

# Year in Review

## Proceedings from a Multitumor CME Symposium Focused on Key Clinical Presentations and Papers in Oncology: 2010-2011

### Select Publications

#### Breast Cancer

Bear HD et al. **The effect on pCR of bevacizumab and/or antimetabolites added to standard neoadjuvant chemotherapy: NSABP protocol B-40.** *Proc ASCO 2011;Abstract LBA1005.*

Brufsky A et al. **Impact of bevacizumab (BEV) on efficacy of second-line chemotherapy (CT) for triple-negative breast cancer (TNBC): Analysis of RIBBON-2.** *Proc ASCO 2011;Abstract 1010.*

Burris HA 3<sup>rd</sup> et al. **Phase II study of the antibody drug conjugate trastuzumab-DM1 for the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer after prior HER2-directed therapy.** *J Clin Oncol 2011;29(4):398-405.*

Chang JCN et al. **TBCRC 006 — A multicenter Phase II study of neoadjuvant lapatinib and trastuzumab in HER2-overexpressing breast cancer (BC).** *Proc ASCO 2011;Abstract 505.*

Cortes J et al. **Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): A phase 3 open-label randomised study.** *Lancet 2011;377(9769):914-23.*

Holmes FA et al. **Correlation of molecular effects and pathologic complete response to preoperative lapatinib or trastuzumab, alone or in combination, prior to neoadjuvant chemotherapy.** *Proc ASCO 2011;Abstract 506.*

Hornberger J, Chien R. **Meta-analysis of the decision impact of the 21-gene breast cancer Recurrence Score in clinical practice.** San Antonio Breast Cancer Symposium 2010;Abstract P2-09-06.

O'Shaughnessy J et al. **A randomized phase III study of iniparib (BSI-201) in combination with gemcitabine/carboplatin (G/C) in metastatic triple-negative breast cancer (TNBC).** *Proc ASCO 2011;Abstract 1007.*

Twelves C et al. **A phase III study (EMBRACE) of eribulin mesylate versus treatment of physician's choice in patients with locally recurrent or metastatic breast cancer previously treated with an anthracycline and a taxane.** *Proc ASCO 2010;Abstract CRA1004.*

Yardley DA et al. **Phase II study evaluating lapatinib in combination with *nab*<sup>®</sup>-paclitaxel in women who have received  $\leq 1$  chemotherapy regimen for HER2-overexpressing metastatic breast cancer.** San Antonio Breast Cancer Symposium 2011;Abstract P1-12-10.

#### Non-Small Cell Lung Cancer

Ciuleanu T et al. **Maintenance pemetrexed plus best supportive care versus placebo plus best supportive care for non-small-cell lung cancer: A randomised, double-blind, phase 3 study.** *Lancet 2009;374(9699):1432-40.*

Fukuoka M et al. **Biomarker analyses from a phase III, randomized, open-label, first-line study of gefitinib (G) versus carboplatin/paclitaxel (C/P) in clinically selected patients (pts) with advanced non-small cell lung cancer (NSCLC) in Asia (IPASS).** *Proc ASCO 2009;Abstract 8006.*

Lee JS et al. **A randomized Phase III study of gefitinib (IRESSA™) versus standard chemotherapy (gemcitabine plus cisplatin) as a first-line treatment for never-smokers with advanced or metastatic adenocarcinoma of the lung.** *Proc WCLC 2009;Abstract PRS.4.*

Miller V et al. **Phase IIb/III double-blind randomized trial of afatinib (BIBW 2992, an irreversible inhibitor of EGFR/HER1 and HER2) + best supportive care (BSC) versus placebo + BSC in patients with NSCLC failing 1-2 lines of chemotherapy and erlotinib or gefitinib (LUX-Lung 1).** *Proc ESMO 2010*;Abstract LBA1.

Mitsudomi T et al. **Gefitinib versus cisplatin plus docetaxel in patients with non-small-cell lung cancer harbouring mutations of the epidermal growth factor receptor (WJTOG3405): An open label, randomised phase 3 trial.** *Lancet Oncol 2010*;11(2):121-8.

Paz-Ares LG et al. **PARAMOUNT: Phase III study of maintenance pemetrexed (pem) plus best supportive care (BSC) versus placebo plus BSC immediately following induction treatment with pem plus cisplatin for advanced nonsquamous non-small cell lung cancer (NSCLC).** *Proc ASCO 2011*;Abstract CRA7510.

Rosell R et al. **Erlotinib versus chemotherapy (CT) in advanced non-small cell lung cancer (NSCLC) patients (p) with epidermal growth factor receptor (EGFR) mutations: Interim results of the European erlotinib versus chemotherapy (EURTAC) phase III randomized trial.** *Proc ASCO 2011*;Abstract 7503.

Shaw AT et al. **Impact of crizotinib on survival in patients with advanced, ALK-positive NSCLC compared with historical controls.** *Proc ASCO 2011*;Abstract 7507.

Socinski MA et al. **Survival results of a randomized, phase III trial of nab-paclitaxel and carboplatin compared with Cremophor-based paclitaxel and carboplatin as first-line therapy in advanced non-small cell lung cancer.** *Proc ASCO 2011*;Abstract 7551.

Spigel DR et al. **Final efficacy results from OAM4558g, a randomized phase II study evaluating MetMab or placebo in combination with erlotinib in advanced NSCLC.** *Proc ASCO 2011*;Abstract 7505.

## Genitourinary Cancers

Ang JE et al. **CYP17 blockade by abiraterone: Further evidence for frequent continued hormone-dependence in castration-resistant prostate cancer.** *Br J Cancer 2009*;100(5):671-5.

De Bono JS et al. **Abiraterone and increased survival in metastatic prostate cancer.** *N Engl J Med 2011*;364(21):1995-2005.

De Bono JS et al. **Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: A randomised open-label trial.** *Lancet 2010*;376(9747):1147-54.

Efstathiou MA et al. **MDV3100 effects on androgen receptor (AR) signaling and bone marrow testosterone concentration modulation: A preliminary report.** *Proc ASCO 2011*;Abstract 4501.

Escudier B et al; AVOREN Trial Investigators. **Bevacizumab plus interferon alfa-2a for treatment of metastatic renal cell carcinoma: A randomised, double-blind phase III trial.** *Lancet 2007*;370(9605):2103-11.

Hussain M et al. **Cabozantinib (XL184) in metastatic castration-resistant prostate cancer (mCRPC): Results from a Phase II randomized discontinuation trial.** *Proc ASCO 2011*;Abstract 4516.

Melichar B et al. **BEVLiN — Prospective study of the safety and efficacy of first-line bevacizumab (BEV) plus low-dose interferon- $\alpha$ 2a (IFN) in patients (pts) with metastatic renal cell carcinoma (mRCC).** *Proc ASCO 2011*;Abstract 4546.

Merchan JR et al. **Final phase II safety and efficacy results of study MC0452: Phase I/II trial of CCI 779 and bevacizumab in advanced renal cell carcinoma.** *Proc ASCO 2011*;Abstract 4548.

Sartor AO et al. **Cabazitaxel or mitoxantrone with prednisone in patients with metastatic castration-resistant prostate cancer (mCRPC) previously treated with docetaxel: Final results of a multinational phase III trial (TROPIC).** Genitourinary Cancers Symposium 2010;Abstract 9.

Scher HI et al. **Improved survival outcomes in clinically relevant patient subgroups from COU-AA-301, a phase III study of abiraterone acetate (AA) plus prednisone (P) in patients with metastatic castration-resistant prostate cancer (mCRPC) after progressing after docetaxel-based chemotherapy.** Genitourinary Cancers Symposium 2011;Abstract 4.

## Non-Hodgkin and Hodgkin Lymphomas

Brice P et al. **Comparison in low-tumor-burden follicular lymphomas between an initial no-treatment policy, prednimustine, or interferon alfa: A randomized study from the Groupe d'Etude des Lymphomes Folliculaires. Groupe d'Etude des Lymphomes de l'Adulte.** *J Clin Oncol 1997*;15(15):1110-7.

Chen R et al. **Results of a pivotal Phase 2 study of brentuximab vedotin (SGN-35) in patients with relapsed or refractory Hodgkin lymphoma.** *Proc ASH 2010*;Abstract 283.

Coiffier B et al. **Final results from a pivotal, multicenter, international, open-label, Phase 2 study of romidepsin in progressive or relapsed peripheral T-cell lymphoma (PTCL) following prior systemic therapy.** *Proc ASH 2010*;Abstract 114.

Fowler N et al. **High response rates with lenalidomide plus rituximab for untreated, indolent, B cell NHL.** *Proc ICML 2011*;Abstract 137.

Kluin-Nelemans JC. **Rituximab maintenance significantly prolongs duration of remission in elderly patients with mantle cell lymphoma. First results of a randomized trial of the European MCL Network.** *Proc 16<sup>th</sup> Congress of the European Hematology Association 2011.*

Piekarz R et al. **Final results of a phase 2 NCI multicenter study of romidepsin in patients with relapsed peripheral T-cell lymphoma (PTCL).** *Proc ASH 2009*;Abstract 1657.

Piekarz RL et al. **Inhibitor of histone deacetylation, depsipeptide (FR901228), in the treatment of peripheral and cutaneous T-cell lymphoma: A case report.** *Blood 2001*;98(9):2865-8.

Salles GA et al. **Rituximab maintenance for 2 years in patients with untreated high tumor burden follicular lymphoma after response to immunochemotherapy.** *Proc ASCO 2010*;Abstract 8004.

Shustov AR et al. **Complete remissions with brentuximab vedotin (SGN-35) in patients with relapsed or refractory systemic anaplastic large cell lymphoma.** *Proc ASH 2010*;Abstract 961.

Trotman J et al. **FDG PET-CT imaging after immunochemotherapy induction is a powerful and independent indicator of outcome for patients with follicular lymphoma: An analysis from the PRIMA study.** *Proc ASH 2010*;Abstract 855.

## Multiple Myeloma

Attal M et al. **Maintenance treatment with lenalidomide after transplantation for MYELOMA: Final analysis of the IFM 2005-02.** *Proc ASH 2010*;Abstract 310.

Demo SD et al. **Antitumor activity of PR-171, a novel irreversible inhibitor of the proteasome.** *Cancer Res 2007*;67(13):6383-91.

Leleu X et al. **Phase 2 study of 2 modalities of pomalidomide (CC4047) plus low-dose dexamethasone as therapy for relapsed multiple myeloma. IFM 2009-02.** *Proc ASH 2010*;Abstract 859.

McCarthy PL et al. **Phase III Intergroup study of lenalidomide versus placebo maintenance therapy following single autologous hematopoietic stem cell transplantation (AHSCT) for multiple myeloma: CALGB 100104.** *Proc ASH 2010*;Abstract 37.

Morgan G et al. **Evaluating the effects of zoledronic acid (ZOL) on overall survival (OS) in patients (Pts) with multiple myeloma (MM): Results of the Medical Research Council (MRC) Myeloma IX study.** *Proc ASCO 2010*;Abstract 8021.

Palumbo AP et al. **Incidence of second primary malignancy (SPM) in melphalan-prednisone-lenalidomide combination followed by lenalidomide maintenance (MPR-R) in newly diagnosed multiple myeloma (MM) patients  $\geq$  65 years.** *Proc ASCO 2010*;Abstract 8007.

Richardson PG et al. **A Phase 1/2 multi-center, randomized, open label dose escalation study to determine the maximum tolerated dose, safety, and efficacy of pomalidomide alone or in combination with low-dose dexamethasone in patients with relapsed and refractory multiple myeloma who have received prior treatment that includes lenalidomide and bortezomib.** *Proc ASH 2010*;Abstract 864.

Richardson PG et al. **Lenalidomide, bortezomib, and dexamethasone combination therapy in patients with newly diagnosed multiple myeloma.** *Blood 2010*;116(5):679-86.

Richardson PG et al. **Single-agent bortezomib in previously untreated multiple myeloma: Efficacy, characterization of peripheral neuropathy, and molecular correlations with response and neuropathy.** *J Clin Oncol 2009*;27(21):3518-25.

Stewart AK et al. **How I treat multiple myeloma in younger patients.** *Blood 2009*;114(27):5436-43.

## Gastrointestinal Cancers

Bang YJ et al. **Trastuzumab in combination with chemotherapy versus chemotherapy alone for treatment of HER2-positive advanced gastric or gastro-oesophageal junction cancer (ToGA): A phase 3, open-label, randomised controlled trial.** *Lancet 2010*;376(9742):687-97.

Conroy T et al. **FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer.** *N Engl J Med 2011*;364(19):1817-25.

Kerr D et al. **A quantitative multigene RT-PCR assay for prediction of recurrence in stage II colon cancer: Selection of the genes in four large studies and results of the independent, prospectively designed QUASAR validation study.** *Proc ASCO 2009*;Abstract 4000.

Roh MS et al. **The impact of capecitabine and oxaliplatin in the preoperative multimodality treatment in patients with carcinoma of the rectum: NSABP R-04.** *Proc ASCO 2011*;Abstract 3503.

Tejpar S et al. **Influence of KRAS G13D mutations on outcome in patients with metastatic colorectal cancer (mCRC) treated with first-line chemotherapy with or without cetuximab.** *Proc ASCO* 2011;Abstract 3511.

Von Wichert G et al. **Insulin-like growth factor-I is an autocrine regulator of chromogranin A secretion and growth in human neuroendocrine tumor cells.** *Cancer Res* 2000;60(16):4573.

Yao JC et al. **Everolimus for advanced pancreatic neuroendocrine tumors.** *N Engl J Med* 2011;364(6):514-23.

Yao JC et al. **Daily oral everolimus activity in patients with metastatic pancreatic neuroendocrine tumors after failure of cytotoxic chemotherapy: A phase II trial.** *J Clin Oncol* 28(1):69-76.

Yao JC et al. **Efficacy of RAD001 (everolimus) and octreotide LAR in advanced low- to intermediate-grade neuroendocrine tumors: Results of a phase II study.** *J Clin Oncol* 2008;26(26):4311-8.

Yoon HH et al. **HER2 expression/amplification: Frequency, clinicopathologic features, and prognosis in 713 patients with esophageal adenocarcinoma (EAC).** *Proc ASCO* 2011;Abstract 4012.

## Ovarian Cancer

Aghajanian C et al. **OCEANS: A randomized, double-blinded, placebo-controlled phase III trial of chemotherapy with or without bevacizumab (BEV) in patients with platinum-sensitive recurrent epithelial ovarian (EOC), primary peritoneal (PPC), or fallopian tube cancer (FTC).** *Proc ASCO* 2011;Abstract LBA5007.

Audeh MW et al. **Oral poly(ADP-ribose) polymerase inhibitor olaparib in patients with BRCA1 or BRCA2 mutations and recurrent ovarian cancer: A proof-of-concept trial.** *Lancet* 2010;376(9737):245-51.

Kristensen G et al. **Result of interim analysis of overall survival in the GCG ICON7 phase III randomized trial of bevacizumab in women with newly diagnosed ovarian cancer.** *Proc ASCO* 2011;Abstract LBA5006.

Ledermann JA et al. **Phase II randomized placebo-controlled study of olaparib (AZD2281) in patients with platinum-sensitive relapsed serous ovarian cancer (PSR SOC).** *Proc ASCO* 2011;Abstract 5003.

Matei D et al. **Activity of sorafenib in recurrent ovarian cancer and primary peritoneal carcinomatosis: A Gynecologic Oncology Group trial.** *J Clin Oncol* 2010;29(1):69-75.

Norquist B et al. **Secondary somatic mutations restoring BRCA1/2 predict chemotherapy resistance in hereditary ovarian carcinomas.** *J Clin Oncol* 2011;29(22):3008-15.

Pignata S et al. **Carboplatin plus paclitaxel versus carboplatin plus pegylated liposomal doxorubicin as first-line treatment for patients with ovarian cancer: The MITO-2 randomized phase III trial.** *J Clin Oncol* 2011;29(27):3629-35.

Pujade-Lauraine E et al. **Pegylated liposomal doxorubicin and carboplatin compared with paclitaxel and carboplatin for patients with platinum-sensitive ovarian cancer in late relapse.** *J Clin Oncol* 2010;28(20):3323-9.