

Year in Review

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

CME Information

TARGET AUDIENCE

This educational activity has been designed to meet the educational needs of medical oncologists, hematologists, hematology-oncology fellows and other allied cancer professionals.

OVERVIEW OF ACTIVITY

Clinical controversies and uncertainties persist in the management of all common cancers, and thousands of ongoing research trials worldwide attempt to provide new answers to long-standing questions. As these trials reach maturity, clinical investigators initially present new data in abridged format at large scientific conferences and subsequently in full data sets formally published as part of peer-reviewed journals. Today, numerous annual oncology conferences release new clinical data and hundreds of peer-reviewed publications feature articles related to cancer research, treatment and practical management. The extensive list of available treatment options poses a challenge to the practicing clinician who must maintain knowledge of appropriate clinical management strategies across a vast spectrum of liquid and solid tumors.

These proceedings from a daylong symposium combine the perspectives of 16 renowned investigators with a review of key recent presentations and publications across acute leukemias, breast cancer, gastrointestinal cancers, genitourinary cancers, lung cancer, lymphomas and chronic lymphocytic leukemia and ovarian cancer to assist medical oncologists, hematologists, hematology-oncology fellows and other allied cancer professionals in the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Effectively apply the results of practice-changing clinical research to the care of patients with breast, lung, gastrointestinal, genitourinary, ovarian and select hematologic cancers.
- Appraise the clinical relevance of recent pivotal cancer research results published in peer-reviewed journals and/or presented at major oncology conferences.
- Recall ongoing trials in breast, lung, gastrointestinal, genitourinary, ovarian and select hematologic cancers, and refer appropriate patients for study participation.

- Use an understanding of tumor biomarkers and single and multigene signatures to individualize the care of patients with cancer.
- Educate patients with diverse hematologic cancers and solid tumors about the benefits and risks of new therapeutic agents and strategies.
- Refine or validate existing cancer-specific treatment algorithms based on exposure to new data sets and the perspectives of tumor-specific clinical investigators.
- Evaluate the mechanisms of action, tolerability and efficacy of promising investigational agents, and consider their potential implications for clinical practice.

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

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RESEARCH TO PRACTICE STAFF AND EXTERNAL

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A monitor set to 1280 x 1024 pixels or more

Internet Explorer 11 or later, Firefox 56 or later,

Chrome 61 or later, Safari 11 or later, Opera 48 or later

Adobe Flash Player 27 plug-in or later

Adobe Acrobat Reader

(Optional) Sound card and speakers for audio

Last review date: December 2018

Expiration date: December 2019

Select Publications

LUNG CANCER

- Antonia SJ et al; PACIFIC Investigators. **Overall survival with durvalumab after chemoradiotherapy in stage III NSCLC.** *N Engl J Med* 2018;[Epub ahead of print].
- Antonia SJ et al; PACIFIC Investigators. **Durvalumab after chemoradiotherapy in stage III non-small-cell lung cancer.** *N Engl J Med* 2017;377(20):1919-29.
- Borghaei H et al. **Nivolumab (Nivo) + platinum-doublet chemotherapy (Chemo) vs chemo as first-line (1L) treatment (Tx) for advanced non-small cell lung cancer (NSCLC) with <1% tumor PD-L1 expression: Results from CheckMate 227.** *Proc ASCO* 2018;Abstract 9001.
- Boutros C et al. **Safety profiles of anti-CTLA-4 and anti-PD-1 antibodies alone and in combination.** *Nat Rev Clin Oncol* 2016;13(8):473-86.
- Camidge DR et al. **Brigatinib versus crizotinib in ALK-positive non-small-cell lung cancer.** *N Engl J Med* 2018;[Epub ahead of print].
- Cappuzzo F et al. **IMpower130: Progression-free survival (PFS) and safety analysis from a randomised phase 3 study of carboplatin + nab-paclitaxel (CnP) with or without atezolizumab (atezo) as first-line (1L) therapy in advanced non-squamous NSCLC.** *Proc ESMO* 2018;Abstract LBA53.
- Carbone DP et al. **Efficacy and safety of rovalpituzumab tesirine in patients with DLL3-expressing, \geq 3rd line small cell lung cancer: Results from the phase 2 TRINITY study.** *Proc ASCO* 2018;Abstract 8507.
- Faivre-Finn C et al. **Efficacy and safety evaluation based on time from completion of radiotherapy to randomization with durvalumab or placebo in pts from PACIFIC.** *Proc ESMO* 2018;Abstract 13630.
- Forde PM et al. **Neoadjuvant PD-1 blockade in resectable lung cancer.** *N Engl J Med* 2018;378(21):1976-86.
- Gandhi L et al; KEYNOTE-189 Investigators. **Pembrolizumab plus chemotherapy in metastatic non-small-cell lung cancer.** *N Engl J Med* 2018;378(22):2078-92.
- Hellmann MD et al. **Nivolumab plus ipilimumab in lung cancer with a high tumor mutational burden.** *N Engl J Med* 2018;378(22):2093-104.
- Horn L et al; IMpower133 Study Group. **First-line atezolizumab plus chemotherapy in extensive-stage small-cell lung cancer.** *N Engl J Med* 2018;[Epub ahead of print].
- Jotte RM et al. **IMpower131: Primary PFS and safety analysis of a randomized phase III study of atezolizumab + carboplatin + paclitaxel or nab-paclitaxel vs carboplatin + nab-paclitaxel as 1L therapy in advanced squamous NSCLC.** *Proc ASCO* 2018;Abstract LBA9000.
- Lopes G et al. **Pembrolizumab (pembro) versus platinum-based chemotherapy (chemo) as first-line therapy for advanced/metastatic NSCLC with a PD-L1 tumor proportion score (TPS) \geq 1%: Open-label, phase 3 KEYNOTE-042 study.** *Proc ASCO* 2018;Abstract LBA4.
- Odegaard JI et al. **Validation of a plasma-based comprehensive cancer genotyping assay utilizing orthogonal tissue- and plasma-based methodologies.** *Clin Cancer Res* 2018;24(15):3539-49.
- Paz-Ares LG et al. **Pembrolizumab plus chemotherapy for squamous non-small-cell lung cancer.** *N Engl J Med* 2018;[Epub ahead of print].
- Peters S et al. **Alectinib versus crizotinib in untreated ALK-positive non-small-cell lung cancer.** *N Engl J Med* 2017;377(9):829-38.
- Ramalingam SS et al. **Mechanisms of acquired resistance to first-line osimertinib: Preliminary data from the phase III FLAURA study.** *Proc ESMO* 2018;Abstract LBA50.
- Ramalingam SS et al. **Tumor mutational burden (TMB) as a biomarker for clinical benefit from dual immune checkpoint blockade with nivolumab (nivo) + ipilimumab (ipi) in first-line (1L) non-small cell lung cancer (NSCLC): Identification of TMB cutoff from CheckMate 568.** *Proc AACR* 2018;Abstract CT078.
- Reungwetwattana T et al. **CNS response to osimertinib versus standard epidermal growth factor receptor tyrosine kinase inhibitors in patients with untreated EGFR-mutated advanced non-small-cell lung cancer.** *J Clin Oncol* 2018;[Epub ahead of print].
- Socinski MA et al; IMpower150 Study Group. **Atezolizumab for first-line treatment of metastatic nonsquamous NSCLC.** *N Engl J Med* 2018;378(24):2288-301.
- Soria JC et al; FLAURA Investigators. **Osimertinib in untreated EGFR-mutated advanced non-small-cell lung cancer.** *N Engl J Med* 2018;378(2):113-25.

Select Publications

Wu YL et al. **CNS efficacy of osimertinib in patients with T790M-positive advanced non-small-cell lung cancer: Data from a randomized phase III trial (AURA3).** *J Clin Oncol* 2018;36(26):2702-9.

Zhong W et al. **Erlotinib versus gemcitabine plus cisplatin as neoadjuvant treatment for stage IIIA-N2 EGFR-mutation non-small-cell lung cancer (EMERGING-CTONG 1103): Multicenter phase 2 randomized study.** *Proc ESMO* 2018;Abstract LBA48_PR.

ACUTE LEUKEMIAS

Borthakur G et al. **Phase II study of CPX-351 (cytarabine: daunorubicin) liposome injection in patients (pts) with newly diagnosed acute myeloid leukemia (AML) at high risk for induction mortality.** *Proc ASH* 2017;Abstract 892.

Cortes JE et al. **Glasdegib in combination with cytarabine and daunorubicin in patients with AML or high-risk MDS: Phase 2 study results.** *Am J Hematol* 2018;93(11):1301-10.

Cortes JE et al. **Phase 3, randomized, placebo-controlled trials evaluating glasdegib in combination with intensive or nonintensive chemotherapy in patients with untreated acute myeloid leukemia.** *Proc ASCO* 2018;Abstract TPS7073.

Cortes J et al. **Quizartinib, an FLT3 inhibitor, as monotherapy in patients with relapsed or refractory acute myeloid leukaemia: An open-label, multicentre, single-arm, phase 2 trial.** *Lancet Oncol* 2018;19(7):889-903.

Cortes J et al. **Quizartinib significantly prolongs overall survival in patients with FLT3-internal tandem duplication–mutated (mut) relapsed/refractory AML in the phase 3, randomized, controlled QuANTUM-R trial.** *Proc EHA* 2018;Abstract LB2600.

DiNardo CD et al. **Durable remissions with ivosidenib in IDH1-mutated relapsed or refractory AML.** *N Engl J Med* 2018;378(25):2386-98.

DiNardo CD et al. **Durable response with venetoclax in combination with decitabine or azacitidine in elderly patients with acute myeloid leukemia (AML).** *Proc ASCO* 2018;Abstract 7010.

DiNardo CD et al. **Mutant IDH (mIDH) inhibitors, ivosidenib or enasidenib, with azacitidine (AZA) in patients with acute myeloid leukemia (AML).** *Proc ASCO* 2018;Abstract 7042.

Gökbuget N et al. **Blinatumomab for minimal residual disease in adults with B-cell precursor acute lymphoblastic leukemia.** *Blood* 2018;131(14):1522-31.

Jabbour E et al. **Impact of minimal residual disease (MRD) status in clinical outcomes of patients with relapsed/refractory (R/R) acute lymphoblastic leukemia (ALL) treated with inotuzumab ozogamicin (InO) in the phase 3 INO-VATE trial.** *Proc ASCO* 2018;Abstract 7013.

Jongen-Lavrencic M et al. **Molecular minimal residual disease in acute myeloid leukemia.** *N Engl J Med* 2018;378(13):1189-99.

Kantarjian H et al. **Inotuzumab ozogamicin in combination with low-intensity chemotherapy for older patients with Philadelphia chromosome-negative acute lymphoblastic leukaemia: A single-arm, phase 2 study.** *Lancet Oncol* 2018;19(2):240-8.

Kantarjian H et al. **Blinatumomab versus chemotherapy for advanced acute lymphoblastic leukemia.** *N Engl J Med* 2017;376(9):836-47.

Lambert J et al. **Gemtuzumab ozogamicin for de novo acute myeloid leukemia: Final efficacy and safety updates from the open-label, phase 3 ALFA-0701 trial.** *Haematologica* 2018;[Epub ahead of print].

Lancet JE et al. **CPX-351 (cytarabine and daunorubicin) liposome for injection versus conventional cytarabine plus daunorubicin in older patients with newly diagnosed secondary acute myeloid leukemia.** *J Clin Oncol* 2018;36(26):2684-92.

Larson RA et al. **An analysis of maintenance therapy and post-midostaurin outcomes in the international prospective randomized, placebo-controlled, double-blind trial (CALGB 10603/RATIFY [Alliance]) for newly diagnosed acute myeloid leukemia (AML) patients with FLT3 mutations.** *Proc ASH* 2017;Abstract 145.

Maude SL et al. **Tisagenlecleucel in children and young adults with B-cell lymphoblastic leukemia.** *N Engl J Med* 2018;378(5):439-48.

Medeiros BC et al. **Big data analysis of treatment patterns and outcomes among elderly acute myeloid leukemia patients in the United States.** *Ann Hematol* 2015;94(7):1127-38.

Perl AE et al. **Selective inhibition of FLT3 by gilteritinib in relapsed or refractory acute myeloid leukaemia: A multicentre, first-in-human, open-label, phase 1-2 study.** *Lancet Oncol* 2017;18(8):1061-75.

Platzbecker U et al. **Minimal-residual disease guided treatment with azacitidine in MDS/AML patients at imminent risk of relapse: Results of the prospective RELAZA2 trial.** *Proc ASH* 2017;Abstract 565.

Select Publications

Pratz K et al. **Preliminary results from a phase 1 study of gilteritinib in combination with induction and consolidation chemotherapy in subjects with newly diagnosed acute myeloid leukemia (AML).** *Proc ASH 2017*;Abstract 722.

Stein EM et al. **Enasidenib in mutant *IDH2* relapsed or refractory acute myeloid leukemia.** *Blood 2017*;130(6):722-31.

Stein EM et al. **Ivosidenib or enasidenib combined with standard induction chemotherapy is well tolerated and active in patients with newly diagnosed AML with an *IDH1* or *IDH2* mutation: Initial results from a phase 1 trial.** *Proc ASH 2017*;Abstract 726.

Stone RM et al. **The addition of midostaurin to standard chemotherapy decreases cumulative incidence of relapse (CIR) in the international prospective randomized, placebo-controlled, double-blind trial (CALGB 10603 / RATIFY [Alliance]) for newly diagnosed acute myeloid leukemia (AML) patients with *FLT3* mutations.** *Proc ASH 2017*;Abstract 2580.

Wei A et al. **Phase 1/2 study of venetoclax with low-dose cytarabine in treatment-naïve, elderly patients with acute myeloid leukemia unfit for intensive chemotherapy: 1-year outcomes.** *Proc ASH 2017*;Abstract 890.

GASTROINTESTINAL CANCERS

A phase III, randomised, double blind, placebo controlled, multicentre study of maintenance olaparib monotherapy in patients with gBRCA mutated metastatic pancreatic cancer whose disease has not progressed on first line platinum based chemotherapy. NCT02184195

Abou-Alfa GK et al. **Cabozantinib in patients with advanced and progressing hepatocellular carcinoma.** *N Engl J Med 2018*;379(1):54-63.

Bekaii-Saab TS et al. **Phase 1b/2 trial of cancer stemness inhibitor napabucasin (NAPA) + nab-paclitaxel (nPTX) and gemcitabine (Gem) in metastatic pancreatic adenocarcinoma (mPDAC).** *Proc ASCO 2018*;Abstract 4110.

Bekaii-Saab TS et al. **Regorafenib dose optimization study (ReDOS): Randomized phase II trial to evaluate escalating dosing strategy and pre-emptive topical steroids for regorafenib in refractory metastatic colorectal cancer (mCRC) — An ACCRU Network study.** *Proc ESMO World Congress on Gastrointestinal Cancer 2018*;Abstract O-014.

Bekaii-Saab TS et al. **Regorafenib dose optimization study (ReDOS): Randomized phase II trial to evaluate dosing strategies for regorafenib in refractory metastatic colorectal cancer (mCRC) — An ACCRU Network study.** Gastrointestinal Cancers Symposium 2018;Abstract 611.

Conroy T et al. **Unicancer GI PRODIGE 24/CCTG PA.6 trial: A multicenter international randomized phase III trial of adjuvant mFOLFIRINOX versus gemcitabine (gem) in patients with resected pancreatic ductal adenocarcinomas.** *Proc ASCO 2018*;Abstract LBA4001.

Finn RS et al. **Outcomes of sequential treatment with sorafenib followed by regorafenib for HCC: Additional analyses from the phase III RESORCE trial.** *J Hepatol 2018*;69(2):353-8.

Fuchs CS et al. **RAINFALL: A randomized, double-blind, placebo-controlled phase III study of cisplatin (Cis) plus capecitabine (Cape) or 5FU with or without ramucirumab (RAM) as first-line therapy in patients with metastatic gastric or gastroesophageal junction (G-GEJ) adenocarcinoma.** Gastrointestinal Cancers Symposium 2018;Abstract 5.

Fuchs CS et al. **Safety and efficacy of pembrolizumab monotherapy in patients with previously treated advanced gastric and gastroesophageal junction cancer: Phase 2 clinical KEYNOTE-059 trial.** *JAMA Oncol 2018*;4(5):e180013.

Golan T et al. **Phase II study of olaparib for BRCAness phenotype in pancreatic cancer.** Gastrointestinal Cancers Symposium 2018;Abstract 297.

Hainsworth JD et al. **Targeted therapy for advanced solid tumors on the basis of molecular profiles: Results from MyPathway, an open-label, phase IIa multiple basket study.** *J Clin Oncol 2018*;36(6):536-42.

Hammel P et al. **Phase II LAPACT trial of nab-paclitaxel (nab-P) plus gemcitabine (G) for patients with locally advanced pancreatic cancer (LAPC).** Gastrointestinal Cancers Symposium 2018;Abstract 204.

Kang YK et al. **Nivolumab in patients with advanced gastric or gastro-oesophageal junction cancer refractory to, or intolerant of, at least two previous chemotherapy regimens (ONO-4538-12, ATTRACTION-2): A randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet 2017*;390(10111):2461-71.

Kudo M et al. **Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: A randomised phase 3 non-inferiority trial.** *Lancet 2018*;391(10126):1163-73.

Overman MJ et al. **Durable clinical benefit with nivolumab plus ipilimumab in DNA mismatch repair-deficient/microsatellite instability-high metastatic colorectal cancer.** *J Clin Oncol 2018*;36(8):773-9.

Select Publications

Sartore-Bianchi A et al. **Dual-targeted therapy with trastuzumab and lapatinib in treatment-refractory, KRAS codon 12/13 wild-type, HER2-positive metastatic colorectal cancer (HERACLES): A proof-of-concept, multicentre, open-label, phase 2 trial.** *Lancet Oncol* 2016;17(6):738-46.

Shitara K et al; KEYNOTE-061 Investigators. **Pembrolizumab versus paclitaxel for previously treated, advanced gastric or gastro-oesophageal junction cancer (KEYNOTE-061): A randomised, open-label, controlled, phase 3 trial.** *Lancet* 2018;392(10142):123-33.

Shitara K et al. **REVERCE: Randomized phase II study of regorafenib followed by cetuximab versus the reverse sequence for metastatic colorectal cancer patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan.** Gastrointestinal Cancers Symposium 2018;Abstract 557.

Shitara K et al. **Trifluridine/tipiracil versus placebo in patients with heavily pretreated metastatic gastric cancer (TAGS): A randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet Oncol* 2018;[Epub ahead of print].

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