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THE MDS NEWS

The Newsletter of The Myelodysplastic Syndromes Foundation

From the Guest Editor's Desk

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Immunosuppression

The myelodysplastic syndromes (MDS) describes a heterogeneous group of diseases of uncertain etiology characterized by abnormal blood counts, ineffective haematopoiesis, marrow dysplasia, and random or specific cytogenetic abnormalities. Although in a substantial proportion of patients MDS eventually proceeds to satisfy criteria for an acute myeloid leukemia (AML), about 50% of patients die of complications of cytopenias without disease progression. For these latter patients effective treatment of the marrow failure without use of cytotoxic drugs should therefore offer significant survival advantage. There is strong evidence that in some cases MDS is the result of an intrinsic, presumably acquired, genetic defect in hematopoietic stem cells. However, other patients clearly have autoimmune basis for their disease, since clinically MDS may be associated with other autoimmune disorders and laboratory evidence has documented activation of the immune system. For example, various investigators have reported over-expression of tumor necrosis factor (TNF), TNF-related apoptosis-inducing ligand (TRAIL),[1] interferon-γ and transforming growth factor-β in patients' cells in culture[2] and plasma.[3] We and others have reported increased T-cell inhibitory activity suppressing hematopoiesis in MDS.[4] The observation of clonal expansion of T cells, identified by their selective use of the T-cell receptor (TCR) variable β chain, and the observation that CD8+ cytotoxic T cells (CTL) can suppress hematopoiesis in coculture both suggest a mechanism for progenitor and stem cell inhibition similar to that seen in aplastic anemia (AA).[5]

Perhaps the best model for the role of cytotoxic T cells in MDS comes from studies of a subgroup of patients with isolated trisomy 8. In our MDS patients, trisomy 8 appeared to be a relatively benign chromosomal abnormality compatible with normal hematopoiesis when it was the sole abnormal cytogenetic finding (though patients with trisomy 8 in conjunction with other cytogenetic abnormalities did poorly). In our experience, patients responding to immunosuppressive therapy (IST) remain clinically stable for relatively long periods despite increases in their trisomy 8 populations,[6,7] and in our cohort no patient presenting with Int-1 MDS and isolated trisomy 8 has yet developed acute leukemia. In the "trisomy 8 syndrome", the cytogenetically abnormal clone over-expresses Fas on the cell surface and appears to more susceptible to apoptosis in comparison to diploid cells.[8] T cell- receptor skewing is consistently present, suggesting an antigen driven process, and these T cells specifically suppress trisomy 8 hematopoietic progenitors[9] in vitro. In

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trisomy 8, as in other types of MDS,[10] apoptosis may not be completed, probably due to compensatory mutations that block the apoptotic signaling pathways. One antigen that could be the target for T cell attack in trisomy 8 MDS is WT1;[9] we and others have shown it to be over-expressed in MDS[11] and that there appears to be a cytotoxic response against WT1 in MDS with trisomy 8 which resolves following successful immunosuppressive therapy.

Like AA, MDS can be successfully treated with cyclosporine (CsA) and antithymocyte globulin (ATG).[12] Preliminary studies using ATG for MDS, based on our laboratory evidence and the known association of autoimmune diseases with MDS, led to the first formal trial of ATG at the National Institutes of Health (NIH) in 1995.[13] Since then many other investigators have reported improvement in cytopenias in MDS patients treated with fully immunosuppressive drugs.[13-18] However, more limited immunosuppression aimed at reversing the abnormal TNF-α production in MDS, including administration of anti-TNF monoclonal antibodies,[19-21] the soluble form of the TNF receptor,[22] and chemical inhibitors of TNF,[23-25] has not been successful. While it is clear that some patients respond to immunosuppression, overall response rates have varied widely (0–66%), but have rarely exceeded 30%. Part of this variation may be related to the differing criteria used to evaluate response, which have now been standardized by an international working group,[26] but most of the variation probably reflects the diversity of the disease.

We need now to identify groups of patients who are most likely to respond to the variety of treatments now available for MDS. For example Revlimid® (generic name, lenalidomide) has a very high response rate in patients with the 5q- variant of MDS[23] and is probably the best treatment for such patients. It may be possible to identify an analogous group of MDS patients most likely to respond to immunosuppression. To identify likely responders we developed a scoring system based on three specific features, namely age, transfusion burden, and presence or absence of HLA-DR15.[27] The system was validated in our own series of patients and we now use IST only patients who are in the high response probability group. It will, however, be important to see whether its apparently strong predictive value can be confirmed in groups of patients treated in other centers.

In the collated data from three NIH trials using immunosuppression for MDS, 129 patients, most with RA and in the Intermediate-1 category of the IPSS, were treated primarily with ATG and followed in the clinic for a mean of four years. We reported a 33% response, defined as a durable freedom from transfusion requirement, in 69 patients given a 4-day course of ATG.[13] Responders had improved platelet and neutrophil counts and fewer of these patients had transformation into acute leukemia when compared with non-responders.[13] Age is the most important variable governing response to therapy. Although hypocellular patients were initially thought more likely to respond, it is now apparent with greater patient accrual that patients with hypercellular or normal cellular marrows were just as likely to respond. Trisomy 8 was highly associated with response to immunosuppression, but patients with other cytogenetic abnormalities, including monosomy 7, also responded.[7] The presence of a PNH clone appears to be of no prognostic value. In the NIH group leukemia occurred almost exclusively in the non-responding patients age >60 years; this age-dependence was similar in the large International MDS Risk Analysis Workshop (IMRAW) cohort which showed significantly more leukemia progression in the Int-1 patients older than sixty.[28]

These findings raise several issues regarding the pathophysiology of MDS, especially the tendency for older patients to die of leukemia, while younger patients are more at risk from the consequences of cytopenias. It also suggests that older patients are not good candidates for immunosuppressive therapy. It is possible that MDS that occurs in younger patients elicits a more powerful anti-myeloid lineage immune response, resulting in more significant cytopenias, while MDS developing in older patients is characterized by more pronounced stem cell defect. We were unable to identify other features, such as duration of disease, marrow cellularity or degree of cytopenia that distinguished younger from older patients in either the NIH.

MDS in younger individuals may in fact share a pathophysiology with aplastic anemia. Increased apoptosis of hematopoietic progenitor cells is believed to be responsible for much of the ineffective hematopoiesis in low-grade MDS[29,30] and its resolution as well the clearing of dysplasia following successful immunosuppression has led some to speculate that both represent the sequalae of immune attack. Cells with cytogenetic abnormalities such as monosomy 7 and trisomy 8 are present in both aplastic anemia as well as MDS and may be a function of their relative viability and survival advantage compared to their diploid counterparts in the face of immune pressure.[31]

The mechanisms of action of polyclonal antithymocyte globulins (ATGs) are still poorly understood and the selection of doses used in both aplastic anemia and MDS are empirical. ATG reduces T-cell numbers in the peripheral blood and lymph nodes. While patients are lymphopenic following ATG treatment the lymphopenia generally resolves rapidly thereafter, yet responses remain durable. Whether or not this is related to modulation of T regulatory cells needs to be investigated.

Although ATG, CsA and the combination of ATG and CsA have met with success it is unclear what the optimal therapy would be. Whether ATG is best combined with cyclosporine or with an anti-TNF agent is unclear. Campath (CD52) antibody, which is more immunosuppressive than ATG, could be useful in patients not responding to less immunosuppressive agents. Improved treatment strategies could then be explored in a targeted, responsive subgroup of patients.

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Raising the Next Generation of MDS Investigators

MDS is an enigmatic disease that is not yet well understood by scientists, physicians, and researchers. It is essential to develop the new generation of researchers so that the causes of these syndromes are identified as soon as possible. To ensure that this future generation of researchers flourishes, the MDS Foundation will award two (2) fellowships of $40,000 each in 2006.

The Foundation is dedicated to furthering the research into MDS and invited young investigators (under 40 years of age) from institutions that form our MDS Centers of Excellence to submit their proposals. Last year, the Foundation initiated this series of grants, two awards will be made this year and subsequent awards will be granted annually.

This year the application deadline was August 15th. Notification of the awards will occur by October 1, 2006 with activation on January 1, 2007.

The two Young Investigator Grants awarded for 2006 will be announced on December 8, 2006 at a formal awards ceremony to be held in conjunction with the American Society of Hematology's annual meeting in Orlando, Florida.

NEXT YEAR'S TIME LINE:

Wednesday, August 15, 2007	*Proposals due*
Tuesday, October 2, 2007	*Notification of awards*
Friday, December 2007	*Award Ceremony*

ANNOUNCING

The Inaugural Meeting of the Puget Sound Myelodysplastic Syndromes Support Group

TUESDAY, OCTOBER 17th, 2006
6:30 PM

Puget Sound Blood Center
921 Terry Avenue
Seattle, WA 98104

Please respond to steve@Qamonline.com for attendance at this meeting and/or to have your name added to the mailing list. For additional information, please contact The MDS Foundation at 800-637-0839.

MDS Patient Registry

The patient registry form has been revised and a patient authorization form has been developed to meet the new HIPAA guidelines. The Patient Registry will help further research into the etiology, diagnosis and treatment of MDS. Currently, the MDS Patient Registry is only accepting patients through our designated Centers of Excellence. A two page data sheet will be forwarded to investigators who wish to contribute patient's names to the Registry. The Registry is located at the MDS Foundation's Statistical Center at the University of Rochester Cancer Center. The Foundation looks forward to building the Patient Registry with our Centers of Excellence. If you would like to become a Center of Excellence, please contact The Foundation at the address below.

The MDS Foundation, Inc.
36 Front Street
P.O. Box 353
Crosswicks, NJ 08515

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

Novartis Patient and Family Forum Held in Vienna, Austria

July 8, 2006. A Patient and Family Forum, chaired by Peter Valent, was held July 8, 2006 in Vienna, Austria. Patients and family members took part in the conference that provided information on the understanding and management of MDS including issues affecting quality-of-life for MDS patients.

Following is the program presented:

9:30 am	**Greeting and Introduction** *Friedrich Wimazal*
9:45 am	**MDS and Quality-of-Life** *Kathy Heptinstall*
11:00 am	**Biology and Illness Course with MDS** *Michael Pfeilstöcker*
12:00 pm	Lunch Buffet
1:00 pm	**New One Therapy Option: Hope for the Future** *Otto Kreiger*
1:30 pm	**Joint Discussion and Ask the Expert**
2:00 pm	**Summary** *Kathy Heptinstall*
2:30 pm	**Patient Initiatives in Austria and MDS Foundation Self-Help Group** *Friedrich Wimazal*

Vienna Patient and Family Forum Attendees

Dr. Friedrich Wimazal

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 preferential referrals to the Foundation's MDS Centers of Excellence. We can also help identify physicians and centers to support you if you are travelling and need assistance.

Please contact us at: 1-800-MDS-0839 (phone) or 609-298-0590 (fax). Outside the US please call: 609-298-1035. You can visit our website at http://www.mds-foundation.org.

Purchase MDS Awareness Pins

The MDS Foundation has enameled lapel pins for you to wear with pride and to increase public awareness about MDS. The pins are available with a $3.99 donation to The MDS Foundation.

To order your pins, call The MDS Foundation at 1-800-MDS-0839.

This item was created especially for The MDS Foundation to contribute to the effort to help people worldwide living with myelodysplastic syndromes. Your donation will help increase awareness of this little known disease, which is the most common of the hematologic malignancies.

Please ask your family and friends to wear these pins in support of our mission!

From the Director's Desk

Kathy Heptinstall, Operating Director

The MDS Foundation

It has been an eventful third quarter for The Foundation. Our Patient Forums have continued in Europe with our May 19th meeting in Marseilles. This meeting was conducted in conjunction with the Groupe Français de Myélodysplasies including an invited presentation on the Foundation's efforts to begin Patient Support Groups within Europe. The first formal MDS Patient Support Group in Europe was established in France. This permanent group was developed around the Patient Forum that was held in Paris earlier this year, a second group is being formed within the United Kingdom and a third in Austria following a very successful Patient and Family Symposia in Vienna supported by Professor Peter Valent's group. Additional Patient Forums have been held in Prague, Czech Republic on September 18 and 19 and in Stockholm, Sweden on September 26. More than 120 patients and family/support persons attended these meetings.

The inaugural meeting of the Puget Sound MDS Support Group is being held on Tuesday, October 17th at the Puget Sound Blood Center in Seattle, Washington. Plans are also underway for Philadelphia and Pittsburgh, Pennsylvania and Scottsdale, Arizona. The firmed up details for all meetings will be available shortly and we hope you join us.

The 9th International Symposium will be held May 16–19, 2007 in Florence, Italy. We will update you on the plans for this important symposium as we receive new information.

As noted in our last addition, an expansive MDS Awareness Program was initiated in September 2005 and will continue, in a multi-segment format, throughout 2006. Segments 1 and 2 are on-line and Segment 3 is currently available. If you are interested in participating in this state-of-the-art continuing education program, please join us through the Foundation's website (www.mds-foundation.org) or call 1-800-MDS-0839. New segments will be available bi-monthly and can be completed via our educational website, CD-ROM, or in writing. All programs have been translated into French, Italian, Spanish, German, and Japanese and are available on our website or by contacting the Foundation.

The Foundation has participated in the American Society of Hematology (ASH) Annual Meeting for eight consecutive years by hosting our booth for physician attendees and conducting adjunct symposia on the Friday immediately preceding the meeting. Our symposia for this year has been accepted — ***Paradigms in MDS Prognosis and Treatment***. Dr. Alan List of Moffitt Cancer Center, and a member of the Foundation's Board of Directors, will once again serve as Chairman for this important program. Dr. List will present the *Program Overview and Objectives* and discuss *Emerging Treatment Options in MDS*, Dr. John M. Bennett, Foundation Chairman, from the University of Rochester Cancer Center will speak on the *Evolution of MDS Morphologic and Response Assessment Criteria Assessment*, Dr. Detlef Haase of George-August-Universität, Göttingen, Germany will provide new insight into *Interrogating Less Common Genetic Abnormalities in MDS*, Professor Michael Lübbert of Freiberg University, Freiberg, Germany will discuss *Therapeutic Targeting of the Epigenome in MDS*, and Dr. Luca Malcovati of the University of Pavia Medical School, Pavia, Italy will present information on *Integrating Transfusion-Dependence and Iron Chelation into Prognostic and Management Models in MDS*.

During 2006 the Foundation, for the third year in a row, participated in the European Society of Hematology's (EHA) Annual Meeting. For the first time the Foundation presented a 2-hour symposium on MDS to this prestigious international body. Our co-Chairmen, Ghulam J. Mufti, MD and Pierre Fenaux, MD led a prestigious group of speakers and topics including: *Problems in the Morphological Diagnosis of MDS* presented by Barbara J. Bain, MB of St. Mary's College, London, UK; *Correlation and Differentiation of New Therapeutic Agents through Uniform Response Criteria in MDS*, John M. Bennett, MD of the University of Rochester Cancer Center, Rochester, NY; *The Relationship of Quality-of-Life to Hgb Levels in MDS* by Eva Hellström-Lindberg, MD, PhD of the Karolinska Institute in Stockholm, Sweden; *The Inter-Relationship of Ineffective Hematopoiesis and Cellular Biology in MDS* presented by Guido Kroemer, MD, PhD of the Institut Gustave-Roussy in Villejuif, France; *Clarifying MDS–A Progress Report on Research in Molecular Biology* by Claudia Haferlach, MD. The symposium was very well received by the more than 250 attendees. This will hopefully be the first of many educational initiatives in conjunction with EHA.

On April 25–27, 2006 The Foundation participated for the first time in the meeting of the European Working Oncology Group (EWOG) focused on pediatric patients. Chaired by Dr. Charlotte Niemeyer of Freiberg University this important program is currently held once every three years. The Foundation has committed to assisting the JMML Foundation in developing assistance and information for JMML patients and their families as well as developing information to further the knowledge base for this related disease. A meeting was held in Geneva, Switzerland on September 15 and 16 immediately prior to the SIOS meeting to begin the process. A prestigious group of pediatric hematologists and experts in transplant attended this meeting and we have been able to set a course to move research forward in JMML.

We also participated for the third year in the Biotechnology Conference (BIO 2006) that was held April 9th–12th in Chicago, Illinois.

The International Working Group on MDS Morphology continues its statistical analysis of the work that has been conducted over the past year. This information will soon be presented for publication by this prestigious international group of morphology experts.

The Foundation held its 3rd Annual Jack Keating Memorial Golf Tournament for MDS that supports our Young Investigator Grant program. PGA Golf Professional on the Champion's Tour, Bruce Fleisher, graciously agreed to put his name and his influence behind this tournament. In 2007 a second tournament will be held in Tampa, Florida and will supply the Foundation with additional funding for this important program. The Moffitt Cancer Center will participate with us in this important event and lend its prestige to this initiative. The Foundation and Moffitt will share the proceeds from this tournament scheduled for February 19, 2007. Hopefully, this is the beginning of significant research funding for the Foundation benefiting the MDS community. The deadline for grant applications for 2007 is August 15th. Interested applicants can request information from the Foundation.

During the remainder of 2006 and into 2007 the Foundation will work to develop satellite offices within the EU. This expansion will assist MDS patients and their families on a more local level and provide influence and a voice within the EU for these patients. I would like to thank our supporters on behalf of the Foundation and its Board of Directors. These supporters, first and foremost, are the MDS patients, their families and friends, who form the core of this Foundation. You are our center and the reason that the Foundation exists. We work for you!

The second group that we would like to thank are the pharmaceutical companies that provide us with so much support and assistance. This assistance is given in the form of grants that fund programs that are non-product related but, rather, are geared toward improved disease knowledge and patient support. We could not do the work they do without this type of support. I look forward to continuing our relationship with you!

Spreading the Word Worldwide

Patient Quality-of-Life Forums

Patient forums have been held to date in:

United States

- New York City, New York
- Tampa, Florida
- Palo Alto, California
- Chicago, Illinois
- Scottsdale, Arizona
- Philadelphia, Pennsylvania
- Pittsburgh, Pennsylvania

Europe

- Paris, France
- Bournemouth, England UK
- London, England UK
- Leeds, England UK
- Edinburgh, Scotland UK
- Marseille, France
- Prague, Czech Republic
- Stockholm, Sweden

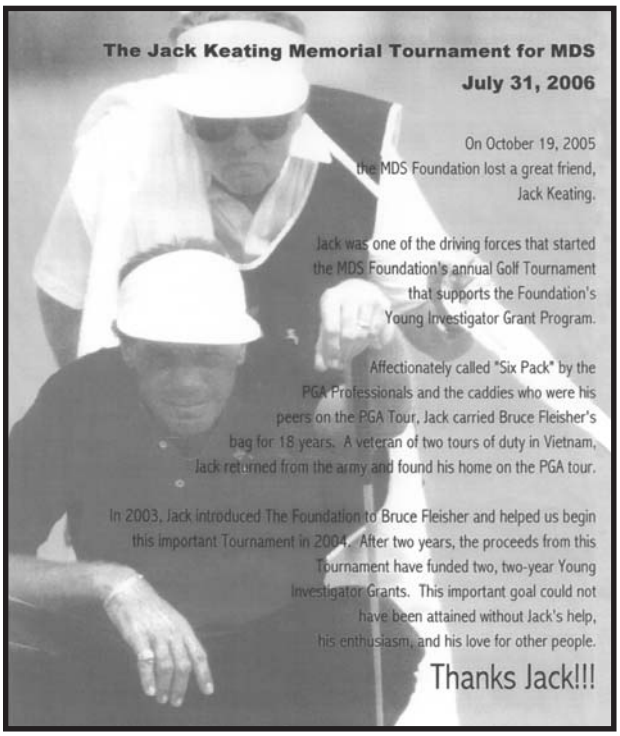
Future forums are scheduled in:

- Athens, Greece:
  October 24, 2006
- Florence, Italy:
  May, 2007

THANKS TO ALL WHO SUPPORTED

Our Annual Charity Golf Tournament

The Jack Keating Memorial Golf Tournament for MDS—A Scorching Success presented by Bruce Fleisher



The Third Annual Charity Golf Tournament to benefit The Myelodysplastic Syndromes Foundation was held on July 31st in near record heat. A very special thank you to all the sponsors, golfing participants, volunteers, and members of the business community who braved the high temperatures to make The Jack Keating Memorial Golf Tournament for MDS such a success.

Tournament participants had various opportunities through putting contests and hole-in-ones to win prizes including a 2006 Porsche donated by Ray Catena. The silent and live auctions were competitive as attendees bid on a number of items ranging from an opportunity to play nine holes with Curtis Strange to rounds of golf at exclusive courses with other PGA professionals. Those attending the event were treated to a two hour long golf clinic with the pros; a fun round of golf, a reception and dinner.

It was a tremendous event, which took a lot of hard work and planning. We would also like to extend a special thanks to the PGA and LPGA professionals who contributed so much to the success of the tournament: Jim Ahern, Amy Alcott, Donna Caponi, Dave Eichelberger, Wayne Levi, John Mahaffey, Jr., Bob Murphy, Curtis Strange, Jim Thorpe, and Bob Toski.

With the success of this tournament we are able to provide additional Young Investigator Grants for Fellows in Hematology working in MDS. Join us again and don't forget to save the date for next year: **Monday, August 6th, 2007.**

Tournament Registration

Dr. John M. Bennett, Chairman, The MDS Foundation explained the basics of MDS to the attendees.

Robert Weinberg, MDS Board of Directors, Guest Speaker shared his story about living with MDS.

Bruce Fleisher teaching the elements of a great swing.

Curtis Strange enlightened the group about the importance of the take away.
Curtis Strange, Bruce Fleisher, and Bob Toski (L to R)

Blood & Marrow Transplant Newsletter

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Mayo Web Based Quality-of-Life Survey of Patients

The Mayo Clinic in Rochester, Minnesota is collecting data through an anonymous web based survey to help better define the issues patients diagnosed with Chronic Lymphocytic Leukemia (CLL) face. The surveys will gather information on what patients are actually experiencing in terms of various symptoms and this data will be a good starting place for concrete efforts and clinical trials to help improve quality-of-life in CLL patients. To participate, please click onto this link: http://survey.venturecs.net/cll.htm.

ICD9 Coding Changes

Changes have been made to the ICD9 codes for MDS. The following sequence reflects the WHO plus the now extinct but still classifiable RAEB-T:

Diagnostic Term	ICD-0-3	
Refractory Anemia	C42.1	M-9980/3
Refractory Anemia with Ringed Sideroblasts	C42.1	M-9982/3
Refractory Anemia with Excess Blasts	C42.1	M-9983/3
Refractory Anemia with Excess Blasts in Transformation	C42.1	M-9984/3
Refractory Cytopenia with Multilineage Dysplasia	C42.1	M-9985/3
Myelodysplastic Syndromes (MDS) with 5q-Syndrome	C42.1	M-9986/3
Therapy-related Myelodysplastic Syndromes (MDS)	C42.1	M-9987/3
Myelodysplastic Syndromes, NOS	C42.1	M-9989/3

Son Raises Funds for MDS Research in Memory of His Father

Richard Cohen from Wakefield, Massachusetts competed in the Mt. Washington Auto Road Bicycle Hillclimb on August 19th to help support the MDS Foundation. He made the commitment in honor of his father, Leon M. Cohen, who passed away last year.

Below is the letter that Richard sent out to friends and colleagues:

Dear Friends,

For my father, it all came down to white blood cells. Something most of us take for granted. Either there was not enough or, in the end, way too many. It started with an infection that just would not go away and it led to a diagnosis of Myelodysplastic Syndromes or MDS. I had never even heard of MDS and had no idea what it meant.

The doctors explained in layman's terms that my father's bone marrow was broken. He was producing immature white blood cells that were not able to fight off infection. No cure exists and the only treatments were prophylactic blood transfusions, antibiotics and various forms of chemotherapy. Unfortunately none of these worked for long.

We need a solution. I believe that with research a cure for MDS and other blood cancers can be found but I need your help.

One of my father's favorite places in the whole world was the top of Mount Washington in New Hampshire. To my family it is truly a spiritual place. Every time Dad, Mom, Robin and I drove up the auto road it was amazing from beginning to end. We all loved the nerve-wracking drive up, the amazing views, beautiful mountain top hikes, ridiculous bumper stickers, and the intense brake-burning drive down. We were always in awe of this earthly wonder right in our back yard.

To raise research funds and awareness for MDS, I will be participating in the Mt Washington Auto Road Bicycle Hillclimb. The race is 7.6 miles long with an average gradient of 12%. Many long sections are up to 18% with the final 100 yards at a heart pounding 22%. I must admit I am nervous but if I can meet this challenge with half the courage, dignity and strength with which my father faced MDS then I will succeed at getting to the top.

Please help find a cure for MDS by donating to the ***Leon M. Cohen Research Fund****. Fill out the enclosed donation form and send it along with your check made payable to the MDS Foundation. Please write the words "Mt Washington" in the memo area so that the total dollars can be tracked. You may also donate by going to www.mds-foundation.org and clicking on the online donation form.*

It is only fitting for me to race to the top of Mount Washington, while raising money and awareness to find a cure for the disease that took my father from all of us. Please help by sponsoring me in the race to the clouds.

Thank you so much,

Rich

Our thanks to Rich and congratulations on completing the course. Without the support of such dedicated people we would find it very difficult to further the causes of the Foundation as their efforts in fundraising help us immensely. 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, Crosswicks, NJ 08515 or call us at 1-800-MDS-0839.

The Leon M. Cohen Research Fund

A memorial fund has been established by the Myelodysplastic Syndromes Foundation in the name of Leon M. Cohen. The Cohen family made a decision to honor their loved one by establishing this fund to be used for research.

Donations have been made by:

Abigail Troy, *Westford, MA*
Al and Lisa Hicks, *Hopkinton, MA*
Alan and Elaine Aarons, *West Yarmouth, MA*
Alan L. Cohen, *Boynton Beach, FL*
Anita and Robert Gokey, *Melrose, MA*
Barnet Cohen, *Mansfield, MA*
Bruce and Fern Green, *Acton, MA*
Candace Higgins, *Marlboro, MA*
Carl and Amy Kruglak, *Needham, MA*
Carolyn (Cary) Mazzone, *Wakefield, MA*
Chuck and Maureen Paul, *Cumberland, MI*
Dan and Jen Green, *New Haven, CT*

David and Robin Leaf, *Middleton, MA*
David and Traci Green, *Cambridge, MA*
David Leaf, *Middleton, MA*
Dennis J. Kelley, *Marlboro, MA*
Diane H. Cohen, *Peabody, MA*
Donald H. Smith, *Wellesley, MA*
Edward and Marie Santoro, *Middleton, MA*
Elizabeth Reis, *Brighton, MA*
George W. Catino, *Shrewsbury, MA*
Gilman Treantos, *Westborough, MA*
Harry and Sheila Romanowitz, *Stanford, CT*
Horacio Padua, *Brookline, MA*
Jaye Carlson, *Lake Oswego, OR*
Jeff and Kate Walker, *Haverhill, MA*
Jeremiah and Carol Brosnan, *Milford, MA*
Joanne Zizza, *North Reading, MA*
Joel and Bobbie Seidman, *Woburn, MA*
John and Christine Schuler, *Milford, CT*
Jon and Linda Cohen, *Framingham, MA*
Kalyanaraman Chadalawada, *Hopkinton, MA*
Lew and Harriet Doctor, *Boynton Beach, FL*
Liza Brew, *Westwood, MA*
Lucille Z. Leaf, *Louisville, KY*
Manner Smith, *Marblehead, MA*
Mary Harvey, *Hopkinton, MA*
Maurice G. Miner, *Nashville, TN*
Melissa Dascoli, *Wakefield, MA*
Michael Horton, *Needham, MA*
Michael, Jody, Max, Carly Seidman, *Needham, MA*
Nancy K. Grohol, *Bradford, MA*
Pam Gruen, *Aptos, CA*
Pavel Baryudin, *Hopkintown, MA*
Richard A. Gelerman, *Norwood, MA*
Richard Cohen, *Wakefield, MA*
Robert and Beverly Yirigian, *West Hartford, CT*
Sarah Watkins, *Wayland, MA*
Sean Cusick, *Chestnut Hill, MA*
Sharon Saklad, *Brighton, MA*
Shel & Ruby Fridson, *Farmington Hill, MI*
Sue Oparowski, *Grafton, MA*
Target Software, Inc. (Anita Gokey), *Cambridge, MA*
Theodore Terry Perlmutter, *Peabody, MA*
William and Stacey Corey, *Windham, NH*
Winston Jenkins, *Boston, MA*

Slone Patient Registry

The Slone Epidemiology Center at Boston University is enrolling patients who have recently been diagnosed with myelodysplastic syndromes in a voluntary research project called the Patient Registries at Slone: MDS. The registry gathers important information about the impact of MDS and its treatments on patients' physical, emotional, social, and economic well-being. Participation in the Registry does not affect the care or treatments that patients receive.

You are eligible to join if:

- You have been diagnosed with MDS within the past 3 months
- You live in the US

You do not need to have received any medicines or other treatments for your MDS to be eligible.

For more information or to enroll, visit http://www.bu.edu/prs/mds, email mdsinfo@slone.bu.edu, or call the registry at 800-231-3769.

Thank you to the East Brunswick Woman's Club

We want to thank the East Brunswick Woman's Club of NJ who raised over $1000.00 through a charity luncheon. We would also like to thank Pat Gonyo for taking the initiative to plan the event held on behalf of her friend, Joan Mangold, who has MDS.

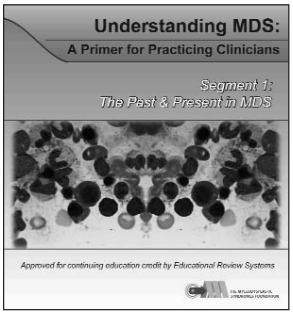
The Foundation Resource Center is Now Online!

This educational center is designed to provide clinicians, researchers, and other healthcare professionals with a comprehensive source for the latest information and educational programming on the myelodysplastic syndromes.

In the Conference section of our website you can view materials presented at MDS conferences or register for upcoming MDS-related symposia.

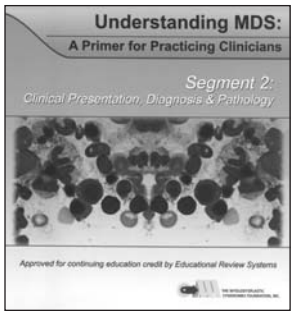
Understanding MDS: A Primer for Practicing Clinicians

Visit **www.mds-foundation.org** and click on The MDS Foundation Resource Center to take advantage of this comprehensive program, and other informative programs coming soon, designed to provide you with tools and information that will assist you in administering the best care to your patients.



Segment 1, *The Past & Present in MDS*.
Segment 1 provides insight into the history of MDS, development of the MDS classification and prognostic systems, and a glimpse into the future of MDS diagnosis, research and treatment.

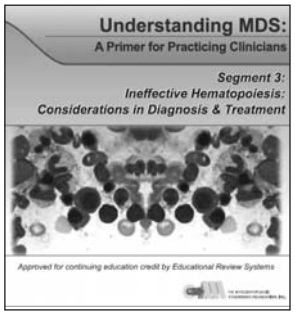
Segment 2, *Clinical Presentation, Diagnosis & Pathology*.
Segment 2 provides insight into the clinical picture of adult and pediatric MDS, primary and secondary MDS, FAB and WHO Classification system, and rationale for the proposed MDS pediatric classification system.



This multi-segment program will allow participants to choose the segments that interest them and to learn at their own pace. Segments may be completed via a written program, on-line in our technologically advanced MDS Foundation Educational Center, or via CD-ROM on their personal computer.

The program is approved for 1 hour of CME credit upon completion. There is no charge for this educational activity.

The Myelodysplastic Syndromes Foundation strives to serve as an effective conduit for information regarding the most updated treatment options, clinical studies, referrals to Centers of Excellence, and other information concerning MDS. Please bookmark our site, www.mds-foundation.org, and check back frequently for new, informative programs.



Segment 3, *Ineffective Hematopoiesis: Considerations in Diagnosis and Treatment*.
Segment 3 provides insight into the pathogenic mechanisms that contribute to the development of MDS, including the altered bone marrow microenvironment of MDS in terms of cells, cytokines, growth factors, receptors, and microvasculature; dyserythropoiesis in MDS, and therapeutic targets and approved drugs for the treatment of MDS.

New MDS Publications

Listed below are citations of some new publications relevant to MDS (pathogenesis, clinical characterization, management, etc.). To access the complete article log on to www.pubmed.gov.

Classification

Malcovati L, Porta MG, Pascutto C, et al. Prognostic factors and life expectancy in myelodysplastic syndromes classified according to WHO criteria: a basis for clinical decision making. *J Clin Oncol*. 2005;23:7594–7603.

Treatment

General

Greenberg PL, Bennett JM, Bloomfield C, et al. NCCN Practice Guidelines for Myelodysplastic Syndromes, Version 2. *J Nat Comp Canc Network*. 2006;4:58–77 (also on web @ www.nccn.org).

Nimer SD. Clinical Management of Myelodysplastic Syndromes with Interstitial Deletion of Chromosome 5q. *J Clin Oncol*. 2006;24(16):2576–82.

Biologic Agents

Naing A, Sokol L, List AF. Developmental Therapeutics for Myelodysplastic Syndromes. *J Natl Compr Cancer Netw*. 2006;4:78–82.

Gore SD. Six (or More) Drugs in Search of a Mechanism: DNA Methyltransferase and Histone Deacetylase Inhibitors in the Treatment of Myelodysplastic Syndromes. *J Natl Compr Cancer Netw*. 2006;4:83–90.

Deeg HJ, Jiang PYZ, Holmberg LA, et al. Hematologic Responses of Patients with MDS to Antithymocyte globulin plus etanercept correlate with improved flow scores of marrow cells. *Leuk Res*. 2004; 28:1177–1180.

Schiller GJ, Slack J, Hainsworth D, et al. Phase II multicenter study of arsenic trioxide in patients with myelodysplastic syndromes. *J Clin Oncol*. 2006; 24(16):2456–64.

Vey N, Bosly A, Guerci A, et al. Arsenic trioxide in patients with myelodysplastic syndromes: a phase II multicenter study. *J Clin Oncol*. 2006;24(16):2465–71.

Ruter B, Wijermans PW, Lüebbert M. Superiority of prolonged low-dose azanucleoside administration? Results of 5-aza-2'-deoxycytidine retreatment in high-risk myelodysplasia patients. *Cancer*. 2006; 106(8):1744-50.

Kantarjian H, Issa JP, Rosenfeld CS, et al. Decitabine improves patient outcomes in myelodysplastic syndromes: results of a phase II randomized study. *Cancer*. 2006;106(8):1650–2.

Balleari E, Rossi E, Clavio M, et al. Erythropoietin plus granulocyte colony-stimulating factor is better than erythropoietin alone to treat anemia in low-risk myelodysplastic syndromes: results from a randomized single-centre study. *Ann Hematol*. 2006;85(3):174–80.

Morgan MA, Reuter CW. Molecularly targeted therapies in myelodysplastic syndromes and acute myeloid leukemias. *Ann Hematol*. 2006;85(3):139–63.

Mesa RA. Tipifarnib: farnesyl transferase inhibition at a crossroads. *Expert Rev Anticancer Ther*. 2006; 6(3):313–9.

Maier SK, Hammond JM. Role of lenalidomide in the treatment of multiple myeloma and myelodysplastic syndromes. *Ann Pharmacother*. 2006;40(2):286–9.

Giagounidis AA, Germing U, Aul C. Biological and prognostic significance of chromosome 5q deletions in myeloid malignancies. *Clin Cancer Res*. 2006;12(1):5–10.

Steensma DP, Bennett JM. The myelodysplastic syndromes: diagnosis and treatment. *Mayo Clin Proc*. 2006;81(1):104–30.

Tehranchi R. Impact of growth factors in the regulation of apoptosis in low-risk myelodysplastic syndromes. *Med Oncol*. 2006;23(1):37–49.

Iron Chelation

Greenberg PL. Myelodysplastic Syndromes: Iron Overload Consequences and Current Chelating Therapies. *J Natl Compr Cancer Netw*. 2006;4:91–96.

Hematopoietic Stem Cell Transplantation

Fukumoto J, Greenberg PL. Management of patients with higher risk myelodysplastic syndromes. *Critical Reviews in Oncology/Hematology*. 2005;56:179–192.

de Lima M, Anagnostopoulos A, Munsell M, et al. Nonablative versus reduced-intensity conditioning regimens in the treatment of acute myeloid leukemia and high-risk myelodysplastic syndrome: dose is relevant for long-term disease control after allogeneic hematopoietic stem cell transplantation. *Blood*. 204;104:865–872.

Wallen H, Gooley TA, Deeg HJ, et al. Ablative allogeneic hematopoietic cell transplantation in adults 60 years of age and older. *J Clin Oncol*. 2005;23:3439–3446.

Scott BL, Sandmaier BM, Storer B, et al. Myeloablative vs nonmyeloablative allogeneic transplantation for patients with myelodysplastic syndrome or acute myelogenous leukemia with multilineage dysplasia: a retrospective analysis. *Leukemia*. 2006;20:128–135.

Kerbauy DMB, Chyou F, Gooley T, et al. Allogeneic hematopoietic cell transplantation for chronic myelomonocytic leukemia. *Biol Blood Marrow Transplant*. 2005;11:713–720.

Scott BL, Sandmaier BM, Storer B, et al. Myeloablative vs nonmyeloablative allogeneic transplantation for patients with myelodysplastic syndrome or acute myelogenous leukemia with multilineage dysplasia: a retrospective analysis. *Leukemia*. 2006;20:128–135.

Books

Greenberg PL, Editor. *Myelodysplastic Syndromes: Clinical and Biological Advances.* Cambridge University Press, Cambridge, England, 2006.

Symposia

ASH Education Session: Myelodysplastic Syndromes

AT Look. *Molecular Pathogenesis of MDS*.

E Hellström-Lindberg. *Update on Supportive Care and New Therapies*.

HJ Deeg. *Optimization of transplant regimens for patients with myelodysplastic syndromes.* In: *Hematology 2005: American Society of Hematology Education Program Book*. Washington, DC: American Society of Hematology, pp 156–173.

11th Congress of the European Hematology Association

June 15–18, 2006
Amsterdam RAI Convention Centre
The Netherlands

The Myelodysplastic Syndromes Foundation presented its first adjunct symposium at The European Hematology Association 11th Annual Meeting in Amsterdam. The symposium was greeted by standing room only, 1000 copies (on CD-ROM) were distributed on Friday and Saturday of the EHA meeting. This educational video and the accompanying slides will be provided to audiences both via our Educational website and on CD for continued use throughout 2006. Translations of educational materials in French, German, Italian, Spanish and Japanese were also provided free of charge at our booth.

SATELLITE SYMPOSIUM SUPPORTED BY THE MYELODYSPLASTIC SYNDROMES (MDS) FOUNDATION:

AN EVOLUTION IN THE UNDERSTANDING OF MYELODYSPLASTIC SYNDROMES

Chairs: G.J. Mufti, *King's College Hospital, London, United Kingdom;* **P. Fenaux**, *Hôpital Avicenne, University of Paris XIII, Bobigny, France*

- **Problems in The Morphological Diagnosis of MDS**
  B. Bain, *St. Mary's Hospital, London, UK*
- **Correlation and Differentiation of New Therapeutic Agents Through Uniform Response Criteria in MDS**
  J. Bennett, *University of Rochester, James P. Wilmot Cancer Center, Rochester, USA*
- **The Relationship of Quality-of-Life to Hgb Levels in MDS**
  E. Hellström-Lindberg, *Karolinska Institutet, Huddinge University Hospital Stockholm, Sweden*
- **The Inter-Relationship of Ineffective Hematopoiesis and Cellular Biology in MDS**
  G. Kroemer, *Institut Gustave Roussy, Villejuif, France*
- **Clarifying MDS – A Progress Report on Research In Molecular Biology**
  C. Schoch, *Laboratory for Leukemia Diagnostics, University Hospital Grosshadern, Munich, Germany*

For a copy of the CD ROM, which contains all of the slide presentations from this session, please contact the MDS Foundation at 1-800-MDS-0839.

The RAI Convention Centre

Nancy Mrzljak and Audrey Hassan provided EHA attendees with up-to-date information from the Foundation

Kathy Heptinstall, Operating Director, The MDS Foundation; and Dr. Ghulam Mufti, Kings College Hospital, UK

NEW

Ask the Doctor Feature

Do you have a question you would like to ask the doctor? We will print answers to questions in future newsletters. Send your questions to the MDS Foundation or email your questions to: patientliaison@mds-foundation.org.

What is MDS?

MDS, or myelodysplastic syndromes, is a collection of disorders in which the bone marrow does not produce enough blood cells.

Normally, the bone marrow produces three major types of blood cells: red blood cells (which carry oxygen to the blood), white blood cells (which help the body fight infections), and platelets (which help blood clot).

In patients with MDS, this process breaks down. Blood cells do not develop properly, and as a result, there is a lack of healthy blood cells in the body.

Is MDS a type of cancer?

MDS is a hematologic neoplasm or malignancy with a variable progression to Acute Myeloid Leukemia (AML) that can be predicted after an initial evaluation is completed. This evaluation includes a bone marrow aspirate and marrow/peripheral blood chromosomal studies.

Why does MDS occur?

MDS is thought to develop due to a primary insult to the bone marrow. Some chemicals or radiation have been determined to cause MDS in some people. A rare, familial form may also develop in patients who have family members with MDS. When patients develop MDS that has no known cause, it is called de novo MDS.

How common is MDS?

It is not known exactly how many people have MDS; however, about 20,000 to 25,000 new cases are diagnosed annually in the United States. It primarily occurs in people older than 60.

What are the symptoms of MDS?

Symptoms vary depending on the individual and the extent of the disease. Typical symptoms include weakness, fatigue, frequent infections, easy bruising, bleeding, fever, weight loss, and a sense of feeling full.

How is MDS classified?

There are several systems that are commonly used to designate the type of MDS that a patient has. These include the French-American-British (FAB) system, the original classification system; the new World Health Organization (WHO) classification system; and the International Prognostic Scoring System (IPSS).

What are the treatment options for MDS?

There are treatment options for patients with myelodysplastic syndromes:

- Most patients will receive supportive care, which includes treatment with erythropoietin +/– G-CSF for raising the hemoglobin level, red blood cell and platelet transfusions. Supportive care also includes close monitoring by everyone on the healthcare team.
- MDS patients who are classified as having MDS deletion 5q can be treated with Revlimid. Revlimid is an immunomodulatory drug that has been approved by the US Food and Drug Administration for use in this type of low-risk MDS. Patients classified as having intermediate-2 or high-risk MDS can be treated with Vidaza or Decitabine, de-methylating agents, approved by the FDA for use in MDS. These patients might include select low or intermediate-1 risk patients.
- In addition, MDS patients might be treated with chemotherapy, bone marrow transplantation, or peripheral blood stem cell transplantation.

How do I know what treatment is right for me?

With MDS, treatment is typically tailored according to the individual's age, general health, type of MDS, and symptoms. For instance, if a patient has low red cells they might be given a red blood cell transfusion or if they have low platelets they might be provided with a platelet transfusions.

For instance, patients younger than 60 are considered better suited for intensive therapies such as bone marrow transplantation.

What is a clinical trial?

A clinical trial is a study conducted by doctors to test investigational therapies or investigational medications. Doctors conduct these trials to see if these investigational treatments can improve on ones they currently use.

The Ninth International Symposium on MDS

The Ninth International Symposium on MDS will be held in Florence, Italy from May 16–19, 2007. Dr. Mario Cazzola is Chairman of the Organizing Committee for the symposium. The Scientific Secretariats are Drs. Matteo G. Della Porta and Luca Malcovati, e-mail address: mds2007@haematologica.org.

The 1st Announcement is currently being distributed. You may obtain a copy of the announcement by writing to the Symposium Secretariat, 9th International MDS Symposium: Studio E.R. Congressi-Gruppo Triumph, Via Marconi, 36-40122 Bologna, Italy.

You may phone the Secretariat at +39 051.4210559 or fax to +39 051.4210174, e-mail address: ercongressi@gruppotriumph.it.

Florence ("Firenze" in Italian) is a beautiful city well known for its cultural and historical sights. Florence is also famous for its art and architecture. A center of medieval European trade and finance, the city is often considered the birthplace of the Italian Renaissance. An attractive social program will be organized for participants and their spouses or guests that will allow you to become acquainted with the beauty and hospitality of Florence.

The Second Announcement will provide details on the Scientific Program, social events, and accommodations.

Florence's world famous skyline

A Call for Papers will be sent in September 2006 and the Deadline for Submission of Abstracts is January 2007.

We are looking forward to welcoming you to the 9th International Symposium on MDS next year!

Seventh Annual Celebration of Life

Hosted by Kimmel Cancer Center at Thomas Jefferson University, Philadelphia, PA

Dr. Emmanuel Besa from our MDS Center of Excellence, Kimmel Cancer Center at Jefferson, extended an invitation to the Foundation to participate in the Seventh Annual Celebration of Life on May 24, 2006. The goal of this annual event is to honor and celebrate the lives of cancer survivors. This year's event was attended by 200 cancer survivors, their family member, and friends. Participants were treated to an art exhibit and writings by cancer survivors and inspirational talks by special guest speakers. It was an enjoyable event and we were able to speak with many of the survivors and caregivers.

Cancer Survivor, Priscilla Jones with a member of our staff enjoying the day's festivities

2006 Ongoing Educational Programs

The MDS Foundation is committed to making a significant contribution to the advancement in understanding and of accurately diagnosing the myelodysplastic syndromes. We will be focusing our efforts in the following initiatives:

- **NEJM Clinical Prospective Publication**
- **Differentiating Anemia (CME Program)**
- **Cytogenetic Working Group in MDS (CWGM)**
- **Quality-of-Life and Patient Advocacy Forums**
- **Young Investigator Grant Program**
- **Participation in all country Society meetings**
- **MDS Practice and Treatment Survey**
- **The International Working Group on MDS Morphology**
- **Transfusion Burden Registry**
- **ADOPT Registry: ATG Dose, Outcomes, and Patient Identification**
- **Centers of Excellence Patient Support Groups**
- **CME Awareness Program for 2006**

Translations available in Spanish, French, Italian, German and Japanese.

- **MDS News 2006**
- **H. Lee Moffitt Cancer Center Golf Tournament for MDS: February 19, 2007**
- **9th International MDS Symposium, Florence, Italy: May 16–19, 2007**
- **Jack Keating Memorial Golf Tournament for MDS: August 6, 2007**

Supported by educational grants from:

Celgene genzyme MGI PHARMA

PHARMION NOVARTIS

Schering-Plough TELIK Innovating for life

MDS

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.

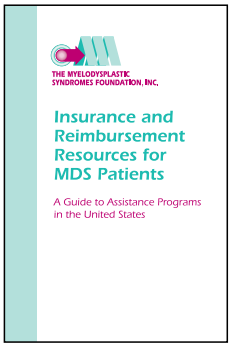
Membership benefits include quarterly issues of the *MDS News*, a special subscription rate of $109 for *Leukemia Research* (a substantial discount from the current institutional subscription rate of $2,373), and the worldwide Centers of Excellence patient referral service.

If you would like additional information, please contact us at: The MDS Foundation
36 Front Street
P.O. Box 353
Crosswicks, NJ 08515

Phone: 1-800-MDS-0839
Fax: 609-298-0590

Outside the US only:
609-298-1035

Now Available From The Foundation



We have assembled a listing of insurance and drug reimbursement resources for MDS patients. It is important to know that there is support for those who cannot afford medicine or other healthcare costs. We hope this new resource will be beneficial in helping you with your medical needs.

This guide to assistance programs in the United States is available for download from the Foundation's website or can be ordered in booklet form upon request.

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:

UNITED STATES

ALABAMA

University of Alabama at Birmingham Comprehensive Cancer Center
Birmingham, Alabama
Peter Emanuel, MD

ARIZONA

Mayo Clinic Hospital
Phoenix, Arizona
James L. Slack, MD

University of Arizona Arizona Cancer Center
Tucson, Arizona
Daruka Mahadevan, MD, PhD

CALIFORNIA

Cedars-Sinai Medical Center UCLA School of Medicine
Los Angeles, California
H. Phillip Koeffler, MD

City of Hope National Medical Center
Duarte, California
Stephen J. Forman, MD

Stanford University Medical Center
Stanford, California
Peter L. Greenberg, MD

University of Southern California Keck School of Medicine
Los Angeles, California
Allen S. Yang, MD, PhD

FLORIDA

Mayo Clinic
Jacksonville, Florida
Alvaro Moreno-Aspitia, MD

University of South Florida H. Lee Moffitt Cancer Center and Research Institute
Tampa, Florida
Alan F. List, MD

ILLINOIS

Loyola University Chicago Cardinal Bernardin Cancer Center
Maywood, Illinois
Scott E. Smith, MD, PhD

Robert H. Lurie Comprehensive Cancer Center of Northwestern University Feinberg School of Medicine
Chicago, Illinois
Olga Frankfurt, MD

Rush University Medical Center
Chicago, Illinois
Stephanie A. Gregory, MD
Jamile Shammo, MD

University of Chicago Medical Center
Chicago, Illinois
Richard A. Larson, MD

INDIANA

Indiana University Medical Center
Indianapolis, Indiana
Larry Cripe, MD

MARYLAND

Johns Hopkins University School of Medicine
Baltimore, Maryland
Steven D. Gore, MD
Charles S. Hesdorffer, MD

National Heart, Lung, and Blood Institute
Bethesda, Maryland
Elaine Sloand, MD

MASSACHUSETTS

Dana-Farber Cancer Institute
Boston, Massachusetts
Richard M. Stone, MD

Tufts University School of Medicine New England Medical Center
Boston, Massachusetts
Geoffrey Chan, MD

University of Massachusetts Medical Center
Worcester, Massachusetts
Azra Raza, MD

MICHIGAN

Barbara Ann Karmanos Cancer Institute Wayne State University
Detroit, Michigan
Charles A.Schiffer, MD

William Beaumont Hospital Cancer Center
Royal Oak, Michigan
Ishmael Jaiyesimi, MD

MINNESOTA

Mayo Clinic
Rochester, Minnesota
David P. Steensma, MD

MISSOURI

Washington University School of Medicine Siteman Cancer Center
St. Louis, Missouri
John F. DiPersio, MD, PhD

NEBRASKA

University of Nebraska Medical Center
Omaha, Nebraska
Lori Maness, MD

NEW JERSEY

The Cancer Center of Hackensack University Medical Center
Hackensack, New Jersey
Stuart Goldberg, MD

NEW MEXICO

University of New Mexico Health Sciences Center
Albuquerque, New Mexico
Robert Hromas, MD

NEW YORK

Albert Einstein College of Medicine Cancer Center
Bronx, New York
Amit Verma, MD

Memorial Sloan-Kettering Cancer Center
New York, New York
Stephen D. Nimer, MD

Mount Sinai School of Medicine
New York, New York
Lewis R. Silverman, MD

New York Medical College/ Westchester Medical Center Zalmen A. Arlin Cancer Center
Valhalla, New York
Karen Seiter, MD

North Shore University Hospital
Manhasset, New York
Steven L. Allen, MD

Roswell Park Cancer Center
Buffalo, New York
Maria R. Baer, MD

University of Rochester Cancer Center
Rochester, New York
John M. Bennett, MD

Weill Medical College of Cornell University New York Presbyterian Hospital
New York, New York
Eric J. Feldman, MD

NORTH CAROLINA

Duke University Medical Center
Durham, North Carolina
Carlos M. deCastro, MD

Wake Forest University School of Medicine Comprehensive Cancer Center
Winston-Salem, North Carolina
Istvan Molnar, MD

OHIO

Cleveland Clinic Foundation Taussig Cancer Center
Cleveland, Ohio
Jaroslaw Maciejewski, MD, PhD

OREGON

Oregon Cancer Center at Oregon Health and Science University
Portland, Oregon
Peter T. Curtin, MD

PENNSYLVANIA

The Western Pennsylvania Cancer Institute
Pittsburgh, Pennsylvania
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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*

As we go to press the National Cancer Institute (NCI) has listed more than 100 clinical trials that focus on Myelodysplastic syndromes. Full study information on these trials is available at www.nci.nih.gov. This information includes basic study information, study lead organizations, study sites, and contact information. To access the information:

- Log on to www.nci.nih.gov
- Click on "Finding Clinical Trials"
- on the next screen look for "Ways to Find Clinical Trials" and
- Click on "Search for Clinical Trials"
- Click on "Type of Cancer" and type in 'myelodysplastic syndromes'
- Hit search

This search will provide you with all the trials currently underway in MDS. You may also sort by trials that only focus on treatment or trials that only focus on supportive care. You can also contact 1-800-4-CANCER for more information.

MDS CLINICAL TRIALS ANNOUNCEMENT

Bone Marrow Failure Disease Consortium. 5405: A Phase I Study of Revlimid® in Combination with Azacitidine in Patients with Advanced Myelodysplastic Syndromes (MDS). Participating Institutions:

- **Cleveland Clinic Foundation**
  Cleveland, OH
  Robin Heggeland, R.N.
  216.445.7648, heggelr@ccf.org
- **Penn State Cancer Institute**
  Hershey, PA
  Lynn Ruiz
  717.531.7377, lruiz@psu.edu
- **University of California at Los Angeles**
  Los Angeles, CA
  Liz Seja
  310.794.6892, eseja@mednet.ucla.edu

Bone Marrow Failure Disease Consortium. 5401: Screening Protocol and Longitudinal Study of Bone Marrow Failure Syndromes and Cytopenias. Participating Institutions:

- **Cleveland Clinic Foundation**
  Cleveland, OH
  Robin Heggeland
  216.445.7648, heggelr@ccf.org
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Celgene. CC-5013-MDS-004: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Study of the Efficacy and Safety of 2 Doses of Lenalidomide Versus Placebo in Red Blood Cell (RBC) Transfusion-Dependent Subjects With Low- or Intermediate-1-Risk Myelodysplastic Syndromes Associated With a Deletion 5Q Cytogenetic Abnormality.

Celgene. CC-401-AML-001: Phase 1 Study to Determine the Optimal Biologic Dose of CC-401 in Subjects With High-Risk Myeloid Leukemia.

Celgene. CDR0000269343: Phase II Pilot Study of Fludarabine, Carboplatin, Topotecan, and Thalidomide in Patients With Relapsed/Refractory or High-Risk Acute Myeloid Leukemia, Chronic Myelogenous Leukemia, or Advanced Myelodysplastic Syndromes.

Genzyme. ID03-0181: A Prospective Randomized Phase I/II Study of Clofarabine and Ara-C Vs Clofarabine and Idarubicin Vs Clofarabine Plus Idarubicin and Ara-C in Patients With First Relapse or First Salvage of Primary Refractory Acute Myeloid Leukemia (AML); and High-Grade Myelodysplastic Syndromes (MDS) (≥10% Blasts); or With Chronic Myeloid Leukemia (CML) in Myeloid Blasts Phase as Front Line Therapy or in First Salvage Chromosome Positive Chronic Myeloid Leukemia).

Genzyme. 2005-0536: Phase II Study of Oral Clofarabine in Myelodysplastic Syndromes (MDS).

MethylGene. MGCD0103-003: A Phase I Study of MGCD0103 Given as a Three-Times Weekly Oral Dose In Patients With Leukemia Or Myelodysplastic Syndromes.

MethylGene. MGCD0103-004: A Phase I Study of MGCD0103 Given as a Twice Weekly Oral Dose in Patients With Leukemia or Myelodysplastic Syndromes.

MethylGene. MGCD0103-005: A Phase I/II Study of MGCD0103 (MG-0103) in Combination With Azacitidine in Patients With High-Risk Myelodysplastic Syndromes or Acute Myelogenous Leukemia.

MGI Pharma. 2004-0468: Phase II Study of Low-Dose Decitabine (5-AZA-2'-Deoxycytidine) in Myelodysplastic Syndromes (MDS) Post Azacytidine (AZA) Failure.

MGI Pharma. ID03-0180: Phase II Randomized Study of Three Different Schedules of Low-Dose Decitabine (5-AZA-2'-Deoxycytidine) in Myelodysplastic Syndromes (MDS).

Novartis. CICL670AUS02: An Open Label, Safety and Tolerability Study of Deferasirox for Treatment of Transfusional Iron Overload in Low-Risk and INT-1, Myelodysplastic Syndromes Patients.

Novartis. CICL670AUS03: An Open Label, Safety and Tolerability Study of Deferasirox for Treatment of Transfusional Iron Overload in Low-Risk and INT-1, Myelodysplastic Patients Using Serum Ferritin Monitoring.

Novartis. CICL670A2409: A Study Assessing the Efficacy and Safety of Deferasirox in Patients With Transfusion-Dependent Iron Overload.

Novartis. CPKC412A2106: Phase I Study of PKC412 Administered Sequentially or Concurrently With Induction Chemotherapy Comprising Daunorubicin and Cytarabine Followed By Consolidation Therapy Comprising High-Dose Cytarabine in Patients With Newly Diagnosed Acute Myeloid Leukemia.

Novartis. CSTI571AUS161: Phase I Study of Cladribine, Cytarabine, and Imatinib Mesylate in Patients With Refractory or Relapsed Acute Myeloid Leukemia or Blastic Phase Chronic Myelogenous Leukemia.

Pharmion. AZA PH US 2004 CL 003: A Multicenter, Randomized, Open-Label Study Comparing Three Alternative Dosing Regimens of Subcutaneous Azacitidine Plus Best Supportive Care for the Treatment of Myelodysplastic Syndromes.

Schering-Plough Research Institute. P02978: A Pivotal Randomized Study of Lonafarnib (SCH 66336) versus Placebo in the Treatment of Subjects With Myelodysplastic Syndromes (MDS) or Chronic Myelomonocytic Leukemia (CMML) Who Are Platelet Transfusion Dependent With or Without Anemia. The purpose of this study is to determine clinical benefit of Lonafarnib plus best supportive care versus Placebo plus best supportive care, measured as achievement of platelet transfusion independence. This Phase III trial will be conducted at approximately 60 sites in US, Canada, Europe, Latin America, Far East. Contact: Sabine Loechner, e-mail: sabine.loechner@spcorp.com; or Antoine Yver, MD, e-mail: antoine.yver@spcorp.com.

Scios. SCIO-469/B008: A Randomized, Multicenter, Open-Label, Modified Dose-Ascension, Parallel Study of the Safety, Tolerability, and Efficacy of Oral SCIO-469 in Patients with Myelodysplastic Syndromes.

Telik. TLK199.1101: Phase 1-2a Dose-Ranging Study of TLK199 Tablets in Myelodysplastic Syndromes (MDS).

Telik. TLK199.1001: Phase 1-2a Study of TLK199 HCl Liposomes for Injection in Myelodysplastic Syndromes. Contact www.clinicaltrials.gov to learn more about other trials for Myelodysplastic Syndromes. Type in "myelodysplastic syndromes" in "Search Clinical Trials" then click on the "Search" button to obtain a listing.

Contact www.clinicaltrials.gov to learn more about other trials for Myelodysplastic Syndromes. Type in "myelodysplastic syndromes" in "Search Clinical Trials" then click on the "Search" button to obtain a listing.

Other U.S. Trials

Barbara Ann Karmanos Cancer Institute, Detroit, MI. D-696: Allogeneic and syngeneic marrow transplantation in patients with acute non-lymphocytic leukemia. Contact: Jared Klein, MD. Phone: 313-963-2533.

Barbara Ann Karmanos Cancer Institute, Detroit, MI. POG A2971: Treatment of Children with Down Syndromes and Acute Myeloid Leukemia, Myelodysplastic Syndromes, or Transient Myeloproliferative Disorder. Contact: Jeffrey Taub, MD. Phone: 313-963-2533.

Cancer and Blood Institute of the Desert, Rancho Mirage, CA. Phase I/II study of arsenic trioxide in combination with cytosine arabinoside in patients with MDS. Contact: R. Lemon. Phone: 760-568-4461.

Cancer Institute Medical Group, Los Angeles, CA. Phase I/IIa Study of TLK199 HCl Liposomes for injection in Myelodysplastic Syndromes. Contact: Lawrence D. Piro, MD. Phone: 310-231-2182.

Case Western Reserve University, Cleveland, OH. CWRU-5Y97: Phase II trial using umbilical cord blood to evaluate the efficacy of transplantation to treat aplastic anemia and myelodysplastic syndromes patients. Eligible patients must have disease not responsive to medical therapy. Contact: Mary J. Laughlin, MD. Phone: 216-368-5693.

Case Western Reserve University, Cleveland, OH. CWRU-6Y01: This is a phase I trial using Umbilical Cord Blood to evaluate the efficacy of Allogeneic Transplantation to treat myelodysplastic syndromes or severe aplastic anemia. The rationale for this study is to investigate whether transplantation of more than one UCB unit is safe and whether this approach may overcome the current problems of primary graft failure and delayed engraftment with single unit UCB. This concept will be evaluated in the setting of non-myeloablative conditioning in attempt to decrease the risk of mortality in the event of primary graft failure. Eligible patients must have hematologic cancer including MDS or severe aplastic anemia requiring allogeneic transplantation. Contact: Mary J. Laughlin, MD. Phone: 216-368-5693.

Cedars-Sinai Medical Center, Los Angeles, CA. 02287: Phase II Trial of Paricalcitol in Myelodysplastic Syndromes to determine if an oral, relatively non-toxic, novel vitamin D_3 compound, paricalcitol, (Zemplar) can improve red, white and platelet counts as well as decrease the risk of development of leukemia, without causing undue toxicity in patients with myelodysplastic syndromes (MDS). Patients will receive oral administration of paricalcitol in increasing doses. Contact: H. Phillip Koeffler, MD. Phone: 310-423-4609.

Children's Hospital of New York Presbyterian, New York, NY. 01-504: Phase II trial using fludarabine, busulfan, and anti-thymocyte globulin (ATG) to evaluate the efficacy of reduced intensity allogeneic stem cell transplantation to treat MDS. Eligible patients must have 1) MDS and ≤5% bone marrow myeloblasts at diagnosis; 2) minimum of ≥10% CD33 positivity; 3) adequate organ function (renal, hepatic, cardiac and pulmonary); 4) age ≤65 years; 5) matched family donor (5/6 or 6/6),unrelated donor (5/6 or 6/6), or cord blood donor (3/6, 4/6, 5/6, 6/6). Contact: Mitchel S. Cairo, MD. Phone: 212-305-8316.

Cleveland Clinic Foundation, Cleveland, OH. IRB6818: Phase II trial of combination therapy with arsenic trioxide (Trisenox) and gemtuzumab ozogamicin (Mylotarg) for the treatment of adult patients with advanced myelodysplastic syndromes. Contact: Liz Kuczkowski. Phone: 216-445-3795.

Cleveland Clinic Foundation, Cleveland, OH. IRB8135: Randomized, multicenter, open-label, modified dose-ascension, parallel study of the safety tolerability, and efficacy of oral SCIO-469 in patients with myelodysplastic syndromes. Contact: Liz Kuczkowski. Phone: 216-445-3795.

Cleveland Clinic Foundation, Cleveland, OH. IRB7671: Phase II trial of combination therapy with thalidomide, arsenic trioxide, dexamethasone, and ascorbic acid (TADA) in patients with chronic idiopathic myelofibrosis or overlap myelodysplastic syndromes. Contact: Liz Kuczkowski. Phone: 216-445-3795.

Comprehensive Cancer Center of Wake Forest University, Winston-Salem, NC. Phase II Study of Arsenic Trioxide and Dose-Escalated Cholecalciferol in Myelodysplastic Syndromes (CCCWFU 29304). Contact: Istvan Molnar, MD. Phone: 336-716-5847.

Comprehensive Cancer Center of Wake Forest University, Winston-Salem, NC. CCCWFU-29203: Orthomolecular Vitamin D in Low-Risk Myelodysplastic Syndromes: Phase II trial using cholecalciferol (Vitamin D_3) to evaluate the efficacy of 2000 IU Vitamin D_3 daily for 6 months to treat MDS. Eligible patients must have MDS; IPSS score 0–1.0; life expectancy >1 year; no other concurrent therapy for MDS; no history of hypercalcemia. Contact: Istvan Molnar, MD. Phone: 336-716-5847.

Comprehensive Cancer Institute. Huntsville, AL. Phase II study of arsenic trioxide (Trisenox) in patients with MDS. Contact: J.M. Waples, MD. Phone: 256-551-6546.

Dana-Farber Cancer Institute, Boston, MA. Phase I Study of Vaccination with Lethally Irradicated, Autologous Acute Myeloblastic Leukemia Cells Engineered by Adenoviral Mediated Gene Transfer to Secrete Human Granulocyte-Macrophage Colony Stimulating Factor in Patients with Advanced Myelodysplasia or acute Myelogenous Leukemia. This is a study to determine the feasibility of preparing lethally irradiated autologous myeloblastic leukemia cells engineered by adenoviral mediated gene transfer to secrete GM-CSF in patients with myelodysplasia or acute myelogenous leukemia. The study will also investigate the safety and biologic activity of vaccination with lethally irradiated, autologous myeloblastic leukemia cells engineered by adenoviral mediated gene transfer to secrete GM-CSF in patients with advanced myelodysplasia or acute myelogenous leukemia. Contact: Ilene Galinsky. Phone: 617-632-3902.

Duke University Medical Center, Durham, NC. 2875: Phase II trial to assess the value of non-myeloablative allogeneic therapy (mini bone marrow transplant) for patients with aplastic anemia or myelodysplastic syndromes. Patients must have severe disease to be eligible and may have either a matched sibling, mismatched family member, or large cord blood unit found for use on our trial. Contact: David A. Rizzieri, MD at Rizzi003@mc.duke.edu.

Fallon Clinic. Worcester, MA. PR01-09-010: Phase II study on the effectiveness of low dose Thalidomide combined with Erythropoietin in the treatment of anemia in patients with low and intermediate risk-1 myelodysplastic syndromes. Contact: Laszlo Leb, MD. Phone: 508-368-3168.

Fox Chase, BMT Program, Philadelphia, PA. 3297: Phase II trials using fludarabine-based regimen to evaluate the efficacy of mini-allogeneic blood stem cell transplantation to treat myelodysplastic syndromes. Eligible patients must have HLA identical donor available, be under age 70 and platelet or red cell transfusion dependent. Patients with matched related donors will be considered up to age 70 with Karnofsky Performance Scale >80%. Patients with matched unrelated donor will be considered to age 65 only. Contact: Marge Bellergeau, RN. Phone: 215-214-3122.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1872: Therapy of Early Stage Myelodysplastic Syndromes (MDS) with ATG and Etanercept. Contact: Bart Scott, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1926: Therapy of Advanced Stage Myelodysplastic Syndromes (MDS) with Azacitidine Given in Combination with Etanercept: A Phase I/II study. Contact: Bart Scott, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #2056: Low-dose TBI Dose Escalation to Decrease Risks of Progression and Graft Rejection after Hematopoietic Cell Transplantation with Nonmyeloablative Conditioning as Treatment for Untreated Myelodysplastic Syndromes or Myeloproliferative Disorders – A Multi-Center Trial. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #6440: Metoclopromide to Treat Anemia in Patients with Myelodysplastic Syndromes (MDS). Contact: Janis Abkowitz, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1432: Phase I Study Combining Escalating Doses of Radiolabeled BC8 (Anti-CD45) Antibody with Fludarabine, Low-Dose TBI, PBSC Infusion and Post-Transplant Immunosuppression with Cyclosporine and Mycophenolate Mofetil to Establish Mixed or Full Donor Chimerism for Elderly Patients with Advanced Acute Myeloid Leukemia or High Risk Myelodysplastic Syndromes. Contact: John Pagel, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1591: Campath® [Alemtuzumab] Dose Escalation, Low-Dose TBI and Fludarabine Followed by HLA Class I Mismatched Donor Stem Cell Transplantation for Patients with Hematologic Malignancies – A Multi-Center Trial. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1629: Phase I/II Study of Total Body Irradiation, Thiotepa, and Fludarabine as Conditioning for Haploidentical CD34+ Purified Peripheral Blood Stem Cell Transplants. Contact: Ann Woolfrey, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1667: Nonmyeloablative Hematopoietic Stem Cell Transplantation for Patients with High-Risk Hematologic Malignancies Using Related, HLA-Haploidentical Donors: A Phase II Trial of Combined Immunosuppression Before and After Transplantation. Contact: Paul O'Donnell, MD, PhD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1813: Multicenter Phase III Study Comparing Nonmyeloablative Conditioning with TBI versus Fludarabine/TBI for HLA-matched Related Hematopoietic Cell Transplantation for Treatment of Hematologic Malignancies. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1860: Phase III Randomized, Multicenter Study Comparing G-CSF Mobilized Peripheral Blood Stem Cell with Marrow Transplantation from HLA Compatible Unrelated Donors. Ann Woolfrey, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1938: Randomized Phase II Study to Determine the Most Promising Postgrafting Immunosuppression for Prevention of Acute GVHD after Unrelated Donor G-CSF mobilized Peripheral Blood Mononuclear Cell (G-PBMC) Transplantation using Nonmyeloablative Conditioning for Patients with Hematologic Malignancies: a Multicenter Trial. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1959: Campath® [Alemtuzumab] Dose Escalation, Low-Dose TBI and Fludarabine II Mismatched Donor Stem Cell Transplantation for Patients with Hematologic Malignancies – A Multicenter Trial. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1898: Multi-Center Study of Nonmyeloablative Conditioning with TBI or Fludarabine/TBI for HLA-matched Related Hematopoietic Cell Transplantation for Treatment of Hematologic Malignancies with Post Grafting Immunosuppression with Tacrolimus and Mycophenolate Mofetil. Contact: David Maloney, MD, PhD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1992: Multicenter Phase III Study Comparing Myeloablative to Nonmyeloablative Transplantation in Patients with Myelodysplastic Syndromes or Acute Myelogenous Leukemia. Contact: Bart Scott, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #2010: Transplantation of Unrelated Umbilical Cord Blood for Patients with Hematological Diseases with Cyclophosphamide/Fludarabine/Total Body Irradiation Myeloablative Preparative Regimen. Contact: Colleen Delaney, MD, MS. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #2012: Transplantation of Unrelated Donor Umbilical Cord Blood in Patients With Hematological Malignancies Using a Non-Myeloablative Preparative Regimen. Contact: Colleen Delaney, MD, MS. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #2041: Conditioning for hematopoietic stem cell transplantation with fludarabine plus targeted IV busulfan and GvHD prophylaxis with thymoglobulin, tacrolimus and methotrexate in patients with myeloid malignancies. Contact: Paul O'Donnell, MD, PhD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #2044: Pilot Study to Evaluate the Co-infusion of Ex Vivo Expanded Umbilical Cord Blood Progenitors with an Unmanipulated Cord Blood Graft in Patients Undergoing Umbilical Cord Blood Transplantation for Hematologic Malignancies. Contact: Colleen Delaney, MD, MS. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #ADVL0319: Phase 1 Study of CC-5013 (Lenalidomide, NSC #703813, IND #70116) in Pediatric Patients with Relapsed/Refractory Solid Tumors or Myelodysplastic Syndromes. Contact: Julie Park, MD. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA. FHCRC #1628: Phase I/II Study of Immunologically Engineered rhG-CSF Mobilized Peripheral Blood Stem Cells (PBSC) for Allogeneic Transplant from HLA Identical, Related Donors for Treatment of Myeloid Malignancies. Contact: Ann Woolfrey, MD. Phone: 206-288-1024.

Froedtert Memorial Lutheran Hospital, Milwaukee, WI. AZA PH GL 2003 CL 001: Multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: David Vesole, MD. Phone: 414-805-4629.

Georgetown University, Washington, DC. P02978: A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Ekatherine Asatiani, MD. Phone: 202-444-3958.

Georgetown University, Washington, DC. Clinical and biologic effects of arsenic trioxide in MDS. Contact: B. Mavromatis, MD. Phone: 202-784-0124.

Georgetown University Medical Center, Lombardi Cancer Center, Washington, DC. 05-064: CALGB: Phase II oral VegF receptor/TKI for MDS high-risk disease. Contact: Jenny Crawford. Phone: 202-687-0893.

Georgetown University Medical Center, Lombardi Cancer Center, Washington, DC. 02053: Gene expression profiling in myelodysplastic syndromes (collection of bone marrow aspirate is needed). Contact: Ekatherine Asatiani, MD. Phone: 202-444-3958.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 14844: Rare Diseases Clinical Research Network Mechanism and Response of Thymoglobulin in Patients with Myelodysplastic Syndromes (MDS) Bone Marrow Failure Disease Consortium. Contact: Kristen Jonathan. Phone: 813-745-3408.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 14408: Bone Marrow Failure Diseases Consortium. Screening protocol and Longitudinal Study of Bone Marrow Failure Syndromes and Cytopenia. Contact: Kristen Jonathan. Phone: 813-745-3408.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 14634: Phase I study of MGCD0103 given as a twice weekly oral dose in patients with Leukemia or myelodysplastic syndromes. Contact: Michelle Burton, RN. Phone: 813-745-3965.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 14454: An open-label, safety and tolerability study of deferasirox for treatment of transfusional iron overload in low risk and intermediate-1 MDS patients using serum ferritin monitoring. Pending. Contact: Lisa Nardelli. Phone: 813-745-4731.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 13937: A Pharmacokinetic and Pharmacodynamic Study of Oral Lenalidomide (Revlimid) in Subjects with Low or Intermediate-1 Risk Myelodysplastic Syndromes. Open. Contact: Kelly Bretz. Phone: 813-745-2071.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 14154 SCIOS: A randomized, multicenter, open-label, modified dose ascension. Parallel study of the safety, tolerability, and efficacy of oral SCIO-469 in low to intermediate-1 risk patients with MDS. Contact: Stacy Moss. Phone: 813-745-8391.

H. Lee Moffitt Cancer Center, Tampa, FL. MCC# 13935 DACO-019: Phase I/II trial of subcutaneous Decitabine (5-AZA-2'Deoxycytidine) maximizing genomic demethylation in patients with myelodysplastic syndromes. Contact: Stacy Moss. Phone: 813-745-8391.

Indiana University Medical Center, Indianapolis, IN. AZA PH GL 2003 CL 001: Multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Larry Cripe, MD. Phone: 317-274-0901.

Johns Hopkins Oncology Center, Baltimore, MD. J0252: Phase II study of the farnesyl transferase inhibitor Zarnestra in complete remission following induction and/or consolidation chemotherapy in adults with poor-risk acute myelogenous leukemia (AML) and high-risk myelodysplasias. Contact: Pamela Powell, RN. Phone: 410-614-1329.

Johns Hopkins Oncology Center, Baltimore, MD. J0443: A Dose-Finding Trial of the Histone Deacetylase Inhibitor MS-275 in Combination with 5-Azacytidine (5AC, NSC 102816) in patients with Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia, and Acute Myeloid Leukemia (AML). Contact: Tianna Dauses, RN. Phone: 410-502-7110.

Johns Hopkins Oncology Center, Baltimore, MD. J0254: Phase I study of Flavopiridol in timed sequential combination with Cytosine Arbinoside and Mitoxantrone for adults with poor-risk Acute Leukemias and Myelodysplasias. Contact: Jackie Greer. Phone: 410-614-1329.

Los Angeles Hematology and Oncology Assoc., Los Angeles, CA. Phase I/II study of arsenic trioxide in combination with cytosine arabinoside in patients with MDS. Contact: C. Gota, MD. Phone: 818-409-0105.

MD Anderson Cancer Center, Houston, TX. Phase II study of combination of Thymoglobulin and cyclosporine in patients with newly diagnosed aplastic anemia or with hypoplastic myelodysplastic syndromes. The purpose of this study is to determine the efficacy of the combination of thymoglobulin, methylprednisone, cyclosporine and G-CSF in achieving response and to assess the effect of treatment on transfusion requirements and overall survival. Eligible patients must have a diagnosis of severe aplastic anemia or MDS with bone marrow cellularity less than 30%, two of three peripheral counts low with ANC less than 500/mL, Plt less than 20,000/mL or reticulocyte count less than 40,000/mL. Patients with MDS who have received prior biological therapy (not chemotherapy), age 15 or greater, adequate renal and hepatic function, no other investigational therapy in the past 14 days, able to comply with the need for contraception during the entire study period. Exclusion criteria include active and uncontrolled pulmonary, cardiac, neurological or other medical illness that would interfere with

study treatment, pregnant or breast-feeding, HIV positive or active and uncontrolled infection. Contact: Farhad Ravandi, MD. Phone: 713-745-0394.

MD Anderson Cancer Center, Houston, TX. Phase I/IIa Study of TLK199 HCl Liposomes for injection in Myelodysplastic Syndromes. Contact: Stefan Faderl, MD. Phone: 713-563-4613.

MD Anderson Cancer Center, Houston, TX. Open-Label, Phase II Study to Evaluate the Efficiency and Safety of the Farnesyltransferase Inhibitor Zarnestra (R115777) in Subjects with High-Risk Myelodysplastic Syndromes (MDS). Contact: Razelle Kurzrock, MD.

MD Anderson Cancer Center, Houston, TX. ID02-266: Therapy of inversion (16) and T (8:21) AML/MDS with fludarabine and Ara-C. Contact Elihu H. Estey, MD. Phone: 713-792-7544.

MD Anderson Cancer Center, Houston, TX. Phase I/II Study of PR1 (NSC698102) Human Leukemia Peptide Vaccine with Incomplete Freund's Adjuvant (NSC 675756). Contact: Jeffrey Molldrem, MD. Phone: 713-745-4820.

MD Anderson Cancer Center, Houston, TX. Phase II Open-Label Study of the Intravenous Administration of Homoharringtonine (CGX-635) in the Treatment of Myelodysplastic Syndromes (MDS). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. Phase II Study of Arsenic Trioxide in The Treatment of Myelodysplastic Syndromes. Contact: Miloslav Beran, MD. Phone: 713-792-2248.

MD Anderson Cancer Center, Houston, TX. Phase II, Multicenter, Open-Label Study of the Safety and Efficacy of High-Dose Pulse Administration DN-101 (Calcitriol) in Patients with Myelodysplastic Syndromes. Contact: Guillermo Garcia-Manero, MD. Phone: 713-745-3428.

MD Anderson Cancer Center, Houston, TX. Randomized, Open-Label, Phase III Trial of Decitabine (5-AZA-2'Deoxycytidine) Versus Supportive Care in Adults With Advanced-Stage Myelodysplastic Syndromes. Contact: Jean-Pierre Issa, MD. Phone: 713-745-2260.

MD Anderson Cancer Center, Houston, TX. Safety And Efficacy Trial of Bevacizumab: Anti-VEGF Humanized Monoclonal Antibody (NSD 704865) Therapy For Myelodysplastic Syndromes (MDS). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. Phase II Study of Neumega (Oprelvekin)(Interleukin-11) in Patients with Myelodysplastic Syndromes. Contact: Razelle Kurzrock, MD. Phone: 713-794-1226.

MD Anderson Cancer Center, Houston, TX. Multicenter Phase I/II Study of Continuous Oral Administration of SCH 66336 in Patients With Advanced Myelodysplastic Syndromes, Acute Myelogenous Leukemia, Chronic Myelogenous Leukemia in Blast Crisis, Acute Lymphoblastic Leukemia. Contact: Jorge Cortes MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. Phase II Study of Intravenous Homoharringtonine in Chronic Myelogenous Leukemia (CML). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. Therapy of Hypereosinophilic Syndromes, Polycythemia Vera, Atypical CML or CMML with PDGF-R Fusion Genes, or Mastocytosis with Gleevec (STI571). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. DCTER: Chemotherapy in Patients Ages 1 Through 49 With Untreated AML or High-Risk Myelodysplasia. Contact: Elihu Estey, MD. Phone: 713-792-7544.

MD Anderson Cancer Center, Houston, TX. Phase II study of clofarabine in combination with cytarabine (Ara-C) in pts ≥50 yrs with newly diagnosed and previously untreated acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) (≥10% bone marrow blasts). Contact: Stefan Faderl, MD. Phone: 713-745-4613.

MD Anderson Cancer Center, Houston, TX. ID03-0181: Phase I/II trial using clofarabine, idarubicin, and/or clofarabine to evaluate the efficacy and safety of clofarabine combinations to treat high-risk myelodysplastic syndrome. Eligible patients must have (as defined in the study title): AML or high-risk MDS. Contact: Stefan Faderl, MD. Phone: 713-745-4613.

MD Anderson Cancer Center, Houston, TX. DM02-203: Phase Ia, Open-Label, 3-Arm, Dose Escalation Study of PTK787/ZK 222584. Contact: Francis Giles, MD. Phone: 713-792-8217.

MD Anderson Cancer Center, Houston, TX. ID03-0044: Phase I Clinical Trial of Oral Suberoylanilide Hydroxamic Acid (SAHA) in Patients with Advanced Leukemias. Contact: Guillermo Garcia-Manero, MD. Phone: 713-745-3428.

MD Anderson Cancer Center, Houston, TX. DM01-646: Phase I Study of ABT-751 in Patients With Refractory Hematologic Malignancies. Contact: Francis Giles, MD. Phone: 713-792-8217.

MD Anderson Cancer Center, Houston, TX. ID99-059: Phase II trial using ATG and Fludarabine or Cyclosporine to evaluate the efficacy of immunosuppression to treat aplastic anemia and myelodysplastic syndromes patients. Eligible patients must have RA or RARS and low blood counts. Contact: Jeffrey Molldrem, MD. Phone: 713-792-7346.

Mayo Clinic, Phoenix, AZ. P02978: Study of Lonafarnib versus placebo in treatment of subjects with myelodysplastic syndromes or chronic myelomonocytic leukemia who are platelet transfusion-dependent with or without anemia. Contact: James Slack, MD. Phone: 480-342-2088.

Mayo Clinic, Phoenix, AZ. CICL670AUS03: Phase II study of Exjade (deferasirox) for treatment of transfusional iron overload in low-risk and intermediate-1 transfusion-dependent MDS patients using ferritin monitoring. Contact: James Slack, MD. Phone: 480-342-2088.

Mayo Clinic, Phoenix, AZ.CICL670AUS03: Open label, safety and tolerability study of deferasirox for treatment of transfusional iron overload in low-risk and intermediate-1 MDS patients using ferritin monitoring. Contact: Elizabeth Rich, MD. Phone: 773-702-0239.

Mayo Clinic, Rochester, MN. DACO-020: Phase II study of decitabine administered daily for 5 days every 4 weeks to adults with advanced stage myelodysplastic syndromes. Contact: David P. Steensma, MD. Phone: 507-538-0107.

Mayo Clinic, Rochester, MN. MC0313: Phase I multicenter trial using high dose cytarabine and 17-allylamino-17-demethoxygeldanamycin (a new signal transduction inhibitor) to identify the maximum tolerated dose of the combination and secondarily to evaluate the efficacy of the combination to treat myelodysplastic syndromes. Eligible patients must have: High grade MDS (RAEB-2) or IPSS MDS prognostic score of >1.5, chronic myelomonocytic leukemia or relapsed/refractory acute leukemia. Contact: Scott H. Kaufmann, MD, Ph.D. Phone: 507-284-8383.

Memorial Sloan-Kettering Cancer Center, New York, NY. 99-057: Phase I study of salicylate for adult patients with advanced myelodysplastic disorders, acute myelogenous leukemia or chronic lymphocytic leukemia. Contact: Virginia Klimek, MD. Phone: 212-639-6519.

Memorial Sloan-Kettering Cancer Center, New York, NY. 00-116: Pilot study of FR901228 or Depsipeptide (NSC#630176) for adult patients with advanced hematologic disorders. Contact: Virginia Klimek, MD. Phone: 212-639-6519.

Memorial Sloan-Kettering Cancer Center, New York, NY. 02-063: Tolerability and PK/PD of multiple oral doses of CT53518 in patients with acute myelogenous leukemia. Contact: Mark Heaney, MD, PhD. Phone: 212-639-2275.

Mount Sinai Medical Center, New York, NY. Phase I-II Pilot Study of Divalproex Sodium and All-Trans-Retinoic Acid (ATRA) in Relapsed or Refractory Acute Myeloid Leukemia (except M3, FAB Classification). Contact: Lewis Silverman, MD. Phone: 212-241-5520.

Mount Sinai Medical Center, New York, NY. AZA PH GL 2003 CL 001: Multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Lewis Silverman, MD. Phone: 212-241-5520.

National Heart, Lung, and Blood Institute, Bethesda, MD. 06-H-0062: Safety of WT1 and PR1 peptide vaccination for patients with MDS. If you or someone you know is 18 years old or older and has been diagnosed with MDS, you may be able to participate in a clinical trial evaluating a new therapy. We believe your immune system might be able to control the abnormal growth of cells that is causing your MDS. This study will test the safety of a vaccine that may increase the number of immune cells responding to the MDS and thereby slow progression of the illness, improve blood counts, reduce the need for transfusions of blood and platelets, or even achieve a remission (but not a complete cure) of the MDS. Contact: Carol Webb, MSRN. Phone: 301-402-0797.

National Heart, Lung, and Blood Institute, Bethesda, MD. 05-H-0201: Metoclopramide to Treat Anemia in Patients with Myelodysplastic Syndromes (MDS). The study drug, metoclopramide, may help increase blood red blood cell counts, reduce anemia symptoms, and/or reduce dependence on transfusions. If eligible to participate, consenting subjects will take metoclopramide by mouth 3 times a day for 20 weeks. Subjects will be followed for safety and effectiveness monitoring at either the NIH or through their home physician. If you have been diagnosed with MDS and are age 18 to 72, you may be able to participate in this clinical trial. Contact: Carol Webb, MSRN. Phone: 301-402-0797.

National Heart, Lung, and Blood Institute, Bethesda, MD. 01-H-0162: Stem Cell Transplantation for Older Patients with Myelodysplastic Syndromes. If you are 55 to 75 years of age and have been diagnosed with MDS, you may be eligible for a transplant procedure designed to decrease a major transplant complication, graft-versus-host disease (GVHD). Under evaluation is a novel method of treating your donor's cells prior to transplant. You must have an HLA-matched brother or sister to participate. We will do the blood testing free of charge to see if your sibling is a match upon request. Contact: Laura Wisch, RN. Phone: 301-402-3595.

National Heart, Lung, and Blood Institute, Bethesda, MD. 04-H-0112: Stem Cell Transplantation and T-Cell Add Back to Treat Myelodysplastic Syndromes. Clinical trial designed to decrease graft versus host disease, promote engraftment, and improve immune system recovery following a bone marrow stem cell transplant. You must have an HLA matched brother or sister donor to participate in this trial. Contact: Laura Wisch, RN. Phone: 301-402-3595.

National Heart, Lung, and Blood Institute, Bethesda, MD. 03-H-0209: Stem Cell Transplant for MDS from a partially HLA-matched family member. Many patients are not considered for a stem cell transplant because an HLA-matched sibling or unrelated donor is unavailable. For such patients, the only curative option is a transplant from a partially HLA-matched family member. If you are 10–50 years of age and have been diagnosed with advanced myelodysplastic syndromes, you may be eligible for a clinical trial of a transplant procedure that evaluates using peripheral blood stem cells from an HLA-mismatched family donor. Eligible patients are not asked to pay for their medical treatment and hospital costs. Contact: Laura Musse, MSRN. Phone: 301-496-3841.

National Heart, Lung, and Blood Institute, Bethesda, MD. 05-H-0206: Pilot Study of Alemtuzumab (Campath®) in Patients with Myelodysplastic Syndromes (MDS). The study drug, a monoclonal antibody, may help increase blood counts, reduce anemia symptoms, and/or reduce dependence on transfusions. If eligible to participate, consenting subjects will receive an intravenous infusion of study medication alemtuzumab (Campath®) once a day for 10 days. Subjects will be admitted to the NIH Clinical Center hospital for study drug initiation. If the study drug infusion is tolerated well, the subject may be discharged and receive the remainder of the treatment course as an outpatient. Contact: Carol Webb, MSRN. Phone: 301-402-0797.

National Heart, Lung, and Blood Institute, Bethesda, MD. 99-H-0050: Non-Myeloablative Allogeneic Peripheral Blood Mobilized Hematopoietic Precursor Cell Transplantation for Hematologic Malignancies in High Risk Patients and in Patients With Debilitating Hematologic Diseases. If you have been diagnosed with MDS, you may be able to participate in a stem cell transplant clinical trial designed to evaluate methods to decrease graft versus host disease, promote engraftment, and improve immune system recovery following a bone marrow stem cell transplant procedure. You must have an HLA-matched family member to participate. You will be given chemotherapy

followed by a transfusion of stem cells and lymphocytes from your donor, which will replace your immune system with the immune system of your healthy donor. Post transplant therapy is designed to reduce the risk of graft versus host disease. We do the blood testing free of charge to see if your family member is a match. We pay for all medical costs related to the transplant procedure. You must be available to live near NIH for approximately 3 months. We also provide a daily allowance to help with living expenses while you are on the study and living away from home. Contact: Rose Goodwin. Phone: 301-594-8013.

New York Medical College/Westchester Medical Center, Valhalla, NY. P02978: A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Dr. Karen Seiter. Phone: 914-493-7514.

New York Medical College/Westchester Medical Center, Valhalla, NY. CLI-033: Phase II study of VNP40101M for patients with acute myelogenous leukemia or high-risk myelodysplasia. Contact: Dr. Karen Seiter. Phone: 914-493-7514.

New York Medical College/Westchester Medical Center, Valhalla, NY. Log 6252: Phase I/II study of a non-myeloablative regimen of pentostatin, mitoxantrone and cytarabine for engraftment of allogeneic hematopoietic progenitor cells in patients with acute leukemia, chronic myelogenous leukemia and myelodysplasia: The mini allo protocol. Contact: Dr. Delong Liu. Phone: 914-493-7514.

New York Presbyterian Hospital, New York, NY. P02978: A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Eric Feldman, MD. Phone: 212-746-3126.

New York Presbyterian Hospital, New York, NY. Phase I/II trial of Trisenox in combination with low dose Ara-C for the treatment of high-risk MDS and poor prognosis AML in patients >60 years. Contact: Gail Roboz, MD. Phone: 212-746-3126.

North Shore University Hospital, Manhasset, NY. 10105: Phase II study of an oral VEGF agent in myelodysplastic syndromes. Contact: Colleen DeGaetano, RN. Phone: 516-562-8976.

Oregon Health & Science University, Portland, OR. 8346: Phase 1-2a Study of TLK199 HCl Liposomes for Injection in Myelodysplastic Syndromes (MDS). Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 7944: Randomized, Double-blind Trial of Fluconazole vs. Voriconazole for the Prevention of Invasive Fungal Infections in Allogeneic Blood and Marrow Transplant Patients. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 8186: Phase III Randomized, Multicenter Trial Comparing G-CSF Mobilized Peripheral Blood Stem Cell with Marrow Transplantation from HLA Compatible Unrelated Donors. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 8343: Prolonged Mycophenolate Mofetil and Truncated Cyclosporine Postgrafting Immunosuppression to Reduce Life-Threatening GvHD after Unrelated Donor Peripheral Blood Cell Transplantation using Nonmyeloablative Conditioning for Patients with Hematologic Malignancies and Renal Cell Carcinoma – A Multicenter Trial. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 7881: Donor Lymphocyte Infusion for the Treatment of Malignancy After Hematopoietic Cell Transplantation Using Non-Myeloablative Conditioning – A Multicenter Trial. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 7039: Randomized Controlled Trial of Posaconazole (SCH56592) vs. Standard Azole Therapy for the Prevention of Invasive Fungal Infections Among High-Risk Neutropenic Patients. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 4352: Transplantation of Unrelated Donor Marrow or Placental Blood Hematopoietic Stem Cells for the Treatment of Hematological Malignancies. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Oregon Health & Science University, Portland, OR. 8119: Phase III trial to compare the non-relapse mortality at 1-year after conditioning with TBI alone vs. fludarabine/TBI in heavily pretreated patients with hematologic malignancies at low/moderate risk for graft rejection who have HLA-matched related donors. Contact: Peter Curtin, MD. Phone: 503-494-5058.

Roswell Park Cancer Institute, Buffalo, NY. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Maria Baer, MD. Phone: 716-845-8840.

Roswell Park Cancer Institute, Buffalo, NY. I35904: A trial of Campath-1H (Alemtuzumab) for Myelodysplastic Syndromes. This is an open label trial of a single course of subcutaneous Campath-1H monotherapy to improve the cytopenias of MDS patients with a Low to Intermediate-2 IPSS score. The study is designed as a two-stage Phase II trial with a total of 20 subjects and stopping rules for both safety and futility. Contact: Minoo Battiwalla, MD. Phone: 716-845-1145.

Roswell Park Cancer Institute, Buffalo, NY. PTK787: Phase II study of an oral VEGF agent in myelodysplastic syndromes. Contact: Maria Baer, MD. Phone: 716-845-8840.

Roswell Park Cancer Institute, Buffalo, NY. RPC-02-03: Treatment of anemia in patients with low-and intermediate-risk MDS with darbepoetin alfa. Multicenter, phase II trial also open at the University of Alabama (Birmingham), Loyola University Medical Center (Chicago), and Rochester General Hospital (Rochester, NY). Contact: Maria Baer, MD. Phone: 716-845-8840.

Stanford University, Stanford, CA. Study of DARBEPOETIN ALFA in Patients with MDS. Primary objectives are 1) to assess erythroid response to DARBEPOETIN ALFA, as determined by changes in hemoglobin and /or red blood cell (RBC) transfusion-dependence. 2) to describe the

safety profile of DARBEPOETIN ALFA in patients with MDS. Phase II trial. Eligibility: IPSS Low, Intermediate-1. Contact: Shahin Shahnia, MD. Phone: 650-723-8598.

Stanford University, Stanford, CA. A Randomized, Multicenter, Open-Label, Modified Dose-Ascension, Parallel Study of the Safety, Tolerability, and Efficacy of Oral SCIO-469 in Patients with Myelodysplastic Syndromes. Contact: Shahin Shahnia, MD. Phone: 650-723-8598.

Stanford University, Stanford, CA. An Open Label, Safety and Tolerability Study of Deferasirox for Treatment of Transfusional Iron Overload in Low-risk and INT-1 Myelodysplastic Patients. Contact: Shahin Shahnia, MD. Phone: 650-723-8598.

St. Francis Hospital, Hartford, CT. CLI-033: Phase II study of VNP40101M for patients with acute myelogenous leukemia or high-risk myelodysplasia. Patients with high risk myelodysplasia must be >60 years old and cannot have received prior cytotoxic chemotherapy (other than hydroxyurea) for treatment of their myelodysplasia. Low-dose single-agent araC, decitabine or 5-azacytidine regimens will not be considered prior cytotoxic chemotherapy for the purpose of this study. Prior treatment with Mylotarg is excluded. Contact: Dr. Bilgrami. Phone: 860-714-4680.

St. Jude Children's Research Hospital, Memphis, TN. INFT2: Allogeneic stem cell and natural killer cell transplantation for children less than 2 years of age with hematologic malignancies. Contact: Wing Leung, MD. Phone: 1-866-278-5833.

St. Jude Children's Research Hospital, Memphis, TN. BEAL1. Clinical Practice Study: Allogeneic bone marrow transplantation for patients with hematologic malignancies and closely matched related donors. This is a "best clinical management" guideline for participants who have leukemia or lymphoma that cannot be cured by standard or normal doses of chemotherapy or radiation therapy. Contact: Gregory Hale, MD. Phone: 1-866-278-5833.

Texas Oncology Medical City Dallas Hospital, Dallas, TX. D-0007: Randomized, open-label, Phase III trial of decitabine (5-aza-2'-deoxycytidine) versus supportive care in adults with advanced-stage myelodysplastic syndromes. This Phase III trial evaluates the efficacy of decitabine to treat MDS. Eligible patients may have de novo or secondary MDS. Growth factors (G-CSF, erythropoietin), steroids, hormones or chemotherapy for treatment of MDS are not allowed for 2 weeks prior to enrollment. Contact: Ronda Waldrop. Phone: 972-566-7790.

Texas Oncology Medical City Dallas Hospital, Dallas, TX. SMC-101-1020: Open-label, prospective, stratified, randomized, controlled, multicenter, phase IIB study of the impact of Thymoglobulin therapy on transfusion needs of patients with early myelodysplastic syndromes. This protocol evaluates Thymoglobulin therapy for 4 days. Eligibility includes low risk MDS (RA, RAEB <10%), IPSS <1.0, transfusion dependence, No prior chemotherapy allowed. Contact: Ronda Waldrop. Phone: 972-566-7790.

Texas Oncology Medical City Dallas Hospital, Dallas, TX. T-MDS-001: Multicenter, randomized, double-blind, placebo-controlled trial comparing best supportive care and thalidomide for the treatment of anemia in patients with myelodysplastic syndromes followed by an open-label treatment with thalidomide. Recently, treatment with thalidomide has been reported to improve the anemia in some patients with MDS. The purpose of this study is to further evaluate the effect of thalidomide or placebo pills (50:50 chance) for 24 weeks. Thereafter, all subjects can receive thalidomide for an additional 24 weeks. The effect of treatment on transfusions and quality of life will be evaluated. Contact: Ronda Waldrop. Phone: 972-566-7790.

Thomas Jefferson University, Philadelphia, PA. P02978: A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Emmanuel C. Besa, MD. Phone: 215-955-0356.

Thomas Jefferson University, Philadelphia, PA. A multicenter, single-arm, open-label study of the efficacy and safety of CC-5013 Monotherapy in RBC transfusion-dependent subjects with Myelodysplastic Syndromes. Contact: Emmanuel C. Besa, MD. Phone: 215-955-0356.

Tufts-New England Medical Center, Boston, MA. E1902: Phase II study of reduced intensity allogeneic stem cell transplant for the treatment of myelodysplastic syndromes. This is a trial by the Eastern Cooperative Oncology Group using a reduced intensity preparative regimen pioneered here at Tufts-NEMC to cure patients with MDS and a genetically compatible related or unrelated donor. Contact: Regina Thornton. Phone: 617-636-7651.

Tufts-New England Medical Center, Boston, MA. RAISCT001: Randomized trial of extracorporeal photophoresis, pentostatin, and total body irradiation versus pentostatin, and total body irradiation in patients undergoing reduced intensity allogeneic stem cell transplantation for the treatment of malignancies. Contact: Carrie Grodman, RN. Phone: 617-636-2682.

Tufts-New England Medical Center, Boston, MA. B008: Randomized, multicenter, open-label, modified dose-ascension, parallel study of the safety, tolerability, and efficacy of oral SCIO-469 in patients with myelodysplastic syndromes. Contact: Carrie Grodman, RN. Phone: 617-636-2682.

University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, AL. Phase I/IIa Study of TLK199 HCl Liposomes for injection in Myelodysplastic Syndromes. Contact: Peter Emanuel, MD. Phone: 205-975-2944.

University of Arizona Cancer Center, Tucson, AZ. 04154: Phase I/II trial of subcutaneous decitabine optimizing genomic methylation in patients with myelodysplastic syndromes. Contact: Daruka Mahedevan, MD. Phone: 520-626-0191.

University of Arizona Cancer Center, Tucson, AZ. HSC #02-11: Safety and efficacy trial of bevacizumab: anti-vegf humanized monoclonal antibody therapy for MDS. Contact: Daruka Mahedevan, MD. Phone: 520-626-0191.

University of California at Los Angeles (UCLA) Medical Center, Los Angeles, CA. Randomized, multicenter, double-blind, placebo controlled trial assessing the safety and efficacy of thalidomide (Thalidomid) for the treatment of anemia in patients with myelodysplastic syndromes.

Recently, treatment with thalidomide has been reported to improve the anemia in some patients with MDS. The purpose of this study is to further evaluate the effect of thalidomide or placebo pills (50:50 chance) for 24 weeks. Thereafter, all subjects can receive thalidomide for an additional 24 weeks. The effect of treatment on transfusions and quality of life will be evaluated. The most common side effects of thalidomide include severe birth defects, drowsiness, weakness, rash, shortness of breath, fluid retention, constipation, low blood pressure, decreased white blood counts, slow heart beats and nerve damage. Contact: Ron Paquette, MD. Phone: 310- 825-5608.

University of Chicago, Chicago, IL. AMG531: Open label sequential cohort, dose escalation study to evaluate the safety and efficacy of AMG 531 in thrombocytopenic subjects with low or intermediate 1 risk MDS. Contact: Margaret Green, RN. Phone: 773-702-0267.

University of Chicago, Chicago, IL. 11884A: High-dose cytarabine/mitoxantrone followed by autotransplantation for therapy-related MDS. Contact: Margaret Green, RN. Phone: 773-702-0267.

University of Chicago, Chicago, IL. 2978: Pivotal randomized study of Lonafarnib (SCH 66336) vs. placebo in the treatment of subjects with Myelodysplastic Syndromes (MDS) or Chronic Myelomonocytic Leukemia (CMML) who are platelet transfusion dependent with or without anemia. Contact: Margaret Green, RN. Phone: 773-702-0267.

University of Chicago, Chicago, IL. 13172B: Phase 1-2a of TLK199 HCl Liposomes for Injection in Myelodysplastic Syndromes. Contact: Margaret Green, RN. Phone: 773-702-0267.

University of Chicago, Chicago, IL. 12981A: Phase II study of an oral VegF receptor tyrosine kinase inhibitor (PTK787/2K222584) (IND #66370, NSC #719335) in Myelodysplastic Syndromes. Contact: Margaret Green, RN. Phone: 773-702-0267.

University of Louisville, Louisville, KY. 541.02: Pilot study of arsenic trioxide and amifostine for the treatment of myelodysplastic syndromes. Eligible patients must have a confirmed diagnosis of MDS. For patients with lower-risk only: documented red blood cell dependence, defined as the inability to maintain a hematocrit of >25% without transfusion support and patients with serum erythropoietin less than 200 IU/mL at screening should have failed to respond to a trial of recombinant erythropoietin (EPO) administered in accordance with institutional guidelines. Patients must have an ECOG PS 0-2 and adequate hepatic and renal function as evidenced by specific laboratory criteria. Contact: R. Herzig, MD. Phone: 800-234-2689.

University of Massachusetts Medical Center, Worcester, MA. Pilot Study to Test the Efficacy of the Anti-CD52 Antibody Campath-1H in Combination with the Growth Factor GM-CSF in Improving the Cytopenias of Patients with Myelodysplastic Syndromes. The purpose of this study is to evaluate the effects of Campath-1H and GM-CSF, in combination, on the low counts seen in MDS. What happens in MDS is a cell in your bone marrow becomes abnormal and starts to grow and multiply. However, the abnormal cells that this bone marrow cell makes die via cell suicide on the way to the blood, resulting in the low blood counts seen in MDS. We hope that Campath-1H will target these abnormal bone marrow cells and cause them to die, while GM-CSF will cause the normal cells to grow and multiply more. If true, these drugs would improve the low blood counts. Both of these drugs must be given by injection (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Pilot study to test the efficacy of coenzyme Q10 in patients with low to intermediate-1 risk myelodysplastic syndromes. The purpose of this study is to test the efficacy of coenzyme Q10 in improving abnormalities seen in bone marrow cells of patients with MDS. One of the abnormalities that tend to occur in the bone marrow cells involves part of the cell called the mitochondria. The mitochondria are like energy producing factories in your cells. Coenzyme Q10 is used by the mitochondria to do their job. Coenzyme Q10 may potentially correct the abnormalities seen in the cells of the bone marrow in MDS. Coenzyme Q10 is a natural, non-toxic substance that can be taken by mouth (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Pilot study to test the efficacy of curcumin and gingerol in patients with myelodysplastic syndromes. The purpose of this study is to test the efficacy of the natural compounds curcumin and gingerol in improving the low blood counts seen in patients with MDS. In MDS, a patient's bone marrow makes more cells than usual that eventually turn into blood cells. However, the increased number of blood cells made die by suicide on the way to the blood. A chemical substance called TNF-α causes the increased cell suicide. Curcumin and gingerol inhibit TNF-α. They are also non-toxic substances, making them ideal for the generally older patient population of MDS, especially since two thirds of the population will not go on to develop acute leukemia. These compounds can be taken at home by mouth (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Oral iron chelation (ICL670) in patients with low to intermediate-1 risk myelodysplastic syndromes. Some patients with MDS are dependent on transfusions to treat their low blood counts. When a patient receives a transfusion, they also get iron that is contained in the blood. This becomes a problem because the body cannot rid itself of iron and a buildup of iron can be toxic and even lethal for the patient. ICL670, also called deferasirox, can get rid of some of this extra iron accumulating in the blood and can thus reduce the morbidity associated with frequent transfusions sometimes required for MDS. Deferasirox can be taken by mouth (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. P02978: A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. This study is attempting to test the efficacy of Lonafarnib against the abnormal cells found in the bone marrow of patients with MDS. Lonafarnib inhibits a certain

protein in your cells that causes the cell to grow and multiply. We believe that Lonafarnib will stop the abnormal cells in the bone marrow from multiplying so that more normal cells can get to the blood. Lonafarnib can be taken by mouth (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase II Trial of Combination Therapy with Thalidomide, Arsenic Trioxide, Dexamethasone, and Ascorbic Acid (TADA) in Patients with Chronic Idiopathic Myelofibrosis or Overlap Myelodysplastic/Myeloproliferative Disorders. The purpose of this study is to see if Thalidomide in combination with arsenic trioxide can improve the low blood counts seen in MDS. In MDS, the cells in the bone marrow are increased, but the blood cells die in greater numbers via cell suicide, resulting in the low blood counts. Thalidomide works to decrease this cell suicide and raise blood counts, while arsenic trioxide works to cause cell suicide of some of the abnormal cells in the bone marrow. We believe the result will be more normal blood cells getting to the blood. The Dexamethasone and Ascorbic Acid are used to improve the function of the Thalidomide and arsenic trioxide. Thalidomide can be taken by mouth, but arsenic must be administered through an IV (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase 1-2a Study of TLK199HCl Liposomes for Injection in Myelodysplastic Syndromes. The purpose of this study is to test the efficacy of TLK in improving the low blood counts seen in MDS. One of the main causes of death seen from MDS is infection. This occurs because the white blood cells that fight infections are lowered in number due to the disease. TLK increases the white blood cell count, making it easier for a patient's body to fight infection and thus lowering their chance of dying from infection. This drug is administered through an IV, so patients must come into the hospital to receive this treatment (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Pilot study to determine efficacy of combining Vidaza and arsenic trioxide for the treatment of patients with intermediate and high risk myelodysplastic syndromes. The purpose of this study is to determine the efficacy of Vidaza and arsenic trioxide, in combination, at improving the low blood counts seen in MDS. As stated in a description above, Vidaza prevents the silencing of good genes in your cell that prevent the cell from growing out of control. This means that Vidaza will hopefully prevent abnormal cells from growing out of control. Arsenic, as described above, works in a different way to do the same thing. Arsenic prevents abnormal cells from growing by causing them to commit suicide. It is hoped that in combination these drugs will increase the blood counts in patients with MDS. Arsenic trioxide must be given via an IV, while Vidaza must be given through an injection (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Pilot Study to Determine the Efficacy of Combining Vidaza and Thalidomide for the Treatment of Myelodysplastic Syndromes and Acute Myeloid Leukemia. This study is assessing the efficacy of Vidaza and Thalidomide, in combination. We hope that these drugs will increase the low blood counts seen in patients with MDS. There are certain genes in your cell that keep it from growing out of control. These genes get what we call 'silenced' in MDS and the now abnormal cell grows out of control. However, the cells that it makes die via cell suicide before they reach the blood, resulting in the low blood count. Vidaza prevents the silencing of the good genes so that the cell does not grow out of control and die on the way to the blood. Thalidomide works to decrease the cell suicide of normal cells and raise blood counts. In combination, we hope that these drugs will raise the blood counts in MDS. Thalidomide can be taken by mouth, while Vidaza must be given via an injection (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase I, multi-dose study of SGN-33 (anti-huCD33mAb; HuM195; lintuzumab) in patients with acute myeloid leukemia and myelodysplastic syndromes (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase II study of Tandutinib (MLN518) in patients with newly diagnosed acute myelogenous leukemia who are considered ineligible for or who decline treatment with standard induction therapy (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase I/II study to evaluate the safety and preliminary activity of ZARNESTRA® (R115777, tipifarnib) in combination with low dose ara-C (LDAC) in patients with myelodysplastic syndrome (MDS) and AML (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase III randomized controlled study of Clofarabine versus low dose Cytarabine (LDAC) in previously untreated older adult patients with acute myeloid leukemia (AML) for whom standard induction chemotherapy is not an appropriate option (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Massachusetts Medical Center, Worcester, MA. Phase III randomized controlled study comparing Clofarabine and Cytarabine versus Cytarabine alone in adult patients ≥60 years old with acute myeloid leukemia (AML) who have relapsed or are refractory after receiving up to two prior induction regimes (PI: Dr. Raza). Contact: Murtaza Mehdi. Phone: 508-856-3509.

University of Michigan Comprehensive Cancer Center, Ann Arbor, MI. Phase II trial of combination therapy with arsenic trioxide (Trisenox) and gemtuzumab ozogamicin (Mylotarg) for the treatment of adult patients with advanced myelodysplastic syndromes. Contact: Harry P. Erba, MD, PhD.

University of Pennsylvania Cancer Center, Philadelphia, PA. A pilot study of valproic acid in patients with MDS. Contact: Selina Luger, MD. Phone: 215-662-6348.

University of Pennsylvania Cancer Center, Philadelphia, PA. Pilot study of arsenic trioxide in patients with MDS. Contact: Selina Luger, MD. Phone: 215-662-6348.

University of Pennsylvania Cancer Center, Philadelphia, PA. 801752: Establishment of a Myelodysplastic Syndromes Tissue Bank. The protocol is intended to expand the availability of MDS patient samples for research into the etiology of these disorders. Contact: James Thompson, MD. Phone: 215-573-7617.

University of Texas Southwestern Medical Center, Dallas, TX. P02978: A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Robert Collins, MD.

University of Texas Health Science Center at San Antonio, San Antonio, TX. Phase I/IIa Study of TLK199 HCl Liposomes for injection in Myelodysplastic Syndromes. Contact: Natalie Callander, MD. Phone: 210-617-5300 Ext. 4720.

University of Texas, UT Health Science Center, San Antonio, TX. Randomized, double-blind, phase II study of the matrix metalloproteases inhibitor Prinomastat in patients having myelodysplastic syndromes. Eligible patients must be over 18 years of age and have a diagnosis of MDS of at least 8 weeks duration, hemoglobin <9.0 g/dL (or be transfusion dependent) with adequate renal/hepatic function of serum creatinine less than or equal to 1.5 mg/dL and serum total bilirubin less than or equal to 2.0 mg/dL. Contact: Natalie Callander, MD. Phone: 210-567-4848.

University of Washington, Seattle, WA. UW-26-245-B: Phase I trial using subcutaneous, outpatient injection to evaluate the efficacy of Interleukin-2 to treat MDS. Eligible patients must have either refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, or chronic myelomonocytic leukemia; more than 30 days since any prior treatment for MDS; Karnofsky performance status >70; serum creatinine <2.0 mg/dL; bilirubin <1.6 mg/dL or SGOT <150. Contact: John A. Thompson, MD. Phone: 206-288-2015.

UPMC Hillman Cancer Center, Pittsburgh, PA. 01-020: Phase II multicenter trial of Calcitrol and Dexamethasone for Adult Myelodysplastic Syndromes to evaluate the efficacy of the combination of the two drugs, will cause apoptosis to treat MDS. Contact: Hillman Cancer Center. Phone: 412-641-8073.

Vanderbilt University Medical Center, Nashville, TN. Phase II study of arsenic trioxide in myelodysplasia. Contact: Shubhada M. Jagasia, MD. Phone: 615-322-4752.

Wake Forest University School of Medicine, Winston-Salem, NC. CCCWFU-29203: Orthomolecular Vitamin D in Low-Risk Myelodysplastic Syndromes: Phase II trial using cholecalciferol (Vitamin D_3) to evaluate the efficacy of 2000 IU Vitamin D_3 daily for 6 months to treat MDS. Eligible patients must have MDS; IPSS score 0–1.0; life expectancy >1 year; no other concurrent therapy for MDS; no history of hypercalcemia. Contact: Istvan Molnar, MD. Phone: 336-716-5847.

Wake Forest University School of Medicine, Winston-Salem, NC. CCCWFU-29304: Phase II Study of Arsenic Trioxide and Dose-Escalated Cholecalciferol in Myelodysplastic Syndromes: The purpose of this study is to determine how many patients with myelodysplastic syndromes (MDS) respond to the combination treatment with arsenic trioxide and cholecalciferol (vitamin D_3). All MDS patients are eligible if they have a life expectancy of at least six months. Arsenic trioxide is administered daily for 5 days intravenously (as a "loading" dose) followed by twice a week administration. Vitamin D_3 is given at 100 microgram/day by mouth and the dose is increased by 50 microgram/d every three months up to a year in patients who have no toxicity and did not achieve complete remission. Bone marrow samples are obtained before and during treatment to look at response with morphological and biological parameters. Patients may remain on the study for up to one year. Contact: Istvan Molnar, MD. Phone: 336-716-5847.

Washington University School of Medicine, St. Louis, MO. 03-1277: Phase III randomized, multicenter trial comparing G-CSF mobilized peripheral blood stem cell with marrow transplantation from HLA compatible unrelated donors. Contact: Nick Fisher. Phone: 314-454-5090.

Washington University School of Medicine, St. Louis, MO. 01-1014: Tissue acquisition for analysis of genetic progression factors in hematologic diseases for AML and MDS. Contact: Nick Fisher. Phone: 314-454-5090.

Washington University School of Medicine, St. Louis, MO. 03-0187: CALGB 100002: Non-myeloablative allogeneic hematopoietic cell transplantation for patients with disease relapse or myelodysplasia after prior autologous transplantation. Contact: Nick Fisher. Phone: 314-454-5090.

Washington University School of Medicine, St. Louis, MO. 03-0349: Pilot study evaluating the safety and efficacy of AMD3100 for the mobilization and transplantation of HLA-matched sibling donor hematopoietic stem cells in patients with advanced hematologic malignancies. Contact: Nick Fisher. Phone: 314-454-5090.

Washington University School of Medicine, St. Louis, MO. 05-0141: Phase I pharmacokinetic trial of decitabine administered as a 3-hour infusion to patients with acute myelogenous leukemia or myelodysplastic syndromes. Contact: Nick Fisher. Phone: 314-454-5090.

Washington University School of Medicine, St. Louis, MO. 04-0337 CALGB10105: A phase II study of an oral VegF receptor tyrosine kinase inhibitor (PTK78/ZK222584) in myelodysplastic syndromes (MDS). Contact: Nick Fisher. Phone: 314-454-5090.

Western Pennsylvania Cancer Institute, Pittsburgh, PA. WPCI2004-17: Arsenic trioxide, ascorbic acid, filgrastim and erythropoietin for the treatment of myelodysplastic syndromes. Contact: Richard K. Shadduck, MD. Phone: 412-578-1034.

Western Pennsylvania Cancer Institute, Pittsburgh, PA. WPCI2004-37/AZA PH US 2004 CL003: Multicenter, randomized, open-label study comparing three alternative dosing regimens of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Richard K. Shadduck, MD. Phone: 412-578-1034.

Western Pennsylvania Cancer Institute, Pittsburgh, PA. WPCI2004-08/CALGB 10105: Phase II study of an oral VegF receptor tyrosine kinase inhibitor (PTK787/ZK222584) in the treatment of myelodysplastic syndromes. Contact: Richard K. Shadduck, MD. Phone: 412-578-1034.

Western Pennsylvania Cancer Institute, Pittsburgh, PA. WPCI2005-19: Azacitidine in the Treatment of Elderly Patients with Acute Myelogenous Leukemia. Contact: James M. Rossetti, D.O. Phone: 412-578-3407.

International Trials

AUSTRALIA

Peter MacCallum Cancer Centre, Victoria. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: John F. Seymour, MD. Phone: +613 9656 1697.

The Newcastle Mater Miseriecordiae Hospital, New South Wales. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Arno Enno. Phone: +61 2 4921 1215.

Princess Alexandra Hospital, Queensland. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Anthony Mills. Phone: +61 7 3240 2086.

Royal Adelaide Hospital, South Australia. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Noemi Horvath. Phone: +61 8 8222 3550.

The Alfred Hospital, Victoria. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Andrew Spencer. Phone: +61 3 9276 3392.

The Royal Perth Hospital, Western Australia. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Richard Herrman, MD. Phone: +61 8 9224 2405.

AUSTRIA

Medical University of Vienna, Austria. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Peter Valent, MD. Phone: + 43 1 40400 6085.

BELGIUM

AZ Sint-Jan AV, Brugge. Idarubicin and AraC in combination with Gemtuzumab Ozogamicin (IAGO) for young untreated patients without an HLA identical sibling with high risk MDS or AML developing after a preceding period with MDS of 6 months duration. A phase II study. EORTC study 06013. Study coordinator: Theo de Witte. Contact person in Belgium: D.Selleslag 3250452321.

AZ Sint-Jan AV, Brugge. Intravenous low dose decitabine versus supportive care in elderly patients with primary myelodysplastic syndrome (>10% blasts or high risk cytogenetics), secondary MDS or CMML who are not eligible for intensive therapy. An EORTC-German MDS Study Group randomised phase III study. EORTC study 06011. Study coordinator: Pierre Wijermans. Contact person in Belgium: D.Selleslag 3250452321.

AZ Sint-Jan AV, Brugge. Randomized phase II trial with Infliximab (Remicade) in patients with a myelodysplastic syndrome and a relatively low risk of developing acute leukemia. EORTC protocol 06023. Study coordinator: Heinz Zwierzina. Contact person in Belgium: D.Selleslag 3250452321.

Cliniques Universitaires Saint-Luc, Bruessel. CLI-033. A Phase II study of VNP40101M for patients with acute myelogenous leukemia or high-risk myelodysplasia. Patients with high risk myelodysplasia must be >60 years old and cannot have received prior cytotoxic chemotherapy (other than hydroxyurea) for treatment of their myelodysplasia. Low-dose single-agent araC, decitabine or 5-azacytidine regimens will not be considered prior cytotoxic chemotherapy for the purpose of this study. Prior treatment with Mylotarg is excluded. Contact: Dr. Ferrant. Phone: 32 2 764 1810 (1880).

CZECH REPUBLIC

Institute of Hematology and Blood Transfusion, Prague. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Jaroslav Cermak, MD. Phone: +4202 2496 2839.

FRANCE

Groupe Français des Myélodysplasies. GFM BAR-C 2005. A multicenter phase I/II study on the combination of Bortézomib and low dose cytarabine in the treatment of high risk MDS patients. Contact: Shanti Natarajan-Amé, MD or Francois Dreyfus, MD. Phone: +33 3 88 12 76 70 shanti.ame@chru-strasbourg.fr; +33 1 58 41 19 96 francois.dreyfus@cch.aphp.fr.

Groupe Français des Myélodysplasies. CC5013-MDS-004. A phase III trial, three arms, randomized multi-center in double blind to evaluate the efficacy and toxicity of two doses of lenalidomide versus placebo in subjects with IPSS low or Intermediate-1 risk MDS associated with deletion 5q and red blood cell transfusion-dependent anemia defined as having received >4 transfusions within 56 days of randomization of symptomatic anemia. Contact: Pierre Fenaux, MD. Phone: +33 1 48 95 70 50/70 51 pierre.fenaux@avc.ap-hp.fr.

Groupe Français des Myélodysplasies. THAL-MDS-200. A phase II multi-center study of Thalidomide at low dose for the treatment of patients with IPSS low or Intermediate-1 risk MDS. Contact: Didier Bouscary, MD. Phone: +33 1 40 51 65 43 bouscary@cochin.inserm.fr.

Groupe Français des Myélodysplasies. ICL670. A multi-center study to evaluate the efficacy and tolerance of treatment by ICL670 (20 mg/kg/d) during 1 year in RBC transfusion-dependent subjects with hemosiderosis. Contact: Christian Rose. Phone: +33 3 20 87 45 32 rose.christian@ghicl.net.

Groupe Français des Myélodysplasies. MAQ2005. A phase II study of intensive chemotherapy combined to quinine in high risk MDS with PGP expression. Contact: Pierre Fenaux, MD. Phone: +33 1 48 95 70 50/70 51 pierre.fenaux@avc.ap-hp.fr. or Stephane de Botton s.de-botton@voila.fr.

Groupe Français des Myélodysplasies. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacytidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Pierre Fenaux, MD. Phone: +33 1 48 95 70 50/70 51 pierre.fenaux@avc.ap-hp.fr.

Groupe Français des Myélodysplasies. GFMaza05. Phase II study on maintenance treatment with azacytidine in high risk MDS patients in response after intensive chemotherapy. Contact: Claude Gardin, MD. Phone: +33 1 48 95 70 50/70 51 claude.gardin@avc.aphp.fr.

Institute Paoli Calmettes, Marseilles. CLI-033. A Phase II study of VNP40101M for patients with acute myelogenous leukemia or high-risk myelodysplasia. Patients with high risk myelodysplasia must be >60 years old and cannot have received prior cytotoxic chemotherapy (other than hydroxyurea) for treatment of their myelodysplasia. Low-dose single-agent araC, decitabine or 5-azacytidine regimens will not be considered prior cytotoxic chemotherapy for the purpose of this study. Prior treatment with Mylotarg is excluded. Contact: Norbert Vey, MD. Phone: +33 4 91223695 veyn@marseille.fnclcc.fr.

Chu Purpan, Toulouse. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Guy Laurent, MD. Phone: +33 5 61772078.

Chu De Nantes, Nantes. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Beatrice Mahe, MD. Phone: +33 2 40083252.

Chu De Lille, Lille. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Bruno Quesnel, MD. Phone: +33 3 20446640.

Hôpital Cochin, Paris. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Francois Dreyfus, MD. Phone: +33 1 58412120.

GERMANY

Heinrich-Heine University Düsseldorf. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Ulrich Germing, MD. Phone: +49 211 811 6500.

Heinrich-Heine University Düsseldorf. A multicenter randomized open-label parallel group Phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Norbert Gattermann, MD. Phone: +49 211 811 6500.

Heinrich-Heine University Düsseldorf. Phase II Trial of Valproic Acid as a Monotherapy or in Combination With All-trans Retinoic Acid for the Treatment of Myelodysplastic Syndromes. Contact: Norbert Gattermann, MD. Phone: +49 211 811 6500.

St. Johannes Hospital, Duisburg. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact A. Giagounidis, MD. Phone: 49-203-5462480.

University Hospital Freiburg. Phase II study of low-dose intravenous decitabine in patients aged >60 years with acute myeloid leukemia who are not eligible for standard induction chemotherapy. Contact: Michael Lübbert, MD, PhD. Phone: +49-761-270-3279.

University Hospital Freiburg. Intravenous low-dose decitabine versus supportive care in elderly patients with primary Myelodysplastic Syndrome (MDS) (>10% blasts or high-risk cytogenetics), secondary MDS or Chronic Myelomonocytic Leukemia (CMML) who are not eligible for intensive therapy: an EORTC-German MDS Study Group randomized Phase III study. Contact: Michael Lübbert, MD, PhD. Phone: +49-761-270-3279.

University Hospital Hamburg. Allo/Treo-Flud/MDSsAML. Allogeneic stem cell transplantation after toxicity-reduced conditioning regimen with treosulfan and fludarabine for patients with MDS or sAML, who were not eligible for a standard conditioning regimen: a phase II study. Contact: Nicolaus Kröger, MD. Phone: +49-40-42803-5864.

University Hospital Hamburg. RICMAC-MDSsAML. EBMT: Dose-reduced versus standard conditioning followed by allogeneic stem cell transplantation in patients with MDS or sAML. A randomized phase III study. Contact: Nicolaus Kröger, MD. Phone: +49-40-42803-5864.

University Hospital Benjamin Franklin, Berlin. SAKK 33/99. Antithymocyte Globulin (ATG) and Cyclosporine (CSA) to treat patients with Myelodysplastic Syndrome (MDS). A randomized trial comparing ATG & CSA with best supportive care. Contact: Prof. Dr. Wolf-K. Hofmann. Phone: +49-30-8445-5903.

University Hospital Benjamin Franklin, Berlin. Phase II clinical trial using vaccination with Wilms-Tumor-Gen 1 (WT1) derived peptide in patients with acute myeloid Leukemia and Myelodysplastic Syndrome. Contact: Prof. D. Wolf-K. Hofmann. Phone: +49-30-8445-5903.

University Hospital Benjamin Franklin, Berlin. AZA PH GL 2003 CL 001. A multicenter, randomized, open-label, parallel-group, Phase 3 trial of subcutaneous Azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Prof. Dr. Wolf-K. Hofmann. Phone: +49-30-8445-5903.

Universitätsklinikum Carl Gustav Carus, Dresden. EVTAC trial. Tacrolimus and everolimus as graft-versus-host disease prophylaxis for patients with MDS or AML receiving hematopoietic stem cells from HLA-compatible siblings or unrelated donors. Contact: Uwe Platzbecker, MD. Phone: +49-351-458-4190.

Universitätsklinikum Carl Gustav Carus, Dresden. AZA PH GL 2003 CL 001. A multicenter, randomized, open-label, parallel-group, Phase 3 trials for subcutaneous Azacitidine plus best supportive care versus conventional care regimens plus best supportive care for treatment of MDS. Contact: Uwe Platzbecker, MD. Phone: +49-351-458-4190.

Universitätsklinikum Carl Gustav Carus, Dresden. 06011 (EORTC). Intravenous low-dose decitabine versus supportive care in elderly patients with primary Myelodysplastic Syndrome (MDS) (>10% blasts or high-risk cytogenetics), secondary MDS or Chronic Myelomonocytic Leukemia (CMML) who are not eligible for intensive therapy: an EORTC-German MDS study group randomized Phase III study. Contact: Uwe Platzbecker, MD. Phone: +49-351-458-4190.

Universitätsklinikum Carl Gustav Carus, Dresden. 2003/4. Radioimmunotherapy with Re-188-anti-CD66-antibody for conditioning of AML and MDS patients above the age of 55 prior to stem cell transplantation. Contact: Martin Bornhäuser, MD. Phone: +49-351-458-2321.

Universitätsklinikum Carl Gustav Carus, Dresden. 2003/2. Tacrolimus and Mycophenolate mofetil as Graft-versus-Host disease Prophylaxis for patients with Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) receiving conditioning with Fludarabine and targeted intravenous Busulfan and Hematopoietic stem cells from HLA-compatible siblings or unrelated donors. Contact: Martin Bornhäuser, MD. Phone: +49-351-458-2321.

HUNGARY

Semmelweis University School of Medicine, Budapest. Investigation of the multifactorial cause of iron overload by testing HFE gene mutations: C282Y and H63D, determination of copper and coeruloplasmin level, analysis of transferring receptor mutation and also TNF-α promoter gene polymorphism in MDS patients. Contact: Judit Varkonyi, MD, PhD. Phone/Fax: 361-355-8251.

ISRAEL

Tel-Aviv Sourasky Medical Center. OCC5013-MDS-004. Randomized 3-arm controlled trial: 2 doses of Revlimid vs control for transfusion-dependent 5q- MDS patients. Contact: Dr. Moshe Mittelman. Phone: +972 (0) 3-697-3366.

ITALY

Unit of Hematology and Stem Cell Transplantation, Centro di Riferimento Oncologico di Basilicata. RIV0106. A phase II trial with high dose darbepoetin +/- Peg-Filgrastim in low-intermediate risk myelodysplastic syndromes. Contact: Dr. Pellegrino Musto. Phone: 39 (0) 972 716117.

Unit of Hematology and Stem Cell Transplantation, Centro di Riferimento Oncologico di Basilicata. RIV0206. A phase I/II trial with bortezomib in low-intermediate risk myelodysplastic syndromes. Contact: Dr. Pellegrino Musto. Phone: 39 (0) 972 716117.

Unit of Hematology and Stem Cell Transplantation, Centro di Riferimento Oncologico di Basilicata. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Dr. Pellegrino Musto. Phone: 39 (0) 972 716117.

Unit of Hematology and Stem Cell Transplantation, Centro di Riferimento Oncologico di Basilicata. AZA PH GL 2003 CL 001. A confirmatory survival randomized trial of azacytidine vs standard of care in patients with high-risk myelodysplastic syndromes. Contact: Dr. Pellegrino Musto. Phone: 39 (0) 972 716117.

Unit of Hematology and Stem Cell Transplantation, Centro di Riferimento Oncologico di Basilicata. GIMEMA MDS 0205. An open-label, phase II trial of 5-azacytidine plus valproic acid +/- ATRA combination in int-2/high risk myelodysplastic syndromes. Contact: Dr. Pellegrino Musto. Phone: 39 (0) 972 716117.

University Tor Vergata, Roma. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Sergio Amadori, MD.

JAPAN

Nippon Medical School, Tokyo. IRB2002-22. Open-label study of the safety and efficacy of Thalidomide in patients with Myelodysplastic Syndrome. Contact: Dr. Kiyoyuki Ogata. Phone: 81-3-3822-2131 (Ext. 6321).

THE NETHERLANDS

Universitaire Ziekenhuis Gasthuiberg, Leuven. CLI-033. A Phase II study of VNP40101M for patients with acute myelogenous leukemia or high-risk myelodysplasia. Patients with high risk myelodysplasia must be >60 years old and cannot have received prior cytotoxic chemotherapy (other than hydroxyurea) for treatment of their myelodysplasia. Low-dose single-agent araC,

decitabine or 5-azacytidine regimens will not be considered prior cytotoxic chemotherapy for the purpose of this study. Prior treatment with Mylotarg is excluded. Contact: Dr. Verhoeft. Phone: 011-32-16-346880.

University of Nijmegen, Nijmegen. AZA PH GL 2003 CL 001. A multicenter, randomized, open-label, parallel-group, Phase 3 trial of subcutaneous Azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Dr. P. Muus. Phone: +31-24-3614762.

University of Nijmegen, Nijmegen. EBMT200502. A prospective 2×2 randomized multicenter study evaluating the role of remission-induction and consolidation chemotherapy prior to allogeneic transplantation and of G-CSF mobilized peripheral blood progenitor cells versus bone marrow stem cells using HLA-identical siblings in patients with Myelodysplastic Syndromes and between 5% and 20% bone marrow blasts. Contact: Prof. Dr. T. de Witte. Phone: +31-24-3614762.

University of Nijmegen, Nijmegen. EORTC 06011. Intravenous low-dose decitabine versus supportive care in elderly patients with primary MDS (>10% blasts or high-risk cytogenetics), secondary MDS of CMMOL who are not eligible for intensive therapy. Contact: Dr. P. Muus. Phone: +31-24-3614762.

University of Nijmegen, Nijmegen. EPO 2003. A Phase 2 clinical trial to evaluate the feasibility of treatment with Aranesp in patients with Myelodysplastic Syndrome (MDS). Contact: Prof. Dr. T. de Witte. Phone: +31-24-3614762.

University of Nijmegen, Nijmegen. EORTC 06013. Idarubicin and Ara-C in combination with Gemtuzumab-Ozogamicin (IAGO) for young untreated patients, without an HLA identical sibling, with high risk MDS or AML developing after a preceding period with MDS during 6 months duration. Contact: Prof. Dr. T de Witte. Phone: +31-24-3614762.

University of Nijmegen, Nijmegen. EORTC 06023. Randomized Phase II trial with Infliximib (Remicade) in patients with Myelodysplastic Syndrome and a relatively low risk of developing acute leukemia. Contact: Dr. P. Muus. Phone: +31-24-3614762.

VU University Medical Center, Amsterdam. Impact on apoptosis of immature myeloid and erythroid progenitor cells and its relation to immune escape mechanisms of a standardized regimen of epoëtine bèta (NeoRecormon®) and granulocyte colony-stimulating-factor (Neupogen®) in low-risk myelodysplasia. Contact: Prof. Dr. G.J. Ossenkoppele or Dr. A.A. van de Loosdrecht. Phone: +31-20-4442604; +31-20-4442642 (www.hematologie.nl).

VU University Medical Center, Amsterdam. Randomized phase II trial with infliximab (Remicade) in patients with myelodysplastic syndrome and a relatively low risk of developing acute leukemia (EORTC 06023). Contact: Prof. Dr. G.J. Ossenkoppele or Dr. A.A. van de Loosdrecht. Phone: +31-20-4442604; +31-20-4442642 (www.eortc.be).

VU University Medical Center, Amsterdam. Antithymocyte globulin (ATG) and cyclosporine (CsA) to treat patients with MDS. A randomized trial comparing ATG and CsA with best supportive care (HOVON60). Contact: Prof. Dr. G.J. Ossenkoppele or Dr. A.A. van de Loosdrecht. Phone: +31-20-4442604; +31-20-4442642 (www.hovon.nl).

VU University Medical Center, Amsterdam. Randomized induction and post induction therapy in adult patients (≤60 yrs of age) with acute myelocytic leukemia (AML) or refractory anemia with excess of blasts (RAEB, RAEB-t) with IPSS score ≥1.5 (HOVON 42). Contact: Prof. Dr. G.J. Ossenkoppele or Dr. A.A. van de Loosdrecht. Phone: +31-20-4442604; +31-20-4442642 (www.hovon.nl).

VU University Medical Center, Amsterdam. Randomized induction and post induction therapy in older patients (≥61 yrs of age) with acute myelocytic leukemia (AML) and refractory anemia with excess of blasts (RAEB, RAEB-t) with IPSS score e 1.5 (HOVON43). Contact: Prof. Dr. G.J. Ossenkoppele or Dr. A.A. van de Loosdrecht. Phone: +31-20-4442604; +31-20-4442642 (www.hovon.nl).

THE NORDIC COUNTRIES

Nordic MDS Group. CC-5013-MDS-004: Multicenter, randomized, double-blind, placebo-controlled, 2-arm study of the efficacy and safety of 2 doses of lenalidomide versus placebo in red blood cell (RBC) transfusion-dependent subjects with low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion (DEL) 5q[31] cytogenetic abnormality. Contact: Dr. Eva Hellström-Lindberg. Phone: 011-46-85-858-0000.

Nordic MDS Group. NMDSG02B: Maintenance treatment with Azacitidine in patients with advanced MDS and MDS-AML, who have obtained CR with intensive chemotherapy study. Phase II study. Contact: Dr. Eva Hellström-Lindberg. Phone: 011-46-85-858-0000.

Nordic MDS Group. NMDSG03A: Effects of anemia in MDS – quality of life, cardiac function and health care costs. An open non-randomised phase II study. Contact: Dr. Eva Hellström-Lindberg. Phone: 011-46-85-858-0000.

Nordic MDS Group. AZA PH GL 2003 CL 001: Multicenter, Randomised, Open-Label, Parallel-Group, Phase 3 Trial of Subcutaneous Azacytidine plus best supportive care vs. conventional care regimens plus best supportive care for treatment of myelodysplastic syndromes. Contact: Dr. Eva Hellström-Lindberg. Phone: 011-46-85-858-0000.

POLAND

Jagiellonian University, Cracow. A randomized trial comparing Antithymocyte Globulin (ATG) and Cyclosporine (CSA) with best supportive care in patients with MDS. Contact: Prof. Aleksander B. Skotnicki, MD. Phone: +48-12-421-3693.

Jagiellonian University, Cracow. Phase I/II study of Thalidomide in low-risk MDS. Contact: Pawel Sledziowski, MD. Phone: +48-12-424-7600.

Jagiellonian University, Cracow. Phase III clinical trial of Amifostine/pentoxifylline/ciprofloxacin/dexamethasone for low-risk MDS. Contact: Janusz Krawczyk, MD. Phone: +48-12-424-7600.

Jagiellonian University, Cracow. Phase I/II study of Arsenic Trioxide in high-risk MDS. Contact: Marcin Sobocinski, MD. Phone: +48-12-424-7600.

SPAIN

Hospital Universitario del Salamanca, Salamanca. P02978. A pivotal randomized study of Lonafarnib vs placebo in the treatment of myelodysplastic syndromes who are platelet transfusion dependent, with or without anemia. Contact: Maria Consuelo del Cañizo, MD. Phone: +34 923 291384.

Hospital Universitario del Salamanca, Salamanca. 2001395. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Maria Consuelo del Cañizo, MD. Phone: +34 923 291384.

Hospital Universitario del Salamanca, Salamanca. 200500045473. Chelation therapy in RBC transfusion-dependent myelodysplastic syndromes (MDS) patients. Contact: Maria Consuelo del Cañizo, MD. Phone: +34 923 291384.

Hospital Clinic, Barcelona. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Benet Nomdedeu, MD. Phone: +34 93 227 55 11.

Hospital Son Llatzer, Palma de Mallorca. A multicenter randomized open-label parallel group phase III trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of Myelodysplastic Syndromes (MDS). Contact: Joan Bargay, MD. Phone: +34 871 20 21 38.

UNITED KINGDOM

Kings College Hospital. AZA PH GL 2003 CL 001. A randomized trial of subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care for the treatment of myelodysplastic syndromes. Contact: Professor Ghulam J. Mufti. Phone: 00 44 207-346-3080.

Kings College Hospital. Randomized controlled trial of prolonged treatment with darbepoetin alpha and recombinant human granulocyte colony stimulating factor (GCSF) versus best supportive care in patients with low-risk MDS. Contact: Professor Ghulam J. Mufti. Phone: 00 44 207-346-3080.

The Leeds Teaching Hospitals. Celgene MDS 004: Multi-centre, randomised, double-blind, placebo-controlled, 3-arm study of the efficacy and safety of 2 doses of lenalidomide versus placebo in red blood cell (rbc) transfusion-dependent subjects with low or intermediate-1-risk myelodysplastic syndromes associated with a deletion of 5q cytogenetic abnormality. Contact: David Bowen, MD. Phone: 44 113 392 2407.

The Leeds Teaching Hospitals. Novartis 2409: A one-year multi-centre clinical trial evaluating the efficacy and safety of ICL670 (20 mg/kg) in patients diagnosed with transfusion-dependent iron overload. Contact: David Bowen, MD. Phone: 44 113 392 2407.

The Royal Bournemouth Hospital. Celgene MDS 004: Multi-centre, randomised, double-blind, placebo-controlled, 3-arm study of the efficacy and safety of 2 doses of lenalidomide versus placebo in red blood cell (rbc) transfusion-dependent subjects with low or intermediate-1-risk myelodysplastic syndromes associated with a deletion of 5q cytogenetic abnormality. Contact: Sally Killick, MD. Phone: 44 (0) 11202 704783.

The Royal Bournemouth Hospital. Celgene MDS 004: Multi-centre, randomised, double-blind, placebo-controlled, 3-arm study of the efficacy and safety of 2 doses of lenalidomide versus placebo in red blood cell (rbc) transfusion-dependent subjects with low or intermediate-1-risk myelodysplastic syndromes associated with a deletion of 5q cytogenetic abnormality. Contact: Sally Killick, MD. Phone: 44 (0) 11202 704783.

The Royal Bournemouth Hospital. Medical Research Council. Working Parties on Leukemia in Adults and Children Acute Myeloid Leukemia 15: AML 15 will evaluate several relevant therapeutic questions in acute myeloid leukemia (AML) as defined by WHO. The trial is open to all patients aged 60 years or over for whom intensive therapy is considered appropriate. Contact: Sally Killick, MD. Phone: 44 (0) 11202 704783.

The Royal Bournemouth Hospital. National Cancer Research Institute. Acute Myeloid Leukemia and High Risk Myelodysplastic Syndromes Trial 16: A Phase 1/2 Trial to assess the feasibility of combining Clofarabine with Daunorubicin and Daunorubicin + Clofarabine with Mylotarg in older patients with Acute Myeloid Leukemia and high Risk Myelodysplastic Syndromes. Contact: Sally Killick, MD. Phone: 44 (0) 11202 704783.

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.

Announcing a New Clinical Research Trial for Platelet Transfusion-Dependent Patients With MDS or CMML

Learn More About P02978

The MDS Foundation wants you to know about clinical trials of investigational treatment options for patients with MDS. In the current clinical research trials, all patients will receive therapy with Lonafarnib, an investigational drug that is being evaluated for treating patients with MDS or CMML who have been regularly receiving at least 1 and not more than 8 platelet transfusions every 4 weeks. The medicine is taken by mouth at home, and although patients will be monitored closely, routine hospital stays are not required.

The Myelodysplastic Syndromes Foundation is assisting in the accrual of patients for Clinical Trial P02978 — A Pivotal Randomized Study of Lonafarnib Versus Placebo in the Treatment of Subjects With Myelodysplastic Syndromes (MDS) or Chronic Myelomonocytic Leukemia (CMML) Who Are Platelet Transfusion Dependent With or Without Anemia.

What is Lonafarnib?

Lonafarnib is a drug that is being investigated to treat patients with MDS or CMML. Lonafarnib is a potent, orally bioavailable, specific inhibitor of farnesyl transferase. Farnesyl transferase is an enzyme that allows a protein, RAS, to adhere to cell membranes and to cause these cells to become neoplastic or cancerous. Lonafarnib blocks farnesylation of RAS and other proteins involved in cell growth and proliferation.

What is the purpose of this trial?

This trial has several goals:

- To measure how effective Lonafarnib is in the treatment of platelet transfusion-dependent MDS patients with or without anemia.
  - This will be determined by whether or not patients need platelet transfusions following treatment with Lonafarnib with no increase in the need for RBC transfusions or decrease in hemoglobin levels.
- To monitor the safety of Lonafarnib among these patients.
- To evaluate hematological response rates.
- To observe the effect of Lonafarnib on red blood cell transfusion requirements.

What are potential side effects?

The most common side effects of Lonafarnib that were seen in previous clinical trials included diarrhea, nausea, vomiting, anorexia, and fatigue. Most of these side effects were mild to moderate in severity.

Who is eligible?

- Patients who have been diagnosed with de novo MDS and who are platelet-transfusion dependent (received at least 1 and no more than 8 platelet transfusions every 4 weeks) with or without anemia
  - This includes refractory anemia (RA), refractory anemia with ringed sideroblasts (RARS), and refractory anemia with excessive blasts (RAEB)], refractory anemia with excess blasts in trans-formation (RAEB-T), and chronic myelomonocytic leukemia (CMML). Diagnosis must be confirmed by bone marrow aspirate
- ECOG Performance Status 0 to 2
- Patients with anemia (red blood cell transfusion dependent or independent)
- Patients with no prior therapy with farnesyl transferase inhibitors
- Patients with no treatment for MDS with the exception of supportive care
- Sexually active women of childbearing age will need to use adequate birth control methods while in the study and will be required to maintain this method throughout the study

How is the trial designed?

Patients will undergo a 4 week prospective screening period. Lonafarnib is a pill that is taken by mouth every day for 28 days. Patients will begin treatment and will repeat this regimen for at least three cycles (1 cycle = 28 days).

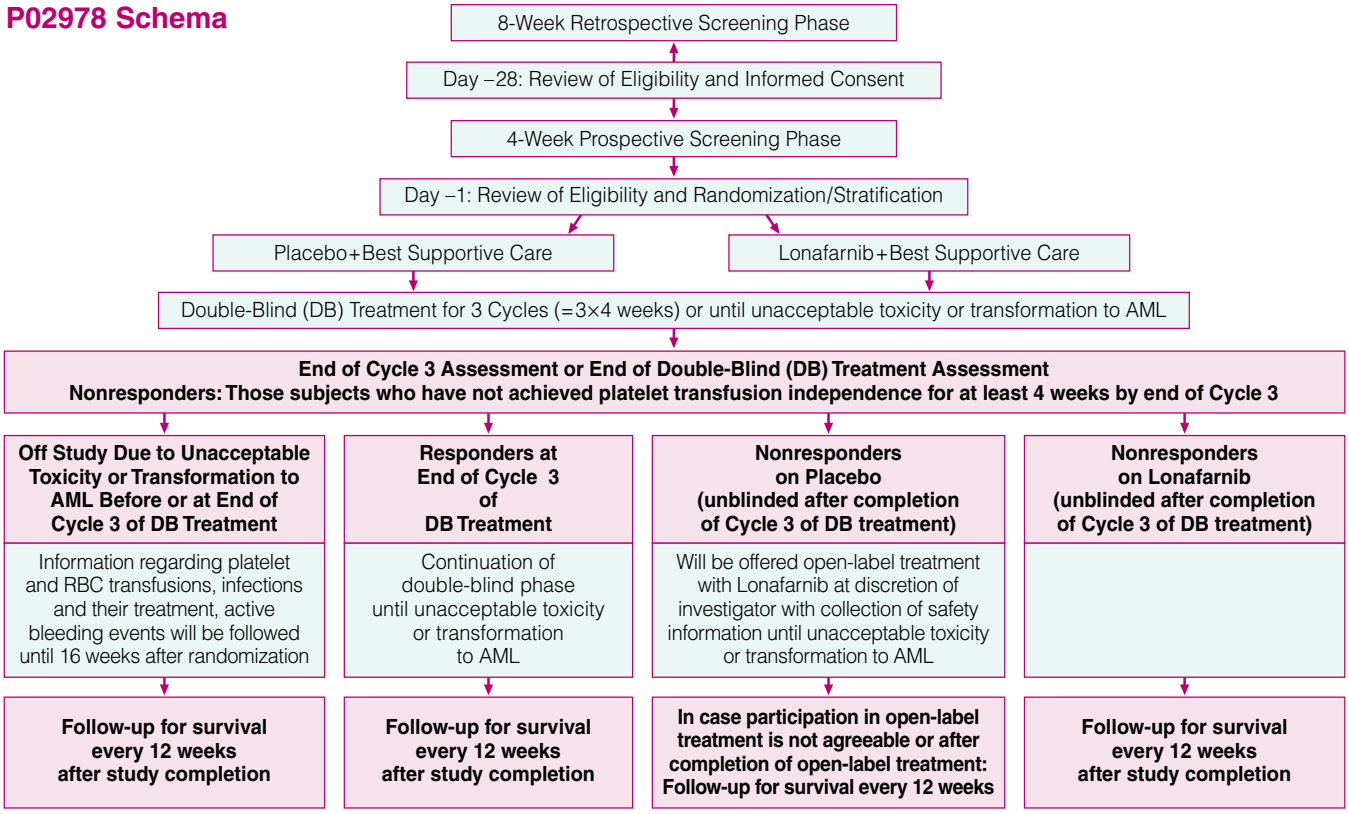
This Phase III trial will be conducted at approximately 60 sites in US, Canada, Europe, Latin America, and the Far East.

In an effort to move the clinical development of Lonafarnib forward as rapidly as possible in the hope of helping platelet transfusion-dependent patients, the Foundation would appreciate hearing from you.

If you are a physician and would like to refer a patient for enrollment into this clinical trial or if you are an MDS patient who receives platelet transfusions, please contact The MDS Foundation at 1-888-813-1260 (outside the US: 609-298-7741).

(continued on page 38)

P02978 Schema



Lonafarnib Clinical Trial Site List

UNITED STATES

Alvin and Luis Lapidus Cancer Institute
Baltimore, MD
Stephen Noga, MD

University of Minnesota
Minneapolis, MN
Mark Reding, MD

Roswell Park Cancer Institute
Buffalo, NY
Maria Baer, MD

Georgia Cancer Specialists
Tucker, GA
Mansoor Saleh, MD

New York Presbyterian Hospital
New York, NY
Eric Feldman, MD

New York Medical College
Valhalla, NY
Karen Seiter, MD

Bethesda Research Center
Boynton Beach, FL
Roger Brito, MD

University of Massachusetts Medical Center
Worcester, MA
Azra Raza, MD

Georgetown University Hospital
Washington, DC
Ekatherine Asatiani, MD

University of Texas Southwestern Medical Center
Dallas, TX
Robert Collins, MD

Thomas Jefferson University, Kimmel Cancer Center
Philadelphia, PA
Emmanuel Besa, MD

James A. Haley Veterans Hospital
Tampa, FL
Hussain Saba, MD

University of South California, Norris Cancer Center
Los Angeles, CA
Dan Douer, MD

Mayo Clinic Hospital
Phoenix, AZ
James Slack, MD

Scripps Cancer Center
La Jolla, CA
James Mason, MD

Leo W. Jenkins Cancer Center
Greenville, NC
Daria Liles, MD

CANADA / LATIN AMERICA

Brazil

Fundacao Pio XII Hospital de Cancer de Barretos
Barretos, Brazil
Eduardo Jose Paton, MD

Laboratorio de Patologia Clinica Brazil
Rio de Janerio, Brazil
Angelo Maiolino, MD

Hospital Nossa Senhora da Conceicao
Porto Alegra, RS, Brazil
Marcelo Capra, MD

Canada

Cross Cancer Institute
Edmonton, Alberta
Robert Turner, MD

Sunnybrook Regional Cancer Center
Toronto, Ontario
Rena Buckstein, MD

Princess Margaret Hospital
Toronto, Ontario
Andre Claudius Schuh, MD

Colombia

Fundacion Santa Fe de Bogota
Bogota, Colombia
Monica Duarte Romero, MD

Instituto de Cancerologica SA
Medellin, Colombia
Amado Karduss, MD

Hospital Militar Central
Bogota, Colombia
Benjamin Ospino, MD

Cardio Diagnostico SA
Barranquilla, Colombia
Miguel Urina, ME

Ecuador

Hospital Carlos Andrade Marin
Quito, Ecuador
Jose Paez, MD

Hospital SOLCA Guayaquil
Guayaquil, Ecuador
Bella Maldonado, MD

Cruz Rojo Ecuatoriana
Quito, Ecuador
Juan Sghirla, MD

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San Salvador, El Salvador
Hector Valencia, MD

Mexico

Centro Medico Nacional Siglo XXI
Mexico, DF, Mexico
Luis A. Mellion-Garcia, MD

Hospital General de Mexico
Mexico, DF, Mexico
Victoria Garcia-Vidrio, MD

Hospital Juarez de Mexico
Mexico, DF, Mexico
Jorge Cruz-Rico

Peru

Hospital Nacional Edgardo Rebaglianti
Jesus Maria, Peru
Juan Navarro, MD

Puerto Rico

Doctors Cancer Center
Manati, Puerto Rico
Kenel Fernandez-Barbosa, MD

San Juan Hospital
San Juan, Puerto Rico
Luis Baez-Diaz, MD

San Juan VA Medical Center
San Juan, Puerto
William Caceres, MD

EUROPE / FAR EAST

Austria

University Clinic of Vienna
Vienna, Austria
Peter Valent, MD

Hanusch Hospital of Vienna
Vienna, Austria
Thomas Noesslinger, MD
Michael Pfeilstoecker, MD

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Institute of Hematology
Prague, Czech Republic
Jaroslav Cermak, MD

University Hospital Olomouc
Olomouc, Czech Republic
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Sergio Amadori, MD

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Prato, Italy
Angelo DiLeo, MD

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Giovanni Rotando, Italy
Pellegrino Musto, MD

Spain

Hospital Universitario
Salamanca, Spain
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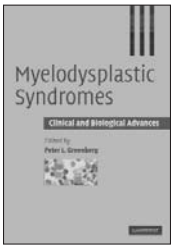
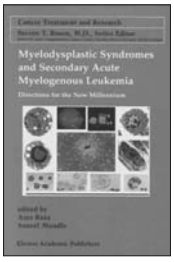


Myelodysplastic Syndromes: Clinical and Biological Advances

Peter L. Greenberg, MD
Stanford University Medical Center
Hardback
Nov. 2005/320pp., illus.
ISBN: 0521496683/$125.00**
Cambridge University press

As the current major comprehensive reference on all aspects of the clinical classification underlying pathogenetic mechanisms and treatment of the myelodysplastic syndromes, Myelodysplastic Syndromes stands out as the definitive text on the genetics, pathophysiology, and clinical management of this wide range of syndromes. Authored by international experts, this book provides a state-of-the-art update of the current status and recent advances in the field. The chapters cover all aspects of the myelodysplastic syndromes, from an in-depth analysis of the multifactorial nature of this disease, including a careful assessment of stromal, immunological and stem cell abnormalities, to a review of recent molecular and cytogenetic discoveries and insights.

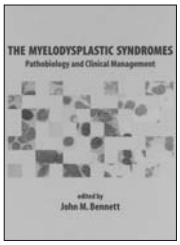
This book will be a valuable resource to clinicians and researchers who wish to learn more about myelodysplastic syndromes.



Myelodysplastic Syndromes & Secondary Acute Myelogenous Leukemia: Directions for the New Millennium **(Cancer Treatment and Research)**
Edited by:
Azra Raza, MD and Suneel D. Mundle, Ph.D.

June 2001/278pp., illus.
ISBN: 0792373660/$198.00**
Springer Science + Business Media, Inc.

Myelodysplastic syndromes are to the bone marrow what pneumonia is to the lungs; the response of an organ to a variety of etiologic insults like aging, toxic exposure, infections and auto-immunity. Among infectious causes alone, pneumonia could be the result of a variety of possible pathogens including bacterial, viral, tuberculous or fungal agents. Similarly, MDS cannot be treated as a single disease. Attempts to harness the inherent complexity of MDS by devising "classifications" which group the various syndromes as one disease is as misguided as saying that a pneumonia is not infectious because it did not respond to antibiotics. Progress in the field will occur faster when we re-analyze this premise. Therefore, until a clearer picture of the disease emerges it is best to treat each of the MDS syndromes as a separate entity. Having no classification is better than a misleading one. This book is our attempt to define the most crucial questions related to MDS that need to be addressed immediately through logic, analysis and rigorous experimentation. If the emerging problems appear daunting, then instead of being overwhelmed by them, we should follow the advice of the great 20th century thinker Antonio Gramsci, "pessimism of the intellect must be faced with the optimism of will".



The Myelodysplastic Syndromes Pathobiology and Clinical Management **(Basic and Clinical Oncology Series/27)**
Edited by:
John M. Bennett
James P. Wilmot Cancer Center of the University of Rochester, Rochester, New York, U.S.A.

May 2002/528 pp., illus.
ISBN: 0-8247-0782-6/$165.00**
CRC Press. 800-272-7737

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

To order call MDS Foundation at 1-800-MDS-0839.

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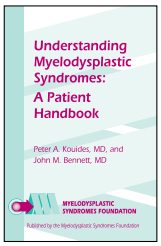
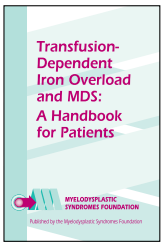
MDS Educational Resources for Clinicians

PATIENT INFORMATION AND EDUCATIONAL MATERIALS AVAILABLE FROM THE MDS FOUNDATION



A. Understanding Myelodysplastic Syndromes: A Patient Handbook

Peter A. Kouides, MD;
John M. Bennett, MD



B. Transfusion-Dependent Iron Overload and MDS: A Handbook for Patients

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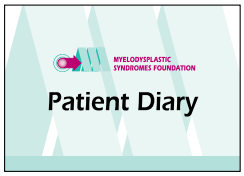

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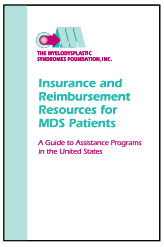

D. Insurance and Reimbursement Resources for MDS Patients

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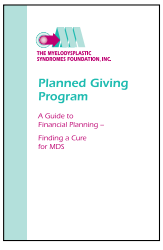


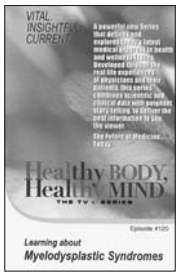
E. Planned Giving Program

Published by
The MDS Foundation

Translations available in Spanish, French, Polish, Czech, Japanese, German and Portuguese.

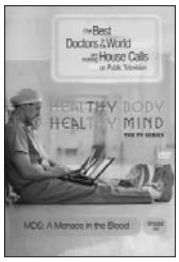
F. Your Journal: Learning About Myelodysplastic Syndromes (MDS)

Supported by a grant from
Celgene Corporation.



G. PBS Program Videotape

Healthy Body, Healthy Mind: Learning About Myelodysplastic Syndromes



H. PBS Program DVD

Healthy Body, Healthy Mind: A Menace in the Blood

All of these materials are available free of charge from the Foundation.

MDS White Paper Available through The MDS Foundation

This MDS White Paper discusses comparative data and the potential clinical benefits of treatments that are either approved by the U.S. FDA or the EMEA or are under consideration by these bodies. This paper and a subsequent peer-review manuscript will hopefully assist physicians in matching patients with treatment. Coupled with the Foundation's other endeavors we hope to impact the care that is available to patients around the world.

To download your free pdf copy, visit our website www.mds-foundation.org or, if you prefer, call 800-MDS-0839 to request a hard copy.

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!

OTHER SITES OF INTEREST:

ASBMT™ American Society for Blood and Marrow Transplantation:

www.asbmt.org

International Bone Marrow Transplant Registry:

www.isbmtr.org

National Marrow Donor Program®:

www.marrow.org

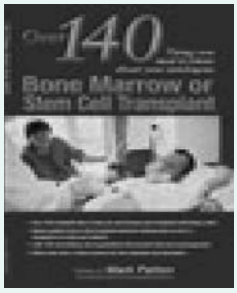
Blood & Marrow Transplant Information Network:

www.bmtinfonet.org

Blood & Marrow Transplant Resources:

www.BMTresources.org

Over 140 Things You Need to Know about Your Autologous Bone Marrow or Stem Cell Transplant is available online at www.BMTresources.org or call (414) 870-4850, ISBN# 0-9768060-0-2/ Price: $11.95.



Contains over 140 invaluable tips to help transplant patients sail through their procedures.

Ways to Support Us

Individual donations of *any amount*. Every penny helps.

Myrna Pearlman lost her beloved husband last year to MDS. He was her best friend and partner for over 50 years. We at the Foundation, were privileged to meet and got to know her husband, Harvey, and we were devastated to learn that he died from complications following a stem cell transplant. In addition to having friends and family donate monies in Harvey's name to our Foundation, Myrna has directed her family and close friends to donate monies to the Foundation in lieu of gifts for her 70th birthday party. Any occasion prompts Myrna to think of us here and to support our mission.

Myrna, we thank you for your continued support during this most difficult time for you.

The MDS Foundation is very grateful for the heartfelt support of its donors. Our work as a non-profit organization depends on public funding. If you would like to contribute or if you have a unique idea of your own, please write to us at:

MDS Foundation
36 Front Street, P.O. Box 353
Crosswicks, NJ 08515
or call us at 1-800-MDS-0839.

All donations are tax-deductible.

Suzanne Fleischman Memorial Fund for Patient Advocacy

A fund has been established by the MDS Foundation in memory of Suzanne Fleischman. Contributions may be sent to the Foundation with a notation designating the Suzanne Fleischman Memorial Fund for Patient Advocacy. New donations have been made by:

Edward Fleischman, *Prescott, AZ*
Eloise B. Fox, *Kensington, CA*
Fay Wanetick, *Pittsburgh, PA*
Ferne Wagman, *Bynton Beach, FL*
Roslyn Raney, *Menlo Park, CA*

A Living Endowment

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

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

A Living Endowment donation has been made in honor of:

Myrna Pearlman's Birthday

This donation has been submitted by:

Peter Aronin
Sarasota, FL

Gordon and Sandra Bratter
New City, NY

Elliot Aronin
Sarasota, FL

Jerry and Rosalie Bergman
Longboat Key, FL

A Living Endowment donation has been made in honor of:

Harold Peterfreund's Birthday

This donation has been submitted by:

Mr. and Mrs. I. Shochat
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A Living Endowment donation has been made in honor of:

Robert Weinberg

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MDS

About the Foundation

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

Until the Foundation was set up, no formal working group had been devoted to MDS. During the past decade we have conducted eight international symposia—in Austria, England, the United States, Spain, Czech Republic, Sweden, France, and Japan. The Ninth International Symposium is being held in May 2007 in Florence, Italy.

A major Foundation effort is our international information network. This network provides patients with referrals to Centers of Excellence, contact names for available clinical trials, sharing of new research and treatment options between physicians, and extension of educational support to both physicians and patients.

In response to the needs expressed by patients, families, and physicians, we have established 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 Website

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

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

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

Mailing Address:

The MDS Foundation, Inc.
36 Front Street
P.O. Box 353
Crosswicks, NJ 08515

Tel: 1-800-MDS-0839
Fax: 609-298-0590
Outside US: 609-298-1035

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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Susan J. Ferber, in memory of Dr. Jerome Ferber *New York, NY*

Dr. Peter L. Greenberg, *Stanford, CA*

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