The Clinical Implications of Key Recent Data Sets in Oncology: A Daylong Multitumor Educational Symposium in Partnership with Florida Cancer Specialists

A CME/MOC- AND NCPD-ACCREDITED HYBRID EVENT

Saturday, October 22, 2022
7:30 AM to 5:30 PM Eastern Time

JW Marriott Orlando, Grande Lakes
Orlando, Florida

FACULTY PRESENTING IN PERSON

BREAST CANCER

Matthew P Goetz, MD
Mayo Clinic
Rochester, Minnesota

Ian E Krop, MD, PhD
Yale Cancer Center
New Haven, Connecticut

CHRONIC LYMPHOCYTIC LEUKEMIA AND LYMPHOMAS

Ann S LaCasce, MD, MMSc
Dana-Farber Cancer Institute
Boston, Massachusetts

Mitchell R Smith, MD, PhD
George Washington University
Washington, DC

GASTROINTESTINAL CANCERS

Wells A Messersmith, MD
University of Colorado Cancer Center
Aurora, Colorado

John Strickler, MD
Duke University
Durham, North Carolina

PROSTATE AND BLADDER CANCERS

Alicia K Morgans, MD, MPH
Dana-Farber Cancer Institute
Boston, Massachusetts

Evan Y Yu, MD
Fred Hutchinson Cancer Center
Seattle, Washington

LUNG CANCER

Corey J Langer, MD
Abramson Cancer Center
Philadelphia, Pennsylvania

Christine M Lovly, MD, PhD
Vanderbilt-Ingram Cancer Center
Nashville, Tennessee

FACULTY PRESENTING VIRTUALLY

ENDOMETRIAL CANCER

Shannon N Westin, MD, MPH
The University of Texas MD Anderson Cancer Center
Houston, Texas

HEPATOBILIARY CANCER

Ghassan Abou-Alfa, MD, MBA
Memorial Sloan Kettering Cancer Center
New York, New York

MELANOMA

Prof Georgina Long, AO, BSc, PhD, MBBS
Melanoma Institute Australia
Wollstonecraft, New South Wales, Australia

CAR-T AND BISPECIFIC THERAPY FOR MULTIPLE MYELOMA

Saad Zafar Usmani, MD, MBA
Memorial Sloan Kettering Cancer Center
New York, New York

OVARIAN CANCER AND PARP INHIBITORS

David M O'Malley, MD
The Ohio State University and The James Cancer Center
Columbus, Ohio

RENAL CELL CARCINOMA

Thomas Powles, MBBS, MRCP, MD
Barts Cancer Institute
Queen Mary University of London
London, United Kingdom

MODERATOR HOSTING IN PERSON

Neil Love, MD
Research To Practice
Miami, Florida

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LEARNING OBJECTIVES

Lung Cancer

- Evaluate available and emerging data documenting the efficacy and safety of anti-PD-1/PD-L1 antibody-based approaches as neoadjuvant, adjuvant or consolidation therapy for nonmetastatic non-small cell lung cancer (NSCLC).
- Acknowledge the FDA approval of adjuvant EGFR tyrosine kinase inhibitor therapy for localized NSCLC with an EGFR mutation, and identify patients for whom treatment with this approach would be warranted.
- Review published research data documenting the efficacy of EGFR tyrosine kinase inhibitors alone or in combination with other systemic approaches for metastatic NSCLC with an EGFR tumor mutation, and appropriately apply this information in patient selection and care.
- Assess the efficacy and safety of commercially available ALK inhibitors for metastatic NSCLC with an ALK rearrangement, and use this information to select these drugs as first- and later-line therapy.
- Recollect other oncogenic pathways (ie, ROS1, HER2, NRG) mediating the pathogenesis of tumors in unique patient subsets, and recall published and emerging data with commercially available and experimental agents exploiting these targets.
- Review recent therapeutic advances related to the use of anti-PD-1/PD-L1 antibodies as monotherapy or in combination with other systemic therapies for metastatic NSCLC, and discern how these approaches can be employed in disease management.
- Reflect on investigational agents and strategies currently in testing for lung cancer, and refer appropriate eligible patients for clinical trial participation.

Chronic Lymphocytic Leukemia and Lymphomas

- Individualize the selection and sequencing of systemic therapy for patients with newly diagnosed or relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL), considering clinical presentation, age, performance status (PS), biomarker profile and coexisting medical conditions.
- Understand published research data informing the selection, sequencing and combining of available therapeutic agents in the nonresearch care of patients with previously untreated or R/R follicular lymphoma (FL).
- Recognize the mechanisms of action, efficacy and safety of approved and investigational agents for the treatment of diffuse large B-cell lymphoma (DLBCL) to determine the current and potential utility of those agents in clinical practice.
- Consider patient age, PS and other clinical and biologic factors in the up-front and subsequent treatment of mantle cell lymphoma (MCL).
- Incorporate available and emerging therapeutic strategies into the best-practice management of newly diagnosed and R/R Hodgkin lymphoma.
- Assess available clinical trial findings informing the use of CD19-directed CAR T-cell therapy for R/R DLBCL, MCL and FL, and counsel appropriately selected patients regarding the potential benefits of this approach.
- Recall new data with agents and strategies currently under investigation for CLL and various lymphoma subtypes, and discuss ongoing trial opportunities with eligible patients.

Prostate and Bladder Cancers

- Evaluate the published research database supporting the use of secondary hormonal agents in the management of nonmetastatic castration-sensitive and castration-resistant prostate cancer, and apply this information in the discussion of nonresearch treatment options.
- Explore available data with cytotoxic or secondary hormonal therapy or combinations of these approaches for metastatic hormone-sensitive prostate cancer, and design effective treatment plans for patients.
- Establish an evidence-based approach to the selection of available therapeutic options for patients with metastatic castration-resistant prostate cancer (mCRPC), considering age, comorbidities, prior therapeutic exposure and other clinical factors.
- Assess the research database supporting the use of PARP inhibitors for mCRPC, and discern how to optimally incorporate these agents into clinical management algorithms.
- Consider available data supporting the use of anti-PD-1 antibody therapy for nonmetastatic urothelial bladder cancer (UBC), and appropriately integrate this strategy into patient care.
- Review available clinical trial evidence with immune checkpoint inhibitors as monotherapy or as maintenance after platinum-based chemotherapy for 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.
- Evaluate investigational agents and strategies currently in testing for prostate cancer and UBC, and refer appropriate eligible patients for clinical trial participation.

Renal Cell Carcinoma

- Evaluate recently presented data with adjuvant anti-PD-1 antibody therapy for patients with renal cell carcinoma (RCC) at high risk for recurrence after nephrectomy, and consider the current role of this strategy.
- Effectively apply evidence-based research findings and other clinical and biologic factors in the best practice selection of first-line therapy for patients with metastatic RCC (mRCC).
- Appraise available clinical trial data evaluating combinations of anti-PD-1/PD-L1 antibodies and multikinase inhibitors for previously untreated mRCC, and counsel patients regarding the risks and benefits of these novel regimens.
- Review the biologic rationale underlying the investigation of anti-PD-1/anti-CTLA-4/multikinase inhibitor combination therapy as first-line treatment for mRCC, and appreciate emerging findings documenting the effectiveness of this approach.
- Recall available data with recently approved agents for RCC, and develop strategies to integrate these treatments into clinical care.

CAR-T and Bispecific Therapy for Multiple Myeloma

- Appraise the scientific rationale for targeting B-cell maturation antigen (BCMA) in the care of patients with multiple myeloma (MM), and assess the similarities and differences among various approved and investigational strategies directed at BCMA.
- Appreciate available data documenting the activity of chimeric antigen receptor (CAR) T-cell therapy targeting BCMA in MM, and use this knowledge to identify patients who may be appropriate for this approach.

LEARNING OBJECTIVES (CONTINUED)

- Develop an understanding of the mechanism of action of and pivotal clinical trial findings with the BCMA-targeted antibody-drug conjugate belantamab mafodotin to facilitate its optimal integration into MM management algorithms.
- Evaluate the biologic rationale for and available efficacy findings with BCMA- and non-BCMA-directed bispecific antibodies for MM, and identify patients for whom a clinical trial of these novel strategies should be considered.
- Recognize adverse events associated with approved and investigational CAR T-cell therapies, antibody-drug conjugates and bispecific antibodies for MM, and implement strategies to educate patients and manage complications.

Hepatobiliary Cancers

- Consider age, PS, degree of liver function and other clinical and logistical factors in the selection of first-line therapy for patients with unresectable or metastatic hepatocellular carcinoma (HCC).
- Appreciate Phase III data leading to the FDA approval of novel first-line treatment strategies for unresectable or metastatic HCC, and discuss how these approaches can be optimally integrated into patient care.
- Evaluate the rationale for and available and emerging data with the use of anti-PD-1/PD-L1 antibodies in combination with anti-CTLA-4 antibodies for HCC in order to determine the current and potential roles of these novel regimens.
- Discuss the biologic justification for the evaluation of immune checkpoint inhibitors for advanced biliary tract cancers, and review available and emerging data with anti-PD-1/PD-L1 antibody-based approaches for these patients.
- Recognize the molecular heterogeneity of cholangiocarcinoma and other biliary tract cancers, and appreciate the biologic rationale for efforts to exploit documented abnormalities in patients.
- Assess key data sets supporting the recent FDA approvals of fibroblast growth factor receptor (FGFR) inhibitors for previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement, and consider how these agents can be appropriately and safely integrated into clinical management algorithms.
- Recall available and emerging data with investigational agents and strategies currently in clinical testing for hepatobiliary cancers, and refer appropriate eligible patients for trial participation.

Breast Cancer

- Implement a long-term clinical management plan for patients with HER2-positive metastatic breast cancer (mBC), incorporating existing and recently approved anti-HER2 therapies.
- Comprehend available findings with CDK4/6 inhibitors for localized ER-positive, HER2-negative breast cancer, and assess the current role of these agents as a component of adjuvant treatment.
- Appraise available research data with commercially available CDK4/6 inhibitors for ER-positive mBC, and optimally incorporate these agents into patient care.
- Appreciate available Phase III data documenting the efficacy of adjuvant PARP inhibition in patients with high-risk HER2-negative localized breast cancer with BRCA mutations, and consider the potential role of this strategy in clinical practice.
- Review published research demonstrating a benefit with chemotherapy in combination with anti-PD-1/PD-L1 antibodies for localized or metastatic triple-negative breast cancer (TNBC), and apply this information in making treatment recommendations to patients.
- Evaluate published research findings guiding the selection and sequencing of available therapeutic agents for patients with PD-L1-negative TNBC or those who experience disease progression on front-line chemoimmunotherapy.
- Recall published efficacy and safety data with PARP inhibitors for patients with mBC harboring BRCA1/2 mutations, and consider the diagnostic and therapeutic implications for nonresearch care.
- Appreciate the incidence, pathologic and molecular characteristics and clinical relevance of HER2-low breast cancer, and understand available and emerging management approaches for this disease subset.
- Assess the biologic rationale for, available and emerging data with and ongoing clinical trials evaluating other novel agents and strategies under development for localized and metastatic breast cancer.

Endometrial Cancer

- Evaluate the importance of microsatellite instability (MSI) and DNA mismatch repair deficiency (dMMR) assessment in endometrial cancer, and adapt current testing practices to optimally identify patients with these genetic abnormalities.
- Review the benefits observed with anti-PD-1/PD-L1 antibodies for MSI-high or dMMR endometrial cancer, and integrate these agents into the care of appropriate patients with R/R endometrial cancer.
- Recognize the biologic rationale for and available data with the use of anti-PD-1/PD-L1 antibodies in combination with agents targeting the VEGF pathway, and select patients with metastatic endometrial cancer for this novel therapeutic approach.
- Design and implement a plan of care to manage side effects and toxicities associated with immune checkpoint inhibitor-based therapies in the treatment of EC to support quality of life and continuation of therapy.
- Describe the scientific justification for, published research data with and toxicity profiles of novel agents and strategies under investigation for endometrial cancer, and effectively prioritize clinical trial opportunities for eligible patients.

Ovarian Cancer and PARP Inhibitors

- Consider available clinical research findings with PARP inhibitors as maintenance therapy after first-line platinum-based chemotherapy for advanced ovarian cancer (OC), and counsel appropriate patients regarding personalized treatment recommendations.
- Assess available clinical trial data with and approved indications for FDA-endorsed PARP inhibitors for recurrent, platinum-sensitive and multiregimen-refractory OC in order to optimally incorporate these agents into patient care.
- Appreciate the biologic rationale for and published clinical research data with the use of PARP inhibitors in combination with other systemic therapies, and consider the current and potential clinical and research implications of these findings for OC management.
- Compare and contrast the toxicities associated with the various PARP inhibitors approved for OC, and offer supportive management strategies to minimize or ameliorate these side effects.

LEARNING OBJECTIVES (CONTINUED)

Gastrointestinal Cancers

- Consider various clinical and biologic factors (age, PS, disease stage, et cetera) to optimize the use of adjuvant chemotherapy for patients with localized colorectal cancer (CRC).
- Develop a long-term plan to guide the selection and sequencing of therapy for patients diagnosed with metastatic CRC, considering biomarker profile, tumor location, prior systemic therapy, symptomatology and personal goals of treatment.
- Use HER2 status, PD-L1 combined positive score and other clinical and biologic factors in the selection and sequencing of systemic therapy for patients with gastric, gastroesophageal junction and esophageal cancers.
- Recall clinical trial data with approved and investigational systemic interventions for localized, locally advanced or metastatic pancreatic adenocarcinoma, and establish an evidence-based approach to selecting therapy for patients.
- Appraise available and emerging data with investigational agents in clinical testing for colorectal, gastroesophageal and pancreatic cancers, and where applicable, refer eligible patients for clinical trial participation.

Melanoma

- Identify factors affecting the risk of recurrence for patients with localized melanoma, and evaluate the role of approved targeted and immunotherapeutic agents as adjuvant therapy.
- Use available clinical trial evidence to safely and effectively incorporate immunotherapeutic, targeted or combination approaches into the management of newly diagnosed metastatic melanoma.
- Consider patient age, PS and other biologic and disease-related factors in the selection of therapy — including potential clinical trial participation — for patients with metastatic melanoma who experience disease progression on front-line immune checkpoint inhibitor-based treatment.
- Assess available efficacy and safety findings with anti-LAG-3 antibodies in combination with anti-PD-1/PD-L1 antibodies for advanced melanoma in order to optimally integrate this strategy into the treatment armamentarium.
- Review available data with investigational strategies currently undergoing evaluation for localized and advanced melanoma, and refer appropriate eligible patients for trial participation.

AGENDA

7:30 AM Module 1: Lung Cancer

Targeted Therapy

- Patient selection for and appropriate incorporation into routine practice of adjuvant osimertinib in light of findings from the Phase III ADAURA trial
- Optimal first-line treatment for patients with metastatic non-small cell lung cancer (NSCLC) with EGFR tumor mutations, including those with CNS metastases
- Spectrum and clinical relevance of resistance mechanisms in patients experiencing disease progression on osimertinib
- Patritumab deruxtecan for metastatic EGFR tyrosine kinase inhibitor (TKI)-resistant NSCLC: Mechanism of action, available data and ongoing evaluation
- Activity and tolerability of amivantamab and lazertinib in the CHRYSALIS-2 trial for patients with NSCLC with EGFR mutations after disease progression on osimertinib and platinum-based chemotherapy
- Key efficacy and safety data informing the FDA approvals of mobocertinib and amivantamab for patients with EGFR exon 20 insertion mutations and disease progression on first-line chemotherapy
- Evidence-based selection and sequencing of mobocertinib and amivantamab for NSCLC with an EGFR exon 20 mutation
- Factors influencing the selection among novel ALK inhibitors (eg, alectinib, brigatinib, lorlatinib) for first-line therapy for patients with NSCLC with ALK rearrangements
- Selection and sequencing of therapy for patients with progressive NSCLC with ALK rearrangements
- Principal efficacy and safety findings, including intracranial response rates, with entrectinib for NSCLC with ROS1 rearrangement; appropriate integration into practice
- Similarities and differences between repotrectinib and approved TKIs targeting ROS1
- Available data with, FDA breakthrough therapy designation for and ongoing evaluation of repotrectinib for NSCLC with ROS1 rearrangement
- Key efficacy and safety outcomes from the Phase II DESTINY-Lung01 study evaluating trastuzumab deruxtecan (T-DXd) for NSCLC with HER2 mutation or overexpression
- Emerging results from the Phase III DESTINY-Lung02 study and the subsequent FDA approval of T-DXd for NSCLC with HER2 mutation
- Incidence of NRG1 fusions in NSCLC; mechanism of action of seribantumab
- Recently presented findings from the Phase II CRESTONE trial assessing seribantumab for advanced solid tumors with NRG1 fusions, including NSCLC

Immunotherapeutic and Other Novel Strategies

- Key findings from the Phase III CheckMate 816 trial evaluating nivolumab in combination with chemotherapy as neoadjuvant therapy for resectable Stage IB to IIIA NSCLC; patient selection for this strategy
- Emerging data from the Phase III AEGEAN study demonstrating an improvement in pathologic complete response rate with the addition of durvalumab to neoadjuvant chemotherapy for resectable NSCLC
- Design, eligibility criteria and published efficacy and safety findings from the Phase III IMpower010 trial evaluating atezolizumab versus best supportive care after adjuvant chemotherapy for completely resected NSCLC; FDA approval and current role of adjuvant atezolizumab
- Emerging overall survival results from the IMpower010 trial and implications for clinical disease management
- Available data from the Phase III PEARLS/KEYNOTE-091 study of pembrolizumab as adjuvant therapy for Stage IB to IIIA NSCLC

- Long-term findings from the Phase III PACIFIC trial evaluating consolidation durvalumab after chemoradiation therapy for patients with unresectable Stage III NSCLC
- Mechanisms of antitumor activity of oleclumab and monalizumab; efficacy and safety observed with durvalumab in combination with oleclumab or monalizumab in the randomized Phase II COAST study
- Key factors in the decision to use anti-PD-1/PD-L1 monotherapy versus combined chemoimmunotherapy versus dual immune checkpoint inhibition for newly diagnosed metastatic NSCLC without a targetable tumor mutation
- Clinical trial database supporting the FDA approvals of pembrolizumab and atezolizumab as monotherapy and combined with chemotherapy as first-line treatment for metastatic NSCLC
- Available data with first-line cemiplimab monotherapy for patients with NSCLC and PD-L1 in ≥50% of tumor cells; current clinical role
- Results from the Phase III EMPOWER-Lung 3 study of cemiplimab in combination with platinum-based chemotherapy as first-line therapy for NSCLC
- Phase III clinical trial results with first-line nivolumab/ipilimumab with and without chemotherapy (CheckMate 227, CheckMate 9LA); patient selection and optimal integration into practice
- Design, eligibility criteria and key findings from the Phase III POSEIDON trial evaluating durvalumab or durvalumab and tremelimumab in combination with platinum-based chemotherapy as first-line therapy for metastatic NSCLC
- Biologic rationale for targeting TROP2 in NSCLC
- Datopotamab deruxtecan for progressive metastatic disease: Mechanism of action, available data and ongoing investigation

8:30 AM Module 2: Chronic Lymphocytic Leukemia and Lymphomas

Chronic Lymphocytic Leukemia (CLL)

- Clinical, biologic and practical factors in the selection of first-line treatment for patients with CLL requiring active therapy
- Long-term follow-up from Phase III studies assessing ibrutinib- and acalabrutinib-based therapy for treatment-naïve CLL
- Published results from the Phase III SEQUOIA trial comparing zanubrutinib to bendamustine/rituximab (BR) as first-line therapy for previously untreated CLL
- Implications for clinical decision-making of the Phase III ELEVATE-RR and ALPINE studies comparing acalabrutinib and zanubrutinib, respectively, to ibrutinib for previously treated CLL
- Key data sets informing the optimal use of venetoclax-based therapy for newly diagnosed CLL
- Results and clinical implications of the Phase III GLOW trial evaluating first-line ibrutinib in combination with venetoclax
- Ongoing clinical trials evaluating other novel combination regimens
- Pharmacologic similarities and differences between the investigational noncovalent Bruton tyrosine kinase (BTK) inhibitor pirtobrutinib and covalent BTK inhibitors; implications for efficacy and tolerability
- Updated results among patients with relapsed/refractory (R/R) CLL in the BRUIN study of pirtobrutinib; potential clinical role for that agent
- CD19-directed chimeric antigen receptor (CAR) T-cell therapy for R/R CLL: Available data, ongoing investigation and potential clinical role

Diffuse Large B-Cell Lymphoma (DLBCL)

- Published results from the Phase III POLARIX study comparing polatuzumab vedotin in combination with chemotherapy to R-CHOP for previously untreated DLBCL; implications for clinical practice
- Key findings with polatuzumab vedotin in combination with BR for R/R DLBCL
- Efficacy and safety outcomes with tafasitamab/lenalidomide for patients with R/R DLBCL
- Mechanism of action of and available data with loncastuximab tesirine for R/R DLBCL
- Long-term data with axicabtagene ciloleucel (axi-cel), tisagenlecleucel (tis-cel) and lisocabtagene maraleucel (liso-cel) for multiregimen-relapsed DLBCL
- Results from key studies evaluating CAR T-cell therapy as second-line treatment for DLBCL; recent FDA approval of axi-cel and liso-cel in this setting
- Clinical and biologic factors in the selection and sequencing of polatuzumab vedotin/BR, tafasitamab/lenalidomide, loncastuximab tesirine and CAR T-cell therapy for patients with R/R DLBCL
- Molecular configurations of different CD20 x CD3 bispecific antibodies in development; implications for activity and tolerability
- Recently presented outcomes with and potential clinical roles of glofitamab and epcoritamab for R/R DLBCL

Follicular Lymphoma (FL)

- Final analysis from the Phase III GALLIUM study comparing obinutuzumab/chemotherapy to rituximab/chemotherapy for previously untreated FL
- Long-term clinical trial findings with lenalidomide/rituximab (R^2) for treatment-naïve and R/R FL; current role in clinical practice
- Principal outcomes from pivotal studies (eg, ZUMA-5, ELARA) evaluating CAR T-cell therapy for FL
- FDA approvals of axi-cel and tis-cel for R/R FL and current role in clinical practice
- Rationale for the evaluation of CD20 x CD3 bispecific antibodies for FL
- Published findings with mosunetuzumab for R/R FL; FDA breakthrough therapy designation and potential clinical role
- Available research with other bispecific antibodies (eg, glofitamab, epcoritamab) under development for FL

Hodgkin Lymphoma (HL)

- Long-term follow-up, including overall survival findings, from the Phase III ECHELON-1 trial of first-line brentuximab vedotin (BV) and AVD (doxorubicin/vinblastine/dacarbazine) for advanced classical HL
- Early findings with BV combined with chemotherapy for early-stage, unfavorable-risk HL
- Current role of BV for older patients with newly diagnosed HL
- Potential role of BV alone or in combination with immune checkpoint inhibition as a bridge to transplant
- Biologic rationale for the investigation of antibody-drug conjugates with alternative targets in HL; mechanism of action and structural components of camidanlumab tesirine
- Principal efficacy and safety findings from the pivotal Phase II study of camidanlumab tesirine for heavily pretreated HL; potential role in practice

AGENDA (CONTINUED)

Mantle Cell Lymphoma (MCL)

- Research database supporting the FDA approvals of ibrutinib, acalabrutinib and zanubrutinib for R/R MCL; key factors in the choice of a BTK inhibitor
- Primary results from the Phase III SHINE study of ibrutinib/BR and maintenance rituximab as first-line treatment for older patients with MCL
- Efficacy and safety findings for patients with R/R MCL in the Phase I/II BRUIN study of pirtobrutinib
- Early-phase research with venetoclax alone or combined with other agents for MCL
- Clinical research findings with brexucabtagene autoleucel and optimal integration into MCL treatment algorithms
- Ongoing assessment of other CAR T-cell platforms (eg, liso-cel) for MCL

9:30 AM – 10:00 AM Break

10:00 AM Module 3: Prostate and Bladder Cancers

Prostate Cancer

- Indications for and selection of androgen deprivation therapy (ADT) for patients with prostate cancer
- Available research findings with and potential clinical role of abiraterone in combination with ADT for high-risk nonmetastatic prostate cancer
- Clinical, biologic and practical factors guiding the selection of enzalutamide, apalutamide or darolutamide for patients with nonmetastatic castration-resistant prostate cancer (CRPC)
- Considerations influencing the choice of abiraterone, enzalutamide, apalutamide or docetaxel to combine with ADT for patients with metastatic hormone-sensitive prostate cancer (mHSPC)
- Key findings from the Phase III ARASENS trial of darolutamide in combination with docetaxel and ADT for mHSPC; recent FDA approval and current clinical role
- Factors in the selection and sequencing of therapy for metastatic CRPC (mCRPC); impact of earlier use of chemotherapy and secondary hormonal therapy
- Findings from the Phase III VISION study evaluating ^{177}Lu-PSMA-617 for progressive PSMA-positive mCRPC; recent FDA approval and appropriate integration into clinical practice
- Early results with and ongoing evaluation of ^{177}Lu-PSMA-617 in combination with other systemic therapies
- Frequency of homologous recombination repair (HRR) gene mutations in prostate cancer; indications for and practical implementation of genetic testing
- Optimal integration of approved PARP inhibitors into management algorithms for mCRPC
- Efficacy and safety findings from the Phase III PROpel trial comparing olaparib in combination with abiraterone to abiraterone alone as first-line therapy for patients with mCRPC with and without HRR gene mutations
- Results of the Phase III MAGNITUDE study of niraparib with abiraterone/prednisone as first-line therapy for patients with mCRPC with and without HRR gene mutations
- Potential clinical role of PARP inhibitors in combination with secondary hormonal therapy as first-line treatment

Urothelial Bladder Cancer (UBC)

- Identification of appropriate patients with high-risk non-muscle-invasive bladder cancer (NMIBC) for pembrolizumab therapy
- Results of the Phase III CheckMate 274 trial comparing nivolumab to placebo after surgery for patients with high-risk muscle-invasive bladder cancer (MIBC)
- FDA approval of adjuvant nivolumab and optimal integration into routine practice
- 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 and MIBC
- Current clinical role of anti-PD-1/PD-L1 antibodies as monotherapy or as maintenance after chemotherapy for patients with previously untreated metastatic UBC (mUBC)
- Long-term outcomes with enfortumab vedotin for patients with progressive mUBC; appropriate integration into the treatment paradigm
- Emerging results from cohort K of the EV-103/ KEYNOTE-869 study of first-line enfortumab vedotin in combination with pembrolizumab; potential clinical role
- 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 patients with progressive mUBC; optimal incorporation in disease management
- Spectrum, incidence and severity of toxicities with enfortumab vedotin, erdafitinib or sacituzumab govitecan; mitigation and management strategies
- Frequency of HER2 expression in mUBC; early data with novel HER2-targeted therapies (eg, disitamab vedotin, T-DXd)

11:00 AM Module 4: Renal Cell Carcinoma

- Key efficacy and safety findings from the Phase III KEYNOTE-564 trial documenting the benefit of adjuvant pembrolizumab for patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence after nephrectomy
- Selection of patients for treatment with adjuvant pembrolizumab
- Ongoing Phase III studies evaluating immune checkpoint inhibitors as neoadjuvant and/or adjuvant therapy for high-risk RCC; implications of the recent failure of the Phase III IMmotion010 trial
- Clinical and biologic factors (eg, risk classification, age, PS, prior (neo)-adjuvant therapy, number and location of metastases, symptomatology) in the selection of first-line therapy for patients with newly diagnosed metastatic RCC (mRCC)
- Long-term findings with nivolumab/ipilimumab, pembrolizumab/axitinib and avelumab/ axitinib for treatment-naïve mRCC
- Principal results from the Phase III CheckMate 9ER trial establishing the efficacy of nivolumab in combination with cabozantinib for previously untreated mRCC; FDA approval and current role
- Major efficacy and safety data from the Phase III CLEAR trial leading to the FDA approval of lenvatinib and pembrolizumab as first-line therapy for mRCC; optimal integration into management algorithms
- Design, eligibility criteria and key efficacy and safety endpoints of the pivotal Phase III COSMIC-313 trial evaluating nivolumab/ipilimumab/cabozantinib versus nivolumab/ipilimumab for previously untreated, advanced, intermediate- or poor-risk RCC

- Achievement of a progression-free survival advantage with nivolumab/ipilimumab/cabozantinib in the COSMIC 313 trial; implications for clinical practice
- Clinical outcomes from the Phase III TIVO-3 trial comparing tivozanib to sorafenib as third- or fourth-line therapy for RCC
- Optimal incorporation of tivozanib into current algorithms and ongoing studies attempting to further define its role in RCC management
- Mechanism of action of belzutifan; proportion of patients with von Hippel-Lindau-associated RCC and optimal role of belzutifan in this population
- Early-phase data with and ongoing evaluation of belzutifan as monotherapy and in combination with other agents for mRCC; potential role in clinical practice

11:20 AM Module 5: CAR-T and Bispecific Therapy for Multiple Myeloma

- Biologic rationale for targeting B-cell maturation antigen (BCMA) in multiple myeloma (MM)
- Structural makeup and manufacturing processes of available BCMA-directed CAR T-cell platforms in therapy for MM
- Principal efficacy and safety results from the Phase II KarMMa trial evaluating idecabtagene vicleucel (ide-cel) for R/R MM
- Key data from the CARTITUDE-1 trial documenting the effectiveness of ciltacabtagene autoleucel (cilta-cel) for patients with pretreated MM
- FDA approvals of ide-cel and cilta-cel for heavily pretreated MM; patient selection for and optimal timing of CAR T-cell therapy
- Structural composition and mechanism of action of the BCMA-directed antibody-drug conjugate belantamab mafodotin
- Principal efficacy and safety findings with belantamab mafodotin monotherapy for R/R MM; FDA approval and incorporation into routine practice
- Early data with and ongoing evaluation of belantamab mafodotin in combination with other systemic therapies and/or in earlier lines of treatment
- Similarities and differences in the cellular targets and mechanisms of action of bispecific antibodies under clinical development for R/R MM
- Antitumor activity observed with teclistamab in the Phase I/II MajesTEC-1 study; FDA breakthrough therapy designation and potential clinical role for teclistamab
- Rates, depth and durability of responses observed with REGN5458 for patients with heavily pretreated MM
- Key findings with other anti-BCMA bispecific antibodies for R/R MM
- Biologic rationale for targeting GPRC5D in MM; available efficacy and safety data with and FDA breakthrough therapy designation for talquetamab for heavily pretreated disease
- Mechanism of action of and early-phase efficacy and safety findings with cevostamab for R/R MM
- Optimal timing of therapy with BCMA and non-BCMA bispecific antibodies for MM and patient selection for clinical trial enrollment
- Spectrum, incidence and severity of toxicities with belantamab mafodotin, CAR T-cell therapy or bispecific antibodies in patients with MM; mitigation and management

11:40 AM Module 6: Hepatobiliary Cancers

- Clinical and biologic factors in the selection of first- and later-line therapy for advanced hepatocellular carcinoma (HCC)
- Long-term efficacy and safety findings from the Phase III IMbrave150 study establishing the benefit of first-line atezolizumab/bevacizumab for unresectable HCC
- Atezolizumab/bevacizumab therapy: Current role, practical integration and patient selection
- Design, eligibility criteria and primary and secondary endpoints from the Phase III HIMALAYA trial evaluating durvalumab/tremelimumab or durvalumab alone as first-line treatment for unresectable advanced HCC
- Achievement of an overall survival (OS) advantage and other efficacy and safety outcomes with durvalumab/tremelimumab in the HIMALAYA trial
- FDA priority review status and potential clinical role of durvalumab/tremelimumab as first-line treatment for HCC
- Early clinical research with lenvatinib in combination with pembrolizumab as first-line therapy for HCC
- Design, eligibility criteria and primary and secondary endpoints of the Phase III LEAP-002 trial evaluating lenvatinib with and without pembrolizumab as first-line treatment for advanced HCC
- Estimated completion date for the LEAP-002 trial and the potential clinical role of lenvatinib/pembrolizumab
- Early data with neoadjuvant or adjuvant immunotherapy-based treatment for HCC and ongoing Phase III studies (eg, CheckMate 9DX, EMERALD-2, IMbrave050, KEYNOTE-937)
- Design, eligibility criteria and key endpoints of the Phase III TOPAZ-1 trial evaluating durvalumab in combination with chemotherapy as first-line treatment for advanced biliary tract cancers
- Major efficacy and safety findings with the addition of durvalumab to first-line chemotherapy in the TOPAZ-1 trial; recent FDA approval and incorporation into clinical practice
- Spectrum of molecular alterations in cholangiocarcinoma and other biliary tract cancers; utility of genomic analyses to identify potentially actionable abnormalities
- Biologic rationale supporting FGFR inhibition as a rational therapeutic strategy for metastatic cholangiocarcinoma
- Pharmacologic and pharmacodynamic similarities and differences among available and investigational FGFR inhibitors with documented efficacy in cholangiocarcinoma (eg, pemigatinib, infigratinib, futibatinib)
- Key efficacy and safety findings leading to the FDA approvals of pemigatinib and infigratinib for previously treated, FGFR-altered locally advanced or metastatic cholangiocarcinoma; optimal integration into current management algorithms
- Available data with, FDA priority review status for and potential clinical role of futibatinib for previously treated cholangiocarcinoma
- Ongoing trials evaluating FGFR inhibitors as first-line therapy for patients with treatment-naïve cholangiocarcinoma (eg, FIGHT-302, PROOF, FOENIX-CCA3)
- Other available and investigational treatment strategies for advanced cholangiocarcinoma and other biliary tract cancers (eg, ivosidenib, T-DXd)

12:00 PM – 2:00 PM Lunch

2:00 PM Module 7: Breast Cancer

HER2-Positive and HER2-Low Disease

- Clinical factors (eg, prior HER2-directed therapy, symptomatology, disease-free interval, sites of metastases) affecting the selection and sequencing of therapy for patients with HER2-positive metastatic breast cancer (mBC)
- Long-term results, including final OS data, from the HER2CLIMB study of tucatinib/trastuzumab/capecitabine for HER2-positive mBC
- Findings from key studies (eg, DESTINY-Breast01, DESTINY-Breast03) evaluating T-DXd for HER2-positive mBC
- FDA approval of T-DXd as second-line treatment and implications for therapeutic sequencing
- CNS activity observed with tucatinib/trastuzumab/capecitabine and T-DXd in the pivotal studies leading to their approvals and in other research (eg, the TUXEDO-1 trial) for patients with brain metastases
- Incidence of HER2-low breast cancer; rationale for the activity of T-DXd in patients with this disease subtype
- Recently published findings from the DESTINY-Breast04 trial evaluating T-DXd versus chemotherapy for previously treated HER2-low advanced breast cancer; recent FDA approval and incorporation into routine practice
- Design, eligibility criteria and key efficacy and safety endpoints of the ongoing DESTINY-Breast06 trial comparing T-DXd to investigator's choice of chemotherapy for HER2-low, HR-positive mBC; potential role of T-DXd in therapy for HER2 ultra-low disease
- Spectrum, frequency and severity of toxicities associated with approved HER2-targeted agents for mBC; recommendations for monitoring, prevention and management

ER-Positive, HER2-Negative Disease

- Clinicopathologic features (eg, patient age/PS, tumor size/grade, nodal status, proliferation index, BRCA mutation status) affecting therapeutic decision-making for ER-positive localized breast cancer
- Major findings from the Phase III RxPONDER trial evaluating the role of chemotherapy in patients with ER-positive, HER2-negative early breast cancer with 1 to 3 positive lymph nodes and a 21-gene Recurrence Score (RS) ≤25
- Other recent clinical research studies informing the use of the 21-gene RS to guide neoadjuvant and adjuvant treatment decision-making
- Key efficacy and safety outcomes observed with the addition of abemaciclib to standard adjuvant hormonal therapy for patients with ER-positive, HER2-negative breast cancer at high risk for recurrence in the Phase III monarchE trial
- Guideline-endorsed indications and identification of appropriate candidates for adjuvant abemaciclib
- Findings with olaparib as adjuvant therapy for patients with ER-positive breast cancer with BRCA mutations in the Phase III OlympiA study; current role of adjuvant olaparib in this population
- Long-term follow-up, including OS data, from pivotal clinical trials of CDK4/6 inhibitors — palbociclib, ribociclib and abemaciclib — for ER-positive mBC
- Evidence-based selection of a CDK4/6 inhibitor and an endocrine partner for premenopausal and postmenopausal patients
- Available data (eg, from the MAINTAIN trial) evaluating the clinical utility of rechallenge with a CDK4/6 inhibitor after disease progression on or after prior CDK4/6 inhibitor therapy; implications for later-line treatment
- Key findings from the Phase III TROPiCS-02 trial evaluating sacituzumab govitecan for ER-positive, HER2-negative mBC; potential role of sacituzumab govitecan

Triple-Negative Disease

- Recommended approaches to biomarker assessment (eg, BRCA, PD-L1) for patients with triple-negative breast cancer (TNBC)
- Major findings from the Phase III KEYNOTE-522 study demonstrating an event-free survival advantage with neoadjuvant pembrolizumab combined with chemotherapy and continued as a single agent after surgery for high-risk localized TNBC
- FDA approval of (neo)adjuvant pembrolizumab; selection of appropriate candidates and practical implementation
- Key efficacy and safety data, including OS, from the Phase III OlympiA trial assessing adjuvant olaparib for patients with high-risk HER2-negative breast cancer and germline BRCA1/2 mutations
- Guideline-endorsed TNBC indications and identification of appropriate candidates for adjuvant olaparib
- Key clinical research findings guiding the optimal use of immune checkpoint inhibitors and PARP inhibitors for metastatic TNBC (mTNBC)
- Final results from the Phase III ASCENT trial comparing sacituzumab govitecan to physician's choice of chemotherapy for mTNBC
- Evidence-based sequencing of sacituzumab govitecan for patients with relapsed/refractory mTNBC

3:00 PM Module 8: Endometrial Cancer

- Clinical relevance of molecular classification in endometrial cancer (EC) and the incidence of microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) advanced disease
- Pharmacologic and pharmacodynamic similarities and differences among dostarlimab, pembrolizumab and other anti-PD-1 antibodies
- Longer-term efficacy and safety data with dostarlimab or pembrolizumab monotherapy for MSI-H/dMMR advanced EC; likelihood, rapidity and durability of response
- Current indications for dostarlimab or pembrolizumab monotherapy and optimal integration into the care of patients with MSI-H/dMMR advanced EC
- Available clinical trial data with anti-PD-1/PD-L1 antibodies as monotherapy for microsatellite stable and mismatch repair-proficient EC
- Biologic rationale for combining immune checkpoint inhibitors with agents targeting the VEGF pathway in EC
- Design, eligibility criteria and major efficacy and safety findings from the Phase III KEYNOTE-775 trial comparing lenvatinib/pembrolizumab to chemotherapy for advanced EC previously treated with a platinum-based regimen
- FDA approval of and patient selection for lenvatinib/pembrolizumab
- Incidence and severity of toxicities associated with lenvatinib/pembrolizumab; appropriate monitoring and management strategies
- Scientific justification for and design of the ongoing Phase III LEAP-001 trial evaluating lenvatinib/pembrolizumab versus platinum-based chemotherapy as first-line treatment for advanced EC
- Ongoing Phase III trials (eg, RUBY, AtTEnd, DUO-E) evaluating paclitaxel/carboplatin with or without anti-PD-1/PD-L1 antibody therapy for recurrent or primary advanced EC

- Mechanism of action and biologic rationale for the use of selinexor for EC; early-phase data for patients with advanced or recurrent disease
- Design, eligibility criteria and key efficacy and safety findings from the Phase III SIENDO trial evaluating selinexor as maintenance therapy after first-line chemotherapy for advanced EC

3:20 PM Break

3:50 PM Module 9: Ovarian Cancer and PARP Inhibitors

- Incidence of germline and somatic BRCA mutations and HRD (homologous recombination deficiency) in patients with advanced ovarian cancer (OC); indications and optimal platforms for genetic testing
- Efficacy and safety findings from Phase III studies (eg, SOLO-1, PRIMA, PRIME, PAOLA-1) supporting the use of olaparib, niraparib and olaparib/bevacizumab as maintenance therapy for newly diagnosed advanced OC
- Optimal integration of up-front PARP inhibitor maintenance; use of clinical characteristics and other factors to select among olaparib, olaparib/bevacizumab and niraparib
- Recently presented efficacy and safety findings from the Phase III ATHENA-MONO study assessing rucaparib as first-line maintenance therapy; impact of recent FDA actions on the developmental timeline for this strategy
- Findings from the Phase II OVARIO study assessing maintenance with niraparib/bevacizumab after front-line platinum-based chemotherapy/bevacizumab for advanced OC; potential clinical role
- Long-term follow-up from pivotal trials evaluating niraparib, olaparib and rucaparib for platinum-sensitive and platinum-resistant recurrent OC; rationale for the voluntary withdrawal of the FDA indication for rucaparib of OC with BRCA mutation after at least 2 prior lines of chemotherapy
- Key findings from the Phase IIIb OReO study evaluating the clinical utility of rechallenge with a PARP inhibitor for patients who have experienced disease progression on or after prior PARP inhibitor therapy; implications for later-line treatment
- Biologic rationale for combining PARP inhibitors with anti-PD-1/PD-L1 antibodies with or without bevacizumab for OC; results from early-phase studies (eg, MEDIOLA, TOPACIO, OPAL, MOONSTONE) evaluating these combinations
- Ongoing Phase III trials (eg, ATHENA-COMBO, FIRST, DUO-O) evaluating PARP inhibitors in combination with immune checkpoint inhibitors for advanced OC
- Incidence, timing and severity of toxicities associated with approved PARP inhibitors in patients with OC; optimal monitoring and management
- Other practical considerations (eg, duration of therapy, optimal dosing strategies) with the use of PARP inhibitors for advanced OC

4:10 PM Module 10: Gastrointestinal Cancers

Colorectal Cancer (CRC)

- Mechanistic rationale for and available data with longitudinal circulating tumor DNA (ctDNA) and minimal residual disease (MRD) measurement in localized CRC
- Ongoing studies examining the clinical utility of ctDNA/MRD testing in treatment decision-making and monitoring for recurrence; potential impact in practice
- Recently presented results from the Phase III PARADIGM trial and implications for the use of EGFR antibody therapy as a component of first-line treatment
- Appropriate integration of encorafenib/cetuximab into clinical practice for patients with BRAF V600E-mutant metastatic CRC (mCRC)
- Early findings with and ongoing evaluation of first-line BRAF-targeted therapy
- Frequency of HER2 overexpression in patients with mCRC; indications for, timing of and optimal approaches to HER2 testing
- Updated data from the Phase II DESTINY-CRC01 study of trastuzumab T-DXd for patients with HER2-expressing mCRC
- Recently presented findings from the pivotal Phase II MOUNTAINEER trial evaluating tucatinib/trastuzumab for previously treated HER2-positive mCRC
- Potential nonresearch roles of T-DXd and tucatinib/trastuzumab in therapy for HER2-positive mCRC
- Final OS results from the Phase III KEYNOTE-177 study evaluating front-line pembrolizumab versus chemotherapy for MSI-H/dMMR mCRC; implications for clinical practice
- Long-term findings with nivolumab/ipilimumab for previously untreated MSI-H/dMMR mCRC; current role, if any, of dual immune checkpoint inhibition in the treatment of newly diagnosed disease
- Rational incorporation of pembrolizumab, nivolumab and nivolumab/ipilimumab into therapy for progressive MSI-H/dMMR mCRC
- Incidence of KRAS G12C mutations in patients with mCRC; early results with and ongoing evaluation of KRAS G12C inhibitors (eg, sotorasib, adagrasib) for KRAS G12C-mutant disease

Gastroesophageal Cancers and Pancreatic Cancer

- Published outcomes from the Phase IIICheckMate 577 study of adjuvant nivolumab for resected esophageal or gastroesophageal junction (GEJ) cancer
- Selection of patients with esophageal or GEJ tumors for adjuvant nivolumab
- Phase III data sets (eg, from the CheckMate 649, CheckMate 648 and KEYNOTE-590 trials) demonstrating the efficacy and safety of first-line checkpoint inhibitor-containing regimens for advanced gastric, GEJ and esophageal cancer
- Evidence-based selection of chemotherapy alone versus combined chemoimmunotherapy versus dual immune checkpoint inhibition for newly diagnosed gastroesophageal cancer; importance of PD-L1 expression, tumor location and histology in decision-making
- Principal outcomes from the Phase III KEYNOTE-811 trial supporting the first-line use of pembrolizumab/trastuzumab/chemotherapy for metastatic HER2-positive gastric/GEJ adenocarcinoma
- Published efficacy and safety data from the DESTINY-Gastric01 and DESTINY-Gastric02 trials of T-DXd for progressive HER2-positive gastric/GEJ cancer
- Optimal sequencing of T-DXd for patients with HER2-positive metastatic gastric/GEJ adenocarcinoma
- Frequency of FGFR2b overexpression in gastroesophageal cancers; mechanism of action of bemarituzumab

- Major efficacy and safety data with and ongoing evaluation of first-line bemarituzumab/chemotherapy for FGFR2b-positive metastatic gastric/GEJ cancer
- Frequency of germline BRCA mutations and other DNA damage repair alterations in pancreatic adenocarcinoma (PAD); indications for and practical implementation of genetic testing
- Long-term findings with and optimal integration of olaparib as maintenance therapy after first-line chemotherapy for patients with metastatic PAD with a germline BRCA mutation

5:10 PM Module 11: Melanoma

- Long-term results from the Phase III COMBI-AD study evaluating dabrafenib/trametinib as adjuvant treatment for high-risk melanoma with BRAF V600 mutation
- Key data sets investigating the efficacy and safety of adjuvant anti-PD-1 antibody therapy for patients with Stage III or IV melanoma
- Published efficacy and safety findings from the Phase III KEYNOTE-716 trial evaluating pembrolizumab as adjuvant treatment for patients with surgically resected, high-risk Stage II melanoma
- Clinical, biologic and practical factors in the decision to administer adjuvant nivolumab, pembrolizumab or dabrafenib/trametinib
- Design, eligibility criteria and key findings of the Phase III DREAMseq trial evaluating the optimal sequence of therapies for patients with BRAF-mutant metastatic melanoma; implications for the sequencing of targeted therapy and immunotherapy in this population
- Biologic rationale for targeting LAG-3 in melanoma; mechanism of action of relatlimab
- Principal efficacy and safety outcomes from the Phase II/III RELATIVITY-047 trial evaluating the combination of relatlimab and nivolumab versus nivolumab alone for previously untreated metastatic or unresectable melanoma
- FDA approval and current clinical role of relatlimab/nivolumab as first-line therapy
- Early clinical activity and tolerability observed with the anti-LAG-3 monoclonal antibody fianlimab combined with cemiplimab in patients with advanced melanoma
- Ongoing Phase III evaluation of fianlimab/cemiplimab for previously untreated disease; potential role in melanoma treatment
- Scientific basis for the evaluation of anti-PD-1/PD-L1 antibodies in combination with agents targeting the VEGF pathway in melanoma
- Available findings from the LEAP-004 study evaluating lenvatinib/pembrolizumab for previously treated metastatic melanoma; ongoing Phase III evaluation of this combination as first-line therapy
- Mechanism of action of the autologous TIL (tumor-infiltrating lymphocyte) therapy lifileucel; manufacturing and administration processes
- Antitumor activity reported with lifileucel for advanced melanoma; FDA RMAT (regenerative medicine advanced therapy) designation, development plans and potential clinical role

5:30 PM End