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THE MDS NEWS

The Newsletter of The Myelodysplastic Syndromes Foundation

A Phoenix? Thalidomide Returns As An Exciting Investigational Therapy for MDS

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Enrollment is on-going for a Phase III clinical trial of the safety and efficacy of thalidomide (Thalomid®) for the treatment of anemia associated with myelodysplastic syndromes (MDS). Thalidomide, you say? That's right, thalidomide may be rising from the ashes of its tragic youth, with its safety profile now well understood and with exciting early results for treating MDS. Indeed, thalidomide is beginning its ascent towards being an approved treatment option for MDS patients.

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The Daunting Old News

Beginning in 1956 in Europe, thalidomide was used as a sedative for treatment of anxiety and insomnia as well as a treatment for nausea and vomiting associated with pregnancy. Within a few short years following its introduction, this drug was known to cause severe birth defects and death of the unborn when administered to pregnant women. In the United States, thalidomide had not been approved for clinical use but the unanticipated effects on the unborn was a stimulus for improved testing of fetoxic and developmental effects of drugs.

The Current Indicated Use

During its early years, thalidomide was observed to successfully treat the painful skin nodules of erythema nodosum leprosum (ENL), a complication of leprosy. These nodules form as small blood vessels become blocked and, if untreated, ultimately lead to loss of feeling and paralysis. Because of the need for treatment and maintenance therapy of these lesions, thalidomide capsules received government approval in 1998 for these limited uses; these are the only uses currently approved for thalidomide. Concurrent with the approvals for treatment of ENL, a System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) was developed and approved by the Food and Drug Administration.

Managing Side Effects

S.T.E.P.S. is a restricted distribution system which requires strict adherence to a well-developed education and safety program. The program includes initial and scheduled pregnancy testing (when applicable), contraception counseling, patient and physician registration, and patient and physician phone surveys at the time of each new prescription. Only registered physicians and pharmacists can prescribe and dispense thalidomide to registered patients and each prescription is limited to a one-month supply. While this education and safety program is unique and may seem cumbersome, S.T.E.P.S. quickly becomes a familiar task to the patient and prescriber. Most importantly, compliance with S.T.E.P.S. is essential for prevention of birth defects.

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In contrast to the effects on the unborn, side effects experienced by the patient are dose-dependent and, for the most part, are reversible when treatment with thalidomide is discontinued. These effects include drowsiness, skin rashes, decreased white cell counts, sudden dizziness upon standing, constipation, and swelling of the lower extremities. The exceptions to reversibility may include peripheral neuropathy which begins as numbness and tingling of the toes and fingers and, rarely, a potentially fatal skin disorder known as Stevens-Johnson syndrome.

Broad Uses and Activity

Thalidomide has potential uses in inflammatory and autoimmune disorders and in various forms of cancer. Disorders include rheumatoid arthritis, lupus, inflammatory bowel disease, macular degeneration, Behcet disease, Crohn disease, graft-vs-host disease, and cachexia (weight loss and wasting) and painful lesions associated with AIDS. Investigations are ongoing for the benefit of thalidomide in treating various types of cancers as well as for treating MDS. Certainly, thalidomide has proven effective in treating refractory multiple myeloma.[1-3]

The broad scope of activity may reflect complexity in the mechanism(s) of action. One possible mechanism is down-regulation of the cytokine TNF-α, a protein (alternatively known as cachectin) which normally is found at very low levels. When overproduced, TNF-α causes inflammatory responses and premature cell death (apoptosis). Thalidomide inhibits production of TNF-α and may also affect the levels of other cytokines, such as transforming growth factor beta (TGF-ß), and growth factors which regulate apoptosis.[4-8]

A second mechanism by which thalidomide may effectively treat cancers is through anti-angiogenesis. Angiogenesis is the growth of new blood vessels and is a necessary function of normal body development and repair. Growth of new blood vessels is also a fundamental need for expansion of tumors. Thalidomide has been shown to slow the development of new blood vessels by inhibiting vascular endothelial growth factor (VEGF) and basic fibroblast growth factor (bFGF).[9-10]

Finally, thalidomide is known to also have immune-modulating activity.[11-15] For example, expression of cell adhesion molecules on endothelial cells is suppressed by thalidomide.[16] Indeed, if changes in types of immune cells and their frequency is a mechanism of action of thalidomide, this drug may differ considerably from current cancer drugs, most of which exert a cytotoxic effect on immune cells.

Utility for Treating MDS

In MDS, overproduction of TNF-α increases apoptosis of bone marrow cells, with apoptotic cells occurring more frequently in early-stage MDS.[17-18] Recent research has also shown that small blood vessels located in the bone marrow may also be found at increased density in MDS and AML patients;[19-20] this form of angiogenesis may benefit survival of the malignant cells and, as a result, further increase the production of cytokines.[19-22] Thus, both the down-regulation of TNF-α overproduction and inhibition of growth factors promoting angiogenesis are possible mechanisms by which thalidomide exerts therapeutic activity in MDS. However, clinical evidence supporting these mechanisms of action remains elusive,[23-24] clearly showing further study is needed to elucidate the activity of thalidomide in MDS.

Clinical trials of thalidomide for treatment of MDS have been limited in number but the results have been impressive for some patients. Within several weeks to months of initiating treatment, hemoglobin levels have increased in many treated patients, to the point that a subset of responders became transfusion independent. In a study of 83 patients where 51 were evaluable, 21 (41%) of the patients treated with

Be a Bone Marrow Donor

For those patients diagnosed with a fatal blood disorder, bone marrow transplantation (BMT) is often the only chance of survival. Related donors provide suitable matches only 33 percent of the time. This leaves nearly 70 percent of patients without a match. The need is especially critical in racial and ethnic minority groups.

Registering as a donor is simple. A blood sample is all you need to enter your tissue type into the National Marrow Donor Program (NMDP) computerized registry. If you are in good health and between the ages of 18 and 55, you can contact NMDP at 1-800-MARROW-2. They will send additional information, including the NMDP center nearest you. Give the Gift of Life!

thalidomide experienced partial remission (mostly patients with early-stage MDS) with eight achieving transfusion independence. Platelet counts also increased in some patients.[25] In another study, where eight of nine patients were evaluable, six responded to thalidomide with three of these becoming transfusion independent and two having resolved neutropenias.[26] Hematologic improvements have been noted in some late-stage patients who had previously been in remission but otherwise benefits for patients with poor-prognosis MDS generally have been less frequent.[26-27] Yet, in a recent study[28] three of five patients initially classified as RAEB-T showed partial remissions and one RAEB-T patient and one of three CMML patients experienced major hematologic improvement, with all five of these responders becoming platelet and transfusion independent. (It is important to note that the other 2 CMML patients experienced progressive MDS.) Finally, for a group of 30 patients classified with early-stage MDS, ten responded (increases in hemoglobin and platelet count) to thalidomide with eight having major responses. Six of these responders became transfusion independent and responses were maintained for more than one year in four of these patients.[24] Thus, while more clinical trials and much more study are needed, thalidomide has the potential of providing excellent therapeutic activity for many MDS patients. The challenge remains to determine which patients will most likely benefit from thalidomide treatment.

Perhaps thalidomide will rise again but this time will rise as a carefully managed tool for hematologic improvement for MDS patients. Also on the horizon with thalidomide are two of its analogues: Revimid and CC1088. These agents, which are in Phase II clinical trials, may prove to have enhanced safety and greater efficacy.

For further information on the thalidomide, Revimid, and CC1088 trials, contact Dr. Robert Knight, Director of Medical Development for Celgene Corporation, at 732-805-3749.

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Erik Johnson Memorial

A memorial fund has been established by the Myelodysplastic Syndromes Foundation in the name of Erik Johnson. Contributions may be sent to the Foundation with a notation designating the *Erik Johnson Memorial Fund.*

MDS Patient Registry

Pharmacia generously provided an unrestricted grant to help support the Myelodysplastic Syndromes Foundation's Patient Registry. The Foundation gratefully acknowledges this support and looks forward to building the Patient Registry with our Centers of Excellence. The Patient Registry will help further research into the treatment of MDS.

MDS RESOURCES

The Myelodysplastic Syndromes
Pathobiology and Clinical Management

(Basic and Clinical Oncology Series/27)

Edited by:
John M. Bennett
James P. Wilmot Cancer Center of the University of Rochester, New York, U.S.A.

May 2002/528 pp., illus.
ISBN: 0-8247-0782-6/$165.00
When ordering, use code PAO50203

This reference provides a comprehensive overview of the latest research detailing the etiology, epidemiology, treatment, and detection of myelodysplastic syndromes (MDS)—identifying effective therapeutic regimens, adverse environmental and genetic factors, and efficient modalities of supportive care that improve patient survival and enhance quality of life.

7th International Symposium on Myelodysplastic Syndromes

May 15–18, 2003
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IMPORTANT INFORMATION

- Second announcement and call for papers: October 2002
- Deadline for abstract submission: February 2003

For further information please contact:

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Patient Referrals

Myelodysplastic syndromes can be difficult to diagnose and treat. It is important for both patients and their families to know that optimal treatment is available and that quality of life can be enhanced.

If you would like information about treatment options, research, or quality of life, we would be glad to help. The Foundation offers a variety of patient services, including referrals to MDS Centers of Excellence.

Please contact us at:
1-800-MDS-0839 (phone)
or 609-298-0590 (fax).

Outside the US please call 609-298-1035.

You can also visit our Web site at *http:www.mds-foundation.org.*

MDS Centers of Excellence

Would you like your treatment center to become part of the referral system for MDS patients and be designated as a Center of Excellence? To be recognized as a Center of Excellence, an institution must have the following:

- An established university (or equivalent) program
- Recognized morphologic expertise in MDS
- Available cytogenetics and/or molecular genetics
- Ongoing research, including Institutional Review Board–approved clinical trials
- Documentation of peer-reviewed publications in the field
- The ability and intention to register patients in the MDS International Registry database

Please contact the Foundation for further information and an application form for your center.

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Antithymocyte Globulin for Treatment of the Bone Marrow Failure Associated with MDS

Jeffrey J. Molldrem, MD; Eric Leifer, PhD; Erkut Baheci, MD; Yogen Saunthararajah, MD; Mary Rivera, RN; Cynthia Dunbar, MD; Johnson Liu, MD; Riotoro Nakamura, MD; Neal S. Young, MD; and A. John Barrett, MD

Background: Almost half of the deaths that result from myelodysplastic syndromes are due to cytopenia associated with bone marrow failure. Treatment is mostly supportive care.

Objective: To determine whether treatment with antithymocyte globulin improves cytopenia and reverses dependence on red blood cell transfusions in patients with myelodysplastic syndromes.

Design: Single-treatment, prospective study.

Setting: Tertiary referral center.

Patients: 61 Patients with myelodysplastic syndromes.

Intervention: Antithymocyte globulin, 40 mg/kg of body weight, given daily for 4 days.

Measurements: Evaluation of bone marrow, blood counts, transfusions, progression, and survival for a median of 30 months (range, 1 to 88 months).

Results: Within 8 months of treatment, 21 of 61 patients (34%) no longer required red blood cell transfusions. This independence from transfusions was maintained in 17 responders (81%) for a median of 36 months (range, 3 to 72 months). Ten of 21 patients (47.5%) with severe thrombocytopenia had sustained platelet count increases, and 6 of 11 patients (55%) with severe neutropenia had sustained neutrophil counts of greater than 1×10^9 cells/L. Characteristics favorable for response were younger patient age ($P = 0.005$) and lower platelet counts ($P = 0.038$). One of the 21 responders (5%) and 22 of the 40 nonresponders (55%) died before the end of the study ($P = 0.008$). One of the 21 responders (5%) and 13 of the 40 nonresponders (33%) had disease progression ($P = 0.086$).

Conclusions: Although this study was a nonrandomized, single-treatment study, 34% of patients treated with antithymocyte globulin became transfusion independent. Response was associated with a statistically significant longer survival and an almost significant decreased time to disease progression. Treatment with antithymocyte globulin did not seem to be detrimental because historical overall median survival times were similar to those of nonresponders.

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Patient Advocacy Groups Are Being Established by the MDS Foundation

The MDS Foundation has been working to develop a strategy for setting up patient groups nationwide. We have now completed this process and would like to have your help.

These volunteers are providing local support to MDS patients and their families, developing new information for patients, and planning fund raising programs to support these activities.

Any member of the Foundation, patients, friends and family members are invited to join with us to move these projects forward.

Please contact the Patient Liason: 800-MDS-0839 to volunteer.

Your help is needed!!

International Clinical Trials: An Update

The following trials are current as of the date of this newsletter. We will update the list in The MDS News each quarter. If you are a treating physician who would benefit from any such study, you may want to contact the appropriate institution. If you are an MDS patient, you may wish to discuss a trial with your primary treating physician to see if you qualify as a candidate.

Clinical trials study new interventions (drugs or procedures) to evaluate their safety and effectiveness in humans. Trials follow a careful set of steps, allowing for the systematic gathering of information to answer questions and confirm hypotheses that were formed earlier, in either laboratory experiments or preliminary trials.

A clinical trial falls into one of four phases:

Phase I. This is the first time a drug is used in humans. The trial is designed to determine dosage, route of administration (oral, intravenous, or by injection), and schedule of administration (how many times a day or week). In this phase researchers also begin to determine the drug's safety. The phase I trial is normally conducted in healthy adults and enrolls only a small number of people.

Phase II. Patients with the disease receive the drug at dose levels determined in the earlier phase. The phase II trial begins to determine the effectiveness of the drug and provides more information about its safety.

Phase III. The drug is tested alone or against an approved standard drug. The typical phase III trial enrolls a large number of patients. If it is a comparison trial, patients may be randomly assigned to receive either the new drug or the standard intervention.

Phase IV. In phase IV the drug, already approved by the FDA and available to the public, undergoes continued evaluation. The phase IV designation is rare.

Some trials—screening studies evaluating supportive care or prevention—are not conducted in phases. In these trials a group following a certain disease combating strategy, such as a detection method, is compared to a control group.

U.S. Trials

NATIONAL CANCER INSTITUTE TRIALS*

NCI-G00-1899. Herbert Irving Comprehensive Cancer Center. Phase II study of allogeneic umbilical cord and placental blood transplantation in patients with chronic myeloid leukemia, acute leukemia, lymphoma, myeloma, myelodysplasia, aplastic anemia, Fanconi's Anemia, histiocytosis, hereditary immunodeficiency, or storage disorder. Contact: David G. Savage, MD. Phone: 212-305-9783.

NCI-G97-1354. Ireland Cancer Center at Case Western Reserve University. Phase II study of allogeneic peripheral blood progenitor cell transplantation using histocompatible sibling-matched donor cells after high-dose busulfan/ cyclophosphamide for hematologic malignancy. Contact: H. Lazarus, MD. Phone: 216-844-3629.

NCI-G98-1429. Ireland Cancer Center at Case Western Reserve University/Ireland Cancer Center. Phase II pilot study of unrelated umbilical cord blood transplantation in patients with high-risk hematologic malignancies. Contact: M. Laughlin, MD. Phone: 216-844-8609.

NCI-G98-1431. Case Western Reserve University/Ireland Cancer Center. Phase II study of unrelated umbilical cord blood transplantation for severe aplastic anemia, inborn errors in metabolism, or inherited hematologic stem cell disorders. Contact: M. Laughlin, MD. Phone: 216-844-8609.

NCI-G99-1523. Fred Hutchinson Cancer Research Center. Phase II study of unrelated umbilical cord blood transplantation in patients with malignant or non-malignant hematological disease. Contact: E. Sievers, MD. Phone: 206-667-5757.

NCI-G99-1544. Johns Hopkins Oncology Center. Phase III study of sargramostim (GM-CSF) following T-cell depleted allogeneic bone marrow transplantation in patients with MDS. Contact: P.V. O'Donnell, MD. Phone: 410-614-0205.

NCI-G99-1573. Cancer Institute of New Jersey. Phase I study of 12-O-tetradecanoylphorbol-13-acetate (TPA) in patients with relapsed or refractory hematologic malignancies or bone marrow disorders. Contact: R. Strair, MD. Phone: 908-235-6777.

NCI-G99-1617. Duke University. 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 risks hematologic malignancies or diseases. Contact: D.A. Rizzieri, MD. Phone: 919-668-1000.

NCI-G99-1660. Robert H. Lurie Comprehensive Cancer Center. Phase I study of unmanipulated bone marrow augmented with CD34+ enriched peripheral blood stem cells in patients with hematologic malignancies undergoing allogeneic transplantation. Contact: Richard K. Burt, MD. Phone: 312-908-5400.

NCI-G99-1661. Memorial Sloan-Kettering Cancer Center. Phase I study of sodium salicylate in patients with advanced MDS or refractory or relapsed acute myelogenous leukemia. Contact: Stephen D. Nimer, MD. Phone: 212-639-7871.

NCI-G00-1759. H. Lee Moffitt Cancer Center and Research Institute. Phase II study of allogeneic bone marrow transplantation in patients with hematologic malignancies. Contact: Steven C. Goldstein, MD. Phone: 813-979-7202.

NCI-G00-1793. Fred Hutchinson Cancer Research Center. Phase II study of anti-thymocyte globulin and tumor necrosis factor receptor IgG chimera in patients with MDS. Contact: H. Joachim Deeg, MD. Phone: 206-667-5985.

NCI-G00-1815. Memorial Sloan-Kettering Cancer Center. Phase I study of Yttrium Y 90 humanized monoclonal antibody M195 and etoposide followed by autologous peripheral blood stem cell transplantation in patients with advanced MDS or refractory leukemia. Contact: Peter Maslak, MD. Phone: 212-639-5518.

NCI-G00-1816. Johns Hopkins Oncology Center. Phase I study of non-myeloablative cyclophosphamide plus haploidentical allogeneic bone marrow transplantation in patients with hematologic malignancies. Contact: Paul V. O'Donnell, MD. Phone: 410-614-0205.

NCI-G00-1868. Ireland Cancer Center. Phase II study of non-myeloablative conditioning using fludarabine, cyclophosphamide, and anti-thymocyte globulin, followed by allogeneic peripheral blood stem cell transplantation in patients with high risk hematologic malignancies or severe anaplastic anemia. Contact: Mary J. Laughlin, MD. Phone: 216-844-8609.

NCI-G00-1891. Herbert Irving Comprehensive Cancer Center. Phase II study of allogeneic peripheral blood stem cell transplantation in patients with hematologic malignancy. Contact: David G. Savage, MD. Phone: 212-305-9783.

NCI-G00-1897. Herbert Irving Comprehensive Cancer Center. Phase II study of fludarabine and melphalan followed by allogeneic

or syngeneic bone marrow or peripheral blood stem cell transplantation in patients with hematologic malignancies or genetic disorders. Contact: David G. Savage, MD. Phone: 212-305-9783.

NCI-G00-1898. Memorial Sloan-Kettering Cancer Center. Phase III randomized study of caspofungin acetate versus amphotericin B liposomal in patients with persistent fever and neutropenia following treatment for cancer. Contact: Kent Sepkowitz, MD. Phone: 212-639-2441.

NCI-G01-1916. Jonsson Comprehensive Cancer Center, UCLA. Phase II/III randomized study of monoclonal antibody ABX-CBL versus anti-thymocyte globulin in patients with steroid resistant acute graft-versus-host disease. Contact: Mary Carol Territo, MD. Phone: 310-825-7768.

NCI-G01-1971. Jonsson Comprehensive Cancer Center, UCLA. Phase II study of arsenic trioxide in patients with MDS. Contact: Gary John Schiller, MD. Phone: 310-825-5513.

NCI-G01-2009. Fred Hutchinson Cancer Research Center. Phase II study of busulfan, cyclophosphamide, and allogeneic peripheral blood stem cell transplantation in patients with low or intermediate-risk MDS. Contact: H. Joachim Deeg, MD. Phone: 206-667-5985.

NCI-H01-0068. Fred Hutchinson Cancer Research Center. Phase I/II study of low-dose radiotherapy and fludarabine followed by allogeneic peripheral blood stem cell transplantation, mycophenolate mofetil, and cyclosporine in patients with hematologic malignancies. Contact: David G. Maloney, MD. Phone: 206-667-5616.

NCI-H01-0070. Memorial Sloan-Kettering Cancer Center. Phase II study of busulfan and melphalan followed by allogeneic bone marrow transplantation in patients with advanced or high-risk hematologic malignancy. Contact: Trudy Small, MD. Phone: 212-639-5965.

NCI-H01-0071. Memorial Sloan-Kettering Cancer Center. Phase I/II study of bismuth Bi 213 monoclonal antibody M195 and cytarabine in patients with advanced myeloid malignancies. Contact: Joseph G. Jurcic, MD. Phone: 212-639-2955.

NCI-P97-0097. Cancer and Leukemia Group B. Phase I/II study of omega-3 fatty acids in advanced cancer patients with cachexia. Contact: C.P. Burns, MD. Phone: 319-356-2038.

NCI-T98-0017. University of Texas–MD Anderson Cancer Center. Phase I/II randomized study of PR1 leukemia peptide vaccine and montanide ISA-51 in patients with chronic myeloid leukemia, AML, or MDS. Contact: Jeffrey J. Molldrem, MD. Phone: 713-792-2933.

NCI-T99-0069. University of Michigan Comprehensive Cancer Center. Phase II study of azacytidine plus amifostine in patients with MDS. Contact: Harry Paul Erba, MD. Phone: 313-647-8921.

NCI-T99-0091. Memorial Sloan-Kettering Cancer Center. Phase II pilot study of phenylbutyrate plus azacytidine in patients with AML, MDS, non-Hodgkin's Lymphoma, Multiple Myeloma, non-small cell lung cancer, or prostate cancer. Contact: Steven Soignet, MD. Phone: 212-639-8984.

NCI-V96-0809. Memorial Sloan-Kettering Cancer Center. Phase II study of T-cell-depleted marrow grafts with G-CSF-stimulated, CD34-selected, E rosette-depleted PBPC from HLA haplotype-matched related donors for patients with leukemia who lack an HLA-matched related or unrelated donor. Contact: R. O'Reilly, MD. Phone: 212-639-5957.

NCI-V96-0848. University of Washington Medical Center. Phase I trial of subcutaneous outpatient interleukin-2 for patients with MDS. Contact: John Thompson, MD. Phone: 206-288-2044.

NCI-V96-0950. Temple University Cancer Center. Phase II study of unrelated bone marrow transplantation with cyclo-phosphamide and total-body irradiation for hematologic malignancies/disorders. Contact: K. Mangan, MD. Phone: 215-221-2847.

NCI-V98-1387. Johns Hopkins Oncology Center. Phase I study of combined chemotherapy and donor lymphocyte infusion for aggressive hematologic malignancies in relapse after allogeneic bone marrow transplantation. Contact: B. Mookerjee, MD. Phone: 410-614-6025.

NCI-V98-1449. Midwestern Regional Medical Center. Phase II study of cytokine-based immunotherapy following high dose chemotherapy and autologous stem cell transplantation in patients with high risk cancer. Contact: Anastasios Raptis, MD. Phone: 847-872-6425.

NCI-V98-1460. Johns Hopkins Oncology Center. Study of stem cell-augmented, elutriated grafts for prevention of graft-versus-host disease in patients undergoing allogeneic bone marrow transplantation. Contact: P. O'Donnell, MD. Phone: 410-614-0205.

NCI-V99-1527. Roswell Park Cancer Institute. Phase II/III study of standard and novel conditioning therapy and allogeneic blood or marrow transplantation in patients with severe aplastic anemia or hematologic malignancy. Contact: P.L. McCarty, Jr, MD. Phone: 716-845-3323.

NCI-V99-1533. City of Hope National Medical Center. Phase II study of amifostine, topotecan and cytarabine in patients with poor risk MDS. Contact: H.C. Fung, MD. Phone: 626-359-8111, x2403.

NCI-V00-1611. Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Phase I/II randomized study of ex vivo expanded megakaryocytes in patients with breast cancer or hematologic malignancies. Contact: Jane N. Winter, MD. Phone: 312-695-6180.

NCI-2. Rush Cancer Institute. Phase II study of azacytidine in patients with relapsed or refractory acute myelogenous leukemia or Myelodysplastic Syndrome. Contact: Harvey D. Preisler, MD. Phone: 312-563-2190.

NCI-38. Stanford University Medical Center. Phase I/II study of R115777 in patients with myeloproliferative disorders. Contact: Peter L. Greenberg, MD. Phone: 650-725-8355.

NCI-42. University of Chicago Cancer Research Center. Phase I randomized study of R115777 in patients with advanced hematologic malignancies. Contact: Mark J. Ratain, MD. Phone: 773-702-4400.

NCI-94. University of Texas–MD Anderson Cancer Center. Phase I study of PS-341 in patients with refractory or relapsed AML, acute lymphoblastic leukemia, MDS, or chronic myeloid leukemia in blast phase. Contact: Jorge Cortes, MD. Phone: 713-794-5783.

NCI-450. University of Texas–MD Anderson Cancer Center. Phase I study of BMS-214662 in patients with acute leukemia, myelodysplastic syndrome, or chronic myeloid leukemia in blast phase. Contact: Jorge Cortes, MD. Phone: 713-794-5783.

NCI-951. Johns Hopkins Oncology Center. Phase I study of Bryostatin 1 and Sargramostim (GM-CSF) in patients with refractory myeloid malignancies. Contact: B. Douglas Smith, MD. Phone: 410-614-5068.

NCI-2490. Marlene & Stewart Greenebaum Cancer Center, University of Maryland. Phase II study of bevacizumab, cytarabine, and mitoxantrone in patients with poor-risk hematologic malignancies. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

NCI-2771. Stanford University Medical Center. Phase I/II study of bevacizumab in patients with MDS. Contact: Peter L. Greenberg, MD. Phone: 650-725-8355.

NCI-2791. Marlene & Stewart Greenebaum Cancer Center, University of Maryland. Phase I study of MS-275 in patients with poor-risk hematologic malignancy. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

NCI-3170. Marlene & Stewart Greenebaum Cancer Center, University of Maryland. Phase I/II study of flavopiridol, cytarabine, and mitoxantrone in patients with poor-risk hematologic malignancies. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

NCI-99-C-0143. National Cancer Institute. Phase I pilot study of donor Th2 cells for prevention of graft-versus-host disease following non-

myeloablative, HLA-matched allogeneic peripheral blood stem cell transplantation in patients with hematologic malignancies. Contact: Michael Bishop, MD. Phone: 301-435-2764.

**For more information on NCI trials, contact cancernet.nci.nih.gov/trialsrch.shtml*

PHARMACEUTICAL TRIALS LISTED WITH NCI

SMC-101-1020. SangStat Medical Corporation. An open-label, prospective, stratified, randomized, controlled, multi-center, phase IIb study of Thymoglobulin® therapy on transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Elizabeth Squiers, MD. Phone: 510-789-4535.

SUGEN-SU541. Called for institution. Phase II study of SU5416 in patients with advanced or refractory hematologic malignancies. Contact: Paul Scigalla, MD. Phone: 650-837-3792.

CHIMERIC-HM01. Chimeric Therapies Incorporated. Phase II/III randomized study of processed versus unprocessed unrelated bone marrow transplantation in patients with acute or chronic leukemia or myelodysplastic syndrome. Contact: Rosemary Satterlee, RN. Phone: 949-347-9640.

SUPERGEN-D-0007. Phase III randomized study of decitabine versus supportive care in patients with advanced myelodysplastic syndrome. Contact: Hussain I. Saba, MD. Phone: 813-972-7582

Other U.S. Trials

Barbara Ann Karmanos Cancer Institute. D-2126. Pilot study of allogenic peripheral blood stem cell transplantation in selected patients with advanced malignancies using non myeloblative chemotherapy and short term post transplant immunosuppression. Contact: Roger Danesy, MD. Phone: 313-966-7436.

Barbara Ann Karmanos Cancer Institute. 2-2341. A multi center, single arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparation from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Jared Klein, MD. Phone: 313-966-7434.

Barbara Ann Karmanos Cancer Institute. 2-2134. A multi center, randomized, single arm, Phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donor (HLA 5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Jared Klein, MD. Phone: 313-966-7434.

Barbara Ann Karmanos Cancer Institute. 2-2045. A multi center, open-label, randomized, active controlled Phase II/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Jared Klein, MD. Phone: 313-966-7434.

Barbara Ann Karmanos Cancer Institute. D-1677. Phase II study of topotecan, high dose Ara-C, amifostine and G-CSF (TAAG) in patients with high risk myelodysplastic syndrome, followed by myeloablative chemotherapy and autologous stem cell rescue. Contact: Roger Danesy, MD. Phone: 313-966-7436.

Barbara Ann Karmanos Cancer Institute. D-696. Allogenic and syngenieic marrow transplantation in patients with acute non-lymphocytic leukemia. Contact: Jared Klein, MD. Phone: 313-966-7434.

Cancer and Leukemia Group B. CLB-69803. Phase I study of 506U78 in patients with hematologic malignancies and renal or hepatic impairment. Contact: Todd S. Zimmerman, MD. Phone: 773-702-4159.

Cedars-Sinai Medical Center. 104864-A/201. Phase III open-label multicenter, randomized, comparative study of topotecan, Ara-C and G-CSF (TAG) VS idarubicin.

Cedars-Sinai Medical Center. Vitamin D trial using a non-calcemic vitamin D for treatment of MDS. Contact: H. Phillip Koeffler, M.D.

Cedars-Sinai Medical Center. Ara-C and G-CSF (IDAG) in patients with RAEB (high risk), RAEB-t or in patients with AML from a preceding phase of MDS. Contact: M. Lill, MD. Phone: 310-423-2997.

Children's Cancer Group. CCG-2961. Multicenter. Phase III randomized study for untreated pediatric acute myelogenous leukemia and MDS: intensively timed induction chemotherapy followed by consolidation with the same chemotherapy versus fludarabine/cytarabine/idarubicin followed by intensification either with high-dose cytarabine/asparaginase with versus without subsequent IL-2 or with A1 BMT. Contact: B. Lange, MD. Phone: 215-590-2249.

Children's Cancer Group. CCG-A2971. Phase III study of children with Down Syndrome and transient myeloproliferative disorder, AML, or MDS. Contact: Alan Scott Gamis, MD. Phone: 816-234-3265.

Children's Oncology Group (cooperative group clinical trial). AAML0122. Phase II window evaluation of the Farnesyl Transferase Inhibitor (R115777) followed by 13-Cis Retinoic Acid, Cytosine Arabinoside and Fludarabine plus Hematopoietic Stem Cell transplantation in children with juvenile myelomonocytic leukemia. This trial is for newly diagnosed patients with JMML (only) and is potentially open at all Children's Oncology Group (C.O.G.) member institutions. Contact: Robert Castleberry, MD. Phone: 205-939-6911.

City of Hope National Medical Center. IRB #97128. Molecular pathogenesis of MDS and AML in the elderly. Contact: R. Bhatia, MD. Phone: 626-359-8111, x2683.

City of Hope National Medical Center. IRB #99041. Phase II study of IV busulfan combined with 12cGy of fractionated TBI and etoposide (VP-16) as a preparative regime for allogeneic bone marrow transplantation for patients with advanced RAEB and RAEB-t hematological malignancies. Contact: A. Stein, MD. Phone: 626-359-8111, x2683.

City of Hope National Medical Center. IRB #99045. Autologous stem cell transplantation for MDS in first remission. Contact: H. Fung, MD. Phone: 626-359-8111, x2405.

City of Hope National Medical Center. IRB 398056. Treatment of poor risk MDS with the combination of amifostine, topotecan and Ara-C as a phase II study. Contact: H. Fung, MD. Phone: 626-359-8111, x2405.

Cleveland Clinic Foundation. IRB 4097/ Sangstat Inc. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multi-center, phase IIb study of Thymoglobulin® therapy on transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Matthew Kalaycio, MD. Phone: 216-444-3705.

Cleveland Clinic Foundation. IRB 4098/ Sangstat Inc. A three year evaluation of the overall and leukemic free survival of patients who received Thymoglobulin® therapy for early MDS. Study begins six months from the date of the first drug dose. Contact: Matthew Kalaycio, MD. Phone: 216-444-3705.

Dana Farber Cancer Institute. #00-297 DECI. Decitabine versus supportive care for myelodysplastic syndrome. A randomized, open-label, Phase III trial of decitabine versus supportive care in adults with advanced stage myelodysplastic syndrome. Contact: Ilene Galinsky, RN. Phone: 613-632-3902.

Dana Farber Cancer Institute. DFC #01-022. Phase II multicenter study of arsenic trioxide in patients with myelodysplastic syndrome. Contact: Ilene Galinsky, RN. Phone: 613-632-3902.

Dana Farber Cancer Institute. #01-227. PKC412 in MDS and AML. An open-label phase II trial of PKC412 monotherapy in patients with acute myeloid leukemia (AML) and patients with high risk myelodysplastic syndrome. Contact: Ilene Galinsky, RN. Phone: 613-632-3902.

Dana Farber Cancer Institute. DFCI 01-066. A phase I/II study of continuous oral administration of SCH66336 in patients with

advanced myelodysplastic syndrome, acute myelogenous leukemia, chronic myelogenous leukemia in blast crisis and acute lymphoblastic leukemia. Contact: Ilene Galinsky, RN. Phone: 613-632-3902.

Dana Farber Cancer Institute. DFCI 99-249. A phase I study of vaccination with lethally irradiated, autologous acute myeloblastic leukemia cells engineered by adenoviral mediated gene transfer to secrete granulocyte macrophage colony stimulating factor in patients with advanced myelodysplasia or acute myelogenous leukemia. Contact: Ilene Galinsky, RN. Phone: 613-632-3902.

Duke University Medical Center. Multicenter trial of induction-type chemotherapy for patients with high-risk MDS as defined by the International Prognostic Scoring System. Contact: C. de Castro, MD. Phone: 919-684-8964.

Duke University Medical Center. Phase II study of amifostine in patients with MDS. Contact: C. de Castro, MD. Phone: 919-684-8964.

Duke University Medical Center. Supergen D-007. Phase III decitabine versus supportive care for patients with IPSS high or Intermediate 2 risk. Contact: Dr. Carlos de Castro. Phone: 919-684-8964.

Duke University Medical Center. T-MDS-001. A randomized, multicenter, double-blind, placebo controlled trial assessing the safety and efficacy of thalidomide for the treatment of anemia in red blood cell transfusion dependent patients with MDS. Contact: C. de Castro, MD. Phone: 919-684-8964.

Duke University Medical Center. D-0007. A randomized, open-label, phase III trial of decitabine versus supportive care in adults with MDS. Contact: C. de Castro, MD. Phone: 919-684-8964.

Eastern Cooperative Oncology Group. E-1996. Phase III study of epoetin alfa with or without filgrastim (G-CSF) vs supportive therapy alone in patients with myelodysplastic syndromes. Contact: Kenneth B. Miller, MD. Phone: 617-956-5144.

Eastern Cooperative Oncology Group. E-2998. Phase III randomized study of Flt3 in patients with acute myeloid leukemia in second or subsequent complete remission. Contact: Richard L. Schilsky, MD. Phone: 773-834-3914.

Fred Hutchinson Cancer Research Center. FRCRC #1536. Transplantation of peripheral blood stem cells from related or unrelated volunteer donors in patients with "less advanced" MDS. Conditioning therapy includes busulfan (targeted to a pre-determined plasma level) and cytoxan (targeted BUCY); patients up to 65 years of age. Contact: H.J. Deeg, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center. FHCRC #1006. Autologous stem cell transplantation for myelofibrosis following conditioning with busulfan. Patients up to 70 years of age. Contact: H.J. Deeg, MD. Phone: 206-667-4324.

Fred Hutchinson Cancer Research Center. FHCRC #1032. Transplantation for myelofibrosis from related or unrelated donors after conditioning with busulfan plus cytoxan or busulfan plus TBI. Patient age limit 65. Contact: H.J. Deeg, MD. Phone: 206-667-4324.

Fred Hutchinson Cancer Research Center. FHCRC #1463. Low-dose TBI and fludarabine followed by unrelated donor stem cell transplantation for patients with hematological malignancies. This multi-center trial targets older (>55 years) patients, and patients who, because of concurrent medical problems, cannot tolerate a traditional transplant. Patients from the following diagnoses are eligible for therapy: CML, AML, ALL, MDS, multiple myeloma, and lymphoma. Contact: M. Maris, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center. #1519. Transplantation of peripheral blood stem cells from related or unrelated donors in patients with "advanced" MDS. Conditioning consists of fludarabine and busulfan (targeted to a predetermined plasma level). Patients up to 65 years are eligible. Contact: Claudio Anasetti, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center. #1555. Transplantation of peripheral blood stem cells from related or unrelated donors for the treatment of "advanced" MDS (CD33+). Conditioning includes Mylotarg (for two doses), fludarabine and 200 cGy of total body irradiation. Patients are being evaluated individually for eligibility. Contact: Eric Sievers, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center. #1596. Transplantation from related donors for high risk patients with MDS. Conditioning includes a "non-myeloblative" regimen of fludarabine and 200 cGy of total body irradiation. Patients are evaluated individually for eligibility. Contact: David Maloney, MD, PhD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center. FHCRC #1478. Non-transplant therapy for "less advanced" MDS with ATG plus Enbrel. No age restrictions. Contact: H.J. Deeg, MD. Phone: 206-667-4324.

Guthrie Clinic, Ltd. ECOG 1996. Phase III evaluation of EPO with or without G-CSF versus supportive therapy alone in the treatment of MDS. Contact: Michele Chaborek, RN. Phone: 510-882-2141.

Hackensack University Medical Center. HUMC 00-05-160. Low dose total body irradiation and fludarabine followed by unrelated donor stem cell transplantation for older patients with hematologic malignancies. Contact: Stuart Goldberg, MD. Phone: 201-996-5849.

Hackensack University Medical Center. HUMC 01-05-072. (SMC-101-1020.) An open-label, prospective, randomized, controlled, multi-center, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early myelodysplastic syndrome. Contact: Stuart Goldberg, MD. Phone: 201-996-5849 or Scott D. Rowley, MD. Phone: 204-996-5900.

Hahnemann University Hospital. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Florence Seelig. Phone: 503-494-1553.

Hahnemann University at MCP. 70612. Phase I/II combination study of topotecan, fludarabine, cytosine, arabinoside and G-CSF (TFLAG) induction therapy in patients with poor prognosis AML, MDS and relapsed/ refractory ALL. Contact: E. Besa, MD. Phone: 215-842-6980.

H. Lee Moffitt Cancer Center and Research Institute. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multi-center, phase IIB study of the impact of thymoglobulin therapy on transfusion needs of patients with early myelodysplastic syndrome. Contact: Hussain Saba, MD, PhD. Phone: 813-972-7582.

Hoosier Oncology Group. Phase II trial of topotecan in patients with MDS. Contact: Paul Walker, MD. Phone: 765-281-2000.

Indiana Blood and Marrow Transplant. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Mary Cangany. Phone: 317-783-8510.

Indiana Blood and Marrow Transplant. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Mary Cangany. Phone: 317-783-8510.

Indiana Blood and Marrow Transplantation, LLC. SMC-101-102. Open-label, prospective, stratified, randomized, controlled, multi-center, Phase IIB study of the impact of Thymoglobulin® therapy on the transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Luke Akard, MD. Phone: 317-865-5500.

Indiana University Medical Center. B3T-MC-JTAH(a). Phase II study of LY335979 plus daunorubicin and cytarabine in subjects with de nova high risk acute myelogenous leukemia or relapsed/refractory acute myelogenous leukemia. Contact: L. Cripe, MD. Phone: 317-274-3545.

Indiana University Medical Center. IU #9907-25. Induction Chemotherapy with the addition of a new MDR inhibitor for patients with RAEB-t or AML that has progressed from a documented phase of MDS. Contact: L. Cripe, MD. Phone: 317-274-3545.

Indiana University School of Medicine. Phase II trial of subcutaneously administered recombinant human interleukin-11 in thrombocytopenic patients with MDS. Contact: L. Cripe, MD. Phone: 317-274-3545.

Indiana University School of Medicine. An Open-label, Phase 2 Study to Evaluate the Efficacy and Safety of the Farnesyl-transferase Inhibitor ZARNESTRA (R11577) in subjects with High-risk Myelodysplastic Syndrome (MDS). Contact: L. Cripe, MD. Phone: 317-274-3545.

Ireland Cancer Center in Cleveland, Ohio. A phase II trial using umbilical cord blood to evaluate the efficacy of transplantation to treat aplastic anemia and myelodysplastic syndromes patients. Contact: Mary Laughlin, MD. Phone: 216-844-8609.

James A. Haley Veteran's Hospital-Tampa. SMC-101-1029. Open-label, prospective, stratified, randomized, controlled, multi-center, Phase IIB study of the impact of Thymoglobulin® therapy on the transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Hussain Saba, MD. Phone: 813-972-7582.

James A. Haley Veterans Hospital. D-0007. A randomized, open-label phase III trial of decitabine versus supportive care in adults with advanced stage myelodysplastic syndrome. Contact Hussain Saba, MD or Rukhsana Azam. Phone: 813-972-7582 or 813-972-2000, ext. 6998.

James Graham Brown Cancer Center. HMO5. A multi-center, single-arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparations from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Roger Herzig, MD. Phone: 502-852-8050.

Johns Hopkins Oncology Center. J0051. Phase I trial: GM-CSF and Bryostatin-1 in combination to treat MDS, AML, and other myeloid malignancies. Therapy is designed to enhance differentiation of myeloid progenitors and blasts to improve marrow function and eliminate tumor cell clone. Contact: Douglas Smith, MD. Phone: 410-614-5068.

Johns Hopkins Oncology Center. J9852. GM-CSF after T-lymphocyte-depleted allogeneic BMT for MDS. Contact: P. O'Donnell, MD, PhD. Phone: 410-614-0205.

Johns Hopkins Oncology Center. J9845. Nonmyeloablative allogeneic BMT for hematologic malignancies. Contact: Ian W. Flinn, MD. Phone: 410-955-8781.

Johns Hopkins Oncology Center. Opened March 2000. A phase I, dose finding trial of sodium phenyl-butyrate in combination with all transretinoic acid in patients with MDS and AML. Contact: Steven Gore, MD. Phone: 410-955-8781.

Karmanos Cancer Institute, Detroit Medical Center. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Roy Baynes, MD. Phone: 313-966-7021.

Karmanos Cancer Institute, Detroit Medical Center. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Roy Baynes, MD. Phone: 313-966-7021.

Karmanos Cancer Institute, Detroit Medical Center. HMO5. A multi-center, single-arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparations from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Roy Baynes, MD. Phone: 313-966-7021.

KUMC Hematology. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of thymoglobulin therapy on transfusion needs of patients with early MDS. Contact: Barry Skiine, MD. Phone: 913-588-6077.

LSU Health Sciences Center-Shreveport. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Barry Weinberger, DO, MPH. Phone: 318-675-5972.

LSU Health Sciences Center-Shreveport. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Barry Weinberger, DO, MPH. Phone: 318-675-5972.

LSU Health Sciences Center-Shreveport. HMO4. A multi-center, non-randomized single-arm, phase I clinical trial to evaluate the safety and efficacy of processed bone marrow from mismatched related doors (HLA3/6 and 4/6) in acute or chronic leukemia patients. Contact: Barry Weinberger, DO, MPH. Phone: 318-675-5972.

LSU Health Sciences Center-Shreveport. HMO5. A multi-center, single-arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparations from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Barry Weinberger, DO, MPH. Phone: 318-675-5972.

Mayo Clinic. 0-215-98. A pilot study of antithymocyte globulin in anemic patients with RA or RAEB. Contact: Doctors A. Tefferi, M. Elliott, L. Letendre, M. Litzow, D. Steensma. Phone: 507-284-2291.

MCP Hahneman University. Protocol #00713-01. A randomized study of the safety and efficacy of 2 dose schedules of Gentuzumab Ozogamicin (mylotarg) in patients with intermediate-2 or high risk MDS. Contact: Carolyn Woodland, RN, OCN Phone: 215-842-7553.

MCP Hahneman University. Protocol #00821. A randomized, multi-center, double-blind, placebo controlled trial assessing the safety and efficacy of thalidomide (Thalomid) for the treatment of anemia in red blood cell transfusion dependent patients with myelodysplastic syndromes. Contact: Carolyn Woodland, RN, OCN Phone: 215-842-7553.

MCP Hahneman University. Protocol # 80303. Evaluation of EPO with or without G-CSF versus supportive therapy alone in the treatment of MDS. Contact: Carolyn Woodland, RN, OCN Phone: 215-842-7553.

MD Anderson Cancer Center. DM01-093. Prospective randomized Phase III study of idarubicin and ara-c versus troxatyl and idarubicin in previously untreated patients 50 years or older with AML, RAEB, or RAEB-t with an unfavorable karyotype. Contact: Francis Giles or Elihu Estey, MD. Phone: 713-792-7305.

MD Anderson Cancer Center. ID00-180. Phase II study of 545416 in patients with refractory acute leukemia, refractory myelo-dysplasia, Philadelphia negative myeloproliferative disorders, chronic myelogenous leukemia in blastic phase, agnogenic myeloid metaplasia and multiple myeloma. Contact: Francis Giles. Phone: 713-792-7305.

MD Anderson Cancer Center. ID00-270. Phase II study of R115777, a farnesyl transferase inhibitor, in refractory hema-tologic cancers. Contact: Hagop Kartarjian. Phone: 713-792-7305.

MD Anderson Cancer Center. ID01-167. Therapy of Bca-ABL negative myeloproliferative diseases (MPD) with Glivec (STI-571). Contact: Hagop Kantarjian. Phone: 713-792-7305.

MD Anderson Cancer Center. DM95-033. Phase II study of topotecan and cytarabine combination in myelodysplastic syndrome. Contact: Miloslav Beran. Phone: 713-792-7305.

MD Anderson Cancer Center. DM97-151. Phase II study of topotecan, cytarabine and GM-CSF combination in high risk refractory anemias. Contact: Miloslav Beran. Phone: 713-792-7305.

MD Anderson Cancer Center. DM01-033. Pilot trial of celocoxib in patients with low risk (less than 10% blasts) MDS. Contact: Robert Quackerbugh. Phone: 713-792-7305.

MD Anderson Cancer Center. ID99-059. ATG +/– cyclosporin +/– fludarabine in RA, RARS, RAEB <10% blasts Contact: Jeff Mollaren, MD. Phone: 713-745-4820.

MD Anderson Cancer Center. DM 00-101. Mylotarg +/– IL-II in AML, RAEB, RAEB-t, CMML, >10% blasts in patients 65 years and older with normal cytogenetics. Contact: Elihu Estey, MD. Phone: 713-794-7544.

MD Anderson Cancer Center. Idarubicin and Ara-C CI in AML, RAEB, RAEB-t, CMML, with >10% blasts in patients 65 years and older with abnormal cytogenetics. Contact: Elihu Estey, MD. Phone: 713-794-7544.

MD Anderson Cancer Center. DM00-186. Thalidomide in RA, RARS, MDS with low to intermediate risk IPSS. Contact: Deborah Thomas, MD. Phone: 713-745-4616.

MD Anderson Cancer Center. IDP00-269. Reverse transcriptase inhibitors in refractory or relapsed MDS, AML, MPD. Contact: Hagop Kartarjian, MD. Phone: 713-792-7026.

MD Anderson Cancer Center. DM99-142. Oral Topotecan in hematologic myeloid malignancies. Contact: Miloslav Beran, MD. Phone: 713-792-2248.

MD Anderson Cancer Center. ID95-124. 9-Nitrocamp-tothecin in MDS, CML, MPD. Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center. Idarubicin and Ara-C double induction in AML, RAEB, RAEB-t, CMML with >10% blasts in patients <50 years old. Contact: Elihu Estey, MD. Phone: 713-792-7544.

MD Anderson Cancer Center. Mylotarg and BID Fludarabine/Ara-C and cyclosporin in AML, RAEB, RAEB-t, CMML with 0.10% blasts in patients aged 50–64 years. Contact: Elihu Estey, MD. Phone: 713-792-7544.

MD Anderson Cancer Center. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Helen Huddleston. Phone: 713-745-1721.

MD Anderson Cancer Center. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Helen Huddleston. Phone: 713-745-1721.

Medical City Dallas Hospital-Texas Oncology, PA. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Craig Rosenfeld, MD. Phone: 972-566-7790.

Medical College of Wisconsin. MCW 91-126. Marrow transplantation for patients with hematologic malignancies. Contact: D. Vesole, MD. Phone: 414-805-4646.

Medical College of Wisconsin. MCW 93-23. Allogeneic marrow transplantation for patients with hematologic malignancies and marrow failure states from genotypically haplo-identical family members. Contact: D. Vesole, MD. Phone: 414-805-4646.

Medical College of Wisconsin. MCW 95-18. T-cell depletion in unrelated-donor marrow transplantation. Contact: D. Vesole, MD. Phone: 414-805-4646.

Medical College of Wisconsin. MCW 97-137. Amifostine/ pentoxifylline/ciprofloxacin/dexamethasone for low-risk MDS. Contact: D. Vesole, MD. Phone: 414-805-4646.

Medical College of Wisconsin. MCW 97-144. Amifostine/ topotecan versus pentoxifylline/ciprofloxacin/dexamethasone for high-risk MDS. Contact: D. Vesole, MD. Phone: 414-805-4646.

Medical College of Wisconsin. MCW 99-10. Total lymphoid irradiation, melphalan and fludarabine for T-cell-depleted allogeneic peripheral-blood stem cell transplantation. Contact: D. Vesole, MD. Phone: 414-805-4646.

Medical College of Wisconsin. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: David Vesole, MD. Phone: 414-805-4646.

Memorial Sloan-Kettering Cancer Center. 99-057. A Phase I study for adult patients with advanced myelodys-plastic disorders or acute myelogenous leukemia. Contact: Steven Nimer, MD. Research Assistant: Rhonda Tang. Phone: 646-227-2194.

Memorial Sloan-Kettering Cancer Center. 00-116. A pilot study of FR901228 or Depsipeptide (NSC#630176) for adult patients with advanced hematologic Cancers. Contact: Virginia Klimek, MD. Research Assistant: Rhonda Tang. Phone: 646-227-2194.

Memorial Sloan-Kettering Cancer Center. 01-094. A randomized, Open-label, phase III trial of Decitabine (5-AZA2'-Deoyxcytidine) versus supportive care in adults with advanced stage myelodysplastic syndrome. Contact: Virginia Klimek, MD. Research Assistant: Rhonda Tang. Phone: 646-227-2194.

Memorial Sloan Kettering Cancer Center. 190. Phase II study of arsenic trioxide in relapsed or refractory, CML. Contact: David Scheinberg, MD. Phone: 212-639-5010.

Mount Sinai Hospital. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multi-center, phase IIb study of Thymoglobulin® therapy on transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Steven Fruchtman, MD. Phone: 212-241-6021.

National Heart, Lung and Blood Institute. NHLBI-99-H-0050. Phase II study of nonmyeloablative allogeneic peripheral blood stem cell transplantation in patients with hematologic disease or cancer. Contact. R.W. Childs, MD. Phone: 301-496-5093.

National Institutes of Health. National Heart Lung and Blood Institute. 00-H-0169. Phase II study of antithymocyte globulin (ATG) and cyclosporine in patients with MDS (RA, RARS, RAEB) who have moderate to severe cytopenias. Contact: Laura B. Wisch, RN. Phone: 301-402-0797.

National Institutes of Health. Clinical Center (Hospital). #98CC0101 study of leucovorin in patients with 5q- syndrome who are transfusion dependent. Researcher: Candido Rivera, MD. Contact: Donna Jo Mayo Phone: 301-496-5150.

National Institutes of Health. National Heart Lung and Blood Institute. 01-H-0162. Phase II clinical study using low intensity allogenic stem cell transplants to treat older patients (age 55–75) with advanced MDS and other hematologic malignancies. Contact: Shiela Phang, RN. Phone: 301-402-3595.

New York Medical College. Non-myeloblative chemotherapy with pentostatin, mitoxantrone and cytarabine for engraftment of allogenic hematopoietic progenitor cells in patients with hematological malignancies. Contact: D. Liu, MD, PhD. Phone: 914-493-8374.

New York Medical College. Phase II study of temozolomide in patients with myelodysplastic syndrome. Contact: Karen Seiter, MD. Phone: 914-493-8374.

New York Medical College. A three year evaluation of the overall and leukemic free survival of patients who received Thymoglobulin® therapy for early myelodysplastic syndrome (MDS). Contact: Karen Seiter, MD. Phone: 914-493-8374.

New York Medical College. 0012-2000. (SMC-101-1020.) An open-label, prospective, stratified, randomized, controlled, multi-center,

Phase IIb study of Thymoglobulin® therapy on transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Karen Seiter, MD. Phone: 914-493-8374.

New York Medical Hospital. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multi-center, phase IIb study of Thymoglobulin® therapy on transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Michael Schuster, MD. Phone: 212-746-2119.

New York Presbyterian Hospital–Columbia Medical Center. 104864-A/201 Study. Phase III open label, randomizes comparative study of topotecan, Ara-C and G-CSF (TAG) vs idarubicin, Ara-C and GCSF (IDAG) in MDS. Over the age of 18 with either: (a) RAEB; (b) RAEB-t; (c) high risk MDS defined by IPSS of 2.0; or (d) AML which has evolved from a pre-existing MDS. Contact: Charles Hesdorffer, MD. Phone: 212-305-4907.

New York Presbyterian Hospital–Columbia Medical Center. Camp 026. Autologous peripheral stem cell harvesting and transplantation for high risk MDS. IPS score greater than 2.0, no allo match, age 18–70. Idarubicin/Ara-C for mobilization followed by BMT with a BU/Cy regimen. Contact: Charles Hesdorffer, MD. Phone: 212-305-4907.

North Central Cancer Treatment Group. NCCTG-N998B. Phase II study of thalidomide in patients with myelodysplastic syndrome. Contact: Gerardo Colon-Otero, MD. Phone: 904-953-2000.

Oklahoma Health Sciences Center. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Boo Bennett. Phone: 405-271-8920.

Oregon Health & Science University Cancer Institute. MOL-00082-L (IRB #6415). Analysis of receptor tyrosine kinase mutations in myelodysplastic/acute myelogenous leukemia (this is a lab study, not a treatment study). Contact: Lea Smith Phone. 503-494-0896.

Oregon Health & Science University Cancer Institute. HEM-999080-L (IRB #5737). Bone marrow stromal dysfunction, clonal evolution and secondary myelodysplasia (this is a lab study, not a treatment study and requires bone marrow and blood samples). Contact: Cara Laney. Phone: 503-494-8476.

Oregon Health & Science University Cancer Institute. HEM-96123-C (IRB #0602-212). CCG-2961: A phase III study in children with untreated acute myelogenous leukemia (AML) or muelodysplastic syndrome (MDS). (This is a CCG cooperative group trial.) Contact: Alisa Eicher. Phone: 503-418-5336.

Oregon Health Sciences Center. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Florence Seelig. Phone: 503-494-1553.

Oregon Health Sciences Center. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Florence Seelig. Phone: 503-494-1553.

Pediatric Oncology Group. POG-9720. Phase II study of idarubicin and cladribine in children with recurrent or refractory AML. Contact: Craig A. Hurwitz, MD. Phone: 207-885-7565.

Pediatric Oncology Group. POG-9362. Phase II study of IFN-A for pediatric HIV-related malignancies. Contact: V.M. Whitehead, MD. Phone: 514-934-4322.

Rocky Mountain Blood and Marrow Transplant Center. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Mark W. Brunvand, MD. Phone: 303-388-4876.

Rocky Mountain Blood and Marrow Transplant Center. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Mark W. Brunvand, MD. Phone: 303-388-4876.

Roswell Park Cancer Institute. DS-01-19. A randomized, open-label, phase III trial of decitabine versus supportive care in adults with advanced stage MDS. Contact: Dr. James Slack. Phone: 716-845-3544.

Roswell Park Cancer Institute. DS-01-07. Phase II multi-center trial of arsenic trioxide in patients with MDS. Contact: Dr. James Slack. Phone: 716-845-3544.

Roswell Park Cancer Institute. DS-01-16. A randomized, multi-center, double-blind, placebo controlled trial assessing the safety and efficacy of thalidomide for the treatment of anemic patients with MDS. Contact: Dr. James Slack. Phone: 716-845-3544.

Rush Cancer Institute. MDS-9914. A pilot study of thalidomide combined with pentoxifylline, ciprofloxacin, and dexamethasone (PCD) in patients with MDS. Contact: A. Raza, MD. Phone: 312-455-8474.

Rush Cancer Institute. MDS 9906. A pilot study of anti-CD-20 monoclonal antibody (Rituxan) in the treatment of patients with MDS. Contact: A. Raza, MD. Phone: 312-455-8474.

Rush Cancer Institute. MDS 2002-01: A Phase II study to determine the clinical efficacy of Trisenox (arsenic trioxide) as a single agent in myelodysplastic syndromes followed by combination therapy with thalidomide in non-responders. Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2000-02. Combination of thalidomide and topotecan in the treatment of patients with high risk MDS. Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2000-04. (SMC-101-1020) An open-label, prospective, randomized, stratified, controlled, multi-center, phase IIb study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: A. Raza, MD. Phone 312-455-8474.

Rush Cancer Institute. MDS 2000-05. A three year evaluation of the overall and leukemic free survival of patients who received thymoglobulin therapy for early MDS. Contact: A. Raza, MD. Phone: 312-455-8474.

Rush Cancer Institute. MDS 2000-08. A pilot study to test the efficacy of glivec (ST1571) in patients with chronic myelomonocytic leukemia. Contact: A. Raza, MD. Phone: 312-455-8474.

Rush Cancer Institute. MDS 2000-10. A pilot study to determine the clinical effects of arsenic trioxide and thalidomide in myelodysplastic syndromes. Contact: Laurie Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2000-11. Pilot study to test the efficacy of Inflaximab (Remicade) in patients with low risk myelodysplastic syndromes. Contact: Laurie Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2001-13: A Randomized, Open-Label, Phase III trial of Decitabine (5-AZA-2'-Deoxycitadine) versus supportive care in adults with advanced-stage myelodysplastic syndromes.

Rush Cancer Institute. MDS 2001-12. A pilot study to determine the clinical effects of the proteasome inhibitor PS-341 in patients with myelodysplastic syndromes. Contact: Laurie Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2001-13. A randomized, open label, Phase III trial of decitabine (5-AZA-2'-deoxycytadine) versus supportive care in adults with advanced–stage myelodysplastic syndromes. Contact: Laurie Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2002-01: A Phase II study to determine the clinical efficacy of Trisenox (arsenic trioxide) as a single agent in myelodysplastic syndromes followed by combination therapy with thalidomide in non-responders. Contact: Laurie Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2002-02: A4061002, A Dose Escalation (Phase I) and Phase II Study of AG013736 in Patients With Secondary Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS). Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2002-03: An Open-Label, Phase II Study to Evaluate the Efficacy and Safety of the Farnesyl-transferase Inhibitor ZARNESTRA (R115777) in Subjects with High-Risk Myelodysplastic Syndrome (MDS). Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2002-04: A Pilot Study to Test the Efficacy of a Combination of Gleevec (STI 571) with Thalidomide in Patients with Idiopathic Primary Myelofibrosis, Myelofibrosis with Myeloid Metaplasia and Myelodysplastic Syndromes who Present with Myelofibrosis. Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 2002-05: "A Phase 2, Multicenter, Open Label Study of the Safety and Efficacy of High-dose Pulse Administration DN-101 (Calcitriol) in Patients with Myelodysplastic Syndrome." Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS 501-001: A pilot study to test the efficacy of cc-5013 in patients with myelodysplastic syndromes. Contact: Laurie A. Lisak, PA-C. Phone: 312-563-2538.

Rush Cancer Institute. MDS-801-001. A multi-center, open label, dose-escalation study to determine the safety, and preliminary efficacy of CC-1088 (Thalidomide) in the treatment of myelodysplastic syndromes. Contact: Laurie Lisak, PA-C. Phone: 312-563-2538.

Saint Louis University School of Medicine. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: John M. Richart, MD. Phone: 314-557-8854.

Saint Luke's Hospital of Kansas/OHAKC. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Joseph McGuirk, MD. Phone: 816-531-1417.

Salick Health Care, Inc. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Sanford Kempin, MD. Phone: 212-604-6011.

Shands Hospital at the University of Florida. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: John R. Wingard, MD. Phone: 352-395-0062.

Shands Hospital at the University of Florida. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: John R. Wingard, MD. Phone: 352-395-0062.

Sinai Hospital of Baltimore. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Stephen Noga, MD. Phone: 410-601-4710.

Stanford University Medical Center. CTEP #2771. Safety and efficacy of Bevacizumab: Humanized monoclonal anti-VEGF antibody therapy for myelodysplastic syndrome. Contact: Peter Greenberg, MD or Kathy Dugan, RN. Phone: 650-723-8594.

Stanford University Medical Center. CTEP #38. Phase I/II study of Farresy/transferase inhibitor R115777 in patients with myeloproliferative disorders. Contact: Peter Greenberg, MD or Kathy Dugan, RN. Phone: 650-723-8594.

Southwest Oncology Group. SWOG-S9920. Phase III randomized study of total body irradiation (TBI) plus busulfan versus TBI plus cyclophosphamide followed by allogeneic peripheral blood stem cell transplantation in patients with advanced MDS or MDS related AML. Contact: Charles A. Coltman, Jr., MD. Phone: 210-616-5580.

Southwest Oncology Group. SWOG-S0020. Phase II study of anti-thymocyte globulin and cyclosporine in patients with myelodysplastic syndrome. Contact: Charles A. Coltman, Jr., MD. Phone: 210-616-5580.

Texas Cancer Center. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. Contact: Craig Rosenfeld, MD. Phone: 972-566-7790.

Texas Transplant Institute. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Frederick Le Maistre, MD. Phone: 210-575-3801.

Texas Transplant Institute. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Frederick Le Maistre, MD. Phone: 210-575-3801.

Texas Transplant Institute. HMO4. A multi-center, non-randomized single-arm, phase I clinical trial to evaluate the safety and efficacy of processed bone marrow from mismatched related doors (HLA3/6 and 4/6) in acute or chronic leukemia patients. Contact: Frederick Le Maistre, MD. Phone: 210-575-3801.

Texas Transplant Institute. HMO5. A multi-center, single-arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparations from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Frederick Le Maistre, MD. Phone: 210-575-3801.

Tulane University Health Science Center. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Hanah Safah, MD. Phone: 504-585-6070.

University of Arizona Cancer Center. A randomized, double-blind, phase II study of the matrix metalloprotease inhibitor prinomastat in patients having MDS. Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. Phase II multicenter study of arsenic trioxide in patients with myelodysplastic syndromes. Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A randomized study of the safety and efficacy of two does schedules of gemtuzumab ozogamicin in patients with Intermediate-2 or high risk myelodysplastic syndromes. Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A phase I/II study of continuous oral administration of SCH 66336 in patients with advanced myelodysplastic syndromes. Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A phase II open label study of the efficacy of CC-5013 (Revimida) treatment for patients with myelodysplastic syndrome. Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. Safety and efficacy trial of bevacizumab: anti-vegf humanized monoclonal antibody (NSC 704865) therapy for myelodysplastic syndrome. Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. Phase II Multicenter Study of Arsenic Trioxide in Patients with Myelodysplastic Syndromes (CTI, HSC 01-196). Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A Phase I/II Study of Continuous Oral Administration of SCH 66336 in Patients With Advanced Myelodysplastic Syndrome, Acute Myelogenous Leukemia, Chronic Myelogenous Leukemia in Blast Crisis, Acute Lymphoblastic Leukemia (Schering Plough, HSC 01-132) Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A Phase II Open Label Study of the Efficacy OF CC-5013 (Revimid‰) Treatment for Patients with MDS (Celegene HSC 01-164) Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A Phase 1A, open-label, 3-arm, dose-escalation study of PTK787/ZK 222584 administered orally on a twice-daily dosing schedule in patients with relapsed or refractory acute myelogenous leukemia (AML) (ARM 1), or patients with secondary and poor prognosis AML, advanced myelodysplastic syndrome (RAEB and RAEBT), and poor prognosis elderly patients with de novo AML (Arm 2), or patients with agnogenic myeloid metaplasia (Arm 3) (Novartis Pharmaceuticals HSC 02-27). Contact Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. Safety and Efficacy Trial of bevacizumab: anti-vegf humanized monoclonal antibody therapy for MDS (HSC # 02-11) Contact: Alan List, MD. Phone: 520-626-2340.

University of Arizona Cancer Center. A Phase II study of SU5416 in patients with hematologic malignancies. Contact: Alsion Stopeck. Phone: 520-626-2816.

University of California, San Diego Cancer Center. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Asad Bashey, MD, PhD. Phone: 858-657-6790.

University of Connecticut Health Center. E1996. Cooperative Group Trial. EPO+/– GCSF VS. supportive care alone. Contact: B. Greenberg, MD. Phone: 860-679-2100.

University of Connecticut Health Center. 99-285. Partial matched related donor allogeneic stem cell transplant with a non-myeloablative preparative regimen. Contact: R. Edwards, MD. Phone: 860-679-3396.

University of Connecticut Health Center. 99-262. Non-myeloablative therapy followed by adoptive immunotherapy with allogeneic HLA matched stem cell transplant. Contact: R. Bona, MD. Phone: 860-679-2257.

University of Chicago. UC 9581. Allogeneic peripheral blood stem cell transplantation using a non-myeloblative preparative regimen for patients with hematologic malignancies. Contact: R.A. Larson, MD. Phone: 773-702-2070.

University of Florida. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Katarzyna Finiewicz, MD. Phone: 352-392-4925.

University of Iowa Hospitals and Clinics. Cancer and Leukemia Group B. CLB-69803. Phase I study of 506U78 in patients with hematologic malignancies and renal or hepatic impairment. Contact: Todd M. Zimmerman, MD. Phone: 773-702-4159.

University of Iowa Hospitals and Clinics. SMC-101-102. Open-label, prospective, stratified, randomized, controlled, multi-center, Phase IIB study of the impact of Thymoglobulin® therapy on the transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Raymond J. Hohl, MD. Phone: 319-356-8110.

University of Kansas Medical Center. SMC-101-102. Open-label, prospective, stratified, randomized, controlled, multi-center, Phase IIB study of the impact of Thymoglobulin® therapy on the transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Barry Skikne, MD. Phone: 913-588-6077.

University of Maryland Greenebaum Cancer Center. UMGCC 0050. Phase I trial of oral medication MS-275, given for 28 days to reinstate the expression of genes which cause cells to mature. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

University of Maryland Greenebaum Cancer Center. UMGCC 0052. Flavopiridol's role in cell death (apoptosis) and proliferation in order to increase sensitivity to Ara-C and mitoxantrone. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

University of Maryland Greenebaum Cancer Center. UMGCC 0001. The use of topotecan, Ara-C, and mitoxantrone TST in aggressive MDS. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

University of Maryland Greenebaum Cancer Center. UMGCC 0076. Use of bevacizumab to inhibit vascular endothelial growth factor (VEGF) production after chemotherapy with Ara-C and Mitoxantrone. Contact: Judith E. Karp, MD. Phone: 410-328-7394.

University of Massachusetts. A pilot study on the effectiveness of Thalomid® Thalidomide combined with Procrit® for the treatment of anemia in patients with low and intermediate risk (IPSS score less than 1.5) in myelodysplastic syndromes. Contact: Laszlo Leb, MD. Phone: 5058-363-9233 ext. 72373.

University of Miami. SMC-101-102. Open-label, prospective, stratified, randomized, controlled, multi-center, Phase IIB study of the impact of Thymoglobulin® therapy on the transfusion needs of patients with early myelodysplastic syndrome (MDS). Contact: Mark Goodman, MD. Phone: 305-243-4995.

University of Michigan Comprehensive Cancer Center. UMCC 0068. A randomized study of the safety and efficacy of two dose schedules of gemtuzumab ozogamicin (Mylotarg) in patients with intermediate-2 or high risk MDS. Contact: Harry P. Erba, MD, PhD. Phone: 734-647-8921.

University of Michigan Medical Center. UMCC 9906. Combination of azacytidine and amifostine in the treatment of adults with MDS. Contact: Harry P. Erba, MD. Phone: 734-647-8921.

University of Michigan Medical Center. Clinical treatment via bone marrow transplant for hematological malignancies. Contact: Dr. Harry D. Erba, MD, PhD. Phone: 734-647-8921.

University of Nebraska Medical Center. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: James Foran, MD. Phone: 402-559-6120.

University of Nebraska Medical Center. IRB 389-00. Allogenic peripheral blood stem cell transplantation with minimally myelosuppressive regimen of pentostatin and low dose total body irradiation followed by postgrafting immunomodulation with GM-CSF for non-responders. Contact: Z. Steven Pavletic, MD. Phone: 402-559-7134.

University of Rochester. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Camille N. Abboud, MD. Phone: 716-275-2881.

University of Rochester. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Sharon Swift. Phone: 585-275-2262.

University of Rochester. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Sharon Swift. Phone: 585-275-2262.

University of Rochester Cancer Center. I8400. A phase 2 study of SU5416 in patients with hematologic malignancies, including refractory acute myeloid leukemia, myelodysplasia, refractory acute lymphocytic leukemia, Philadelphia negative myelo-proliferative disorders or chronic myelogenous leukemia. Contact: Jane Pantoja. Phone: 585-275-6753.

University of Rochester Cancer Center. 19400. A randomized study of the safety and efficacy of two dose schedules of gemtuzumab ozogamicin in patients with intermediate-2 or high risk MDS. Contact: Jane Pantoja. Phone: 585-275-4915.

University of Texas Health Science Center. IRB #978-5008-302. Sequential antithymocyte globulin (ATG) and amifostine for the treatment of MDS. ATG is given as an intravenous infusion in the hospital over 4 days. Skin testing for sensitivity to ATG performed prior to the first dose. Amifostine is given as an IV pus. Contact: J. Anderson, MD. Phone: 210-567-4848.

University of Washington, Seattle Cancer Care Alliance. 95-04570-A 05. Determining safety, tolerance, and maximum tolerated dose of SC Interleukin-2 in MDS patients. Contact: John A. Thompson, MD. Phone: 206-288-2041.

University of Washington. 95-0457-A-05. A Phase I trial of subcutaneous, outpatient interleukin-2 for patients with myelodysplastic syndrome. Contact: Beth Easterday. Phone: 206-288-2041.

VCUHS MCV Hospitals, Virginia. Bone Marrow Transplant Program. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Kathy Candler. Phone: 804-828-4360.

VCUHS MCV Hospitals, Virginia. Bone Marrow Transplant Program. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Sharon Swift. Phone contact: Kathy Candler. Phone: 804-828-4360.

VCUHS MCV Hospitals, Virginia. Bone Marrow Transplant Program. HMO5. A multi-center, single-arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparations from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Kathy Candler. Phone: 804-828-4360.

Wake Forest University. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Kenneth Zamkoff, MD. Phone: 336-716-7972.

Washington Cancer Institute. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Joseph P. Catlett, MD. Phone: 202-877-4635.

Washington University in St. Louis. 95-0384. Washington University School of Medicine. A phase II study to evaluate the tumor response rate and toxicity of granulocyte-colony stimulating factor (G-CSF) primed donor leukocyte infusion administered to patients with relapsed hematologic malignancy occurring after allogeneic bone marrow or peripheral blood stem cell transplant. Contact: D.R. Adkins, MD. Phone: 314-454-8490.

Washington University in St. Louis. 95-0763. Washington University School of Medicine. High dose rate/low total dose-single exposure total body irradiation as conditioning for related donor allogeneic peripheral blood stem cell transplantation. A phase II study to evaluate engraftment and duration of neutropenia. Contact: D. Adkins, MD. Phone: 314-454-8490.

Washington University in St. Louis. 97-0793. Washington University School of Medicine. High dose rate/low total dose-single exposure total body irradiation as conditioning for unrelated and mismatched related donor bone marrow transplantation: A phase II study to evaluate engraftment. Contact: D. Adkins, MD. Phone: 314-454-8490.

Washington University in St. Louis. 98-0502. Washington University School of Medicine. Stem cell transplantation for Aplastic Anemia and various malignancies. Contact: R. Brown, MD. Phone: 314-454-8227.

Washington University (Wohl Hospital) in St. Louis. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: John F. DiPersio, MD, PhD. Phone: 314-454-8313.

Washington University in Saint Louis. 101-1022. A three year evaluation of the overall and leukemic free survival of patients who received thymoglobulin therapy for early MDS. Contact: John F. DiPersio, MD, PhD. Phone: 314-454-8317. Carol Rush, Reg. Coord.

Westchester County Medical Center, NYC Medical College. HMO1. A multi-center, open-label, randomized, active controlled phase I/III clinical trial to evaluate the safety and efficacy of processed unrelated bone marrow in patients with acute or chronic leukemia. Contact: Karen Seiter, MD. Phone: 914-285-8374.

Westchester County Medical Center, NYC Medical College. HMO3. A multi-center, non-randomized single arm, phase I clinical trial to evaluate the efficacy and safety of processed bone marrow from mismatched unrelated donors (HLA5/6) in acute or chronic leukemia patients who are older than 35 years of age. Contact: Karen Seiter, MD. Phone: 914-285-8374.

Westchester County Medical Center, NYC Medical College. HMO5. A multi-center, single-arm, open label, phase I clinical trial to evaluate the efficacy and safety of processed hematopoietic stem cell preparations from unrelated or partially matched related donors in patients with poor prognosis hematologic disorders. Contact: Karen Seiter, MD. Phone: 914-285-8374.

Westchester Medical Center, New York Medical College. 008/2000. Non-myeloblative chemotherapy with pentostatin, mitoxantrone and cytarabine for engraftment of allogeneic hematopoietic progenitor cells in patients with hematological malignancies. Contact: Delong Liu, MD and Karen Seiter, MD. Phone: 914-493-8374.

Westchester Medical Center, New York Medical College. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. Contact: Karen Seiter, MD. Phone: 914-493-8374.

The Western Pennsylvania Hospital. WPCI 2001-30 (Celgene # T-MDS-001). A randomized, multi-center, double-blind, placebo-controlled trial assessing the safety and efficacy of thalidomide for the treatment of anemia in red blood cell transfusion dependent patients with myelodysplastic syndromes. Contact: Laura Gibson, RN. Phone: 412-578-1034.

The Western Pennsylvania Hospital. WPCI 9614. Special Exception use of 5 Azacitidine in Myelodysplastic Syndromes. Sponsored by The National Cancer Institute. Contact: Laura Gibson, RN. Phone: 412-578-1034.

Wilford-Hall Medical Center. HMO4. A multi-center, non-randomized single-arm, phase I clinical trial to evaluate the safety and efficacy of processed bone marrow from mismatched related doors (HLA3/6 and 4/6) in acute or chronic leukemia patients. Contact: Major David Ririe, MD, USAF, MC. Phone: 210-292-7391.

William Beaumont Hospital. T-MDS-001. A randomized multi-center, double-blind, placebo-controlled trial assessing the safety and efficacy of thalidomide for the treatment of anemia in red blood cell transfusion dependent patients with myelodysplastic syndromes. Contact: Ingrid Tibbits, RN, BSN, OCN.

Winship Cancer Institute/Emory University. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Elliott Winton, MD. Phone 404-778-5851.

CELGENE

T-MDS-001. Phase III study of thalidomide for the treatment of anemia in patients with myelodysplastic syndromes. Contact: Sherrie Roberts. Phone: (190) 772-6960.

Canadian Trials

Foothills Hospital/Calgary. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Ramakrishnan Parameswaran, MD. Phone: 403-670-1564.

Princess Margaret Hospital/Toronto. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Joseph Brandwein, MD. Phone: 416-946-4595.

Vancouver Hospital. SMC-101-1020. An open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin® therapy on transfusion needs of patients with early MDS. Contact: Thomas J. Nevill, MD. Phone: 604-875-4552.

Canadian Inherited Marrow Failure Registry (CIMFR). This is a study looking prospectively at the development of severe aplastic anemia, myelodysplastic syndromes and leukemia in patients with inherited marrow failure syndromes in Canada. Contact: Yigal Dror MD. Phone: (416) 813-5630.

Canadian Inherited Marrow Failure Registry (CIMFR). Hematopoietic stem cell transplantation in inherited marrow failure syndromes with severe aplastic anemia, myelodysplastic syndromes or leukemia. Contact: Yigal Dror MD. Phone: (416) 813-5630.

European Trials

EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER

EORTC-19951. EORTC. Phase III randomized study of amphotericin B-lipid complex initiated 72–84 hours versus 144–156 hours after onset of febrile episode in cancer patients with granulocytopenia and persistent unexplained fever refractory to antibacterials. Contact: B.E. DePauw, MD. Phone: 011-31-24-3614515.

EORTC-06961. Multicenter. Phase III randomized com-parison of autologous peripheral-blood stem cell transplantation versus second intensive consolidation with high-dose cytarabine following common induction and consolidation in patients with poor-prognosis MDS and acute myelogenous leukemia secondary (sAML) to MDS of more than 6 months' duration. Contact: Theo De Witte, MD. Phone: 024-361-47-62 (Nijmegen, Netherlands).

EORTC-06962. Multicenter. Phase III randomized study to assess intensification of the conditioning regimen for allogeneic stem cell transplantation for leukemia or MDS with a high risk of relapse. Contact: Theo De Witte, MD. Phone: 024-361-47-62 (Nijmegen, Netherlands).

EROTC-58921. EORTC Children's Leukemia Group. Phase III randomized comparison of IDA vs DHAD combined with ARA-C/VP-16 for induction and combined with high-dose ARA-C for intensification in children with newly diagnosed AML or Myelodysplastic Syndrome. Contact: Catherine Behar, MD. Phone: 011-03-26-78-77-89.

EU-98010. Medical Research Council's Working Party on Leukemia in Adults and Children. Phase III randomized study of two induction chemotherapy regimens followed by two or three additional chemotherapy regimens or one or two additional chemotherapy regimen(s) with allogeneic BMT in children with de novo or secondary AML. Contact: E.C. Gordon-Smith, MD. Phone: 011-44-208-725-5448.

EU-98031. Riverside Haematology Group. Phase III randomized study of idarubicin and etoposide vs mitoxantrone, etoposide, and cytarabine as consolidation therapy in patients over 55 years old with AML in first complete remission. Contact: Graham Jackson, MD. Phone: 011-191-222-7632.

EU-99029. Swiss Institute for Applied Cancer Research. Phase III randomized study of antithymocyte globulin and cyclosporine versus best supportive care in patients with low or intermediate risk MDS. Contact: A. Tichelli, MD. Phone: 011-41-61-265-42-54.

EU-20008. Medical Research Council's Working Party on Leukemia in Adults and Children. Phase III randomized study of induction chemotherapy with cytarabine, daunorubicin, and etoposide versus fludarabine and cytarabine and induction chemotherapy with versus without filgrastim (G-CSF) or tretinoin in patients with high risk AML. Contact: D.W. Milligan, MD. Phone: 011-44-1-21-766-6611.

EU-20016. Medical Research Council's Working Party on Leukemia in Adults and Children. Phase III randomized study of intensive versus nonintensive chemotherapy in older patients with acute myeloid leukemia or high risk MDS. Contact: Alan K. Burnett, MD. Phone: 011-222-742-375.

AUSTRALIA

Peter McCullum Cancer Institute. 00/58. A phase II multi-center, open label, dose escalation trial of the safety and efficacy of E2IR in adults with CMML. Contact: John Seymour, MD. Phone: +613-9656-1190.

Peter McCullum Cancer Institute. 00/66. A randomized study of the safety and efficacy of two dose schedule of gemtuzumab ologamicin in patients with intermediate II or high risk MDS. Contact: John Seymour. Phone: +613-9656-1190.

ENGLAND

Kings College Hospital/Guys-Kings-Thomas School of Medicine. Reduced intensity transplants in elderly with MDS and AML using Campath: (CD52) in the conditioning. Contact: Professor G.J. Mufti. Phone: 004-4207-346-3080.

Kings College Hospital/Guys-Kings-Thomas School of Medicine. Thalidomide in good risk MDS. Contact: Professor G.J. Mufti. Phone: 004-4207-346-3080.

Kings College Hospital/Guys-Kings-Thomas School of Medicine. GCSF and Epo versus supportive care. Contact: Professor G.J. Mufti. Phone: 004-4207-346-3080.

FRANCE

French MDS Group. A phase II study of CPT 11 (irinotecan) in high risk MDS. Contact: V. Ribzag, MD. Fax: 33-1-42-11-5270.

Lille University Hospital. Co-sponsored by the Groupe Français des Myélodysplasies. Phase II study of fludarabine phosphate in adult chronic myelomonocytic leukemia (CMML). Contact: P. Fenaux, MD, PhD. Fax: 33-320-44-40-94 (Lille).

Lille University Hospital. Intensive chemotherapy with dose-adjusted quinine in high-risk MDS with P-glycoprotein expression. Contact: P. Fenaux, MD, PhD. Fax: 33-320-44-40-94.

Lille University Hospital. Phase II study of intensive chemotherapy with mitoxantrone (MXN), cytarabine (Ara-C), and fludarabine (FAMP) in high-risk MDS without expression of the P-glycoprotein. Contact: P. Fenaux, MD, PhD. Fax: 33-320-44-40-94.

Groupe Hospitalier Cochin. Phase II study of CPTII in high-risk MDS. Contact: V. Ribrag, MD. Phone: 31-42-11-42-11.

Groupe Hospitalier Cochin. Danatrol in thrombopenic MDS. Contact: P. Fenaux, MD, PhD. Phone: 33-20-44-40-94 (Lille).

GERMANY

Johannes-Hospital Duisburg. A phase II trial. Efficacy of all transretinoic acid in MDS patients with isolated 5q- defect. Contact: Carlos Aul. Phone: 011-49-203-5462480.

Hannover Medical School. Phase II study to evaluate thalidomide in the myelodysplastic syndromes. Contact: Arnold Ganser, MD. Phone: 049-511-5362-8205.

Hannover Medical School. SAKK 33/99. Antithymocyte globulin (ATG) and cyclosporine (CSA) to treat patients with myelo-dysplastic syndromes. A randomized phase III trial comparing ATG and CSA with best supportive care. Contact: Jakob Passweg, MD or Arnold Ganser, MD. Phone: 49-511-532-9257.

Heinrich-Heine University. Dusseldorf. HHU-1648. Phase II clinical trial of thalidomide for patients with myelodysplastic syndromes or idiopathic myelofibrosis. Contact: Norbert Gatterman, MD, PhD. Phone: 49-211-81-16500.

University Hospital Frankfort/Main. ATG and CSA versus ATG in patients with MDS. Contact: Wolf K. Hoffman. Phone: +49-69-6307-5794.

University Hospital Frankfort/Main. Treatment of patients with MDS with thalidomide. Contact: Wolf K. Hoffman. Phone: +49-69-6307-5794.

University Hospital Frankfort/Main. All transretinoic acid in patients with MDS (5q- syndrome). Contact: Wolf K. Hoffman. Phone: +49-69-6307-5794.

University Hospital Frankfort/Main. Antithymocyte Globulin (ATG) and Cyclosporine (CSA) to Treat Patients with Myelodysplastic Syndromes. A randomized trial comparing ATG+CSA with best supportive care Amended Protocol SAKK 33/99. Contact: Wolf K. Hoffman. Phone: +49-69-6307-5794.

University Hospital Frankfort/Main. Phase II Study with Thalidomide in patients with myelodysplastic syndromes. Contact: Wolf K. Hoffman. Phone: +49-69-6307-5794.

University Hospital Frankfort/Main. Intravenous low-dose decitabine versus supportive care in elderly patients with primary Myelodysplastic Syndrome (MDS) (>10% blasts or high-risk cytogenetics), secondary MDS or Chronic Myelomonocytic Leukemia (CMML) who are not eligible for intensive therapy: an EORTC-German MDS Study Group randomized phase III study. Contact: Wolf K. Hoffman. Phone: +49-69-6307-5794.

GREECE

University of Patras Medical School. MDS-5. Treatment of patients younger than or equal to 65 years old with aggressive MDS or acute leukemia secondary to preexisting MDS with a combination of Topotecan and Aracytin or Idarubicin and Aracyn. A comparative randomized study. Contact: A. Symeonidis, MD, N. Zoumbos, MD. Phone:+30-610-999-247, +30-610-999526.

University of Patras Medical School. MDS-6. Treatment of elderly patients with aggressive MDS or acute leukemia secondary to preexisting MDS with Topotecan or Mitoxantrone and infusional standard dose of Aracytin. A comparative randomized study. Contact: A. Symeonidis, MD, N. Zoumbos, MD. Phone: +30-610-999-247, +30-610-999526.

University of Patras Medical School. MDS-7. Maintainance treatment of patients with proliferative or poor prognosis Chronic myelomonocytic leukemia with pulses of Topotecan and intermediate dose Aracytin or hydroxyurea. A comparative randomized study. Contact: A. Symeonidis, MD, N. Zoumbos, MD. Phone: +30-610-999-247, +30-610-999526.

University of Patras Medical School. MDS-8. Non myeloablative stem cell transplantation for patients 51-65 years old with aggressive MDS in first complete remission after 2 cycles of systemic chemotherapy. Contact: A. Symeonidis, MD, N. Zoumbos, MD. Phone: +30-610-999-247, +30-610-999526.

University of Patras Medical School. MDS-9. The role of amifostine as a cytoprotective agent for patients with aggressive MDS or acute leukemia superimposing a preexisting MDS with poor performance status or coexisting morbidity, treated with the standard chemotherapeutic protocols. Contact: A. Symeonidis, MD, N. Zoumbos, MD. Phone: +30-610-999-247, +30-610-999526.

University of Patras Medical School. MDS-10. Treatment of anemic patients with less aggressive MDS and low probability of response to erythropoiten plus G-CSF, with the combination of infliximab and escalated doses of erythropoiten. Contact: A. Symeonidis, MD, N. Zoumbos, MD. Phone: +30-610-999-247, +30-610-999526.

ISRAEL

Rabin Medical Center-Hasharon Hospital. Israel MDS-II (ICG). Low dose idarubicidin (I) and low dose G-CSF for Intermediate (IPSS I and II) and high risk patients. Contact: Mosh Mittelman, MD. Phone: 972-3-937-2361.

ITALY

Unit of Hematology and Stem Cell Transplantation, IRCCS "Casa Sollievo della Sofferenza" Hospital. A clinical trial with high dose, weekly, or b.i.w. administration of recombinant erythropoiten for the treatment of low risk myelodysplastic syndromes: focus on effects on anemia, fatigue and other psycho-social findings. Contact: Dr. Pellegrino. Phone: (0) 882-411389.

Unit of Hematology and Stem Cell Transplantation, IRCCS "Casa Sollievo della Sofferenza" Hospital. A phase I/II clinical trial for the treatment of transfusion-dependent, low-risk myelodysplastic syndromes with low dose thalidomide, alone or in combination with erythropoiten. Contact: Dr. Pellegrino. Phone: (0) 882-411389.

Unit of Hematology and Stem Cell Transplantation, IRCCS "Casa Sollievo della Sofferenza" Hospital. A clinical trial for the treatment of elderly patients with high risk myelodysplastic syndromes with low dose melphalan. Contact: Dr. Pellegrino. Phone: (0) 882-411389.

Unit of Hematology and Stem Cell Transplantation, IRCCS "Casa Sollievo della Sofferenza" Hospital. A clinical study on allogenic "mini" (non-myelosuppressive) peripheral blood stem cell transplantation in patients with high risk myelodysplastic syndromes aged up to 60. Contact: Dr. Pellegrino. Phone: (0) 882-411389.

KOREA

Samsung Medical Center. Manipulation of L-ascorbic acid level for the treatment of selected cases of MDS and AML. Contact: Chan H. Park. Phone: 011-822-341-3450.

NETHERLANDS

University Medical Center St. Radboud. Study for younger patients with high-risk MDS/MDS-AML. Contact: Theo de Witt, MD. Phone: 011-31-24-3618810.

POLAND

Autologous or mini-allo bone marrow/haematopoietic stem cell transplantation in MDS patients. Contact: Aleksander B. Skotnicki MD, PhD.

Effect of thalidomide on clinical and haematological parameters in MDS patients. Contact: Aleksander B. Skotnicki, MD, PhD.

SCANDINAVIA

Aarhus University Hospital. Effect of transfusion iron, iron chelation, and EPO on erythropoiesis in MDS patients. Contact: J. Ellegaard, MD. Phone: 45-89-49-75-58 (Denmark).

MAP Study. Diagnostic study on hypoplastic MDS, aplastic anemia and PHN. Contact: Torben Plesner, MD. Phone: 011-46-85-858-0000.

Scandinavian MDS Group. ATG-CyA 1999. Clinical phase II trial in which patients with RA and RAEB with <10% blasts and no sideroblasts are included. Treatment: ATG followed by cyclosporine A for six months. Contact: Eva Hellstrom-Lindberg, MD, PhD. Phone: 011-46-8-585-800-00.

VU University Medical Center/Amsterdam. HOVON 42. Randomized induction and post induction therapy in adult patients (<60 years of age) with AML, RAEB, RAEB-t with IPSS score greater or equal to 1.5. Contact: Dr. G.J. Ossenkoppele. Phone: +31-20-4442604.

VU University Medical Center/Amsterdam. HOVON 43. Randomized induction and post induction therapy in older patients (≥61 years of age) with AML, RAEB, RAEB-t. Contact: Dr. G.J. Ossenkoppele. Phone: +31-20-4442604.

VU University Medical Center/Amsterdam. In-vivo detection of apoptosis in MDS and AML with technetium 99mTc-Annexin-V (Apomate-TM). The role of EPO and G-CSF Contact: Dr.A.A. van de Loosdreceht. Phone: +31-20-4442604.

SCOTLAND

Ninewells Hospital, Dundee/King's College Hospital. UK MDS Therapy Working Group. A phase I/II trial of thalidomide therapy for low-risk MDS. Contact: David Bowen, MD. Phone: 011-44-1382-86011.

Ninewells Hospital University of Dundee. Identification of markers for early response to the combination of epoietin and G-CSF in the anemia of MDS. Contact: David Bowen, MD. Phone: 011-44-1382-660111.

SOUTH AFRICA

University of Cape Town and Groote Schiur Hospital. MDS/97. The effects of systemic cytokine modulation on haematopoiesis. Studies the effect of ciprofloxacin 500 mg BID, pentoxifylline 800 mg TID and dexamethasone 4 mg TID on blood parameters and clonogenic efficacy of piogenitor cells. Contact: N. Novitzky, MD. Phone: 27-21-404-3073.

SPAIN

Hospital Universitario De Salamanca. SMD-FLAG-IDA-97. Induction therapy with FLAG-IDA with or without PBSCT in high risk MDS patients and secondary AML. Contact: M.C. del Canizo, MD/J.F. San Miguel, MD. Phone: 011-34-923-291384.

SWEDEN

Huddinge University Hospital Karolinska Institutet. Scandinavian MDS-group ATG-CyA/99. Treatment of patients with myelodysplastic syndromes I and II (RA and RAEB) with ATG and cyclosporin A. Phase II trial enrolling patients with refractory anemia and RAEB with less than 10% blasts. Contact: Eva Hellstrom-Lindberg, MD, PhD. Phone: +46-8-585-80-000.

Huddinge University Hospital Karolinska Institutet. Nordic MDS-group Decitabine/02. Maintenance treatment with decitabine versus consolidation treatment with high-dose chemotherapy in patients with advanced MDS and MDS-AML, who have obtained CR with high dose chemotherapy. Randomized phase II study. Remission induction with 2+7. In CR randomization with conventional maintenance (2+7) and low dose decitabine. Contact: Eva Hellstrom-Lindberg, MD, PhD. Phone: +46-8-585-80-000.

SWITZERLAND

Swiss Institute for Applied Cancer Research. CCG-2961. Phase III randomized study of antithymocyte globulin and cyclosporine versus best supportive care in patients with low or intermediate risk Myelodysplastic Syndrome. Contact: Monica Castiglione-Gertsch, MD. Phone: 011-41-31-389-91-91.

THAILAND

King Chulalongkorn Memorial Hospital. MDSCU 9803. To determine the association of RAS-mutation and occupational and environmental exposures in patients with AML and MDS. Contact: Tanin Intragumtornchai, MD. Phone: 011-622-2564564.

UNITED KINGDOM

King's College. Mini and micro allogeneic transplants in MDS. Contact: Professor G.J. Mufti. Phone: 44-207-346-3080.

King's College Hospital. London. A phase I/II trial of thalidomide therapy for low risk MDS. Contact: Professor G.J. Mufti. Phone: 44-207-346-3080.

King's College. Reduced intensity transplant in elderly with MDS and AML using Campath: (CD52) in the conditioning. Contact: Siobhan Lim. Phone: 0207-346-3148.

King's College. Phase i/II study of thalidomide therapy or patients with low risk MDS. Contact: Siobhan Lim. Phone: 0207-346-3148.

King's College. An open label, phase 2 study to evaluate the efficacy and safety of the Farnesyl-transferase inhibitor ZARNESTRA (R115777) in subjects with high-risk MDS. Contact: Siobhan Lim. Phone: 0207-346-3148.

Royal Victoria Infirmary. RHG-AML97, EU-98031. Phase III randomized study of idarubicin and etoposide vs mitoxantrone, etoposide, and cytarabine as consolidation therapy in patients over 55 years old with acute myeloid leukemia in first complete remission. Contact: Graham Jackson, MD. Phone: 0191-222-7632.

Saint George's Medical Center. MRC-LEUK-AML12CH, EU-98010. Phase III randomized study of two induction chemotherapy regimens followed by two or three additional chemotherapy regimens or one or two additional chemotherapy regimen(s) with allogeneic bone marrow transplantation in children with de novo or secondary acute myeloid leukemia. Contact: E.C. Gordon-Smith, MD. Phone: 44-181-725-5448.

The Royal Bournemouth Hospital. Phase II trial of EB 1089, a vitamin D analogue with minimal effect of blood calcium for use in low-grade MDS in patients with Hb <10 g/dl, neutrophils $<1\times10^9$/1 or platelets $<100\times10^9$/1. Contact: Professor T.J. Hamblin. Phone: 01-202-303626 (Bournemouth).

To submit information on your clinical trials for publication, you can fax (609-298-0590) us at the Foundation. Please include a contact person, a phone number, and if applicable, the trial number.

MDS Board of Directors

MDS

About the Foundation

The Myelodysplastic Syndromes Foundation was established by an international group of physicians and researchers to provide an ongoing exchange of information relating to MDS.

Until the Foundation was set up, no formal working group had been devoted to MDS. During the past decade we have conducted seven international symposia—in Austria, England, the United States, Spain, Czech Republic, and Sweden. The Seventh International Symposium will be held May 15-18, 2003 in Paris, France.

One major role of the Foundation is our international information network. This network provides patients with referrals to Centers of Excellence, contact names for available programs, sharing of new research and treatment options, and extension of educational support to both physicians and patients. Ultimately, we hope to provide funding and oversight for international studies in MDS.

In response to the needs expressed by patients, families, and physicians, we have established patient advocacy groups.

The MDS Foundation is a publicly supported organization, exempt from federal income tax under section 501(C)(3) of the IRS code.

Our Website

The MDS Foundation Web page is for healthcare professionals, patients, and other interested people. The Professional Forum and the Patient Forum are integral parts of our Web site.

The Website is constantly being updated to better serve the needs of our patients, their families, and the physicians who treat them.

We welcome your suggestions.

Please visit us at *http://www.mds-foundation.org*

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Membership benefits include quarterly issues of the *MDS News*, a special subscription rate of $105 for *Leukemia Research* (a substantial discount from the current subscription rate of $1,193), and the worldwide Centers of Excellence patient referral service.

If you would like additional information, please contact us at:

The MDS Foundation
P.O. Box 353
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Crosswicks, NJ 08515

Phone: 1-800-MDS-0839
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New York, NY

Mr. Ronald E. Smith, *Albuquerque, NM*

Mr. and Mrs. Vincent and Emily Celino
Meriden, CT

Ms. Naomi Sapp, *Dansville, NY*

United Way of Delaware, *Wilmington, DE*

First Energy Corporation, *Akron, OH*

Ms. Alice J. Lorentz, *Mercer Island, WA*

Cavanaugh, Hagan & Pierson
Washington, DC

Patient Services

The MDS Foundation is pleased to share with our patients and their families that flight services are available within the continental United States to assist with special medical needs.

AirLifeLine is a nationwide organization of over 1,100 pilots who are caring, committed and compassionate individuals donating their time, aircraft and fuel to provide **free transportation** for patients in financial need.

Generally, the criteria for patient travel with us are:

- The patient must be ambulatory or be mobile enough to board and exit the aircraft. The patient must be able to sit in a seat and wear a seatbelt. Patient may bring along a family member or a support person to assist them. In the case of a child, both parents may travel.
- The patient should be medically stable and able to fly in an unpressurized aircraft. Our pilots are not medically trained and their planes are not medically equipped. Oxygen is allowed with the pilot's consent.
- The patient must demonstrate financial need and be unable to afford other means of commercial transportation. We do waive this requirement for financial need if the patient has a time critical situation such as an organ transplant.
- The patient's flight should be less than approximately 1,000 from his or her home to the medical destination. The average mission is between 250–500 miles. However, we can coordinate flights up to 1,000 miles one way.

It is the mission of ***Angel Flight*** to ensure that no financially needy patient is denied access to distant, specialized treatment for lack of means of air transportation.

AirLifeLine	800-446-1231
Angel Flight	800-296-1191
Corporate Angel Network	914-328-1313
National Patient Travel Center	800-296-1217

Thank You to Our Pharmaceutical Partners

We would like to thank our pharmaceutical partners for their support of the Foundation and its work. They have contributed in the form of unrestricted educational grants, which support not only this newsletter but also the development of the MDS home page on the World Wide Web, the Centers of Excellence program, continuing medical education programs, the Patient Registry, and the dissemination of patient information.

A Living Endowment

A Living Endowment donation has been made in honor of:

Ms. Jennifer Horowitz

This donation has been submitted by:

Andrew and Ina Feuerstein*, Brooklyn, NY*

Many families are affected by living with the reality of MDS. There is an extraordinary way to contribute to the MDS Foundation and support our mission of working as a resource for patients, families, and healthcare professionals.

A commitment to donate to the Foundation on occasions of loss, birthdays and anniversary remembrances can be made. Honor your friends or family members on these occasions with a donation, and The MDS Foundation will send an acknowledgment to the recipient, recognizing the occasion.

The MDS Foundation is grateful for community support. Our work as a non-profit organization depends on public funding. If you would like to contribute in this way, please write to us at PO Box 353, 36 Front Street, Crosswicks, NJ 08515, or call us at 1-800-MDS-0839.