Program Status Reports for BREAST -May 2009

Breast

E2103 A Phase II Trial of Trastuzumab Plus Weekly Ixabepilone (BMS-247550) and Carboplatin in Patients with HER2/neu-Positive Metastatic Breast Cancer

E2104 Phase II Feasibility Trial Incorporating Bevacizumab Into Dose Dense-Doxorubicin and Cyclophosphamide Followed by Paclitaxel in Patients with Lymph Node Positive Breast Cancer

N0434 The Association of Breast Density Changes, Plasma Hormone Changes, and Breast Cancer Recurrence: A Companion Study To NCIC CTG MA.27

N0436 Phase II Trial of Irinotecan plus Cetuximab in Patients with Advanced Breast Cancer with Prior Anthracycline and/or Taxane-Containing Therapy

N0537 Phase II Trial of VEGF Trap in Patients with Metastatic Breast Cancer - Previously Treated with Anthracyline and/or Taxane

N0539 Phase II Trial of Fulvestrant and Bevacizumab in Patients with Metastatic Breast Cancer Previously Treated with an Aromatase Inhibitor

N063D BIG 2-06/N063D/EGF106708, ALTTO: Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Study - A randomised, multi-centre, open label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer

N063I Changes in Breast Density and Plasma Hormone Levels After One Year of Aromatase Inhibitor Therapy

N0733 Phase II Trial of Capecitabine and Lapatinib with or without IMC-A12 in Patients with HER2 Positive, Breast Cancer Previously Treated with Trastuzumab and an Anthracycline and/or a Taxane

N0735 Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

N083E Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer
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N9831 Phase III Trial of Doxorubicin and Cyclophosphamide (AC) Followed by Weekly Paclitaxel With or Without Trastuzumab as Adjuvant Treatment for Women With HER-2 Over-expressing or Amplified Node Positive or High-Risk Node Negative Breast Cancer

Z0011 A Randomized Trial of Axillary Node Dissection in Women with Clinical T1 or T2 N0 M0 Breast Cancer Who Have a Positive Sentinel Node

Other Closed Trials

N0337 Phase II Study of Capecitabine in Combination with Vinorelbine and Trastuzumab for the First- or Second-Line Treatment of HER2+Metastatic Breast Cancer

N0338 Phase II Trial of Docetaxel and Carboplatin Administered Every Two Weeks as Induction Therapy for Stage II or III Breast Cancer

N0437 Phase II Trial of CT-2103 (Xyotax) with Capecitabine as First-Line Chemotherapy for Patients with Metastatic Breast Cancer

N0531 Phase II Trial of Weekly nab (nanoparticle albumin bound)-Paclitaxel (nab-paclitaxel) (Abraxane) in Combination with Gemcitabine in Patients with Metastatic Breast Cancer

CTSU

24-02-CTSU A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer (SOFT)

25-02 A Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer (TEXT)

40101 Cyclophosphamide and Doxorubicin (CA x 4 Cycles) Versus Paclitaxel (4Cycles) as Adjuvant Therapy for Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes: A Phase III Randomized Study

49907 (CALGB) A Randomized Trial of Adjuvant Chemotherapy with Standard Regimens, Cyclophosphamide, Methotrexate, and Fluorouracil-"CMF"Doxorubicin and Cyclophosphamide -."AC" Versus Capecitabine in Wo65 Years and Older with Node Positive or Node Negative Stage Breast Cancer
B-30 A Three-Arm Randomized Trial to Compare Adjuvant Adriamycin and Cyclophosphamide Followed by Taxotere (AC-T); Adriamycin and Taxotere(AT); and Adriamycin, Taxotere, and Cyclophosphamide (ATC) in Breast Cancer Patients With Positive Axillary Lymph Nodes

B-33 A Randomized, Placebo-controlled, Double-blind Trial Evaluating the Effect of Exemestane in Clinical cT1-3N0-1M0 Postmenopausal Breast Cancer Patients Completing at Least Five Years of Tamoxifen Therapy

B-34 A Clinical Trial Comparing Adjuvant Clodronate Therapy vs. Placebo in Early-Stage Breast Cancer Patients Receiving Systemic Chemotherapy and/or Tamoxifen or No Therapy

B-35 A Clinical Trial Comparing Anastrozole with Tamoxifen in Post-menopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy

B-36 Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC) With or Without Celecoxib, in Patients with Node-Negative Breast Cancer

B-38 A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-Positive Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC->P); DDAC Followed by DD Paclitaxel Plus Gemcitabine (DD AC->PG)

B-39 NSABP B-39, "A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I or II Breast Cancer"

E2100 E2100, A Randomized Phase III Trial of Paclitaxel versus Paclitaxel plus Bevacizumab (rhuMAb VEGF) as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer

MA.20 A Phase III Study of Regional Radiation Therapy in Early Breast Cancer

MA.21 A Phase III Adjuvant Trial of Sequenced EC + Filgrastim + Epoetin Alfa Followed by Paclitaxel Versus Sequenced AC Followed by Paclitaxel Versus CEF as Therapy for Premenopausal Women and EARly Postmenopausal Women Who Have Had Potentially Curative Surgery for Node Positive or High Risk Node Negative
MA.27  A Randomized Phase III Trial of Exemestane Versus Anastrozole in Postmenopausal Women with Receptor Positive Primary Breast Cancer

S0221  Phase III Trial of Continuous Schedule AC + G vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node Negative Breast Cancer