Consensus or Controversy?
Clinical Investigators Provide Perspectives on the Current and Future Management of Prostate Cancer

A special audio supplement to a CME symposium held during the 2019 Genitourinary Cancers Symposium featuring expert comments on the application of emerging research to patient care

Faculty Interviews
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Editor
Neil Love, MD

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Consensus or Controversy?
OVERVIEW OF ACTIVITY
Cancers of the genitourinary (GU) system affect hundreds of thousands of individuals in the United States each year and account for more than one fourth of all cancer diagnoses. Of this diverse array of distinct diseases, tumors of the prostate are among the most prevalent and thus the focus of extensive ongoing clinical research. A result of this research is that the clinical management of both early and more advanced presentations of prostate cancer (PC) is constantly evolving, necessitating rapid and consistent access to learning opportunities for clinicians who care for these patients. These 2 postmeeting interviews with faculty from a satellite symposium held during the 2019 Genitourinary Cancers Symposium explore the most significant therapeutic advances of the past year by using the perspectives of leading PC experts to gain a better understanding of new management strategies and lingering clinical controversies facing the GU cancer community.

This activity will help medical oncologists and other allied healthcare professionals to find answers to the individualized questions and concerns they frequently encounter and to in turn provide high-quality cancer care.

LEARNING OBJECTIVES
• Evaluate the published research database supporting the recent FDA approvals of secondary hormonal agents in the management of nonmetastatic PC, and consider this information in the discussion of nonresearch treatment options for patients.
• Explore available data on the use of cytotoxic and secondary hormonal therapy in the setting of hormone-sensitive metastatic PC to design effective treatment plans for appropriate patients.
• Consider patient and disease characteristics and published clinical trial data in the selection and sequencing of available local and systemic treatment modalities for patients with metastatic PC.
• Describe the rationale for testing patients with metastatic PC for BRCA1/2 mutations, and advise individuals found to harbor these genetic abnormalities about participation in clinical trials evaluating the role of a PARP inhibitor.
• Recall the design of ongoing research studies evaluating other novel agents and therapeutic strategies for PC, and counsel appropriate patients about availability and participation.

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Interview with Emmanuel S Antonarakis, MD

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**Video Program**

View the corresponding video interviews with (from left) Drs Antonarakis and Smith by Dr Love at [www.ResearchToPractice.com/GUCancers19/Interviews/Video](http://www.ResearchToPractice.com/GUCancers19/Interviews/Video)
SELECT PUBLICATIONS


Armstrong AJ et al. Phase 3 study of androgen deprivation therapy (ADT) with enzalutamide (ENZA) or placebo (PBO) in metastatic hormone-sensitive prostate cancer (mHSPC): The ARCHES trial. Genitourinary Cancers Symposium 2019; Abstract 687.

Cohen R et al. Association of primary resistance to immune checkpoint inhibitors in metastatic colorectal cancer with misdiagnosis of microsatellite instability or mismatch repair deficiency status. JAMA Oncol 2018; [Epub ahead of print].


Fizazi K et al. ARAMIS: Efficacy and safety of darolutamide in nonmetastatic castration resistant prostate cancer (nmCRPC). Genitourinary Cancers Symposium 2019; Abstract 140.

Fizazi K et al. Final analysis of phase III LATITUDE study in patients (pts) with newly diagnosed high-risk metastatic castration-naïve prostate cancer (NDx-HR mCNPC) treated with abiraterone acetate + prednisone (AA+P) added to androgen deprivation therapy (ADT). Genitourinary Cancers Symposium 2019; Abstract 141.


Marin M et al. ARV7 and ARFL mRNA in blood to predict androgen receptor inhibitors and docetaxel response in castration-resistant prostate cancer patients. Genitourinary Cancers Symposium 2019; Abstract 207.


Scher HI et al. Assessment of circulating tumor cell number as a transitional surrogate endpoint for survival in phase II trials for metastatic castration-resistant prostate cancer. Genitourinary Cancers Symposium 2019; Abstract 143.

Sharma P et al. Initial results from a phase II study of nivolumab (NIVO) plus ipilimumab (IPI) for the treatment of metastatic castration-resistant prostate cancer (mCRPC; CheckMate 650). Genitourinary Cancers Symposium 2019; Abstract 142.

Small EJ et al. Updated analysis of progression-free survival with first subsequent therapy (PFS2) and safety in the SPARTAN study of apalutamide (APA) in patients (pts) with high-risk nonmetastatic castration-resistant prostate cancer (nmCRPC). Genitourinary Cancers Symposium 2019; Abstract 144.


Yu EY et al. KEYNOTE-365 Cohort A: Pembrolizumab (pembro) plus olaparib in docetaxel-pretreated patients (pts) with metastatic castrate-resistant prostate cancer (mCRPC). Genitourinary Cancers Symposium 2019; Abstract 145.
QUESTIONS (PLEASE CIRCLE ANSWER):

1. Initial results of the Phase III ARAMIS trial evaluating darolutamide or placebo with continued ADT for patients with nonmetastatic CRPC demonstrated a statistically significant improvement in metastasis-free survival with darolutamide.
   a. True
   b. False

2. The ongoing randomized Phase III ARASENS trial is evaluating darolutamide or placebo in combination with standard ADT and ________ for patients with metastatic HSPC.
   a. Radiation therapy to the prostate
   b. Docetaxel

3. Data published by Smith and colleagues evaluating patients with nonmetastatic CRPC indicate that a PSA doubling time of ________ or less is a prognostic indicator of progression to metastatic disease.
   a. 5 months
   b. 10 months
   c. 15 months

4. An updated analysis of progression-free survival with first subsequent therapy (PFS2) in the Phase III SPARTAN trial of apalutamide or placebo for high-risk nonmetastatic CRPC, presented at the 2019 Genitourinary Cancers Symposium, upheld the previously observed ________ in PFS2 with early intervention with apalutamide.
   a. Benefit
   b. Lack of benefit

5. The Phase III ARCHES trial evaluating ADT with either enzalutamide or placebo for patients with metastatic HSPC demonstrated a statistically significant improvement in ________ with enzalutamide.
   a. Overall survival
   b. Progression-free survival
   c. Both a and b

6. Presence of AR-V7 is associated with favorable clinical response to treatment with ________ in patients with metastatic CRPC.
   a. Androgen receptor signaling inhibitors
   b. Taxane therapy

7. Preliminary results of the Phase II GALAHAD study evaluating the PARP inhibitor niraparib as monotherapy for metastatic CRPC with biallelic DNA repair gene defects reported PSA and objective responses particularly in patients with ________ mutations identified by a blood-based assay.
   a. BRCA1/2
   b. Non-BRCA

8. MSI-H/dMMR molecular phenotype occurs in approximately ________ of patients with prostate cancer.
   a. 3%
   b. 15%
   c. 45%

9. Data from the Phase II KEYNOTE-199 trial evaluating pembrolizumab monotherapy for patients with metastatic CRPC previously treated with docetaxel demonstrated ________ antitumor activity in the PD-L1-positive and PD-L1-negative cohorts compared to the bone-predominant cohort.
   a. Equivalent
   b. Better
   c. Less

10. Initial results of the Phase II CheckMate 650 trial evaluating nivolumab with ipilimumab for patients with metastatic CRPC demonstrated an approximately 25% overall response rate with this combination for patients ________.
    a. Who had not yet received chemotherapy
    b. Who had experienced disease progression after chemotherapy
**Consensus or Controversy? Clinical Investigators Provide Perspectives on the Current and Future Management of Prostate Cancer**

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?**

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<th>Topic</th>
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<td>Effect of PSA doubling time on time to metastasis in nonmetastatic CRPC and improvement in metastasis-free survival with androgen receptor antagonist therapy</td>
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<td>LATITUDE: Final efficacy data from the Phase III trial of abiraterone/prednisone added to ADT for patients with newly diagnosed, high-risk castration-naïve metastatic prostate cancer</td>
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<td>Association between AR-V7 expression and outcomes with secondary hormonal therapy and chemotherapy in patients with metastatic CRPC</td>
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<td>Frequency of MSI-H/dMMR molecular phenotype in prostate cancer and role of immune checkpoint inhibitors for patients with metastatic CRPC with and without MSI-H/dMMR disease</td>
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<td>Activity and tolerability, FDA breakthrough therapy designations and ongoing evaluation of the PARP inhibitors rucaparib and olaparib for patients with metastatic CRPC and BRCA1/2 mutations</td>
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**Practice Setting:**
- Academic center/medical school
- Community cancer center/hospital
- Group practice
- Solo practice
- Government (e.g., VA)
- Other (please specify)

Approximately how many new patients with prostate 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:

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<th>LO</th>
<th>4 = Yes</th>
<th>3 = Will consider</th>
<th>2 = No</th>
<th>1 = Already doing</th>
<th>N/M = LO not met</th>
<th>N/A = Not applicable</th>
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<td>1.</td>
<td>As a result of this activity, I will be able to:</td>
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<td>Evaluate the published research database supporting the recent FDA approvals of secondary hormonal agents in the management of nonmetastatic PC, and consider this information in the discussion of nonresearch treatment options for patients.</td>
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<td>Explore available data on the use of cytotoxic and secondary hormonal therapy in the setting of hormone-sensitive metastatic PC to design effective treatment plans for appropriate patients.</td>
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EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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

• Consider patient and disease characteristics and published clinical trial data in the selection and sequencing of available local and systemic treatment modalities for patients with metastatic PC. .............................................. 4 3 2 1 N/M N/A

• Describe the rationale for testing patients with metastatic PC for BRCA1/2 mutations, and advise individuals found to harbor these genetic abnormalities about participation in clinical trials evaluating the role of a PARP inhibitor. .................... 4 3 2 1 N/M N/A

• Recall the design of ongoing research studies evaluating other novel agents and therapeutic strategies for PC, and counsel appropriate patients about availability and 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

<table>
<thead>
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<th>Faculty</th>
<th>Knowledge of subject matter</th>
<th>Effectiveness as an educator</th>
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<td>Emmanuel S Antonarakis, MD</td>
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<td>Matthew R Smith, MD, PhD</td>
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<td>Editor</td>
<td>Knowledge of subject matter</td>
<td>Effectiveness as an educator</td>
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<tr>
<td>Neil Love, MD</td>
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REQUEST FOR CREDIT — Please print clearly

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

Professional Designation: ☐ MD ☐ DO ☐ PharmD ☐ NP ☐ RN ☐ PA ☐ Other: .................................

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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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