VOL 1 | ISSUE 1

# Pancreatic Cancer™

## UPDATE

## Conversations with Oncology Investigators

### Bridging the Gap between Research and Patient Care

**FACULTY INTERVIEWS**

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Ramesh K Ramanathan, MD

**EDITOR**

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# Pancreatic Cancer™ UPDATE



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|---|---|
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## OVERVIEW OF ACTIVITY

Pancreatic cancer is the fourth most common cause of cancer-related death among US men and women. The overwhelming majority of pancreatic cancers are ductal adenocarcinomas (approximately 90%). Unfortunately, many patients diagnosed with pancreatic adenocarcinoma (PAD) do not exhibit disease-specific symptoms (eg, weight loss, jaundice, pain, dyspepsia, nausea) until the cancer has reached a more advanced stage, and for all stages of PAD the combined 1-year survival rate for patients who do not receive surgery is approximately 29% and the 5-year rate is an appalling 7%. Published results from ongoing trials have led to the emergence of new therapeutic targets and regimens, and the poor clinical course for many patients with progressive PAD mandates the investigation of even more new approaches. 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, *Pancreatic Cancer Update* presents one-on-one discussions 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

- Develop an evidence-based strategy for the treatment of resectable or borderline-resectable PAD, exploring the role of neoadjuvant and adjuvant chemotherapy and/or radiation therapy.
- Consider age, performance status and other clinical and logistical factors in the selection of systemic therapy for patients with locally advanced or metastatic PAD.
- Educate patients with PAD about the potential side effects of various chemotherapeutic regimens, and provide preventive and emergent strategies to reduce or ameliorate these toxicities.
- Appreciate the efficacy and tolerability profile of nanoliposomal irinotecan for treatment-refractory metastatic PAD, and optimally incorporate this agent into patient-care algorithms.
- Recall available and emerging data with other investigational agents currently in clinical testing for PAD and, where applicable, refer eligible patients for trial participation.

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

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### 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.

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## Interview with Philip A Philip, MD, PhD

### Tracks 1-26

## Interview with Ramesh K Ramanathan, MD

### Tracks 1-20

| | |
|---|---|
| **Track 1** | ASCO Clinical Practice Guidelines for metastatic pancreatic cancer |
| **Track 2** | Genomic drivers in pancreatic ductal adenocarcinoma |
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| **Track 4** | Testing for microsatellite instability in patients with metastatic pancreatic cancer |
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| **Track 7** | Tumor reduction in primary and metastatic pancreatic cancer with gemcitabine/*nab* paclitaxel |
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| **Track 14** | Correlation between MRI-detected ferumoxytol uptake in tumor lesions and response to nal-IRI |
| **Track 15** | **Case:** A 63-year-old woman presents with obstructive jaundice, is diagnosed with borderline-resectable pancreatic cancer and receives neoadjuvant modified FOLFIRINOX |
| **Track 16** | Clinical experience with adjuvant gemcitabine/capecitabine |
| **Track 17** | **Case:** A 74-year-old man with metastatic pancreatic cancer receives first-line gemcitabine/*nab* paclitaxel and second-line nal-IRI |
| **Track 18** | Importance of palliative care in managing the formidable symptoms of pancreatic cancer |
| **Track 19** | **Case:** A 74-year-old woman presents with an isolated lung lesion 3 years after undergoing a pancreatic tail resection for a T2N0 adenocarcinoma |
| **Track 20** | **Case:** A 51-year-old woman with a family history of breast and ovarian cancer is diagnosed with metastatic pancreatic cancer and undergoes BRCA testing |

## SELECT PUBLICATIONS


**A phase 3, randomized, double-blind, placebo-controlled, multicenter study of pegylated recombinant human hyaluronidase (PEGPH20) in combination with *nab*-paclitaxel plus gemcitabine compared with placebo plus *nab*-paclitaxel and gemcitabine in participants with hyaluronan-high stage IV previously untreated pancreatic ductal adenocarcinoma. NCT02715804**

Barrett MT et al. **Clinical study of genomic drivers in pancreatic ductal adenocarcinoma.** *Br J Cancer* 2017;117(4):572-82.

Borazanci EH et al. **A phase II pilot trial of nivolumab (N) + albumin bound paclitaxel (AP) + paricalcitol (P) + cisplatin (C) + gemcitabine (G) (NAPPCG) in patients with previously untreated metastatic pancreatic ductal adenocarcinoma (PDAC).** Gastrointestinal Cancers Symposium 2018;**Abstract 358**.

Carnevale J, Ashworth A. **Assessing the significance of BRCA1 and BRCA2 mutations in pancreatic cancer.** *J Clin Oncol* 2015;33(28):3080-1.

Chiorean GE et al. **Randomized phase II study of 2nd-line FOLFIRI versus modified FOLFIRI with PARP inhibitor ABT-888 (veliparib) (NSC-737664) in metastatic pancreatic cancer (mPC): SWOG S1513.** *Proc ASCO* 2017;**Abstract TPS4147**.

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

Davendra S et al. **SWOG S1505: A randomized phase II study of perioperative mFOLFIRINOX vs gemcitabine/*nab*-paclitaxel as therapy for resectable pancreatic adenocarcinoma.** *Proc ASCO* 2017;**Abstract TPS4152**.

Doherty GJ et al. **HALO-109-301: A Phase III trial of PEGPH20 (with gemcitabine and *nab*-paclitaxel) in hyaluronic acid-high stage IV pancreatic cancer.** *Future Oncol* 2017;14(1):13-22.

Goldstein D et al. **Nomogram for predicting overall survival (OS) in patients (pts) treated with *nab*-paclitaxel (*nab*-P) plus gemcitabine (gem) or gem alone for metastatic pancreatic cancer (MPC).** *Proc ASCO* 2017;**Abstract 4109**.

Goldstein D et al. ***Nab*-paclitaxel plus gemcitabine for metastatic pancreatic cancer: Long-term survival from a phase III trial.** *J Natl Cancer Inst* 2015;107(2).

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.

Jameson GS et al. **A phase Ib/II pilot trial with *nab*-paclitaxel plus gemcitabine plus cisplatin in patients (pts) with stage IV pancreatic cancer.** Gastrointestinal Cancers Symposium 2017;**Abstract 341**.

Kaufman B et al. **Olaparib monotherapy in patients with advanced cancer and a germline BRCA1/2 mutation.** *J Clin Oncol* 2015;33(3):244-50.

Kunzmann V et al. **Tumor reduction in primary and metastatic pancreatic cancer lesions with *nab*-paclitaxel and gemcitabine: An exploratory analysis from a phase 3 study.** *Pancreas* 2017;46(2):203-8.

Neoptolemos JP et al. **Comparison of adjuvant gemcitabine and capecitabine with gemcitabine monotherapy in patients with resected pancreatic cancer (ESPAC-4): A multicentre, open-label, randomised, phase 3 trial.** *Lancet* 2017;389(10073):1011-24.

Nywening TM et al. **Targeting tumour-associated macrophages with CCR2 inhibition in combination with FOLFIRINOX in patients with borderline resectable and locally advanced pancreatic cancer: A single-centre, open-label, dose-finding, non-randomised, phase 1b trial.** *Lancet Oncol* 2016;17(5):651-62.

Ouyang G et al. **Gemcitabine plus cisplatin versus gemcitabine alone in the treatment of pancreatic cancer: A meta-analysis.** *World J Surg Oncol* 2016;14:59.

Picozzi VJ et al. **Initial gemcitabine/*nab*-paclitaxel (GA) followed by sequential (S) mFOLFIRINOX or alternating (A) mFOLFIRI in metastatic pancreatic cancer (mPC): The SEENA-1 study.** Gastrointestinal Cancers Symposium 2017;**Abstract 359**.

Ramanathan RK et al. **Correlation between ferumoxytol uptake in tumor lesions by MRI and response to nanoliposomal irinotecan in patients with advanced solid tumors: A pilot study.** *Clin Cancer Res* 2017;23(14):3638-48.

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

## QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The ongoing Phase II SWOG-S1505 trial is evaluating perioperative _____ for patients with resectable adenocarcinoma of the pancreas.**
   a. FOLFOXIRI
   b. Modified FOLFIRINOX
   c. Gemcitabine/*nab* paclitaxel
   d. All of the above
   e. Both a and b
   f. Both a and c
   g. Both b and c

2. **Nal-IRI is FDA approved _____ for patients with metastatic pancreatic cancer who have already received a gemcitabine-based regimen.**
   a. As monotherapy
   b. In combination with 5-FU/LV

3. **Which of the following categories reflects the mechanism of action of veliparib?**
   a. Antibody-drug conjugate
   b. Anti-PD-1/PD-L1 antibody
   c. Cancer stemness inhibitor
   d. PARP inhibitor

4. **The ongoing Phase II SWOG-S1513 trial is evaluating FOLFIRI alone versus modified FOLFIRI with veliparib as _____ for metastatic pancreatic cancer.**
   a. First-line therapy
   b. Second-line therapy
   c. Late-line therapy

5. **BRCA mutations occur in approximately _____ of patients with pancreatic cancer.**
   a. 0%
   b. 1% to 10%
   c. 11% to 20%
   d. 21% to 30%

6. **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

7. **During Phase II studies with PEGPH20, some patients experienced _____ requiring prophylaxis.**
   a. Fatigue
   b. Nausea
   c. Venous thromboembolic events
   d. All of the above

8. **PEGPH20 in combination with _____ has demonstrated encouraging activity in patients with metastatic pancreatic ductal adenocarcinoma.**
   a. FOLFIRINOX
   b. Gemcitabine/*nab* paclitaxel
   c. Both a and b
   d. Neither a nor b

9. **An exploratory analysis of the Phase III MPACT trial, which evaluated gemcitabine alone or in combination with *nab* paclitaxel as first-line therapy for metastatic pancreatic cancer, demonstrated significant tumor shrinkage benefit with the combination for both primary pancreatic and metastatic lesions.**
   a. True
   b. False

10. **A meta-analysis published by Sonbol and colleagues suggested the combination of 5-FU and irinotecan-containing regimens to be _____ to 5-FU and oxaliplatin as second-line therapy for pancreatic ductal adenocarcinoma.**
    a. Equivalent
    b. Inferior
    c. Superior

## EDUCATIONAL ASSESSMENT AND CREDIT FORM

### *Pancreatic 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 |
|---|---|---|
| Choice and ongoing evaluation of gemcitabine/*nab* paclitaxel or FOLFIRINOX as neoadjuvant therapy for locally advanced pancreatic cancer | 4 3 2 1 | 4 3 2 1 |
| Efficacy and safety of PEGPH20 in combination with standard chemotherapy for untreated metastatic pancreatic adenocarcinoma | 4 3 2 1 | 4 3 2 1 |
| SEENA-1: Results of a Phase II trial of gemcitabine/*nab* paclitaxel followed by sequential modified FOLFIRINOX or alternating with modified FOLFIRI for untreated metastatic pancreatic cancer | 4 3 2 1 | 4 3 2 1 |
| Ongoing Phase II trial of nivolumab/*nab* paclitaxel/paricalcitol/cisplatin/gemcitabine for untreated metastatic pancreatic ductal adenocarcinoma | 4 3 2 1 | 4 3 2 1 |
| Activity and ongoing investigation of PARP inhibitors for patients with BRCA mutation-positive advanced 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).....

**Approximately how many new patients with pancreatic cancer do 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:**

- Develop an evidence-based strategy for the treatment of resectable or borderline-resectable PAD, exploring the role of neoadjuvant and adjuvant chemotherapy and/or radiation therapy..... 4 3 2 1 N/M N/A
- Consider age, performance status and other clinical and logistical factors in the selection of systemic therapy for patients with locally advanced or metastatic PAD..... 4 3 2 1 N/M N/A
- Educate patients with PAD about the potential side effects of various chemotherapeutic regimens, and provide preventive and emergent strategies to reduce or ameliorate these toxicities..... 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:**

- Appreciate the efficacy and tolerability profile of nanoliposomal irinotecan for treatment-refractory metastatic PAD, and optimally incorporate this agent into patient-care algorithms. . . . . 4 3 2 1 N/M N/A
- Recall available and emerging data with other investigational agents currently in clinical testing for PAD and, where applicable, refer eligible patients for trial participation. . . . . 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** |
|---|---|---|
| Philip A Philip, MD, PhD | 4 3 2 1 | 4 3 2 1 |
| Ramesh K Ramanathan, 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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