

VIII SIMPOSIO NACIONAL
de ONCOLOGÍA de PRECISIÓN

Vigo, 19 y 20 de febrero de 2026



Melanoma: lo mejor de 2025

Maria Gonzalez Cao
Hospital Universitari Dexeus
Barcelona, Spain

1. Lifleucel 5 years (ASCO 2025)
2. Sequential updated data DREAMseq (ASCO 2025)
3. Adjuvant Relativity (ASCO 2025)
4. Nivolumab adjuvant final results (ESMO 2025)
5. Neoadjuvant update SWOG and Nadina (ESMO 2025)
6. RELA+NIVO 1st line, update (JCO 2025)
7. IMA 203 : Phase 1 (ASCO 2025) , uveal (ESMO/SMR 2025)
8. Neoadjuvant uveal darovasertib (ESMO 2025)
9. TIL uveal melanoma (SITC 2025)
10. Cemi adjuvant SQ (ASCO 2025)
11. Daramun neoadjuvant SQ and BCC (ESMO 2025)
12. Plasmaferesis (ESMO 2025)
13. MERKEL adjuvant (ESMO 2025)
14. RP1

Supone un cambio en el standard de práctica clínica

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Confirman lo que podría ya ser standard

Podrían en un futuro llegar a ser standard

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Ponen en duda el standard actual

Confirman lo que podría ya ser standard

Podrían en un futuro llegar a ser standard

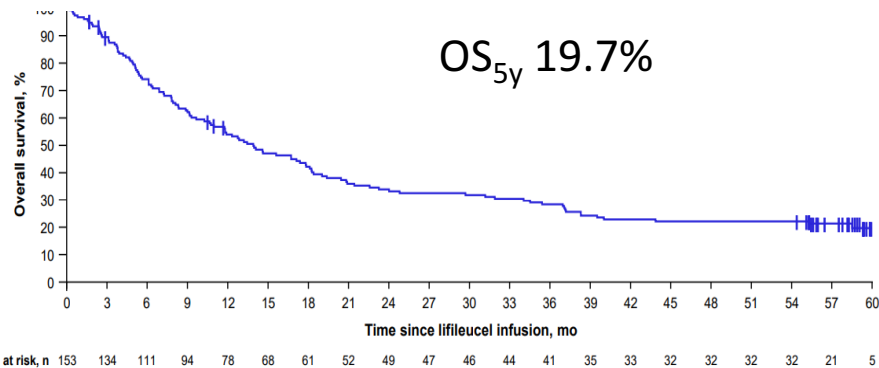
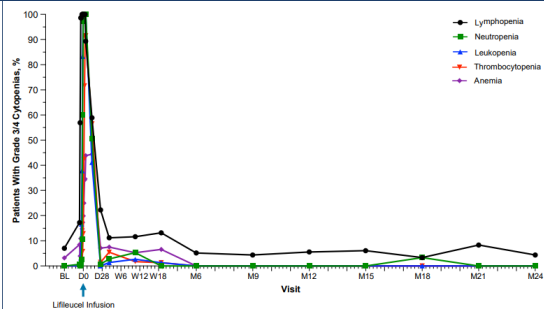
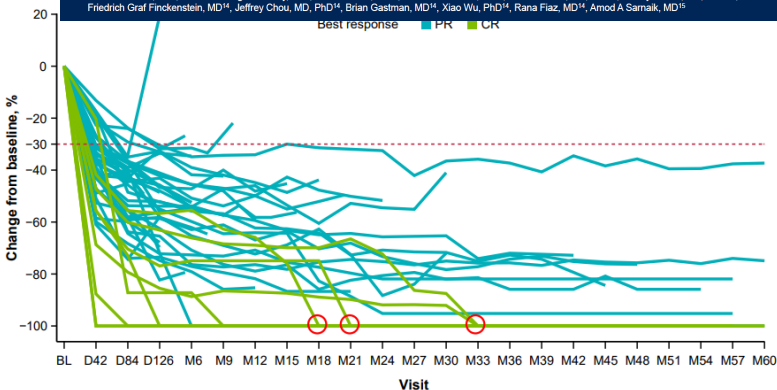
Original

1. TIL therapy : long survivors confirmed (again)

2025 ASCO ANNUAL MEETING

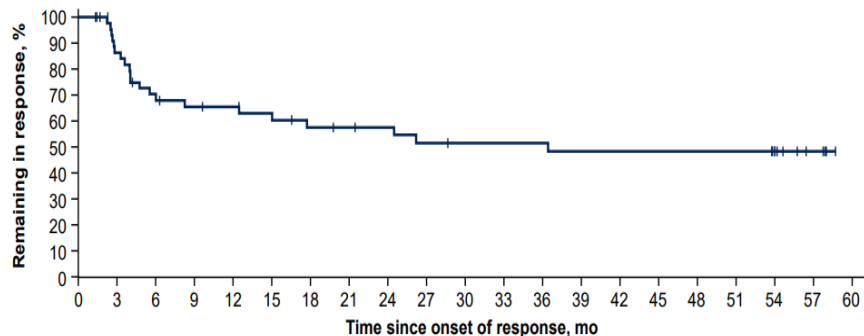
Lifileucel in patients with advanced melanoma: 5-year outcomes of the C-144-01 study

Theresa Medina, MD¹, Jason A Chesney, MD, PhD², Harriet M Kluger, MD³, Omid Hamid, MD⁴, Eric D Whitman, MD⁵, Mike Cusin, MD⁶, Sejeva A Thomas, MD⁷, Martin Wernke, MD⁸, Evidio Domingo-Musibay, MD⁹, Gao Q Phan, MD¹⁰, John M Kirkwood, MD¹¹, James Larkin, MD, PhD¹², Jeffrey Weber, MD, PhD¹³, Friedrich Graf Finckenstein, MD¹⁴, Jeffrey Chou, MD, PhD¹⁴, Brian Gastman, MD¹⁴, Xiao Wu, PhD¹⁴, Rana Fiaz, MD¹⁴, Amod A Sarnaik, MD¹⁵



- The ORR was 31.4% (complete response [CR], 5.9%; partial response [PR], 25.5%), and 79.3% of patients had a reduction in tumor burden
- The median duration of IRC-assessed response was 36.5 months (95% CI: 8.3–NR)
- 31.3% (15/48) of responders completed the 5-year assessment with ongoing responses

Duration of Response



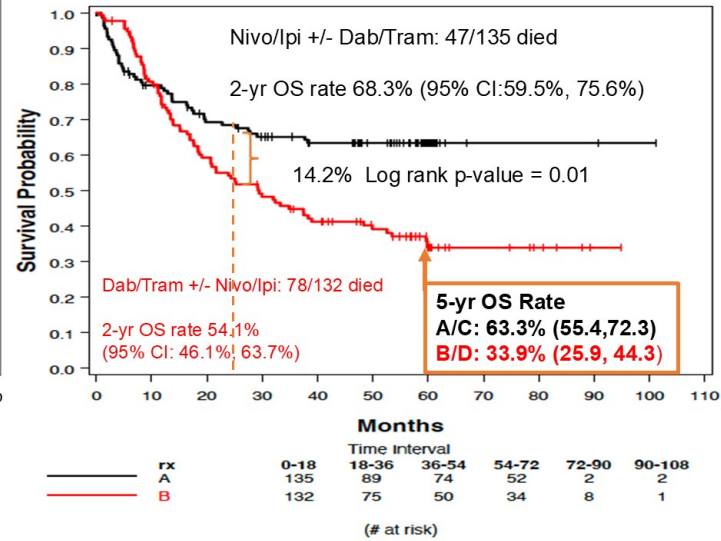
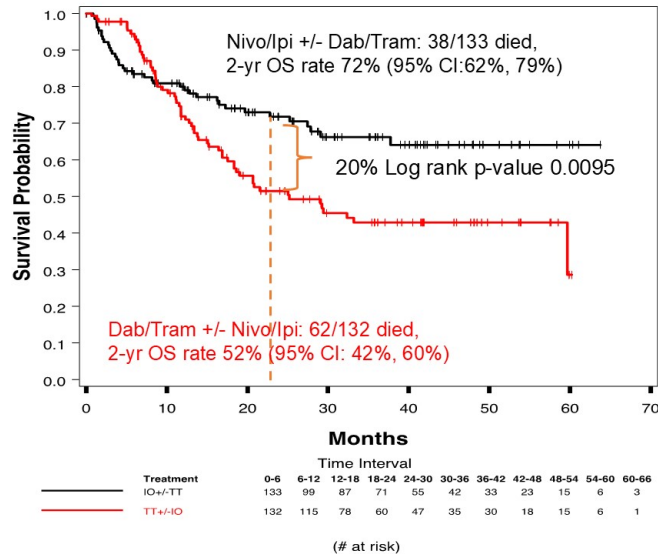
Patients at risk, n

2. With longer follow-up, the survival benefit of starting with immunotherapy becomes even more pronounced, particularly at 5 years

Updated DREAMseq OS: Step 1 +/- Step 2

July 2021

July 2024



4. Neoadjuvant trials: both confirm benefit with longer follow up

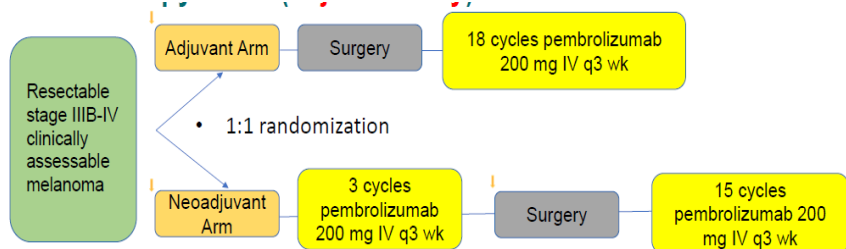


3-year survival with neoadjuvant-adjuvant pembrolizumab from SWOG S1801

Sapna P. Patel, Megan Othrus, Victor G. Prieto, Michael C. Lowe, Elizabeth I. Buchbinder, Yuanbin Chen, G. Paul Wright, Jr., John Hyngstrom, Christopher Lao, Thach-Giao Truong, Sunandana Chandra, Kari Kendra, Craig Devoe, Ankit Mangla¹, Alexandra Ikeguchi, John Kirkwood, Larissa Korde, James Moon, Vernon K. Sondak, Antoni Ribas

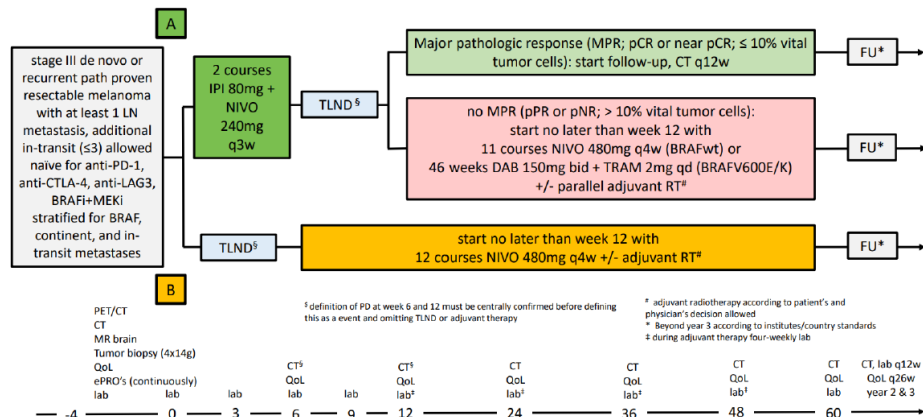
Abstract 16010

20 October 2025

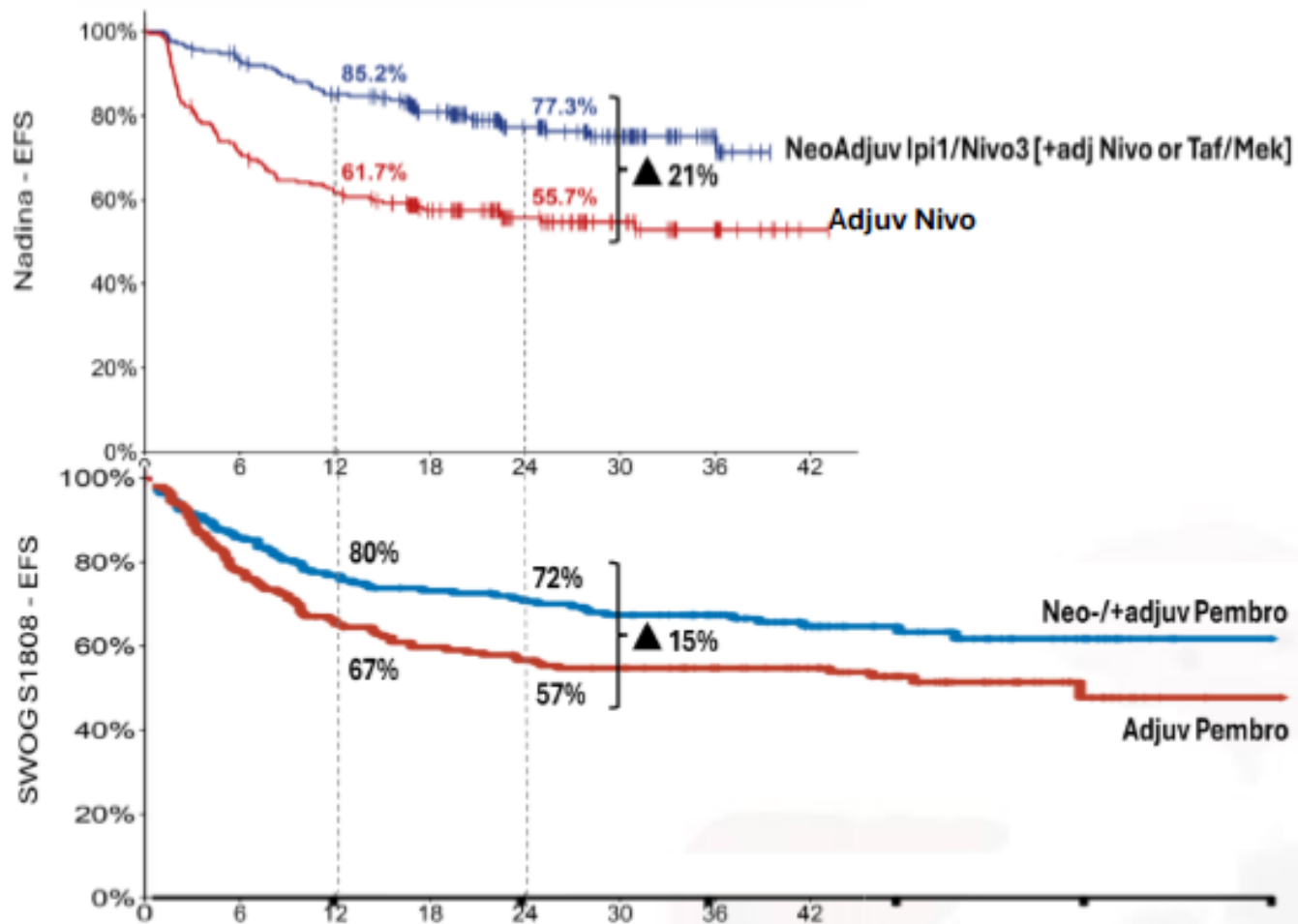


Two-year clinical update and first biomarker analyses of the phase 3 NADINA trial comparing neoadjuvant nivolumab plus ipilimumab versus adjuvant nivolumab in resectable stage III melanoma

M.W. Lucas, A.M. Menzies, P. Dimitriadis, S. Wijnen, M. Lopez-Yurda, R.A. Scolyer, B.W. van de Wiel, R.P.M. Saw, A. Kuijpers, A. Torres-Acosta, J. Sanders, 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^{*}, C.U. Blank^{*}

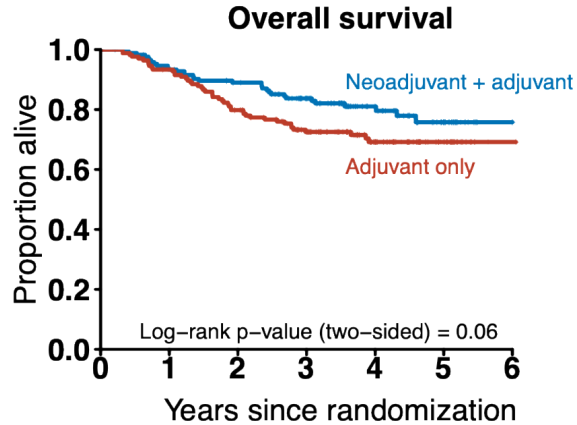


Primary endpoint: event-free survival



HR (95% CI)	Log Rank P-value
0.40 (0.28-0.57)	<0.001
0.67 (0.42-0.94)	0.02

Neoadjuvant immunotherapy improves distant control and may translate into an OS benefit with longer follow-up



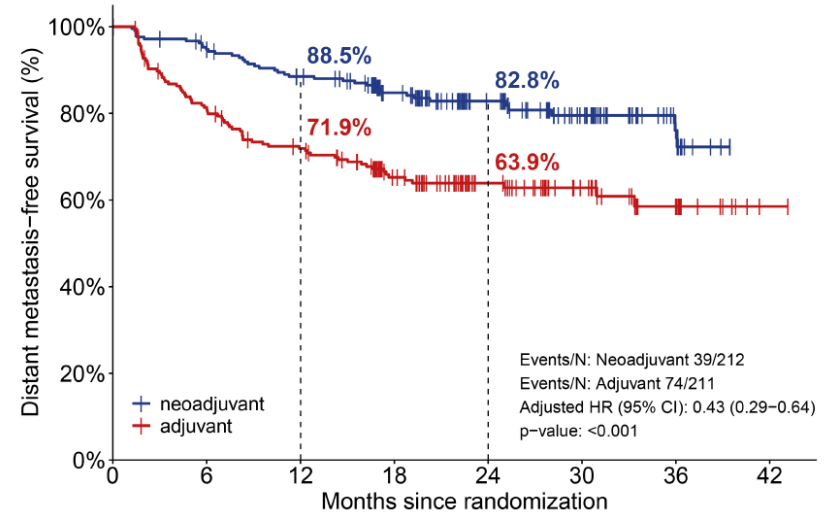
N at risk

172	152	138	110	58	22	
173	153	129	97	54	20	1

All randomized participants

Estimate (95% CI)	Neoadjuvant + adjuvant	Adjuvant only
N	172	173
Deaths	32	47
1-year OS	93% (90-97%)	93% (90-97%)
2-year OS	89% (84-94%)	80% (74-86%)
3-year OS	84% (78-90%)	73% (70-80%)
Hazard ratio	0.66 (0.42-1.02)	

Neoadjuvant + adjuvant
Adjuvant only



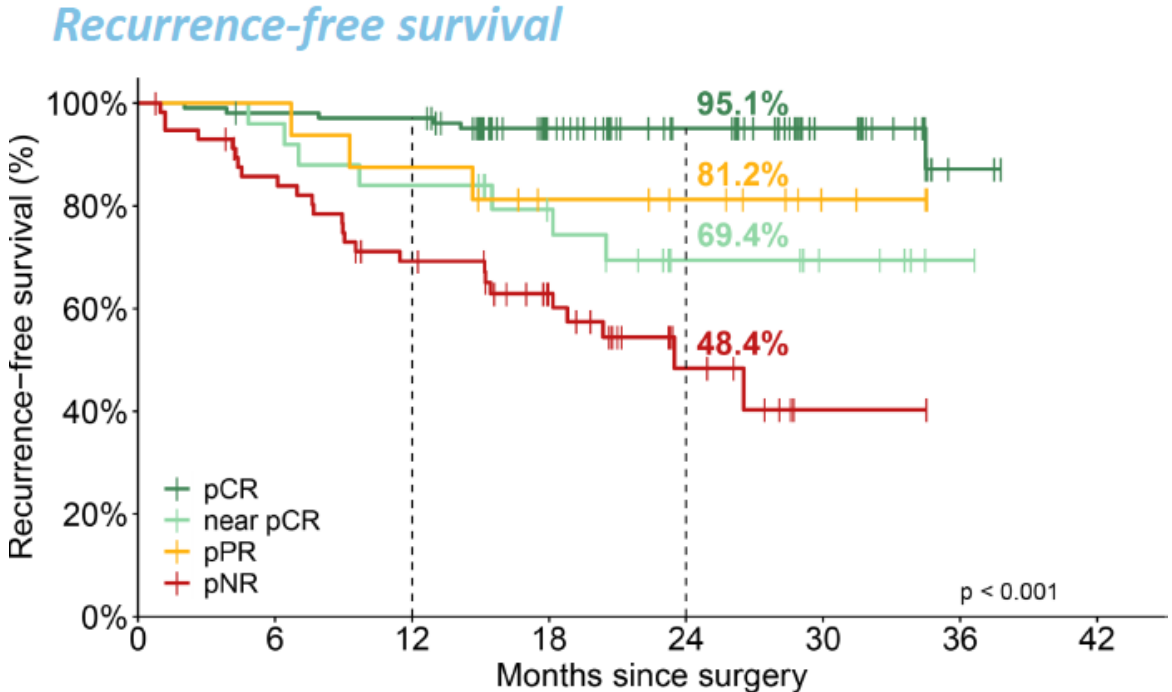
neoadjuvant	212	198	181	140	95	56	21	0
adjuvant	211	165	142	99	61	39	19	1

Data cut-off May 2025



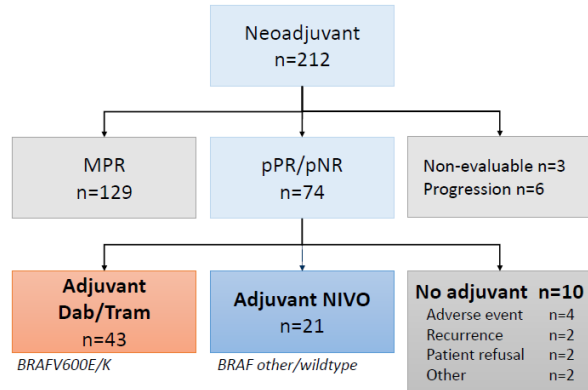
Option of no adjuvant in case of MPR after 2 cycles IPI-NIVO (64%)

NADINA

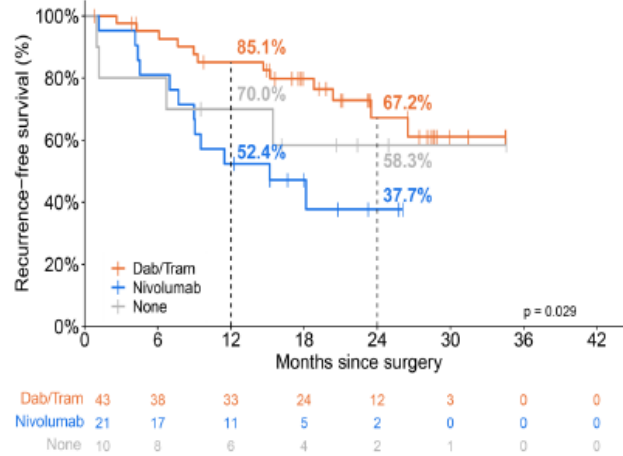


pCR	104	101	100	67	47	27	2	0
near pCR	25	24	21	16	8	5	1	0
pPR	16	16	14	10	8	3	0	0
pNR	58	47	36	23	8	1	0	0

NADINA and Pennsylvania study: selecting adjuvant treatment according to MPR

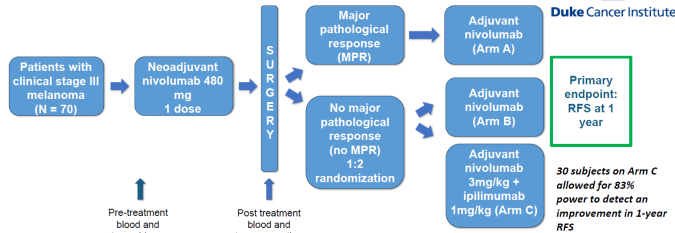


NADINA: RFS according to adjuvant treatment after pPR or pNR in the neoadjuvant arm

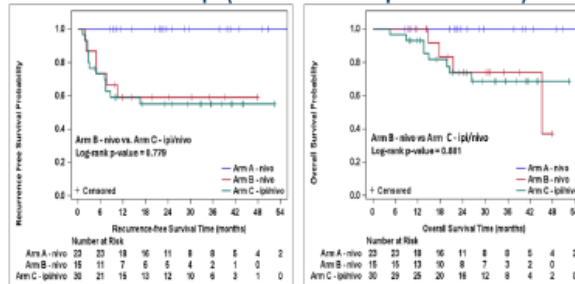


- Adjuvant dabrafenib/trametinib remains justified for *BRAF*^{V600E} mutant melanoma patients who do not obtain a MPR following neoadjuvant ICB
- Opportunity for prospective studies

Escalation of adjuvant therapy based on path response - NCT04013854



No RFS or OS difference in patients without MPR treated with nivo or nivo/ipi (median follow up 24.2 months)

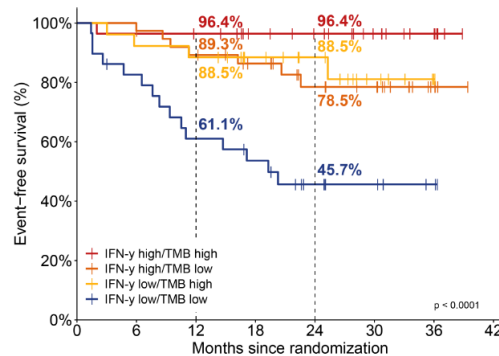


- There is no role for dual ICB as adjuvant therapy in patients without a MPR following neoadjuvant PD-1 ICB

NADINA

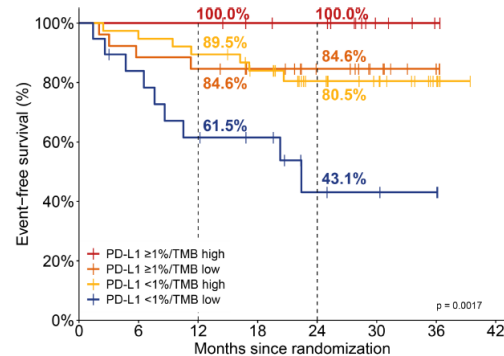
multi-parameter
biomarker platforms
could help predict
neoadjuvant benefit in
future studies

Event-free survival: IFN- γ + TMB



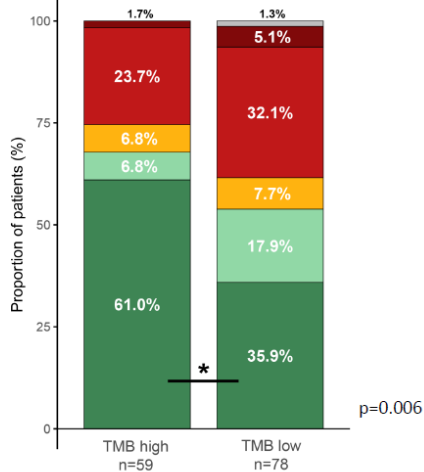
IFN- γ high/TMB high	28	27	26	21	18	12	7	0
IFN- γ high/TMB low	38	37	33	28	19	16	6	0

Event-free survival: PD-L1 + TMB

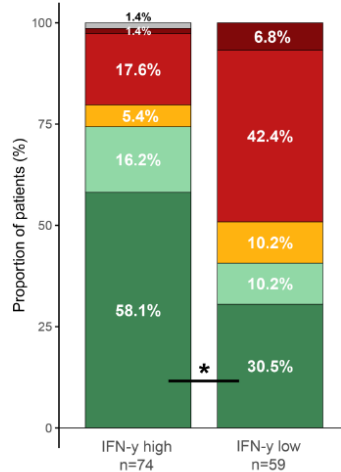


PD-L1 \geq 1%/TMB high	14	14	14	12	11	4	1	0
PD-L1 \geq 1%/TMB low	26	23	22	18	13	8	3	0

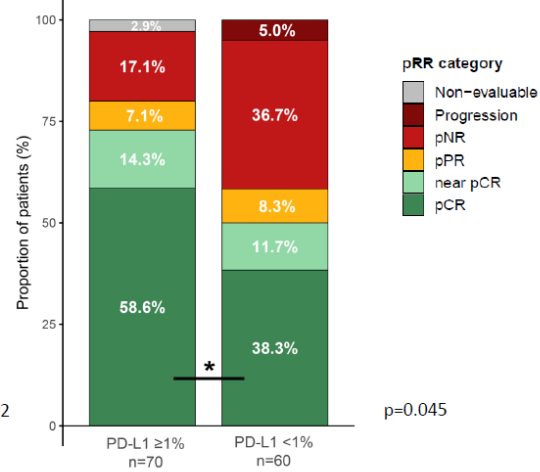
Tumor mutational burden



IFN- γ signature



PD-L1 expression

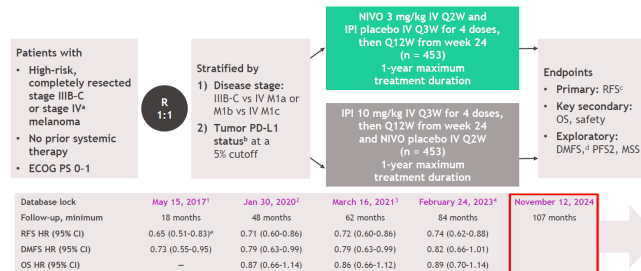


5. Longer follow up of djuvant nivo: no OS benefit

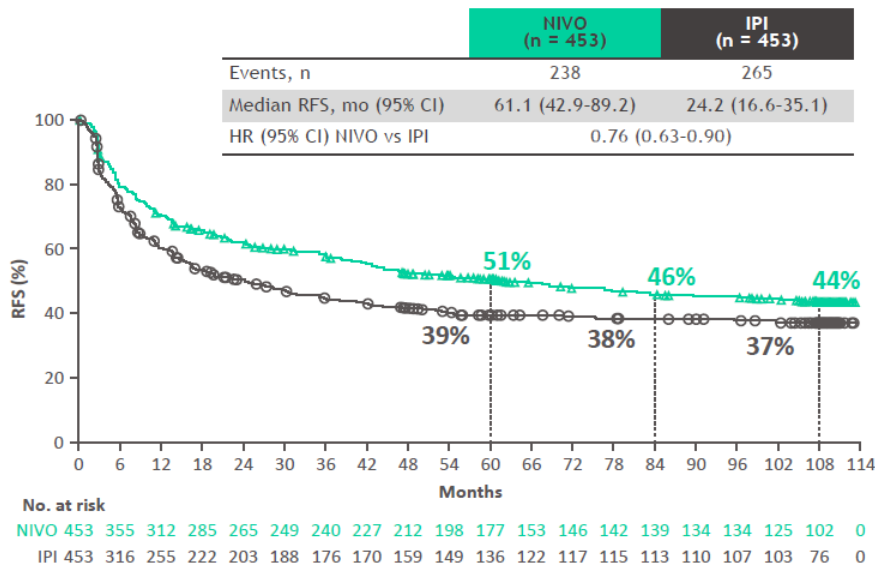
Final, 9-year results from the CheckMate 238 phase 3 trial of adjuvant nivolumab vs ipilimumab in resected stage IIIB-C or IV melanoma

Paolo A. Ascierto,¹ Michele Del Vecchio,² Barbara Merelli,³ Helen Gogas,⁴
 Ana M. Arance Fernandez,⁵ Stéphane Dalle,⁶ Charles Lance Cowey,⁷ Michael Schenker,⁸
 Caroline Gaudy-Marqueste,⁹ Jacopo Pigozzo,¹⁰ Iván Márquez-Rodas,¹¹ Marcus Butler,¹²
 Anna Maria Di Giacomo,¹³ Mark R. Middleton,¹⁴ Oleg Gligich,¹⁵ Luis De La Cruz-Merino,¹⁶
 Raheela Soomro,¹⁷ Dhanrajsinh Rathod,¹⁷ Margarita Askelson,¹⁷ James Larkin¹⁸

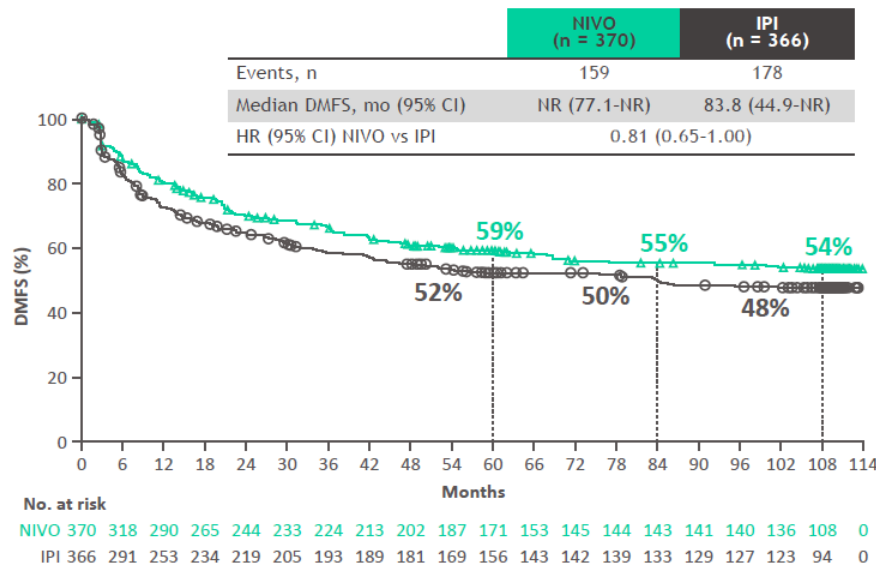
CheckMate 238 study design



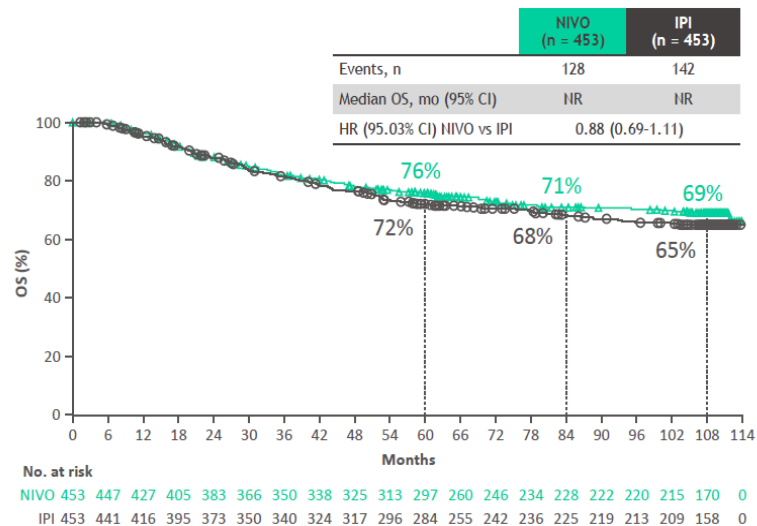
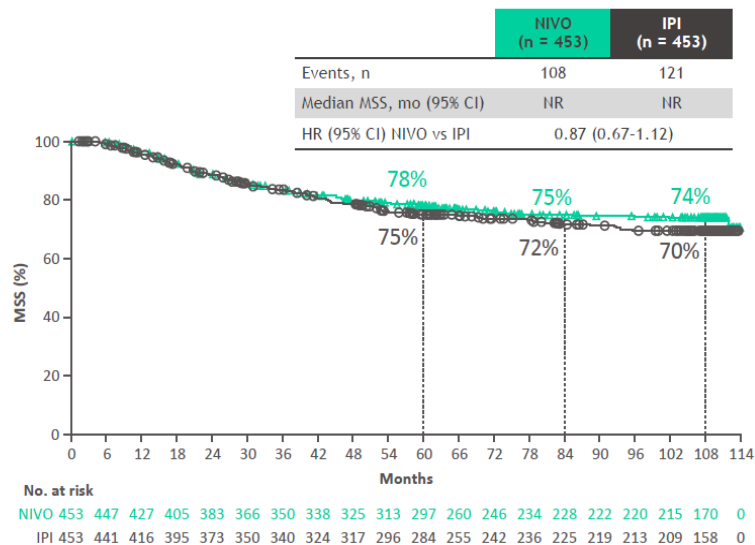
RFS



DMFS



OS

MSS^a

Changing Role of Adjuvant Therapy in Stage III Melanoma

Paul B. Chapman, M.D.,¹ and Jedd D. Wolchok, M.D., Ph.D.¹

The concept of adjuvant therapy for cancer was developed at a time when systemic cancer treatment was limited to cytotoxic chemotherapy that could only be administered intermittently but

rarely resulted in a complete response. Skipper¹ and others hypothesized that if treatment were started early in the disease course, before the tumor was clinically apparent and when the tumor

N ENGL J MED 394:4 NEJM.ORG JANUARY 22, 2026

“Since one third of patients are not going to have a relapse, a strategy of deferring therapy would spare patients from the risk of permanent endocrinopathies (in 10 to 15% of patients) and other, rarer, permanent adverse events or isolated instances of treatment-related death”

6. Longer follow up of RELATIVITY: confirm rela-nivo as a option for 1st line

Study design ASCO 2023.

RELATIVITY-047 is a global, randomized, double-blind, phase 2/3 study

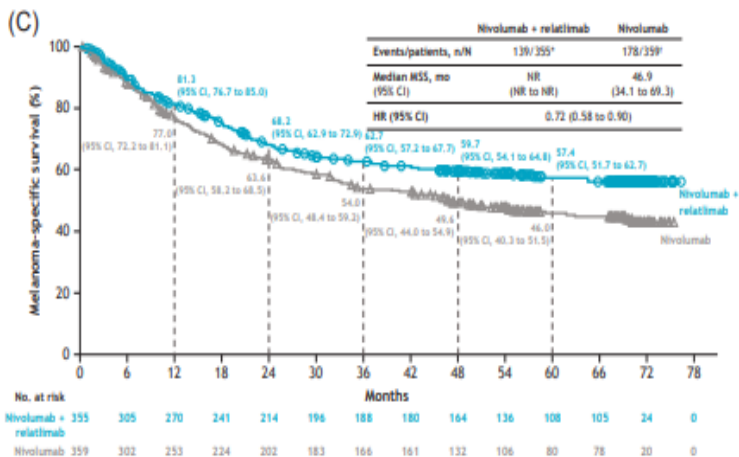
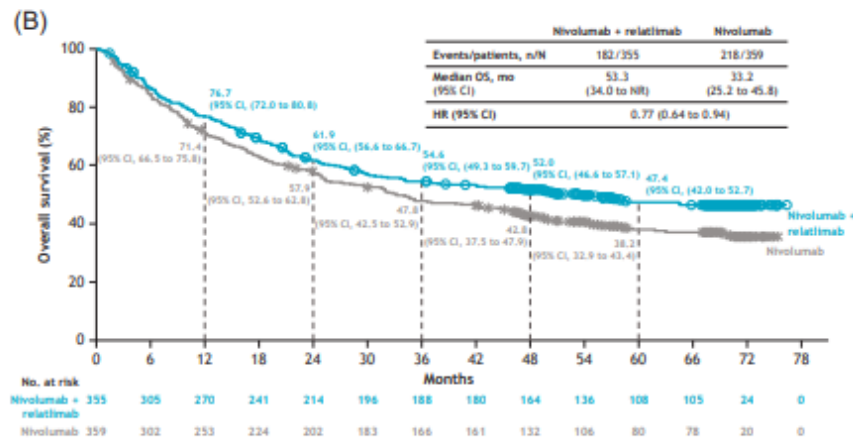
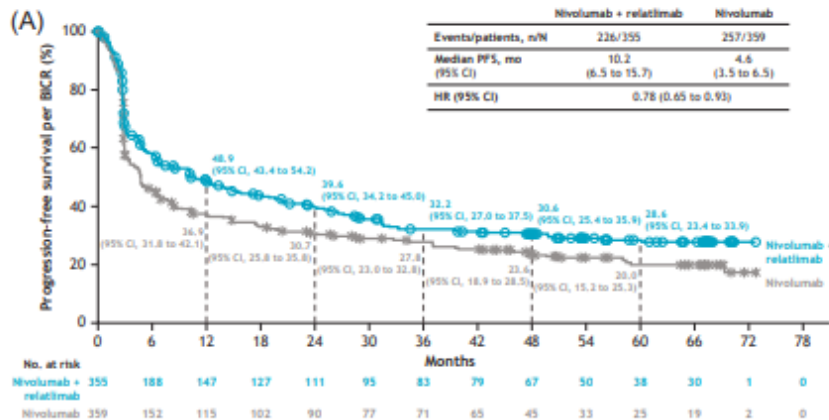
Key eligibility criteria • Previously untreated, unresectable, or metastatic melanoma • ECOG PS 0-1	R	NIVO 480 mg + RELA 160 mg FDC IV Q4W	Primary endpoint • PFS by BICR ^a Secondary endpoints • OS ^b • ORR by BICR ^c
	1:1	NIVO 480 mg IV Q4W	

Stratified by: LAG-3, PD-L1, BRAF, and AJCC v8 M stage
Endpoints were tested in hierarchy: PFS → OS → ORR

Database lock	March 9, 2021	October 28, 2021	October 27, 2022
Min. follow-up/	1.3 months	8.7 months	21.0 months
Median follow-up	13.2 months	19.3 months	25.3 months
Endpoint(s)	PFS per BICR	OS, ORR per BICR, and updated PFS per BICR	Updated PFS per BICR, OS, and ORR per BICR

RELATIVITY-047

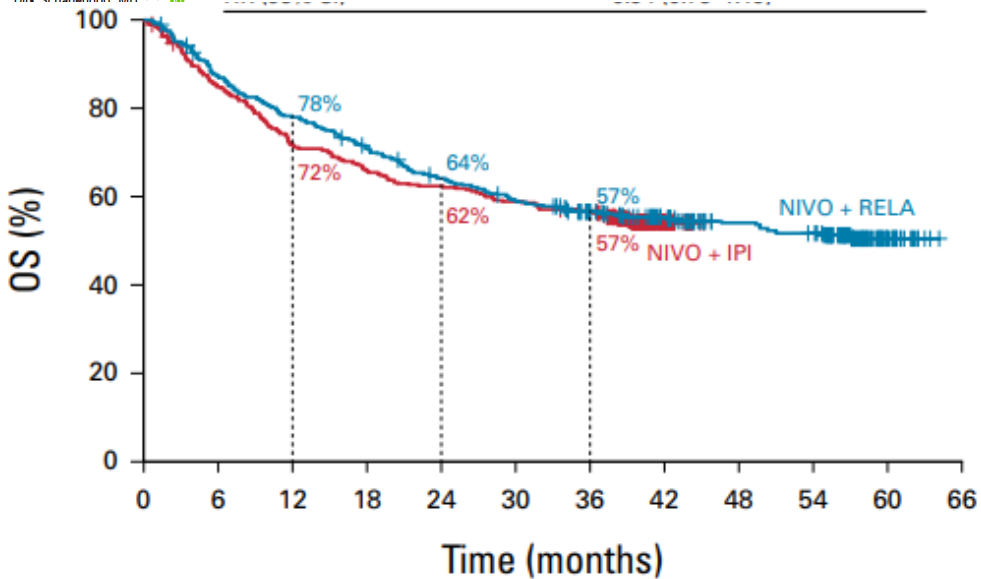
dit.



First-Line Nivolumab Plus Relatlimab Versus Nivolumab Plus Ipilimumab in Advanced Melanoma: An Indirect Treatment Comparison Using RELATIVITY-047 and CheckMate 067 Trial Data

Georgina V. Long, PhD, MBBS¹; Evan J. Lipson, MD²; F. Stephen Hodi, MD³; Paolo A. Ascierto, MD⁴; James Larkin, MD, PhD⁵; Christopher Lao, MD⁶; Jean-Jacques Grob, MD, PhD⁷; Flavia Ejzykowicz, PhD⁸; Andriy Moshyk, MD, MSc⁹; Viviana Garcia-Horton, PhD⁹; Zheng-Yi Zhou, PhD⁹; Yiqiao Xin, PhD, MSc⁹; Jennell Palaia, PharmD, MS⁹; Laura McDonald, PhD, MSc⁹; Sarah Keidel, BM BCh⁹; Anthony Salvatore, PharmD, MBA⁹; Divya Patel, PharmD⁹; Leon A. Sakkal, PharmD⁹; Hussein Tawbi, MD, PhD¹⁰; and Nirik Scharlendorf, MD^{11,12,13}

AE, n (%)	NIVO + RELA (n = 355)		NIVO (n = 359)	
	Any grade	Grade 3-4	Any grade	Grade 3-4
Any AE	352 (99)	161 (45)	344 (96)	139 (39)
TRAE	301 (85)	78 (22)	262 (73)	43 (12)
Leading to discontinuation	61 (17)	34 (10)	31 (9)	14 (4)
Treatment-related deaths ^a	4 (1)		2 (1)	



lo. at risk:

	0	6	12	18	24	30	36	42	48	54	60	66
NIVO + RELA	339	295	263	237	212	195	170	141	111	105	21	0
NIVO + IPI	297	250	211	195	184	174	167	21	0	0	0	0

- NIVO-IPI PREFERRED IN:
1. absence of tumor PD-L1 expression,
 2. presence of brain metastases,
 3. acral or mucosal primaries,
 4. elevated LDH,
 5. and possibly BRAFv600-mutated tumor

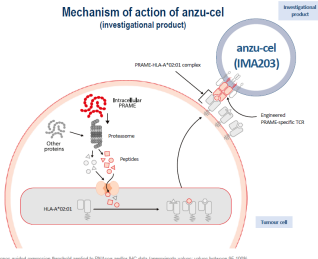
7. Cell therapy with TCR-T: high activity melanoma cutaneous and uveal

Anzu-cel (IMA203): TCR-based Therapy Targeting PRAME

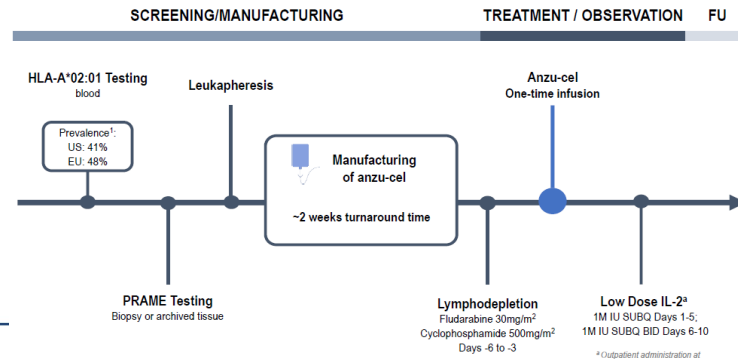
PRAME is expressed in more than 50 cancers

Indication	% PRAME+ Patients*
Cutaneous melanoma	65%
Uterine carcinoma	66%
Uterine carcinosarcoma	65%
Cervical carcinoma	62%
Uveal melanoma	60%
Mucosal melanoma	60%
Ovarian carcinoma (clear cell, endometrioid)	65%
Squamous cell NSCLC	70%
Triple-negative breast carcinoma	65%
Small cell lung cancer	45%
Esophageal small cell carcinoma	45%
Renal papillary cell carcinoma	40%
Cholangiocarcinoma	35%
HER2-enriched breast carcinoma	30%
Adenocarcinoma NSCLC	29%
Head & neck squamous cell carcinoma	25%
Hepatocellular carcinoma	20%
Bladder carcinoma	20%

Mechanism of action of anzu-cel (investigational product)

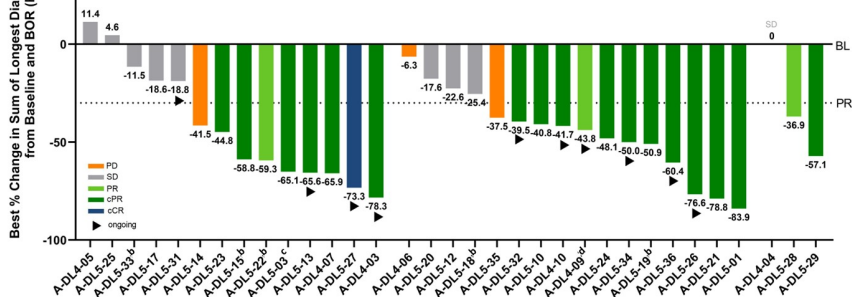


Patient Journey



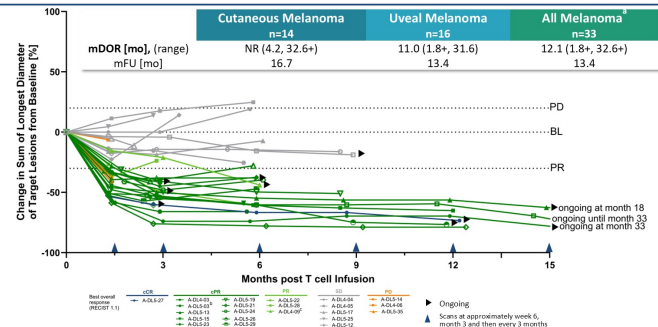
IMA203: Best Overall Response in Melanoma Efficacy Population

	Cutaneous Melanoma n=14	Uveal Melanoma n=16	Melanoma (other) n=3	All Melanoma ^a n=33
cORR	50% (7/14)	67% (10/15)	1/3	56% (18/32)
ORR	57% (8/14)	69% (11/16)	2/3	64 % (21/33)
DCR	93% (13/14)	88% (14/16)	3/3	91% (30/33)



Data cutoff: April 7, 2025.
^a Includes melanoma (other) n=3; mucosal melanoma n=2, melanoma of unknown primary n=1; Melanoma efficacy population excludes 1 uveal melanoma patient with ongoing unconfirmed PR from cORR
^b Maximum change of target lesions and RECIST1.1 response at different timepoints. [†] Patient out of study due to PD (external assessment); [‡] Patient out of study at data-cut (withdrew consent)
 BL, baseline; BOR, best overall response; (c)CR, (confirmed) complete response; (c)JRR, (confirmed) objective response rate; (c)PR, (confirmed) partial response; DCR, disease control rate at week 6; PD, progressive disease; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

IMA203: Duration of Response in Melanoma Efficacy Population



Data cutoff: April 7, 2025.
^a Includes melanoma (other) n=3; mucosal melanoma n=2, melanoma of unknown origin n=1; Patient out of study due to PD (external assessment); [†] Patient out of study at data-cut (withdrew consent)
 BL, baseline; (c)CR, (confirmed) complete response; (c)PR, (confirmed) partial response; mDOR, median duration of response; mFU, median follow-up; PD, progressive disease; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

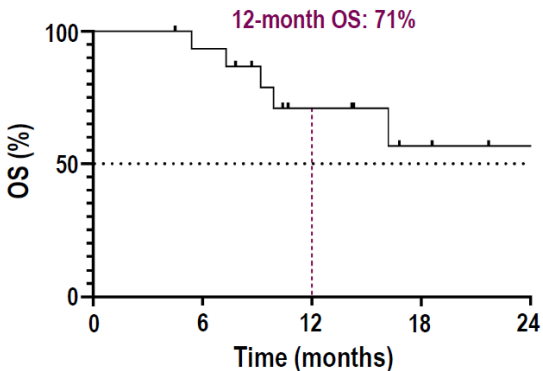
Efficacy and Safety of Anzutresgene Autoleucel (IMA203), a PRAME-directed T-cell Receptor T-cell Therapy, in Patients with Previously Treated Advanced or Metastatic Uveal Melanoma from a Phase 1 Trial

S.P. Patel¹, A.M. Tsimberidou², J.J. Luke³, W. Alsdorf⁴, A. Busse⁵, S.C. DeVane⁶, S. Hengler⁷, N. Hilff⁸, M.A. Kursunel⁹, A. Mayer-Mokler⁷, D. Pankov⁶, C.M. Britten⁷, M. Wermke⁸, L.F. Hernandez-Aya

¹University of Colorado, Aurora, CO; ²University of Texas MD Anderson Center, Houston, TX; ³University of Pittsburgh, Pittsburgh, PA; ⁴University Medical Center Hamburg-Eppendorf, Hamburg, Germany; ⁵Charité University Medicine Berlin, Berlin, Germany; ⁶Inmatics US Inc, Stafford, TX; ⁷Inmatics GmbH, Tübingen, Germany; ⁸University Hospital Dresden, Dresden, Germany; ⁹University of Miami, Miller School of Medicine, Miami, FL

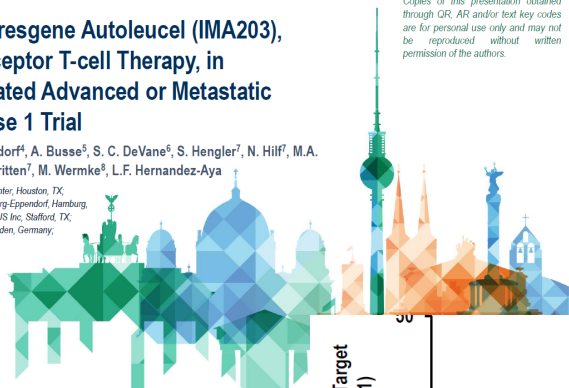
Sapna Patel, MD
 Presidential Symposium III
 Proffered Paper #1600O
 20 October 2025

Median OS: not reached (range: 4.3+, 34.2+)

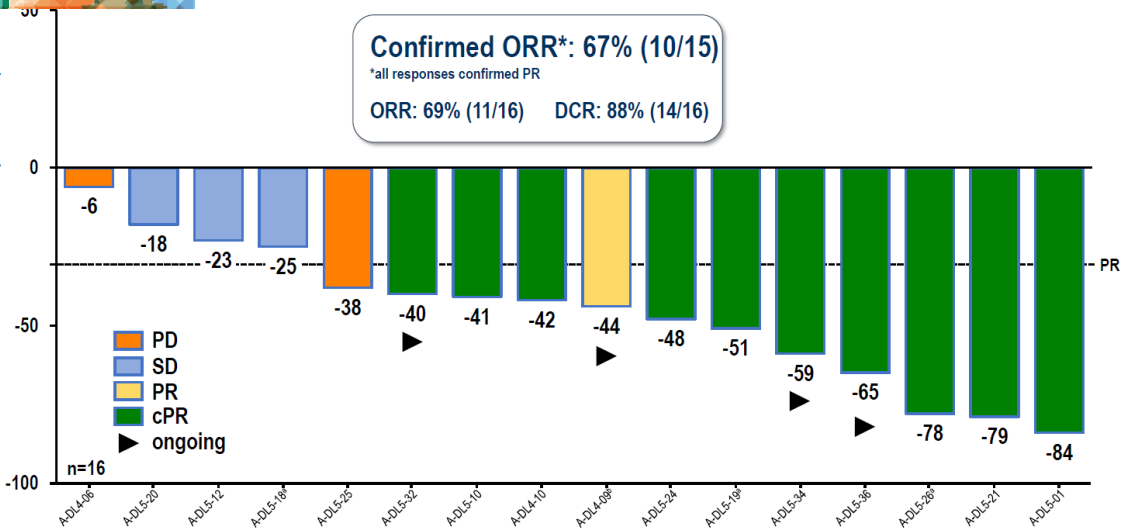


nts at risk	16	14	7	3	1
ts	0	1	4	5	5

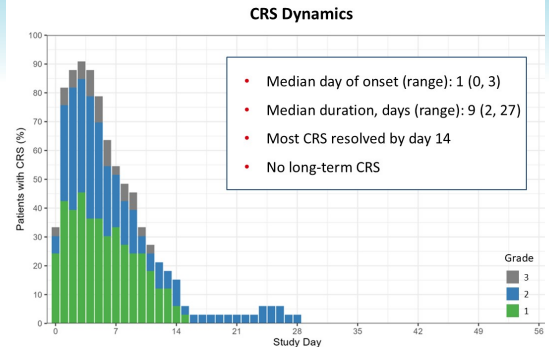
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Best % Change in Sum of Longest Diameter of Target Lesions from Baseline and BOR (RECIST 1.1)



Data cutoff: Sep 24, 2025.
 Uveal melanoma population excludes 1 patient with ongoing unconfirmed PR from cORR. *Maximum change of target lesions and RECIST 1.1 response at different timepoints. *Patient off study at data cutoff date (withdrew consent).
 14/16 patients had liver target lesions with median best change of longest diameter of liver target lesions (range) of -49.6% (-100, 10).
 cPR, (confirmed) partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; PD, objective response rate; DCR, disease control rate at week 6.
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7. TIL activity in uveal melanoma

Phase 2 Trial of TIL Therapy for Metastatic Uveal Melanoma:
Evaluating Cellular Potency and Tumor Transcriptomic
Predictors of Response

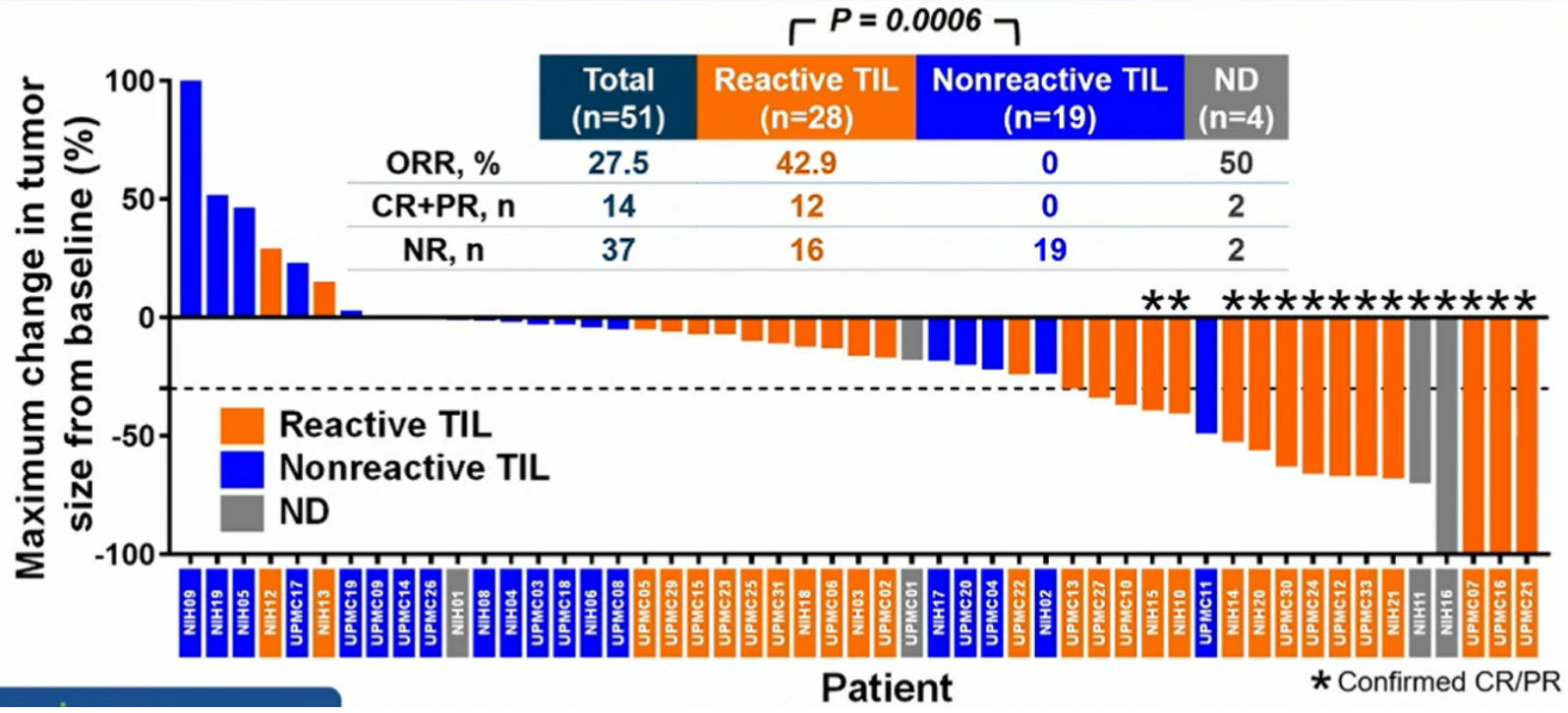
Chaitani Bhaskar^{1*}, Shrawan Leonard-Murali^{1*}, Chanchayam S. Yadav^{1*}, Aqisama Lakkhande^{1*}, Honghao Zhou^{1*},
Aishwari Ganguly^{1*}, Jeevesha A. Taran^{1*}, Dnyanesh Bhargava^{1*}, Laurence Salinas^{1*}, Allyson Wilcox^{1*}, Divyanshu Shrivastava^{1*},
and Udit S. Kulkarni^{1*}

¹UMMC Melanoma Cancer Center, University of Pittsburgh, Pittsburgh, PA, USA; ²Medical Tumor Center, Immunotherapy Program, UPMC Hillman
Cancer Center, University of Pittsburgh, Pittsburgh, PA, USA; ³Division of Surgical Oncology, Department of Surgery, University of Pittsburgh,
Pittsburgh, PA, USA; ⁴Department of Biostatistics, University of Pittsburgh, Pittsburgh, PA, USA; ⁵Department of Surgical Oncology, Department of
Surgery, Allegheny Health Network, Pittsburgh, PA, USA; ⁶Neuroleukia Family, UPMC Hillman Cancer Center, University of Pittsburgh, Pittsburgh,
PA, USA; ⁷Cancer Research Genealogy, UPMC Hillman Cancer Center, University of Pittsburgh, Pittsburgh, PA, USA; ⁸Center for
Molecular and Cellular Pharmacokinetics, University of Pittsburgh, Pittsburgh, PA, USA.

*CB and SLM contributed equally to this work
*Correspondence: CBK_bhaskar@upmc.edu

NCT03467516 & NCT01814046: Pooled Efficacy of TIL Therapy

Infusion of tumor reactive TIL resulted in significantly greater ORR compared to nonreactive TIL



8. DAROVASERTIB in neoadjuvant uveal melanoma

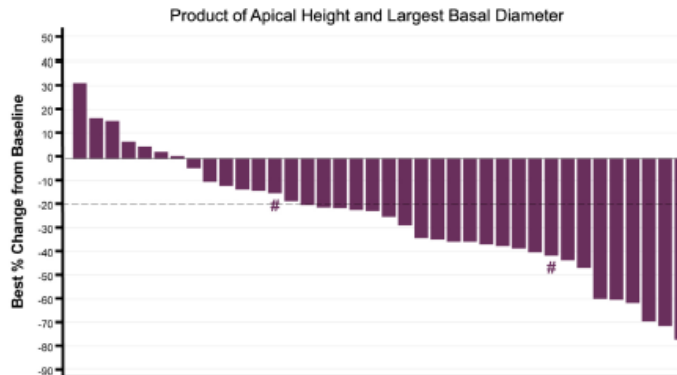
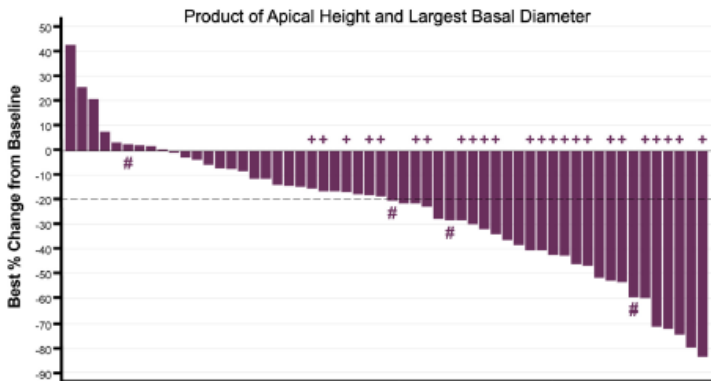
Efficacy

April 2025: FDA breakthrough therapy designation

16020 (OptimUM-09: Phase II Neo-adjuvant Darovasertib*, Enucleation Prevention and Vision Preservation in Primary Uveal Melanoma)

Cohort 1: Enucleation

Cohort 2: Plaque Brachytherapy



	Cohort 1 (N=42)
Eye Preservation Rate, n (%)	24/42 (57.1)**

Reduction in Predicted Risk of Severe Vision Loss at 3 Years Following PB (N =37)*^

Visual Acuity 20/200 or Worse	N=37
Risk Reduction, n (%)	24 (64.9)

Tumor shrinkage in >80%, Eye Preservation and Potential Vision Preservation in a considerable proportion of patients but short term data (e.g. no RFS); registration study ongoing OptimUM-10

Marcus Butler, modified by Marco Donia

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9. CEMIPLIMAB adjuvant squamous cut

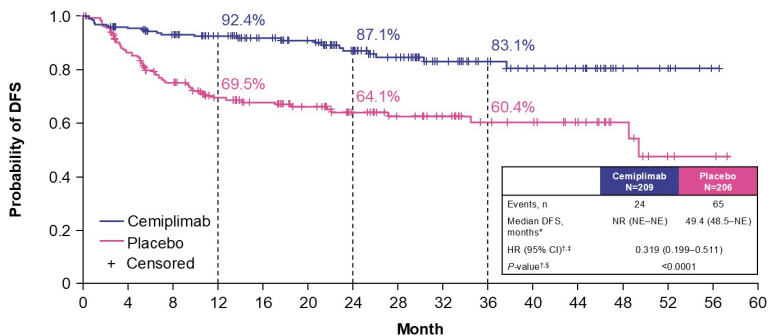
VIII SIMPOSIO NACIONAL de ONCOLOGÍA de PRECISIÓN

2025 ASCO ANNUAL MEETING

Phase 3 trial of adjuvant cemiplimab versus placebo for high-risk cutaneous squamous cell carcinoma (C-POST)

Danny Rischin,¹ Sandro Porceddu,² Fiona Day,³ Daniel P. Brungs,^{4,5} Hayden Christie,⁶ James E. Jackson,⁷ Brian N. Stein,⁸ Yungpo Bernard Su,⁹ Rahul Ladwa,¹⁰ Gerard Adams,¹¹ Samantha E. Bowyer,¹² Zulfiquer Otty,¹³ Naoya Yamazaki,¹⁴ Paolo Bossi,^{15,16} Amarnath Challapalli,¹⁷ Axel Hauschild,¹⁸ Annette L. Lim,¹ Vishal Patel,¹⁹ Joanna Walker,²⁰ Maite De Liz Vassen Schurmann,²¹ Paolo Queirolo,²² Javier Cañete,²³ Flavio Augusto Ferreira da Silva,²⁴ Alexander Stratigos,²⁵ Alexander Guminski,²⁶ Charles Lin,^{27,28} Fernanda Damjan,²⁹ Lukas Flatz,³⁰ Anne E. Taylor,³¹ David R. Cair,³² Samuel Harris,³³ Dmitry Kiribaya,³⁴ Cecilia Queiroz,³⁵ Piotr Butkiewicz,³⁶ Nicole Bassal Segura,³⁷ Nithil K. Khushalani,³⁸ Caroline Robert,³⁹ Haseon Ju,⁴⁰ Camara Joseph,⁴¹ Shikha Bansal,⁴² Christl

Disease-free survival



No. of patients at risk:

	0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60
Cemiplimab	209	172	157	132	116	104	83	66	47	33	27	22	9	6	1	0
Placebo	206	161	130	94	82	69	53	42	36	26	24	18	10	4	2	0

NE, not evaluable; NR, not reached.

[†]Based on Kaplan-Meier method. [‡]Stratified by anatomic region of resected high-risk tumor & geographical region. [§]Based on stratified proportional hazards model. ^{||}Two-sided P-value. Significance threshold set to 0.0045 using the O'Brien Fleming alpha spending function.

2025 ASCO ANNUAL MEETING

#ASCO25

PRESENTED BY: Danny Rischin

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ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER

Phase 3 Randomized Trial (KEYNOTE-630) of Adjuvant Pembrolizumab Versus Placebo for High-Risk Locally Advanced Cutaneous Squamous Cell Carcinoma Following Surgery and Radiation

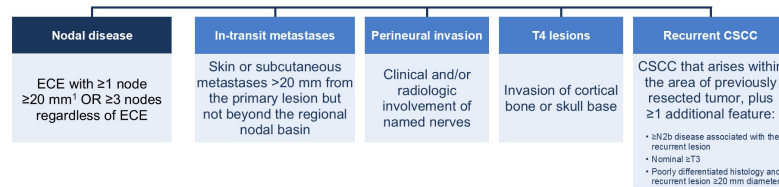
Shilpa A. Koyfman¹, Jenny H. Lee², Laurent Morlier³, Ase Brattand⁴, Noal E. Luna-Romero⁵, Michael Chohan⁶, Marco Dizon⁷, Mahesh Kishore⁸, Jeremy E. H. Long⁹, Dmitry Kiribaya¹⁰, Marcus Morone¹¹, Markus Gilron¹², John Kaszmar¹³, Jennifer Dalmona¹⁴, Angela Zambrano Harvey¹⁵, Cecile Pages-Laurent¹⁶, Juan Shen¹⁷, Janda Yuan¹⁸, Barak Gurunsky¹⁹, Michael Schreiber²⁰

¹University of Colorado, Denver, CO, USA; ²University of Colorado, Denver, CO, USA; ³University of Colorado, Denver, CO, USA; ⁴University of Colorado, Denver, CO, USA; ⁵University of Colorado, Denver, CO, USA; ⁶University of Colorado, Denver, CO, USA; ⁷University of Colorado, Denver, CO, USA; ⁸University of Colorado, Denver, CO, USA; ⁹University of Colorado, Denver, CO, USA; ¹⁰University of Colorado, Denver, CO, USA; ¹¹University of Colorado, Denver, CO, USA; ¹²University of Colorado, Denver, CO, USA; ¹³University of Colorado, Denver, CO, USA; ¹⁴University of Colorado, Denver, CO, USA; ¹⁵University of Colorado, Denver, CO, USA; ¹⁶University of Colorado, Denver, CO, USA; ¹⁷University of Colorado, Denver, CO, USA; ¹⁸University of Colorado, Denver, CO, USA; ¹⁹University of Colorado, Denver, CO, USA; ²⁰University of Colorado, Denver, CO, USA

FDA and EMA approval oct/nov 2025

Methods: High-risk criteria

Nodal and non-nodal high-risk criteria*



*High-risk CSCC with both nodal and non-nodal features was categorized as high-risk nodal disease.

ECE, extracapsular extension

¹ Corroly et al. Proc ASCO 2025; 2025: 225-1045

2025 ASCO ANNUAL MEETING

#ASCO25

PRESENTED BY: Danny Rischin

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ORIGINAL ARTICLE

f X in e W

Adjuvant Cemiplimab or Placebo in High-Risk Cutaneous Squamous-Cell Carcinoma

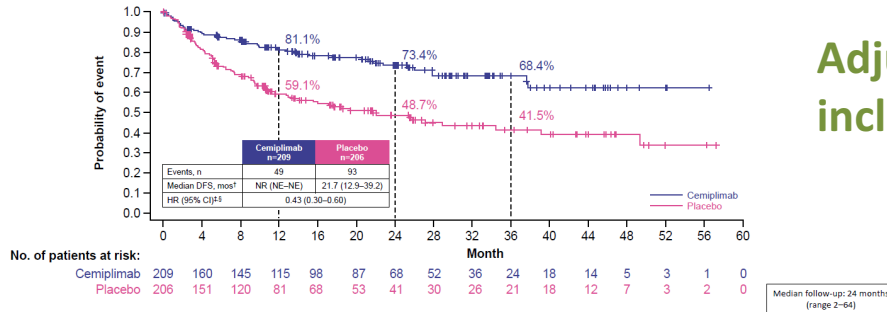
Authors: Danny Rischin, M.D., Sandro Porceddu, M.D., Fiona Day, M.B., B.S., Ph.D., Daniel P. Brungs, M.B., B.S., M.Med., Ph.D., Hayden Christie, M.B., B.S., James E. Jackson, M.B., B.S., Ph.D., Brian N. Stein, M.B., B.S., ³⁹⁹, for the C-POST Trial Investigators[†] Author Info & Affiliations

Published May 31, 2025 | N Engl J Med 2025;393:774-785 | DOI: 10.1056/NEJMoa2502449 | VOL. 393 NO. 8

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C-POST: Analysis including 1st SPT with DFS events

- In a post-hoc analysis in which SPTs were included with DFS events (recurrence + death), efficacy favored cemiplimab (HR 0.43; 95% CI: 0.30–0.60) vs placebo.



^aBased on Kaplan-Meier method. ^bStratified by anatomic region of resected high-risk tumor & geographical region. [†]Based on stratified proportional hazards model. Danny Rischin, M.D. Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.



Adjuvant cemiplimab improves DFS, including first secondary primary tumors (HR 0.43)

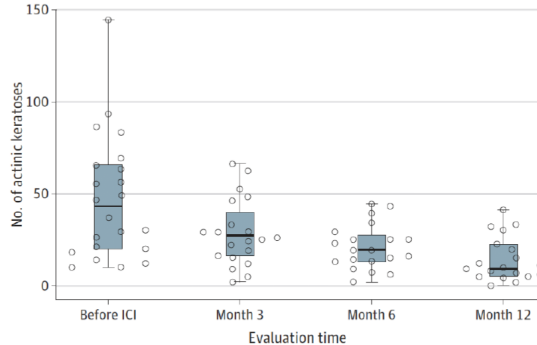
JAMA Dermatology | Original Investigation

Immune Checkpoint Inhibitors in Field Cancerization and Keratinocyte Cancer Prevention

Charlotte Cox, MD, MPHil, MPHTM, BMSt; Susan Brown, BA; Euan Walpole, MBBS(Hons); Edwige Roy, PharmD, PhD; Lea Dousset, MD, PhD; Rahul Ladwa, MBChB, BSc, MPHil; Kiarash Khosrotehrani, MD, PhD

Number of Clinical Actinic Keratoses at Each Time Point After Starting Immune Checkpoint Inhibitor Therapy

Circles represent individual patients; midlines, means; and whiskers, SDs. $aP < .001$, paired t test



JAMA Dermatol. doi:10.1001/jamadermatol.2024.5750
Published online February 12, 2025.

Immune checkpoint inhibitors are associated with a progressive reduction in actinic keratoses

10. Daromun local advanced BCC: 53% pCR, RECIST CR 44%

Danielli et al. J Immunol Immunot 2015

M1a/III non resectable

L19-IL2 and L19-TNF once weekly for up to 4 weeks



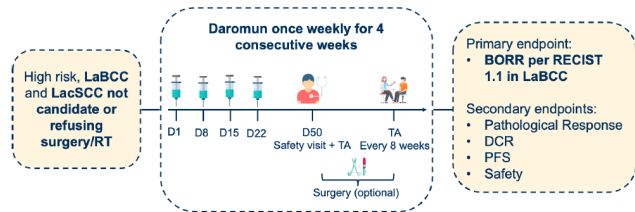
Favorable activity and safety of intralesional L19IL2/L19TNF in high-risk laBCC and lacSCC patients

Flatz L., Cuzzola A., Haldrup S., Rubakov P., Nasal J. C., Lohr U., Kulkarni, Wimal J., Ranaivosoa E., Egner T., Anwar T.



Prof. Lukas Flatz, MD

18 October 2025



STATISTICS:

- LaBCC cohort: initial 12 patients, 59 additional patients in the expanded cohort (SE 57 patients shown)
- LacSCC cohort (exploratory): 21 patients included as exploratory analysis (not shown in this presentation)

Median follow up: 44.14 weeks

Primary endpoint
BORR per RECIST 1.1

	RECIST 1.1	
	N=57	(%)
BORR		57.8
DCR		87.7
CR	25*	43.8
PR	8*	14.0
SD	17*	29.8
PD	4	7.0
Not Evaluable**	3	5.2

*Unconfirmed: CR: 2, PR: 3, SD: 1 (assessed before 6th week from treatment start)

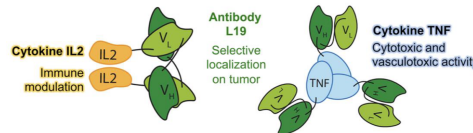
** Not Evaluable: missing assessments

Prof. Lukas Flatz

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Daromun: a combination of two immunocytokines, L19IL2 and L19TNF

L19 recognizes an alternatively spliced fibronectin-in-oncofetal protein preferentially expressed during development and in tumors



Secondary endpoint
Pathological Response

	Pathological Response	
	N=57	(%)
pCR	30	52.6
pPR	3	5.2
pNR	13	22.8
Not Evaluable***	11	19.3

*** Not Evaluable: pathological assessment not performed

- 81% of locally assessed pCR were confirmed by ICR
- Time to CR/PR per RECIST 1.1: 7.14 weeks



10. TVEC neoadjuvant loBCC: 33% pCR, RECIST CR 33%

nature cancer

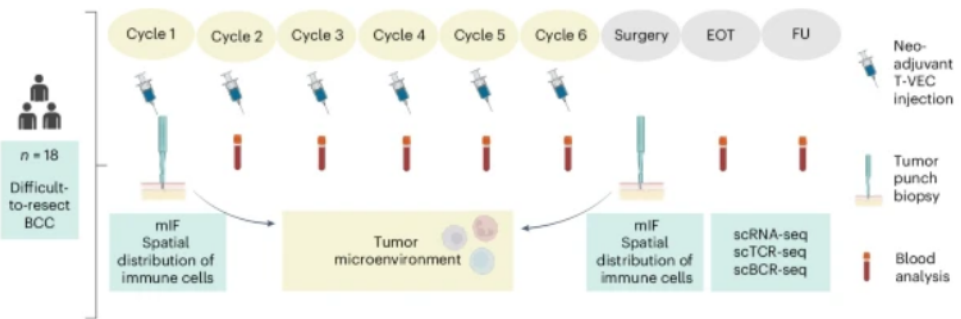
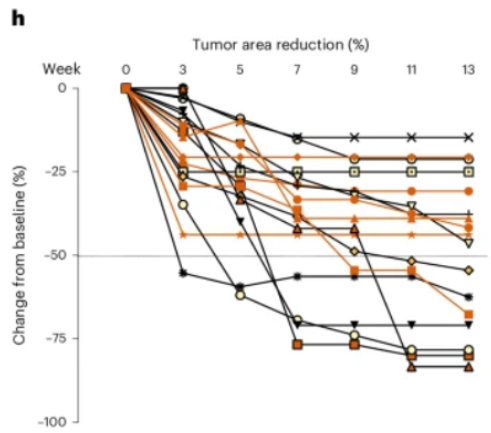
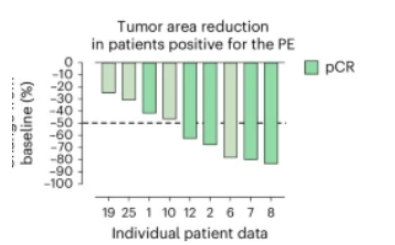
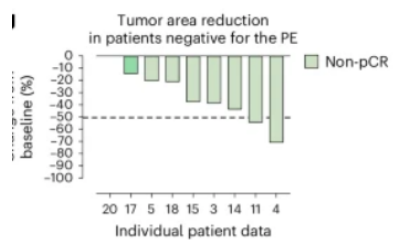
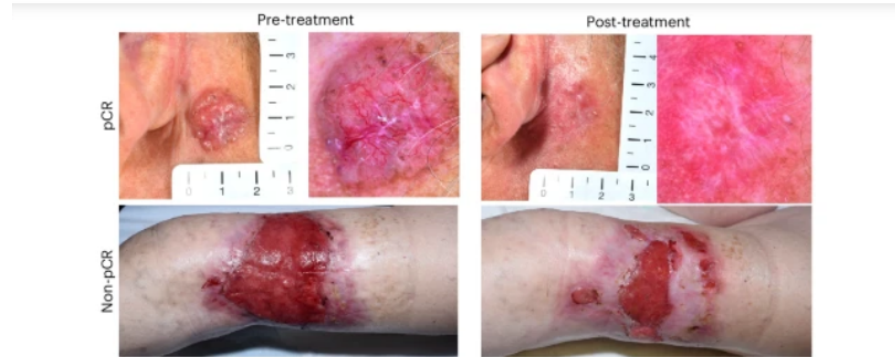


Article <https://doi.org/10.1038/s43018-024-00879-x>

Efficacy and tolerability of neoadjuvant therapy with Talimogene laherparepvec in cutaneous basal cell carcinoma: a phase II trial (NeoBCC trial)

Received: 18 July 2023
 Accepted: 13 November 2024
 Published online: 16 January 2025
[Check for updates](#)

Julia Maria Ressler¹, Maud Plaschka^{1,2}, Rita Silmbrod¹, Victoria Bachmayr¹, Lisa Ellen Shaw¹, Thomas Silly¹, Nina Zila^{1,3}, Andreas Stepan¹, Anna Kusienicka¹, Philipp Tschandl¹, Julia Tittes^{1,4}, Florian Roka¹, Werner Haslik⁴, Peter Petzelbauer^{1,5}, Franz Koenig⁶, Rainer Kunstfeld¹, Matthias Farlik¹, Florian Halbritter², Wolfgang Weninger¹ & Christoph Hoeller¹



10. RP1 intratumoral : melanoma 2nd line

RP1 Combined With Nivolumab in Advanced Anti-PD-1-Failed Melanoma (IGNYTE)

Michael K. Wong, MD, PhD, FRCP¹; Mohammed M. Milhem, MBBS²; Joseph J. Sacco, PhD, MBChB, FRCP^{3,4}; Judith Michels, MD, PhD⁵; Gino K. In, MD, MPH⁶; Eva Muñoz Couso, MD, PhD⁷; Dirk Schadendorf, MD⁸; Georgia M. Beasley, MD⁹; Jiaxin Niu, MD, PhD¹⁰; Bartosz Chmielowski, MD, PhD¹¹; Trisha M. Wise-Draper, MD, PhD¹²; Tawnya Lynn Bowles, MD¹³; Katy K. Tsai, MD¹⁴; Céleste Lebbe, MD, PhD¹⁵; Caroline Gaudy-Marqueste, MD, PhD¹⁶; Mark R. Middleton, PhD, FRCP¹⁷; Aglaia Skolariki, MD¹⁸; Adel Samson, PhD, MBChB¹⁹; Jason A. Chesney, MD, PhD¹⁹; Ari M. VanderWalde, MD²⁰; Yousef Zakharia, MD²¹; Kevin J. Harrington, PhD, MBBS²¹; Elizabeth Appleton, PhD, MBChB²¹; Praveen K. Bommareddy, PhD, MS, BPharm²²; Junhong Zhu, PhD²²;

RP1 is administered intratumorally every 2 weeks

Nivo iv

OR 33%
70% ongoing at 1y

Home > Annals of Surgical Oncology > Article

RP-1 Fires Up Tumors but Fails to Get FDA Approval

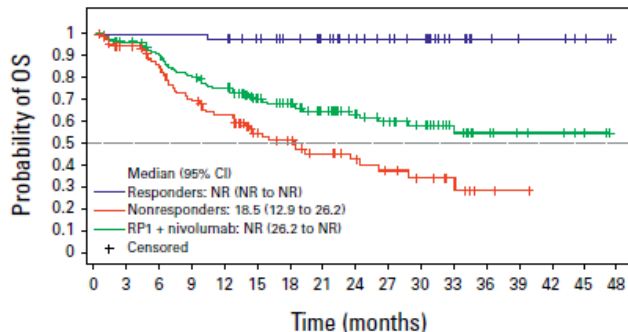
ASO Perspectives | Published: 04 January 2026

(2026) Cite this article

Pendiente de nueva valoración
FDA en 2026

Wong M (C Robert), JCO July 2025

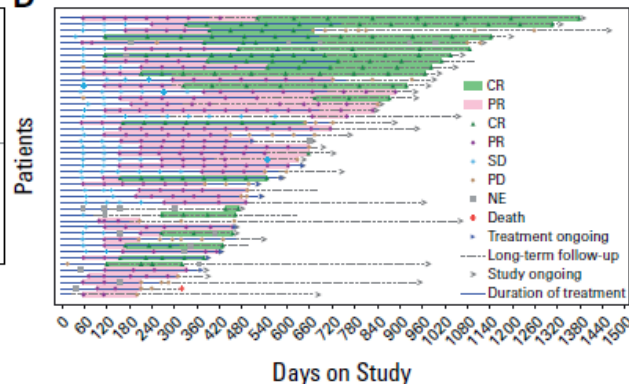
C



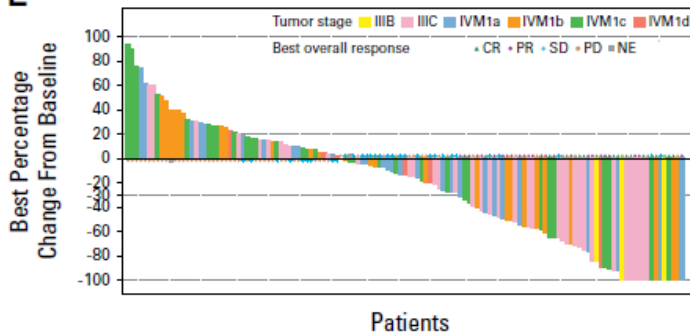
Number at risk:

Responders	46	46	46	46	45	39	35	31	26	23	20	11	7	5	5	3	0
Nonresponders	94	81	70	58	50	34	28	21	17	12	9	6	2	1	0		
RP1 + nivolumab	140	127	116	104	95	73	63	52	43	35	29	17	9	6	5	3	0

D



E

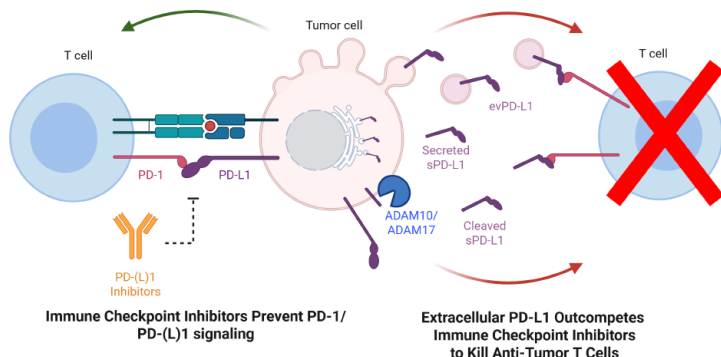
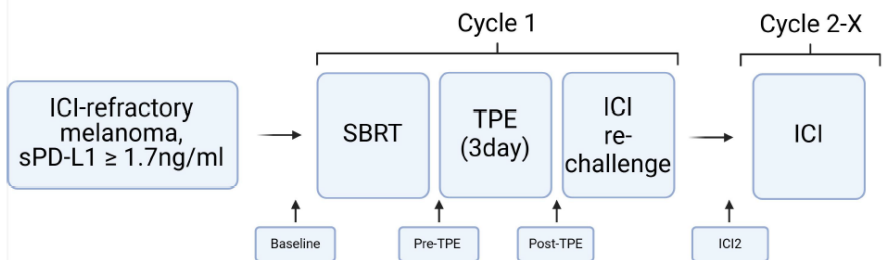


10. Plasma exchange–mediated removal of immunosuppressive factors may help overcome resistance to immunotherapy in melanoma

RO 11/18 (61%) (primary resistant ORR 40%)

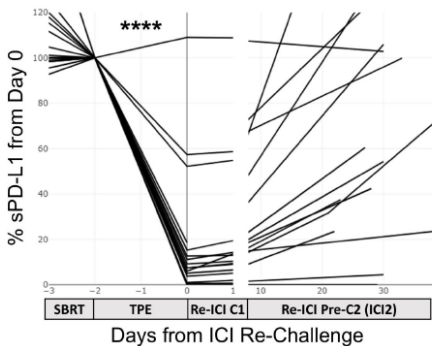
BERLIN 2025 ESMO congress

Rescuing Cancer Immunotherapy with Plasma Exchange in Melanoma

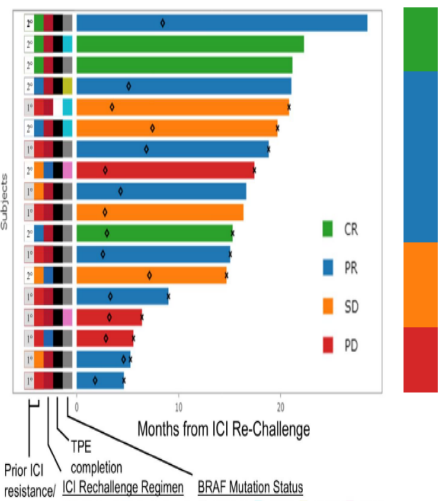
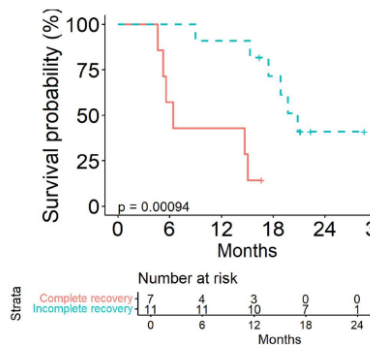


DOCIEM M1

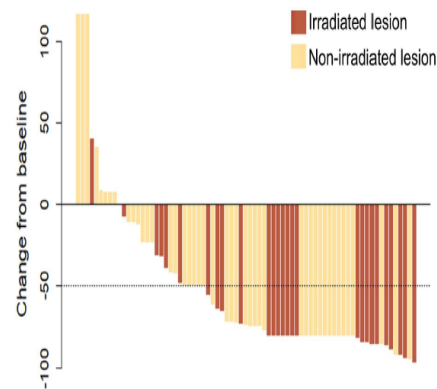
Change in sPD-L1 Level



Overall Survival by sPD-L1 recovery



Maximum SUV response by lesion



10. Pembrolizumab adjuvant MERKEL

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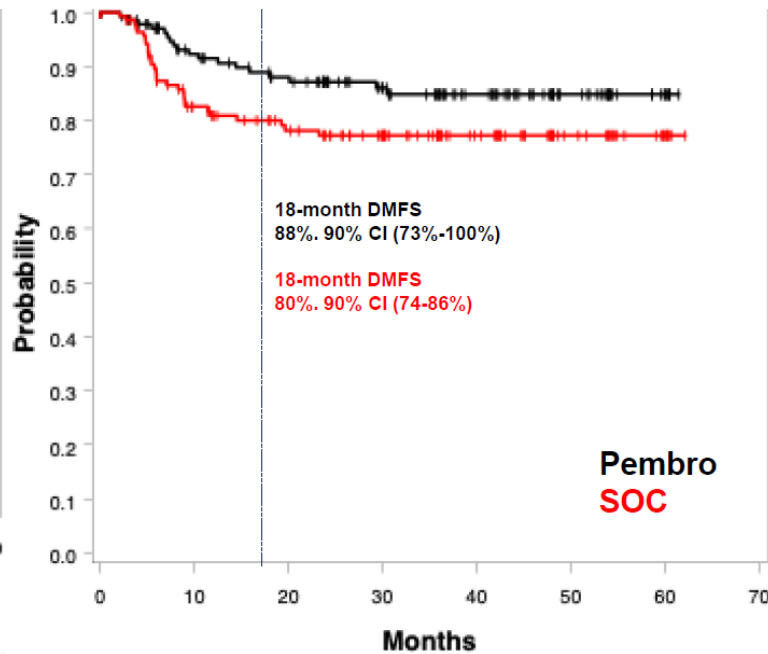
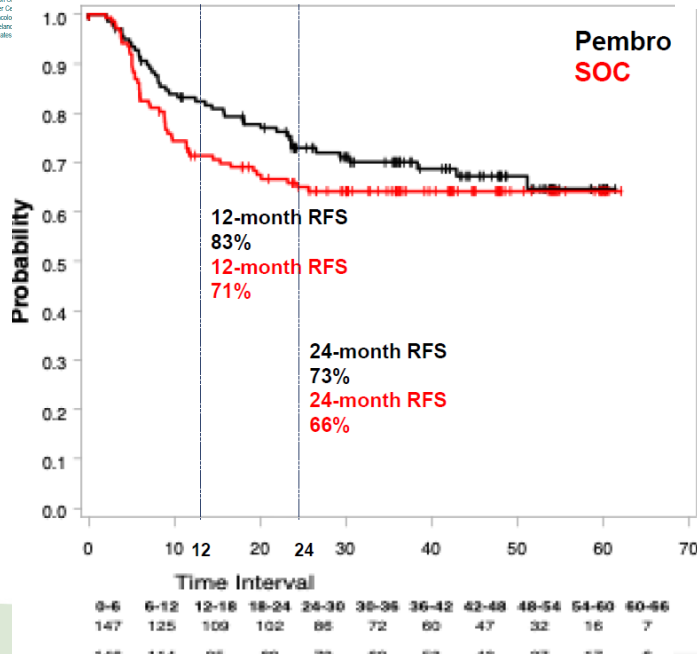
EA6174: STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial

J. M. Mehnert¹, S. Lee², B. Gastman³, C. Hsu⁴, G. Cohen⁵, D. Eichele⁶, P. Funchain⁷, A. Silk⁸, D.M. Miller⁹, E. Wuthrick¹⁰, J. Wolchok¹¹, A. Chakravarthy¹², J. M. Kirkwood¹³

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- EA6174, the first phase III report of adjuvant immunotherapy in Merkel cell carcinoma, demonstrated that pembrolizumab given after surgery resulted in a trend toward improved RFS
- Pembrolizumab resulted in significantly prolonged DMFS
- OS data will be presented at future conferences as well as further subset analysis, and will be important to contextualize these findings for practice
- This is the largest Phase 3 Trial to be conducted in this disease **IN THE WORLD**



Conclusiones

- Adyuvancia escamoso : cemiplimab
- Novedades en cutáneos no melanoma
- Terapia celular
- Tratamiento intratumorales