

AN EVENING WITH THE INVESTIGATORS

Perspectives on Key Questions and Emerging Research in the Management of Gastrointestinal Cancers



A special audio supplement to a CME symposium held during the 2018 American Society of Clinical Oncology Annual Meeting featuring expert comments on the application of emerging research to patient care

Faculty Interviews

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An Evening with the Investigators: Perspectives on Key Questions and Emerging Research in the Management of Gastrointestinal Cancers

A Continuing Medical Education Activity

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, noncolorectal gastrointestinal (GI) cancers account for more cancer-related deaths per annum than deaths attributed to tumors of the colon and rectum combined. Among this collection of distinct tumor types, a few in particular — namely gastric, pancreatic and hepatocellular cancer — have undergone several recent advances that have altered or have the potential to drastically alter current treatment considerations and approaches. These 2 faculty interviews recorded after a satellite symposium held during the 2018 ASCO Annual Meeting explore key data sets from the meeting and emerging research in the field of GI cancers. Using the perspectives of investigators to frame a discussion of how this information can aid in the refinement of current clinical practice, this activity will help medical oncologists and other allied healthcare professionals find answers to the individualized questions and concerns that they frequently encounter and in turn provide high-quality cancer care.

LEARNING OBJECTIVES

- Review recent data on therapeutic advances and changing practice standards in colorectal and noncolorectal GI cancers, and integrate this information, as appropriate, into current clinical care.
- Develop a long-term care plan for individuals diagnosed with metastatic CRC, considering biomarker profile, tumor location, prior systemic therapy, symptomatology, performance status (PS) and personal goals of treatment.
- Use disease characteristics and patient preferences to optimize the selection and sequence of systemic therapy for locally advanced or metastatic gastric/gastroesophageal cancer.
- Consider age, PS and other clinical and logistical factors in the selection of systemic therapy for patients with localized, locally advanced or metastatic pancreatic adenocarcinoma.
- Communicate the benefits and risks of available and emerging systemic interventions to patients with locally advanced or metastatic hepatocellular carcinoma.
- Appraise the rationale for and clinical data with commercially available and developmental immune checkpoint inhibitors in the treatment of GI cancers.

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Interview with Axel Grothey, MD

Tracks 1-14

Track 1	Increased incidence of colorectal cancer (CRC) in people younger than age 50	Track 8	Role of checkpoint inhibitors in the treatment of mismatch repair-deficient, microsatellite instability (MSI)-high mCRC
Track 2	Molecular profiling for patients with metastatic CRC (mCRC)	Track 9	Response to monotherapy with anti-PD-1/PD-L1 antibodies
Track 3	Therapeutic options for patients with HER2-amplified mCRC	Track 10	MSI testing for patients with metastatic solid tumors
Track 4	Significance of BRAF mutation status and left or right primary tumor site in therapeutic decision-making for mCRC	Track 11	Biologic rationale for targeting cancer stemness pathways in colorectal and gastric cancer
Track 5	Clinical experience with the combination of EGFR antibodies and BRAF and MEK inhibitors	Track 12	Available clinical trial data on the efficacy of the cancer stemness inhibitor napabucasin in gastric and colorectal cancer
Track 6	ReDOS Phase II trial of regorafenib dosing strategies and associated side effects	Track 13	Selection and sequencing of therapy, including checkpoint inhibitors, for patients with advanced gastric cancer
Track 7	Optimal sequence of TAS-102 and regorafenib for mCRC	Track 14	Novel agents and strategies under investigation for gastric cancer

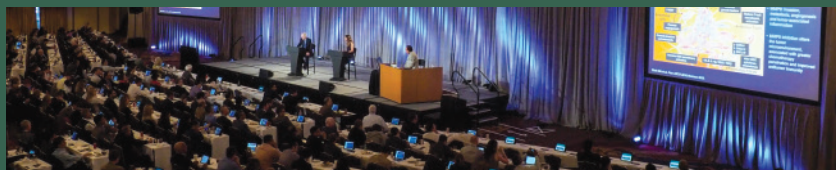
Interview with Philip A Philip, MD, PhD

Tracks 1-17

Track 1	PRODIGE 24 trial: Adjuvant modified FOLFIRINOX versus gemcitabine for patients with resected pancreatic ductal adenocarcinoma (PDAC)	Track 9	Emerging clinical data with napabucasin in patients with pancreatic cancer
Track 2	Role of postoperative radiation therapy in the treatment of PDAC	Track 10	First-line treatment options for patients with hepatocellular carcinoma (HCC)
Track 3	APACT trial: Ongoing Phase III evaluation of gemcitabine with nanoparticle albumin-bound (<i>nab</i>) paclitaxel as adjuvant therapy	Track 11	Lenvatinib as first-line treatment of HCC
Track 4	Neoadjuvant therapy for patients with potentially resectable metastatic PDAC (mPDAC)	Track 12	Regorafenib, nivolumab and other therapeutic options for HCC in the second-line setting
Track 5	Nanoliposomal irinotecan and other second-line therapy options for mPDAC	Track 13	Activity of immune checkpoint inhibitors for HCC
Track 6	Activity and tolerability of nanoliposomal irinotecan/5-FU/LV	Track 14	Role of tyrosine kinase inhibitors for patients with HCC and compromised liver function
Track 7	BRCA mutation testing and efficacy of PARP inhibitors for patients with pancreatic cancer	Track 15	Transarterial chemoembolization for patients with HCC
Track 8	Mechanism of action of cancer stemness inhibitor napabucasin	Track 16	Efficacy of the anti-VEGFR antibody ramucirumab for patients with HCC
		Track 17	Targeting DNA repair pathways and other novel approaches under investigation for pancreatic cancer

Related Video Program

Visit www.ResearchToPractice.com/GIIInvestigators18/Video for the full video proceedings and accompanying slide sets from the related CME event at the 2018 ASCO Annual Meeting.



Topics covered include:

- ▶ Selection and sequencing of therapy for patients with advanced gastric cancer
- ▶ Integration of anti-PD-1/PD-L1 therapy into the care of patients with advanced HCC
- ▶ Clinical and patient-specific factors influencing the selection of first- and second-line treatment of mPDAC
- ▶ Practical implementation of MSI and mismatch repair testing for patients with mCRC

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SELECT PUBLICATIONS

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An Evening with the Investigators: Perspectives on Key Questions and Emerging Research in the Management of Gastrointestinal Cancers

QUESTIONS (PLEASE CIRCLE ANSWER):

1. The results of the Phase III PRODIGE 24 trial demonstrated _____ for patients with resected PDAC who received modified FOLFIRINOX versus gemcitabine.
 - a. A significant improvement in disease-free survival
 - b. A significant improvement in overall survival
 - c. Fewer side effects
 - d. All of the above
 - e. Both a and b

2. Patients with mPDAC enrolled on the Phase III NAPOLI-1 trial had a significantly higher _____ with nanoliposomal irinotecan and 5-FU/LV compared to 5-FU/LV alone.
 - a. Progression-free survival
 - b. Overall survival
 - c. Both a and b

3. Results from the Phase III REACH-2 trial presented at ASCO 2018 by Zhu and colleagues _____ a significant improvement in overall survival with ramucirumab versus placebo as second-line treatment in patients with advanced HCC and elevated baseline alpha-fetoprotein.
 - a. Demonstrated
 - b. Did not demonstrate

4. Patients with BRAF mutation-positive mCRC do not respond to treatment with immune checkpoint inhibitors.
 - a. True
 - b. False

5. Which of the following categories reflects the drug class of the agent PEGPH20?
 - a. Anti-PD-1/PD-L1 antibody
 - b. MEK inhibitor
 - c. Recombinant human hyaluronidase enzyme
 - d. Cancer stemness inhibitor
 - e. None of the above

6. Which of the following patients with mCRC do not derive clinical benefit from the addition of EGFR antibodies to chemotherapy?
 - a. Patients with left-sided primary tumors
 - b. Patients with right-sided primary tumors

7. The FDA has approved pembrolizumab for all patients with unresectable or metastatic MSI-high or mismatch repair-deficient solid tumors who have experienced disease progression after prior treatment and who have no satisfactory alternative treatment options.
 - a. True
 - b. False

8. A Phase III trial comparing lenvatinib to sorafenib as first-line treatment for HCC demonstrated _____ with lenvatinib versus sorafenib.
 - a. Noninferiority with respect to overall survival
 - b. Improvement in progression-free survival
 - c. Both a and b

9. The hand-foot skin reaction associated with regorafenib typically occurs _____ in the course of treatment.
 - a. Early
 - b. Late

10. The KEYNOTE-061 study demonstrated a significant improvement in overall survival with pembrolizumab versus paclitaxel for patients with previously treated, advanced gastric or gastroesophageal junction cancer.
 - a. True
 - b. False

An Evening with the Investigators: Perspectives on Key Questions and Emerging Research in the Management of Gastrointestinal Cancers

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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 PRODIGE 24 trial of adjuvant modified FOLFIRINOX versus gemcitabine in resected PDAC	4 3 2 1	4 3 2 1
Mechanism of action, early clinical data and ongoing investigation of napabucasin in colorectal and pancreatic cancer	4 3 2 1	4 3 2 1
Optimal dosing of regorafenib for patients with mCRC	4 3 2 1	4 3 2 1
Activity of checkpoint inhibitors for patients with HCC	4 3 2 1	4 3 2 1
Emerging Phase III data with ramucirumab for patients with advanced HCC and elevated alpha-fetoprotein	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? Colorectal cancer
 Gastric cancer..... Hepatocellular carcinoma..... Pancreatic 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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.....

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:

- Review recent data on therapeutic advances and changing practice standards in colorectal and noncolorectal GI cancers, and integrate this information, as appropriate, into current clinical care. 4 3 2 1 N/M N/A
- Develop a long-term care plan for individuals diagnosed with metastatic CRC, considering biomarker profile, tumor location, prior systemic therapy, symptomatology, performance status (PS) and personal goals of treatment. 4 3 2 1 N/M N/A
- Use disease characteristics and patient preferences 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

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As a result of this activity, I will be able to:

- Consider age, PS and other clinical and logistical factors in the selection of systemic therapy for patients with localized, locally advanced or metastatic pancreatic adenocarcinoma. 4 3 2 1 N/M N/A
- Communicate the benefits and risks of available and emerging systemic interventions to patients with locally advanced or metastatic hepatocellular carcinoma. 4 3 2 1 N/M N/A
- Appraise the rationale for and clinical data with commercially available and developmental immune checkpoint inhibitors in the treatment of GI cancers. 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

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Philip A Philip, MD, PhD	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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