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Recent Advances and Future Directions in Oncology: A Daylong Multitumor Educational Symposium in Partnership with the North Carolina Oncology Association and the South Carolina Oncology Society

A CME/MOC- AND NCPD-ACCREDITED HYBRID EVENT

Saturday, February 18, 2023
9:00 AM – 4:30 PM Eastern Time

Charlotte Convention Center*
Charlotte, North Carolina

FACULTY

BREAST CANCER

Harold J Burstein, MD, PhD
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GASTROINTESTINAL CANCERS

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GENITOURINARY CANCERS (JOINING VIRTUALLY)

Daniel P Petrylak, MD
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New Haven, Connecticut

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CHRONIC LYMPHOCYTIC LEUKEMIA AND LYMPHOMAS

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To be announced

GYNECOLOGIC CANCERS

Michael J Birrer, MD, PhD
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LUNG CANCER

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MODERATORS

BREAST CANCER AND GASTROINTESTINAL CANCERS

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GENITOURINARY CANCERS AND CLL AND LYMPHOMA

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GYNECOLOGIC CANCERS AND LUNG CANCER

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This activity is being hosted in association with

South Carolina Oncology Society

North Carolina Oncology Association

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This event is free of charge.

* A walkway from the back of The Westin Charlotte hotel connects the hotel to the Charlotte Convention Center. For convention center parking, the recommended option is the NASCAR Hall of Fame parking garage at 500 S Brevard Street.

LEARNING OBJECTIVES

Breast Cancer

- Assess published research to guide the selection and duration of neoadjuvant, adjuvant and extended-adjuvant therapy for patients with HER2-overexpressing localized breast cancer.
- Evaluate the results of genomic assays and other patient- and treatment-related factors to personalize adjuvant systemic therapy for newly diagnosed ER-positive breast cancer.
- Consider available clinical trial findings with CDK4/6 inhibitors for localized ER-positive, HER2-negative breast cancer, and assess the optimal role of these agents as neoadjuvant or adjuvant treatment.
- Appreciate available Phase III data documenting the efficacy of adjuvant PARP inhibition for high-risk HER2-negative localized breast cancer with a BRCA mutation, and consider the role of this strategy in clinical practice.
- Review published data demonstrating the benefit of chemotherapy in combination with anti-PD-1/PD-L1 antibodies for localized triple-negative breast cancer (TNBC), and use this information to make appropriate treatment recommendations.
- Implement a long-term clinical plan for the management of HER2-positive metastatic breast cancer (mBC), incorporating established and recently approved anti-HER2 therapies.
- Individualize the selection and sequencing of systemic therapy for patients with ER-positive mBC, considering age, menopausal status, prior treatment course, PIK3CA mutation status, level of HER2 expression, comorbidities, symptomatology and extent and sites of disease.
- Evaluate published research findings guiding the selection and sequencing of available therapeutic agents for metastatic TNBC.
- Appraise 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.
- Recall the mechanisms of action of, early data with and ongoing clinical trials evaluating other novel agents and treatment strategies under development for localized and metastatic breast cancer.

Gastrointestinal Cancers

- Optimize the use of adjuvant chemotherapy for localized colorectal cancer (CRC), considering various clinical and biologic factors such as patient age, performance status, disease stage, et cetera.
- Develop a long-term care plan for metastatic CRC, considering the patient's 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 to optimize the selection and sequencing of systemic therapy for patients with gastric, gastroesophageal junction and esophageal cancers.
- Consider age, performance status, degree of liver function and other clinical factors in the selection of first- and later-line therapy for patients with unresectable or metastatic hepatocellular carcinoma.
- Evaluate available data documenting the efficacy and safety of anti-PD-L1 antibody therapy in combination with chemotherapy as first-line treatment for advanced biliary tract cancers (BTCs), and consider the role of this therapeutic strategy.
- Recognize the molecular heterogeneity of cholangiocarcinoma and other BTCs, and appreciate the biologic rationale for efforts to exploit documented abnormalities in patients with these diseases.
- Recall clinical trial data with approved and investigational systemic interventions for metastatic pancreatic adenocarcinoma, and establish an evidence-based approach to selection of therapy for patients.
- Appraise available and emerging data with investigational agents currently in clinical testing for gastrointestinal cancers, and as applicable, refer eligible patients for clinical trial participation.

Genitourinary 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 and secondary hormonal therapy or combinations of these approaches for metastatic hormone-sensitive prostate cancer to design effective treatment plans for patients.
- Establish an evidence-based approach to the selection and sequencing of therapeutic options for patients with metastatic castration-resistant prostate cancer (mCRPC), considering age, comorbidities, prior therapeutic exposure and other factors.
- Assess available and emerging research supporting the use of PARP inhibitors for mCRPC, and discern how to optimally incorporate these agents into current and future clinical management algorithms.
- 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 urothelial bladder cancer (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 agents would be appropriate.
- Apply research findings and other clinical and biologic factors in the best-practice selection of first-line therapy for metastatic renal cell carcinoma (mRCC).
- Develop a rational approach to the selection and sequencing of systemic therapies for patients with mRCC who experience disease progression on first-line treatment.
- Consider available data supporting the use of anti-PD-1 antibody therapy for nonmetastatic UBC or RCC, and determine how this strategy can be appropriately integrated into patient care.
- Reflect on available and emerging data with investigational agents and strategies currently in testing for prostate cancer, UBC and RCC, and as applicable, refer 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.

LEARNING OBJECTIVES (CONTINUED)

- Understand published research data informing the selection, sequencing or 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 and the efficacy and safety of approved and investigational agents for 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 (chimeric antigen receptor) T-cell therapy for R/R DLBCL, MCL or FL, and counsel appropriately selected patients regarding the potential benefits of this strategy.
- Recall new data with agents and strategies currently under investigation for CLL and various lymphoma subtypes, and discuss ongoing trial opportunities with eligible patients.

Gynecologic Cancers

- Assess available clinical trial data with and approved indications for FDA-endorsed PARP inhibitors for newly diagnosed and recurrent ovarian cancer (OC) to optimally incorporate these agents into patient care.
- Appreciate the biologic rationale for and published trial data with the combination of PARP inhibitors with other systemic therapies, and consider the implications for current and future OC management and research.
- Recognize the rationale for targeting folate receptor alpha in OC, and determine optimal testing methods and the current role of novel approaches to therapeutically exploit this newly relevant biomarker.
- Review the benefits observed with anti-PD-1/PD-L1 antibodies for advanced microsatellite instability-high or mismatch repair-deficient endometrial cancer (EC), and appropriately integrate these agents into patient care.
- Consider the biologic rationale for and available data with the combination of anti-PD-1/PD-L1 antibodies with agents targeting the VEGF pathway, and select patients with metastatic EC for this novel therapeutic approach.
- Interrogate published efficacy and safety findings with anti-PD-1 antibodies as monotherapy or in combination with chemotherapy for metastatic cervical cancer (CC), and consider the current and potential role of immune checkpoint inhibition in therapy for this disease.
- Recognize the incidence of tissue factor expression in patients with CC, and evaluate the current and future roles of novel agents designed to exploit this therapeutic target.
- Reflect on investigational agents and strategies currently in testing for OC, EC and CC, and as applicable, refer eligible patients for clinical trial participation.

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 patients with nonmetastatic non-small cell lung cancer (NSCLC).
- Acknowledge the FDA approval of adjuvant EGFR tyrosine kinase inhibitor therapy for patients with localized NSCLC with EGFR mutations, and identify those for whom treatment with this approach would be warranted.
- Counsel patients with metastatic NSCLC with EGFR mutations regarding available therapeutic considerations, explaining the relevance of mutation type, symptomatology, sites and extent of metastases and other factors.
- Understand the biology of EGFR exon 20 insertion mutations, and evaluate how recently approved agents should be employed in the care of patients with these abnormalities.
- Assess the efficacy and safety of commercially available and investigational agents for patients with metastatic NSCLC with an ALK or ROS1 rearrangement, and use this information to select first- and later-line therapy.
- Recall published and emerging data with commercially available and experimental agents exploiting other oncogenic pathways (ie, RET, MET, HER2, KRAS G12C) mediating the pathogenesis of tumors in unique patient subsets.
- Review recent therapeutic advances related to anti-PD-1/PD-L1 antibodies as monotherapy or in combination with chemotherapy, chemobiologic therapy or anti-CTLA-4 antibodies for metastatic NSCLC, and discern how these approaches can be optimally employed in the management of this disease.
- Develop a long-term care plan, including the option of clinical trial participation, for patients with progressive NSCLC, considering prior systemic therapy, symptomatology, performance status and personal goals of treatment.
- Reflect on investigational agents and strategies currently in testing for lung cancer, and as applicable, refer eligible patients for clinical trial participation.

AGENDA

9:00 AM Module 1: Breast Cancer

Localized Breast Cancer

- Clinicopathologic factors affecting the risk of recurrence and the decision to consult a genomic classifier for ER-positive localized breast cancer
- Recommended approaches to biomarker assessment (eg, BRCA, PD-L1, Ki-67) for localized breast cancer
- Long-term findings from the Phase III TAILORx and RxPONDER trials; implications for practice
- Other recent studies informing the use of the 21-gene Recurrence Score® to guide neoadjuvant and adjuvant treatment decision-making
- Current approaches to the management of ER-positive localized disease in premenopausal patients; optimal duration and timing of ovarian suppression
- Key efficacy and safety outcomes from the Phase III monarchE trial with the addition of abemaciclib to standard adjuvant hormonal therapy for patients with ER-positive, HER2-negative breast cancer who are at high risk for recurrence
- Guideline-endorsed indications for the use of adjuvant abemaciclib; identification of appropriate patients for this strategy
- 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 triple-negative breast cancer (TNBC)
- FDA approval of (neo)adjuvant pembrolizumab; practical implementation and selection of appropriate candidates for this treatment strategy
- Key efficacy and safety data, including overall survival outcomes, from the Phase III OlympiA trial evaluating adjuvant olaparib versus placebo for patients with high-risk HER2-negative breast cancer and germline BRCA1/2 mutations
- Guideline-endorsed indications for the use of adjuvant olaparib; identification of patients for this approach
- Key clinical factors in the selection of neoadjuvant and adjuvant systemic therapy for HER2-positive localized breast cancer
- Published clinical research with postadjuvant neratinib for HER2-positive localized breast cancer; identification of patients for treatment with neratinib
- Dose escalation and other available approaches to mitigate neratinib-associated gastrointestinal toxicities

Metastatic Breast Cancer (mBC)

- 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 mBC
- Long-term results, including final overall survival (OS) data, from the HER2CLIMB study of tucatinib/trastuzumab/capecitabine for HER2-positive mBC
- Findings from key studies (eg, DESTINY-Breast01, DESTINY-Breast03) evaluating trastuzumab deruxtecan (T-DXd) for HER2-positive mBC
- CNS activity observed with tucatinib/trastuzumab/capecitabine and T-DXd in the pivotal studies leading to their approvals and other research efforts (eg, the TUXEDO-1 trial) for patients with brain metastases
- Spectrum, frequency and severity of toxicities associated with approved HER2-targeted agents for mBC; recommendations for monitoring, prevention and management
- Long-term follow-up, including OS findings, from pivotal clinical trials of the 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 (eg, MAINTAIN trial) and emerging (eg, PACE trial) data evaluating the clinical utility of rechallenge with a CDK4/6 inhibitor in patients who have experienced disease progression on or after prior CDK4/6 inhibitor therapy; implications for later-line treatment
- Incidence of HER2-low breast cancer; optimal timing and approach to testing
- Published findings from the DESTINY-Breast04 trial evaluating T-DXd versus chemotherapy in patients with previously treated HER2-low advanced breast cancer; FDA approval and optimal integration into current algorithms
- Key findings from the Phase III TROPiCS-02 trial evaluating sacituzumab govitecan for ER-positive, HER2-negative mBC; potential role of sacituzumab govitecan for this population
- Design, eligibility criteria and emerging efficacy and safety data from the Phase III CAPItello-291 study evaluating capivasertib and fulvestrant versus placebo and fulvestrant for recurrent HR-positive, HER2-negative mBC; potential clinical role
- Available and emerging findings with oral SERDs (eg, elacestrant, camizestrant, imlunestrant)
- Mechanism of action of and available data with datopotamab deruxtecan for mBC
- Key clinical research findings guiding the optimal use of immune checkpoint inhibitors and PARP inhibitors for metastatic TNBC (mTNBC)
- 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 relapsed/refractory mTNBC

10:00 AM Module 2: Gastrointestinal Cancers

Colorectal Cancer (CRC) and Gastroesophageal Cancers

- Mechanistic rationale for and available data with longitudinal circulating tumor DNA (ctDNA)/minimal residual disease (MRD) monitoring for localized CRC
- Ongoing studies examining the clinical utility of ctDNA/MRD testing for treatment decision-making and monitoring for recurrence; potential clinical impact
- 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 BRAF V600E-mutant metastatic CRC (mCRC)
- Updated data from the Phase II DESTINY-CRC01 study of trastuzumab deruxtecan (T-DXd) for HER2-expressing mCRC
- Efficacy and safety findings from the pivotal Phase II MOUNTAINEER trial evaluating tucatinib/trastuzumab for previously treated HER2-positive mCRC
- Potential nonresearch role of T-DXd and tucatinib/trastuzumab for HER2-positive 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

- Key data informing the rational incorporation of pembrolizumab, nivolumab and nivolumab/ipilimumab into therapy for microsatellite instability-high/mismatch repair-deficient mCRC
- Long-term findings from pivotal Phase III trials assessing regorafenib and TAS-102 for multiregimen-relapsed CRC
- Patient selection and practical considerations, including optimal dosing, for the use of regorafenib in mCRC
- Available data with TAS-102 in combination with bevacizumab for mCRC; emerging findings from the Phase III SUNLIGHT trial and implications for clinical practice
- Published outcomes from the Phase III CheckMate 577 study of adjuvant nivolumab for resected esophageal or gastroesophageal junction (GEJ) cancer; appropriate selection of candidates for this strategy
- Available (eg, CheckMate 649, CheckMate 648, KEYNOTE-590 trials) and emerging (eg, KEYNOTE-859 trial) Phase III data sets 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, combined chemoimmunotherapy or dual immune checkpoint inhibition for newly diagnosed gastroesophageal tumors; impact of PD-L1 expression, tumor location and histology on decision-making
- Principal outcomes from the Phase III KEYNOTE-811 trial supporting the use of first-line pembrolizumab/trastuzumab/chemotherapy for HER2-positive metastatic 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 in therapy for HER2-positive metastatic gastric/GEJ adenocarcinoma
- Biologic rationale for and ongoing evaluation of tucatinib-containing therapy for patients with previously treated HER2-positive gastric/GEJ adenocarcinoma
- Published findings with and optimal integration of ramucirumab into current clinical algorithms for metastatic gastric/GEJ cancer; role for patients experiencing disease progression on an immune checkpoint inhibitor
- Biologic rationale for targeting claudin 18.2 in gastric/GEJ cancer; mechanism of action of and early efficacy and safety data with zolbetuximab
- Emerging positive findings from the Phase III SPOTLIGHT study of first-line zolbetuximab in combination with chemotherapy for claudin 18.2-positive metastatic gastric/GEJ cancer
- Major efficacy and safety data with and ongoing evaluation of bemarituzumab/chemotherapy as first-line therapy for FGFR2b-positive metastatic gastric/GEJ cancer

Hepatobiliary Cancers and Pancreatic Cancer

- Clinical and biologic factors affecting 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
- Current role of atezolizumab/bevacizumab; practical integration and patient selection
- Design, eligibility criteria and key endpoints of the Phase III HIMALAYA trial evaluating durvalumab/tremelimumab versus durvalumab alone as first-line treatment for unresectable advanced HCC
- Overall survival advantage and other key efficacy outcomes with durvalumab/tremelimumab in the HIMALAYA trial; recent FDA approval and current clinical role
- Mechanism of action of tislelizumab; comparison to commercially available anti-PD-1/PD-L1 antibodies
- Available results from the Phase III RATIONALE 301 trial comparing tislelizumab to sorafenib as first-line treatment for advanced unresectable HCC; potential clinical role
- Current clinical utility of tyrosine kinase inhibitor monotherapy as first-line treatment for unresectable HCC; recently presented findings demonstrating a potential advantage with lenvatinib compared to atezolizumab/bevacizumab for nonviral disease
- Long-term outcomes with approved anti-angiogenic agents (eg, regorafenib, cabozantinib, ramucirumab) among patients with progressive HCC
- Key findings with anti-PD-1/PD-L1 and anti-CTLA-4 combination regimens for progressive HCC
- Design, eligibility criteria and key efficacy and safety findings from the Phase III TOPAZ-1 trial evaluating durvalumab in combination with chemotherapy as first-line treatment for advanced biliary tract cancers (BTCs)
- Published findings evaluating the addition of liposomal irinotecan (nal-IRI) to 5-FU/leucovorin for progressive metastatic BTCs
- Spectrum of molecular alterations in cholangiocarcinoma and other BTCs; utility of genomic analyses to identify potentially actionable molecular abnormalities
- Key efficacy and safety findings leading to the FDA approvals of pemigatinib, infigratinib and futibatinib for previously treated, FGFR-altered locally advanced or metastatic cholangiocarcinoma; optimal integration of these agents into current disease management algorithms
- Ongoing trials evaluating FGFR inhibitors as first-line therapy for patients with treatment-naïve cholangiocarcinoma (eg, FIGHT-302, PROOF, FOENIX-CCA3)
- Published outcomes from the Phase III ClarIDHy study of ivosidenib for cholangiocarcinoma with an IDH1 mutation; FDA approval and optimal incorporation of this agent into clinical practice
- Efficacy and safety of T-DXd in patients with HER2-positive and HER2-low BTCs in the Phase II HERB study
- Optimal selection of first- and later-line treatment for patients with metastatic pancreatic adenocarcinoma (PAD); impact of age, comorbidities and prior therapy
- Emerging findings from the Phase III NAPOLI-3 trial demonstrating a statistically significant improvement in overall survival with the combination of nal-IRI, 5-FU/ leucovorin and oxaliplatin (NALIRIFOX) compared to *nab* paclitaxel/gemcitabine for previously untreated PAD; clinical implications
- Patient selection for and practical integration of nal-IRI for relapsed metastatic PAD
- Frequency of germline BRCA mutations and other DNA damage repair alterations in 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 metastatic PAD with a germline BRCA mutation
- Potential role of KRAS mutation as a therapeutic target in PAD; early results with and ongoing evaluation of sotorasib and adagrasib for KRAS G12C-mutant advanced disease

11:00 AM – 11:20 AM Break

11:20 AM Module 3: Genitourinary Cancers

Prostate Cancer

- Indications for and selection of androgen deprivation therapy (ADT) for patients with prostate cancer
- Available research findings with abiraterone in combination with ADT for high-risk nonmetastatic prostate cancer; potential clinical role
- Major efficacy and safety results 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; implications for practice
- Ongoing clinical trials evaluating androgen receptor (AR) pathway inhibitors in combination with ADT and/or radiation therapy for patients with 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 in the choice of abiraterone, enzalutamide, apalutamide or docetaxel in combination with ADT for metastatic hormone-sensitive prostate cancer (mHSPC)
- Design, eligibility criteria and key efficacy and safety data from the Phase III PEACE-1 study of docetaxel with or without abiraterone with or without local radiation therapy for mHSPC
- Key findings from the Phase III ARASENS trial of darolutamide in combination with docetaxel and ADT for mHSPC; FDA approval and current clinical role
- Factors in the selection and sequencing of therapy for patients with metastatic CRPC (mCRPC)
- Radium-223 chloride: Published research, optimal clinical use and ongoing evaluation
- Phase III findings leading to the FDA approval of ^{177}Lu-PSMA-617 for progressive PSMA-positive mCRPC; integration into clinical practice
- Design, eligibility criteria and emerging findings from the Phase III PSMAfore trial comparing ^{177}Lu-PSMA-617 to a change in AR-directed therapy for mCRPC previously treated with an alternate AR pathway inhibitor but not exposed to taxane-containing chemotherapy
- Early results with and ongoing evaluation of ^{177}Lu-PSMA-617 in combination with other systemic therapies
- Appropriate integration of cabazitaxel into current mCRPC treatment algorithms and practical considerations for its use
- 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 the care of men with mCRPC
- Results from the Phase III TRITON3 trial evaluating rucaparib versus physician's choice of therapy for patients with mCRPC and HRR pathway abnormalities; implications for management algorithms
- 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
- Design, eligibility criteria and emerging efficacy and safety findings from the Phase III TALAPRO-2 trial comparing talazoparib in combination with enzalutamide to enzalutamide alone for patients with mCRPC with and without HRR gene mutations
- Potential clinical role of PARP inhibitors in combination with AR pathway inhibitors as first-line treatment for patients with and without HRR mutations

Bladder and Kidney Cancer

- Identification of patients with high-risk non-muscle-invasive bladder cancer (NMIBC) appropriate 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
- Current clinical research attempting to further define the role of anti-PD-1/PD-L1 antibodies in therapy for NMIBC and MIBC; ramifications of the recent voluntary indication withdrawal for atezolizumab
- Mechanism of antitumor activity of the novel intravesical drug delivery system TAR-200; early trial data
- Ongoing studies of TAR-200 with and without the anti-PD-1 antibody cetrelimab for NMIBC and MIBC
- Current clinical roles of anti-PD-1/PD-L1 antibodies as monotherapy and as maintenance therapy for patients with previously untreated metastatic urothelial bladder cancer (mUBC)
- Long-term outcomes with enfortumab vedotin for patients with progressive mUBC; appropriate integration into the treatment paradigm
- Recently presented results from cohort K of the EV-103/KEYNOTE-869 study of first-line enfortumab vedotin in combination with pembrolizumab; implications for disease management
- 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
- Spectrum, incidence and severity of toxicities with enfortumab vedotin, erdafitinib or sacituzumab govitecan; mitigation and management strategies
- 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
- Identification of patients for treatment with adjuvant pembrolizumab
- Clinical and biologic factors 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 findings 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 with pembrolizumab as first-line therapy for mRCC; optimal integration into current management algorithms
- Design, eligibility criteria and key efficacy and safety findings from the pivotal Phase III COSMIC-313 trial evaluating nivolumab/ipilimumab/cabozantinib versus nivolumab/ipilimumab for previously untreated advanced intermediate- or poor-risk RCC; implications for patient care

- Clinical and biologic factors in the selection of treatment for patients with mRCC who experience disease progression on first-line therapy
- Optimal incorporation of tivozanib into current management algorithms; ongoing studies attempting to further define the role of this agent in RCC management
- Mechanism of action of belzutifan; available data, ongoing evaluation and current clinical role in therapy for kidney cancer

12:20 PM – 1:05 PM Lunch

1:05 PM Module 4: Chronic Lymphocytic Leukemia and Lymphomas

Chronic Lymphocytic Leukemia (CLL) and Follicular Lymphoma (FL)

- Clinical, biologic and practical factors in the selection of first-line treatment for patients with CLL
- Long-term follow-up from Phase III studies assessing ibrutinib- and acalabrutinib-based therapy for patients with 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 of the Phase III ELEVATE-RR and ALPINE studies evaluating acalabrutinib and zanubrutinib, respectively, versus ibrutinib for previously treated CLL
- Key data sets informing the optimal use of venetoclax-based therapy for newly diagnosed CLL
- Importance, if any, of minimal residual disease (MRD) assessment in determining the duration of venetoclax-based up-front therapy; current and future roles of MRD in clinical decision-making
- Results from and clinical implications of the Phase III GLOW trial evaluating first-line ibrutinib in combination with venetoclax
- Ongoing trials evaluating other novel combination regimens with Bruton tyrosine kinase (BTK) and Bcl-2 inhibitors
- Pharmacologic similarities and differences between the investigational noncovalent BTK inhibitor pirtobrutinib and covalent BTK inhibitors; implications for efficacy and tolerability
- Updated results for patients with relapsed/refractory (R/R) CLL in the BRUIN study of pirtobrutinib; potential clinical role
- Available data with, ongoing investigation of and potential role for CD19-directed chimeric antigen receptor (CAR) T-cell therapy for R/R CLL
- Long-term clinical trial findings with lenalidomide/rituximab for treatment-naïve and R/R FL; current role in practice
- Key findings from the Phase III CHRONOS-3 trial evaluating copanlisib with rituximab for R/R FL
- Incidence of EZH2 mutations in patients with FL; key findings with and optimal use of tazemetostat for R/R FL with and without EZH2 mutations
- Principal outcomes from pivotal studies (eg, ZUMA-5, ELARA) evaluating CAR T-cell therapy for FL
- FDA approvals of axicabtagene ciloleucel (axi-cel) and tisagenlecleucel (tis-cel) for R/R FL; current roles in clinical practice
- Rationale for the evaluation of CD20 x CD3 bispecific antibodies for FL
- Published findings with mosunetuzumab for R/R FL; FDA priority review status and potential clinical role
- Available research with other bispecific antibodies under development for FL (eg, glofitamab, epcoritamab)

Diffuse Large B-Cell Lymphoma (DLBCL), Hodgkin Lymphoma (HL) and Mantle Cell Lymphoma (MCL)

- 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 axi-cel, tis-cel or 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
- Emerging results with other CAR T-cell platforms (eg, rapcabtagene autoleucel) for DLBCL
- Molecular configurations of different CD20 x CD3 bispecific antibodies in development; implications for activity and tolerability
- Recently presented outcomes with glofitamab and with epcoritamab for R/R DLBCL; potential clinical roles
- Long-term follow-up, including overall survival findings, from the Phase III ECHELON-1 trial of first-line brentuximab vedotin (BV) with 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
- Research database supporting the FDA approvals of ibrutinib, acalabrutinib and zanubrutinib for R/R MCL; key factors in choosing a BTK inhibitor
- Available (SHINE trial) and emerging (TRIANGLE trial) Phase III data sets evaluating ibrutinib-based therapy for newly diagnosed MCL
- Early data with other BTK inhibitor-based combination regimens for previously untreated MCL
- Efficacy and safety findings from the Phase I/II BRUIN study of pirtobrutinib for R/R MCL
- 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

2:05 PM Module 5: Gynecologic Cancers

Ovarian Cancer (OC)

- Incidence of germline and somatic BRCA mutations and homologous recombination deficiency in patients with advanced OC; indications and optimal platforms for genetic testing

- Long-term efficacy and safety findings, including overall survival outcomes, from the Phase III SOLO-1 and PAOLA-1 studies of olaparib and olaparib/bevacizumab, respectively, as maintenance therapy for newly diagnosed advanced OC
- Key efficacy and safety data from the Phase III PRIMA and PRIME studies supporting the use of first-line maintenance niraparib
- Optimal integration of up-front maintenance therapy with PARP inhibitors; use of clinical characteristics and other factors to select among olaparib, olaparib/bevacizumab and niraparib
- Recently presented efficacy and safety data from the Phase III ATHENA-MONO study assessing rucaparib as first-line maintenance therapy; impact of recent FDA actions on the developmental timeline for up-front maintenance rucaparib
- Findings from the Phase II OVARIO study assessing maintenance therapy 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 various indications for approved PARP inhibitors
- 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 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)
- Ongoing Phase III trials evaluating PARP inhibitors in combination with immune checkpoint inhibitors for advanced OC (eg, ATHENA-COMBO, FIRST, DUO-O)
- Biologic rationale for targeting folate receptor alpha in OC; mechanism of action of mirvetuximab soravtansine
- Published efficacy and safety outcomes from the Phase III SORAYA study of mirvetuximab soravtansine for patients with platinum-resistant OC and high folate receptor alpha expression
- Recent FDA approval of mirvetuximab soravtansine; implications for biomarker assessment and current management
- Spectrum, frequency and management of toxicities, including ocular events, associated with mirvetuximab soravtansine
- Ongoing trials evaluating mirvetuximab soravtansine for advanced OC (eg, MIRASOL, PICCOLO, GLORIOSA)
- Rationale for targeting NaPi2b in OC; mechanism of antitumor activity and structural components of upifitamab rilsodotin (UpRi)
- Clinical research documenting the efficacy and safety of UpRi for pretreated, advanced OC; ongoing trials for platinum-sensitive and platinum-resistant disease (eg, UPLIFT, UP-NEXT, UPGRADE)
- Mechanism of action of tumor treating fields and biologic rationale for their use in combination with chemotherapy for platinum-resistant OC
- Early-phase efficacy and safety data with tumor treating fields in combination with chemotherapy for advanced OC; ongoing Phase III INNOVATE-3 study

Endometrial Cancer (EC) and Cervical Cancer (CC)

- Incidence of microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) advanced EC; appropriate methods and timing for testing
- Long-term data with dostarlimab or pembrolizumab monotherapy for MSI-H/dMMR advanced EC; likelihood, rapidity and durability of responses
- Current indications for and optimal integration of dostarlimab and pembrolizumab monotherapy into the care of patients with MSI-H/dMMR advanced EC
- Available clinical trial data with anti-PD-1/PD-L1 antibodies as monotherapy in patients with microsatellite-stable/mismatch repair-proficient EC
- Biologic rationale for combining immune checkpoint inhibitors with agents targeting the VEGF pathway for EC
- Long-term efficacy and safety findings from the Phase III KEYNOTE-775 trial comparing lenvatinib/pembrolizumab to chemotherapy for patients with 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; monitoring and management strategies
- Design, eligibility criteria, primary and secondary endpoints and anticipated completion date of the Phase III LEAP-001 trial evaluating lenvatinib/pembrolizumab as first-line treatment for advanced EC
- Ongoing Phase III trials evaluating paclitaxel/carboplatin with or without anti-PD-1/PD-L1 antibody therapy for recurrent or primary advanced EC (eg, RUBY, AtTEnd, DUO-E)
- Mechanism of action of selinexor and biologic rationale for its evaluation for EC
- Key efficacy and safety data from the Phase III SIENDO trial evaluating selinexor versus placebo as maintenance after first-line chemotherapy for advanced EC; potential role of selinexor as front-line maintenance therapy
- Major findings from the Phase III KEYNOTE-826 trial of pembrolizumab in combination with platinum-based chemotherapy with or without bevacizumab as up-front therapy for advanced CC
- Optimal integration of first-line pembrolizumab/chemotherapy into the care of patients with CC
- Available data with anti-PD-1/PD-L1 antibodies as monotherapy for progressive advanced CC
- Ongoing trials evaluating anti-PD-1/PD-L1 antibodies in combination with chemotherapy, chemoradiation therapy or anti-CTLA-4 antibodies for locally advanced or metastatic CC
- Rationale for targeting tissue factor in CC; mechanism of action and structural components of tisotumab vedotin
- Key efficacy outcomes observed with tisotumab vedotin in patients with recurrent metastatic CC who experience disease progression after chemotherapy; optimal integration into clinical care
- Frequently observed toxicities with tisotumab vedotin; recommended algorithms for the prevention and management of ocular and other adverse events
- Early data with and ongoing evaluation of tisotumab vedotin in combination with other anticancer therapies (eg, chemotherapy, pembrolizumab) for metastatic CC

3:05 PM – 3:20 PM Break

3:20 PM Module 6: Lung Cancer

Targeted Therapy

- Patient selection for adjuvant osimertinib and appropriate incorporation into routine practice on the basis 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-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 who have experienced disease progression on first-line chemotherapy
- Evidence-based selection and sequencing of mobocertinib and amivantamab for NSCLC with EGFR exon 20 mutation
- Factors influencing the selection of a novel ALK inhibitor (eg, alectinib, brigatinib, lorlatinib) as first-line therapy for patients with ALK-rearranged NSCLC
- Selection and sequencing of therapy for patients with progressive ALK-positive NSCLC
- Principal efficacy and safety findings, including intracranial response rates, with entrectinib for ROS1-positive NSCLC; appropriate integration into practice
- Available data with, FDA breakthrough therapy designation for and ongoing evaluation of repotrectinib for NSCLC with ROS1 rearrangements
- Key efficacy and safety outcomes from the Phase II DESTINY-Lung02 study evaluating trastuzumab deruxtecan (T-DXd) for NSCLC with HER2 mutation or overexpression
- Recent FDA approval of T-DXd for NSCLC with HER2 mutation; optimal incorporation into practice
- Principal efficacy and safety findings with sotorasib for pretreated KRAS G12C-mutated NSCLC; recent FDA approval and current role in patient care
- Key data with adagrasib for previously treated KRAS G12C-mutated disease; potential clinical role of this agent
- Antitumor activity observed with selpercatinib and with pralsetinib in patients with RET fusion-driven advanced NSCLC, including those with previously untreated disease
- Optimal integration of and selection between selpercatinib and pralsetinib in therapy for metastatic NSCLC with RET fusion
- Key findings with capmatinib and tepotinib for NSCLC with MET exon 14 mutation
- Role of capmatinib and tepotinib in current clinical practice; individualized selection between these agents

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; selection of appropriate patients for this strategy
- Emerging data from the Phase III AEGEAN study demonstrating an improvement in pathologic complete response rate with durvalumab added to neoadjuvant chemotherapy compared to chemotherapy alone 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
- 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
- Key factors affecting the selection of anti-PD-1/PD-L1 monotherapy, combined chemoimmunotherapy or dual immune checkpoint inhibition for newly diagnosed metastatic NSCLC without a targetable tumor mutation
- Clinical trial data supporting the FDA approvals of pembrolizumab, atezolizumab and cemiplimab administered as monotherapy for the first-line treatment of metastatic NSCLC
- Documented antitumor activity and safety of anti-PD-1/PD-L1 monotherapy in patients with poor performance status
- Emerging results demonstrating the noninferiority of subcutaneous atezolizumab compared to standard intravenous therapy for patients with advanced NSCLC; implications for practice
- Results from the Phase III EMPOWER-Lung 3 study of cemiplimab in combination with platinum-based chemotherapy as first-line therapy for NSCLC; recent FDA approval and current clinical role
- Phase III results with first-line nivolumab/ipilimumab with and without chemotherapy in the CheckMate 227 and CheckMate 9LA trials; 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
- Recent FDA approval of durvalumab/tremelimumab/chemotherapy and current role of this combination in clinical practice
- Biologic rationale for targeting TROP2 in NSCLC
- Datopotamab deruxtecan for progressive metastatic disease: Mechanism of action, available data and ongoing investigation
- Biologic justification for targeting CEACAM5 in NSCLC
- Tusamitamab ravtansine for advanced nonsquamous NSCLC: Mechanism of antitumor activity, early efficacy and safety data and ongoing evaluation

4:20 PM – 4:30 PM Closing remarks