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Gastrointestinal Cancer™

UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Scott Kopetz, MD, PhD

David P Ryan, MD

EDITOR

Neil Love, MD

ABIM CME MOC ACCREDITED

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 (mCRC), and develop an evidence-based algorithm to sequence available options based on disease- and patient-specific characteristics.
- 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.
- Develop an evidence-based plan of care for the treatment of peritoneal carcinomatosis of CRC origin.
- Assess available data with currently approved and investigational agents with documented activity in gastroesphageal cancer, and develop a clinical algorithm for optimal patient care including the option of participating in clinical research.
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials.

ACCREDITATION STATEMENT

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Successful completion of this CME activity enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

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

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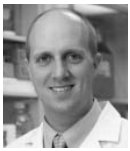
CME INFORMATION

FACULTY AFFILIATIONS



Scott Kopetz, MD, PhD
Associate Professor
Department of Gastrointestinal Medical Oncology
Division of Cancer Medicine
The University of Texas
MD Anderson Cancer Center
Houston, Texas

David P Ryan, MD
Chief, Hematology/Oncology
Clinical Director
Mass General Cancer Center
Boston, Massachusetts

EDITOR

Neil Love, MD
Research To Practice
Miami, Florida

CONTENT VALIDATION AND DISCLOSURES

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Kopetz** — Consulting Agreements: Agendia, Amgen Inc, Array BioPharma Inc, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Genentech BioOncology, GlaxoSmithKline, Merrimack Pharmaceuticals Inc, Roche Laboratories Inc, Sanofi, Sysmex Inostics, Taiho Oncology Inc; Contracted Research: Agendia, Amgen Inc, Biocartis, Genentech BioOncology, GlaxoSmithKline, Guardant Health Inc, Roche Laboratories Inc, Sanofi, Sysmex Inostics. **Dr Ryan** — Advisory Committee: Pfizer Inc.

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SELECT PUBLICATIONS

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**.

Cercek A et al. **Treatment of peritoneal carcinomatosis of colorectal origin.** *Am Soc Clin Oncol Educ Book* 2015;35:e208-11.

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Conroy T et al; PRODIGE Intergroup. **FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer.** *N Engl J Med* 2011;364(19):1817-25.

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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.

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Phase III study evaluating the use of systemic chemotherapy and chemohyperthemia intraperitoneal preoperatively (CHIP) and after maximum resection of peritoneal carcinomatosis originating with colorectal cancer. NCT00769405

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

Tabernero J et al. **Prognostic factors of survival in a randomized phase III trial (MPACT) of weekly *nab*-paclitaxel plus gemcitabine versus gemcitabine alone in patients with metastatic pancreatic cancer.** *Oncologist* 2015;20(2):143-50.

Verwaal VJ et al. **Randomized trial of cytoreduction and hyperthermic intraperitoneal chemotherapy versus systemic chemotherapy and palliative surgery in patients with peritoneal carcinomatosis of colorectal cancer.** *J Clin Oncol* 2003;21(20):3737-43.

Von Hoff DD et al. **Increased survival in pancreatic cancer with *nab*-paclitaxel plus gemcitabine.** *N Engl J Med* 2013;369(18):1691-703.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **A recent study published in *The New England Journal of Medicine* demonstrated that patients with mCRC and _____ responded to treatment with the immune checkpoint inhibitor pembrolizumab.**
   a. MSI-high tumors
   b. Microsatellite stable tumors
   c. Both a and b
   d. None of the above

2. **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

3. **Results of a randomized Phase III trial of TAS-102 for patients with mCRC 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

4. **Approximately what percent of patients with colon cancer have HER2-amplified disease?**
   a. ≤5%
   b. 15% to 20%
   c. 30% to 35%
   d. 60% to 65%

5. **Results of the Phase II HERACLES study demonstrated that approximately one third of patients with HER2-amplified mCRC responded to the combination of trastuzumab and lapatinib.**
   a. True
   b. False

6. **Which of the following statements is true regarding the toxicity associated with regorafenib?**
   a. Dose reduction can be used to mitigate adverse events
   b. Severe side effects include hand-foot reaction, fatigue and diarrhea
   c. Both a and b
   d. None of the above

7. **A Phase Ib study of vemurafenib in combination with irinotecan and cetuximab demonstrated the combination to be efficacious for patients with _____ mCRC.**
   a. BRAF-mutated
   b. HER2-amplified
   c. MSI-high

8. **An ongoing Phase III French trial is evaluating systemic chemotherapy with or without _____ as treatment for patients undergoing cytoreductive surgery for peritoneal carcinomatosis of CRC origin.**
   a. Anti-PD-1 therapy
   b. Hyperthermic intraperitoneal chemotherapy (HIPEC)
   c. TAS-102

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Gastrointestinal Cancer Update — Issue 2, 2015

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 mCRC	4 3 2 1	4 3 2 1
Survival benefit with the recently FDA-approved oral nucleoside TAS-102 in refractory mCRC and considerations for the future sequencing of regorafenib and TAS-102	4 3 2 1	4 3 2 1
Biologic rationale for and preliminary clinical data with anti-PD-1/PD-L1 antibodies for patients with mCRC or advanced gastric cancer	4 3 2 1	4 3 2 1
Rationale for the investigation of cancer stem cell inhibitors in gastric cancer	4 3 2 1	4 3 2 1
HERACLES: Results of a Phase II trial of trastuzumab and lapatinib in HER2-amplified mCRC	4 3 2 1	4 3 2 1
Clinical significance of and emerging management strategies for BRAF V600E-positive CRC	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 (mCRC), 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
- 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
- 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

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

- 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
- Develop an evidence-based plan of care for the treatment of peritoneal carcinomatosis of CRC origin. . . . . 4 3 2 1 N/M N/A
- Assess available data with currently approved and investigational agents with documented activity in gastroesphageal cancer, and develop a clinical algorithm for optimal patient care including the option of participating in clinical research. . 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: .....

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
Scott Kopetz, MD, PhD	4 3 2 1	4 3 2 1
David P Ryan, 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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Name: ..... Specialty: .....

Professional Designation:

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Gastrointestinal Cancer™ UPDATE

Contact Information	Neil Love, MD Research To Practice One Biscayne Tower 2 South Biscayne Boulevard, Suite 3600 Miami, FL 33131 Fax: (305) 377-9998 Email: DrNeilLove@ResearchToPractice.com
For CME/CNE Information	Email: CE@ResearchToPractice.com

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U P D A T E

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