



*Accelerating
the
Search
for a
Cure*

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MYELOMA FOCUS

Newsletter of the

MMRF

Friends For Life Fall Gala Raises Over \$1 Million

The Sixth Annual MMRF Friends for Life Fall Gala was held on November 2nd at the Greenwich Hyatt in Greenwich, CT. The Gala was a huge success, raising over \$1 million for myeloma research.

Olympic champion, Scott Hamilton, was joined by Corporate Chair, Linda McMahon, CEO of World Wrestling Entertainment, Inc. (WWE) as the Gala's Honorees. Master of Ceremonies, Deborah Norville of Inside Edition, Event Chairs, Geraldine Ferraro, and Ann Curry played host to another sell-out Gala crowd with over 700 people having attended. Weekend Today's David Bloom, with wife Melanie also came out to show their support.



(L-R) Geraldine Ferraro, Ann Curry
and Scott Hamilton

A long-time champion of philanthropic causes and community involvement, Corporate Chair,

Linda McMahon talked about the importance of the critical and urgent work being done by the MMRF. Since she and her husband both lost their fathers to cancer, they have been instrumental in support of cancer research and have seen the progress that has come about as a result of hard work and dedication.



(L-R) Kathy Giusti, David Bloom, Linda McMahon and Deborah Norville

Welcome Letter

Families Funding Research

Dear Friends,

Since the MMRF was founded, we have operated with one clear goal -- to advance myeloma research and accelerate the search for a cure. We are committed to raising significant funds and ensuring that every possible dollar supports research and programming. It is this commitment that has allowed us to fund \$4 million in research grant awards this year and to budget \$5.5 million to grant awards in 2003.

Whenever I review the MMRF's strong financials, I am reminded of how grateful I am for the incredible work of our dedicated volunteers. The MMRF Races for Research, fundraising dinners, advocacy day and administrative tasks could not happen without the efforts of so many generous and capable people. Their support has given the MMRF large company-size manpower while keeping expenses to a minimum.

As 2002 comes to a close, I urge everyone to join us in funding new therapies for multiple myeloma patients. Please make your donation to our annual appeal today.

On behalf of all of us at the MMRF, have a wonderful holiday season.



The Year End 2002 Appeal will be hitting your mailboxes by Thanksgiving. Please support the MMRF's efforts to continue the accelerated search for a cure. Your donations are important in helping us reach that goal.

Paul Sunko and Family

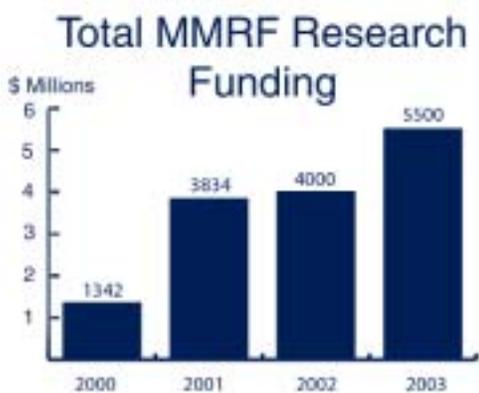
Taking the time to write a letter can make a big difference. That's what Paul Sunko, a Chicago-based college professor, thought when he originally embarked on his letter-writing campaign weeks before the MMRF Race for Research in Chicago. After participating in last year's MMRF Race for Research, he decided that this year he would set his own finish line goal -- a goal to raise \$10,000 for myeloma research.

Diagnosed with multiple myeloma 3 years ago, Paul considers himself the fortunate recipient of a successful stem cell transplant, excellent medical care and the unfailing love and support of his family and friends. He decided that now it was his turn to give back to all that had been given to him.

He personally sent out more than 300 letters and he received 153 responses totaling over \$12,500 in contributions. "The response was incredible," he said, "and especially rewarding since it came in small amounts from so many people."

Paul's enthusiasm was not only effective, but it was also contagious. His two daughters, Shawn and Cammy, were inspired by their father's ambition and decided to initiate their own letter writing campaigns. They each wrote to their own friends and acquaintances and raised an additional \$2,000 -- bringing the Sunko family total contribution to well over Paul's original \$10,000 goal.

Paul's oldest daughter, Shawn, was up for another challenge as well. After her dad beat her in last year's race, she was determined to outpace him in this year's rematch. She did in fact, beat him by about 3 minutes, but Paul still came home with the first place prize for his age group. In the end, Paul, his family and research for multiple myeloma were all the big winners!



Paul Sunko



Friends For Life Fall Gala Raises Over \$1 Million (cont.)

Linda explained that her meeting with the MMRF's co-founders, Kathy Giusti and Karen Andrews, was not only an introduction to "the most dynamic tag team around," but also a glimpse of "their passion, commitment and devotion to each other as sisters that overwhelmed [her] with the opportunity to serve as Corporate Chair." Linda's leadership and support, along with the support of several WWE-affiliated sponsors, was key to the evening's incredible success.

Scott Hamilton was presented with the MMRF Public Awareness Award and he reflected on the loss of his mother to cancer and his own battle with the disease, stating that, "cancer is the worst thing that happened to me; and cancer is the best thing that happened to me. It is amazing what it can awaken and inspire in us." After his mother's death, it inspired him on to four national world titles and an Olympic gold medal, and inspired him back to the ice only five months after his own diagnosis. It also made him "proud and humbled" to be an inspiration to thousands of other cancer patients and to the hundreds gathered that evening in support of multiple myeloma research.

The Fall Gala's success was complemented by an auction of unique and impressive items and packages donated by MMRF supporters. Among several vacation packages auctioned were a 3-day VIP experience of the 2003 Grammy Awards (donated by Charles Ortner and the Academy of Recording



(L-R) Paul Giusti, Kathleen McCabe, Dana LaForge, Cynthia Anderson and Dr. Ken Anderson



Donna Zaccaro, Geraldine Ferraro and Scott Hamilton

Photos by Studio A



Sol Barer and Lori Ingber with Dr. Mohamad Hussein and Dr. Ivan Borrello

Arts and Sciences); a 12-day Mediterranean Sea Odyssey (donated by Silversea Cruises); a week-long Barbados vacation at the luxurious Crystal Cove Hotel (donated by Elegant Hotels); a romantic Italian getaway (donated by the Bauer Hotel and Villa d'Este) and VIP invitations for two to the Sportsman of the Year Celebration (donated by Sports Illustrated).

After meeting several long-time, avid supporters of the MMRF and learning that the evening would raise over \$1 million dollars, Hamilton proclaimed confidently, "you'll beat this -- I know you will beat this."

Gala Benefactors: (\$25,000)

Joseph J. Cassano
Celgene Corporation
Elizabeth Donald
Millennium Pharmaceuticals
SAAB Cars USA
World Wrestling Entertainment, Inc.

Gala Sponsors: (\$15,000)

Cell Therapeutics, Inc.
Jerry S. McDevitt, Esq.
The McMahon Family
Novartis Oncology
The Ortner Family
Tullett & Tokyo Liberty Investment Corp.
UBS Warburg

Dinner Chairs:

John Andrews
Chris Blackwell
Jeffery Epstein
Paul Giusti
Diana & Tom Maguire
Lori Marcus
William Morgan
Pam & Jack Santoni
Vincent Tomasi

MMRF - ANN LANDERS RACE FOR RESEARCH

Chicago Race Raises \$170,000 For Research



Runners at the start of the MMRF Race for Research

The MMRF-Ann Landers Race for Research, held September 21st in Chicago, IL, was a smashing success! Nearly 700 participants came out to the shores of Lake Michigan to walk or run the beautiful 5K course. In addition to having a wonderful time, event participants and sponsors helped raise over \$170,000 as well as a great deal of awareness for multiple myeloma.

A very special thank you goes out to Baxter International, the event's flagship sponsor. Mr. Alan Heller, Chief Operating Officer at Baxter, led over 125 of his employees out onto the course. Baxter helped to raise more than \$35,000.

The MMRF would also like to thank Tony Kesman, Robin Colon, Dr. Ann Traynor and her team, Bill Ligas, James Bond, Brian Feltzin, the Assink Family, Deb and Rob McVicker, the Sunko Family, Mary Prendergast and the Chicagoland myeloma community for all of their help in coordinating the event. We would also like to acknowledge the event sponsors who helped make the day the success that it was: Baxter International, Celgene Corporation, Fujisawa Healthcare, Levy Cares Foundation, Jay's Potato Chips, Tribune Company, Daily Herald, Gale Street Inn, NeoPharm, Allegiance Healthcare, Barton Beers and the Wrigley Corporation.

Race Photos by Deborah McVicker



Scott Santarella (center) with race winners Scott Stein and Susan Slade

An amazing effort from a wonderful, dedicated community! Thank you all.



Baxter International's Outstanding Team

Visit the MMRF's website at www.multiplemyeloma.org for the dates of the 2003 MMRF 5k Walk/Run Race for Research events:

San Francisco - April 13, 2003
Boston - May, 2003
Seattle - July 19, 2003
Philadelphia - September, 2003
Chicago - September 20, 2003
Atlanta - October, 2003

FUNDRAISING

Celebrate the Holidays With 1-800-flowers.com

Spread holiday cheer by ordering flowers and gifts through the MMRF's fundraising relationship with 1-800-FLOWERS.COM™. 1-800-FLOWERS.COM will give 10% of the net proceeds to the MMRF when you make a purchase and use the promotional code **MMRF** when ordering.

Send the freshest flowers, sweets, novelty items and giftware to friends and family near and far while supporting the MMRF this holiday season. Go to www.1800flowers.com or order by phone at 1-800-FLOWERS (1-800-356-9377).

*Items may vary and are subject to delivery rules and times. Offer valid online and by phone. Offers can not be combined, are not available on all products and are subject to restrictions and limitations. Offer valid through 9/1/03. Void where prohibited. 1-800-FLOWERS.COM™ uses Secure Socket Layer (SSL) encryption technology to secure its Web site.



Lester Knight

Chicago Awards Dinner

The MMRF will be holding the Chicago Awards Dinner on March 4, 2003, at the Four Seasons Hotel. The second annual Chicago Awards

Dinner promises to be a huge success.

Lester B. Knight, Founding Partner of RoundTable Healthcare Partners, is spearheading this year's event. An extremely well respected member of Chicago's business community, Mr. Knight will serve as the Event Chairman. He will have plenty of help toward reaching his fundraising goal for myeloma research. Baxter International, Allegiance Healthcare and AON Corporation will all be involved as corporate sponsors of the event. For sponsorship opportunities or more information, please call Craig Robertson, MMRF Director of Development, at (203)972-1250.

Teeing Off in New York For a Cure



Albany, NY: The first annual Albert G. Young Memorial Golf Tournament was held recently and raised over \$7,000 for myeloma research. The Young family, spearheaded by Tim Young, coordinated the event, which attracted over 70 local golfers. Special thanks goes out to the Young family, pictured above, and the numerous local businesses that helped make this inaugural event a big success.

Miles Conquer Myeloma in Connecticut

Goshen, CT: The second annual Miles Conquer Myeloma MMRF Race for Research was held on September 28th at the Canine Sports Center in Goshen, CT. Nearly 100 attended the event that raised over \$6,000 for myeloma research. Special thanks goes out to Nancy Wadhams and her two children, Andree and Gene Stone, for coordinating the event. The MMRF would also like to thank the many friends and businesses in the Torrington/Goshen area that made the event possible.

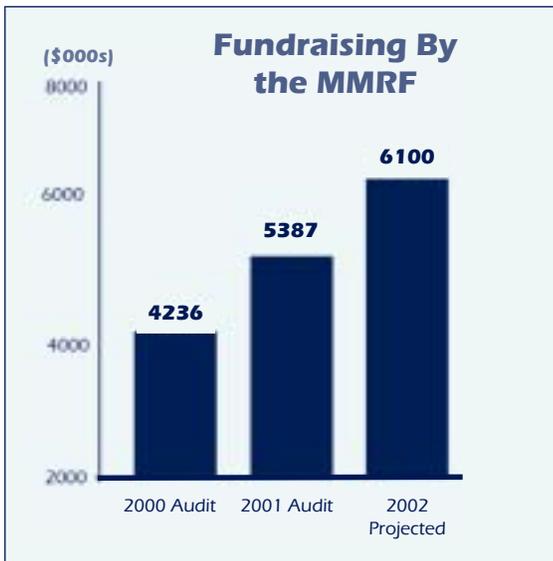


The Wadhams Family

Audit Reveals Commitment to Research

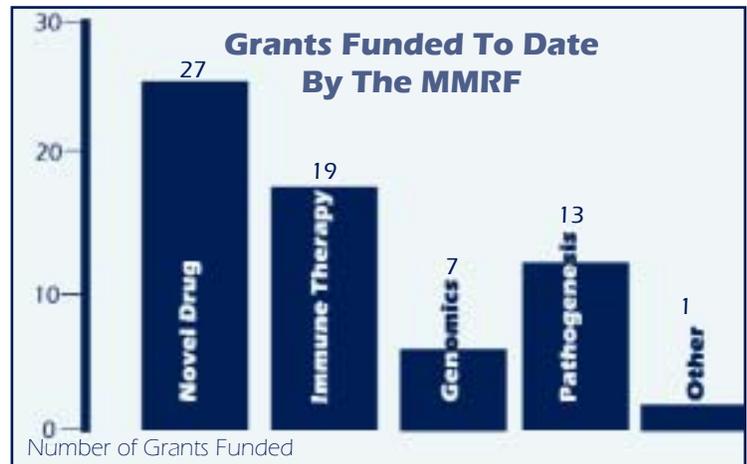
MMRF 2001 AUDIT REPORTS FISCAL RESPONSIBILITY NETS CONTINUED GROWTH

The MMRF is proud to report that an independent audit reaffirms our strong growth and fiscal responsibility. Specifically, our 2001 audit reported that the MMRF raised over \$5 million -- a 27% increase over 2000.



process used by the NCI. Many of our grant applications are focused on new therapeutic options such as targeted therapies and immune therapies. In fact, we have funded 27 grants on targeted therapies and 19 grant awards on immune therapy. As a result, we are seeing novel drugs like Velcade™, Revimid™, Genasense™ and Trisenox® enter clinical trials -- improving lives of myeloma patients worldwide.

It is our sincerest hope that you will help us to continue accelerating the search for a cure. Please donate today knowing that your support will fund much needed research.



Most importantly, the audit also reported that 93% of each dollar raised was applied directly to research and related programming. A mere 4% of funds were needed for the foundation's operating and administrative expenses and only 3% supported fundraising.



As a donor, you should feel proud to know that your support is invested in the most promising myeloma research in the world. All of the grant applications are put through a stringent review process, modeled after the

The MMRF funds more research grants on novel drugs than on any other topic, bringing new treatment options and hope to myeloma patients.

The MMRF applies 93% of its dollars raised to research and programming. As a basis for comparison, the non-profit industry's acceptable standard is 60%.

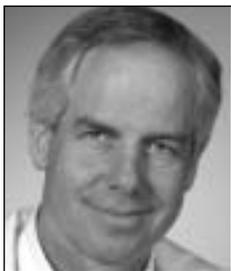
As a donor, you should feel proud to know that your support is invested in the most promising myeloma research in the world. All of the grant applications are put through a stringent review process, modeled after the

The MMRF Thanks the following corporations for their support of Myeloma Focus



THE MMRF AWARDS \$1.3M IN SENIOR GRANTS

The MMRF is proud to announce the funding of 13 Senior Research Grant Awards as part of our continuing commitment to support leading researchers in their pursuit of a cure for multiple myeloma. These awards provide a one-year, \$100,000 grant to investigators who have been working in blood cancer research for a minimum of five years. These recipients are leaders in myeloma research and are helping to accelerate the development and availability of promising new drugs. We are confident that this research will lead to significant breakthroughs in myeloma, and will provide patients with much needed hope and therapeutic options.



Bjarne Bogen, MD, PhD, University of Oslo
Title: Immunotherapy of MM: Reversal of Tolerance and Improved Id-Vaccination

An attractive possibility for treatment of multiple myeloma (MM) is to activate the immune system so that it attacks the myeloma cells. T lymphocytes that recognize the myeloma protein can successfully combat the MM cells in experimental models. Alas, in MM patients, the increasingly high myeloma protein concentration probably incapacitates (tolerizes) such T cells. We wish to understand the mechanism of T cell tolerance induction, reverse it, and apply powerful vaccination strategies so that T cells attack and eliminate residual MM cells.

Marta Chesi, PhD, Weill Medical College of Cornell University
Title: The Role of MMSET in MM



Many blood cancers originate from the dysregulation of critical oncogenes as a result of chromosomal rearrangements within the tumor cells. In the first few cases that these oncogenes have been specifically targeted, we have been able to develop more specific, effective and less toxic therapy (e.g. Gleevec®). In MM we have identified similar translocations and oncogenes, and we now propose to study their contribution in the pathogenesis of MM, hoping that they may represent novel therapeutic targets.



Daniel J. Donoghue, PhD, University of California, San Diego
Title: Pyk2 Phosphorylation by FGFR3 in MM

Multiple myeloma represents 10% of hematopoietic cancers. Mutations in the receptor protein, fibroblast growth factor receptor - 3 (FGFR3) occur in 25% of MM patients. We have demonstrated an interaction between FGFR3 and another important regulatory protein, Pyk2, which controls scheduled cell death of MM cells. We are exploring how the molecular mechanism whereby FGFR3/Pyk2 interaction contributes to the cancerous properties of MM cells.



Laurie H. Glimcher, MD, Harvard School of Public Health
Title: Is the Transcription Factor XBP-1 a Critical Target for Proteasome Inhibitors in MM?

A new class of drugs that inhibit a pathway in MM cells called the proteasome has proved amazingly effective in chemotherapy -- and stem cell transplant -- refractory patients. It is not clear, however, how these drugs work. We have cloned a new gene, XBP-1, that is vital for the development of plasma cells/MM cells, and we believe that this new class of drugs might be working via XBP-1. This proposal is designed to test this idea. Knowledge gained by these experiments should aid in the discovery and development of new agents for the successful treatment of MM.



Benedikt Kessler, PhD, Harvard Medical School
Title: Probing the Ubiquitin-Proteasome Pathway in MM

Multiple myeloma remains incurable and novel treatment approaches are needed that target mechanisms whereby MM cells grow and survive in the bone marrow. Encouraging results were obtained recently with a proteasome inhibitor that decreased tumor cell growth, and Phase II clinical trials demonstrated remarkable clinical activity, even complete responses, in patients with refractory,

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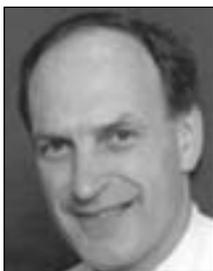
2002 SENIOR RESEARCH GRANT AWARD WINNERS

relapsed disease. We intend to define the underlying molecular mechanisms of this novel class of drugs in MM pathogenesis. These studies will provide the framework for development of more potent inhibitors and novel effective therapies.



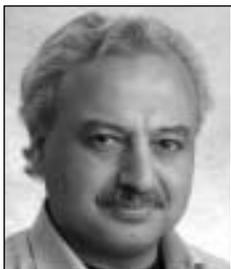
Weiqun Li, MD, Georgetown University Medical School
Title: Dissecting the PI3K/PTEN/Akt/NF-kB Pathway in Myeloma Malignant Transformation

Our laboratory has recently found that loss of a tumor suppressor gene, PTEN, is responsible for myeloma cell survival and growth through activation of a signaling pathway called PI3K/Akt/NF-kB. We would like to test if this pathway activation and PTEN deletion are also present in patients. We will also analyze if inhibitors targeting this pathway can effectively kill myeloma cells, either alone or together, with anti-myeloma drugs. Our results may provide new prognostic factors and novel treatment options for myeloma patients.



Derek Nigel John Hart, MB, ChB, DPhil, Mater Medical Research Institute, Australia
Title: Purified Blood DC Vaccination with MM

Dendritic cells (DC) are specialized white blood cells that initiate and direct the immune response. They circulate in small numbers in blood. Our basic science program has developed new blood DC counting technology and methods to collect these cells from patients. We now plan to optimize the techniques for clinical use in MM patients and to test them for safety and efficacy. We anticipate that application for this new technology will create a platform for large collaborative studies to optimize DC vaccination protocols, which harness the immune response to treat MM.



Surinder S. Sahota, PhD, Southampton University Hospital
Title: Identifying New Antigens for Targeted Therapy in MM

Active research is expanding therapeutic options available to treat MM. Our strategy is focused on using a novel

vaccine design, using a DNA cassette, to target myeloma-specific markers (or antigens) and elicit anti-tumor immune responses. We will use the observation that some antigens are common to germ cells and tumor cells, and use emerging technology to carry out a genome-wide comparison of germ cells and myeloma cells to identify gene that are expressed in both, but not in normal cells. This will allow a specific attack on myeloma antigens using our DNA vaccine.



Yu Tzu-Tai, PhD, Dana-Farber Cancer Institute
Title: Biologic Sequelae of CD40 Signaling in Human MM

CD40 is a protein expressed on the surface of B cells and a variety of tumor cells, including human MM. Since MM is a universally fatal disease characterized by infiltration of malignant plasma cells in the bone marrow, which migrate to the peripheral blood during advanced stages of the disease, understanding the mechanisms whereby CD40 regulates MM cell growth and migration may both enhance our understanding of MM progression and suggest novel therapies. This project will investigate CD40 activation mechanisms regulating MM cell migration and identify new potential drug targets for the treatment of MM and CD40-related diseases.



Amittha Wickrema, PhD, University of Chicago
Title: Glycogen Synthase Kinase 3 as a Potential Target for Therapy in MM

Multiple myeloma is a malignant blood disease that is incurable in most patients. Despite progress in understanding the biology of MM, patients lack effective long-term treatment for the disease. Our data show that glycogen synthase kinase (GSK3) plays an important role in regulation of myeloma cell proliferation. In order to uncover new modes of treatment, we will test two novel compounds in MM cells that have been shown to inhibit cell growth by blocking the enzyme activity of GSK3. These studies should provide pre-clinical data and reveal targets for therapy in myeloma.

2001 SENIOR RENEWAL GRANT AWARD WINNERS



Dr. Teru Hideshima, Dana-Farber Cancer Institute:
Using PS-1145 to Specifically Turn Off NF-kB in Studies of Human MM Growth

NF-kB is a switch in myeloma cells and bone marrow that promotes their growth in spite of conventional treatments. In this study, I will use PS-1145 to specifically turn this switch off in laboratory and animal studies of human MM growth. These studies will provide the basis for clinical trials of PS-1145 in MM.



Dr. Nicholas Mitsiades, Dana-Farber Cancer Institute:
Defining The Effects of TRM-1 on MM Cells

MM is a bone marrow cancer that responds poorly to traditional chemotherapy. TRAIL is a protein that kills cancer cells without affecting normal cells. As I have demonstrated, TRAIL is effective against MM cells, even

those that do not respond to chemotherapy, yet does not cause serious side effects. A Phase I clinical trial of TRM-1, a novel monoclonal antibody that mimics the actions of TRAIL, will soon begin in our Institute. In this proposal, I will define the effects of TRM-1 on MM cells, alone or in combination with other drugs.



Dr. Keith Stewart, Princess Margaret Hospital, Toronto, Ontario:
Developing A Website - The Myeloma Gene Index - To Catalog All Genes Expressed in Myeloma Cells

Multiple myeloma is caused by the activation of cancer genes by chromosomal rearrangement. We have been developing a website which we call the Myeloma Gene Index that would catalog all genes expressed in myeloma cells. We hope to use this information to develop a myeloma microarray (where all genes in myeloma cells are spotted on a glass microscope slide), a high throughput tool that would help us understand the differences among patients, thereby helping us in the future to tailor patient specific therapeutic strategies.



MMRF CLINICAL TRIALS MONITOR (CTM)

The MMRF Clinical Trials Monitor (CTM) currently lists more than 80 trials at more than 100 sites worldwide. CTM is continuously updated to include the most cutting-edge pharmaceutical and single-institution trials.

| Trials Posted on CTM | Contact Information |
|--|---|
| Assessment of Proteasome Inhibition for Extending Remissions (APEX) www.multiplemyeloma.org/ClinicalTrials/CTM-72.html | Visit the link to find more than 40 sites worldwide. |
| A Phase III Trial of Thalidomide + Dexamethasone versus Dexamethasone for Newly Diagnosed Myeloma www.multiplemyeloma.org/ClinicalTrials/CTM-70.html | Mayo Clinic (MN) Tami Simmons, CRA, (507) 266-0733 simmons.tamera@mayo.edu |
| A Phase II Trial of Study of Genasense in Combination with Thalidomide and Dexamethasone in Relapsed and Refractory MM www.multiplemyeloma.org/ClinicalTrials/CTM-74.html | University of Maryland Greenebaum Cancer Center Ashraf Badros, MD, (410) 328-1230 abadros@umm.edu |
| A Multicenter, Controlled, Parallel-Group, Randomized, Open-Label Study to Evaluate the Efficacy and Safety of CC5013 Dose Regimens When Used Alone or in Combination with Dexamethasone for the Treatment of Subjects With Relapsed or Refractory MM. www.multiplemyeloma.org/ClinicalTrials/CTM-68.html | Dana Farber Cancer Institute Kathy Kelly, RN, 617-632-6303, kakelly1@partners.com St. Vincent's Comprehensive Cancer Center Syed Rizvi, 212-367-1885 Mayo Clinic Ann Birgin, birgin.ann@mayo.edu |

MMRF ROUNDTABLE ON NOVEL TARGETED THERAPEUTICS

Bringing New Therapies from the Bench to the Bedside

The MMRF's ninth Research Roundtable session accomplished an amazing feat -- it brought together leading clinicians and researchers from academia, the pharmaceutical and biotech industry, along with the National Cancer Institute (NCI). The focus of the roundtable was to discuss new and promising therapies for myeloma, how they fit into the overall scheme of myeloma treatment and ways to move them into clinical trials -- and to patients -- more quickly.



Guest Speaker: Edward Sausville, MD, PhD. Associate Director, NCI

The roundtable was held October 4-5 in New York

City, and was co-chaired by Kenneth Anderson MD (Dana-Farber), Bart Barlogie MD, PhD (Arkansas Cancer Research Center), James Berenson MD (Cedars Sinai) and William Dalton MD, PhD (Moffitt Cancer Center). The session was funded by the MMRF with support from Celgene, Cell Therapeutics, Genta, McCarty Cancer Foundation, Millennium Pharmaceuticals, Novartis Pharmaceuticals and Genentech.

There was an exciting exchange of information that identified promising compounds based on their specific mechanisms of action (see table below), to determine what compounds might work well together, and to identify the trials needed to get these compounds tested quickly. "We have new treatments from all angles -- from treating myeloma itself to treating bone disease -- there are a lot of new possibilities," Dr. Berenson noted. "For the first time, a lot of the basic myeloma research in the laboratory has actually reached the patient's bedside."



According to Dr. Anderson, one of the most important outcomes of the meeting was that the participants discussed ways to conduct trials faster and more efficiently by having institutions work together. "This will help provide novel effective therapies to our patients more quickly."

(Top Row) L-R: Julian Adams, MD, PhD, Millennium, Bart Barlogie, MD, PhD, and Jim Berenson, MD, Ken Anderson, MD, Bill Dalton, MD
(Bottom Row) L-R: David Stirling, PhD, Celgene, Anne Quinn Young, MPH, and Kyle Chan, PhD

Novel Targeted Therapeutics for Multiple Myeloma

| Agents that target the tumor and its microenvironment | | Agents that interrupt cell signaling pathways | |
|---|------------------------------|---|-------------------------|
| Thalomid® (thalidomide) | IMiDs™ | Panzem™ (ZME2) | Genasense™ |
| Velcade™ (PS-341) | Trisenox® (arsenic trioxide) | FTI-R1 15777 | JNK inhibitors |
| | | Mcl-1 inhibitors | |
| Therapies that target tumor sites | | Novel supportive therapies | |
| PTK787 (VEGFR inhibitor) | BLyS™/TRAIL | Zometa® (zoledronic acid) | RANK - Fc |
| Anti-CD40 | Neovastat™ | Osteoprotegerin (OPG) | AP23451 (Src inhibitor) |
| PD173074 (FGFR3 inhibitor) | | MIP-1α-receptor antagonists | |

ASK THE EXPERT



Dr. S. Vincent Rajkumar

This issue's **Ask the Expert** features Dr. S. Vincent Rajkumar, Consultant in the Division of Hematology at the Mayo Clinic and Associate Professor of Medicine at the Mayo Medical School, Rochester, MN.

1. Dr. Rajkumar, why is neuropathy so common in patients with myeloma?

Neuropathy is a nerve disorder that can result in abnormal sensations, such as burning or tingling, or pain.

It usually occurs because there has been some type of nerve damage. The reasons why patients with myeloma often experience neuropathy have to do with the disease itself and some of the medications used to treat it.

In some instances, the monoclonal paraprotein can be directly toxic to nerve cells. This is because the paraprotein is itself an abnormal immunoglobulin (antibody), which can react with the covering of the nerve (the myelin sheath) and damage it. In about 10% of patients, fragments of the paraprotein (amyloid protein) can be deposited on the nerve, damaging it (see figure right).

Neuropathy is also a side effect of certain medications. One of these is vincristine, a component of VAD (vincristine-adriamycin-doxorubicin) therapy, one of the most common regimens for myeloma. A number of patients who receive thalidomide for extended periods of time (longer than 6 months) may also experience mild neuropathy. We're not sure why this occurs, but in some way the drug affects the nerves.

2. How is neuropathy managed?

If neuropathy is present, treating the disease will help control the neuropathy. With monoclonal gammopathies that are not normally treated (MGUS, smoldering myeloma, etc.), patients may require treatment if the neuropathy is progressive or causing significant symptoms. Treatments include plasma exchange, which physically removes the excess paraprotein

from the blood; intravenous immune globulin, which is believed to decrease the production and activity of the damaging paraprotein; interferon; or sometimes chemotherapy.

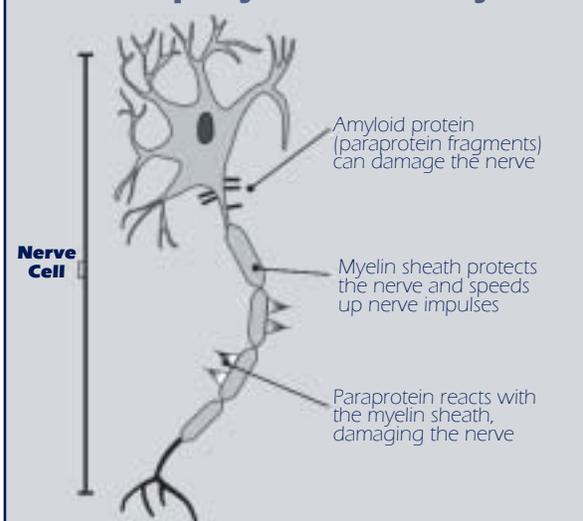
If neuropathy is due to vincristine, a physician may try to limit the use of VAD by using dexamethasone alone or simply omitting the vincristine. Stopping the drug usually leads to resolution of the neuropathy. With thalidomide, the drug can be stopped and restarted at a reduced dose. If a patient has limited options for therapy and there is a reluctance to stop thalidomide, a physician may slowly lower the dose and try to maintain a response.

There are also medications that can provide symptomatic relief of neuropathy, particularly when it is severe or interfering with activities. These include carbamazepine (Tegretol®), as well as drugs such as amitriptyline, sertraline (Zoloft®), and gabapentin (Neurotonin®), which have been shown to be effective in relieving symptoms.

Simple supportive care measures like moisturizing lotions and comfortable, well-fitting footwear can help. Because of sensory loss in the hands and feet, patients may not realize when something is hurting them (eg, when handling or being exposed to hot or sharp objects). Therefore, proper care to prevent complications is important.

According to a recent MMRF survey of 2,123 patients, 39% of respondents noted neuropathy as a symptom that was most difficult for them to deal with.

How Neuropathy Can Occur in Myeloma



Medical Corner

Genetics: Key to the Molecular Management of Myeloma

Genetic studies hold great promise in helping us manage myeloma. Although various genetic findings are already being utilized and further evaluated as prognostic factors, genetic studies are starting to be used to diagnose and stage patients more accurately, to determine how a patient might respond to therapy and most importantly, to identify new targets for therapy.

In this issue's **Medical Corner**, Leif Bergsagel, MD, Associate Professor of Medicine at Weill Medical College and John Shaughnessy, Jr., PhD, Director of the Lambert Laboratory of Myeloma Genetics at the University of Arkansas, provide insight into this exciting field.



Leif Bergsagel, MD

How Genetics are Studied

Until recently, genetic studies were limited to chromosome analysis of a patient's myeloma cells to identify abnormalities in chromosome structure or number. This is done through conventional karyotyping or fluorescence in situ hybridization (FISH).

Today, many new techniques are being used. Genes are composed of DNA, which is expressed as RNA, and becomes translated into proteins in a cell. New microarray technologies are being used to study thousands of genes at a time at each of these levels. For example, techniques such as Genetic Profiling are used to study genes at the DNA level. Gene Expression Profiling, pioneered by Dr. Shaughnessy, is used at the RNA level.

The Gene Expression Profile of the RNA reflects the end result of all of the underlying genetic abnormalities present. One can think of this as the "smoke" pointing towards the underlying defects in the DNA -- the "fires" that are detected by Genetic Profiling. These techniques provide unique "fingerprints" for each patient and identify considerable genetic variation in myeloma.

Diagnosis and Staging

According to Dr. Shaughnessy, genetics are beginning to be utilized in the "molecular management of myeloma" in many ways. One of these is for diagnosis and staging. The ultimate goal is to establish profiles of patients with myeloma and normal individuals, as well as patients with MGUS and other plasma cell disorders, in order to accurately diagnose and stage the disease, and to determine prognosis and appropriate treatment. "For example, we'd like to use these genetic fingerprints to identify patients with smoldering myeloma (SMM) who might be at high risk for progressing to active myeloma," noted Dr. Shaughnessy. Although most patients with SMM would not normally be treated, these high-risk patients could then be monitored more closely, and possibly even be treated early.

Dr. Bergsagel notes that specific chromosome translocations (the joining of parts of two different chromosomes) appear to be the initiating genetic defect in myeloma and can also identify homogeneous groups of patients that share a similar prognosis. Importantly, this grouping appears independent of other prognostic factors, suggesting that the translocations are in fact identifying different diseases that all fall within the category of "myeloma." This is similar to what has been found in many leukemias and lymphomas.

Determining Response to Therapy

The treatment outcome for patients with myeloma is highly variable, and there is currently no good way to identify which patients will do better on one particular therapy over another. Although research in this area is still in its infancy, Genetic Profiling is beginning to be incorporated into clinical trials to better characterize genes that may affect response to therapy.

The way this works is that patients entering a trial have a baseline genetic analysis performed. "These patients are then fol-



John Shaughnessy, Jr., PhD

Medical Corner

lowed to see how they respond to an individual treatment and we will try to identify particular genetic 'signatures' associated with outcome," noted Dr. Shaughnessy (see figure to the right). When these are identified, future patients would be profiled and treated based on which profile they fit.

Researchers are also following patients' genetic profiles as they receive therapy in order to identify genes associated with development of drug resistance. "If a common pattern is seen across a group of patients who develop resistance, we can try to determine the specific mechanism of resistance and try to develop new drugs that get around it," noted Dr. Shaughnessy.

Identifying New Treatment Options

According to Dr. Bergsagel, genetic studies are key to identifying new treatment options for myeloma. "For example, it appears that important genes (tumor suppressor genes) get lost when chromosome deletions occur, while other genes (tumor-causing genes) are amplified when chromosomal regions are gained by duplication," he noted. "If we can identify these genes, we can identify the specific cellular pathways that are affected. We can then find drugs that will correct the defect and treat the disease."

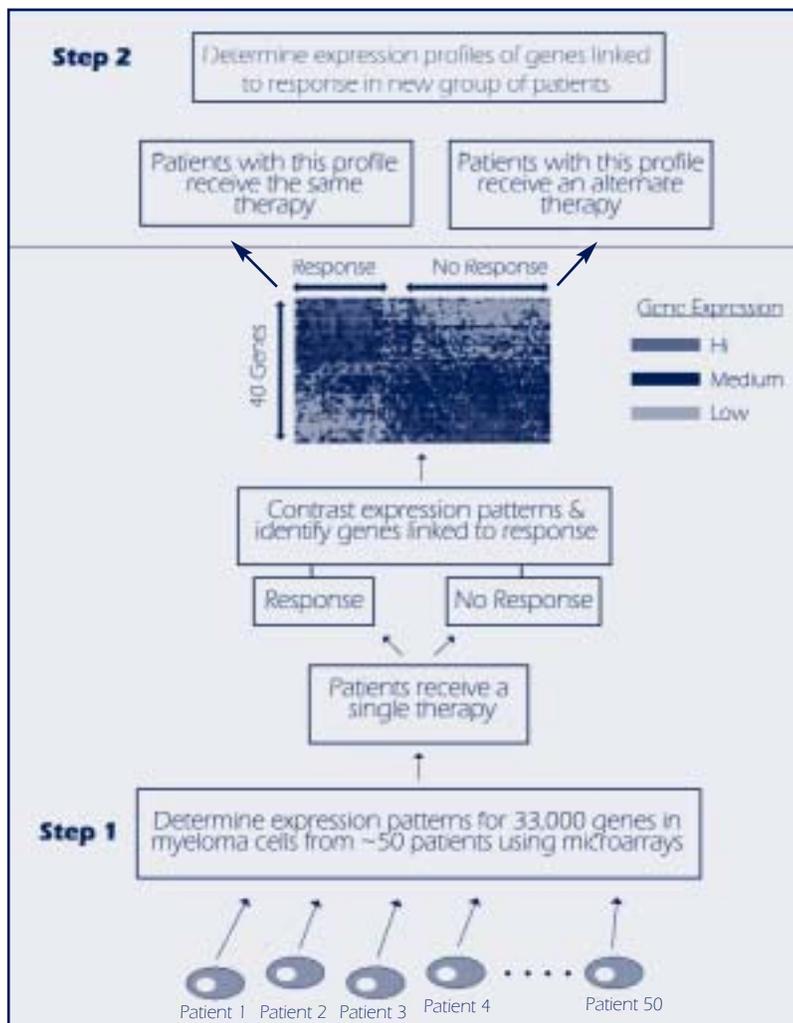
Genetic analysis holds the promise of targeted therapy for myeloma. Comparison of the number of DNA copies of thousands of individual genes in myeloma cells compared with normal cells can pinpoint the genes that are gained and lost in myeloma. These abnormal genes represent the "fire" that can turn on a whole program of gene expression (RNA): the "smoke." This "fire" represents very attractive potential targets for directed myeloma therapy. Genetic Profiling and Gene Expression Profiling will ultimately lead to individualized treatment regimens.

Genetic analysis has already led to the identification of several potential targets, as well as novel targeted therapies. For example, a particular genetic defect noted in about 15% to 20% of patients -- a translocation known as 4:14 -- appears to turn on two genes associated with cancer. One of these is the gene for fibroblast growth factor receptor-3 (FGFR3) and the other is MMSET. "We have pinpointed a genetic defect that can initiate

myeloma, and we are testing several drugs that may be able to target this genetic defect," noted Dr. Bergsagel.

By characterizing other translocations present in myeloma, several critical cancer genes have been identified, including cyclinD1, c-maf and c-myc. According to Dr. Bergsagel, "We have to be cautious, though, because the genetic defects in myeloma are very complex." It's likely that these targeted therapies will have to be used as part of combination therapy, perhaps a cocktail individualized for each patient's particular set of genetic defects.

Taken together, genetic studies are truly helping us understand the complexity of myeloma and offer much promise for future therapies.



INDUSTRY UPDATE

Combination Thalidomide and Dexamethasone Therapy Effective for Newly Diagnosed Myeloma

Results of the first peer-reviewed study evaluating the use of the combination of thalidomide and dexamethasone in newly diagnosed myeloma were published in the November 1, 2002 issue of *Journal of Clinical Oncology*. The data show that the oral regimen is a feasible and active regimen for the initial treatment of myeloma. This issue's Expert, Dr. S. Vincent Rajkumar of the Mayo Clinic (see page 11), was primary author of the article.

The study involved 50 patients with symptomatic, newly diagnosed myeloma, most of whom had high-risk disease. Patients received thalidomide at 200 mg/day, in addition to dexamethasone on a monthly cycle. After 4 cycles of therapy, patients could pursue stem cell harvest and transplantation if eligible.

A confirmed response, defined as a reduction of serum and urine M protein by at least 50%, was seen in 32 patients (64%). An additional 14 patients had stable disease (see table right). Altogether, 92% of patients had achieved at least a 25% reduction in M protein. A response to therapy was accompanied by improvements in blood cell counts and symptoms.

The response rate seen is similar to that expected with intravenous vincristine, adriamycin and dexamethasone (VAD) and the regimen merits further study as an oral alternative to VAD

and other chemotherapy regimens currently used as initial therapy for myeloma in preparation for stem cell transplant.

Overall, the combination was well tolerated. The most common minor side effects were constipation, sedation, neuropathy, edema, infection, and bone pain. Major toxicities were observed in 16 patients (32%) and the most common were deep vein thrombosis, constipation, difficulty breathing and rash.

At this point, Dr. Rajkumar is recommending a randomized trial comparing the combination to other standard therapies before it is incorporated into routine clinical practice as initial therapy for newly diagnosed myeloma. In this regard, he is leading an Eastern Cooperative Oncology Group (ECOG) Phase III trial comparing thalidomide and dexamethasone versus dexamethasone alone as induction therapy for patients with previously untreated myeloma.

Responses Seen with Combination Thalidomide Plus Dexamethasone in Newly Diagnosed Myeloma

| Response (reduction in M protein) | # Patients (%) |
|------------------------------------|----------------|
| Confirmed response ($\geq 50\%$) | 32 (64%) |
| Stable disease (25% - 49%) | 14 (28%) |
| Progressive disease ($< 25\%$) | 4 (8%) |

You Need To Know

Salamanca

The MMRF will be attending the IXth International Workshop on Myeloma in Salamanca, Spain from May 23-27, 2003. The congress, which takes place every other year, focuses on continuing to educate and raise discussions on the scientific progress made in the experimental, clinical and therapeutic areas of multiple myeloma. Poster sessions, oral sessions and meet the expert sessions will be scheduled to promote interaction with recognized leaders in multiple myeloma research.

ASH Webcast

This December 6-10, 2002, in Philadelphia, PA, marks the date for the 44th Annual American Society of Hematology Meeting

and Exposition. The MMRF will be broadcasting a webcast from this meeting, which will be hosted by the leading myeloma researchers speaking at the Corporate Friday session. Information will also be based on the new announcements made over the weekend regarding breakthrough research.

Teleconference: "Updates from ASH"

The MMRF will host a free teleconference with Cancer Care on December 19th, from 1 PM to 2 PM, EST. The call will focus on the announcements made at this year's annual ASH meeting being held in Philadelphia. Dr. Ken Anderson and Dr. Jean-Luc Harousseau will be the hosts of the teleconference.

MEET OUR BOARD

Al Heller

When Kathy Giusti came into Al Heller's office 6 years ago, he knew that what she had to say was important. As her manager (and Chief Operating Officer at Searle, a Chicago-based pharmaceutical company), he quickly raced through arguments in his head of how to convince her to stay, in preparation for what he thought would be a resignation notice. He could never have predicted that, instead, Kathy was coming to inform him of her diagnosis with an incurable disease. The conversation turned personal and emotional; and though Al had never heard of multiple myeloma before that day, he became instantly interested and attached to the cause of finding a cure.

Al's longstanding and accomplished career includes over 20 years at G.D. Searle & Co., ultimately as the Co-President and Chief Operating Officer. He led the launch of some of the company's most successful pharmaceutical introductions and established his standing as a leading pharmaceutical executive. His incredible experience and insight made him an obvious choice to serve on the MMRF Board. He was among the first people Kathy invited to be a part of the newly formed MMRF in 1998.

Kathy knew that Al's in-depth knowledge and expertise would be a critical asset to the board's strategic approaches to supporting targeted therapies. He,

on the other hand, knew that the experience would be exciting and rewarding. "I knew that the same drive that put Kathy on the fast track at Searle would be applied to the objectives of the foundation. There was no doubt in my mind that it would be a great success, and I was more than willing to help out in any way that I could."



Al Heller

Since then, some of Al's greatest contributions to the MMRF have come in the form of helping to broaden support in the Midwest region. As a key player in the 1999 MMRF Chicago Gala—one of the foundation's most successful fundraisers featuring Paula Zahn and actress Bonnie Hunt, and a critical supporter of the most recent 5K Walk/Run in Chicago, Al, now a Senior Vice President of Baxter Healthcare Corporation and Baxter World Trade, is more than living up to his promise to help.

Al has also brought his business-minded expertise to the foundation's financial planning and review. He sits on the Board's Audit Committee, which recently reviewed the MMRF's 2001 audit. According to him, the numbers point to great news. "From a business standpoint, the MMRF has every sign of a well-run organization. It keeps its expenses way down and its support for research has grown exponentially since I've come on board." Thanks in part, no doubt, to the strategic leadership he provides.



DATES TO REMEMBER

December 19, 2002 Teleconference

Update from ASH hosted by Ken Anderson, MD, Dana-Farber Cancer Institute and Jean-Luc Harousseau, MD, University Hospital Nantes, France. Noon to 1 PM, EST and available thereafter for one year.

February 7-8, 2003 Miami, FL

*Institutional Insights on Myeloma.

March 1, 2003 Mystic, CT

"Friends Together" Gala Dinner
The first annual "Friends Together" Gala will be held at the Mystic, CT Marriott. For more information, please contact Christine Cardillo at chcardill@aol.com.

March 4, 2003 Chicago, IL

Chicago Awards Dinner will be held at the Four Seasons Hotel. For more information, please contact Craig Robertson at 203-972-1250.

March 6-7, 2003 Boston, MA

*Institutional Insights on Myeloma.

March 25-26, 2003 Cleveland, OH

*Institutional Insights on Myeloma.

May 23-27, 2003 Salamanca, SPAIN

IXth International Workshop on Multiple Myeloma

June 20, 2003 New York, NY

*Institutional Insights on Myeloma.

Continual Programs:

MMRF Webcast

<http://multiplemyeloma.org>

Past Myeloma Teleconferences

www.multiplemyeloma.org/events/teleconference.html

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www.multiplemyeloma.org/events/seminars.html or call (203) 972-1250

MMRF INSTITUTIONAL INSIGHTS



INSTITUTIONAL INSIGHTS ON MYELOMA

The MMRF's Institutional Insights program recently held symposia in Philadelphia at the University of Pennsylvania School of Medicine and in New York City with Weill Medical College of Cornell University. Dr. Edward Stadtmauer chaired the Philadelphia program and Dr. Leif Bergsagel chaired the New York City program. The MMRF would like to thank all of the speakers for their time dedicated to and in support of our programs.

The September 24th program in Philadelphia proved to be a great success with over 280 patients and 86 professionals attending. The MMRF would like to thank BettyAnne Williams, who was instrumental in marketing the program, along with the Philadelphia Multiple Myeloma Networking Group, Gabrielle Schmitt, and the Wellness Center. The speakers were Dr. Phil Greipp, Dr. Paul Richardson, Dr. David Roodman, and Dr. Donna Weber.

The New York City program, held October 3rd, hosted over 400 patients and caregivers. The MMRF would like to thank Carol Goldschein, Sue Korn, Gabrielle Schmitt, Jo Cavallo, Laurie Goldschein and Jonathan Solar for their help with registration, as well as Jay Levy who wrote the following article about the program.

A Patient's View: New Hope in the Battle Against Multiple Myeloma by Jay Levy, Ridgewood, NJ

The outlook for multiple myeloma patients is optimistic as researchers are making dramatic progress in the battle against myeloma. That was the message to over 400 patients and their caregivers earlier this month who attended the MMRF Institutional Insights program in NYC titled, *Novel Therapeutic Approaches in the Treatment of Multiple Myeloma*. Some of the highlights of the meeting are summarized here.

*Dr. Niesvizky explained how malignant plasma cells cause the various symptoms of the disease and emphasized that renal disease, infec-

tions and bone damage can now be prevented and treated.

* Dr. Roodman discussed the effectiveness of the bisphosphonates Aredia® and Zometa® in arresting bone destruction and described new compounds in development for treating bone disease.

* Dr. Barlogie espoused the need for an aggressive and integrated plan of attack against myeloma. He also discussed the benefits of tandem (multiple) stem cell transplants and the effectiveness of dose-intensive therapies.

* Dr. Bergsagel, host of the symposium, described several mutations that lead to the development of malignant plasma cell tumors. The objective is to develop specific drugs to target these fundamental abnormalities.

* Dr. Anderson reported that preliminary results from a Phase II trial of Velcade™

and a Phase I/II trial of Revimid™ indicate that the majority of the patients evaluated so far respond to the drugs or were stable.

This writer, a myeloma patient himself, and his wife and others at the meeting, were impressed and heartened by the upbeat mood and tone that prevailed. This was influenced in part by the positive news that was being reported, but also by the obvious commitment and dedication of the MMRF staff that organized the meeting and by the doctors making the presentations.



Philadelphia II Meeting (L-R): Dr. Edward Stadtmauer, Anne Quinn Young, Dr. Paul Richardson, Gabrielle Schmitt, Dr. Phil Greipp, Dr. David Roodman, Sarah Davis, Dr. Donna Weber (not pictured)



NYC II Meeting: (L-R) Dr. Leif Bergsagel, Dr. David Roodman, Sarah Davis, Dr. Ken Anderson, Scott Santarella, Jill Shook, Gabrielle Schmitt and Dr. Ruben Niesvizky. Dr. Bart Barlogie not pictured.

THANK YOU TO ALL OF OUR SPRING ANNUAL APPEAL DONORS

The MMRF's Spring Annual Appeal resulted in a tremendous showing of support. As of press time, over \$75,000 has been raised by more than 500 generous supporters. These overwhelming results bring us closer to our Annual Appeal goal of \$150,000. With the Fall Appeal soon to hit mailboxes, we have an excellent chance to exceed our goal by the end of the fiscal year on December 31st.

MMRF President, Kathy Giusti, is touched by the outpouring of support. "I am so grateful to the individuals and corporations who have supported this effort. Their generous support of this initiative is crucial to our success and has a direct impact on the

services that we are able to provide and the research that we are able to fund. The investment that people are making today is providing hope for tomorrow."

This year's Annual Appeal is nearing the homestretch. Today, more than ever we need your help. Please consider joining the hundreds of people who have already supported this wonderful effort and help us reach our goal. For more information on the Annual Appeal, please contact MMRF Development Director, Craig Robertson, at (203) 972-1250.

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Ann Curry enjoys a moment with NBC Colleague, David Bloom and with Lori & James Marcus of New Canaan.



(L-R): Robert Wolf, Linda McMahon, Karen Andrews and Vincent McMahon