Clinical Research Protocols: Clinical Research Protocols in Malignant Melanoma

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For more information on these protocols, please call PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER.

Adjuvant Trials

**NCI High-Priority Clinical Trial EST-1690** Phase III Study of Adjuvant Postoperative Interferon Alpha in Melanoma Patients at High Risk for Recurrence: High Dose for 1 Year vs Chronic Low Dose vs No Treatment (Summary Last Modified 07/94)


**ARG-CO/BR-1** Phase III Postsurgical Maintenance Immunotherapy With Corynebacterium Granulosum p40 for Patients With Colon and Breast Cancer and Melanoma Residual Following Surgery (Summary Last Modified 04/93)

Chairman: Hugo Omar De Carli, Centro Oncologico de Excelencia, Buenos Aires, Argentina. Lead Organization: Centro Oncologico de Excelencia. Acceptable age range: 20 to 80

**EORTC-18871** Phase III Randomized Study of Adjuvant Treatment With IFN-A vs IFN-G vs No Adjuvant Therapy in Patients With Resected High-Risk Stage IIIIB Malignant Melanoma (Summary Last Modified 06/88)


**EORTC-DKG-80-1** Phase III Randomized Trial of Adjuvant Treatment With IFN-A vs IFN-G vs Mistletoe Extract (Icador M) vs No Further Treatment Following Curative Resection of High-Risk Stage IIIIB Malignant Melanoma (Summary Last Modified 11/93)


**NCTCG-897051** Phase III Randomized Double-Blind Study of Postoperative Clinical Adjuvant Therapy With MEG vs Placebo in Patients With Poor-Profosis Stage III Malignant Melanoma (Summary Last Modified 03/94)

Chairman: Robert J. Dalton, Duluth Clinic, Duluth, Minn. Lead Organization: North Central Cancer Treatment Group. Acceptable age range: 18 and over

**RTOG-9002** Phase III Randomized Study of Postoperative Adjuvant Radiotherapy in Patients With Cutaneous Melanoma of the Head and Neck (Summary Last Modified 12/93)

Chairman: Robert M. Byers, M.D. Anderson Cancer Center, University of Texas, Houston, Tex. Lead Organization: Radiation Therapy Oncology Group. Acceptable age range: 18 and over

**SWOG-9003** Phase III Randomized Trial of Adjuvant Immunotherapy With an Allogeneic Melanoma Vaccine for Patients With Intermediate-Thickness, Node- Negative Malignant Melanoma (Summary Last Modified 03/95)

Chairman: Vernon K. Sondak, Taubman Medical Center, University of Michigan, Ann Arbor, Mich. Lead Organization: Southwest Oncology Group. Acceptable age range: 18 and over

Locally Advanced Disease Trials

**NCI-92-C-0105E, NCI-T91-0238** Phase III Randomized Study of Hyperthermic Isolated Limb Perfusion With L-PAM vs L-PAM/TNF/IFN-G in Patients With Stage IIIA/IIIB Malignant Melanoma Confined to an Extremity (Summary Last Modified 10/94)

Chairman: Douglas L. Fraser, Surgery Branch, COP, DCT, National Cancer Institute, Bethesda, Md. Lead Organization: Clinical Oncology Program. Acceptable age range: 18 and over

**MSKCC-94041, NCI-V94-04712** Phase II Pilot Study of Vaccination With GN2-KLH Plus QS211 in Stage III/IV Melanoma (Summary Last Modified 06/95)

Chairman: Paul B. Chapman, Memorial Sloan-Kettering Cancer Center, New York, NY. Lead Organization: Memorial Sloan-Kettering Cancer Center. Acceptable age range: no age specified

**MSKCC-94029, NCI-V94-0467** Phase I/II Study of Vaccination With Tyrosinase Peptides or Proteins or Tyrosinase-KLH Conjugate Plus QS-21 in High-Risk Stage III/IV Melanoma (Summary Last Modified 06/95)

Chairman: Alan N. Houghton, Jr., Memorial Sloan-Kettering Cancer Center, New York, NY. Lead Organization: Memorial Sloan-Kettering Cancer Center. Acceptable age range: no age specified

**MSKCC-94078, NCI-V94-0538** Phase I/II Pilot Study of Anti-Idiotypic MOAD BEC2 Conjugated to KLH Plus BCG as Adjuvant in Completely Resected Melanoma (Summary Last Modified 03/95)

Chairman: Paul B. Chapman, Memorial Sloan-Kettering Cancer Center, New York, NY. Lead Organization: Memorial Sloan-Kettering Cancer Center. Acceptable age range: 18 and over

**METASTATIC DISEASE TRIALS**

**MSKCC-91140, NCI-V92-0030, UPCC-2691** Phase III Randomized Study of CDDP/DTIC/BCNU/TMX vs DTIC Alone in Patients With Advanced Melanoma (Summary Last Modified 06/95)
Chairman: Michael L. Meyers, Memorial Sloan-Kettering Cancer Center, New York, NY. Lead Organization: Memorial Sloan-Kettering Cancer Center. Acceptable age range: 18 and over

Phase III Randomized Comparison of CVD (CDDP/VBL/DTIC) vs DTIC Alone in Patients With Metastatic Melanoma (Last Modified 09/93)

Chairman: Sewa Singh Legha, M.D. Anderson Cancer Center, University of Texas, Houston, Tex. Lead Organization: M.D. Anderson Cancer Center, University of Texas. Acceptable age range: 16 to 80

Phase III Randomized Study of CDDP/BCNU/DTIC With vs Without TMX in Patients With Advanced Malignant Melanoma (Summary Last Modified 09/94)

Chairman: Robert J. Dalton, Duluth Clinic, Duluth, Minn. Lead Organization: North Central Cancer Treatment Group. Acceptable age range: 18 and over

Phase II Study of TMX/CDDP/DTIC/IFN-A Followed by TIL/IL-2 in Patients With Metastatic Malignant Melanoma Who Have Not Previously Received CDDP/DTIC, IFN-A or IL-2 Systemically (Summary Last Modified 06/95)

Chairman: Steven A. Rosenberg, Surgery Branch, COP, DCT, National Cancer Institute, Bethesda, Md. Lead Organization: Clinical Oncology Program. Acceptable age range: 18 and over

Phase II Study of Phenylacetate by 6-Day Continuous Infusion for Metastatic Melanoma (Summary Last Modified 01/95)


Phase II Study of IMRT/CT in Patients With Metastatic Renal Cell Carcinoma and Melanoma (Summary Last Modified 06/95)

Chairman: Robert O. Dillman, Hoag Memorial Hospital Presbyterian, Hoag Cancer Center, Newport Beach, Calif. Lead Organization: National Biotherapy Study Group. Acceptable age range: 18 and over

Phase II Study of BCNU/DTIC/IFN-A/IL-2/TMX Followed by IFN/A or IL-2 for Advanced Melanoma (Summary Last Modified 04/95)


Phase II Combination Chemotherapy With CCNU/TG/PCB/DD followed by 5-FU/HU for Brain Metastases From Adenocarcinomas of the Breast and Colon, Melanoma, and Germ Cell Tumors (Summary Last Modified 01/95)

Chairman: Victor Alan Levin, M.D. Anderson Cancer Center, University of Texas, Houston, Tex. Lead Organization: M.D. Anderson Cancer Center, University of Texas. Acceptable age range: 16 and over

Phase II Study of Taxotere in Patients With Advanced Melanoma Previously Untreated With Cytotoxic Chemotherapy (Summary Last Modified 06/93)

Chairman: Avi Israel Einzig, Jack D. Weiler Hospital of the Albert Einstein College of Medicine, Bronx, NY. Lead Organization: Albert Einstein Cancer Research Center. Acceptable age range: 18 and over

Phase II Evaluation of IL-1A, Indomethacin and VP-16 in Patients With Metastatic Malignant Melanoma (Summary Last Modified 06/93)

Chairman: Langdon L. Miller, Biological Response Modifiers Program, National Cancer Institute, Frederick, Md. Lead Organization: Biological Response Modifiers Program. Acceptable age range: 18 and over

Phase II Randomized Study of TMX/CDDP/DTIC With or Without IFN-A/IL-2 in Patients With Metastatic Melanoma (Summary Last Modified 06/95)

Chairman: Steven A. Rosenberg, Surgery Branch, COP, DCT, National Cancer Institute, Bethesda, Md. Lead Organization: Clinical Oncology Program. Acceptable age range: 18 and over

Phase II Study of Immunomodulation Using Indomethacin With TIL/IL-2/CTX or With LAK/IL-2 for Advanced Melanoma (Summary Last Modified 09/94)


Phase II Study of TMX/CDDP/DTIC/IFN-A Followed by TIL/IL-2 for Advanced Melanoma (Summary Last Modified 03/95)


Phase II Study of the Antitumor Efficacy of In Vitro-Sensitized Lymphocytes Harvested from Tumor Vaccine-Draining Lymph Nodes Plus IL-2 in Patients With Metastatic or Recurrent Melanoma or Renal Cell Carcinoma (Summary Last Modified 07/95)

Chairman: Theodore F. Logan, University of Pittsburgh School of Medicine, Pittsburgh, Pa. Lead Organization: University of Pittsburgh Cancer Institute. Acceptable age range: 18 and over

Phase II Study of Phenylacetate by 6-Day Continuous Infusion for Metastatic Melanoma (Summary Last Modified 01/95)
Phase II Study of IFN-A/Hydralazine in Patients With Metastatic Renal Cell Carcinoma or Metastatic Melanoma (Summary Last Modified 04/93)

Chairman: Marc Stuart Earnst, Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, Lebanon, NH. Lead Organization: Norris Cotton Cancer Center. Acceptable age range: over 18

Phase II Study of 6-Thioguanine in Patients With Metastatic Melanoma (Summary Last Modified 01/91)

Chairman: Jamie Hayden Von Roenn, Northwestern University Oncology Center, Chicago, Ill. Lead Organization: Illinois Cancer Center Closeout Project. Acceptable age range: any age

Phase II Study of Autologous Tumor Cell Vaccine Therapy Followed by Adoptive Immunotherapy With Peripheral Blood Mononuclear Cells/IL-2 for Stage IV Melanoma (Summary Last Modified 07/94)

Chairman: Gary W. Wood, University of Kansas Medical Center, Kansas City, Kan. Lead Organization: University of Kansas Medical Center. Acceptable age range: 18 and over

Phase II Study of BSO/L-PAM in Patients With Metastatic Cutaneous Melanoma (Summary Last Modified 07/94)

Chairman: Gerald Batist, Jewish General Hospital, Montreal, Quebec, Canada. Lead Organization: McGill University Department of Oncology. Acceptable age range: 18 and over

Phase II Randomized Study of TMX/CDDP/DTC With or Without IFN-A/IL-2 in Patients With Metastatic Melanoma (Summary Last Modified 05/95)

Chairman: Steven A. Rosenberg, Surgery Branch, COP, DCT, National Cancer Institute, Bethesda, Md. Lead Organization: Clinical Oncology Program. Acceptable age range: 18 and over

Phase II Study of Immune Stimulation by Infusion of Autologous Buffy Coat Cells Treated With Methoxsalen and Ultraviolet Radiation in Patients With Metastatic Melanoma, Renal Cell Carcinoma or Nonsmall Cell Lung Cancer (Summary Last Modified 04/95)

Chairman: John R. Murren, Yale Comprehensive Cancer Center, New Haven, Conn. Lead Organization: Yale Comprehensive Cancer Center. Acceptable age range: over 18

Phase IB Study of Anti-CD3 MOAB OKT 3 Plus IL-2 for Metastatic Melanoma and Other Malignancies (Summary Last Modified 03/95)

Chairman: Barry L. Gause, Outpatient Clinic, BRMP, National Cancer Institute, Frederick, Md. Lead Organization: Biological Response Modifiers Program. Acceptable age range: 18 and over

Phase I Study of Intravenous BSO, Administered as an Initial Bolus Followed by a 24- to 48-Hour Continuous Infusion, Given With Intravenous L-PAM in Patients With Advanced Malignancies Including Melanoma and Ovarian Epithelial Cancer (Summary Last Modified 12/93)


Phase I Study of NG-Monomethyl-L-Arginine for IL-2-Induced Hypotension in Patients With Metastatic Melanoma (Summary Last Modified 08/95)

Chairman: David R. Parkinson, Cancer Therapy Evaluation Program, DCT, National Cancer Institute, Bethesda, Md. Lead Organization: Clinical Oncology Program. Acceptable age range: 18 and over

Phase I Study of Immunization With a MAGE-3 Vaccine Consisting of Cytolytic and Helper T Cell Peptides in HLA-A1-Positive Patients With Resectable Stage III/IV Melanoma (Summary Last Modified 07/95)

Chairman: Jeffrey S. Weber, USC/Norris Comprehensive Cancer Center, University of California School of Medicine, Los Angeles, Calif. Lead Organization: USC/Norris Comprehensive Cancer Center. Acceptable age range: 18 and over

Phase I Study of Chimeric MOAB 14.18 Plus GM-CSF for Metastatic Melanoma (Summary Last Modified 05/95)

Chairman: J. Lee Murray, M.D. Anderson Cancer Center, University of Texas, Houston, Tex. Lead Organization: M.D. Anderson Cancer Center, University of Texas. Acceptable age range: 18 to physiologic 70

Legend for Abbreviations:

AECM = Albert Einstein College of Medicine
ARG-CO = Centro Oncologico de Excelencia, Argentina
BRMP = Biological Response Modifiers Program
DMS = Dartmouth-Hitchcock Medical Center
EORTC = European Organization for Research on Treatment of Cancer
EST = Eastern Cooperative Oncology Group
ICC = Illinois Cancer Center
KUMC = University of Kansas Medical Center
LAC-USC = University of Southern California-Norris Comprehensive Cancer Center
MCGIll = McGill University Department of Oncology
MDA = M.D. Anderson Cancer Center
MSKCC = Memorial Sloan-Kettering Cancer Center
NBGS = National Biotherapy Study Group
NCCCG = North Central Cancer Treatment Group
NCI = National Cancer Institute
NYU = Kaplan Comprehensive Cancer Center