

Currently Active Melanoma Oncology Clinical Trials

Updated 4/22/2011

Adjuvant

1. Pegylated Interferon + Peptide (2006-0816) Phase I NCT00861406
Principal Investigator: Wen-Jen Hwu, MD, PhD
Research Nurse: Tracey Moffatt, RN
Patients must be free of disease after surgical resection for AJCC stage II or III (T2b, T3a, T3b, T4a, T4b, and N1a or N2a) melanoma. Patients must be HLA-A0201 and have had surgical resection within 90 days.
2. Study of Biological Response to Dasatinib Treatment in Patients with Acral Lentiginous, Mucosal, or Chronic Sun-damaged Melanoma (2009-0447) Phase II NCT01092728
Principal Investigator: Kevin Kim, MD
Research Nurse: Sandy Mahoney, RN
Patients with acral lentiginous, mucosal melanoma or melanoma of chronic sun-damaged skin. Patients at any stage with surgically resectable tumors or biopsiable tumors(s) are eligible.

Neoadjuvant

1. Temozolomide Alone or with Pegylated Interferon-alpha 2b (2005-0143) Phase II NCT00525031
Principal Investigator: Wen-Jen Hwu, MD, PhD
Research Nurse: Tracey Moffatt, RN
Temozolomide is a drug that is designed to work by stopping cancer cells from making new DNA. Pegylated Interferon-alpha 2b is a protein made by the human immune system that helps to fight viral infections regulate cell function. Patients should not have any prior systemic chemotherapy.

Chemotherapy-naïve Patients

1. IPILIMUMAB plus Temozolomide in Patients with Metastatic Melanoma (2009-0408) Phase II NCT01119508
Principal Investigator: Agop Bedikian, MD
Research Nurse: Suzanne Cain, RN
For patients with unresectable Stage III/IV melanoma. No previous cytotoxic drugs, targeted therapies or anti-CTLA-4. Patients with brain lesions will be evaluated by the principal investigator or his designee as to eligibility.

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2. Trial of High Dose Interleukin-2 (HDIL-2) with Recombinant MAGE-A3 Protein Combined with Adjuvant System AS15 in Patients with Unresectable or Metastatic Melanoma (2010-0113) Phase II NCT01266603

Principal Investigator: Jade Homsy, MD

Research Nurse: MaryAnne LaFontaine, RN

Patients with at least one biopsible lesion and/or access to paraffin-embedded tissue block sample.

Patients who have had previous chemotherapy

1. T-Cells +/- Dendritic Cells (2004-0069) Phase II NCT00338377

Principal Investigator: Patrick Hwu, MD

Research Nurse: Sandy Mahoney, RN

In this study, T-cells capable of recognizing and killing melanoma will be isolated from tumor biopsies and expanded in the laboratory. The T-cells will then be reinfused into the patients with or without dendritic cells, which are immune cells capable of potentially activating T-cells. This study is for patients with a good performance status, with measurable metastatic melanoma, and a site that can easily be biopsied.

2. Activation of pDCs at Tumor and Vaccine Sites with TLR Agonist (2008-0416) Phase II NCT00960752

Principal Investigator: Patrick Hwu, MD and Richard Royal, MD

Research Nurse: MaryAnne Lafontaine, RN

For patients with metastatic melanoma with measurable disease, Stage IIIC (in transit lesions) or Stage IV (M1a) Patients must be HLA-A0201 and DP4 positive to participate and have at least 4 biopsiable lesions. No previous exposure to gp100 or MAGE-3.

3. TPI 287 in Combination with Temozolomide (2009-0357) Phase I/II NCT01067066

Principal Investigator: Agop Bedikian, MD

Research Nurse: MaryAnne LaFontaine, RN

This study combines the cytotoxic agent Temozolomide with a novel microtubule inhibitor TPI287. Patients with unresectable Stage II or Stage IV, including bulky Stage III and M13. Patients who have brain metastases must be off medication for at least one week.

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4. LOC-Paclitaxel (2009-0432) Phase I NCT01039844
Principal Investigator: Agop Bedikian, MD
Research Nurse: Karen Woodard, RN
Patients who have failed all conventional therapies and no other therapies are available. No CNS metastases allowed.

5. Study of E7080 (2010-0356) Phase II NCT01136967
Principal Investigator: Kevin Kim, MD
Research Nurse: Abby Yu, RN
Patients not previously treated with targeted therapy and with measurable disease.

6. GSK BRAF I + MEK I (2009-0949) Phase I/II NCT01072175
Principal Investigator: Kevin Kim, MD
Research Nurse: Abby Yu, RN
Expansion Part C, BRAF mutation (+) tumors, archived tissue. No previous MEK or BRAF inhibitors.

Patients with Metastatic Choroidal Melanoma

1. Study of Genasense-Carboplatin-Paclitaxel-combination in Uveal Melanoma (2010-0188) Phase II NCT01200342
Principal Investigator: Agop Bedikian, MD
Research Nurse: Tracey Moffat, RN
Patients must have histologic or cytologic confirmation of malignant uveal melanoma and documented metastatic disease with measurable disease. Patients may have had previous treatment except hepatic chemoembolization is not allowed. Patients with brain metastases or history of brain metastases are not allowed.

2. Hepatic Arterial Infusion of Abraxane (2006-0603) Phase I NCT00833807
Principal Investigator: Agop Bedikian, MD
Research Nurse: Karen Woodard, RN
Patients must have at least one clearly measurable metastatic lesion in the liver that is more than 2cm in the largest dimension. Patients must not have received prior systemic chemotherapy with regimens including taxanes. Prior adjuvant treatment with immunotherapy, or vaccine therapy is allowed provided there is documentation of disease progression in the liver.

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Patients with Brain Metastases

1. GSK113929 Single Agent in Treatment Naïve and Previously Treated Subjects with BRAF Mutation-Positive Mets Melanoma to the Brain (2010-0841) Phase II NCT01266967
Principal Investigator: Michael Davies, MD
Research Nurse: Tracey Moffatt, RN
Metastatic Melanoma (stage IV), carrying BRAF V600E- or V600k-mutation as determined by central testing.

Laboratory Protocols

1. Biomarkers of High Dose IL-2 Responsiveness (LAB06-0762)
Principal Investigator: Laszlo Radvanyi, PhD
Research Coordinator: Edwina Washington, LVN
Interleukin-2 (IL-2) therapy has been used extensively over the past fifteen years to effectively treat patients with advanced metastatic melanoma and renal cell carcinoma. This study will aide to map out a complete picture of what IL-2 is doing in the PBMC and tumor site in melanoma patients. Patients must receive High Dose IL-2 in order to qualify for this study.
2. Blood & Tumor Sample Collection for Long Term Storage (2005-0466) NCT00507325
Principal Investigator: Kevin Kim, MD
Research Coordinator: Edwina Washington, LVN
This study will collect blood and tumor samples from patients with suspected or confirmed melanoma and place these samples in long-term storage for future biological and/or surrogate marker studies.

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