

# Head & Neck Cancer™

U P D A T E

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

**FACULTY INTERVIEWS**

Robert I Haddad, MD

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Neil Love, MD



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# Head & Neck Cancer™

U P D A T E

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### OVERVIEW OF ACTIVITY

Head and neck cancers account for approximately 3% of all cancers in the United States. Treatment for patients with head and neck cancer is complex and requires a multidisciplinary team of individuals with specialized expertise. Thyroid cancer is one of the most rapidly increasing cancers in the United States with an estimated 56,870 new cases expected to be diagnosed in 2017. Most patients with thyroid cancer can be cured with local treatments and radioactive iodine. Medical oncology intervention typically only occurs for those patients with progressive metastatic disease.

Published results from ongoing trials lead to the continuing 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 — the practicing medical oncologist must be well informed of these advances. This program uses one-on-one discussion with leading oncology investigators about treatment controversies and the integration of key data sets into the practical management of cancers of the head, neck and thyroid.

### 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 consider this information as part of protocol and nonresearch treatment planning.
- Appreciate available safety and efficacy data with the use of cetuximab alone or in combination with other local or systemic therapies, and appropriately integrate this agent into the management of locally advanced, recurrent or metastatic SCCHN.
- Appraise the rationale for and clinical data with investigational anti-PD-1/PD-L1 antibodies in patients with SCCHN, and use this information to counsel appropriate individuals regarding clinical trial opportunities or expanded access programs with these agents.
- Communicate the benefits and risks of approved targeted biologic therapies to patients with metastatic thyroid cancer (TC), and develop an evidence-based algorithm to sequence available options based on disease- and patient-specific characteristics.
- Appreciate the recent FDA approval of lenvatinib for metastatic differentiated TC, and discern how this agent can be optimally integrated into clinical practice.
- Recognize the roles of cabozantinib and vandetanib in the management of metastatic medullary TC, and ensure appropriate supportive care measures to minimize the side effects associated with these agents.

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Tracks 1-22

- Track 1** **Case discussion:** A 55-year-old man with squamous cell carcinoma of the tongue with extracapsular extension undergoes glossectomy and neck dissection followed by concurrent cisplatin and radiation therapy
- Track 2** Effect of primary tumor location and HPV status on selection of up-front treatment modality in localized head and neck cancer
- Track 3** **Case discussion:** A 67-year-old man with HPV-positive metastatic squamous cell carcinoma of the tonsil receives the EXTREME regimen of platinum/5-FU/cetuximab
- Track 4** Ongoing trials of immune checkpoint inhibitors for the first-line treatment of metastatic head and neck cancer
- Track 5** Toxicity of anti-PD-1/PD-L1 and anti-CTLA-4 combination therapy compared to standard chemotherapy for metastatic head and neck cancer
- Track 6** Unique tolerability concerns for patients with metastatic head and neck cancer receiving immune checkpoint inhibitor therapy
- Track 7** CheckMate 141: Results of a Phase III study of nivolumab versus investigator's choice of single-agent methotrexate, docetaxel or cetuximab for patients with recurrent squamous cell carcinoma of the head and neck
- Track 8** Response rate and potential predictors of response to anti-PD-1/PD-L1 inhibitors in advanced head and neck cancer
- Track 9** Available data with pembrolizumab in advanced head and neck cancer and practical considerations influencing the selection of an anti-PD-1 antibody
- Track 10** Ongoing studies of the anti-PD-L1 antibody durvalumab alone and in combination for patients with advanced head and neck cancer
- Track 11** Use of cetuximab for head and neck cancer in the front-line metastatic setting and in later lines of therapy
- Track 12** Investigational approaches combining anti-PD-1/PD-L1 antibodies with chemotherapy and/or radiation therapy and potential integration of immunotherapeutic agents into earlier lines of therapy
- Track 13** Results of a pilot randomized trial evaluating the effect of acupuncture on chemoradiation therapy-related dysphagia in head and neck cancer
- Track 14** Future directions and areas of ongoing interest in the treatment of head and neck cancer
- Track 15** Overview of the thyroid cancer treatment landscape
- Track 16** **Case discussion:** A 45-year-old man with metastatic papillary thyroid cancer and increasing shortness of breath who experienced a prolonged response and improvement of symptoms with lenvatinib
- Track 17** Management of lenvatinib-related hypertension, fatigue and weight loss
- Track 18** Effect of sorafenib-related hand-foot syndrome on quality of life for patients receiving long-term treatment for thyroid cancer
- Track 19** Ongoing research interest in combining VEGF tyrosine kinase inhibitors (TKIs) and immune checkpoint inhibitors for patients with anaplastic and poorly differentiated thyroid cancer
- Track 20** Sequencing of treatments for metastatic thyroid cancer
- Track 21** **Case discussion:** A 55-year-old woman with medullary thyroid cancer, bone and liver metastases and rising CEA and calcitonin experiences an ongoing response to vandetanib
- Track 22** Efficacy and side-effect profiles of the TKIs vandetanib and cabozantinib in advanced medullary thyroid cancer

Tracks 1-19

- |                |   |                 |  |
|----------------|---|-----------------|--|
| <b>Track 1</b> | Importance of the multidisciplinary team in preserving the overall well-being of patients undergoing curative treatment for local or locally advanced head and neck cancer  | <b>Track 10</b> | Perspective on the effect of radiation therapy on the tumor microenvironment   |
| <b>Track 2</b> | Unique psychosocial considerations for patients with head and neck cancer   | <b>Track 11</b> | Response rate and potential predictors of response with immune checkpoint inhibitor therapy  |
| <b>Track 3</b> | <b>Case discussion:</b> A 52-year-old man with p16-positive locally advanced oral pharynx cancer and renal dysfunction who is not eligible for treatment with a platinum agent receives cetuximab and radiation therapy | <b>Track 12</b> | Efficacy and tolerability data leading to the approvals of sorafenib and lenvatinib in radioiodine-refractory thyroid cancer   |
| <b>Track 4</b> | Ongoing Phase III RTOG-1016 trial of radiation therapy and cetuximab versus chemoradiation therapy in HPV-associated oropharynx cancer  | <b>Track 13</b> | <b>Case discussion:</b> A man with a large tracheal mass who experienced a sustained response to lenvatinib  |
| <b>Track 5</b> | Efficacy and side-effect profile of cetuximab/radiation therapy and management of cetuximab-associated dermatologic toxicity  | <b>Track 14</b> | Ongoing investigations in thyroid cancer management  |
| <b>Track 6</b> | Review of ERBB2 family inhibitors in the treatment of head and neck cancer  | <b>Track 15</b> | Factors affecting the sequencing of therapy for metastatic thyroid cancer, including the role of observation in select patients  |
| <b>Track 7</b> | <b>Case discussion:</b> A 63-year-old man with squamous cell carcinoma of the tonsil presents with dermal and lung metastases and experiences a complete clinical response to treatment with nivolumab                  | <b>Track 16</b> | Therapeutic options for patients with metastatic thyroid cancer after disease progression on lenvatinib and sorafenib  |
| <b>Track 8</b> | Approved and investigational use of immune checkpoint inhibitor therapy, alone and in combination, in the treatment of head and neck cancer   | <b>Track 17</b> | Medullary and anaplastic thyroid cancer treatment landscape  |
| <b>Track 9</b> | Effect of HPV and smoking status on treatment benefit with immune checkpoint inhibitors   | <b>Track 18</b> | <b>Case discussion:</b> A man with HPV-positive metastatic squamous cell cancer of the tonsil who underwent local therapy for an isolated lung and liver metastasis and is currently free of disease |
|                |   | <b>Track 19</b> | Benefits of individualized bioselection treatment methods in patients with advanced laryngeal cancer   |

## SELECT PUBLICATIONS

**A multicenter, randomized, double-blind phase 2 trial of lenvatinib (E7080) in subjects with 131I-refractory differentiated thyroid cancer to evaluate whether an oral starting dose of 18 mg daily will provide comparable efficacy to a 24-mg starting dose, but have a better safety profile. NCT02702388**

Argiris A et al. **A randomized, open-label, phase 3 study of nivolumab in combination with ipilimumab vs EXTREME regimen (cetuximab + cisplatin/carboplatin + fluorouracil) as first-line therapy in patients with recurrent or metastatic squamous cell carcinoma of the head and neck-CheckMate 651. Proc ESMO 2016;Abstract 1016TiP.**

Bauml J et al. **Pembrolizumab for platinum- and cetuximab-refractory head and neck cancer: Results from a single-arm, phase II study. J Clin Oncol 2017;35(14):1542-9.**

Bonner JA et al. **Radiotherapy plus cetuximab for locoregionally advanced head and neck cancer: 5-year survival data from a phase 3 randomised trial, and relation between cetuximab-induced rash and survival. Lancet Oncol 2010;11(1):21-8.**

Brose MS et al. **Effect of age on the efficacy and safety of lenvatinib in radioiodine-refractory differentiated thyroid cancer in the phase III SELECT trial. J Clin Oncol 2017;[Epub ahead of print].**

Brose MS et al. **Timing of multikinase inhibitor initiation in differentiated thyroid cancer. Endocr Relat Cancer 2017;24(5):237-42.**

Brose MS et al. **Vemurafenib in patients with BRAF(V600E)-positive metastatic or unresectable papillary thyroid cancer refractory to radioactive iodine: A non-randomised, multi-centre, open-label, phase 2 trial. Lancet Oncol 2016;17(9):1272-82.**

Brose MS et al; DECISION Investigators. **Sorafenib in radioactive iodine-refractory, locally advanced or metastatic differentiated thyroid cancer: A randomised, double-blind, phase 3 trial. Lancet 2014;384(9940):319-28.**

Cohen EE et al. **Axitinib is an active treatment for all histologic subtypes of advanced thyroid cancer: Results from a phase II study. J Clin Oncol 2008;26(29):4708-13.**

**Combination targeted therapy with pembrolizumab and lenvatinib in progressive, radioiodine-refractory differentiated thyroid cancers. NCT02973997**

Elisei R et al. **Cabozantinib in progressive medullary thyroid cancer. J Clin Oncol 2013;31(29):3639-46.**

Fakhry C et al. **The prognostic role of sex, race, and human papillomavirus in oropharyngeal and nonoropharyngeal head and neck squamous cell cancer. Cancer 2017;123(9):1566-75.**

Ferris RL et al. **Nivolumab for recurrent squamous-cell carcinoma of the head and neck. N Engl J Med 2016;375(19):1856-67.**

Klochikhin A et al. **Phase 3 trial of pembrolizumab as a first-line treatment in subjects with recurrent/metastatic head and neck squamous cell carcinoma: KEYNOTE-048. ESMO Symposium on Immuno-Oncology 2015;Abstract 11TiP.**

Licitra L et al. **Phase 3 study of durvalumab (MEDI4736) alone or in combination with tremelimumab versus standard of care (SoC) in platinum-resistant recurrent or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN): EAGLE. Proc ESMO 2015;Abstract 341TiP.**

Lu W et al. **Acupuncture for chemoradiation therapy-related dysphagia in head and neck cancer: A pilot randomized sham-controlled trial. Oncologist 2016;21(12):1522-9.**

**Phase III trial of radiotherapy plus cetuximab versus chemoradiotherapy in HPV-associated oropharynx cancer. NCT01302834**

Sacco AG, Worden FP. **Molecularly targeted therapy for the treatment of head and neck cancer: A review of the ErbB family inhibitors. Onco Targets Ther 2016;9:1927-43.**

Schlumberger M et al. **Lenvatinib versus placebo in radioiodine-refractory thyroid cancer. N Engl J Med 2015;372(7):621-30.**

Seiwert TY et al. **Safety and clinical activity of pembrolizumab for treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-012): An open-label, multicentre, phase 1b trial. Lancet Oncol 2016;17(7):956-65.**

Wolf GT et al. **Survival rates using individualized bioselection treatment methods in patients with advanced laryngeal cancer. JAMA Otolaryngol Head Neck Surg 2017;143(4):355-66.**

## QUESTIONS (PLEASE CIRCLE ANSWER):

1. The prognosis for patients with HPV-positive head and neck cancer is more favorable than that for patients with HPV-negative head and neck cancer.
  - a. True
  - b. False
2. In the EXTREME study, patients with previously untreated recurrent or metastatic head and neck cancer who received a 3-drug combination of \_\_\_\_\_ experienced 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
3. In the Phase III CheckMate 141 trial evaluating nivolumab versus investigator's choice for recurrent squamous cell carcinoma of the head and neck (SCCHN), which of the following groups of patients who received nivolumab experienced a survival benefit?
  - a. Those with HPV-positive disease
  - b. Those with HPV-negative disease
  - c. Both a and b
  - d. Neither a nor b
4. Which of the following EGFR antibodies is FDA approved for the treatment of advanced SCCHN?
  - a. Cetuximab
  - b. Panitumumab
  - c. Both a and b
  - d. Neither a nor b
5. Response rates for patients with head and neck cancer treated with anti-PD-1 antibodies are approximately \_\_\_\_\_.
  - a. 5%
  - b. 15%
  - c. 40%
6. The anti-PD-1 antibody \_\_\_\_\_ was recently approved by the FDA for the treatment of recurrent or metastatic SCCHN.
  - a. Pembrolizumab
  - b. Nivolumab
  - c. Both a and b
  - d. Neither a nor b
7. Which of the following is the mechanism of action of durvalumab?
  - a. Anti-PD-1 antibody
  - b. Anti-PD-L1 antibody
  - c. ERBB2 family inhibitor
  - d. VEGF TKI
8. Which of the following VEGF TKIs is FDA approved for the treatment of advanced papillary or medullary thyroid cancer?
  - a. Cabozantinib
  - b. Lenvatinib
  - c. Sorafenib
  - d. Vandetanib
  - e. All of the above
  - f. Both a and d
  - g. Both b and c
9. The Phase III RTOG-1016 trial is evaluating radiation therapy with \_\_\_\_\_ versus chemoradiation therapy for patients with HPV-associated oropharynx cancer.
  - a. Cabozantinib
  - b. Cetuximab
  - c. Lenvatinib
  - d. Nivolumab
  - e. Sorafenib
10. The DECISION trial demonstrated a statistically significant improvement in \_\_\_\_\_ for patients with radioactive iodine-refractory, locally advanced or metastatic differentiated thyroid cancer treated with sorafenib versus placebo.
  - a. Progression-free survival
  - b. Overall survival
  - c. Both a and b
  - d. Neither a nor b



**EDUCATIONAL ASSESSMENT AND CREDIT FORM**

*Head and Neck Cancer Update — Volume 4, Issue 1*

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?**

	4 = Excellent    3 = Good    2 = Adequate    1 = Suboptimal							
	BEFORE		AFTER					
Recent FDA approvals and indications for use of the anti-PD-1 antibodies pembrolizumab and nivolumab for patients with SCCHN	4	3	2	1	4	3	2	1
CheckMate 141: Results of a Phase III study of nivolumab versus investigator's choice of single-agent methotrexate, docetaxel or cetuximab for patients with recurrent SCCHN	4	3	2	1	4	3	2	1
Risk-benefit ratios for choice of VEGF TKI therapeutic options in medullary thyroid cancer (cabozantinib, vandetanib) and differentiated thyroid cancer (sorafenib, lenvatinib)	4	3	2	1	4	3	2	1
Role of HPV in the etiology of SCCHN and its effect on prognosis and response to treatment	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?**

SCCHN ..... Thyroid cancer .....

**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): .....

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- Yes     No    If no, please explain: .....

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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 consider this information as part of protocol and nonresearch treatment planning. .... 4 3 2 1 N/M N/A
- Appreciate available safety and efficacy data with the use of cetuximab alone or in combination with other local or systemic therapies, and appropriately integrate this agent into the management of locally advanced, recurrent or metastatic SCCHN. . . 4 3 2 1 N/M N/A
- Appraise the rationale for and clinical data with investigational anti-PD-1/PD-L1 antibodies in patients with SCCHN, and use this information to counsel appropriate individuals regarding clinical trial opportunities or expanded access programs with these agents. .... 4 3 2 1 N/M N/A
- Communicate the benefits and risks of approved targeted biologic therapies to patients with metastatic thyroid cancer (TC), and develop an evidence-based algorithm to sequence available options based on disease- and patient-specific characteristics. . . 4 3 2 1 N/M N/A

**EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)**

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- Appreciate the recent FDA approval of lenvatinib for metastatic differentiated TC, and discern how this agent can be optimally integrated into clinical practice. . . . . 4 3 2 1 N/M N/A
- Recognize the roles of cabozantinib and vandetanib in the management of metastatic medullary TC, and ensure appropriate supportive care measures to minimize the side effects associated with these agents. . . . . 4 3 2 1 N/M N/A

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Yes       No

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Robert I Haddad, MD	4	3	2	1	4	3	2	1	
Francis Paul Worden, MD	4	3	2	1	4	3	2	1	
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# Head & Neck Cancer™

U P D A T E

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