Hepatocellular Carcinoma™

UPDATE

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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ABIM CME MOC ACCREDITED

CME Certified

Hepatocellular Carcinoma™

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OVERVIEW OF ACTIVITY

Hepatocellular carcinoma (HCC), the most common form of liver cancer, is the third leading cause of cancer-related death worldwide. The rising incidence, multiple etiologies, genetic heterogeneity and concurrent chronic liver disease challenge the selection of treatment for patients with this cancer. HCC is often diagnosed in the advanced stage and as such is associated with a poor prognosis. Recent breakthroughs in the understanding of the etiology and pathogenesis of HCC have led to the advent of new treatment modalities and investigational therapies, and in order to offer optimal patient care, the practicing oncologist must be well informed of these advances. To bridge the gap between research and patient care, this issue of *Hepatocellular Carcinoma Update* uses one-on-one discussions with leading oncology investigators. By providing access to the latest research developments and expert perspectives on the disease, this CME program will assist medical oncologists and gastroenterology specialists in the formulation of up-to-date clinical management strategies for HCC.

LEARNING OBJECTIVES

- Appraise available clinical trial data guiding the use of systemic therapies for patients with advanced HCC.
- Review the efficacy and safety data with regorafenib, and formulate a plan to incorporate this information into the treatment of HCC in patients who experience disease progression on sorafenib.
- Understand the scientific rationale for and recall available clinical data with investigational immune checkpoint inhibitors in the treatment of HCC.
- Recall available and emerging data with other investigational agents currently in clinical trials for HCC, and counsel appropriately selected patients about trial participation.

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Interview with Anthony El-Khoueiry, MD

Tracks 1-21

Track 1	Recent advances in the management of hepatocellular carcinoma (HCC)
Track 2	Epidemiology and etiology of HCC
Track 3	Biologic rationale for the investigation of immune checkpoint inhibitors for HCC
Track 4	Improvement in overall survival with sorafenib as first-line therapy for advanced HCC
Track 5	Results of the placebo-controlled Phase III RESORCE trial evaluating the role of regorafenib for patients with HCC and disease progression after treatment with sorafenib
Track 6	Phase III Study 304 comparing lenvatinib to sorafenib as first-line therapy for patients with unresectable HCC
Track 7	Clinical experience with regorafenib and sorafenib
Track 8	Side effects associated with regorafenib for patients with HCC
Track 9	Interim analysis of the Phase I/II CheckMate 040 trial evaluating the safety and antitumor activity of nivolumab in patients with advanced HCC
Track 10	Durable objective responses to nivolumab in advanced HCC
Track 11	Potential role of immune checkpoint inhibitors in the clinical management of HCC
Track 12	Combination immunotherapy approaches under investigation for HCC
Track 13	Efficacy of anti-CTLA-4 antibodies alone and in combination with anti-PD-1 antibodies
Track 14	**Case discussion:** A 74-year-old man with chronic hepatitis B presents with a single lesion, is diagnosed with HCC and remains disease free 4 years after surgical resection
Track 15	Selection of patients for liver transplantation
Track 16	**Case discussion:** A 71-year-old man with chronic hepatitis B infection is diagnosed with Child-Pugh A cirrhosis and Barcelona Clinic Liver Cancer (BCLC) Stage C HCC
Track 17	Response and tolerability with nivolumab as second-line therapy for HCC
Track 18	**Case discussion:** A 68-year-old woman with metabolic syndrome, diabetes and nonalcoholic steatohepatitis-related HCC receives transarterial chemoembolization (TACE) as first-line therapy
Track 19	Importance of appropriate patient selection for TACE
Track 20	Dosing and tolerability of sorafenib
Track 21	Novel approaches to the treatment of HCC

Interview with Josep M Llovet, MD, PhD

Tracks 1-13

Track 1	**Case discussion:** A patient with a history of hepatitis C infection presents with a single 6-cm lesion and is diagnosed with HCC
Track 2	Liver resection versus transplant for patients with HCC
Track 3	Rate of HCC recurrence after segmental resection
Track 4	TACE for patients with intermediate-stage HCC and well-preserved liver function
Track 5	BCLC staging system and treatment schedule for HCC
Track 6	Therapeutic options for patients with advanced HCC and macrovascular invasion
Track 7	Available research data and ongoing trials in the second-line setting for HCC
Track 8	Efficacy and toxicity profile of regorafenib as second-line therapy in the RESORCE trial
Track 9	Dose modifications and adjustments with regorafenib
Track 10	Activity and tolerability of lenvatinib for unresectable HCC

Interview with Dr Llovet (continued)

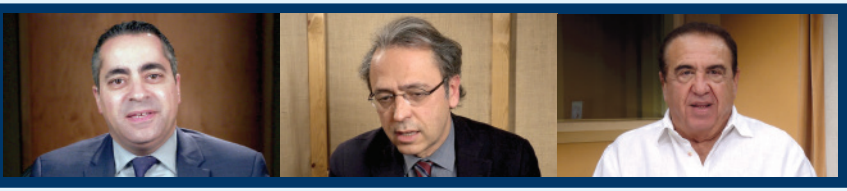
Track 11 Potential utility of immune checkpoint inhibitors in the management of HCC

Track 12 Predictors of response to immune checkpoint inhibitors

Track 13 Viewpoint on the potential integration of nivolumab into the treatment algorithm for HCC

Related Video Program

Visit www.ResearchToPractice.com/HCCU117/Video to view video highlights of the interviews with (from left) Drs El-Khoueiry and Llovet by Dr Love and earn additional *AMA PRA Category 1 Credit™*.



Topics covered include:

- Epidemiology and etiology of HCC
- Efficacy and safety data with regorafenib in patients with HCC progressing on sorafenib
- Activity and tolerability of lenvatinib for patients with unresectable HCC
- Biologic rationale for and emerging data with investigational immune checkpoint inhibitors in the management of HCC
- Other novel approaches under investigation for the treatment of HCC

Have Questions or Cases You Would Like Us to Pose to the Faculty?

Submit them to us via Facebook or Twitter and we will do our best to get them answered for you

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SELECT PUBLICATIONS

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Eligibility for the Phase III RESORCE trial evaluating regorafenib versus placebo for patients with HCC and disease progression on sorafenib included _____.**
   a. Child-Pugh A liver function
   b. Radiologic progression on sorafenib
   c. Intolerance to sorafenib
   d. Both a and b
   e. Both b and c

2. **Risk factors associated with the etiology of HCC include _____.**
   a. Chronic hepatitis B or C infection
   b. Obesity
   c. Diabetes
   d. All of the above

3. **Investigators for Study 304, comparing lenvatinib to sorafenib as first-line therapy for patients with unresectable HCC, reported which of the following preliminary results with respect to lenvatinib?**
   a. Noninferiority in terms of overall survival
   b. Significant improvement in time to disease progression
   c. Significant benefit in response rate
   d. All of the above

4. **Results of the Phase I/II CheckMate 040 study evaluating the safety and antitumor activity of nivolumab in patients with advanced HCC indicated _____.**
   a. An overall response rate of approximately 20%
   b. Responses only in patients who were uninfected by the hepatitis B or C virus
   c. Responses irrespective of prior treatment with sorafenib
   d. All of the above
   e. Both a and c

5. **Tivantinib, an agent under investigation for HCC, is a _____.**
   a. c-Met inhibitor
   b. VEGFR inhibitor
   c. WNT pathway inhibitor

6. **A Phase II study by Sangro and colleagues demonstrated that immune checkpoint blockade with _____ as a single agent resulted in an overall response rate of approximately 20% for patients with HCC and chronic hepatitis C virus infection.**
   a. Nivolumab
   b. Pembrolizumab
   c. Tremelimumab

7. **The incidence of liver toxicity (AST/ALT elevations) with nivolumab on the CheckMate 040 study for patients with HCC was higher than that with nivolumab in other tumor types.**
   a. True
   b. False

8. **Side effects associated with regorafenib therapy after disease progression on sorafenib in patients with HCC include _____.**
   a. Hypertension
   b. Diarrhea
   c. Hand-foot skin reaction
   d. All of the above
   e. Only a and c

9. **Data from the SHARP and Asia-Pacific trials demonstrated an improvement in overall survival with _____ versus placebo for patients with advanced HCC and established it as a standard first-line treatment.**
   a. Regorafenib
   b. Lenvatinib
   c. Sorafenib

10. **The multitargeted tyrosine kinase inhibitor sunitinib has an acceptable safety profile in the treatment of advanced HCC.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Hepatocellular Carcinoma Update — Volume 2, 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
Improvement in overall survival with regorafenib for patients with HCC and disease progression on sorafenib in the Phase III RESORCE trial	4 3 2 1	4 3 2 1
Preliminary data from the Phase III Study 304 evaluating lenvatinib versus sorafenib as first-line therapy for unresectable HCC	4 3 2 1	4 3 2 1
Results from a Phase II study of tremelimumab for patients with HCC	4 3 2 1	4 3 2 1
Hepatic toxicity with nivolumab in patients with advanced HCC in the CheckMate 040 study	4 3 2 1	4 3 2 1
Dosing recommendations with regorafenib for patients with HCC	4 3 2 1	4 3 2 1
Emerging data with novel agents and approaches for the treatment of HCC	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).....

How many new patients with HCC 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:

- Appraise available clinical trial data guiding the use of systemic therapies for patients with advanced HCC. ..... 4 3 2 1 N/M N/A
- Review the efficacy and safety data with regorafenib, and formulate a plan to incorporate this information into the treatment of HCC in patients who experience disease progression on sorafenib.. ..... 4 3 2 1 N/M N/A
- Understand the scientific rationale for and recall available clinical data with investigational immune checkpoint inhibitors in the treatment of HCC. ..... 4 3 2 1 N/M N/A
- Recall available and emerging data with other investigational agents currently in clinical trials for HCC, and counsel appropriately selected patients about 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: .....

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
Anthony El-Khoueiry, MD	4 3 2 1	4 3 2 1
Josep M Llovet, 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

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and editor for this activity:

.....

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UPDATE

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