Prostate Cancer™ UPDATE

Conversations with Urologic Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY

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MODERATOR

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SPECIAL ISSUE

Proceedings from a Clinical Investigator Think Tank

CME Certified

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Prostate Cancer Update
A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Prostate cancer is the most frequently diagnosed cancer in men, with an estimated 220,000 new cases and approximately 60,000 patients becoming resistant to castration levels of testosterone in the United States every year. Recently published randomized controlled studies have led to the emergence of novel therapeutic strategies for patients with castration-resistant prostate cancer. The treatment landscape and available options for prostate cancer have thus broadened, making choices more challenging for many healthcare professionals and patients despite the recent gains made in the management of this disease. Determining which treatment approach is most appropriate for a given patient requires careful consideration of patient-specific characteristics, physician expertise and available health system resources. Oncology clinicians must possess a clear understanding of the benefits and risks of each of the various available options and how best to integrate the emerging data and new agents into the therapeutic algorithm. To bridge the gap between research and patient care, this activity is designed to expose oncology clinicians to peer-reviewed evidence and expert perspectives that can be translated into strategies for optimal patient care.

LEARNING OBJECTIVES

- Assess the efficacy and safety of radiation therapy after radical prostatectomy for patients with high-risk early-stage prostate cancer.
- Optimize the management of asymptomatic, mildly symptomatic or symptomatic castration-resistant prostate cancer (CRPC) through rational integration of prospective Phase III data.
- Communicate the benefits and risks of taxane-based chemotherapy regimens to patients with newly diagnosed or recurrent CRPC.
- Use clinical risk factors and tests to identify patients at risk for developing skeletal fractures, and develop a management approach to preserve bone health.
- Summarize emerging efficacy and safety data with targeted agents in CRPC, including microtubule stabilizers, endothelin A receptor antagonists, cellular immunotherapy and novel inhibitors of testosterone synthesis or activity.
- Counsel appropriately selected patients about the availability of ongoing clinical trials in which they may be eligible to participate.

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CREDIT DESIGNATION STATEMENT

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HOW TO USE THIS CME ACTIVITY

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This program is supported by educational grants from Amgen Inc, AstraZeneca Pharmaceuticals LP, Aureon Laboratories Inc, Dendreon Corporation, Millennium Pharmaceuticals Inc and Sanofi-Aventis.

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UPDATE

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FACULTY — The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Dreicer** — Advisory Committee: AstraZeneca Pharmaceuticals LP, Celgene Corporation, Centocor Ortho Biotech Services LLC, EMD Serono Inc, Millennium Pharmaceuticals Inc; Speakers Bureau: Sanofi-Aventis. **Dr Freedland** — Advisory Committee: Amgen Inc, AstraZeneca Pharmaceuticals LP, GlaxoSmithKline, Myriad Genetics Inc; Consulting Agreement: Amgen Inc; Speakers Bureau: Amgen Inc, AstraZeneca Pharmaceuticals LP, Aureon Laboratories Inc. **Dr Kantoff** — Advisory Committee: Amgen Inc, Millennium Pharmaceuticals Inc, Pfizer Inc. **Dr Moul** — Advisory Committee: AstraZeneca Pharmaceuticals LP, Ferring, GlaxoSmithKline; Consulting Agreements: Amgen Inc, AstraZeneca Pharmaceuticals LP; Speakers Bureau: Aureon Laboratories Inc, Ferring, Sanofi-Aventis. **Dr Sandler** — Advisory Committee: Genentech BioOncology; Consulting Agreements: Calypso, Centocor Ortho Biotech Services LLC, Varian Medical Systems Inc; Stock Ownership: Biogen Idec. **Dr Sartor** — Advisory Committee: Bristol-Myers Squibb Company, GlaxoSmithKline; Consulting Agreements: Algeta ASA, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Celgene Corporation, Dendreon Corporation, GlaxoSmithKline, GPC Biotech, Johnson & Johnson Pharmaceuticals, Medivation, OncoGenex Pharmaceuticals Inc, Pfizer Inc, Sanofi-Aventis; Paid Research: Algeta ASA, AstraZeneca Pharmaceuticals LP, Cougar Biotechnology Inc, GlaxoSmithKline, Johnson & Johnson Pharmaceuticals, Sanofi-Aventis; Speakers Bureau: EUSA Pharma. **Dr Smith** — Consulting Agreement: Amgen Inc.

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Which of the following biomarkers provides value in the prognostication of recurrent PSA-only prostate cancer?**
   a. Absolute PSA level
   b. PSA doubling time
   c. Both a and b
   d. Neither a nor b

2. **Sipuleucel-T is a(n) _____.**
   a. Chemotherapy agent
   b. Targeted small-molecule tyrosine kinase inhibitor
   c. *E coli*-derived antibody to PSA
   d. Autologous cellular immunotherapy agent

3. **When compared to placebo in randomized trials, sipuleucel-T has demonstrated improvement in _____ among patients with CRPC.**
   a. PSA response
   b. Progression-free survival
   c. Overall survival
   d. All of the above

4. **Which of the following prostate cancer subtypes was included in the pivotal IMPACT trial comparing sipuleucel-T to placebo?**
   a. Asymptomatic or mildly symptomatic CRPC
   b. Moderately symptomatic CRPC
   c. Severely symptomatic CRPC

5. **_____ has not shown an overall survival benefit in a randomized Phase III trial in CRPC.**
   a. Sipuleucel-T
   b. Mitoxantrone/prednisone
   c. Docetaxel/prednisone
   d. Cabazitaxel/prednisone

6. **Cabazitaxel/prednisone has demonstrated a survival advantage compared to _____ in the Phase III TROPIC study in CRPC.**
   a. Sipuleucel-T
   b. Docetaxel/prednisone
   c. Prednisone
   d. Mitoxantrone/prednisone

7. **According to the FDA recommendations, prophylactic growth factor support should be considered for patients receiving cabazitaxel who have high-risk clinical features that predispose them to increased complications from prolonged neutropenia.**
   a. True
   b. False

8. **In a double-blind, Phase III study for patients receiving androgen deprivation therapy for nonmetastatic prostate cancer, denosumab was associated with which of the following effects compared to placebo?**
   a. Increased bone mineral density
   b. Reduction in the incidence of new vertebral fractures
   c. Both a and b

9. **In a double-blind, Phase III study for patients with metastatic CRPC, denosumab demonstrated superiority to zoledronic acid in delaying or preventing skeletal-related events.**
   a. True
   b. False

10. **Drugs with which of the following mechanisms are being studied in CRPC?**
    a. Lyase inhibition
    b. Endothelin A inhibition
    c. Both a and b

11. **The Prostate Px® test has been demonstrated to predict the likelihood of disease progression after primary treatment of prostate cancer.**
    a. True
    b. False

12. **In studies with the Prostate Px® test, the definition of disease progression includes which of the following?**
    a. Development of castrate-resistant prostate cancer
    b. Development of metastatic disease
    c. PSA recurrence only
    d. Both a and b

Post-test answer key: 1c, 2d, 3c, 4a, 5b, 6d, 7a, 8c, 9a, 10c, 11a, 12d

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Prostate Cancer Update — Think Tank 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 ONE — 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
IMPACT: A Phase III trial of sipuleucel-T versus placebo for asymptomatic or mildly symptomatic CRPC	4 3 2 1	4 3 2 1
Efficacy of denosumab in men receiving androgen deprivation therapy for prostate cancer	4 3 2 1	4 3 2 1
Rationale for the development of lyase inhibitors, such as abiraterone and TAK-700, for both hormone-responsive and castration-resistant prostate cancer	4 3 2 1	4 3 2 1
TROPIC: A Phase III trial of the novel microtubule stabilizer cabazitaxel for docetaxel-refractory CRPC	4 3 2 1	4 3 2 1

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No

If no, please explain:.....

Will this activity help you improve patient care?

☐ Yes ☐ No ☐ Not applicable

If no, please explain:.....

Did the activity meet your educational needs and expectations?

☐ 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:

- Assess the efficacy and safety of radiation therapy after radical prostatectomy for patients with high-risk early-stage prostate cancer..... 4 3 2 1 N/M N/A
- Optimize the management of asymptomatic, mildly symptomatic or symptomatic castration-resistant prostate cancer (CRPC) through rational integration of prospective Phase III data..... 4 3 2 1 N/M N/A
- Communicate the benefits and risks of taxane-based chemotherapy regimens to patients with newly diagnosed or recurrent CRPC..... 4 3 2 1 N/M N/A
- Use clinical risk factors and tests to identify patients at risk for developing skeletal fractures, and develop a management approach to preserve bone health..... 4 3 2 1 N/M N/A
- Summarize emerging efficacy and safety data with targeted agents in CRPC, including microtubule stabilizers, endothelin A receptor antagonists, cellular immunotherapy and novel inhibitors of testosterone synthesis or activity..... 4 3 2 1 N/M N/A
- Counsel appropriately selected patients about the availability of ongoing clinical trials in which they may be eligible to participate..... 4 3 2 1 N/M N/A

What other practice changes will you make or consider making as a result of this activity?

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What additional information or training do you need on the activity topics or other oncology-related topics?

.....

Additional comments about this activity:

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As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

☐ Yes, I am willing to participate. ☐ No, I am not willing to participate.

PART TWO — Please tell us about the faculty and moderator for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter	Effectiveness as an educator
Robert Dreicer, MD, MS	4 3 2 1	4 3 2 1
Stephen J Freedland, MD	4 3 2 1	4 3 2 1
Philip Kantoff, MD	4 3 2 1	4 3 2 1
Judd W Moul, MD	4 3 2 1	4 3 2 1
Howard Sandler, MD, MS	4 3 2 1	4 3 2 1
A Oliver Sartor, MD	4 3 2 1	4 3 2 1
Matthew R Smith, MD, PhD	4 3 2 1	4 3 2 1
Moderator	**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 moderator for this activity:

.....

REQUEST FOR CREDIT — Please print clearly

Name: ..... Specialty: .....

Professional Designation:

☐ MD ☐ DO ☐ PharmD ☐ NP ☐ RN ☐ PA ☐ Other .....

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City, State, Zip: .....

Telephone: ..... Fax: .....

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I certify my actual time spent to complete this educational activity to be _____ hour(s).

Signature: ..... Date: .....

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