2016

Investigator Perspectives on Emerging Concepts in the Management of Genitourinary Cancers

A Special Edition Interview Program

FACULTY INTERVIEWS

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Investigator Perspectives on Emerging Concepts in the Management of Genitourinary Cancers

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Cancers of the genitourinary (GU) system affect hundreds of thousands of individuals within the United States each year and account for almost 30% of new cancer diagnoses. Although GU cancers are a diverse array of distinct diseases, tumors of the bladder, kidney (and renal pelvis) and prostate are among the most prevalent and, thus, are the topic of extensive ongoing clinical research. As such, the clinical management of these diseases is currently in a state of evolution, necessitating rapid and consistent access to learning opportunities for clinicians who provide care for these patients. Featuring information on the latest research developments along with expert perspectives, this CME program is designed to assist medical oncologists, urologists and radiation oncologists with the formulation of up-to-date clinical management strategies for the care of patients with GU cancers.

LEARNING OBJECTIVES

- Explore emerging data on the use of cytotoxic therapy in the setting of hormone-sensitive advanced prostate cancer (PC), and consider this information when formulating initial treatment plans for appropriate individuals.
- Recall existing and emerging research information demonstrating the effects of secondary hormonal interventions on quality and quantity of life for patients with castration-resistant PC, and use this information to guide therapeutic decision-making.
- Effectively apply evidence-based research findings in the determination of best-practice sequencing of available immunotherapeutic, chemotherapeutic and secondary hormonal agents for patients with metastatic PC.
- Develop an evidence-based approach to the sequencing of systemic therapies for patients with advanced renal cell carcinoma (RCC), incorporating tyrosine kinase inhibitors, anti-VEGF antibodies, mTOR inhibitors and immunotherapeutic agents.
- Recognize toxicities attributable to diverse molecular-targeted treatments for RCC, and offer preventive or emergent interventions to minimize or ameliorate these side effects.
- Appraise the rationale for and clinical data with approved and investigational anti-PD-1 and anti-PD-L1 antibodies in patients with metastatic RCC and bladder cancer.
- Recognize immune-related adverse events and other common side effects associated with approved and developmental immunotherapeutics in order to offer supportive management strategies.

ACCREDITATION STATEMENT

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through a joint providership of the Yale School of Medicine and Research To Practice. The Yale School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

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Visit **www.ResearchToPractice.com/GUPerspectives16/Video** for video highlights from the interviews with the faculty.

Interview with Daniel P Petrylak, MD

Tracks 1-15

Track 1 **Case discussion:** A 47-year-old man with previously treated HER2-positive muscle-invasive bladder cancer attains a complete response with the anti-PD-L1 antibody atezolizumab (MPDL3280A) on a clinical trial

Track 2 Investigation of novel targeted therapies for patients with HER2-positive bladder cancer

Track 3 Duration of therapy with checkpoint inhibitors

Track 4 Activity, durability of response and tolerability of atezolizumab for locally advanced or metastatic urothelial bladder cancer (UBC)

Track 5 Low rates of pseudoprogression among patients with UBC receiving anti-PD-1/PD-L1 antibodies

Track 6 Ongoing trials of pembrolizumab, nivolumab and atezolizumab for advanced UBC

Track 7 Investigation of combination therapy with anti-PD-1/PD-L1 and anti-CTLA-4 antibodies for UBC

Track 8 Perspective on the use of immune checkpoint inhibitors in clinical practice for patients with genitourinary cancers

Track 9 **Case discussion:** A 58-year-old man with de novo metastatic prostate cancer (PC) receives treatment with androgen deprivation therapy and docetaxel

Track 10 Activity of taxane-based chemotherapy in men with androgen receptor splice variant 7 (AR-V7)-positive metastatic castration-resistant PC (mCRPC)

Track 11 Potential effects of the CHAARTED and STAMPEDE trial results on clinical practice

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Track 14 Sequencing chemotherapy and/or endocrine therapy for patients whose disease progresses on enzalutamide or abiraterone

Track 15 ARMOR3-SV: An ongoing Phase III trial of galeterone versus enzalutamide for men with mCRPC expressing AR-V7 splice variant

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Track 1 Clinical overview of immunotherapies in the treatment of cancer

Track 2 Efficacy and adverse events associated with combination anti-PD-1 and CTLA-4 therapy

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Track 4 Rationale for combining immune checkpoint inhibitors and radiation therapy

Track 5 Transcriptional signatures associated with lack of response to anti-PD-1 therapy in patients with renal cell carcinoma (RCC)

Track 6 Correlation between PD-L1 expression and response to immune checkpoint blockade

Track 7 STARVE-PC: An ongoing biomarker-driven Phase II trial of combined immune checkpoint blockade with nivolumab and ipilimumab for patients with AR-V7-expressing mCRPC

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Track 9 Mechanisms of action and rationale for the use of chimeric antigen receptor T-cell and tumor infiltrating lymphocyte therapies

Track 10 Viewpoint on attempting to combine immune checkpoint inhibitors with chemotherapy

Track 11 Potential correlation between high mutational load and higher likelihood of response to immune checkpoint blockade

Interview with Dr Drake (continued)

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Track 13 CheckMate 214: An ongoing Phase III trial of nivolumab and ipilimumab versus sunitinib monotherapy for patients with previously untreated advanced or metastatic RCC

Track 14 Biologic rationale for combining immunotherapy and anti-VEGF therapies in RCC

Track 15 Rates of prolonged response with anti-PD-1 antibodies versus everolimus for patients with RCC

Track 16 Trials of up-front anti-PD-1/PD-L1 therapy for RCC

Track 17 Use of immune checkpoint blockade in patients with prior autoimmune disorders

Track 18 Mechanistic underpinnings of Bacillus Calmette-Guerin (BCG) immunotherapy for patients with bladder cancer

Track 19 Results of the Phase II IMvigor 210 trial of atezolizumab for patients with platinum-treated locally advanced or metastatic UBC

Track 20 Integration of anti-PD-1/PD-L1 antibodies into the clinical algorithm for metastatic bladder cancer

Interview with Daniel J George, MD

Tracks 1-15

Track 1 Dosing and tolerability of pazopanib versus sunitinib for patients with mRCC

Track 2 Importance of exercise to combat VEGF tyrosine kinase inhibitor (TKI)-associated muscle wasting and fatigue

Track 3 Clinical experience with cabozantinib in the treatment of mRCC

Track 4 Status of the Phase II Alliance A031203 trial: Cabozantinib versus sunitinib for previously untreated locally advanced or metastatic RCC

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Track 6 Survival advantage with the combination of lenvatinib and everolimus versus everolimus alone for mRCC

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Track 8 Antitumor activity, safety and ongoing investigation of atezolizumab alone or in combination with bevacizumab or sunitinib in mRCC

Track 9 Activity and tolerability of nivolumab/ipilimumab for mRCC

Track 10 **Case discussion:** A 62-year-old man with locally advanced Gleason Score 9 (4 + 5) PC and a rising PSA after prostatectomy

Track 11 Approach to patients with PC with PSA-only disease and progression on androgen deprivation therapy

Track 12 Clinical implications of STRIVE: A Phase II study of enzalutamide versus bicalutamide for men with nonmetastatic or metastatic CRPC

Track 13 Approach to choosing among sipuleucel-T, secondary hormonal therapy and chemotherapy for asymptomatic patients with mCRPC

Track 14 Selection and sequencing of abiraterone and enzalutamide for patients with mCRPC

Track 15 Development of circulating molecular predictors of chemotherapy and hormonal therapy benefit in men with mCRPC

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Tracks 1-10

Track 1 Use of neoadjuvant chemotherapy for patients with muscle-invasive bladder cancer

Track 2 Organ preservation versus cystectomy in patients with muscle-invasive bladder cancer

Track 3 Perspective on the use of standard versus robot-assisted cystectomy

Track 4 Blue light cystoscopy in the initial diagnosis of bladder cancer

Track 5 Investigation of anti-PD-1/PD-L1 antibodies for patients with BCG-unresponsive, high-risk non-muscle-invasive bladder cancer

Track 6 Ongoing efforts to identify genomic modifications and predictors of response in bladder cancer

Track 7 Assessment of corticosteroid-associated adverse events with long-term exposure to low-dose prednisone administered with abiraterone for patients with mCRPC

Track 8 Management of enzalutamide-associated seizures and weakness/fatigue

Track 9 AR-V7 and resistance to enzalutamide and abiraterone in mCRPC

Track 10 Investigation of novel agents (eg, galeterone, ARN-509) in PC

SELECT PUBLICATIONS

Antonarakis ES et al. **Androgen receptor splice variant 7 and efficacy of taxane chemotherapy in patients with metastatic castration-resistant prostate cancer.** *JAMA Oncol* 2015;1(5):582-91.

Antonarakis ES et al. **AR-V7 and resistance to enzalutamide and abiraterone in prostate cancer.** *N Engl J Med* 2014;371(11):1028-38.

Fizazi K et al. **Low incidence of corticosteroid-associated adverse events on long-term exposure to low-dose prednisone given with abiraterone acetate to patients with metastatic castration-resistant prostate cancer.** *Eur Urol* 2016;[Epub ahead of print].

Hammers HJ et al. **Phase I study of nivolumab in combination with ipilimumab in metastatic renal cell carcinoma (mRCC).** *Proc ASCO* 2014;**Abstract 4504**.

Montgomery B et al. **Androgen receptor modulation optimized for response (ARMOR) Phase I and II studies: Galeterone for the treatment of castration-resistant prostate cancer.** *Clin Cancer Res* 2015;[Epub ahead of print].

Motzer RJ et al. **Nivolumab versus everolimus in advanced renal-cell carcinoma.** *N Engl J Med* 2015;373(19):1803-13.

Motzer R et al. **Randomized phase II, three-arm trial of lenvatinib (LEN), everolimus (EVE), and LEN+EVE in patients (pts) with metastatic renal cell carcinoma (mRCC).** *Proc ASCO* 2015;**Abstract 4506**.

Penson D et al. **A multicenter Phase 2 study of enzalutamide versus bicalutamide in men with nonmetastatic or metastatic castration-resistant prostate cancer: The STRIVE trial.** *Proc AUA* 2015;**Abstract LBA10**.

Petrylak D et al. **A phase Ia study of MPDL3280A (anti-PDL1): Updated response and survival data in urothelial bladder cancer (UBC).** *Proc ASCO* 2015;**Abstract 4501**.

Plimack ER et al. **Pembrolizumab (MK-3475) for advanced urothelial cancer: Updated results and biomarker analysis from KEYNOTE-012.** *Proc ASCO* 2015;**Abstract 4502**.

Rosenberg J et al. **Atezolizumab in patients (pts) with locally-advanced or metastatic urothelial carcinoma (mUC): Results from a pivotal multicenter phase II study (IMvigor 210).** *Proc ECCO* 2015;**Abstract 21LBA**.

Taplin ME et al. **Androgen receptor modulation optimized for response: Splice variant (ARMOR3-SV) — Randomized, open-label, multicenter, controlled study of galeterone vs enzalutamide in men with metastatic castration-resistant prostate cancer expressing AR-V7 splice variant.** *Proc ASCO* 2015;**Abstract TPS5069**.

POST-TEST

Investigator Perspectives on Emerging Concepts in the Management of Genitourinary Cancers

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Approximately what percent of patients with bladder cancer have HER2-positive disease?**
   a. ≤5%
   b. 15%
   c. 30%
   d. 60%

2. **On the Phase II IMvigor 210 trial, which of the following patient populations with locally advanced or metastatic UBC treated with the anti-PD-L1 antibody atezolizumab (MPDL3280A) experienced higher response rates?**
   a. Those with weak or no expression of PD-L1
   b. Those with high expression of PD-L1
   c. Neither (response rates were equivalent in both patient populations)

3. **Presence of AR-V7 in circulating tumor cells of patients with mCRPC may be associated with resistance to which of the following agents?**
   a. Abiraterone
   b. Enzalutamide
   c. Taxane-based chemotherapy
   d. Both a and b
   e. All of the above

4. **The Phase III CHAARTED trial evaluating hormonal therapy with or without docetaxel for patients with hormone-sensitive mPC demonstrated that the combination of standard androgen deprivation therapy and 6 cycles of docetaxel significantly improved overall survival compared to standard androgen deprivation therapy alone in men with high-volume disease.**
   a. True
   b. False

5. **Which of the following is the mechanism of action of galeterone?**
   a. Androgen receptor antagonist
   b. Anti-PD-1/PD-L1 antibody
   c. VEGF TKI

6. **A study by Gomella and colleagues that assessed more than 2,000 patient-years of exposure to low-dose prednisone administered with abiraterone for mCRPC led to the conclusion that the incidence of corticosteroid-associated adverse events _____ with increased duration of exposure to prednisone.**
   a. Increases
   b. Remains low
   c. Both a and b
   d. Neither a nor b

7. **The ongoing Phase III ARMOR3-SV trial is evaluating galeterone versus enzalutamide for men with mCRPC _____.**
   a. And disease progression on chemotherapy
   b. Expressing AR-V7 splice variant
   c. Both a and b
   d. None of the above

8. **Results of the randomized Phase III CheckMate 025 trial for patients with advanced RCC _____ a statistically significant improvement in overall survival with nivolumab compared to everolimus.**
   a. Demonstrated
   b. Did not demonstrate

9. **An ongoing Phase III trial is evaluating atezolizumab in combination with _____ versus sunitinib in patients with untreated advanced RCC.**
   a. Bevacizumab
   b. Cabozantinib
   c. Pazopanib
   d. All of the above

10. **Which of the following observations is true for pazopanib as compared to sunitinib in the treatment of advanced RCC?**
    a. Equivalent overall and progression-free survival
    b. Less frequent hand-foot syndrome
    c. More frequent liver function changes
    d. All of the above

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Investigator Perspectives on Emerging Concepts in the Management of Genitourinary Cancers

Research To Practice and Yale Continuing Medical Education are 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
Activity, duration of response and tolerability of the anti-PD-L1 antibody atezolizumab (MPDL3280A) for locally advanced or metastatic UBC	4 3 2 1	4 3 2 1
Current clinical utility of AR-V7 status to identify patients with mCRPC unlikely to benefit from treatment with enzalutamide or abiraterone acetate	4 3 2 1	4 3 2 1
Dosing and tolerability of pazopanib versus sunitinib for patients with mRCC	4 3 2 1	4 3 2 1
Clinical implications of STRIVE: A Phase II study of enzalutamide versus bicalutamide for men with nonmetastatic or metastatic CRPC	4 3 2 1	4 3 2 1
Low incidence of corticosteroid-associated adverse events with long-term exposure to low-dose prednisone administered with abiraterone for mCRPC	4 3 2 1	4 3 2 1
Results of the Phase III CheckMate 025 trial: Survival advantage with the recently FDA-approved agent nivolumab versus everolimus for advanced RCC	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 the following do you see per year?

Prostate cancer:..... Renal cell carcinoma:..... Bladder cancer:.....

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:

- Explore emerging data on the use of cytotoxic therapy in the setting of hormone-sensitive advanced prostate cancer (PC), and consider this information when formulating initial treatment plans for appropriate individuals. . . . . 4 3 2 1 N/M N/A
- Recall existing and emerging research information demonstrating the effects of secondary hormonal interventions on quality and quantity of life for patients with castration-resistant PC, and use this information to guide therapeutic decision-making. . . . . 4 3 2 1 N/M N/A
- Effectively apply evidence-based research findings in the determination of best-practice sequencing of available immunotherapeutic, chemotherapeutic and secondary hormonal agents for patients with metastatic PC. . . . . 4 3 2 1 N/M N/A
- Develop an evidence-based approach to the sequencing of systemic therapies for patients with advanced renal cell carcinoma (RCC), incorporating tyrosine kinase inhibitors, anti-VEGF antibodies, mTOR inhibitors and immunotherapeutic agents.. . . . . 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:

- Recognize toxicities attributable to diverse molecular-targeted treatments for RCC, and offer preventive or emergent interventions to minimize or ameliorate these side effects. . . . . 4 3 2 1 N/M N/A
- Appraise the rationale for and clinical data with approved and investigational anti-PD-1 and anti-PD-L1 antibodies in patients with metastatic RCC and bladder cancer. . . . . 4 3 2 1 N/M N/A
- Recognize immune-related adverse events and other common side effects associated with approved and developmental immunotherapeutics in order to offer supportive management strategies. . . . . 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
Daniel P Petrylak, MD	4 3 2 1	4 3 2 1
Charles G Drake, MD, PhD	4 3 2 1	4 3 2 1
Daniel J George, MD	4 3 2 1	4 3 2 1
Leonard G Gomella, 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

Please recommend additional faculty for future activities:

. . . . . .

Other comments about the faculty and editor for this activity:

. . . . . .

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