BREAKFAST WITH THE INVESTIGATORS Management of Renal Cell Carcinoma

CME Information

TARGET AUDIENCE

This program is intended for medical oncologists, hematologyoncology fellows and other allied healthcare professionals involved in the treatment of renal cell carcinoma (RCC).

OVERVIEW OF ACTIVITY

A recent explosion of clinical research developments has added renewed excitement and optimism to the field of RCC treatment. Specifically, over the past few years a number of scientific breakthroughs related to the care of patients with relapsed/refractory RCC have translated into new therapeutic options, the rapid emergence of which has added complexity to traditional decision-making. Similarly, the unique toxicities and practical nuances associated with the use of these agents have created additional and important considerations that clinicians must weigh and account for in order to make the best possible treatment recommendations. In addition, as is common across cancer medicine, much interest has been expressed in moving the increasing number of treatments for metastatic RCC into earlier lines of therapy in the hopes of improving outcomes for patients with localized disease.

These video proceedings from a CME symposium held during the 2018 ASCO Annual Meeting feature discussions with leading researchers with an expertise in genitourinary cancers regarding actual cases of RCC from their practices and the published data that drive clinical decision-making for patients in those and diverse other situations. By providing information on the latest research developments and their potential application to routine practice, this activity is designed to assist medical oncologists, hematology-oncology fellows and other allied healthcare professionals with the formulation of up-todate clinical management strategies.

LEARNING OBJECTIVES

- Appraise recent data on diagnostic and therapeutic advances in RCC, and integrate this information, as appropriate, into current clinical care.
- Develop an evidence-based approach to the sequencing of systemic therapies for patients with advanced RCC, incorporating tyrosine kinase inhibitors, anti-VEGF antibodies, mTOR inhibitors and immunotherapeutic agents.

- Appreciate the recent FDA approval of nivolumab in combination with ipilimumab as front-line treatment for intermediate- and poor-risk advanced RCC, and develop strategies to optimally integrate these agents into the clinical care of patients.
- Recognize toxicities attributable to diverse systemic treatments for RCC, and offer preventive or emergent interventions to minimize or ameliorate these side effects.
- Appraise emerging clinical trial data evaluating anti-PD-1/ PD-L1 antibodies in combination with other immunotherapeutic or targeted agents for previously untreated or relapsed metastatic RCC, and prepare for the potential availability of these approaches in routine practice.
- Recall available and emerging data with other investigational agents and strategies currently in testing for RCC and, where applicable, refer eligible patients for trial participation or other expanded access programs.

ACCREDITATION STATEMENT

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CREDIT DESIGNATION STATEMENT

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AMERICAN BOARD OF INTERNAL MEDICINE (ABIM) — MAINTENANCE OF CERTIFICATION (MOC)

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.25 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Please note, this program has been specifically designed for the following ABIM specialty: **medical oncology**.

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HOW TO USE THIS CME ACTIVITY

This CME activity consists of a video component. To receive credit, the participant should review the CME information, watch the video, complete the Post-test with a score of 80% or better and fill out the Educational Assessment and Credit Form located at **ResearchToPractice.com/ASCORCC18/CME**.

CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-theart education. We assess conflicts of interest with faculty, planners and managers of CME activities. Conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Consulting Agreements: Array BioPharma Inc, Bristol-Myers Squibb Company, Eisai Inc, Exelixis Inc, Genentech, Merck, Novartis, Pfizer Inc; **Contracted Research:** Bristol-Myers Squibb Company, Prometheus Laboratories Inc.

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Advisory Committee: Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Dendreon Pharmaceuticals Inc, Exelixis Inc, Genentech, Janssen Biotech Inc, Merck, Pfizer Inc, Sanofi Genzyme; Consulting Agreements: Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Dendreon Pharmaceuticals Inc, Exelixis Inc, Genentech, Janssen Biotech Inc, Merck, Pfizer Inc, Sanofi Genzyme.

MODERATOR — **Dr Love** is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Acerta Pharma — A member of the AstraZeneca Group, Adaptive Biotechnologies, Agendia Inc. Agios Pharmaceuticals Inc. Amgen Inc. Ariad Pharmaceuticals Inc, Array BioPharma Inc, Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Baxalta Inc, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, CTI BioPharma Corp, Dendreon Pharmaceuticals Inc, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech, Genomic Health Inc, Gilead Sciences Inc, Halozyme Inc, ImmunoGen Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Kite Pharma Inc, Lexicon Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, NanoString Technologies, Natera Inc, Novartis, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc. Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro Inc, Teva Oncology and Tokai Pharmaceuticals Inc.

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Hardware/Software Requirements:

A high-speed Internet connection A monitor set to 1280 x 1024 pixels or more Internet Explorer 11 or later, Firefox 56 or later, Chrome 61 or later, Safari 11 or later, Opera 48 or later Adobe Flash Player 27 plug-in or later Adobe Acrobat Reader (Optional) Sound card and speakers for audio

Release date: August 2018

Expiration date: August 2019

Select Publications

A phase II, randomized study of atezolizumab (anti-PD-L1 antibody) administered as monotherapy or in combination with bevacizumab versus sunitinib in patients with untreated advanced renal cell carcinoma. NCT01984242

A phase 3, randomized, open-label study of nivolumab combined with ipilimumab versus sunitinib monotherapy in subjects with previously untreated, advanced or metastatic renal cell carcinoma. NCT02231749

Atkins MB et al. Axitinib in combination with pembrolizumab in patients with advanced renal cell cancer: A non-randomised, open-label, dose-finding, and dose-expansion phase 1b trial. *Lancet Oncol* 2018;19(3):405-15.

Atkins M et al. IMmotion150: A phase II trial in untreated metastatic renal cell carcinoma (mRCC) patients (pts) of atezolizumab (atezo) and bevacizumab (bev) vs and following atezo or sunitinib (sun). *Proc ASCO* 2017; Abstract 4505.

Brahmer JR et al. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy: American Society of Clinical Oncology clinical practice guideline. *J Clin Oncol* 2018;[Epub ahead of print].

Brahmer JR et al. Phase I study of single-agent anti-programmed death-1 (MDX-1106) in refractory solid tumors: Safety, clinical activity, pharmacodynamics, and immunologic correlates. *J Clin Oncol* 2010;28(19):3167-75.

Choueiri TK et al. Preliminary results for avelumab plus axitinib as first-line therapy in patients with advanced clear-cell renal-cell carcinoma (JAVELIN Renal 100): An open-label, dose-finding and dose-expansion, phase 1b trial. *Lancet Oncol* 2018;19(4):451-60.

Choueiri TK 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.

Choueiri TK et al. First-line avelumab + axitinib therapy in patients (pts) with advanced renal cell carcinoma (aRCC): Results from a phase lb trial. *Proc ASCO* 2017; Abstract 4504.

Choueiri TK et al. Progression-free survival (PFS) by independent review and updated overall survival (OS) results from Alliance A031203 trial (CABOSUN): Cabozantinib versus sunitinib as initial targeted therapy for patients (pts) with metastatic renal cell carcinoma (mRCC). *Proc ESMO* 2017; Abstract LBA38.

Escudier B et al. CheckMate 214: Efficacy and safety of nivolumab + ipilimumab (N+I) v sunitinib (S) for treatment-naïve advanced or metastatic renal cell carcinoma (mRCC), including IMDC risk and PD-L1 expression subgroups. *Proc ESMO* 2017; Abstract LBA5.

Escudier B et al. Treatment beyond progression in patients with advanced renal cell carcinoma treated with nivolumab in CheckMate 025. *Eur Urol* 2017;72(3):368-76.

Lee C-H et al. A phase 1b/2 trial of lenvatinib plus pembrolizumab in patients with renal cell carcinoma. *Proc ESMO* 2017; Abstract 8470.

McDermott DF et al. Pembrolizumab monotherapy as first-line therapy in advanced clear cell renal cell carcinoma (accRCC): Results from cohort A of KEYNOTE-427. ASCO 2018; Abstract 4500.

McDermott DF et al. Survival, durable response, and long-term safety in patients with previously treated advanced renal cell carcinoma receiving nivolumab. *J Clin Oncol* 2015;33(18):2013-20.

Mejean A et al. CARMENA: Cytoreductive nephrectomy followed by sunitinib versus sunitinib alone in metastatic renal cell carcinoma — Results of a phase III noninferiority trial. ASCO 2018; Abstract LBA3.

Motzer RJ et al; CheckMate 214 Investigators. **Nivolumab plus ipilimumab versus sunitinib in advanced renal-cell carcinoma.** *N Engl J Med* 2018;378(14):1277-90.

Motzer RJ et al. IMmotion151: A randomized phase III study of atezolizumab plus bevacizumab vs sunitinib in untreated metastatic renal cell carcinoma (mRCC). Genitourinary Cancers Symposium 2018; Abstract 578.

Motzer RJ et al. Independent assessment of lenvatinib plus everolimus in patients with metastatic renal cell carcinoma. *Lancet Oncol* 2016;17(1):e4-5.

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.

Soria F et al. **Pseudoprogression and hyperprogression during immune checkpoint inhibitor therapy for urothelial and kidney cancer.** *World J Urol* 2018;[Epub ahead of print].