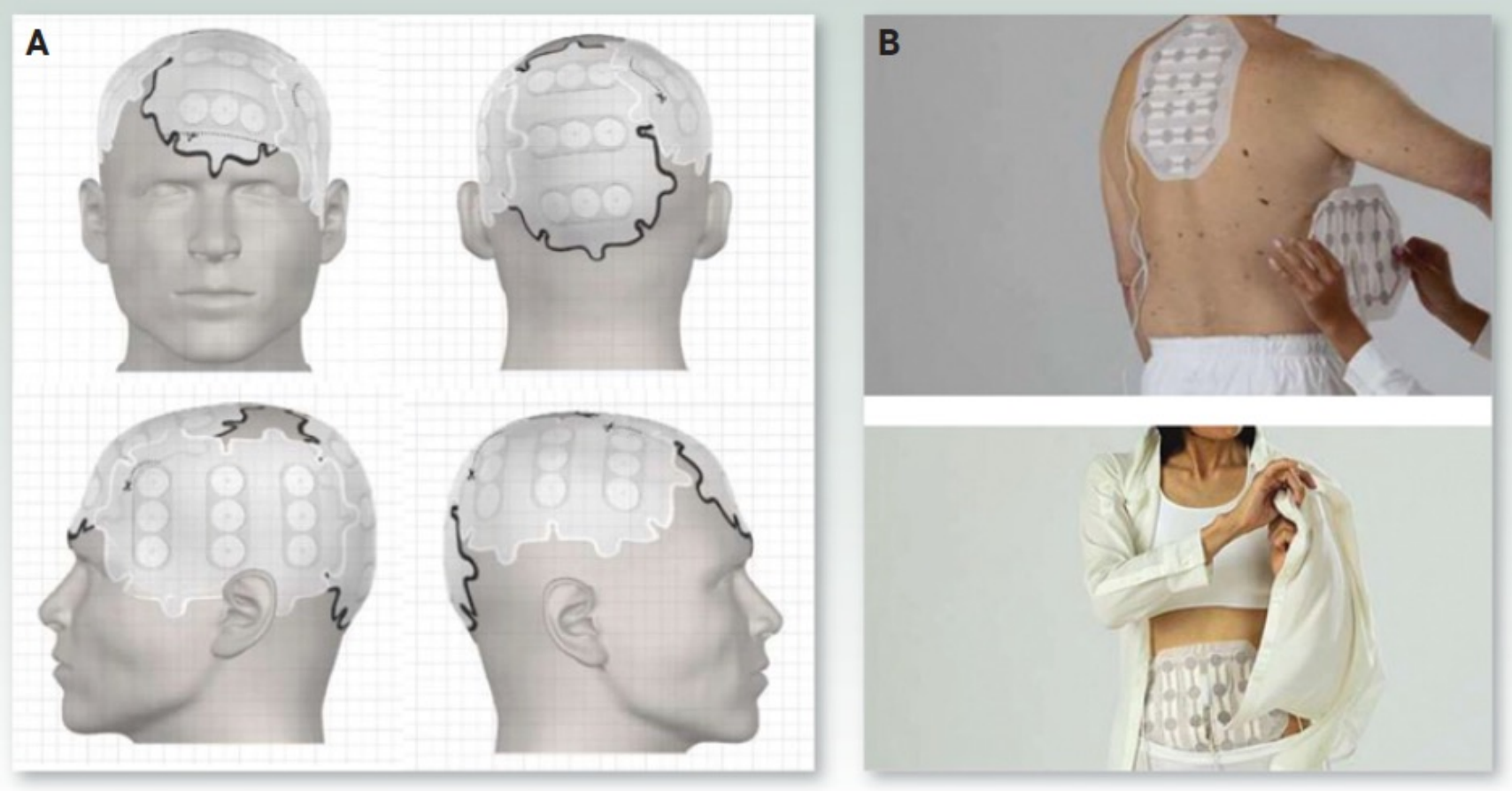
C. Carrying pouch

D. Two pairs of disposable ceramic transducer arrays

Mun EJ et al. *Clin Cancer Res* 2018;24(2):266-75.

RTP Year in Review 2023

TTFields Application in the Clinic: Transducer Array Placement



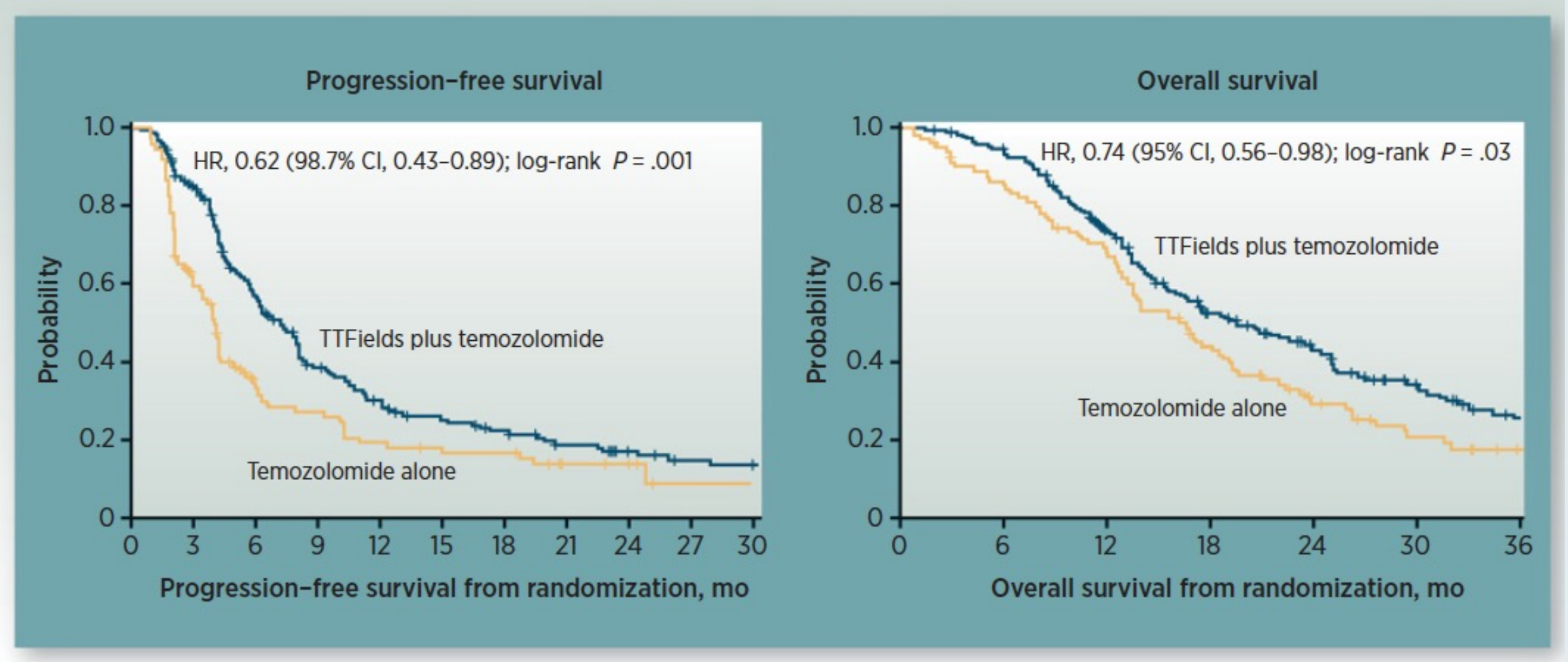
A. For glioblastoma multiforme, placement of arrays on patient's shaved scalp. An array map used as guidance for optimal placement of transducer arrays based on tumor size and location.

The array map is personalized for each patient and generated using NovoTAL™ System software. The customization of the array layout is dependent on the patient's size and location of the tumor.

B. Transducer arrays attached to the device, Optune, are placed on patient's body, for lung cancer (top) and ovarian cancer (bottom).

Mun EJ et al. *Clin Cancer Res* 2018;24(2):266-75.

EF-14: Results from a Phase III Trial of TTFields/Temozolomide versus Temozolomide Alone for Newly Diagnosed Glioblastoma



Mun EJ et al. *Clin Cancer Res* 2018;24(2):266-75; Stupp R et al. *JAMA* 2015;314(23):2535-43.

A phase I/II trial of Tumor Treating Fields (TTFields) therapy in combination with pemetrexed for advanced non-small cell lung cancer

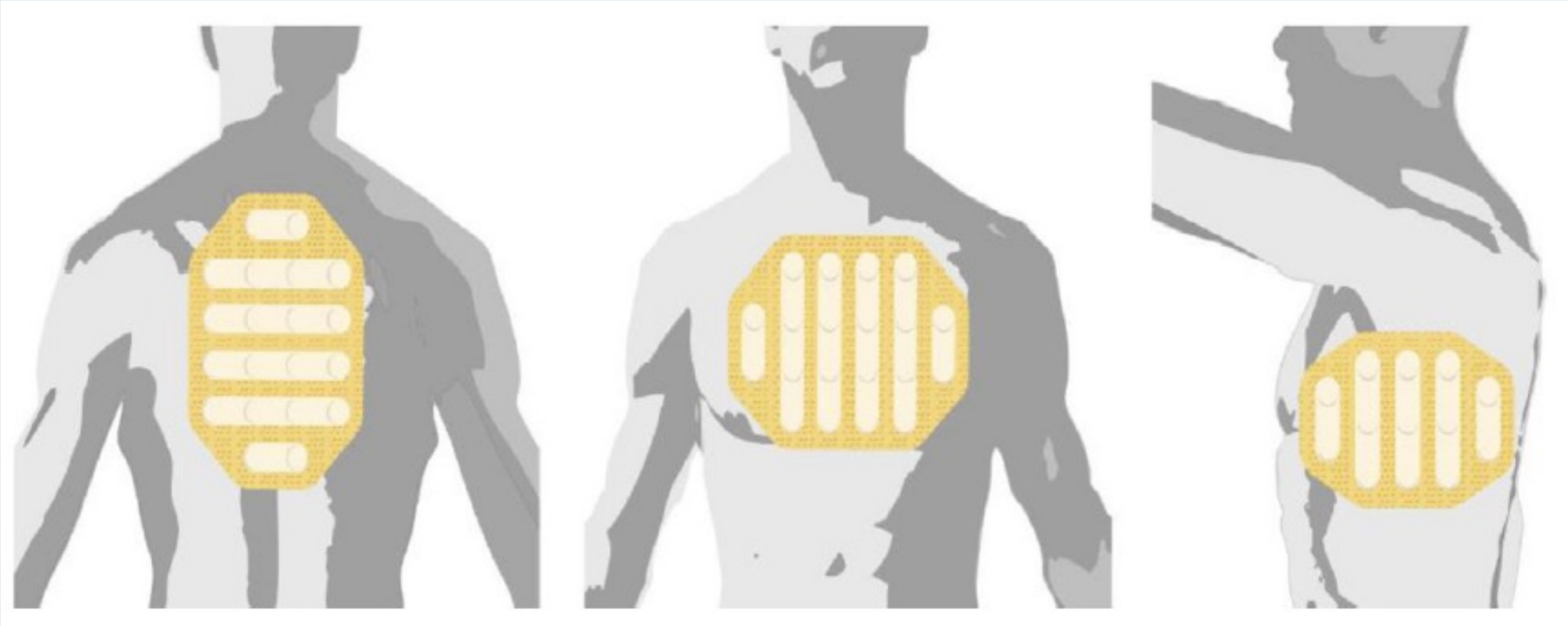
Miklos Pless[a,*], Cornelia Droege[b], Roger von Moos[c], Marc Salzberg[d], Daniel Betticher[e]

[a] *Medical Oncology, Kantonsspital Winterthur, Switzerland*
[b] *Medical Oncology, University Hospital Basel, Switzerland*
[c] *Medical Oncology, Kantonsspital Graubünden, Switzerland*
[d] *Medpace Inc., USA*
[e] *Medical Oncology, Cantonal Hospital Fribourg, Switzerland*

JAMA 2015;314(23):2535-43.

Author Conclusions: *"The combination of TTFields and pemetrexed as a second line therapy for NSCLC is safe and potentially more effective than pemetrexed alone. TTFields improved disease control within the treatment field and a Phase III study is planned to further investigate its role as a novel treatment in NSCLC."*

TTFields in Combination with Pemetrexed for Advanced NSCLC: Electrode Application Sites



Four single-use transducer arrays are placed on the thorax so as to generate perpendicular fields in the chest of the patient

Pless M et al. *JAMA* 2015;314(23):2535-43.

Pivotal LUNAR Study in non-small cell lung cancer meets primary overall survival endpoint [press release]. Kotecha R et al. KEYNOTE B36: A pilot study of first-line tumor treating fields (150 kHz) plus pembrolizumab for advanced or metastatic NSCLC. WCLC 2022;Abstract EP08.01-076

- January 5, 2023: *The LUNAR study met its primary endpoint*
- Tumor Treating Fields (TTFields) are a locoregional, anti-mitotic treatment modality approved for glioblastoma and unresectable malignant pleural mesothelioma. Preclinical data have shown that TTFields induce immunogenic cell death and enhance the efficacy of PD-1 inhibitors
- The LUNAR study is a pivotal, open-label, randomized study evaluating the safety and efficacy of TTFields when used together with immune checkpoint inhibitors or docetaxel (experimental arm) versus immune checkpoint inhibitors or docetaxel alone (control arm) for patients with stage 4 NSCLC who progressed during or after platinum-based therapy
- The LUNAR study showed a statistically significant and clinically meaningful improvement in OS w/TTFields + ICI vs ICI alone and a positive trend in OS when patients were treated with TTFields and docetaxel versus docetaxel alone.. TTFields therapy was well tolerated by patients enrolled in the experimental arm of the study.
- KEYNOTE B36 (NCT04892472) is a multicenter, single arm, phase 2 open-label study designed to evaluate the safety and efficacy of TTFields (150 kHz) plus pembrolizumab for first-line treatment of advanced NSCLC

Promising novel therapy
Await full data
Unclear if patients will be accepting

Courtesy of Heather Wakelee, MD

Agenda

Introduction: Looking Back at IOs

MODULE 1: Metastatic Disease

MODULE 2: Localized NSCLC

- Adjuvant and neoadjuvant IO-containing regimens
- Locally advanced unresectable disease: Durvalumab alone or in combination, other studies

MODULE 3: SCLC

MODULE 4: Appendix

i+12
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UNIVERSIDAD COMPLUTENSE MADRID

Year in Review — Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology: Immunotherapy and other Non-Targeted Approaches for Lung Cancer Edition

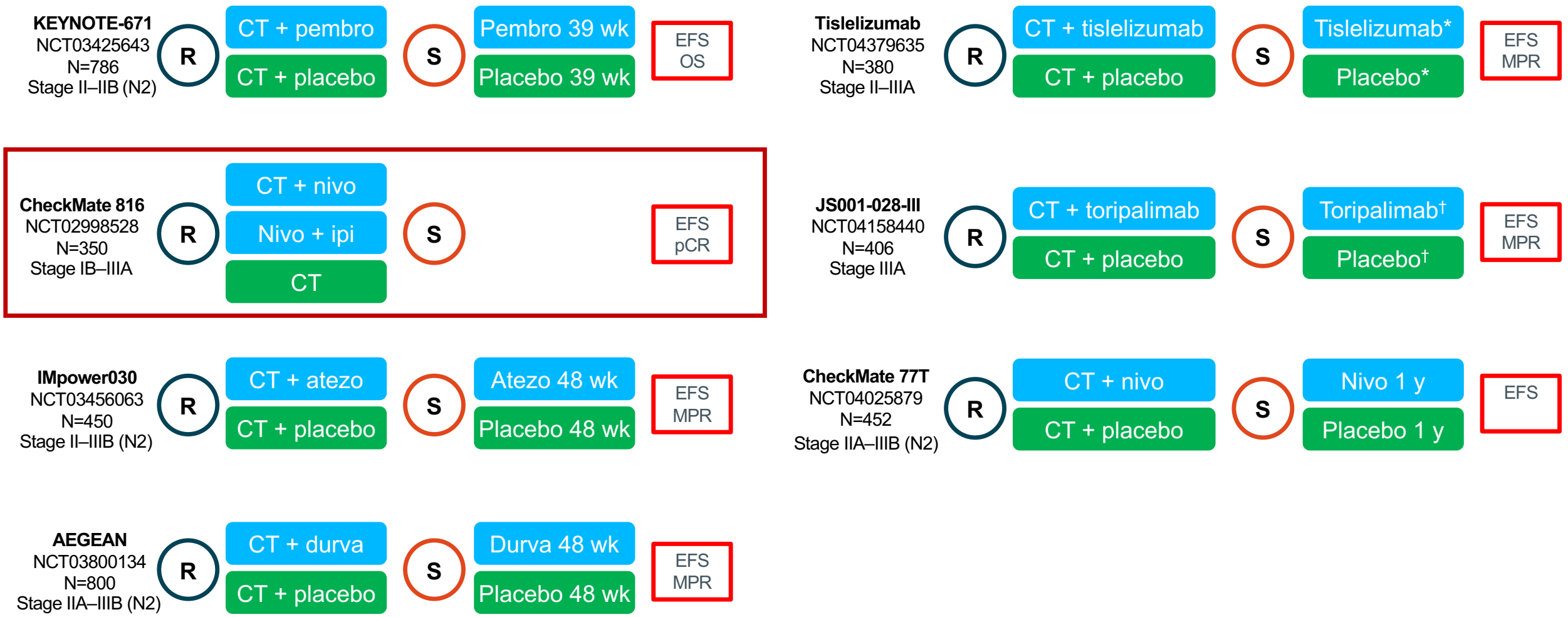
Luis Paz-Ares

Hospital Universitario 12 de Octubre

Adjuvant and Neoadjuvant IO-Containing Regimens

- Forde PM et al. **Neoadjuvant nivolumab** plus chemotherapy in **resectable** lung cancer. *N Engl J Med* 2022;386(21):1973-85.
- Wakelee H et al. **IMpower010**: Overall survival interim analysis of a Phase III study of **atezolizumab** vs best supportive care in **resected** NSCLC. WCLC 2022;Abstract PL03.09.
- O'Brien M et al. **Pembrolizumab** versus placebo as **adjuvant** therapy for **completely resected** stage IB-IIIA non-small-cell lung cancer (**PEARLS/KEYNOTE-091**): An interim analysis of a randomised, triple-blind, phase 3 trial. *Lancet Oncol* 2022;23(10):1274-86.

Ongoing Phase 3 perioperative IO trials



CT = chemotherapy; S = surgery.
*Up to 12 cycles of 21 or 42 days. †Duration not specified.

Courtesy of Luis Paz-Ares, MD, PhD

Durvalumab plus chemotherapy significantly improved pathologic complete response in AEGEAN Phase III trial in resectable non-small cell lung cancer

Phase 3 KEYNOTE-671 Trial met Primary Endpoint of Event-Free Survival (EFS) in patients with Resectable Stage II, IIIA, or IIB Non-Small Cell Lung Cancer

Courtesy of Luis Paz-Ares, MD, PhD

Positive High-Level Results Announced from the Phase III AEGEAN Trial Evaluating Durvalumab with Chemotherapy for Resectable NSCLC

Press Release – March 9, 2023

"Positive high-level results from a planned interim analysis of the AEGEAN Phase III, placebo-controlled trial showed that treatment with durvalumab in combination with neoadjuvant chemotherapy before surgery and as adjuvant monotherapy after surgery demonstrated a statistically significant and clinically meaningful improvement in event-free survival (EFS) versus neoadjuvant chemotherapy alone followed by surgery for patients with resectable early-stage (IIA-IIIB) non-small cell lung cancer (NSCLC).

Results from the final pathologic complete response (pCR) and major pathologic response (mPR) analyses were consistent with previously announced positive results. The trial will continue as planned to assess key secondary endpoints including disease-free survival (DFS) and overall survival (OS). ... Adding durvalumab to neoadjuvant chemotherapy was consistent with the known profile for this combination and did not increase complications or adverse events, or compromise patients' ability to undergo surgery versus chemotherapy alone.

These data will be presented at a forthcoming medical meeting and shared with global health authorities."

https://www.astrazeneca-us.com/media/press-releases/2023/imfinzi-significantly-improved-event-free-survival-in-aegean-phase-iii-trial-for-patients-with-resectable-non-small-cell-lung-cancer-03092023.html

RTP RESEARCH TO PRACTICE

Interim Analysis of the Phase III KEYNOTE-671 Trial Evaluating Pembrolizumab with Chemotherapy for Resectable NSCLC

Press Release – March 1, 2023

"[It was] announced today that the Phase 3 KEYNOTE-671 trial investigating [the anti-PD-1 therapy pembrolizumab] met one of its dual primary endpoints, event-free survival (EFS), as a perioperative treatment regimen for patients with resectable stage II, IIIA or IIIB non-small cell lung cancer (NSCLC). ... The trial will continue to evaluate the other dual primary endpoint of overall survival (OS).

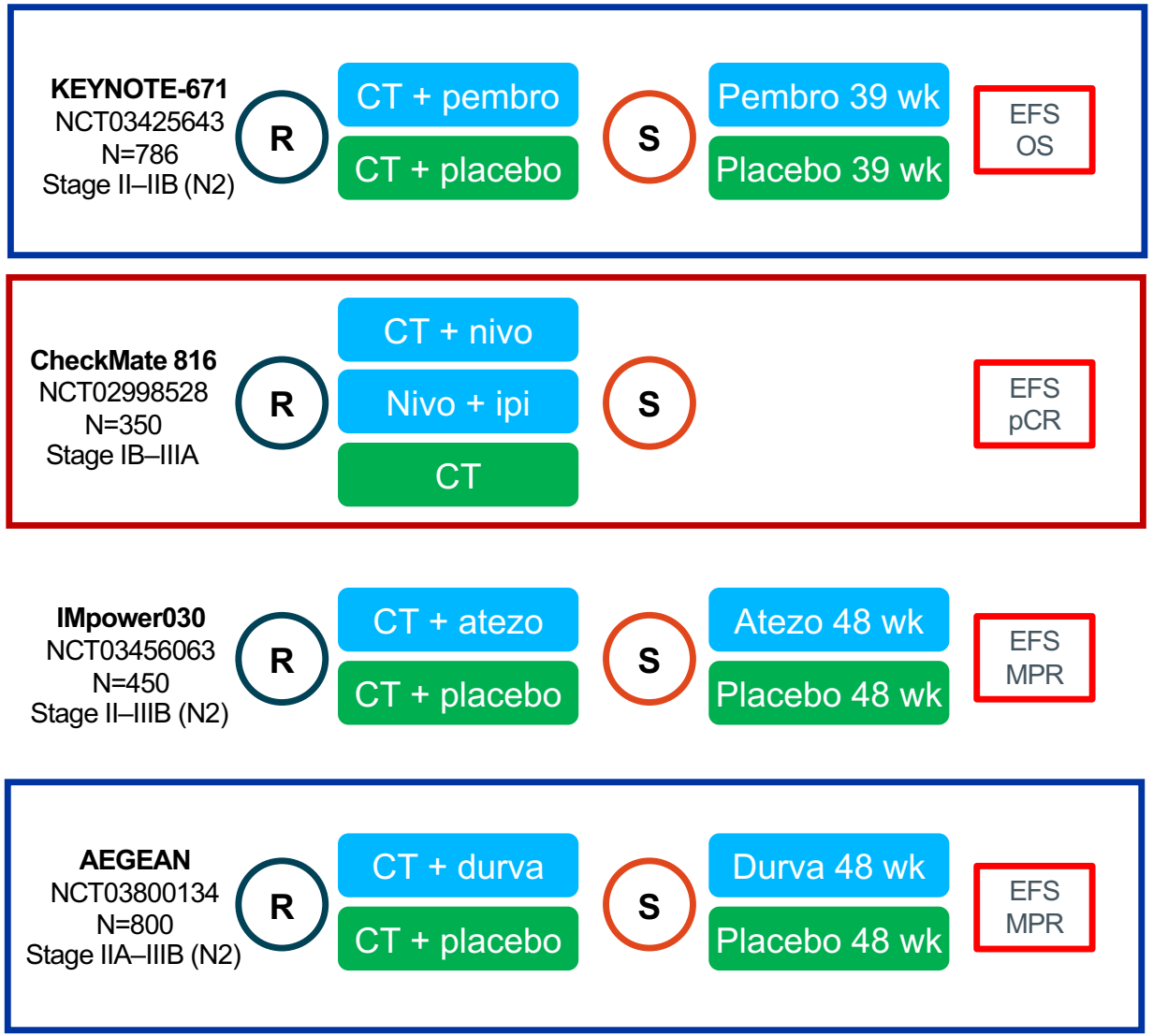
At a prespecified interim analysis conducted by an independent Data Monitoring Committee, neoadjuvant pembrolizumab plus chemotherapy followed by resection and adjuvant single-agent pembrolizumab demonstrated a statistically significant and clinically meaningful improvement in EFS compared to neoadjuvant placebo plus chemotherapy followed by adjuvant placebo. Statistically significant improvements in the trial's key secondary endpoints of pathological compete response (pCR) and major pathological response (mPR) were also demonstrated at this analysis. No new safety signals were observed.

Results will be presented at an upcoming medical meeting."

https://www.merck.com/news/merck-announces-phase-3-keynote-671-trial-met-primary-endpoint-of-event-free-survival-efs-in-patients-with-resectable-stage-ii-iiia-or-iiib-non-small-cell-lung-cancer/

RTP RESEARCH TO PRACTICE

Ongoing Phase 3 perioperative IO trials



CT = chemotherapy; S = surgery.
*Up to 12 cycles of 21 or 42 days. †Duration not specified.

Courtesy of Luis Paz-Ares, MD, PhD

Take home – Early stages

- Neoadjuvant chemo-IO (CM 816) improves pCR rates, EFS and OS in early stage resectable NSCLC
  - Outcome after pCR appears favourable, despite absence of adjuvant therapy
- Adjuvant IO decreases the probability of relapse (Atezo, Pembro) and appears to improve survival (Atezo)
  - Benefit proportional to PD-L1 expression (Atezo, Pembro??)
- Perioperative IO improves outcomes in resectable NSCLC
  - **Nadim (pCR, EFS, OS), Aegean (pCR) and KN 671 (EFS)**
  - Actual data awaited

Courtesy of Luis Paz-Ares, MD, PhD

Locally Advanced Unresectable Disease: Durvalumab Alone or in Combination, Other Studies

- Spigel DR et al. **Five-year** survival outcomes from the **PACIFIC** trial: **Durvalumab** after chemoradiotherapy in **Stage III** non-small-cell lung cancer. *J Clin Oncol* 2022;40(12):1301-11.
- Senan S et al. Outcomes with **durvalumab** after chemoradiotherapy in **stage IIIA-N2** non-small-cell lung cancer: An **exploratory** analysis from the **PACIFIC** trial. *ESMO Open* 2022;7(2):100410.
- Girard N et al. **Real-world** overall survival (OS) with **durvalumab** (D) after chemoradiotherapy (CRT) in patients (pts) with unresectable Stage III non-small-cell lung cancer (NSCLC): Interim analysis from the **PACIFIC-R** study. ESMO Immuno-Oncology Congress 2022;Abstract 58O.
- Garassino MC et al. **Durvalumab** after sequential chemoradiotherapy in **Stage III, unresectable** NSCLC: The Phase 2 **PACIFIC-6** trial. *J Thorac Oncol* 2022;17(12):1415-27.
- Herbst RS et al. **COAST**: An open-label, Phase II, multidrug platform study of **durvalumab** alone or in combination with **oleclumab or monalizumab** in patients with **unresectable, Stage III** non-small-cell lung cancer. *J Clin Oncol* 2022;40(29):3383-93.

Take home – Unresectable Stage III

- Durvalumab consolidation therapy (Pacific regimen) has a remarkable long term impact in unresectable stage III patient outcomes
  - Improved 5 year PFS (19% v 33%) and OS (33% v 43%)
  - Validation in RWD
  - Valid strategy as well following sequential chemo-radiotherapy
- Strategies of further treatment optimization include:
  - Consolidation with combination IO (durvalumab plus monalizumab or oleclumab) based on the encouraging Coast phase II results
  - Concurrent chemo-radio-immunotherapy approaches

Courtesy of Luis Paz-Ares, MD, PhD

Agenda

Introduction: Looking Back at IOs

MODULE 1: Metastatic Disease

MODULE 2: Localized NSCLC

MODULE 3: SCLC

- Current and future role of IOs; lurbinectedin
- Bispecific antibodies, antibody-drug conjugates (ADCs)

MODULE 4: Appendix

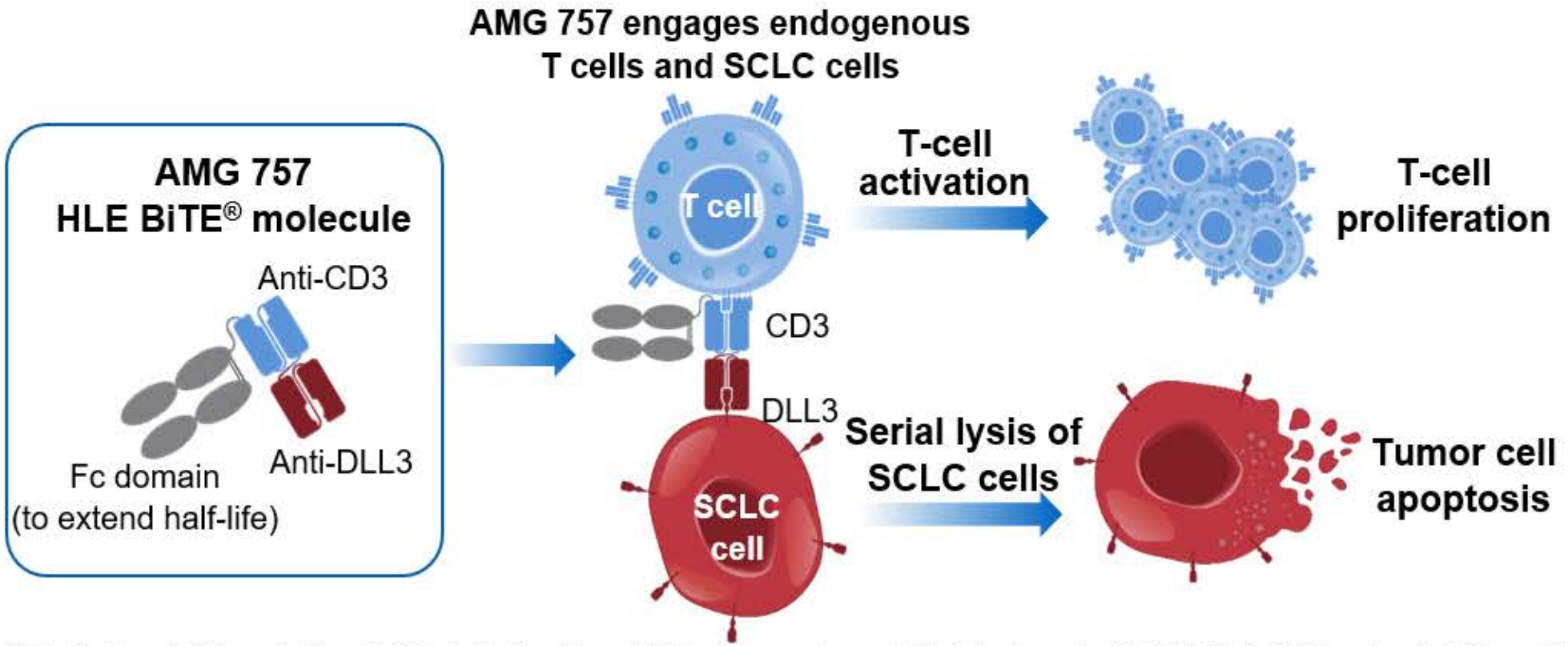
Current and Future Role of IOs; Lurbinectedin

- Reck M et al. Brief report: Exploratory analysis of maintenance therapy in patients with **extensive-stage SCLC** treated **first line** with **atezolizumab** plus **carboplatin and etoposide**. *J Thorac Oncol* 2022;17(9):1122-9.
- Paz-Ares L et al. **Durvalumab**, with or without **tremelimumab**, plus platinum-etoposide in **first-line** treatment of extensive-stage small-cell lung cancer: **3-year** overall survival update from **CASPIAN**. *ESMO Open* 2022;7(2):100408.
- Aix SP et al. Combination **lurbinectedin** and doxorubicin versus physician's choice of chemotherapy in patients with **relapsed** small-cell lung cancer (**ATLANTIS**): A multicentre, randomised, open-label, **phase 3** trial. *Lancet Respir Med* 2023;11(1):74-86.
- Calles A et al. A phase 1/2 trial of **lurbinectedin** (L) in combination with **pembrolizumab** (P) in **relapsed** small cell lung cancer (SCLC): The **LUPER** study. ASCO 2022;Abstract 8581.

Bispecifics Antibodies, ADCs

- Paz-Ares L et al. **Tarlatamab**, a first-in-class **DLL3-targeted bispecific T-cell engager**, in **recurrent** small cell lung cancer: An open-label, Phase I study. *J Clin Oncol* 2023;[Online ahead of print].
- Doi T et al. **DS-7300 (B7-H3 DXd** antibody-drug conjugate [**ADC**]) shows durable antitumor activity in advanced solid tumors: Extended follow-up of a phase I/II study. ESMO 2022;Abstract 453O.

AMG 757: 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.

- BiTE molecules engage a patient's own T cells to attack and eradicate cancer cells[1–3]

1.Stieglmaier J, et al. *Expert Opin Biol Ther*. 2015;15:1093-1099. 2. Einsele H, et al. *Cancer.* 2020;126:3192-3201.
3. Bargou R, et al. *Science.* 2008;321:974-977.

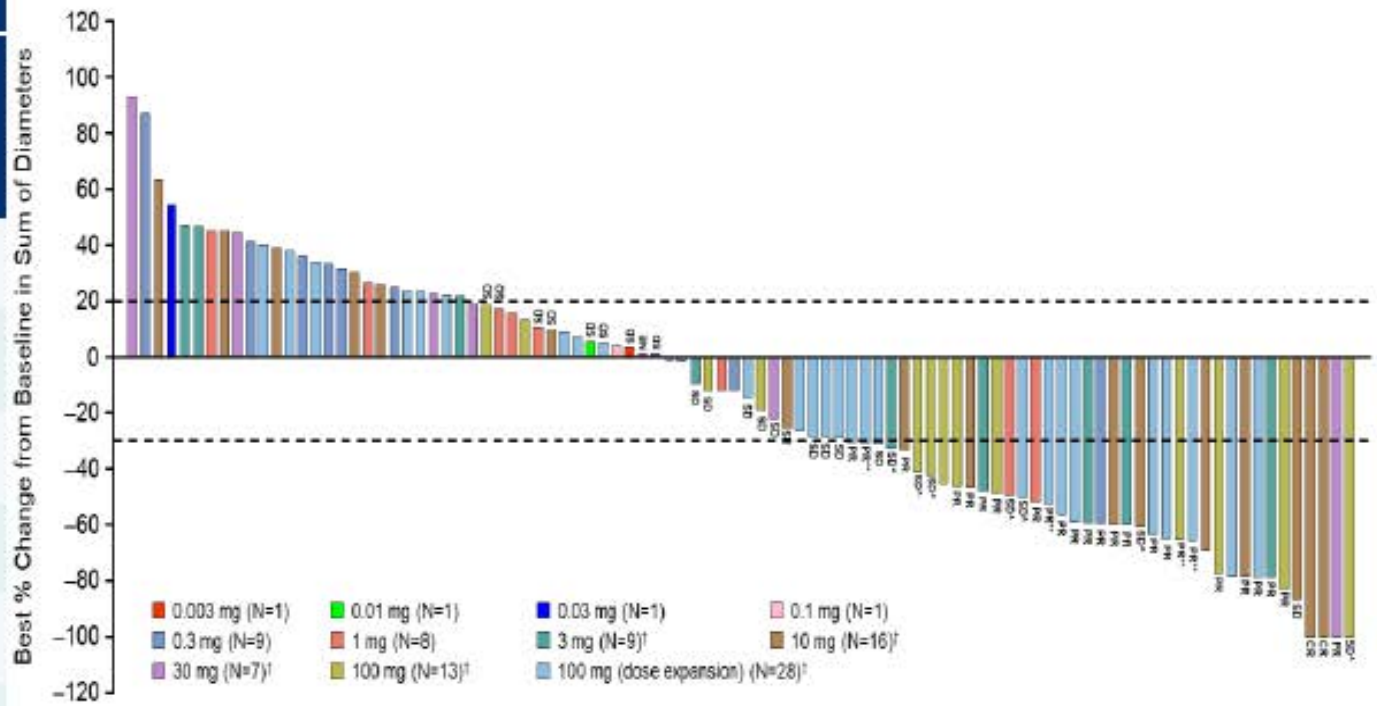
Courtesy of Luis Paz-Ares, MD, PhD

Tarlatamab FIH- Response and Safety

Treatment-Related Adverse Events Summary

Treatment-related AEs (by preferred term)	Patients (N = 106)	
	All Grades, n (%)	Grade ≥ 3, n (%)*
Any treatment-related AE	97 (92)	33 (31)
Treatment-related AEs occurring in > 15% of patients (by preferred term)		
CRS	56 (53)	1 (1)
Pyrexia	40 (38)	2 (2)
Dysgeusia	24 (23)	0
Fatigue	23 (22)	3 (3)
Nausea	21 (20)	0

Tarlatamab Induces Response in Previously Treated SCLC



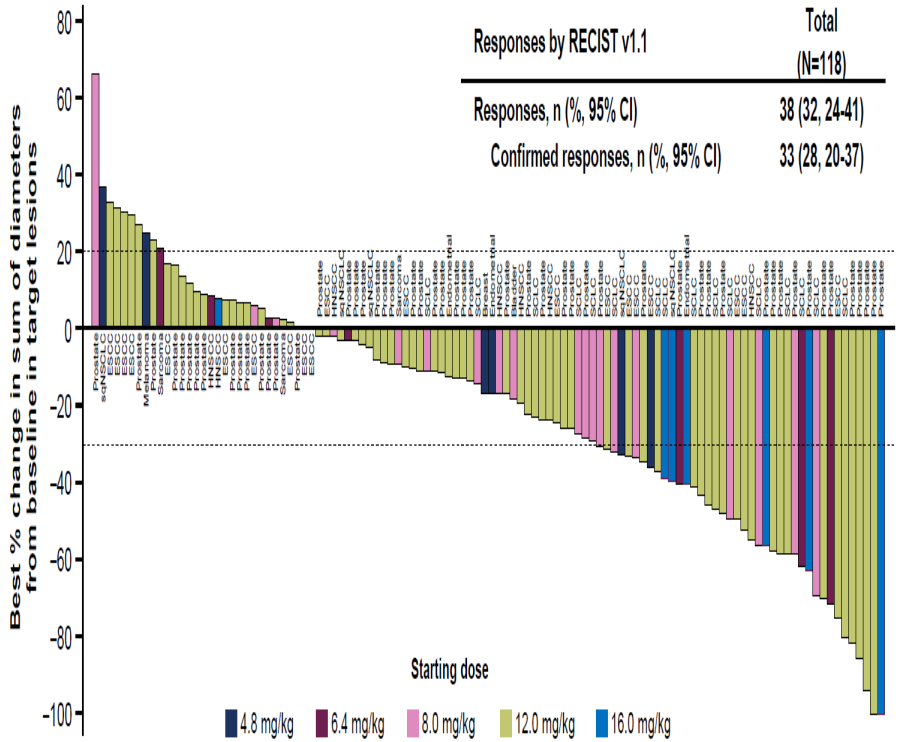
Confirmed ORR, 23% (2 CRs, 22 PRs);
37% of patients with tumor shrinkage ≥ 30%

Courtesy of Luis Paz-Ares, MD, PhD

Paz-Ares et al. J Clin Oncol 2023

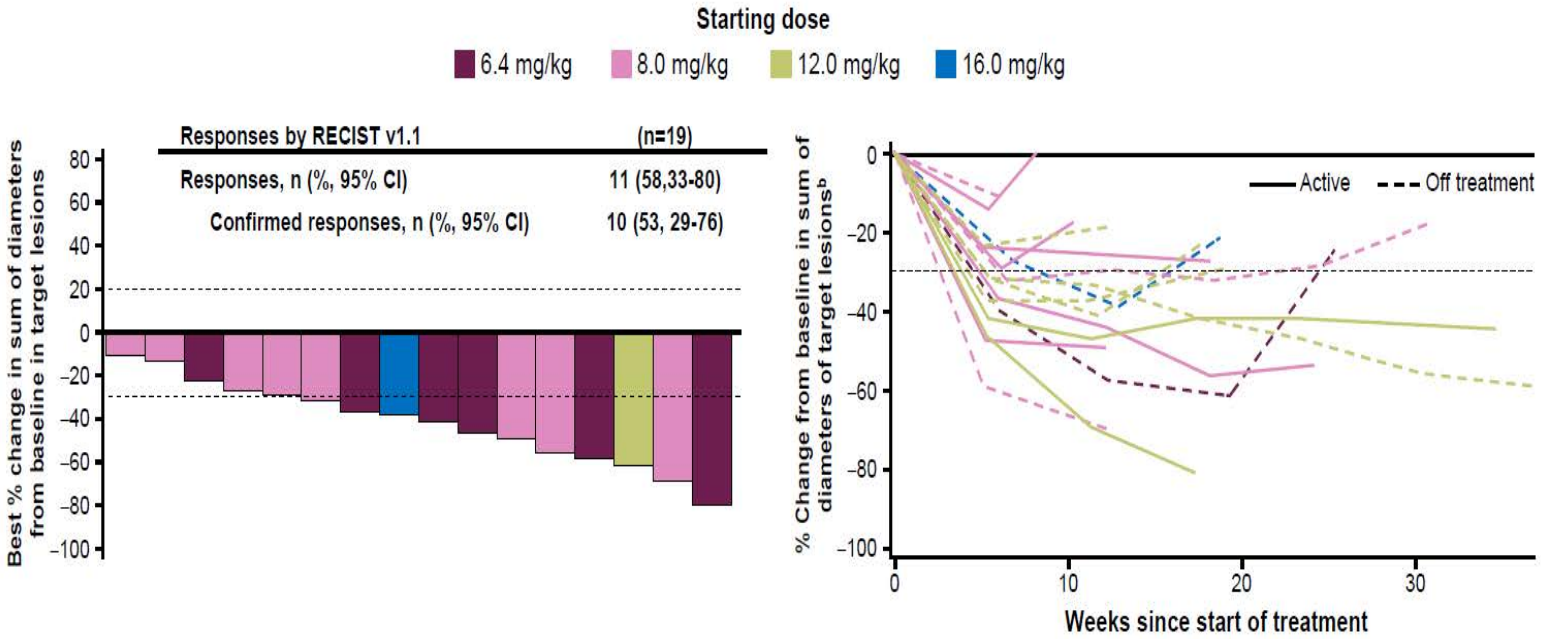
Ifinatamab deruxtecan (DS 7300)- An ADC targeting B7H3

Preliminary Efficacy Across Tumor Types[a]



DCO, data cutoff; ESCC, esophageal squamous cell carcinoma; HNSCC, head and neck squamous cell carcinoma; mCRPC, metastatic castration-resistant prostate cancer; RECIST, Response Evaluation Criteria in Solid Tumours; SCLC, small cell lung cancer; sqNSCLC, squamous non-small cell lung cancer.
[a] Patients from dose escalation and expansion parts with measurable disease at baseline and a least 2 post-baseline tumor scans and/or discontinued the treatment at DCO are included in best overall response calculations.

Antitumor Activity: SCLC Subset[a]



- All patients with a post-baseline scan had a reduction in target lesions
- Median time to response was 1.2 months (95% CI, NA-1.4)
- Median duration of response was 5.5 months (95% CI, 2.8-NR); 4 responders remain on treatment
- Median follow-up (months [95% CI]): 4.9 (3.3-8.8)

CR, complete response; DCO, data cutoff; NA, not available; NR, not reached; RECIST, Response Evaluation Criteria in Solid Tumours; SCLC, small cell lung cancer.
[a] Patients from dose escalation with measurable disease at baseline and a least 2 post-baseline tumor scans and/or discontinued the treatment at DCO are included in best overall response calculations. 3 patients did not have post-baseline tumor scans and are not included in the waterfall or spider plots. [b] 80% reduction is considered CR because the remaining target lesions/nontarget lesions (lymph nodes) are nonpathologic (those with short axis <10 mm).

Courtesy of Luis Paz-Ares, MD, PhD

T Doi et al. ESMO 2022

Take home – SCLC

- PE plus PD-L1/PD-1 blockade represents the standard of care in front-line SCLC-EE
  - Substantial impact in the long term: Tripled survival at 3 years

- Encouraging preliminary data with a number of approaches in the relapse setting
  - Lurbinectedin in combination with IO (atezolizumab, pembrolizumab) but not with doxorubicin (ATLANTIS trial)
  - Tarlatamab and DS 7300.

Courtesy of Luis Paz-Ares, MD, PhD

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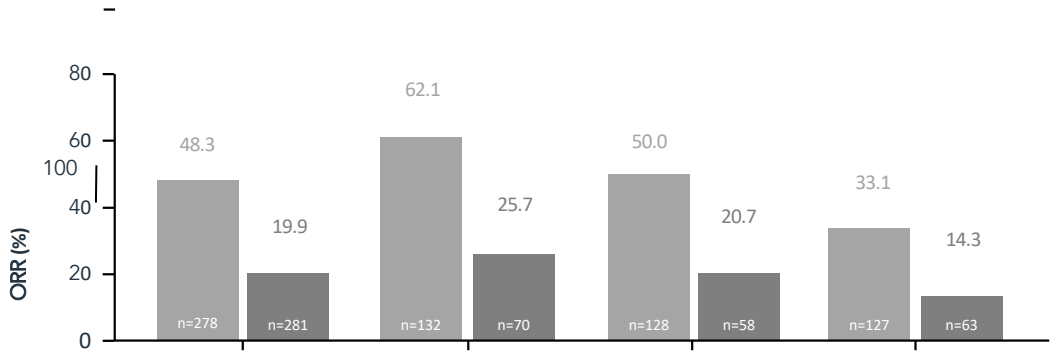
Metastatic Disease

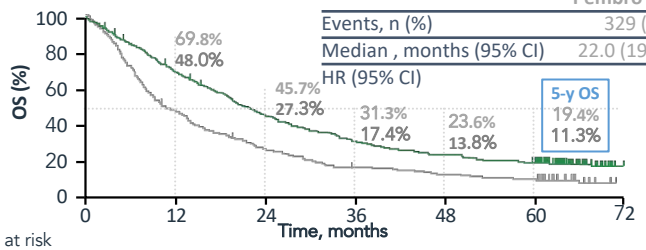
Garassino MC et al. Pembrolizumab plus pemetrexed and platinum in nonsquamous non-small-cell lung cancer: 5-year outcomes from the Phase 3 KEYNOTE-189 study. J Clin Oncol 2023

Tumor response



	ITT		PD-L1 TPS ≥50%		PD-L1 TPS 1% - 49%		PD-L1 TPS <1%	
	Pembro + chemo	Placebo + chemo	Pembro + chemo	Placebo + chemo	Pembro + chemo	Placebo + chemo	Pembro + chemo	Placebo + chemo
DOR[b] Median (range),[b] months	12.7 (1.1+ to 68.3+)	7.1 (2.4 to 31.5)	15.3 (1.2+ to 68.3+)	7.1 (3.4 to 31.5)	13.6 (2.1+ to 67.6+)	7.6 (2.4 to 31.0+)	10.8 (1.1 to 59.4+)	7.8 (4.1 to 28.3+)

OS (ITT population)



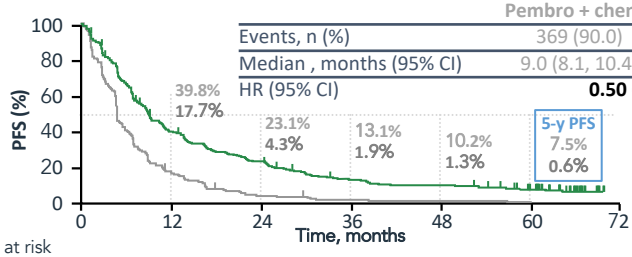
	Pembro + chemo	Placebo + chemo
Events, n (%)	329 (80.2)	183 (88.8)
Median , months (95% CI)	22.0 (19.5, 24.5)	10.6 (8.7, 13.6)
HR (95% CI)	**0.60 (0.50, 0.72)**	

No. at risk

Pembro + chemo	410	283	184	126	95	77	0
Placebo + chemo	206	96	55	34	27	22	0

	PD-L1 TPS ≥50%		PD-L1 TPS 1% - 49%		PD-L1 TPS <1%	
	Pembro + chemo (n=132)	Placebo + chemo (n=70)	Pembro + chemo (n=128)	Placebo + chemo (n=58)	Pembro + chemo (n=127)	Placebo + chemo (n=63)
OS HR (95% CI)	0.68 (0.49, 0.96)		0.65 (0.46, 0.90)		0.55 (0.39, 0.76)	
5-y OS rate[b], %	29.6	21.4	19.8	7.7	9.6	5.3

PFS (ITT population)



	Pembro + chemo	Placebo + chemo
Events, n (%)	369 (90.0)	201 (97.6)
Median , months (95% CI)	9.0 (8.1, 10.4)	4.9 (4.7, 5.5)
HR (95% CI)	**0.50 (0.42, 0.60)**	

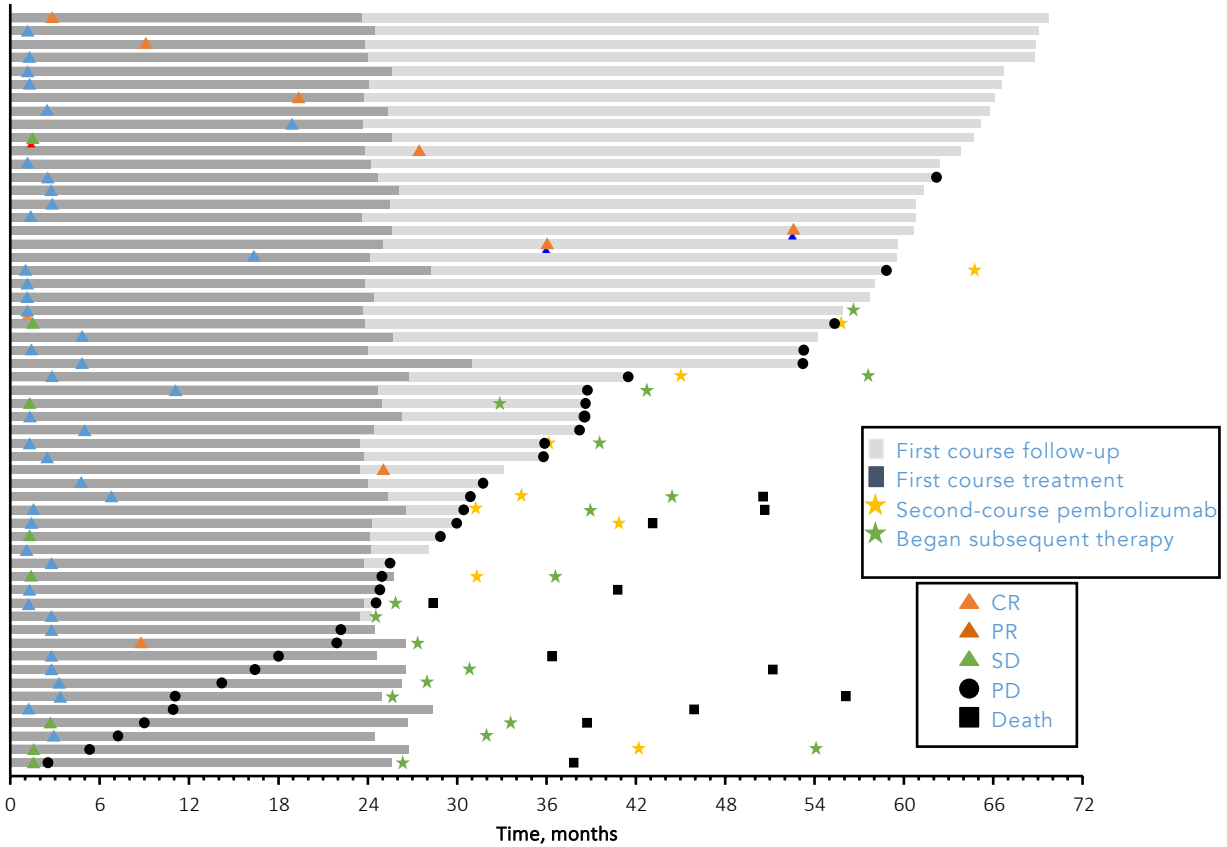
No. at risk

Pembro + chemo	410	158	91	49	37	21	0
Placebo + chemo	208	35	8	3	2	1	0

	PD-L1 TPS ≥50%		PD-L1 TPS 1% - 49%		PD-L1 TPS <1%	
	Pembro + chemo (n=132)	Placebo + chemo (n=70)	Pembro + chemo (n=128)	Placebo + chemo (n=58)	Pembro + chemo (n=127)	Placebo + chemo (n=63)
PFS HR (95% CI)	0.35 (0.25, 0.49)		0.57 (0.41, 0.80)		0.67 (0.49, 0.92)	
5-y PFS rate[b], %	12.8	0	6.5	1.9	2.4	0

Courtesy of Heather Wakelee, MD

Garassino MC et al. Pembrolizumab plus pemetrexed and platinum in nonsquamous non-small-cell lung cancer: 5-year outcomes from the Phase 3 KEYNOTE-189 study. J Clin Oncol 2023



	N=57
ORR (95% CI),[a] %	86.0 (74.2, 93.7)
Best overall response, n (%)	
CR	8 (14.0)
PR	41 (71.9)
Median DOR (range),[b] months	57.7 (4.2–68.3)
3-year OS rate after completing 35 cycles[c]	71.9%
Alive without PD or subsequent therapy, n (%)	23 (40.4)

- This update confirms long-term benefit of the KN189 regimen including OS, despite crossover
- Benefit is seen regardless of PD-L1 level, but best survival in those with high PD-L1
- Reporting long term benefit of the long term responders is biased

Courtesy of Heather Wakelee, MD

Johnson ML et al. Durvalumab with or without tremelimumab in combination with chemotherapy as first-line therapy for metastatic non-small-cell lung cancer: The Phase III POSEIDON study. J Clin Oncol 2023;41(6):1213-27; ESMO 2022 4 yr survival update LBA59

N=1013

Key eligibility

- Stage IV NSCLC
- No *EGFR* or *ALK* alterations
- Treatment naïve for metastatic disease
- ECOG PS 0–1

R 1:1:1

- **Durvalumab** 1500 mg + CT Q3W (4 cycles) followed by maintenance
- **Durvalumab** 1500 mg + **tremelimumab** 75 mg +CT* Q3W (4 cycles) followed by maintenance
- **Platinum-based CT** Q3W (up to 6 cycles) followed by maintenance

Stratification factors

- PD-L1 expression
- Disease stage
- Histology

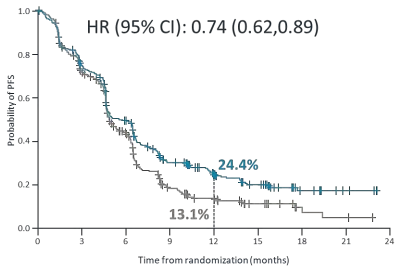
Primary endpoints:

- PFS (BICR)
- OS

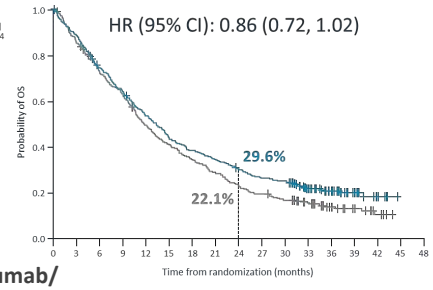
Key secondary endpoints:

- ORR, DoR, BOR
- HRQoL Safety

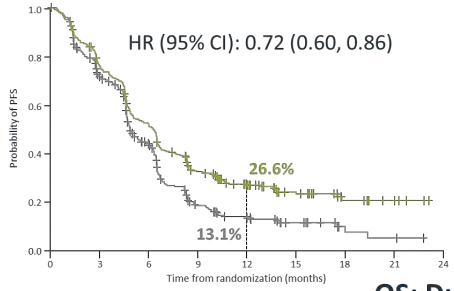
PFS: Durvalumab +chemo vs chemo[1]



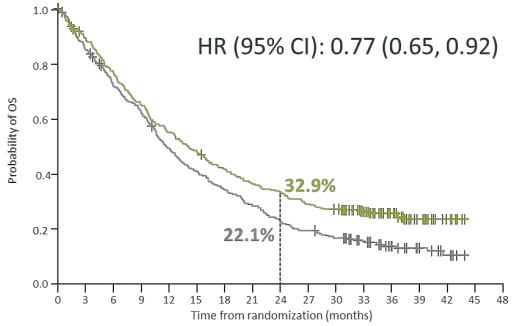
OS: Durvalumab + chemo vs chemo[1]



PFS: Durvalumab + tremelimumab/ chemo vs chemo[1]

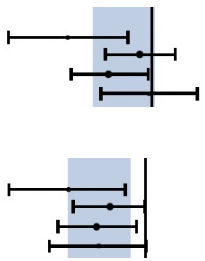


OS: Durvalumab + tremelimumab/ chemo vs chemo[1]



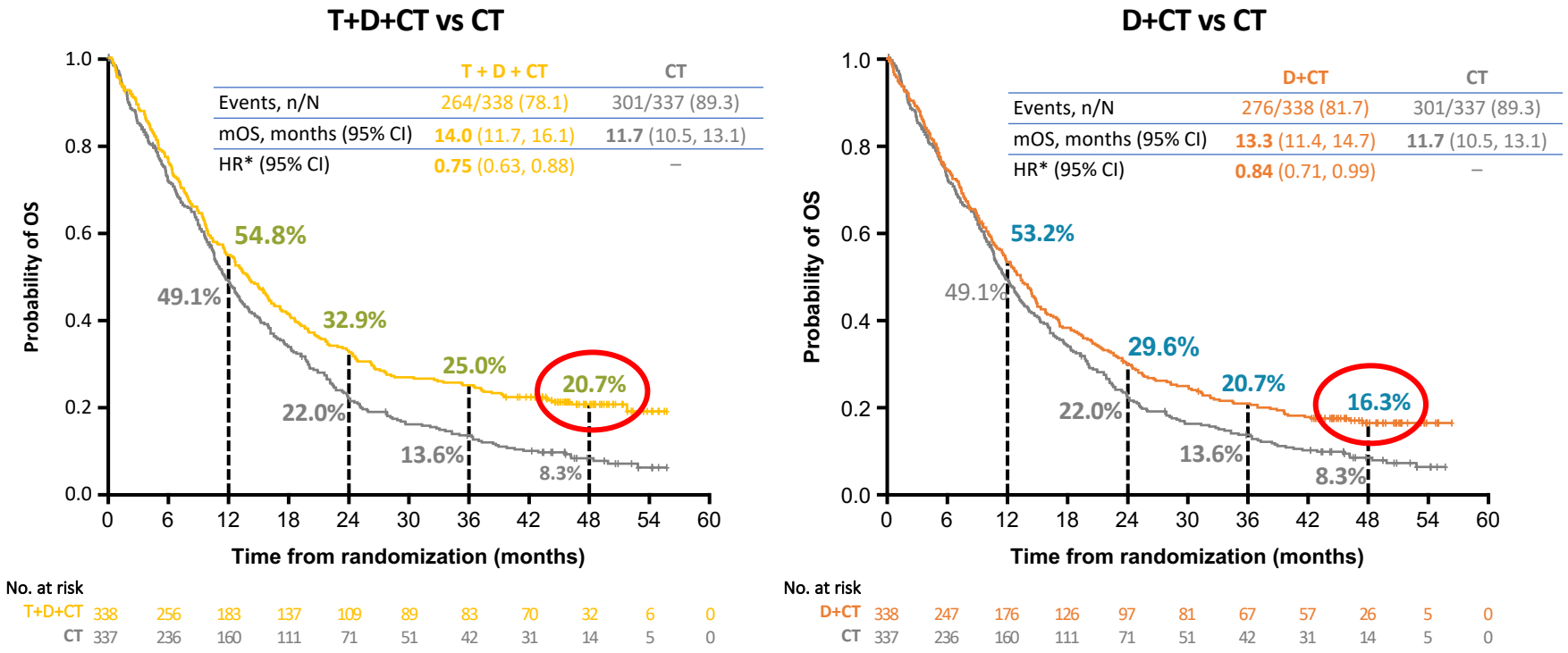
Tumor PD-L1 expression	D+C	C	HR
TC ≥ 50%	64/94	80/97	0.63 (0.45 to 0.88)
TC < 50%	200/243	205/240	0.94 (0.77 to 1.14)
TC ≥ 1%	165/224	170/207	0.79 (0.64 to 0.98)
TC < 1%	99/113	115/130	0.99 (0.76 to 1.30)

Tumor PD-L1 expression	T+D+C	C	HR
TC ≥ 50%	69/101	80/97	0.65 (0.47 to 0.89)
TC < 50%	182/237	205/240	0.82 (0.67 to 1.00)
TC ≥ 1%	151/213	170/207	0.76 (0.61 to 0.95)
TC < 1%	100/125	115/130	0.77 (0.58 to 1.00)



Courtesy of Heather Wakelee, MD

Johnson ML et al. Durvalumab with or without tremelimumab in combination with chemotherapy as first-line therapy for metastatic non-small-cell lung cancer: The Phase III POSEIDON study. J Clin Oncol 2023;41(6):1213-27; ESMO 2022 4 yr survival update LBA59



Long term benefit (~20% survival at 4 years) with T+D+CT,
Benefit regardless of PD-L1 with T+D, but PD-L1 dependent for D alone

Courtesy of Heather Wakelee, MD

Localized NSCLC

KEYNOTE-091/PEARLS: Study design

Randomised, triple-blind, Phase 3 trial

Eligibility for Registration

- Confirmed stage IB (T ≥4 cm), II or IIIA NSCLC (per TNM 7th edition)
- Complete surgical resection with negative margins (R0)
- Provision of tumor tissue for PD-L1 testing

PD-L1 testing
done centrally using
PD-L1 IHC
22C3 pharmDx

Eligibility for Randomisation

- No evidence of disease
- ECOG PS 0 or 1
- Adjuvant chemotherapy
  - Considered for stage IB (T ≥4 cm)
  - Strongly recommended for stage II and IIIA
  - Limited to ≤4 cycles

R 1:1

Pembrolizumab 200 mg Q3W for ≤18 cycles (~1 y)

Placebo 200 mg Q3W for ≤18 cycles (~1 y)

Stratification factors

- Disease stage (IB vs II vs IIIA)
- PD-L1 TPS (<1% vs 1–49% vs ≥50%)
- Receipt of adjuvant chemotherapy (yes vs no)
- Geographic region (Asia vs Eastern Europe vs Western Europe vs rest of world)

Dual primary end points

- DFS in the overall population
- DFS in the PD-L1 TPS ≥50% population

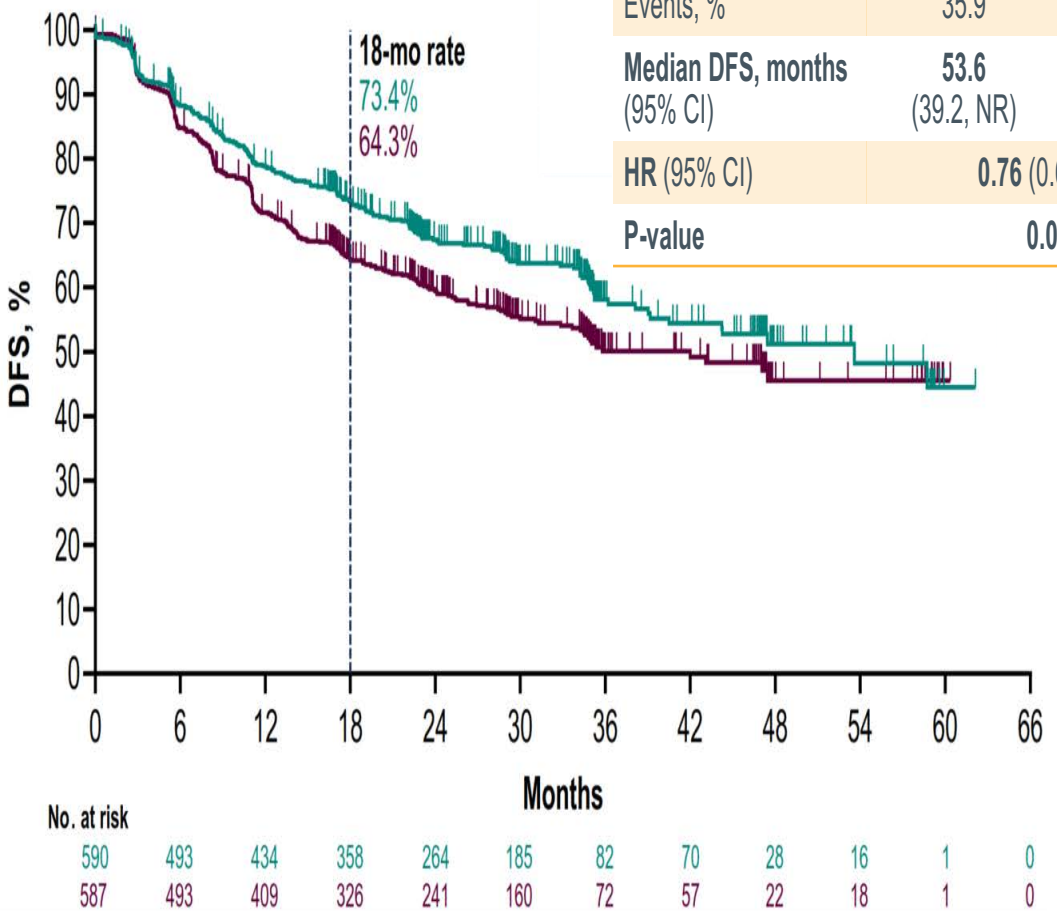
Secondary end points

- DFS in the PD-L1 TPS ≥1% population
- OS in the overall, PD-L1 TPS ≥50% and PD-L1 TPS ≥1% populations
- Lung cancer-specific survival in the overall population
- Safety

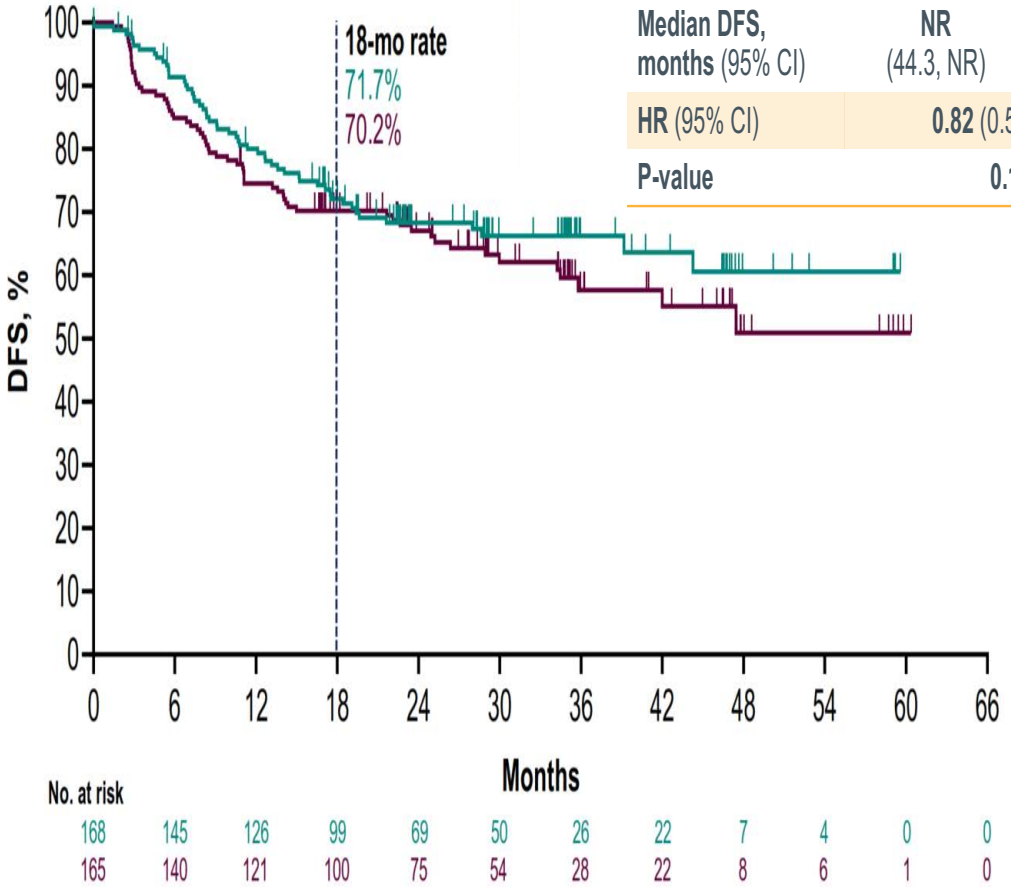
Paz-Ares L et al ESMO Virtual Plenary 2022; O´Brien M et al. Lancet Oncol 2022

Courtesy of Luis Paz-Ares, MD, PhD

PEARLS Trial: DFS in ITT and PD-L1 ≥50% Populations



	Pembrolizumab	Placebo
Events, %	35.9	44.3
Median DFS, months (95% CI)	**53.6** (39.2, NR)	**42.0** (31.3, NR)
HR (95% CI)	**0.76** (0.63, 0.91)	
P-value	**0.0014**	

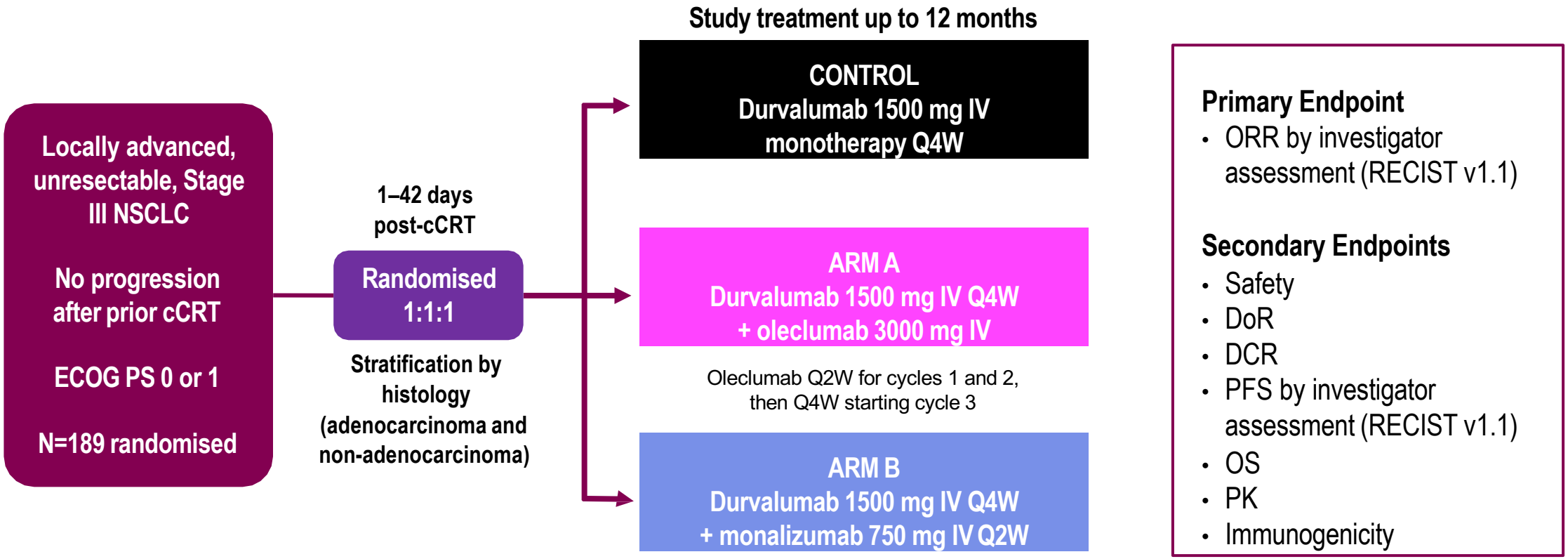


	Pembrolizumab	Placebo
Events, %	32.1	38.2
Median DFS, months (95% CI)	**NR** (44.3, NR)	**NR** (35.8, NR)
HR (95% CI)	**0.82** (0.57, 1.18)	
P-value	**0.14**	

Courtesy of Luis Paz-Ares, MD, PhD

Paz-Ares L et al ESMO Virtual Plenary 2022; O´Brien M et al. Lancet Oncol 2022

COAST: Phase 2, randomised open-label study



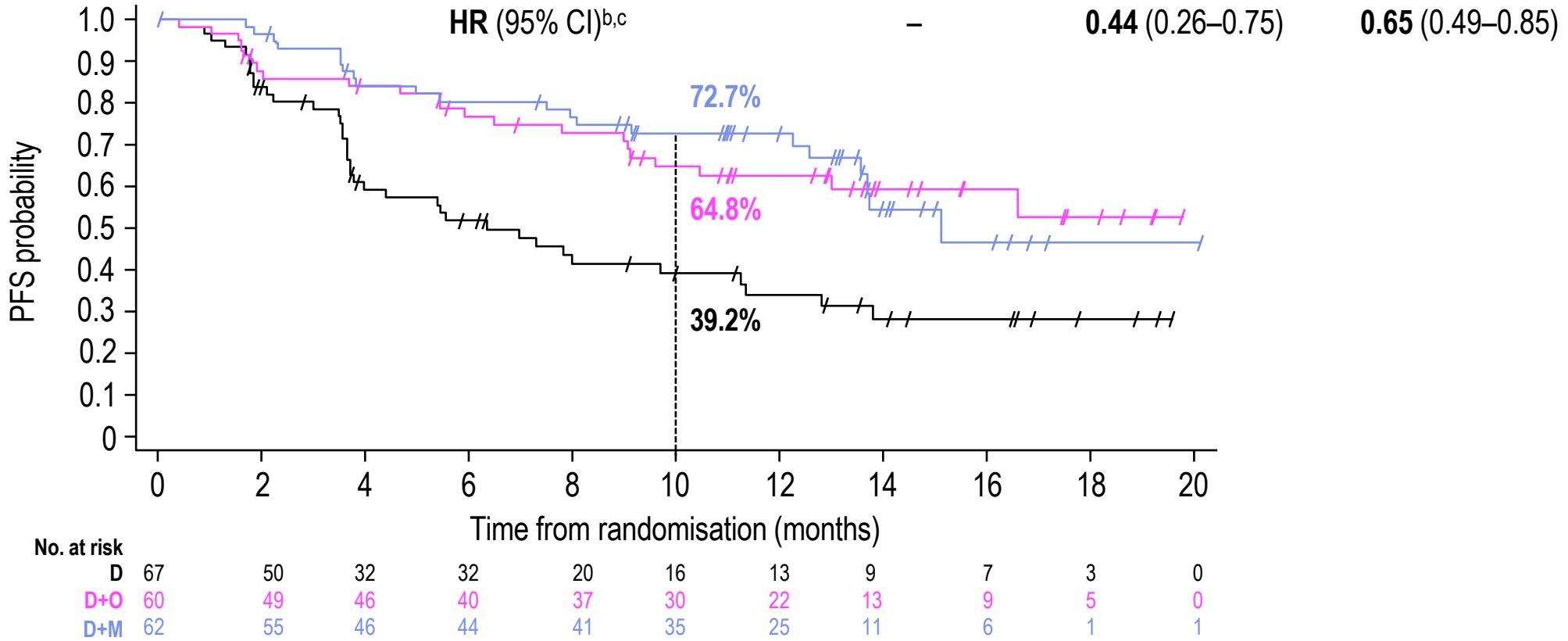
- A planned sample size of 60 patients per arm was designed to provide acceptable precision in estimating antitumour activities in an early phase setting
- Between Jan 2019 and Jul 2020, 189 patients were randomised of whom 186 received D (n=66), D+O (n=59) or D+M (n=61)
- As of 17 May 2021, all patients had a minimum of 10 months potential follow-up and the median actual follow-up was 11.5 months (range, 0.4–23.4; all patients)

Courtesy of Luis Paz-Ares, MD, PhD

Herbst RS et al. J Clin Oncol 2022

COAST: PFS by investigator assessment
(interim analysis; ITT population)

	D	D+O	D+M
Events/patients, n	38/67	22/60	21/62
mPFS, months (95% CI)[a]	**6.3** (3.7–11.2)	**NR** (10.4–NE)	**15.1** (13.6–NE)
HR (95% CI)[b,c]	–	**0.44** (0.26–0.75)	**0.65** (0.49–0.85)



Herbst RS et al. J Clin Oncol 2022

Courtesy of Luis Paz-Ares, MD, PhD

SCLC

Summary: Chemo-Immunotherapy in SCLC

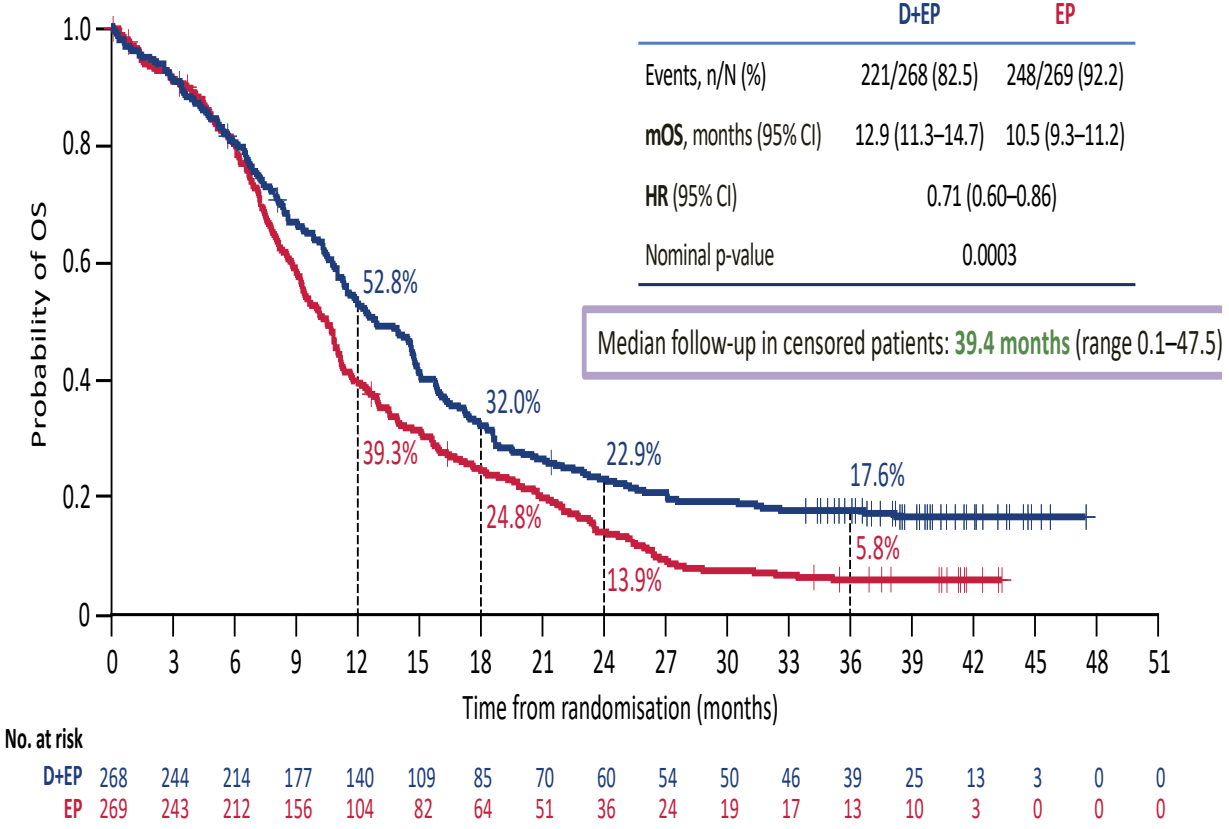
Study	IMPOWER 133 NEJM 2018		CASPIAN Lancet 2019		KEYNOTE 604 JCO 2020		CAPSTONE-1 Wang et al. Lancet Oncology 2022		ASTRUM 005 Cheng et al. ASCO 2022	
Arm	Atezo (PD-L1)	Control	Durva(PD-L1)	Control	Pembro (PD-1)	Control	Adebrelimab (anti-PD-L1)	Control	Serplulimab (anti-PD-1)	Control
Patients	201	202	268	269	228	225	230	232	389	196
OS*	12.3	10.3	13.0	10.3	10.8	9.7	15.3	12.8	15.4	10.9
HR (OS) (p value)	0.70 (p=0.0069)		0.73 (p= 0.0047)		0.8 (p=0.0164)		0.72 (p=0.0017)		0.63 (p<0.001)	
G3-4 AEs	67 vs 63 %		61 vs 62 %		77 vs 75 %		39 vs 28% TRSAEs		82.5 vs 80.1 %	
Comment			8% PCI (Control arm only)		Primary endpoint not met		Chinese population		30% Caucasian patients	

F Blackhall. ESMO 2022

Courtesy of Luis Paz-Ares, MD, PhD

CASPIAN Trial – OS after 3 years

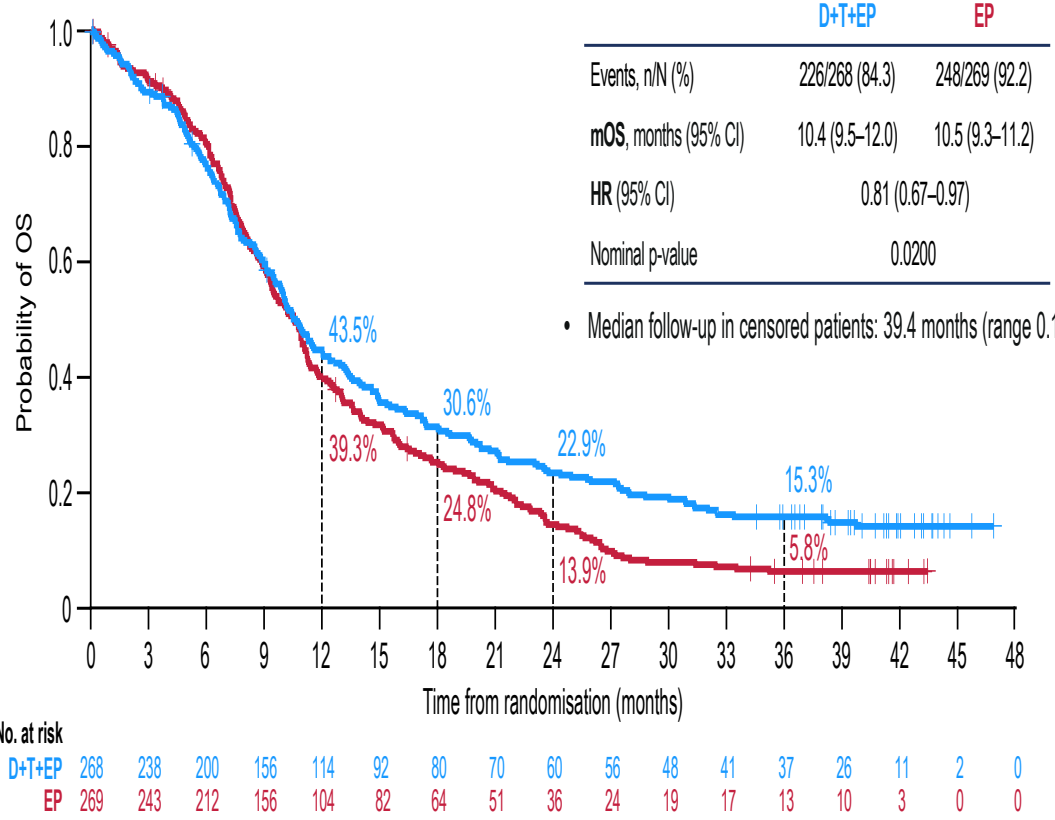
3-year Overall Survival Update: D+EP vs EP



	D+EP	EP
Events, n/N (%)	221/268 (82.5)	248/269 (92.2)
mOS, months (95% CI)	12.9 (11.3–14.7)	10.5 (9.3–11.2)
HR (95% CI)	0.71 (0.60–0.86)	
Nominal p-value	0.0003	

Median follow-up in censored patients: **39.4 months** (range 0.1–47.5)

3-year Overall Survival Update: D+T+EP vs EP



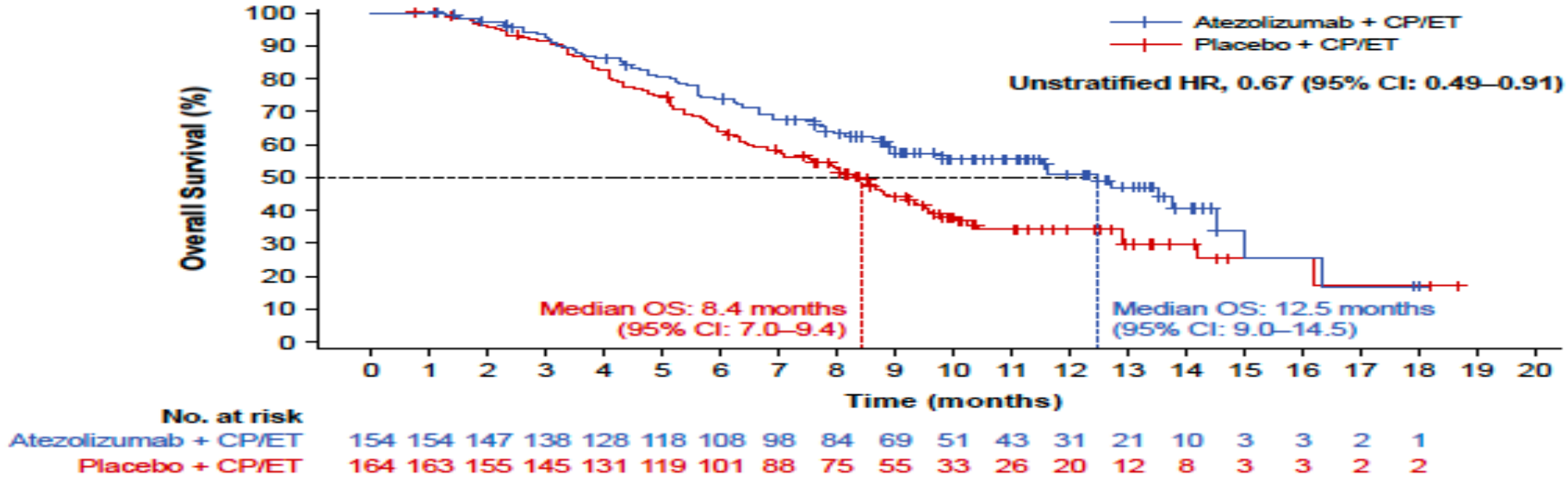
	D+T+EP	EP
Events, n/N (%)	226/268 (84.3)	248/269 (92.2)
mOS, months (95% CI)	10.4 (9.5–12.0)	10.5 (9.3–11.2)
HR (95% CI)	0.81 (0.67–0.97)	
Nominal p-value	0.0200	

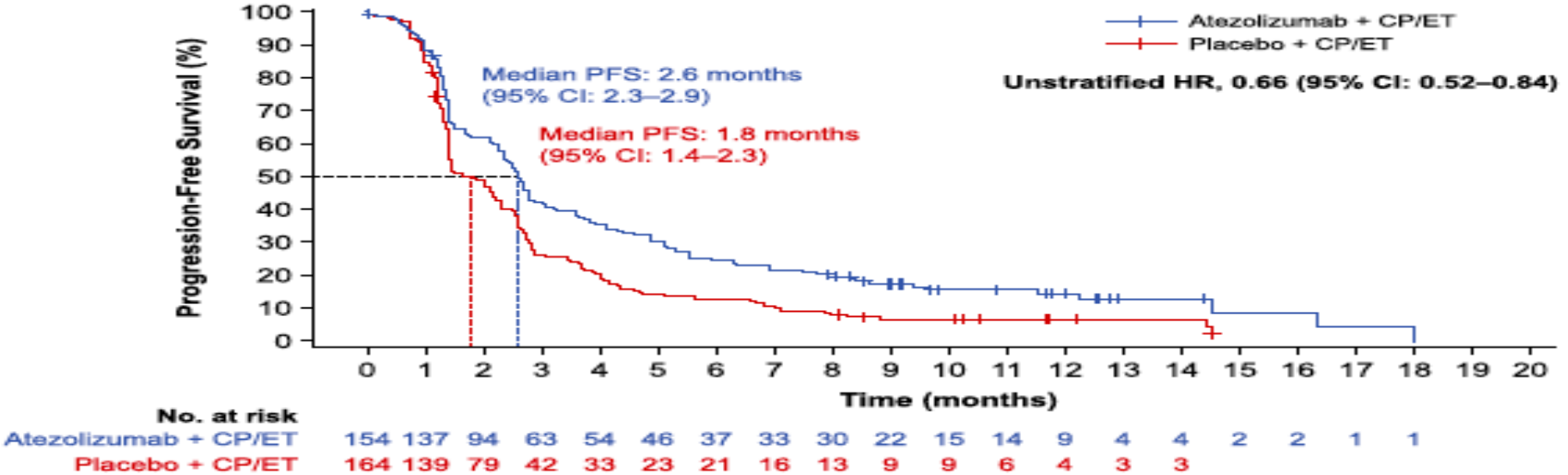
- Median follow-up in censored patients: 39.4 months (range 0.1–47.5)

Courtesy of Luis Paz-Ares, MD, PhD

Paz-Ares et al. ESMO Open 2022

IMpower133 Trial: Maintenance Atezolizumab





Courtesy of Luis Paz-Ares, MD, PhD

M Reck et al. JTO 2022

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Colorectal Cancer

Wednesday, April 19, 2023
5:00 PM – 6:00 PM ET

Faculty

Pashtoon M Kasi, MD, MS

Wells A Messersmith, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

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 up to 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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