

Listing of Ongoing Cancer Clinical Trials in the Salinas Valley

Winter 2008

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I. Solid Tumors

1. Breast Cancer

1. CALGB-40101 Phase III Randomized Study of Two Different Schedules of Adjuvant Cyclophosphamide and Doxorubicin Versus Paclitaxel in Women With Operable Breast Cancer and 0-3 Positive Axillary Lymph Nodes
2. Phase III Endocrine Therapy With or Without Inhibition of EGF and HER2 Growth Factor Receptors: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial for Postmenopausal Women with Estrogen-Receptor Positive Advanced Breast Cancer

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Salinas Valley Memorial Hospital, and
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3. **IBCSG-25-02 Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer**
4. CAN-NCIC-MA27 Randomized Phase III Trial of Exemestane Versus Anastrozole in Postmenopausal Women with Receptor Positive Primary Breast Cancer
5. **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**
6. S0230 Phase III Trial of LHRH Analog Administration During Chemotherapy to Reduce Ovarian Failure Following Chemotherapy in Early Stage, Hormone-Receptor Negative Breast Cancer
7. **S0307 Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer**
8. S0500 Randomized Phase III Trial to Test the Strategy of Changing Therapy versus Maintaining Therapy for Metastatic Breast Cancer Patients who Have Elevated Circulating Tumor Cell Levels at First Follow Up Assessment
9. **Genomic Profiling for Breast Cancer in Node Negative, ER-Positive and /or PR-Positive Breast Cancer Candidate for Adjuvant Cytotoxic Therapy in Addition to Hormonal Therapy**
10. ECOG-PACCT-1 Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial

2. Central Nervous System Tumors

1. **E1F05 Phase II Study of Rituximab Given in Conjunction with Standard Chemotherapy in Primary Central Nervous System (CNS) Lymphoma**
2. N0574 Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases

3. Gastrointestinal Cancers

A. Colorectal Cancer

1. **Phase III Comparison of Combination Chemotherapy Regimens With or Without Cetuximab in Treating Patients Who Have Undergone Surgery For Stage III Colon Cancer**
2. Phase III Trial of Cetuximab, Bevacizumab and 5FU/Leucovorin Versus Oxaliplatin, Bevacizumab and 5FU/Leucovorin in Metastatic Colorectal Cancer (**Monterey Bay Oncology**)
3. **E5202 Phase III 5-FU Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers**
4. C80405 Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Pre-operative Chemoradiation
5. **A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum**

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6. E3204 Phase II Study of Preoperative Radiation with Concurrent Capecitabine, Oxaliplatin and Bevacizumab Followed by Surgery and Postoperative 5-FU, Leucovorin, Oxaliplatin (FOLFOX) and Bevacizumab in Patients with Locally Advanced Rectal Cancer
7. **E3205 Phase II Trial of Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma**
8. E4203 Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer
9. **E5204 Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Preoperative Chemoradiation**
10. N0147 A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer
11. **NSABPR04 Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with Preoperative Radiation Therapy and Continuous Intravenous Infusion (CVI) of 5-Fluorouracil (5-FU) in the Treatment of Patients with Operable Carcinoma of the Rectum**
12. S0600 Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) with or without Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with Either FOLFOX, OPTIMOX, or XELOX

B. Esophageal Cancer

1. **CALGB 80101 Phase III Adjuvant Chemotherapy and Radiation Therapy After Surgery in Treating Patients With Stomach or Esophageal Cancer**
2. 80403 Phase II Study of ECF-C, IC-C, or Folfox-C in Metastatic Esophageal and GE Junction cancer
3. **E2202 Minimally Invasive Esophagectomy (MIE): A Multicenter Feasibility Study**

C. Pancreatic Cancer

1. E2204 Phase II Bevacizumab or Cetuximab Combined With Gemcitabine, Capecitabine, and Radiation Therapy in Treating Patients With Pancreatic Cancer That Has Been Completely Removed By Surgery

4. Gynecologic Cancers

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A. Ovarian/Peritoneal Cancer

1. A randomized study of Tamoxifen vs Thalidomide in Patients with Biochemical Recurrence- only Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After Chemotherapy
2. **IBCSG-2402 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)**

B. Uteral Cancer

1. Trial of Doxorubicin (Adriamycin)/Cisplatin (Platinol)/Paclitaxel (Taxol)/ G-CSF (Neupogen) vs Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer

5. Head & Neck Cancer

1. **E1302 Phase III Randomized, Placebo Controlled, Trial of Docetaxel Versus Docetaxel Plus ZD1839 (Iressa, Gefitinib) In Performance Status 2 Or Previously Treated Patients With Recurrent Or Metastatic Head And Neck Cancer**
2. E1304 Phase II Two Arm Trial of the Proteasome Inhibitor, PS-341 (VELCADE™) in Combination with Irinotecan or PS-341 Alone Followed by the Addition of Irinotecan at Time of Progression in Patients with Locally Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

6. Lung

1. **E1504 Phase II Study of C225 (Cetuximab) for the Treatment of Patients with Advanced Bronchioloalveolar Carcinoma (BAC) or Adenocarcinoma with BAC Features**
2. E1505 Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (≥ 4 cm) - IIIA Non-Small Cell Lung Cancer (NSCLC)
3. **E1C99 Phase II Study of Carboplatin plus Paclitaxel Treatment of Advanced Thymoma or Thymic Carcinoma**
4. E5501 Phase II Study: Sequencing Topoisomerase Inhibitors for EXtensive Stage Small Cell Lung Cancer (SCLC); Topotecan Sequenced with Etoposide/Cisplatin, and Irinotecan/Cisplatin Sequenced with Etoposide
5. **R0212 Phase II/III Randomized Trial of Two Doses (Phase III-Standard Vs. High) and Two High Dose Schedules (Phase II-Once Vs. Twice Daily) For Delivering Prophylactic Cranial Irradiation For Patients with Limited Disease Small Cell Lung Cancer**
6. S0424 Molecular Epidemiology Case-Series of Non-small Cell Lung Cancer in Smoking and Non-Smoking Women and Men
7. **S9925 Lung Cancer Specimen Repository Protocol, Ancillary**

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8. E5597 Phase III Chemoprevention Trial of Selenium Supplementation in Persons with Resected Stage I Non Small Cell Lung Cancer

7. Melanoma

1. **E1602 Phase II Trial of Multi-epitope Vaccination with Melanoma Peptides for Cytotoxic T-Cells and Helper T-Cells for Patients with Metastatic Melanoma**
2. E1697 Phase III Randomized Study of Four Weeks High Dose IFN-A2B in Stage T2B NO, T3A-B NO, T4A-B NO, and T1-4, N1A, 2A, 3 (microscopic) Melanoma
3. **E2602 Phase II Study of Low Dose Peginterferon Alfa-2b in Patients with Metastatic Melanoma Over-Expressing Basic Fibroblast Growth Factor**
4. E2603 Double-Blind, Randomized, Placebo-Controlled Phase III Trial of Carboplatin, Paclitaxel, and BAY 43-9006 versus Carboplatin, Paclitaxel and Placebo in Patients with Unresectable Locally Advanced or Stage IV Melanoma
5. **S0008 Phase III Trial of High Dose Interferon Alpha 2b vs Cisplatin, Vinblastine, DTIC +IL-2 and Interferon in Patients with High Risk Melanoma**

8. Prostate Cancer

1. Phase III Docetaxel and Prednisone With or Without Bevacizumab in Treating Patients With Prostate Cancer That Did Not Respond to Hormone Therapy
2. **Phase III DN-101 in Combination With Docetaxel in Androgen-Independent Prostate Cancer (AIPC) (AIPC Study of Calcitriol Enhancing Taxotere [ASCENT-2]) (Monterey Bay Oncology)**
3. Phase III Randomized, Double-Blind, Placebo Controlled Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men With Prostate Cancer Metastatic to Bone
4. **CALGB90202 Randomized, Double Blind, Placebo-Controlled Phase III Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone**
5. C90203 Randomized Phase III Study of Neoadjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer
6. **90401 Randomized Double-Blinded Placebo Controlled Phase III Trial Comparing Docetaxel and Prednisone with and without Bevacizumab (IND #7921, NSC #704865) in Men with Hormone Refractory Prostate Cancer**
7. Phase II E7389 in Treating Patients With Metastatic Prostate Cancer That Did Not Respond to Hormone Therapy
8. **E3803 Phase II Study of a Weekly Schedule of BMS-247550 for Patients with Hormone Refractory Prostate Cancer**
9. E3805 ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer
10. **E5805 Phase II Trial of E7389 (Halichondrin B Analog), in Patients with Metastatic Hormone Refractory Prostate Cancer**

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11. E9802 Phase II Study of PROSTVAC-V (Vaccinia)/TRICOM and PROSTVAC-F (Fowlpox)/TRICOM with GM-CSF in Patients with PSA Progression After Local Therapy for Prostate Cancer
12. **S9346 Phase III Study of Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer**

9. Urologic Cancers (other)

A. Bladder

1. R0233 Phase II Randomized Trial for Patients with Muscle-invading Bladder Cancer Evaluating Transurethral Surgery and Bid Irradiation Plus Either Paclitaxel and Cisplatin Followed by Selective Bladder Preservation and Gemcitabine/Paclitaxel/Cisplatin Adjuvant Chemotherapy
2. **R0524 Phase I/II Trial of a Combination of Paclitaxel and Trastuzumab With Daily Irradiation or Paclitaxel Alone With Daily Irradiation Following Transurethral Surgery For Non-Cystectomy Candidates With Muscle-Invasive Bladder Cancer**

B. Kidney Cancer

1. Phase III Sunitinib or Sorafenib in Treating Patients With Kidney Cancer That Was Removed By Surgery
2. **E2804 Phase II Study of VEGF, RAF kinase and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma**
3. E2805 Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma

C. Urethral

1. **Phase II Trial of Sorafenib (BAY43-9006) (IND 69896; NSC 724772) in Patients with Advanced Urothelial Cancer**

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1. Leukemia

1. 10101 Phase II Trial of Intravenous Pentostatin For the Treatment of Patients with Refractory Chronic Graft-Versus-Host Disease
2. **E1900 Phase III Trial in Adult Acute Myeloid Leukemia:Daunorubicin Dose Intensification and Gemtuzumab-Ozogamicin Consolidation Therapy Prior to Autologous Stem Cell Transplantation**
3. E1902 Phase II Study of Reduced Intensity Allogeneic Stem Cell Transplant for the Treatment of Myelodysplastic Syndromes
4. **E1904 Phase II Study of MOAD (Methotrexate, Vincristine, L-asparaginase, and Dexamethasone) with Subcutaneous Campath (NSC 715969) for Adults with Relapsed or Refractory Acute Lymphocytic Leukemia (ALL)**
5. E1905 Randomized Phase II Trial of Azacitidine with or without the Histone Deacetylase Inhibitor MS-275 for the Treatment of Myelodysplastic Syndrome, Chronic Myelomonocytic Leukemia (dysplastic type), and Acute Myeloid Leukemia with Multilineage Dysplasia
6. **E2902 Phase III Randomized Study of Farnesyl Transferase Inhibitor R115777 in Acute Myeloid Leukemia (AML) Patients in Second or Subsequent Remission or Remission after Primary Induction Failure or Patients over Age 60 in First Remission**
7. E2903 Phase II Trial of Pentostatin, Cyclophosphamide, and Rituximab (PCR) Followed By Campath-1H For Previously Treated Relapsed or Refractory Patients With Chronic Lymphocytic Leukemia
8. **E3903 Ancillary laboratory protocol for collecting diagnostic material on patients considered for ECOG treatment trials for leukemia or related hematologic disorders**
9. E5998 Phase II Study of Initial Treatment with Methotrexate in Large Granular Lymphocytic (LGL) Leukemia
10. **E0325 Phase IIb Study of Molecular Responses to Imatinib at Standard or Increased, or Dasatinib (BMS 354825) (NSC 732517), for Previously Untreated Patients with Chronic Myelogenous Leukemia (CML) in Chronic Phase**

2. Lymphoma

1. E1402 Phase II Study of Reduced Intensity Allogeneic Bone Marrow Transplantation for the Treatment of Relapsed Non-Hodgkin and Hodgkin Lymphoma
2. **E1405 Phase II Study of VcR-CVAD with Rituximab Maintenance for Untreated Mantle Cell Lymphoma**
3. E2402 Phase II Study of Cyclosporine in the Treatment of Angioimmunoblastic T-Cell Lymphoma
4. **E2404 Bevacizumab and CHOP (A-CHOP) in Combination for Patients with Peripheral T-Cell or Natural Killer Cell Neoplasms**
5. E3402 Phase II Trial of R-CHOP Followed by Zevalin Radioimmunotherapy for Patients with Previously Untreated Stages I and II CD20+ Diffuse Large Cell Non-Hodgkin's Lymphoma
6. **E4402 Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent non-Hodgkin's Lymphoma**

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7. S0016 Phase III Trial of CHOP + Rituximab vs CHOP + Iodine-131-Labeled Monoclonal Anti-B1 Antibody (Tositumomab) For Treatment of Newly Diagnosed Follicular Non-Hodgkin's Lymphomas
8. **S9704 Phase III Trial Comparing Early High Dose Chemoradiotherapy and an Autologous Stem Cell Transplant to Conventional Dose CHOP Chemotherapy Plus Rituximab for CD20 + B Cell Lymphomas (With Possible Late Autologous Stem Cell Transplant) for Patients with Diffuse Aggressive Non-Hodgkin's Lymphoma in the High-Intermediate and High Risk International Classification Prognostic Groups**
9. E3404 Response-Adapted Therapy for Aggressive non-Hodgkin's Lymphomas based on early [18F] FDG-PET Scanning
10. **An Observational Study of Treatment, Outcomes, and Prognosis in Patients With Follicular Non-Hodgkin's Lymphoma (Monterey Bay Oncology)**

3. Myeloma

1. 10104 Phase III Randomized Double-Blind Study of Maintenance Therapy with CC-5013 or Placebo Following Autologous Stem Cell Transplantation for multiple Myeloma
2. **E1A95 Phase III Trial of Consolidation Therapy with Bortezomib(Velcade), CC-5013 & Dexamethasone(VRD) VS. Bortezomib(Velcade) & Dexamethasone(VD) for Patients With Multiple myeloma who have completed a Dexamethasone Based Induction Regimen**
3. E3A05 Ancillary Laboratory Protocol for Collecting Diagnostic Material on Patients Considered for Studies of Plasma Cell Disorders
4. **JMY10 Phase III Study of Thalidomide and Prednisone as Maintenance Therapy Following Autologous Stem Cell Transplant in Patients with Multiple Myeloma**
5. U1099 Oral Antibiotic Prophylaxis of Early Infection in Multiple Myeloma

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