# 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**

Emmanuel S Antonarakis, MD

Matthew R Smith, MD, PhD

**Editor**

Neil Love, MD


**Contents**

1 Audio CD

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

## 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.

## ACCREDITATION STATEMENT

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## CME INFORMATION

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## Interview with Emmanuel S Antonarakis, MD

### Tracks 1-26

**Track 1** Initial evaluation of prognostic indicators in hormone-sensitive prostate cancer (HSPC) versus castration-resistant prostate cancer (CRPC)

**Track 2** Effect of prostate-specific antigen (PSA) doubling time on time to metastasis and overall survival in nonmetastatic CRPC; improvement in metastasis-free survival with androgen receptor antagonist therapy

**Track 3** Perspective on the use of intermittent androgen deprivation therapy (ADT) for patients with nonmetastatic HSPC and rising PSA levels

**Track 4** Structural and mechanistic similarities and differences between available (apalutamide, enzalutamide) and investigational (darolutamide) androgen receptor antagonists

**Track 5** Initial results of the Phase III ARAMIS trial: Metastasis-free survival improvement and tolerability of darolutamide versus placebo for nonmetastatic CRPC

**Track 6** ARASENS: An ongoing Phase III trial evaluating darolutamide versus placebo in combination with standard ADT and docetaxel for patients with metastatic HSPC

**Track 7** Perspective on the new drug application and potential FDA approval of darolutamide for nonmetastatic CRPC

**Track 8** Spectrum and frequency of systemic and CNS-related side effects associated with apalutamide, enzalutamide and darolutamide

**Track 9** Updated analysis of progression-free survival with first subsequent therapy (PFS2) in the SPARTAN study of apalutamide for high-risk nonmetastatic CRPC

**Track 10** ARCHES: Design, efficacy and tolerability results from a Phase III trial of ADT with enzalutamide or placebo for metastatic HSPC

**Track 11** Selection and sequencing of therapy for patients with metastatic prostate cancer

**Track 12** Correlation between the presence of androgen receptor splice variant 7 (AR-V7) and outcomes with secondary hormonal therapy and chemotherapy in metastatic CRPC

**Track 13** Prevalence and detection of AR-V7 in patients with metastatic CRPC

**Track 14** Overview of BRCA1/2 and other DNA repair gene mutations that may confer sensitivity to PARP inhibition

**Track 15** Efficacy and FDA breakthrough therapy designations for olaparib and rucaparib for metastatic CRPC

**Track 16** GALAHAD: Preliminary results of a Phase II trial of niraparib for patients with metastatic CRPC and biallelic DNA repair gene defects

**Track 17** Response to PARP inhibitor therapy in patients with metastatic CRPC with BRCA1/2 versus ATM mutations

**Track 18** Activity of platinum-based chemotherapy in patients with metastatic CRPC and germline BRCA mutations

**Track 19** Clinical experience with PARP inhibitor-associated side effects in men with metastatic CRPC

**Track 20** Perspective on the negative results of the Phase III ERA 223 trial evaluating radium-223 dichloride in combination with abiraterone acetate for patients with chemotherapy-naïve metastatic CRPC and bone metastases

**Track 21** Appropriate use of radium-223 for the treatment of symptomatic metastatic CRPC

**Track 22** Biologic rationale for and ongoing investigation of lutetium-177-prostate-specific membrane antigen (PSMA)-617 for progressive PSMA-positive metastatic CRPC

**Track 23** KEYNOTE-199: Updated analysis of a Phase II trial of pembrolizumab monotherapy for patients with metastatic CRPC previously treated with docetaxel

**Track 24** Initial results of the Phase II CheckMate 650 trial of nivolumab with ipilimumab for metastatic CRPC

**Track 25** Prevalence of microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) molecular phenotype and response to immune checkpoint blockade in patients with prostate cancer

**Track 26** Emerging data with olaparib in combination with anti-PD-1/PD-L1 checkpoint blockade for metastatic CRPC

## Interview with Matthew R Smith, MD, PhD

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**Track 1** Recent advances in the treatment of nonmetastatic CRPC

**Track 2** Effect of PSA doubling time on prognosis for patients with nonmetastatic disease

**Track 3** PSA doubling time and clinical decision-making for patients with M0 disease

**Track 4** Counseling patients with nonmetastatic disease about goals of therapy and expected side effects

**Track 5** Similarities and differences in the design, entry criteria and efficacy endpoints among the ARAMIS, SPARTAN and PROSPER trials

**Track 6** Comparison of the side-effect profiles of apalutamide, enzalutamide and darolutamide

**Track 7** Counseling patients receiving long-term ADT about treatment-related fatigue

**Track 8** Comparison of primary (metastasis-free survival) and secondary outcomes among the ARAMIS, SPARTAN and PROSPER trials

**Track 9** Choosing among darolutamide, apalutamide and enzalutamide

**Track 10** SPARTAN trial: PFS2 improvement with apalutamide for high-risk nonmetastatic CRPC

**Track 11** Outcomes, tolerability and appropriate use of abiraterone in combination with prednisone

**Track 12** Similarities and differences in the design, entry criteria and efficacy endpoints between the LATITUDE (ADT with abiraterone/prednisone or placebo) and ARCHES (ADT with enzalutamide or placebo) trials for patients with metastatic HSPC

**Track 13** Key clinical and practical factors guiding the selection of docetaxel versus abiraterone/prednisone for metastatic HSPC

**Track 14** Perspective on the intensification of therapy for patients with metastatic HSPC and suboptimal responses to ADT

**Track 15** Spectrum and frequency of somatic and germline DNA repair gene mutations in prostate cancer; activity of PARP inhibitors in patients with metastatic CRPC

**Track 16** Incidence of MSI-H/dMMR molecular phenotype in patients with prostate cancer; indications for testing and current role of immune checkpoint inhibitors

**Track 17** Results of a Phase II prospective trial of lutetium-177-PSMA-617 theranostics in metastatic CRPC

**Track 18** Novel immune checkpoint inhibitor-based combinations for metastatic CRPC

## Video Program

**View the corresponding video interviews with (from left) Drs Antonarakis and Smith by Dr Love at www.ResearchToPractice.com/GUCancers19/Interviews/Video**

## SELECT PUBLICATIONS


Antonarakis ES et al. **Pembrolizumab for metastatic castration-resistant prostate cancer (mCRPC) previously treated with docetaxel: Updated analysis of KEYNOTE-199.** Genitourinary Cancers Symposium 2019;**Abstract 216**.

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].

De Giorgi U et al. **A phase III, randomized, double-blind, placebo-controlled study of enzalutamide in men with nonmetastatic castration-resistant prostate cancer: Post-hoc analysis of PROSPER by prior therapy.** Genitourinary Cancers Symposium 2019;**Abstract 185**.

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**.

Hofman MS et al. **[$^{177}$Lu]-PSMA-617 radionuclide treatment in patients with metastatic castration-resistant prostate cancer (LuPSMA trial): A single-centre, single-arm, phase 2 study.** *Lancet Oncol* 2018;19(6):825-33.

Karzai F et al. **A phase 2 study of olaparib and durvalumab in metastatic castrate-resistant prostate cancer (mCRPC) in an unselected population.** *Proc ASCO* 2018;**Abstract 163**.

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**.

Marshall CH et al. **Response to PARP inhibitor therapy in metastatic castrate-resistant prostate cancer (mCRPC) patients with BRCA1/2 versus ATM mutations.** Genitourinary Cancers Symposium 2019;**Abstract 154**.

Parker C et al; ALSYMPCA Investigators. **Alpha emitter radium-223 and survival in metastatic prostate cancer.** *N Engl J Med* 2013;369(3):213-23.

Saad F et al. **Association between urinary, bowel, and hormonal treatment-related symptoms and clinical outcomes in nonmetastatic castration-resistant prostate cancer (nmCRPC): PROSPER study.** Genitourinary Cancers Symposium 2019;**Abstract 233**.

Sartor AO et al. **A retrospective analysis of treatment patterns in metastatic castration-resistant prostate cancer patients treated with radium-223.** Genitourinary Cancers Symposium 2019;**Abstract 180**.

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**.

Smith M et al. **Addition of radium-223 to abiraterone acetate and prednisone or prednisolone in patients with castration-resistant prostate cancer and bone metastases (ERA 223): A randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet Oncol* 2019;20(3):408-19.

Smith MR et al. **Phase II study of niraparib in patients with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD): Preliminary results of GALAHAD.** Genitourinary Cancers Symposium 2019;**Abstract 202**.

Smith MR et al; SPARTAN Investigators. **Apalutamide treatment and metastasis-free survival in prostate cancer.** *N Engl J Med* 2018;378(15):1408-18.

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**.

POST-TEST

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

**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 with ADT 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

## EDUCATIONAL ASSESSMENT AND CREDIT FORM

### 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?**

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

| | BEFORE | AFTER |
|---|---|---|
| Effect of PSA doubling time on time to metastasis in nonmetastatic CRPC and improvement in metastasis-free survival with androgen receptor antagonist therapy | 4 3 2 1 | 4 3 2 1 |
| 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 | 4 3 2 1 | 4 3 2 1 |
| Association between AR-V7 expression and outcomes with secondary hormonal therapy and chemotherapy in patients with metastatic CRPC | 4 3 2 1 | 4 3 2 1 |
| 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 | 4 3 2 1 | 4 3 2 1 |
| 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 | 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 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:**

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:**

- 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..... 4 3 2 1 N/M N/A
- 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. ..... 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:**

- 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**

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

| Faculty | Knowledge of subject matter | Effectiveness as an educator |
|---|---|---|
| Emmanuel S Antonarakis, MD | 4 3 2 1 | 4 3 2 1 |
| Matthew R Smith, 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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