



*This list of clinical research protocols relating to melanoma is compiled for your convenience.*

*For more information on these protocols, please call PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER. The PDQ Web site is accessible at <http://cancer.net.nci.nih.gov/trialsrch.shtml>.*

*A searchable Web site developed by the National Library of Medicine is also available at <http://clinicaltrials.gov>.*

## SELECTED CLINICAL RESEARCH PROTOCOLS FOR MELANOMA

### Phase II

#### **MSKCC-99004, NCI-G99-1619**

Phase II Pilot Study of Fludeoxyglucose F 18 Positron Emission Tomography and CT Imaging in Preoperative Evaluation of Patients With Stage III or IV Melanoma

Chairperson: Mary Susan Brady. Telephone: 212-639-8347. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

**E-1696** Phase II Randomized Study of Immunization With an HLA-A2 Multiepitope Peptide Vaccine Comprised of MART-1:27-35, gp100:209-217 (210M), and Tyrosinase:368-376 (370D) Peptides Alone or in Combination With Sargramostim (GM-CSF) and/or Interferon alfa-2b in HLA-A2 Positive Patients With Metastatic Melanoma

Chairperson: John Munn Kirkwood. Telephone: 412-648-6570. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**CWG-UIC-T98-0027, NCI-T98-0027** Phase II Randomized Study of Mutated gp100 Melanoma Peptide With High Dose Interleukin-2 in HLA-A2.1 Positive Patients With Metastatic Melanoma

Chairperson: Jeffrey A. Sosman. Telephone: 312-996-1588. Lead organization: University of Illinois at Chicago Health Sciences Center. Age range: 16 and over.

**NCI-01-C-0193, NCI-5369** Phase II Randomized Study of Tyrosinase-Related Protein-2:180-188 Peptide Vaccine With or Without Interleukin-2 in Patients With

HLA-A0201-Positive Refractory Metastatic Melanoma

Chairperson: Steven A. Rosenberg. Telephone: 301-496-4164. Lead organization: Surgery Branch, Bethesda, Maryland. Age range: 16 and over.

**DUMC-1340-99-7, NCI-G99-1617** Phase II Study of Allogeneic Mixed Chimerism Peripheral Blood Stem Cell Transplantation Utilizing In Vivo and In Vitro Monoclonal Antibody CD52 (Campath-1H) in Patients With High Risk Hematologic Malignancies or Diseases

Chairperson: David A. Rizzieri. Telephone: 919-668-1040. Lead organization: Duke Comprehensive Cancer Center. Age range: 18 and over.

**NCI-98-C-0095, NCI-T98-0012** Phase II Study of Cloned Peripheral Blood Lymphocytes Sensitized In Vitro to the gp209-2M Immunodominant Peptide Alone or in Conjunction With Interleukin-2 in Patients With Metastatic Melanoma Who Have Failed Prior Vaccine Therapy

Chairperson: Steven A. Rosenberg. Telephone: 301-496-4164. Lead organization: Center for Cancer Research. Age range: 18 and over.

**SWOG-9430** Phase II Study of Complete Surgical Resection in Patients With Stage IV Melanoma

Chairperson: Jeffrey A. Sosman. Telephone: 312-996-1588. Lead organization: Southwest Oncology Group. Age range: 18 and over.

**NCI-98-C-0086** Phase II Study of DNA Encoding the gp100 Anti-

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gen Alone or in Combination With Interleukin-2 in Patients With Recurrent Metastatic Melanoma

Chairperson: Steven A. Rosenberg. Telephone: 301-496-4164. Lead organization: Center for Cancer Research. Age range: 16 and over.

**CLB-509901** Phase II Study of gp100 Human Melanoma Peptide Vaccine and Interleukin-2 in Patients With Advanced Melanoma

Chairperson: John D. Roberts. Telephone: 804-628-1940. Lead organization: Cancer and Leukemia Group B. Age range: 18 and over.

**MDA-ID-01284, NCI-5345** Phase II Study of Imatinib Mesylate (STI571) in Patients With Metastatic Melanoma

Chairperson: Omar Eton. Telephone: 713-792-2921. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: not specified.

**SWOG-S0026** Phase II Study of Interferon alfa and Thalidomide in Patients With Stage IV Melanoma

Chairperson: Laura Fulper Hutchins. Telephone: 501-686-8511. Lead organization: Southwest Oncology Group. Age range: not specified.

**MSKCC-99047, NCI-G99-1664** Phase II Study of Isolated Limb Infusion With Melphalan and Dactinomycin in Patients With Primary or Recurrent, Unresectable Regional Melanoma or Soft Tissue Sarcoma of the Extremity

Chairperson: Mary Susan Brady. Telephone: 212-639-8347. Lead organization: Memorial Sloan-

Kettering Cancer Center. Age range: over 18.

**FHCRC-1462.00, NCI-G00-1841** Phase II Study of Nonmyeloablative Allogeneic Peripheral Blood Stem Cell Transplantation With Fludarabine and Total Body Irradiation, Followed By Cyclosporine and Mycophenolate Mofetil, Followed By Donor Lymphocyte Infusion in Patients With Stage IV Melanoma

Chairperson: John A. Thompson. Telephone: 206-288-2041. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 18 to 64.

**UCCRC-10325, NCI-T99-0111, CWRU-1699** Phase II Study of O6-Benzylguanine and Carmustine in Patients With Unresectable Locally Recurrent or Metastatic Melanoma

Chairperson: Thomas F Gajewski. Telephone: 773-702-4601. Lead organization: University of Chicago Cancer Research Center. Age range: 18 and over.

**JHOC-98111005, NCI-T96-0116, JHOC-JH9875, JHOC-T96-0116** Phase II Study of Pyrazoloacridine in Patients With Metastatic Cutaneous or Ocular Melanoma

Chairperson: William Howard Sharfman. Telephone: 410-583-2970. Lead organization: Johns Hopkins Oncology Center. Age range: 18 and over.

**MSKCC-01005, NCI-G01-2031** Phase II Study of Temozolomide and Pegylated Interferon alfa in Patients With Advanced Melanoma

Chairperson: Wen-Jen Hwu. Telephone: 212-639-5096. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

**UTHSC-IDD-99-27, NCI-66, SACT-IDD-99-27** Phase II Study of Thalidomide and SU5416 in Patients With Metastatic Melanoma

Chairperson: Eric Keith Rowinsky. Telephone: 210-616-5945. Lead organization: University of Texas Health Science Center at San Antonio. Age range: 18 and over.

### Phase III

**E-1697** Phase III Randomized Adjuvant Study of High Dose Interferon Alfa-2b Therapy in Patients With Stage II and III Melanoma

Chairperson: Sanjiv S. Agarwala. Telephone: 412-648-6507. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**MDA-ID-95196, NCI-G96-1089, MDA-DM-95196** Phase III Randomized Adjuvant Study of Interferon Alfa-2b (IFN-A) Alone vs Biochemotherapy Using Cisplatin, Vinblastine, Dacarbazine (DTIC), IFN-A, and Interleukin-2 (IL-2) in Melanoma Patients With Regional Lymph Node Metastases

Chairperson: Agop Y. Bedikian. Telephone: 713-792-2921. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: 10 to 70.

**JWCI-MC-3-001A, NCI-V99-1576, CV-MMAIT-3-001** Phase III Randomized Study of BCG Plus a

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Polyvalent Melanoma Vaccine (CancerVax) Versus BCG Plus Placebo in Patients With Resected Stage III Melanoma

Chairperson: Donald L. Morton. Telephone: 310-829-8363. Lead organization: John Wayne Cancer Institute. Age range: 18 to 80.

**GENTA-GM301** Phase III Randomized Study of Dacarbazine With or Without Augmerosen in Patients With Advanced Malignant Melanoma

Chairperson: Stanley R. Frankel. Telephone: 908-286-9800. Lead organization: Genta Incorporated. Age range: any age.

**NCI-T98-0085, NCI-99-C-0051B** Phase III Randomized Study of High Dose Interleukin-2 With or Without gp100 Antigen in Patients With Metastatic Cutaneous Melanoma

Chairperson: Douglas Jay Schwartzentruber. Telephone: 301-496-2132. Lead organization: Center for Cancer Research. Age range: 18 and over.

**ACOSOG-Z0020** Phase III Randomized Study of Hyperthermic Isolated Limb Perfusion and Melphalan With or Without Tumor Necrosis Factor in Patients With Localized, Advanced, Extremity Melanoma

Chairperson: Douglas L. Fraker. Telephone: 215-662-7866. Lead organization: American College of Surgeons Oncology Group. Age range: 18 and over.

**JWCI-MC-4-001, NCI-G98-1492, CV-MMAIT-4-001, RPCI-DS-98-16** Phase III Randomized

Study of Immunotherapy With Polyvalent Melanoma Vaccine (CancerVax) Plus BCG Versus BCG Plus Placebo Following Surgery in Patients With Stage IV Melanoma

Chairperson: Donald L. Morton. Telephone: 310-829-8363. Lead organization: John Wayne Cancer Institute. Age range: 18 to 80.

**SWOG-S0008** Phase III Randomized Study of Interferon alfa Versus Cisplatin, Vinblastine, and Dacarbazine Plus Interferon alfa and Interleukin-2 in Patients With High-Risk Melanoma

Chairperson: Lawrence E. Flaherty. Telephone: 313-745-9155. Lead organization: Southwest Oncology Group. Age range: 18 and over.

**E-4697** Phase III Randomized Study of Sargramostim (GM-CSF) and Peptide Vaccination Comprised of Tyrosinase:368-376, gp100:209-217 Antigen, and MART-1:27-35 Peptide Versus Peptide Vaccination Alone Versus GM-CSF Alone Versus Placebo in Patients With Locally Advanced or Metastatic Melanoma

Chairperson: David H. Lawson. Telephone: 404-778-4189. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**UAB-9735, NCI-G99-1654, UAB-F970925009** Phase III Study of Adjuvant Interferon alfa-2b in Patients With Invasive Cutaneous Melanoma With Early Lymph Node Metastasis Detected By Intraoperative Lymphatic Mapping and Sentinel Lymph Node Biopsy

Chairperson: Marshall McLean Urist. Telephone: 205-934-3028.

Lead organization: University of Alabama at Birmingham Comprehensive Cancer Center. Age range: 18 to 70.

**E-E3695** Phase III Study of Cisplatin, Vinblastine, and Dacarbazine With or Without Interleukin-2 and Interferon alfa-2b in Patients With Metastatic Malignant Melanoma

Chairperson: Michael Benjamin Atkins. Telephone: 617-667-4599. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**Sunbelt Melanoma Trial (SMT):** A Multicenter Trial of Adjuvant Interferon Alfa-2b for Early Melanoma Nodal Metastasis Detected by Lymphatic Mapping and Sentinel Lymph Node Biopsy (Protocol #11497)

Chairperson: Kelly M. McMasters. Telephone: 502-852-5211. Lead organization: University of Louisville, James Graham Brown Cancer Center. Age range: any age.