

Inside the Issue: Optimizing the Management of Nonmelanoma Skin Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, October 3, 2023

5:00 PM – 6:00 PM ET

Faculty

Nikhil I Khushalani, MD

Anna C Pavlick, DO, MBA

Moderator

Neil Love, MD

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



Anna C Pavlick, DO, MBA

Professor of Medicine
Division of Hematology and Medical Oncology
Associate Director for Clinical Research
Weill Cornell Medicine Meyer Cancer Center
Founding Director of the Cutaneous Oncology Program
Weill Cornell Medicine and NewYork-Presbyterian
New York, New York

Commercial Support

This activity is supported by an educational grant from Regeneron Pharmaceuticals Inc.

Dr Love — Disclosures

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

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Faculty

Dr Khushalani — Disclosures

Advisory Committee	Bristol Myers Squibb, Castle Biosciences Incorporated, Genzyme Corporation, Instil Bio, Iovance Biotherapeutics, Merck, Nektar, Novartis, Regeneron Pharmaceuticals Inc, Replimune
Contracted Research	Bristol Myers Squibb, Celgene Corporation, GSK, HUYA Bioscience International, Merck, Modulation Therapeutics, Novartis, Regeneron Pharmaceuticals Inc, Replimune
Data and Safety Monitoring Board/Committee	AstraZeneca Pharmaceuticals LP, Incyte Corporation
Stock Options/Ownership — Public Company	Amarin Corporation, Asensus Surgical, Bellicum Pharmaceuticals Inc
Study Steering Committee	Bristol Myers Squibb, Nektar, Regeneron Pharmaceuticals Inc, Replimune
Travel Remuneration	Regeneron Pharmaceuticals Inc

Faculty

Dr Pavlick — Disclosures

Advisory Committee	Bristol Myers Squibb, Regeneron Pharmaceuticals Inc, Replimune
Consulting Agreements	Bristol Myers Squibb, Merck, Regeneron Pharmaceuticals Inc, Replimune
Contracted Research	Merck, Replimune

Survey Participant

Dr Hamid — Disclosures

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Speakers Bureau	Bristol Myers Squibb, Immunocore, Novartis, Pfizer Inc, Regeneron Pharmaceuticals Inc
Nonrelevant Financial Relationship	Vial

Survey Participant

Dr Lipson — Disclosures

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Contracted Research	Bristol Myers Squibb, Merck, Regeneron Pharmaceuticals Inc, Sanofi

Survey Participant Dr Reddy — Disclosures

No relevant conflicts of interest to disclose.

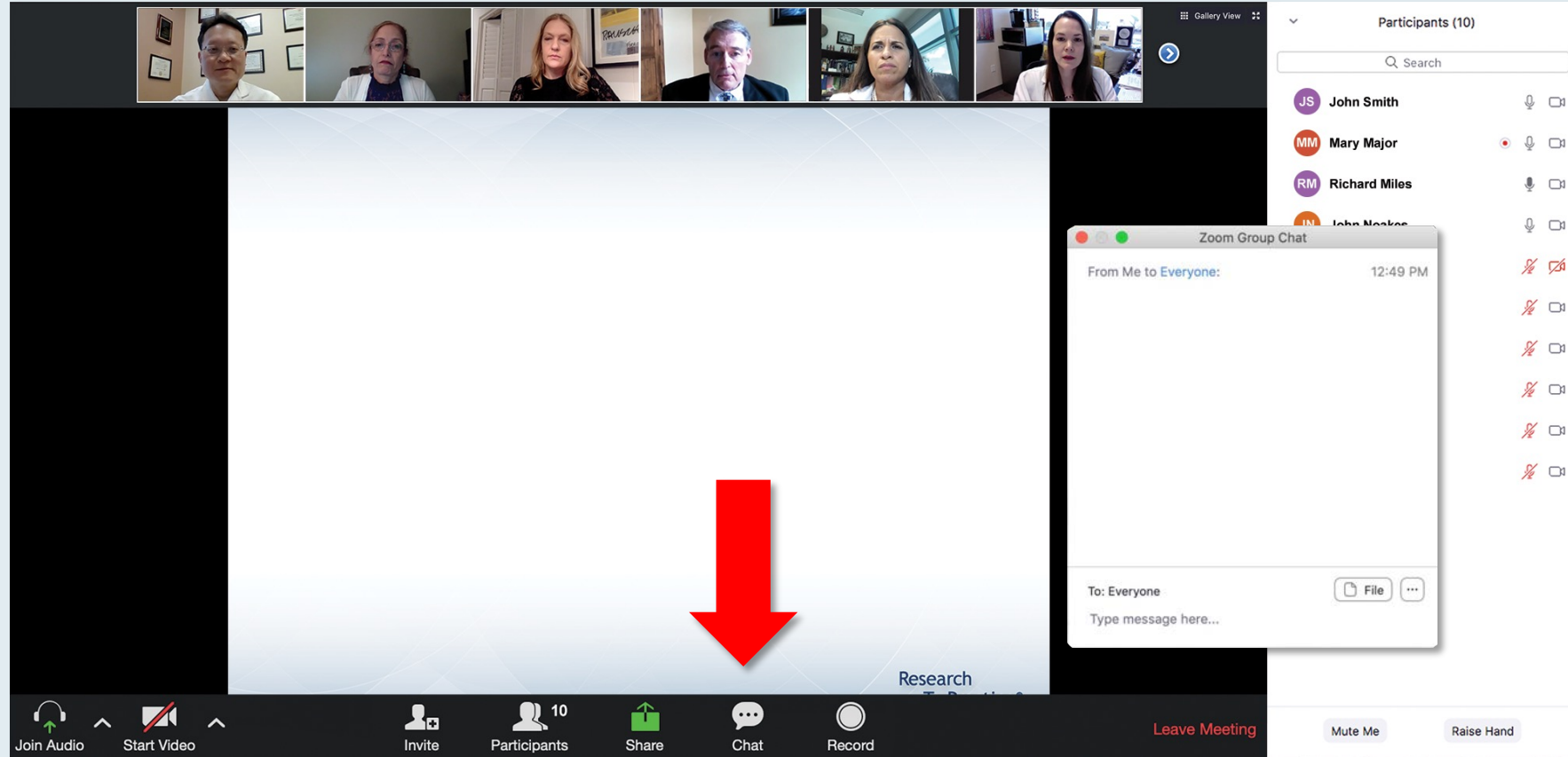
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Dr Weber — Disclosures

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Equity (Options)	Biond Biologics, OncoC4
Patents	Moffitt Cancer Center filed a patent on an ipilimumab biomarker and on TIL preparation that I am named on, and Biodesix filed a PD-1 patent that I was named on
Research Support to Institution	AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, GSK, Merck, Moderna, Novartis, Pfizer Inc
Scientific Advisory Board	Biond Biologics, CytomX Therapeutics, ImCheck Therapeutics, Incyte Corporation, Instil Bio, NexImmune, OncoC4, SELLAS Life Sciences

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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 Participating Faculty" featuring six faculty members:

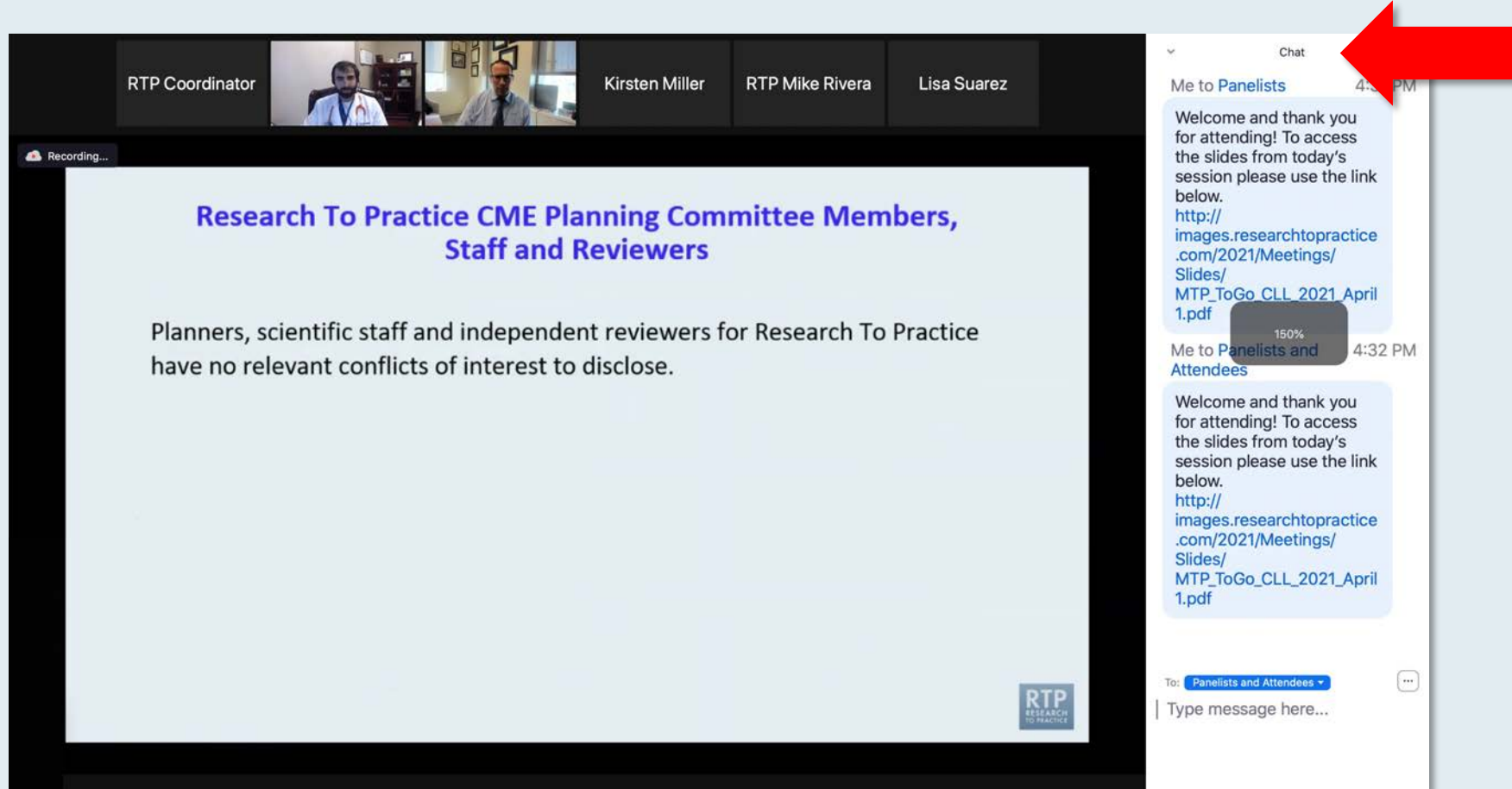
- Nancy L Bartlett, MD**
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- Jonathan W Friedberg, MD, MMSc**
Samuel E Durand Professor of Medicine
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- Carla Casulo, MD**
Associate Professor of Medicine
Division of Hematology/Oncology
Director, Hematology/Oncology Fellowship Program
University of Rochester
Wilmot Cancer Institute
Rochester, New York
- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio
- Christopher R Flowers, MD, MS**
Chair, Professor
Department of Lymphoma/Myeloma
The University of Texas MD Anderson Cancer Center
Houston, Texas
- Brad S Kahl, MD**
Professor of Medicine
Washington University School of Medicine
Director, Lymphoma Program
Siteman Cancer Center
St Louis, Missouri

On the right side of the interface is a chat window. It shows two messages from "Me to Panelists" and "Me to Panelists and Attendees" at 4:31 PM and 4:32 PM respectively. The messages contain a welcome message and a link to a PDF file: http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April1.pdf. At the bottom of the chat window, there is a "To:" dropdown menu set to "Panelists and Attendees" and a text input field labeled "Type message here...". A red arrow points to the white line above the text input field, indicating where to drag to expand the submission 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



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

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys

The screenshot shows a Zoom meeting window. At the top, a row of seven participant video thumbnails is visible. The main content area displays a presentation slide with the following text:

Meet The Professionals
Optimizing the Selection and Timing of Therapy for Patients with Gastrointestinal Cancer
Wednesday, August 25, 2021
5:00 PM – 6:00 PM EST
Faculty
Wells A Messersmith, MD
Moderator
Neil Love, MD

Overlaid on the slide is a "Quick Survey" form with the following options:

- ☐ Certizomib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Certizomib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
- ☐ Elotuzumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Isaxomib + Rd
- Other

A "Submit" button is at the bottom of the survey. To the right of the main content is a "Participants (10)" list showing names and status icons. The bottom toolbar includes icons for Join Audio, Start Video, Invite, Participants, Share, Chat, Record, and a red "Leave Meeting" button.

The screenshot shows a Zoom meeting window. At the top, a row of seven participant video thumbnails is visible. The main content area displays a presentation slide with the following text:

Regulatory and reimbursement issues aside, which treatment would you recommend for a 65-year-old patient with clear cell renal cell carcinoma (ccRCC) if a follow-up 3 years later is found to have asymptomatic (PS 0)?

1. Nivolumab/ipilimumab
2. Avelumab/axitinib
3. Pembrolizumab/axitinib
4. Pembrolizumab/lenvatinib
5. Nivolumab/cabozantinib
6. Tyrosine kinase inhibitor (TKI) monotherapy
7. Anti-PD-1/PD-L1 monotherapy
8. Other

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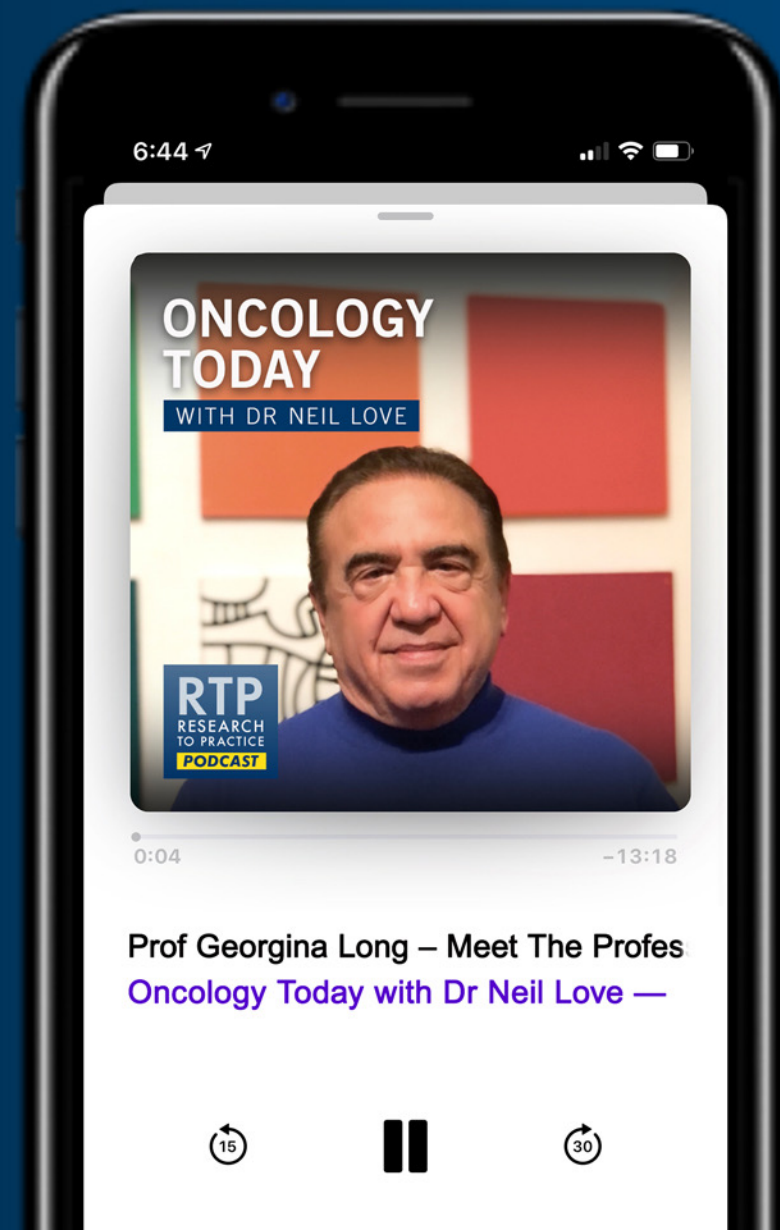
ONCOLOGY TODAY

WITH DR NEIL LOVE

Meet The Professor: Optimizing the Management of Melanoma



PROF GEORGINA LONG
MELANOMA INSTITUTE AUSTRALIA



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Current Approaches and Future Strategies in Oncology

*A Multitumor Educational Symposium in Partnership
with Florida Cancer Specialists & Research Institute*

Saturday, October 7, 2023

ER-Positive Breast Cancer

7:15 AM – 8:15 AM ET

Faculty

**Harold J Burstein, MD, PhD
Komal Jhaveri, MD**

Prostate Cancer

8:15 AM – 9:15 AM ET

Faculty

**Alicia K Morgans, MD, MPH
Matthew R Smith, MD, PhD**

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Non-Small Cell Lung Cancer

9:30 AM – 10:30 AM ET

Faculty

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Heather Wakelee, MD, FASCO

Colorectal and Gastroesophageal Cancers

10:30 AM – 11:30 AM ET

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Chronic Lymphocytic Leukemia

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Saturday, October 14, 2023

Lymphoma

**9:30 AM – 10:30 AM PT
(12:30 PM – 1:30 PM ET)**

Faculty

**Christopher R Flowers, MD, MS
Ann S LaCasce, MD, MMSc**

Urothelial Bladder Cancer and Renal Cell Carcinoma

**10:30 AM – 11:30 AM PT
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Faculty

**Thomas E Hutson, DO, PharmD
Guru P Sonpavde, MD**

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Anthony El-Khoueiry, MD**

Gynecologic Cancers

**1:30 PM – 2:30 PM PT
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Multiple Myeloma

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**Amrita Krishnan, MD
Robert Z Orlowski, MD, PhD**

HER2-Positive and Triple-Negative Breast Cancer

**3:50 PM – 4:50 PM PT
(6:50 PM – 7:50 PM ET)**

Faculty

**Sara A Hurvitz, MD, FACP
Heather McArthur, MD, MPH**

**Moderator
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The Annual National General Medical Oncology Summit

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Educational Conference Developed in Partnership
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MARCH 22-24, 2024

JW Marriott Miami Turnberry Resort and Spa

To Learn More or to Register, Visit
www.ResearchToPractice.com/Meetings/GMO2024

Thank you for joining us!

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

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New York, New York

Survey Participants



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Chief of Research/Immuno-Oncology
Co-Director, Cutaneous Malignancy Program
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Clinical Associate Professor, Medicine – Oncology
Cutaneous Oncology Program in Palo Alto
Stanford University
Stanford Cancer Institute
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Evan J Lipson, MD

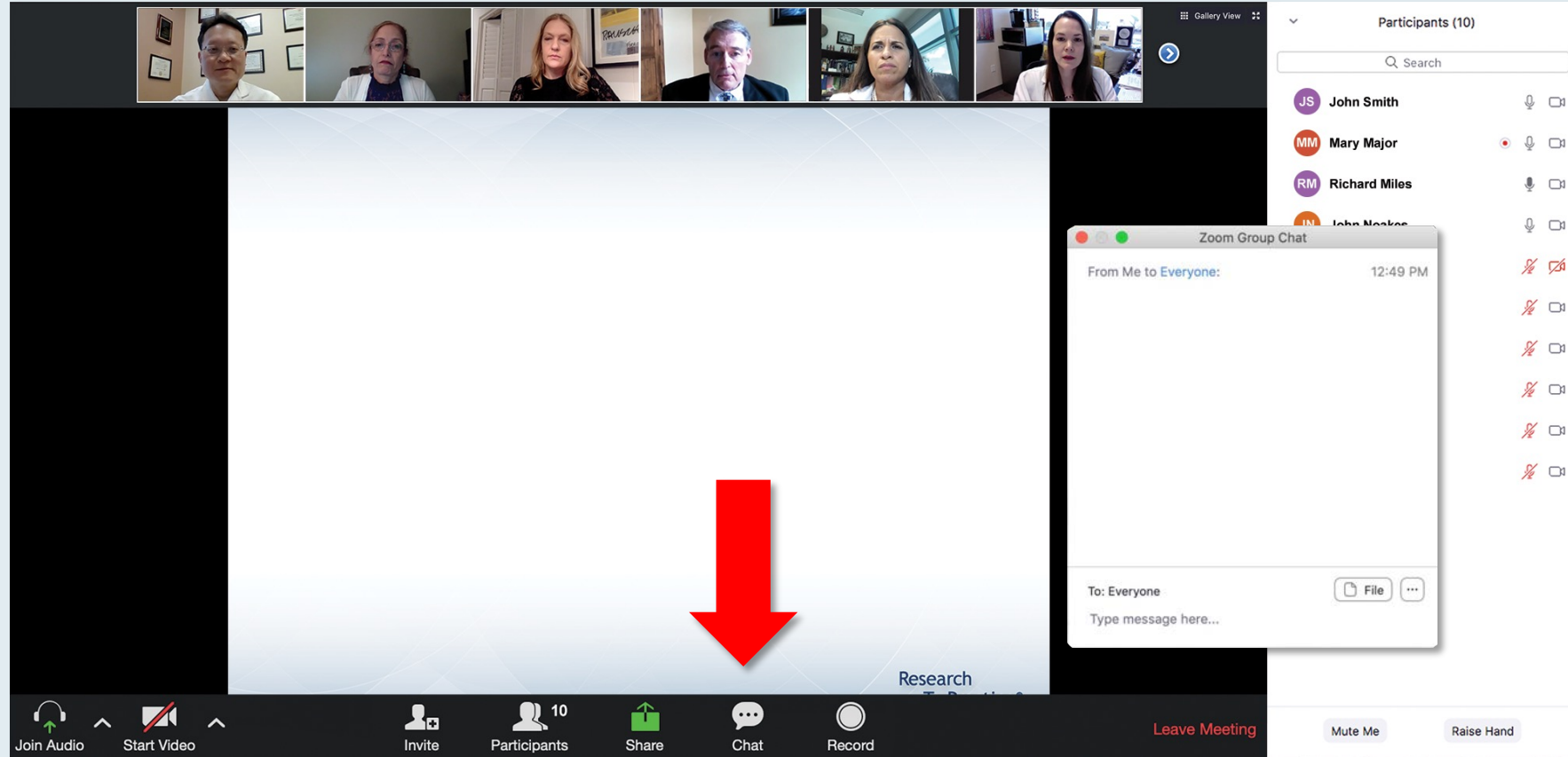
Associate Professor, Medical Oncology
Bloomberg-Kimmel Institute for Cancer
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Jeffrey S Weber, MD, PhD

Deputy Director
Laura and Isaac Perlmutter Cancer Center
(NCI-Funded Comprehensive Cancer Center)
Professor of Medicine
NYU Grossman School of Medicine
New York, New York

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Wednesday, August 25, 2022
5:00 PM – 6:00 PM EST
Faculty
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Moderator
Neil Love, MD
The RTP Research to Practice logo is in the bottom right corner of the slide. A 'Quick Survey' pop-up window is centered over the slide, listing several treatment combinations with radio button options. To the right of the main window is a 'Participants (10)' sidebar showing a list of names with their respective status icons (microphone, video, chat). At the bottom of the Zoom window is a toolbar with icons for 'Join Audio', 'Start Video', 'Invite', 'Participants', 'Share', 'Chat', 'Record', and a 'Leave Meeting' button.

Quick Survey

- ☐ Ceritinib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Ceritinib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
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- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Isaxozim + Rd
- ☐ Other

Participants (10)

- JS John Smith
- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
- JP Jane Perez
- RS Robert Stiles
- JF Juan Fernandez
- AK Ashok Kumar
- JS Jeremy Smith

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Regulatory and reimbursement issues aside, which treatment would you recommend for a 65-year-old patient with clear cell renal cell carcinoma (ccRCC) who has a follow-up 3 years later is found to have asymptomatic (PS 0)?
The slide lists eight options:
1. Nivolumab/ipilimumab
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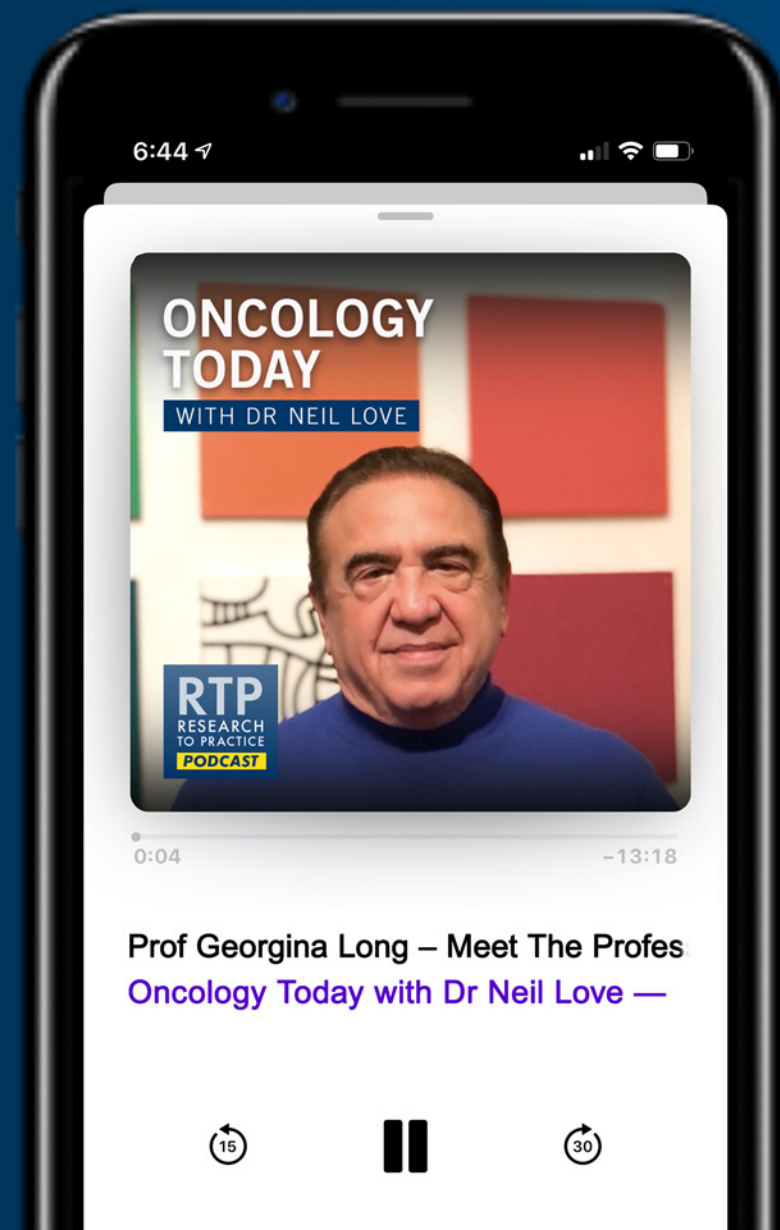
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MELANOMA INSTITUTE AUSTRALIA



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Stock Options/Ownership — Public Company	Amarin Corporation, Asensus Surgical, Bellicum Pharmaceuticals Inc
Study Steering Committee	Bristol Myers Squibb, Nektar, Regeneron Pharmaceuticals Inc, Replimune
Travel Remuneration	Regeneron Pharmaceuticals Inc

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Dr Hamid — Disclosures

Advisory Committee and Consulting Agreements	Alkermes, Amgen Inc, Bactonix, BeiGene Ltd, BioAtla, Bristol Myers Squibb, Eisai Inc, Genentech, a member of the Roche Group, Georgiamune, GigaGen, GSK, Grit Bio, Idera Pharmaceuticals Inc, Immunocore, Incyte Corporation, Instil Bio, IO Biotech, Iovance Biotherapeutics, Janssen Biotech Inc, KSQ Therapeutics, Merck, Moderna, Novartis, Obsidian Therapeutics, Pfizer Inc, Regeneron Pharmaceuticals Inc, Sanofi, Seagen Inc, Tempus, Zelluna Immunotherapy AS
Contracted Research	Akeso Inc, Amgen Inc, Arcus Biosciences, BioAtla, Bristol Myers Squibb, Chinook Therapeutics, CytomX Therapeutics, Exelixis Inc, Genentech, a member of the Roche Group, GSK, Idera Pharmaceuticals Inc, Immunocore, Incyte Corporation, Iovance Biotherapeutics, Merck, Merck Serono, Moderna, NextCure, Novartis, Pfizer Inc, Regeneron Pharmaceuticals Inc, Repertoire Immune Medicines, Seagen Inc, Zelluna Immunotherapy AS
Speakers Bureau	Bristol Myers Squibb, Immunocore, Novartis, Pfizer Inc, Regeneron Pharmaceuticals Inc
Nonrelevant Financial Relationship	Vial

Survey Participant

Dr Lipson — Disclosures

Advisory Committee	Bristol Myers Squibb, Genentech, a member of the Roche Group, Merck
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Contracted Research	Bristol Myers Squibb, Merck, Regeneron Pharmaceuticals Inc, Sanofi

Survey Participant Dr Reddy — Disclosures

No relevant conflicts of interest to disclose.

Survey Participant

Dr Weber — Disclosures

Advisory Board	Bristol Myers Squibb
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Equity (Options)	Biond Biologics, OncoC4
Patents	Moffitt Cancer Center filed a patent on an ipilimumab biomarker and on TIL preparation that I am named on, and Biodesix filed a PD-1 patent that I was named on
Research Support to Institution	AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, GSK, Merck, Moderna, Novartis, Pfizer Inc
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Cutaneous Squamous Cell Carcinoma

Nikhil I. Khushalani, MD

Assistant Center Director, Clinical Research Review and Partnerships
Vice-Chair and Senior Member, Cutaneous Oncology
Moffitt Cancer Center

Department of Cutaneous Oncology



Basal Cell Carcinoma

Anna C. Pavlick, DO, MBA

Weill Cornell Medicine, Professor of Medicine and Dermatology
WCM-Meyer Cancer Center, Associate Director for Clinical Research
WCM-Meyer Cancer Center, Founding Director, Melanoma and Cutaneous Oncology

Key Data Sets

Nikhil I Khushalani, MD

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Key Data Sets

Anna C Pavlick, DO, MBA (continued)

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Key Data Sets

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Agenda

INTRODUCTION: Why did it take so long?

MODULE 1: Cutaneous Squamous Cell Carcinoma – Dr Khushalani

MODULE 2: Basal Cell Carcinoma – Dr Pavlick

MODULE 3: Ongoing Clinical Trials

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How many patients with either basal cell carcinoma (BCC) or cutaneous squamous cell carcinoma (cSCC) are currently in your practice (total)?

1. 0

2. 1

3. 2

4. 3

5. 4

6. 5-10

7. 11-20

8. More than 20

How many patients with either BCC or cSCC to whom you've administered an anti-PD-1/PD-L1 antibody have not required additional treatment for 3 or more years?

1. 0

2. 1

3. 2

4. 3

5. 4

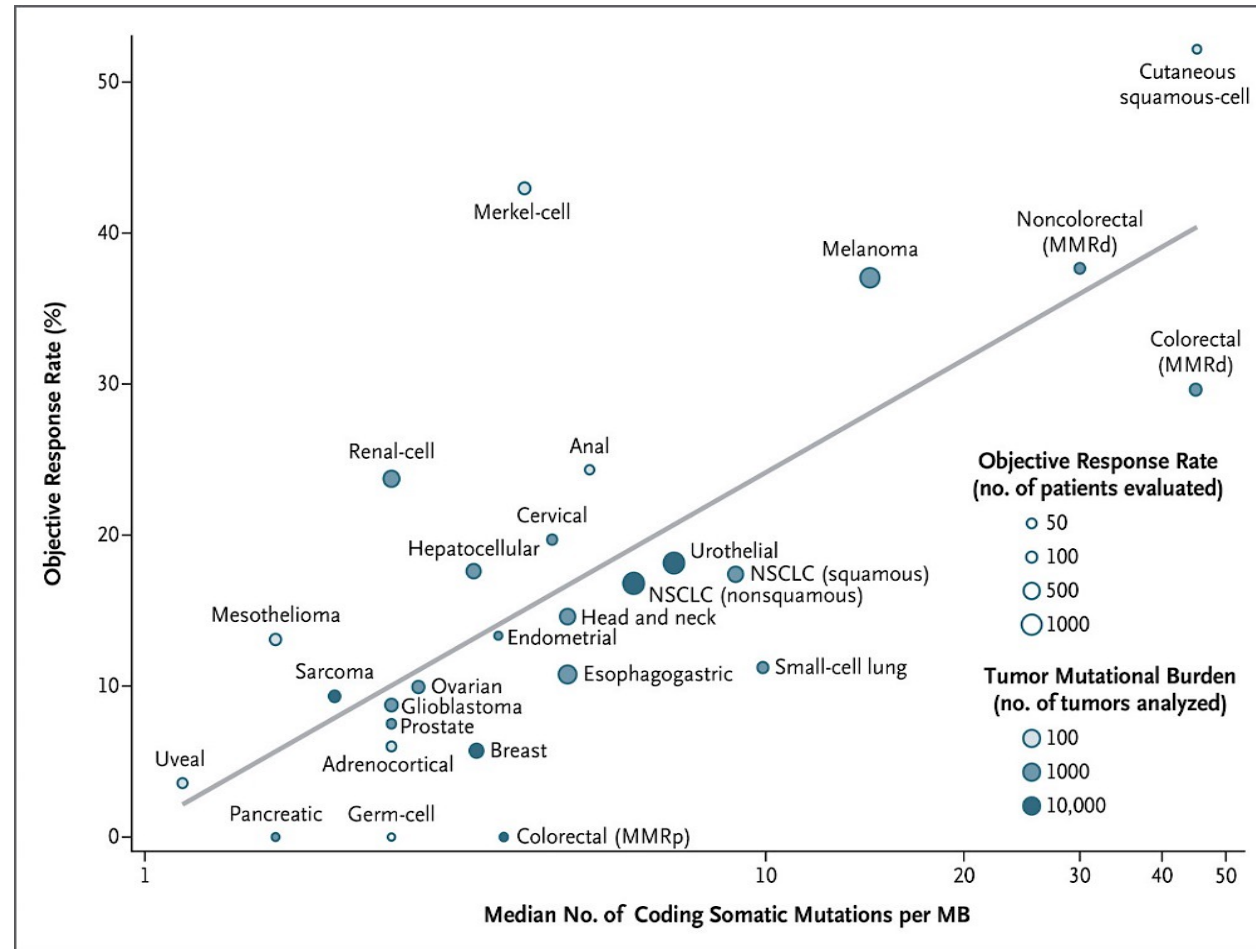
6. 5-10

7. 11-20

8. More than 20

9. I have not used an anti-PD-1/PD-L1 antibody for a patient with BCC or cSCC

TMB and Response to anti-PD1 Therapy



Yarchoan M. N Engl J Med. 2017;377:2500.

Immunosuppression and Skin Cancer

	BCC	CSCC	Melanoma	MCC	KS
Transplant	10	65-250	2-5	5-50	80-500
CLL	8*	8*	2-4	-	-
HIV	2	5	1	2-10	100,000

- Skin is the most common site of malignancy post solid organ transplant
- Incidence rate: 1437/100,000 person-years
 - CSCC: 812/100,000 person-years
 - Male, white race, increased age and thoracic organ transplant conferred higher risk

Garrett, Blanc, et al. *JAMA Dermatol* 2017;153:296; Collins, Quinn, et al. *Dermatol Clin.* 2019;37-83

Agenda

INTRODUCTION: Why did it take so long?

MODULE 1: Cutaneous Squamous Cell Carcinoma – Dr Khushalani

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Cemiplimab: EMPOWER Study

Phase 1 (n = 26): adult patients with locally advanced or metastatic cSCC who are not candidates for surgery

Phase 2 (n = 59): cSCC with distant or regional metastases

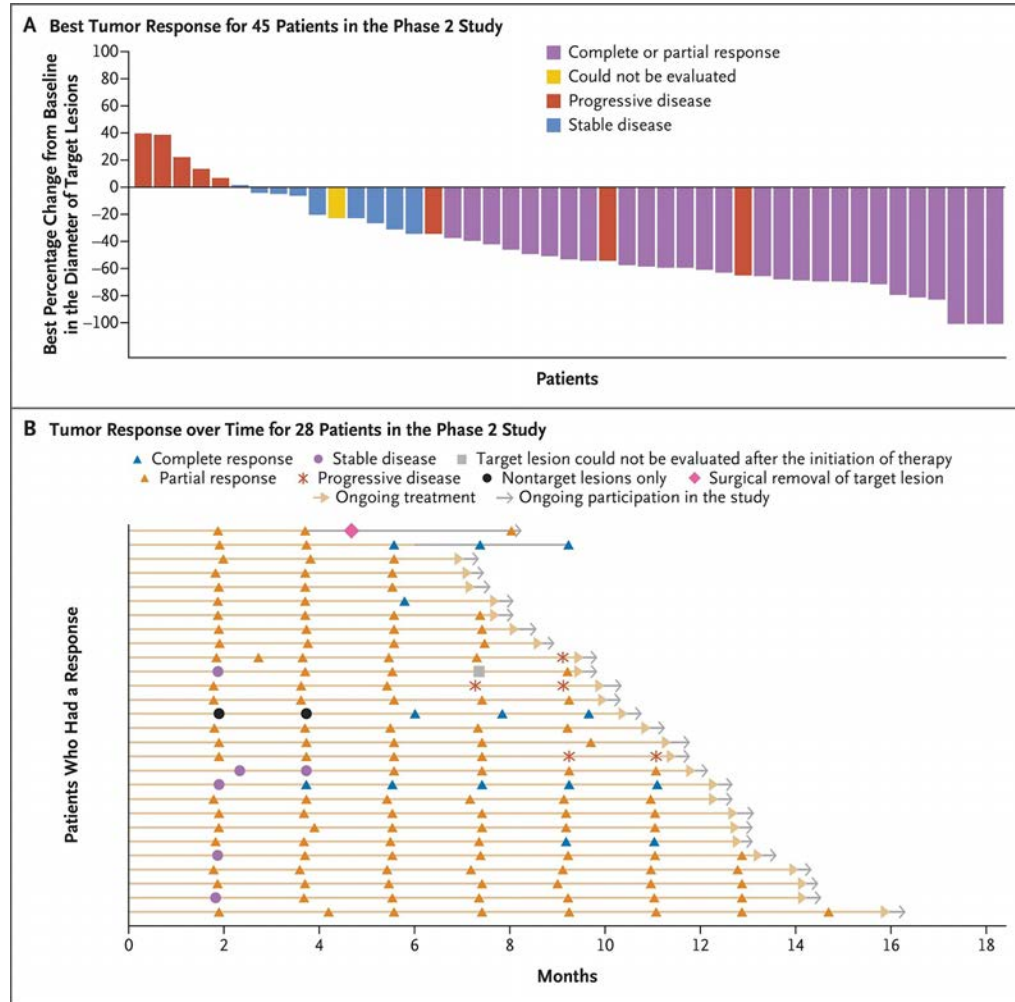
IV cemiplimab
(3 mg/kg of body weight)
Q2W for up to 48 weeks
(phase 1) or up to 96
weeks (phase 2)

Inclusion criteria: ECOG of 0 or 1, adequate organ function, at least 1 lesion that could be measured (RECIST 1.1)

Exclusion criteria: Ongoing or recent autoimmune disease treated with systemic immunosuppressive therapy, previous treatment with anti-PD-1 or PD-L1 therapy, solid organ transplantation, concurrent cancer

Migden MR, et al. N Engl J Med. 2018;379:341

EMPOWER: Summary of Results



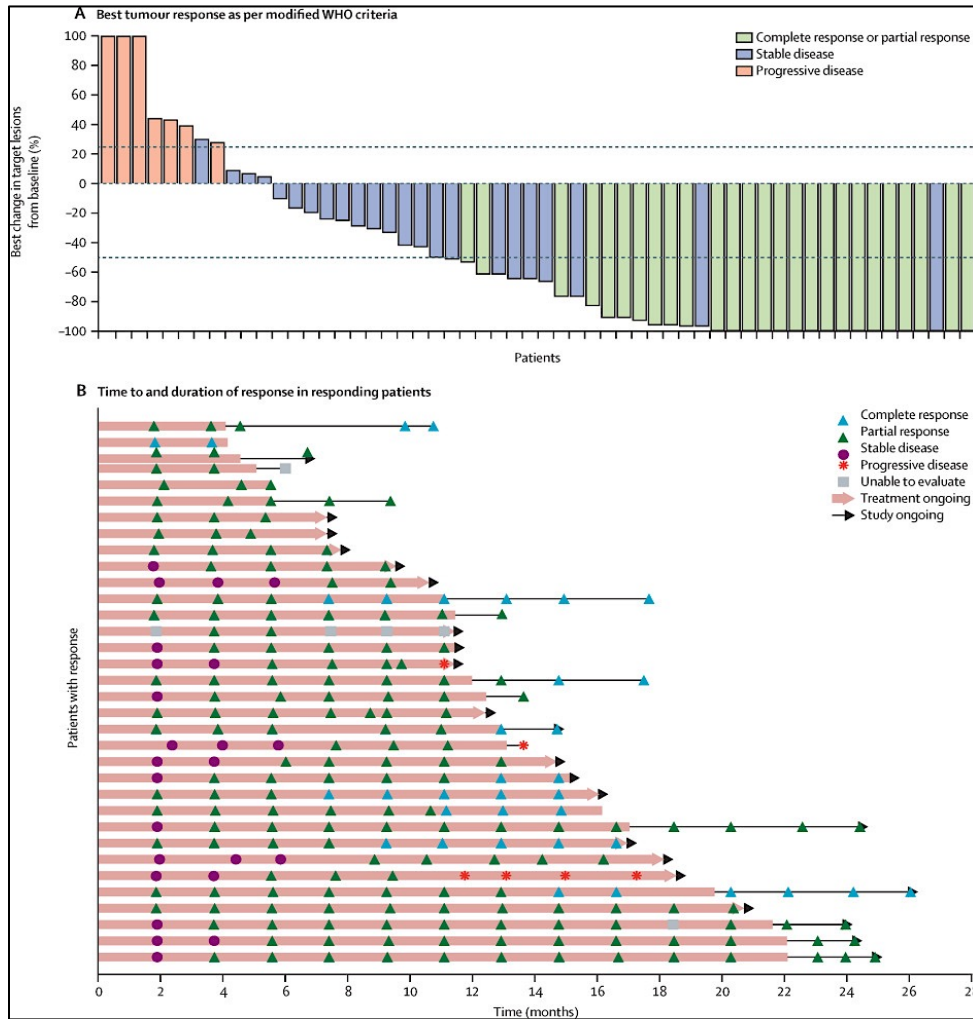
Migden MR, et al. N Engl J Med. 2018;379:341

Results:

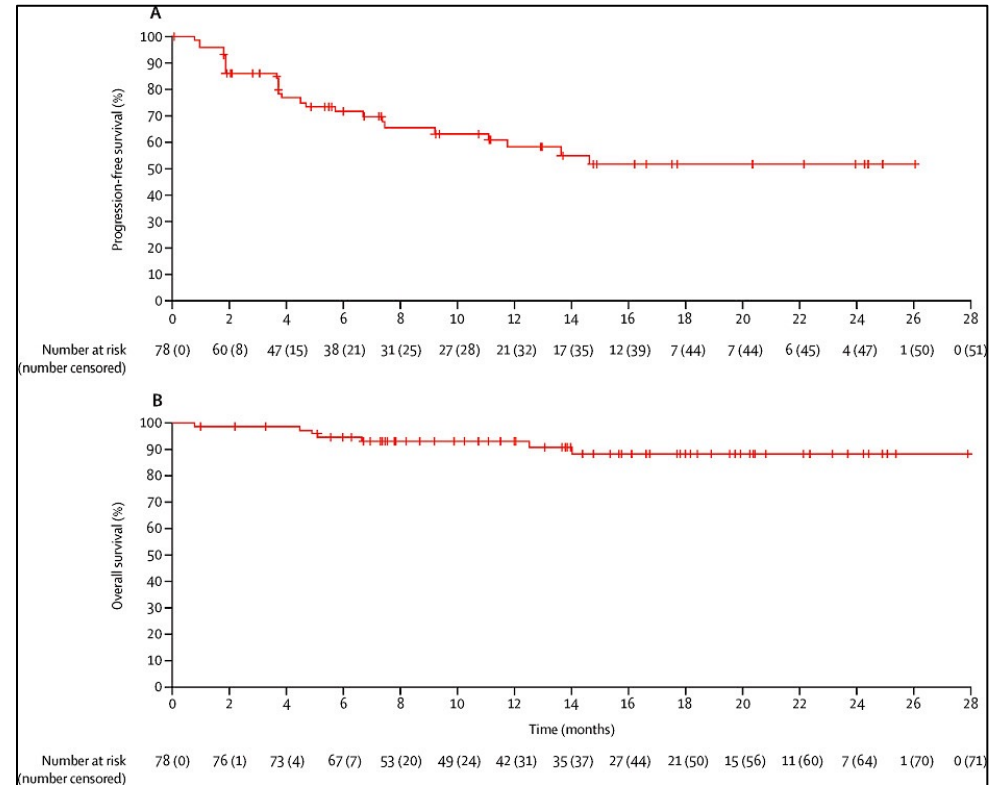
➤ Response Rate

- 50% in phase 1 study
- 47% in phase 2 study
- Duration of response exceeded 6 months in 57% of patients with a response
- 82% of patients with a response continued to have a response at the time of data cutoff

EMPOWER: Locally Advanced Cohort



Migden MR, Khushalani NI, et. al Lancet Oncol 2020;21:294



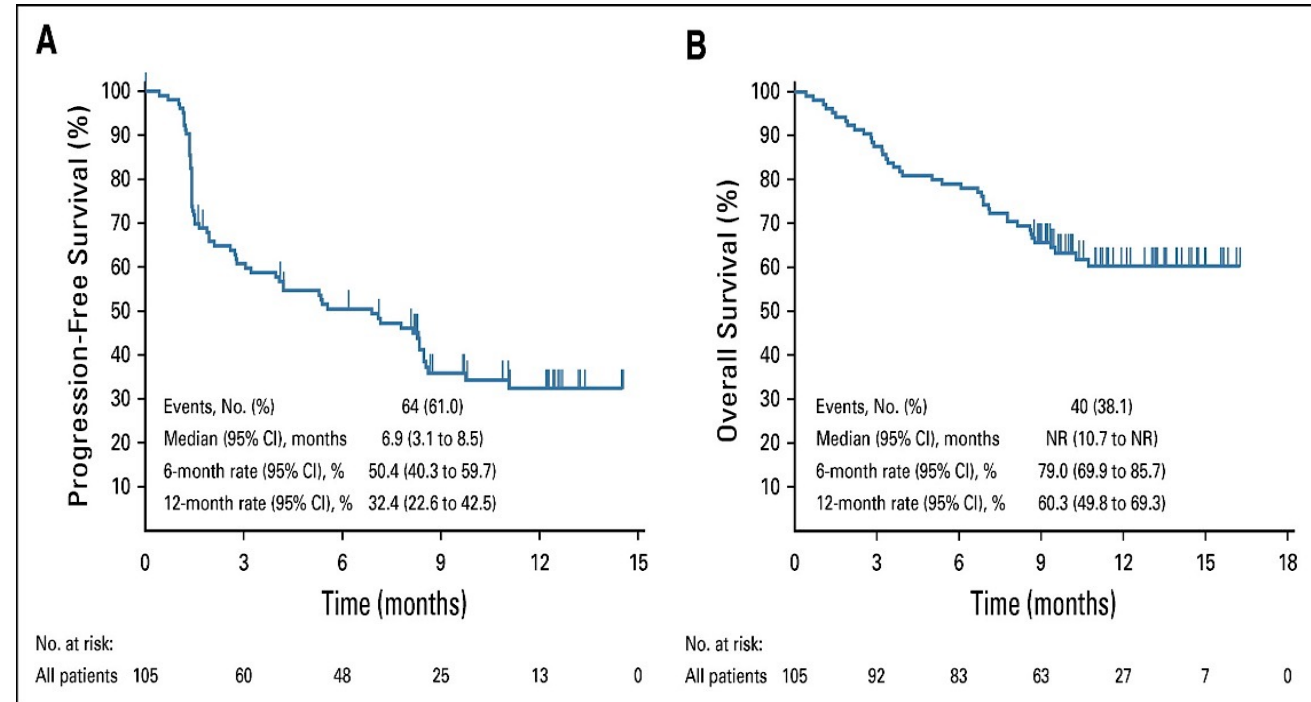
N=78; ORR **44%** (13% CR)

G3/4 treatment emergent
adverse events: 44%

KEYNOTE-629

Pembrolizumab for Advanced CSCC

Endpoint	Patients (N = 105)
Median follow up	11.4 (0.4-16.3) months
Objective RR	34.3%
Best overall response	
• CR	3.8%
• PR	30.5%
• SD	29.5%
• Progressive disease	26.7%
• Not evaluable	1.9%
Disease control (CR+PR+SD)	52.4%
SD ≥12 weeks	18.1%
Median time to response	1.5 months
Median DoR	NR
Estimated 12-month PFS/OS	32.4%/60.3%



Grob. J Clin Oncol 2020;38:2916

CARSKIN

Pembrolizumab for Advanced CSCC

- Phase II; chemotherapy-naïve, unresectable, LA or metastatic cSCC
 - Median age: 79 years
- PEMBRO: 200 mg every 3 weeks
- Primary endpoint: ORR at 15 weeks
- Secondary endpoints: DoR, OS, PFS
- Expanded cohort (N = 57) for analysis of response by PD-L1 status

Maubec. J Clin Oncol. 2020;38:3051

Endpoint	Patients (n = 39)
Objective RR	41% (26-58)
Best overall response <ul style="list-style-type: none"> • CR • PR 	8 8
At median follow up of 22.4 months: <ul style="list-style-type: none"> • PFS • DoR • OS 	6.7 months NR 25.3 months
Objective RR by PD-L1 status <ul style="list-style-type: none"> • Overall • TPS ≥1 • TPS <1 	N = 57 42% 55% 17%

Response to Pembrolizumab



Pretreatment

Day 15

Image Courtesy: Khushalani NI

Response to Pembrolizumab



Left Image Courtesy: Khushalani NI
Grob. J Clin Oncol 2020;38:2916



Phase II Neoadjuvant Study (CSCC)

Primary endpoint:

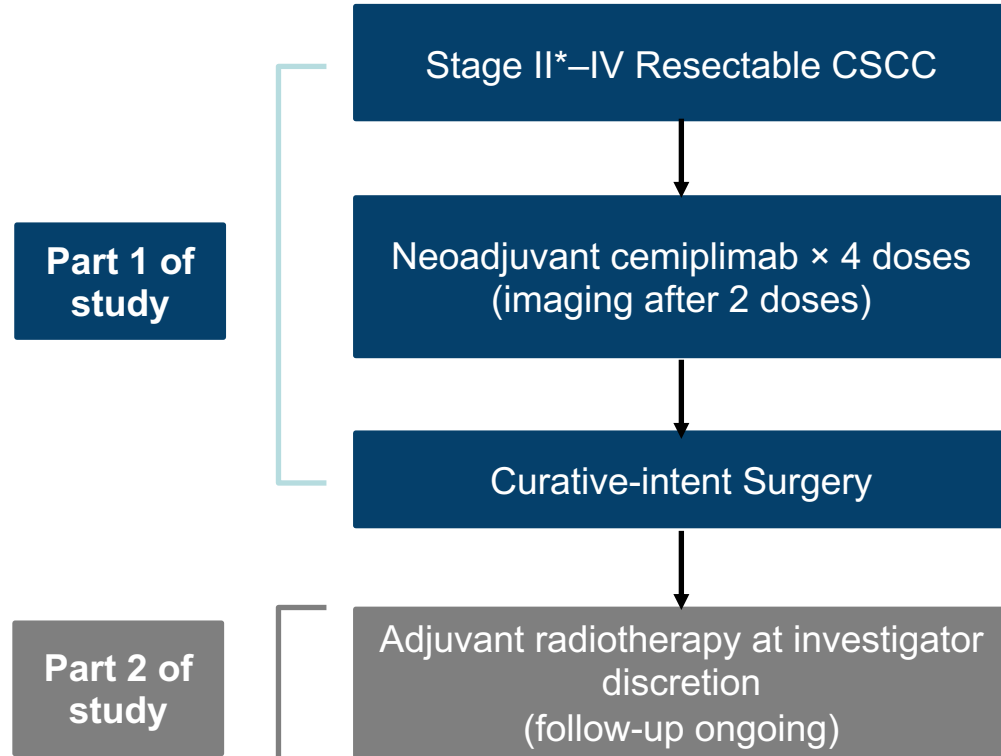
- **pCR** (0% viable tumor) rate per ICPR
 - null hypothesis: pCR rate = 25%

Secondary endpoints:

- **MPR** (>0% but ≤10% viable tumor) rate per ICPR
- **pCR** and **MPR** rates per local pathology review
- **Radiological ORR** per RECIST 1.1
- **Safety** and **tolerability**

Correlative analyses:

- Exploration of TMB and PD-L1 expression with treatment response



*Stage II required to have primary tumor ≥3 cm in an aesthetically-sensitive region.

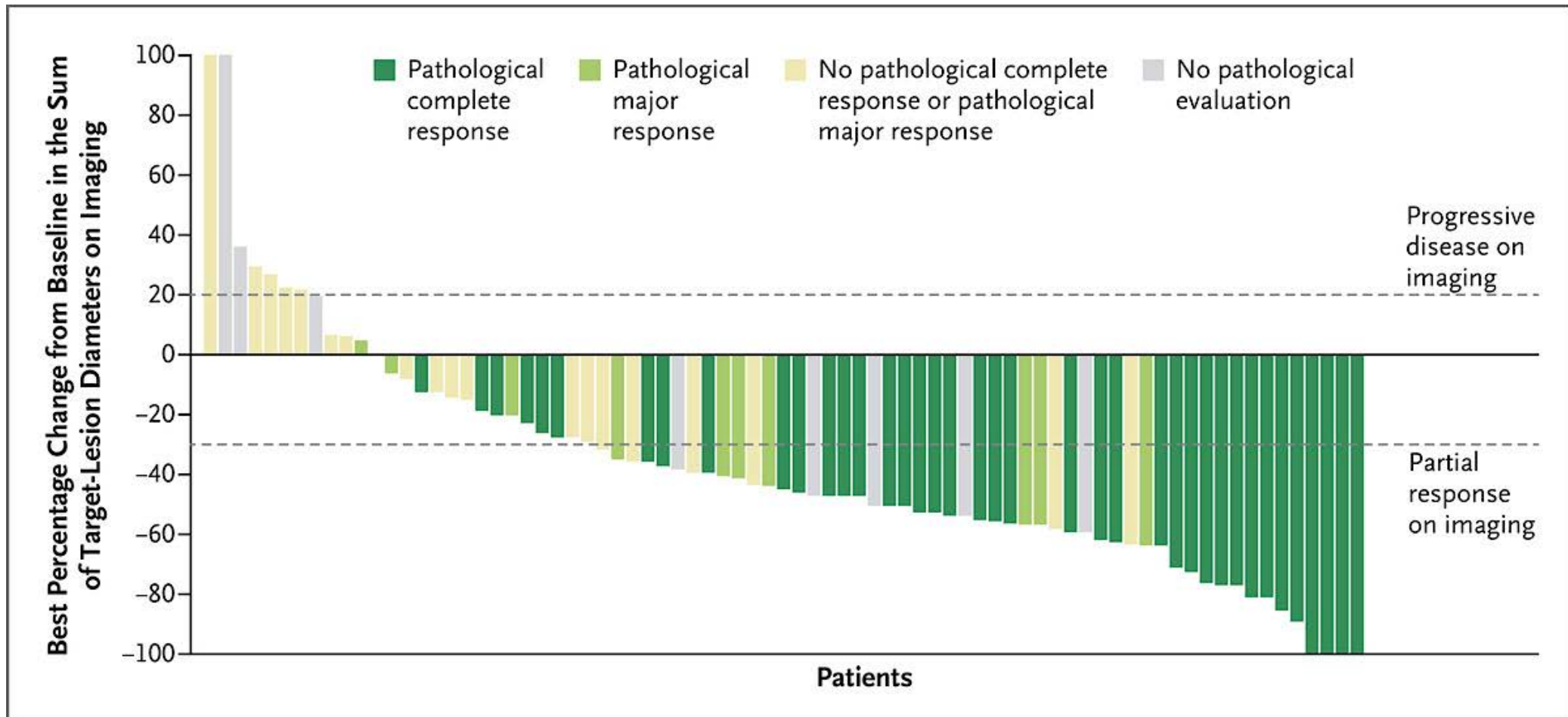
Gross, Miller, Khushalani, et al. *N Engl J Med* 2022;387:1557

Pathologic Response

Neoadjuvant cemiplimab (N=79)		
Pathologic response	ICPR N (%) [95% CI]	Local pathology review N (%) [95% CI]
pCR (0% viable tumor cells)	40 (50.6) [39.1–62.1]	42 (53.2) [41.6–64.5]
MPR (>0% and ≤10% viable tumor cells)	10 (12.7) [6.2–22.0]	10 (12.7) [6.2–22.0]
Combined pathologic response (pCR + MPR)	50 (63.3) [51.7–73.9]	52 (65.8) [54.3–76.1]
Non-pCR/MPR	20 (25.3)	NA*
Not evaluable (no surgery)	9 (11.4)	9 (11.4)
Radiological response		Local imaging review N (%) [95% CI]
Objective response rate (ORR), RECIST 1.1		54 (68.4) [56.9–78.4]
Best overall response		
Complete response		5 (6.3)
Partial response		49 (62.0)
Stable disease		16 (20.3)
Progressive disease		8 (10.1)
Not evaluable		1 (1.3)

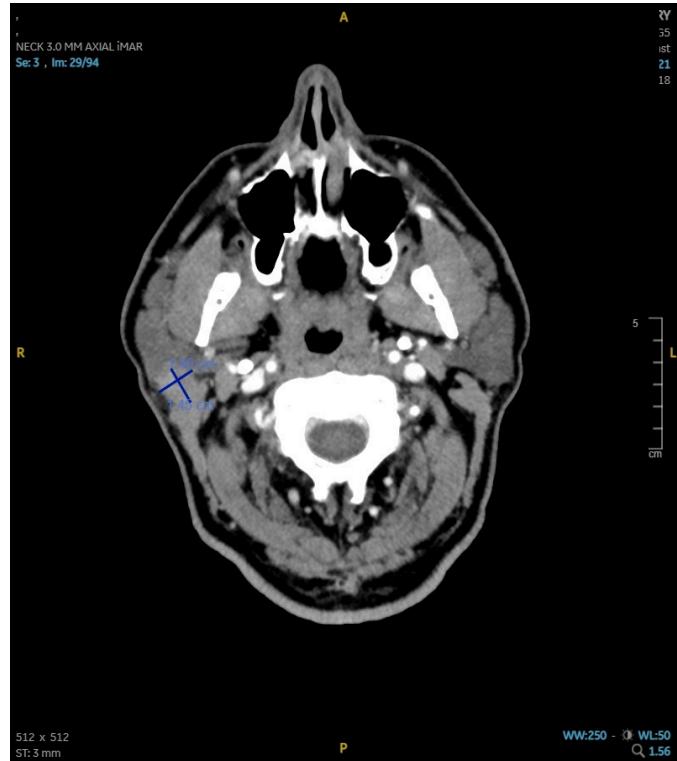
Gross, Miller, Khushalani, et al. *N Engl J Med* 2022;387:1557

Response: RECIST and Pathology



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

Neoadjuvant Cemiplimab Case

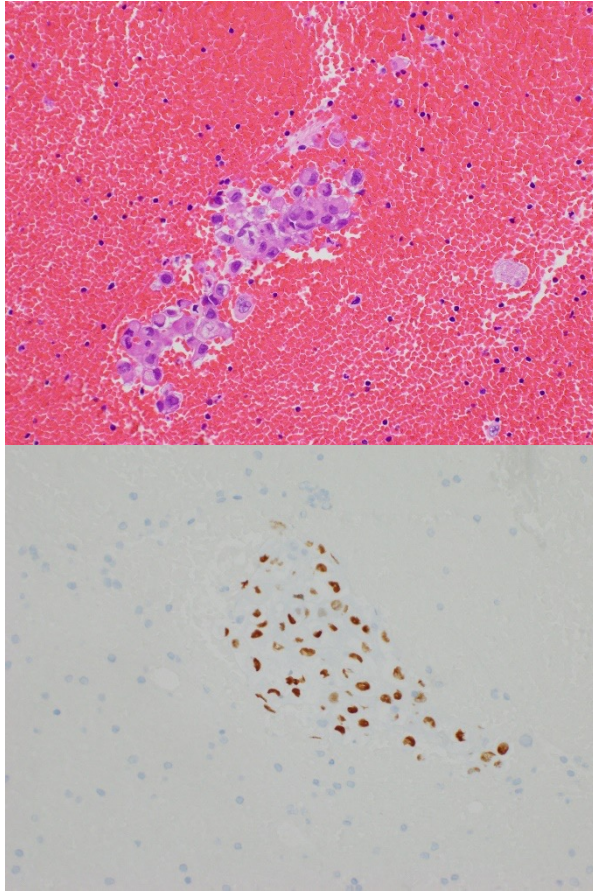


Pre-treatment

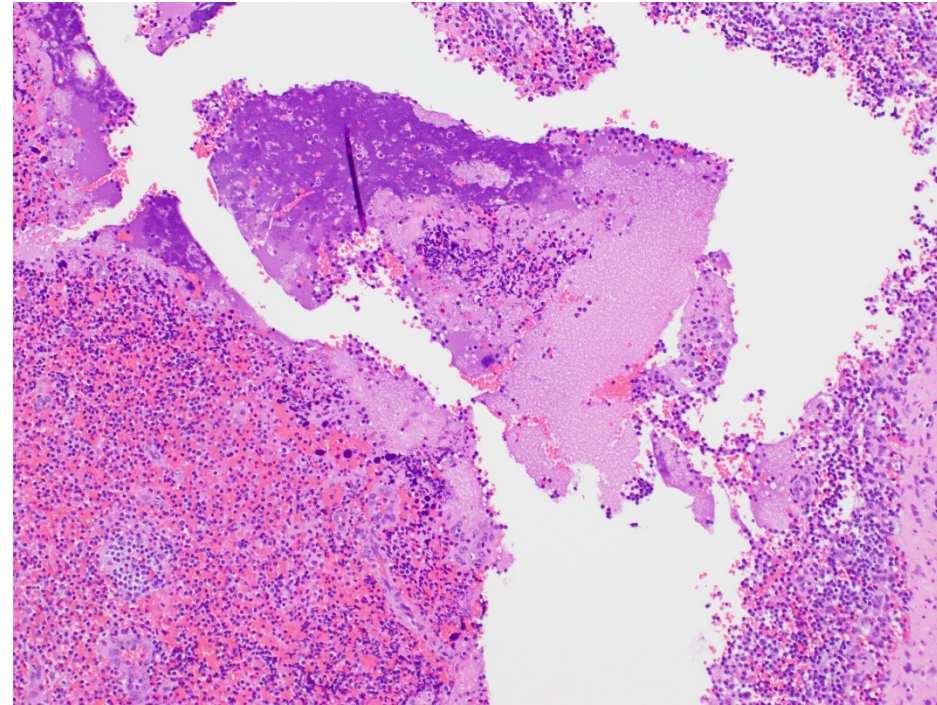
Image Courtesy: Khushalani NI



Post 4 cycles of
cemiplimab



Pre-Rx FNA (H&E and p40 IHC)



Post Rx Excision – LN with area of necrosis

Image courtesy: Ken Tsai, MD, PhD

Another case...



Image Courtesy: Khushalani NI

Post-neoadjuvant Cemiplimab: is surgery even needed?









Image Courtesy: Khushalani NI

Unanswered Questions

- Duration of neoadjuvant therapy?
- Correlation of radiographic response to pathologic response
- Need for adjuvant therapy?
- Risk-stratification by pathologic response?

Think of the last patient with cSCC to whom you administered systemic therapy for local recurrence after radiation therapy. What was their ...?

		Age	Sex	Treatment	Outcome
	Dr Khushalani	78 years	Male	Cetuximab	PD after 4 cycles
	Dr Pavlick	79 years	Male	Cetuximab	Resolution of disease
	Dr Hamid	79 years	Female	Cemiplimab	Disease control and deep PR
	Dr Lipson	66 years	Male	Cemiplimab	Complete response per RECIST v1.1
	Dr Reddy	Have not done this	—	—	—
	Dr Weber	52 years	Male	Pembrolizumab	Good response, resection with residual tumor

PD = progressive disease; PR = partial response

For patients with locally advanced, recurrent or metastatic cSCC for whom radiation therapy or surgery is not feasible, what is your preferred anti-PD-1/PD-L1 antibody?



Dr Khushalani

Cemiplimab



Dr Pavlick

Cemiplimab



Dr Hamid

Cemiplimab



Dr Lipson

Cemiplimab



Dr Reddy







Pembrolizumab



Dr Weber

Pembrolizumab

Do you believe level of PD-L1 expression or tumor mutational burden (TMB) is useful in predicting the benefit of anti-PD-1/PD-L1 antibodies for patients with advanced cSCC?

		PD-L1 expression	TMB
	Dr Khushalani	No	No
	Dr Pavlick	No	No
	Dr Hamid	No	Yes, somewhat useful
	Dr Lipson	No	Yes, somewhat useful
	Dr Reddy	Yes, somewhat useful	Yes, very useful
	Dr Weber	Yes, somewhat useful	Yes, somewhat useful

How long do you typically continue anti-PD-1/PD-L1 antibody therapy for a patient with advanced cSCC who achieves a complete response and is tolerating treatment well?



Dr Khushalani

Will consider discontinuation after 9-12 months of therapy



Dr Pavlick

Minimum 1 year and maximum 2 years



Dr Hamid

No clear data so I continue until toxicity. Sometimes I discuss 6 months after CR, sometimes discuss full 2 years



Dr Lipson

Once the patient experiences a CR, I generally treat for another 6-12 weeks, then stop



Dr Reddy

1-2 years depending on overall potential morbidity using 3 months after CR as a guide









Dr Weber

No more than 12 months

CR = complete response

What would you estimate is the likelihood that a patient receiving an anti-PD-1/PD-L1 antibody for advanced cSCC will need to have therapy held or discontinued due to tolerability issues?

In your experience, what are the 3 most common autoimmune complications experienced by patients with advanced cSCC who are receiving anti-PD-1/PD-L1 antibody therapy?

		Chance of hold or discontinuation	Common autoimmune complications
	Dr Khushalani	15%	Rash, hypothyroidism, diarrhea
	Dr Pavlick	<5%	Rash, pruritus, hypothyroidism
	Dr Hamid	15%-18%	Itching/rash, fatigue, hypothyroidism
	Dr Lipson	10%	Dermatitis, thyroiditis, sicca syndrome
	Dr Reddy	10%-20%	Rash, hypothyroidism, fatigue
	Dr Weber	15%-20%	Skin, endocrine, GI

What is the age of the oldest patient with cSCC you have treated with an anti-PD-1/PD-L1 antibody? Did the patient respond to therapy? Did the patient tolerate therapy?

		Age	Responded?	Tolerated?
	Dr Khushalani	92 years	Yes	Yes
	Dr Pavlick	101 years	Yes	Yes
	Dr Hamid	Late 80s	Yes	Yes
	Dr Lipson	98 years	Yes	Yes
	Dr Reddy	90 years	No	Yes
	Dr Weber	92 years	Yes	Yes

Have you administered an anti-PD-1/PD-L1 antibody to a patient who developed cSCC after a solid organ transplant, and if so, what was the patient's age and clinical outcome?



Dr Khushalani

Yes, 75-year-old patient with kidney transplant had PR, but developed allograft rejection and is on dialysis, and 58-year-old patient with liver transplant expired due to PD, but without rejection



Dr Pavlick

No



Dr Hamid

No



Dr Lipson

Yes, for a 63-year-old patient who experienced a partial tumor response; allograft remained functional



Dr Reddy

Yes, for a 60-year-old patient who did not experience a response and passed away



Dr Weber

Yes, 59-year-old patient, rapid progression, passed away

Have you administered an anti-PD-1/PD-L1 antibody to a patient who developed cSCC after an allogeneic hematopoietic stem cell transplant, and if so, what was the patient's age and clinical outcome?



Dr Khushalani

No



Dr Pavlick

Yes; 57 years and minimal response due to continued immunosuppressants but no graft loss



Dr Hamid

No



Dr Lipson

Yes, for a 72-year-old patient who experienced disease progression and passed away



Dr Reddy







No



Dr Weber

No

What is your usual second-line systemic therapy for a patient with advanced cSCC who has experienced disease progression on first-line anti-PD-1/PD-L1 antibody therapy?

	Dr Khushalani	Cetuximab
	Dr Pavlick	Cetuximab + chemotherapy
	Dr Hamid	Carboplatin + paclitaxel
	Dr Lipson	Cetuximab
	Dr Reddy	Carboplatin + paclitaxel OR Nivolumab + ipilimumab OR T-VEC
	Dr Weber	Cetuximab + chemotherapy

T-VEC = talimogene laherparepvec

Do you or your institution employ intralesional therapy alone or in combination with anti-PD-1/PD-L1 antibody therapy for cSCC, and if so, what type of intralesional therapy do you employ and in which situations?



Dr Khushalani

Yes, dermatologists have used interleukin or methotrexate alone; combination with anti-PD-1/PD-L1 therapy is on clinical trial



Dr Pavlick

Yes, on clinical trial; dermatologists will inject with methotrexate and medical oncology has a clinical trial with RP1 and nivolumab



Dr Hamid

Yes, T-VEC or IL-2



Dr Lipson

No



Dr Reddy







Yes, sometimes; T-VEC or clinical trial



Dr Weber







No

Think of the last patient with cutaneous squamous cell carcinoma (cSCC) to whom you administered neoadjuvant systemic therapy. What was their ...?







		Age	Sex	Treatment	Outcome
	Dr Khushalani	64 years	Male	Cemiplimab	pCR
	Dr Pavlick	75 years	Male	Pembrolizumab	Complete pCR
	Dr Hamid	84 years	Female	Cemiplimab	Resection
	Dr Lipson	79 years	Male	Cemiplimab	Complete pathologic response
	Dr Reddy	80 years	Male	Radiation therapy	Faring okay
	Dr Weber	62 years	Female	Pembrolizumab	Excellent response, minimal resection needed

pCR = pathologic complete response

Which anti-PD-1/PD-L1 antibody do you generally employ as neoadjuvant therapy for patients with cSCC, and how many cycles do you typically administer?

		Preferred agent	Number of cycles
	Dr Khushalani	Cemiplimab	4
	Dr Pavlick	Pembrolizumab	2 to 3
	Dr Hamid	Cemiplimab	3
	Dr Lipson	Cemiplimab	3 to 4
	Dr Reddy	Pembrolizumab	3
	Dr Weber	Pembrolizumab	4

Regulatory and reimbursement issues aside, would you present the option of adjuvant anti-PD-1/PD-L1 antibody therapy to a patient with cSCC and ... ?

		Nodal disease with ECE	In-transit metastases	T4 lesion
	Dr Khushalani	No	No	No
	Dr Pavlick	Yes, cemiplimab and XRT	Yes, cemiplimab	No
	Dr Hamid	No	No	No
	Dr Lipson	No	No	No
	Dr Reddy	Yes, no preference	Yes, but would not encourage pembrolizumab	No
	Dr Weber	Yes, pembrolizumab	Yes, pembrolizumab	Yes, pembrolizumab

ECE = extracapsular extension; XRT = radiation therapy

Regulatory and reimbursement issues aside, would you present the option of adjuvant anti-PD-1/PD-L1 antibody therapy to a patient with cSCC and perineural invasion?



Dr Khushalani

No



Dr Pavlick

No



Dr Hamid

No



Dr Lipson

No



Dr Reddy

No



Dr Weber

No

Regulatory and reimbursement issues aside, would you present the option of adjuvant anti-PD-1/PD-L1 antibody therapy to a patient with cSCC and locally recurrent disease with no evidence of disease after surgical resection?



Dr Khushalani

No



Dr Pavlick

No



Dr Hamid

Yes, cemiplimab



Dr Lipson

No



Dr Reddy

Yes, I would present it as an option to the patient



Dr Weber

Yes, pembrolizumab for a high-risk lesion

In which situations, if any, do you recommend postoperative radiation therapy for patients who undergo resection of cSCC?



Dr Khushalani

Perineural invasion, recurrent disease, multiple nodes involved, ECE, R1/R2 resection



Dr Pavlick

Close margins, perineural invasion, multifocal disease



Dr Hamid

Positive margins, ECE, perineural extension



Dr Lipson

Nodal disease with ECE, in-transit metastases, T4 lesion, perineural invasion, locally recurrent disease NED after resection



Dr Reddy

Positive margins or 2 to 3 risk factors



Dr Weber

Lack of clean negative margin or extensive local disease/nodal involvement

ECE = extracapsular extension; NED = no evidence of disease

Case Presentation – Dr Khushalani: A man with locally advanced cSCC



Image Courtesy: Khushalani NI

Case Presentation – Dr Khushalani: A man with locally advanced cSCC (continued)

Dramatic Response



Post one dose
pembrolizumab



Post two doses of
pembrolizumab

Image Courtesy: Khushalani NI

Case Presentation – Dr Khushalani: A man with locally advanced cSCC (continued)

Post 6 months therapy



Completed 1 year of therapy with clinical CR – then lost to follow-up.
Primary irAE of G1-2 arthritis

Image Courtesy: Khushalani NI

Case Presentation – Dr Khushalani: A man in his late 60s with moderately to poorly differentiated SCC

- M/67; right forehead SCC in 2015 – surgery
- 2017 – local recurrence – electron beam RT (52.5 Gy)
- Several additional local recurrences requiring multiple surgical resections including tangential craniectomy – pathology with moderately to poorly differentiated SCC
- In 2022 – new right forehead mass; biopsy shows SCC

Image Courtesy: Khushalani NI



Case Presentation – Dr Khushalani: A man in his late 60s with moderately to poorly differentiated SCC (continued)

- Multi-disciplinary evaluation
 - Unresectable; infiltration of the dura with sub-dural collection and infiltration of the right frontal sinus
- Plan for Cemiplimab plus palliative course of IMRT due to pain and location with ocular compressive symptoms
- Re-irradiation: 40 Gy
- Dramatic clinical and radiographic response within 2 cycles of cemiplimab



Image Courtesy: Khushalani NI

Case Presentation – Dr Khushalani: A man in his late 60s with moderately to poorly differentiated SCC (continued)

- Progressive improvement in tumor and symptoms.
- Completed 12 months of Cemiplimab – now on surveillance

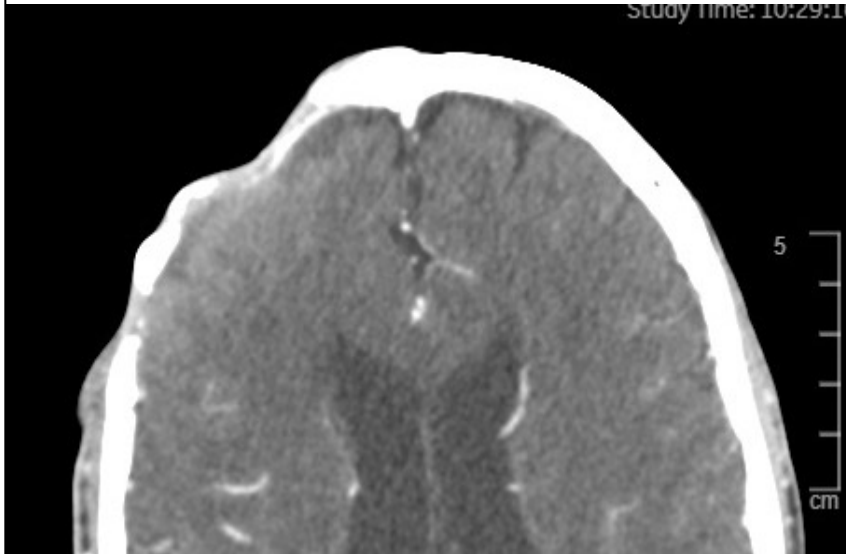


Image Courtesy: Khushalani NI

Case Presentation – Dr Khushalani: A man in his late 50s with poorly differentiated SCC

- M/57: flesh colored mass on right forearm that increased over 2 years; then developed a palpable right axillary swelling.
- CT imaging: 7.5cm X 4.4cm X 10.3cm mass of the distal forearm encasing cephalic vein; 3.9cm right axillary nodal mass
- Biopsy of right axillary mass: Poorly differentiated SCC (p40+)
- Started cemiplimab

Case Presentation – Dr Khushalani: A man in his late 50s with poorly differentiated SCC (continued)

Pre-Cemiplimab Images



Image Courtesy: Khushalani NI



Case Presentation – Dr Khushalani: A man in his late 50s with poorly differentiated SCC (continued)

Progression on Cemiplimab (4 Cycles)



Case Presentation – Dr Khushalani: A man in his late 50s with poorly differentiated SCC (continued)

**Cetuximab + concurrent RT
(35 fractions, 2 Gy each; forearm and axilla)**



Last week of RT



Ongoing cetuximab; 4m post RT

Agenda

INTRODUCTION: Why did it take so long?

MODULE 1: Cutaneous Squamous Cell Carcinoma – Dr Khushalani

MODULE 2: Basal Cell Carcinoma – Dr Pavlick

MODULE 3: Ongoing Clinical Trials

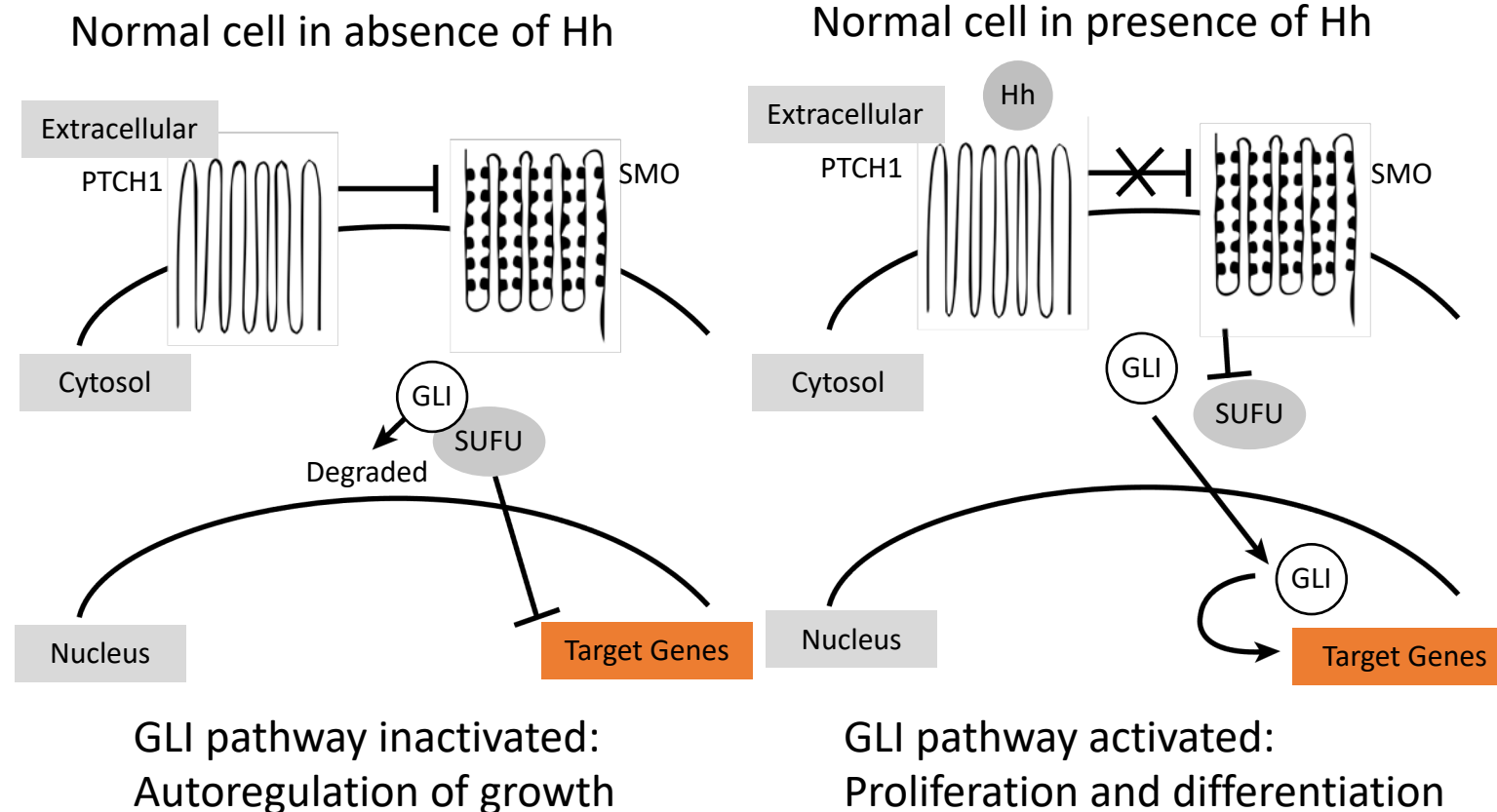
Pathophysiology and Molecular Characteristics

- Hedgehog signaling pathway controlled by Hh genes (Sonic, Indian, Desert) is crucial to normal basal cell proliferation and dysregulated in $\geq 85\%$ of BCC
- Genetic characteristics
 - Mutations in sonic Hh pathway genes: *PTCH1* and *SMO*
 - Mutations in *TP53* due to UV/radiation exposure
 - Very high TMB due to UV damage (median 47.3 mut/Mb)
 - Other mutations of interest: *EGFR* (38%), *ERBB2*, *PIK3CA*, *RAS* (all $<10\%$)
- Molecular characteristics
 - Approximately 90% have high PD-L1 expression on IHC
 - PD-L1 intensity increases with number of prior treatment types

Hh = hedgehog; IHC = immunohistochemistry; mut/Mb = mutations per megabase; TMB = tumor mutation burden.

Cives. Int J Mol Sci. 2020;21:5394. Goodman. OncoImmunol. 2018;7:e1404217. Habashy. Cureus. 2021;13:e13859. NCCN. Basal Cell Cancer. Version 2.2021. www.nccn.org. Nikanjam. Ann Oncol. 2018;29:2192.

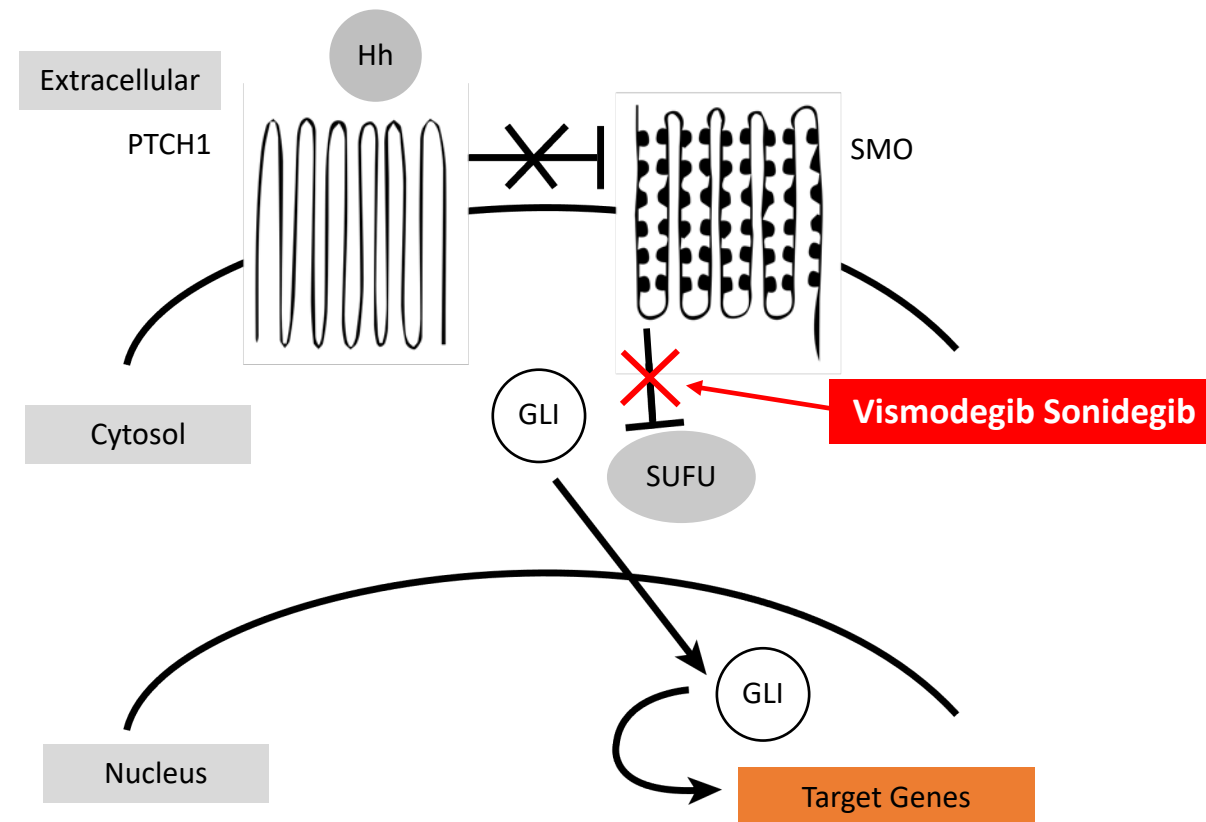
Molecular Pathways in BCC



- *PTCH1* or *SMO* mutations trigger constitutive activation of GLI downstream pathway
- *TP53* mutations potentiate Hh signaling
- Frequency in advanced BCC
 - *PTCH1*: 67% to 73%
 - *TP53*: 40% to 61%
 - *SMO*: 10% to 20%
- Frequency in mBCC
 - *PTCH1*: 32%
 - *TP53*: 79%
 - *SMO*: 17%

Hedgehog Inhibitors

- HHIs bind the SMO receptor to prevent inactivation of SUFU and downstream activation of GLI, which facilitates restoration of normal cell regulation
- 2 HHIs currently approved for BCC
 - Vismodegib
 - Sonidegib
- Each is a once-daily oral medication



HHI = hedgehog inhibitor.

Habashy. Cureus. 2021;13:e13859. Nikanjam. Ann Oncol. 2018;29:2192.

Frequent AEs With HHIs

AE, %	Vismodegib 150 mg		Sonidegib 200 mg	
	Any grade	Grade 3 or 4	Any Grade	Grade 3 or 4
Muscle spasms	68	4	52	3
Alopecia	63	0	49	0
Dysgeusia	51	0	41	0
Weight loss	46	5	29	3
Fatigue	36	4	29	4
Nausea	29	1	35	1
Appetite loss	23	3	23	1
Diarrhea	22	1	30	1
Potential serious AE	<ul style="list-style-type: none"> Severe cutaneous reactions Embryo-fetal toxicity: females must use effective contraception, and males must use condom with pregnant partner or female partner of reproductive potential because of potential risk of exposure through semen Premature fusion of epiphyses 			

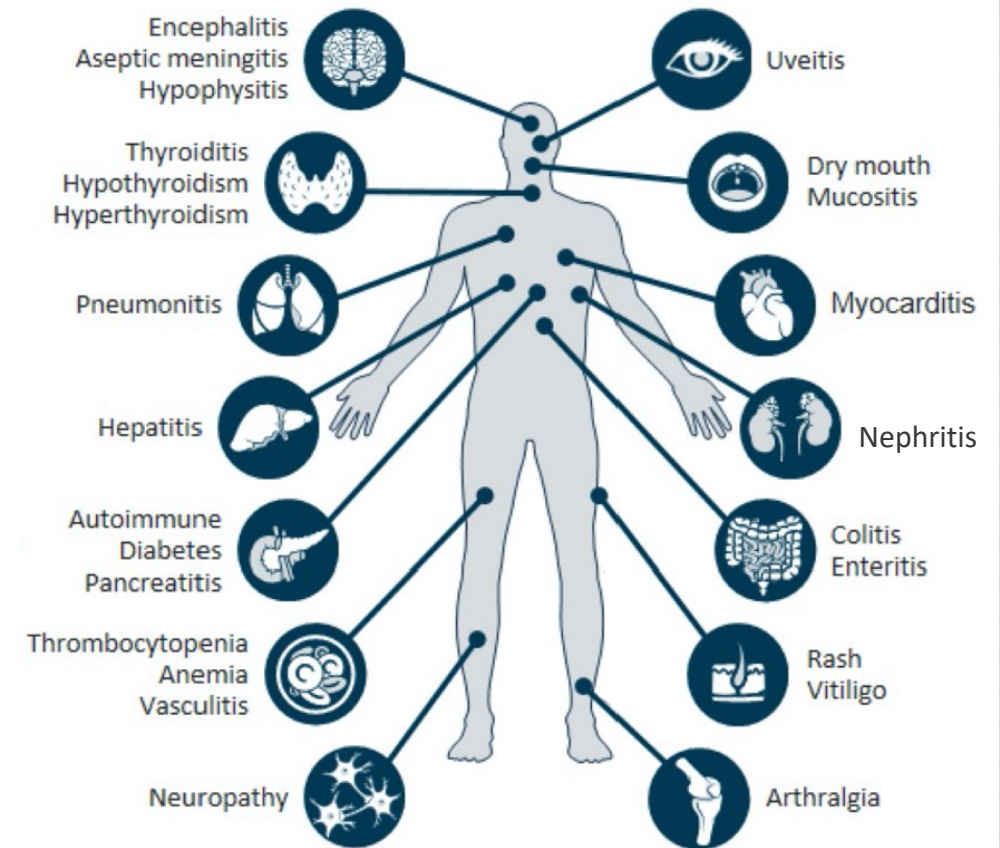
Suggested Management of HHI AEs

AE	Grade 0	Grade 1-2
Muscle spasms	<ul style="list-style-type: none"> Maintain hydration, gentle physical activity Sonidegib only: check creatinine kinase before/during treatment 	<ul style="list-style-type: none"> Passive stretching, heat, cold, massage Consider CCBs, gabapentin, magnesium If abdominal: CCBs, antimuscarinics
Dysgeusia	<ul style="list-style-type: none"> Nutrition counseling, patient education 	<ul style="list-style-type: none"> THC or zinc supplements Check renal function
Alopecia	<ul style="list-style-type: none"> Rule out other causes; consider prophylactic minoxidil or other 	<ul style="list-style-type: none"> Camouflage (eg, wig) Minoxidil, oral DHTi, bimatoprost (eyelid)
Weight loss	<ul style="list-style-type: none"> Nutrition counseling, patient education 	<ul style="list-style-type: none"> Ongoing nutrition support and evaluate and correct deficiencies THC, megestrol, corticosteroids
Fatigue	<ul style="list-style-type: none"> Maintain physical activity, yoga or other, physical rehab 	<ul style="list-style-type: none"> Test/treat anemia Consider psychostimulants
All	<ul style="list-style-type: none"> Any severe (grade ≥ 3) or intolerable AE: Continue grade 1-2 management plus 2-4 week drug holiday or change regimen (alternate agent or alternate day/week dosing) 	

Immune Related Adverse Effects

- Unique to ICIs and related to immune system damage to healthy organs
 - Activated T-cells mistakenly attack healthy tissue
 - Inflammatory or autoimmune-type symptoms
- Maintain high level of suspicion for irAE with any changes in patient on ICI
 - Bloating or weight loss
 - Bowel, vision, or mood changes
 - Cough, dyspnea, chest pain
 - Headache
 - Rash and/or itchy skin
 - Severe fatigue or muscle weakness/pain

irAEs Can Affect Any Organ System



General Guidance for Management of irAEs

Maintain Low Threshold for Systemic Steroids With Grade 2-3 irAE

Grade	Management*
1 (mild)	<ul style="list-style-type: none">• Symptomatic management (eg, topical steroid)• Continue therapy (some cardiac, neurologic, or hematologic reaction may require discontinuation)
2 (mild to moderate)	<ul style="list-style-type: none">• Symptomatic management• Hold ICI for most grade 2 until resolution to grade 1; consider rechallenge after resolution; permanently discontinue if reaction reoccurs• Initiate low-dose or topical corticosteroids (eg, prednisone 0.5-1.0 mg/kg/d)
3 (moderate to severe)	<ul style="list-style-type: none">• Hold ICI• Initiate high-dose corticosteroids (eg, prednisone 1-2 mg/kg/d), taper steroids over 4-6 weeks• At resolution to grade ≤1, cautious rechallenge with ICI, especially in patients with early development of irAE
4 (severe)	<ul style="list-style-type: none">• Permanently discontinue ICI, except for endocrinopathies controlled with hormone replacement

*Consult prescribing information for detailed recommendations.

Brahmer. J Clin Oncol. 2018;36:1714. Cemiplimab PI. NCCN. Management of immunotherapy-related toxicities, v3.2021. www.nccn.org. Pembrolizumab PI.

What is your usual first-line systemic therapy for a patient with advanced basal cell carcinoma (BCC) not amenable to radiation therapy or surgery?



Dr Khushalani

Sonidegib or vismodegib, no preference



Dr Pavlick

Vismodegib



Dr Hamid

Anti-PD-1 antibody



Dr Lipson

Anti-PD-1 antibody



Dr Reddy

Vismodegib



Dr Weber

Sonidegib or vismodegib, no preference

How long do you typically continue hedgehog inhibitor therapy for a patient with advanced BCC who achieves a complete response (CR) and is tolerating treatment well?



Dr Khushalani

Usually 9-12 months



Dr Pavlick

If no toxicity, usually an additional 3 months past CR



Dr Hamid

Indefinitely



Dr Lipson

**Once the patient experiences a CR,
I stop hedgehog inhibitor therapy right away**



Dr Reddy

3 months after CR, depending on tolerance









Dr Weber

12 months

What would you estimate is the likelihood that a patient receiving a hedgehog inhibitor for advanced BCC will need to have therapy held or discontinued due to tolerability issues?

In your experience, what are the 3 most common toxicities experienced by patients with advanced BCC who are receiving hedgehog inhibitor therapy?

		Chance of hold or discontinuation	Common toxicities
	Dr Khushalani	100%	Muscle cramps, dysgeusia, fatigue and alopecia
	Dr Pavlick	65%	Dysgeusia, anorexia, muscle cramps
	Dr Hamid	80%	Dysgeusia, alopecia, cramps
	Dr Lipson	75%	Hair loss, dysgeusia, muscle cramps
	Dr Reddy	50%	Taste alterations, fatigue, bowel disturbances
	Dr Weber	100%	Dysgeusia, muscle spasms, loss of hair

What supportive care measures do you employ to manage dysgeusia in patients receiving hedgehog inhibitor therapy?



Dr Khushalani

None for dysgeusia per se, suggest small volume frequent meals to ensure adequate caloric intake and prevent weight loss



Dr Pavlick

Interrupt therapy or have patients eat spicier or sour tasting food



Dr Hamid

Therapy hold



Dr Lipson

Avoidance of metal silverware, addition of salt or hot sauce



Dr Reddy

Use of extreme tastes such as lemon, discuss utilizing bland foods



Dr Weber

Intermittent dosing and zinc

What other supportive care measures do you employ to manage other side effects in patients receiving hedgehog inhibitor therapy?



Dr Khushalani

Adequate oral fluid intake; consider tonic water if cramps noted



Dr Pavlick

Increase exercise and hydration with sports drinks to decrease muscle cramps, small frequent meals to keep up calories



Dr Hamid

Hydration, muscle stretches, treatment holiday/hold



Dr Lipson

IV fluids, exercise/yoga



Dr Reddy

None



Dr Weber

Dietary consult for the weight loss and dysgeusia

Outside of a clinical trial, have you administered or would you administer the alternative hedgehog inhibitor to a patient with advanced BCC who had experienced disease progression on prior hedgehog inhibitor therapy?



Dr Khushalani

I have not and would not



Dr Pavlick

I have not and would not



Dr Hamid

I have not and would not



Dr Lipson

I have not and would not



Dr Reddy

I have



Dr Weber

I have not and would not

What is your usual second-line systemic therapy for a patient with advanced BCC who has experienced disease progression on first-line hedgehog inhibitor therapy?



Dr Khushalani

Cemiplimab



Dr Pavlick

Cemiplimab



Dr Hamid

Cemiplimab



Dr Lipson

Cemiplimab



Dr Reddy

Cemiplimab or pembrolizumab




Dr Weber

Cemiplimab

What is the longest duration of response (DoR) you have observed in a patient with advanced BCC receiving anti-PD-1/PD-L1 antibody therapy?

How long do you typically continue anti-PD-1/PD-L1 antibody therapy for a patient with advanced BCC who achieves a CR and is tolerating treatment well?







		Longest DoR	Duration of anti-PD-1/PD-L1 therapy
	Dr Khushalani	12+ months and ongoing	Will consider discontinuation after 9-12 months
	Dr Pavlick	3 years	3 months after CR and PET/CT with no avidity
	Dr Hamid	3 years	Indefinitely
	Dr Lipson	5 years	Once the patient experiences a CR, I generally treat for another 12-16 weeks, then stop
	Dr Reddy	6 months	3 months after CR
	Dr Weber	Multiple years	At least 12 months

What is the age of the oldest patient with BCC you have treated with an anti-PD-1/PD-L1 antibody? Did the patient respond to therapy? Did the patient tolerate therapy?

		Age	Responded?	Tolerated?
	Dr Khushalani	74 years	Yes	Yes
	Dr Pavlick	99 years	Yes	Yes
	Dr Hamid	78 years	Yes	Yes
	Dr Lipson	97 years	Yes	Yes
	Dr Reddy	90 years	No	Yes
	Dr Weber	88 years	Yes	Yes

How many patients with nevoid BCC syndrome (Gorlin syndrome) have you cared for?

What role, if any, do you believe anti-PD-1/PD-L1 antibodies play in treating this syndrome, and for approximately how many patients have you employed topical patidegib gel?

		No. of patients	Role of anti-PD-1/ PD-L1 therapy	No. administered patidegib gel
	Dr Khushalani	2	Similar indications as sporadic BCC	0
	Dr Pavlick	6	Unclear	0
	Dr Hamid	2	Therapeutic option	0
	Dr Lipson	10	Potentially effective therapy, though little data in this patient population	0
	Dr Reddy	2	It is worth considering	0
	Dr Weber	2 or 3	May be useful	0

Case Presentation – Dr Pavlick: A man in his late 80s with advanced BCC

- An 88-year-old man who grew up in Puerto Rico presents to the dermatologist with a non-healing ulcer on the lateral aspect of his nose.
- A biopsy is done which demonstrates invasive BCC.
- What are this man's treatment options?



Case Presentation – Dr Pavlick: A man in his late 80s with advanced BCC (continued)

The location and size of this lesion made surgery and radiation difficult and not without significant side effects. He refused surgery and Radiation therapy.



Case Presentation – Dr Pavlick: A man in his late 80s with advanced BCC (continued)

- He was started on vismodegib 150 mg po daily.
- He had a dramatic response to therapy.
- After approximately 6 months on vismodegib, he developed muscle cramps in his lower extremities that would wake him up from his sleep.
- As he had resolution of his lesion, the vismodegib was stopped and his cramps resolved.

Case Presentation – Dr Pavlick: A man in his late 80s with advanced BCC (continued)

- As the vismodegib was stopped, he was then sent to the dermatologist for several blind biopsies in the area.
- All biopsies were negative for BCC
- He remains disease free and is monitored closely by dermatology.



Case Presentation – Dr Pavlick: A man in his early 80s with advanced BCC receives cemiplimab

- An 80-year-old man who has recurrent BCC
- First diagnosed with 1.5 cm basal cell lesion on his scalp 8 years ago
 - Underwent extensive Mohs surgery to remove lesion
 - No sign of local spread
- Presents today for follow-up with concerns about a lesion in the same area
- Workup reveals
 - 5 cm lesion with poorly defined borders
 - No evidence of other lesions on full-skin exam
 - Imaging reveals no distant disease

Case Presentation – Dr Pavlick: A man in his early 80s with advanced BCC receives cemiplimab (continued)

- Patient was referred to medical oncology for a discussion of medical therapy, since he refused surgery and radiation therapy.
- He was started on a hedgehog inhibitor, but within 3 months he lost his desire to eat as food had no taste and he lost almost 20 pounds.
- The HHI was stopped and when he recovered from this toxicity, he was offered immunotherapy with cemiplimab 350mg IV every 3 weeks which he agreed to.
- He tolerated this infusion well and denied any IRAE's.
- He received treatment for nearly 2 years with complete resolution of his recurrent BCC.

Case Presentation – Dr Pavlick: A man in his early 80s with advanced BCC receives cemiplimab (continued)

Tumor Response to Cemiplimab

A **Baseline** **Week 8** **Week 20**



Case Presentation – Dr Pavlick: A man in his mid-70s with hedgehog inhibitor refractory advanced BCC

- A 76-year-old man who noticed a pink nodule on his right upper outer arm in July 2020. He was afraid it was cancer, so he ignored it hoping it would go away.
- The lesion continued to grow, then the COVID pandemic hit and he refused to seek any medical care for fear of contracting COVID and dying.
- In January 2022, he collapsed at home and was rushed to the ER. He was found to be septic due to an infected large fungating right upper arm mass. He recovered from the sepsis and the large fungating mass was removed. The pathology was consistent with basal cell carcinoma.

Case Presentation – Dr Pavlick: A man in his mid-70s with hedgehog inhibitor refractory advanced BCC (continued)

- He was referred to medical oncology and on exam was found to have a nodular, fungating mass in his right axilla with RUE edema and decreased fine motor skills in his hand.
- His metastatic work up demonstrated this right axillary mass encircling the right brachial plexus which was deemed unresectable.
- He was started on vismodegib 150 mg po daily.
- He tolerated this well except for occasional muscle cramps and hair loss.
- While on vismodegib, his right axillary mass started to grow and he developed new right chest wall nodules.
- Metastatic work up was negative for any distant disease.
- Vismo was stopped and he was started on cemiplimab.

Case Presentation – Dr Pavlick: A man in his mid-70s with hedgehog inhibitor refractory advanced BCC (continued)

- He had some decrease in the axillary mass, but the chest wall nodules continued to increase in size.
- Cemiplimab was stopped after 6 months due to progression of disease.
- The patient was offered a clinical trial using a herpes simplex virus vaccine that would be injected directly into his tumors in conjunction with an anti-PD-1 agent.
- The patient has been on therapy for 18 months with resolution of his chest wall nodules and improvement of his axillary mass. He continues treatment on this research study with slow but continued improvement. He has no adverse reactions throughout the course of his treatment.



Case Presentation – Dr Pavlick: A man in his mid-70s with hedgehog inhibitor refractory advanced BCC (continued)

Axillary mass and chest wall lesions prior to starting clinical trial.



Case Presentation – Dr Pavlick: A man in his mid-70s with hedgehog inhibitor refractory advanced BCC (continued)

Axillary mass and chest wall lesions after 18 months on a clinical trial with an intratumoral vaccine and systemic anti-PD-1



Agenda

INTRODUCTION: Why did it take so long?

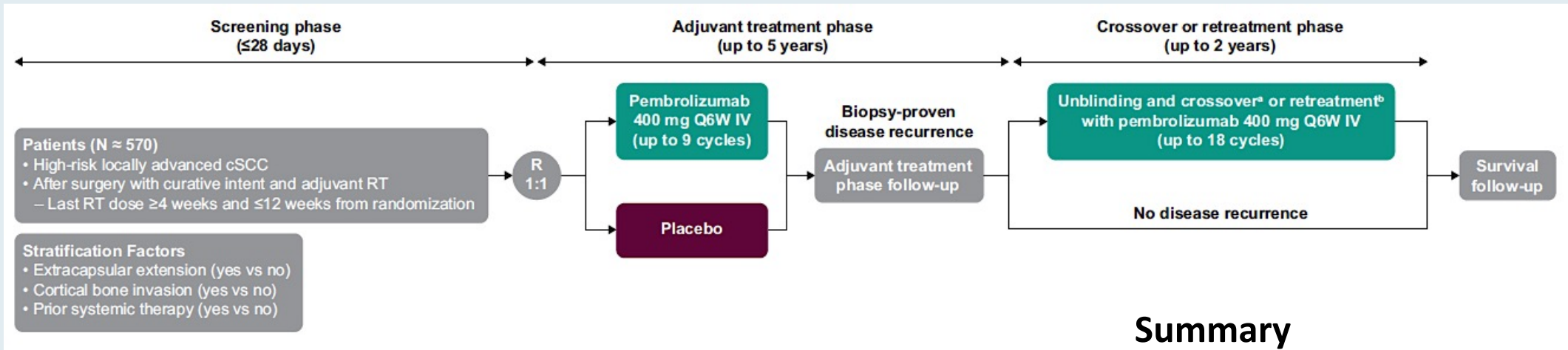
MODULE 1: Cutaneous Squamous Cell Carcinoma – Dr Khushalani

MODULE 2: Basal Cell Carcinoma – Dr Pavlick

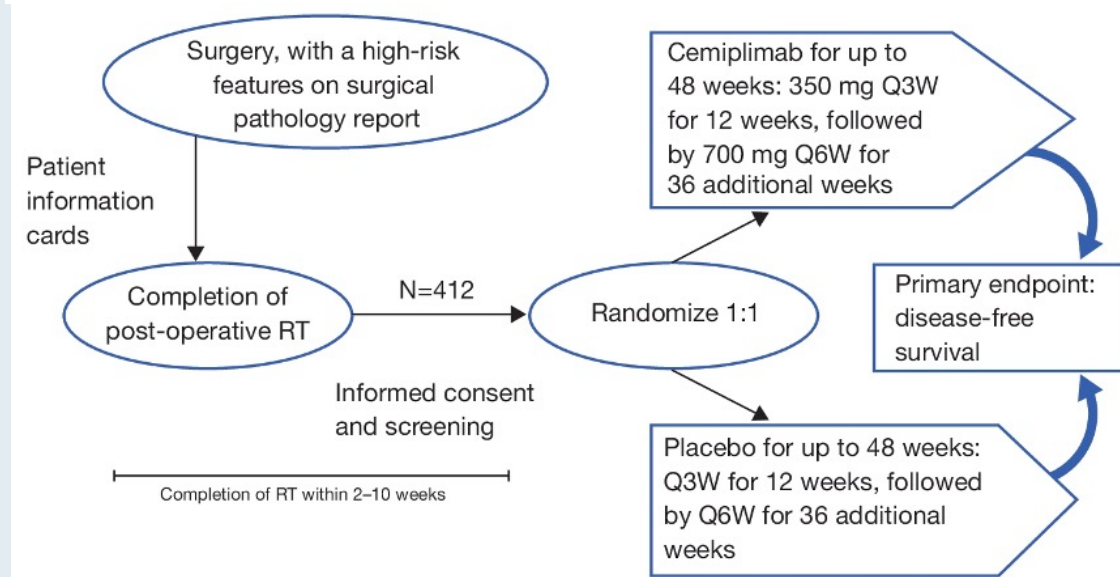
MODULE 3: Ongoing Clinical Trials

Ongoing Phase III Trials Evaluating the Role of Adjuvant PD-L1 Antibodies in Patients with High-Risk cSCC After Surgery and RT

KEYNOTE-630



C-POST



Summary

- Patients with high-risk cSCC often experience relapse with locoregional recurrence or distant metastases. There is an unmet need to reduce the risk of cSCC recurrence in these patients who are not candidates for curative surgery or radiation.
- Cemiplimab, an anti-PD-1 antibody, was the first immunotherapy to demonstrate clinical benefit in advanced cSCC, based on a clinically meaningful rate of objective responses that were durable and a manageable safety profile.
- The C-POST study is evaluating the efficacy of cemiplimab as adjuvant therapy for patients with high-risk cSCC after surgery and postoperative radiotherapy.

cSCC = cutaneous squamous cell carcinoma; RT = radiotherapy

NEO-CESQ Study: Neoadjuvant plus Adjuvant Treatment with Cemiplimab in Surgically Resectable, High Risk Stage III/IV (M0) Cutaneous Squamous Cell Carcinoma

Ascierto PA et al.

ASCO 2023;Abstract 9576.

Winship 4851-19: A Pilot Study of Neoadjuvant and Adjuvant Cemiplimab for High-Risk Cutaneous Squamous Cell Carcinoma

Lowe MC et al.

ASCO 2021;Abstract TPS9593.

A Randomized, Controlled, Open-Label, Phase 2 Study of Cemiplimab ± RP1 in Patients with Advanced Cutaneous Squamous Cell Carcinoma (CERPASS)

Haydon AM et al.

ASCO 2022;Abstract TPS9593.

An Open-Label, Multicenter, Phase 1b/2 Study of RP1, A First-in-Class, Enhanced Potency Oncolytic Virus in Solid Organ Transplant Recipients with Advanced Cutaneous Malignancies (ARTACUS)

Migden MR et al.

ASCO 2022;Abstract TPS9597.

Investigation of Calcium Electroporation (CaEP) Therapy in Malignant Cutaneous and Subcutaneous Tumours: A Non-Randomized Phase II Clinical Trial of a Novel Palliative Therapy

Pervan M et al.

ESMO 2022;Abstract 1295TiP.

Nivolumab (NIVO) + Tacrolimus (TACRO) + Prednisone (PRED) +/- Ipilimumab (IPI) for Kidney Transplant Recipients (KTR) with Advanced Cutaneous Cancers

Schnek KM et al.

ASCO 2022;Abstract 9507.

Towards Organ Preservation and Cure via 2 Infusions of Immunotherapy Only, in Patients Normally Undergoing Extensive and Mutilating Curative Surgery for Cutaneous Squamous Cell Carcinoma: An Investigator-Initiated Randomized Phase II Trial — The MATISSE Trial

Zuur CL et al.

ASCO 2023;Abstract 9507.

Join Us In Person or Virtually

Current Approaches and Future Strategies in Oncology

*A Multitumor Educational Symposium in Partnership
with Florida Cancer Specialists & Research Institute*

Saturday, October 7, 2023

ER-Positive Breast Cancer

7:15 AM – 8:15 AM ET

Faculty

**Harold J Burstein, MD, PhD
Komal Jhaveri, MD**

Prostate Cancer

8:15 AM – 9:15 AM ET

Faculty

**Alicia K Morgans, MD, MPH
Matthew R Smith, MD, PhD**

Moderator

Neil Love, MD

Join Us In Person or Virtually

Current Approaches and Future Strategies in Oncology

*A Multitumor Educational Symposium in Partnership
with Florida Cancer Specialists & Research Institute*

Saturday, October 7, 2023

Non-Small Cell Lung Cancer

9:30 AM – 10:30 AM ET

Faculty

Gregory J Riely, MD, PhD

Heather Wakelee, MD, FASCO

Colorectal and Gastroesophageal Cancers

10:30 AM – 11:30 AM ET

Faculty

Tanios Bekaii-Saab, MD

Philip A Philip, MD, PhD, FRCP

Moderator

Neil Love, MD

Join Us In Person or Virtually

Current Approaches and Future Strategies in Oncology

*A Multitumor Educational Symposium in Partnership
with Florida Cancer Specialists & Research Institute*

Saturday, October 7, 2023

Chronic Lymphocytic Leukemia

11:30 AM – 12:30 PM ET

Faculty

Asher Chanan-Khan, MD

Brad S Kahl, MD

Moderator

Neil Love, MD

Thank you for joining us!

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

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