



This list of clinical research protocols relating to myeloma and gefitinib 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://www.cancer.gov/clinical_trials.

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

SELECTED CLINICAL RESEARCH PROTOCOLS RELATING TO MYELOMA AND GEFITINIB

Phase I/II

MSGCC-0065, NCI-V02-1709, UPCC-6401 Phase I/II Randomized Study of High-Dose Therapy and Autologous Peripheral Blood Stem Cell Transplantation Followed by Immunotherapy With Costimulated Autologous T Cells Plus Pneumococcal Conjugate Vaccine in Patients With Multiple Myeloma
Chairperson: Aaron Rapoport, MD. Telephone: 410-328-1230. Lead organization: Marlene and Stewart Greenebaum Cancer Center, University of Maryland. Age range: 18 to 80.

FHCRC-1743.00 Phase I/II Study of Allogeneic Hematopoietic Stem Cell Transplantation in Patients With Previously Treated Multiple Myeloma
Chairperson: Marco Mielcarek, MD. Telephone: 206-667-2827. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 18 to 70.

SCCC-20010, NCI-43, SCCC-NCI-43 Phase I/II Study of Arsenic Trioxide Plus Ascorbic Acid in Patients With Recurrent or Refractory Multiple Myeloma
Chairperson: Kelvin Lee, MD. Telephone: 305-243-4387. Lead organization: Sylvester Cancer Center, University of Miami. Age range: over 18.

CWRU-PHAR-1A02, PHAR-MACIA-196-ONC-0100-006 Phase I/II Study of Brostallicin in Patients With Recurrent or Refractory Multiple Myeloma
Chairperson: Hillard Lazarus, MD. Telephone: 216-844-3629; 1-

800-641-2422. Lead organization: Ireland Cancer Center. Age range: 18 and over.

NEORX-0102, FHCRC-1704.00 Phase I/II Study of Holmium Ho 166 DOTMP With Melphalan and Peripheral Blood Stem Cell Support in Patients With Multiple Myeloma
Chairperson: Richard Ghalie, MD. Telephone: 206-281-7001, ext. 502. Lead organization: NeoRx. Age range: 18 to 70.

JHOC-J0115, JHOC-K0007, JHOC-01011706, NCI-G01-2020 Phase I/II Study of Induction Chemotherapy Followed by Autologous Tumor Cell Vaccine and Autologous Peripheral Blood Stem Cell Transplantation in Patients With Multiple Myeloma
Chairperson: Ivan Borrello, MD. Telephone: 410-955-8964. Lead organization: Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. Age range: 18 to 70.

NCI-00-C-0201, NCI-1029 Phase I/II Study of Purified Myeloma Protein Immunization in Sibling Peripheral Blood Stem Cell (PBSC) Donors and in Patients With Multiple Myeloma Who Are Undergoing Nonmyeloablative Chemotherapy and HLA-Matched Allogeneic PBSC Transplantation
Chairperson: Sattva Neelapu, MD. Telephone: 301-846-1321. Lead organization: Center for Cancer Research. Age range: 18 to 75.

Phase II

RPCI-RP-0215 Phase II Pilot Study of Vincristine, Doxorubicin,

Dexamethasone, and Low-Dose Thalidomide in Patients With Newly Diagnosed Stage I, II, or III Multiple Myeloma

Chairperson: Asher Chanan-Khan, MD. Telephone: 716-845-1348; 1-800-767-9355. Lead organization: Roswell Park Cancer Institute. Age range: 18 and over.

MAYO-979202, NCI-P00-0163 Phase II Randomized Chemoprevention Study of Dehydroepiandrosterone (DHEA) Versus Clarithromycin in Patients With Monoclonal Gammopathy of Undetermined or Borderline Significance

Chairperson: John A. Lust, MD, PhD. Telephone: 507-284-2511. Lead organization: Mayo Clinic Cancer Center. Age range: 18 and over.

CHNMC-PHII-30, CHNMC-IRB-01006, NCI-2712 Phase II Randomized Study of Bevacizumab With or Without Thalidomide in Patients With Relapsed or Refractory Multiple Myeloma

Chairperson: George Somlo, MD. Telephone: 626-359-8111; 1-800-826-4673. Lead organization: City of Hope Comprehensive Cancer Center. Age range: 18 and over.

UMN-MT-9216, UMN-MT-1992-16 Phase II Randomized Study of Filgrastim (G-CSF) Versus Sargramostim (GM-CSF) Plus High-Dose Chemotherapy Followed by Autologous Peripheral Stem Cell Transplantation Followed by Interferon alfa in Patients With Multiple Myeloma

Chairperson: Daniel Weisdorf, MD. Telephone: 612-626-8484; 1-888-226-2376. Lead organization:

University of Minnesota Cancer Center. Age range: 70 and under.

CTI-1060, MSKCC-01012, NCI-G01-1951 Phase II Study of Arsenic Trioxide and Dexamethasone in Patients With Recurrent or Refractory Stage II or III Multiple Myeloma

Chairperson: Scott Stromatt, MD. Telephone: 206-272-4355. Lead organization: Cell Therapeutics, Inc. Age range: over 18.

FHCRC-1461.00, NCI-G00-1845 Phase II Study of Autologous or Syngeneic Peripheral Blood Stem Cell Transplantation, Melphalan, and Interleukin-2 Followed by Interferon Alfa in Patients With Advanced Multiple Myeloma

Chairperson: Leona Holmberg, MD, PhD. Telephone: 206-667-6447. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 18 to 69.

CLB-100001 Phase II Study of Autologous Peripheral Blood Stem Cell (PBSC) Transplantation Followed by Non-Myeloablative Allogeneic PBSC Transplantation in Patients With Multiple Myeloma

Chairperson: Kenneth Anderson, MD. Telephone: 617-632-2144. Lead organization: Cancer and Leukemia Group B. Age range: under 65.

MAYO-MC018B, NCI-5758 Phase II Study of Flavopiridol in Patients With Relapsed or Refractory Multiple Myeloma

Chairperson: Angela Dispenzieri, MD. Telephone: 507-284-2511. Lead organization: Mayo Clinic Cancer Center. Age range: 18 and over.

CPMC-CAMP-009, CPMC-IRB-7328, NCI-G00-1882 Phase II Study of High-Dose Chemotherapy With Autologous Hematopoietic Stem Cell Support in Patients With Multiple Myeloma or Primary Systemic Amyloidosis

Chairperson: Charles Hesdorfer, MD. Telephone: 212-305-9327. Lead organization: Herbert Irving Comprehensive Cancer Center. Age range: 18 and over.

TUHSC-2797, NCI-V96-0951 Phase II Study of High-Dose Melphalan Followed by Autologous Peripheral Blood Stem Cell Transplantation in Primary Amyloidosis or Amyloidosis Secondary to Multiple Myeloma

Chairperson: Kenneth Mangan, MD. Telephone: 215-707-2847. Lead organization: Fox Chase - Temple Cancer Center. Age range: 16 to 65.

MSKCC-00067, NCI-G00-1895 Phase II Study of Melphalan and Filgrastim (G-CSF) for Peripheral Blood Stem Cell Mobilization in Patients With Multiple Myeloma

Chairperson: Raymond L. Comenzo, MD. Telephone: 212-639-8086. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

CWRU-1A96, NCI-T97-0021 Phase II Study of O6-Benzylguanine Combined With Carmustine in Patients With Previously Untreated or Refractory Multiple Myeloma

Chairperson: Stanton L. Gerson, MD. Telephone: 216-844-5432; 1-800-641-2422. Lead organization: Ireland Cancer Center. Age range: not specified.

MSGCC-210421, NCI-5824 Phase II Study of Oblimersen, Thalidomide, and Dexamethasone in Patients With Relapsed or Refractory Multiple Myeloma

Chairperson: Ashraf Brados, MD. Telephone: 410-328-1230. Lead organization: Marlene and Stewart Greenebaum Cancer Center, University of Maryland. Age range: 18 and over.

CHNMC-IRB-99021, NCI-G99-1583 Phase II Study of Sequential High Dose Melphalan, Busulfan, and Cyclophosphamide Followed by Peripheral Blood Stem Cell Rescue, Interferon Alfa, Pamidronate, and Thalidomide in Patients With Multiple Myeloma

Chairperson: George Somlo, MD. Telephone: 626-359-8111; 1-800-826-4673. Lead organization: City of Hope Comprehensive Cancer Center. Age range: 65 and under.

SWOG-S0204 Phase II Study of Thalidomide and Dexamethasone Induction Followed by Tandem Melphalan and Peripheral Blood Stem Cell Transplantation Followed by Prednisone and Thalidomide Maintenance in Patients With Multiple Myeloma

Chairperson: Mohamad Ahmed Hussein, MD. Telephone: 216-445-6830. Lead organization: Southwest Oncology Group. Age range: 18 to 66.

CAN-NCIC-IND145, ZENECA-6474IL/0004 Phase II Study of ZD6474 in Patients With Relapsed Multiple Myeloma

Chairperson: Michael Kovacs, MD. Telephone: 519-685-8500, ext.

55182. Lead organization: NCIC-Clinical Trials Group. Age range: 18 and over.

Phase III

MILLENNIUM-M34101-039, FHCRC-1746.00, NCI-G02-2130 Phase III Randomized Study of Bortezomib Versus High-Dose Dexamethasone in Patients With Relapsed or Refractory Multiple Myeloma

Chairperson: Denise Collins. Telephone: 866-835-2233. Lead organization: Millennium Pharmaceuticals Inc. Age range: 18 and over.

GENTA-GMY302, UF-G-29-2001 Phase III Randomized Study of Dexamethasone With or Without Oblimersen in Patients With Relapsed or Refractory Multiple Myeloma

Chairperson: Stanley Frankel, MD. Telephone: 908-286-9800. Lead organization: Genta Inc. Age range: 18 and over.

CKVO-2001-02, EU-20133, HOVON-50MM, HOVON-CKVO-2001-02 Phase III Randomized Study of Doxorubicin, Dexamethasone, and High-Dose Melphalan With or Without Thalidomide in Patients With Multiple Myeloma

Chairperson: H. Lokhorst, MD. Telephone: +30-250-7230. Lead organization: Commissie Voor Klinisch Toegepast Onderzoek. Age range: 18 to 65.

WSLG-H31, EU-20032 Phase III Randomized Study of Induction Therapy Comprised of Idarubicin

and Dexamethasone vs Vincristine, Doxorubicin, and Dexamethasone in Patients With Multiple Myeloma

Chairperson: Gordon Cook, MD. Telephone: +44-1236-748-748. Lead organization: West of Scotland Lymphoma Group. Age range: 75 and under.

CAN-NCIC-MY7, NCI-V95-0713 Phase III Randomized Study of Melphalan Combined With Dexamethasone or Prednisone as Induction Therapy With or Without Dexamethasone as Maintenance Therapy in Patients With Previously Untreated Stage I-III Multiple Myeloma

Chairperson: Chaim Shustik, MD. Telephone: 514-398-1444. Lead organization: NCIC-Clinical Trials Group. Age range: 18 and over.

CAN-NCIC-MY10 Phase III Randomized Study of Thalidomide and Prednisone as Maintenance Therapy After Autologous Stem Cell Transplantation in Patients With Multiple Myeloma

Chairperson: Keith Stewart, MD. Telephone: 416-946-4566. Lead organization: NCIC-Clinical Trials Group. Age range: 16 and over.

NU-97H6T, NCI-G99-1632 Phase III Study of High Dose Melphalan Followed by Peripheral Blood Stem Cell Transplantation as Standard Therapy in Patients With Symptomatic Multiple Myeloma

Chairperson: Ann Traynor, MD. Telephone: 312-908-0059. Lead organization: Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Age range: not specified.

URCC-U10994, NCI-C95-0001, NCI-P96-0073, URCC-10994P(M), URCC-URRSRB-6993

Randomized Study of Co-Trimoxazole Versus Ciprofloxacin or Ofloxacin Versus No Prophylaxis for the Prevention of Early Infection in Patients With Multiple Myeloma

Chairperson: Jane T. Hickok, MD, MPH. Telephone: 585-275-5513. Lead organization: James P. Wilmot Cancer Center. Age range: any age.

Gefitinib (Iressa, ZD1839)

UCHSC-01460, NCI-4551
Phase I Study of Gefitinib and Radiotherapy With or Without Cisplatin in Patients With Locally Advanced Squamous Cell Carcinoma of the Head and Neck

Chairperson: David Raben, MD. Telephone: 720-848-0100. Lead organization: University of Colorado Cancer Center. Age range: 18 and over.

UCHSC-01479, NCI-3858
Phase I Study of Gefitinib, Capecitabine, and Celecoxib in Patients With Advanced Solid Tumors

Chairperson: Michele Basche, MD. Telephone: 720-848-0300; 1-800-473-2288. Lead organization: University of Colorado Cancer Center. Age range: 18 and over.

NABTC-0102 Phase I Study of ZD 1839 and Temozolomide in Patients With Malignant Primary Glioma

Chairperson: Michael Del Prados, MD. Telephone: 415-353-2966.

Lead organization: North American Brain Tumor Consortium. Age range: 18 and over.

UAB-0162, AVENTIS-GIA-12139, ZENECA-ZD1839US-0207

Phase I/II Randomized Study of Neoadjuvant Chemoradiotherapy With or Without Gefitinib in Patients With Stage IIIA or Stage IIIB Non-Small Cell Lung Cancer

Chairperson: Francisco Robert, MD, FACP. Telephone: 205-934-5077; 1-800-822-0933. Lead organization: University of Alabama at Birmingham Comprehensive Cancer Center. Age range: 19 and over.

PBTC-007 Phase I/II Study of Gefitinib and Brain Irradiation in Children With Newly Diagnosed Brain Stem Tumors or Incompletely Resected Supratentorial Malignant Gliomas

Chairperson: J. Russell Geyer, MD. Telephone: 206-987-6664. Lead organization: Pediatric Brain Tumor Consortium. Age range: 3 to 21.

NABTC-0001 Phase I/II Study of Gefitinib in Patients With Recurrent or Progressive Supratentorial Malignant Gliomas or Brain or Spinal Meningiomas

Chairperson: Frank Scott Lieberman, MD. Telephone: 412-692-2600; 1-800-237-4724. Lead organization: North American Brain Tumor Consortium. Age range: 18 and over.

NCI-02-C-0303, NCI-5561
Phase II Pilot Study of Gefitinib in Patients With Ovarian Epithelial Cancer or Cervical Cancer

Chairperson: Mahrukh Husain, MD. Telephone: 301-435-0591.

Lead organization: Center for Cancer Research. Age range: 18 and over.

E-4101 Phase II Randomized Study of Anastrozole and Gefitinib Versus Fulvestrant and Gefitinib in Postmenopausal Women With Recurrent or Metastatic Hormone Receptor-Positive Breast Cancer

Chairperson: Robert Carlson, MD. Telephone: 650-723-7621. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

CTRC-IDD-0219, CTRC-IDD-0228, CTRC-IDD-1839US

Phase II Study of Anastrozole and ZD 1839 in Post-Menopausal Women With Estrogen Receptor-Positive, Hormone Refractory, Metastatic Breast Cancer

Chairperson: Johann Sebastian de Bono, MD. Telephone: 210-616-5970. Lead organization: Institute for Drug Development. Age range: 18 and over.

NCCTG-N0222 Phase II Study of Gefitinib Alone or With Carboplatin and Paclitaxel in Older Patients With Unresectable or Metastatic Non-Small Cell Lung Cancer

Chairperson: Aminah Jatoi, MD. Telephone: 507-284-2511. Lead organization: North Central Cancer Treatment Group. Age range: 65 and over.

EORTC-62022 Phase II Study of Gefitinib in Patients With Locally Advanced or Metastatic Synovial Sarcoma Expressing HER1

Chairperson: Jean-Yves Blay, MD, PhD. Telephone: +33-7878-

2828. Lead organization: EORTC Soft Tissue and Bone Sarcoma Group. Age range: 18 and over.

GOG-0229C Phase II Study of Gefitinib in Patients With Persistent or Recurrent Endometrial Carcinoma
Chairperson: Kimberly Leslie, MD. Telephone: 505-272-6386. Lead organization: Gynecologic Oncology Group. Age range: 18 and over.

UUMC-8429-01, NCI-1701 Phase II Study of Gefitinib in Patients With Recurrent and/or Metastatic Squamous Cell Cancer of the Head and Neck

Chairperson: Richard Wheeler, MD. Telephone: 801-585-0601; 1-877-585-0303. Lead organization: Huntsman Cancer Institute. Age range: 18 and over.

SWOG-S0126 Phase II Study of Gefitinib in Patients With Stage IIIB or IV Bronchoalveolar Carcinoma
Chairperson: Howard West, MD. Telephone: 206-386-2424. Lead organization: Southwest Oncology Group. Age range: 18 and over.

UPCC-06202, NCI-5894 Phase II Study of Gefitinib, Fluorouracil, Leucovorin Calcium, and Irinotecan in Patients With Advanced or Recurrent Colorectal Cancer
Chairperson: Peter J. O'Dwyer, MD, BCh. Telephone: 215-662-8636. Lead organization: Abramson Cancer Center of the University of Pennsylvania. Age range: 18 and over.

SUMC-670, NCI-4370 Phase II Study of Gefitinib, Oxaliplatin, Fluorouracil, and Leucovorin Calcium in Patients With Advanced Solid Tumors or Colorectal Adenocarcinoma

Chairperson: Branimir Ivan Sikic, MD. Telephone: 650-723-7688. Lead organization: Stanford University Medical Center. 18 and over.

CLB-30106 Phase II Study of Paclitaxel, Carboplatin, and Gefitinib Followed by Radiotherapy With or Without Paclitaxel and Carboplatin Followed by Gefitinib in Patients With Stage III Non-Small Cell Lung Cancer

Chairperson: Neal Ready, MD. Telephone: 401-444-5391. Lead organization: Cancer and Leukemia Group B. Age range: 18 and over.

E-1100 Phase II Study of Trastuzumab (Herceptin) and Gefitinib in Patients With Metastatic Breast Cancer That Overexpresses HER2-neu

Chairperson: Carlos Arteaga, MD. Telephone: 615-936-1782; 1-800-811-8480. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

DUMC-2421-03-2R2, NCI-1253 Phase II Study of ZD 1839 in Patients With Glioblastoma Multiforme in First Relapse

Chairperson: Henry S. Friedman, MD. Telephone: 919-684-3377. Lead organization: Duke Comprehensive Cancer Center. Age range: 18 and over.

CAN-NCIC-BR19, CTSU, E-CAN-NCIC-BR19, SWOG-CAN-NCIC-BR19 Phase III Randomized Study of Adjuvant Gefitinib in Patients With Completely Resected Primary Stage IB, II, or IIIA Non-Small Cell Lung Cancer

Chairperson: Timothy Winton,

MD. Telephone: 780-407-3624. Lead organization: NCIC-Clinical Trials Group. Age range: 18 and over.

SWOG-S0023, CAN-NCIC-BR.15, CTSU, NCCTG-S0023 Phase III Randomized Study of Cisplatin, Etoposide, Radiotherapy, and Docetaxel With or Without Gefitinib in Patients With Unresectable Stage III Non-Small Cell Lung Cancer

Chairperson: Karen Kelly, MD. Telephone 303-315-8801; 800-473-2288. Lead organization: Southwest Oncology Group. Age range: not specified.