Year in Review



A Multitumor Regional Symposium Focused on the Application of Emerging Research Information to the Care of Patients with Common Cancers

When
Saturday, October 12, 2019
8:00 AM – 4:00 PM

Where
Loews Santa Monica Beach Hotel
1700 Ocean Avenue
Santa Monica, California

Arcadia Ballroom (Fifth Floor)
Breakfast and lunch provided

Moderator
Neil Love, MD
Research To Practice
Miami, Florida

This activity is being hosted in association with

Medical Oncology Association Of Southern California, Inc.

Faculty and Topics

Acute Leukemias

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Breast Cancer

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Lymphoma and Chronic Lymphocytic Leukemia

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Gynecologic Cancers

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Lung Cancer

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Gastrointestinal Cancers

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Genitourinary Cancers

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To register or to learn more please visit:

www.ResearchToPractice.com/Meetings/YIR2019/CA

This event is free of charge.

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Agenda

Each module will include a moderated slide presentation reviewing key publications, presentations and ongoing trials in addition to a clinical decision-making track facilitated through the use of networked iPad technology. All events will take place from 8:00 AM to 4:00 PM or 8:30 AM to 4:30 PM (breakfast and lunch buffets to be provided). Please consult **www.ResearchToPractice.com/Meetings/YIR2019** for a detailed schedule including module order and times for each program.

Module 1: Lung Cancer

- Optimal long-term treatment for patients with non-small cell lung cancer (NSCLC) and EGFR tumor mutations, including those with CNS metastases; documentation of an overall survival benefit with osimertinib as first-line therapy
- Clinical and biologic factors influencing the selection of first- and later-line therapy for advanced NSCLC with an ALK rearrangement
- Current and emerging treatment considerations for patients with NSCLC with ROS1 rearrangement
- Mechanism of action of, available data with and ongoing evaluation of novel agents (eg, LOXO-292, BLU-667) in patients with RET fusion-driven NSCLC
- Identification and off-protocol management of NSCLC with NTRK gene fusions
- Early clinical trial results with and ongoing evaluation of novel agents targeting MET exon 14 mutations (eg, capmatinib, tepotinib)
- Available data with and recent FDA approval of carboplatin/etoposide/atezolizumab for newly diagnosed extensive-stage small cell lung cancer (SCLC); appropriate integration into current SCLC management
- Emerging results from the Phase III CASPIAN trial documenting the benefit of durvalumab in combination with etoposide and platinum-based chemotherapy versus chemotherapy alone as first-line therapy for extensive-stage SCLC
- Efficacy and safety data with the use of anti-PD-1/PD-L1 antibodies alone or in combination with anti-CTLA-4 antibodies for patients with progressive metastatic SCLC
- Patient selection for and practical implementation of sequential durvalumab in the management of unresectable Stage III NSCLC
- Ongoing evaluation of other anti-PD-1/PD-L1 antibodies in the localized and locally advanced settings
- Clinical and biologic factors affecting the selection of anti-PD-1/PD-L1 monotherapy versus combined chemotherapy/immune checkpoint inhibition
- Implications of the recent FDA approval of atezolizumab/bevacizumab in combination with carboplatin/paclitaxel for chemotherapy-naïve metastatic nonsquamous NSCLC
- Similarities and differences among Phase III trials evaluating anti-PD-1/PD-L1 antibodies in combination with platinum-based chemotherapy for patients with newly diagnosed metastatic squamous NSCLC; current role of combination chemoimmunotherapy as first-line treatment for this population
- Emerging results from the Phase III CheckMate 227 trial documenting an overall survival advantage with nivolumab/low-dose ipilimumab versus chemotherapy as first-line treatment for patients with NSCLC and PD-L1 tumor expression ≥1%

Module 2: Acute Leukemias

- Published efficacy and safety data supporting the recent FDA approval of venetoclax in combination with azacitidine, decitabine or low-dose cytarabine for patients with newly diagnosed acute myeloid leukemia (AML) who are not candidates for intensive induction chemotherapy
- Optimal integration of venetoclax into current AML management: Dose, schedule, identification and management of toxicities, incidence and prophylaxis of tumor lysis syndrome
- Design, entry criteria and key efficacy and safety findings from the Phase II BRIGHT 1003 trial of glasdegib in combination with low-dose cytarabine for newly diagnosed AML in older patients or those who are unable to receive intensive induction chemotherapy; recent FDA approval of glasdegib and integration into current care
- Available research data with gilteritinib for FLT3 mutation-positive AML; recent FDA approval of gilteritinib for relapsed/refractory (R/R) disease and appropriate integration into routine practice
- Published research database supporting FDA approvals of the IDH inhibitors enasidenib and ivosidenib for AML
- Available efficacy and safety data with and FDA approval of CPX-351; current role in clinical practice and ongoing evaluation in other populations with AML
- Initial management of Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL); comparison of adult and pediatric treatment regimens
- FDA-endorsed use of blinatumomab for patients with minimal residual disease (MRD)-positive ALL in first or second complete remission or those with R/R disease
- Current role of MRD assessment in ALL management and selection of optimal testing platform
- Biologic rationale for the evaluation of chimeric antigen receptor (CAR) T-cell therapy in patients with ALL; FDA approval of tisagenlecleucel for pediatric and young adult patients and published clinical trial experience with CAR T-cell therapy in adult patients with ALL
- Current management of acute promyelocytic leukemia

Module 3: Lymphomas and Chronic Lymphocytic Leukemia (CLL)

- Clinical implications of recent Phase III data sets comparing ibrutinib-based therapy to standard chemoimmunotherapy approaches for younger (ECOG-E1912) and older (Alliance A041202) patients with treatment-naïve CLL
- Design, eligibility requirements and primary and secondary outcomes achieved in the Phase III CLL14 trial evaluating venetoclax/obinutuzumab

Agenda (continued)

versus chlorambucil/obinutuzumab for patients with treatment-naïve CLL and coexisting medical conditions; clinical implications of the recent FDA approval of this regimen

- Clinical and biologic factors influencing the selection of first-line treatment regimen for patients with newly diagnosed CLL requiring active therapy
- Available platforms for, clinical significance of and current protocol and nonresearch applications of MRD assessment in CLL
- Key findings from the Phase III ASCEND trial comparing acalabrutinib to rituximab in combination with either idelalisib or bendamustine for patients with R/R CLL; ongoing Phase III ELEVATE-RR study of acalabrutinib versus ibrutinib for high-risk R/R disease
- Emerging results from the Phase III ELEVATE-TN trial comparing obinutuzumab/chlorambucil, acalabrutinib/obinutuzumab and acalabrutinib for patients with previously untreated CLL
- Long-term outcomes of the Phase III MURANO trial comparing venetoclax/rituximab to bendamustine/rituximab (BR) for R/R CLL
- Key efficacy and safety outcomes from the Phase III DUO trial evaluating duvelisib versus ofatumumab for R/R CLL; FDA approval of duvelisib and optimal role of PI3 kinase inhibition in patients with R/R CLL
- Ongoing randomized trials evaluating novel combination approaches for newly diagnosed CLL
- Clinical and research implications of Phase III trials (RELEVANCE, AUGMENT) evaluating the "R-squared" regimen of lenalidomide/rituximab in newly diagnosed and R/R follicular lymphoma (FL); recent FDA approval of this approach for previously treated FL and marginal zone lymphoma
- Role of obinutuzumab-based induction and maintenance therapy for previously untreated FL; integration of obinutuzumab into current algorithms for treatment-naïve and R/R disease
- Patient selection for PI3 kinase inhibition in R/R FL; appropriate integration of idelalisib, copanlisib and duvelisib into current management algorithms
- Early activity and safety data with ibrutinib alone or in combination with other systemic therapies for previously untreated mantle cell lymphoma (MCL); ongoing and planned Phase III trials (eg, TRIANGLE, SHINE, SYMPATICO)
- Research database supporting the FDA approval of acalabrutinib in R/R MCL; patient selection for its use
- Early activity, ongoing trials and current nonresearch role, if any, of venetoclax in R/R MCL
- Long-term follow-up from clinical trials of approved and investigational CAR T-cell platforms in diffuse large B-cell lymphoma (DLBCL); appropriate referral for consideration of CAR T-cell therapy in general practice
- Available efficacy and safety data leading to the FDA approval of polatuzumab vedotin in combination with BR for patients with R/R DLBCL; optimal incorporation into current management algorithms
- Role of brentuximab vedotin (BV) in combination with doxorubicin/vinblastine/dacarbazine as first-line therapy for advanced classical Hodgkin lymphoma (HL); experience with North American patients in the ECHELON-1 trial and implications, if any, for the adoption of BV
- Ongoing evaluation of immune checkpoint inhibitors alone or in combination with other systemic approaches (eg, chemotherapy, BV) for newly diagnosed or R/R HL
- Recent FDA approval of BV in combination with chemotherapy for previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas

Module 4: Gynecologic Cancers

- Key outcomes from the Phase III SOLO-1 trial evaluating maintenance olaparib after first-line platinum-based chemotherapy for patients with advanced ovarian cancer (OC) and a BRCA mutation
- Emerging results and clinical implications of the Phase III PRIMA study evaluating maintenance niraparib after first-line platinum-based chemotherapy for patients with advanced OC regardless of biomarker status
- Design, eligibility criteria and emerging efficacy and safety data from the Phase III PAOLA-1 trial comparing olaparib in combination with bevacizumab to bevacizumab alone as maintenance therapy for patients with advanced OC who responded to first-line treatment with platinum-based chemotherapy and bevacizumab
- Findings from the Phase III SOLO-3 trial comparing olaparib monotherapy to chemotherapy for platinum-sensitive relapsed OC with a germline BRCA mutation
- Results and clinical implications of the Phase II QUADRA study of niraparib for patients with relapsed OC, regardless of mutation status, who have received 3 or 4 prior chemotherapy regimens
- Long-term follow-up from other data sets informing the safe and effective use of PARP inhibitors for platinum-sensitive and platinum-refractory advanced OC
- Biologic rationale and eligibility criteria for ongoing trials of PARP inhibitors combined with immune checkpoint inhibitors, anti-angiogenic agents or other systemic approaches
- Incidence of microsatellite instability (MSI) in patients with advanced gynecologic cancers; recommended testing algorithms and activity of anti-PD-1/PD-L1 antibodies in individuals with MSI-high disease
- Available data with, FDA breakthrough therapy designation for and ongoing evaluation of pembrolizumab/lenvatinib for advanced endometrial cancer (EC)
- Preliminary safety and efficacy associated with the use of the anti-PD-1 antibody dostarlimab in patients with advanced or recurrent EC; ongoing evaluation and future development plans
- Efficacy and safety associated with the use of pembrolizumab in patients with advanced cervical cancer (CC) enrolled on the Phase II KEYNOTE-158 trial
- FDA approval of pembrolizumab for PD-L1-positive recurrent or metastatic CC with disease

progression on or after chemotherapy and patient selection for its use in routine practice

- Mechanism of action of and published efficacy and safety outcomes with the use of tisotumab vedotin in R/R CC; ongoing and planned trials evaluating the role of tisotumab vedotin in R/R and previously untreated metastatic CC
- Ongoing clinical trials evaluating anti-PD-1/PD-L1 antibodies alone and in combination with other systemic therapies for patients with advanced OC, EC and CC
- Other promising agents or strategies under investigation for advanced gynecologic cancers

Module 5: Breast Cancer (BC)

- Key efficacy and safety results from the Phase III KATHERINE study of adjuvant T-DM1 versus trastuzumab for patients with HER2-positive primary BC and residual disease after preoperative therapy
- Optimal integration of pertuzumab and neratinib into the management of HER2-positive early BC
- Available research data with neratinib/capecitabine for patients with HER2-positive mBC, including those with CNS metastases
- Structural makeup of and early efficacy and tolerability data with the use of trastuzumab deruxtecan in patients with HER2-positive mBC; emerging pivotal data from the Phase II DESTINY-Breast01 trial
- Mechanism of action of and early activity and safety data with the selective HER2 inhibitor tucatinib; activity in patients with HER2-positive brain metastases and ongoing evaluation
- Available Phase III data with and potential clinical role of margetuximab
- Implications of the TAILORx intermediate-risk cohort results for adjuvant treatment for pre- and postmenopausal patients with early BC; utility of classic clinical features to complement 21-gene Recurrence Score® findings in various patient subsets
- Research data with and current clinical role of CDK4/6 inhibitors for premenopausal, postmenopausal and elderly patients with ER-positive mBC
- Key efficacy and safety findings of the Phase III SOLAR-1 trial leading to the FDA approval of alpelisib/fulvestrant for men and postmenopausal women with ER-positive, HER2-negative mBC with PIK3CA mutations
- FDA approval of atezolizumab/*nab* paclitaxel for patients with PD-L1-positive unresectable locally advanced or metastatic triple-negative BC; integration of this approach into clinical practice
- Emerging results from the Phase III KEYNOTE-522 trial documenting the benefit of neoadjuvant pembrolizumab with chemotherapy versus chemotherapy alone for triple-negative BC
- Ongoing Phase III evaluation of anti-PD-1/PD-L1 antibodies alone or in combination with other systemic therapies for localized or metastatic BC
- Therapeutic implications of Phase III data sets supporting the FDA approvals for olaparib (OlympiAD) and talazoparib (EMBRACA) for HER2-negative mBC with a BRCA germline mutation

Module 6: Gastrointestinal Cancers

- Key outcomes from and clinical implications of the randomized Phase III Unicancer GI PRODIGE 24/CCTG PA.6 trial comparing adjuvant mFOLFIRINOX to gemcitabine for resected pancreatic adenocarcinoma (PAD)
- Key efficacy results and clinical implications of the Phase III APACT trial evaluating adjuvant *nab* paclitaxel/gemcitabine versus gemcitabine alone
- Use of contemporary chemotherapy regimens (mFOLFIRINOX, *nab* paclitaxel/gemcitabine) with or without radiation therapy as neoadjuvant treatment for resectable or borderline-resectable PAD
- Published research experience with, patient selection for and practical integration of nal-IRI (nanoliposomal irinotecan) for relapsed metastatic PAD; ongoing evaluation in earlier disease settings
- Design, entry criteria and key efficacy and safety findings from the Phase III POLO trial evaluating olaparib as maintenance therapy for patients with metastatic PAD and a germline BRCA mutation after first-line chemotherapy; diagnostic and clinical implications
- FDA approval of lenvatinib as first-line therapy for unresectable hepatocellular carcinoma (HCC) and patient selection for its use in routine practice
- Emerging results from the Phase III CheckMate 459 trial evaluating nivolumab as first-line treatment for advanced HCC; clinical and research implications
- Key findings from the Phase III REACH-2 study of ramucirumab for patients with progressive HCC and an alpha-fetoprotein level of ≥400 ng/mL; recent FDA approval of ramucirumab for this patient population
- Sequence and selection of approved agents (nivolumab, regorafenib, cabozantinib, pembrolizumab, ramucirumab) for patients whose disease has progressed on first-line therapy
- Biologic rationale for and early trial data leading to the FDA breakthrough therapy designations for atezolizumab/bevacizumab and pembrolizumab/lenvatinib as first-line therapy for advanced HCC
- Early safety and efficacy with and ongoing evaluation of combined anti-PD-1/PD-L1 and anti-CTLA-4 antibodies in HCC (eg, nivolumab/ipilimumab, durvalumab/tremelimumab)
- Active Phase III trials attempting to improve outcomes over standard biologic therapy for patients with newly diagnosed, advanced HCC (eg, IMbrave150, LEAP-002, COSMIC-312, HIMALAYA)
- Available research data exploring the correlation between tumor location and long-term outcomes in metastatic colorectal cancer (mCRC); emerging data linking tumor sidedness to response to specific therapeutic interventions
- Rational incorporation of EGFR antibodies, regorafenib and TAS-102 into current treatment algorithms for mCRC
- Indications for MSI assessment in mCRC; patient selection for anti-PD-1 monotherapy versus combined anti-PD-1/anti-CTLA-4 antibody therapy in patients with MSI-high/mismatch repair-deficient (dMMR) tumors
- Biologic rationale for, available data with and ongoing investigation of regorafenib in combination with nivolumab for patients with microsatellite stable mCRC

Agenda (continued)

- Published research findings from the Phase III BEACON CRC trial comparing encorafenib/cetuximab with or without binimetinib to irinotecan/cetuximab or FOLFIRI/cetuximab for patients with mCRC and BRAF V600E mutations
- Integration of ramucirumab into current clinical algorithms for metastatic gastric/gastroesophageal junction (GEJ) cancer; ongoing evaluation of ramucirumab for other clinical presentations beyond disease progression on first-line therapy
- Research supporting the FDA approval of pembrolizumab for recurrent locally advanced or metastatic gastric/GEJ adenocarcinoma with a PD-L1 combined positive score ≥1 after 2 or more lines of chemotherapy and, if appropriate, HER2-targeted therapy; clinical and research implications of the Phase III KEYNOTE-061 and KEYNOTE-062 trials
- Early experience and ongoing research combining immune checkpoint inhibitors with chemotherapy, targeted therapy or other immunotherapeutic agents for patients with metastatic gastric/GEJ cancer
- Primary and secondary endpoints achieved in the Phase III TAGS study of TAS-102 for heavily pretreated metastatic gastric cancer; FDA approval and patient selection in routine practice
- Results from the Phase III KEYNOTE-181 trial evaluating second-line pembrolizumab versus chemotherapy for locally advanced or metastatic squamous cell carcinoma and adenocarcinoma of the esophagus; FDA approval of pembrolizumab for progressive, PD-L1-positive advanced esophageal cancer
- Emerging efficacy and safety findings from the Phase III ATTRACTION-3 trial comparing nivolumab to chemotherapy for unresectable advanced or recurrent esophageal cancer that is refractory to or intolerant of fluoropyrimidine with platinum-based therapy

Module 7: Genitourinary Cancers

- Published findings from the Phase III PROSPER, SPARTAN and ARAMIS trials evaluating enzalutamide, apalutamide and darolutamide, respectively, for patients with nonmetastatic castration-resistant prostate cancer (CRPC); FDA approvals of these agents and optimal integration into current clinical algorithms
- Key clinical and practical factors guiding the selection of docetaxel or abiraterone acetate and prednisone in combination with androgen deprivation therapy (ADT) for men with metastatic hormone-sensitive PC (mHSPC)
- Design, eligibility criteria and key efficacy outcomes from the Phase III ARCHES and TITAN studies comparing enzalutamide and apalutamide, respectively, in combination with ADT to ADT alone for patients with mHSPC
- Benefit associated with enzalutamide in combination with ADT versus other nonsteroidal antiandrogen agents (eg, bicalutamide, nilutamide, or flutamide) with ADT for patients with mHSPC in the Phase III ENZAMET trial
- Early clinical trial data with the use of olaparib and rucaparib for patients with progressive mCRPC; FDA breakthrough therapy designations and ongoing investigation
- Emerging results from the Phase III PROfound trial evaluating olaparib versus enzalutamide or abiraterone for mCRPC after failure of prior hormonal therapy in patients with homologous recombination repair gene mutations
- Research database examining the utility of androgen receptor splice variant 7 expression as a predictive marker for response to secondary hormonal therapy in patients with mCRPC; commercially available platforms and current clinical role
- Patient selection for, practical implementation of and ongoing evaluation of radium-223 dichloride
- Supporting research database underlying the FDA approvals of pembrolizumab/axitinib, axitinib/avelumab, nivolumab/ipilimumab and cabozantinib for patients with newly diagnosed metastatic renal cell carcinoma (mRCC)
- Clinical and biologic factors influencing the selection of first-line therapy for patients with newly diagnosed mRCC
- Available data with and ongoing evaluation of other anti-PD-1/PD-L1 antibody/multikinase inhibitor combinations (eg, pembrolizumab/lenvatinib, nivolumab/ipilimumab/cabozantinib) as first-line therapy for advanced RCC; FDA breakthrough therapy designation for front-line pembrolizumab/lenvatinib
- Evidence-based and guideline-endorsed approaches to the treatment of mRCC progressing on first-line therapy
- Optimal integration of anti-PD-1/PD-L1 antibodies into the management of progressive metastatic urothelial bladder cancer (UBC)
- Current indications for the use of anti-PD-1/PD-L1 antibodies in previously untreated metastatic UBC; significance of PD-L1 status and platinum eligibility
- Emerging results from the Phase III IMvigor130 trial documenting the benefit of atezolizumab with platinum-based chemotherapy versus chemotherapy alone for previously untreated locally advanced or metastatic UBC
- Rationale for and ongoing evaluation of novel regimens combining anti-PD-1/PD-L1 antibodies with anti-CTLA-4 antibodies, chemotherapy or targeted therapy
- Available data with and ongoing Phase III trials of immune checkpoint inhibitors for patients with nonmetastatic UBC
- Efficacy and safety data supporting the recent FDA approval of erdafitinib for patients with locally advanced or metastatic UBC with susceptible FGFR3 or FGFR2 genetic alterations who have experienced disease progression on or after platinum-based chemotherapy
- Preliminary data from the pivotal Phase II EV-201 trial evaluating enfortumab vedotin in patients with locally advanced or metastatic UBC who previously received immune checkpoint inhibitor therapy; FDA breakthrough therapy designation and potential clinical role