Beyond The Guidelines

Urologic Oncology Investigators Provide Perspectives on the Optimal Management of Urothelial Bladder Cancer and Prostate Cancer

Join Us Sunday, April 30, 2023 — In Person or Virtually

A 2-Part CME Satellite Symposium Series Held in Conjunction with the American Urological Association Annual Meeting 2023 (AUA2023)

Urothelial Bladder Cancer

7:30 AM – 8:00 AM CT — Registration and Breakfast Buffet
8:00 AM – 10:00 AM CT — Educational Meeting

Prostate Cancer

5:30 PM – 6:00 PM CT — Registration and Dinner Buffet
6:00 PM – 8:00 PM CT — Educational Meeting

McCormick Place Convention Center
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MODERATOR

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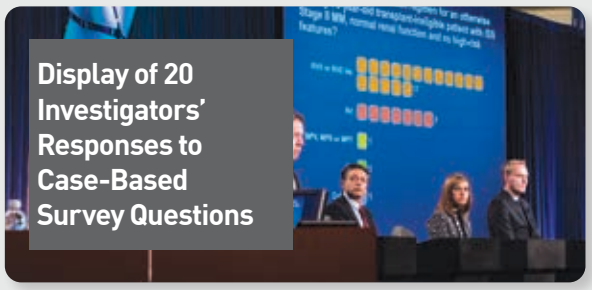

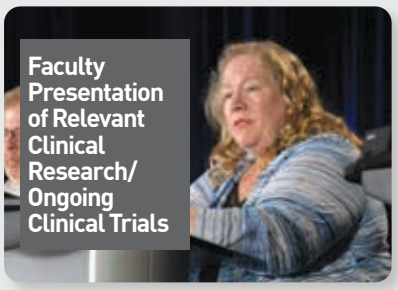

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Target Audience

This activity has been designed to meet the educational needs of medical and radiation oncologists, urologists and other allied healthcare professionals involved in the treatment of urothelial bladder cancer (UBC).

Learning Objectives

At the conclusion of this activity, participants should be able to

- Consider available data supporting the use of anti-PD-1 antibody therapy for high-risk non-muscle-invasive bladder cancer (NMIBC) that is unresponsive to BCG, and determine how this strategy can be appropriately integrated into current care.
- Evaluate the FDA-approved indication for adjuvant anti-PD-1 antibody therapy for patients with high-risk muscle-invasive bladder cancer (MIBC), and consider the current role of this strategy.
- Recognize how biologic and patient-specific factors influence the selection and sequencing of treatment for metastatic UBC.
- Review available clinical trial evidence with immune checkpoint inhibitors as monotherapy or as maintenance after platinum-based chemotherapy in the treatment of newly diagnosed metastatic UBC, and determine the current utility of these agents in clinical practice.
- Recall pivotal clinical trial findings leading to the FDA approval of novel compounds with unique mechanisms of action for previously treated locally advanced or metastatic UBC, and identify patients for whom these approaches would be appropriate.
- Appreciate the biologic rationale for combining anti-PD-1/PD-L1 antibodies with other systemic agents with established efficacy in UBC, and assess the current and potential roles of these regimens in patient care.
- Implement a plan of care to recognize and manage side effects and toxicities associated with recently approved and emerging systemic therapies for advanced or metastatic UBC.
- Develop an understanding of the biologic rationale for, available research findings with and ongoing studies evaluating promising investigational agents and strategies for NMIBC, MIBC and metastatic UBC.

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AGENDA — Urothelial Bladder Cancer 8:00 AM – 10:00 AM

MODULE 1: Current Role of Anti-PD-1/PD-L1 Antibodies in the Treatment of Non-Muscle-Invasive Bladder Cancer (NMIBC) — Dr Meeks

- Appropriate risk stratification of NMIBC; outcomes observed with historical management approaches for patients with BCG-unresponsive or BCG-refractory disease
- Key findings from the KEYNOTE-057 trial assessing pembrolizumab for patients with high-risk NMIBC who are unresponsive or refractory to BCG therapy
- FDA approval of and patient selection for pembrolizumab for NMIBC
- Biologic rationale for combining anti-PD-1/PD-L1 antibodies with BCG for NMIBC
- Ongoing Phase III trials investigating the combination of BCG and anti-PD-1/PD-L1 antibodies for BCG-naïve and BCG-unresponsive NMIBC (eg, ALBAN, POTOMAC, KEYNOTE-676, CheckMate 7G8)

MODULE 2: Contemporary Management of Muscle-Invasive Bladder Cancer (MIBC) — Prof Witjes

- Clinical and biologic factors that confer a high risk of recurrence for patients with MIBC
- Rates of pathologic complete response and other clinically relevant endpoints achieved in early trials evaluating neoadjuvant anti-PD-1/PD-L1 antibody therapy for resectable MIBC
- Extended follow-up from the Phase III CheckMate 274 trial comparing nivolumab to placebo after radical surgery for high-risk MIBC
- FDA approval of and patient selection for nivolumab after surgery for high-risk MIBC
- Early data and ongoing research with combinations of anti-PD-1/PD-L1 antibodies, radiation therapy and/or other systemic therapies, such as chemotherapy, targeted agents or other immunotherapy, for patients with MIBC in the neoadjuvant and adjuvant settings

MODULE 3: Novel Strategies Under Investigation for Nonmetastatic Urothelial Bladder Cancer (UBC) — Dr Daneshmand

- Mechanism of antitumor activity and early data with the novel intravesical drug delivery system TAR-200
- Ongoing studies of TAR-200 with and without the anti-PD-1 antibody cetrelimab for NMIBC (eg, SunRISe-1, SunRISe-3) and MIBC (eg, SunRISe-2, SunRISe-4)
- Rationale for the investigation of the IL-15 superagonist N-803 in combination with BCG for BCG-unresponsive NMIBC carcinoma in situ
- Key efficacy and safety data from the Phase II/III QUILT 3.032 trial evaluating N-803 combined with BCG for BCG-unresponsive NMIBC
- FDA fast track designations for TAR-200 and N-803 and potential roles in practice
- Early results with and ongoing evaluation of other novel agents, such as enfortumab vedotin and FGFR-targeted therapy, for patients with nonmetastatic UBC

MODULE 4: Current and Future Up-Front Management of Metastatic UBC (mUBC) — Dr Milowsky

- Key data defining the current clinical role of pembrolizumab monotherapy as first-line treatment for mUBC
- Long-term follow-up from the JAVELIN Bladder 100 trial of maintenance avelumab after front-line chemotherapy for mUBC
- Available efficacy and safety results from cohort K of the EV-103/KEYNOTE-869 study of enfortumab vedotin alone and in combination with pembrolizumab for cisplatin-ineligible patients with previously untreated mUBC
- Recent FDA approval of enfortumab vedotin in combination with pembrolizumab as first-line treatment for mUBC in patients who are ineligible for cisplatin-containing chemotherapy; optimal integration into routine clinical practice
- Preliminary data with erdafitinib in combination with cetrelimab for patients with previously untreated mUBC with FGFR3 or FGFR2 genetic alterations

MODULE 5: Selection and Sequencing of Therapy for Relapsed/Refractory mUBC — Dr Siefker-Radtke

- Long-term outcomes with enfortumab vedotin for patients with progressive mUBC
- Extended follow-up with erdafitinib for patients with mUBC and FGFR3 or FGFR2 genetic alterations; current role in clinical practice
- Principal efficacy and safety findings with sacituzumab govitecan for progressive mUBC; optimal incorporation into disease management
- Mechanism of action of the antibody-drug conjugate disitamab vedotin; efficacy and safety findings for HER2-positive and HER2-low mUBC
- Preliminary data with and ongoing studies of other promising agents and strategies, such as trastuzumab deruxtecan, PARP inhibitors and FGFR inhibitors beyond erdafitinib, for mUBC

FACULTY — Prostate Cancer

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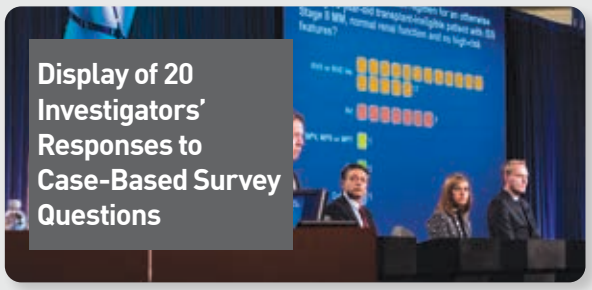

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Target Audience

This activity has been designed to meet the educational needs of medical and radiation oncologists, urologists and other allied healthcare professionals involved in the treatment of prostate cancer.

Learning Objectives

At the conclusion of this activity, participants should be able to

- Appraise published and emerging research findings and current guideline recommendations on optimal management approaches for biochemical recurrence after local treatment for prostate cancer, and appropriately counsel patients about the potential benefits of systemic therapy.
- Evaluate the research supporting the FDA approvals of secondary hormonal agents in the management of nonmetastatic castration-resistant prostate cancer (CRPC), and present appropriate nonresearch treatment options to patients.
- Explore available data with treatment intensification using cytotoxic therapy, secondary hormonal therapy or combinations of both for metastatic hormone-sensitive prostate cancer, and effectively integrate these strategies into clinical management algorithms.
- Establish an evidence-based approach to the selection and sequencing of therapies for patients with metastatic CRPC (mCRPC), considering age, comorbidities, prior therapeutic exposure and other clinical and biologic factors.
- Assess available research with PARP inhibitors as monotherapy for patients with mCRPC harboring a homologous recombination repair (HRR) gene alteration, and discern how to optimally incorporate these agents into clinical management algorithms.
- Understand the rationale for, available data with and ongoing research evaluating PARP inhibitors with androgen receptor-targeted therapy, and consider the potential role of these novel regimens in therapy for patients both with and without HRR gene mutations.
- Recall the design of ongoing clinical trials evaluating other novel agents and strategies for prostate cancer, and appropriately counsel patients about availability and participation.

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AGENDA — Prostate Cancer 6:00 PM – 8:00 PM

MODULE 1: Management Approaches for Nonmetastatic Prostate Cancer — Dr Freedland

- Indications for and selection of androgen deprivation therapy (ADT) for patients with prostate cancer
- Key data with and FDA-approved indications for relugolix
- Findings from the STAMPEDE trial of abiraterone and prednisolone with or without enzalutamide in combination with ADT for men with high-risk nonmetastatic prostate cancer
- Key findings from the Phase III PRESTO study evaluating ADT intensification with apalutamide with or without abiraterone for patients with biochemically recurrent prostate cancer and a rapid PSA doubling time
- Design, eligibility criteria and emerging efficacy and safety findings from the Phase III EMBARK trial evaluating enzalutamide alone or with leuprolide for patients with nonmetastatic prostate cancer and high-risk biochemical recurrence
- Long-term findings with apalutamide, enzalutamide or darolutamide for patients with nonmetastatic castration-resistant prostate cancer (CRPC)
- Factors guiding the selection of enzalutamide, apalutamide or darolutamide for patients with nonmetastatic CRPC

MODULE 2: Optimizing the Care of Patients with Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) — Dr Saad

- Key factors in the selection of systemic therapy for patients with mHSPC
- Long-term data with docetaxel, abiraterone, enzalutamide and apalutamide, each in combination with ADT, for mHSPC
- Major findings from the Phase III PEACE-1 study of ADT and docetaxel, with or without local radiation therapy, with or without abiraterone and prednisone for mHSPC
- Published results from the Phase III ARASENS trial of darolutamide with docetaxel and ADT for mHSPC; FDA-approved indication and optimal incorporation into management algorithms
- Ongoing Phase III trials attempting to further define the optimal management of mHSPC (eg, TALAPRO-3, CYCLONE 3, PSMAddition, CAPItello-281)

MODULE 3: Therapeutic Considerations for Patients with Newly Diagnosed Metastatic CRPC (mCRPC) — Dr Shore

- Key factors in the selection of therapy for patients with newly diagnosed mCRPC; impact of earlier use of chemotherapy and secondary hormonal therapy on current treatment algorithms
- Key findings from clinical trial and real-world data sets exploring the efficacy and safety of sipuleucel-T for mCRPC; effect on outcomes of patient age, race, PSA level and other factors
- Biologic basis for combining PARP inhibitors with antiandrogen therapies for prostate cancer; rationale for the activity of these combinations as front-line therapy in patients without homologous recombination repair (HRR) gene mutations
- Available data with PARP inhibitors in combination with secondary hormonal therapies in previously untreated mCRPC from the Phase III PROpel, MAGNITUDE and TALAPRO-2 studies
- Biologic rationale for the evaluation of CDK4/6 inhibitors in patients with mCRPC
- Design, eligibility criteria and primary and secondary endpoints of the Phase II/III CYCLONE 2 trial evaluating first-line abiraterone and prednisone with or without abemaciclib for mCRPC

MODULE 4: Contemporary Management of mCRPC in Patients Harboring an HRR Gene Alteration — Dr Smith

- Incidence and clinical implications of BRCA1/2 and other HRR abnormalities among patients with prostate cancer
- Mechanistic similarities and differences between approved and investigational PARP inhibitors with documented activity in patients with mCRPC
- Available data with PARP inhibitor monotherapy for patients with mCRPC
- FDA-approved indications for olaparib and rucaparib for mCRPC and optimal integration into management algorithms
- Key findings among patients with HRR gene alterations from the Phase III PROpel, MAGNITUDE and TALAPRO-2 trials; ramifications for current and future practice

MODULE 5: Current and Emerging Strategies in the Treatment of Recurrent mCRPC — Dr Beltran

- Available data with, ongoing evaluation of and patient selection for treatment with radium-223 chloride
- Clinical relevance of PSMA expression in prostate cancer; mechanism of action of the novel radioligand therapy lutetium Lu 177 vipivotide tetraxetan
- Published (eg, VISION) and emerging (eg, PSMAfore) data sets informing the use of lutetium Lu 177 vipivotide tetraxetan for PSMA-positive mCRPC; appropriate integration into clinical practice
- Major findings from the CARD study and other recently reported trials investigating cabazitaxel for mCRPC; appropriate integration into the treatment algorithm and practical considerations with its use
- Other promising novel agents and strategies under investigation for mCRPC (eg, capivasertib, ODM-208, cabozantinib/atezolizumab)