Investigator Perspectives on Available Research and Challenging Questions in Melanoma and Nonmelanoma Skin Cancers: A Post-ASCO 2024 Annual Review

Tuesday, June 11, 2024
5:00 PM – 6:00 PM ET

Faculty

Nikhil I Khushalani, MD
Jason J Luke, MD

Moderator

Neil Love, MD

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Faculty

Nikhil I Khushalani, MD
Senior Member and Vice Chair
Department of Cutaneous Oncology
Moffitt Cancer Center
Tampa, Florida

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Jason J Luke, MD
Associate Director for Clinical Research
Director, Immunotherapy and Drug Development Center
Associate Professor of Medicine
UPMC Hillman Cancer Center and University of Pittsburgh
Pittsburgh, Pennsylvania

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Dr Love — Disclosures

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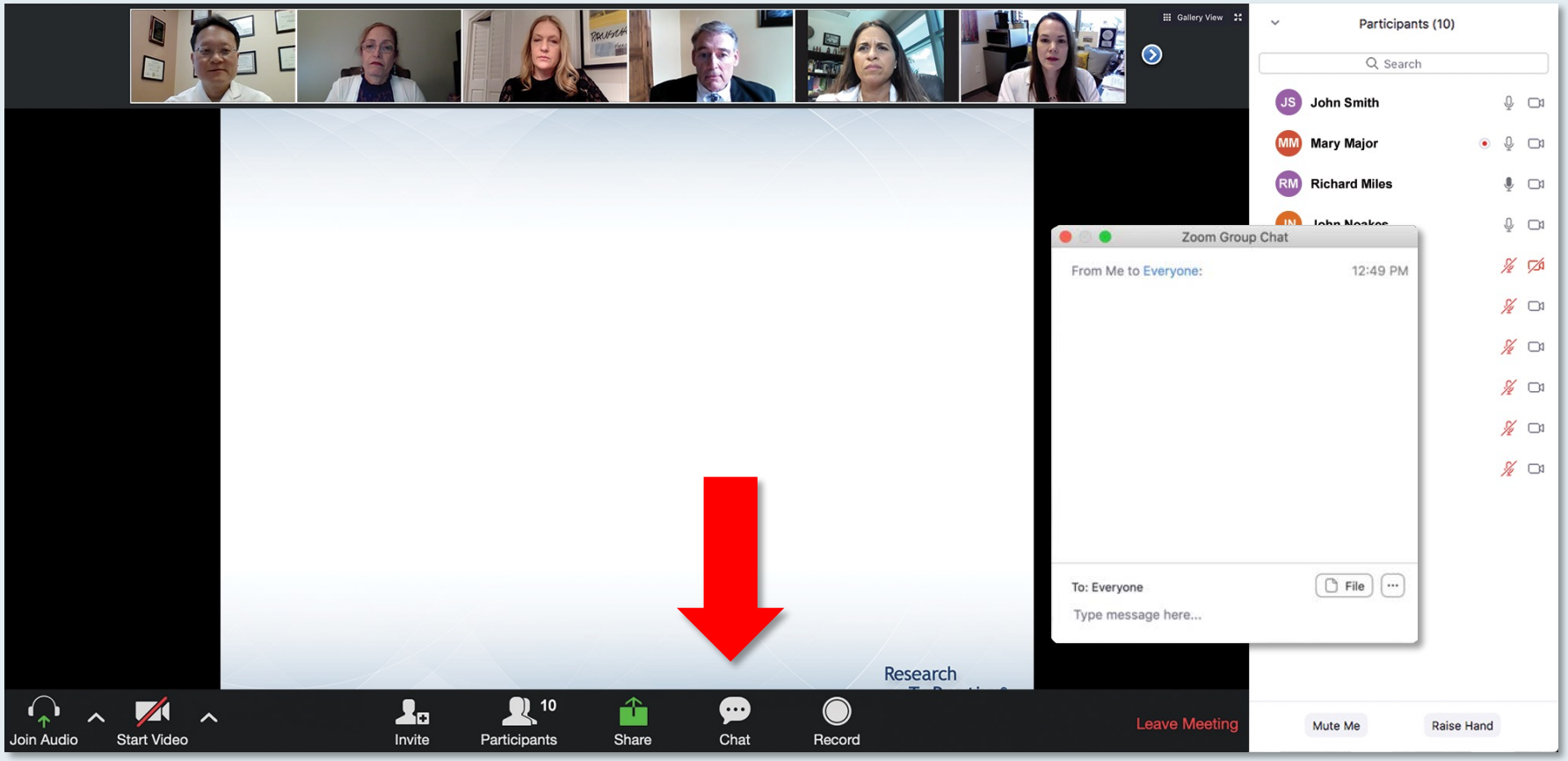

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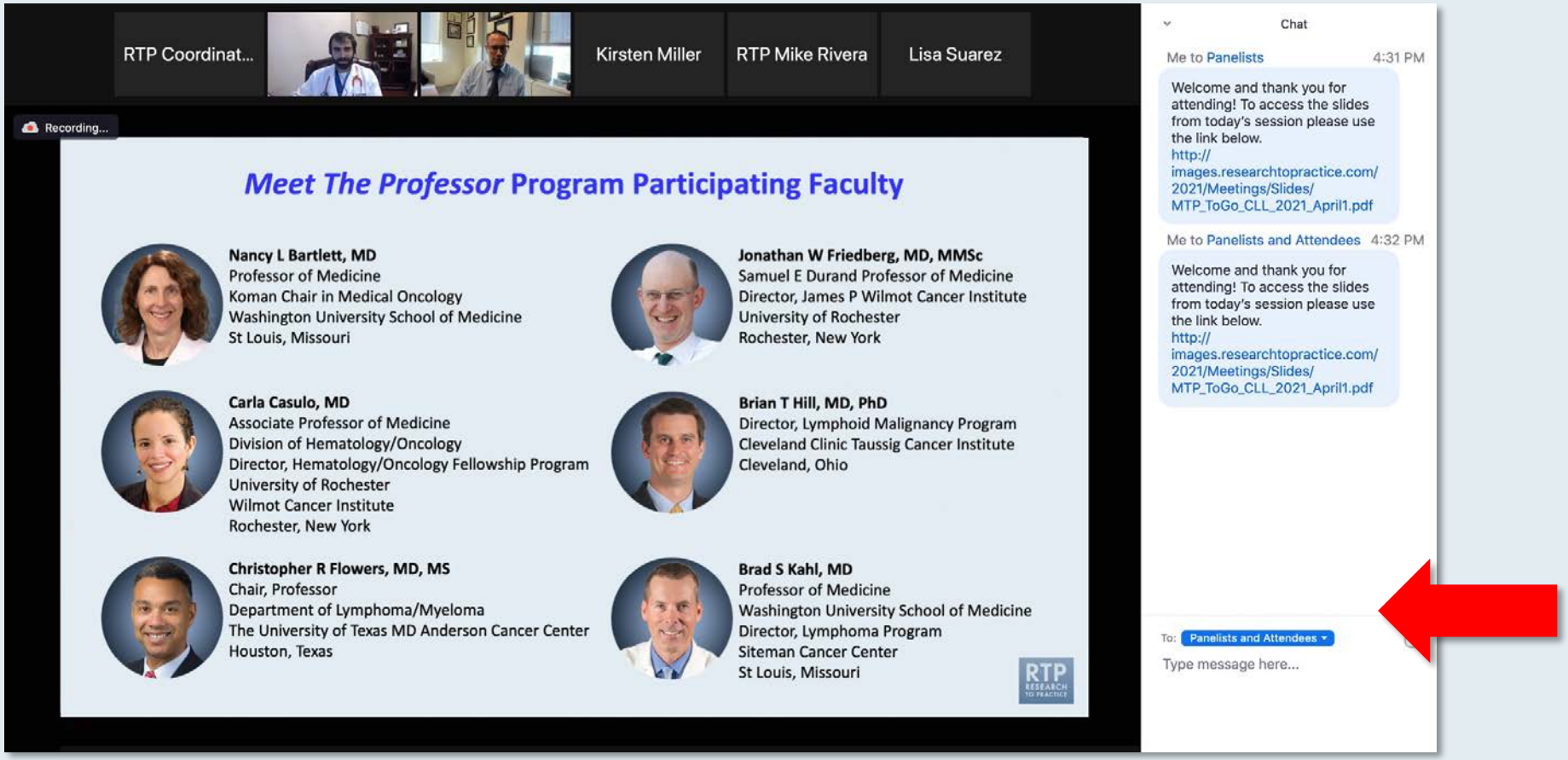

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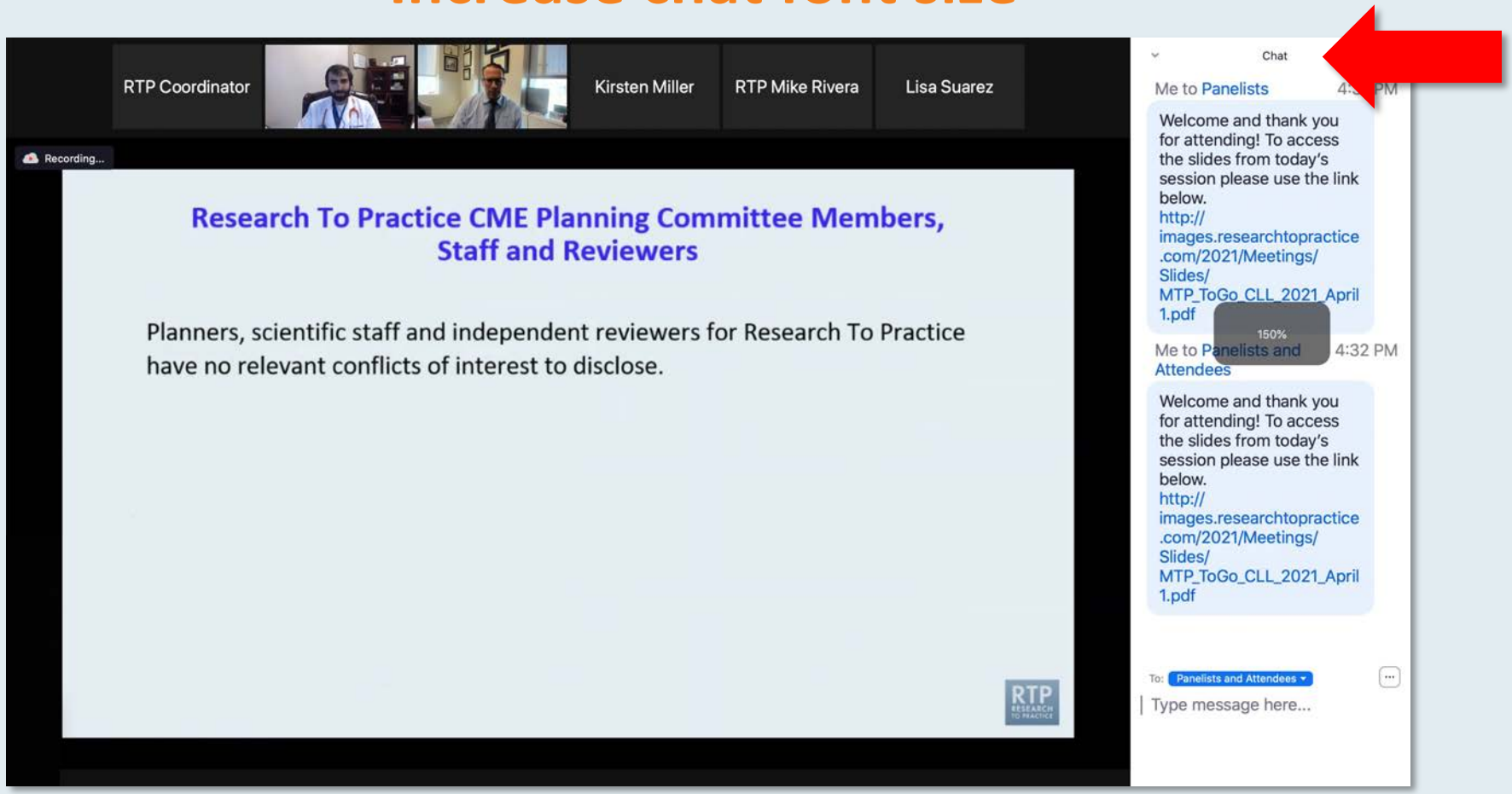

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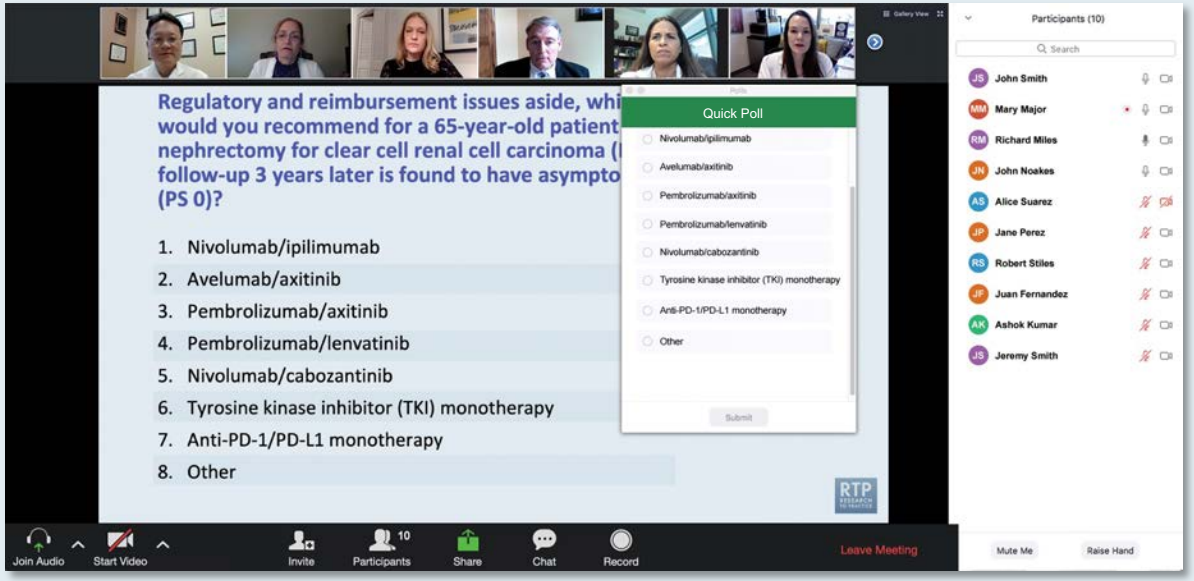

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WITH DR NEIL LOVE

Inside the Issue: Optimizing the Management of Nonmelanoma Skin Cancer

DR NIKHIL KHUSHALANI
MOFFITT CANCER CENTER

DR ANNA PAVLICK
WEILL CORNELL MEDICINE MEYER CANCER CENTER

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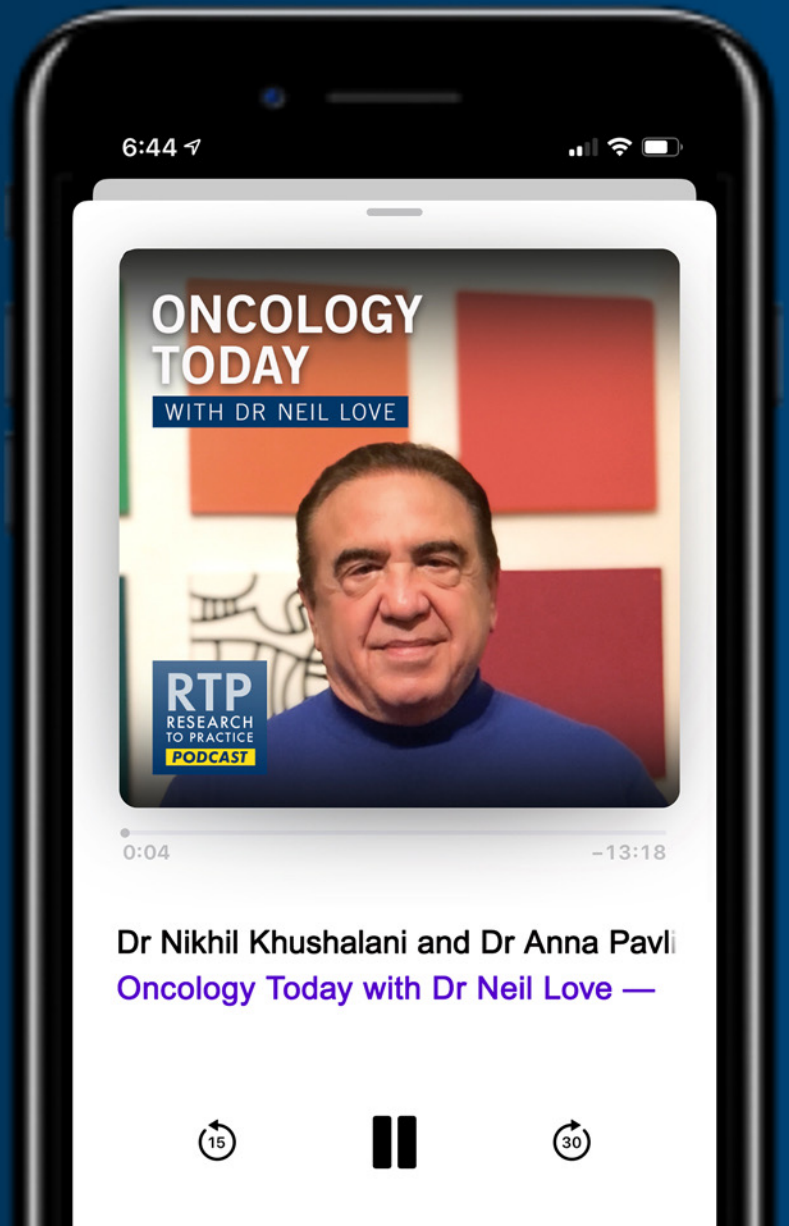

Year in Review: Immunotherapy and Other Nontargeted Approaches for Lung Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, June 18, 2024
5:00 PM – 6:00 PM ET

Faculty

Matthew Gubens, MD, MS

Moderator

Neil Love, MD

RTP Year in Review 2024

Investigator Perspectives on Available Research and Challenging Questions in Renal Cell Carcinoma – A Post-ASCO Annual Review

A CME/MOC-Accredited Live Webinar

Wednesday, June 19, 2024
5:00 PM – 6:00 PM ET

Faculty

Rana R McKay, MD
Thomas Powles, MBBS, MRCP, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know About the Management of Triple-Negative Breast Cancer

A CME/MOC-Accredited Live Webinar

Thursday, June 20, 2024
5:00 PM – 6:00 PM ET

Faculty

Kevin Kalinsky, MD, MS
Heather McArthur, MD, MPH

Moderator

Neil Love, MD

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Year in Review: Gynecologic Oncology

A CME/MOC-Accredited Live Webinar

Tuesday, June 25, 2024
5:00 PM – 6:00 PM ET

Faculty

Dana M Chase, MD

Moderator

Neil Love, MD

RTP Year in Review 2024

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

A CME/MOC-Accredited Live Webinar

Wednesday, June 26, 2024
5:00 PM – 6:00 PM ET

Faculty

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

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

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

A CME/MOC-Accredited Live Webinar

Thursday, June 27, 2024
5:00 PM – 6:00 PM ET

Faculty

Professor Solange Peters, MD, PhD
Additional faculty to be announced

Moderator

Neil Love, MD

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Thank you for joining us!

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

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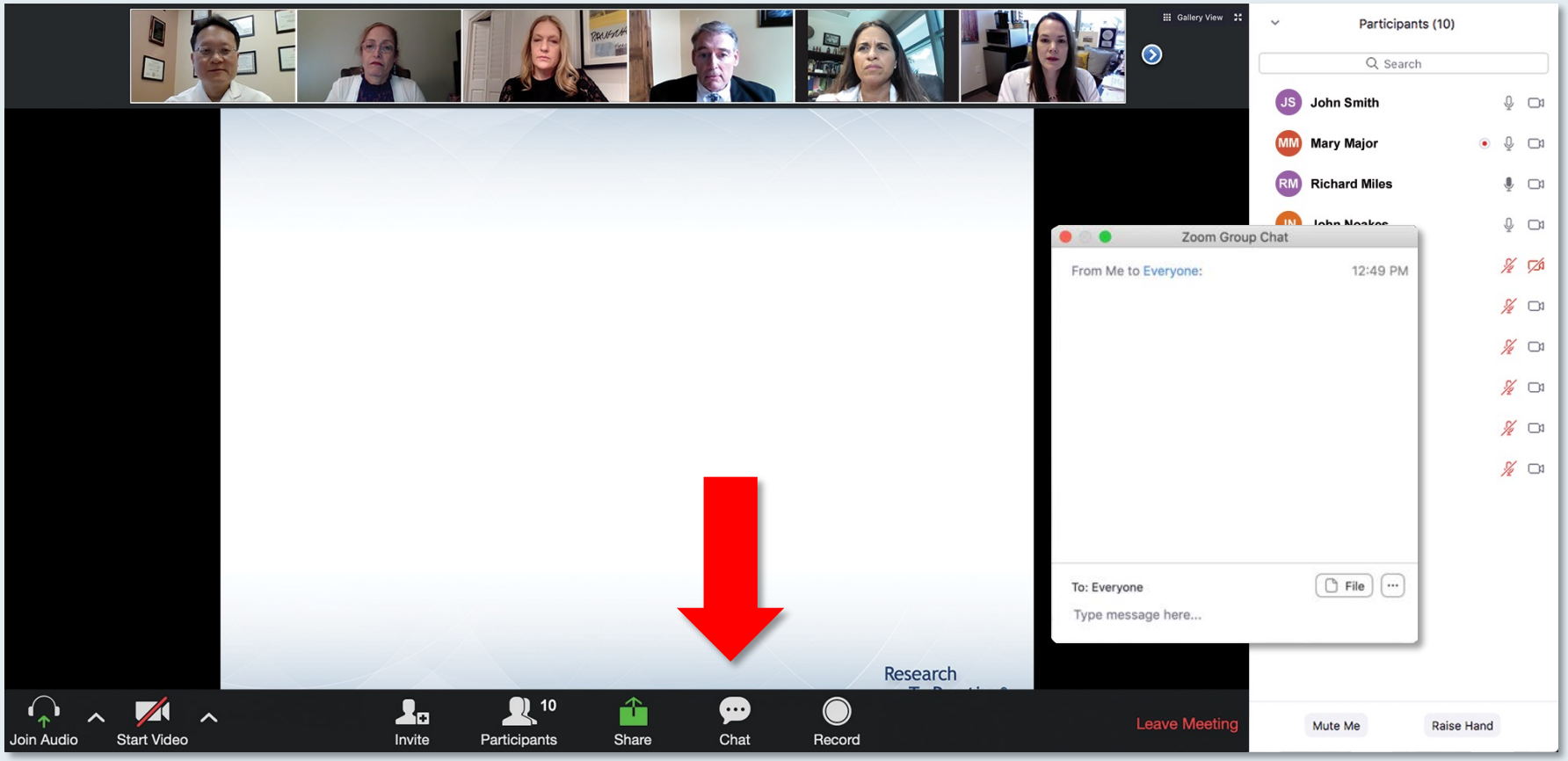

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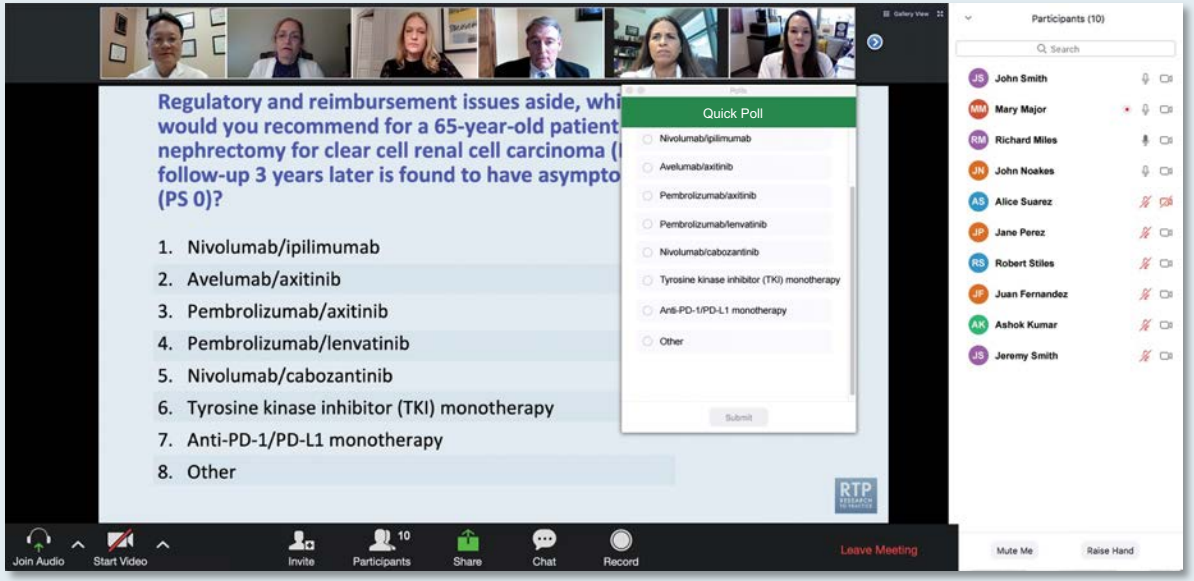

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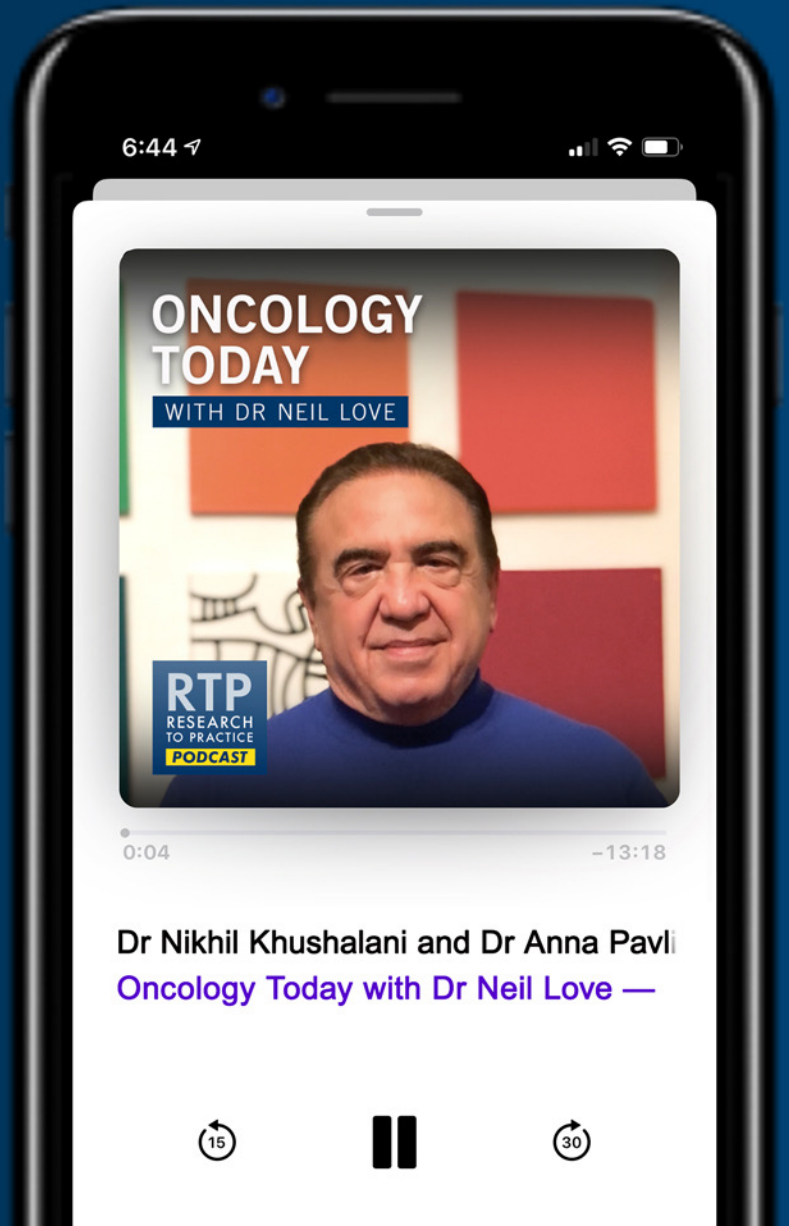

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Agenda

Introduction

Module 1: Evidence-Based Treatment of Nonmetastatic and Metastatic Melanoma — Dr Luke

Module 2: Optimizing the Management of Nonmelanoma Skin Cancers — Dr Khushalani

Agenda

Introduction

Module 1: Evidence-Based Treatment of Nonmetastatic and Metastatic Melanoma — Dr Luke

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Key ASCO 2024 Data Sets

- Blank CU et al. Neoadjuvant nivolumab plus ipilimumab versus adjuvant nivolumab in macroscopic, resectable stage III melanoma: The phase 3 NADINA trial. Abstract LBA2.
- Hauschild A et al. Long-term follow up for adjuvant dabrafenib plus trametinib in stage III BRAF-mutated melanoma: Final results of the COMBI-AD study. Abstract 9500.
- Weber JS et al. Individualized neoantigen therapy mRNA-4157 (V940) plus pembrolizumab in resected melanoma: 3-year update from the mRNA-4157-P201 (KEYNOTE-942) trial. Abstract LBA9512.
- Tawbi HA et al. Nivolumab plus relatlimab vs nivolumab in previously untreated metastatic or unresectable melanoma (RELATIVITY-047): Overall survival and melanoma-specific survival outcomes at 3 years. Abstract 9524.
- Thomas SS et al. Efficacy and safety of lifileucel, an autologous tumor-infiltrating lymphocyte cell therapy, and pembrolizumab in patients with immune checkpoint inhibitor-naive unresectable or metastatic melanoma: Updated results from IOV-COM-202 cohort 1A. Abstract 9505.

Key ASCO 2024 Data Sets

- Muñoz-Cousleo E et al. Pembrolizumab for locally advanced or recurrent/metastatic cutaneous squamous cell carcinoma: Long-term results of the Phase 2 KEYNOTE-629 Study. Abstract 9554.
- Ladwa R et al. Using serial ^{18}F-FDG PET/CT PERCIST response to predict long-term efficacy to immune checkpoint inhibitors in patients with advanced cutaneous squamous cell carcinoma. Abstract 9548.
- Amatore F et al. Neoadjuvant pembrolizumab produces high pathologic response rates in locally advanced (LA) resectable cutaneous squamous cell carcinoma (cSCC): Final results. Abstract 9591.
- Ladwa R et al. A phase 2 study of de-escalation in resectable, locally advanced cutaneous squamous cell carcinoma (cSCC) with the use of neoadjuvant pembrolizumab: De-Squamate. Abstract 9514.

Agenda

Introduction

Module 1: Evidence-Based Treatment of Nonmetastatic and Metastatic Melanoma — Dr Luke

Module 2: Optimizing the Management of Nonmelanoma Skin Cancers — Dr Khushalani

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Where Are We Now with the Management of Melanoma?

- Neoadjuvant
- Adjuvant
- Metastatic
  - BRAF mutated
  - BRAF wild-type

Evidence-Based Treatment of Nonmetastatic and Metastatic Melanoma

Jason J Luke, MD
Director of the Cancer Immunotherapeutics Center
UPMC Hillman Cancer Center
Associate Professor of Medicine
University of Pittsburgh
Pittsburgh, Pennsylvania

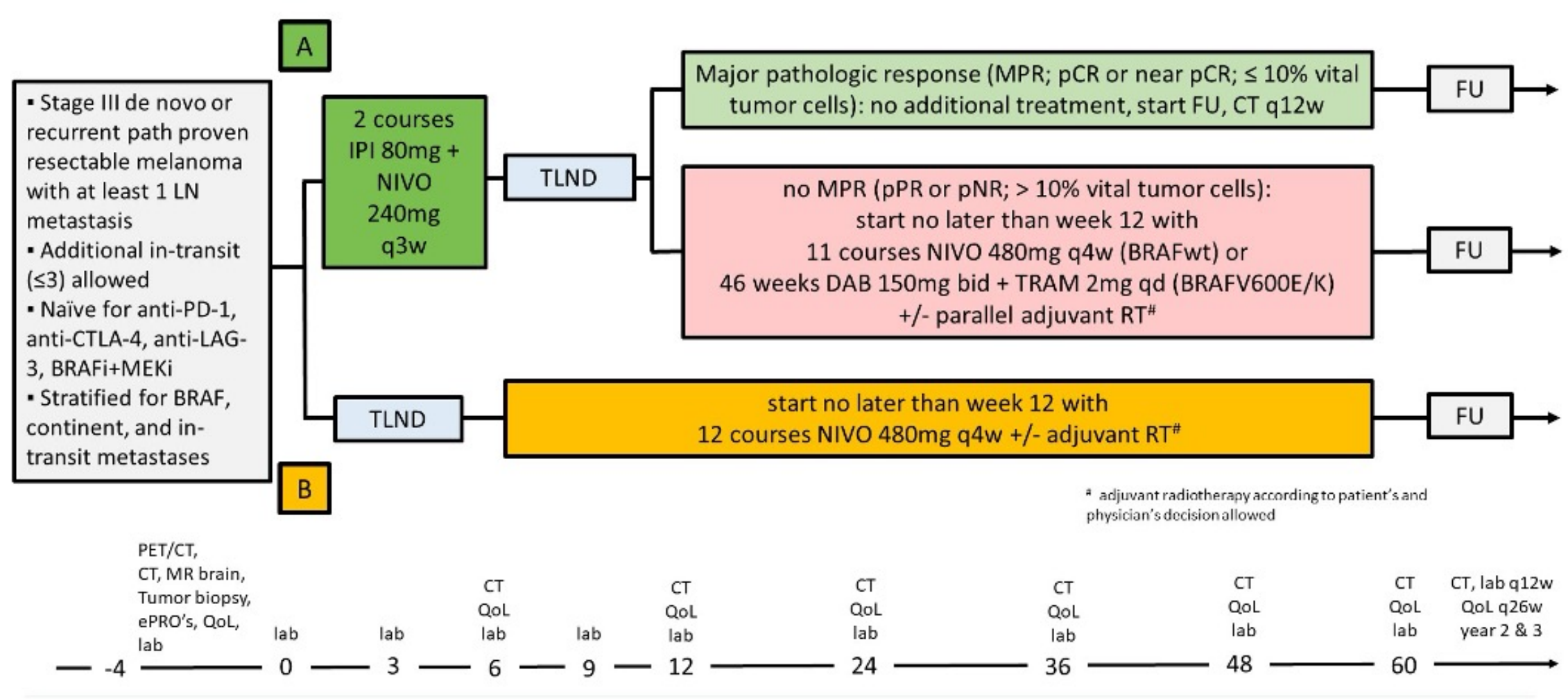
2024 ASCO ANNUAL MEETING

Abstract LBA2

Neoadjuvant Nivolumab Plus Ipilimumab Versus Adjuvant Nivolumab in Macroscopic, Resectable Stage III Melanoma: The Phase 3 NADINA Trial

Christian U. Blank, M.W. Lucas, R.A. Scolyer, B.A. van de Wiel, A.M. Menzies, M. Lopez-Yurda, A.C.J. van Akkooi, W.J. van Houdt, R.P.M. Saw, A. Torres-Acosta, S.N. Lo, G.A.P. Hospers, M.S. Carlino, J.W.B. de Groot, E. Kapiteijn, K.P.M. Suijkerbuijk, P. Rutkowski, S. Sandhu, A.A.M. van der Veldt, G.V. Long

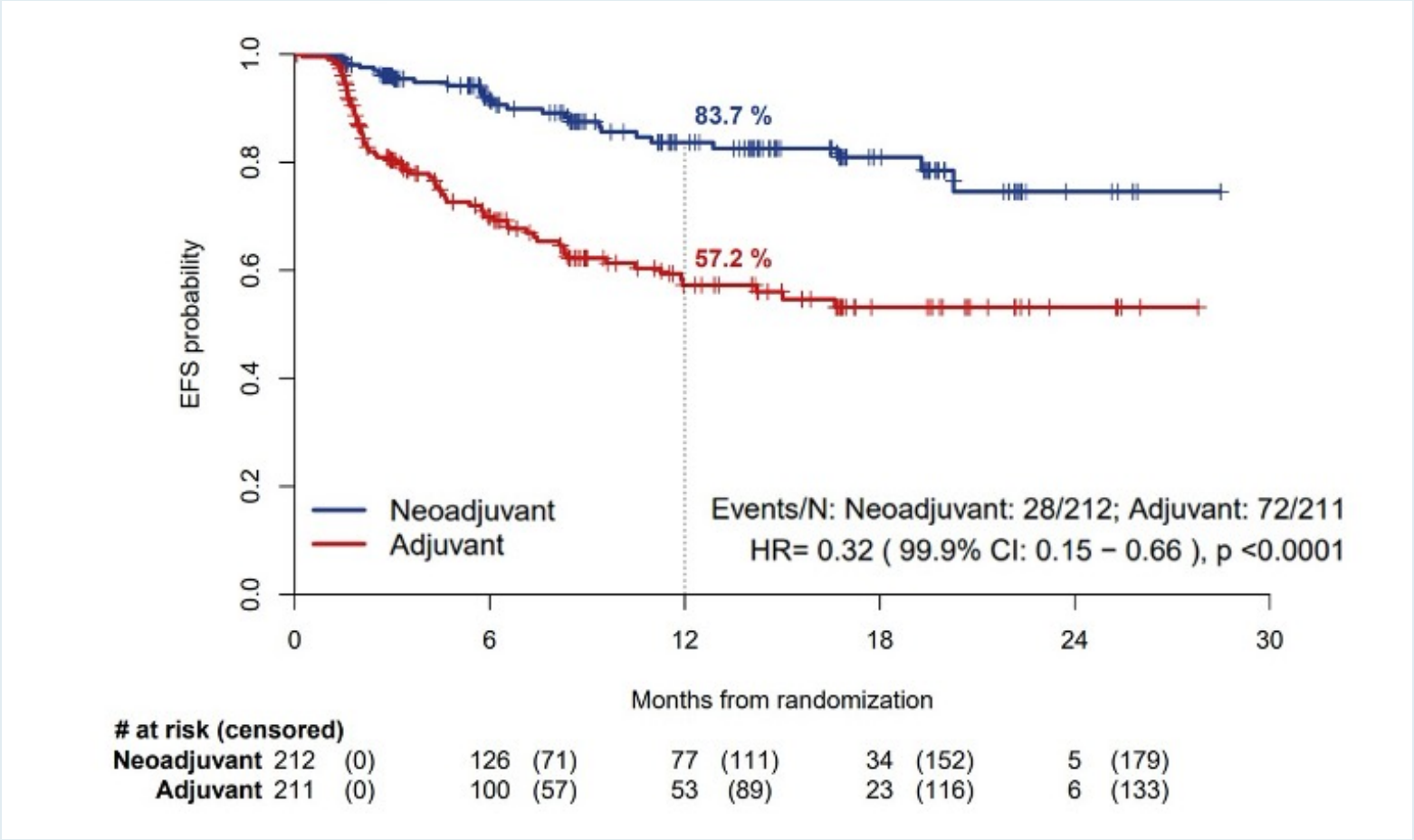
NADINA Trial Design

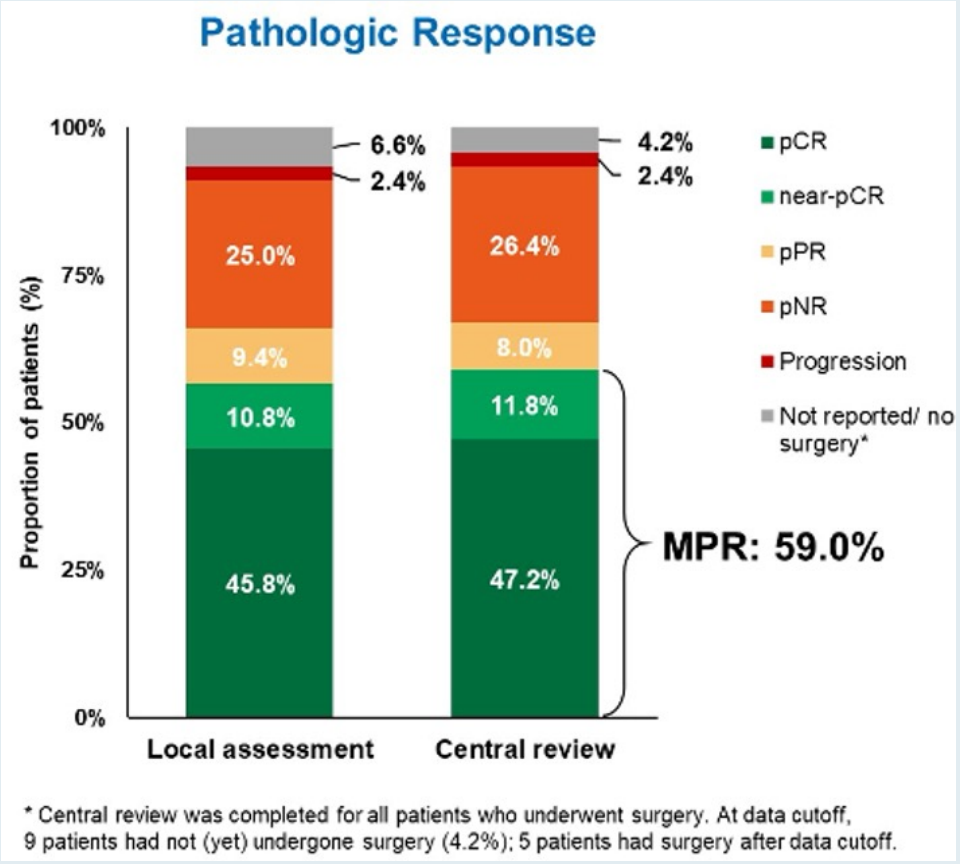


TLND = therapeutic lymph node dissection

Blank CU et al. ASCO 2024;Abstract LBA2.

NADINA Event-Free Survival (EFS) and Pathologic Response





pCR = pathologic complete response; pPR = pathologic partial response; pNR = pathologic nonresponse

- All key subgroups had an EFS benefit with neoadjuvant ipilimumab/nivolumab

Blank CU et al. ASCO 2024;Abstract LBA2.

FDA-Approved Adjuvant Immunotherapy Options for Melanoma

Monotherapy	FDA approval	Pivotal study	Stage	HR RFS	HR OS
Nivolumab	10/13/23	CheckMate 76K	IIB, IIC	0.42	NA
Pembrolizumab	12/3/21	KEYNOTE-716	AJCC 8th IIB, IIC	0.62	NA
Pembrolizumab	2/15/19	KEYNOTE-054	AJCC 7th IIIA, IIIB, IIIC	0.61	NA
Nivolumab	12/20/17	CheckMate 238	AJCC 7th IIIB, IIIC, IV	0.72	0.86
Ipilimumab	10/28/15	EORTC-18071	AJCC 7th IIIA, IIIB, IIIC	0.75	0.73

HR = hazard ratio; RFS = relapse- or recurrence-free survival; OS = overall survival; NA = not available

Kirkwood JM et al. *Nat Med* 2023;29:2835-43; Luke JJ et al. *J Clin Oncol* 2024;42:1619-24; Eggermont AMM et al. *NEJM Evid* 2022; 1(11):EVIDoa2200214; Larkin J et al. *Clin Cancer Res* 2023;29:3352-61; Eggermont AMM et al. *Eur J Cancer* 2019;119;1-10.

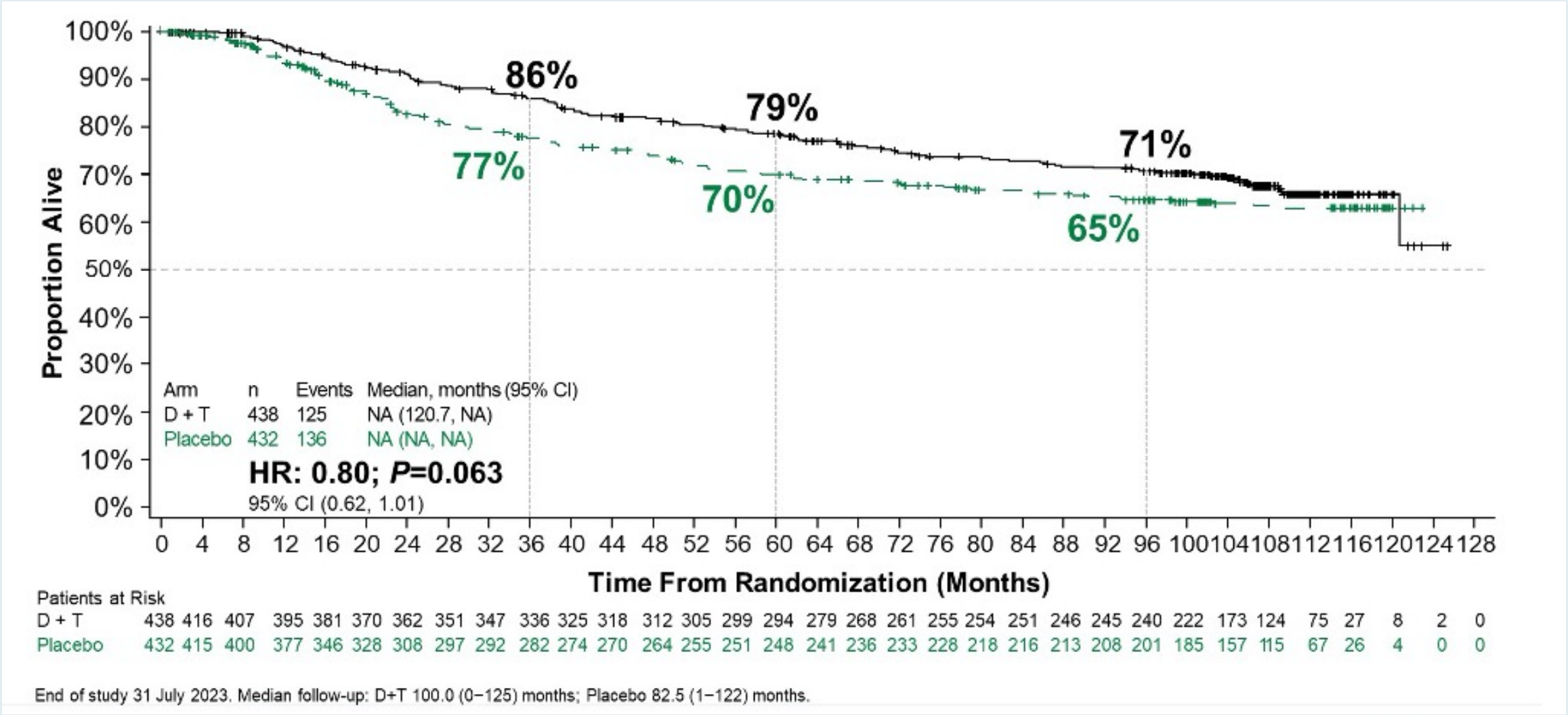
2024 ASCO ANNUAL MEETING

Abstract 9500

Long-Term Follow-Up for Adjuvant Dabrafenib Plus Trametinib in Stage III BRAF-Mutated Melanoma: Final Results of the COMBI-AD Study

Axel Hauschild, Reinhard Dummer, Mario Santinami, Victoria Atkinson, Mario Mandala, Barbara Merelli, Vanna Chiarion-Sileni, Andrew Mark Haydon, Jacob Schachter, Dirk Schadendorf, Thierry Lesimple, Elizabeth Ruth Plummer, James Larkin, Monique Tan, Sachin Bajirao Adnaik, Paul Burgess, Tarveen Jandoo, Georgina V. Long

Final Analysis of COMBI-AD: Overall Survival (ITT Population)

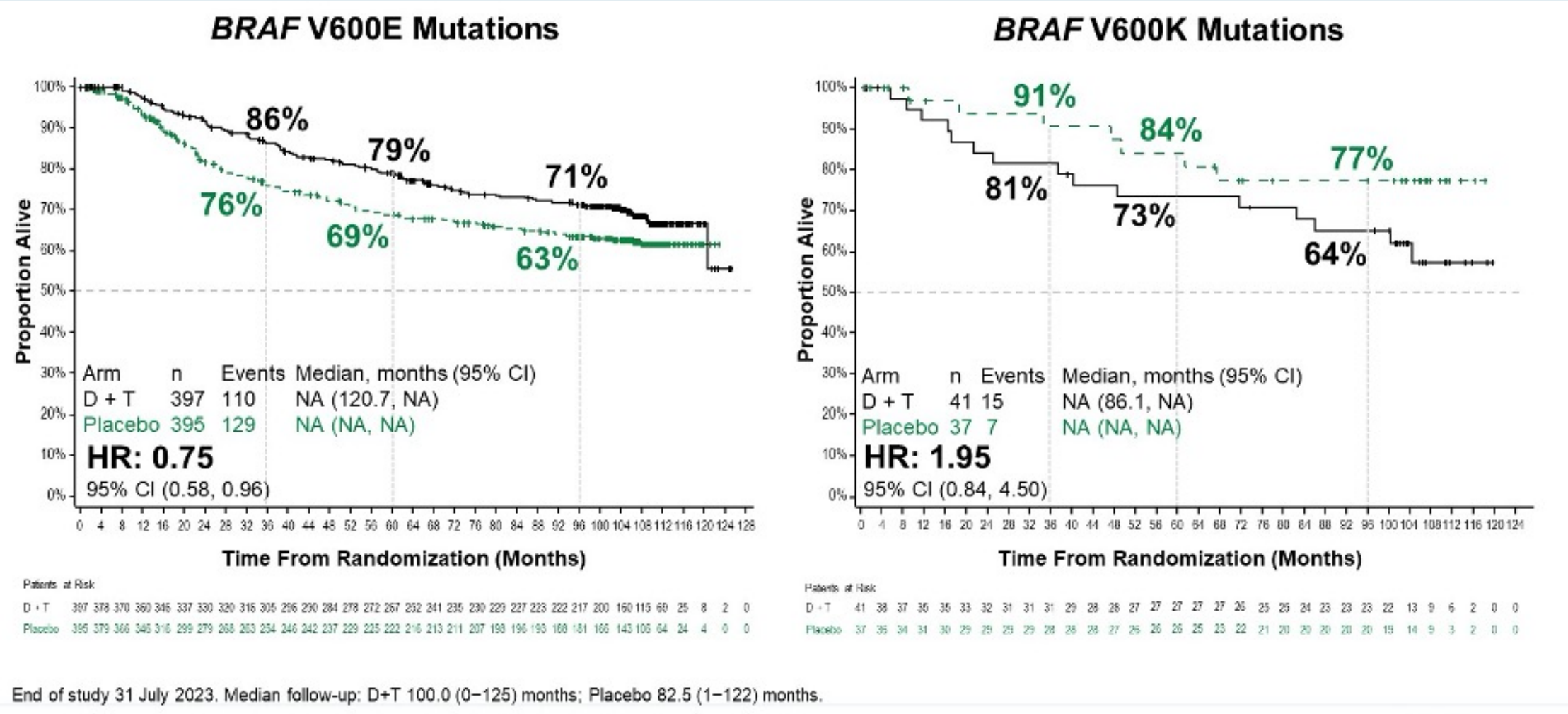


ITT = intent to treat

Hauschild A et al. ASCO 2024;Abstract 9500.

RTP RESEARCH TO PRACTICE

Subgroup Analysis of COMBI-AD: Effect of Treatment on Overall Survival by BRAF V600 Mutations (ITT Population)



End of study 31 July 2023. Median follow-up: D+T 100.0 (0–125) months; Placebo 82.5 (1–122) months.

Hauschild A et al. ASCO 2024;Abstract 9500.

RTP RESEARCH TO PRACTICE

Questions?

RTP
RESEARCH
TO PRACTICE

2024 ASCO ANNUAL MEETING

Abstract LBA9512

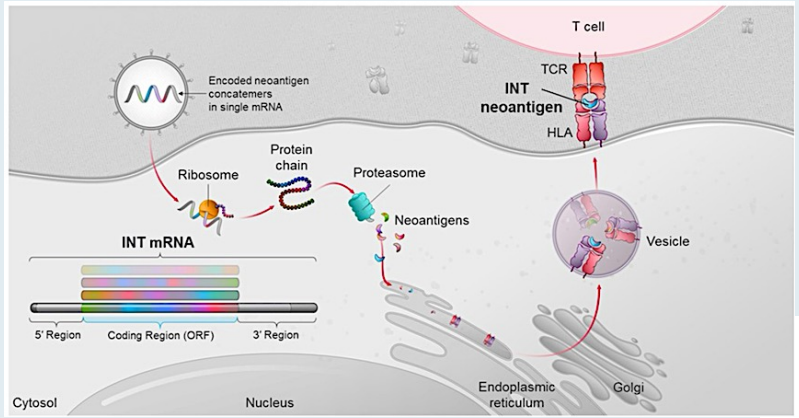
Individualized neoantigen therapy mRNA-4157 (V940) plus pembrolizumab in resected melanoma: 3-year update from the mRNA-4157-P201 (KEYNOTE-942) trial

Jeffrey S. Weber,[1] Muhammad Adnan Khattak,[2] Matteo S. Carlino,[3] Tarek Meniawy,[4] Matthew H. Taylor,[5] George Ansstas,[6] Kevin B. Kim,[7] Meredith McKean,[8] Ryan J. Sullivan,[9] Mark B. Faries,[10] Thuy Tran,[11] C. Lance Cowey,[12] Theresa M. Medina,[13] Jennifer M. Segar,[14] Victoria Atkinson,[15] Geoffrey T. Gibney,[16] Jason J. Luke,[17] Elizabeth I. Buchbinder,[18] Georgina V. Long,[19] INT Research and Development Author Group,[20,21,a] Robert S. Meehan[20]

[a]Manju Morrissey,[20] Igor Feldman,[20] Vasudha Sehgal,[20] Huzhang Mao,[20] Jia Guo,[20] Min Liu,[20] Anjali Rao,[20] Wei Zheng,[20] Praveen Aanur,[20] Lakshmi Srinivasan,[20] Mo Huang,[21] Tal Zaks,[20] Michelle Brown,[20] Tracey Posadas[20]

[1]Laura and Isaac Perlmutter Cancer Center at NYU Langone Health, New York, NY, USA; [2]Hollywood Private Hospital and Edith Cowan University, Perth, Australia; [3]Melanoma Institute Australia and Westmead Hospital, Sydney, Australia; [4]Saint John of God Subiaco Hospital, Subiaco, Australia; [5]Earle A. Chiles Research Institute, Portland, OR, USA; [6]Washington University School of Medicine, St Louis, MO, USA; [7]California Pacific Medical Center Research Institute, San Francisco, CA, USA; [8]Sarah Cannon Research Institute, Nashville, TN, USA; [9]Massachusetts General Hospital, Boston, MA, USA; [10]The Angeles Clinic and Research Institute, Los Angeles, CA, USA; [11]Yale-New Haven Hospital, New Haven, CT, USA; [12]Baylor Charles A. Sammons Cancer Center, Dallas, TX, USA; [13]University of Colorado, Aurora, CO, USA; [14]University of Arizona Cancer Center, Tucson, AZ, USA; [15]Princess Alexandra Hospital, Woolloongabba, Australia; [16]Lombardi Comprehensive Cancer Center, Washington, DC, USA; [17]UPMC Hillman Cancer Center, Pittsburgh, PA, USA; [18]Dana-Farber Cancer Institute, Boston, MA, USA; [19]Melanoma Institute Australia, Sydney, Australia; [20]Moderna, Inc., Cambridge, MA, USA; [21]Merck & Co., Inc., Rahway, NJ, USA.

KEYNOTE-942 Trial Design: Pembrolizumab with or without Individualized Neoantigen Therapy (INT)



Randomized, phase 2, open-label study in patients with adjuvant resected melanoma at high risk of recurrence

Key eligibility criteria

- Resected stage IIIB,[a] IIIC, IIID, or IV cutaneous melanoma
- Complete surgical resection within 13 weeks prior to first pembrolizumab dose
- Disease free at study entry
- ECOG PS score 0–1
- Tissue available for NGS

2:1 randomization

Stratified by disease stage[b]

Combination treatment arm: mRNA-4157 (V940) + pembrolizumab
Up to 1 year of pembrolizumab treatment
mRNA-4157 (V940) 1 mg IM Q3W for up to 9 doses +
pembrolizumab 200 mg IV Q3W for up to 18 cycles
(n = 107)

Control treatment arm: pembrolizumab monotherapy
Up to 1 year of pembrolizumab treatment
Pembrolizumab 200 mg IV Q3W for up to 18 cycles
(n = 50)

Primary endpoint:
RFS

Secondary endpoints:
DMFS,
safety, tolerability

Follow-up:
up to 5 years following the first dose of pembrolizumab

Designed with 80% power to detect a hazard ratio of 0.5 with 40 RFS events (with a 1-sided alpha of 0.1 per protocol)
Primary analysis **triggered after a minimum of 1-year planned follow-up[c]** (November 14, 2022 data cut) and at least 40 RFS events have been observed. DMFS analysis was prespecified for testing following positive RFS in the ITT population

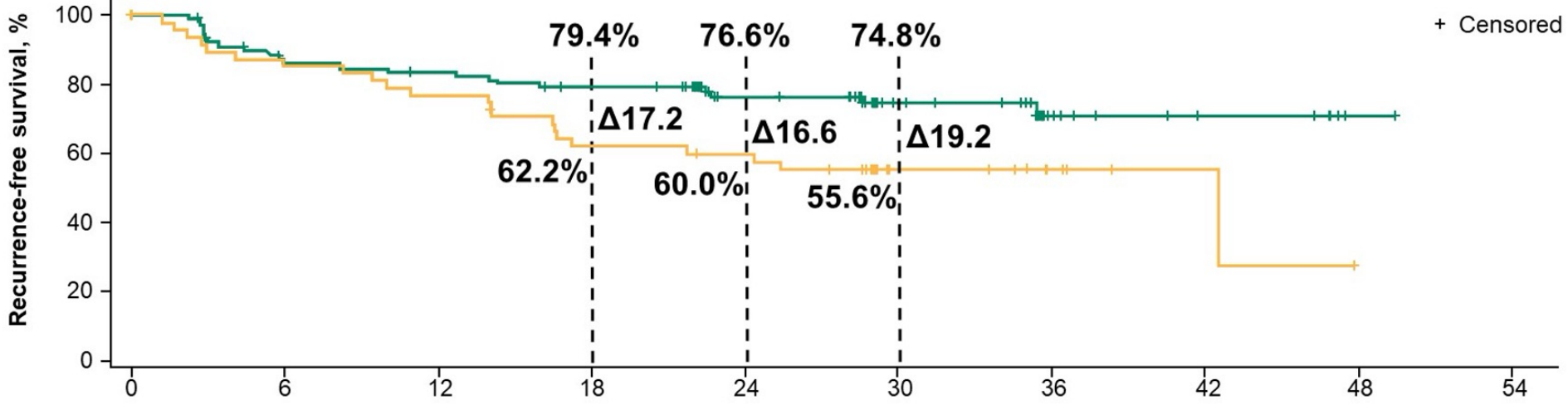
Supportive analysis was **triggered after a minimum of 2 years of planned follow-up[c]** (November 3, 2023 data cut)
Median planned follow-up[c]: ~3yrs

[a]Patients with stage IIIB disease were eligible only if relapse occurred within 3 months of prior surgery of curative intent; [b]According to the 8th edition of the American Joint Committee on Cancer Staging Manual [c]Defined as the time from the first dose date (or date of randomization if not treated) to date of clinical cut-off.
ECOG PS, Eastern Cooperative Oncology Group performance status; IM, intramuscular; ITT, intent-to-treat; IV, intravenous; NGS, next-generation sequencing; Q3W, every 3 weeks.

Weber JS et al. ASCO 2024;Abstract LBA9512.

RTP RESEARCH TO PRACTICE

KEYNOTE-942 Primary Endpoint: Recurrence-Free Survival



Patients at risk										
mRNA-4157 (V940) + pembrolizumab	107	87	83	77	52	29	12	6	1	0
Pembrolizumab	50	41	37	29	27	10	5	2	0	0

	Median (95% CI), months	Events, % (n/N)	Hazard ratio (95% CI)[a]
mRNA-4157 (V940) + pembrolizumab	NE	23.4 (25/107)	0.510 (0.288–0.906) *P* = 0.019[b]
pembrolizumab	42.51 (16.59–NE)	44.0 (22/50)	

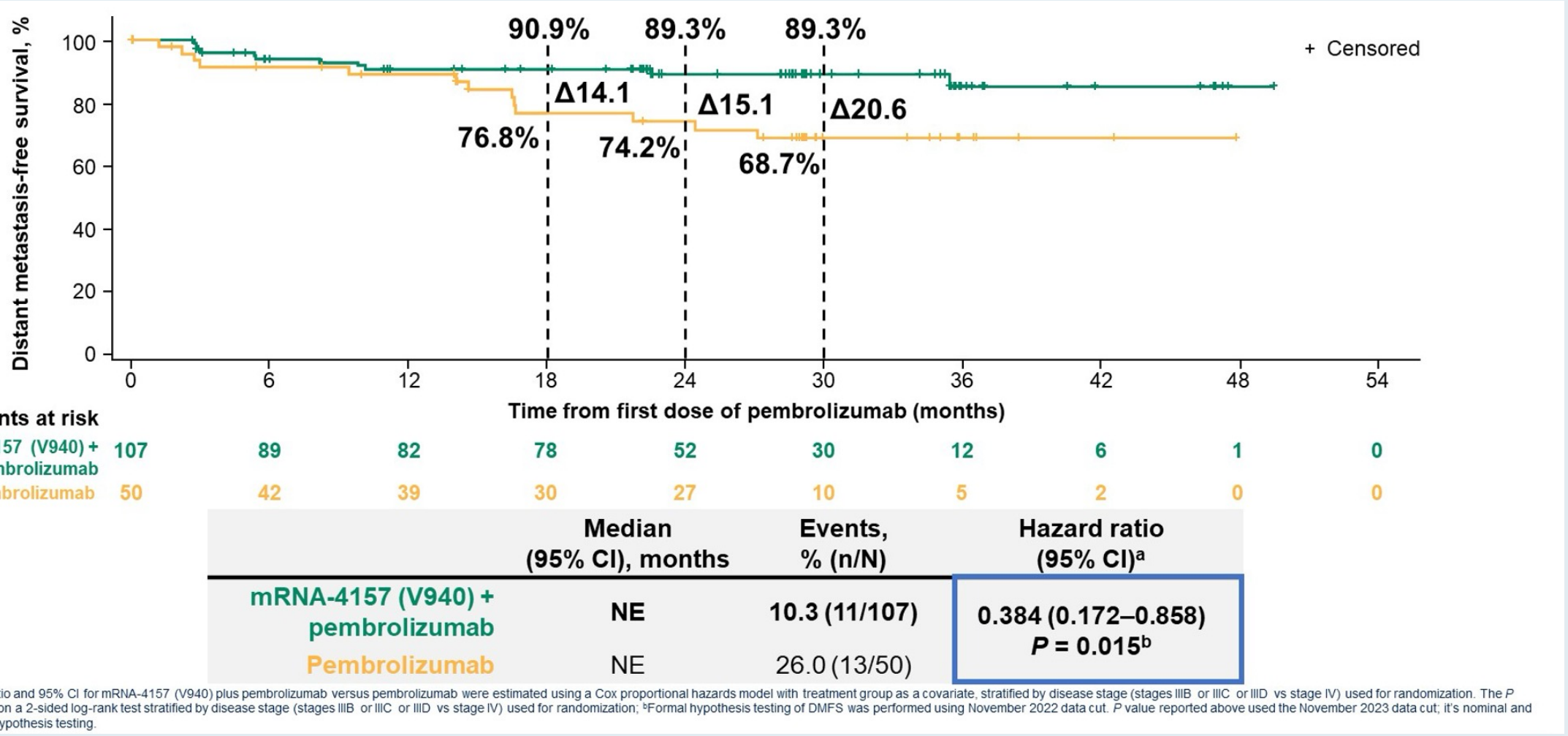
[a]The hazard ratio and 95% CI for mRNA-4157 (V940) + pembrolizumab versus pembrolizumab were estimated using a Cox proportional hazards model with treatment group as a covariate, stratified by disease stage (stages IIIB or IIIC or IIID vs stage IV) used for randomization. The *P* value is based on a 2-sided log-rank test stratified by disease stage (stages IIIB or IIIC or IIID vs stage IV) used for randomization; [b]Formal hypothesis testing of RFS was performed using November 2022 data cut. *P* value reported above used the November 2023 data cut; it's nominal and not for formal hypothesis testing. NE, not estimable.

- Translational analyses suggest mRNA-4157 (V940) + pembrolizumab may benefit a broad patient population irrespective of the status of PD-L1, tumor mutational burden, ctDNA and HLA heterozygosity

Weber JS et al. ASCO 2024;Abstract LBA9512.

RTP RESEARCH TO PRACTICE

KEYNOTE-942: Distant Metastasis-Free Survival

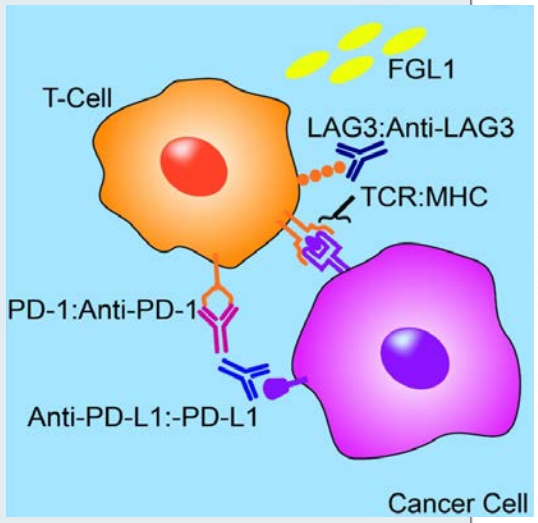


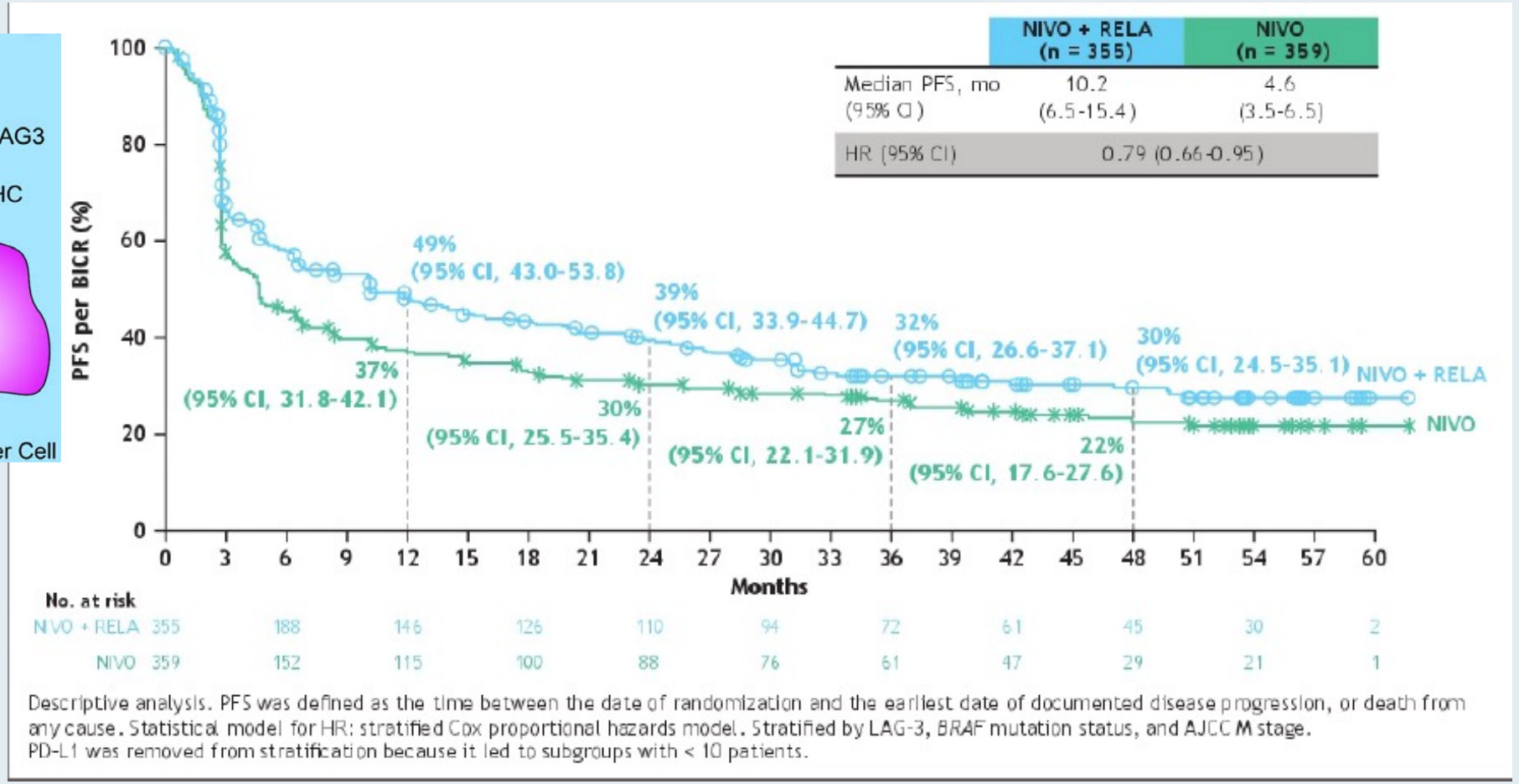
	Median (95% CI), months	Events, % (n/N)	Hazard ratio (95% CI)[a]
mRNA-4157 (V940) + pembrolizumab	NE	10.3 (11/107)	0.384 (0.172–0.858) *P* = 0.015[b]
Pembrolizumab	NE	26.0 (13/50)	

[a]The hazard ratio and 95% CI for mRNA-4157 (V940) plus pembrolizumab versus pembrolizumab were estimated using a Cox proportional hazards model with treatment group as a covariate, stratified by disease stage (stages IIIB or IIIC or IIID vs stage IV) used for randomization. The *P* value is based on a 2-sided log-rank test stratified by disease stage (stages IIIB or IIIC or IIID vs stage IV) used for randomization; [b]Formal hypothesis testing of DMFS was performed using November 2022 data cut. *P* value reported above used the November 2023 data cut; it's nominal and not for formal hypothesis testing.

Weber JS et al. ASCO 2024;Abstract LBA9512.

RELATIVITY-047 Trial: Nivolumab (Anti-PD-1) and Relatlimab (Anti-LAG-3)



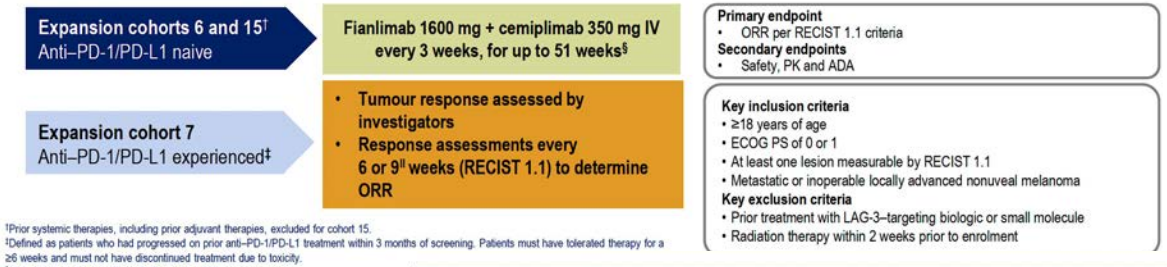


- Median overall survival: 51.0 vs 33.2 months (HR 0.80)
- Objective response rate: 44% vs 34%

Tawbi HA et al. ASCO 2024;Abstract 9524.

RTP RESEARCH TO PRACTICE

Phase I Expansion Cohort of Fianlimab and Cemiplimab for Patients with Advanced Melanoma: Anti-PD-1/PD-L1 Naïve Group



†Prior systemic therapies, including prior adjuvant therapies, excluded for cohort 15.
‡Defined as patients who had progressed on prior anti–PD-1/PD-L1 treatment within 3 months of screening. Patients must have tolerated therapy for a ≥6 weeks and must not have discontinued treatment due to toxicity.
§With an option for an additional 51 weeks.
¶Response assessments were every 6 weeks for the first 24 weeks, then 9 weeks for the
1. Tawbi HA et al. *N Engl J Med*. 2022;386:24–34. 2. Long GV et al. *J Clin Oncol*. 2022;4
2019;18:2051–2062. 4. Burova E et al. *Mol Cancer*. 2017;16:861–870. 5. Hamid O et al.

% (n), unless otherwise stated	Anti–PD-(L)1 naive† Cohort 6 (N=40)	Anti–PD-(L)1 naive† Cohort 15 (N=40)	Cohorts 6 + 15 (N=80)
ORR, % (95% CI)	**62.5 (45.8, 77.3)**	**65 (48.3, 79.4)**	**63.8 (52.2, 74.2)**
Complete response	15.0 (6)	2.5 (1)	8.8 (7)
Partial response	47.5 (19)	62.5 (25)	55.0 (44)
Stable disease	17.5 (7)	15.0 (6)	16.3 (13)
Progressive disease	15.0 (6)	15.0 (6)	15.0 (12)
NE	5.0 (2)	5.0 (2)	5.0 (4)
DCR	80.0 (32)	80.0 (32)	80.0 (64)
KM-estimated PFS, median (95% CI), months	**24 (4.2, NE)**	**NR (7.5, NE)**	**24 (9.9, NE)**
DOR, median (95% CI), months	NR (11.9, NE)	NR (6.3, NE)	NR (22.6, NE)
ORR: baseline LDH, n/N1 (%)			
LDH > ULN	10/17 (58.8)	6/11 (54.5)	16/28 (57.1)
LDH normal	15/23 (65.2)	18/24 (75.0)	33/47 (70.2)
ORR: liver metastasis, n/N2 (%)			
Yes	6/14 (42.9)	3/5 (60.0)	9/19 (47.4)
No	19/26 (73.1)	23/35 (65.7)	42/61 (68.9)

% (n), unless otherwise stated	Anti–PD-(L)1 naive† Cohort 6 (N=40)	Anti–PD-(L)1 naive† Cohort 15 (N=40)	Cohorts 6 + 15 (N=80)
Patients completed planned treatment‡	15.0 (6)	5.0 (2)	10.0 (8)
Ongoing treatment	15.0 (6)	52.5 (21)	33.8 (27)
Discontinued treatment	70.0 (28)	42.5 (17)	56.3 (45)
Disease progression	45.0 (18)	17.5 (7)	31.3 (25)
AE	15.0 (6)	15.0 (6)	15.0 (12)
Patient decision	5.0 (2)	0	2.5 (2)
Death	2.5 (1)	5.0 (2)	3.8 (3)
Physician decision	2.5 (1)	5.0 (2)	3.8 (3)
Duration of exposure, median (range), weeks	**37.1 (2–110)**	**24.2 (3–56)**	**30.9 (2–110)**

†Prior systemic therapies, including prior adjuvant therapies, excluded for cohort 15.
‡Planned treatment; 1 year + additional 1 year given based on investigator discretion.

CI, confidence interval; DCR, disease control rate; DOR, duration of response; KM, Kaplan-Meier; LDH, lactase dehydrogenase; n, number; N1, proportion of patients with the listed LDH status; N2, proportion of patients with the listed liver metastasis status; NE, not evaluable; NR, not reached; ORR, objective response rate; PD-1, programmed cell death-1; PD-L1, programmed cell death-ligand 1; PFS, progression-free survival; ULN, upper limit of normal.

Hamid O et al. ESMO 2022;Abstract 790MO.

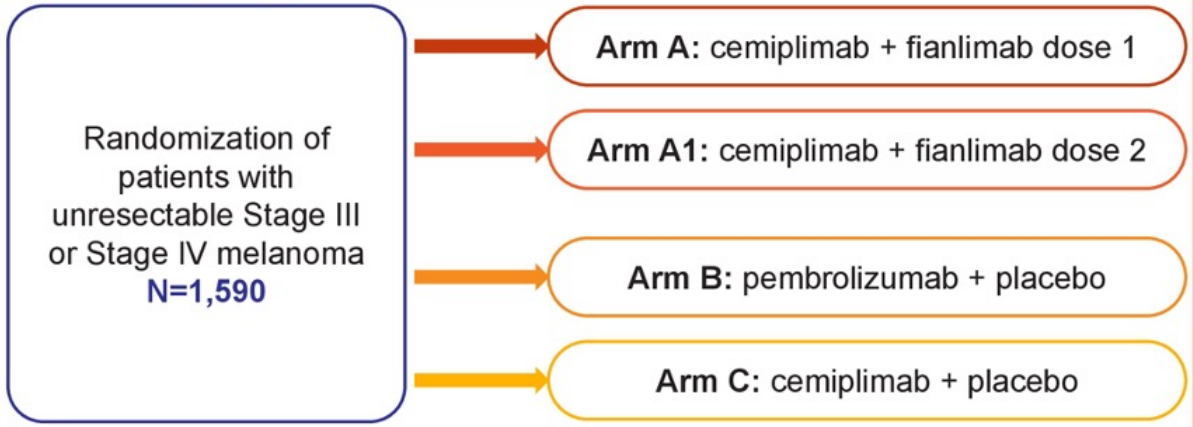
Phase III Trial of Fianlimab/Cemiplimab versus Pembrolizumab for Patients with Previously Untreated Unresectable Locally Advanced or Metastatic Melanoma

Primary endpoint: to compare PFS (per Response Evaluation Criteria in Solid Tumours [RECIST] v1.1 based on blinded independent central review [BICR]) following treatment with fianlimab plus cemiplimab combination versus pembrolizumab in patients with previously untreated unresectable locally advanced or metastatic melanoma.

Key secondary endpoints:
- Overall survival (OS).
- ORR.

Additional secondary endpoints:
- Disease control rate (DCR).
- DoR.
- Safety.
- Pharmacokinetic.
- Immunogenicity.
- Patient-reported outcomes.

Figure 1. Study design



LDH, lactate dehydrogenase; PD-1, programmed death-1; PD-L1, programmed death-ligand 1.

Baramidze A et al. ASCO 2023;Abstract TPS9602.

PFS = progression-free survival; ORR = objective response rate

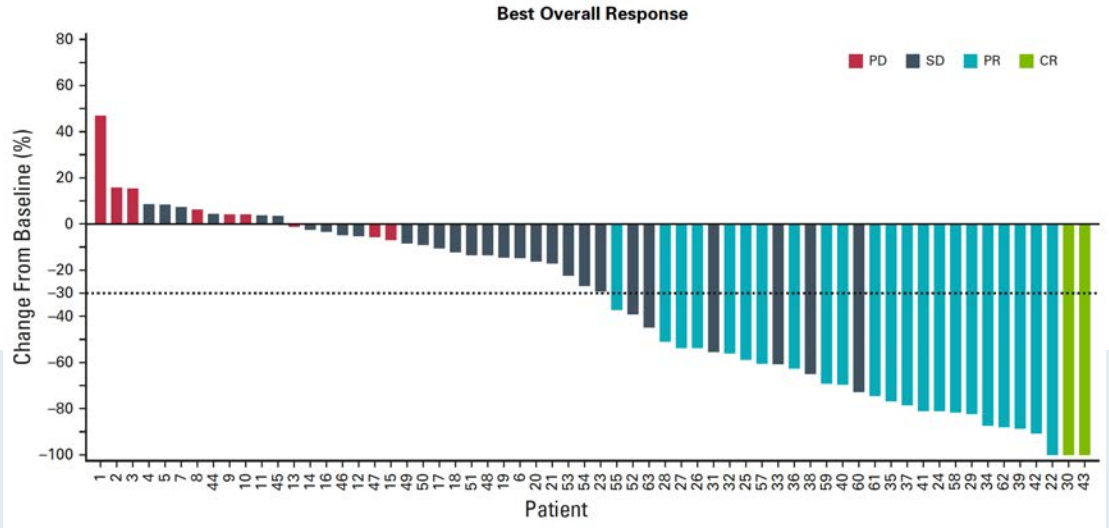
FDA Grants Accelerated Approval to Lifileucel for Unresectable or Metastatic Melanoma

Press Release: February 16, 2024

rapid communications

Lifileucel, a Tumor-Infiltrating Lymphocyte Therapy, in Metastatic Melanoma

Amod A. Sarnaik, MD[1]; Omid Hamid, MD[2]; Nikhil I. Khushalani, MD[1]; Karl D. Lewis, MD[3]; Theresa Medina, MD[3]; Harriet M. Kluger, MD[4]; Sajeve S. Thomas, MD[5]; Evidio Domingo-Musibay, MD[6]; Anna C. Pavlick, DO, MBA[7]; Eric D. Whitman, MD[8]; Salvador Martin-Algarra, MD, PhD[9]; Pippa Corrie, PhD, FRCP[10]; Brendan D. Curti, MD[11]; Judit Oláh, MD, DSc[12]; Jose Lutzky, MD[13]; Jeffrey S. Weber, MD, PhD[7]; James M. G. Larkin, MD, PhD[14]; Wen Shi, MD, PhD[15]; Toshimi Takamura, BA, BS[15]; Madan Jagasia, MD[15]; Harry Qin, PhD[15]; Xiao Wu, PhD[15]; Cecile Chartier, PhD[15]; Friedrich Graf Finckenstein, MD[15]; Maria Fardis, PhD, MBA[15]; John M. Kirkwood, MD[16]; and Jason A. Chesney, MD, PhD[17]



J Clin Oncol 2021;39:2656-66.

RTP RESEARCH TO PRACTICE

Abstract 9505

2024 ASCO Annual Meeting
May 31–June 4, 2024 | Chicago, IL, USA

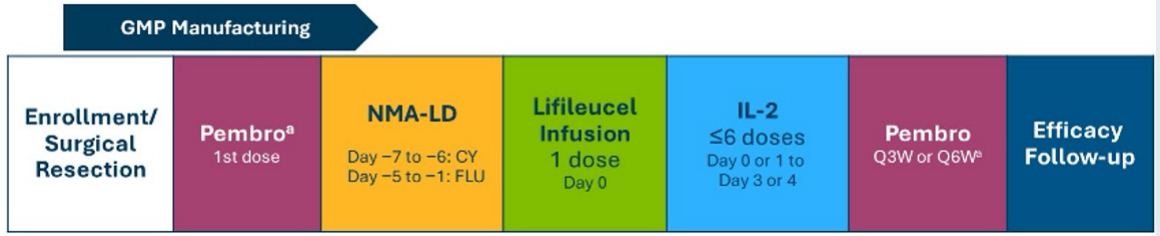
Efficacy and safety of lifileucel, an autologous tumor-infiltrating lymphocyte cell therapy, and pembrolizumab in patients with immune checkpoint inhibitor-naive unresectable or metastatic melanoma: updated results from IOV-COM-202 Cohort 1A

Sajeve Thomas,[1] Helen Gogas,[2] Young Ki Hong,[3] Gino K. In,[4] Bernard Doger de Speville Uribe,[5] Andrew J.S. Furness,[6] Almudena Garcia Castano,[7] Simon Häfliger,[8] Kai He,[9] Theresa Medina,[10] Donald Lawrence,[11] Sylvia Lee,[12] Juan Martin-Liberal,[13] Friedrich Graf Finckenstein,[14] Brian Gastman,[14] Jeffrey Chou,[14] Rana Fiaz,[14] Melissa Catlett,[14] Guang Chen,[14] Patrick Terheyden[15]

[1]Orlando Health Cancer Institute, Orlando, FL, USA; [2]Laiko General Hospital, School of Medicine, National and Kapodistrian University of Athens, Athens, Greece; [3]Cooper University Hospital, Camden, NJ, USA; [4]University of Southern California, Norris Comprehensive Cancer Center, Los Angeles, CA, USA; [5]START Madrid Fundación Jiménez Díaz, Madrid, Spain; [6]The Royal Marsden NHS Foundation Trust, London, UK; [7]Hospital Universitario Marqués de Valdecilla, Santander, Spain; [8]Inselspital, Bern University Hospital, Bern, Switzerland; [9]James Cancer Center, The Ohio State University, Columbus, OH, USA; [10]University of Colorado Cancer Center – Anschutz Medical Campus, Aurora, CO, USA; [11]Massachusetts General Hospital Cancer Center, Boston, MA, USA; [12]Fred Hutchinson Cancer Center, Seattle, WA, USA; [13]ICO L'Hospitalet – Hospital Duran i Reynals, Barcelona, Spain; [14]Iovance Biotherapeutics, Inc., San Carlos, CA, USA; [15]University of Lübeck, Lübeck, Germany

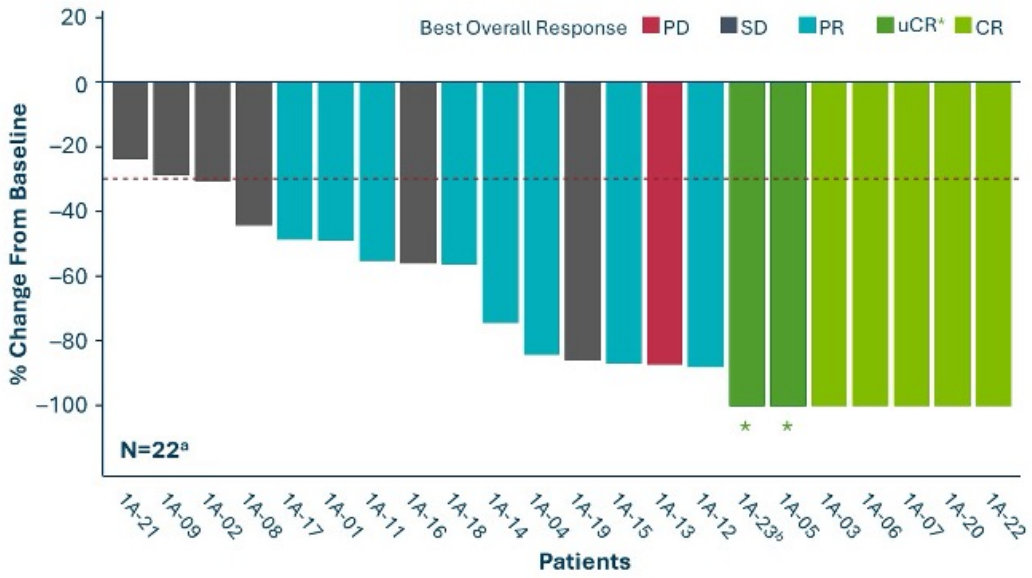
IOV-COM-202 Cohort 1A: Response Summary

Treatment Schema



ORR was 65.2%; CR rate was 30.4%

Best Percentage Change From Baseline in Target Lesion SOD



Investigator-Assessed Response (RECIST v1.1)

	N=23
ORR, n (%)	15 (65.2)
(95% CI)	(42.7, 83.6)
CR	7 (30.4)
PR	8 (34.8)
SD	6 (26.1)
PD	1 (4.3)
NE	1 (4.3)

All response-evaluable patients demonstrated regression of target lesions

*** The two uCRs have been confirmed post-data cut**

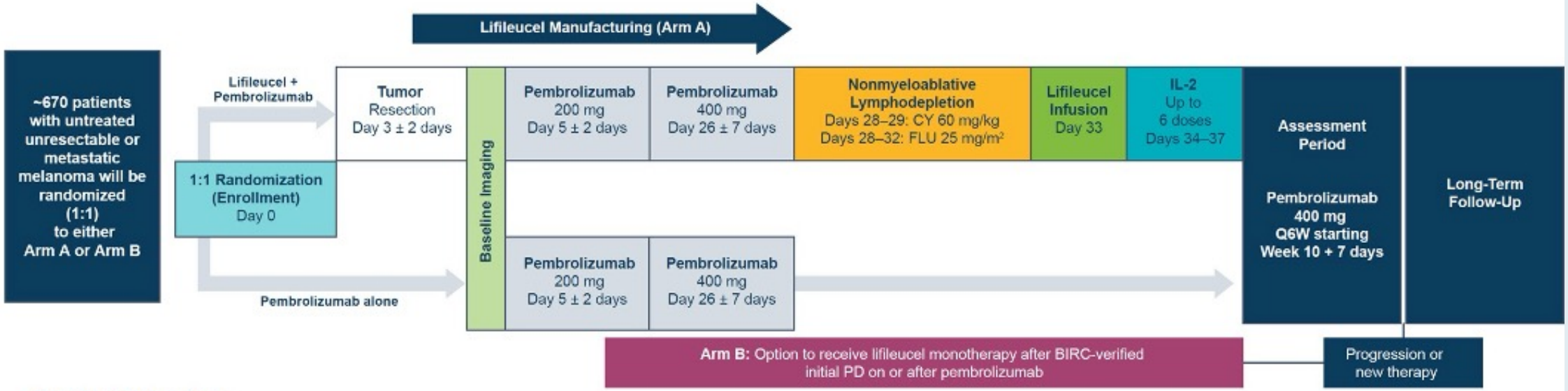
[a]One patient without a postdose tumor response assessment was not included. [b]Target lesion lymph node at baseline decreased by 50% is no longer pathological, and thus is shown here as -100% representing uCR. CI, confidence interval; CR, complete response; NE, not evaluated; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOD, sum of diameters; uCR, unconfirmed complete response.

Thomas S et al. ASCO 2024;Abstract 9505.

RTP RESEARCH TO PRACTICE

TILVANCE-301: An Ongoing Phase III Confirmatory Trial

Randomized study to evaluate lifileucel + pembrolizumab in frontline advanced melanoma Enrolling in Europe, North America, and Australia



Study Endpoints

Dual primary efficacy endpoints

- BIRC-assessed ORR per RECIST v1.1
  - Potential for accelerated approval and confirmation of post anti-PD1 approval based on early interim analysis
- BIRC-assessed PFS per RECIST v1.1

Key secondary efficacy endpoint

- OS

Additional secondary endpoints

- BIRC-assessed CR rate, DOR, EFS per RECIST v1.1
- Investigator-assessed ORR, PFS, CR rate, DOR, EFS, PFS2 per RECIST v1.1
- Safety

[a]NCT05727904.

BIRC, blinded independent review committee; CR, complete response; CY, cyclophosphamide; EFS, event-free survival; FLU, fludarabine; IL-2, interleukin-2; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-1, programmed cell death protein-1; PFS, progression-free survival; PFS2, progression-free survival 2; Q6W, every 6 weeks; RECIST, Response Evaluation Criteria in Solid Tumors.

Thomas S et al. ASCO 2024;Abstract 9505.

Agenda

Introduction

Module 1: Evidence-Based Treatment of Nonmetastatic and Metastatic Melanoma — Dr Luke

Module 2: Optimizing the Management of Nonmelanoma Skin Cancers — Dr Khushalani

Where Are We Now with the Management of Nonmelanoma Skin Cancers?

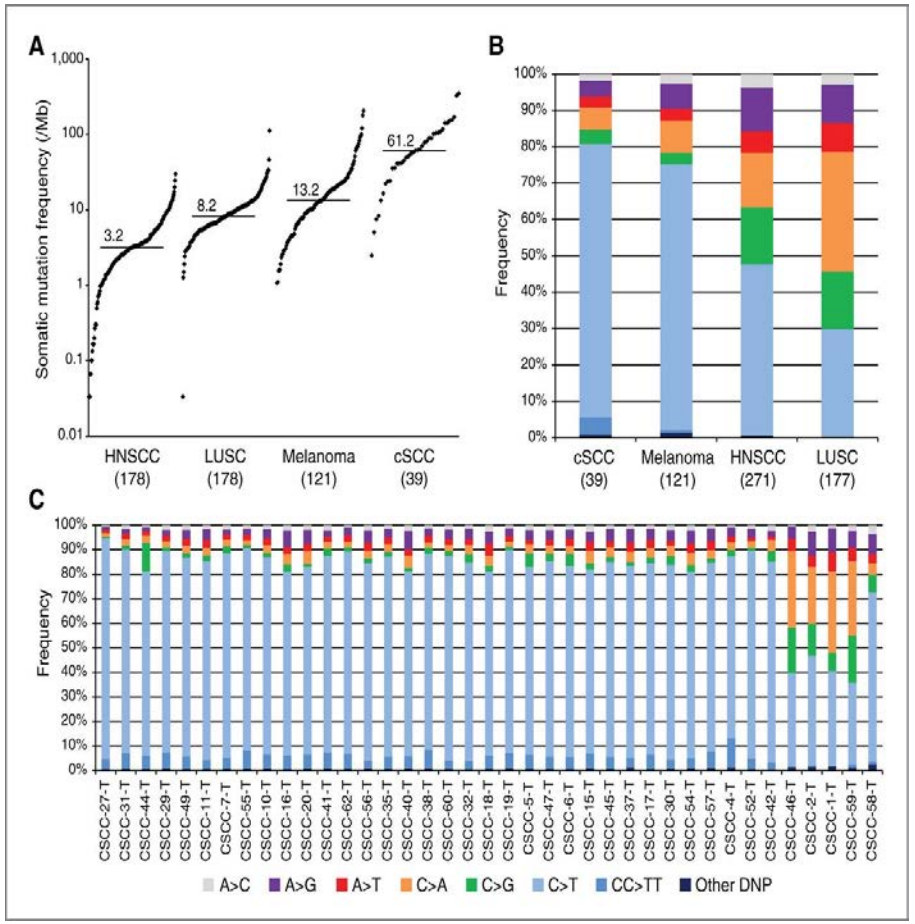
- Cutaneous squamous cell carcinoma
  - Neoadjuvant
  - Adjuvant
  - Metastatic/recurrent
- Basal cell carcinoma

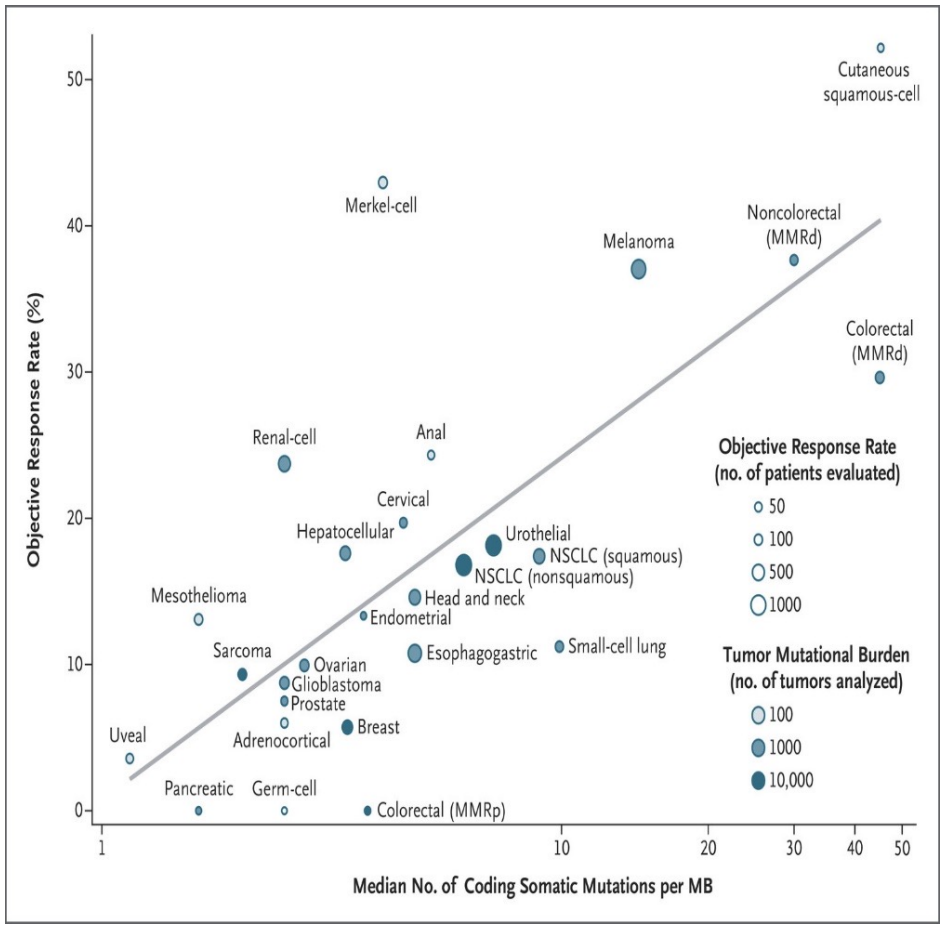
Optimizing the Management of Non-Melanoma Skin Cancer: Updates from ASCO 2024

Nikhil I. Khushalani, MD
Assistant Center Director, Clinical Research Review and Partnerships
Vice-Chair and Senior Member, Cutaneous Oncology
Moffitt Cancer Center, Tampa, FL

Long Term Data for Anti-PD1 Therapy for Advanced Cutaneous Squamous Cell Carcinoma

TMB and Response to Anti-PD1 Therapy

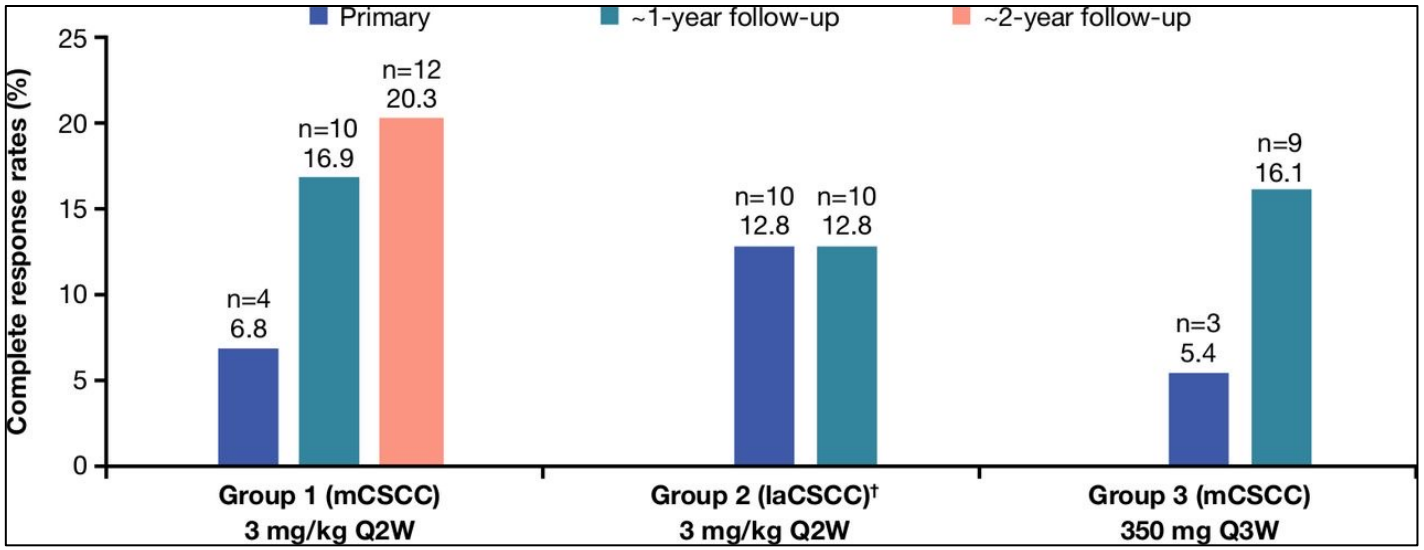




Pickering CR. *Clin Cancer Res.* 2014;20:6582; Yarchoan M. *N Engl J Med.* 2017;377:2500.

EMPOWER-CSCC 1: Cemiplimab in Advanced CSCC

N=193	Cohort 1	Cohort 2	Cohort 3
Dose	3mg/kg q2w	3mg/kg q2w	350mg q3w
ORR (%)	**50.8**	**44.9**	**42.9**
CR (%)	20.3	12.8	16.1
mPFS	18.1 months (95% CI, 10.3-24.3)		



Rischin D, Khushalani NI, et al. *J Immunother Cancer* 2021;e002757

KEYNOTE-629
Pembrolizumab in Advanced CSCC

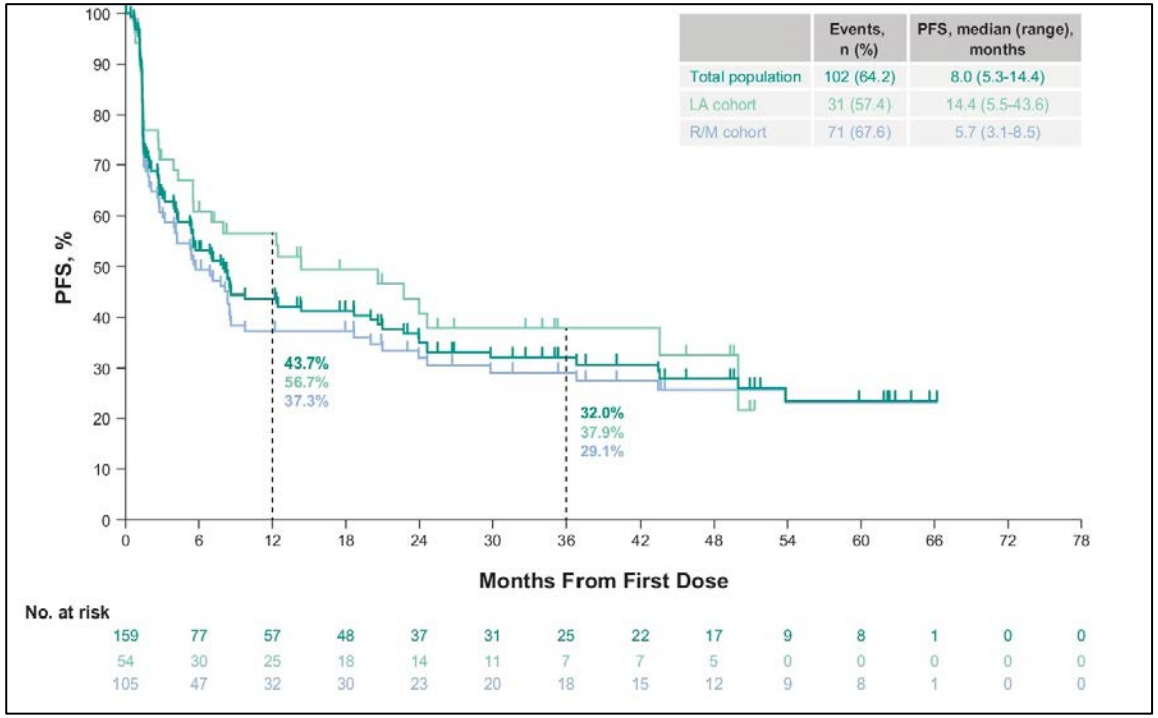
N=159	Locally Advanced (54)	Recurrent/Metastatic (105)
ORR %	50	35.2
CR %	16.7	10.5
DCR %	64.8	52.4
Median PFS (m)	NR (95% CI, 5.5-NR)	5.7 (95% CI, 3.1-8.5)

ASCO 2024 UPDATE (Median Follow-Up 63.1 months)		
ORR %	51.9	**35.2**
CR %	22.2	12.4
Median PFS (m)	14.4 (95% CI, 5.5-43.6)	5.7 (95% CI, 3.1-8.5)
Median OS (m)	NR (95% CI, 33.3-NR)	23.8 (95% CI, 13.4-30.9)

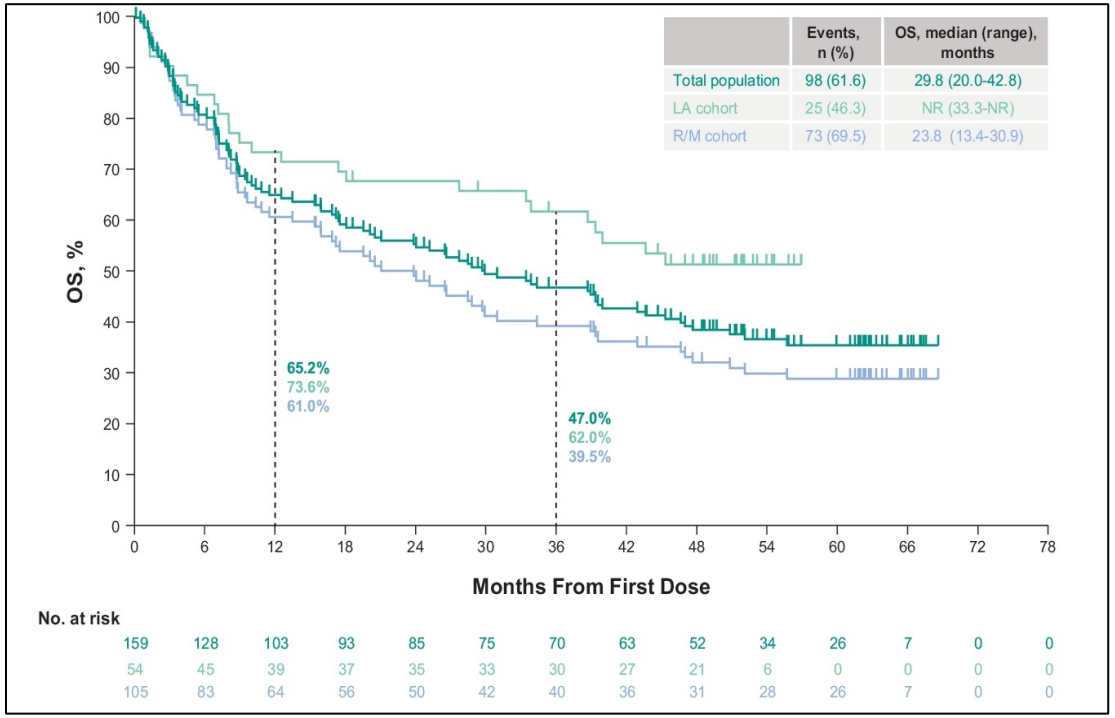
Hughes BGM, Munoz-Couselo E, et al. *Ann Oncol* 2021;32:P1276; Munoz-Couselo E, et al. ASCO 2024, Abstract 9554

Survival on KEYNOTE-629

PFS



OS



Munoz-Couselo E, et al. *ASCO 2024*, Abstract 9554

KEYNOTE-629 Safety

- Grade 3-5 treatment related AEs: 11.3%
- TRAE leading to treatment discontinuation: 8.8%
- Immune related AEs requiring steroids: 11.3%

No new safety signals with longer follow-up

Munoz-Couselo E, et al. *ASCO 2024*, Abstract 9554

Conclusion:

Anti-PD1 monotherapy with cemiplimab or pembrolizumab can provide deep and durable responses in advanced, unresectable CSCC

Unanswered Questions:

1. Do we need to explore combination IO therapy?

2. Biomarkers of response needed

PET-CT as a Prognostic Biomarker

- Retrospective study (n=53)
- Baseline + at least 1 PET-CT < 4m from starting IO

PERCIST 1.0		Investigator assessed progressive disease			
	Baseline response	6 Months	12 Months	18 Months	≥ 24 months
	N=53	N=52	N=38	N=30	N=17
CMR	29 (55%)	0	0	0	1
PMR	8 (15%)	1	1	1	1
PSD	6 (11%)	2	2	2	2
PMD	10 (19%)	7	7	7	7

- Estimated 12m PFS was 100% for CMR versus 30% in PMD

Ladwa R, et al. *ASCO 2024*, Abstract 9548

Questions?

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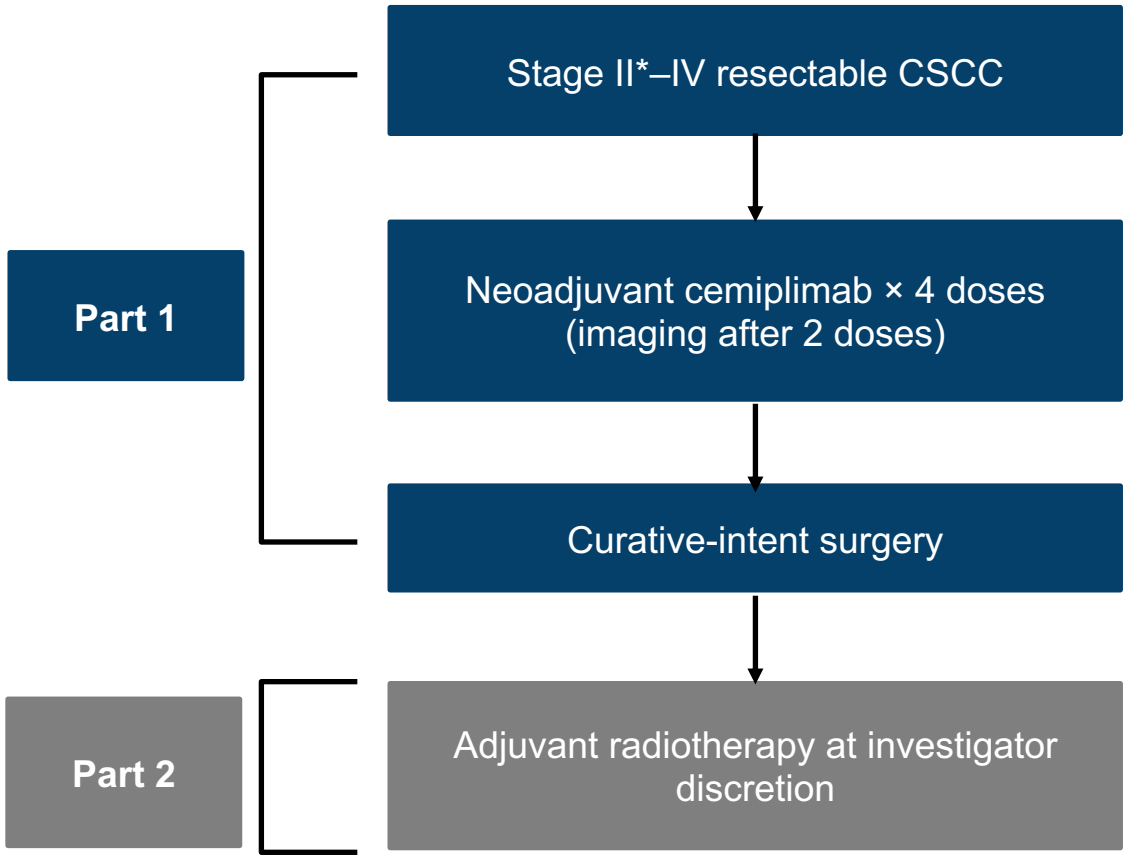
Neoadjuvant Therapy for Resectable High-Risk Cutaneous Squamous Cell Carcinoma

Neoadjuvant Cemiplimab in Resectable CSCC



Gross ND, Miller D, Khushalani NI, et al. *N Engl J Med* 2022;387:1557.

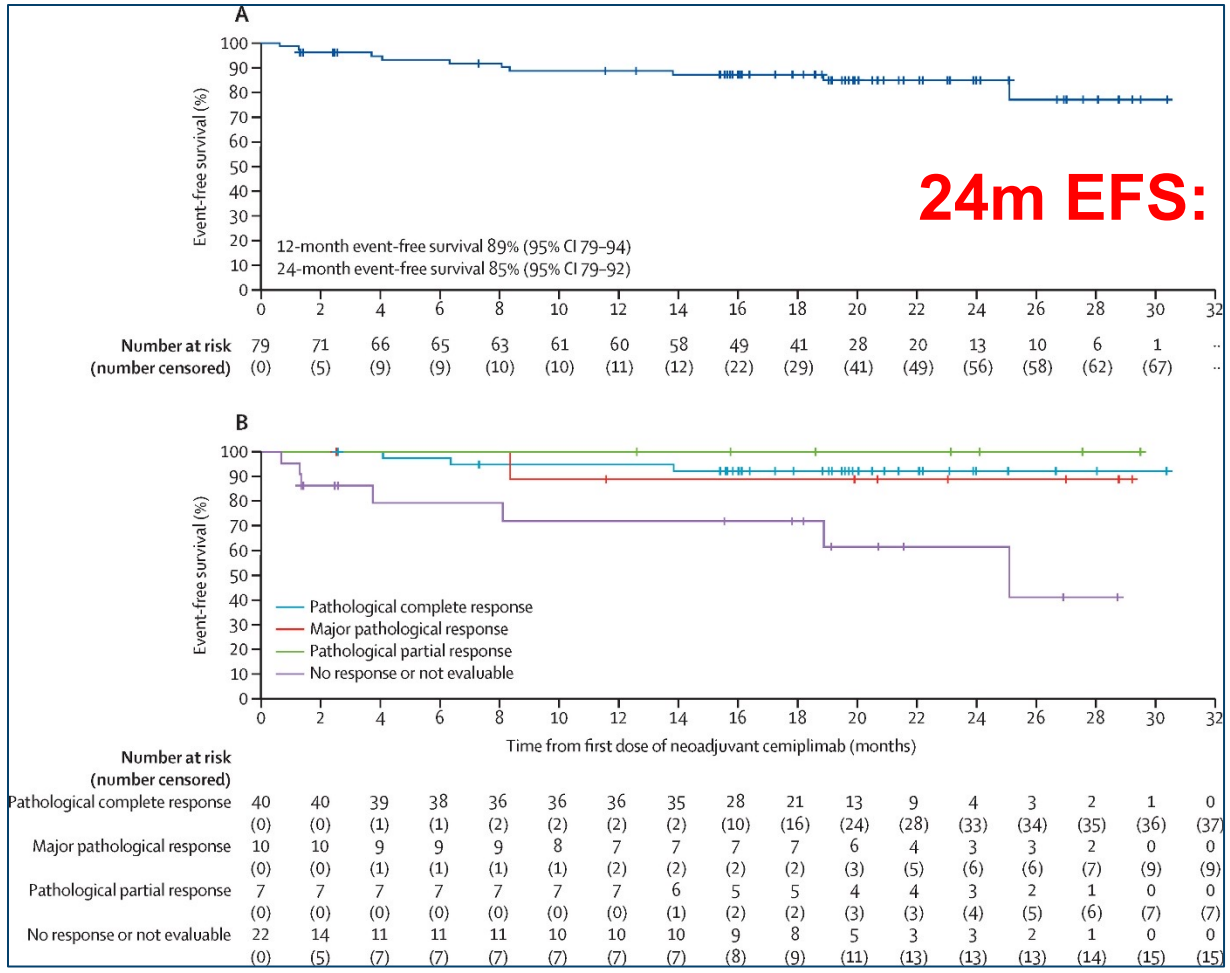
Neoadjuvant Cemiplimab

Primary End Point: Pathologic Complete Response (pCR) Rate

Pathologic Response	Independent Review	Radiographic Response
pCR	50.6%	ORR: 68.4% CR: 6.3%
MPR	12.7%	
Non-pCR/MPR	25.3%	
Not evaluable	11.4%	

Gross ND, Miller D, Khushalani NI, et al. *N Engl J Med* 2022;387:1557.

Event-free Survival with Neoadjuvant Cemiplimab



24m EFS: 85%

Gross ND, Miller DM, Khushalani NI, et al. *Lancet Oncol* 2023;24:1196.

Neoadjuvant Pembrolizumab in CSCC

- N=30; single arm study
- 2 cycles of pembrolizumab → surgery → 15 cycles of pembrolizumab
- Median age 77 years (55-89)
- pCR rate: 59%

Amatore F, et al. *ASCO 2024*, Abstract 9591

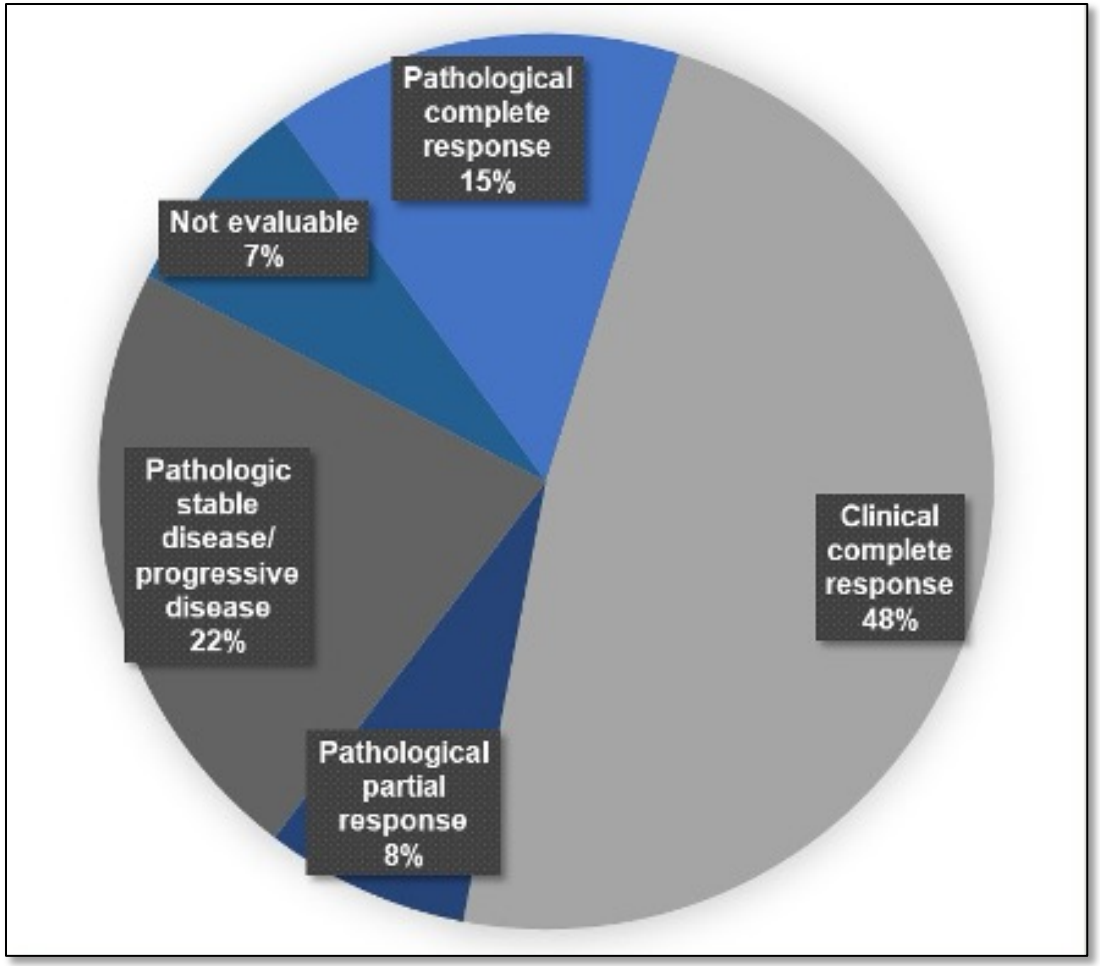
DESQUAMATE Study

- N=27
- Aimed to de-escalate from planned surgery +/- post-operative radiotherapy (PORT) following 4 cycles of neoadjuvant pembrolizumab in resectable high-risk stage II-IV CSCC
- If complete clinical + radiographic (PET-CT) response + mapping biopsy negative, then NO surgery/RT
- If non-complete clinical response, then surgery + risk adaptive post-operative therapy based on pathologic response
  - If pCR/MPR – only pembro post-op
  - If > 10% viable tumor – PORT + pembro post-op

Ladwa R, et al. *ASCO 2024*, Abstract 9514

DESQUAMATE Results

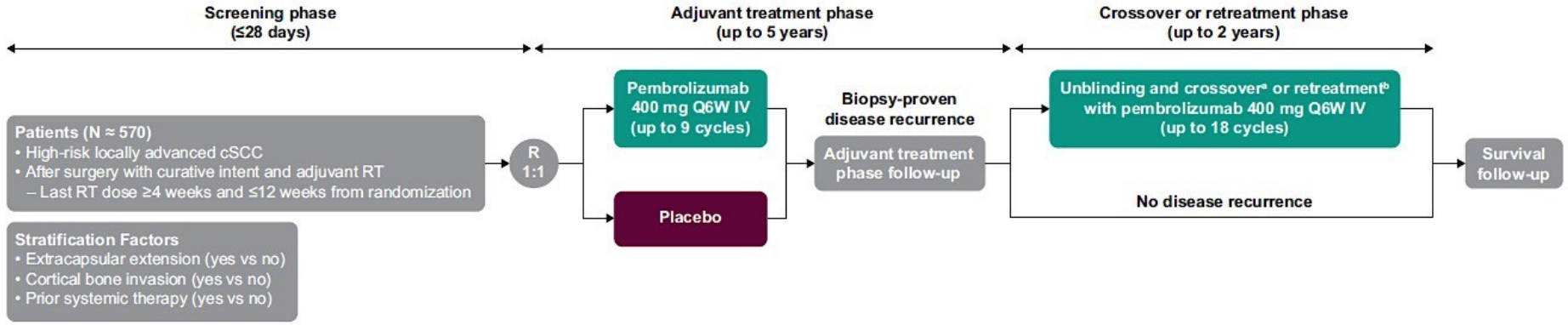
- De-escalation in **63%**
- Pts with CCR, PCR or PPR with 100% RFS at 12 months
  - Both surgery and PORT eliminated in 48%
  - PORT only in 15%
- All recurrences (n=3) in pts with > 50% viable tumor at surgery



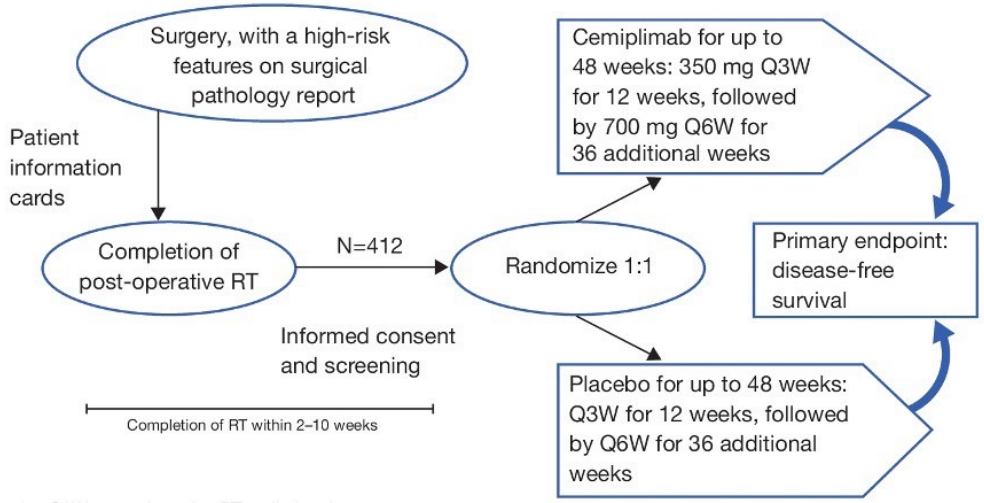
Ladwa R, et al. *ASCO 2024*, Abstract 9514

Adjuvant Trials in High-Risk CSCC

KEYNOTE-630



C-POST



KEYNOTE-630: accrual completed

C-POST: recruiting

Schenker M et al. AACR-AHNS 2023; Abstract PO-009; Rischin D et al. ASCO 2022;Abstract TPS9592.

Hedgehog Inhibitors in BCC

VISMODEGIB

ERIVANCE BCC Trial

- N=104
- ORR: 60.3% (LA), 48.5% (Metastatic, M)
- Median DOR: 26.2m (LA), 14.8m (M)
- Median PFS: 12.9m (LA), 9.3m (M)
- Median OS: NE (LA), 33.4m (M)

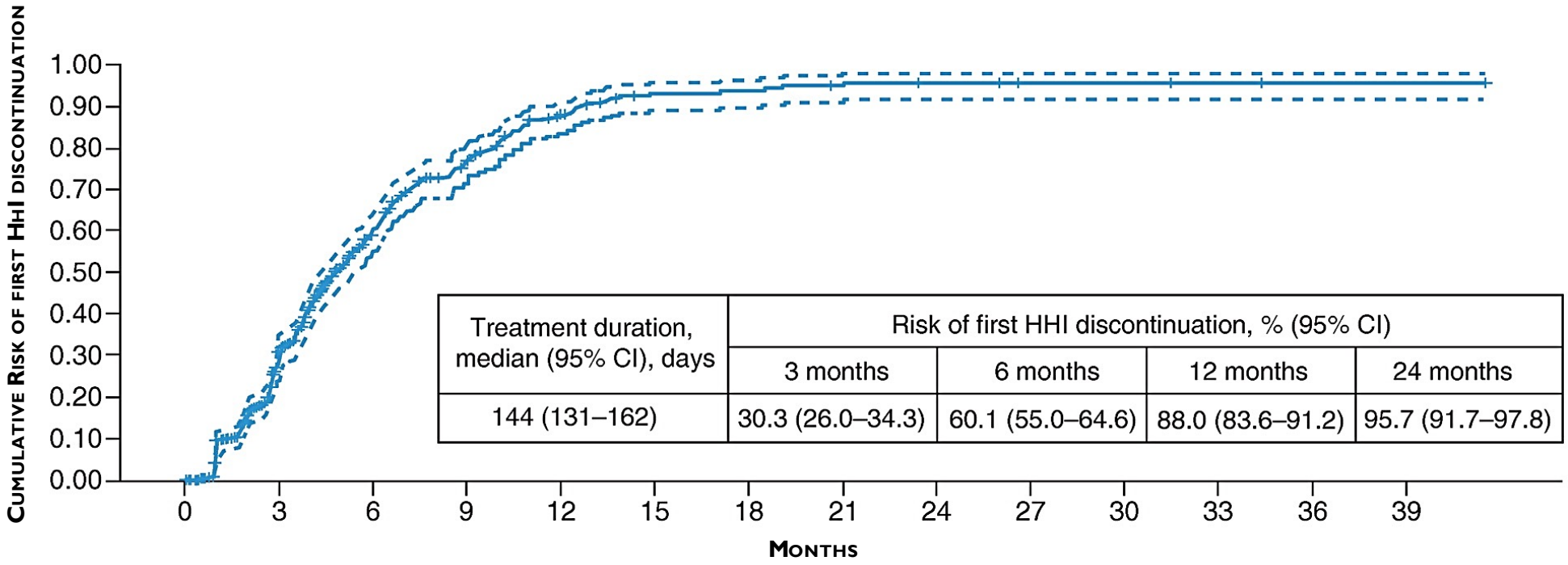
SONIDEGIB

BOLT Trial

- N=230
- 48-month final analysis
- ORR (200mg cohort): 56% (LA), 8% (M)
- Median DOR: 26.1m (LA), 24.0m (M)
- Median PFS: 22.1m (LA), 13.1m (M)

Sekulic A et al. *BMC Cancer* 2017;332:s12885; Dummer et al, *Br J Dermatol* 2020;182:1369.

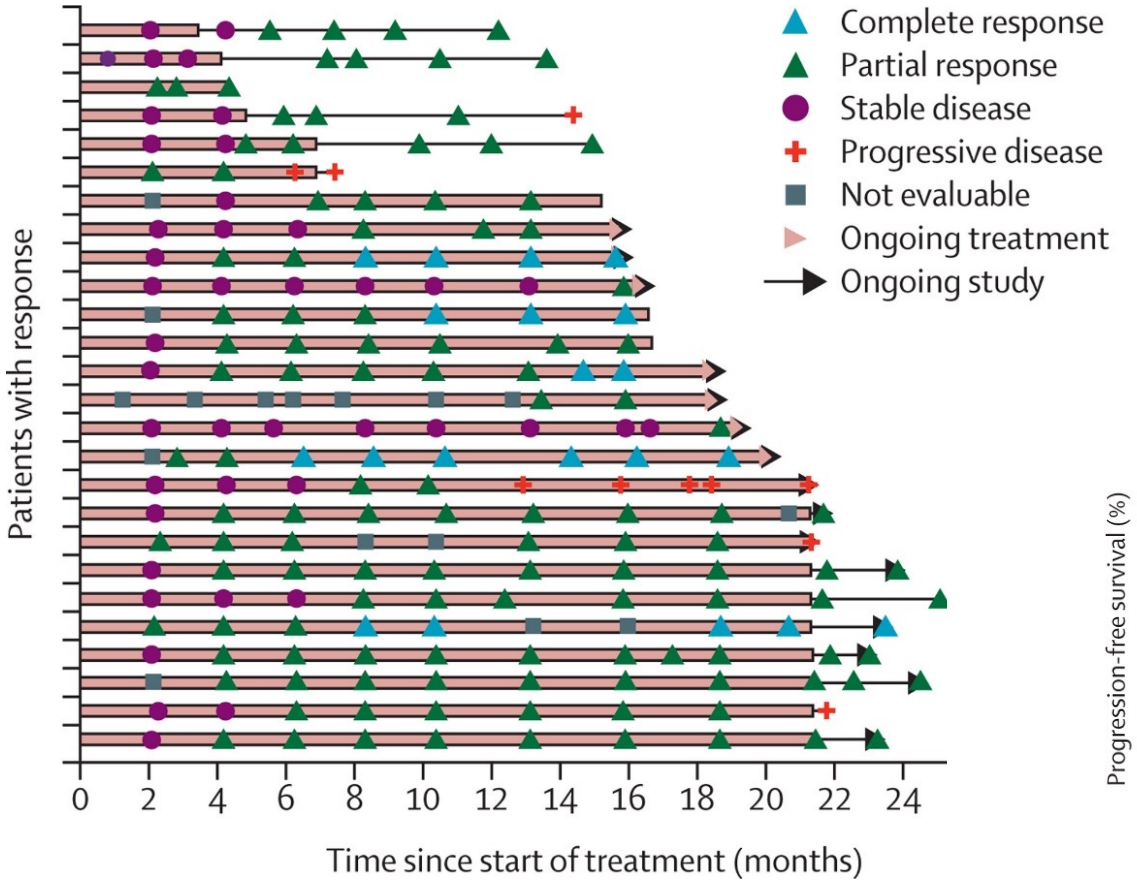
Real World Data in BCC: HHI Discontinuation Is Common



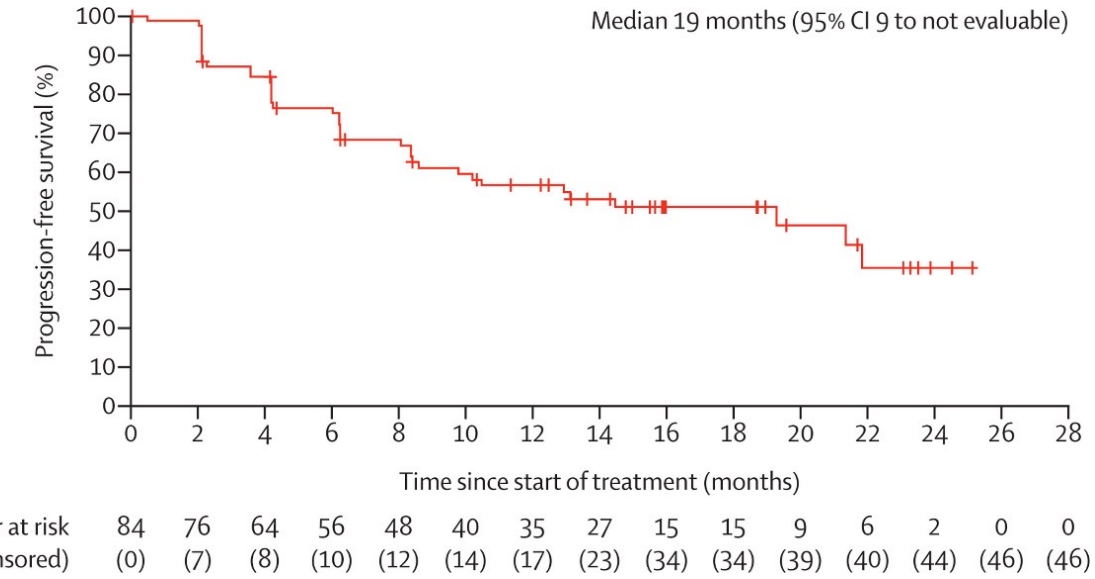
Treatment duration, median (95% CI), days	Risk of first HHI discontinuation, % (95% CI)			
	3 months	6 months	12 months	24 months
144 (131–162)	30.3 (26.0–34.3)	60.1 (55.0–64.6)	88.0 (83.6–91.2)	95.7 (91.7–97.8)

Ge W, et al. *Future Oncol*. 2022 Jul;18(23):2561-2572.

Cemiplimab in Basal Cell Carcinoma



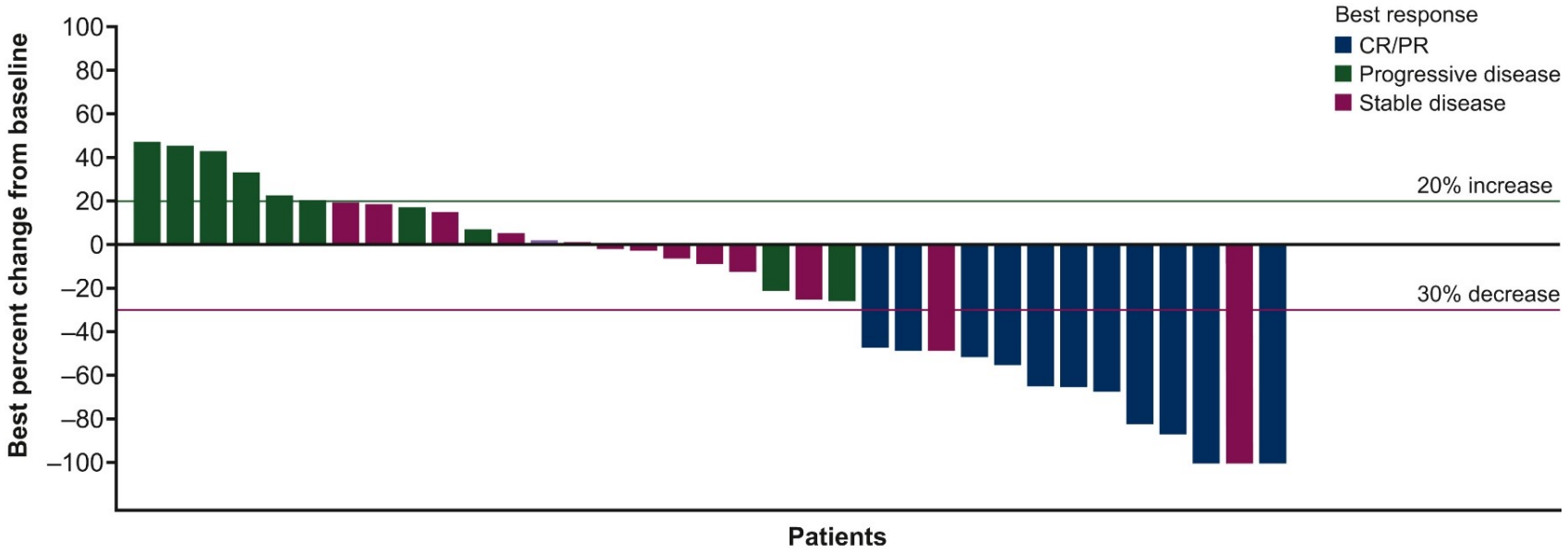
- **Locally advanced BCC; intolerant or PD on HHI, or SD X 9 months**
- **ORR 32.1% (7.1% CR)**
- **DCR 79.8%**



Stratigos AJ, Sekulic A, et al. *Lancet Oncol* 2021;22:848

Stratigos AJ, Sekulic A, et al. *J Am Acad Dermatol* 2024;90:414

Cemiplimab For Metastatic BCC After HHI



ORR: 22%; CR: 4%

mPFS: 10 months (95% CI, 4-16)

Lewis KD, Peris K, et al. *Ann Oncol* 2024;35(2):221-28

Nivolumab + Relatlimab in Advanced BCC

- N=19
  - 13 (NIVO alone); ORR 46%
    - 9 HHI naïve (5/9: ORR 56%)
  - 5 (NIVO + RELA)
    - ORR 20% (1/5); SD 60% (3/5)
  - 1 (NIVO + IPI)
    - No response

Schenk et al. ESMO 2022; Poster 820P

Therapies of Interest in NMSC

- Intralesional
  - RP1 (CERPASS, ARTACUS): CSCC
  - Daromun (L19IL2 + L19TNF): BCC
  - IFX-Hu2.0: Merkel cell carcinoma (MCC)

- Systemic
  - Neoadjuvant nivolumab plus relatlimab: MCC

Conclusions

- Anti-PD1-based therapy is SOC front-line treatment for advanced CSCC
- Neoadjuvant anti-PD1 therapy is effective with high pCR rate in CSCC
- Early promise of IT in HHI-refractory BCC is encouraging and warrants investigation as front-line therapy

Year in Review: Immunotherapy and Other Nontargeted Approaches for Lung Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, June 18, 2024
5:00 PM – 6:00 PM ET

Faculty

Matthew Gubens, MD, MS

Moderator

Neil Love, MD

RTP Year in Review 2024

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

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

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