

Meet The Professor

Current and Future Role of Immunotherapy in the Management of Lung Cancer

Charu Aggarwal, MD

Leslye M Heisler Associate Professor for Lung Cancer Excellence
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Commercial Support

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Dr Love — Disclosures

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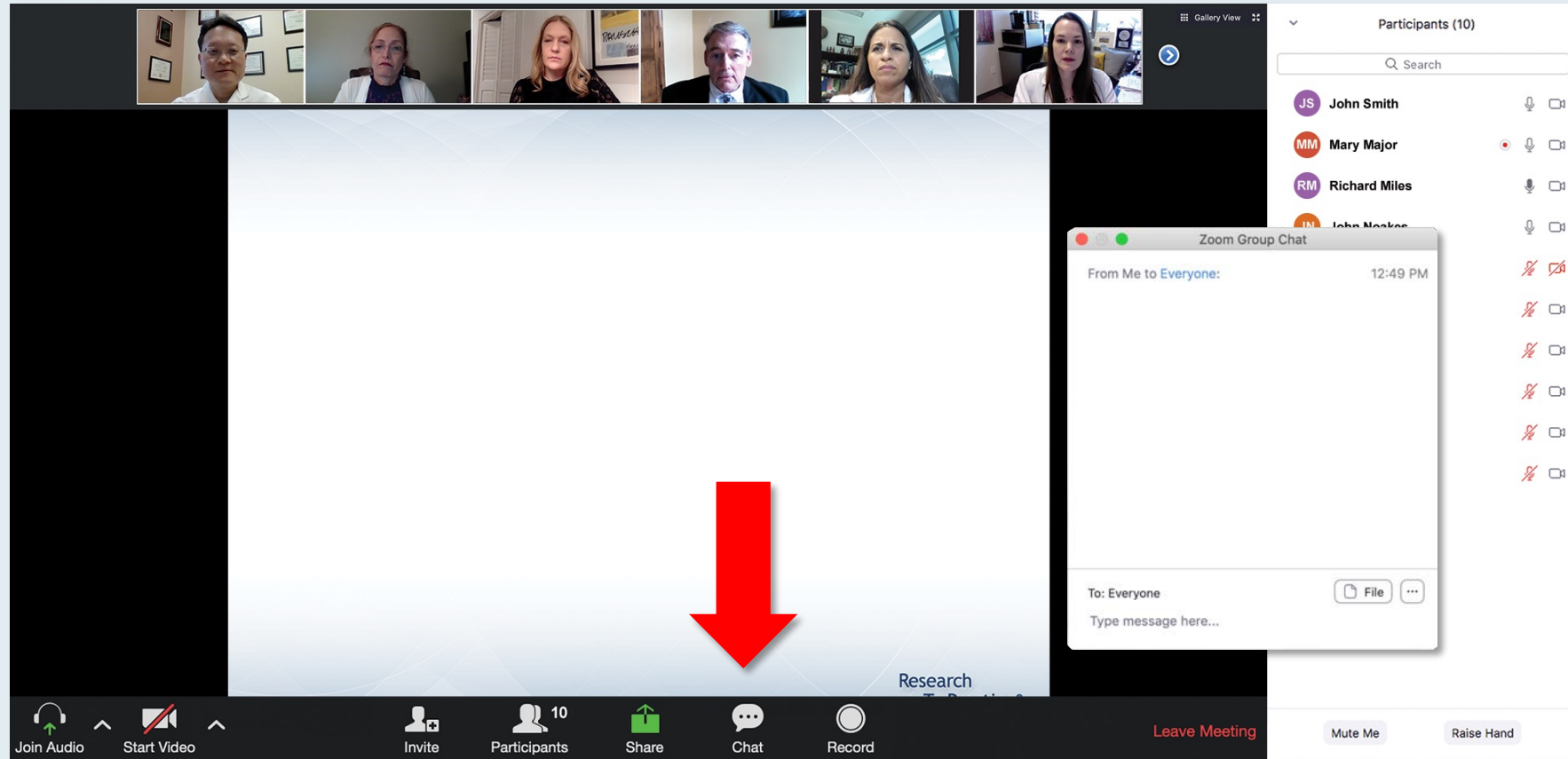
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Dr Aggarwal — Disclosures

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We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a slide titled "Meet The Professor Program Steering Committee" with six members listed:

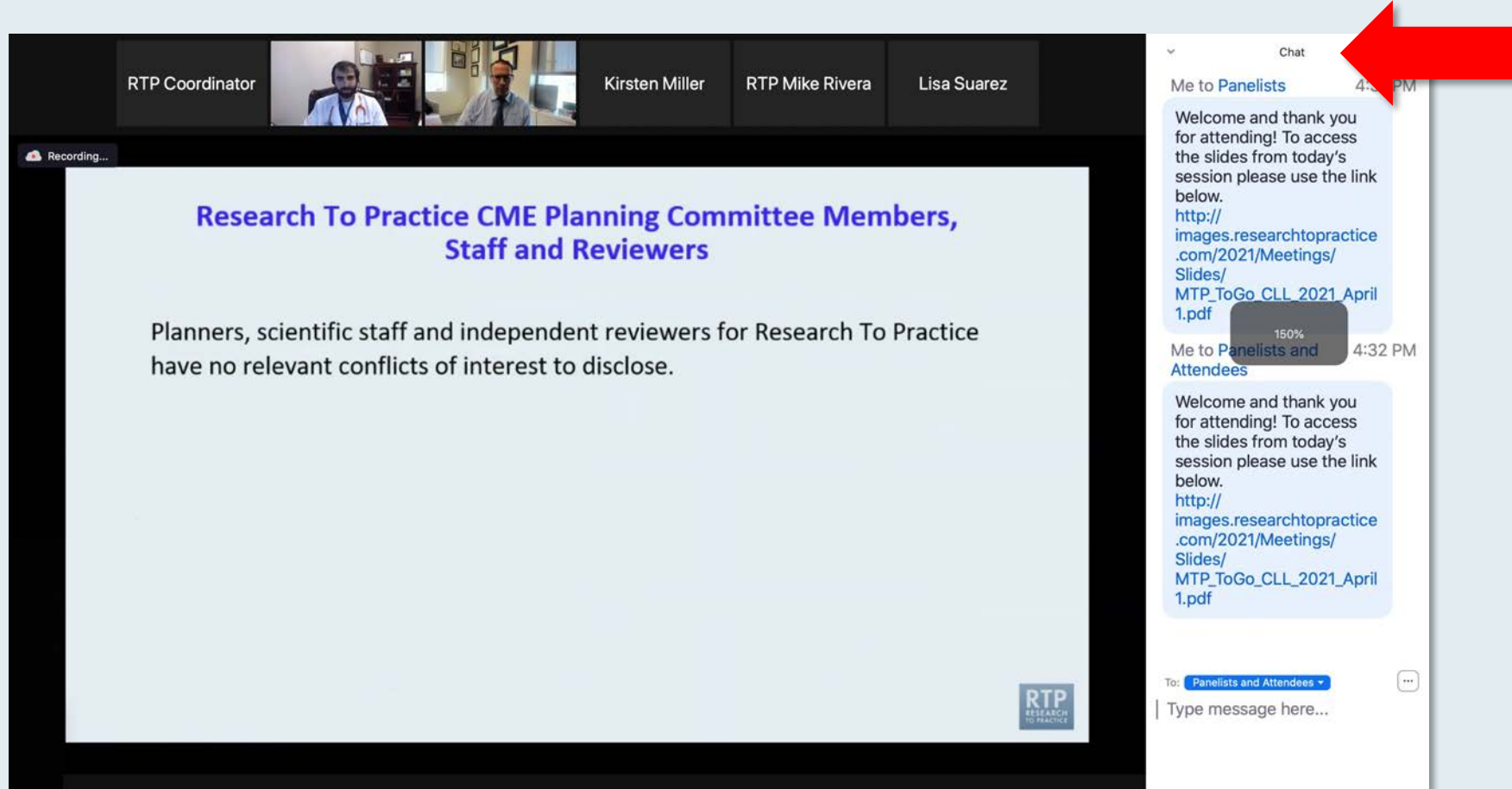
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Professor of Medicine (Hematology)
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- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

The chat window on the right is expanded, showing two messages from "Me to Panelists" and "Me to Panelists and Attendees". A red arrow points to the white line above the chat submission box, indicating where to drag to expand the box.

Drag the white line above the submission box up to create more space for your message.

Familiarizing Yourself with the Zoom Interface

Increase chat font size



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**Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.**

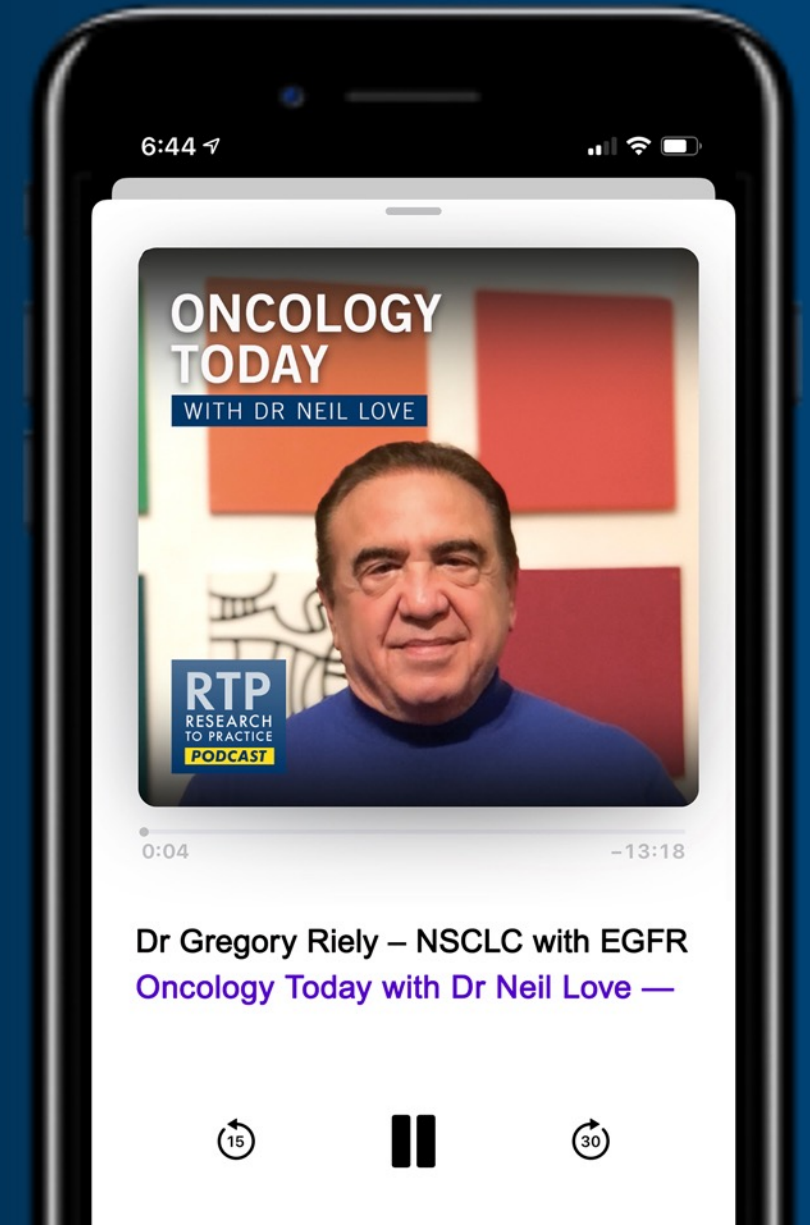
ONCOLOGY TODAY

WITH DR NEIL LOVE

NSCLC with EGFR Exon 20 Insertion Mutations



DR GREGORY RIELY
MEMORIAL SLOAN KETTERING CANCER CENTER



Year in Review: Kidney and Bladder Cancer

**Tuesday, March 8, 2022
5:00 PM – 6:00 PM ET**

Faculty

**Elizabeth R Plimack, MD, MS
Thomas Powles, MBBS, MRCP, MD**

Moderator

Neil Love, MD

Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia

Wednesday, March 9, 2022

5:00 PM – 6:00 PM ET

Faculty

Rebecca L Olin, MD, MSCE

Moderator

Neil Love, MD

Meet The Professor

Current and Future Management of Myelofibrosis

Thursday, March 10, 2022

5:00 PM – 6:00 PM ET

Faculty

Srdan Verstovsek, MD, PhD

Moderator

Neil Love, MD

Meet The Professor

Optimizing the Clinical Management of Hodgkin and Non-Hodgkin Lymphomas

**Tuesday, March 15, 2022
5:00 PM – 6:00 PM ET**

Faculty

Sonali M Smith, MD

Moderator

Neil Love, MD

Meet The Professor

Current and Future Management of Chronic Lymphocytic Leukemia

Thursday, March 17, 2022

5:00 PM – 6:00 PM ET

Faculty

Peter Hillmen, MB ChB, PhD

Moderator

Neil Love, MD

**Data + Perspectives: Clinical Investigators
Discuss the Current and Future Management
of Ovarian Cancer**

Saturday, March 19, 2022

2:30 PM – 4:00 PM ET

Faculty

**Mansoor Raza Mirza, MD
Kathleen N Moore, MD, MS
David M O'Malley, MD**

Moderator

Robert L Coleman, MD

Thank you for joining us!

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

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Meet The Professor Program Participating Faculty



Charu Aggarwal, MD
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Associate Professor of Medicine
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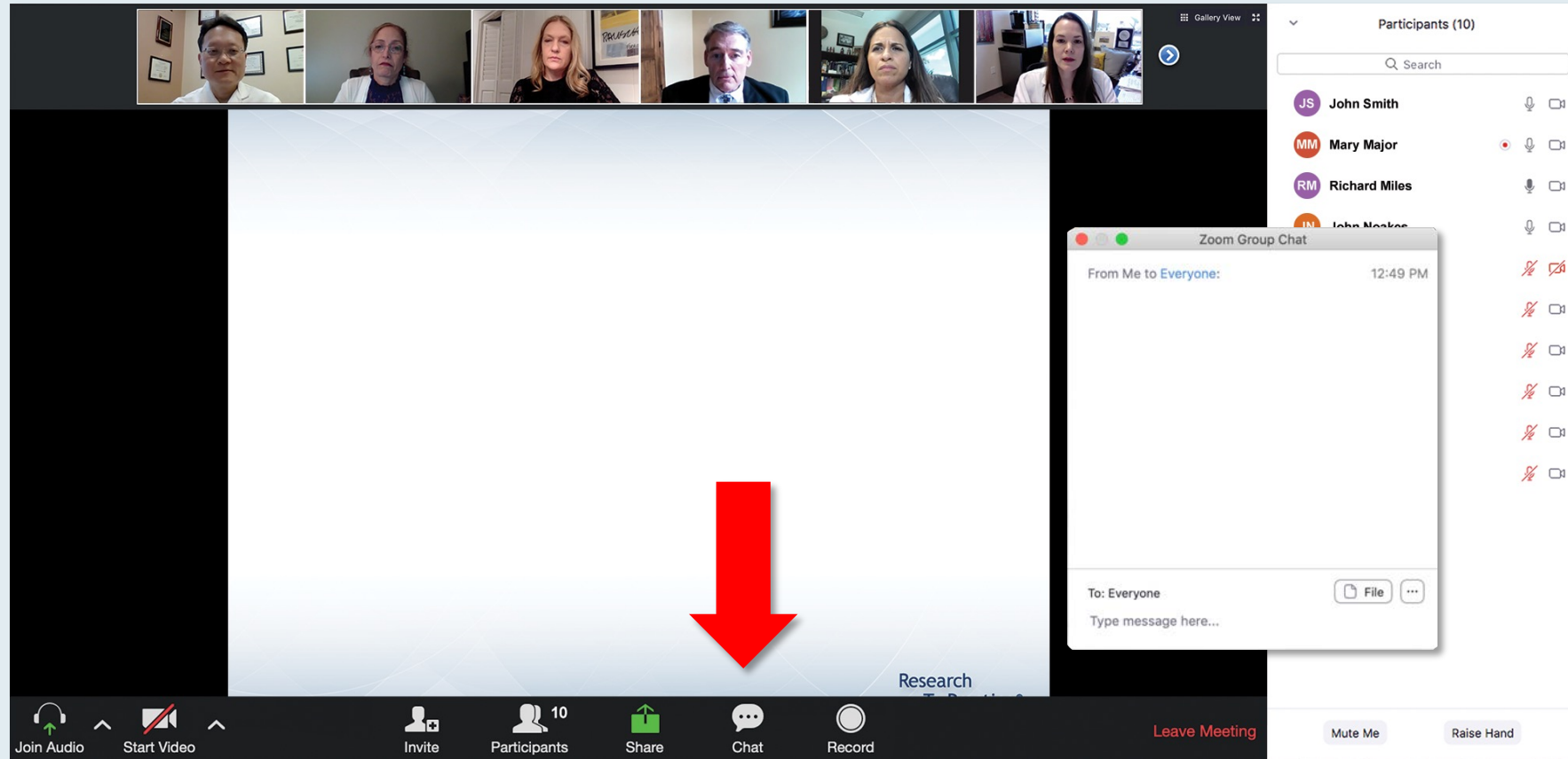


MODERATOR
Neil Love, MD
Research To Practice



Stephen V Liu, MD
Associate Professor of Medicine
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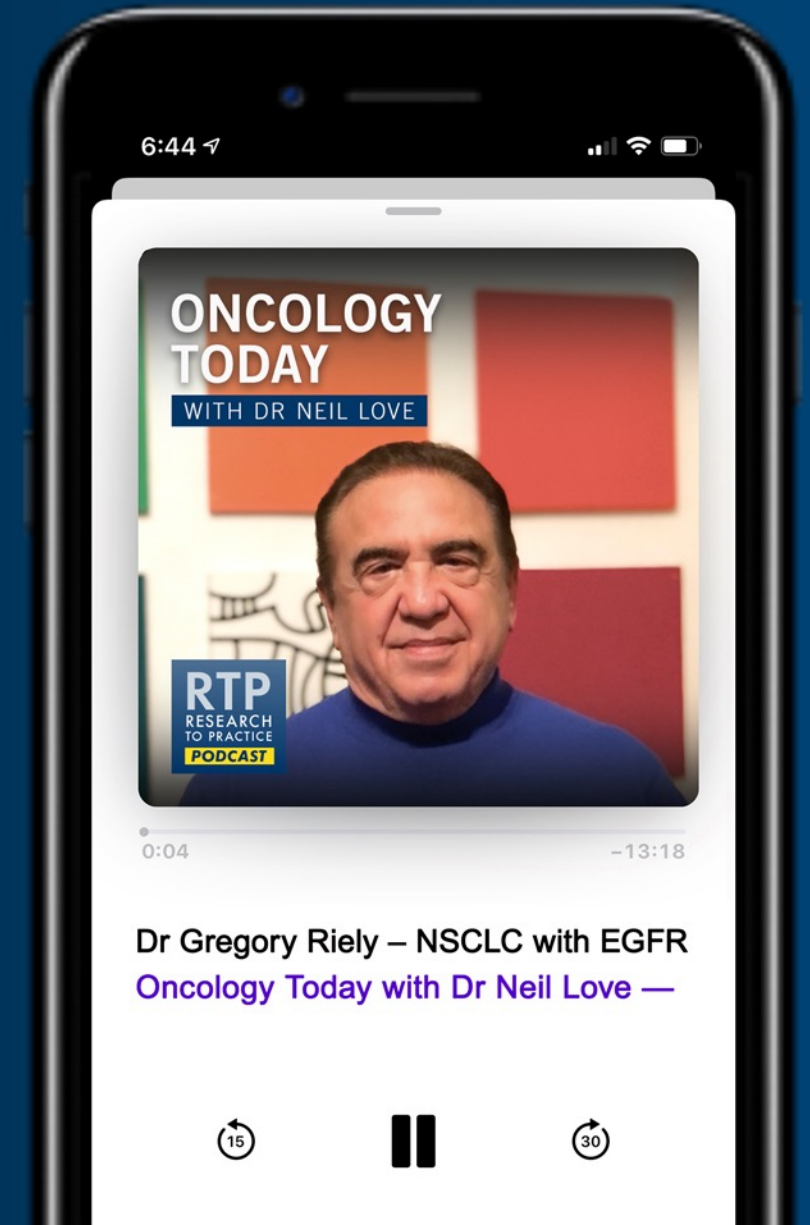
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Julia Saylor, MD
Charleston Oncology
North Charleston, South Carolina

Meet The Professor with Dr Aggarwal

MODULE 1: Adjuvant and Neoadjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

- Dr Gubens: A 59-year-old man with Stage IIA squamous cell carcinoma of the lung who received neoadjuvant pembrolizumab and radiation therapy on a clinical trial
- Dr Mohamed: A 62-year-old woman with 1.7-cm adenocarcinoma of the lung and 1.5-cm small cell lung cancer

MODULE 2: Stage III Unresectable NSCLC

- Dr Choksi: A 71-year-old woman with Stage III adenocarcinoma of the lung

MODULE 3: Metastatic NSCLC

- Dr Mitchell: A 54-year-old woman with adenocarcinoma of the lung and multiple brain metastases
- Dr Matt-Amaral: A 67-year-old man with adenocarcinoma of the lung (no actionable mutations, PD-L1 >50%)
- Dr Gosain: A 62-year-old man with metastatic squamous cell carcinoma of the lung and PD-L1 >50%
- Dr Morganstein: A 66-year-old man with metastatic adenocarcinoma of the lung (PD-L1 TPS 20%)

MODULE 4: Small Cell Lung Cancer (SCLC)

- Dr Saylor: A 60-year-old woman with extensive-stage SCLC
- Dr Yang: An 87-year-old man with extensive-stage SCLC and PD-L1 >50%

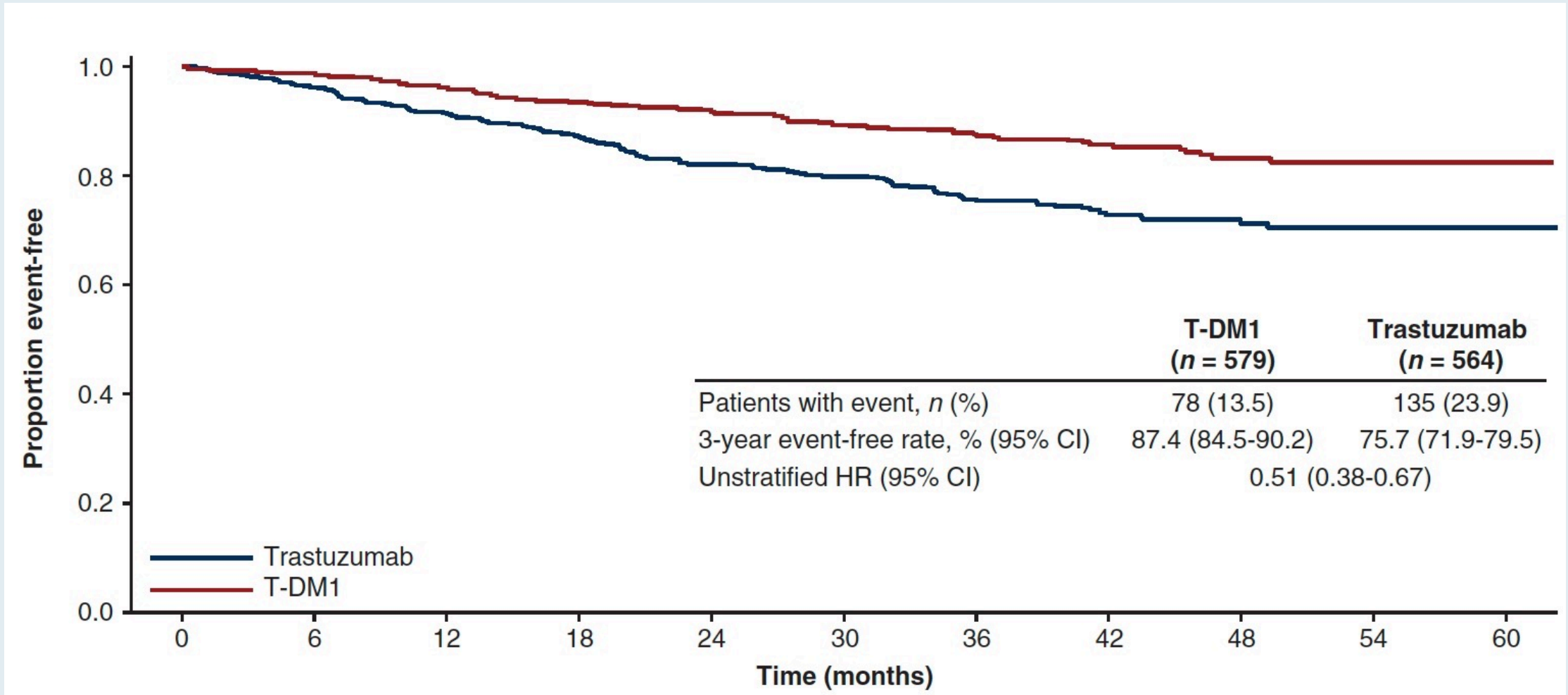
MODULE 5: Appendix of Key Data Sets

ORIGINAL ARTICLE

Adjuvant T-DM1 versus trastuzumab in patients with residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer: subgroup analyses from KATHERINE

E. P. Mamounas^{1,2*}, M. Untch³, M. S. Mano⁴, C.-S. Huang⁵, C. E. Geyer Jr^{1,6}, G. von Minckwitz⁷, N. Wolmark^{1,8}, X. Pivot⁹, S. Kuemmel^{10,11}, M. P. DiGiovanna¹², B. Kaufman¹³, G. Kunz^{7,14}, A. K. Conlin^{1,15}, J. C. Alcedo¹⁶, T. Kuehn¹⁷, I. Wapnir^{1,18}, A. Fontana¹⁹, J. Hackmann^{7,20}, J. Polikoff^{1,21}, M. Saghatchian²², A. Brufsky^{1,23}, Y. Yang²⁴, M. Zimovjanova²⁵, T. Boulet²⁶, H. Liu²⁷, D. Tesarowski²⁸, L. H. Lam²⁸, C. Song²⁸, M. Smitt^{28,29} & S. Loibl^{7,30}

Time to First Invasive Disease-Free Survival Event for Patients Who Received Anthracycline-Based Neoadjuvant Therapy



Meet The Professor with Dr Aggarwal

MODULE 1: Adjuvant and Neoadjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

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MODULE 5: Appendix of Key Data Sets

FDA Approves Neoadjuvant Nivolumab and Platinum-Doublet Chemotherapy for Localized NSCLC

Press Release: March 4, 2022

“The Food and Drug Administration approved nivolumab with platinum-doublet chemotherapy for adult patients with resectable non-small cell lung cancer (NSCLC) in the neoadjuvant setting. This represents the first FDA approval for neoadjuvant therapy for early-stage NSCLC.

Efficacy was evaluated in CHECKMATE-816 (NCT02998528), a randomized, open label trial in patients with resectable, histologically confirmed Stage IB (≥ 4 cm), II, or IIIA NSCLC (AJCC/UICC staging criteria) and measurable disease (RECIST v1.1.). Patients were enrolled regardless of the tumor PD-L1 status. A total of 358 patients were randomized to receive either nivolumab plus platinum-doublet chemotherapy administered every 3 weeks for up to 3 cycles, or platinum-chemotherapy alone administered on the same schedule.

The main efficacy outcome measures were event-free survival (EFS) and pathologic complete response (pCR) by blinded independent central review. Median EFS was 31.6 months in the nivolumab plus chemotherapy arm and 20.8 months for those receiving chemotherapy alone. The hazard ratio was 0.63 ($p=0.0052$). The pCR rate was 24% in the nivolumab plus chemotherapy arm and 2.2% in the chemotherapy alone arm.”

Recent FDA Approvals for Localized NSCLC

“On October 15, 2021, the Food and Drug Administration approved atezolizumab for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on $\geq 1\%$ of tumor cells, as determined by an FDA-approved test. Today, the FDA also approved the VENTANA PD-L1 (SP263) Assay as a companion diagnostic device to select patients with NSCLC for adjuvant treatment with atezolizumab.”

“On March 4, 2022, the Food and Drug Administration approved nivolumab with platinum-doublet chemotherapy for adult patients with resectable non-small cell lung cancer (NSCLC) in the neoadjuvant setting. This represents the first FDA approval for neoadjuvant therapy for early-stage NSCLC.”

Case Presentation: A 59-year-old man with Stage IIA squamous cell carcinoma of the lung who received neoadjuvant pembrolizumab and radiation therapy on a clinical trial



Dr Matthew Gubens (San Francisco, California)

Case Presentation: A 62-year-old woman with 1.7-cm adenocarcinoma of the lung and 1.5-cm small cell lung cancer



Dr Mohamed Mohamed (Greensboro, North Carolina)

In what situations, if any, are you currently recommending neoadjuvant chemotherapy (with or without an anti-PD-1/PD-L1 antibody) for your patients with NSCLC?

 Dr Aggarwal	None	 Dr Hanna	None
 Dr Goldberg	Select patients with Stage III disease	 Dr Liu	Resectable N2+ disease
 Dr Govindan	N2 disease with adequate pulmonary reserve	 Dr Ramalingam	Resectable N2 disease

Based on available data and your clinical experience, does neoadjuvant immunotherapy (alone or with chemotherapy) increase the risk of surgical complications in patients with NSCLC?



Dr Aggarwal

No



Dr Hanna

No



Dr Goldberg

No



Dr Liu

No



Dr Govindan

No



Dr Ramalingam

It is too early to tell

In general, what adjuvant treatment, if any, would you recommend for an otherwise healthy 65-year-old patient with Stage IIB nonsquamous NSCLC and PD-L1 TPS = 50%?



Dr Aggarwal

**Cisplatin/pemetrexed
→ atezolizumab**



Dr Hanna

**Cisplatin/pemetrexed
→ atezolizumab**



Dr Goldberg

**Cisplatin/pemetrexed
→ atezolizumab**



Dr Liu

**Cisplatin/pemetrexed
→ atezolizumab**



Dr Govindan

**Cisplatin/pemetrexed
→ atezolizumab**



Dr Ramalingam

**Cisplatin/pemetrexed
→ atezolizumab**

In general, what adjuvant treatment, if any, would you recommend for an otherwise healthy 65-year-old patient with Stage IB nonsquamous NSCLC and PD-L1 TPS = 50%?

 Dr Aggarwal	None	 Dr Hanna	Cisplatin/pemetrexed
 Dr Goldberg	None	 Dr Liu	None
 Dr Govindan	None	 Dr Ramalingam	None

Regulatory and reimbursement issues aside, in general, what adjuvant treatment, if any, would you recommend for an otherwise healthy 65-year-old patient with Stage IB nonsquamous NSCLC with an EGFR activating mutation and PD-L1 TPS = 50%?

 Dr Aggarwal	None	 Dr Hanna	None
 Dr Goldberg	None	 Dr Liu	Osimertinib
 Dr Govindan	Chemotherapy	 Dr Ramalingam	Chemotherapy → osimertinib

Regulatory and reimbursement issues aside, in general, what adjuvant treatment, if any, would you recommend for an otherwise healthy 65-year-old patient with Stage IIA nonsquamous NSCLC with an EGFR activating mutation and PD-L1 TPS = 50%?



Dr Aggarwal

Chemotherapy →
osimertinib



Dr Hanna

Chemotherapy →
osimertinib



Dr Goldberg

Chemotherapy →
osimertinib



Dr Liu

Chemotherapy →
osimertinib



Dr Govindan

Osimertinib



Dr Ramalingam

Chemotherapy →
osimertinib

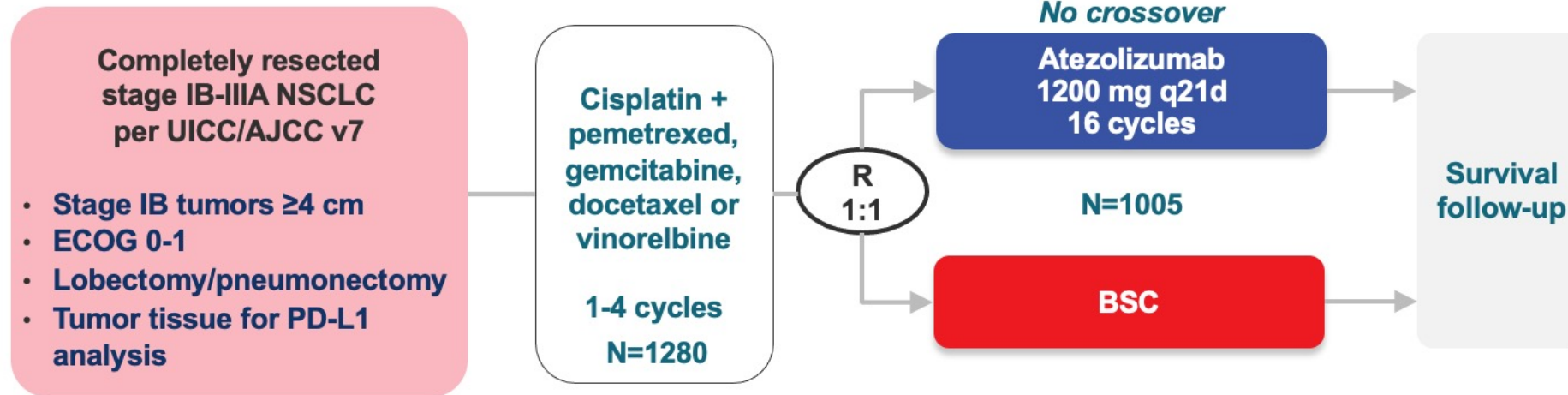
Lancet 2021;398:1344-57



Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB–IIIA non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial

*Enriqueta Felip, Nasser Altorki, Caicun Zhou, Tibor Csőszi, Ihor Vynnychenko, Oleksandr Goloborodko, Alexander Luft, Andrey Akopov, Alex Martinez-Marti, Hirotsugu Kenmotsu, Yuh-Min Chen, Antonio Chella, Shunichi Sugawara, David Voong, Fan Wu, Jing Yi, Yu Deng, Mark McClelland, Elizabeth Bennett, Barbara Gitlitz, Heather Wakelee, for the IMpower010 Investigators**

IMpower010: A Phase III Trial of Adjuvant Atezolizumab After Chemotherapy for Resected Stage IB-III A NSCLC



Stratification factors

- Male/female
- Stage (IB vs II vs IIIA)
- Histology
- PD-L1 tumor expression status^a: TC2/3 and any IC vs TC0/1 and IC2/3 vs TC0/1 and IC0/1

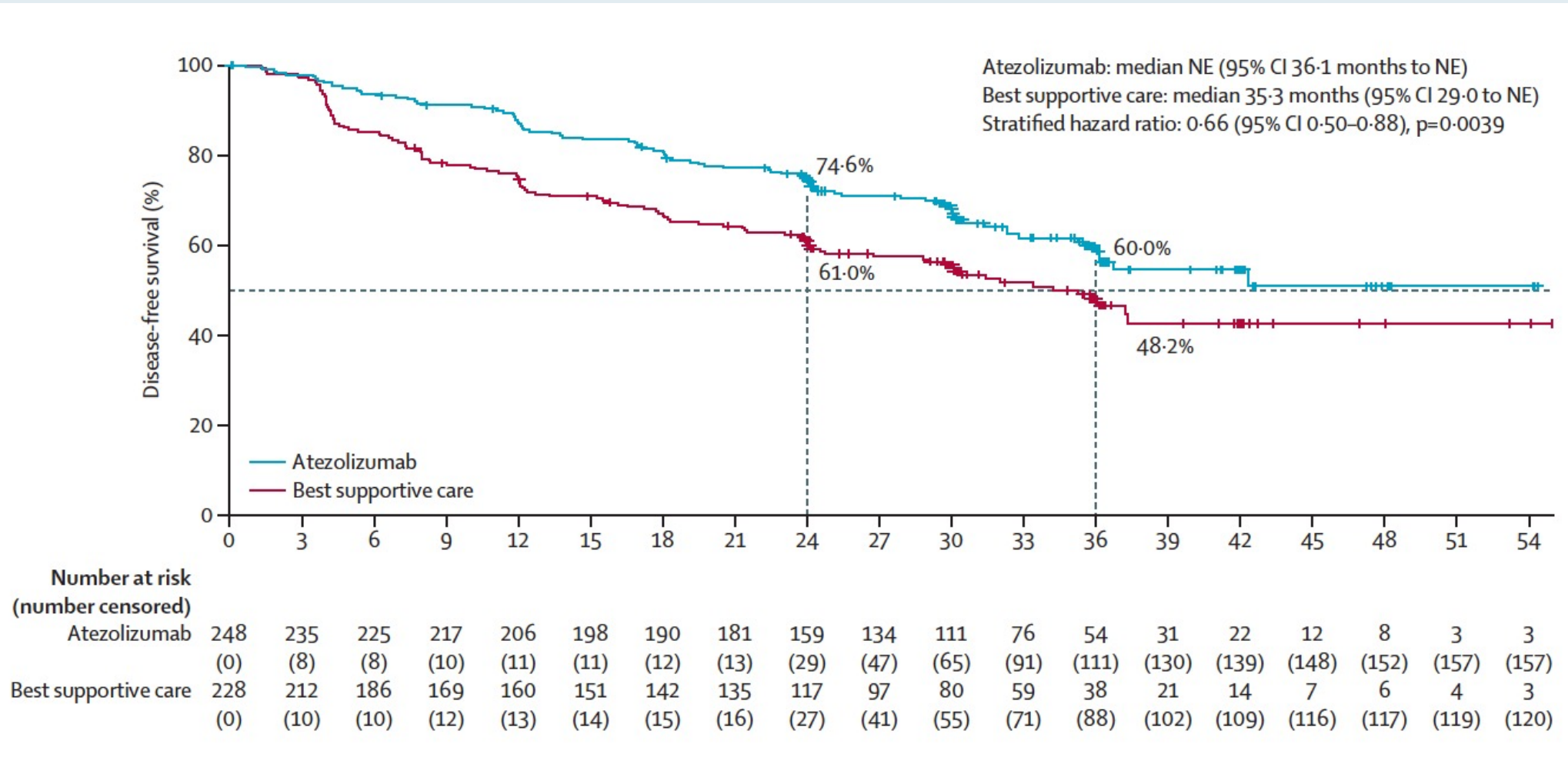
Primary endpoints

- Investigator-assessed DFS tested hierarchically:
 - **PD-L1 TC ≥1% (per SP263) stage II-III A population**
 - **All-randomized stage II-III A population**
 - **ITT population (stage IB-III A)**

Key secondary endpoints

- OS in ITT population
- DFS in PD-L1 TC ≥50% (per SP263) stage II-III A population
- 3-y and 5-y DFS in all 3 populations

IMpower010 Primary Endpoint: Disease-Free Survival in the PD-L1 $\geq 1\%$ Tumor Cells Stage II-III A Population



IMpower010: Characterization of Stage IB-IIIA NSCLC Patients by Type and Extent of Therapy Prior to Adjuvant Atezolizumab

Nasser Altorki,¹ Enriqueta Felip,² Caicun Zhou,³ Eric Vallieres,⁴ Vladimir Moiseyenko,⁵ Alexey Smolin,⁶ Achim Rittmeyer,⁷ Roman Vereshchako,⁸ Maurice Perol,⁹ Wolfgang Schutte,¹⁰ Jian Fang,¹¹ Min Tao,¹² Encarnacao Teixeira,¹³ Young-Chul Kim,¹⁴ Virginia McNally,¹⁵ Fan Wu,¹⁶ Yu Deng,¹⁷ Elizabeth Bennett,¹⁷ Barbara Gitlitz,¹⁷ Heather Wakelee¹⁸

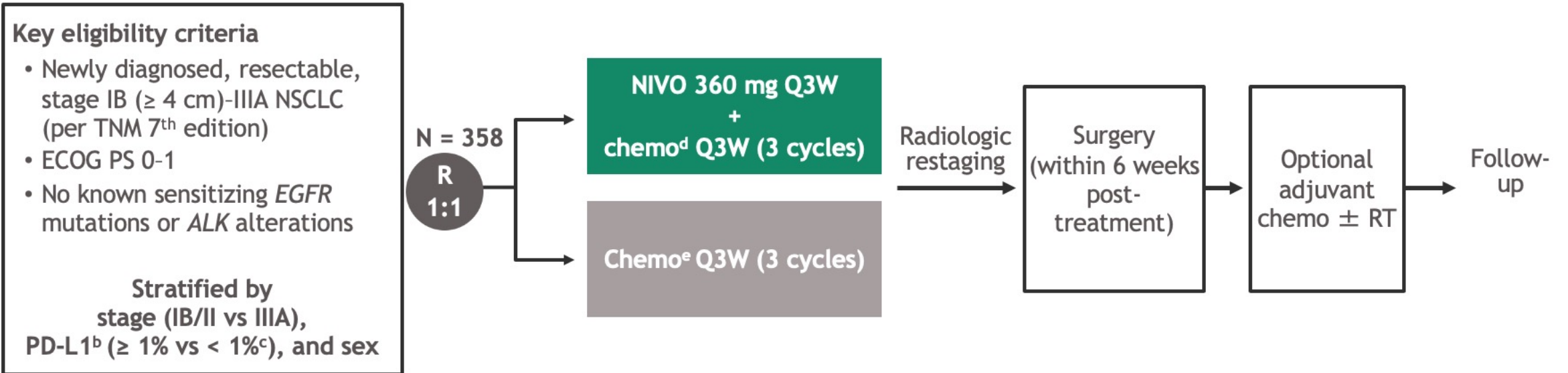
¹ New York-Presbyterian Hospital, Weill Cornell Medicine, New York, NY; ² Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology (VHIO), Barcelona, Spain; ³ Tongji University Affiliated Shanghai Pulmonary Hospital, Shanghai, China; ⁴ Swedish Cancer Institute, Seattle, WA; ⁵ GBUZ Saint Petersburg Clinical Research Center of Specialized Types of Care (Oncology), Saint Petersburg, Russia; ⁶ Principal Military Clinical Hospital n.a. N.N. Burdenko, Moscow, Russia; ⁷ Lungenfachklinik Immenhausen, Immenhausen, Germany; ⁸ Kyiv Railway Clinical Hospital #3 of Branch Health Center of the PJSC Ukrainian Railway, Kyiv, Ukraine; ⁹ Centre Léon Bérard, Lyon, France; ¹⁰ Krankenhaus Martha-Maria; Halle-Dolau gGmbH, Halle, Germany; ¹¹ Beijing Cancer Hospital, Beijing, China; ¹² First Affiliated Hospital of Soochow University, Jiangsu, China; ¹³ Centro Hospitalar de Lisboa Norte E.P.E – Hospital Pulido Valente, Lisbon, Portugal; ¹⁴ Chonnam National University Medical School, and CNU Hwasun Hospital, Jeollanam-do, South Korea; ¹⁵ F. Hoffmann-La Roche Ltd., Basel, Switzerland; ¹⁶ Roche (China) Holding Ltd, Shanghai, China; ¹⁷ Genentech Inc, South San Francisco, CA; ¹⁸ Stanford University School of Medicine/Stanford Cancer Institute, Stanford, CA

IMpower010: Sites of Relapse and Subsequent Therapy From a Phase 3 Study of Atezolizumab vs Best Supportive Care After Adjuvant Chemotherapy in Resected Stage IB-IIIA NSCLC

Enriqueta Felip,¹ Eric Vallieres,² Caicun Zhou,³ Heather Wakelee,⁴ Igor Bondarenko,⁵ Hiroshi Sakai,⁶ Haruhiro Saito,⁷ Grygorii Ursol,⁸ Koji Kawaguchi,⁹ Yunpeng Liu,¹⁰ Evgeny Levchenko,¹¹ Nikolay Kislov,¹² Martin Reck,¹³ Rüdiger Liersch,¹⁴ Virginia McNally,¹⁵ Qian Zhu,¹⁶ Beiying Ding,¹⁶ Elizabeth Bennett,¹⁶ Barbara Gitlitz,¹⁶ Nasser Altorki¹⁷

¹Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology (VHIO), Barcelona, Spain; ²Swedish Cancer Institute, Seattle, WA, USA; ³Tongji University Affiliated Shanghai Pulmonary Hospital, Shanghai, China; ⁴Stanford University School of Medicine/Stanford Cancer Institute, Stanford, CA, USA; ⁵Dnipro State Medical University, Dnipro, Ukraine; ⁶Saitama Cancer Center, Saitama, Japan; ⁷Kanagawa Cancer Center, Yokohama, Japan; ⁸Acinus, Kropyvnytskyi, Ukraine; ⁹Mie University Graduate School of Medicine, Mie, Japan; ¹⁰First Hospital, China Medical University, Shenyang, China; ¹¹Scientific Research Oncology Institute, St Petersburg, Russia; ¹²Regional Clinical Oncology Hospital, Yaroslavl, Russia; ¹³Lung Clinic Grosshansdorf, Airway Research Center North, German Center of Lung Research, Grosshansdorf, Germany; ¹⁴Clemenshospital Münster, Münster, Germany; ¹⁵Roche Products Ltd, Welwyn Garden City, United Kingdom; ¹⁶Genentech Inc, South San Francisco, CA, USA; ¹⁷New York-Presbyterian Hospital, Weill Cornell Medicine, New York, NY, USA

CheckMate 816: A Phase III Trial of Neoadjuvant Nivolumab with Chemotherapy for Newly Diagnosed, Resectable, Stage IB-IIIA NSCLC



Primary endpoints

- pCR by BIPR
- EFS by BICR

Key secondary endpoints

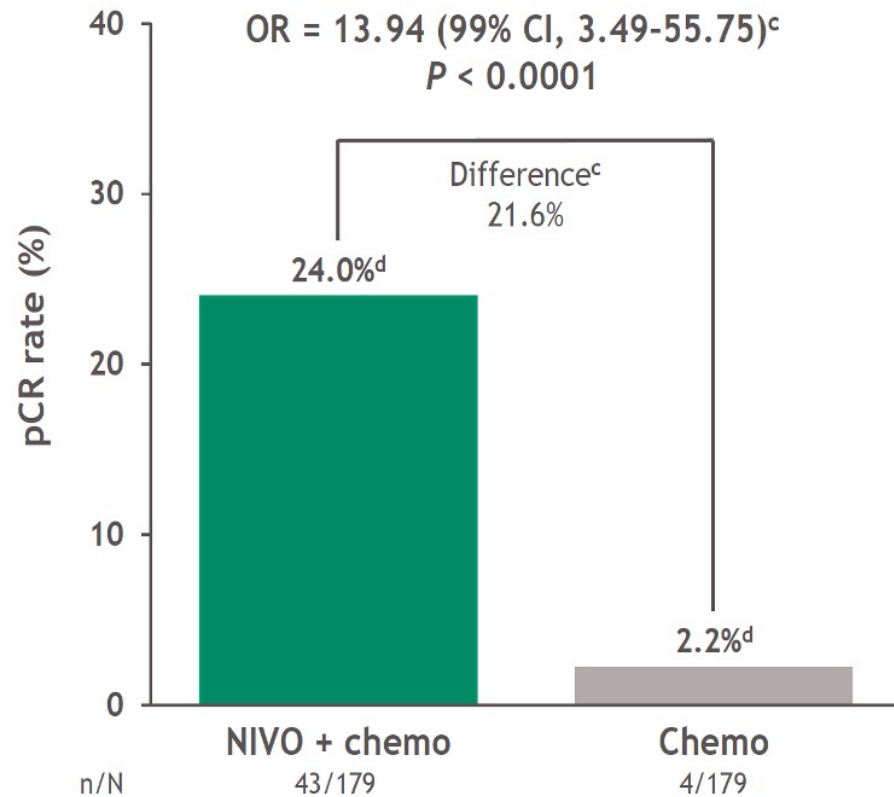
- MPR by BIPR
- OS
- Time to death or distant metastases

Key exploratory endpoints included

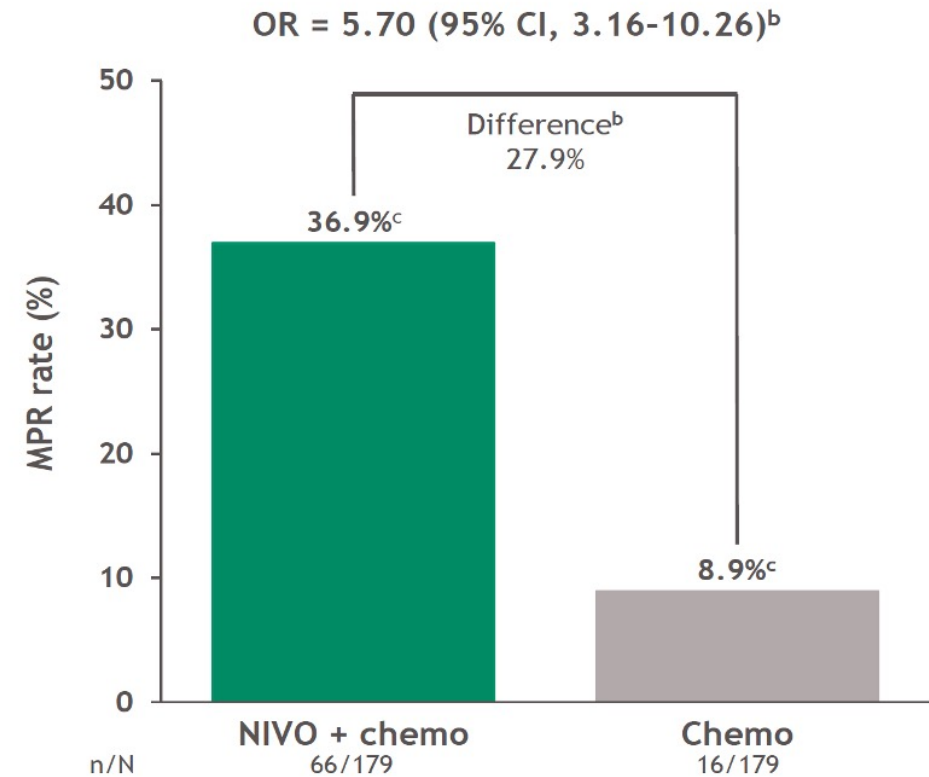
- ORR by BICR
- Feasibility of surgery; peri- and post-operative surgery-related AEs

CheckMate 816 Coprimary Endpoint: Pathologic Complete Response (pCR)

Primary endpoint: ITT (ypTON0)^b

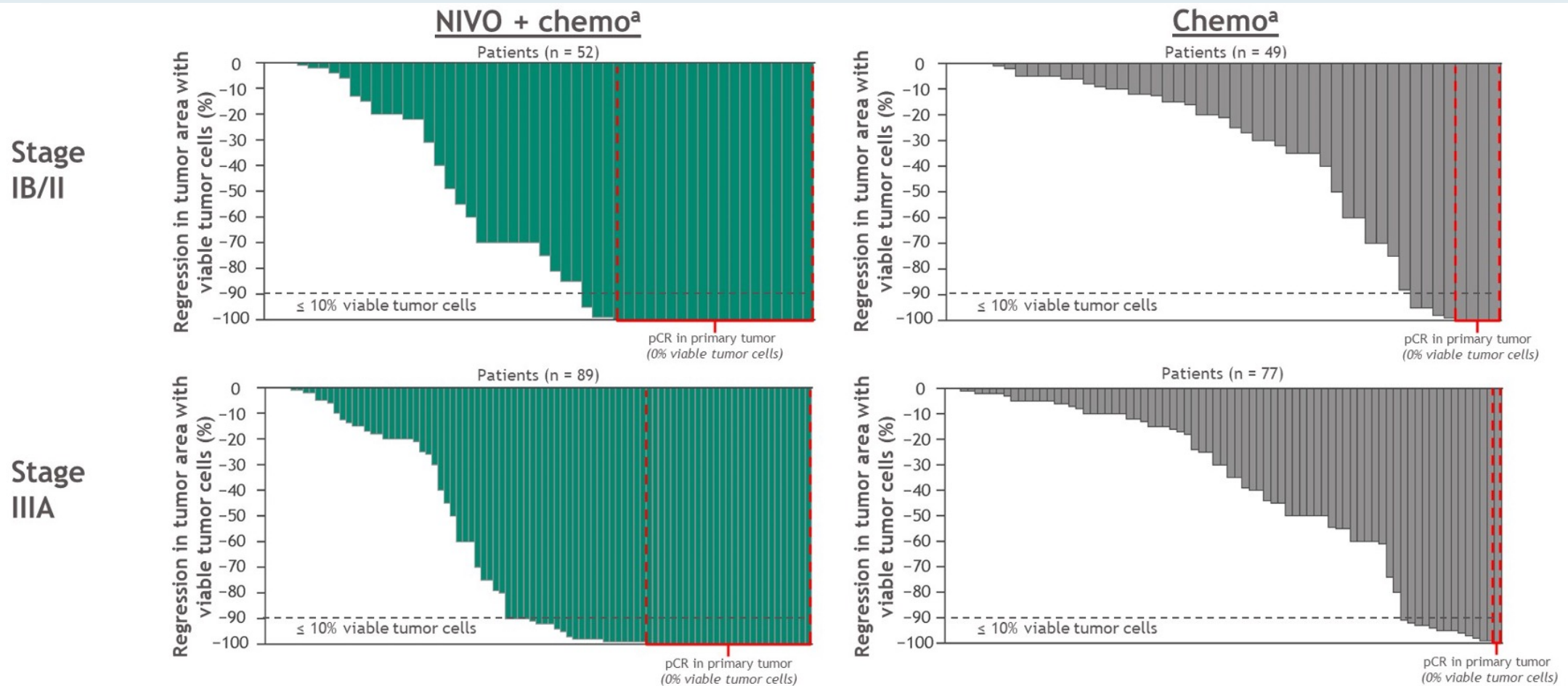


ITT



• pCR rate in the exploratory NIVO + IPI arm (ITT) was 20.4% (95% CI, 13.4-29.0)

CheckMate 816: Depth of Pathologic Regression in Primary Tumor by Stage



- The median residual viable tumor percentage in stage IB/II and IIIA was 28% and 8% with NIVO + chemo vs 79% and 70% with chemo, respectively

^aResponse-evaluable patients.

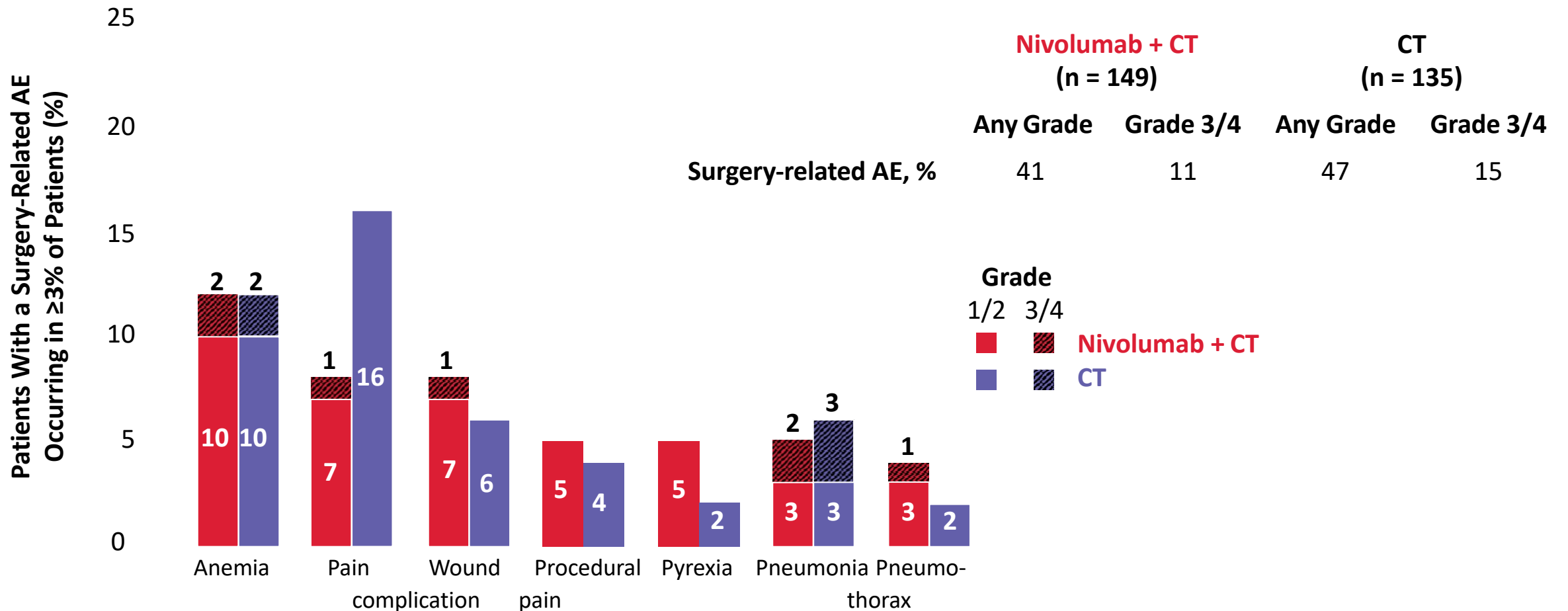
CheckMate 816: Impact of Neoadjuvant Immunotherapy on Surgery

Neoadjuvant immunotherapy did not negatively affect surgery outcomes

Surgery-Related Parameter in All Randomized Patients	Nivolumab + CT (n = 179)	CT (n = 179)
Surgery received/cancelled, %	83/16	75/21
	184 (130-252)*	217 (150-283)†
Surgery approach, %		
▪ Thoracotomy	59‡	63§
▪ Minimally invasive	30‡	22§
▪ Minimally invasive → open	11‡	16§
Type of surgery, %#		
▪ Lobectomy	77‡	61§
▪ Pneumonectomy	17‡	25§
Complete resection (R0), %	83	78

*n = 122. †n = 121. ‡n = 149. §n = 135. #Calculated from patients who received definitive surgery. Patients may have had ≥1 surgery type. Patients who received other types of surgery (eg, sleeve lobectomy, bilobectomy) not shown.

CheckMate 816: Surgery-Related Complications up to 90 Days After Definitive Surgery



Surgery-related AEs not shown: subcutaneous emphysema, atrial fibrillation, cough, pleural effusion, nausea, dyspnea, pulmonary fistula, non-cardiac chest pain. n = 2 grade 5 surgery-related AEs (pulmonary embolism, aortic rupture) in nivolumab + CT arm considered unrelated to study drug by investigator. n = 2 intraoperative complications (intraoperative hemorrhage, aortic rupture) in nivolumab + CT arm deemed not related to study drug.

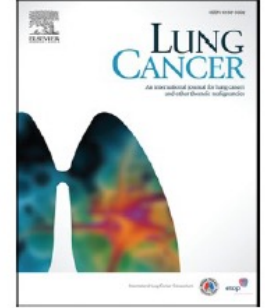


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Lung Cancer

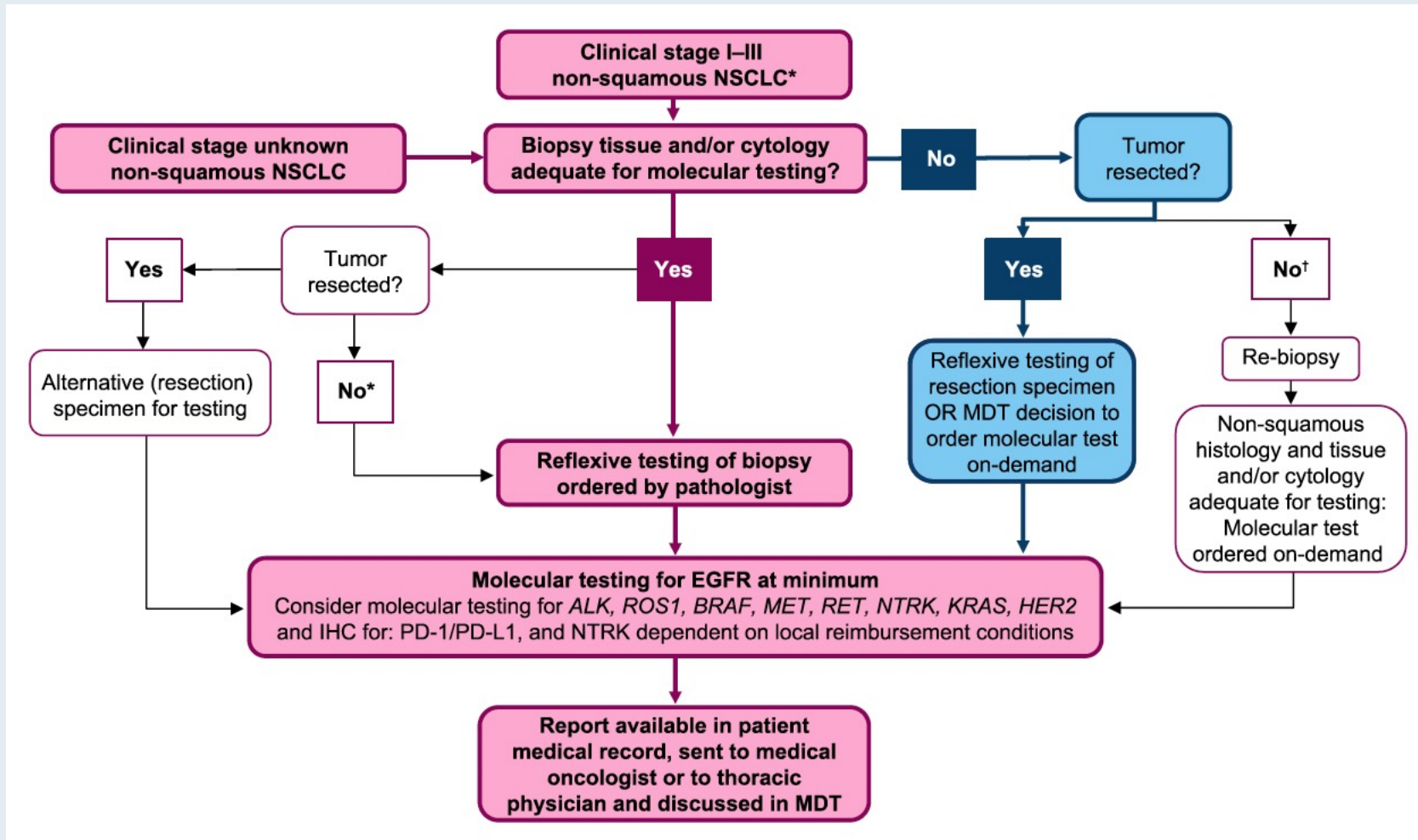
journal homepage: www.elsevier.com/locate/lungcan



Molecular testing in stage I–III non-small cell lung cancer: Approaches and challenges

Charu Aggarwal^{a,1}, Lukas Bubendorf^{b,1}, Wendy A. Cooper^{c,d,e,1}, Peter Illei^{f,1},
Paula Borrvalho Nunes^{g,h,1}, Boon-Hean Ong^{i,1}, Ming-Sound Tsao^{j,1}, Yasushi Yatabe^{k,1}, Keith
M. Kerr^{l,*}

Proposed Algorithm for Molecular Testing for Patients with Stage I-III NSCLC (Resectable and Unresectable)



Meet The Professor with Dr Aggarwal

MODULE 1: Adjuvant and Neoadjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

- Dr Gubens: A 59-year-old man with Stage IIA squamous cell carcinoma of the lung who received neoadjuvant pembrolizumab and radiation therapy on a clinical trial
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- Dr Morganstein: A 66-year-old man with metastatic adenocarcinoma of the lung (PD-L1 TPS 20%)

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- Dr Yang: An 87-year-old man with extensive-stage SCLC and PD-L1 >50%

MODULE 5: Appendix of Key Data Sets

Case Presentation: A 71-year-old woman with Stage III adenocarcinoma of the lung



Dr Mamta Choksi (New Port Richey, Florida)

What would you most likely recommend as consolidation treatment for a patient with locally advanced NSCLC who has completed chemoradiation therapy and is found to have an EGFR activating mutation?



Dr Aggarwal

Observation



Dr Hanna

No further therapy



Dr Goldberg

Durvalumab



Dr Liu

Osimertinib



Dr Govindan







Durvalumab



Dr Ramalingam

Durvalumab

What would you most likely recommend as consolidation treatment for a patient with locally advanced NSCLC who has completed chemoradiation therapy and is found to have a RET fusion?

 Dr Aggarwal	Observation	 Dr Hanna	Durvalumab
 Dr Goldberg	Durvalumab	 Dr Liu	Pralsetinib
 Dr Govindan	Durvalumab	 Dr Ramalingam	Durvalumab

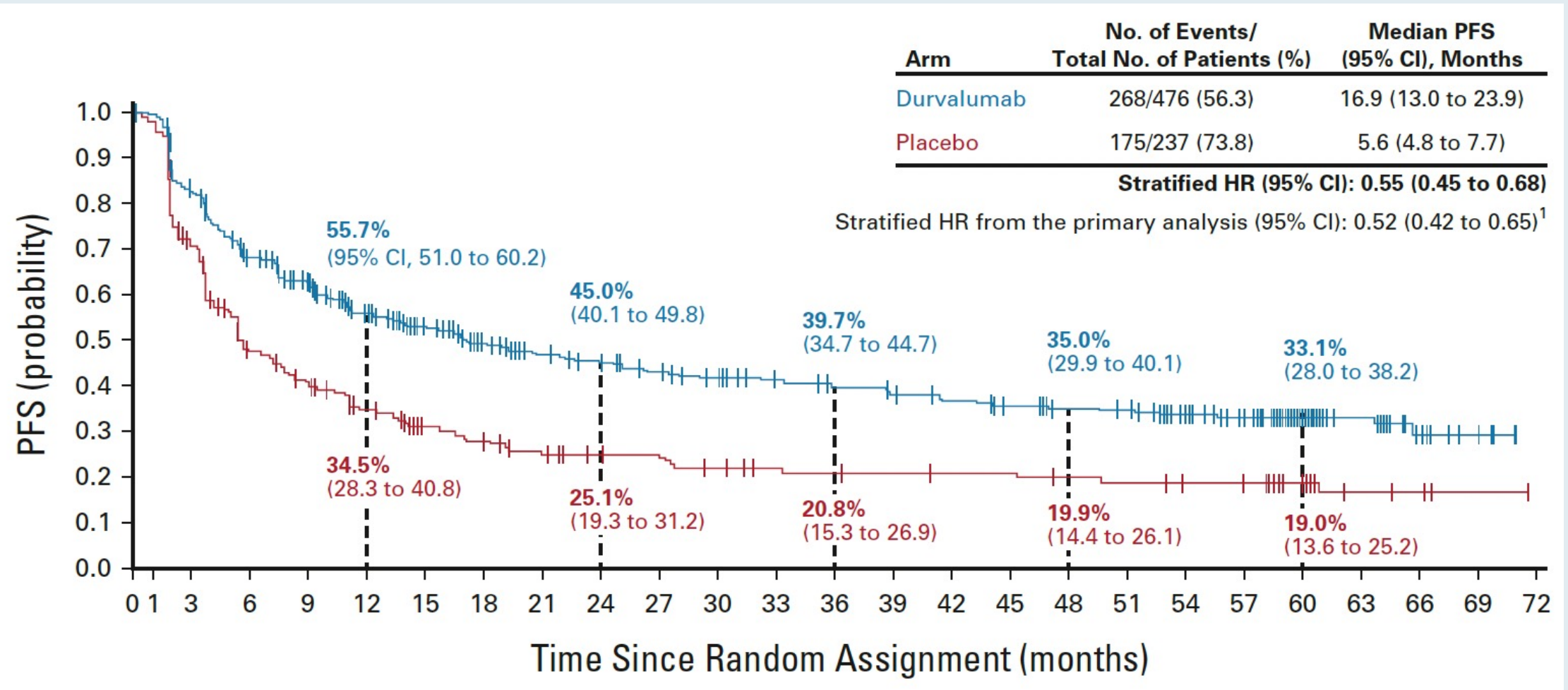
original reports

Five-Year Survival Outcomes From the PACIFIC Trial: Durvalumab After Chemoradiotherapy in Stage III Non–Small-Cell Lung Cancer

David R. Spigel, MD¹; Corinne Faivre-Finn, MD, PhD²; Jhanelle E. Gray, MD³; David Vicente, MD⁴; David Planchard, MD, PhD⁵; Luis Paz-Ares, MD, PhD⁶; Johan F. Vansteenkiste, MD, PhD⁷; Marina C. Garassino, MD^{8,9}; Rina Hui, PhD¹⁰; Xavier Quantin, MD, PhD¹¹; Andreas Rimner, MD¹²; Yi-Long Wu, MD¹³; Mustafa Özgüroğlu, MD¹⁴; Ki H. Lee, MD¹⁵; Terufumi Kato, MD¹⁶; Maïke de Wit, MD, PhD¹⁷; Takayasu Kurata, MD¹⁸; Martin Reck, MD, PhD¹⁹; Byoung C. Cho, MD, PhD²⁰; Suresh Senan, PhD²¹; Jarushka Naidoo, MBBCH, MHS²²; Helen Mann, MSc²³; Michael Newton, PharmD²⁴; Piruntha Thiyagarajah, MD²³; and Scott J. Antonia, MD, PhD³; on behalf of the PACIFIC Investigators

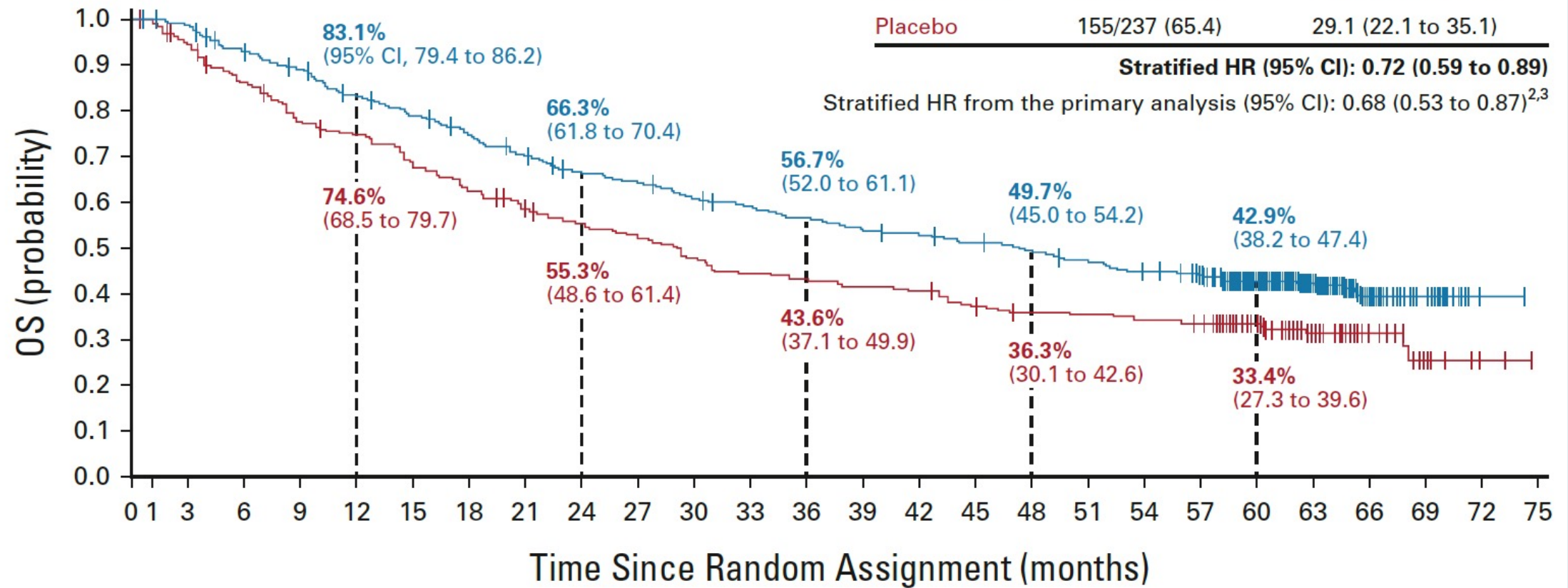
J Clin Oncol 2022;[Online ahead of print].

PACIFIC: Five-Year Progression-Free Survival (PFS) with Durvalumab After Chemoradiation Therapy for Stage III NSCLC



PACIFIC: Five-Year Overall Survival (OS) with Durvalumab After Chemoradiation Therapy for Stage III NSCLC

Arm	No. of Events/ Total No. of Patients (%)	Median OS (95% CI), Months
Durvalumab	264/476 (55.5)	47.5 (38.1 to 52.9)
Placebo	155/237 (65.4)	29.1 (22.1 to 35.1)



FDA Approves Durvalumab for Fixed-Dose Use in NSCLC, Bladder Cancer Indications

Press Release: November 20, 2020

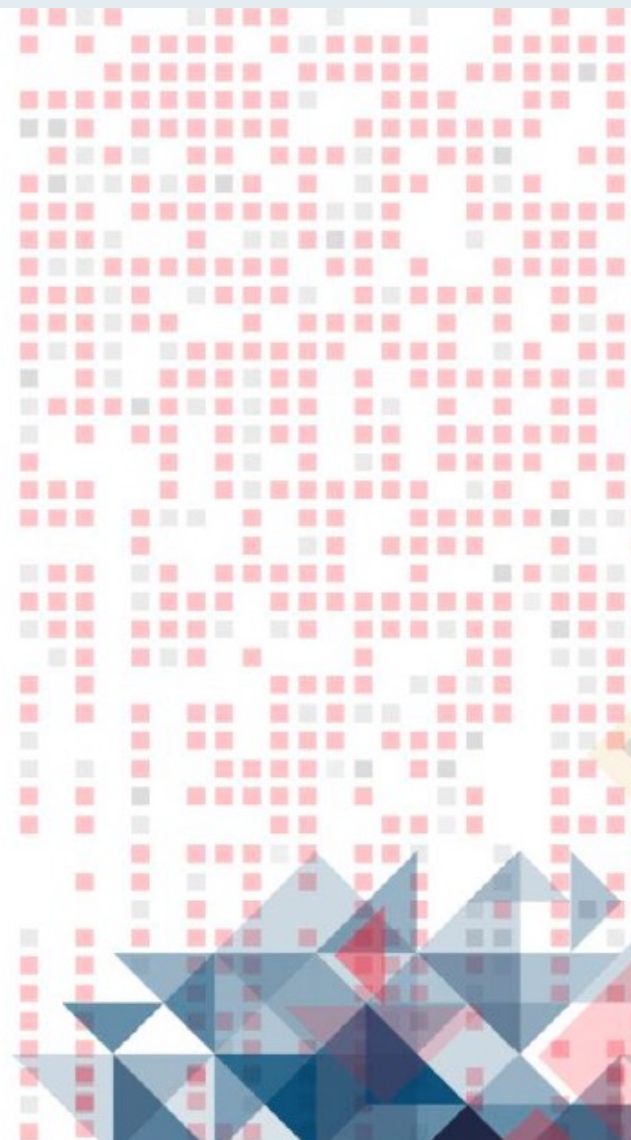
“The FDA has approved durvalumab for an additional dosing option, a fixed dose of 1500 mg every 4 weeks, in the approved indications of unresectable stage III non-small cell lung cancer after chemoradiation and previously treated advanced bladder cancer.

This new dosing option is consistent with the dosing for the agent that has been approved in extensive-stage small cell lung cancer (ES-SCLC); this will serve as an alternative option for patients who weigh more than 30 kg rather than the weight-based dosing of 10 mg/kg that is administered every 2 weeks.

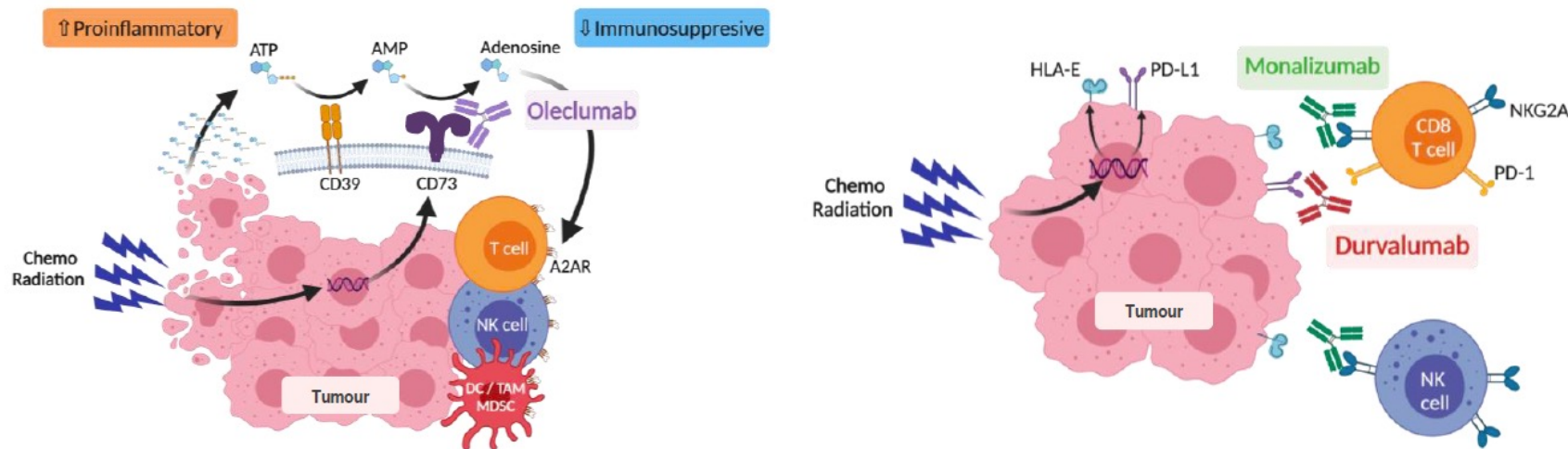
The regulatory decision was based on data from several clinical trials examining the agent, including the phase 3 PACIFIC trial (NCT02125461), which supported the 2-week, weight-based dosing in patients with unresectable stage III NSCLC, and the phase 3 CASPIAN trial (NCT03043872), which examined a 4-week, fixed-dose during maintenance treatment in patients with ES-SCLC.”

COAST: an open-label, Phase 2, multidrug platform study of durvalumab alone or in combination with novel agents in patients with locally advanced, unresectable, Stage III NSCLC

Alex Martinez-Marti¹, Margarita Majem², Fabrice Barlesi³, Enric Carcereny⁴, Quincy Chu⁵, Isabelle Monnet⁶, Alfredo Sanchez-Hernandez⁷, Shaker Dakhil⁸, D. Ross Camidge⁹, Peng He¹⁰, Yee Soo-Hoo¹⁰, Zachary A. Cooper¹⁰, Rakesh Kumar¹⁰, John Bothos¹⁰, Charu Aggarwal¹¹, Roy S. Herbst¹²



Rationale for combining durvalumab with oleclumab (anti-CD73) or monalizumab (anti-NKG2A)



- RT induces expression of CD73 and HLA-E (NKG2A ligand), which inhibit antitumour immune response¹⁻⁴
- Oleclumab inhibits CD73 to reduce extracellular adenosine production, thereby promoting antitumour immunity.⁵ Oleclumab combined with durvalumab produced durable responses with manageable safety in a Ph I study of advanced *EGFR*m NSCLC⁶
- Monalizumab blocks NKG2A to reduce inhibition of NK and CD8+ T cells.⁷ Monalizumab combined with cetuximab had promising activity with manageable safety in a Ph I/II trial of patients with R/M HNSCC⁸
- Combinations of RT and anti-CD73/NKG2A ± anti-PD-(X) show increased antitumour activity in preclinical models^{1,2,4}

ATP, adenosine triphosphate; AMP, adenosine monophosphate; DC, dendritic cell; *EGFR*m, epidermal growth factor receptor mutant; MDSC, myeloid-derived suppressor cell; NK, natural killer; PD-(L)1, programmed cell death (ligand) 1; R/M HNSCC, recurrent/metastatic head and neck squamous cell carcinoma; RT, radiotherapy; TAM, tumour-associated macrophages
 1. Wennerberg E, et al. *Cancer Immunology Res* 2020;8:465-478; 2. Tsukui H, et al. *BMC Cancer* 2020;20:411; 3. Nguyen AM, et al. *Mol Cell Proteomics*, 2020;19:375-389;
 4. Battaglia NG, et al. *J Immunol* 2020;204:241.24; 5. Geoghegan JC, et al. *MAbs* 2016;8:454-467; 6. Bendell J, et al. *J Clin Oncol* 2021;39.no. 15_suppl:9047;
 7. André P, et al. *Cell* 2018;175:1731-1743.e13; 8. Cohen RB et al. *J Clin Oncol* 38: 2020 (suppl; abstr 6516). Figures created with BioRender.com.

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Approximately how many patients with metastatic NSCLC in your practice are alive without evidence of disease progression 4 or more years after their initial diagnosis of metastatic disease?

1. 0

2. 1

3. 2-5

4. 6-10

5. More than 10

Case Presentation: A 54-year-old woman with adenocarcinoma of the lung and multiple brain metastases (PD-L1 TPS 60%)



Dr William Mitchell (Charlotte, North Carolina)

Case Presentation: A 67-year-old man with adenocarcinoma of the lung (no actionable mutations, PD-L1 >50%)



Dr Laurie Matt-Amaral (Akron, Ohio)

Case Presentation: A 62-year-old man with metastatic squamous cell carcinoma of the lung and PD-L1 >50%



Dr Rahul Gosain (Corning, New York)

Case Presentation: A 66-year-old man with metastatic adenocarcinoma of the lung (PD-L1 TPS 20%)



Dr Neil Morganstein (Summit, New Jersey)

Which first-line treatment regimen would you recommend for a 65-year-old patient with metastatic nonsquamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 0%?



Dr Aggarwal

**Carboplatin/pemetrexed/
pembrolizumab**



Dr Hanna

**Carboplatin/pemetrexed/
pembrolizumab**



Dr Goldberg

**Carboplatin/pemetrexed/
pembrolizumab**



Dr Liu

**Carboplatin/pemetrexed/
pembrolizumab**



Dr Govindan

**Carboplatin/pemetrexed/
pembrolizumab**



Dr Ramalingam

Ipilimumab/nivolumab

For a patient with metastatic NSCLC and a high PD-L1 TPS (>50%) to whom you've decided to administer anti-PD-1/PD-L1 antibody monotherapy, if one of the 3 approved agents, pembrolizumab, atezolizumab or cemiplimab, were priced 50% below the other 2 agents, would you preferentially use it?

1. Yes
2. Yes, depending on the agent
3. No

FDA-Approved Single-Agent Immunotherapy Options for First-Line Therapy

Monotherapy	FDA approval	Pivotal study	Histologic type	HR (OS)
Pembrolizumab ^{1,2} (q3wk or q6wk)	4/11/19 10/24/16	KEYNOTE-042 KEYNOTE-024	PD-L1 TPS ≥1%	0.63
Atezolizumab ³ (q2wk, q3wk or q4wk)	5/18/20	IMpower110	PD-L1 TPS ≥50, EGFR and/or ALK wt	0.59
Cemiplimab ⁴ (q3wk)	2/22/21	EMPOWER-Lung 1 (Study 1624)	PD-L1 TPS ≥50, EGFR and/or ALK and/or ROS1 wt	0.57

¹ Mok. *Lancet* 2019. ² Reck. *J Clin Oncol* 2019. ³ Herbst. *N Engl J Med* 2020. ⁴ Sezer. *Lancet* 2021.

EMPOWER-Lung 3: First-Line Cemiplimab with Platinum-Doublet Chemotherapy for Advanced NSCLC

Key eligibility criteria

- Treatment-naïve advanced NSCLC (non-squamous and squamous histology; Stage IIIb/c†, IV)
- Any PD-L1 expression
- No *EGFR*, *ALK*, or *ROS1* mutations
- ECOG PS 0 or 1
- Treated, clinically stable CNS metastases ‡

Stratification factors

- PD-L1 expression: <1% vs 1–49% vs ≥50%
- Histology: non-squamous vs squamous

Endpoints

- Primary: OS
- Key secondary: PFS and ORR
- Additional secondary: DOR, BOR, safety, and PRO

R 2:1

Arm A

Cemiplimab 350 mg Q3W + investigator's choice platinum-doublet chemo Q3W for 4 cycles[§]

PD or 108 weeks

Arm B

Placebo Q3W + investigator's choice platinum-doublet chemo Q3W for 4 cycles[§]

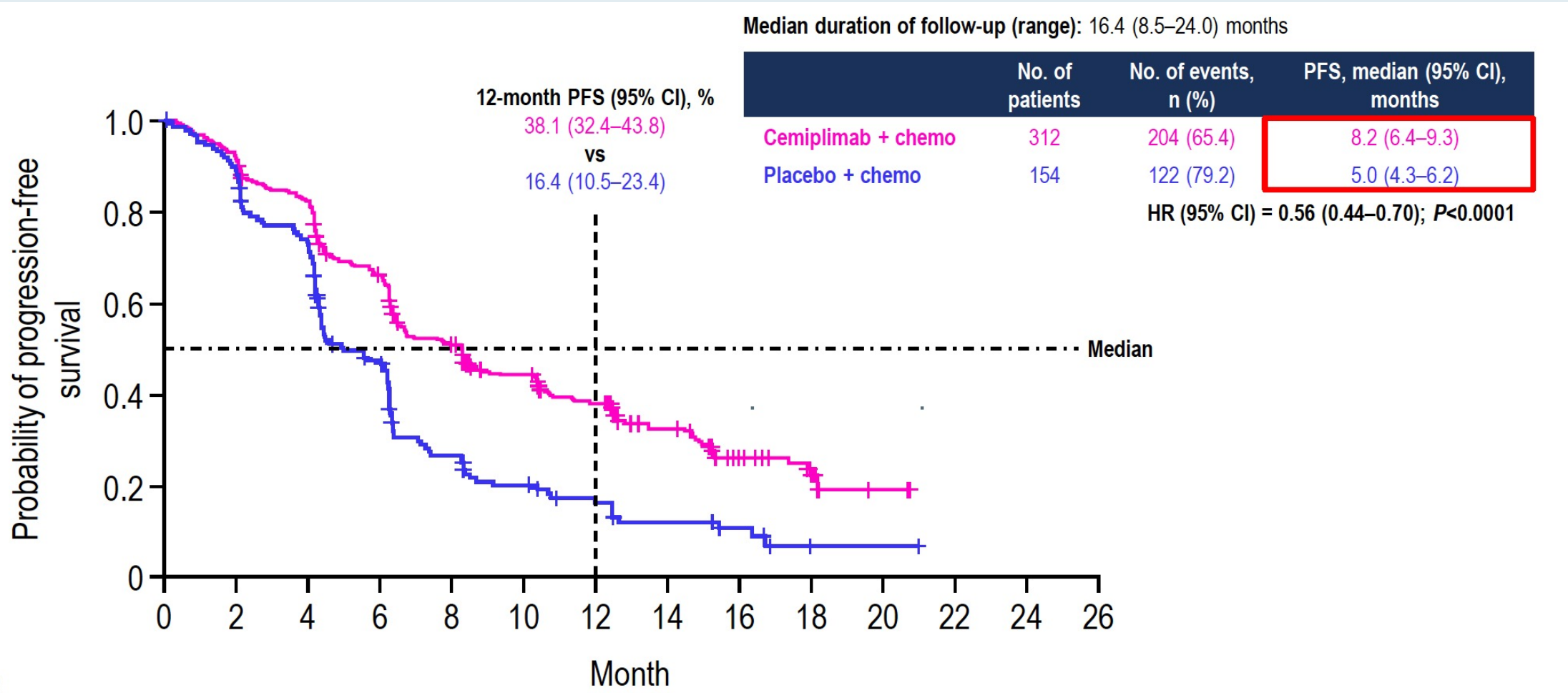
PD or 108 weeks

Follow-up

N=466

Two interim analyses were prespecified per protocol
Second interim analysis (14 June 2021) presented here

EMPOWER-Lung 3: Progression-Free Survival

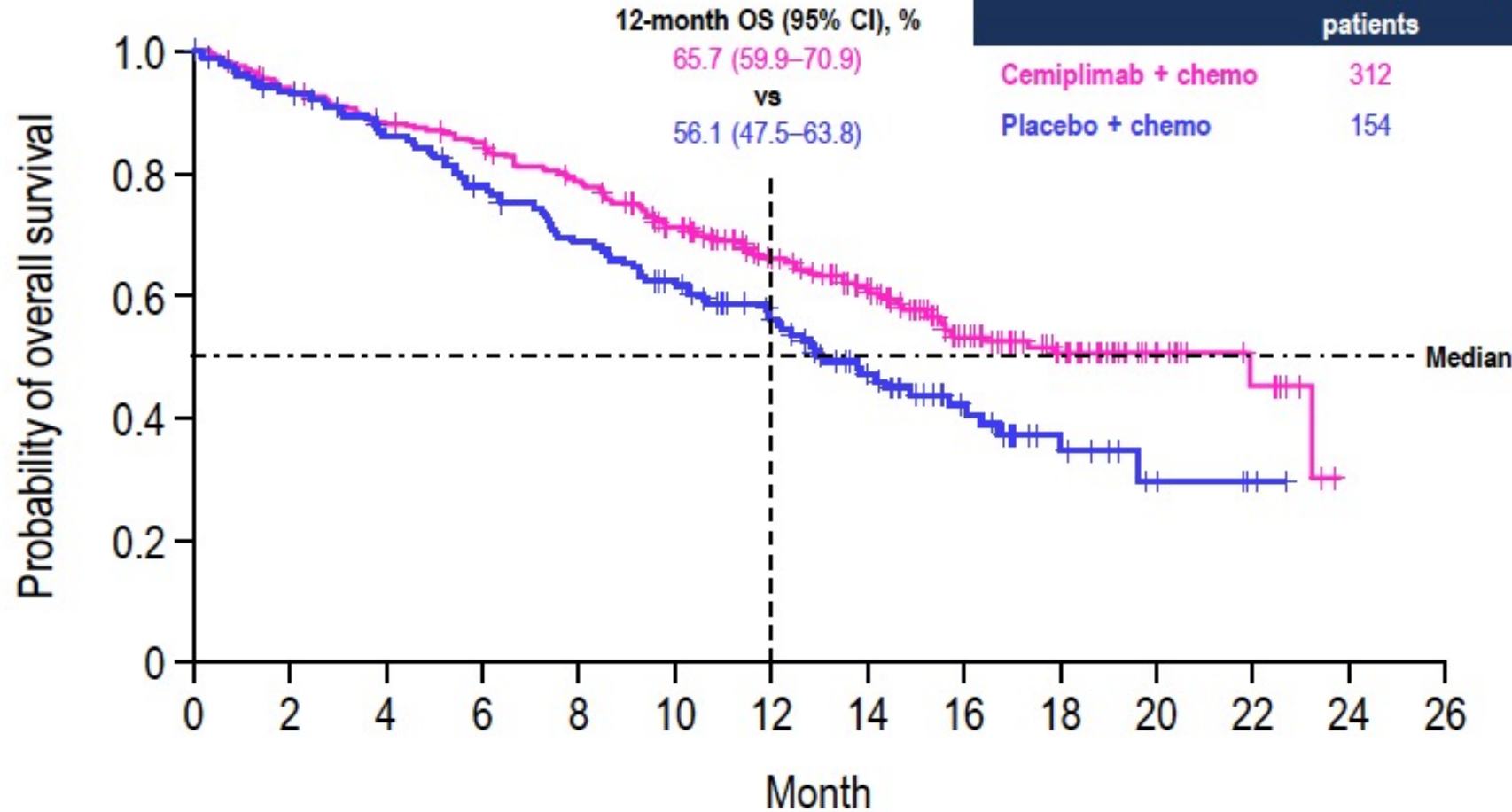


EMPOWER-Lung 3: First-Line Cemiplimab with Platinum-Doublet Chemotherapy for Advanced NSCLC

Median duration of follow-up (range): 16.4 (8.5–24.0) months

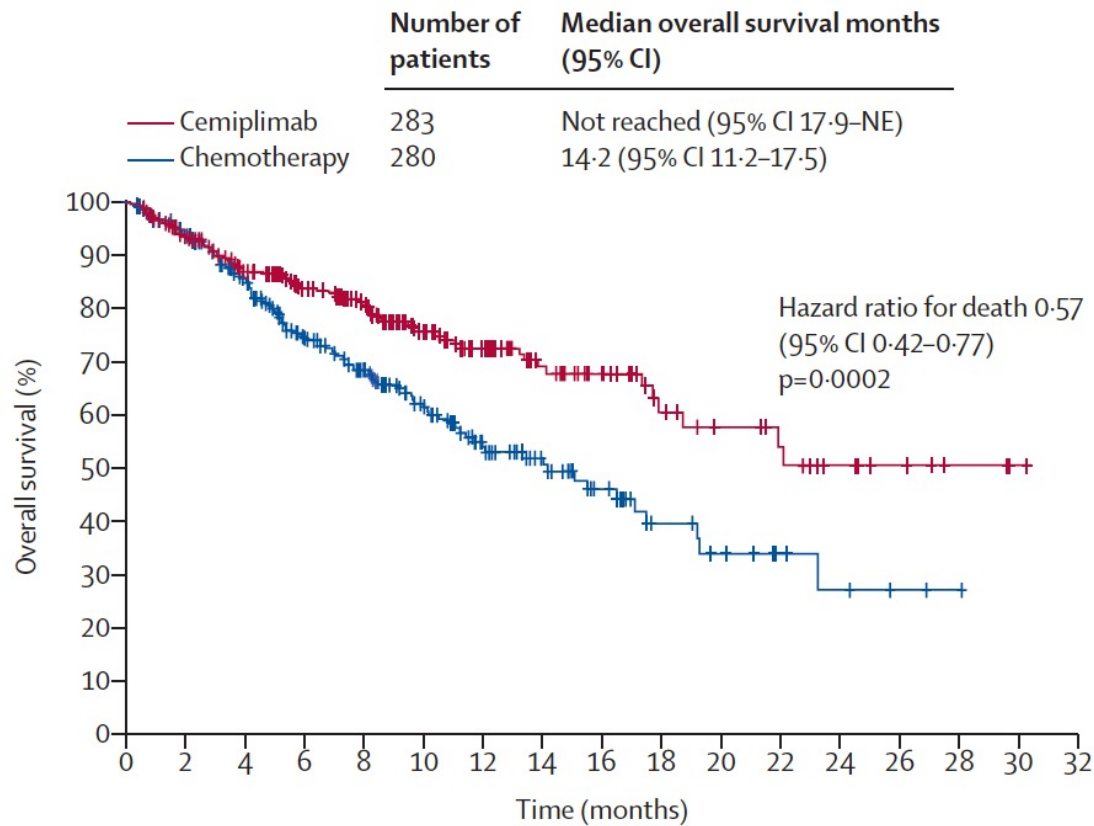
	No. of patients	No. of events, n (%)	OS, median (95% CI), months
Cemiplimab + chemo	312	132 (42.3)	21.9 (15.5–NE)
Placebo + chemo	154	82 (53.2)	13.0 (11.9–16.1)

HR (95% CI) = 0.71 (0.53–0.93); P=0.014

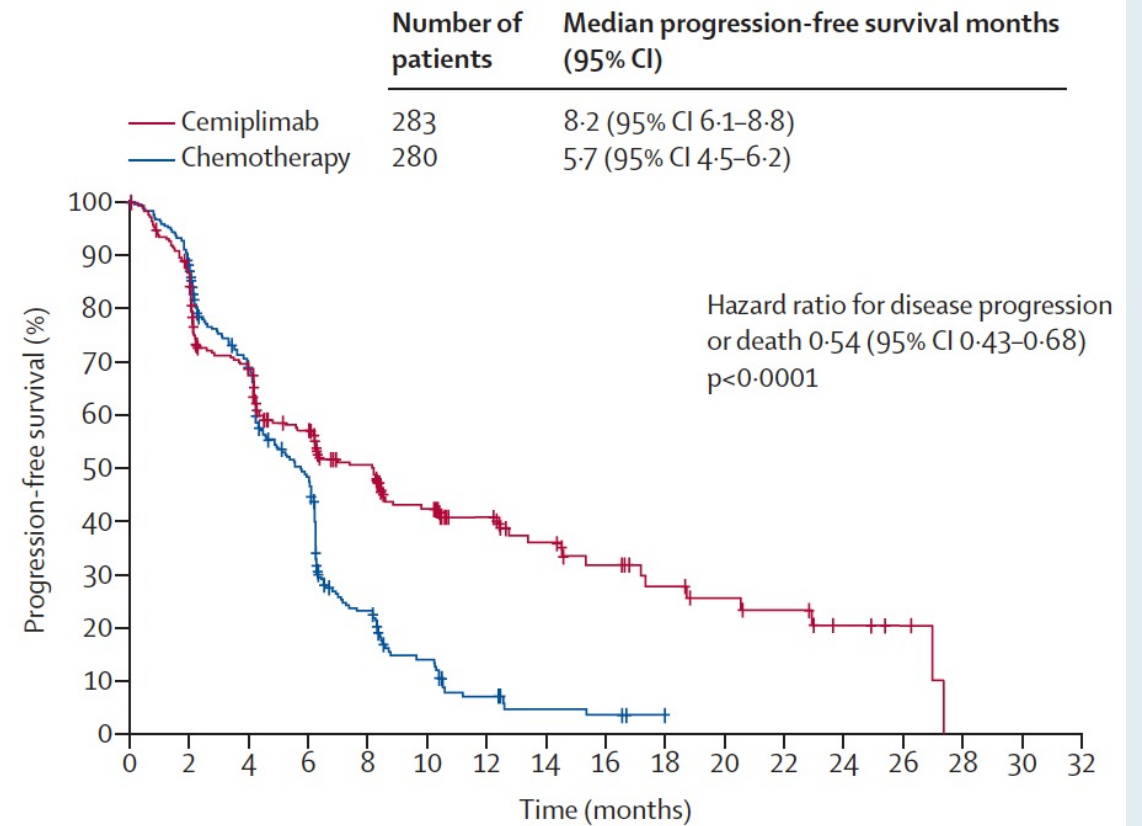


EMPOWER-Lung 1: A Phase III Trial of Cemiplimab Monotherapy for First-Line Treatment of NSCLC with PD-L1 $\geq 50\%$

Overall Survival



Progression-Free Survival



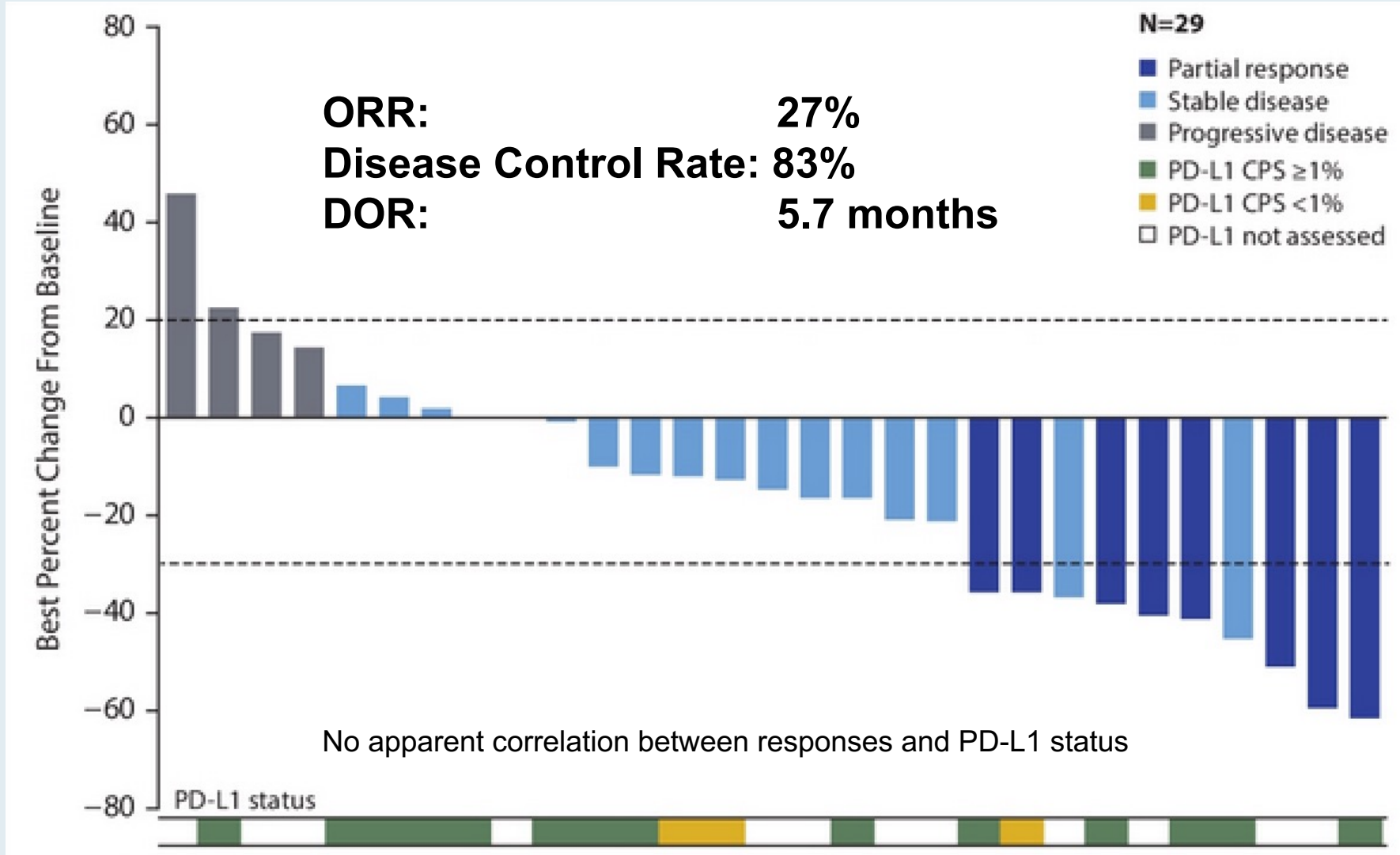
FDA-Approved Immunotherapy Combination Options for First-Line Therapy

Combination regimen	FDA approval	Pivotal study	Histologic type	HR (OS)
Pembrolizumab (q3wk or q6wk) + Platinum and pemetrexed ¹	8/20/18	KEYNOTE-189	Nonsquamous	0.56
Pembrolizumab (q3wk or q6wk) + Carboplatin, paclitaxel or <i>nab</i> paclitaxel ²	10/30/18	KEYNOTE-407	Squamous	0.71
Atezolizumab (q3wk) + Carboplatin and paclitaxel and bevacizumab ³	12/6/18	IMpower150	Nonsquamous	0.80
Atezolizumab (q3wk) + Carboplatin and <i>nab</i> paclitaxel ⁴	12/3/19	IMpower130	Nonsquamous	0.79
Nivolumab (q2wk) + Ipilimumab ⁵	5/15/20	CheckMate 227	PD-L1 TPS ≥1, EGFR and/or ALK wt	0.76
Nivolumab (q3wk) + Ipilimumab and chemotherapy ⁶	5/26/20	CheckMate 9LA	EGFR and/or ALK wt	0.72

¹ Rodriguez-Abreu. *Ann Oncol* 2021. ² Paz-Ares. *J Thorac Oncol* 2020. ³ Socinski *J Thorac Oncol* 2021. ⁴ West. *Lancet Oncol* 2019.

⁵ Paz-Ares. ASCO 2021;Abstract 9016. ⁶ Reck. ASCO 2021;Abstract 9000.

COSMIC-021 (Cohort 7): Best Change from Baseline with Cabozantinib/Atezolizumab for Metastatic NSCLC



Patient population

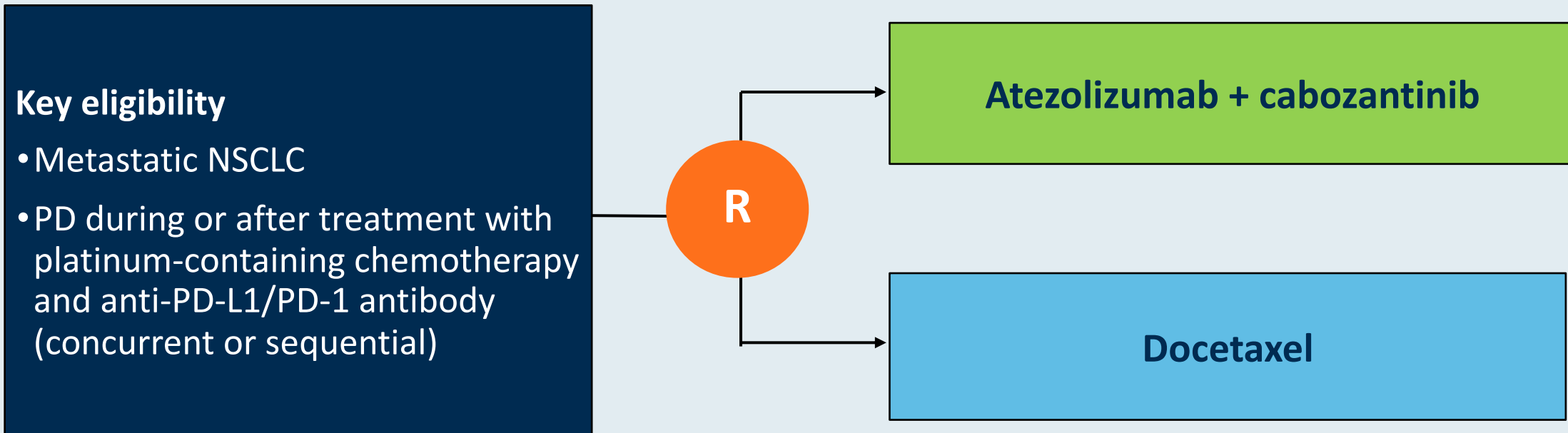
- Radiographic progression on or after 1 prior ICI treatment
- ≤2 lines of prior systemic anticancer therapy for metastatic NSCLC
- No EGFR mutations, ALK or ROS1 rearrangements or BRAF V600E mutation

COSMIC-021 (Cohort 7): Immune-Related Adverse Events with Cabozantinib/Atezolizumab for Metastatic NSCLC

	NSCLC Cohort 7 (N=30)	
	Any Grade	Grade 3
Any AE, n (%)	6 (20)	0
Hyperthyroidism	1 (3.3)	0
Hypothyroidism	1 (3.3)	0
Lipase increased	1 (3.3)	0
Myocarditis*	1 (3.3)	0
Pain	1 (3.3)	0
Pneumonitis*	1 (3.3)	0
Rash	1 (3.3)	0

*One patient experienced grade 5 pneumonitis and myocarditis; pneumonitis was assessed as the cause of death

CONTACT-01 Phase III Study Design



Primary endpoint: Overall survival

Secondary endpoints: PFS, ORR, DOR, others

Background: TIGIT Pathway

- TIGIT (T cell immunoreceptor with Ig and ITIM domains) is a novel inhibitory receptor expressed on multiple immune cells, including T cells and NK cells¹⁻³
- TIGIT inhibits T cells and NK cells by binding to its ligand PVR on tumor cells and antigen-presenting cells (APCs)
- TIGIT expression strongly correlates with PD-1 expression, especially in tumor-infiltrating T cells in lung cancer
- Hypothesis: Anti-TIGIT antibodies, which prevent TIGIT from binding to its ligand, could restore the anti-tumor response and could complement the activity of anti-PD-L1/PD-1 antibodies

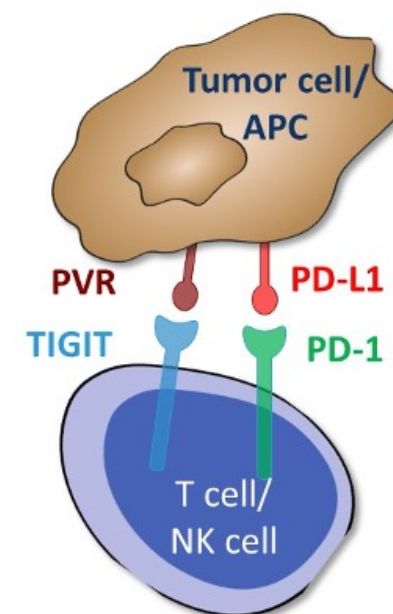
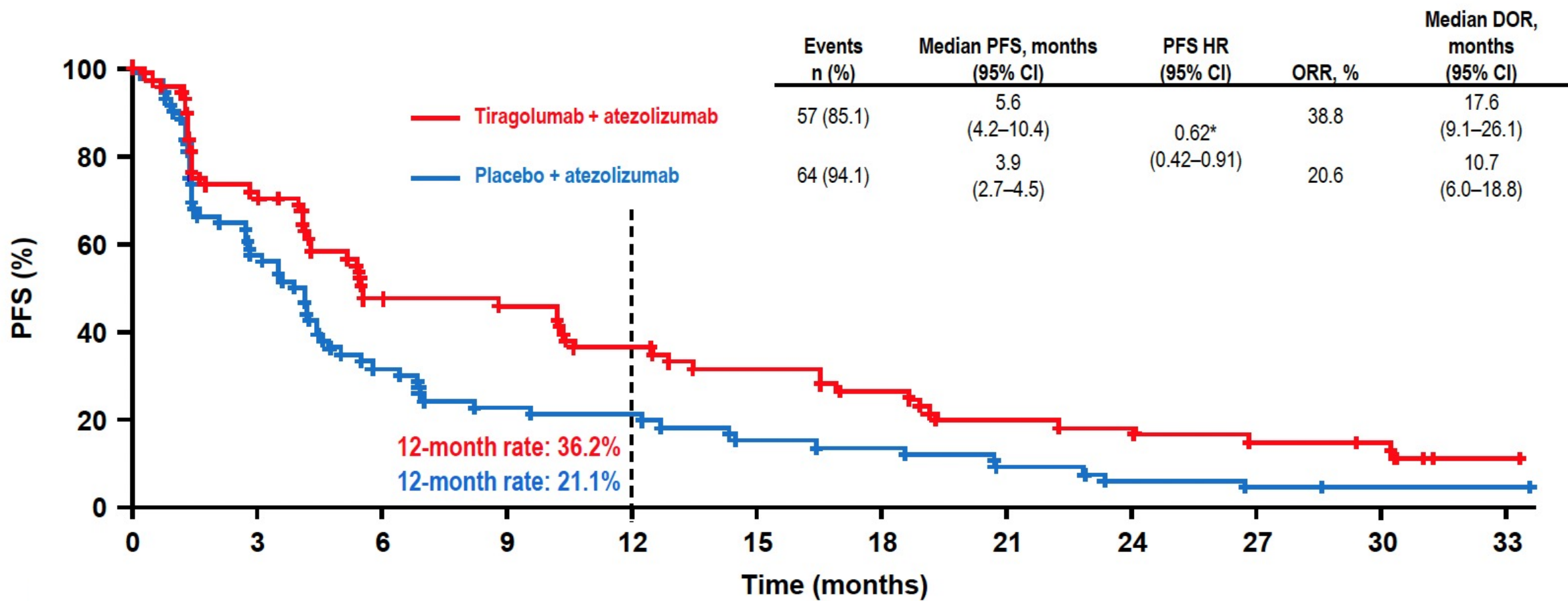


Figure adapted from Manieri et al.
Trends Immunology 2017

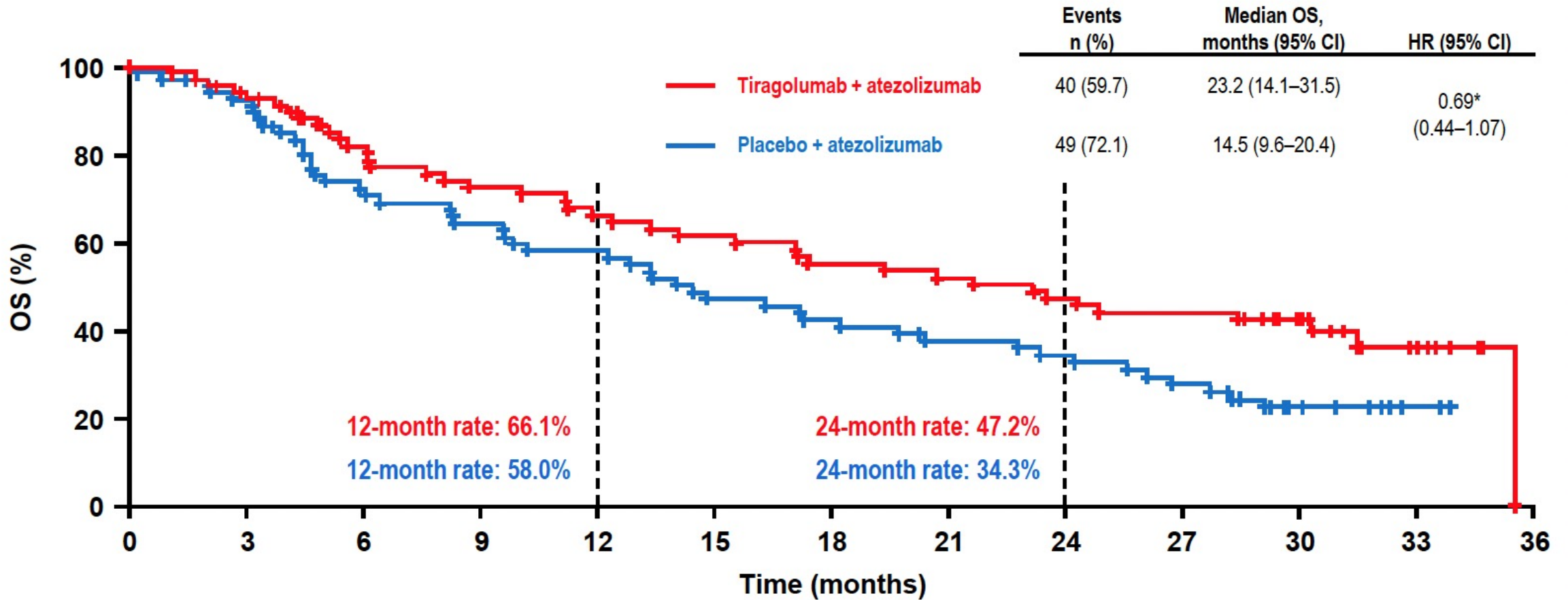
NK, natural killer; PVR, poliovirus receptor

¹ Manieri et al. *Trends Immunology* 2017; ² Rotte et al. *Annals of Oncology* 2018; ³ Yu et al. *Nature Immunology* 2009

CITYSCAPE: Investigator-Assessed PFS (ITT)



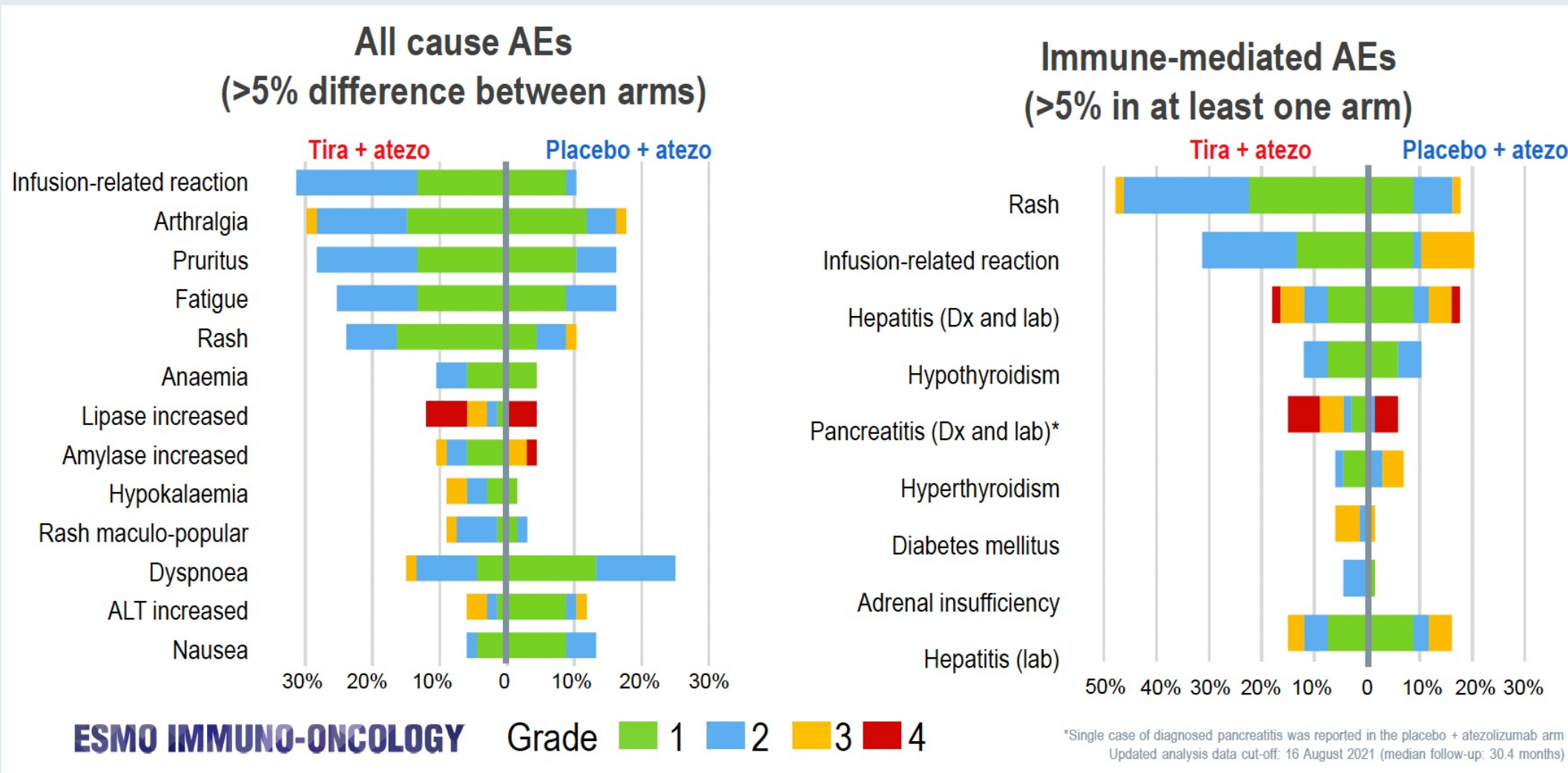
CITYSCAPE: Investigator-Assessed OS (ITT)



CITYSCAPE: Safety Summary

	Tiragolumab + atezolizumab (n=67)	Placebo + atezolizumab (n=68)
Median treatment duration, months (min–max)	4.99 (0–34.5)	2.81 (0–30.3)
Any-cause AEs, n (%)	66 (98.5)	66 (97.1)
Grade 3–4 AEs	35 (52.2)	27 (39.7)
Grade 5	3 (4.5)	7 (10.3)
Serious AEs	35 (52.2)	28 (41.2)
Treatment-related AEs, n (%)	55 (82.1)	48 (70.6)
Grade 3–4 AEs	15 (22.4)	17 (25.0)
Grade 5*	2 (3.0)	0
Serious AEs	14 (20.9)	12 (17.6)
Immune-mediated AEs, n (%)	51 (76.1)	32 (47.1)
Grade 3–4	13 (19.4)	11 (16.2)
AEs leading to dose modification/interruption, n (%)	33 (49.3)	24 (35.3)
AEs leading to treatment withdrawal, n (%)	10 (14.9)	9 (13.2)

CITYSCAPE: Incidence of Adverse Events



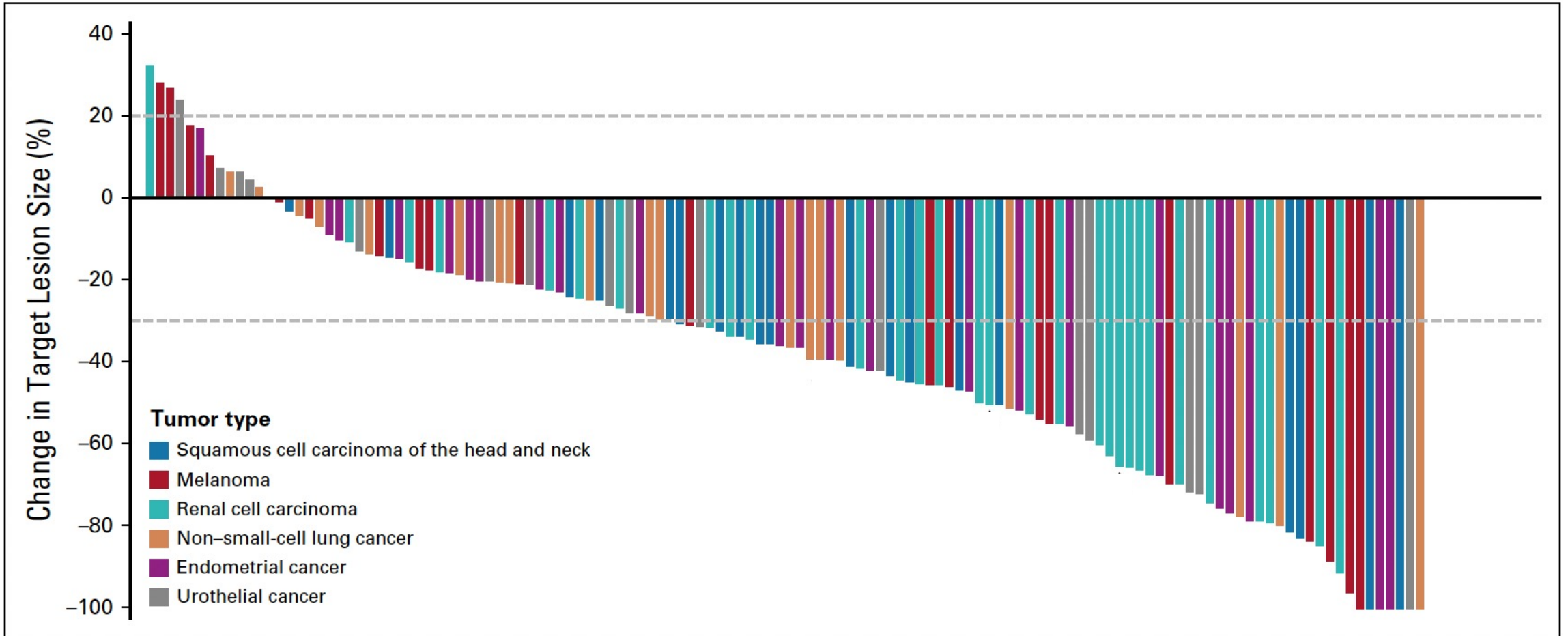
original reports

Phase IB/II Trial of Lenvatinib Plus Pembrolizumab in Patients With Advanced Renal Cell Carcinoma, Endometrial Cancer, and Other Selected Advanced Solid Tumors

Matthew H. Taylor, MD¹; Chung-Han Lee, MD, PhD²; Vicky Makker, MD²; Drew Rasco, MD³; Corina E. Dutcus, MD⁴; Jane Wu, PhD⁴; Daniel E. Stepan, MD⁵; Robert C. Shumaker, PhD⁴; and Robert J. Motzer, MD²

J Clin Oncol 2020;38:154-63

KEYNOTE-146: Maximum Change in Target Lesion Size (All Patients)



KEYNOTE-146: Phase IB/II Trial of Lenvatinib/Pembrolizumab in Advanced Solid Cancers

Efficacy in the Metastatic NSCLC Population				
N	Line of therapy	ORR	Median DOR	Median PFS
21	Any	33%	10.9 mo	5.9 mo

DOR = duration of response

Summary of Treatment-Related Adverse Events (TREAs): All Patients	
Parameter	(N = 137)
Serious AEs	26%
TREAs leading to pembrolizumab dose interruption	45%
TREAs leading to pembrolizumab discontinuation	15%
TREAs leading to lenvatinib dose reduction and/or interruption	85%
TREAs leading to lenvatinib discontinuation	13%

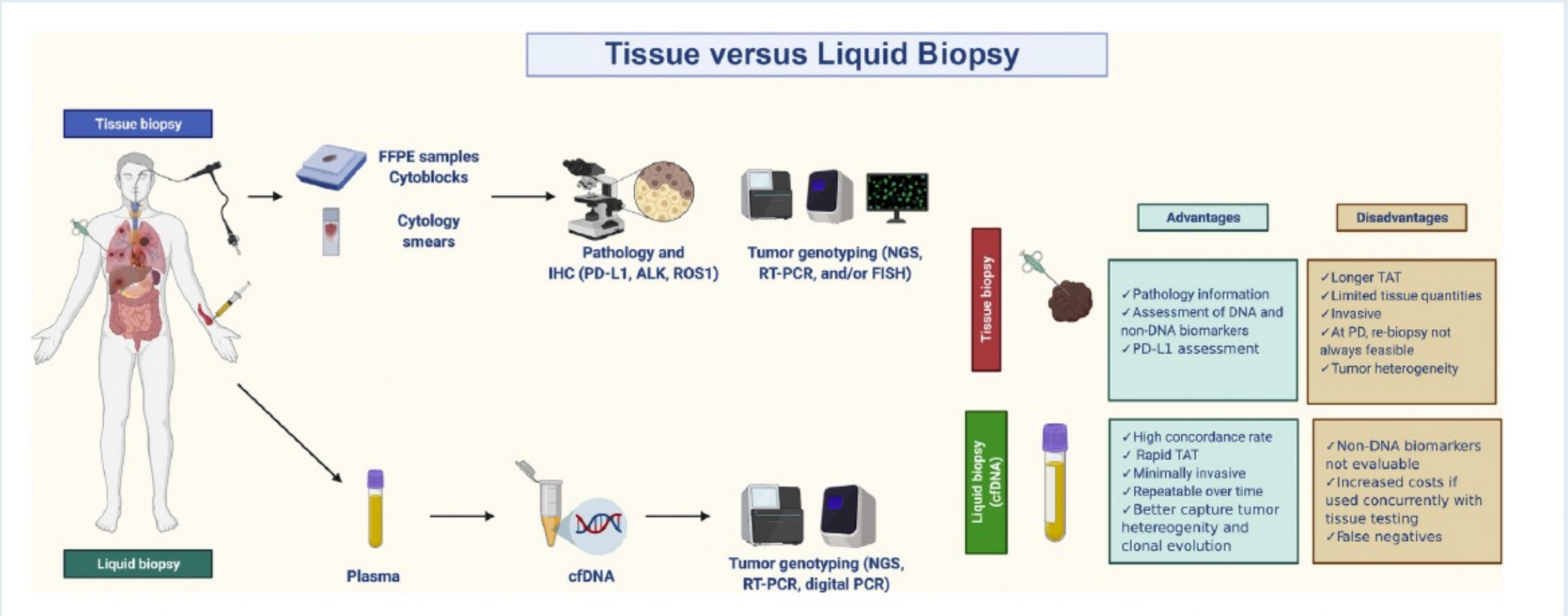
Ongoing LEAP Phase III Trials in NSCLC

Trial ID	N	Patient population	Line of therapy	Treatment
LEAP-006	726	Previously untreated metastatic nonsquamous NSCLC	1L	<ul style="list-style-type: none"> • Pemetrexed + platinum chemo + Pembrolizumab + lenvatinib • Pemetrexed + platinum chemo + pembrolizumab + placebo
LEAP-007	620	Previously untreated, advanced (Stage IV), PD-L1 positive (TPS $\geq 1\%$) NSCLC	1L	<ul style="list-style-type: none"> • Lenvatinib + pembrolizumab • Placebo + pembrolizumab
LEAP-008	405	Metastatic NSCLC that progressed during/after platinum doublet chemotherapy or on treatment with anti-PD-1/PD-L1 monoclonal antibody as monotherapy or combination therapy	$\geq 2L$	<ul style="list-style-type: none"> • Lenvatinib + pembrolizumab • Standard chemotherapy • Lenvatinib

Liquid Biopsy for Advanced NSCLC: A Consensus Statement From the International Association for the Study of Lung Cancer

Christian Rolfo, MD, PhD, MBA, Dr.hc.,^a Philip Mack, PhD,^a
Giorgio V. Scagliotti, MD, PhD,^b Charu Aggarwal, MD, MPH,^c Maria E. Arcila, MD,^d
Fabrice Barlesi, MD, PhD,^{e,f} Trevor Bivona, MD, PhD,^{g,h,i}
Maximilian Diehn, MD, PhD,^{j,k} Caroline Dive, PhD,^{l,m} Rafal Dziadziuszko, MD, PhD,ⁿ
Natasha Leighl, BSc, MSc, MD,^o Umberto Malapelle, PhD,^p Tony Mok, MD,^q
Nir Peled, MD, PhD,^r Luis E. Raez, MD,^s Lecia Sequist, MD, MPH,^{t,u,v}
Lynette Sholl, MD,^w Charles Swanton, BSc, PhD, FRCP,^{x,y} Chris Abbosh, MD, PhD,^y
Daniel Tan, MBBS, PhD,^{z,aa} Heather Wakelee, MD,^{bb} Ignacio Wistuba, MD,^{cc}
Rebecca Bunn, MSc,^{dd} Janet Freeman-Daily, MS, ENG,^{ee} Murry Wynes, PhD,^{cc}
Chandra Belani, MD,^{ff} Tetsuya Mitsudomi, MD, PhD,^{gg} David Gandara, MD^{hh,*}

Advantages and Disadvantages of Tissue and Liquid Biopsy for Tumor Genotyping in Advanced or Metastatic NSCLC



Clin Lung Cancer 2022;[Online ahead of print].

Original Study

Platinum Re-Exposure as a Non-Small Cell Lung Cancer (NSCLC) Treatment Strategy in the Age of Immunotherapy

Melina E. Marmarelis,^a Yu-Xiao Yang,^a Wei-Ting Hwang,^b Ronac Mamtani,^a
Aditi Singh,^a Christine Ciunci,^a Charu Aggarwal,^a Roger B. Cohen,^a
Corey J. Langer^a

Meet The Professor with Dr Aggarwal

MODULE 1: Adjuvant and Neoadjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

- Dr Gubens: A 59-year-old man with Stage IIA squamous cell carcinoma of the lung who received neoadjuvant pembrolizumab and radiation therapy on a clinical trial
- Dr Mohamed: A 62-year-old woman with 1.7-cm adenocarcinoma of the lung and 1.5-cm small cell lung cancer

MODULE 2: Stage III Unresectable NSCLC

- Dr Choksi: A 71-year-old woman with Stage III adenocarcinoma of the lung

MODULE 3: Metastatic NSCLC

- Dr Mitchell: A 54-year-old woman with adenocarcinoma of the lung and multiple brain metastases
- Dr Matt-Amaral: A 67-year-old man with adenocarcinoma of the lung (no actionable mutations, PD-L1 >50%)
- Dr Gosain: A 62-year-old man with metastatic squamous cell carcinoma of the lung and PD-L1 >50%
- Dr Morganstein: A 66-year-old man with metastatic adenocarcinoma of the lung (PD-L1 TPS 20%)

MODULE 4: Small Cell Lung Cancer (SCLC)

- Dr Saylor: A 60-year-old woman with extensive-stage SCLC
- Dr Yang: An 87-year-old man with extensive-stage SCLC and PD-L1 >50%

MODULE 5: Appendix of Key Data Sets

Case Presentation: A 60-year-old woman with extensive-stage SCLC



Dr Julia Saylor (North Charleston, South Carolina)

Case Presentation: An 87-year-old man with extensive-stage SCLC and PD-L1 >50%



Dr John Yang (Fall River, Massachusetts)

In general, what would be your preferred first-line treatment regimen for a 65-year-old patient with extensive-stage small cell lung cancer (SCLC)?



Dr Aggarwal

**Carboplatin/etoposide
+ atezolizumab**



Dr Hanna

**Carboplatin/etoposide
+ atezolizumab**



Dr Goldberg

**Carboplatin/etoposide
+ atezolizumab**



Dr Liu

**Carboplatin/etoposide
+ atezolizumab**



Dr Govindan

**Carboplatin/etoposide
+ atezolizumab**



Dr Ramalingam

**Carboplatin/etoposide
+ atezolizumab**

In what situations if any, do you administer trilaciclib to patients with extensive-stage SCLC who are receiving platinum/etoposide- or topotecan-containing regimens to reduce the incidence of chemotherapy-induced myelosuppression?



Dr Aggarwal

I do not



Dr Hanna

I have not yet done so



Dr Goldberg

Intolerance to G-CSF



Dr Liu

I have not used trilaciclib but might consider it if multilineage myelosuppression noted with topotecan



Dr Govindan







None



Dr Ramalingam

I have not used this in my practice

The benefits and risks of adding durvalumab to platinum/etoposide and of adding atezolizumab to carboplatin/etoposide are very similar, and from a clinical point of view selecting between the 2 regimens as first-line treatment for a patient with extensive-stage SCLC can be considered a “coin flip.”

 Dr Aggarwal	Agree	 Dr Hanna	Agree
 Dr Goldberg	Agree	 Dr Liu	Agree
 Dr Govindan	Agree	 Dr Ramalingam	Agree

In general, what is your preferred second-line treatment for a patient with extensive-stage SCLC with metastases and disease progression on chemotherapy/atezolizumab?



Dr Aggarwal

Lurbinectedin



Dr Hanna

Lurbinectedin



Dr Goldberg

Lurbinectedin



Dr Liu

Lurbinectedin



Dr Govindan

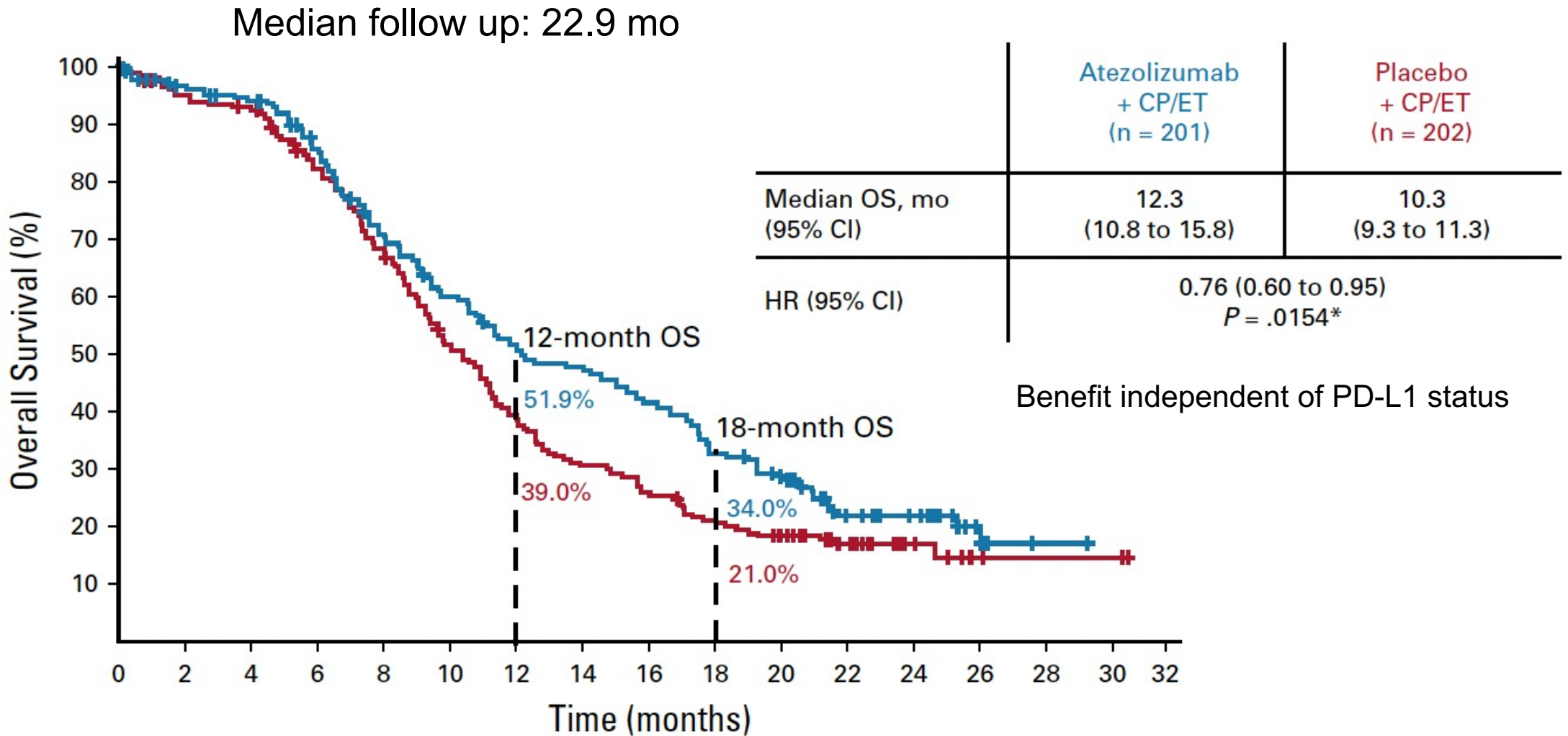
Topotecan or irinotecan



Dr Ramalingam

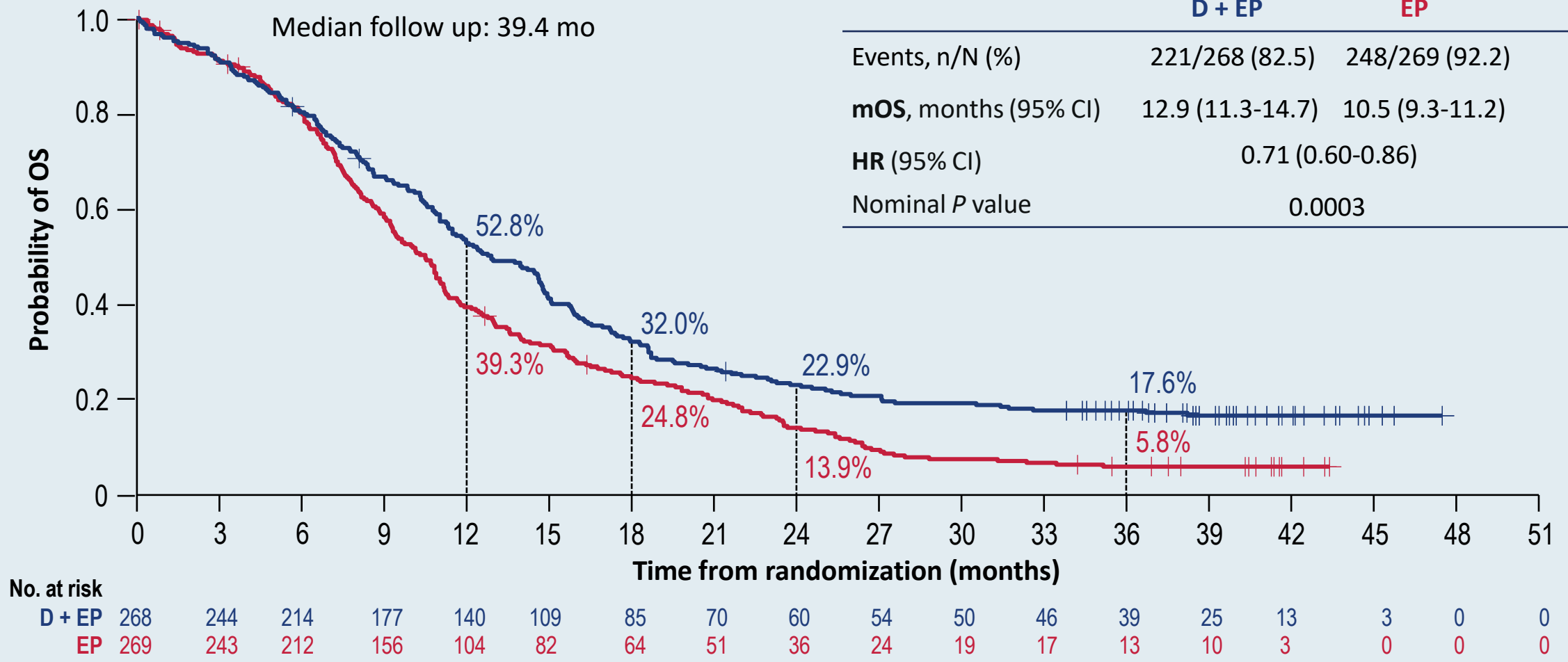
Lurbinectedin

IMpower133: Updated OS in Extensive-Stage SCLC (ES-SCLC) Treated with First-Line Atezolizumab, Carboplatin and Etoposide



CASPIAN: Three-Year Updated OS with First-Line Durvalumab, Platinum and Etoposide for ES-SCLC

	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	



**SKYSCRAPER-02: A Phase III, Randomized,
Double-Blind, Placebo-Controlled Study of
Atezolizumab plus Carboplatin and Etoposide
with or without Tiragolumab in Patients with
Untreated Extensive-Stage SCLC**

Changes Over Time in COVID-19 Severity and Mortality in Patients Undergoing Cancer Treatment in the United States: Initial Report From the ASCO Registry


Kathryn F. Mileham, MD¹; Suanna S. Bruinooge, MPH²; Charu Aggarwal, MD³; Alicia L. Patrick, MA¹; Christiana Davis, MD³; Daniel J. Mesenhowski, BA⁴; Alexander Spira, MD, PhD⁵; Eric J. Clayton, MS⁶; David Waterhouse, MD, MPH⁶; Susan Moore, CNS⁷; Abdul-Rahman Jazieh, MD⁸; Ronald C. Chen, MD⁹; Melinda Kaltenbaugh, MBA²; Jen Hanley Williams, MA²; Julie R. Gralow, MD²; Richard L. Schilsky, MD²; and Elizabeth Garrett-Mayer, PhD²

JCO Oncol Pract 2021;[Online ahead of print].

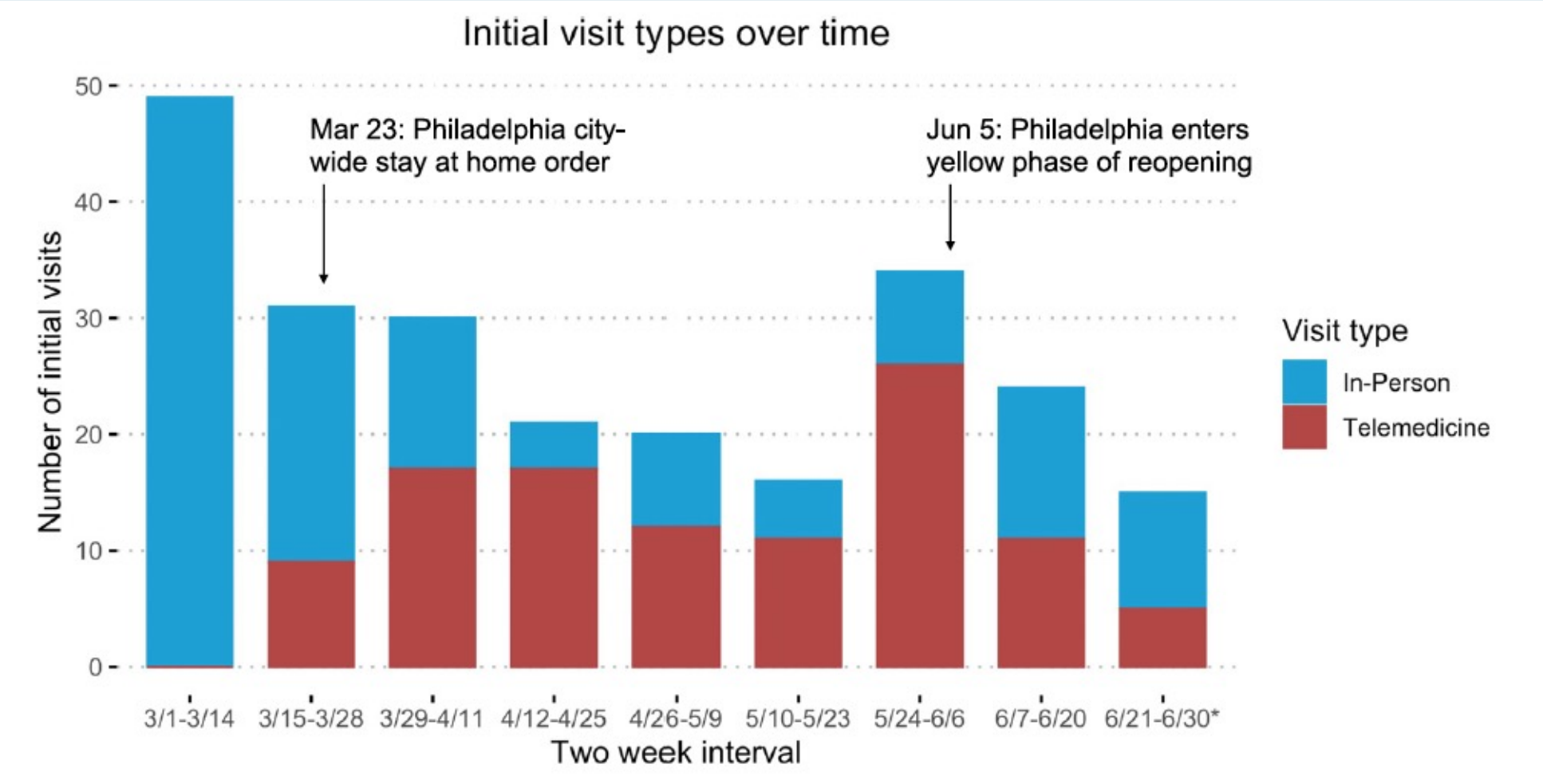
RESEARCH ARTICLE

Open Access

Impact of telemedicine adoption on accessibility and time to treatment in patients with thoracic malignancies during the COVID-19 pandemic

Vivek Nimgaonkar¹, Charu Aggarwal², Abigail T. Berman³, Peter Gabriel³, Lawrence N. Shulman², John Kucharczuk⁴, Megan Roy², Joshua M. Bauml², Aditi P. Singh², Roger B. Cohen², Corey J. Langer² and Melina E. Marmarelis^{2*} 

Telemedicine Adoption During a COVID-19 Surge



Meet The Professor with Dr Aggarwal

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Appendix

Recent Advances in Adjuvant Systemic Treatment of Solid Tumors

Disease	Agent or regimen			
NSCLC	Atezolizumab (10-15-21)	Osimertinib (12-18-20)	Durvalumab (2-16-18)	Nivolumab/chemotherapy*
Breast	Abemaciclib (10-13-21)	Olaparib	Pembrolizumab (7-26-21)	T-DM1 (5-3-19)
Upper GI	Nivolumab (5-20-21)			
RCC	Pembrolizumab (11-17-21)			
Bladder	Nivolumab (8-19-21)	Pembrolizumab [†] (1-8-2020)		
Ovarian	Olaparib/bevacizumab (5-8-20)	Niraparib (4-29-20)	Olaparib (12-19-18)	
Melanoma	Dabrafenib/trametinib (4-30-18)	Pembrolizumab (2-15-19)	Nivolumab (12-20-17)	
Prostate	Abiraterone (+ LHRH agonist)			

* Neoadjuvant therapy

[†] Indicated for patients with non-muscle-invasive bladder cancer who are not eligible for cystectomy but who may have undergone TURBT

FDA Approves Atezolizumab as Adjuvant Treatment for NSCLC

Press Release – October 15, 2021

“The Food and Drug Administration approved atezolizumab for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on $\geq 1\%$ of tumor cells, as determined by an FDA-approved test.

Today, the FDA also approved the VENTANA PD-L1 (SP263) Assay (Ventana Medical Systems, Inc.) as a companion diagnostic device to select patients with NSCLC for adjuvant treatment with atezolizumab.

The major efficacy outcome measure was disease-free survival (DFS) as assessed by the investigator in the primary efficacy analysis population (n=476) of patients with stage II-III A NSCLC with PD-L1 expression on $\geq 1\%$ of tumor cells (PD-L1 $\geq 1\%$ TC). Median DFS was not reached (95% CI: 36.1, NE) in patients on the atezolizumab arm compared with 35.3 months (95% CI: 29.0, NE) on the BSC arm (HR 0.66; 95% CI: 0.50, 0.88; p=0.004).”

Select Ongoing Phase III Trials of Immunotherapy in the Neoadjuvant Setting

Trial identifier	N	Patient population	Study arms
IMpower030 (NCT03456063)	453	Resectable Stage II, IIIA or select IIIB (T3N2 only) NSCLC Squamous or nonsquamous histology	<ul style="list-style-type: none"> • Atezolizumab + platinum-based chemotherapy • Placebo + platinum-based chemotherapy
KEYNOTE-671 (NCT03425643)	786	Resectable Stage II, IIIA or resectable IIIB (T3-4N2) NSCLC	<ul style="list-style-type: none"> • Pembrolizumab + platinum-based chemotherapy • Placebo + platinum-based chemotherapy
AEGEAN (NCT03800134)	800	Resectable Stage IIA to select (ie, N2) Stage IIIB NSCLC	<ul style="list-style-type: none"> • Durvalumab + platinum-based chemotherapy • Placebo + platinum-based chemotherapy

Select Ongoing Phase III Trials of Immunotherapy in the Adjuvant Setting

Trial identifier	N	Patient population	Study arms
BR31 (NCT02273375)	1,360	Stage IB (≥ 4 cm in the longest diameter), II or IIIA after complete resection	<ul style="list-style-type: none"> • Durvalumab • Placebo
KEYNOTE-091/ PEARLS (NCT02504372)	1,177	Stage IB with T ≥ 4 cm, II-III A NSCLC after complete surgical resection with or without adjuvant chemotherapy	<ul style="list-style-type: none"> • Pembrolizumab • Placebo
ANVIL (NCT02595944)	903	Complete surgical resection of Stage IB (≥ 4 cm), II or IIIA NSCLC with adjuvant chemotherapy Negative for ALK translocation and EGFR exon 19 deletion or exon 21 L858R mutation	<ul style="list-style-type: none"> • Nivolumab • Placebo

Year in Review: Kidney and Bladder Cancer

**Tuesday, March 8, 2022
5:00 PM – 6:00 PM ET**

Faculty

**Elizabeth R Plimack, MD, MS
Thomas Powles, MBBS, MRCP, MD**

Moderator

Neil Love, MD

Thank you for joining us!

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