

Year ⁱⁿ Review

On Demand — Significance and Relevance of Recent Data Sets and Publications in the Management of Gastrointestinal Cancers

CME Information

TARGET AUDIENCE

This activity is intended for medical oncologists, hematologists, hematology-oncology fellows and other healthcare professionals involved in the treatment of gastrointestinal (GI) cancers.

OVERVIEW OF ACTIVITY

Because of the prevalent nature of the disease, extensive resources are allocated to colorectal cancer (CRC) research and education. Interestingly, however, although individually less frequently encountered, the collection of other, “non-CRC” gastrointestinal (GI) cancers accounts for more cancer-related deaths per annum than those attributed to tumors of the colon and rectum combined. Therefore, educational opportunities relevant to the clinical management of both CRC and the most prevalent non-CRC GI tumors — including gastric, pancreatic and hepatocellular cancer — are essential to the general oncologist’s delivery of comprehensive cancer care.

As it is simply not possible for one general oncologist to review and make sense of the massive volume of information emerging across one disease, let alone all of the tumor types he or she is responsible for treating, the overarching objective of RTP’s Year in Review On Demand video program is to provide an efficient and timely overview of key presentations and publications emerging over the course of the past 12 months and provide perspectives on how this information can and should be applied to patient care.

To bridge the gap between research and patient care, the YiR On Demand video program features one-on-one discussions with leading medical oncology investigators. By providing information on the latest clinical developments in the context of expert perspectives, this CME activity assists medical oncologists, hematology-oncology fellows and other allied healthcare professionals with the formulation of evidence-based and current therapeutic strategies.

LEARNING OBJECTIVES

- Compare and contrast the clinical applicability of emerging research findings, as published in peer-reviewed journals and/or presented at major oncology conferences, specific to GI cancers, including colorectal, pancreatic and gastric cancer and hepatocellular carcinoma.

- Develop a long-term care plan for patients diagnosed with metastatic CRC, considering biomarker profile, tumor location, prior systemic therapy, symptomatology, performance status (PS) and personal goals of treatment.
- Consider HER2 status, PD-L1 combined positive score, clinical factors and patient preferences to tailor the selection and sequence of systemic therapy for locally advanced or metastatic gastric or gastroesophageal cancer.
- Use age, PS and other clinical and logistical factors in the selection of systemic therapy for patients with localized, locally advanced or metastatic pancreatic adenocarcinoma.
- Discuss with patients the benefits and risks of available and emerging systemic interventions for locally advanced or metastatic hepatocellular carcinoma.
- Evaluate the rationale for and clinical data with commercially available and investigational immune checkpoint inhibitors in the treatment of GI cancers.
- Appropriately select and counsel patients with GI cancers about participation in ongoing clinical trials evaluating novel therapeutic agents and strategies.

ACCREDITATION STATEMENT

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CREDIT DESIGNATION STATEMENT

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AMERICAN BOARD OF INTERNAL MEDICINE (ABIM) — MAINTENANCE OF CERTIFICATION (MOC)

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 3.75 Medical Knowledge 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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HOW TO USE THIS CME ACTIVITY

This CME activity consists of slide and video components. To receive credit, the participant should review the slide presentations, watch the video, complete the Post-test with a score of 80% or better and fill out the Educational Assessment and Credit Form located at [ResearchToPractice.com/YIROnDemand18/GI/CME](https://www.researchtopractice.com/YIROnDemand18/GI/CME).

CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-the-art education. We assess conflicts of interest with faculty, planners and managers of CME activities. Conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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RESEARCH TO PRACTICE CME PLANNING COMMITTEE

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Hardware/Software Requirements:

A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 11 or later, Firefox 56 or later, Chrome 61 or later, Safari 11 or later, Opera 48 or later
Adobe Flash Player 27 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: September 2018

Expiration date: September 2019

Select Publications

- Abou-Alfa GK et al. **Cabozantinib (C) versus placebo (P) in patients (pts) with advanced hepatocellular carcinoma (HCC) who have received prior sorafenib: Results from the randomized phase III CELESTIAL trial.** *Gastrointestinal Cancers Symposium 2018;Abstract 207.*
- Abou-Alfa GK et al. **Cabozantinib in patients with advanced and progressing hepatocellular carcinoma.** *N Engl J Med 2018;379(1):54-63.*
- Bekaii-Saab T et al. **Phase 1b/2 trial of cancer stemness inhibitor napabucasin (NAPA) + nab-paclitaxel (nPTX) and gemcitabine (gem) in metastatic pancreatic adenocarcinoma (mPDAC).** *Proc ASCO 2018;Abstract 4110.*
- Bekaii-Saab TS et al. **Regorafenib dose optimization study (ReDOS): Randomized phase II trial to evaluate dosing strategies for regorafenib in refractory metastatic CRC (mCRC) — An ACCRU Network study.** *Gastrointestinal Cancers Symposium 2018;Abstract 611.*
- Bekaii-Saab T et al. **Regorafenib dose optimization study (ReDOS): Randomized phase II trial to evaluate escalating dosing strategy and pre-emptive topical steroids for regorafenib in refractory metastatic colorectal cancer (mCRC) — An ACCRU Network study.** *Proc ESMO World Congress on Gastrointestinal Cancer 2018;Abstract O-014.*
- Bendell J et al. **Efficacy and safety results from IMblaze370, a randomised phase III study comparing atezolizumab + cobimetinib and atezolizumab monotherapy vs regorafenib in chemotherapy-refractory metastatic colorectal cancer.** *Proc ESMO World Congress on Gastrointestinal Cancer 2018;Abstract LBA-004.*
- Bendell J et al. **Phase Ib/II study of cancer stemness inhibitor napabucasin in combination with FOLFIRI ± bevacizumab in mCRC patients.** *Proc ESMO World Congress on Gastrointestinal Cancer 2017;Abstract LBA-003.*
- Bruix J et al. **Updated overall survival (OS) analysis from the international, phase 3, randomized, placebo-controlled RESORCE trial of regorafenib for patients with hepatocellular carcinoma (HCC) who progressed on sorafenib treatment.** *Proc ESMO World Congress on Gastrointestinal Cancer 2017;Abstract O-009.*
- Cats A et al; CRITICS Investigators. **Chemotherapy versus chemoradiotherapy after surgery and preoperative chemotherapy for resectable gastric cancer (CRITICS): An international, open-label, randomized phase 3 trial.** *Lancet Oncol 2018;19(5):616-28.*
- Conroy T et al. **Unicancer GI PRODIGE 24/CCTG PA.6 trial: A multicenter international randomized phase III trial of adjuvant mFOLFIRINOX versus gemcitabine (gem) in patients with resected pancreatic ductal adenocarcinomas.** *Proc ASCO 2017;Abstract LBA4001.*
- Dahan L et al. **FOLFIRINOX until progression, FOLFIRINOX with maintenance treatment, or sequential treatment with gemcitabine and FOLFIRI.3 for first-line treatment of metastatic pancreatic cancer: A randomized phase II trial (PRODIGE 35-PANOPTIMOX).** *Proc ASCO 2018;Abstract 4000.*
- El-Khoueiry AB et al. **Nivolumab in patients with advanced hepatocellular carcinoma (CheckMate 040): An open-label, non-comparative, phase 1/2 dose escalation and expansion trial.** *Lancet 2017;389(10088):2492-502.*
- Fuchs CS et al. **Pembrolizumab (pembro) vs paclitaxel (PTX) for previously treated advanced gastric or gastroesophageal junction (G/GEJ) cancer: Phase 3 KEYNOTE-061 trial.** *Proc ASCO 2018;Abstract 4062.*
- Fuchs CS et al. **RAINFALL: A randomized, double-blind, placebo-controlled phase III study of cisplatin (cis) plus capecitabine (cape) or 5FU with or without ramucirumab (RAM) as first-line therapy in patients with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma.** *Gastrointestinal Cancers Symposium 2018;Abstract 5.*
- Fuchs CS et al. **Safety and efficacy of pembrolizumab monotherapy in patients with previously treated advanced gastric and gastroesophageal junction cancer: Phase 2 clinical KEYNOTE-059 trial.** *JAMA Oncol 2018;4(5):e180013.*
- Grothey A et al. **Duration of adjuvant chemotherapy for stage III colon cancer.** *N Engl J Med 2018;378(13):1177-88.*
- Hingorani SR et al. **HALO 202: Randomized phase II study of PEGPH20 plus nab-paclitaxel/gemcitabine versus nab-paclitaxel/gemcitabine in patients with untreated, metastatic pancreatic ductal adenocarcinoma.** *J Clin Oncol 2018;36(4):359-66.*
- Kang YK et al. **Nivolumab in patients with advanced gastric or GEJ cancer refractory to, or intolerant of, at least two previous chemotherapy regimens (ONO-4538-12, ATTRACTION-2): A randomised, double-blind, placebo-controlled, phase III trial.** *Lancet 2017;390(10111):2461-71.*
- Kudo M et al. **Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: A randomised phase 3 non-inferiority trial.** *Lancet 2018;391(10126):1163-73.*
- Overman MJ et al. **Durable clinical benefit with nivolumab plus ipilimumab in DNA mismatch repair-deficient/microsatellite instability-high mCRC.** *J Clin Oncol 2018;36(8):773-9.*
- Schilsky RL. **A new IDEA in adjuvant chemotherapy for colon cancer.** *N Engl J Med 2018;378(13):1242-4.*

Select Publications

Shitara K et al; KEYNOTE-061 Investigators. **Pembrolizumab versus paclitaxel for previously treated, advanced gastric or gastro-oesophageal junction cancer (KEYNOTE-061): A randomised, open-label, controlled, phase 3 trial.** *Lancet* 2018;392(10142):123-33.

Shitara K et al. **Reverce: Randomized phase II study of regorafenib followed by cetuximab versus the reverse sequence for mCRC patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan.** *Gastrointestinal Cancers Symposium* 2018;Abstract 557.

Sohal DPS et al. **Metastatic pancreatic cancer: ASCO Clinical Practice Guideline Update.** *J Clin Oncol* 2018;36(24):2545-56.

Sonbol MB et al. **Second-line treatment in patients with pancreatic ductal adenocarcinoma: A meta-analysis.** *Cancer* 2017;123(23):4680-6.

Tabernero J et al. **Overall survival results from a phase III trial of trifluridine/tipiracil versus placebo in patients with metastatic gastric cancer refractory to standard therapies (TAGS).** *Proc ESMO World Congress on Gastrointestinal Cancer* 2018;Abstract LBA-002.

Van Tienhoven G et al. **Preoperative chemoradiotherapy versus immediate surgery for resectable and borderline resectable pancreatic cancer (PREOPANC-1): A randomized, controlled, multicenter phase III trial.** *Proc ASCO* 2018;Abstract LBA4002.

Xu J et al. **Results of a randomized, double-blind, placebo-controlled, phase III trial of TAS-102 monotherapy in Asian patients with previously treated mCRC: The TERRA study.** *J Clin Oncol* 2018;36(4):350-8.

Zhu AX et al. **Pembrolizumab in patients with advanced hepatocellular carcinoma previously treated with sorafenib (KEYNOTE-224): A non-randomised, open-label phase 2 trial.** *Lancet Oncol* 2018;19(7):940-52.

Zhu AX et al. **REACH-2: A randomized, double-blind, placebo-controlled phase 3 study of ramucirumab versus placebo as second-line treatment in patients with advanced hepatocellular carcinoma (HCC) and elevated baseline alpha-fetoprotein (AFP) following first-line sorafenib.** *Proc ASCO* 2018;Abstract 4003.