

Dermatologic Oncology™

U P D A T E

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Jeffrey Weber, MD, PhD

Keith T Flaherty, MD

Adil Daud, MD

Jason J Luke, MD

EDITOR

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Dermatologic Oncology Update

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Melanoma and nonmelanoma skin cancers (basal cell carcinoma [BCC] and cutaneous squamous cell cancer [SCC]), taken together, likely represent the most prevalent form of human cancer. The vast majority of skin cancer presents as minimally invasive BCC and SCC and is highly curable with local treatment alone. However, in rare instances these characteristically indolent lesions progress and necessitate systemic intervention with the support of limited randomized clinical evidence. In contrast, malignant melanoma is the most aggressive form of skin cancer with a predilection toward distant metastases, even when identified in the early stages. Thus melanoma and nonmelanoma skin cancers are distinct entities, each posing unique challenges to the oncology community. Featuring up-to-date information on the latest research developments along with expert perspectives, this CME activity is designed to assist medical oncologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Use biomarkers, clinical characteristics and mutational analyses to select individualized front-line and subsequent treatment approaches for patients with advanced melanoma.
- Recall available clinical trial evidence to safely and effectively incorporate targeted and immunotherapeutic approaches into the management of metastatic BRAF mutation-positive melanoma.
- Recognize immune-related adverse events associated with immune checkpoint inhibitors, and formulate strategies to minimize and/or manage these side effects.
- Assess the rationale for and clinical trial data with anti-PD-1/PD-L1 antibodies for patients with Merkel cell carcinoma, and optimally integrate available agents into current treatment algorithms.
- Formulate a long-term clinical plan for the management of locally advanced or metastatic BCC incorporating existing and investigational treatments.
- Appraise new data with investigational agents and strategies demonstrating promising activity in melanoma and nonmelanoma skin cancer, and discuss ongoing trial opportunities with eligible patients.

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6 POST-TEST

7 EDUCATIONAL ASSESSMENT AND CREDIT FORM

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EDITOR



Neil Love, MD
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Miami, Florida

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Interview with Jeffrey Weber, MD, PhD

Tracks 1-23

Track 1	COMBI-AD: Results from a Phase III trial of adjuvant dabrafenib and trametinib for resected Stage III BRAF-mutated melanoma	Track 14	with anti-PD-1 antibodies in melanoma Efficacy and safety profiles of the BRAF/MEK inhibitor combinations dabrafenib/trametinib, vemurafenib/cobimetinib and encorafenib/binimetinib for BRAF-mutant melanoma
Track 2	CheckMate 238: Efficacy and safety of adjuvant nivolumab versus ipilimumab in resected Stage III/IV melanoma	Track 15	Association of the diversity and composition of the gut microbiome with response to anti-PD-1 blockade in patients with metastatic melanoma
Track 3	Potential benefit of targeted therapy in the adjuvant versus the metastatic setting	Track 16	Ongoing trials of immunotherapy combinations in patients with melanoma refractory to immune checkpoint inhibitors
Track 4	Choosing between dabrafenib/trametinib and nivolumab as adjuvant therapy for BRAF-mutant melanoma	Track 17	Case: A 72-year-old man with basal cell carcinoma (BCC) achieves a very good partial response to the hedgehog inhibitor vismodegib
Track 5	Therapeutic options for patients who experience disease progression on adjuvant treatment	Track 18	Efficacy and tolerability of the hedgehog inhibitors vismodegib and sonidegib
Track 6	Risk of disease relapse with adjuvant immunotherapy versus targeted therapy for patients with node-positive disease	Track 19	Monitoring and management of immune-related adverse events associated with immune checkpoint inhibitors
Track 7	Emerging data with checkpoint inhibitors added to BRAF/MEK inhibitor combinations for metastatic melanoma	Track 20	Case: A 37-year-old man with Stage IIIC resected melanoma discontinues adjuvant nivolumab after 9 months due to a stress fracture of the left tibial plateau
Track 8	Long-term survival rates for patients with metastatic melanoma after treatment with targeted agents or immunotherapy	Track 21	Role of chimeric antigen receptor T-cell therapy in melanoma
Track 9	Checkpoint inhibitor-associated immune-related adverse events	Track 22	Case: A 45-year-old man with recurrent BRAF wild-type Stage IV melanoma and scleroderma achieves a complete response to pembrolizumab after disease progression on multiple therapies
Track 10	Choice of nivolumab and ipilimumab versus either therapy alone for newly diagnosed BRAF wild-type metastatic melanoma	Track 23	Use of immune checkpoint inhibitors in patients with preexisting autoimmune diseases
Track 11	Role of PD-L1 expression as a predictive marker of response to immune checkpoint inhibitors		
Track 12	Biologic rationale for the addition of HDAC inhibitors to immunotherapy		
Track 13	Activity and tolerability of the IDO inhibitor epacadostat in combination		

Interview with Keith T Flaherty, MD

Tracks 1-23

Track 1	Effects of novel therapies on the long-term outcomes of patients with metastatic melanoma	Track 2	Survival of patients with metastatic melanoma who receive immunotherapy compared to targeted therapy
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Interview with Dr Flaherty (continued)

Track 3	Selection of targeted agents versus immunotherapy in the front-line setting for patients with BRAF mutation-positive melanoma	Track 13	Selection of first-line therapy for patients with BRAF-mutant metastatic melanoma
Track 4	Effect of PD-L1 expression on response to immune checkpoint inhibitors	Track 14	Ongoing trials of MEK inhibitors with or without anti-PD-1/PD-L1 antibodies in NRAS-mutated melanoma
Track 5	Comparison of the efficacy and safety of combination therapy versus monotherapy with immune checkpoint inhibitors	Track 15	Rationale for the investigation of immune checkpoint inhibitors in combination with MEK inhibitors
Track 6	Duration of immunotherapy and targeted therapies to achieve optimal clinical benefit	Track 16	Mechanism of action and activity of the cancer stemness inhibitor napabucasin
Track 7	Correlation between tumor mutational burden and response to immune checkpoint inhibitors	Track 17	Choice of vismodegib versus sonidegib for advanced BCC
Track 8	Activity and tolerability of BRAF/MEK inhibitors in combination with anti-PD-1/PD-L1 antibodies	Track 18	Dose modifications and treatment holidays to mitigate the side effects associated with hedgehog inhibitors
Track 9	Association between the gut microbiome and response to anti-PD-1 antibody-based therapy in metastatic melanoma	Track 19	Case: A 72-year-old woman who presents with a rapidly enlarging subcutaneous nodule on her right arm is diagnosed with Merkel cell carcinoma
Track 10	Effect of disease burden and type of response on outcomes of patients with metastatic melanoma	Track 20	Pathophysiology of Merkel cell carcinoma and rationale for the use of anti-PD-1/PD-L1 antibodies
Track 11	Potential implications of results of the COMBI-AD and CheckMate 238 trials for adjuvant decision-making for patients with resected Stage III/IV melanoma	Track 21	Incidence and clinical presentation of Merkel cell carcinoma
Track 12	Comparison of the mechanisms of action, activity and safety profiles of encorafenib/binimetinib, dabrafenib/trametinib and vemurafenib/cobimetinib for BRAF-mutant melanoma	Track 22	Neoadjuvant therapy for melanoma
		Track 23	Case: A 21-year-old woman with node-positive, BRAF V600E mutation-positive Stage III melanoma receives dabrafenib/trametinib after disease progression on talimogene laherparepvec and anti-PD-1/anti-CTLA-4 therapy

Interview with Adil Daud, MD

Tracks 1-17

Track 1	Incidence and spectrum of immune-related adverse events associated with immune checkpoint inhibitors	Track 4	Viewpoint on the use of immune checkpoint inhibitors or targeted therapy in the adjuvant setting
Track 2	Perspective on the utility of immune checkpoint inhibitors in patients with preexisting autoimmune diseases	Track 5	Hepatic and dermatologic side effects associated with immunotherapy
Track 3	Case: A 35-year-old man with Stage III melanoma and a history of Guillain-Barré syndrome develops diabetes after receiving adjuvant pembrolizumab	Track 6	Management of brain metastases in patients with melanoma
		Track 7	Approach to single-agent versus combination treatment with immune checkpoint inhibitors as first-line therapy for metastatic melanoma

Interview with Dr Daud (continued)

Track 8	Effect of the gut microflora on response to immunotherapy		(dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib)
Track 9	Emerging data with immunotherapy combinations in patients with melanoma	Track 14	Clinical outcomes for patients with metastatic uveal melanoma treated with anti-PD-1/PD-L1 antibodies
Track 10	Biology of Merkel cell carcinoma and implications for treatment with anti-PD-1/PD-L1 antibodies	Track 15	Targeting NRAS mutations with CDK4/6 inhibitors in patients with melanoma
Track 11	Benefits and risks of adjuvant nivolumab versus dabrafenib/trametinib for BRAF-mutated melanoma	Track 16	Case: A 58-year-old man with metastatic BCC experiences a good response to vismodegib but discontinues treatment due to dysgeusia
Track 12	Case: A 47-year-old man with previously treated BRAF mutation-positive metastatic melanoma receives vemurafenib/cobimetinib	Track 17	Incidence and management of KIT-mutated melanoma
Track 13	Indirect comparison of the activity and tolerability profiles of BRAF/MEK inhibitor combinations		

Interview with Jason J Luke, MD

Tracks 1-21

Track 1	Results of the Phase I/II ECHO-202/KEYNOTE-037 trial of the IDO inhibitor epacadostat in combination with pembrolizumab in advanced melanoma	Track 9	Risk factors, incidence and mortality rates of melanoma and nonmelanoma skin cancers
Track 2	Mechanism of action and safety-profile of epacadostat alone or in combination with an immune checkpoint inhibitor	Track 10	ONTRAC: Results of a Phase III trial of nicotinamide for nonmelanoma skin cancer chemoprevention
Track 3	Emerging role of LAG-3 and TIM-3 inhibition in immune checkpoint blockade strategies	Track 11	Pathophysiology of BCC
Track 4	ADVISE: A planned Phase I adaptive study to match patients with solid tumors to various immunotherapy combinations based on biomarker assessment	Track 12	Role of the hedgehog signaling pathway inhibitors in BCC
Track 5	Diagnostic comparison of CT scans and colonoscopy for immune-related colitis in patients with ipilimumab-treated advanced melanoma	Track 13	Side-effect profiles of hedgehog inhibitors
Track 6	Underlying pathobiology leading to immune-related adverse events in patients receiving immunotherapy	Track 14	Case: A 62-year-old man receives vismodegib for locally recurrent, unresectable BCC
Track 7	Activity of immune checkpoint inhibitors and targeted therapies in patients with advanced melanoma and brain metastases	Track 15	Vismodegib-associated side effects
Track 8	Role of radiation therapy in the treatment algorithm for patients with melanoma and brain metastases	Track 16	Epidemiology and biology of Merkel cell carcinoma
		Track 17	Management of Merkel cell carcinoma
		Track 18	Response to PD-1/PD-L1 blockade in Merkel cell carcinoma
		Track 19	Case: A 61-year-old man with metastatic Merkel cell carcinoma
		Track 20	Activity and tolerability of anti-PD-1/anti-CTLA-4 combination therapy for Merkel cell carcinoma
		Track 21	Epidemiology, etiology and therapeutic options for squamous cell carcinoma of the skin

QUESTIONS (PLEASE CIRCLE ANSWER):

- Which of the following is true regarding the Phase III COMBI-AD study evaluating adjuvant dabrafenib/trametinib compared to placebo for patients with Stage III melanoma and BRAF mutations?
 - The study enrolled patients with completely resected Stage III disease
 - The study failed to meet its primary endpoint of relapse-free survival
 - Fewer than 5% of patients discontinued treatment due to drug-related or treatment-related toxicity
- The Phase III CheckMate 238 study investigating adjuvant nivolumab versus ipilimumab for resected Stage III/IV melanoma demonstrated _____.
 - A significantly longer recurrence-free survival in favor of nivolumab
 - A lower rate of Grade 3/4 adverse events with ipilimumab
 - Both a and b
- Which of the following statements is true regarding Merkel cell carcinoma?
 - It progresses rapidly
 - It often metastasizes to the pancreas
 - Only the virus-associated form responds to anti-PD-1/PD-L1 antibodies
 - All of the above
 - Both a and b
- Patients with melanoma treated with the combination of vemurafenib/cobimetinib are more likely to experience _____ than those receiving the combination of dabrafenib/trametinib or encorafenib/binimetinib.
 - Palmar-plantar erythrodysesthesia
 - Photosensitivity
- The target of the monoclonal antibody relatlimab is _____.
 - PD-1
 - CTLA-4
 - LAG-3
- The Phase I/II ECHO-202/KEYNOTE-037 trial of epacadostat in combination with pembrolizumab for patients with advanced melanoma demonstrated _____.
 - An overall response rate of about 60%
 - Median progression-free survival of about 1 year
 - Both a and b
- The Phase III ONTRAC study demonstrated that the use of nicotinamide was effective in reducing the rates of which of the following skin cancers?
 - BCC
 - Melanoma
 - Squamous cell carcinoma
 - All of the above
 - Both a and c
 - Both b and c
- The hedgehog inhibitor sonidegib when used in the treatment of BCC _____.
 - Can cause changes in taste, muscle spasms and hair loss
 - Can achieve response after the reinitiation of therapy following a treatment holiday to mitigate toxicities
 - Is not as well tolerated as vismodegib
 - All of the above
 - Both a and b
 - Both a and c
- Patients with metastatic uveal melanoma typically have _____.
 - Durable responses to single-agent anti-PD-1/PD-L1 antibody therapy
 - Mutations in G proteins
 - Both a and b
- Squamous cell carcinoma of the skin is associated with long-term unprotected sun exposure, and metastasis to distant sites occurs only in a small percent of patients.
 - True
 - False

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PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
COMBI-AD: Results from a Phase III trial of adjuvant dabrafenib and trametinib for Stage III BRAF-mutated melanoma after surgical resection	4 3 2 1	4 3 2 1
CheckMate 238: Efficacy and safety of adjuvant nivolumab versus ipilimumab in resected Stage III/IV melanoma	4 3 2 1	4 3 2 1
Activity and tolerability of the IDO inhibitor epacadostat in combination with immune checkpoint inhibition for patients with advanced melanoma	4 3 2 1	4 3 2 1
Efficacy and side-effect profile of the hedgehog inhibitors vismodegib and sonidegib for advanced BCC	4 3 2 1	4 3 2 1

Practice Setting:

- Academic center/medical school Community cancer center/hospital Group practice
 Solo practice Government (eg, VA) Other (please specify).....

Approximately how many new patients with the following do you see per year?

Melanoma: BCC: Merkel cell carcinoma:

Was the activity evidence based, fair, balanced and free from commercial bias?

- Yes No

If no, please explain:

Please identify how you will change your practice as a result of completing this activity (select all that apply).

- This activity validated my current practice
 Create/revise protocols, policies and/or procedures
 Change the management and/or treatment of my patients
 Other (please explain):

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

- Yes No If no, please explain:

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Use biomarkers, clinical characteristics and mutational analyses to select individualized front-line and subsequent treatment approaches for patients with advanced melanoma. 4 3 2 1 N/M N/A
- Recall available clinical trial evidence to safely and effectively incorporate targeted and immunotherapeutic approaches into the management of metastatic BRAF mutation-positive melanoma. 4 3 2 1 N/M N/A
- Recognize immune-related adverse events associated with immune checkpoint inhibitors, and formulate strategies to minimize and/or manage these side effects. 4 3 2 1 N/M N/A
- Assess the rationale for and clinical trial data with anti-PD-1/PD-L1 antibodies for patients with Merkel cell carcinoma, and optimally integrate available agents into current treatment algorithms. 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Formulate a long-term clinical plan for the management of locally advanced or metastatic BCC incorporating existing and investigational treatments.4 3 2 1 N/M N/A
- Appraise new data with investigational agents and strategies demonstrating promising activity in melanoma and nonmelanoma skin cancer, and discuss ongoing trial opportunities with eligible patients.. . . .4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

.....

Would you recommend this activity to a colleague?

Yes No

If no, please explain:

PART 2 — Please tell us about the faculty and editor for this educational activity

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal				
Faculty	Knowledge of subject matter				Effectiveness as an educator			
Jeffrey Weber, MD, PhD	4	3	2	1	4	3	2	1
Keith T Flaherty, MD	4	3	2	1	4	3	2	1
Adil Daud, MD	4	3	2	1	4	3	2	1
Jason J Luke, MD	4	3	2	1	4	3	2	1
Editor	Knowledge of subject matter				Effectiveness as an educator			
Neil Love, MD	4	3	2	1	4	3	2	1

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Dermatologic Oncology™

U P D A T E

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