Bladder Cancer™ UPDATE

Renal Cell Cancer™ UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS
BLADDER CANCER

Matthew D Galsky, MD
Elizabeth R Plimack, MD, MS

FACULTY INTERVIEWS
RENAL CELL CARCINOMA

Robert J Motzer, MD
Brian I Rini, MD

EDITOR

Neil Love, MD

ABIM CME MOC ACCREDITED

CME Certified

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OVERVIEW OF ACTIVITY

Cancers of the genitourinary (GU) system affect hundreds of thousands of individuals within the United States each year. Among these, tumors of the bladder, kidney and renal pelvis are among the most prevalent and are therefore 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

- Develop an evidence-based approach to the sequencing of systemic therapies for patients with advanced renal cell carcinoma (RCC), incorporating cytokines, multikinase inhibitors, anti-VEGF antibodies, mTOR inhibitors and immune checkpoint inhibitors.
- Appreciate the recent FDA approvals in advanced RCC, and develop strategies to optimally integrate these agents into the management of this disease.
- Recognize toxicities attributable to diverse molecular-targeted treatments for RCC, and offer preventive or emergent interventions to minimize or ameliorate these side effects.
- Recall the unique mechanism of action of, available clinical trial data with and clinical indications for the use of atezolizumab in patients with relapsed/refractory advanced urothelial bladder cancer, and use this information to guide nonprotocol treatment planning.
- Recognize immune-related adverse events and other common side effects associated with approved and developmental immunotherapeutics in order to offer supportive management strategies.
- Recall available and emerging data with novel anti-PD-1/PD-L1 antibodies currently under investigation for bladder cancer and RCC, and, where applicable, refer eligible patients for trial participation or expanded access programs.

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BLADDER CANCER

Interview with Matthew D Galsky, MD

Tracks 1-16

Track 1	**Case discussion:** A 52-year-old man who initially receives treatment for nonmuscle-invasive urothelial bladder cancer (UBC) presents 2 years later with metastatic disease
Track 2	Incidence and management of metastatic UBC
Track 3	Selection of first-line therapy for metastatic UBC
Track 4	Activity and tolerability of the recently FDA-approved anti-PD-L1 antibody atezolizumab for advanced UBC
Track 5	Mechanism of action of anti-PD-L1 antibodies
Track 6	Results of the Phase II IMvigor 210 trial of atezolizumab for patients with locally advanced or metastatic UBC
Track 7	Activity of anti-PD-1 antibodies for patients with previously treated UBC
Track 8	Efficacy of the anti-PD-L1 antibody durvalumab
Track 9	Predictors of response to immune checkpoint inhibitors
Track 10	Clinical experience with checkpoint inhibitor-associated immune-related adverse events
Track 11	Ongoing trials evaluating checkpoint inhibitors in the adjuvant and metastatic settings
Track 12	**Case discussion:** A 62-year-old man with metastatic UBC experiences severe diarrhea 1 year after initiation of nivolumab but achieves a near complete response after resuming therapy
Track 13	Incidence of diabetes and pancreatitis associated with immune checkpoint blockade
Track 14	Investigation of cabozantinib alone or in combination with checkpoint inhibitors for patients with UBC
Track 15	Clinical experience with the VEGF tyrosine kinase inhibitors (TKIs) sunitinib and pazopanib
Track 16	Role of next-generation sequencing in identifying clinical trial options for patients with relapsed/refractory UBC

Interview with Elizabeth R Plimack, MD, MS

Tracks 1-12

Track 1	Benefits of (neo)adjuvant treatment for UBC
Track 2	Indications for neoadjuvant treatment
Track 3	Chemotherapeutic regimens commonly used in the neoadjuvant and adjuvant settings
Track 4	Approach to (neo)adjuvant treatment for patients with UBC
Track 5	Available data on the impact of adjuvant chemotherapy on the risk of recurrence
Track 6	**Case discussion:** A 71-year-old man and former smoker with localized small cell UBC whose disease progresses through several lines of chemotherapy receives immunotherapy
Track 7	Response of smokers versus never smokers to pembrolizumab on the Phase III KEYNOTE-045 trial
Track 8	Effect of PD-L1 levels on response to anti-PD-1/PD-L1 antibodies
Track 9	Overview of immune checkpoint blockade in metastatic UBC
Track 10	Perspective on using checkpoint inhibitors as first-line therapy for metastatic UBC
Track 11	Duration of response to checkpoint inhibitors and viewpoint on discontinuing therapy
Track 12	Challenges in identifying targeted therapies for metastatic UBC

RENAL CELL CARCINOMA

Interview with Robert J Motzer, MD

Tracks 1-16

Track 1	Results of the ASSURE and S-TRAC trials investigating adjuvant sorafenib or sunitinib for unfavorable/high-risk renal cell carcinoma (RCC)
Track 2	Differences in design and eligibility criteria for the ASSURE and S-TRAC trials
Track 3	Management of dermatological toxicities associated with sunitinib
Track 4	Efficacy and safety of combining anti-VEGF antibodies and checkpoint inhibitors for patients with RCC
Track 5	Results of trials evaluating cabozantinib versus everolimus (METEOR) or sunitinib (CABOSUN) for advanced RCC
Track 6	Clinical experience with cabozantinib versus sunitinib
Track 7	Optimal sequencing of VEGF TKIs for RCC
Track 8	Integration of lenvatinib/everolimus into the clinical algorithm for patients with RCC
Track 9	Role of genomic testing and novel targeted and immunotherapeutic agents for RCC
Track 10	Rationale for the use of immune checkpoint blockade for RCC
Track 11	Results of the Phase III CheckMate 025 study: Activity and tolerability of nivolumab versus everolimus for advanced RCC
Track 12	Immune-related adverse events associated with checkpoint blockade
Track 13	Response to checkpoint inhibitors and duration of therapy
Track 14	Recent clinical data with checkpoint inhibitors alone or in combination for RCC
Track 15	**Case discussion:** A 71-year-old man with metastatic clear cell RCC receives cabozantinib on a clinical trial after disease progression on pazopanib
Track 16	**Case discussion:** A 66-year-old man with metastatic RCC achieves a long duration of stable response with everolimus

Interview with Brian I Rini, MD

Tracks 1-15

Track 1	Selection of first-line therapy for metastatic RCC
Track 2	Choice of second-line therapy for metastatic RCC
Track 3	Results of the METEOR and CABOSUN trials with cabozantinib for advanced RCC
Track 4	Side-effect profile and dosing of cabozantinib
Track 5	Perspective on the efficacy and tolerability of lenvatinib and everolimus as single agents and in combination
Track 6	**Case discussion:** A man in his early fifties with metastatic RCC who was enrolled on a clinical trial of nivolumab and ipilimumab achieves a good response to therapy but develops hypopituitarism
Track 7	Management of nivolumab/ipilimumab-associated hypopituitarism
Track 8	Duration of response to checkpoint inhibitors and perspective on discontinuing treatment
Track 9	Mechanism of action, activity and tolerability of hypoxia-inducing factor inhibitors for RCC
Track 10	Activity of nivolumab alone and in combination with ipilimumab for metastatic RCC (mRCC)
Track 11	Ongoing trials evaluating immunotherapies in combination with targeted therapies for mRCC
Track 12	Use of immune checkpoint blockade in patients with preexisting autoimmune disease
Track 13	Clinical experience with single-agent nivolumab in mRCC
Track 14	Response of nonclear cell RCC to systemic therapies
Track 15	Approach to first-line therapy for patients with metastatic RCC and uncontrolled hypertension

SELECT PUBLICATIONS

Bladder Cancer

Apolo AB et al. **Avelumab (MSB0010718C; anti-PD-L1) in patients with metastatic urothelial carcinoma from the JAVELIN solid tumor phase 1b trial: Analysis of safety, clinical activity, and PD-L1 expression.** *Proc ASCO* 2016;**Abstract 4514**.

Balar AV et al. **Atezolizumab as first-line treatment in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: A single-arm, multicentre, phase 2 trial.** *Lancet* 2017;389(10064):67-76.

Balar AV et al. **Atezolizumab (atezo) as first-line (1L) therapy in cisplatin-ineligible locally advanced/metastatic urothelial carcinoma (mUC): Primary analysis of IMvigor210 cohort 1.** *Proc ASCO* 2016;**Abstract LBA4500**.

Balar AV et al. **Pembrolizumab (pembro) as first-line therapy for advanced/unresectable or metastatic urothelial cancer: Preliminary results from the phase 2 KEYNOTE-052 study.** *Proc ESMO* 2016;**Abstract LBA32_PR**.

Bellmunt J et al. **KEYNOTE-045: Randomized phase 3 trial of pembrolizumab (MK-3475) versus paclitaxel, docetaxel, or vinflunine for previously treated metastatic urothelial cancer.** *Proc ASCO* 2015;**Abstract TPS4571**.

Galsky MD et al. **Comparative effectiveness of cisplatin-based and carboplatin-based chemotherapy for treatment of advanced urothelial carcinoma.** *Ann Oncol* 2012;23(2):406-10.

Massard C et al. **Safety and efficacy of durvalumab (MEDI4736), a PD-L1 antibody, in urothelial bladder cancer.** *Proc ASCO* 2016;**Abstract 4502**.

Rosenberg JE et al. **Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: A single-arm, multicentre, phase 2 trial.** *Lancet* 2016;387(10031):1909-20.

Sharma P et al. **Efficacy and safety of nivolumab monotherapy in metastatic urothelial cancer (mUC): Results from the phase I/II CheckMate 032 study.** *Proc ASCO* 2016;**Abstract 4501**.

Renal Cell Carcinoma

A study of atezolizumab in combination with bevacizumab versus sunitinib in participants with untreated advanced renal cell carcinoma [IMmotion151]. NCT02420821

Atkins MB et al. **Axitinib in combination with pembrolizumab in patients (pts) with advanced renal cell carcinoma (aRCC): Preliminary safety and efficacy results.** *Proc ESMO* 2016;**Abstract 773PD**.

Choueri T et al. **Cabozantinib versus sunitinib as initial targeted therapy for patients with metastatic renal cell carcinoma of poor or intermediate risk: The Alliance A031203 CABOSUN trial.** *J Clin Oncol* 2017;35(6):591-7.

Choueri T et al. **Cabozantinib versus everolimus in advanced renal-cell carcinoma.** *N Engl J Med* 2015;373(19):1814-23.

Haas NB et al. **Initial results from ASSURE (E2805): Adjuvant sorafenib or sunitinib for unfavorable renal carcinoma, an ECOG-ACRIN-led, NCTN phase III trial.** *Proc ASCO* 2015;**Abstract 403**.

Hammers HJ et al. **Updated results from a phase I study of nivolumab (Nivo) in combination with ipilimumab (Ipi) in metastatic renal cell carcinoma (mRCC): The CheckMate 016 study.** *Proc ESMO* 2016;**Abstract 1062P**.

Hammers HJ et al. **CheckMate 214: A phase III, randomized, open-label study of nivolumab combined with ipilimumab versus sunitinib monotherapy in patients with previously untreated metastatic renal cell carcinoma.** *Proc ASCO* 2015;**Abstract TPS4578**.

McDermott DF et al. **Long-term overall survival (OS) with nivolumab in previously treated patients with advanced renal cell carcinoma (aRCC) from phase I and II studies.** *Proc ASCO* 2016;**Abstract 4507**.

Motzer RJ et al. **Lenvatinib, everolimus, and the combination in patients with metastatic renal cell carcinoma: A randomised, phase 2, open-label, multicentre trial.** *Lancet Oncol* 2015;16(15):1473-82.

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

Motzer RJ et al. **Pazopanib versus sunitinib in metastatic renal-cell carcinoma.** *N Engl J Med* 2013;369(8):722-31.

Ravaud A et al. **Adjuvant sunitinib in high-risk renal-cell carcinoma after nephrectomy.** *N Engl J Med* 2016;375(23):2246-54.

POST-TEST

Renal Cell Cancer Update & Bladder Cancer Update

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Which of the following is a potential explanation for the differing results reported in the ASSURE and S-TRAC trials, which investigated adjuvant sorafenib or sunitinib for unfavorable/high-risk RCC?**
   a. Histological presence of at least a component of clear cell was mandatory in S-TRAC, whereas ASSURE included patients with nonclear cell disease
   b. Patients with Stage T1 and T1b tumors were allowed in ASSURE, whereas the S-TRAC study included only patients with Stage T3 disease or higher
   c. S-TRAC emphasized the full 50-mg dose of sunitinib, whereas ASSURE allowed for dose reductions to 37.5 mg and 25 mg
   d. All of the above
   e. Both a and b
   f. Both a and c

2. **Which of the following toxicities of sunitinib appears to interfere the most with activities of daily living?**
   a. Diarrhea
   b. Hand-foot skin reaction
   c. Fatigue

3. **Results of the Phase III METEOR trial evaluating cabozantinib versus everolimus for patients with advanced RCC and disease progression after VEGFR TKI therapy demonstrated significant improvement(s) in _____ for patients who received cabozantinib.**
   a. Progression-free survival
   b. Overall response rate
   c. Overall survival
   d. All of the above

4. **The Phase III COMPARZ trial, which evaluated pazopanib versus sunitinib for patients with advanced RCC, reported pazopanib to be _____ in comparison to sunitinib.**
   a. Inferior
   b. Noninferior
   c. Superior

5. **PD-L1 expression has been demonstrated to be predictive of benefit from anti-PD-1/anti-PD-L1 antibodies in patients with advanced RCC.**
   a. True
   b. False

6. **The NCCN Clinical Practice Guidelines for Bladder Cancer principles of perioperative chemotherapy indicate that it _____ acceptable to substitute carboplatin for cisplatin in this setting for patients who are not candidates for cisplatin.**
   a. Is
   b. Is not

7. **Which of the following is the mechanism of action of durvalumab?**
   a. Anti-PD-L1 antibody
   b. mTOR inhibitor
   c. VEGF TKI

8. **On the Phase III KEYNOTE-45 trial evaluating pembrolizumab versus investigator's choice of chemotherapy for previously treated metastatic UBC, which of the following groups of patients experienced the most benefit with pembrolizumab?**
   a. Current smokers
   b. Never smokers
   c. Response rates were equivalent in both patient populations

9. **The combination of lenvatinib and everolimus was recently approved by the FDA for the treatment of advanced RCC after 1 anti-angiogenic therapy.**
   a. True
   b. False

10. **Which of the following PD-1/PD-L1 inhibitors is FDA approved for the treatment of advanced UBC?**
    a. Atezolizumab
    b. Avelumab
    c. Durvalumab
    d. Nivolumab
    e. Pembrolizumab
    f. All of the above
    g. Both a and e
    h. Both c and d

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Renal Cell Cancer Update & Bladder Cancer Update

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
Biologic rationale for effectiveness of cabozantinib as second- or later-line therapy and overall survival benefit versus everolimus in patients with mRCC whose disease has progressed on 1 or more prior VEGF-targeted therapies	4 3 2 1	4 3 2 1
Magnitude of benefit and duration of response for patients with cisplatin-ineligible locally advanced or metastatic UBC treated with first-line atezolizumab on the Phase II IMvigor 210 trial	4 3 2 1	4 3 2 1
Scheduling, predictors of response and current investigational strategies with anti-PD-1/anti-PD-L1 antibodies in UBC	4 3 2 1	4 3 2 1
Risk-benefit ratio for patients with advanced RCC treated with lenvatinib/everolimus on a Phase II study	4 3 2 1	4 3 2 1
Potential factors contributing to the different outcomes in the ASSURE and S-TRAC trials evaluating adjuvant TKI therapies for unfavorable/high-risk 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 bladder cancer do you see per year? ..... patients

Approximately how many new patients with renal cell carcinoma 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:

- Develop an evidence-based approach to the sequencing of systemic therapies for patients with advanced renal cell carcinoma (RCC), incorporating cytokines, multikinase inhibitors, anti-VEGF antibodies, mTOR inhibitors and immune checkpoint inhibitors..... 4 3 2 1 N/M N/A
- Appreciate the recent FDA approvals in advanced RCC, and develop strategies to optimally integrate these agents into the management of this disease..... 4 3 2 1 N/M N/A
- 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

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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- Recall the unique mechanism of action of, available clinical trial data with and clinical indications for the use of atezolizumab in patients with relapsed/refractory advanced urothelial bladder cancer, and use this information to guide nonprotocol treatment planning. . . . . 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
- Recall available and emerging data with novel anti-PD-1/PD-L1 antibodies currently under investigation for bladder cancer and RCC, and, where applicable, refer eligible patients for trial participation or expanded access programs. . . . . 4 3 2 1 N/M N/A

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.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No If no, please explain: .....

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Faculty	Knowledge of subject matter	Effectiveness as an educator
Matthew D Galsky, MD	4 3 2 1	4 3 2 1
Elizabeth R Plimack, MD, MS	4 3 2 1	4 3 2 1
Robert J Motzer, MD	4 3 2 1	4 3 2 1
Brian I Rini, 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

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Bladder Cancer™ UPDATE

Renal Cell Cancer™ UPDATE

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Bladder Cancer™ UPDATE

Renal Cell Cancer™ UPDATE

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