

Gastric Cancer™

U P D A T E

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

FACULTY INTERVIEWS

Peter C Enzinger, MD

Yelena Y Janjigian, MD

EDITOR

Neil Love, MD



Gastric Cancer™

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Gastric Cancer Update

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Approximately 45,000 people will be diagnosed with gastric or esophageal cancer in the United States in 2017 alone, with nearly 26,700 of these individuals succumbing to their disease. Published results from ongoing trials continuously lead to the emergence of new therapeutic targets and regimens, thereby altering existing management algorithms. 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. To bridge the gap between research and patient care, *Gastric Cancer Update* uses one-on-one discussion with leading gastrointestinal oncology investigators. By providing access to the latest scientific developments and the perspectives of experts in the field, this CME activity assists medical oncologists with the formulation of up-to-date management strategies.

LEARNING OBJECTIVES

- Appraise recent data on therapeutic advances and changing practice standards in gastric/gastroesophageal cancer, and integrate this information, as appropriate, into current clinical care.
- Use HER2 status, clinical factors and patient perspectives to optimize the selection and sequence of systemic therapy for locally advanced or metastatic gastric/gastroesophageal cancer.
- Describe available and emerging research with immune checkpoint inhibitors in gastric/gastroesophageal cancers, and use this information to inform trial participation.
- Counsel patients regarding the incidence and manifestation of side effects and toxicities associated with commonly used systemic agents/regimens in the management of advanced gastric/gastroesophageal cancer.
- Discuss the proposed mechanisms of action of and recall new data with other investigational agents demonstrating promising activity in gastric/gastroesophageal cancer, and refer appropriate patients for participation in ongoing trials evaluating these approaches.

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Please note, this program has been specifically designed for the following ABIM specialty: **medical oncology**.

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This activity is supported by educational grants from Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company and Lilly.

Release date: November 2017; Expiration date: November 2018

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Interview with Peter C Enzinger, MD

Tracks 1-18

- | | | | |
|----------------|--|-----------------|---|
| Track 1 | FLOT4-AIO: Results of a Phase III trial evaluating the effect of neoadjuvant chemotherapy followed by surgical resection on survival in patients with limited metastatic gastric or gastro-esophageal junction (GEJ) carcinoma | Track 9 | Case: A 72-year-old man with previously treated metastatic gastric cancer receives ramucirumab/paclitaxel |
| Track 2 | Perspective on the results of KEYNOTE-059 Cohort 1: Efficacy and safety of pembrolizumab monotherapy in patients with previously treated gastric cancer | Track 10 | Angiogenesis inhibitors in gastric cancer |
| Track 3 | Activity of anti-PD-1 antibodies alone or in combination with ipilimumab for advanced gastroesophageal cancers | Track 11 | RAINFALL: A Phase III trial of cisplatin/fluoropyrimidine with or without ramucirumab as first-line therapy for metastatic gastric or GEJ adenocarcinoma |
| Track 4 | MSI testing for patients with gastric cancer | Track 12 | Incidence of pseudoprogression with the use of immune checkpoint inhibition in gastric cancer |
| Track 5 | Incorporation of anti-PD-1 immune checkpoint inhibitors into the therapeutic algorithm for advanced gastric cancer | Track 13 | Checkpoint inhibitor-associated autoimmune toxicities |
| Track 6 | Comparison of neoadjuvant chemotherapy regimens for locally advanced esophageal cancer | Track 14 | Case: A 58-year-old man presents with HER2-positive GEJ cancer and receives CAPOX with bevacizumab and trastuzumab on a clinical trial |
| Track 7 | Results of the Phase II FAST study: Progression-free and overall survival advantage with the addition of the anti-CLDN18.2 antibody claudiximab (IMAB362) to epirubicin/oxaliplatin/capecitabine as first-line therapy for patients with advanced CLDN18.2-positive gastric and GEJ adenocarcinoma | Track 15 | Perspective on anti-angiogenic therapy |
| Track 8 | Status of the Phase III BRIGHTER trial evaluating weekly paclitaxel with or without nabucasin (BBI608) for previously treated advanced gastric or GEJ adenocarcinoma | Track 16 | Phase I/II trial of the anti-HER2 monoclonal antibody margetuximab in combination with pembrolizumab for relapsed/refractory advanced HER2-positive gastric or GEJ cancer |
| | | Track 17 | Second-line therapy options for patients with metastatic gastroesophageal cancer |
| | | Track 18 | Activity of anti-PD-1 checkpoint inhibitors for recurrent or metastatic gastric or GEJ adenocarcinoma |

Interview with Yelena Y Janjigian, MD

Tracks 1-12

- | | | | |
|----------------|---|----------------|--|
| Track 1 | Case: A 47-year-old man with heavily pretreated advanced gastric cancer experiences a prolonged response with nivolumab and ipilimumab on the Phase I/II CheckMate 032 trial | | advanced chemotherapy-refractory gastric, esophageal or GEJ cancer |
| Track 2 | Incidence of microsatellite instability (MSI)-high tumors in advanced gastroesophageal cancer | Track 4 | Perspective on duration of immune checkpoint inhibitor therapy |
| Track 3 | Results of CheckMate 032: Efficacy and tolerability of nivolumab alone or in combination with ipilimumab for | Track 5 | Ongoing investigations of immune checkpoint inhibitors in the (neo)adjuvant setting |
| | | Track 6 | Sequencing of chemotherapeutic regimens and immune checkpoint inhibitors for metastatic gastric cancer |

Interview with Dr Janjigian (continued)

Track 7 **Case:** A 52-year-old woman with MSI-high, Stage IV GEJ adenocarcinoma

Track 8 **Case:** A 60-year-old man with HER2-positive GEJ adenocarcinoma and liver and lung metastases

Track 9 **Case:** A 62-year-old woman with metastatic gastric cancer previously treated with FOLFOX who is now receiving ramucirumab/paclitaxel

Track 10 **Case:** A 70-year-old woman with metastatic gastric adenocarcinoma and a history of congestive heart failure

Track 11 New agents on the horizon in gastric cancer

Track 12 **Case:** A 68-year-old woman with locally advanced gastric adenocarcinoma

Video Program

View the corresponding video interviews with (from left) Drs Enzinger and Janjigian by Dr Love at ResearchToPractice.com/GastricCancerUpdate117/Video



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

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SELECT PUBLICATIONS

A phase III clinical trial of BBI608 plus weekly paclitaxel vs placebo plus weekly paclitaxel in adult patients with advanced, previously treated gastric and gastro-oesophageal junction adenocarcinoma. NCT02178956

Al-Batran SE et al. **Effect of neoadjuvant chemotherapy followed by surgical resection on survival in patients with limited metastatic gastric or gastroesophageal junction cancer: The AIO-FLOT3 trial.** *JAMA Oncol* 2017;[Epub ahead of print].

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Boku N et al. **A phase 3 study of nivolumab (nivo) in previously treated advanced gastric or gastroesophageal junction (G/GEJ) cancer: Updated results and subset analysis by PD-L1 expression (ATTRACTION-02).** *Proc ESMO* 2017;**Abstract 617O.**

Cancer Genome Atlas Research Network. **Integrated genomic characterization of oesophageal carcinoma.** *Nature* 2017;541(7636):169-75.

Catenacci D et al. **A phase 1b/2, open label, dose-escalation study of margetuximab (M) in combination with pembrolizumab (P) in patients with relapsed/refractory advanced HER2+ gastroesophageal (GEJ) junction or gastric (G) cancer.** *Gastrointestinal Cancers Symposium* 2017;**Abstract TPS219.**

Ford HE et al. **Docetaxel versus active symptom control for refractory oesophagogastric adenocarcinoma (COUGAR-02): An open-label, phase 3 randomised controlled trial.** *Lancet Oncol* 2014;15(1):78-86.

Fuchs CS et al. **KEYNOTE-059 cohort 1: Efficacy and safety of pembrolizumab (pembro) monotherapy in patients with previously treated advanced gastric cancer.** *Proc ASCO* 2017;**Abstract 4003.**

Fuchs CS et al. **A randomized, double-blind, placebo-controlled phase III study of cisplatin plus a fluoropyrimidine with or without ramucirumab as first-line therapy in patients with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (RAINFALL, NCT02314117).** *Gastrointestinal Cancers Symposium* 2016;**Abstract TPS178.**

Gerson JN et al. **Perspectives of HER2-targeting in gastric and esophageal cancer.** *Expert Opin Investig Drugs* 2017;26(5):531-40.

Hubbard JM, Grothey A. **Napabucasin: An update on the first-in-class cancer stemness inhibitor.** *Drugs* 2017;77(10):1091-103.

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Lordick F et al. **New agents on the horizon in gastric cancer.** *Ann Oncol* 2017;28(8):1767-75.

Muro K et al. **Pembrolizumab for patients with PD-L1-positive advanced gastric cancer (KEYNOTE-012): A multicentre, open-label, phase 1b trial.** *Lancet Oncol* 2016;17(6):717-26.

Sanford NN et al. **A retrospective comparison of neoadjuvant chemoradiotherapy regimens for locally advanced esophageal cancer.** *Dis Esophagus* 2017;30(7):1-8.

Singh P et al. **Anti-claudin 18.2 antibody as new targeted therapy for advanced gastric cancer.** *J Hematol Oncol* 2017;10(1):105.

Taberner J et al. **Pertuzumab (P) + trastuzumab (H) + chemotherapy (CT) for HER2-positive metastatic gastric or gastro-oesophageal junction cancer (mGC/GEJ): Final analysis of a Phase III study (JACOB).** *Proc ESMO* 2017;**Abstract 616O.**

Wilke H et al. **Ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (RAINBOW): A double-blind, randomised phase 3 trial.** *Lancet* 2014;15(11):1224-35.

QUESTIONS (PLEASE CIRCLE ANSWER):

- 1. The Phase III FLOT4-AIO study evaluating the effect of neoadjuvant chemotherapy followed by surgery in patients with limited metastatic gastric or GEJ cancer demonstrated statistically significant improvements in _____ for patients who received ECF/ECX versus FLOT.**
 - a. Progression-free survival
 - b. Overall survival
 - c. Both a and b
- 2. The Phase III ONO-4538 study evaluating nivolumab versus placebo as salvage treatment after second- or later-line chemotherapy for advanced gastric or GEJ cancer reported an overall survival advantage with nivolumab.**
 - a. True
 - b. False
- 3. Which of the following categories reflects the mechanism of action of claudiximab (IMAB362)?**
 - a. Anti-CLDN18.2 antibody
 - b. Anti-HER2 antibody
 - c. Anti-PD-1/PD-L1 antibody
- 4. The Phase II FAST study evaluating first-line epirubicin/oxaliplatin/capecitabine with or without claudiximab for patients with advanced gastric and GEJ adenocarcinoma demonstrated statistically significant improvements in _____ for patients who received claudiximab.**
 - a. Progression-free survival
 - b. Overall survival
 - c. Both a and b
- 5. Which of the following categories reflects the mechanism of action of napabucasin (BBI608)?**
 - a. Cancer stem cell pathway inhibitor
 - b. Anti-PD-1/PD-L1 antibody
- 6. In the Phase III RAINFALL study the addition of ramucirumab to first-line cisplatin with a fluoropyrimidine for metastatic gastric or GEJ cancer failed to improve progression-free or overall survival.**
 - a. True
 - b. False
- 7. A Phase I/II trial is evaluating margetuximab in combination with pembrolizumab for patients with _____ advanced HER2-positive gastric or GEJ cancer.**
 - a. Previously untreated
 - b. Relapsed or refractory
- 8. In comparing metastatic to nonmetastatic gastric cancer, which of the following statements is true about the incidence of MSI-high tumors?**
 - a. It is higher in the metastatic setting
 - b. It is higher in the nonmetastatic setting
- 9. The Phase III BRIGHTER trial is evaluating weekly paclitaxel with or without _____ for previously treated gastric or GEJ adenocarcinoma.**
 - a. Napabucasin
 - b. Nivolumab
 - c. Ramucirumab
- 10. Results from Cohort 1 of the Phase II KEYNOTE-059 trial of pembrolizumab monotherapy for patients with pretreated advanced gastric/GEJ cancer demonstrated encouraging clinical activity.**
 - a. True
 - b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Gastric Cancer Update — Volume 1, 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					
Results of the Phase I/II CheckMate 032 trial: Efficacy and tolerability of nivolumab alone or in combination with ipilimumab for advanced chemotherapy-refractory gastric, esophageal or GEJ cancer	4	3	2	1	4	3	2	1
The concept of “stemness” and emerging clinical data with the stem cell inhibitor napabucasin (BBI608) in advanced gastric cancers	4	3	2	1	4	3	2	1
RAINFALL: A Phase III trial of cisplatin/fluoropyrimidine with or without ramucirumab as first-line therapy for metastatic gastric or GEJ adenocarcinoma	4	3	2	1	4	3	2	1
FLOT4-AIO: Results of a Phase III trial evaluating the effect of neoadjuvant chemotherapy followed by surgical resection on survival in patients with limited metastatic gastric or GEJ carcinoma	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 gastric or GEJ cancer to 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:

.....

.....

.....

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:

- Appraise recent data on therapeutic advances and changing practice standards in gastric/gastroesophageal cancer, and integrate this information, as appropriate, into current clinical care. 4 3 2 1 N/M N/A
- Use HER2 status, clinical factors and patient perspectives to optimize the selection and sequence of systemic therapy for locally advanced or metastatic gastric/gastroesophageal cancer. 4 3 2 1 N/M N/A
- Describe available and emerging research with immune checkpoint inhibitors in gastric/gastroesophageal cancers, and use this information to inform trial participation. 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:

- Counsel patients regarding the incidence and manifestation of side effects and toxicities associated with commonly used systemic agents/regimens in the management of advanced gastric/gastroesophageal cancer. 4 3 2 1 N/M N/A
- Discuss the proposed mechanisms of action of and recall new data with other investigational agents demonstrating promising activity in gastric/gastroesophageal cancer, and refer appropriate patients for participation in ongoing trials evaluating these approaches. 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			
Peter C Enzinger, MD	4	3	2	1	4	3	2	1
Yelena Y Janjigian, 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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Release date: November 2017
Expiration date: November 2018
Estimated time to complete: 2.25 hours