



THE MDS NEWS

The Newsletter of The Myelodysplastic Syndromes Foundation

From the Guest Editor's Desk

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Treatment of Myelodysplastic Syndromes

Selection of the treatment plan for a patient with myelodysplastic syndromes (MDS) depends upon the prognosis for the disease course. Currently, the best approach for assessing prognosis is to utilize the International Prognostic Scoring System (IPSS). The IPSS incorporates the results from three types of analyses—the levels of blood counts, the percent of immature cells (“blasts”) in the bone marrow, and the karyotype (chromosome pattern) of the bone marrow cells—to distinguish four prognostic risk groups; the four groups are Low, Intermediate-1, Intermediate-2, and High. Patients having lower risk (Low and Intermediate-1 groups) generally do not have excess blasts in the bone marrow but rather have blood counts which are mildly to moderately abnormal. Higher risk patients, meaning those in the Intermediate-2 or High Risk groups, have severely abnormal blood counts, excess blasts in the marrow, and/or chromosomal abnormalities. The higher risk patients are more likely to experience MDS transformation into acute myeloid leukemia (AML) and to have shorter survival, often less than 1-2

years, whereas those with lower risk can expect to survive for several years, even without treatment.

Once the prognostic grouping is determined, the treatment plan is developed. Relatively low intensity treatments are recommended for patients with low risk. Higher intensity treatments, such as chemotherapy, are not usually recommended for these patients as the risks associated with the treatments themselves may be greater than those associated with the disease. Furthermore, adverse effects of the high-intensity treatments may preclude the patient from benefiting from new treatments which are under development. Patients in the high risk groups, however, are candidates for both low- and high- intensity therapies.

While it is important to note that no therapy for MDS has been shown to prolong survival, it is equally important to comment that new approaches may be successful in this regard. After all, effective treatments have only recently been developed for diseases like tuberculosis, hypertension, and HIV infection. Of course, determination of the effectiveness of potential treatments must be first proven through formal clinical trials before the treatment program can be broadly available. Participation in clinical trials of new MDS therapies will bring all patients closer to improved treatment systems.

Clinical trials and experience have also shown that some therapies may no longer be appropriate. Included on this list are androgens (male hormones such as danazol) and amifostine (Ethyol®), except for certain uses undergoing evaluation in clinical trials. In addition, “colony-stimulating factors” (such as G-CSF, also known as filgrastim or Neupogen®, and GM-CSF, also known as sargramostim or Leukine®) are no longer recommended as solo treatments; while G-CSF and GM-CSF effectively increase the number of normal white blood cells, these treatments do not prevent infection or prolong life expectancy.

Recommendations for other treatments vary. Some treatments, such as transfusions of red cells and/or platelets, remain an important part of the management of MDS. Management also includes monitoring for iron overload that often accompanies frequent red cell transfusions as well as administration of deferoxamine (Desferal®) which counteracts iron overload, thus lessening the risk of future heart and liver problems and diabetes. Other treatments are less broadly used, such as the combination of G-CSF and erythropoietin, because only certain patients are

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likely to respond, as has been shown in this case by Dr. Eva Hellstrom-Lindberg.

New low- and high-intensity treatments are under investigation and are providing encouraging results, with patience as a key part of the treatment program. When used to treat MDS, 3-4 months may be required before response to the various low-intensity approaches can be observed. Response to high-intensity approaches may be observed within 1-2 months.

Low-Intensity Therapies Being Evaluated for Treatment of MDS

1. *Inhibitors of Ras* – Ras is a protein that participates in signaling abnormal cells to continue to divide which, in turns, leads to an excess of blast cells. Drugs known as farnesyl transferase inhibitors block the functioning of Ras and, therefore, slow the accumulation of blast cells. In a study of R115777, a farnesyl transferase inhibitor, for treatment of acute myeloid leukemia, some patients did respond to the treatment, although the exact response rate is unknown and at least some of the patients might have responded to standard therapies.
2. *Inhibitors of angiogenesis* – Angiogenesis is the term applied to the formation of new blood vessels. Because the bone marrow of MDS patients often has an abnormally high number of blood vessels, therapies that inhibit angiogenesis are of interest. Two such therapies include SU5416 and bevacizumab. The former has been reported to produce responses in both AML and MDS although, once again, the benefit over standard therapies has not yet been established.
3. *Thalidomide* – This drug, which was removed from the marketplace in the 1950s after it produced fetal malformations, has been shown to have remarkable activity for treatment of myeloma (cancer of a type of white blood cell). Thalidomide has also been reported to increase blood counts in MDS patients, although these reports as yet require confirmation.
4. *Decitabine* – Through inappropriate methylation, genes that normally suppress cancer become inactivated in MDS. Demethylation of these genes, therefore, slows the development of cancer. An inducer of demethylation, 5-azacytidine, was shown to improve blood counts and quality of life for patients with MDS. Decitabine is similar to 5-azacytidine but, being a more potent inducer of demethylation, decitabine may be even more effective.
5. *ATG + cyclosporine or fludarabine* – Inappropriate activity of the immune system may result in low blood counts, a characteristic of MDS. The

immunosuppressive drug ATG has been shown to occasionally raise blood counts in MDS and is now being combined with other immunosuppressive agents, such as cyclosporine and fludarabine, for evaluation.

High-Intensity Therapies Being Evaluated for Treatment of MDS

1. *Chemotherapy* – While chemotherapy is a standard procedure, new drugs and combinations of new drugs with both older drugs are being evaluated for treatment of MDS. Some of the new combination drugs are troxacitabine, Mylotarg®, and a drug (“genasense”) that opposes the action of Bcl2, a protein that prevents the killing of cancer cells by chemotherapy.
2. *Bone marrow transplantation* – New methods of transplantation are being investigated, with the goal of reducing the intensity of the chemotherapy treatment which is administered prior to the transplant. If successful, older patients will have less risk associated with the procedure. New methods to specifically reduce complications of transplant are also being investigated.

For further information about treatments for MDS or about MDS in general, go to www.mds-foundation.org or www.conference-cast.com/webtie/sots/leukemia2/transcripts.htm, a website established by the National Cancer Institute to disseminate information shared at a “State of the Science” meeting on MDS held in October 2000.

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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.



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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 five international symposia — in Austria, England, the United States, Spain, and the Czech Republic. The Sixth International Symposium will be held in Stockholm, Sweden, June 14–17, 2001.

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 are establishing patient advocacy groups, research funding, and physician education.

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

Our Web Site

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

The Web site has recently been 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>



ORTHO BIOTECH

Ortho Biotech, Inc., has supplied the MDS Foundation with an unrestricted educational grant.

Patient Advocacy Committee Established by the MDS Foundation

The MDS Foundation has been working to develop a strategy for setting up patient groups nationwide. Until recently, we did not have the resources to move ahead as rapidly as we wished. Thanks to the generosity of families and friends of patients lost to this disease, the Foundation was able to establish a Patient Advocacy Committee.

This volunteer Committee is charged with forming nationwide patient advocacy groups, developing new information for patients and planning fund raising programs to support these activities. Committee members include Jennifer Rand, Jody Simon, Joe and Charlotte Pagano, and Foundation representatives: Kathy Heptinstall, John Bennett, Betty Anne Nixon, Laura Ciesielski, and Bob Weinberg.

Any member of the Foundation, patients, friends and family members are invited to join with us to move these projects forward. Please contact Betty Anne Nixon at the Foundation office: 800-MDS-0839 to volunteer.

Your help is needed!!

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!

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

AMGEN

The MDS Foundation is supported by an unrestricted educational grant from Amgen, Thousand Oaks, California.

6th International Symposium on Myelodysplastic Syndromes

**June 14-17, 2001
Stockholm, Sweden**

SCIENTIFIC TOPICS

- Classification – lump or split?
- Management – adaptation to risk?

SCIENTIFIC PROGRAM

Thursday, June 14, 2001

- Management of MDS
- Classification of Myelodysplastic Syndrome: FAB vs. WHO, and Pediatric MDS
- Genetics
- Autologous Transplantation

Friday, June 15, 2001

- Apoptosis
- Pediatric MDS
- Immunology

Suzanne Fleishman Memorial Lecture

Hosted by The Myelodysplastic Syndromes Foundation, Inc.

- Complimentary and Alternative Therapies

Saturday, June 16, 2001

- Development & Transformation
- Biology
- Chemotherapy
- Mini Symposium – Sideroblastic Anemia
- The Role of Mitochondria in Iron Transport and Sideroblast Formation

Sunday, June 17, 2001

- Allogeneic Transplantation
- New Approaches

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Additional information available from the Congress website: <http://www.congrex.com/mds2001>.

A Living Endowment

One Family's Pledge

The family of MDS patient, Eugene Lee, is one of many thousands of families living with the reality of MDS. They have come up with an extraordinary way to contribute to the MDS Foundation and support our mission of working as a resource for patients, families, and healthcare professionals.

Eugene and Meta Lee recently learned of friends who had experienced the unfortunate loss of their mother. The Lees made a decision to honor their friends and their mother by making a donation to the MDS Foundation. The Foundation sent a personal

condolence card to the family, making them aware of the gift. The Lees have made a commitment to continue to donate to the Foundation, not only on occasions of loss, but even as remembrances for birthdays and anniversaries. The Foundation sends a handwritten acknowledgement card to the family, making them aware of these gifts in the Lees name. A fund has been initiated established in Eugene's name for this purpose, and the funds will be used for patient outreach and education.

The MDS Foundation is very grateful for the heartfelt support of Eugene and Meta Lee. Our work as a non-profit organization depends on public funding. If you would like to contribute in this way, or if you have a unique idea of your own, please write to us at PO Box 353, 36 Front Street, Crosswicks, NJ 08515, or call us at 1-800-MDS-0839.

Selected Abstracts in MDS

Adapted from abstracts presented at the American Society of Hematology, December 2000, San Francisco, California

Biologic Determinants of Clinical Response to Thalidomide in Myelodysplasia

S. Mundle, F. Zorat,* V. Shetty, K. Allampallam, S. Alvi,* L. Lisak,* L. Little,* L. Dean,* R. Nascimben,* M. Ekbal,* M. duRandt,* E. Broderick,* P. Venugopal, A. Raza

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Based on the earlier observations of increased levels of tumor necrosis factor α (TNF α) and excessive apoptosis in the bone marrow (BM) of patients with myelodysplastic syndromes (MDS), a suppressor of TNF α ; Thalidomide, was used in the therapy of MDS at our center on a protocol approved by the IRB of RPSLMC. Thalidomide was administered at an initial total daily oral dose of 100 mg PO increased to 400 mg as tolerated. Thirty-one patients [refractory anemia (RA)-18, RA with ringed sideroblasts (RARS)-6, RA with excess blasts (RAEB)-6 and chronic myelomonocytic leukemia (CMML)-1] completed 12 weeks of therapy. Significant hematological responses were noted in 16 patients (11/18 RA and 5/6 RARS). In order to determine the biologic correlates of these responses, patients' sera were assessed by ELISA for the levels of TNF α , transforming growth factor β (TGF β), basic fibroblast growth factor (bFGF) and vascular endothelial growth factor (VEGF). Additionally, plastic embedded bone marrow biopsy sections were examined for the extent of apoptosis by in situ end labeling (ISEL) and for the presence of TNF α , and TGF β by immunohistochemistry using a subjective rating scale of 1+ to 8+. In the sera of both responders [R] and non-responders [NR] the VEGF levels correlated positively with TGF β and TNF α levels. Interestingly, a significant correlation was seen with bFGF ($r=0.679$, $p=0.04$) only in NR. Also, while VEGF correlated negatively with hemoglobin (Hgb) levels in this group ($r=-0.8$, $p=0.03$), demonstrated a positive correlation with Hgb in R group ($r=0.609$, $p=0.058$). Surprisingly, in the R group, BM biopsies showed significantly lower median levels of apoptosis, TGF β and TNF α , (1+, $p=0.19$; 1+, $p=0.012$, and 2+, $p=0.04$ respectively), as compared to those in the NR group

(4.5+, 6+ and 3+ respectively). Clearly, patients with low cytokine and apoptosis levels appear to benefit from the treatment with Thalidomide. This constitutes a biologically recognizable subgroup of good-risk patients who are likely to respond to manipulations of cytokine pathways. The precise mechanism of Thalidomide activity in MDS remains obscure and is most likely a result of its anti-angiogenic, anti-cytokine and immunomodulatory effects.

Thalidomide as a Single Agent or in Combination With Topotecan, Pentoxifylline and/or Enbrel in Myelodysplastic Syndromes (MDS)

A. Raza, L. Lisak,* L. Little,* M. Ekbal,* M. du Rant,* E. Ali,* F. Nascimben,* M. Tareen,* P. Venugopal

Rush Cancer Institute, Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL

Recent biologic insights have led to the development of novel therapeutic venues for the treatment of MDS designed to suppress pro-inflammatory cytokines and/or angiogenesis, as well as modulation of the immune system. Thalidomide has activity in all three areas. In our first trial, 83 MDS patients received thalidomide starting at 100 mg PO and increasing as tolerated to 400 mg PO for 12 weeks; 32 went off study due to side effects (26) or disease progression (6) while 51 are evaluable for response. The median age of these 51 patients was 68 years, there were 36 males/15 females, 48 had primary and 3 had secondary MDS, 44 had normo- or hypercellular and 7 had a hypocellular marrow. Initial FAB showed 28 RA, 9 RARS, 12 RAEB, 1 RAEB-t, and 1 CMMoL. IPSS scoring showed that 17 had low risk, 26 had int-1, 4 had int-2 and 4 had high risk disease. Abnormal cytogenetics were present in 35 while 16 had normal karyotypes. There were no complete responders, partial responses were seen in 21/51 (41%) patients, 8 patients who were transfusion dependent became completely independent of transfusions. The median duration of response has not been reached yet, the longest treated patients having completed 1 year of therapy. Responses were noted in all three lineages, but were most effective in the erythroid series. Low risk patients with no excess blasts and higher pre-therapy platelets were more likely to respond. In half the RAEB cases, the blasts remained unaffected even though hematopoiesis improved significantly. Several cases responded 1-10 weeks after stopping therapy. Currently, low risk MDS are treated with either a combination of thalidomide with Enbrel, or PCD (pentoxifylline, Cipro, dexamethasone), while topotecan is administered initially to reduce the blast count in

high-risk patients followed by thalidomide. Initial results on these combination therapies appear to be superior to thalidomide alone. Mechanism of response remains unclear, although post-therapy levels of pro-inflammatory cytokines, apoptosis and angiogenesis were decreased. Delayed responses appear to indicate immune-modulation as the likely mechanism in at least a subset of patients. In conclusion, thalidomide appears to be a promising addition to MDS therapeutic armament and deserves further study.

Danazol for the Treatment of Thrombocytopenia in Myelodysplastic Syndrome

**Geoffrey W. Chan,* Gina DiVenuti,*
Kenneth B. Miller**

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New England Medical Center, Boston, MA, USA**

Therapy for thrombocytopenia in myelodysplastic syndrome remains limited. Danazol, an attenuated androgen with immunomodulatory properties, is effective in some patients with ITP. We report on 29 MDS patients, 9 RA, 11 RAEB, 5 RAEB-t, 4 CMML, who were treated with danazol 200 mg po tid. Median age was 68.5 years (range 44 to 93 years) with 18 males and 11 females. Cytogenetic studies revealed 4 patients with 5q-, 4 with monosomy 7, 3 with three or more chromosomal abnormalities, 10 with other abnormalities, and 8 with normal karyotypes. Median platelet count prior to therapy was 41,000 per mm³ (range 10,000 to 97,000 per mm³). Seven patients required platelet transfusions prior to initiating therapy. After six weeks, 22 out of 29 patients (76%) responded with elevations in platelet counts ranging from 1,000 to 181,000 per mm³. Nine responders had started with platelet counts less than 30,000 per mm³ and another seven responders had started with platelet counts between 30,000 and 50,000 per mm³. Ten patients (34%) increased their platelet counts by more than 50%, 14 of 22 responders increased their platelet counts above 50,000 per mm³, and 5 responders who were platelet transfusion dependent no longer required platelets. After three months, 18 out of 26 patients (72%) had an elevation in platelet counts. Thirteen patients (50%) had increased their platelet counts by more than 50%. Responses were seen in all FAB subtypes at six weeks (9/9 RA, 9/11 RAEB, 1/5 RAEB-t, 4/4 CMML) and at twelve weeks (7/9 RA, 6/10 RAEB, 3/3 RAEB-t, 3/4 CMML). There was no correlation between the pretreatment platelet count and response to danazol. No appreciable increases in the hematocrit or white blood cell counts were observed. Mean duration of treatment was 9.4

months with 6 patients maintaining their responses for over 12 months. Headaches and nausea were the most common reported side effects but they were not severe enough to interrupt therapy in any patients. Liver function tests did not rise significantly above baseline. At the time of analysis, 12 patients remain alive and free from progression. Ten patients transformed to AML. Of the remaining 7 patients, 1 died from intracranial hemorrhage, 1 from perforated bowel, 2 from other causes, and 3 were lost to follow-up. In conclusion, danazol may be effective in MDS patients with symptomatic thrombocytopenia.

Low Dose Interleukin-11 is Well-Tolerated and Induces Platelet Responses in Myelodysplasia and Other Bone Marrow Failure States

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M. Talpaz**

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Interleukin-11 (IL-11) is a thrombopoietic cytokine that attenuates post-chemotherapy thrombocytopenia. The dose used post-chemotherapy is $\approx 50 \mu\text{g/kg/day}$ s.c. Very little is known about the activity of IL-11 in bone marrow failure states. Our preliminary experience with IL-11 at doses of $50 \mu\text{g/kg/day}$ suggested that bone marrow failure patients developed significant peripheral and pulmonary edema after the prolonged dosing necessary for treating these conditions. We therefore initiated a study of low-dose IL-11 ($10 \mu\text{g/kg/d}$). Response criteria included doubling of platelets and rise to $>50 \times 10^9/\text{L}$ or tripling of platelets and rise to $>20 \times 10^9/\text{L}$. Sixteen patients are evaluable for response. Their median age was 58 years (range, 5 to 84 years). Six patients had diploid cytogenetics; the others had a variety of chromosomal abnormalities. Six of 16 patients (38%) showed a platelet response to IL-11 and two had a multi-lineage response (to IL-11 alone [N=1]; to IL-11 + G-CSF and EPO [N=1]). Responders included 5 of 11 patients with myelodysplasia (MDS) and 1 of 4 patients with aplastic anemia (AA). Response duration was 12, 13, 14+, 22+, 25 and 30 weeks. Side-effects of IL-11 were mild (peripheral edema, N=7; conjunctival injection, N=7 or myalgia [N=1]) (all grade 1). Seven patients had no side-effects. Our pilot study suggests that administration of low dose IL-11 ($10 \mu\text{g/kg/day}$) can raise platelet counts, without significant toxicity, in selected thrombocytopenic patients with bone marrow failure.

High Dose (HD) Chemotherapy in High Risk (HR) Myelodysplastic Syndrome (MDS): Covariate Adjusted Comparison of Five Regimens

Miloslav Beran,¹ Yu Shen,^{*2} Hagop Kantarjian,¹ Simona Despa,^{*2} Elihu Estey¹

¹Leukemia, The University of Texas MD Anderson Cancer Center, Houston, TX; ²Biomathematics, The University of Texas MD Anderson Cancer Center, Houston, TX

To further define the role of high dose combination chemotherapy in patients with diagnosis (Dx) of HR MDS (RAEB, RAEBt) we have analyzed (a) association between covariates and CR status, (b) relationship between diagnosis and CR status (c) significance of treatment effect for time to relapse and death (d) covariate-adjusted activity of five consecutive treatment regimens. In the cohort of 394 patients, 229 (58%) achieved CR. The CR rates by regimens are summarized below:

Status	IA*	FA*	FAI*	TA*	CAT*	p value
CR(%)	48 (72)	46 (61)	57 (48)	44 (59)	34 (58)	0.041
NO CR (%)	19 (28)	30 (39)	61 (52)	30 (41)	25 (42)	

*I=idarubicin; F=fludarabine; A=intermediate or high dose cytosine arabinoside; T=topotecan; C=cyclophosphamide.

In multivariate analysis, disease duration (AHD), performance status (PS), protected environment (PE) and days to response but not IPSS were significant predictors of CR (two-sided $p < 0.05$). With covariate adjustment, treatment groups (TG) showed comparable CR rates. Dx was not associated with CR status in IA, CAT, FA and FAI; within TA group RAEB was more likely to achieve CR than RAEBt ($p = 0.01$). Overall logrank test documented significant treatment effect in terms of overall survival ($p < 0.01$), and time to relapse ($p = 0.01$). The trend for time to relapse was the same as for time to death among five treatment groups. Multivariate analysis for time to death revealed treatment, cytogenetics, age, prior chemotherapy, PE, PS, hemoglobin and platelets independent risk factors. Survival for IA patients was comparable to TA, both being superior to FAI, FA and CAT. IA was more effective in sustaining remission than FA or FAI but not different from TA. In summary, no difference between anthracycline or non-anthracycline-containing regimens were observed. Effective in inducing CR, particularly in e.g. -5/-7 karyotype, HD therapy is not associated with improvement in CR duration and survival.

Comparison of Interphase Fish and Metaphase Cytogenetics to Study Myelodysplasia: An Eastern Cooperative Oncology Group (ECOG) Study

G. Dewald,* G. Hicks,* R. Higgins,* C. Griffin,* A. Cherry*, J. Rowe, M. Tallman, J. Bennett, K. Miller

Mayo Clinic, Rochester, MN, USA

This investigation compared standard metaphase chromosome studies with interphase studies using chromosome specific DNA probes with fluorescence in situ hybridization (FISH) to detect neoplastic clones in bone marrow from patients with myelodysplastic syndromes (MDS). FISH was used with chromosome specific DNA probes to detect abnormalities of chromosomes 5, 7, 8, 11, 13 and 20. For each patient, the percentage of neoplastic nuclei in 200 consecutive cells for each probe was established. Chromosome studies were done on ≤ 25 metaphases for the same specimens. FISH was done on 34 fixed cell pellets from cytogenetic studies and 8 bone marrow aspirate smears from morphology studies. Patients included 5 with high risk MDS (E3996) and 37 with low risk MDS (E1996). Excluding -Y as a marker of clonality, an abnormal clone was identified in metaphases from 14/42 (33.3%) patients and 28 (66.7%) were normal. By comparison, interphase FISH studies on these same specimens detected an abnormal clone in 11/41 (26.8%), only normal nuclei in 30 (73.2%) and failed in 1 (2.4%). Among patients with an abnormal clone by cytogenetics 1 had RA, 3 RARS, 8 RAEB and 2 RAEB-T. Among patients with normal cytogenetics 4 had RA, 13 RARS, 7 RAEB, 2 RAEB-T and 1 CMML. Abnormalities were detected in metaphases of 3 patients that were not evident by FISH in interphase cells either because the FISH strategy was not designed to detect the abnormality or probe hybridization failed. Each of the 28 patients with only normal metaphases also had only normal interphase cells. FISH detected ≥ 1 abnormalities of chromosome 5,7,8, 11,13 and 20 in 2,3,4, 0,0 and 4 patients, respectively. FISH failed for all probes in 1/34 fixed cell pellets, for chromosome 11 in 1/8 smears, and for chromosome 20 in 3/8 smears. Results of this study dispel the argument that patients with MDS often have chromosome abnormalities that are missed by chromosome studies due to sampling errors. The results indicate that approximately 70% of patients with low risk MDS do not have abnormalities that are detectable by either chromosome studies or FISH. The results suggest that the sensitivity of interphase FISH studies for MDS is nearly as good as cytogenetic

studies. FISH may be useful in clinical practice to study bone marrow specimens when chromosome studies are not successful or when only smears are available.

Clonal Cytogenetic Anomalies Suggestive of A Myelodysplastic Syndrome in Patients With Morphologically Normal Bone Marrow Aspirates

David P. Steensma, Gordon W. Dewald,* Janice M. Hodnefield,* Ayalew Tefferi, Curtis A. Hanson

Mayo Clinic, Rochester, MN, USA

Clonal cytogenetic abnormalities are found in the bone marrow cells of 40 to 60% of patients with myelodysplastic syndromes (MDS). We have occasionally observed patients with morphologically normal bone marrow aspirates, but with clonal abnormalities on conventional cytogenetic analysis suggestive of MDS. Between October 1994 and April 2000, 58 such patients were seen at our institution (36 men, 22 women; age range, 19–88 years; median age, 71). The indications for marrow aspiration in this group were cytopenias alone (32 patients), staging or follow-up of a lymphoproliferative or plasma cell disorder (21 patients), or another miscellaneous reason (5 patients). 27 of the 58 patients had previously been treated with an alkylating agent (14 cyclophosphamide, 7 melphalan, 4 chlorambucil, 1 BCNU, 1 nitrogen mustard) starting a median of 68 months earlier. 51 patients were anemic, 30 had erythrocyte macrocytosis, 30 were leukopenic, and 40 were thrombocytopenic; 26 were pancytopenic. The marrow was hypocellular in 21 cases, normocellular in 14, and hypercellular in 23. As of August 2000, with a median follow-up of 7 months, 18 of the 58 patients were dead. Of these 18 patients, 1 died of acute myelogenous leukemia (AML), 4 of complications related to cytopenias, 6 of a previously diagnosed lymphoproliferative disorder, and 7 of unrelated causes. The cytogenetic findings were as follows: among those with 1 or 2 clonal cytogenetic anomalies, the most common abnormality was del(20)q [11 patients], followed by: del(7)q or monosomy 7 [6 patients], trisomy 8 [4 patients], del(5)q [3 patients], del(13)q [3 patients], and t(1;7)(q10;p10) [2 patients]. 21 patients had other unique clonal cytogenetic anomalies, and 11 patients had a complex karyotype (3 or more anomalies). There were no significant differences between the karyotypes of patients treated with alkylating agents and untreated patients. We conclude that a clonal cytogenetic anomaly suggestive of MDS in the absence of

morphologic findings of marrow dysplasia still carries a risk of leukemia transformation or death from cytopenias. The cytogenetic abnormalities in this group are generally typical of MDS, with del(20)q being the most frequently encountered. Del(20)q was seen alone in 19% of our patients; in a recent series of 640 MDS patients, this anomaly was seen alone in only 2% of cases with the refractory anemia FAB subtype. Continued follow-up will more clearly define the prognosis in this heterogeneous cohort.

Addition of Thalidomide (T) to Chemotherapy Did Not Increase Remission Rate in Poor Prognosis AML/MDS

Elihu Estey, Maher Albitar, Jorge Cortes, Francis Giles, Deborah Thomas, Charles Koller, Miloslav Beran, Hagop Kantarjian

M.D. Anderson Cancer Center, Houston, TX, USA

Marrow microvascular density (MVD) appears increased in AML (*Blood* 95:309, 2000) and high levels of cellular vascular epithelial growth factor (VEGF) seem independently associated with worse treatment outcome (*Blood* 95:2637,2000). Therefore we randomly assigned adults with newly-diagnosed AML, RAEB-t, or RAEB to receive liposomal daunorubicin (LD, 100 mg/m² daily days 1–3) and ara-C (A, 1 g/m² daily days 1–4) with or without the “anti-angiogenesis” agent T (400 mg daily × 1 week, then 600 mg daily) for remission induction. In remission, patients received 6 mos of LDA, +/- T as originally assigned. Eligibility required an abnormal karyotype other than t(15;17), t(8;21), or inv (16). A Bayesian design stipulated that accrual into either arm would stop should the probability become <0.02 that the early CR (ECR, *Blood* 95:72,2000) rate was not at least 20% higher than the 46% rate seen in patients with the described cytogenetics given other regimens 1991–99. With this stopping rule, the probability of early termination should the true ECR rate with an arm be >0.66 (0.46+0.2) was 0.07. 74 patients were randomized:

LDA (38 patients) LDA+T (36 patients)

Median Age	65 years	66 years
Poor performance status	11%	11%
Chromosome 5 or 7 involved	50%	58%
History abnormal blood count	50%	53%
RAEB or RAEB-t	29%	31%
Early CR rate (CR rate)	50% (53%)	42% (44%)

These ECR rates led to termination of both arms. In particular, the probability that the ECR rate with LDA+T is $\geq 20\%$ higher than historical is <0.01 ; the probability that it is $\geq 10\%$ higher is .05. Early death (weeks 1–7) rates were 24% LDA, 19% LDA+T; relapse rates also appear similar. The median daily dose of T was only 57% of that scheduled, principally because of fatigue. Achievement of ECR was unrelated to daily administered T dose ($p=0.91$) or pre-Rx values of MVD ($p=0.69$, assessed in 18 patients, 10 ECRs) or plasma VEGF ($p=0.33$ assessed in 40, 19 ECRs); the latter observations also applied considering only the LDA+T group. Addition of T to LDA seems unlikely to improve average remission rate in poor prognosis AML/MDS.

HLA DR15 (DR2) is Over-Represented in Myelodysplastic Syndrome (MDS) and is Associated With a Response to Immunosuppression

Yogen Sauntharajah, Ryotaro Nakamura, Jamie Robyn, Fausto Loberiza, Kevin E. Brown, Neal S. Young, A. John Barrett

Hematology Branch, National Heart, Lung, and Blood Institute, National Institute of Health, Bethesda, MD, USA

In vitro and clinical data suggests that immune-mediated marrow suppression, well defined in aplastic anemia (AA), is also a feature of some patients with MDS. However autoimmune mechanisms in MDS, and the characteristics of patients likely to respond to immunosuppression remain incompletely defined. Since HLA-DR2 and its commonest defined allele HLA DR15 are known to be overexpressed in AA, we studied serologically-defined HLA DR frequencies in 1752 AA and 707 MDS (RA, RAEB, and RARS) patients undergoing stem cell transplants reported to the International Bone Marrow Transplant Registry (IBMTR) and molecularly-defined HLA DR frequencies in patients with AA ($n=100$) or MDS ($n=82$) treated with immunosuppressive regimens at NIH. Compared with 14.2% ($n=3978$) in healthy North American controls, the frequencies of HLA DR-2 in MDS and AA patients were 26.5% ($\chi^2=62$, $p\leq 0.0001$) and 38% ($\chi^2=400$, $p<0.0001$), respectively. In the NIH Caucasian patients, molecular typing revealed that HLA-DR 15 frequency (constituting $>80\%$ of the serologically defined HLA DR2 allele) was increased in both AA (58%, $\chi^2=92$, $p<0.0001$) and MDS (41% $\chi^2=30$, $p<0.0001$) compared with Caucasian controls (14.4%, $n=4980$). In multivariate analysis of NIH MDS patients, HLA DR15 was significantly associated with

transfusion-independence following ATG or cyclosporine ($p<0.05$). HLA DR15 frequency in responders was 57% compared with 31% for non-responders ($p=0.03$). The high frequency of HLA DR15 in MDS, comparable to that seen in AA, suggests a link between HLA DR2/15 and immune-mechanisms of marrow failure in MDS and AA. Furthermore, DR15 typing could help predict MDS patients most likely to improve marrow function after immunosuppressive treatment.

Validation of the WHO Proposals for a New Classification of Myelodysplastic Syndromes: Analysis of 1640 Patients

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Dept. of Hematology, Heinrich-Heine-University, Düsseldorf; Dept. of Hematology, St. Johannes Hospital, Duisburg, Germany

A working group of the World Health Organisation proposed a new classification of MDS. Myeloproliferative CMML and RAEB-T were removed and RAEB was split into two groups, with medullary blast counts below and above 10%. A group of patients with less than 5% medullary blasts but multilineage dysplasia was defined. MDS patients with 5q- were considered a separate group. The present study validates this classification with respect to prognosis and cytogenetic features in a large series of patients ($n=1640$) with a long-term follow up.

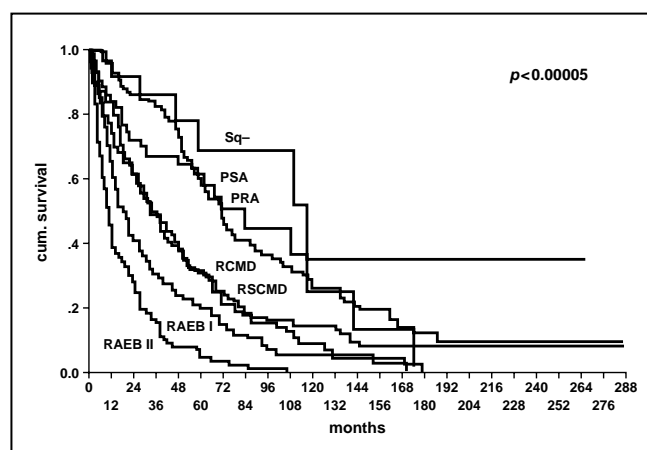


Figure 1. PSA=pure sideroblastic anemia; PRA=pure refractory anemia; RCMD=refractory cytopenia with multilineage dysplasia; RSCMD=refractory sideroblastic anemia with multilineage dysplasia.

We confirmed a significant difference in survival and frequency of AML evolution between RAEB I and RAEB II, and a striking difference between pure refractory anemia and multilineage dysplasia (with or

without ring sideroblasts). Karyotype anomalies were more frequent in patients with multilineage dysplasia. The good prognosis of 5q- patients was restricted to those with medullary blast below 5%. The WHO classification defines morphological subgroups that clearly differ with respect to prognosis.

Myelodysplastic Syndromes, from FAB to WHO: Comparison of Classifications on 431 Unselected Patients from a Single Institution

**T. Noesslinger,* R. Reisner,* H. Gruener,*
H. Tuechler,* E. Pittermann,* M. Pfeilstoecker***
(Intr. by Renate Heinz)

3rd Med. Dept. for Haematology and Ludwig Boltzmann Institute for Hematology and Leukemia Research, both Hanusch Hospital Vienna, Vienna, Austria

In 1976 the FAB group established for the first time diagnostic criteria for myelodysplastic syndromes (MDS). In 1982 the same group introduced the FAB-classification (RA, RARS, RAEB, RAEB-t, CMML). In 1999 a revised classification (WHO) was published: RA, RARS, Refractory Cytopenia with multilineage dysplasia (RC+Dys), RAEB, 5q- syndrome and MDS unclassifiable; CMML and RAEB-t should be excluded.

Between 1976 and 1999 431 patients (median survival 30 months) were diagnosed at our institution as primary MDS according to FAB-classification: 142 RA (med. surv. 66 mo), 47 RARS (73 mo), 92 RAEB (15 mo), 51 RAEB-t (9 mo), 99 CMML (24 mo). 281 patients (median survival 43 months) were classifiable according to WHO: 43 RA (66 mo), 4 RARS (65 mo), 91 RC+Dys (86 mo, in FAB: 65 RA, 26 RARS), 92 RAEB (15 mo), 1 5q-syndrome, 50 MDS unclassifiable (67 mo, in FAB: 33 RA, 17 RARS). We compared both classifications using morphological and clinical data, as well as cytogenetics. In addition we studied the homogeneity of the above mentioned subgroups by evaluating prognostic scoring systems, especially the IPSS, taking into account cytogenetic data. The first expected phenomenon was a significant patient shift into the lower risk groups according to the IPSS (FAB 58% vs. WHO 76% of the patients in low- and intermediate-1 risk group).

Our data stress the necessity of incorporating cytogenetic results in classification parameters. Consequences for future clinical trials and also for future prognostic systems will be discussed.

Gifts to the Foundation

The MDS Foundation relies entirely on gifts and membership fees to further its work. We would like to acknowledge the generosity of the following individuals and organizations that have recently provided gifts to the Foundation:

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Long Beach, NY

Mr. Aaron Rabinowitz
Melbourne, FL

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The Foundation extends its sincerest thanks to these donors.

MDS Patient Registry

PHARMACIA

Pharmacia & Upjohn 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.

PHARMACIA



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.

The following centers have qualified as MDS Centers of Excellence:

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In Memorium

A memorial fund has been established in the name of Mr. Frank T. Akins

Donations have been made in Mr. Akins' memory by:

Barry Mizes and Ellen Bern, *Saint Louis, MO*

A memorial fund has been established in the name of Mrs. Frances N. Artuso

Donations have been made in Mrs. Artuso's memory by:

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Ralph & Norma Dreby <i>Medford, NJ</i>	Fred Croger <i>Palmyra, NJ</i>
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Wade, Kathleen & Brian Lundquist <i>New Canaan, CT</i>	Robert & Adele Lynch <i>Haddonfield, NJ</i>
Elaine Zeigler Neely <i>Haddonfield, NJ</i>	

A memorial fund has been established in the name of Mr. Eduardo Perez Casalduc

Donations have been made in Mr. Casalduc's memory by:

Daniel & Maria Helena & Ms. Lotte Feldsberg <i>Miami, FL</i>	Bob & Tony Viera <i>Coral Springs, FL</i>
	The Coffee Bean, Inc. <i>Miami, FL</i>

A memorial fund has been established in the name of Mr. Kenneth Dale Cash

Donations have been made in Mr. Cash's memory by:

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Gary and Marjorie Ligget <i>Decatur, TX</i>	Bobbie Robicheaux <i>Fort Worth, TX</i>

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Pamela R. French <i>Kernersville, NC</i>	Richard & Sarah Owen <i>Chapel Hill, NC</i>
Mrs. Kenneth Temple <i>Charlotte, NC</i>	The Burks Family <i>Roanoke, VA</i>
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Michael & Meg Connolly <i>Charlotte, NC</i>	Hartmut & Irene Kossack <i>Charlotte, NC</i>
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David & Nina Depenbrock <i>Charlotte, NC</i>	Cedar Forest Racquet Club <i>Charlotte, NC</i>
Joe G. Browder <i>Charlotte, NC</i>	Melody Macklay <i>Asheville, NC</i>

A memorial fund has been established in the name of Mr. Jerry Dashe

Donations have been made in Mr. Dashe's memory by:

Sharie D. Carter <i>San Diego, CA</i>	Ann Dashe <i>La Jolla, CA</i>
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Donations have been made in Mrs. Diossy's memory by:

Gary and Janice Summerhill <i>Niles, IL</i>	Dorothy Willard <i>Palatine, IL</i>
Denise G. Paul <i>Chicago, IL</i>	Tops Club <i>Palatine, IL</i>
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A memorial fund has been established in the name of Mrs. Jean Hackney

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A memorial fund has been established in the name of Mrs. Irene Kulnis

Donations have been made in Mrs. Kulnis' memory by:

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Helen Smolenski <i>Rutherford, NJ</i>	Millivoi Family <i>Secaucus, NJ</i>
	Mr. & Mrs. A. Adamczyk <i>Pompton Plains, NJ</i>

A memorial fund has been established in the name of Mr. Henry Lauro

Donations have been made in Mr. Lauro's memory by:

Robert & Jo-Ann Freund, *Oakland, NJ*

A memorial fund has been established in the name of Mrs. Marianne Lottes

Donations have been made in Mrs. Lottes's memory by:

Julie Stoddard, *Tucson, AZ*

A memorial fund has been established in the name of Mr. David Miquelon

Donations have been made in Mr. Miquelon's memory by:

Donna Peterson Byron Family, *Collins, OK*

A memorial fund has been established in the name of Mrs. Anna M. Pagano

Donations have been made in Mrs. Pagano's memory by:

Charles & Patricia Gallagher, *Fairfield, NJ*

A memorial fund has been established in the name of Mr. Eduardo Perez

Donations have been made in Mr. Perez's memory by:

Michaelina McCarthy, *Miami, FL*

A memorial fund has been established in the name of Mr. Leo Pompliano

Donations have been made in Mr. Pompliano's memory by:

David Pompliano, *Centreville, MD*

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-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-G98-1406. Roswell Park Cancer Center. Phase II study of cord blood transplantation for hematologic malignancies. Contact: R. Wells, MD. Phone: 513-636-4266.

NCI-G98-1429. Ireland Cancer Center at Case Western Reserve University. 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-G98-1444. Memorial Sloan-Kettering Cancer Center. Phase II study of decitabine for MDS. Contact: S. Nimer, MD. Phone: 212-639-7871.

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

NCI-G99-1542. Phase I pilot study of RAS peptide cancer vaccine and sargramostim (GM-CSF) in patients with MDS. Contact: S.D. Nimer, MD. Phone: 212-639-7871.

NCI-G99-1543. Phase II study of allogeneic bone marrow transplantation in patients with hematologic malignancies. Contact: P.V. O'Donnell, MD. Phone: 410-614-0205.

NCI-G99-1544. 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-G99-1603. UCLA-Jonsson Comprehensive Cancer Center. Phase I pilot study of nonmyeloablative chemotherapy followed by unrelated peripheral blood stem cell transplantation in patients with advanced hematologic malignancies. Contact: C. Emmanouilides, MD. Phone: 310-206-0716.

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-G99-1618. University of Chicago. Phase II study of allogeneic peripheral blood stem cell transplantation following non-myeloblastic chemotherapy in patients with hematologic malignancies. Contact: T. Zimmerman, MD. Phone: 773-702-4145.

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-G99-1658. Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Phase III randomized

study of captopril in patients undergoing autologous bone marrow or stem cell transplantation. Contact: Leo I. Gordon, MD. Phone: 312-695-4546.

NCI-G00-1686. Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Phase II study of high dose busulfan and cyclophosphamide followed by allogeneic bone marrow transplantation in patients with AML or MDS. Contact: Martin Stuart Tallman, MD. Phone: 312-695-6180.

NCI-G00-1688. Robert H. Lurie Comprehensive Cancer Center, Northwestern University Phase II pilot study of busulfan and etoposide with autologous bone marrow transplantation and filgrastim (G-CSF) in patients with acute myelogenous leukemia or MDS. Contact: Martin Stuart Tallman, MD. Phone: 312-695-6180.

NCI-G00-1691. Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Phase I pilot study of T-cell depleted partially matched related donor hematopoietic stem cell transplantation using intense pre- and post-transplantation immunosuppression and megadose CD34 "Veto" cells in patients with high risk hematologic malignancies. Contact: Richard K. Burt, MD. Phone: 312-908-5400.

NCI-G00-1732. Ireland Cancer Center. Phase I study of fludarabine, carboplatin, and topotecan in patients with relapsed or refractory acute leukemia or advanced MDS. Contact: Brenda Cooper, MD. Phone: 216-844-3213.

NCI-G00-1742. University of Texas—MD Anderson Cancer Center. Phase I study of psoralen (S-59) treated allogeneic cellular immunotherapy plus mega T-cell depleted HLA nonidentical blood progenitor cell transplantation in patients with hematologic malignancies or bone marrow failure. Contact: James Gajewski, MD. Phone: 713-792-2933.

NCI-G00-1755. H. Lee Moffitt Cancer Center and Research Institute. Phase II study of allogeneic bone marrow transplantation using closely matched related and unrelated donors in patients with malignant or nonmalignant hematologic disorders. Contact: Steven C. Goldstein, MD. Phone: 813-979-7202.

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-G00-1762. Fred Hutchinson Cancer Research Center. Phase I pilot study of fludarabine and low dose total body irradiation, followed by unrelated donor stem cell transplantation, followed by unrelated donor lymphocyte infusions in patients with hematologic malignancies. Contact: Michael Maris, MD. Phone: 206-667-2480.

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-G00-1801. Dana-Farber Cancer Institute. Phase I study of HLA haploidentical bone marrow transplantation after ex vivo exposure to anti-B7 antibodies in patients with refractory, high risk hematologic malignancies or bone marrow failure. Contact: Eva Guinan, MD. Phone: 617-632-4932.

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 nonmyeloablative 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 nonmyeloablative 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 aplastic 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 (summary last modified 01/2001). 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-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-G00-1900. Fred Hutchinson Cancer Research Center. Phase II study of gemtuzumab ozogamicin, fludarabine, and total body irradiation followed by allogeneic peripheral blood stem cell or bone marrow transplantation with cyclosporine and mycophenolate mofetil in patients with advanced acute myeloid leukemia or myelodysplastic syndrome. Contact: Eric Sievers, MD. Phone: 206-667-5757.

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-H98-0023. Johns Hopkins Oncology Center. Phase I study of total body irradiation, tacrolimus, and mycophenolate mofetil with HLA-identical related-donor bone marrow transplantation. Contact: E. Fuchs, MD. Phone: 410-955-8143.

NCI-H99-0028. Phase II study of iodine I 131 mono-clonal antibody BC8 plus cyclophosphamide and total body irradiation followed by HLA matched related or unrelated

bone marrow transplantation in patients with advanced acute myeloid leukemia or MDS. Contact: D.C. Matthews, MD. Phone: 206-667-2966.

NCI-H99-0031. Phase II study of donor lymphocyte infusion in patients with relapsed malignancies after allogeneic hematopoietic transplantation. Contact: M.E.D. Flowers, MD. Phone: 206-667-6557.

NCI-H00-0051. Memorial Sloan-Kettering Cancer Center. Phase I study of suberoylanilide hydroxamic acid (SAHA) in patients with advanced malignancies. Contact: William K. Kelly, MD. Phone: 212-639-7992.

NCI-H00-0054. Fred Hutchinson Cancer Research Center. Phase II study of bone marrow transplantation using unrelated donors incompatible for 1 HLA locus antigen in patients with hematologic malignancies. Contact: Claudio Anasetti, MD. Phone: 206-667-7115.

NCI-H01-0067. Fred Hutchinson Cancer Research Center. Phase I/II study of beclomethasone in patients with intestinal graft-versus-host disease with contraindication to high-dose immunosuppressive therapy. Contact: David Hockenbery, MD. Phone: 206-667-4611.

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-P00-0168. North Central Cancer Treatment Group. Phase III randomized study of ondansetron in patients with advanced cancer and chronic nausea and emesis not due to antineoplastic therapy. Contact: Steven R. Alberts, MD. Phone: 507-284-4918.

NCI-T97-0027. Indiana University Cancer Center. Phase I study of recombinant human interleukin-12 (IL-12) after high-dose chemotherapy and autologous hematopoietic stem cell support in patients with hematologic malignancies and solid tumors. Contact: M. Robertson, MD. Phone: 317-274-0843.

NCI-T98-0001. MD Anderson Cancer Center. Phase I study of Dolastatin 10 in patients with refractory or relapsed acute leukemia, MDS, or chronic myelogenous leukemia in blast phase. Contact: J. Cortes, MD. Phone: 713-794-5783.

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-T98-0068. Johns Hopkins Oncology Center. Phase I study of phenylbutyrate and tretinoin in patients with Myelodysplastic Syndromes, chronic myelomonocytic leukemia, or acute myeloid leukemia. Contact: Steven D. Gore, MD. Phone: 000-0000.

NCI-T99-0013. Cancer Research Campaign, Glasgow. Phase I/II study of geldanamycin analogue (AAG) in patients with advanced malignancies. Contact: S.B. Kaye, MD. Phone: 011-1-41-221-2824.

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

NCI-T-99-0071. Mayo Clinic Cancer Center. Phase I study of PS-341 in patients with advanced malignancies or B-cell lymphoproliferative disorders. Contact: Alex A. Adjei, MD. Phone: 507-284-2511.

NCI-T99-0080. Division of Clinical Sciences. Phase I study of arsenic trioxide in pediatric patients with refractory leukemia or lymphoma. Contact: Frank Milton Balis, MD. Phone: 301-496-0085.

NCI-T99-0092. Johns Hopkins Oncology Center. Phase I study of azacitidine in combination with phenylbutyrate in patients with recurrent, refractory, or untreated AML or MDS. Contact: Carole Miller, MD. Phone: 410-955-8603.

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-V96-0941. Memorial Sloan-Kettering Cancer Center. Phase II study of high-dose cytarabine with a single high dose of idarubicin for newly diagnosed acute myelogenous leukemia: the AML-3 protocol. Contact: P. Maslak, MD. Phone: 212-639-5518.

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

NCI-V97-1361. Ireland Cancer Center at Case Western Reserve University. Phase II study of busulfan, cyclophosphamide, and allogeneic bone marrow transplantation in patients with leukemia, MDS, multiple myeloma, or lymphoma. Contact: H. Lazarus, MD. Phone: 216-844-3629.

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-V98-1433. Marlene and Stewart Greenebaum Cancer Center at University of Maryland. Phase IV study of allogeneic bone marrow transplantation depleted of T cells by CD34 selection in patients undergoing transplantation with a matched or mismatched antigen donor. Contact: M. Fax, MD. Phone: 410-328-1230.

NCI-V98-1447. Phase II Study of amifostine and high dose cytarabine and mitoxantrone in patients with high risk and relapsed acute myeloid leukemia and blast crisis chronic myelogenous leukemia. Contact: H.D. Preisler, MD. Phone: 312-563-2190.

NCI-V98-1455. Phase I/II study of high dose melphalan with autologous peripheral blood stem cell support and amifostine cytoprotection in cancer patients. Contact: G.L. Phillips, MD. Phone: 606-23-5768.

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.



Membership Information

The MDS Foundation would like to have you as a member. Membership is US\$35 a year for physicians and other professionals. Patients, their families, and others interested in MDS may join at the reduced rate of \$20.

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
36 Front Street
Crosswicks, NJ 08515

Phone: 1-800-MDS-0839
Fax: 609-298-0590
Outside the US only: 609-298-6746

NCI-V98-1485. Allegheny University Hospitals. Phase I/II study of topotecan, fludarabine, cytarabine, and filgrastim (T-FLAG) induction therapy followed by maintenance therapy of either peripheral blood stem cells or isotretinoin in patients with poor-prognosis acute myeloid leukemia, MDS, and recurrent or refractory acute lymphocytic leukemia. Contact: E. Besa, MD. Phone: 215-842-6980.

NCI-V98-1501. San Antonio Cancer Institute. Phase I study of R115777 with gemcitabine in patients with advanced cancer. Contact: S.G. Eckhardt, MD. Phone: 210-616-5798.

NCI-V99-1527. 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. Phase II study of amifostine, topotecan and cytarabine in patients with poor risk MDS. Contact: H.C. Fung, MD. Phone: 626-359-8111.

NCI-V99-1545. Phase II study of arsenic trioxide in patients with recurrent or refractory acute myeloid leukemia, blast crisis chronic myeloid leukemia, or MDS. Contact: Janice P. Dutcher, MD. Phone: 718-920-1100.

NCI-V00-1588. Marlene & Stewart Greenebaum Cancer Center. Phase I pilot study of combined chemotherapy and donor lymphocyte infusion in patients with hematologic malignancies in relapse after allogeneic stem cell transplantation. Contact: Bijoyesh Mookerjee, MD. Phone: 410-614-6025.

NCI-V00-1608. Washington University Barnard Cancer Center. Phase I/II study of arsenic trioxide with or without tretinoin in patients with refractory hematologic malignancies. Contact: Randy A. Brown, MD. Phone: 314-454-8227.

NCI-V00-1624. Marlene & Stewart Greenebaum Cancer Center, University of Maryland. Phase II study of nonmyeloablative conditioning regimen followed by HLA matched sibling donor peripheral blood stem cell transplantation in patients with hematologic malignancies. Contact: Bijoyesh Mookerjee, MD. Phone: 410-328-7394.

NCI-2. Rush Cancer Institute. Phase II study of azacitidine 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 Bryostatins 1 and Sargramostim (GM-CSF) in patients with refractory myeloid malignancies. Contact: B. Douglas Smith, MD. Phone: 410-614-5068.

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.

PHARMACEUTICAL TRIALS LISTED WITH NCI

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: James N. Lowder, MD. Phone: 949-347-9640.

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

OTHER U.S. TRIALS

CLB-69803. Cancer and Leukemia Group B. 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, 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-2951. Children's Hospital Medical Center. Phase II study of salvage chemotherapy for acute myeloid leukemia or MDS in first relapse or refractory to initial remission-induction therapy and for secondary acute myeloid leukemia. Contact: R. Wells, MD. Phone: 513- 636-4266.

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 Cancer Group. CCG-B942. Detection of minimal residual disease in children receiving therapy for AML or MDS. Contact: E. Sievers, MD. Phone: 206-667-5757.

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. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. Contact: Matthew Kalaycio, MD. Phone: 216-444-3705.

Dana Farber Cancer Institute. DFCI 99-249. Vaccine trial-phase I-patients with MDS or relapsed acute myelogenous leukemia. Cells will be harvested via bone marrow biopsy and aspirate or phersis. Injection will be administered via sub-Q at specified times. Contact: D. DeAngelo, MD. Phone: 617-632-2645.

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.

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 ligand 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-myeloblastic" 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.

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.

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

Indiana University Medical Center. B3T-MC-JTAH(a). Phase II study of LY335979 plus daunorubicin and cytarabine in subjects with de novo 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.

James Haley Veterans Hospital-Tampa. SMC-101-1029. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. Contact: Hussain Saba, MD. Phone: 813-972-7582.

Johns Hopkins Oncology Center. J0051. Phase I trial: GM-CSF and Bryostat-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. Non-myeloablative allogeneic BMT for hematologic malignancies. Contact: Ian W. Flinn, MD. Phone: 410-955-8781.

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

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. 0903-B1-207-US. A randomized study of the safety and efficiency of 2 dose schedules of Gentuzumab Ozogomicin (mylotarg) in patients with Intermediate-2 or High Risk MDS. Contact: Emmanuel Besa, MD. Phone: 215-842-6980.

MCP Hahneman University. A Phase II study of a combination of topotecan, fludarabine, ARA-C and G-CSF CT-Flag. Contact: Emmanuel Besa, MD. Phone: 215-842-6980.

MCP Hahneman University. E1996. Phase III evaluation of EPO with or without G-CSF versus supportive therapy alone in the treatment of MDS. Contact: Emmanuel Besa, MD. Phone: 215-842-6980.

MCP Hahneman University. T-MDS-001. A randomized, double blind, placebo-controlled trial composing best supportive care and thalidomide for the treatment of anemic patients with MDS followed by an open-label treatment with thalidomide. Contact: Emmanuel Besa, MD. Phone: 215-842-6980.

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 Kantarjian, 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-Nitrocampothecin 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 Fludarabide/Ara-C and cyclosporin in AML, RAEB, RAEB-t, CMML with .10% blasts in patients aged 50-64 years. Contact: Elihu Estey, MD. Phone: 713-792-7544.

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.

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.

Multicenter. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. Contact: Elizabeth Squiers, MD. Phone: 510-789-4535.

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 Heart Lung and Blood Institute. Phase II study of leucovorin in patients with 5q- syndrome. MDS subtypes RA, RARS, and RAEB are eligible. Patients must have 5q- as their sole cytogenetic abnormality and meet criteria for moderate to severe cytopenias. Phone: 301-496-5150.

National Heart Lung and Blood Institute. Clinical protocol studying the use of G-CSF-mobilized T-depleted donor peripheral blood progenitor/stem cells followed by delayed donor T cells to optimize graft-verses-tumor effects in patients with hematologic malignancies. Phone: 301-496-5150.

National Heart Lung and Blood Institute. 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.

New York Medical College. 30/38. A phase III, open-label, multicenter, randomized, comparative study of topotecan, Ara-C and G-Csf (TAG) versus idarubicin, Ara-C and G-CSF (IDAG) in MDS patients RAEB (high risk), RAEB-t or in patients with AML from a preceding phase of MDS. Contact: Karen Seiter, MD. Phone: 914-493-8374.

New York Medical College. 0012-2000. 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: Karen Seiter, MD. Phone: 914-493-8374.

New York Medical Hospital. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. 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.

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: C. Hesdorffer, MD. Phone: 212-305-4907.

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.

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 2000-02. Combination of thalidomide and topotecan in the treatment of patients with high risk MDS. Contact: A. Raza, MD. Phone: 312-455-8474.

Rush Cancer Institute. MDS 2000-03. Combination of etanercept (TNFR:Fc) and thalidomide in the treatment of patients with MDS. Contact: A. Raza, MD. Phone: 312-455-8474.

Rush Cancer Institute. MDS 2000-04. An open label, prospective, randomized, stratified, controlled, multicenter, 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. 0903B1-207-US. A randomized study of the safety and efficacy of two dose schedules of gemtuzumab ozogamycin in patients with intermediate-2 or high risk 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 Presbyterian. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. Contact: Azra Raza, MD. Phone: 312-455-8474.

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.

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.

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-myeloblastic preparative regimen for patients with hematologic malignancies. Contact: R.A. Larson, MD. Phone: 773-702-2070.

University of Florida. SMC-101-1020. Phase IIb study of thymoglobulin in transfusion dependent patients with RA or RAEB. 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 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 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 azacitadine and amifostine in the treatment of adults with MDS. Contact: Harry P. Erba, MD. Phone: 734-647-8921. JoAnn Goodson, Data Manager.

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 Rochester Cancer Center. 18400. A phase 2 study of SU5416 in patients with hematologic malignancies, including refractory acute myeloid leukemia, myelodysplasia, refractory acute lymphocytic leukemia, Philadelphia negative myeloproliferative disorders or chronic myelogenous leukemia. Contact: Wanda Bates, Administrative Assistant. Phone: 716-275-6753.

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: Wanda Bates Administrative Assistant. Phone: 716-275-4915.

University of Texas Health Science Center. IRB # 978-5008-302. Sequential anti-thymocyte 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.

Wake Forest. SMC-101-1020. Phase IIb study of thalidomide in transfusion dependent patients with RA or RAEB. Contact: Kenneth Zamkoff, MD. Phone: 336-716-7972.

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 in St. Louis. 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: 314-454-8317. Carol Rush, Reg. Coord.

Washington University in St. 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 Medical Center, New York Medical College. 008/2000. Non-myeloblastic 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. 0012/2000. 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: Karen Seiter, MD. Phone: 914-493-8374.

Westchester Medical Center, New York Medical College. 0101/2001. Phase I/II Study of Temozolomide in patients with MDS. Contact: 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.

Canadian Trials

CAN-NCIC-SC17. NCIC-Clinical Trials Group. Phase III randomized study of two different sustained release formulations of morphine followed by dextromethorphan or placebo plus morphine for patients with chronic cancer pain. Contact: E. Bruera, MD. Phone: 403-450-7730.

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 comparison 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).

EORTC-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-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.

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-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.

AUSTRALIA

Peter McCullum Cancer Institute. A phase II multicenter, open label, dose escalapan trial of the safety and efficacy of ERIR in adults with CMML. Contact: John Seymour, MD. Phone: 011-03-9656-1111.

Peter McCullum Cancer Institute. A randomized study of the safety and efficacy of a dose schedule of gemtuzumab ologamicin in patients with intermediate II or high risk MDS. Contact: John Seymour. Phone: 011-03-9656-1111.

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).

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 (Lille).

Groupe Français des Myélodysplasies. Randomized study of erythropoietin plus G-CSF versus supportive care in low-risk MDS. Contact: N. Casadevall, MD. Fax: 31-47-10-79-53 (Paris).

Groupe Hospitalier Cochin. Fludarabine, aracytine, and novantrone (FLAM) for high-risk MDS (-) patients. Contact: E. Wattel, MD. Phone: 33-20-44-66-40.

Groupe Hospitalier Cochin. In collaboration with EORTC. Aracytine plus novantrone with quinine (MAQ) for high-risk MDS (+) patients; for patients in complete remission, randomized peripheral-blood stem cell transplantation versus chemotherapy with aracytine. Contact: E. Wattel, MD. Phone: 33-20-44-66-40.

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).

Groupe Hospitalier Cochin. G-CSF and erythropoietin in low- and intermediate-risk MDS. Contact: N. Casadevall, MD. Fax: 31-47-10-79-53 (Paris).

Groupe Hospitalier Cochin. Amifostine in low- and intermediate-risk MDS. Contact: B. Mahe, MD. Phone: 32-40-08-32-71.

GERMANY

Johannes-Hospital Duisburg. A phase II trial. Efficacy of all transretinoic acid in MDS patients with isolated 5q-defect. Contact: Carlos Xxxx. Phone: 000-0000.

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.

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: 000-0000.

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.

SCOTLAND

Ninewells Hospital, Dundee/King's College Hospital. UK MDS Therapy Working Group. A phase I/II trial of thalidamide 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 Schuur 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.

University of Cape Town and Groote Schuur Hospital. 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. Phone: 0000.

SPAIN

Hospital Universitario De Salamanca. IPPS greater than 1. FLAG-IDA. If complete remission and less than 65 years

old leading to autologous transplantation. If less than 35 years old leading to allogeneic transplantation. Contact: M.C. del Canizo, MD/J.F. San Miguel, MD. Phone: 011-34-923-291384.

SWITZERLAND

Swiss Institute for Applied Cancer Research. CCG-2961. Phase III randomized study of anti-thymocyte 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: 011-44-207-346-3080.

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 <1×10⁹/l or platelets <100×10⁹/l. 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.**

Erik Johnson Memorial

A memorial fund has been established by the Myelodysplastic Syndromes Foundation in the name of Erik Johnson. Erik was 21 when he passed away, August 10, 1996, from complications related to a bone marrow transplant. Over 500 people attended his funeral — there was an outpouring of love. Jim Davidson, Erik's Lacrosse coach from Kean College, told the people in attendance that Erik faced his illness the same way he faced games — stay calm and you would get through it. Erik fit into any group and people delighted in his company. Erik's unselfishness and willingness to help anyone in need was genuine. One of Erik's friends characterized him as a hero, because he understood adversity and faced it with courage. Erik is survived by his parents, Susan and Edward, Tara Johnson and many friends.

A raffle was held to raise money in Erik's name for the MDS Foundation. Ms. Donna Gioello ran the raffle and we would like to thank her for her efforts. The funds will be used for patient education and advocacy.

Suzanne Fleischman Memorial Fund for Patient Advocacy

A fund has been established by the Myelodysplastic Syndromes Foundation in memory of Suzanne Fleischman. Donations to this fund will be deposited into a separate account and utilized to provide patient education conferences at the Foundation's Centers of Excellence, to help patients who can't afford care, and to provide Suzanne's writings in booklet form to patients and families. The fund was established with an initial donation of \$500 from Foundation. Contributions may be sent to the Foundation with a notation designating the *Suzanne Fleischman Memorial Fund for Patient Advocacy*.

Donations have recently been made in Ms. Fleischman's memory by:

Eugene & Eloise Fox, *Kensington, CA*

Elizabeth C. Traugott, *Berkeley, CA*

Jacques E. Merceron, *Bloomington, IN*

F. Ralph Berberich, MD, *Berkley, CA*

Paul & Joan Lloyd, *Media, PA*

In Memorium (continued from page 13)

A memorial fund has been established in the name of

Mr. Norman A. Sayer

Donations have been made in Mr. Sayer's memory by:

Violet M. Sayer, *Methuen, MA*

A memorial fund has been established in the name of

Mr. Alvan Sievers

Donations have been made in Mr. Sievers' memory by:

Jane Seivers, *Mechanicsburg, PA*

A memorial fund has been established in the name of

Mr. Hershel E. Trapp

Donations have been made in Mr. Trapp's memory by:

Lori, Kirk, Kyle, Kara Schwarzkorf, *Delphi, IN*

A memorial fund has been established in the name of

Mr. James P. Wilson

Donations have been made in Mr. Wilson's memory by:

Kendra W. Bates, *Fort Walton Beach, FL*

A memorial fund has been established in the name of

Mr. Frank A. Yakovac

Donations have been made in Mr. Yakovac's memory by:

Fire Protection District #9 Aux, *Colville, WA*

The Foundation extends its sincerest thanks to these donors.

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 609-298-6746.

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