EIGHTH INTERNATIONAL SYMPOSIUM ON MYELODYSPLASTIC SYNDROMES: AN OVERVIEW

Nagasaki, Japan, May 12–15, 2005

The MDS Foundation’s International Symposium was held for the first time in Asia. About 500 doctors and scientists attended, 70% from abroad including twenty doctors from Asian countries other than Japan. There were 72 plenary oral presentations and 124 papers as poster presentations. Dr. John M. Bennett presented the opening address — a concise report on the activities of the MDS Foundation since its establishment in 1994 and information on the previous seven international symposia.

Many new research achievements were highlighted including:

**Epidemiology.** Dr. David Bowen (UK) showed an interesting figure of gradual increase in MCV long before hemoglobin began to drop and the diagnosis was established. Dr. Masako Iwanaga (Japan) gave new evidence that atomic bomb radiation has been inducing MDS in a distance-dependent manner during the past 25 years.

**Diagnosis and Classification.** Dr. Akira Matsuda (Japan) reported a significant difference in the clinical feature of refractory anemia (RA) between Japan and Germany; Japanese RA patients were much younger and lived longer. Dr. Ulrich Germing (Germany) talked about the usefulness and problems of WHO classification based on a huge number of 2262 registered cases. He also pointed out that the application rate of IPSS to MDS patients remains low in Germany, due to the low rate of chromosome analysis.

**Stem Cell Biology.** Dr. Tatsutoshi Nakahata (Japan), Dr. Koichi Akashi (Japan) and Dr. Connie Eaves (Canada) gave important overviews on stem cell expansion, plasticity, molecular sequence of myeloid and lymphoid differentiation and model mice for MDS. Dr. Rose Ann Padua (France) reported on a reversible two-step animal model of MDS using RAS and BCL2 transgene technique.

**Molecular Biology.** Many papers were presented on the molecular pathology of MDS. New technologies such as micro-array CGH and proteomics were employed. However, in spite of many new findings disclosed, genuine molecular cause(s) of MDS such as responsible gene(s) for 5q- and 7q- remains unclear. Dr. Stephen D. Nimer (USA) and Dr. H. Phillip Koeffler (USA) gave comprehensive overviews on the mechanism of methylation of genomes and effects of demethylating agents, suggesting important pathways towards new drug development. Dr. Seishi Ogawa (Japan) gave results of an extensive analysis of MDS cases using a newly
developed high-resolution automatic micro-CGH analyzer. Dr. Kinuko Mitani (Japan) succeeded in inducing dysplastic definitive hematopoiesis by establishing AML1/Evi-1 knock-in embryo. Dr. Ying-Wei Lin (USA) established a mouse model for human MDS using NUP98-HOX13 transgenic mice.

**Immunosuppressive therapy.** Dr. Jeffrey Molldrem (USA) presented a summary of ATG therapy on low-risk MDS and presence of clonal expansion of CD8 T-cells against MDS cells. He also introduced a new vaccination approach against HLA-A2-restricted peptide PR1 that derived from proteinase 3 and elastase of MDS cells. He stressed that CD8 T-cells are a foe of the MDS clone but at the same time a friend of MDS patients if appropriately stimulated with the vaccine to eradicate MDS clones. Dr. Hideki Tsushima (Japan) showed a consistent response (41%) of Japanese RA patients to cyclosporine A. Dr. Shinji Nakao (Japan) emphasized that the appearance of the PNH clone, at very low frequency, in MDS cases is a good predictor of response to immunosuppressive therapy.

**New Treatment.** Dr. Alan F. List (USA) highlighted the most recent results on lenalidomide (Revlimid®) focusing on the effects on 5q- syndrome (WHO classification) patients. Cytogenetic effects in this group of MDS patients was again confirmed with 44% complete response, but the effect was found much wider including other MDS subtypes with single 5q- or 5q- plus other chromosome abnormalities (complex). This new drug also induced erythroid response (51%) in non-(5q-) patients. Dr. Martin Jaderson (Sweden) observed a selective inhibition in vitro of (5q-) carrying erythroid components by lenalidomide for the first time. Dr. Richard M. Stone (USA) gave an excellent overview on new therapy for MDS and emphasized the importance of more research into the molecular pathology of MDS to further promote drug development. The effects of demethylating drugs, 5-azacytidine (Vidaza®) and decitabine (Dacogen®), were summarized by Dr. Lewis Silverman (USA), Dr. Pierre W. Wijermans (Netherlands) and others. Although complete response rate by these drugs in single use is not high, around 25%, there was an accumulation of data of consistent effects providing a prolongation of overall survivals. Future studies will be designed by combining a demethylating drug and other drug(s) with different mechanisms of action. Dr. Michael Lübbert (Germany) reported cytogenetic remission with 5-azacytidine in patients with complex karyotypes that were almost always resistant to conventional drugs. Dr. Norbert Vey (France) reported on the effects of arsenic trioxide (Trisenox®), but showed a low response rate (21%). As a cytokine therapy, dalbopoietin, a highly glycosylated form with longer half-life in blood was reported by the French group to have very promising effects on MDS patients with lower EPO levels.

**Iron chelation.** Development of new oral iron chelators was another highlight in this symposium. At a satellite symposium, an international consensus meeting was held with 60 doctors participating, discussing the importance of oral chelation therapy in the management of MDS patients who are transfusion-dependent for the long term. Dr. Peter Jensen (Denmark) gave an excellent overview on iron overload and oral chelator development. Dr. Norbert Gattemann (Germany) summarized the above mentioned consensus meeting. Dr. Peter Greenberg chaired a very nice session for a new oral iron chelator, ICL670 (Exjade), with these speakers.

**Intensive chemotherapy.** Dr. Arnold Ganser (Germany) and Dr. Elihu Estey (USA) summarized the positioning of intensive chemotherapy for high-risk MDS.

**Stem Cell Transplantation.** Drs. Theo de Witte (Netherlands) and Ghulam Mufti (UK) presented their summary data of non-myeloablative therapy on MDS patients ages 50 to 65. Overall results are still unsatisfactory but they viewed this data as important progress and raised several key points to further improve non-relapse survivals. For ablative transplant, Dr. Joachim Deeg (USA) reported on the Fred-Hutchinson experience and stressed that the policy of waiting until progression of MDS among low-risk patients is an important factor to gain longer overall survival. Dr. Miguel Sanz (Spain) introduced the European experience of cord blood transplant to treat adult MDS patients suggesting a promising result in the near future. Dr. Shin-ichiro Okamoto (Japan) reported on the overall results of the Japan Marrow Donor Program and ongoing results of non-myeloablative transplant and showed similar results in the elderly population.

**Susanne Fleischman Memorial Lecture.** Dr. Timothy E. Quill, University Rochester Medical Center, Center for Palliative Care and Clinical Ethics, gave the most informative lecture on palliative care and quality-of-life for MDS patients by presenting a case with RAEB.

**Report from International Working Group (IWG) on Morphology of MDS.** At the final plenary
session, Drs. Bennett and Mufti reported on the aim and the results of two meetings held in Lisbon and Nagasaki. Recognizing that the WHO classification is a major step forward in the classification of MDS, this IWG is trying to improve diagnostic accuracy by establishing morphological criteria for minimal dysplastic changes. Dr. Masao Tomonaga (Japan), the President of this symposium, gave a summary talk. He emphasized that MDS researchers are now passing an important time with several new drugs that suppress MDS clones or reduce ineffective hematopoiesis of MDS clones, achieving even a complete cytogenetic remission as seen in CML with Gleevec or actual incremental improvement of Hgb value. This is a real dawn of practical drug therapy for MDS to prolong overall survival of MDS patients in the near future. Moreover, as a sole curative therapy at this moment, HSCT is rapidly being applied to the increasing number of elderly patients with MDS. We are thus entering a promising era towards longer survival or even a cure for MDS that was seen in the AML field some 30 years ago. The 9th International MDS Symposium will be held in Florence, Italy and chaired by Professor Mario Cazzola will surely present an acceleration of such a progress in 2007.

Symposium Highlights
The abstracts of the 8th International Symposium on MDS published by *Leukemia Research* are now available upon request by contacting the MDS Foundation at 800-637-0839.

The Mayor of Nagasaki, Iccho Itoh; and President of the Organizing Committee, Masao Tomonaga, MD.

International Working Group on MDS Morphology participating in microscopic research.
Golfers Tee It Up for MDS

On August 1st, the MDS Foundation hosted its 2nd Annual Charity Golf Tournament at Olde York Country Club in Chesterfield NJ.

Senior PGA Professional, Bruce Fleischer, returned this year as our Master of Ceremonies. Reflecting on last year’s golf tournament, Bruce brought along additional professional help including Bob Toski, Hall of Fame Golf Instructor; Bob Murphy, Jay Sigel, Jim Thorpe, and Bobby Wadkins from the PGA Champions Tour; Joe Thiesmann, former Washington Redskins Quarterback; Jim Palmer, three-time Cy Young Award Winner and Baltimore Orioles baseball Hall of Famer; and Mike Schmidt, former Philadelphia Phillies World Series Winner.

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. Many took the opportunity to bid on fantastic golf equipment, which will hopefully enhance their game, as well as other terrific prizes during a silent auction.

The MDS Foundation would like to thank all of the businesses and organizations that supported this fundraiser. It was a tremendous event, which took a lot of hard work and planning. We would also like to extend a special thank you to our celebrity guests who came out to support this most meaningful event. The proceeds from this tournament will be donated to The Young Investigator’s Grant Fund for Fellows in Hematology that will provide resources to further MDS research and hopefully, to one day find a cure.

Don’t forget to save the date for next year:
Monday, August 7th, 2006!
Foundation Plans
International Symposia
Through 2011

The MDS Foundation has approved applications for the next three International Symposia. These symposia are scheduled for 2007 in Florence, Italy; 2009 in Patras, Greece; and 2011 in Dundee, Scotland.

Ninth International Symposium –
Spring 2007
Florence, Italy
Sponsor: Mario Cazzola, MD

Tenth International Symposium –
Spring 2009
Patras, Greece
Sponsor: Nicholas C. Zoumbos, MD

Eleventh International Symposium –
Spring 2011
Dundee, Scotland
Sponsor: David T. Bowen, MD

NBC Commentator Bob Murphy displays an excellent swing as well as analysis.
MDS Awareness Day

On Friday, April 15th, the first ever MDS Awareness Day was held in New York City, supported by a grant from Pfizer.

Prominent MDS physicians and researchers, representatives of the MDS Foundation and well-known advocate, Mia Hamm, treated approximately 70 guests to informative presentations. The audience included patients and their guests along with colleagues from MDS Centers of Excellence.

Mia Hamm’s older brother Garrett was diagnosed with MDS and sadly died at the age of 28, shortly after having a bone marrow transplant. Thanks to her, the MDS Foundation is getting the word out that more people should consider being bone marrow transplant donors.

**Guest Speakers (in order of appearance)**

**John M. Bennett, MD**  
Chairman, The MDS Foundation, Inc.  
Professor of Medicine,  
Laboratory Medicine and Pathology, Emeritus  
University of Rochester Medical Center  
James P. Wilmot Cancer Center, Rochester, New York

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

**Kathy Heptinstall, RN, BSN**  
Operating Director  
The MDS Foundation

**Robert J. Weinberg, Esq.**  
Member  
MDS Foundation Board of Directors
MDS Foundation Plans 2006 Initiatives

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 for the upcoming year:

- **CME Awareness Program**
- **MDS Practice and Treatment Survey**
- **The International Morphology Working Group**
- **MDS Patient’s Quality-of-Life Forums**
- **Transfusion Burden Initiative**
  Supported by grants from:

- **The ADOPT Registry**
  Supported by a grant from:

- **Centers of Excellence Patient Support Groups**
  Supported by grants from:

- **MDS Foundation 3rd Annual Charity Golf Tournament**
  Supported by future grants
Suzanne Fleischman
Memorial Lecture:
Palliative Care and
Myelodysplasia

Presented at the Eighth International
Symposium on Myelodysplastic Syndromes
Timothy E. Quill, MD

The Suzanne Fleischman Memorial Lecture, established in 2001, is a perpetual lectureship in honor of Professor Suzanne Fleischman, our friend and devoted MDS Foundation member who died from MDS in February of 2000. The lectures, delivered at the biannual MDS International Symposia, will focus on the many concerns eloquently expressed by Suzanne during her lifetime as an advocate for patients with MDS. The 2005 Suzanne Fleischman Memorial lecturer was Dr. Timothy Quill, Director of the Center for Palliative Care and Clinical Ethics, University of Rochester Medical Center in Rochester, New York. Dr. Quill is the author of three books and numerous articles on palliative care and end-of-life issues. He is a Professor of Medicine, Psychiatry, and Medical Humanities at the University of Rochester School of Medicine and Dentistry in New York.

Today, people are living longer, and while medicine has extended the average lifespan, living longer for many often means living longer with a serious or potentially fatal illness. Although some people with serious medical illnesses may remain relatively healthy and functional for many years, others with the same serious medical illness may have their lives end unexpectedly due to complications of their medical condition. The traditional approaches to healing are based on models of restoration or cure; with such models, death is viewed as a medical failure. These approaches are inadequate if we are going to truly care for patients through the end of their life. Helping people live as long and as well as possible, while at some point making dying peaceful as possible are all legitimate goals of medicine.

A useful, broad approach to medical care includes death as part of and the natural end to the life cycle. Maximizing quality-of-life for all patients with serious illness is a central role of palliative care, but also supporting them through this last phase of his or her life is an ethical obligation of all involved healthcare professionals and caregivers. Physicians can make a world of difference when they jointly seek solutions to care-related issues with patients throughout their illnesses. Shying away from difficult decisions when the path is uncertain or when death is imminent is not helpful to the patient or their daily caregivers.

Seriously ill patients need a committed, caring, skilled physician who will not abandon them if their suffering becomes severe. Physicians must recognize pain and suffering are factors to be considered in treatment decisions for all patients with potentially fatal conditions. Is there an opportunity for the patient to stay at home in a supportive, caring environment with family or friends, rather than be admitted to a restrictive, medical environment? Such questions should be explored with all seriously ill patients. In the United States today, nearly 80% of patients with serious illnesses die in the hospital or in a nursing home, even though surveys indicate that such patients would prefer to die at home. Medical rituals have replaced religious rituals at the end of life in our society. The loss of personal control experienced when a diagnosis of a terminal or life-threatening illness is made can be ameliorated when patients understand the options available to them and they make decisions based upon reliable information. People need to participate in their own care, and many patients have experienced a renewed sense of meaning in their lives by being empowered with decision-making with regard to their own care. Whether a patient seeks aggressive treatment for their illness or not, the challenge is to provide them with the care they deserve.
away from aggressive treatment of their underlying disease (with its focus on prolongation of life) toward intensive treatment of symptoms. Often disease treatment and palliation exist side by side, and it is only toward the end of life where the main aim is palliation, which then frequently includes hospice care. (Figure 1)

Palliative care is the biopsychosocial and spiritual care of persons whose diseases are not responsive to curative treatment. Some MDS patients may be at the stage where the underlying ineffective hematopoiesis does not respond to any curative treatment strategy. And some MDS patients may have concomitant medical conditions that, for a variety of reasons, preclude them from attempting potentially curative treatments. The primary goal of palliative care is to provide the best possible medical treatment of disease and the best quality of life for the patient and family. Palliative care should offer relief of pain and other disease-related symptoms, find ways to preserve the patient's quality of life and dignity, respect the patient's values and choices regarding treatment goals, support the treatment decisions of the patient and their families, provide emotional and spiritual support, and when necessary, assist in end-of-life decision-making. Palliative care should be part of the treatment plan for all seriously ill patients. Informed consent requires a balanced discussion of both curative and palliative treatment options with patients, which includes the notion that most patients want to have the best of both worlds.

The benefits of palliative care include improved pain and symptom management, a fresh look at medical goals and priorities, and an opportunity to consider life closure issues— with respect to family and community, as well as to fiscal and legal affairs. Palliative care does not have the rigid requirements of hospice care, which is considered the gold standard of home care for those who accept that they are dying (i.e., a life expectancy of six months or less and accept no treatment directed at the underlying disease). Many patients would like to continue to receive some potentially effective treatments, even when the likelihood of success is low. Such patients can clearly receive palliative care with their other medical treatments, but they will not qualify for hospice under these circumstances even if death is imminent.

Discussion of palliative care is commonly reserved for patients that are in imminent danger of death. However, palliative care should be discussed with all patients who are seriously ill. The time to introduce the idea of palliative care should be while discussing prognosis or when discussing the patient's hopes and fears about their illness. Typically, discussion begins with open-ended questions and is followed up by the healthcare professional asking additional, more layered questions using the patient's words with the ultimate goal of learning how best to care for this particular patient given their expressed wishes and concerns in light of their medical condition. During the discussion, it is critical to listen carefully to the patient's responses. When responding to the patient, respond to associated emotions, reassure the patient whenever possible, and importantly, ask if there are ways you can help enhance the quality and meaning of their lives.

Patients who fear suffering will be reassured by the potential effectiveness of palliative care, and patients who may be dying must know and have the opportunity for growth and closure. The job of the physician is not only to fight the disease, but also to aggressively manage disease-related symptoms when the fight becomes difficult in order to provide the patient with the highest quality of life.

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.

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.

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.
Share Your Stories

The Foundation would like to invite patients and their families to share their stories with others in the MDS community. Living with MDS poses challenges and many of you have stories that provide hope to others. Please contact the Foundation, if you would like us to publish your story.

Now here’s Aldeane Sööt’s story…

A Survivor’s Story
by Aldeane Sööt

My name is Aldeane Sööt and I am a survivor of MDS through a bone marrow transplant. My story began in September 2002 at age 52. I felt my life was near perfect. Our youngest child, one of seven, was engaged to be married the following year leaving my husband, Peet, and I on our own. I had just finished watching my grandson on a daily basis, as he was old enough to enter preschool. Peet and I could now have more time to ourselves.

It was time for my yearly checkup and I was feeling so fantastic it crossed my mind not to go, but Peet has always felt that it is a must to keep track of your health. So I went. My doctor was so pleased with what he saw; he even said he wished all his patients were as healthy as I was. I had a blood test; the results were to be sent to me later. I felt on top of the world.

Then the next day the phone rang. My white blood cells were very low and I needed to go in for another blood draw in case a mistake had been made the first time. Unfortunately, it was right. I then was sent to a hematologist for further testing. Eventually a bone marrow aspiration was done and I heard for the first time about a disease called MDS. I was told a bone marrow transplant was the only cure, but I could wait for a few months to see what happened before going to that stage.

After getting all the information from my local doctors, and the Internet, I decided I needed a second opinion from the best MDS/bone marrow transplant facility I could find. Luckily I live in Lake Oswego, Oregon a short three-hour drive to Seattle, Washington, and the Fred Hutchinson Cancer Research Center. I was up there getting my second opinion within three weeks of my first diagnosis. As you can see I am not a procrastinator, I wanted to be well.

The doctors there agreed that a bone marrow transplant was needed. I immediately asked my one and only sibling, my sister Dorcas, if she would be tested to be my donor. She agreed at once and went the next day to have a blood sample sent to Fred Hutch for HLA testing. My miracle was starting to happen. She was a perfect match.

My BMT was scheduled for November 27, 2002. To accomplish this, my husband and I were told to move to Seattle for at least four months. By November 1st we were in a condo in Seattle with all the needed equipment and files to keep running our consulting business. Little did we know how intense the transplant and recovery would be for me and how little time there would be for business or any other outside activity for Peet, as the caregiver. He lived in my hospital room the entire time I was there.

I entered the hospital on November 23. The transplant took place on the 27th as scheduled. There were ups and downs, as always is the case with a transplant, but I got to leave the hospital on Christmas Day. A week later, I was back in the hospital with a respiratory infection. Another two weeks in the hospital before I was able to stay at the condo for the rest of local recovery. The great encouragement was that the stem cells had engrafted and my MDS was gone.

During the Seattle recovery there were numerous visits back to the clinic to continue treatment for graft vs. host disease (GvHD). One series of treatments included being put in a tanning booth to fight skin GvHD. There were also new treatments for a virus that my donor’s blood harbored, that her immune system could handle, but my compromised immune system needed help from new drugs that had been developed to help AIDS patients. I continued my recovery in Seattle and was finally able to return home on March 1.

The next 16 months at home were again a roller coaster. Various infections, from ingrown toenails to a fungal infection of the lungs, were interspersed with moments of sheer happiness over minor victories like improved blood counts. An attempt at getting off of cyclosporine (the immune suppressant drug that helps fight GvHD) was unsuccessful. That meant at least 9 more months of this medication before they would let me try again to taper off of the drug.

Finally, about six months ago, there began to be a consistent improvement in my stamina and strength. I could not be sure, but it seemed as if everything started to improve. There were still periodic questions about the weekly blood tests, but hope became more persistent.
It is now two years after the transplant. I am cancer free and on my final taper (hopefully) of cyclosporine. The miracle for me is that I feel as healthy and strong as I did that September day when I went into my doctor’s office for my yearly checkup. There were times in my recovery that I felt I would never have my strength and vigor back, but I kept on track—one day at a time. My reward was Christmas this year with my fantastic husband, our seven children, four daughters-and sons-in-law and six grandchildren plus the expectation of many more holidays with them all.

My prayers and wish to be with my family gave me the strength to survive my transplant and my MDS. Just as important were the prayers from all my friends and family, who joined me in this amazing journey.

I am a survivor!

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.
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**

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

The Cancer Center of Hackensack
University Medical Center
Hackensack, New Jersey
Stuart Goldberg, MD
Charles S. Hesdorffer, MD

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

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

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

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

Fred Hutchinson Cancer Research Center
Seattle, Washington
Joachim Diep, MD

Georgetown University Hospital
Lombardi Comprehensive Cancer Center
Washington, DC
Ekatherina Asatiani, MD

Indiana University
Indiana University Medical Center
Indianapolis, Indiana
Larry Cripe, MD

Johns Hopkins Oncology Center
Johns Hopkins Institutions
Baltimore, Maryland
Steven D. Gore, MD

Mayo Clinic
Phoenix, Arizona
James L. Slack, MD

Mayo Clinic
Jacksonville, Florida
Alvaro Moreno-Aspitia, MD

Mayo Clinic
Rochester, Minnesota
David P. Steensma, MD

MCP Hahnnemann University
Philadelphia, Pennsylvania

Medical College of Wisconsin
Bone Marrow Transplant Program
Milwaukee, Wisconsin
David H. Vesole, MD, PhD, FACP

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

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

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

New York Medical College/
Westchester Medical Center
Valhalla, New York
Karen Seiter, MD

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

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

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

Rush Cancer Institute
Rush–Presbyterian–St. Luke’s Medical Center
Chicago, Illinois

Seattle Cancer Care Alliance
University of Washington
Seattle, Washington
John A. Thompson, MD

Southwest Regional Cancer Center
Austin, Texas
Richard Helmer, III, MD

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

St. Jude Children’s Research Hospital
Memphis, Tennessee
Gregory Hale, MD

Thomas Jefferson University
Kimmel Cancer Center
Philadelphia, Pennsylvania
Emmanuel C. Basa, MD

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

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

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

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

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

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

University of Pennsylvania
University of Pennsylvania Cancer Center
Philadelphia, Pennsylvania
Selina Luger, MD

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

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

University of Texas
MD Anderson Cancer Center
Houston, Texas
Elihu H. Estey, MD

University of Texas Southwestern Medical School
Dallas, Texas
Amit Verma, MD

University of Wisconsin, Madison Medical School
Madison, Wisconsin
Mark B. Juckett, MD

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

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

**Advanced Cancers: A new transplant method**

Researchers at the National Institutes of Health (NIH/DHHS) are investigating a new method of improving transplant results in individuals with advanced cancers. If you or someone you know are between the ages of 10 to 50 years old and have one of the following cancers: Myelodysplastic Syndromes, Leukemia, or Myeloproliferative Disorder, you may be able to participate in this clinical trial. To find out if you qualify, please call 1-800-411-1222 or visit www.cc.nih.gov.

**MethylGene Inc.,** of Montreal, initiated the first of two dose-escalating Phase I trials for MGCD0103 in hematological cancers. MGCD0103 is a rationally designed isotopic selective small-molecule inhibitor of histone deacetylase. The second hematologic cancer trial is scheduled to be initiated in early 2005. Both trials will evaluate the safety, pharmacokinetics, pharmacodynamics and tolerability of MGCD0103 in patients with leukemias or myelodysplastic syndrome.

**Novartis.** EXJADE Trial CICL670AUS02. An open label, safety and tolerability study of deferasirox for treatment of transfusional iron overload in low-risk and INT-1 myelodysplastic patients. Thirty patients will be enrolled into this open-label, single-arm trial designed to assess the safety and tolerability of oral deferasirox in adult transfusion dependent myelodysplastic syndrome (MDS) patients with iron overload. Patients enrolled in this study will have low or intermediate (INT-1) risk MDS per International Prognostic Scoring System (IPSS) criteria. All patients will initiate treatment with 20mg/kg/day deferasirox. Deferasirox will be administered orally once per day for 12 months.

**Novartis.** EXJADE Trial 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. This trial is being conducted to assess safety and tolerability of an investigational drug in patients with low or intermediate (INT-1) risk Myelodysplastic Syndrome and are iron overloaded. This investigational drug removes excess iron from the body. All patients who are eligible to participate in this clinical trial will receive treatment with deferasirox which is administered orally once per day for 12 months. For further information please contact 800-340-6843 or visit www.clinicaltrials.gov—in the search area, enter Exjade and Myelodysplastic Syndromes.

**Novartis.** Phase I, open-label, dose escalating study to evaluate the safety, biologic activity and pharmacokinetic profile of LAQ824 in patients with relapsed or refractory AML, CLL, or CML in blast crisis, or advanced MDS. The primary
objective of this study is to determine the Maximum Tolerated Dose (MTD) and Dose Limiting Toxicity (DLT) of LAQ824 as a single agent when administered by intravenous infusion as outlined in the protocol.

**Novartis.** An Open-label Phase II Trial of PKC412 Monotherapy in Patients with Acute Myeloid Leukemia and Patients with Myelodysplastic Syndromes PKC4122104. Patients who agree to participate in this trial will be screened for the FLT3 mutation. If positive, they will have a physical exam, blood test, EKG, chest x-ray, bone marrow aspirate and a pregnancy test.

**Pharmion.** AZA PH GL 2003 CL 001. A Survival Study in Patients with High Risk Myelodysplastic Syndromes Comparing Azacitidine versus Conventional Care. The purpose of this study is to determine whether patients with high-risk myelodysplastic syndromes (MDS) treated with azacitidine have improved survival compared to conventional care treatments. The study will also assess the effect of treatments on response, duration of response, and transformation to acute myeloid leukemia (AML).

**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 (CMMI) 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 Mary Sugrue, MD, e-mail: mary.sugrue@spcorp.com.

**Telik, Inc.** Phase I-Ila trial to evaluate the safety and efficacy of TLK199 in patients with myelodysplastic syndromes (MDS). Eligible patients must have a diagnosis of MDS, be at least 18 years old and ineligible or refusing bone marrow transplant.

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 Syndrome and Acute Myeloid Leukemia, Myelodysplastic Syndrome, or Transient Myeloproliferative Disorder. Contact: Jeffrey Taub, MD. Phone: 313-963-2533.


**Cancer Institute Medical Group, Los Angeles, CA.** Phase I/Ila 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.** 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: Donna Kane, RN. Phone: 216-844-8609.

**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. Phone: 216-844-8609.

**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 D₃ 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% CD34 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.** 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.

**Comprehensive Cancer Center of Wake Forest University, Winston-Salem, NC.** Phase II Study of Arsenic Trioxide and Dose-escalated Cholecalciferol in Myelodysplastic Syndrome (CCWFU 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 Syndrome: Phase II trial using cholecalciferol (Vitamin D3) to evaluate the efficacy of 2000 IU Vitamin D3 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. Waves, MD. Phone: 256-551-6546.

**Dana-Farber Cancer Institute, Boston, MA.** Phase I Study of Vaccination with Lethally Irradiated, 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.** 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.** FHRC #1297. Radiolabeled BC8 (anti-CD45) Antibody Combined with Cyclophosphamide and Total Body Irradiation Followed by HLA-Matched Related or Unrelated Stem Cell Transplantation as Treatment for Advanced Acute Myeloid Leukemia and Myelodysplastic Syndrome. Phase II trial to determine the efficacy (as measured by survival and disease-free survival) and toxicity of a regimen of cyclophosphamide, TBI, plus the maximum tolerated dose of I labeled BC8 (anti-CD45) antibody in patients with AML beyond first remission receiving HLA matched related hematopoietic stem cell transplants. Contact: J. Pagel, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1432. Phase I trial to determine the maximum tolerated dose of radiation delivered via BC8 antibody when combined with the non-myeloablative regimen of fludarabine, TBI+CSP/MMF in elderly patients (>50 and <70 years) with advanced AML or high risk MDS. Contact: J. Pagel, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1809. Phase I trial to determine the maximum tolerated dose of radiation delivered via BC8 antibody when combined with the non-myeloablative regimen of fludarabine, TBI+CSP/MMF in patients (<50 years) with advanced AML or high risk MDS. Contact: J. Pagel, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1591. Phase I trial to determine whether stable allogeneic engraftment from related and unrelated HLA-mismatched stem cell donors can be safely established using a non-myeloablative conditioning regimen plus escalating doses of the anti-CD52mAb Campath® in patients with hematologic malignancies. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1732. Phase II trial to evaluate the efficacy of non-myeloablative allogeneic HCT from related and unrelated donors for the treatment of patients with MDS and MPD, who are not candidates for conventional allogeneic HCTG due to advanced age or serious comorbid conditions. Contact: B. Sandmaier, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1813. 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: B. Sandmaier, MD. Phone: 206-288-1024.

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

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1756. Transplantation from related donors for high-risk patients with MDS. Conditioning includes a “non-myeloablative” regimen of fludarabine and 200 cGy of total body irradiation. Patients are evaluated individually for eligibility. Contact: David Maloney, MD, PhD. Phone: 206-288-1024.


**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1117. Uses a combination of ATG and cyclophosphamide (CY) for the conditioning of patients with AA who are transplanted from HLA-identical family members. Contact: R. Storb, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #800. Uses a combination of ATG, CY and low dose (200 cGy) TBI for conditioning of patients with AA (up to 55 years of age) to be transplanted from unrelated donors. Contact: H.J. Deeg, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1641. Transplantation from unrelated donors for high-risk patients with MDS. Conditioning will be with a “non-myeloablative” approach using 200 cGy of TB1 and fludarabine. No age restriction (other exclusion criteria exist). Contact: M. Maris, MD. Phone: 206-288-1024.

**Fred Hutchinson Cancer Research Center, Seattle, WA.** FHRC #1723. Transplantation from related or unreleased donors for patients with advanced MDS or myeloproliferative disorders. Conditioning includes busulfan (targeted to a predetermined plasma level) and Cytoxan (targeted BUCY) with the addition of thymoglobulin; patients up to 65 years of age. Contact: H.J. Deeg, MD. Phone: 206-288-1024.
Fred Hutchinson Cancer Research Center, Seattle, WA.

Fred Hutchinson Cancer Research Center, Seattle, WA.
FHCRC #1628. Uses a targeted busulfan plus cyclophosphamide approach for conditioning. G-SCF-mobilized peripheral blood cells will be partially T-cell depleted with the intent of reducing the GVHD frequency and severity. Eligible are patients with MDS or high-risk AML who have an HLA-identical sibling donor. Contact: A. Woolfrey. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA.
FHCRC #1913. Combines targeted busulfan with fludarabine plus Thymoglobulin. This protocol enrolls patients with MDS, myeloproliferative disorders, and other myeloid diseases. The objective is to further reduce non-relapse mortality. Patients with related and unrelated donors will be eligible. Contact: P. O’Donnell Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA.
FHCRC #1668. Uses combinations of fludarabine and low-dose TBI for the conditioning of “older” patients or patients with clinically significant co-morbid conditions to be transplanted from related or unrelated donors. Contacts: M. Maris, B. Sandmaier. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA.
FHCRC #1872. Uses a combination of ATG given for 4 days, followed by intermittent injection of Enbrel for patients with low or intermediate-1 risk disease by IPSS. Generally these are patients with <10% marrow blasts. ATG is administered at the Center; the administration of Enbrel can be done by the patients themselves at home or in your office. Contact: B. Scott. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA.
FHCRC #1888. Uses a combination of Enbrel plus arsenic trioxide (Trisenox) in patients with more advanced MDS (generally IPSS intermediate-2 or high risk) or patients who have failed to respond in Protocol #1872. Contact: B. Scott. Phone: 206-288-1024.

Fred Hutchinson Cancer Research Center, Seattle, WA.
FHCRC #1926. Uses a combination of Enbrel plus 5-azacitidine (Vidaza) for patients with advanced MDS or patients who fail to respond to treatment in Protocol #1872. The Protocol is currently being reviewed by the IRB. Contact: B. Scott. Phone: 206-288-1024.


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# 13727. A Phase I/II, two-arm, multicenter, dose-escalation study of LBHS89 administered intravenously on two dose schedules in adult patients with advanced hematologic malignancies. Inclusion criteria: Patients with a cytopathologically confirmed diagnosis of AML, MDS, (RAEB, RAEBT), ALL, CLL, CML, multiple myeloma, NHL including CTCL who are either relapsed after or refractory to standard therapy, and are considered inappropriate candidates for standard therapy. Patients with a cytopathologically confirmed diagnosis of AML, MDS, (RAEB, RAEBT) who are previously untreated but due to age, poor prognosis, or concurrent medical conditions are considered inappropriate candidates for standard induction therapy, or those who refuse standard induction therapy. Contact: Stacy Moss. Phone: 813-745-8391.

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.


Johns Hopkins Oncology Center, Baltimore, MD. 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. Judith Karp. Phone: 410-502-5399.


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: Jackie Greer. Phone: 410-614-1329.


Johns Hopkins Oncology Center, Baltimore, MD. J0434. Phase II study of VNP40101M for patients with Acute Myelogenous Leukemia or high-risk Myelodysplasia. Contact: Jackie Greer. Phone: 410-614-1329.

Los Angeles Hematology and Oncology Assoc., Los Angeles, CA. Phase 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 Thymoglobin 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 thymoglobin, 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 TLK198 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 Syndrome (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 Elhhu H. Estey, MD. Phone: 713-792-7544.

MD Anderson Cancer Center, Houston, TX. Phase 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 Syndrome (MDS). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. Phase II Study ofArsenic 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 Syndrome. 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 Syndrome. 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 Syndrome (MDS). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

MD Anderson Cancer Center, Houston, TX. Phase II Study Of Neumega (Opreleukin)(Interleukin-11) In Patients With Myelodysplastic Syndrome. Contact: Razelle Kurzrock, MD. Phone: 713-794-1226.

MD Anderson Cancer Center, Houston, TX. Multicenter Phase II Study Of Continuous Oral Administration of SCH 66336 In Patients With Advanced Myelodysplastic Syndrome, Acute Myelogenous Leukemia, Chronic Myelogenous Leukemia In Blast Crisis, Acute Lymphoblastic Leukemia. 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 Syndrome, Polycythemia Vera, Atypical CML or CMMML with PDGF-R Fusion Genes, or Mastocytosis with Gleevec (STI571). Contact: Jorge Cortes, MD. Phone: 713-794-5783.

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 syndrome (MDS) (≥10% bone marrow blasts). Contact: Stefan Faderl, MD. Phone: 713-745-4613.

MD Anderson Cancer Center, Houston, TX. Phase II trial using ATG/CSA; ATG/Fludarabine. Eligible patients must have MDS of subtype RA, blasts ≤50,000/mℓ, platelet count ≥2,000,000/mℓ, neutrophil count ≥4000/mℓ, IPSS score ≤2. Contact: Jeffrey Molldrem, MD. Phone: 713-745-4820.

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: 713-745-4820.

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 MDS of subtype RA, blasts ≤50,000/mℓ, platelet count ≥2,000,000/mℓ, neutrophil count <4000/mℓ, IPSS score ≥2. Contact: Jeffrey Molldrem, MD. Phone: 713-745-4820.

Mayo Clinic, Phoenix, AZ. PO2978. Study of Lonafermin 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, Rochester, MN. DACO-020. A 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.

Memorial Sloan-Kettering Cancer Center, New York, NY. PO2978. 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.

Memorial Sloan-Kettering Cancer Center, New York, NY. 05-H-0201. Metoclopramide to Treat Anemia in Patients with Myelodysplastic Syndrome (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 Syndrome. 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 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.

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.

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 syndrome, 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.

05-H-0206. A Pilot Study of Alemtuzumab (Campath®) in Patients with Myelodysplastic Syndrome (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.

99-H-0050. Non-Myeloablative Allogeneic Peripheral Blood Mobilized Hematopoietic Precursor Cell Transplantation For Hematologic Malignancies In High Risk Patients and In Patients With Debitating 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.**

Pivotal randomized study of Lonafarnib Versus Placebo in the treatment of subjects with MDS or CMML 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.**


**New York Presbyterian Hospital, New York, NY.**

Phase I/I 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.

**Oregon Health & Science University, Portland, OR.**


8186. A 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.


7881. Placebo in the treatment of subjects with MDS or CMML who are platelet transfusion dependent with or without anemia. Contact: Dr. Karen Seiter. Phone: 914-493-7514.
**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.** 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.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 99-14. Pilot study of Thalidomide (Thalidomid) combined with Pentoxifylline, Ciprofloxacin and Dexamethasone (PCD) in patients with myelodysplastic syndromes. This is a phase II trial using anticytokine and antiangiogenic therapy to evaluate the efficacy of Thalidomide (Thalomid) to treat MDS. Eligible patients must have MDS (RA, RARS or RAEB). Addendum: Reduced dose of Pentoxifylline (400 mg po TID), No Cipro, No Decadron. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 801-001. Multicenter, open-label, dose-escalation study to determine the safety and preliminary efficacy of CC-1088 in treatment of myelodysplastic syndromes. Eligible patients must have RA or RARS. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2000-04. Phase IIB study using Thymoglobulin in transfusion dependent patients with myelodysplastic syndrome. Open to FAB types RA, RARS, RAEB. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2000-11. Pilot study to test the efficacy of infliximab (Remicade) in patients with low-risk myelodysplastic syndromes. Eligible patients must be transfusion dependent or hemoglobin <9 grams, and an IPSS score <1.5, and cannot have a history of clinically significant cardiac disease or CHF. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2001-12. Pilot study to determine the clinical effects of the proteasome inhibitor PS-341 in patients with myelodysplastic syndromes. All FAB types are eligible. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.


**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2002-02. Phase II trial to evaluate the efficacy of Trisenox in patients with MDS, followed by thalidomide in non-responders. Eligible patients must belong to IPSS int 1 or higher, have adequate hepatic and renal function as defined by specific laboratory parameters, and have an ECOG PS of 0–2. Patients will receive Trisenox alone for six months. Patients who do not respond will have thalidomide added to the regimen at 6 months. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2000-08. Pilot Study to Test The Efficacy of Gleevec (STI 571) in Patients with Myelodysplastic Syndromes. Given the clinical and molecular similarities between CML and CMMoL, especially those related to the activation of tyrosine kinase induced downstream events suggest that suppression of the same kinase in CMMoL by using an agent like Gleevec may produce clinical benefit in these individuals. We propose to test this hypothesis by treating one cohort of 15 CMMoL patients with Gleevec or STI571 at 400 mg po daily. The second cohort of 15 patients [having translocation (5;12)] will likewise receive Gleevec or STI571 at 400 mg po daily. Response assessment will be made every 8 weeks and in case of disease progression, the patient will be removed from the study. Responding patients or those with stable disease will be treated for one year at least with the drug provided by Novartis. After the one-year period, further therapy will depend upon the discretion of the physician. Disease progression is defined as occurrence of acute leukemia, increase in BM blasts by 50% over pre-therapy values if the blast count was >5% to begin with, and worsening cytopenia. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2002-04. Pilot Study to Test The Efficacy of a Combination of Gleevec with Thalidomide in Patients with Idiopathic Primary Myelofibrosis, Myelofibrosis with Myeloid Metaplasia and Myelodysplastic Syndromes Who Present With Myelofibrosis. We propose to use a combination of thalidomide and Gleevec for the treatment of patients with MMM and MDS who present with Grade 3+ and greater myelofibrosis. The rationale for this combination is that the anti-angiogenic and anti-TNF effects of thalidomide may be potentiated by the anti-TGF-b, anti-PDGF effects of Gleevec to reduce marrow fibrosis in this group of patients. We propose to treat 30 patients on this study using Thalidomide starting at a dose of 100 mg per day and increasing to 400 mg per day and Gleevec at 600 mg per day. Treatment will be continued for one year or until disease progression. Bone marrows will be obtained at 16 weeks and then at the end of the study. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Rush-Presbyterian-St. Luke’s Medical Center, Chicago, IL.** MDS 2003-01. Pilot Study to Determine the Clinical Efficacy of Coenzyme Q10 in Patients with Myelodysplastic Syndromes. We propose to treat 40 patients belonging to RA and or RARS or low risk and Int-1 categories of MDS patients with CoQ10 at a starting dose of 300 mg escalating as tolerated to 1200mg po qday. Patients will begin taking 300 mg po BID with meals for Days 1–3. On Days 4–6, patients will take 300 mg po TID with meals. On Days 7 and onward, patients will take 300 mg po QID with meals. Patients will be treated for up to a year unless intolerable side effects and/or disease progression are noted. Responses will be continuously evaluated by weekly CBCs and bone marrows repeated every 16 weeks. Contact: Laurie A. Lisak, MMS. Phone: 312-563-2535.

**Stanford University Medical Center, Stanford, CA.** Phase I/II trial: Decitabine treatment of MDS. Eligibility: IPSS High, Intermediate-2. Contact: Kathy Dugan, RN. Phone: 650-723-8594.
**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: Sylvia Quesada, R.N. Phone: 650-725-4041.

**St. Francis Hospital, Hartford, CT.** 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. Bilgrami. Phone: 860-714-4680.

**St. Jude Children's Research Hospital, Memphis, TN.** Phase II trial: Exjade (ICL670) oral iron chelator treatment of MDS patients with iron overload. Contact: Kathy Dugan, RN. Phone: 650-723-8594.

**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: 901-495-3300.

**St. Jude Children's Research Hospital, Memphis, TN.** AML02. Collaborative trial for the treatment of patients with newly diagnosed acute myeloid leukemia or myelodysplasia. Contact: Jeffrey Rubnitz, MD, PhD. Phone: 901-495-3300.

**St. Jude Children's Research Hospital, Memphis, TN.** REFSCT. Pilot study to evaluate haploidentical stem cell transplantation utilizing T-Cell depletion as therapy for patients with refractory hematologic malignancies. Contact: Ely Benaim, MD. Phone: 901-495-3300.

**Texas Oncology Medical City Dallas Hospital, Dallas, TX.** D-0007. Randomized, open-label, Phase III trial of decitabine (5-aza-2'-deoxocytidine) versus supportive care in adults with advanced-stage myelodysplastic syndrome. 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 IIIB study of the impact of Thymoglobulin therapy on transfusion needs of patients with early myelodysplastic syndrome. 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 syndrome 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.


**Tufts-New England Medical Center, Boston, MA.** 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: Geoffrey Chan, MD. Phone: 617-636-2520.

**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.** 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.** 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. A pivotal randomized study of Lonafarnib (SCH 66326) vs. placebo in the treatment of subjects with Myelodysplastic Syndromes (MDS) or Chronic Myelomonocytic Leukemia (CML) 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. A 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 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 syndrome. Contact: Harry P. Erba, MD, PhD.


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.

University of Wisconsin, Department of Medicine, Madison, WI. HO 02403. Phase II trial using Doxercalciferol (Vitamin D) to treat MDS. Patients must have no prior exposure to doxercalciferol and must be at least 18 years old. Contact: Mark Jucket, MD. Phone: 608-263-1836.

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 Syndrome: Phase II trial using doxercalciferol (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 Syndrome: The purpose of this study is to determine how many patients with myelodysplastic syndrome (MDS) respond to the combination treatment with arsenic trioxide and cholecalciferol (vitamin D3). 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. A 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. A 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. A 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 (PTK787/ZK222584) in myelodysplastic syndromes (MDS). Contact: Nick Fisher. Phone: 314-454-5090.


European Trials

AUSTRALIA


The Newcastle Mater Misericordiae 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.


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 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.

BELGIUM

Cliniques Universitaires Saint-Luc, Brussel. 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).

ENGLAND


Kings College Hospital/Guys-Kings-Thomas School of Medicine. 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 Royal Bournemouth Hospital. Multi-centre study of the role of 5-Azacytidine in high risk MDS. Contact: Sally Killick, MD. Phone: 44 (0) 11202 704783.

The Royal Bournemouth Hospital. Multi-centre trial of CEP-701 in older patients with AML. Contact: Sally Killick, MD. Phone: 44 (0) 11202 704783.

FRANCE

Groupe Français des Myelodysplasies. 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 Myelodysplasies. 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 Myelodysplasies. ICL670. A multicenter 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@ghici.net.

Groupe Français des Myelodysplasies. 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 Myelodysplasies. 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: Pierre Fenaux, MD. Phone: +33 1 48 95 70 50/70 51, pierre.fenaux@avc.ap-hp.fr.
Groupe Français des Myelodysplasies. GFMaza05. Phase II study on maintenance treatment with azacitidine 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.


GERMANY


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.

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: Nikolaus 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: Nikolaus 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.


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. 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. 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.

**ITALY**

Unit of Hematology and Stem Cell Transplantation, IRCCS “Casa Sollievo della Sofferenza” Hospital. 26. A randomized trial comparing a single, weekly dose of recombinant erythropoietin (IAGO) for young untreated patients, without an HLA identical sibling donor, who are platelet transfusion dependent. Contact: Dr. Pellegrino Musto. Phone: 39 (0) 882-410295-539.

**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-alpha 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.

**JAPAN**


**THE NETHERLANDS**


**University of Nijmegen, Nijmegen.** EBMT200502. A prospective 2 x2 randomized muticenter 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 Infliximab (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 (d 60 yrs of age) with acute myelocytic leukemia (AML) or refractory anemia with excess of blasts (RAEB, RAEB-t) with IPSS score e1.5 (HOVON42). 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 (e 61 yrs of age) with acute myelocytic leukemia (AML) and refractory anemia with excess of blasts (RAEB, RAEB-t) with IPSS score e1.5 (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.** NMDSG02B. Phase II study on maintenance treatment with Azacytidine in patients with advanced MDS and MDS-AML, who have obtained CR with intensive chemotherapy. Contact: Dr. Eva Hellström-Lindberg. Phone: 011-46-85-858-0000.

**Nordic MDS Group.** NMDSG03A. An open, non-randomized Phase II study on the effects of anemia in MDS quality of life, cardiac function and health care costs. Contact: Herman Nilsson-Ehle. Phone: 011-46-85-858-0000.


**An Update:**

The MDS Foundation will soon be working with the European Hematology Association’s MDS Working Group (EHA) to standardize information on clinical trials in Europe. This will aid physicians and patients in identifying and contacting centers about participating in these trials. We’ll keep you up to date!

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**SPAIN**

**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.

**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.

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.

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**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.
MDS Educational Resources for Clinicians

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
When ordering, use code PAO50203

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

A NEW CME PROGRAM AVAILABLE IN CD-ROM FORMAT


You may request this program by contacting the Foundation at 800-MDS-0839 or by logging on to our website: www.mds-foundation.org.

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
Published by The Myelodysplastic Syndromes Foundation

C. Patient Diary
Published by The MDS Foundation

D. Your Journal: Learning About Myelodysplastic Syndromes (MDS)
Supported by a grant from Celgene Corporation.
Translations available in Spanish, French, Polish, Czech, Japanese, German and Portuguese.

E. PBS Program Videotape
Healthy Body, Healthy Mind: Learning About Myelodysplastic Syndromes

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

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!
**Patient Services**

*Angel Flight:* For nearly 25 years, *Angel Flight* has helped people overcome the obstacle of distance and access to healthcare. Through a nationwide network of 1,500 volunteer pilots, Angel Flight coordinates *free* air transportation for people in need. Angel Flight’s generous and compassionate volunteer pilots—men and women from all 50 states with a wide variety of backgrounds—donate flights in their personal general aviation aircraft. Passengers fly *totally free*, as often as necessary and for as long as needed, to reach medical care or for numerous other humanitarian needs. Since 1978, Angel Flight volunteer pilots have flown over 30,000 missions.

In 2002, Angel Flight volunteer pilots provided free air transportation for nearly 9,500 passengers (men, women, and children), saving them over $4 million in commercial travel expenses, helping them reach medical treatment that would otherwise be inaccessible. Although the vast majority of its passengers fly for medical reasons, Angel Flight pilots also offer free flights for other humanitarian reasons. Each summer, Angel Flight’s volunteer pilots distribute the children from Chernobyl to host homes across the U.S. for a two-month summer respite. They also transport hundreds of children to health-related summer camps each year. And, within 48 hours of the terrorist attacks on 9/11/01 and while most aircraft were still grounded, Angel Flight volunteer pilots were in the air transporting emergency service personnel, disaster victims, blood and medical supplies in support of disaster relief efforts in New York City and Washington, D.C.

Angel Flight is a non-profit 501 (c) (3) organization that relies 100% on the generosity of volunteer pilots, as well as individual, corporate, and foundation contributions. Angel Flight is the oldest and largest national volunteer pilot organization in the United States. For more information about Angel Flight, visit www.angelflight.org or call toll-free (888) 4-AN-ANGEL (888-426-2643).

**Contact AF:**

**Mailing Address**
Angel Flight
3161 Donald Douglas Loop South
Santa Monica, CA 90405
info@angelflight.org

**Phone:**
Main number (310) 390-2958
Toll-Free number (888) 4-AN-ANGEL
Automated Voice Mail (310) 398-6123
24-Hour Emergency Response (310) 317-1000
Fax (310) 397-9636

**Information**

*General Information*
info@angelflight.org

*Prospective Pilot Information*
pilotinfo@angelflight.org

*Social Worker Information*
swinfo@angelflight.org

*Member Information*
memberinfo@angelflight.org

**Program Description:**
Since 1978, Angel Flight has helped to ensure equal access to healthcare and improve the quality of life for thousands of people throughout the United States by coordinating free air transportation for those in need.

**Services Provided:**
Angel Flight coordinates the following services:

1. Transporting people with medical and financial need to reach medical care far from home.
2. Transporting people with time-critical needs associated with a transplant procedure.
3. Transporting precious cargo such as organs, blood, tissue and medical supplies.
4. Providing free air support for disaster relief efforts in times of crisis.
5. Providing flights for numerous other humanitarian needs.

**Funding Source:**
Angel Flight is a national non-profit 501(c)(3), charitable organization funded entirely by tax deductible donations from individuals, foundations and corporations and the generosity of our volunteer pilots who donate the direct costs of every flight. Over 94% of all support and contributions donated to Angel Flight goes directly to program services.

**Volunteer Opportunities:**
Angel Flight is currently seeking volunteer pilots in many areas of the country. For more information, visit www.angelflight.org or call (888) 4-AN-ANGEL.
**Passenger Eligibility:**
Our volunteer pilots fly passengers free of charge and as often as necessary for diagnosis, treatment, and follow-up care, and for other humanitarian reasons.

1. Angel Flight passengers must be ambulatory or need little or no assistance to board and exit the aircraft.
2. Passengers must be medically stable and able to fly in an unpressurized aircraft.
3. Passengers must demonstrate financial need.

**Application Method:**
To request a free flight, just call toll-free (888) 4-AN-ANGEL (888-426-2643). In urgent situations, a coordinator can be paged after normal business hours. Just call (888) 4-AN-ANGEL and follow the paging instructions on the voice mail message.

You may also request a flight by visiting www.angelflight.org.

**Service Area:**
All U.S. states, parts of Canada and Mexico.

**Cost/Fees:**
None, but donations accepted.

**Waiting List:**
None, but 1–2 weeks advance notice is preferred.

**Target Group:**
Anyone with financial need who needs air transportation.

**Age Range:**
All

**Handicap Access:**
Somewhat, depending on type and size of aircraft.

**Languages:**
English and Spanish

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**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:

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

Laura Breyer, Chicago, IL

Joseph Artuso, Ridgefield, CT

Henry Blume, Menlo Park, CA

Ken Lanik, Sugar Land, TX

Richard Brown, Houston, TX

David and Nicole Vasquez, Houston, TX

Tara McKnight, Houston, TX

Lisa Maultsby, Chester, PA

William Shulevitz, New York, NY

Susan Cloos, Ozark, AR

Michael Drake, Collierville, TN

Sidney and Norma Weinberg, Margate, NJ

Robert J. Wolfe, Ringoes, NJ

Neil Zylich, Fernandina Beach, FL

Tibor Enekes, Ontario, Canada

Beverly Sebastian, Green Valley, AZ

John W. Morris, Rolling Meadows, IL

Margaret Yamato, Honolulu, HI

Karen Christine Rowe, Massapequa, NY

Frieda Gutfriend, Woodmere, NY

Harvey Pearlman, Longboat Key, FL

Mabel Rocamora, Rochester Hills, MI

James Hester, Lilburn, GA

Norman Greer, Long Beach, NY

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:

36 Front Street, PO Box 353
Crosswicks, NJ 08515

or call us at 1-800-MDS-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
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

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.

The MDS Foundation is grateful for community support. Our work as a non-profit organization depends on public funding.

If you would like to contribute in this way, please write to us at:
36 Front Street, P.O. Box 353, Crosswicks, NJ 08515
or call us at 1-800-MDS-0839.

A Living Endowment donation has been made in honor of Kay Whittey

This donation has been submitted by:
Sid and Norma Weinberg, Margate, New Jersey

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

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

We welcome your suggestions.

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

Genzyme has provided the MDS Foundation with an educational grant to support the Foundation’s work.
In Memorium

A memorial fund has been established in the name of
Mr. Paul A. Allen
Donations have been made in Mr. Allen’s memory by:
Jack and Christina Sangalli
Pekin, IL
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Donations have been made in Ms. Bayer’s memory by:
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A memorial fund has been established in the name of
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Donations have been made in Mr. Beeson’s memory by:
Doug and Rebecca Pruitt, Phoenix, AZ

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Ms. Ernestine Beltrami
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Canton, MA
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Shelton, CT

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Donations have been made in Mr. Blanco’s memory by:
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North Richland, TX
Gary and Pam Pippen
El Paso, TX

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Donations have been made in Ms. Brand’s memory by:
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Milwaukee, WI
Kate Schubert
Morton Grove, IL
Leonora Leibik
Chicago, IL
Betty Szwowicz
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Col. F. Raymond Caulder
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Isle of Palms, SC
Russell & Elizabeth Dehder
Mt. Pleasant, SC
Kim Pugh
Charleston, SC
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Toni Thompson
Mt. Pleasant, SC

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Carl and Colette Reddel
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Carolyn Wallace
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Mr. John Lawrence Conn
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John and Susan Pucheu, Tranquility, CA

A memorial fund has been established in the name of
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Angela Fay
Katy, TX
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Donations have been made in Ms. Beltrami’s memory by:
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Donations have been made in Mr. Conn’s memory by:
John and Susan Pucheu, Tranquility, CA

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A memorial fund has been established in the name of
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Rogersville, MO
Colleen Berding
St. Louis, MO
Barbara Sutton
St. Louis, MO

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Mr. William H. Hesson
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Fresno County Roadriders Club, Inc., Fresno, CA

A memorial fund has been established in the name of
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A memorial fund has been established in the name of
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Donations have been made in Mr. Joslyn’s memory by:
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Geri and Tom Zasadny
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Steven and Linda Fry
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Mike Vitkевич
Covina, CA
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Lana Sassi
Phoenix, AZ
Gary and Lisa Prokuski
Huntley, IL

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Donations have been made in Mr. Novak's memory by:
Joseph and Diane Linder
Hampshire, IL
Marilyn Novak
Park Ridge, IL

A memorial fund has been established in the name of Ms. Dorothy Petta
Donations have been made in Ms. Petta's memory by:
Rita Wismer, Gurnee, IL

A memorial fund has been established in the name of Mrs. Picardi
Donations have been made in Mrs. Picardi's memory by:
Norma and Sidney Weinberg, Margate, NJ

A memorial fund has been established in the name of Mr. Jack Plauché
Donations have been made in Mr. Plauché's memory by:
Kayla Harper
Stephen and Darbie Higgs
Vienna, WV

A memorial fund has been established in the name of Mr. Kenneth Platt
Donations have been made in Mr. Platt's memory by:
Sylvia Graifer
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