Year in Review

Proceedings from a Multitumor CME Symposium Focused on Key Clinical Presentations and Papers in Oncology

Select Publications

Multiple Myeloma (Sagar Lonial, MD)

Attal M et al; IFM Investigators. **Lenalidomide maintenance after stem-cell transplantation for multiple myeloma.** *N Engl J Med* 2012;366(19):1782-91.

Jakubowiak AJ et al. **Stringent complete response (sCR) in patients (pts) with newly diagnosed multiple myeloma (NDMM) treated with carfilzomib (CFZ), lenalidomide (LEN), and dexamethasone (DEX).** *Proc ASCO* 2012;**Abstract 8011**.

McCarthy PL et al. **Lenalidomide after stem-cell transplantation for multiple myeloma.** *N Engl J Med* 2012;366(19):1770-81.

Moreau P et al. **A randomized phase II study of elotuzumab with lenalidomide and low-dose dexamethasone in patients with relapsed/refractory multiple myeloma.** *Proc ASCO* 2012;**Abstract 8020**.

Moreau P et al. **Subcutaneous versus intravenous administration of bortezomib in patients with relapsed multiple myeloma: A randomised, phase 3, non-inferiority study.** *Lancet Oncol* 2011;12(5):431-40.

Richardson PG et al. **Oral weekly MLN9708, an investigational proteasome inhibitor, in combination with lenalidomide and dexamethasone in patients (pts) with previously untreated multiple myeloma (MM): A phase I/II study.** *Proc ASCO* 2012;**Abstract 8033**.

Vij R et al. **Pomalidomide (POM) with or without low-dose dexamethasone (LoDEX) in patients (pts) with relapsed/refractory multiple myeloma (RRMM): Outcomes in pts refractory to lenalidomide (LEN) and/or bortezomib (BORT).** *Proc ASCO* 2012;**Abstract 8016**.

Dermatologic Oncology (Karl Lewis, MD)

Chapman PB et al. **Updated overall survival (OS) results for BRIM-3, a phase III randomized, open-label, multicenter trial comparing BRAF inhibitor vemurafenib (vem) with dacarbazine (DTIC) in previously untreated patients with BRAF^{V600E}-mutated melanoma.** *Proc ASCO* 2012;**Abstract 8502**.

Flaherty KT et al. **Combined BRAF and MEK inhibition in melanoma with BRAF V600 mutations.** *N Engl J Med* 2012;367(18):1694-703.

Flaherty KT et al. **Improved survival with MEK inhibition in BRAF-mutated melanoma.** *N Engl J Med* 2012;367(2):107-114.

Hodi FS et al. **Clinical activity and safety of anti-PD-1 (BMS-936558, MDX-1106) in patients with advanced melanoma (MEL).** *Proc ASCO* 2012;**Abstract 8507**.

Kirkwood JM et al. **BREAK-MB: A phase II study assessing overall intracranial response rate (OIRR) to dabrafenib (GSK2118436) in patients (pts) with BRAF V600E/k mutation-positive melanoma with brain metastases (mets).** *Proc ASCO* 2012;**Abstract 8501**.

Long GV et al. **Phase II three-arm randomised study of the BRAF inhibitor (BRAFi) dabrafenib alone vs combination with MEK1/2 inhibitor (MEKi) trametinib in pts with BRAF V600 mutation-positive metastatic melanoma (MM).** *ESMO* 2012;**Abstract LBA27_PR**.

Topalian SL et al. **Safety, activity, and immune correlates of anti-PD-1 antibody in cancer.** *N Engl J Med* 2012;366(26):2443-54.

Renal Cell Carcinoma and Prostate Cancer (David I Quinn, MBBS, PhD)

A Phase III study of radium-223 dichloride in patients with symptomatic hormone refractory cancer with skeletal metastases (ALSYMPCA). NCT00699751

CALGB-90802: Randomized phase III trial comparing everolimus plus placebo versus everolimus plus bevacizumab for advanced renal cell carcinoma progressing after treatment with tyrosine kinase inhibitors. NCT01198158

Motzer RJ et al. **Randomized, open label, phase III trial of pazopanib versus sunitinib in first-line treatment of patients with metastatic renal cell carcinoma (mRCC): Results of the COMPARZ trial.** *Proc ESMO* 2012;**Abstract LBA8_PR**.

Oudard S et al. **First-line use of cabazitaxel in chemotherapy-naive patients with metastatic castration-resistant prostate cancer (mCRPC): A three-arm study in comparison with docetaxel.** *Proc ASCO* 2012;**Abstract TPS4696**.

Parker C et al. **Updated analysis of the phase III, double-blind, randomized, multinational study of radium-223 chloride in castration-resistant prostate cancer (CRPC) patients with bone metastases (ALSYMPCA).** *Proc ASCO* 2012;**Abstract LBA4512**.

Parker C et al. **Updated survival, quality of life (QOL), and safety data of radium-223 chloride (ra-223) in patients with castration-resistant prostate cancer (CRPC) with bone metastases from the phase 3 double-blind, randomized, multinational study (ALSYMPCA).** *Proc ESMO* 2012;**Abstract 898P**.

Ryan CJ et al. **Interim analysis (IA) results of COU-AA-302, a randomized, phase III study of abiraterone acetate (AA) in chemotherapy-naive patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).** *Proc ASCO* 2012;**Abstract LBA4518**.

Scher HI et al. **Increased survival with enzalutamide in prostate cancer after chemotherapy.** *N Engl J Med* 2012;367(13):1187-97.

Chronic Myeloid Leukemia (Hagop M Kantarjian, MD)

Baccarani M et al. **Chronic myeloid leukemia: An update of concepts and management recommendations of European LeukemiaNet.** *J Clin Oncol* 2009;27(35):6041-51.

Cortes JE et al. **PACE: A pivotal phase II trial of ponatinib in patients with CML and Ph+ ALL resistant or intolerant to dasatinib or nilotinib, or with the T315I mutation.** *Proc ASCO* 2012;**Abstract 6503**.

Cortes JE et al. **Safety and efficacy of bosutinib (SKI-606) in chronic phase Philadelphia chromosome-positive chronic myeloid leukemia patients with resistance or intolerance to imatinib.** *Blood* 2011;118(17):4567-76.

Harrison C et al. **JAK inhibition with ruxolitinib versus best available therapy for myelofibrosis.** *N Engl J Med* 2012;366(9):787-98.

Hochhaus A et al. **Dasatinib versus imatinib (IM) in newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP): DASISION 3-year follow-up.** *Proc ASCO* 2012;**Abstract 6504**.

Jabbour E et al. **Inotuzumab ozogamycin (I0), a CD22 monoclonal antibody conjugated to calecheamicin, given weekly, for refractory-relapse acute lymphocytic leukemia (R-R ALL).** *Proc ASCO* 2012;**Abstract 6501**.

Kantarjian H et al. **Nilotinib versus imatinib in patients (pts) with newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP): ENESTnd 3-year (yr) follow-up (f/u).** *Proc ASCO* 2012;**Abstract 6509**.

Kantarjian H et al. **Monitoring the response and course of chronic myeloid leukemia in the modern era of BCR-ABL tyrosine kinase inhibitors: Practical advice on the use and interpretation of monitoring methods.** *Blood* 2008;111(4):1774-80.

Lipton JH et al. **Switch to nilotinib versus continued imatinib in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) with detectable BCR-ABL after 2 or more years on imatinib: ENESTcmr 12-month (mo) follow-up.** *Proc ASCO* 2012;**Abstract 6505**.

Saglio G et al. **Nilotinib versus imatinib in patients (pts) with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase (CML-CP): ENESTnd 36-month (mo) follow-up.** *Proc ASH* 2011;**Abstract 452**.

Saglio G et al. **Nilotinib versus imatinib for newly diagnosed chronic myeloid leukemia.** *N Engl J Med* 2010;362(24):2251-9.

Soverini S et al. **BCR-ABL kinase domain mutation analysis in chronic myeloid leukemia patients treated with tyrosine kinase inhibitors: Recommendations from an expert panel on behalf of European LeukemiaNet.** *Blood* 2011;118(5):1208-15.

Topp M et al. **Effect of anti-CD19 BiTE blinatumomab on complete remission rate and overall survival in adult patients with relapsed/refractory B-precursor ALL.** *Proc ASCO* 2012;**Abstract 6500**.

Verstovsek S et al. **A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis.** *N Engl J Med* 2012;366(9):799-807.

Colorectal Cancer (Daniel G Haller, MD)

Arnold D et al. **Bevacizumab (BEV) plus chemotherapy (CT) continued beyond first progression in patients with metastatic colorectal cancer (mCRC) previously treated with BEV plus CT: Results of a randomized phase III intergroup study (TML study).** *Proc ASCO* 2012;**Abstract CRA3503**.

Grothey A et al. **Bevacizumab beyond first progression is associated with prolonged overall survival in metastatic colorectal cancer: Results from a large observational cohort study (BRiTE).** *J Clin Oncol* 2008;26(33):5326-34.

Van Cutsem E et al. **Phase III CORRECT trial of regorafenib in metastatic colorectal cancer (mCRC).** *Proc ASCO* 2012;**Abstract 3502**.

Van Cutsem E et al. **Intravenous (IV) aflibercept versus placebo in combination with irinotecan/5-FU (FOLFIRI) for second-line treatment of metastatic colorectal cancer (mCRC): Results of a multinational phase III trial (EFC10262-VELOUR).** *ESMO* 2011;**Abstract O-0024**.

Noncolorectal GI Cancers (Bert H O'Neil, MD)

Blanke CD et al. **Optimal duration of adjuvant therapy for patients with resected gastrointestinal stromal tumors.** *JAMA* 2012;307(12):1312-4.

CALGB-80701: Randomized Phase II study of everolimus alone versus everolimus plus bevacizumab in patients with locally advanced or metastatic pancreatic neuroendocrine tumors. NCT01229943

Demetri GD et al. **Randomized phase III trial of regorafenib in patients (pts) with metastatic and/or unresectable gastrointestinal stromal tumor (GIST) progressing despite prior treatment with at least imatinib (IM) and sunitinib (SU): GRID trial.** *Proc ASCO* 2012;**Abstract LBA10008**.

ECOG-E1208: A Phase III randomized, double-blind trial of chemoembolization with or without sorafenib in unresectable hepatocellular carcinoma (HCC) in patients with and without vascular invasion. NCT01004978

El-Khoueiry AB et al. **Second interim analysis of the Global Investigation of Therapeutic Decisions in Unresectable HCC and of Its Treatment with Sorafenib (GIDEON): Sorafenib dosing and safety in US patients.** Gastrointestinal Cancers Symposium 2012;**Abstract 302**.

George S et al. **Efficacy and safety of regorafenib in patients with metastatic and/or unresectable GI stromal tumor after failure of imatinib and sunitinib: A multicenter phase II trial.** *J Clin Oncol* 2012;30(19):2401-7.

Joensuu H et al. **One vs three years of adjuvant imatinib for operable gastrointestinal stromal tumor: A randomized trial.** *JAMA* 2012;307(12):1265-72.

Joensuu H et al. **Twelve versus 36 months of adjuvant imatinib (IM) as treatment of operable GIST with a high risk of recurrence: Final results of a randomized trial (SSGXVIII/AIO).** *Proc ASCO* 2011;**Abstract LBA1**.

Marrero JA et al. **Global Investigation of Therapeutic Decisions in Hepatocellular Carcinoma and of its Treatment with Sorafenib (GIDEON) second interim analysis in more than 1,500 patients: Clinical findings in patients with liver dysfunction.** *Proc ASCO* 2011;**Abstract 4001**.

Wilke H et al. **A randomized, multicenter, double-blind, placebo (PBO)-controlled phase III study of paclitaxel (PTX) with or without ramucirumab (IMC-1121B; RAM) in patients (pts) with metastatic gastric adenocarcinoma, refractory to or progressive after first-line therapy with platinum (PLT) and fluoropyrimidine (FP).** *Proc ASCO* 2012;**Abstract TPS4139**.

Yao JC et al. **Multivariate analysis including biomarkers in the phase III RADIANT-2 study of octreotide LAR plus everolimus (E+O) or placebo (P+O) among patients with advanced neuroendocrine tumors (NET).** *Proc ASCO* 2012;**Abstract 4014**.

Zhu AX et al. **A multicenter, randomized, double-blind, phase III study of ramucirumab (IMC-1121B; RAM) and best supportive care (BSC) versus placebo (PBO) and BSC as second-line treatment in patients (pts) with hepatocellular carcinoma (HCC) following first-line therapy with sorafenib (SOR).** *Proc ASCO* 2012;**Abstract TPS4146**.

Breast Cancer (Kathy D Miller, MD)

Baselga J et al. **Everolimus in postmenopausal hormone-receptor-positive advanced breast cancer.** *N Engl J Med* 2012;366(6):520-9.

Baselga J et al. **Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer.** *N Engl J Med* 2012;366(2):109-19.

Blackwell KL et al. **Primary results from EMILIA, a phase III study of trastuzumab emtansine (T-DM1) versus capecitabine (X) and lapatinib (L) in HER2-positive locally advanced or metastatic breast cancer (MBC) previously treated with trastuzumab (T) and a taxane.** *Proc ASCO* 2012;**Abstract LBA1**.

Cortes J et al. **Pertuzumab monotherapy after trastuzumab-based treatment and subsequent reintroduction of trastuzumab: Activity and tolerability in patients with advanced human epidermal growth factor receptor 2-positive breast cancer.** *J Clin Oncol* 2012;30(14):1594-600.

Hurvitz SA et al. **Trastuzumab emtansine (T-DM1) versus trastuzumab plus docetaxel in previously untreated HER2-positive metastatic breast cancer.** *ESMO* 2011;**Abstract 5001**.

Mamounas EP et al. **Prognostic impact of the 21-gene recurrence score (RS) on disease-free and overall survival of node-positive, ER-positive breast cancer patients (pts) treated with adjuvant chemotherapy: Results from NSABP B-28.** Breast Cancer Symposium 2012;**Abstract 1**.

Mehta RS et al. **Combination anastrozole and fulvestrant in metastatic breast cancer.** *N Engl J Med* 2012;367(5):435-44.

Rugo HS et al. **CALGB 40502/NCCTG N063H: Randomized phase III trial of weekly paclitaxel (P) compared to weekly nanoparticle albumin bound *nab*-paclitaxel (NP) or ixabepilone (Ix) with or without bevacizumab (B) as first-line therapy for locally recurrent or metastatic breast cancer (MBC).** *Proc ASCO* 2012;**Abstract CRA1002**.

Seah DS et al. **Use and duration of chemotherapy (CT) in patients (pts) with metastatic breast cancer (MBC) according to tumor subtype (TS) and line of therapy (tx).** *Proc ASCO* 2012;**Abstract 6089**.

Verma S et al; the EMILIA Study Group. **Trastuzumab emtansine for HER2-positive advanced breast cancer.** *N Engl J Med* 2012;367(19):1783-91.

Verma S et al. **Updated overall survival results from EMILIA, a phase 3 study of trastuzumab emtansine (T-DM1) vs capecitabine (X) and lapatinib (L) in HER2-positive locally advanced or metastatic breast cancer (MBC).** *Proc ESMO* 2012;**Abstract LBA12**.

Non-Small Cell Lung Cancer (Corey J Langer, MD)

Brahmer JR et al. **Clinical activity and safety of anti-PD1 (BMS-936558, MDX-1106) in patients with advanced non-small-cell lung cancer (NSCLC).** *Proc ASCO* 2012;**Abstract 7509**.

Chih-Hsin J et al. **LUX-Lung 3: A randomized, open-label, phase III study of afatinib versus pemetrexed and cisplatin as first-line treatment for patients with advanced adenocarcinoma of the lung harboring EGFR-activating mutations.** *Proc ASCO* 2012;**Abstract LBA7500**.

ECOG-E5508: Randomized Phase III study of maintenance therapy with bevacizumab, pemetrexed, or a combination of bevacizumab and pemetrexed following carboplatin, paclitaxel and bevacizumab for advanced non-squamous NSCLC. NCT01107626

Neal JW et al. **The SELECT study: A multicenter phase II trial of adjuvant erlotinib in resected epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC).** *Proc ASCO* 2012;**Abstract 7010**.

Patel JD et al. A **randomized, open-label, phase III, superiority study of pemetrexed (Pem) + carboplatin (Cb) + bevacizumab (Bev) followed by maintenance Pem + Bev versus paclitaxel (Pac)+Cb+Bev followed by maintenance Bev in patients with stage IIIB or IV non-squamous non-small cell lung cancer (NS-NSCLC).** Chicago Multidisciplinary Symposium in Thoracic Oncology 2012;**Abstract LBPL1**.

Riely G et al. **Results of a global Phase II study with crizotinib in advanced *ALK*-positive non-small cell lung cancer (NSCLC).** *Proc IASLC/ASTRO* 2012;**Abstract 3**.

Rosell R et al. **Erlotinib versus standard chemotherapy as first-line treatment for European patients with advanced EGFR mutation-positive non-small-cell lung cancer (EURTAC): A multicentre, open-label, randomised phase 3 trial.** *Lancet Oncol* 2012;13(3):239-46.

Shaw AT et al. **Clinical activity of crizotinib in advanced non-small cell lung cancer (NSCLC) harboring ROS1 gene rearrangement.** *Proc ASCO* 2012;**Abstract 7508**.