spring 2012: volume 18, issue 1

mdsnews
newsletter of the myelodysplastic syndromes foundation

TABLE OF CONTENTS

From the Guest Editor's Desk

A Tribute to Professor Terence "Terry" John Hamblin

Professor Terence Hamblin

The following statement appeared as a guest editorial prepared by Drs. John M. Bennett, David Bowen and Daniel Catovsky, long time professional associates of Professor Hamblin in Leukemia Research.[1]

With great sorrow we report the death of Professor Terry Hamblin on Sunday, 8 January 2012 from complications of a metastatic bowel carcinoma.

Born in Worcester, England in 1943; schooled at Farnborough, Hampshire 1954–62; University 1962–67 and junior doctor posts 1967–74 in Bristol; he became Consultant Haematologist, Bournemouth 1974–2003 and Professor of Immuno-haematology at the University of Southampton 1986 to 2012. He also was Honorary Consultant Haematologist at Kings College Hospital, London, 2004–2012.

He was instrumental in the establishment of the first three International Symposia on MDS and served on the MDS-F Board of Directors and as its treasurer for a quarter of a century. His achievements in the field of MDS improved greatly how patients were managed. His group in Bournemouth developed the first scoring system for prognosis and published many of the early seminal clinical papers defining this disorder.

He served with great distinction as co-Editor-in-Chief of *Leukemia Research* for 26 years.

Professor Hamblin was awarded the Binet-Rai medal for outstanding research in Chronic Lymphocytic Leukemia (CLL) in 2002 and stated "This has been my most successful area of research." His seminal work on the prognostic value of the IgH gene mutation status has become a cornerstone in the risk stratification of CLL patients. This important research discovery characterized two subtypes of chronic lymphocytic leukaemia those with or without somatic mutation of the immunoglobulin heavy chain variable region genes. The survival of patients with IgH mutation averages 25 years, if no mutations closer to 8 years.

In addition his contributions in the fields of apheresis, stem cell transplantation, myeloma, antibody therapy, cytokine therapy and DNA vaccines are well known. Professor Hamblin's articles numbered over 200 peer-reviewed publications. In retirement he embraced the social network, writing an eloquent and informed 'blog', which embraced his varied interests in life including medicine, sports and religion.

For those who knew Terry, he will be remembered as a gregarious and spirited Englishman, ready to step in with an anecdote, a yarn or a joyful dance at social gatherings. He leaves his wife, Diane–married for 45 years–and 4 children, Karen, Richard, Angela and David, and grandchildren.

1. Bennett JM, Catovsky D, Bowen D. *Leukemia Research*. 2012;36:383–384.

Meeting Highlights and Announcements

THE AMERICAN SOCIETY OF HEMATOLOGY 53RD ANNUAL MEETING & EXPOSITION

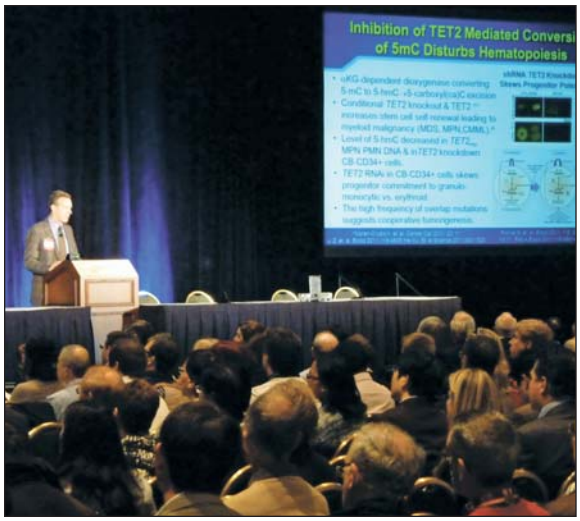
On behalf of the MDS Foundation and our Board of Directors, thank you for joining us for our recent Satellite Symposium:

Next Generation Approaches for Evaluation and Treatment of MDS

Manchester Grand Hyatt
San Diego, California
December 9, 2011

The MDS Foundation held its 13th consecutive satellite symposium on Friday preceding the American Society of Hematology's annual meeting. This symposium entitled "*Next Generation Approaches for Evaluation and Treatment of MDS*," was chaired by Dr. Stephen D. Nimer of Memorial Sloan-Kettering Cancer Center in New York City and Chairman of the MDS Foundation and its Board of Directors. The room was filled to capacity with an audience of approximately 700 hematologists from around the world.

Highlights from 53rd ASH Annual Meeting and Exposition



Download our ASH Presentations online at
www.mds-foundation.org

- Introduction Presentation:
  Next Generation Approaches for Evaluation and Treatment of MDS
- Revised International Prognostic Scoring System (IPSS-R):
  Developed by the International Working Group for Prognosis in MDS (IWG-PM)
- Molecular Characterization of MDS & Predisposition
- Impaired ribosome function and the molecular biology of the 5q- syndrome
- Combinational therapy and newer agents in MDS
- Advances in HSC Transplantation for Myelodysplasia: Cord Blood Transplantation & RIC

The MDS Foundation is blessed with a strong and supportive circle of members and friends…

mds foundation
the myelodysplastic syndromes foundation, inc.

The 12th International Symposium on MYELODYSPLASTIC SYNDROMES

Advancing Research & Patient Care: Join over 1,600 International Leukemia, Hematology, and Oncology professionals

Symposium Chairmen:
Arnold Ganser, M.D., Ph.D. Hannover Medical School, Germany
Wolf-Karsten Hofmann, M.D., Ph.D. University Hospital Mannheim, Germany



MDS 2013 will be held in central Berlin surrounded by the world famous cultural and historical sites the city has to offer

VISIT KENES.COM/MDS TO LEARN MORE.

VISIT THE MDS FOUNDATION BOOTH #839

LUNCHEON SYMPOSIUM

On behalf of The Myelodysplastic Syndromes Foundation and our Board of Directors, we invite you to join us for our Satellite Symposium:

The Myelodysplastic Syndromes: Challenges and Strategies for Effective Outpatient Management

May 3, 2012 • New Orleans, Louisiana
Hilton New Orleans Riverside

Understanding the pathophysiology of the disease, risk-adapted treatment selection, triggers for active therapies, and strategies for managing anticipated disease and treatment related adverse events will provide the oncology nursing professional with the tools to assist patients and their families in meeting the challenge of living with MDS. Providing the best support possible requires an appreciation of the true experience of the patient and family. A summary of patient and family experiences, and identified needs for education and support, will provide the tools needed by the oncology nurse to support this patient population.

The International Nurse Leadership Board for the MDS Foundation will introduce a supplement to the *Clinical Journal of Oncology Nursing* which incorporates an update on the science of MDS, practical tools for clinical management of MDS including iron overload, a discussion of quality of life in the patient living with MDS, and a review of strategies and resources for support.

LEARNING OBJECTIVES

Upon completion of this program, participants should be better able to:

- Correlate diagnostic findings and patient specific factors as they relate to risk stratification, treatment selection and prognosis in MDS.
- Operationalize strategies to identify treatment triggers, facilitate treatment initiation, proactively identify and manage treatment related adverse events.
- Identify best practice models for outpatient management of the older adult with MDS including supportive care strategies.
- Discuss the patient and family perspective relative to living with MDS and developing systems for active participation and support.

AGENDA

12:00–12:05 pm

Welcome and Introduction

Sandra E. Kurtin, RN, MS, AOCN, ANP-C

12:05–12:45 pm

Scientific Update: Recent Advances in Strategies for the Treatment of MDS — From Prognosis to Treatment Selection

Updates on the pathobiology of the disease and risk adapted treatment selection including the IPSS-R

Jean Ridgeway, MSN, APN, NP-C, AOCN

12:45–1:00 pm

Setting Expectations for the Initial Treatment of MDS: Practical Tools for Effective Management

Treatment triggers and supportive care strategies: cytopenias, iron overload, outpatient management

Sandra E. Kurtin, RN, MS, AOCN, ANP-C

1:00–1:15 pm

Patient and Family Support Throughout the Continuum of Care

Patient and Family Forums — what we learn from our patients

Jayshree Shah, APN-C, MSN, RN, BSN, BS

1:15–1:30 pm

Navigating the Web for MDS: Web-based Resources for Patients and Nurses

Sara M. Tinsley, ARNP, AOCN

FACULTY

Sandra E. Kurtin, RN, MS, AOCN, ANP-C
Hematology/Oncology Nurse Practitioner
Arizona Cancer Center
Clinical Assistant Professor of Nursing
Clinical Assistant Professor of Medicine
University of Arizona
Tucson, Arizona, USA

Jean A. Ridgeway, MSN, APN, NP-C, AOCN
Leukemia/Stem Cell Transplant Nurse Practitioner
University of Chicago Medical Center
Department of Hematology Oncology
Chicago, Illinois, USA

Jayshree Shah, APN-C, MSN, RN, BSN, BS
Nurse Practitioner – Leukemia Division
John Theurer Cancer Center
Hackensack University Medical Center
Hackensack, New Jersey, USA

Sara M. Tinsley, ARNP, AOCN
Malignant Hematology Nurse Practitioner
H. Lee Moffitt Cancer Center
Tampa, Florida, USA

"helping you give hope..."

The MDS Foundation is a multi-disciplinary, international organization devoted to support, research, treatment, and education for patients, caregivers, physicians, and other health care providers. The organization is based upon the premise that international cooperation will accelerate the process leading to the control and cure of these diseases.

Please join us as a member of the Foundation.

JOIN US AS AN MDS CENTER OF EXCELLENCE

Apply for The Centers of Excellence Program:

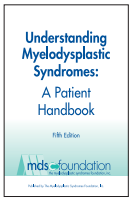
Would you like your treatment center to become part of the Foundation's research network and referral system for MDS patients?

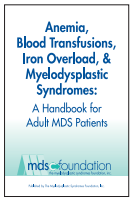
Please call us for more information and an application.

MDS FOUNDATION PUBLICATIONS

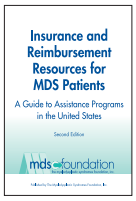
The MDS Foundation provides the following information to physicians and patients, free of charge:

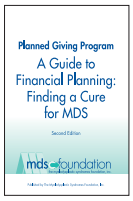
- The MDS News
- The MDS Messenger (Free E-News)
- Patient Diary
- What Does My Bone Marrow Do?
- Understanding Myelodysplastic Syndromes: A Patient Handbook*
- Anemia, Blood Transfusions, Iron Overload, & Myelodysplastic Syndromes: A Handbook for Adult MDS Patients*





- Insurance and Reimbursement Resources for MDS Patients
- Planned Giving Program: A Guide to Financial Planning





***Select MDS Patient Handbooks are available in English and the following languages:**

FOUNDATION INITIATIVES FOR 2012 AND BEYOND...

- **WORLDWIDE PATIENT QUALITY-OF-LIFE FORUMS**
- **WORLDWIDE PATIENT SUPPORT GROUPS**
- **INTERNATIONAL NURSE LEADERSHIP BOARD**

VISIT OUR WEBSITE AND LINK TO OUR EDUCATIONAL RESOURCE CENTER:

www.mds-foundation.org

INTERNATIONAL WORKING GROUP FOR PROGNOSIS IN MDS

This international group of physicians, coordinated through the MDS Foundation, is dedicated to the revision and refinement of the International Prognostic Scoring System (IPSS).

THANK YOU TO OUR SPONSORS FOR THEIR SUPPORT

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TARGETING CANCER | PROTECTING HEALTHY CELLS

SPREADING THE NEWS WORLDWIDE: ITALY

MDS Italy Patient Support Group Meetings

Reggio Calabria and Rome, Italy

A special thank you to AIL Pazienti for their collaboration!

The inaugural meeting in conjunction with AIL Pazienti was held on November 25, 2011 in Reggio Calabria. It was a huge success – almost fifty patients attended. Patients were stunned and emotional because of all of the attention they were receiving from our collaboration.

The second one was held in Rome on January 19, 2012. Almost 100 people attended. AIL will support future meetings as much as possible, and are organizing our next meetings in Florence & Treviso.

Thank you to Professor Mandelli, Drs. Oliva and Latagliata, and Maria Rita Grattarola for their hard work and contributions. Well done AIL. Thank you all for making this happen in Italy!

Inaugural MDS Belgium Patient Support Group Meeting

February 11, 2012

A special thank you to our guest speakers: Dr. Dominik Selleslag and Nurse Vanessa Prockl and AZ Sint-Jan AV in Brugge for hosting this event!

Hamilton Health Sciences MDS Support Group

February 25, 2012

Emmanual United Church
871 Upper Ottawa Street, Hamilton, Ontario

"Caring for the Caregiver"

Presenter: Corinna McCracken
Social Worker, Juravinski Hospital and Cancer Centre

Group Facilitators:
Nurses Tammy De Gelder and Karen Running

Mark Your Calendars!

2012 MDS Patient-Caregiver Education Forum Dates

After our huge successes with our past signature events, the MDS Foundation is happy to announce the dates of our 2012 Patient-Caregiver Forums.

This year, we are holding conferences in:

- Tampa, FL: February 29, 2012
- Philadelphia, PA: March 3, 2012
- Palo Alto, CA: March 24, 2012
- San Antonio, TX: April 11, 2012
- Columbus, OH: May 12, 2012
- Minneapolis, MN: TBD
- Milwaukee, WI: TBD
- Durham, NC: TBD
- Pittsburgh, PA: TBD
- Long Island, NY: TBD
- Boston, MA: TBD

For more information on our upcoming forums, please visit www.mds-foundation.org.

We are thrilled to have been able to reach so many members of the MDS community in 2011, and look forward to continuing doing so in 2012!

Thank You to Our Pharmaceutical Supporters

We would like to thank our pharmaceutical supporters for their commitment to the Foundation and its work. They have contributed in the form of educational grants, which maintain not only this newsletter but also the development of the MDS homepage on the World Wide Web, the Center of Excellence program, continuing medical education programs, and the dissemination of patient information.

Would you like to join a local support group in the Philadelphia, PA area?

It is our goal to initiate and meet on a regular basis to:

- **Bring individuals together including patients and caregivers**
- **Meet others with similar challenges**
- **Share hopes and frustrations, gather information**
- **Provide information to better understand MDS treatment options**
- **Listen to physician and nurse presentations**
- **Socialize**

If you are interested in joining a support group for patients who have MDS, please contact Audrey Hassan at 1-800-MDS-0839 or email ahassan@mds-foundation.org.

We have found that family members and caregivers will benefit as much as patients!

National Doctors' Day

A Holiday Established in 1990 to Honor Physicians

March 30th of every year is National Doctors' Day—a special day set aside to honor the skill and commitment of the dedicated men and women who devote their lives to providing hope and healing.

A tribute gift has been made to the MDS Foundation in your honor by someone who appreciates your skill, care, and commitment:

Dr. Erica Warlick
Wayne Sether, *St. Paul, MN*

Dr. Gary Grad
John W. Morris, *Rolling Meadows, IL*

Dr. Michael K. Gornet
Carolyn M. Long, *Anchorage, AK*

Dr. John Adamson
Harvey and Dr. Randi Helsel
San Diego, CA

Dr. Theodore Braich
Ray Gann, *Bend, OR*

Dr. M. Thirman
David Hensel, *Oak Forest, IL*

Dr. Bart Scott
Steve and Carolyn Kessler, *Bellevue, WA*

Dr. E. Randolph Broun
Evelyn D. Forney, *Cincinnati, OH*

Dr. Sushma Nakka
Donald and Kathe Dempster
Lakeland, FL

Dr. Mark Moskowitz
Mary Roberts, *Naples, FL*

Dr. A. Tom Andrews
Harold C. Ryder
Mechanicsburg, PA

Dr. Kelly McCaul
Lucille B. Nase, *Centerville, SD*

Dr. Luigi F. Bertoli
Lois Smith, *Clanton, AL*

Dr. Stuart Goldberg
Michael & Mary Ann Maher
Summit, NJ

Dr. Ajay Dar
Sheila Martin, *Fairfax, VA*

Dr. Aftab Mahmood
Robert E. Forest
Corpus Christi, TX

Dr. Alan List
Joan Weidenfeld
Boca Raton, FL

Dr. Suzanne Fanning
Harriet Brenner, *Greenville, SC*

Dr. Douglas Testori
Page Wingfield, *Hampstead, NC*

Dr. Kathleen Stewart
Dorothea Friar
Three Churches, WV

Dr. Paramjeet Singh
Roselyn B. Woolord, *Raleigh, NC*

Dr. Timothy J. Ernst
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Dr. Hussain Saba
William Hamilton, *Lake Como, NJ*

Dr. Georgia I. Karp
Herbert Vine, *East Brunswick, NJ*

Dr. Jane Brooks
Elizabeth Benso, *Matamoras, PA*

Dr. Alan List
Arthur G. Lipman, *Northbrook, IL*

Dr. Virginia Klimek
Marjorie Brittenham and Family
Poughkeepsie, NY

Dr. Michael Duggan
David Pressley, *Terre Haute, IN*

Dr. Valeria Santini
Roberto Degl'Innocenti, *Miami, FL*

Dr. Stephen D. Nimer
Barry & Naomi Cooper, *Brooklyn, NY*

Hematopoietic Stem Cell Transplantation: A Therapeutic Option for Selected Patients with Myelodysplastic Syndromes

Erik Aerts, RN
Sandra Kurtin, RN, MS AOCN, ANP-C
On behalf of the MDS Foundation Nursing Leadership Board

Hematopoietic stem cell transplantation (HCT) remains the only potentially curative treatment option for the myelodysplastic syndromes.[1] The pathobiology of MDS includes abnormalities within the myeloid clone which can only be completely eliminated by treating the disease aggressively with high dose chemotherapy followed by a stem cell rescue using donor stem cells. This is known as an allogeneic stem cell transplant. Autologous HCT (use of the patients own stem cells) is used infrequently for the treatment of MDS due to inferior long-term relapse-free periods. However, not all patients with MDS will be eligible for HCT based on commonly used criteria for patient evaluation and selection: 1) performance status (ability to perform daily task independently); 2) major organ function (liver, heart, kidneys, lungs); 3) the presence of co-morbidities (number and how well controlled); 4) response to disease modifying treatments (hypo-methylating agents, immunomodulating agents, chemotherapy, clinical trials); 5) the availability of a suitable donor; 6) availability of a consistent caregiver; 7) age; and 8) patient wishes after informed consent.[2-4]

The best outcomes for patients undergoing HCT for MDS are felt to be in those patients who meet these eligibility criteria and who have had effective treatment for their MDS using disease modifying therapies. The use of disease modifying treatments prior to HCT is recommended to reduce the tumor burden and improve the potential for a favorable outcome. Disease that is not responsive to standard therapies is more likely to relapse early after HCT or not respond to the HCT preparative regimen. Patients with lower risk MDS (IPSS low or Intermediate 1) are less likely to transform early to acute leukemia and may be more effectively treated with disease modifying therapies. Due to the high risk for morbidity and mortality with HCT in a predominantly older population, careful evaluation of the individual patient, their disease, personal attributes, and resources for support is critical.

The type of donor available is also a critical consideration. Matched sibling donors offer reduced post-transplant complications such as severe graft-vs-host disease (GVHD) and other organ failure. Matched unrelated donor (MUD) HCT carries much greater risk of transplant related morbidity and mortality. Given the majority of patients diagnosed with MDS are 70–75 years of age, this is not a feasible option for most patients due to common co-morbidities with secondary organ damage, the lack of a suitable matched donor, and the risk associated with the procedure. The probability of locating a HLA matched sibling donor is approximately 25%. If there is no sibling donor, a search will be initiated for the worldwide marrow donor registry which has approximately 8 million HLA typed volunteers. The probability of finding a matched donor is 40–60% for the general population, but under 10% for ethnic minorities.

For those patients who are deemed eligible for HCT, the timing of the HCT and what type of preparative regimen should be used is another consideration. The majority of data describing the timing for transplant has been based on retrospective analyses.[4] Koerth and colleagues conducted a pro-spective analysis of 513 MDS patients' ages 60–70 years who received reduced intensity chemotherapy (RIC) Allogeneic HCT.[5] Early RIC HCT in lower-risk MDS patients was associated with inferior life expectancy 38 months vs 77 months) quality adjusted life expectancy (35 months vs 65 months) than patients who did not have an early RIC HCT. However, early RIC HCT was associated with superior overall life expectancy (36 months vs 28 months) and quality adjusted life expectancy (33 months vs 15 months) in patients with higher risk MDS. Transfusion independent patients in both groups did better than their transfusion dependent counterparts. A retrospective analysis of 291 patients with MDS undergoing allogeneic HCT from the Spanish MDS registry found that high risk cytogenetics, higher risk IPSS category, and lack of benefit from disease modifying treatments prior to transplant were associated with inferior survival outcomes.[6] The OS rate after 2.6 years of follow-up was 33%, and infection (61%) represented the largest cause of transplant-related mortality (41%). These data stress the importance of a complete diagnostic evaluation including calculation of the IPSS category and the importance of disease modifying treatments to achieve transfusion dependence early in the course of disease and prior to HCT. Although RIC HCT may limit treatment-related morbidity and mortality, the risk of early relapse is increased. The selection of pre-transplant disease modifying therapies will vary by region throughout the world based on approved agents and current practice guidelines for each country.[7]

For those patients found to be eligible for HCT, the pre-transplant evaluation will be very thorough to confirm adequate organ function, social support, psychological health, and financial resources. Immediately prior to the transplant, the patient and their designated caregiver(s) will have a meeting to obtain informed consent for the treatment. Support of the patient and their family during the transplant evaluation, the preparative treat-ment and stem cell infusion, and the post-transplant period requires a well-organized multidisciplinary team including medical oncologist, oncology nurse specialists, dieticians, social workers, spiritual counselors, financial counselors, and a number of other health care providers as needed for individual patients. The majority of patients will spend several weeks

in the inpatient setting and once discharged will be followed closely at the transplant center outpatient clinic. Careful monitoring is required to detect early or late onset of toxicities including GVHD or other organ dysfunction. With early intervention, many of these potential toxicities can be effectively treated. Treatment as a part of a registered clinical trial is recommended to allow further characterization of the best treatment approaches and supportive care strategies for patients with MDS.

References:

1. Center for International Blood & Marrow Transplant Research, 2011.
2. Kurtin S. *J Adv Pract Oncol.* 2010;1:19–29.
3. Scott and Deeg. *Annu Rev Med.* 2010;53: 345–358.
4. Cutler. *Hematol Oncol Clin North Am.* 2010; 24:469–476.doi:10.1016/j.hoc.2010.02.006.
5. Koreth et al. 2011–ASH Abstract 115.
6. Diez Campelo M, Cordoba I, Gomez-Garcia S, et al. L*eukemia Research.* 2011;35 (supplement 1):s131.
7. Greenberg PL. *British Journal of Haematology.* 2010;150(2):131–143.doi:10.1111/j. 1365–2141.2010.08226.x

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Get Involved!

Join the MDSF Development Committee!

The MDS Foundation is seeking members to join our Development Committee. Whether your contribution is time, skills, funds, or ideas you can make a difference! For more information contact Tracey Iraca at **tiraca@mds-foundation.org** or call **800.637.0839**.

Support the MDSF!

Please make a tax-deductible donation today. Kindly use the enclosed donation envelope or go to **www.mds-foundation.org** to make your donation. Thank you for your continued support!

Sign up to volunteer!

If you are interested in helping out in the MDS Foundation office or in attending events as a representative of the MDSF, please call us at **800.637.0839**.

International physician and nursing symposia, interactive/web-based continuing education initiatives, abstracts and manuscripts.

Connect on our PATIENT FORUM

Don't miss out on our MDS Patient Forum! This feature hosted by the MDS Foundation and monitored by health professionals is a free online discussion board of information exchanged between patients, caregivers, and family members.

Connect today at **www.mds-foundation.org**

mds centers of excellence

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

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

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

The following centers have qualified as MDS Centers of Excellence:

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ARIZONA

Mayo Clinic Hospital
Phoenix, Arizona
Ruben Mesa, MD/James Slack, MD

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

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UCLA School of Medicine
Los Angeles, California
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City of Hope National Medical Center
Duarte, California
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Peter L. Greenberg, MD

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Gainesville, Florida
Christopher R. Cogle, MD

University of South Florida
H. Lee Moffitt Cancer Center
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Alan F. List, MD

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Emory University School of Medicine
Atlanta, Georgia
Amelia Langston, MD

The Blood and Marrow Transplant Program at Northside Hospital
Atlanta, Georgia
Asad Bashey, MD

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

Rush University Medical Center
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Stephanie A. Gregory, MD
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Tufts Medical Center
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The Cancer Center of Hackensack University Medical Center
Hackensack, New Jersey
Stuart Goldberg, MD

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Cancer Center
Bronx, New York
Amit Verma, MD

Columbia University
Medical Center
New York, New York
Azra Raza, MD

Memorial Sloan-Kettering Cancer Center
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Virginia M. Klimek, MD

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

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

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Lake Success, New York
Steven L. Allen, MD

Roswell Park Cancer Center
Buffalo, New York
James E. Thompson, MD

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

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

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Durham, North Carolina
Carlos M. deCastro, MD

Wake Forest University
School of Medicine
Comprehensive Cancer Center
Winston-Salem, North Carolina
Bayard L. Powell, MD

OHIO

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

The Ohio State Comprehensive Cancer Center
James Cancer Hospital and Solove Research Institute
Columbus, Ohio
Alison R. Walker, MD

PENNSYLVANIA

The Western Pennsylvania Cancer Institute
Pittsburgh, Pennsylvania
James M. Rossetti, DO

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

University of Pennsylvania Cancer Center
Philadelphia, Pennsylvania
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Pittsburgh, Pennsylvania
Anastasios Raptis, MD

TENNESSEE

Vanderbilt University Medical Center
Nashville, Tennessee
Madan Jagasia, MD
Stephen Strickland, MD

TEXAS

Cancer Care Centers of South Texas
San Antonio, Texas
Roger Lyons, MD

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

University of Texas MD Anderson Cancer Center
Houston, Texas
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Hagop Kantarjian, MD

WASHINGTON

Fred Hutchinson Cancer Research Center University of Washington Seattle Cancer Care Alliance
Seattle, Washington
Joachim Deeg, MD/Elihu Estey, MD

WASHINGTON, DC

Georgetown University Hospital Lombardi Comprehensive Cancer Center
Washington, D.C.
Catherine Broome, MD

WISCONSIN

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Milwaukee, Wisconsin
Parameswaran Hari, MD

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

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Tunis, Tunisia
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Sanatorio Sagrado del Corazón
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Peter MacCallum Cancer Institute University of Melbourne
East Melbourne, Australia
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University of Tasmania Royal Hobart Hospital
Hobart, Tasmania, Australia
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Hemocentro da UNICAMP
University of Campinas
Campinas, Brazil
Irene Lorand-Metze, MD

Servico de Hematologia do Hospital das Clinicas da Faculdade de Medicina da Universidade de São Paulo
São Paulo, Brazil
Elvira R.P. Velloso, MD, PhD

Universidade Federal de Ceará
Ceará, Brazil
Silvia Maria M. Magalhães, MD, PhD

Universidade Federal de São Paulo
São Paulo, Brazil
Maria de Lourdes Chauffaille, MD, PhD

CANADA

Princess Margaret Hospital
Toronto, Ontario, Canada
Karen Yee, MD

Toronto Sunnybrook Regional Cancer Centre
Toronto, Ontario, Canada
Richard A. Wells, MD

University of Toronto Hospital for Sick Children
Toronto, Ontario, Canada
Yigal Dror, MD

CHINA

Institute of Hematology and Blood Diseases Hospital Chinese Academy of Medical Sciences
Tianjin, China
Zhijian Xiao, MD

CROATIA

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Zagreb, Croatia
Boris Labar, MD, PhD
Ranka Serventi-Seiwerth, MD

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DENMARK

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Odense, Denmark
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Rigshospitalet National University Hospital
Copenhagen, Denmark
Lars Kjeldsen, MD, PhD

University of Århus The University Hospital
Århus, Denmark
Mette Skov Holm, MD, PhD

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Angers, France
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Centre Hospitalier Universitaire (CHU) de Nancy
Nancy, France
Agnés Guerci-Bresler, MD, PhD

Hôpital Avicenne/ University Paris XIII
Bobigny, France
Pierre Fenaux, MD

Hôpital Claude Huriez, CHU Lille Service des Maladies du Sang
Lille, France
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Hôpital Cochin/ University Paris V
Paris, France
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Hôpital Saint Louis/ University Paris VII
Paris, France
Christine Chomienne, MD, PhD

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Marseille, France
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Hannover, Germany
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Munich, Germany
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MLL Münchner Leukämielabor
Munich, Germany
Torsten Haferlach, MD

St. Johannes Hospital
Heinrich-Heine Universität
Duisburg, Germany
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Albert-Ludwigs-
Universität Freiburg
Freiburg, Germany
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Universitätsklinikum
Carl Gustav Carus
Dresden, Germany
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University Children's Hospital
Freiburg, Germany
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Universitätsklinikum
Benjamin Franklin
Berlin, Germany
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University Hospital Mannheim
Mannheim, Germany
Wolf-Karsten Hofmann, MD, PhD

GREECE

G. Papanikolaou General
Hospital of Thessaloniki
University of Thessaloniki
Thessaloniki, Greece
Charikleia Kelaidi, MD

Patras University Hospital
Patras, Greece
Argiris Symeonidis, MD

University of Athens
Laikon Hospital
Athens, Greece
Nora Viniou, MD

University General Hospital Attikon
Athens, Greece
Vassiliki Pappa, MD

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School of Medicine
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Kolkata, India
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Tata Memorial Hospital
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Medical Center
Tel-Aviv, Israel
Moshe Mittelman, MD

Chaim Sheba
Medical Center
Tel Hashomer, Israel
Drorit Grizim Merkel, MD

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Centro di Riferimento
Oncologico di Basilicata
(CROB)
Rionero in Vulture (PZ), Italy
Pellegrino Musto, MD

Istituto di Ematologia
Universita' Cattolica
Sacro Cuore
Roma, Italy
Giuseppe Leone, MD
Maria Teresa Voso, MD

University of Florence
Azienda OSP Careggi
Florence, Italy
Valeria Santini, MD

University of Pavia
Medical School
Pavia, Italy
Mario Cazzola, MD

JAPAN

Kyoto University Hospital
Kyoto, Japan
Akifumi Takaori, MD

Nagasaki University Hospital
School of Medicine
Atomic Bomb Disease Institute
Nagasaki City, Japan
Masao Tomonaga, MD

Nippon Medical School
Tokyo, Japan
Kiyoyuki Ogata, MD, PhD

Saitama International
Medical Center
Saitama Medical University
Hidaka, Saitama, Japan
Akira Matsuda, MD

Tokyo Medical College
Tokyo, Japan
Kazuma Ohyashiki, MD, PhD

KOREA

Catholic Blood and Marrow
Transplantation Center
The Catholic University of Korea
Seoul, Korea
Yoo-Jin Kim, MD

Seoul National University Hospital
Seoul National University
College of Medicine
Seoul, Korea
Dong Soon Lee, MD, PhD

THE NETHERLANDS

University Medical Center
Nijmegen St. Radboud
Nijmegen, The Netherlands
Theo J.M. de Witte, MD, PhD

Vrije Universiteit
Medical Center
Amsterdam, The Netherlands
Gert J. Ossenkoppele, MD, PhD

POLAND

Jagiellonian University
Collegium Medicum
Kraków, Poland
Aleksander Skotnicki, MD, PhD

PORTUGAL

Hospital de Santa Maria
Lisbon, Portugal
Joao F. Lacerda, MD

SAUDI ARABIA

King Faisal Specialist
Hospital & Research Centre
Riyadh, Saudi Arabia
Mahmoud Deeb Aljurf, MD

King Khaled University Hospital
King Saud University
Riyadh, Saudi Arabia
Ak Almomen, MD

SINGAPORE

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Hospital Universitario La Fe
Valencia, Spain
Miguel A. Sanz, MD, PhD

Hospital Universitario
Vall d'Hebron Laboratorio
del Citologia-Citogénetica
Barcelona, Spain
Maria Teresa Vallespi-Sole, MD, PhD

SWEDEN

Karolinska Institutet
Huddinge University Hospital
Stockholm, Sweden
Eva Hellström-Lindberg, MD, PhD

TAIWAN

National Taiwan University Hospital
Taipei, Taiwan
Hwei-Fang Tien, MD, PhD

THAILAND

King Chulalongkorn Memorial Hospital
Pathumwan, Bangkok, Thailand
Tanin Intragumtornchai, MD

TURKEY

Ankara University
School of Medicine Hospital
Ankara, Turkey
Osman Ilhan, MD

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Kiev, Ukraine
Dimitry Bazyka, MD

UNITED KINGDOM

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Aberdeen University
School of Medicine
Foresterhill, Aberdeen, Scotland
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Addenbrooke's Hospital
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NHS Foundation Trust
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Alan J. Warren, PhD, FRCP, FRCPath

King's College Hospital
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London, United Kingdom
Ghulam J. Mufti, MD

Queen Elizabeth Hospital
University Hospital Birmingham
NHS Trust
Birmingham, United Kingdom
Charles Craddock, MD

Radcliffe Hospitals
and University of Oxford
Oxford, United Kingdom
Paresh Vyas, MD

Royal Bournemouth Hospital
Bournemouth, United Kingdom
Sally Killick, MD

St. James's University Hospital
St. James's Institute of Oncology
Leeds, United Kingdom
David T. Bowen, MD

University Hospital of Wales
Cardiff, Wales
Jonathan Kell, MD

Information on Clinical Trials

New Research Protocol Listing

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.cancer.gov. This information includes basic study information, study lead organizations, study sites, and contact information. To access the information:

- Log on to www.cancer.gov
- 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.

To view listings of additional studies you can log onto www.clinicaltrials.gov. For telephone support, call the National Cancer Institute at 1-800-4-CANCER.

Announcing New Clinical Trials

NAME OF INSTITUTION:
Novartis Pharmaceuticals

TRIAL NUMBER: NCT00940602

Title of Trial or Description:

Myelodysplastic Syndromes (MDS) Event Free Survival With Iron Chelation Therapy Study (TELESTO)

A Multi-center, Randomized, Double-blind, Placebo-controlled Clinical Trial of Deferasirox in Patients With Myelodysplastic Syndromes (Low/Int-1 Risk) and Transfusional Iron Overload

Currently Recruiting Participants.

The primary purpose of this study is to prospectively assess the efficacy and safety of iron chelation therapy with deferasirox compared to placebo in patients with myelodysplastic syndromes (low/int-1 risk) and transfusional iron overload.

Contact the Novartis Clinical Trials Hotline at 800-340-6843 or go to **www.clinicaltrials.gov** *for additional information and to view the active sites.*

NAME OF INSTITUTION:
Celgene Corporation

TRIAL NUMBER: NCT01029262

Title of Trial or Description:

A Study of Lenalidomide Versus Placebo in Subjects With Transfusion Dependent Anemia in Low Risk Myelodysplastic Syndrome (MDS) Without Del 5Q (MDS-005)

Currently Recruiting Participants.

The primary purpose of this study is to compare the efficacy of Lenalidomide (Revlimid®) versus placebo in achieving red blood cell transfusion independence in the overall study population and in a pre-specified subgroup of patients with an erythroid differentiation gene expression signature predictive of Lenalidomide response.

Access www.clinicaltrials.gov for additional information.

Clinical Trials: Economic Value, supported by Clinical Efficacy

With the emergence of new methods of treatment for myelodysplastic syndromes (MDS), comes the realization that new treatment options support the opportunity for life extending and cost effective alternatives for patients, especially the relapsed or refractory patient to presently approved drug therapies versus the cost of supportive care.

Economic Analyses in Clinical Trials

Health economics are rarely the primary purpose of an experimental study, yet these economic attributes are measured today in the common design of the latest studies, ensuring that the trial will provide the data necessary for a high quality economic analysis of the study outcome.

Carrying out an economic evaluation within a controlled-randomized trial allows detailed information to be collected, including:

- Description and analysis of treatment related costs to health care systems, payers, and society
- Measurement of costs and consequences (clinical, economic, and humanistic) of medications, devices, and services

Health economic measurements are an important area of evaluation within the ONTIME trial (ON 01910.NA) Trial In Myelodysplastic syndromE

The primary purpose of the ONTIME study is to compare overall survival (OS) in patients receiving rigosertib plus best supportive care (BSC), to the OS of patients receiving BSC alone. This MDS patient population has excess blasts (5% to 30% bone marrow blasts) and have failed, or become intolerant too, or relapsed after treatment with azacitidine or decitabine.

Consider the ONTIME Trial for the treatment of MDS— Accrual of patients is ongoing

If you would like additional information regarding ONTIME or would like to refer a patient for enrollment into this clinical trial OR if you are an MDS patient who has failed, become intolerant, or relapsed after Vidaza® (azacitidine) or Dacogen® (decitabine) treatment, please call the ONTIME Trial Help Line at 1-855-609-6564.

Learn More

More information can be found at www.mdstrial.com or clinicaltrials.gov, the identifier is NCT01241500.

Online Search Tool for Clinical Trials

TrialCheck® | Clinical trials information and products powered by: Coalition of Cancer Cooperative Groups

TrialCheck is another online search tool that helps you gather information about cancer clinical trials to discuss with your doctor. This user-friendly tool allows you to search for trials according to your type of cancer and according to your zip code. This will help you locate physicians and hospitals near your home that offer trials.

TrialCheck searching is based on nine simple questions. Depending upon the answers you provide, TrialCheck generates a list of trials in which you may be eligible to enroll.

www.CancerTrialsHelp.org

New Research Protocol Listings

The MDS Foundation wants you to know about clinical trials of investigational treatment options for patients with MDS and has updated its International Clinical Trials list on our website and for distribution.

Please contact us for a detailed listing featuring new protocols:

Website: www.mds-foundation.org

Email: *patientliaison@mds-foundation.org* or call 800-MDS-0839 and the current clinical trials will be sent to you.

Clinical trials often have very specific eligibility requirements. Please talk with your doctor to help decide which, if any, trials might be right for you. Please note that the information is provided strictly as a resource and is not an endorsement of any physician, institution, or treatment.

Educational Resources

Highlights of Latest Literature in MDS

Suneel D. Mundle, PhD
Anuj Marathe

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

DIAGNOSIS/PROGNOSIS:

1. Germing U et al. Evaluation of dysplasia through detailed cytomorphology in 3156 patients from the Düsseldorf Registry on myelodysplastic syndromes. *Leukemia Research.* 2012, Mar 13 [Epub ahead of print].

   This study extensively assessed dysplastic features in peripheral blood and bone marrow of 3156 Düsseldorf MDS registry patients to demonstrate most common features of dysplasia in the three hematopoietic lineages as follows: (a) megaloblastoid changes and oligonuclearity in erythropoiesis, (b) pseudo Pelger Huet cells and hypogranularity in granulopoiesis and (c) micromegakaryocytes and mononuclear megakaryocytes.

2. Kikuchi S et al. Prognostic significance of serum ferritin level at diagnosis in myelodysplastic syndrome. *Int J Hematol.* 2012, Mar 11 [Epub ahead of print].

   The study showed increased levels of serum ferritin in non-transfused MDS patients as compared to healthy individuals. Among the MDS patients, the serum ferritin levels were higher in high risk categories of IPSS, and in patients with cytogenetic abnormalities. A significantly higher leukemia free survival and overall survival rates were noted if the serum ferritin levels were <500 ng/mL.

3. Meytes D et al. The long-term risk of myelodysplastic syndromes among anemia patients: a population-based study. *Leukemia Research.* 2012;36(3):327–330.

   A study based on Israel's nationwide health plan data showed MDS incidence of 3.32 per 100,000, which increases significantly among the anemic individuals over 40 years of age (56.7 per 100,000). The study also highlighted that only 44% of MDS patients had bone marrow examination recorded in the database and that the time taken to reach diagnosis of MDS from the first indication of anemia was 3.5 years.

4. Schanz J et al. New Comprehensive Cytogenetic Scoring System for Primary Myelodysplastic Syndromes (MDS) and Oligoblastic Acute Myeloid Leukemia After MDS Derived From an International Database Merge. *J Clin Oncol.* 2012;30(8):820–829.

   This pivotal study assessed 2902 patients from four large MDS patient databases to propose a new and comprehensive cytogenetic scoring system. Approximately 45% patients had cytogenetic abnormalities with del(5q) and trisomy 8 being the most frequently noted abnormalities. In total 19 cytogenetic categories were defined to construct five prognostic subgroups with significant differences in median overall survival, ranging from very good–61 mo, good–49 mo, intermediate–26 mo, to poor–16 mo and very poor–6 mo. The majority of patients (65.7%) with cytogenetics

abnormalities in this study group were classified under "Good" prognostic group within the newly proposed cytogenetic scoring system.

TREATMENT:

Reviews and Perspectives

The following two articles provide significant perspective on the current therapeutic landscape of MDS and identify need for additional prospective studies.

1. Schecter J et al. MDS: Refining existing therapy through improved biologic insights. *Blood Rev.* 2012;26(2):73–80.
2. Ornstein MC and Sekeres MA. Combination strategies in myelodysplastic syndromes. *Int J Hematol.* 2012;95(1):26–33.

Transfusions:

1. Niscola P et al. Transfusions at home in patients with myelodysplastic syndromes. *Leukemia Research.* 2012, Feb 13 [Epub ahead of print].

   An Italian 5 year study (2006–2010), reveals feasibility of using a dedicated home care program for blood transfusions to MDS patients. Authors suggest that such a service helps maintain quality of life and provides a comfortable treatment option to the elderly and frail MDS patients.

IMiDs:

1. Wei W et al. A combination of thalidomide and arsenic trioxide is effective and well tolerated in patients with myelodysplastic syndromes. *Leukemia Research.* 2012, Jan 23 [Epub ahead of print].

   Twenty-two patients each were assessed on treatment with a combination of thalidomide plus arsenic trioxide (ATO) or supportive care. The treatment arm demonstrated 18.2% CR and 68.2% hematopoietic improvement rate which were significantly higher than in those receiving only supportive care on the control arm. The progression free- and overall survival were also significantly higher with the active treatment than the controls (26 vs. 10 months and 36 vs. 16 months respectively). No severe AEs were noted.
2. Sibon D et al. Lenalidomide in lower-risk myelodysplastic syndromes with karyotype other than deletion 5q and refractory to erythropoiesis-stimulating agents. *Br J Haematol.* 2012;156(5):619–25.

   Thirty-one consecutive lower risk non-del(5q) MDS cases refractory to ESA received lenalidomide with or without ESA. Erythroid response was noted in 48% patients (37% transfusion independence), median response duration was 2 years. The erythroid response was higher in patients receiving lenalidomide +ESA than lenalidomide alone (55% vs. 36%).

Demethylating Agents:

1. Itzykson R et al. Does addition of erythropoiesis stimulating agents improve the outcome of higher-risk myelodysplastic syndromes treated with azacitidine. *Leukemia Research.* 2012; 36(4):397–400.

   A retrospective study of 282 higher risk MDS patients treated with azacytidine in combination with ESA (n=32) or alone (n=250) demonstrated significantly higher rate of erythroid response, transfusion independence rate, and improved survival with the addition of ESA to azacytidine.

Other Agents:

1. Gatterman N et al. Hematologic responses with deferasirox therapy in transfusion-dependent myelodysplastic syndromes patients. *Haematologica.* 2012, Mar 14 [Epub ahead of print].

   This post-hoc analysis of the EPIC trial with deferasirox (Exjade®) demonstrated hematologic responses in all three hematopoietic lineages (erythroid–21.5%, platelets–13% and neutrophil–22%) with a trend of greater ferritin reduction in responding patients as compared to the non-responders. The authors concluded that treatment with deferasirox up to 1 year may yield hematopoietic responses in some MDS patients.
2. Faderl S et al. A randomized study of two dose levels of intravenous clofarabine in the treatment of patients with higher-risk myelodysplastic syndrome. *Cancer.* 2012;118(3): 722–728.

   Intravenous clofarabin was evaluated in high risk MDS patients at 15 mg/m^2 vs. 30 mg/m^2 daily × 5 days. Among the total of 58 patients, the ORR was 41% vs. 29% with 15 and 30 mg doses respectively. The median survival for all patients was 7.4 months (21.7 months in those with CR). Hepatic and renal AE >grade 2 were seen with 30 mg dose and in general myelosuppression and infections were frequent with treatment.

PATHOBIOLOGY:

1. Yoshida A et al. Marked up-regulation of Survivin and Aurora-B kinase are associated with disease progression in the myelodysplastic syndromes. *Haematologica.* 2012, Mar 14 [Epub ahead of print].

   Survivin is apoptosis inhibitor and, Survivin and Aurora-B kinase play an important role in maintaining genomic stability. This study reports assessment of Survivin and Aurora-B kinase m-RNA expression in CD34+ cells from 64 MDS or in leukemic blasts from 50 de novo *AML cases. The expression of both genes was increased in RAEB-1/2 and tAML patients as compared to normal controls and correlated with disease progression. The authors suggest that the role of increased expression of these two genes in evolution of complex karyotypic abnormalities in MDS needs to be explored further.*
2. Damm F et al. Mutations affecting m-RNA splicing define distinct clinical phenotypes and correlate with patient outcome in myelodysplastic syndromes. *Blood.* 2012, Feb 17 [Epub ahead of print].

   SF3B1, SRSF2, ZRSR2, and U2AF35 gene mutations were analyzed in a cohort of 221 MDS patients. The total incidence of these mutations was approximately 43% and these were mutually exclusive. The report describes that each genotype corresponded with unique clinicopathologic features.
3. Thol F et al. Frequency and prognostic impact of mutations in SRSF2, U2AF1, and ZRSR2 in patients with myelodysplastic syndromes. *Blood.* 2012, Mar 2 [Epub ahead of print].

   Mutations in the genes of the splicing machinery are increasingly assessed in MDS. The present study assessed 193 MDS patients. Mutations were detected in a total of 34.7% patients in SRSF2, U2AF1, ZRSR2 and SF3B1 genes of which SRSF2 was the one shown to have a negative prognostic impact on leukemic transformation and overall survival.
4. Tsushima H et al. Late effect of Atomic bomb radiation on myeloid disorders: leukemia and myelodysplastic syndromes. *Int J Hematol.* 2012;95(3):232–238.

   Increased risk of leukemia was previously shown amongst the survivors of atomic bomb radiation exposure. Recent analysis suggests persistence of this risk even after six decades since the initial exposure. High-risk MDS and complex karyotypes were found to be more frequent in patients with higher dose radiation exposure.
5. Craig BM et al. Underreporting of myeloid malignancies by United States cancer registries. *Cancer Epidemiology Biomarkers.* 2012;21(3):474–481.

   The authors constructed specific algorithms based on four claims databases to estimate the incidence of myeloid malignancies and compared the outcome with that reported by the SEER national registry of the USA. The study revealed over 50% underreporting of the incidence of myeloid malignancies in SEER database.

We would like to thank Suneel Mundle, a member of the MDS Foundation, for his assistance in monitoring these important peer-review publications on MDS.

Contributions to the MDS Foundation

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Ramiro Peaherrera
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Stephen Molello
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Grand Rapids, Michigan

Joe Artuso, *Berwyn, Pennsylvania*

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Manalapan, New Jersey

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Collegeville, Pennsylvania

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Marilyn Rodd
Pleasant Valley, New York

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Lodi, New Jersey

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Sarasota, Florida

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Sheila Martin, *Fairfax, Virginia*

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Lincolnshire, Illinois

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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.

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