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Gastrointestinal Cancer™

UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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CME Certified

Gastrointestinal Cancer Update

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Colorectal cancer (CRC) is a common and potentially lethal type of cancer, and its clinical management is constantly evolving. Although "non-CRC" gastrointestinal (GI) tumors are less frequently encountered individually, the cancer-related deaths in that subcategory surpass those attributed to CRC. Published results from ongoing trials continuously lead to the emergence of novel biomarkers and 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, *Gastrointestinal Cancer Update* uses one-on-one discussion with leading GI 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

- Apply existing and emerging data to the best-practice management of diverse GI cancers.
- Communicate the benefits and risks of approved anti-VEGF, anti-EGFR and other targeted biologic therapies to patients with metastatic CRC, and develop an evidence-based algorithm to sequence available options based on disease- and patient-specific characteristics.
- Individualize local and systemic treatment for patients with metastatic CRC that is isolated to the lung or liver.
- Appraise the rationale for and clinical data with investigational anti-PD-1 and/or anti-PD-L1 antibodies in patients with CRC or gastric cancer.
- Consider age, performance status and other clinical factors in the selection of systemic therapy for patients with metastatic pancreatic adenocarcinoma.
- Coordinate comprehensive biomarker analysis for patients diagnosed with advanced CRC, and use this information to guide evidence-based care for these patients.
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials.

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CME INFORMATION

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SELECT PUBLICATIONS

Bang Y-J et al. **Relationship between PD-L1 expression and clinical outcomes in patients with advanced gastric cancer treated with the anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) in KEYNOTE-012.** *Proc ASCO* 2015;**Abstract 4001**.

Becerra C et al. **Phase Ib/II study of cancer stem cell (CSC) inhibitor BBI608 combined with paclitaxel in advanced gastric and gastroesophageal junction (GEJ) adenocarcinoma.** *Proc ASCO* 2015;**Abstract 4069**.

Doi T et al. **Pembrolizumab (MK-3475) for patients (pts) with advanced esophageal carcinoma: Preliminary results from KEYNOTE-028.** *Proc ASCO* 2015;**Abstract 4010**.

Fuchs CS et al. **Candidate biomarker analyses in gastric or gastro-esophageal junction carcinoma: REGARD trial of single-agent ramucirumab (RAM) vs placebo (PL).** *Proc ASCO* 2015;**Abstract 4029**.

Hobday TJ et al. **Multicenter phase II trial of temsirolimus and bevacizumab in pancreatic neuroendocrine tumors.** *J Clin Oncol* 2015;33(14):1551-6.

Le DT et al. **PD-1 blockade in tumors with mismatch-repair deficiency.** *N Engl J Med* 2015;372(26):2509-20.

Mayer RJ et al; RECOURSE Study Group. **Randomized trial of TAS-102 for refractory metastatic colorectal cancer.** *N Engl J Med* 2015;372(20):1909-19.

Ng K et al. **Vitamin D status and survival of metastatic colorectal cancer patients: Results from CALGB/SWOG 80405 (Alliance).** *Proc ASCO* 2015;**Abstract 507**.

Shah MA et al. **The BRIGHTER trial: A phase III randomized double-blind study of BBI608 + weekly paclitaxel versus placebo (PBO) + weekly paclitaxel in patients (pts) with pretreated advanced gastric and gastro-esophageal junction (GEJ) adenocarcinoma.** *Proc ASCO* 2015;**Abstract TPS4139**.

Siena S et al. **Trastuzumab and lapatinib in HER2-amplified metastatic colorectal cancer patients (mCRC): The HERACLES trial.** *Proc ASCO* 2015;**Abstract 3508**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **A recent study published in *The New England Journal of Medicine* demonstrated that more than a third of patients with mismatch repair-deficient colorectal tumors responded to pembrolizumab.**
   a. True
   b. False

2. **The KEYNOTE-028 trial demonstrated a response rate of approximately 20% for patients with advanced esophageal cancer treated with _____.**
   a. BBI608
   b. Pembrolizumab
   c. Regorafenib
   d. TAS-102

3. **A correlative analysis evaluating the association between vitamin D levels and overall survival among patients with metastatic CRC treated with chemotherapy and biologics on the CALGB/SWOG-80405 trial demonstrated that _____ concentrations of plasma vitamin D were associated with a significant improvement in survival.**
   a. Higher
   b. Lower

4. **Which of the following is the mechanism of action of TAS-102?**
   a. Oral nucleoside
   b. Anti-angiogenic
   c. Antibody-drug conjugate
   d. Anti-PD-1 antibody

5. **Results of a Phase III trial of TAS-102 for patients with metastatic CRC that is refractory to standard therapies _____ a statistically significant improvement in overall survival with TAS-102 and best supportive care (BSC) compared to placebo/BSC.**
   a. Demonstrated
   b. Did not demonstrate

6. **A recently published Phase II trial evaluating the combination of temsirolimus and _____ in patients with pancreatic neuroendocrine tumors reported substantial activity and reasonable tolerability with the combination.**
   a. Bevacizumab
   b. Ramucirumab
   c. Regorafenib
   d. All of the above

7. **_____ is a novel cancer stem cell inhibitor that has shown promising activity in early studies for patients with advanced gastric cancer.**
   a. Ruxolitinib
   b. Pembrolizumab
   c. BBI608

8. **Approximately what percentage of patients with colon cancer have HER2-amplified disease?**
   a. ≤5%
   b. 15% to 20%
   c. 30% to 35%

EDUCATIONAL ASSESSMENT AND CREDIT FORM

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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
Correlation between mismatch repair status and benefit from immune checkpoint blockade in metastatic CRC	4 3 2 1	4 3 2 1
Survival benefit with the recently FDA-approved oral nucleoside TAS-102 in refractory metastatic CRC and considerations for the future sequencing of regorafenib and TAS-102	4 3 2 1	4 3 2 1
Importance of molecular profiling and its impact on therapeutic approach for patients with metastatic gastrointestinal stromal tumors	4 3 2 1	4 3 2 1
Incidence of central tumor necrosis observed radiographically in patients receiving anti-angiogenic agents	4 3 2 1	4 3 2 1
Efficacy and ongoing investigation of the cancer stem cell inhibitor BBI608 in combination with paclitaxel for advanced gastric and gastroesophageal junction adenocarcinoma	4 3 2 1	4 3 2 1
Clinical factors affecting the selection of first-line therapy for patients with metastatic pancreatic cancer	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).....

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:

- Apply existing and emerging data to the best-practice management of diverse GI cancers..... 4 3 2 1 N/M N/A
- Communicate the benefits and risks of approved anti-VEGF, anti-EGFR and other targeted biologic therapies to patients with metastatic CRC, 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
- Individualize local and systemic treatment for patients with metastatic CRC that is isolated to the lung or liver..... 4 3 2 1 N/M N/A
- Appraise the rationale for and clinical data with investigational anti-PD-1 and/or anti-PD-L1 antibodies in patients with CRC or gastric cancer..... 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:

- Consider age, performance status and other clinical factors in the selection of systemic therapy for patients with metastatic pancreatic adenocarcinoma. . . . 4 3 2 1 N/M N/A
- Coordinate comprehensive biomarker analysis for patients diagnosed with advanced CRC, and use this information to guide evidence-based care for these patients. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials. . . . . 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: .....

Additional comments about this activity:

.....

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
Charles S Fuchs, MD, MPH	4 3 2 1	4 3 2 1
Heinz-Josef Lenz, 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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U P D A T E

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