Head and Neck Cancer Update
A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY
Approximately 53,640 new cases of head and neck cancer are estimated to occur in the United States during 2013, and more than 11,000 patients will die from the disease. The most common sites of this condition, which is predominantly of squamous cell origin, include the oral cavity, pharynx and larynx. Accounting for 3% of all new cancers, head and neck cancers represent a group of tumors largely arising from identifiable and preventable environmental carcinogens, including smoking and alcohol use.

Treatment for patients with head and neck cancer is complex and requires a multidisciplinary team of individuals with expertise in the special care needs of these patients. The site and extent of disease and pathologic findings dictate the appropriate surgical approach, radiation field, dose and fractionation and indications for chemotherapy and/or biologic therapy. Published results from ongoing clinical trials lead to the continuous emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care — including the option of clinical trial participation — practicing medical oncologists and radiation oncologists must be well informed of these advances. To bridge the gap between research and patient care, Head and Neck Cancer Update features one-on-one discussions with leading oncology investigators. By providing access to the latest research developments and expert perspectives, this CME program assists physicians with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES
• Counsel patients with HPV-positive squamous cell carcinoma of the head and neck (SCCHN) about the contribution of the virus to the etiology and prognosis of their disease, and use this information and other relevant clinical factors to guide treatment decision-making.
• Identify patients with SCCHN who may be appropriate candidates for induction chemotherapy prior to chemoradiation therapy, and counsel these individuals accordingly regarding the risks and benefits of this approach.
• Formulate an evidence-based approach to the use of chemoradiation therapy alone or in combination with EGFR monoclonal antibody therapy for patients with locally advanced SCCHN.
• Develop evidence-based multimodality treatment approaches for patients with recurrent or metastatic SCCHN whose disease has progressed following platinum-based treatment.
• Evaluate novel surgical approaches (eg, transoral robotic surgery) for patients with oropharyngeal SCC previously considered to be unresectable, and refer appropriate cases for consultation with an experienced thoracic surgeon.
• Recall the efficacy and tolerability of promising investigational VEGFR and EGFR inhibitors being evaluated in SCCHN.
• Counsel appropriately selected patients about participation in ongoing clinical trials.

ACCREDITATION STATEMENT
Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT
Research To Practice designates this enduring material for a maximum of 2.75 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

HOW TO USE THIS CME ACTIVITY
This CME activity contains an audio component. To receive credit, the participant should review the CME information, listen to the CDs, complete the Post-test with a score of 70% or better and fill out the Educational Assessment and Credit Form located in the back of this booklet or on our website at ResearchToPractice.com/HNCU113/CME.

This activity is supported by educational grants from Boehringer Ingelheim Pharmaceuticals Inc and Lilly USA LLC.

Last review date: April 2013; Release date: April 2013; Expiration date: April 2014
## FACULTY INTERVIEWS

<table>
<thead>
<tr>
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<th>Name</th>
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<tbody>
<tr>
<td>3</td>
<td>Marshall Posner, MD</td>
<td>Director, Head and Neck Medical Oncology, Professor of Medicine, The Tisch Cancer Institute, Division of Hematology/Medical Oncology, Mount Sinai School of Medicine, New York, New York</td>
</tr>
<tr>
<td>3</td>
<td>Barbara Burtness, MD</td>
<td>Associate Director for Clinical Research, Professor of Medical Oncology, Chief of Head and Neck Oncology, Co-Leader, Developmental Therapeutics Program, Fox Chase Cancer Center, Chair, ECOG Head and Neck Committee, Philadelphia, Pennsylvania</td>
</tr>
<tr>
<td>4</td>
<td>Robert Haddad, MD</td>
<td>Disease Center Leader, Center for Head and Neck Oncology, Dana Farber Cancer Institute, Associate Professor of Medicine, Harvard Medical School, Boston, Massachusetts</td>
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<tr>
<td>4</td>
<td>Ezra EW Cohen, MD</td>
<td>Associate Professor, Section of Hematology/Oncology, Department of Medicine, Co-Director, Head and Neck Cancer Program, Director, Hematology/Oncology Fellowship Program, Associate Director for Education, University of Chicago Comprehensive Cancer Center, Editor-in-Chief, Oral Oncology, Chicago, Illinois</td>
</tr>
</tbody>
</table>

## SELECT PUBLICATIONS

## POST-TEST

## EDUCATIONAL ASSESSMENT AND CREDIT FORM

This educational activity contains discussion of published and/or investigational uses of agents that are not indicated by the Food and Drug Administration. Research To Practice does not recommend the use of any agent outside of the labeled indications. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications and warnings. The opinions expressed are those of the presenters and are not to be construed as those of the publisher or grantors.

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FACULTY — Dr Haddad had no real or apparent conflicts of interest to report. 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 Posner — Advisory Committee: Novartis Pharmaceuticals Corporation; Data and Safety Monitoring Board: Eisai Inc; Paid Research: Lilly USA LLC. Dr Burtness — Advisory Committee: Bristol-Myers Squibb Company; Contracted Research: Boehringer Ingelheim Pharmaceuticals Inc, Genentech BioOncology, Novartis Pharmaceuticals Corporation. Dr Cohen — Advisory Committee: Lilly USA LLC; Consulting Agreements: Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company.

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Have Questions or Cases You Would Like Us to Pose to the Faculty?

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
### Marshall Posner, MD

**Tracks 1-17**

| 1 | Prognosis and treatment of human papillomavirus (HPV)-related head and neck (H&N) cancer |
| 2 | **Case discussion:** A 72-year-old asymptomatic never smoker with Stage III, p16-positive, HPV-positive squamous cell carcinoma of the head and neck (SCCHN) |
| 3 | Prognoses for HPV-positive and HPV-negative Stage III SCCHN |
| 4 | Potential benefit with induction chemotherapy in HPV-negative SCCHN |
| 5 | Targeting EGFR in SCCHN |
| 6 | Phase III study of postoperative chemoradiation therapy followed by the second-generation, oral EGFR tyrosine kinase inhibitor (TKI) afatinib in SCCHN |
| 7 | Reducing the dose of radiation therapy (RT) in the treatment of HPV-positive SCCHN |
| 8 | Challenges in studying interventions to reduce chemoradiation therapy (CRT)-induced mucositis |
| 9 | **Case discussion:** A 57-year-old former smoker with dysarthria and dysphagia is diagnosed with Stage IVa, p16-negative, HPV-negative SCCHN and achieves a very good partial response to docetaxel/cisplatin/5-fluorouracil (TPF) |
| 10 | Carboplatin/paclitaxel/cetuximab in combination with RT in patients who do not achieve a complete response to initial TPF therapy |
| 11 | Use of panitumumab for patients with SCCHN who have experienced an allergic reaction to cetuximab |
| 12 | Long-term adverse effects of RT in SCCHN |
| 13 | Therapeutic options for patients whose disease relapses after TPF in combination with RT |
| 14 | Potential synergy of cetuximab and JAK inhibitors in SCCHN |
| 15 | **Case discussion:** A 52-year-old nonsmoker with an HPV-positive oropharyngeal squamous cell carcinoma at the base of the tongue |
| 16 | Quarterback: A Phase III study comparing reduced-dose RT with carboplatin/cetuximab to standard-dose RT with carboplatin for locally advanced HPV16-positive oropharyngeal squamous cell carcinoma |
| 17 | RTOG-1216: Phase II/III study of postoperative RT with concurrent cisplatin versus docetaxel versus docetaxel and cetuximab for high-risk SCCHN |

### Barbara Burtness, MD

**Tracks 1-16**

| 1 | Subset analysis of the Phase III EXTREME trial: Efficacy of cisplatin/5-FU and cetuximab in HPV-positive and HPV-negative recurrent and/or metastatic SCCHN |
| 2 | LUX-Head&Neck 2: A Phase III trial of adjuvant afatinib following CRT for patients with unresected Stage III, IVa or IVb locoregionally advanced SCCHN |
| 3 | Activity of the irreversible EGFR TKI afatinib and the EGFR monoclonal antibodies cetuximab and panitumumab in SCCHN |
| 4 | Management of blepharitis, corneal abrasions and dermatologic toxicities related to long-term cetuximab therapy |
| 5 | Rationale for the effectiveness of dual EGFR inhibition — cetuximab in combination with erlotinib or gefitinib — in SCCHN |
| 6 | Potential mechanisms of resistance to cetuximab |
| 7 | A Phase III study of chemotherapy with or without bevacizumab for recurrent or metastatic H&N cancer |
| 8 | Bevacizumab and erlotinib with CRT for SCCHN |
| 9 | Percutaneous endoscopic gastrostomy tubing for patients receiving CRT for H&N cancer |
| 10 | Role of neck dissection after CRT in patients with residual lymphadenopathy |
| 11 | Treatment of CRT-induced mucositis |
| 12 | Advantages of intensity-modulated RT versus conventional RT |
| 13 | Up-front treatment modality for a patient with locally advanced, unresectable SCCHN |
| 14 | Frequently asked questions about the treatment of H&N cancer |
| 15 | Transoral robotic surgery for oropharyngeal cancer |
| 16 | Perspective on the results of the DeCIDE and PARADIGM trials evaluating induction chemotherapy followed by CRT in locally advanced SCCHN |
Available evidence comparing sequential versus concurrent CRT in SCCHN

Implications of the Phase III PARADIGM study results comparing sequential therapy to concurrent CRT in locally advanced H&N cancer

Implications of the Phase III DeCIDE trial of TPF induction chemotherapy for patients with N2/N3 locally advanced SCCHN

Selection of appropriate patients for induction TPF chemotherapy in SCCHN

Relationship between HPV status, smoking and SCCHN

Sexual activity and the increasing incidence of HPV-related SCCHN

Overcoming resistance to EGFR inhibitors in SCCHN

LUX-Head&Neck 1: An ongoing Phase III trial of afatinib versus methotrexate for patients with recurrent/metastatic SCCHN whose disease progressed after platinum-based therapy

Case discussion: A 45-year-old smoker with newly diagnosed squamous cell carcinoma of the right lateral tongue and ipsilateral neck adenopathy remains in remission after surgery and concurrent CRT

Case discussion: A 50-year-old man with a Stage Iva, HPV-positive oropharyngeal squamous cell carcinoma

Case discussion: A 59-year-old man who underwent CRT 3 years ago for laryngeal cancer presents with asymptomatic lung metastases

Investigation of anti-PD1 immune therapy in HPV-related solid tumors

Initial primary management of locally advanced laryngeal cancer

Weekly cisplatin or carboplatin as alternatives to bolus cisplatin

Principal investigator’s perspective on the results of the DeCIDE trial of TPF induction chemotherapy in locally advanced SCCHN

Impact of HPV status on outcomes in the DeCIDE trial

Current role of induction chemotherapy in SCCHN

Available data with and ongoing investigation of the addition of cetuximab to CRT in H&N cancer

Phase III SPECTRUM trial: Panitumumab in HPV-positive and HPV-negative recurrent/metastatic SCCHN

Prognostic significance of HPV positivity in H&N cancer

Cetuximab-based treatment in SCCHN and management of dermatologic toxicities

Mechanism of action and ongoing evaluation of afatinib for locally advanced and metastatic SCCHN

Rationale for the ongoing Phase III ECOG-E1305 trial of chemotherapy with or without bevacizumab for patients with recurrent or metastatic H&N cancer

Results from the Phase III EXAM trial of cabozantinib for patients with medullary thyroid cancer and documented RECIST progression

Efficacy of the newly FDA-approved agent vandetanib for patients with locally advanced or metastatic medullary thyroid cancer

Mechanisms of action and responses with cabozantinib and vandetanib in medullary thyroid cancer

Side effects and tolerability of cabozantinib and vandetanib

Frequently asked questions by medical oncologists about the treatment of H&N cancer

Transoral robotic surgery for advanced oropharyngeal cancer

Off-protocol management of T2N2B SCCHN

Counseling spouses of patients with HPV-positive H&N cancer

Performance and quality-of-life outcomes for patients with T4N1 laryngeal cancer treated with induction chemotherapy followed by CRT

Perspective on the efficacy of cisplatin/5-FU and cetuximab (EXTREME trial regimen) in recurrent or metastatic SCCHN
SELECT PUBLICATIONS

A Phase III randomized trial of chemotherapy with or without bevacizumab in patients with recurrent or metastatic head and neck cancer. NCI00588770
Ang KK et al. A randomized phase III trial (RTOG 0522) of concurrent accelerated radiation plus cisplatin with or without cetuximab for stage III-IV head and neck squamous cell carcinomas (HNC). Proc ASCO 2011;Abstract 5500.


Haddad R et al. The PARADIGM trial: A phase III study comparing sequential therapy (ST) to concurrent chemoradiotherapy (CRT) in locally advanced head and neck cancer (LAHNC). Proc ASCO 2012;Abstract 5501.


Machiels JH et al. LUX-H&N 1: A phase III, randomized trial of afatinib versus methotrexate (MTX) in patients (pts) with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) who progressed after platinum-based therapy. Proc ASCO 2012;Abstract TPS5598.


Psyrri A et al. Safety and efficacy of cisplatin plus 5-FU and cetuximab in HPV-positive and HPV-negative recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN): Analysis of the phase III EXTREME trial. Proc ESMO 2012;Abstract 1018O.


Schoffski P et al. An international, double-blind, randomized, placebo-controlled phase III trial (EXAM) of cabozantinib (XL184) in medullary thyroid carcinoma (MTC) patients (pts) with documented RECIST progression at baseline. Proc ASCO 2012;Abstract 5508.

Stoechlmacher-Williams J et al. Safety and efficacy of panitumumab (pmab) in HPV-positive (+) and HPV-negative (-) recurrent/metastatic squamous cell carcinoma of the head and neck (R/M SCCHN): Analysis of the global phase III SPECTRUM trial. Proc ASCO 2012;Abstract 5504.

Vermorken JB et al. Safety and efficacy of panitumumab in HPV positive and HPV negative recurrent/metastatic squamous cell carcinoma of the head and neck: Analysis of the phase 3 SPECTRUM trial. Proc European Multidisciplinary Cancer Congress 2011;Abstract 25LBA.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. HPV infection is associated with cancer of the _______.
   a. Hypopharynx
   b. Larynx
   c. Oropharynx
   d. Nasopharynx
   e. All of the above

2. The prognosis of patients with HPV-positive oropharyngeal cancer is better than that for patients with HPV-negative oropharyngeal cancer.
   a. True
   b. False

3. On the Phase III PARADIGM trial, which compared sequential therapy to concurrent CRT in locally advanced H&N cancer but reported no survival differences between arms, the authors attributed these findings to which of the following?
   a. The study was underpowered
   b. Some selection bias existed among the patient population
   c. A lack of prospective stratification existed between HPV-positive and HPV-negative disease for patients with oropharyngeal cancer
   d. All of the above

4. The Phase III DeCIDE trial, which randomly assigned patients with N2/N3 locally advanced SCCHN to CRT alone or RT followed by TPF induction chemotherapy, reported statistically significant improvement(s) in for patients receiving induction chemotherapy.
   a. Overall survival
   b. Relapse-free survival
   c. Cumulative incidence of distant failure
   d. All of the above

5. In the EXTREME study, patients with previously untreated recurrent or metastatic H&N cancer who received a 3-drug combination of _______ had a better overall survival than those who received a 2-drug combination.
   a. Docetaxel/platinum/5-FU
   b. Cetuximab/platinum/5-FU
   c. Both a and b
   d. Neither a nor b

6. The ongoing Phase III LUX-Head&Neck 1 trial is evaluating _______ versus methotrexate for patients with recurrent/metastatic SCCHN whose disease progressed after platinum-based therapy.
   a. Afatinib
   b. Erlotinib
   c. Gefitinib
   d. All of the above

7. Authors of the Phase III SPECTRUM trial that evaluated panitumumab for recurrent or metastatic SCCHN reported improved overall and progression-free survival in which of the following patient populations?
   a. Those with HPV-negative disease
   b. Those with HPV-positive disease
   c. Both a and b
   d. Neither a nor b

8. The ongoing Phase III ECOG-E1305 trial is evaluating chemotherapy with or without _______ for patients with recurrent or metastatic H&N cancer.
   a. Afatinib
   b. Bevacizumab
   c. Cetuximab
   d. Erlotinib
   e. Panitumumab
**EDUCATIONAL ASSESSMENT AND CREDIT FORM**

*Head and Neck Cancer Update — Issue 1, 2013*

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>4 = Excellent</th>
<th>3 = Good</th>
<th>2 = Adequate</th>
<th>1 = Suboptimal</th>
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<td><strong>BEFORE</strong></td>
<td><strong>AFTER</strong></td>
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- Role of HPV in the etiology of oropharyngeal cancer and its impact on prognosis and response to treatment
  - 4 3 2 1
- Results and limitations from recent Phase III trials — DeCIDE and PARADIGM — evaluating induction chemotherapy prior to CRT
  - 4 3 2 1
- Ongoing Phase III studies of the irreversible EGFR TKI afatinib in locoregionally advanced (LUX-Head&Neck 2) or recurrent/metastatic (LUX-Head&Neck 1) SCCHN
  - 4 3 2 1
- Transoral robotic surgery for advanced oropharyngeal cancer
  - 4 3 2 1
- Phase III EXTREME trial results with cisplatin/5-FU and cetuximab in HPV-positive and negative recurrent and/or metastatic SCCHN
  - 4 3 2 1
- Management of blepharitis, corneal abrasions and dermatologic toxicities related to long-term cetuximab therapy
  - 4 3 2 1

**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:**

<table>
<thead>
<tr>
<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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</thead>
</table>

**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:**

- As a result of this activity, I will be able to:
  - Counsel patients with HPV-positive squamous cell carcinoma of the head and neck (SCCHN) about the contribution of the virus to the etiology and prognosis of their disease, and use this information and other relevant clinical factors to guide treatment decision-making. ................................................................. 4 3 2 1 N/M N/A
  - Identify patients with SCCHN who may be appropriate candidates for induction chemotherapy prior to chemoradiation therapy, and counsel these individuals accordingly regarding the risks and benefits of this approach. ................................................................. 4 3 2 1 N/M N/A
  - Formulate an evidence-based approach to the use of chemoradiation therapy alone or in combination with EGFR monoclonal antibody therapy for patients with locally advanced SCCHN. ................................................................. 4 3 2 1 N/M N/A
  - Develop evidence-based multimodality treatment approaches for patients with recurrent or metastatic SCCHN whose disease has progressed following platinum-based treatment. ................................................................. 4 3 2 1 N/M N/A
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  - Recall the efficacy and tolerability of promising investigational VEGFR and EGFR inhibitors being evaluated in SCCHN. ................................................................. 4 3 2 1 N/M N/A
  - Counsel appropriately selected patients about participation in ongoing clinical trials. ................................................................. 4 3 2 1 N/M N/A
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>Marshall Posner, MD</td>
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Editor

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</table>

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

Street Address: ..........................................................  Box/Suite: ........................................

City, State, Zip: ..........................................................

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Email: ..........................................................

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I certify my actual time spent to complete this educational activity to be _________ hour(s).

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

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