

# Head & Neck Cancer™

U P D A T E

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

**FACULTY INTERVIEWS**

Marshall Posner, MD  
Barbara Burtness, MD  
Robert Haddad, MD  
Ezra EW Cohen, MD

**EDITOR**

Neil Love, MD

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2 Audio CDs



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## *Head and Neck Cancer Update*

### A Continuing Medical Education Audio Series

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#### 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.

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

FACULTY INTERVIEWS



**3 Marshall Posner, MD**  
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



**3 Barbara Burtness, MD**  
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



**4 Robert Haddad, MD**  
Disease Center Leader  
Center for Head and Neck Oncology  
Dana Farber Cancer Institute  
Associate Professor of Medicine  
Harvard Medical School  
Boston, Massachusetts



**4 Ezra EW Cohen, MD**  
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

**5 SELECT PUBLICATIONS**

**6 POST-TEST**

**7 EDUCATIONAL ASSESSMENT AND CREDIT FORM**

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## EDITOR



**Neil Love, MD**  
Research To Practice  
Miami, Florida

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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 III/III study of postoperative RT with concurrent cisplatin versus docetaxel versus docetaxel and cetuximab for high-risk SCCHN

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

Tracks 1-14

- 1 Available evidence comparing sequential versus concurrent CRT in SCCHN
- 2 Implications of the Phase III PARADIGM study results comparing sequential therapy to concurrent CRT in locally advanced H&N cancer
- 3 Implications of the Phase III DeCIDE trial of TPF induction chemotherapy for patients with N2/N3 locally advanced SCCHN
- 4 Selection of appropriate patients for induction TPF chemotherapy in SCCHN
- 5 Relationship between HPV status, smoking and SCCHN
- 6 Sexual activity and the increasing incidence of HPV-related SCCHN
- 7 Overcoming resistance to EGFR inhibitors in SCCHN
- 8 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
- 9 **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
- 10 **Case discussion:** A 50-year-old man with a Stage IVa, HPV-positive oropharyngeal squamous cell carcinoma
- 11 **Case discussion:** A 59-year-old man who underwent CRT 3 years ago for laryngeal cancer presents with asymptomatic lung metastases
- 12 Investigation of anti-PD1 immune therapy in HPV-related solid tumors
- 13 Initial primary management of locally advanced laryngeal cancer
- 14 Weekly cisplatin or carboplatin as alternatives to bolus cisplatin

Tracks 1-19

- 1 Principal investigator's perspective on the results of the DeCIDE trial of TPF induction chemotherapy in locally advanced SCCHN
- 2 Impact of HPV status on outcomes in the DeCIDE trial
- 3 Current role of induction chemotherapy in SCCHN
- 4 Available data with and ongoing investigation of the addition of cetuximab to CRT in H&N cancer
- 5 Phase III SPECTRUM trial: Panitumumab in HPV-positive and HPV-negative recurrent/metastatic SCCHN
- 6 Prognostic significance of HPV positivity in H&N cancer
- 7 Cetuximab-based treatment in SCCHN and management of dermatologic toxicities
- 8 Mechanism of action and ongoing evaluation of afatinib for locally advanced and metastatic SCCHN
- 9 Rationale for the ongoing Phase III ECOG-E1305 trial of chemotherapy with or without bevacizumab for patients with recurrent or metastatic H&N cancer
- 10 Results from the Phase III EXAM trial of cabozantinib for patients with medullary thyroid cancer and documented RECIST progression
- 11 Efficacy of the newly FDA-approved agent vandetanib for patients with locally advanced or metastatic medullary thyroid cancer
- 12 Mechanisms of action and responses with cabozantinib and vandetanib in medullary thyroid cancer
- 13 Side effects and tolerability of cabozantinib and vandetanib
- 14 Frequently asked questions by medical oncologists about the treatment of H&N cancer
- 15 Transoral robotic surgery for advanced oropharyngeal cancer
- 16 Off-protocol management of T2N2B SCCHN
- 17 Counseling spouses of patients with HPV-positive H&N cancer
- 18 Performance and quality-of-life outcomes for patients with T4N1 laryngeal cancer treated with induction chemotherapy followed by CRT
- 19 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.**

Bonner JA et al. **Radiotherapy plus cetuximab for squamous-cell carcinoma of the head and neck.** *N Engl J Med* 2006;354(6):567-78.

Burtneß B et al. **LUX Head and Neck 2: A randomized, double-blind, placebo-controlled, phase III study of afatinib as adjuvant therapy after chemoradiation in primarily unresected, clinically high-risk, head and neck cancer patients.** *Proc ASCO* 2012;**Abstract TPS5599.**

Burtneß B. **Commentary: Bevacizumab and erlotinib with chemoradiation for head and neck cancer.** *Cancer J* 2011;17(5):273-5.

Chung CH, Schwartz DL. **Impact of HPV-related head and neck cancer in clinical trials: Opportunity to translate scientific insight into personalized care.** *Otolaryngol Clin North Am* 2012;45(4):795-806.

Cohen EEW et al. **DeCIDE: A phase III randomized trial of docetaxel (D), cisplatin (P), 5-fluorouracil (F) (TPF) induction chemotherapy (IC) in patients with N2/N3 locally advanced squamous cell carcinoma of the head and neck (SCCHN).** *Proc ASCO* 2012;**Abstract 5500.**

D'Souza G et al. **Case-control study of human papillomavirus and oropharyngeal cancer.** *N Engl J Med* 2007;356(19):1944-56.

Haddad RI 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.**

Hainsworth JD et al. **Combined modality treatment with chemotherapy, radiation therapy, bevacizumab, and erlotinib in patients with locally advanced squamous carcinoma of the head and neck: A phase II trial of the Sarah Cannon oncology research consortium.** *Cancer J* 2011;17(5):267-72.

Joseph AW, D'Souza G. **Epidemiology of human papillomavirus-related head and neck cancer.** *Otolaryngol Clin North Am* 2012;45(4):739-64.

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.**

Martins R et al. **Randomized phase II trial of cisplatin and radiotherapy with or without erlotinib in patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).** *Proc ASCO* 2012;**Abstract 5503.**

Mouw KW et al. **Performance and quality of life outcomes for T4 laryngeal cancer patients treated with induction chemotherapy followed by chemoradiotherapy.** *Oral Oncol* 2012;48(10):1025-30.

Psyrris 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 10180.**

Rabinowitz G, Haddad RI. **Overcoming resistance to EGFR inhibitor in head and neck cancer: A review of the literature.** *Oral Oncol* 2012;48(11):1085-9.

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.**

Stoehlmacher-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.**

Wells SA Jr et al. **Vandetanib in patients with locally advanced or metastatic medullary thyroid cancer: A randomized, double-blind phase III trial.** *J Clin Oncol* 2012;30(2):134-41.

## 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



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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

	<b>BEFORE</b>	<b>AFTER</b>
Role of HPV in the etiology of oropharyngeal cancer and its impact on prognosis and response to treatment	4 3 2 1	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	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	4 3 2 1
Transoral robotic surgery for advanced oropharyngeal cancer	4 3 2 1	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	4 3 2 1
Management of blepharitis, corneal abrasions and dermatologic toxicities related to long-term cetuximab therapy	4 3 2 1	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:**

**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:**

- 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
- 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. .... 4 3 2 1 N/M N/A
- 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:

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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**

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

Faculty	Knowledge of subject matter				Effectiveness as an educator			
Marshall Posner, MD	4	3	2	1	4	3	2	1
Barbara Burtness, MD	4	3	2	1	4	3	2	1
Robert Haddad, MD	4	3	2	1	4	3	2	1
Ezra EW Cohen, 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

Please recommend additional faculty for future activities:

Other comments about the faculty and editor for this activity:

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

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# Head & Neck Cancer™

U P D A T E

Neil Love, MD  
Research To Practice  
One Biscayne Tower  
2 South Biscayne Boulevard, Suite 3600  
Miami, FL 33131

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