Dermatologic Oncology Update

Systemic Management of Malignant Melanoma and Basal Cell Carcinoma
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS
Adil Daud, MD
Mario Sznol, MD
Omid Hamid, MD
Kim Margolin, MD

EDITOR
Neil Love, MD

CONTENTS
2 Audio CDs
Dermatologic Oncology Update
A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY
Taken together, melanoma and nonmelanoma skin cancer — basal cell carcinoma (BCC) and cutaneous squamous cell cancer (SCC) — likely represent the most prevalent form of human cancer. Fortunately, the vast majority of skin cancer presents as minimally invasive BCC and SCC and, as such, 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, cutaneous melanoma is the most aggressive form of skin cancer, with a predilection toward distant metastases, even when identified in the early stages. Thus melanomas and nonmelanoma skin cancer 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.
• Counsel patients regarding the risk of BRAF inhibitor associated secondary nonmelanoma skin cancers and other adverse events, and implement appropriate surveillance and management strategies.
• Recognize immune-related adverse events associated with ipilimumab, and offer supportive management strategies to minimize and/or manage these side effects.
• Appraise the recent FDA-approved indication for pembrolizumab for patients with metastatic melanoma, and discuss how this information can be optimally integrated into clinical practice.
• Recognize the rationale for and clinical trial data with investigational anti-PD-1 and anti-PD-L1 antibodies for advanced melanoma.
• Identify patients with locally advanced or metastatic BCC for whom vismodegib may be an appropriate treatment consideration.

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This activity is supported by educational grants from Genentech BioOncology, Merck, Novartis Pharmaceuticals Corporation and Prometheus Laboratories Inc.

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Associate Chief, Medical Oncology
Yale Cancer Center
Smilow Cancer Hospital, Yale-New Haven Hospital
Yale University School of Medicine
New Haven, Connecticut

4 Omid Hamid, MD
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Director of Melanoma Program
The Angeles Clinic and Research Institute
Los Angeles, California

4 Kim Margolin, MD
Professor of Medicine
Co-Director, Pigmented Lesion and Melanoma Program
Stanford University Medical Center
Stanford Cancer Institute
Stanford, California

5 SELECT PUBLICATIONS

6 POST-TEST

7 EDUCATIONAL ASSESSMENT AND CREDIT FORM

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FACULTY — Dr Margolin had no real or apparent conflicts of interest to disclose. The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: Dr Daud — Advisory Committee: Amgen Inc, Genentech BioOncology, GlaxoSmithKline, OncoSec Medical; Consulting Agreements: Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, OncoSec Medical; Contracted Research: Bristol-Myers Squibb Company, Genentech BioOncology, GlaxoSmithKline, Merck, Novartis Pharmaceuticals Corporation, Pfizer Inc, Roche Laboratories Inc. Dr Sznol — Advisory Committee: Amphivena Therapeutics Inc, Anaeropharma Science Inc, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Genentech BioOncology, Immune Design, Kyowa Hakko Kirin Co Ltd, Lion Biotechnologies, Merus BV, Pfizer Inc, Seattle Genetics, Symphogen A/S; Consulting Agreements: Amphivena Therapeutics Inc, Anaeropharma Science Inc, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Genentech BioOncology, Immune Design, Kyowa Hakko Kirin Co Ltd, Lion Biotechnologies, Merck, Merus BV, Pfizer Inc, Seattle Genetics, Symphogen A/S. Dr Hamid — Advisory Committee: Amgen Inc, Bristol-Myers Squibb Company, Genentech BioOncology, Merck; Consulting Agreements: Bristol-Myers Squibb Company, Genentech BioOncology, Merck, Pfizer Inc; Contracted Research: Abbott Laboratories, Amgen Inc, Bristol-Myers Squibb Company, Celgene Corporation, Eisai Inc, EMD Serono Inc, Genentech BioOncology, GlaxoSmithKline, Lilly, MedImmune Inc, Merck, Millennium: The Takeda Oncology Company, Novartis Pharmaceuticals Corporation, Roche Laboratories Inc; Speakers Bureau: Bristol-Myers Squibb Company, Genentech BioOncology.

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Submit them to us via Facebook or Twitter and we will do our best to get them answered for you

Facebook.com/ResearchToPractice or Twitter @DrNeilLove
Interview with Adil Daud, MD

Tracks 1-13

Track 1  Rationale for dual targeting of BRAF and MEK in melanoma
Track 2  Tolerability and side effects of BRAF (dabrafenib, vemurafenib) and MEK inhibitor (cobimetinib, trametinib) combinations
Track 3  Incidence and management of MEK inhibitor-associated ophthalmic and cardiac toxicities
Track 4  Overview of efficacy and toxicity profiles of dabrafenib with or without trametinib and vemurafenib with or without cobimetinib
Track 5  Up-front treatment decision-making for patients with BRAF mutation-positive metastatic melanoma
Track 6  Sequencing of immunotherapeutic options for BRAF-mutant metastatic melanoma
Track 7  Mechanisms of resistance to BRAF inhibitors
Track 8  Management of brain metastases in patients with BRAF mutation-positive melanoma
Track 9  Key ongoing adjuvant clinical trials of BRAF/MEK inhibitors and immunotherapy

Interview with Mario Sznol, MD

Tracks 1-14

Track 1  Immune checkpoint blockade strategies — CTLA4 inhibition, anti-PD-1 and anti-PD-L1 antibodies
Track 2  Mechanisms of action of anti-PD-1 and anti-PD-L1 antibodies
Track 3  Activity and safety of the novel anti-PD-1 antibody nivolumab
Track 4  Efficacy of pembrolizumab in patients with ipilimumab-naïve and ipilimumab-treated advanced or unresectable melanoma
Track 5  Rapid antitumor responses observed with anti-PD-1 immunotherapy
Track 6  Activity and side effects of combined anti-CTLA4 and anti-PD-1 immunotherapy
Track 7  Sequence and selection of first-line therapy for patients with metastatic melanoma — Role of immunotherapy versus BRAF inhibition
Track 8  Ipilimumab-associated side effects
Track 9  Endocrinopathies in patients receiving ipilimumab for metastatic melanoma
Track 10  Radiographic pseudoprogression in melanoma treated with ipilimumab
Track 11  Ipilimumab-induced colitis
Track 12  Immunotherapeutic options in the adjuvant setting
Track 13  Spectrum of mutations in melanoma
Track 14  Oncogenic driver mutations and the use of targeted therapy
### Interview with Omid Hamid, MD

<table>
<thead>
<tr>
<th>Track</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Track 1</strong></td>
<td>Efficacy of the hedgehog inhibitor vismodegib in metastatic or locally advanced basal cell carcinoma (BCC) and ongoing investigation in the neoadjuvant setting</td>
</tr>
<tr>
<td><strong>Track 2</strong></td>
<td>Clinical experience with and management of vismodegib-associated dysgeusia and muscle cramping</td>
</tr>
<tr>
<td><strong>Track 3</strong></td>
<td>Consideration of treatment holidays for patients with locally advanced or metastatic BCC receiving vismodegib</td>
</tr>
<tr>
<td><strong>Track 4</strong></td>
<td>Additional hedgehog inhibitors currently in development for patients with advanced BCC</td>
</tr>
<tr>
<td><strong>Track 5</strong></td>
<td><strong>Case discussion:</strong> A 50-year-old patient with a history of multiple BCCs and metastatic disease in the lungs treated with vismodegib on the ERIVANCE trial</td>
</tr>
<tr>
<td><strong>Track 6</strong></td>
<td>Teratogenic effects of vismodegib</td>
</tr>
<tr>
<td><strong>Track 7</strong></td>
<td>Treatment of BRAF V600 mutation-positive melanoma with BRAF and MEK inhibitors</td>
</tr>
<tr>
<td><strong>Track 8</strong></td>
<td>Dual targeting of BRAF and MEK in melanoma</td>
</tr>
<tr>
<td><strong>Track 9</strong></td>
<td>Efficacy and toxicity profiles of the FDA-approved BRAF inhibitors vemurafenib and dabrafenib</td>
</tr>
<tr>
<td><strong>Track 10</strong></td>
<td>Perspective on combining BRAF inhibitor-associated photosensitivity and secondary squamous cell carcinomas</td>
</tr>
<tr>
<td><strong>Track 11</strong></td>
<td>Counseling patients about BRAF inhibitor-associated photosensitivity and secondary squamous cell carcinomas</td>
</tr>
<tr>
<td><strong>Track 12</strong></td>
<td>Available data with and ongoing evaluation of dual checkpoint inhibition in metastatic melanoma</td>
</tr>
<tr>
<td><strong>Track 13</strong></td>
<td>Choice of first-line therapy for BRAF mutation-positive metastatic melanoma</td>
</tr>
</tbody>
</table>

### Interview with Kim Margolin, MD

<table>
<thead>
<tr>
<th>Track</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Track 1</strong></td>
<td>Initial choice between immunotherapy and BRAF/MEK inhibitors in BRAF mutation-positive metastatic melanoma</td>
</tr>
<tr>
<td><strong>Track 2</strong></td>
<td>Perspective on the use of anti-PD-1 inhibitors and ipilimumab in sequence or in combination</td>
</tr>
<tr>
<td><strong>Track 3</strong></td>
<td>Anti-PD-L1 immunotherapy for advanced melanoma</td>
</tr>
<tr>
<td><strong>Track 4</strong></td>
<td>Management of side effects and toxicities associated with ipilimumab</td>
</tr>
<tr>
<td><strong>Track 5</strong></td>
<td>Use of ipilimumab in patients with a history of inflammatory bowel disease</td>
</tr>
<tr>
<td><strong>Track 6</strong></td>
<td>Treatment for patients with melanoma and brain metastases</td>
</tr>
<tr>
<td><strong>Track 7</strong></td>
<td>Activity of single-agent BRAF inhibitors versus immunotherapy as treatment for patients with BRAF mutation-positive melanoma and CNS metastases</td>
</tr>
<tr>
<td><strong>Track 8</strong></td>
<td>Dosing and administration of pembrolizumab</td>
</tr>
<tr>
<td><strong>Track 9</strong></td>
<td>Approach to re-treatment with ipilimumab after disease relapse</td>
</tr>
<tr>
<td><strong>Track 10</strong></td>
<td><strong>Case discussion:</strong> A 46-year-old patient with BRAF V600E mutation-positive melanoma and widespread metastases</td>
</tr>
<tr>
<td><strong>Track 11</strong></td>
<td>Results of the Phase III EORTC-18071 trial of adjuvant ipilimumab versus placebo in patients with Stage III melanoma</td>
</tr>
<tr>
<td><strong>Track 12</strong></td>
<td>Response to pembrolizumab followed by ipilimumab for metastatic melanoma</td>
</tr>
</tbody>
</table>
SELECT PUBLICATIONS


Chapman PB et al. Updated overall survival (OS) results for BRIM-3, a phase III randomized, open-label, multicenter trial comparing BRAF inhibitor vemurafenib (vem) with dacarbazine (DTIC) in previously untreated patients with BRAF\(^{V600E}\)–mutated melanoma. *Proc ASCO* 2012; Abstract 8502.


Eggermont AM et al. Ipilimumab versus placebo after complete resection of stage III melanoma: Initial efficacy and safety results from EORTC 18071 phase III trial. *Proc ASCO* 2014; Abstract LBA9008.


Migden MR et al. Randomized, double-blind study of sonidegib (LDE225) in patients (pts) with locally advanced (La) or metastatic (m) basal-cell carcinoma (BCC). *Proc ASCO* 2014; Abstract 9009a.

Puzansov I et al. Primary analysis of a phase 1b multicenter trial to evaluate safety and efficacy of talimogene laherparepvec (T-VEC) and ipilimumab (ipi) in previously untreated, unresected stage IIIIB–IV melanoma. *Proc ASCO* 2014; Abstract 9029.


Ribas A et al. Efficacy and safety of the anti-PD-1 monoclonal antibody MK-3475 in 411 patients (pts) with melanoma (MEL). *Proc ASCO* 2014; Abstract LBA9000.


Sznol M et al. Survival and long-term follow-up of safety and response in patients (pts) with advanced melanoma (MEL) in a phase I trial of nivolumab (anti-PD-1; BMS-936558; ONO-4538). *Proc ASCO* 2013; Abstract CRA9006.


**POST-TEST**

**Dermatologic Oncology Update — Issue 1, 2014**

**QUESTIONS (PLEASE CIRCLE ANSWER):**

1. Dabrafenib can lead to which of the following adverse events when used in the treatment of BRAF V600 mutation-positive melanoma?
   - a. Fever
   - b. Fatigue
   - c. Cutaneous squamous cell carcinomas
   - d. All of the above

2. The addition of the MEK inhibitor trametinib to the BRAF inhibitor dabrafenib seems to reduce the risk of squamous cell carcinomas.
   - a. True
   - b. False

3. What proportion of patients with BCC have a mutation in the hedgehog pathway, which is targeted by vismodegib?
   - a. 10%
   - b. 50%
   - c. 90%

4. In the Phase II ERIVANCE trial of vismodegib for patients with locally advanced or metastatic BCC, vismodegib was associated with which of the following side effects?
   - a. Alopecia
   - b. Dysgeusia
   - c. Muscle cramps
   - d. All of the above
   - e. None of the above

5. The 1-year overall survival rate for patients with advanced melanoma treated with the single-agent anti-PD-1 antibody pembrolizumab was in excess of 60%.
   - a. True
   - b. False

6. Approximately what proportion of patients receiving ipilimumab for advanced melanoma require steroids?
   - a. 10% to 15%
   - b. 30% to 40%
   - c. 50% to 60%

7. _________ is an anti-PD-1 antibody that was recently approved for the treatment of unresectable or metastatic melanoma with disease progression after ipilimumab and is a BRAF inhibitor in BRAF V600E mutation-positive disease.
   - a. Pembrolizumab
   - b. Lambrolizumab
   - c. Ipilimumab

8. Which of the following mutations is responsive to BRAF inhibitors?
   - a. BRAF V600E
   - b. BRAF V600K
   - c. BRAF V600D
   - d. All of the above

9. Which of the following agents and/or combination regimens is associated with febrile episodes?
   - a. Vemurafenib with or without cobimetinib
   - b. Dabrafenib with or without trametinib
   - c. Neither a nor b
   - d. Both a and b

10. Side effects and toxicities associated with the use of MEK inhibitor therapy include _________.
    - a. Ophthalmic toxicity
    - b. Cardiac toxicity
    - c. Both a and b
**EDUCATIONAL ASSESSMENT AND CREDIT FORM**

**Dermatologic Oncology Update — Issue 1, 2014**

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

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

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

<table>
<thead>
<tr>
<th>Topic</th>
<th>BEFORE</th>
<th>AFTER</th>
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<tbody>
<tr>
<td>Rationale for dual targeting of BRAF and MEK signaling in melanoma</td>
<td>4 3 2 1</td>
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<tr>
<td>Management of MEK inhibitor-associated ophthalmic and cardiac toxicities</td>
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<td>4 3 2 1</td>
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<tr>
<td>Management of ipilimumab-associated autoimmune side effects</td>
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<td>Recent FDA approval of pembrolizumab for the treatment of advanced melanoma</td>
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<td>Dysgeusia, alopecia and muscle cramps associated with vismodegib</td>
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<td>4 3 2 1</td>
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<tr>
<td>Patient selection for immunotherapy versus BRAF/MEK inhibitors as first-line treatment for BRAF mutation-positive melanoma</td>
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</table>

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 dermatologic cancer do you see per year? ........... patients

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:

不但。该内容匹配了我当前（或潜在）的实践范围。
- [ ] Yes
- [ ] No

If no, please explain: ...........................................................................................................................

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

<table>
<thead>
<tr>
<th>LO</th>
<th>4 = Yes</th>
<th>3 = Will consider</th>
<th>2 = No</th>
<th>1 = Already doing</th>
<th>N/M = LO not met</th>
<th>N/A = Not applicable</th>
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<tr>
<td>Use biomarkers, clinical characteristics and mutational analyses to select individualized front-line and subsequent treatment approaches for patients with advanced melanoma.</td>
<td>4 3 2 1</td>
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<td>Counsel patients regarding the risk of BRAF inhibitor-associated secondary nonmelanoma skin cancers and other adverse events, and implement appropriate surveillance and management strategies.</td>
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<td>N/M</td>
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<td>Recall existing and emerging research information demonstrating the impact of combining BRAF and MEK inhibitors for patients with BRAF mutation-positive metastatic melanoma, and use this information to guide treatment planning for these patients.</td>
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<td>Recognize immune-related adverse events associated with ipilimumab, and offer supportive management strategies to minimize and/or manage these side effects.</td>
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<td>N/M</td>
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<td>Appreciate the recent FDA-approved indication for pembrolizumab for patients with metastatic melanoma, and discern how this agent can be optimally integrated into clinical practice.</td>
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<td>N/M</td>
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EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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:

Additional comments about this activity:

As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

☐ Yes, I am willing to participate in a follow-up survey.

☐ No, I am not willing to participate in a follow-up survey.

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

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Knowledge of subject matter</th>
<th>Effectiveness as an educator</th>
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<tbody>
<tr>
<td>Adil Daud, MD</td>
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<tr>
<td>Neil Love, MD</td>
<td>4 3 2 1</td>
<td>4 3 2 1</td>
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</tbody>
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Please recommend additional faculty for future activities:

Other comments about the faculty and editor for this activity:

REQUEST FOR CREDIT — Please print clearly

Name: .................................................. Specialty: .................................. Professional Designation:

☐ MD  ☐ DO  ☐ PharmD  ☐ NP  ☐ RN  ☐ PA  ☐ Other ..................................

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Signature: .................................................. Date: ..................................

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