

# Year in Review

## Proceedings from a Multitumor CME 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 clinical 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 lung cancer, gastrointestinal cancers, melanoma, genitourinary cancers, multiple myeloma, breast cancer and Hodgkin and non-Hodgkin lymphoma 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, dermatologic 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, dermatologic 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.
- Recognize immune-related adverse events and other common side effects associated with approved and developmental immunotherapeutics in order to offer supportive management strategies.
- Evaluate the mechanisms of action, tolerability and efficacy of promising investigational agents, and consider their potential implications for clinical practice.

#### ACCREDITATION STATEMENT

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

Successful completion of this CME activity enables the participant to earn up to 7 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

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

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This CME activity consists of a video component. To receive credit, the participant should watch the video, complete the Post-test with a score of 80% or better and fill out the Educational Assessment and Credit Form located at [ResearchToPractice.com/YiRMultitumor16/CME](https://ResearchToPractice.com/YiRMultitumor16/CME).

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#### **Hardware/Software Requirements:**

A high-speed Internet connection

A monitor set to 1280 x 1024 pixels or more

Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later

Adobe Flash Player 10.2 plug-in or later

Adobe Acrobat Reader

(Optional) Sound card and speakers for audio

**Last review date:** February 2017

**Expiration date:** February 2018

## Select Publications

### Non-Small Cell Lung Cancer

#### Naiyer Rizvi, MD

Antonia S. **Safety and antitumour activity of durvalumab plus tremelimumab in non-small cell lung cancer: A multicentre, phase 1b study.** *Lancet Oncol* 2016;17(3):299-308.

Barlesi F et al. **Primary analysis from OAK, a randomized phase III study comparing atezolizumab with docetaxel in 2L/3L NSCLC.** *Proc ESMO* 2016;Abstract LBA44\_PR.

Hellmann MD et al. **CheckMate 012: Safety and efficacy of first-line (1L) nivolumab (nivo; N) and ipilimumab (ipi; I) in advanced (adv) NSCLC.** *Proc ASCO* 2016;Abstract 3001.

Kelly K et al. **Adjuvant erlotinib versus placebo in patients with stage IB-IIIA non-small-cell lung cancer (RADIANT): A randomized, double-blind, phase III trial.** *J Clin Oncol* 2015;33(34):4007-14.

Langer C et al. **Carboplatin and pemetrexed with or without pembrolizumab for advanced, non-squamous non-small-cell lung cancer: A randomised, phase 2 cohort of the open-label KEYNOTE-021 study.** *Lancet Oncol* 2016;17(11):1497-508.

Langer C et al. **Randomized, phase 2 study of carboplatin and pemetrexed with or without pembrolizumab as first-line therapy for advanced NSCLC: KEYNOTE-021 cohort G.** *Proc ESMO* 2016;Abstract LBA46\_PR.

Reck M et al. **KEYNOTE-024: Pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) as first-line therapy for advanced NSCLC with a PD-L1 tumor proportion score (TPS)  $\geq$ 50%.** *Proc ESMO* 2016;Abstract LBA8\_PR.

Reck M et al. **Pembrolizumab versus chemotherapy for PD-L1–positive non–small-cell lung cancer.** *N Engl J Med* 2016;375:1823-33.

Socinski M et al. **CheckMate 026: A phase 3 trial of nivolumab vs investigator's choice (IC) of platinum-based doublet chemotherapy (PT-DC) as first-line therapy for stage iv/ recurrent programmed death ligand 1 (PD-L1)–positive NSCLC.** *Proc ESMO* 2016;Abstract LBA7\_PR.

#### Geoffrey R Oxnard, MD

Ahn MJ et al. **Phase I study of AZD3759, a CNS penetrable EGFR inhibitor, for the treatment of non-small-cell lung cancer (NSCLC) with brain metastasis (BM) and leptomeningeal metastasis (LM).** *Proc ASCO* 2016;Abstract 9003.

Kim D et al. **Brigatinib in patients with crizotinib-refractory ALK+ non-small cell lung cancer: First report of efficacy and safety from a pivotal randomized phase 2 trial (ALTA).** *Proc ASCO* 2016;Abstract 9007.

Nokihara H et al. **Alectinib versus crizotinib in ALK-inhibitor naive ALK-positive non-small cell lung cancer: Primary results from the J-ALEX study.** *Proc ASCO* 2016;Abstract 9008.

Oxnard G et al. **Plasma genotyping for predicting benefit from osimertinib in patients (pts) with advanced NSCLC.** *Proc ESMO* 2016;Abstract 1350\_PR.

Oxnard GT et al. **Association between plasma genotyping and outcomes of treatment with osimertinib (AZD9291) in advanced non-small-cell lung cancer.** *J Clin Oncol* 2016;34(28):3375-82.

Park K et al. **Afatinib versus gefitinib as first-line treatment of patients with EGFR mutation-positive non-small-cell lung cancer (LUX-Lung 7): A phase 2B, open-label, randomised controlled trial.** *Lancet Oncol* 2016;17(5):577-89.

Paz-Ares L et al. **Afatinib (A) vs gefitinib (G) in patients (pts) with EGFR mutation-positive (EGFRm+) non-small-cell lung cancer (NSCLC): Overall survival (OS) data from the phase IIb trial LUX-Lung 7 (LL7).** *Proc ESMO* 2016;Abstract LBA43.

Wakelee HA et al. **Epidermal growth factor receptor (EGFR) genotyping of matched urine, plasma and tumor tissue from non-small cell lung cancer (NSCLC) patients (pts) treated with rociletinib.** *Proc ASCO* 2016;Abstract 9001.

Yang JC et al. **Osimertinib activity in patients with leptomeningeal (LM) disease from non-small cell lung cancer (NSCLC): Updated results from BLOOM, a phase I study.** *Proc ASCO* 2016;Abstract 9002.

Yu HA et al. **Antitumor activity of ASP8273 300 mg in subjects with EGFR mutation-positive non-small cell lung cancer: Interim results from an ongoing phase 1 study.** *Proc ASCO* 2016;Abstract 9050.

#### Melissa Johnson, MD

Drilon AE et al. **Efficacy and safety of crizotinib in patients with advanced MET exon 14-altered non-small cell lung cancer (NSCLC).** *Proc ASCO* 2016;Abstract 108.

## Select Publications

Drilon AE et al. **Phase II study of cabozantinib for patients with advanced *RET*-rearranged lung cancers.** *Proc ASCO* 2015;Abstract 8007.

Govindan R et al. **ALCHEMIST trials: A golden opportunity to transform outcomes in early-stage non-small cell lung cancer.** *Clin Cancer Res* 2015;21(24):5439-44.

Gridelli C et al. ***Nab*-paclitaxel + carboplatin (*nab*-P/C) in advanced non-small cell lung cancer (NSCLC): Outcomes in elderly patients (pts) with squamous (SCC) histology.** *Proc ELCC* 2016;Abstract 216PD.

**Lung-MAP: A biomarker-driven master protocol for previously treated squamous cell lung cancer.** NCT02154490

Papadimitrakopoulou V et al. **Lung-MAP (S1400) lung cancer master protocol: Accrual, demographics, and molecular markers.** *Proc ASCO* 2016;Abstract 9088.

Planchard D et al. **Dabrafenib plus trametinib in patients with previously treated BRAF(V600E)-mutant metastatic non-small cell lung cancer: An open-label, multicentre phase 2 trial.** *Lancet Oncol* 2016;17(7):98493.

Rudin CM et al. **Safety and efficacy of single-agent rovalpituzumab tesirine (SC16LD6.5), a delta-like protein 3 (DLL3)-targeted antibody-drug conjugate (ADC) in recurrent or refractory small cell lung cancer (SCLC).** *Proc ASCO* 2016;Abstract LBA8505.

Schrock AB et al. **Comprehensive genomic profiling identifies frequent drug-sensitive EGFR exon 19 deletions in NSCLC not identified by prior molecular testing.** *Clin Cancer Res* 2016;22(13):3281-5.

### Breast Cancer

#### George W Sledge Jr, MD

Adams S et al. **Phase Ib trial of atezolizumab in combination with *nab*-paclitaxel in patients with metastatic triple-negative breast cancer (mTNBC).** *Proc ASCO* 2016;Abstract 1009.

Chan A et al. **Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): A multicentre, randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet Oncol* 2016;17(3):367-77.

Gianni L et al. **ETNA (Evaluating Treatment with Neoadjuvant Abraxane) randomized phase III study comparing neoadjuvant *nab*-paclitaxel (*nab*-P) versus paclitaxel (P) both followed by anthracycline regimens in women with HER2-negative high-risk breast cancer: A MICHELANGO study.** *Proc ASCO* 2016;Abstract 502.

Emens LA et al. **IMpassion130: A Phase III randomized trial of atezolizumab with *nab*-paclitaxel for first-line treatment of patients with metastatic triple-negative breast cancer (mTNBC).** *Proc ASCO* 2016;Abstract TPS1104.

**IMpassion130: A phase III, multicenter, randomized placebo-controlled study of atezolizumab (anti-PD-L1 antibody) in combination with *nab*-paclitaxel compared with placebo with *nab*-paclitaxel for patients with previously untreated metastatic triple negative breast cancer.** NCT02425891

Nanda R et al. **Pembrolizumab in patients with advanced triple-negative breast cancer: Phase Ib KEYNOTE-012 study.** *J Clin Oncol* 2016;34(21):2460-67.

**OlympiAD: A phase III, open label, randomized, controlled, multi-centre study to assess the efficacy and safety of olaparib monotherapy versus physicians choice chemotherapy in the treatment of metastatic breast cancer patients with germline BRCA1/2 mutations.** NCT02000622

Rugo HS et al. **Adaptive randomization of veliparib-carboplatin treatment in breast cancer.** *N Engl J Med* 2016;375(1):23-34.

Toi M et al. **A phase III trial of adjuvant capecitabine in breast cancer patients with HER2-negative pathologic residual invasive disease after neoadjuvant chemotherapy (CREATE-X, JBCRG-04).** San Antonio Breast Cancer Symposium 2015;Abstract S1-07.

Untch M et al. ***Nab*-paclitaxel versus solvent-based paclitaxel in neoadjuvant chemotherapy for early breast cancer (Gepar-Septo-GBG 69): A randomised, phase 3 trial.** *Lancet Oncol* 2016;17(3):345-56.

Urruticoechea A et al. **PHEREXA: A phase III study of trastuzumab (H) + capecitabine (X) ± pertuzumab (P) for patients (pts) who progressed during/after one line of H-based therapy in the HER2-positive metastatic breast cancer (MBC) setting.** *Proc ASCO* 2016;Abstract 504.

Yamamoto Y et al. **PRECIOUS: A randomized, open-label phase III trial of pertuzumab retreatment in HER2-positive locally advanced/metastatic breast cancer patients who were previously treated with pertuzumab, trastuzumab, and chemotherapy.** *Proc ASCO* 2016;Abstract TPS636.

## Select Publications

### William J Gradishar, MD

Cardoso F et al. **70-gene signature as an aid to treatment decisions in early-stage breast cancer.** *N Engl J Med* 2016;375(8):717-29.

Dickler MN et al. **MONARCH1: Results from a Phase 2 study of abemaciclib, a CDK4 and CDK6 inhibitor, as monotherapy, in patients with HR+/HER2- breast cancer, after chemotherapy for metastatic disease.** *Proc ASCO* 2016;Abstract 510.

Fasching PA et al. **Phase III study of ribociclib (LEE011) plus fulvestrant for the treatment of postmenopausal patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer (aBC) who have received no or only one line of prior endocrine treatment (ET): MONALEESA-3.** *Proc ASCO* 2016;Abstract TPS624.

Finn RS et al. **PALOMA-2: Primary results from a Phase 3 trial of palbociclib plus letrozole compared with placebo plus letrozole in postmenopausal women with ER+/HER2- advanced breast cancer.** *Proc ASCO* 2016;Abstract 507.

Goss PE et al. **A randomized trial (MA.17R) of extending adjuvant letrozole for 5 years after completing an initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen in postmenopausal women with early-stage breast cancer.** *Proc ASCO* 2016;Abstract LBA1.

Goss PE et al. **Extending aromatase-inhibitor adjuvant therapy to 10 years.** *N Engl J Med* 2016;375(3):209-19.

Hortobagyi GN et al. **First-line ribociclib + letrozole for postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2-), advanced breast cancer.** *Proc ESMO* 2016;Abstract LBA1\_PR.

Hortobagyi GN et al. **Ribociclib as first-line therapy for HR-positive, advanced breast cancer.** *N Engl J Med* 2016;375(18):1738-48.

Hurvitz S et al. **Interim results from neoMONARCH: A neoadjuvant Phase II study of abemaciclib in postmenopausal women with HR+/HER2- breast cancer (BC).** *Proc ESMO* 2016;Abstract LBA13.

**MONALEESA-3: A randomized double-blind, placebo-controlled study of ribociclib in combination with fulvestrant for the treatment of men and postmenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer who have received no or only one line of prior endocrine treatment.** NCT02422615

**neoMONARCH: A phase 2 neoadjuvant trial comparing the biological effects of 2 weeks of abemaciclib (LY2835219) in combination with anastrozole to those of abemaciclib monotherapy and anastrozole monotherapy and evaluating the clinical activity and safety of a subsequent 14 weeks of therapy with abemaciclib in combination with anastrozole in postmenopausal women with hormone receptor positive, HER2 negative breast cancer.** NCT02441946

Pan H et al. **Predictors of recurrence during years 5-14 in 46,138 women with ER+ breast cancer allocated 5 years only of endocrine therapy (ET).** *Proc ASCO* 2016;Abstract 505.

Roberts MC et al. **Breast cancer-specific survival in patients with node-positive hormone receptor positive invasive breast cancer and Oncotype DX recurrence score results in the SEER database.** *Proc ASCO* 2016;Abstract 6575.

Zhang Y et al. **Validation of a prognostic model integrating Breast Cancer Index (BCI) with tumor size and grade for prediction of distant recurrence in hormone receptor-positive (HR+) breast cancer with 1-3 positive nodes.** *Proc ASCO* 2016;Abstract 541.

### Multiple Melanoma

#### Jason J Luke, MD

Algazi A et al. **Clinical outcomes in metastatic uveal melanoma treated with PD-1 and PD-L1 antibodies.** *Cancer* 2016;122(21):3344-53.

Goldberg S et al. **Pembrolizumab for patients with melanoma or non-small-cell lung cancer and untreated brain metastases: Early analysis of a non-randomised, open-label, phase 2 trial.** *Lancet Oncol* 2016;17:976-83.

Puzanov I et al. **Talimogene laherparepvec in combination with ipilimumab in previously untreated, unresectable Stage IIIB-IV melanoma.** *J Clin Oncol* 2016;34:2619-26.

Robert C et al. **Three-year overall survival for patients with advanced melanoma treated with pembrolizumab in KEYNOTE-001.** *Proc ASCO* 2016;34:Abstract 9503.

Schachter J et al. **Pembrolizumab versus ipilimumab for advanced melanoma: Final overall survival analysis of KEYNOTE-006.** *Proc ASCO* 2016;Abstract 9504.

## Select Publications

### Jeffrey Weber, MD, PhD

Dummer R et al. **Results of NEMO: A phase III trial of binimetinib (BINI) vs dacarbazine (DTIC) in *NRAS*-mutant cutaneous melanoma.** *Proc ASCO* 2016;Abstract 9500.

Eggermont AMM et al. **Ipilimumab (IPI) vs placebo (PBO) after complete resection of stage III melanoma: Final overall survival results from the EORTC 18071 randomized, double-blind, phase 3 trial.** *Proc ESMO* 2016;Abstract LBA2\_PR.

Eggermont AMM et al. **Prolonged survival in Stage III melanoma with ipilimumab adjuvant therapy.** *N Engl J Med* 2016;[Epub ahead of print].

Hodi FS et al. **Combined nivolumab and ipilimumab versus ipilimumab alone in patients with advanced melanoma: 2-year overall survival outcomes in a multicentre, randomised, controlled, phase 2 trial.** *Lancet Oncol* 2016;17(11):1558-68.

Weber JS et al. **Sequential administration of nivolumab and ipilimumab with a planned switch in patients with advanced melanoma (CheckMate 064): An open-label, randomised, phase 2 trial.** *Lancet Oncol* 2016;17(7):943-55.

### Genitourinary Cancers

#### David I Quinn, MBBS, PhD

James ND et al. **Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE): Survival results from an adaptive, multiarm, multistage, platform randomised controlled trial.** *Lancet* 2016;387(10024):1163-77.

Penson DF et al. **Enzalutamide versus bicalutamide in castration-resistant prostate cancer: The STRIVE trial.** *J Clin Oncol* 2016;34(18):2098-106.

Saad F et al. **Radium-223 and concomitant therapies in patients with metastatic castration-resistant prostate cancer: An international, early access, open-label, single-arm phase 3b trial.** *Lancet Oncol* 2016;17(9):1306-16.

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