MYELOMA TODAY

SUMMER 2008
VOLUME 7 NUMBER 7

A Publication of the International Myeloma Foundation

Dedicated to improving the quality of life of myeloma patients while working towards prevention and a cure.

Scientific & Clinical News

Dr. Brian Durie, IMF Chairman and Scientific Advisor and multiple myeloma specialist at the Cedars-Sinai Comprehensive Cancer Center in Los Angeles, reports on the **2008 IMF Scientific Advisory Board Retreat** with an overview of the meeting agenda, a discussion pertaining to response criteria, and a recap of ongoing activities within the IMF Bank On A Cure® research project, as well as other initiatives. Dr. Durie also addresses the recent FDA approval of bortezomib (VELCADE®) for frontline treatment of newly diagnosed myeloma patients. ***PAGES 7***

Dr. S. Vincent Rajkumar, IMF Scientific Advisor and Professor of Medicine at Mayo Clinic, talks with *Myeloma Today* about significant myeloma-related presentations made at the 44th annual meeting of the **American Society of Clinical Oncology**, including his findings from the Phase III Eastern Cooperative Oncology Group frontline trial of lenalidomide (Revlimid®) and other highlights. Dr. Rajkumar also offers his opinion on complete response and very good partial response as appropriate end points and predictors of eventual overall survival. ***PAGE 10***

Prof. Dr. Hermann Einsele, IMF Scientific Advisor and chairman of the **German Multiple Myeloma Study Group**, discusses the group's current research activities, the work of his team at the Würzburg University Hospital, and the state of available myeloma treatments in Germany in frontline and relapsed/refractory disease, both within and outside the clinical trial setting. He also comments on the strong relationship that has been established in Germany between the medical and the patient communities. ***PAGE 9***

Special Event

The 2008 IMF Support Group Leaders' Retreat is recapped by myeloma patient **Paula Van Riper**, leader of the Central New Jersey Myeloma Support Group. The ninth annual retreat, which had 70 leaders and 125 participants in attendance, provided training and leadership for the representatives of the myeloma patient and caregiver communities from across the US, Canada, and Europe. Paula summarizes the event agenda and spotlights the three new technology-based IMF initiatives introduced at the retreat.. ***PAGE 16***

LOOKING FOR A LOCAL MYELOMA SUPPORT GROUP?

If you are interested in joining a support group, please visit our website at **www.myeloma.org** or call the IMF at **800-452-CURE** (2873).

Profiles in the News

Loraine Boyle, a member of the **IMF Board of Directors** and wife of the actor Peter Boyle, has been involved with community organizations and fundraising efforts for many years. After Peter's battle with myeloma, Loraine has remained proactive in helping to put an end to this disease. Through the Peter Boyle Memorial Fund, she has chaired a new annual event for the IMF, an evening of comedy to raise funds to support research and to raise public awareness of myeloma. ***PAGE 4***

Dr. Sagar Lonial, a new member of the **IMF Scientific Advisory Board**, became interested in the field of myeloma about five years ago. He splits his time between a clinical practice, laboratory work, and writing or reviewing clinical trials at the Winship Cancer Institute of Emory University in Atlanta, GA. In an introductory interview with *Myeloma Today*, Dr. Lonial shares his excitement about the new science that is broadening the scope of available treatment for myeloma and improving patient outcome. ***PAGE 5***

Joanna FitzPatrick talks about joining the ranks of "e-patients" as a result of her husband's myeloma diagnosis. Like many others, she turned to the Internet to access valuable information, enhance her education about the disease, and seek emotional support from others coping with myeloma. Through the myeloma listserv, Joanna has found hope and a compassionate and knowledgeable community of patients and caregivers, united in the fight against myeloma and determined to find its cure. ***PAGE 19***

Supportive Care

IMF Hotline Coordinators, who answer your questions and emails to help you address the various aspects of myeloma in a more informed way, respond to an inquiry about maintenance therapy following a stem cell transplant. ***PAGE 14***

Page Bertolotti, RN, BSN, OCN, talks with *Myeloma Today* about gastrointestinal side effects associated with anti-myeloma therapies. These side effects – constipation, diarrhea, nausea, and vomiting – are some of the most manageable side effects of cancer therapy, and may be treated with appropriate medical interventions, thereby minimizing their impact on the patient's quality of life and adherence to therapy. ***PAGE 13***

Also in this issue...

This issue of *Myeloma Today* is supported by Celgene Corporation, Millennium Pharmaceuticals, and Ortho Biotech.

International Myeloma Foundation

Headquarters

12650 Riverside Drive, Suite 206, North Hollywood, CA 91607-3421 U.S.A.
Tel: 818-487-7455 or 800-452-CURE (2873)
Fax: 818-487-7454 E-mail: TheIMF@myeloma.org Website: www.myeloma.org

International Myeloma Foundation

Dear Reader,

By now, many of you are aware that the IMF formed a Nurse Leadership Board (comprised of 19 nurses from institutions around the country), and have been following the many achievements of this Board. The IMF is very proud of the NLB, their dedication, and their determination to establish an entity that would improve the lives of myeloma patients and the care they receive. Nurses ensure optimal care as they are the crucial link between the patient and the doctor.

You read that they had an abstract accepted at the International Myeloma Workshop that took place in Kos, Greece last summer – an unprecedented accomplishment for nurses. Many of you have had the pleasure of meeting members of the NLB as they have participated at our Patient & Family Seminars and know first hand how they are helping to re-shape the way patients are cared for across America.

In the age of novel therapies, it became clear that nurses who care for patients needed guidelines on how to manage the side effects often associated with these new drugs. As wonderful as they are – and they are – they also come with some challenges. The good news is that the challenges patients experience – side effects – can be properly managed to allow patients to achieve the maximum benefit of these novel drugs, putting them into good long-term remissions and getting their day-to-day lives back on track.

The abstract was just the beginning of what would become Managing the Side Effects of Novel Agents for Multiple Myeloma: Guidelines and Patient Education Sheets from the International Myeloma Foundation Nurse Leadership Board, recently published in the Clinical Journal of Oncology Nursing. These guidelines cover the most common side effects often associated with novel therapies.

They include: myelosuppression, thromboembolic events, peripheral neuropathy, gastrointestinal side effects, and steroid-associated side effects.

Next project for the NLB is the Long-Term Care Taskforce, which you'll read about in this issue in the interview with Elizabeth Bilotti, who is the taskforce leader on the project. She is an MSN at St. Vincent's Comprehensive Cancer Center in New York.

Our goal is to ensure that every nurse has a copy of the Guidelines, and I encourage you to contact the IMF for a free copy of this important paper and take it to your nurse on your next visit.

We're extremely proud of the NLB and are very grateful to them for all their hard work and dedication to helping patients.

As always, if you have any thoughts or suggestions you'd like to share, please don't hesitate to contact me.

Warm regards,

Susie Novis

Letters to the IMF

The Hotline

Thanks for your thoughtful response to my inquiry about maintenance. It must be stated that your organization is a godsend to me. My information needs sometimes present themselves so suddenly that there is not sufficient time to research them effectively and that is where you come in. I try to plan and anticipate my information needs but even that sometimes fails me. Thanks for being able to answer questions.

Ellen Barrett

I guess one really needs to be one's own advocate if at all possible. The IMF has, and continues to be, a great source of information and support for me. There truly are no words to say how much it continues to mean to me, knowing that you folks are there. It is a true blessing and a gift beyond measure.

Ann Milstead

Seattle IMF Patient & Family Seminar

I want to send my compliments for your well-organized recent meeting in Seattle. Dr. Durie was great as Chairman of the program and his sense of humor was appreciated. Dr. Vescio was very patient with our questions in the breakout sessions, and we appreciated his courtesy. The hotel facilities were perfect. Best wishes for continued success.

Joseph & Jean Buhaly

The IMF

I don't think that I am alone in saying that I had never even heard of multiple myeloma before I was diagnosed, so the first thing I did was research what I had. The old dire statistics and web references were a somber slap that I was in deep trouble. Dark beginnings to a lonely and hopeless journey? My doctor told me at my first visit, almost nine years ago, "Don't think of this as a death sentence. Get all the information you would like, but know that information is from statistics. It is not about you. You are not a statistic. If you want to know about you, you talk to me." Those golden words were full of hope. So I began to look for information, not statistics. And I found the IMF. The IMF opens doors to hope. The IMF is where one could turn for support, communication with peers, an online list serve, Patient & Family Seminars, medical and clinical trial information, an opportunity to add to research (especially Bank on a Cure®), and just the empowerment of knowing one is not alone. No doom, no gloom, but real current information, support, and fellowship. Real people, not statistics. A light in the darkness! I was changed from a "myeloma victim" mindset to an individual with a life to live who also has myeloma. I became full of the knowledge that I'm not the first to experience this journey, and I'm not the last, but surely, I'm not alone. Thank you for opening the "doors to hope."

Hal Gleason

Please note that David Smith, IMF Executive Director, has legally changed his name to David Girard. Years of confusion with so many others of the same name have made this change necessary. David's new email address is dgirard@myeloma.org. If you have any questions, please call him at the IMF.

MYELOMA TODAY IN CONVERSATION WITH LORAINE BOYLE

Please tell a little about your professional background.

My background is in journalism, as a writer and editor. I wrote mainly about music and personalities for *Rolling Stone*, the *New York Times*, the *Detroit Free Press*, and other publications.

How did you meet your husband, the actor Peter Boyle?

In 1974, I was living in New York, but I went out to Los Angeles to work on a story about Mel Brooks, who was in the middle of filming *Young Frankenstein*. Peter starred in that film, and we met on the set. We were married in 1977.

Loraine Boyle

Did you continue to work in your profession?

Yes, until we started our family. After Lucy and Amy were born, I concentrated on being a wife and mother. Once the children started school, I became involved in several New York City community organizations. I volunteered for the Carl Schurz Park Association, the Chapin School Parents Association, and the Asphalt Green athletic facility. My volunteerism was focused on areas that involved my children and my community. I was active in fundraising for the school our girls attended, and I ran a book fair and other such projects. When Lucy and Amy attended Brown University, I was a member of the Parents' Leadership Committee.

How did you balance family life with the demands of Peter's career?

For the nine years that Peter worked on *Everybody Loves Raymond*, he would be in California from August to March, and every third week he would return to New York for one week. For the children's school vacations, we would fly to Los Angeles.

When was Peter diagnosed with multiple myeloma?

In 1990, Peter had a stroke, and in 1999, he had a heart attack. In early 2003, Peter started to experience breathlessness. We assumed this was due to heart problems, but the cardiologist sent us to a hematologist. The diagnosis was myeloma, a disease we had never heard of.

How did the family cope with the diagnosis?

We were told that myeloma is incurable but treatable. I tend to be a very optimistic person, so that's what I focused on. We had a lot of hope. Without hope, I don't know how we would have gotten though the day.

Peter was put on an aggressive high-dose regimen and, shortly thereafter, landed in the emergency room. We were fortunate that we were about to return to the West Coast; we were referred to Dr. Brian Durie in Los Angeles. Brian, in turn, recommended Dr. Joseph Ruggierio to take care of Peter when we were in New York. Brian also adjusted Peter's medication and, for a while, this seemed to work. Then Peter was put on other therapies, but his pre-existing heart disease limited the range of myeloma treatment options. The balancing act of medications seemed more like an art than a science.

Through Brian, Peter and I were introduced to Susie Novis and the IMF. I fully participated in Peter's care and found the IMF publications to be very educational. Through the IMF, we also learned about several long-term myeloma survivors, and this helped us to remain hopeful. We never lost hope.

Did you have a strong support network?

Yes, we had an extensive network of family and friends who supported us throughout this time. And Susie and I became good friends so, in essence, she became my myeloma support group. She had already experienced everything I was experiencing, and I could call her at any time. Professionally, however, we chose to keep Peter's diagnosis quiet. In show business, if you want to continue to work, it's not good to advertise your illnesses. Because Peter suffered his heart attack in his *Everybody Loves Raymond* dressing room, his heart disease was not a secret, but we never mentioned the word "cancer."

But he continued to work.

Peter continued to work after *Everybody Loves Raymond* went off the air, until approximately six months before he passed away in December, 2006. He was 71.

Please tell us about the 2007 IMF Gala – *Celebrating Peter Boyle, an evening of comedy with family & friends* – which benefited the IMF research program.

Many of the people we met in the course of Peter's career are helping keep his memory alive. Amy, Lucy, and I are so grateful that our family has friends like Ray Romano, Stu Smiley, Tom Caltabiano, and Robert Morton who put together a great comedy show to benefit the Peter Boyle Memorial Fund at the IMF. The evening was hosted by Ray and featured Patricia Heaton, Doris Roberts, Fred Willard, Jeff Garlin, Richard Lewis, and Martin Short. This has now become an annual event for the IMF, and Ray Romano has already agreed to headline our next evening of comedy, which is scheduled to take place at Wilshire Ebell Theatre in Los Angeles on November 15, 2008.

After Peter's passing, why did you choose to become more involved with the IMF and accept the invitation to join its Board of Directors?

Like Susie, who lost Brian Novis to myeloma, I feel the need to be proactive and do all I can to put an end to this disease. And I want to give back to the myeloma community everything that Brian and Susie did for my family during Peter's four-year battle with the disease. We have to find a cure for this disease, and we must come to a better understanding of what causes myeloma and how to prevent it. Could it be genetic? Are my children at risk? If, as some researchers suggest, it's environmental factors that trigger myeloma, then we are all potentially at risk. So is there something we can do about our exposure to toxins and pollutants? The research funded by the IMF aims to answer these questions. I am not a scientist or an educator, but I can work on behalf of the IMF to raise funds to support research efforts and to raise public awareness of myeloma. **MT**

MYELOMA TODAY IN CONVERSATION WITH DR. SAGAR LONIAL

Please tell us a little about your background.

My interest in medicine started back in high school, when I wrote a paper on oncogenes and decided that I wanted to work in cancer research. I went to John Hopkins for college, where I worked in the leukemia laboratory. From then on, I was focused on hematologic malignancies. I did my internal medicine residency at the Baylor College of Medicine in Houston, TX. I spent an additional year as a Chief Medical Resident at the Ben Taub General Hospital, as well as the Texas Heart Institute and St Luke's Hospital. I completed my hematology/oncology training at Emory University. I have worked in the field of immunotherapy and cancer since my arrival at Emory. I am now an Associate Professor at the Winship Cancer Institute of Emory University, Director of Translational Research, B-cell malignancy program, as well as Associate Director of Hematology-Oncology Fellowship Program. I work both on the transplant service as well as in the B-cell malignancy clinic. Most recently, I have focused on combinations of novel agents as therapy for myeloma and lymphoma, particularly evaluating combinations that may result in synergistic inhibition of the PI3-K/Akt pathway.

Sagar Lonial, MD
Winship Cancer Institute
of Emory University
Atlanta, GA

How did you become interested in the field of myeloma?

I was drawn into the field about five years ago. I found the new science exciting, and the possibility of being able to change the available treatment for myeloma patients very intriguing. This is an incredibly interesting time in the field of myeloma – the science and the biology of what we do is so readily available to patients, and the clinical trials that test drug combinations are based on such good laboratory science. There are a number of promising myeloma trials open at our center at this time.

What is the focus of the current trials?

Firstly, there are a number of classes of drugs that are already known to be very active against myeloma. We have established that immunomodulatory agents like thalidomide and lenalidomide (Revlimid®) are very active anti-myeloma agents. Proteasome inhibitors like bortezomib (Velcade®) are also very active. These drugs have very clear activity, so what we are focused on now is combining those two novel agents with other drugs in order to improve their efficacy, tailoring therapies to make them more effective while keeping the toxicities in check. We are working with heat shock proteins (HSP), histone deacetylases (HDACs), and other drugs that may not have great single-agent activity but may enhance the activity of the novel drugs we already have. Secondly, besides working with existing agents, we are also looking for new single agents. Thirdly, we are looking at monoclonal antibodies that have been widely used in other fields of oncology but not yet in the field of myeloma. However, we now have two to four potential candidate proteins on the surface of plasma cells that monoclonal proteins are now being directed at, and I think that it is only a matter of time until we find an effective antibody for myeloma.

Will you please briefly explain monoclonal antibodies and their mechanisms of action?

A monoclonal antibody is a protein that has been manufactured outside the body to target a specific protein on the surface of a given cell. In myeloma, if a large number of monoclonal antibodies are created outside the body, they can then be given back to patients as a treatment. Once the antibody is hooked onto a protein on the surface of a plasma cell, the immune system kills that cell.

How do you divide your time between your various responsibilities?

Our center sees between 250 and 300 new myeloma patients each year. I split my time between my clinical practice, our laboratory, and writing or reviewing clinical trials at our center and for multi-center studies.

What is your relationship with the IMF?

The IMF is a great place for patient information and education, and an excellent forum through which available treatments become known to the patient community. The IMF has also played an important role in helping clinicians to evaluate and develop diagnostic and treatment guidelines. Within the last year, I was invited to join the IMF Scientific Advisory Board. It is an amazing group to be a part of. So far, I have participated in several meetings aimed at creating guidelines, and I am honored to work with myeloma experts who have contributed to such dramatic changes in the care of patients. Now we are working on identifying subsets of patients who may not gain great benefits from the available upfront treatments, and on determining how to best risk-stratify such patients. The IMF guidelines aim to assist practitioners who may not see many myeloma patients to effectively treat those patients and to minimize the potential complications that may arise as a result of therapies. The IMF is having a significant impact on the care of patients both at major cancer centers and in local community practices.

What is your outlook for the future?

I hope to see better treatments available to more patients who stand to benefit from them. To that end, the only way to know if a treatment is or is not effective is to test it within a well-designed clinical trial that is based on sound laboratory data and good methodology. In the last five years, such clinical trials have allowed the care of myeloma patients to advance more than the care of patients with other cancers has advanced during this same time period. And it is due to patient participation in myeloma clinical trials that we have been able to make these gains in the field. So I would like to encourage patients to continue to take part in studies, so that we can continue to make progress in fighting this disease. **MT**

Editor's Note: Dr. Lonial is on the editorial board for *Clinical Lymphoma and Myeloma* and *The American Journal of Clinical Oncology*, as well as an ad hoc reviewer for *Blood, Cancer Research, Clinical Cancer Research, Haematologica*, and other journals. He has authored or co-authored over 40 papers and abstracts, and was recently appointed to vice-chair for the ECOG myeloma committee.

WARNING: Biaxin and statins

Co-comitant administration of Biaxin® with a variety of other medications can alter drug metabolism and potentially cause problems. This is because Biaxin can affect drug metabolism in the liver affecting the CYP3A enzyme system. A very important example is that Biaxin® (clarithromycin) can greatly accentuate the muscle toxicity that can be caused by statin drugs. Therefore, any combined use of Biaxin with drugs such as atorvastatin (Lipitor®), lovastatin (Advicor®, Altoprev®, Mevacor®), simvastatin (Zocor®), or other statins must be with great caution or not at all. If you are taking a statin, you should not take Biaxin as an antibiotic or as part of your myeloma regimen at the same time. If you are currently taking both drugs, please talk to your doctor and have your creatine phosphokinase (CPK) enzyme measured via a blood test. If you are experiencing any muscle pain or cramping, report this to your doctor immediately. Since a number of other drugs can be affected by Biaxin®, please review any combined use of Biaxin® with other drugs very carefully with your physician and/or pharmacist.

IMF Myeloma Manager™ Personal Care Assistant™

The IMF is pleased to introduce the Myeloma Manager™ Personal Care Assistant™, the first software product of its kind designed specifically to help myeloma patients and their caregivers deal with their growing mountain of medical records and the ever increasing complexity of myeloma treatment programs. This software program, which is NOT web-based, instead runs on the user's computer and stores all personal data on the user's computer. It is password-protected and encrypts (scrambles) the data so that it is accessible only to the user and cannot be accessed from outside of the Myeloma Manager™. The program provides a tool to capture laboratory results and display and print tables and charts to show how those results change over time. None of the user's data is transmitted to anyone. The software also includes real-time news feeds from the IMF website and a reference shelf with links to useful publications and web pages. Features currently under development include a calendar for doctor's appointments and treatment regimens, an "address book" for storage of important phone numbers and addresses, and a notes section that will allow for creation of a journal of past events as well as for making notes about things that need to be done in the future. Integrated scanning functions will allow for scanning of medical reports or imaging studies directly into the tool to be attached to an appointment, contact, or note. Users will also be able to attach other documents (PDFs, spreadsheets, etc.) to appointments, contacts, or notes. At present, the IMF is focused on bringing the functions we've already designed to fruition and then making the tool available to the public. Early users of the Myeloma Manager™ will play an important role in helping the IMF refine and enhance this software so that it can be most useful to patients and caregivers. We invite myeloma patients and caregivers who are Windows XP or Vista users to visit www.myeloma.org and to download the Myeloma Manager™ in order to help us identify what we can do to make this software even more valuable. We very much look forward to your feedback and suggestions.

Revlimid® meets important quality of life issues

A study presented at the British Society for Haematology Annual Meeting demonstrates that Revlimid® (lenalidomide) has the ability to add years to myeloma patients' lives, and that these years fall within the quality-adjusted life years (QALY) guidelines, a measurement of cost-effectiveness of a drug based on quality of life achieved, not just the number of years. The study showed that Revlimid plus high-dose dexamethasone added at least three years of life compared to dexamethasone alone. Reviewers found the data so impressive that the trial, intended to last 10 years, was stopped after just 18 months to allow all patients in the study to take advantage of the therapy. Last year, a similar study by the Southwest Oncology Group (SWOG), a US consortium, was also stopped early because of the impressive results of the Revlimid-dexamethasone combination. A study from the Eastern Cooperative Oncology Group (ECOG), led by Mayo Clinic, demonstrated that lowering the dose of the accompanying dexamethasone could achieve better results and further improve patient quality of life. These myeloma findings provide more evidence that blood cancers can be managed, allowing patients to feel good and maintain active, productive lives.

New indication provides treatment-free interval as an option

On June 23, the US Food and Drug Administration (FDA) expanded the benefits of Velcade® (bortezomib) for injection to a wider range of myeloma patients. Since 2003, Velcade has been approved for relapsed patients who have had at least one prior therapy. The FDA has now granted the use of Velcade to previously untreated patients with multiple myeloma. The approval is based on positive data from the international VISTA trial of Velcade plus melphalan and prednisone (VcMP) compared to melphalan and prednisone (MP) alone. VISTA is the largest ever Phase III clinical trial in newly diagnosed myeloma patients.

Pre-ASCT therapy in newly diagnosed myeloma patients

Researchers at Mayo Clinic in Rochester, MN, have studied the effect of pre-transplant therapy in 472 newly diagnosed myeloma patients undergoing autologous stem cell transplantation (ASCT). Previous studies have suggested a lack of impact of the initial therapy on the outcome after ASCT. Patients received initial therapy with vincristine, Adriamycin, and dexamethasone (VAD); thalidomide and dexamethasone; or lenalidomide and dexamethasone. Among the groups, the nature of initial treatment utilized had no long-term impact on the outcome of ASCT, post-transplant complications, or treatment-related mortality.

NLB Consensus on Care

On May 16, "Consensus on Care: New Insights on Novel Therapies in Multiple Myeloma," a large symposium presented by IMF's Nurse Leadership Board (NLB), took place at the Pennsylvania Convention Center during the 33rd annual congress of the Oncology Nursing Society (ONS). The NLB was created by the IMF to foster a partnership with the country's most experienced myeloma nurses. With our support, they are able to provide a leadership role in the prevention, diagnosis, and management of emergent treatment side effects associated with novel therapeutics. These twenty outstanding nurses have identified and addressed the unmet needs of the general myeloma nursing community, as well as those of their patients. The NLB's consensus recommendations were developed by the NLB through a rigorous examination of scientific-based evidence and practitioner experience; they provide for optimal management of clinical challenges presented by myeloma therapies that include novel agents. Besides providing nurses across America with the tools for improving patient care, the NLB symposium also brought the nurses up to date on current advances in myeloma research and clinical trial data. **MT**

2008 IMF SCIENTIFIC ADVISORY BOARD RETREAT

Myeloma Today in conversation with Dr. Brian G.M. Durie

Please give us a brief overview of the agenda of the recent IMF Scientific Advisory Board Retreat held April 17-20 in Bermuda.

Drs. Gösta Gahrton, S. Vincent Rajkumar, and Brian Durie

The topic for the 2008 retreat was: "Clinical Trials – Looking at the Next Questions 2008." Individual sessions covered response criteria, new clinical trial designs, prognostic factors, new management guidelines, molecular testing, and new brainstorming priorities. The role of complete response (CR) as an indicator of treatment benefit was a particular aspect discussed in detail. Mario Boccadoro emphasized that CR can be "cosmetic" – that it might not translate into longer-term remissions. It is much more important to focus on the duration or length of response versus the depth of the response. For example, very good partial response (VGPR), which means that the level of myeloma has dropped by ≥ 90%, is an excellent cutoff level when combined with some indicator of length of response, such as time to progression (TTP, time until myeloma protein starts to increase again) or progression-free survival (PFS, how long patients have been living in a remission state). The recommendation was to use CR + VGPR (combined) to assess response, and TTP and PFS to determine treatment benefit as well as the longer-term outcome.

Which other aspects were emphasized at the retreat?

Dr. Vincent Rajkumar discussed the use of the new "Uniform Response Criteria" developed by the International Myeloma Working Group (IMWG). There has been wide acceptance of the new criteria by the Food and Drug Administration (FDA), Southwest Oncology Group (SWOG), and Eastern Cooperative Oncology Group (ECOG), as well as other clinical trial groups. However, there is an ongoing need to provide updates as new information becomes available. Developments with the Freelite® serum free light chain assay and molecular testing, as well as imaging (such as MRI and CT/PET scanning), are good examples of this. We plan to publish new guidelines to cover new developments in each area. Dr. John Crowley, the chief statistician for the IMWG, discussed the need for what is called "landmark analysis." This means that long-term survival, which is fortunately occurring much more commonly, must be interpreted with care. The impact of new treatments, such as thalidomide, Revlimid®, and VELCADE® is demonstrating a greater likelihood of survival for longer than 4–7 years. To study this trend carefully, one can assess all patients who were doing well at 2, 3, or 4 years (for example) and see how many such patients are still doing well beyond 10 years. A recent study by Dr. Bart Barlogie showed survival benefit with thalidomide use only after more than 7 years of follow-up. It is very encouraging that we now have the need and the opportunity to use such techniques.

What is the status of the IMF Bank On A Cure® research initiative?

Phase one of Bank On A Cure has been completed. We've looked at single nucleotide polymorphisms (SNPs) of thousands of myeloma patients. We've delved into the issue of deep-vein thrombosis and we've looked at myeloma bone disease. Of the new initiatives, one of the most important things we are looking at is the genetic predisposition to myeloma – why people develop this disease in the first place. Dr. Dalsu Baris is comparing the genetic features of people who get myeloma versus those who do not. In addition to the Bank On A Cure data set of myeloma patients, she has access to thousands of controls available through the National Cancer Institute (NCI), where she is a staff scientist in the Division of Cancer Epidemiology. For the first time ever, it is possible to examine these two huge data sets that will allow us to identify and characterize the genetic predisposition to myeloma.

How might this be accomplished?

It is a statistical issue of identifying the top genes which occur in myeloma patients versus the individuals from the normal population (controls). Once the genes are identified, we will be able to characterize those genes. For example, the category of genes that I found in my study of bone SNPs, and what Dr. Baris' work seems to be confirming, showed that people who get myeloma have an impaired ability to break down environmental pollutants. It seems that people who get myeloma have defective metabolism of toxic agents, such as dioxins, rendering them less able to clear toxins from their systems. Such individuals may also have an intrinsically defective immune system and/or a molecular defect. If we can identify the Achilles' heel of why people get myeloma, we can delineate a reverse fingerprint to identify the exposures that put people at risk.

Our next step is to correlate the toxic levels with the presence of the abnormal genes or with an immune defect. We are also looking at infection – if a person cannot clear particular bacteria, then we can correlate the presence of that bacteria with an immune defect. This takes us to the next step of confirming in a positive way the presence of the factors that are triggering the myeloma – we must correlate susceptibility with the presence of the factor that the person is susceptible to. This is very exciting, leading us back to the first key observation of SNPs that link to myeloma.

What is the timeline for this work?

We have the data, and Dr. Baris has been "crunching the numbers" for several months already. She presented her preliminary finding at the retreat in Bermuda. This work should be ready in abstract form in August, in time for submission to 50th annual meeting and exposition of the American Society of Hematology (ASH). The manuscript would then be prepared for presentation at the ASH meeting in December 2008. We already have a lot of data on the pattern of myeloma, which is determined by a combination of the SNPs and the GEP.

CONTINUES ON PAGE 8

SAB RETREAT — continued from page 7

What is GEP?

GEP stands for gene expression profile, the measurement of the profile of the high or low activity of genes in myeloma cells. The GEP of myeloma can, for example, reflect the aggressiveness or the pattern of the disease, and the susceptibility or the ability of the microenvironment to resist it. The GEP pattern of myeloma has been studied by Dr. John Shaughnessy in the US, by Dr. Herve Avet-Loiseau on behalf of the French Myeloma Cooperative Group, by Dr. Pieter Sonneveld for the European Myeloma Network, by the Italian myeloma cooperative group, and by a number of other groups. We have substantial SNP information to correlate with the GEP. For example, I have already done this in my study of myeloma bone disease, showing that this susceptibility correlated with the DKK-1 GEP pattern. Our follow-up studies are using the genome-wide screening chip, a chip that identified SNPs throughout all the chromosomes.

Would you please explain genome-wide screening?

For Bank On A Cure, we developed a custom SNP chip and selected the 3400 genes that we saw as being most relevant to myeloma. There are obviously many more genes, and the question is whether or not there are other genes related to myeloma that we have not yet identified. The genome-wide screening chip identifies the whole genome, starting with chromosome #1 and continuing through the genome in segments, identifying if myeloma is correlated with abnormalities in any of the segments. Because each segment contains a number of genes, genome-wide screening doesn't reveal the specific gene but rather identifies which segments are important to explore further. This is a slightly different methodological approach, but it is important for us to know if the custom SNP we have developed is missing any relevant genes.

One tool that would be very useful is to be able to do DNA testing with a simple blood test, so I have been working on this project with Dr. Howard Urnovitz. We have been looking at genome-wide screening, studying DNA patterns present in myeloma blood samples obtained during the course of treatment. The resulting information will be summarized in an abstract being submitted to ASH, followed by a manuscript.

What is the status of the Bank On A Cure "swish and spit" kits?

We are finishing up the analysis on the kits that were collected during the first phase of this project. We have linked the kits with an epidemiological survey completed by each person who has submitted a kit. As a result, we will be able to evaluating the patients' history of exposure and infection with their SNP panel. This is the first step in correlating what causes myeloma. Dr. Brian Van Ness is currently running the DNA analysis on the patients. For controls, we used patients' family members. Dr. Baris, who is an expert on the survey forms, is involved with this project as well.

Were there any other initiatives addressed at this retreat?

Another thing that happened at the 2008 IMF Scientific Advisory Board Retreat is that we convened an advisory board for Proteolix Inc., a company developing carfilzomib, a second-generation proteasome inhibitor (VELCADE® being first generation). Carfilzomib seems to be more potent than bortezomib and does not cause neuropathy. Proteolix wanted to get input from IMF's advisors about the best trial design to speed the approval process of carfilzomib. The drug is currently in Phase I and II trials, with Phase III trials moving toward registration. Advice was provided concerning best trial design. **MT**

VELCADE as Frontline Therapy for Myeloma

By Brian G.M. Durie, MD

In a recent trial (presented at ASH 2007 and currently in press) with Prof. Jesus San Miguel as the senior investigator (see last issue *Myeloma Today*), it was shown that combining VELCADE® (bortezomib) with melphalan and prednisone (VMP) gave results much better than with melphalan and prednisone (MP) alone. Based upon the results of this pivotal trial, the FDA approved the use of VELCADE's indication to include the frontline setting on June 20, 2008.

This is great news for all myeloma patients, who will now have greater and easier access to VELCADE for frontline use. VELCADE is specifically approved as part of the VMP regimen. However, it is anticipated that there will be a broad and expanding role for VELCADE for previously untreated patients not eligible for stem cell transplantation, as well as for patients receiving induction in preparation for harvesting and autologous transplantation. For example, in the transplant situation, VELCADE has been combined with dexamethasone, Cytoxan®, thalidomide, and Doxil®.

Right now the search is on to determine which combination will work best. In the meantime, it is a challenge for physicians and patients alike to assess which combination is promising on an individual case-by-case basis. The choices are not made any easier by the availability of not just VELCADE combinations, but those involving thalidomide or Revlimid. In addition, the VELCADE plus thalidomide and dexamethasone (VTD) regimen is very promising. In the trial setting the combination of VELCADE plus Revlimid® (lenalidomide) plus low-dose dexamethasone is especially attractive since excellent results have occurred in Phase I/II trials.

Thus the difficulty is to make the best choice. The good news is that even better combinations are becoming available to achieve longer remissions, with the option to improve both quality of life and long-term survival. **MT**

Current IMWG Projects and Lead Authors

- ***AMD 3100 (plerixafor) as a stem cell mobilizer for patients with myeloma: guidelines*** – Sergio Giralt, Brian Durie, Bill Bensinger, Edward Stadtmauer
- ***Lenalidomide and stem cell harvesting guidelines*** – Shaji Kumar, Brian Durie, Vincent Rajkumar, Paul Richardson
- ***Overall lenalidomide guidelines*** – Hermann Einsele, Antonio Palumbo, Brian Durie
- ***International Myeloma Working Group guidelines for serum free light chain analysis in multiple myeloma and related disorders*** – Angela Dispenzieri
- ***Monoclonal Gammopathy of Undetermined Significance (MGUS) and Smoldering (Asymptomatic) Multiple Myeloma: Risk Factors for Progression*** – Robert Kyle
- ***Long-term Follow-up with ISS Staging, project with CRAB*** – Brian Durie
- ***Molecular Genetics Guidelines*** – Herve Avet-Loiseau, Rafael Fonseca
- ***Survival as an Endpoint*** – Vincent Rajkumar, Brian Durie
- ***Anemia, EPOGEN Guidelines*** – Heinz Ludwig, Kenneth Anderson
- ***Role of PET SCAN/ Imaging*** – Meletios Dimopoulos, Orhan Sezer
- ***Role of Allogeneic Stem Cell Transplant Guidelines*** – Henk Lokhorst
- ***Albumin, B2-Microglobulin Methodology for Staging*** – Philip Greipp, Roman Hajek
- ***Updated Response Criteria*** – Brian Durie, Vincent Rajkumar

DSMM: DEUTSCHE STUDIENGRUPPE MULTIPLES MYELOMA

Myeloma Today in conversation with Prof. Dr. Hermann Einsele

You are Chairman of DSMM. Please tell us a little about the group's founding.

DSMM (Deutsche Studiengruppe Multiples Myeloma), the German multiple myeloma study group, was founded in 1994. At that time, there were several doctors in Germany who were very interested in the field of myeloma. We participated in pre-clinical and clinical studies, and we decided to join forces to move the field of myeloma forward in a more efficient and productive way. It has now been 14 years that we have been collaborating on performing myeloma clinical studies.

Would you please share with us an overview of the current activities of DSMM members?

In Germany, there is much ongoing investigative activity in the field of myeloma. Currently, there are interesting projects underway by Prof. Orhan Sezer (Berlin), who is an expert on bone metabolism and myeloma bone disease, Dr. Peter Liebisch (Ulm), who is studying molecular cytogenetics of myeloma, Dr. Dirk Hose (Heidelberg), who is working on gene expression profiling of myeloma cells, Dr. Christian Straka (Munich), who is focusing on new treatment strategies for elderly myeloma patients, and Dr. Monika Engelhardt (Friberg), who is developing mouse models for myeloma.

Hermann Einsele, MD
Würzburg University Hospital
Würzburg, Germany

And what about the research being performed at your center in Würzburg?

My group in Würzburg is concentrating on three separate areas of research. One group is working on pre-clinical models for myeloma to try to define new targets, as well as on interphasing various clinical studies. From our pre-clinical models, we have several novel agents that are tested primarily here in Würzburg, then developed for clinical studies. Another group is developing ways to improve the outcome of both autologous and allogeneic stem cell transplantation (SCT). In addition, we have a group of doctors looking at gene and immune-therapy, both with and without transplantation.

In Würzburg, we have very good pre-clinical models from myeloma cell lines. We can actually use primary myeloma cells, and we have animal models as well. We are testing a lot of new drugs in the pre-clinical setting and, therefore, we get a very clear sense of which drugs are likely to progress to the clinical setting. In addition, we work with colleagues from the chemistry and pharmaceutical departments and we use our models to pre-screen a wide range of different drugs for potential anti-myeloma efficacy.

We conducted a large Phase I/II study of the Revlimid® (lenalidomide), doxorubicin, and dexamethasone (RAD) protocol. In patients with relapsed or refractory myeloma, we have found this protocol to be extremely effective, with a rate of complete remissions (CR) of nearly 70%. Now we are studying the RAD protocol as frontline therapy prior to transplant.

One recent Phase III multi-center DSMM trial for newly diagnosed myeloma patients under 60 years of age, recruiting more than 800 patients, evaluated risk-stratification by the means of a chromosomal aberration as a tool to discriminate between standard and high-risk disease. Risk-adapted therapy is based on allogeneic transplantation versus tandem autologous transplant for high-risk subjects with chromosome 13 deletion who have an HLA-identical stem cell donor available.

We are looking at a new protocol of bortezomib, cyclosphomide, and dexamethasome (VCD) as upfront treatment for high-risk younger patients. Nearly 300 patients were treated with VCD as induction therapy. In addition, bortezomib (Velcade®) consolidation therapy post-transplant is evaluated in a randomized study. We hope that the data we are generating will facilitate the approval of bortezomib for the frontline treatment of myeloma patients in Germany.

Do members of DSMM collaborate with other myeloma cooperative groups?

Yes, we collaborate with other myeloma cooperative groups, including GIMEMM (Italian Cooperative Group) and HOVON (the Dutch-Belgian Hemato-Oncology Group). In addition, we collaborate with other myeloma experts in the European Union. For example, Prof. Henk Lokhorst (University Hospital Utrecht) and I are currently co-chairing the working group on allogeneic stem cell transplantation for myeloma.

Outside the clinical trial setting, what myeloma therapies are currently available to patients in Germany as frontline treatment?

Thalidomide has been recently licensed in Germany, but only in the frontline setting and only for the treatment of elderly patients in combination with melphalan and prednisone. Bortezomib is not yet available for frontline treatment but it looks like it may get approval in September or October of this year. We are also hopeful that lenalidomide (Revlimid®) will become available to elderly patients either by the end of this year or at the beginning of next year. I personally feel that younger patients who will undergo transplant would also benefit from these novel agents, and this position is supported by preliminary results of several studies.

What about myeloma therapies in Germany for relapse/refractory disease?

In Germany, unlike other countries in Europe, relapsed/refractory patients have access to all the novel agents, both as single agent and in combination therapies. In addition, in younger patients we offer allogeneic SCT for patients relapsing after auto-SCT.

It seems that members of DSMM have a strong relationship with the patient community. Is this impression correct?

Yes, in Germany there is very close contact between patient groups and the myeloma specialists. We hold joint meetings at least every two months. We provide education to the patient groups, which are very effective at providing support to their members. I would say that the myeloma patient support groups are the best organized and most effective of the various patient groups in Germany.

CONTINUES ON PAGE 11

UPDATE FROM ASCO

Myeloma Today in conversation with Dr. S. Vincent Rajkumar

At the 44th annual meeting of the American Society of Clinical Oncology (ASCO), which concluded at the beginning of June, you presented continuing results of the E4A03 trial, which is coordinated by the Eastern Cooperative Oncology Group (ECOG). What can you tell us about your findings?

E4A03 is a Phase III trial of lenalidomide (REVLIMID®) plus high-dose dexamethasone versus lenalidomide plus low-dose dexamethasone in patients with newly diagnosed multiple myeloma. In the primary trial analysis of E4A03, we found that the overall survival (OS) at one year and two years was in favor of the low-dose arm. At one year, the OS rate was an unprecedented 96%. The two-year OS for the lenalidomide plus low-dose dexamethasone arm of the study was 88%, compared with 78% for the lenalidomide plus high-dose dexamethasone arm. I must emphasize that at this time we don't have long-term data on how long these OS differences will last.

S. Vincent Rajkumar, MD
Professor of Medicine
Mayo Clinic
Rochester, MN

What can you tell us about the landmark analysis of the ongoing results?

A landmark analysis begins from a point within a study, so measurements all proceed from that set point. In this case, landmark analysis began at completion of four cycles of lenalidomide/dexamethasone, when decisions on further treatment had to be made. At this time point, 431 of the 445 patients were alive, and 255 elected to stay on lenalidomide/dexamethasone therapy, while the remainder stopped protocol therapy. Of those who stopped protocol therapy, about half went on to have transplant, and the remaining half decided to either just stop therapy or go on to other regimens.

The two-year OS in the three groups were as follows: 70% for patients who stopped therapy after four cycles, about 93% for patients who went on to transplant after four cycles, and about 93% for patients in the lenalidomide low-dose dexamethasone arm who took therapy beyond four cycles.

What comes next?

In the next cooperative group trial in the US, lenalidomide plus low-dose dexamethasone regimen is used as the "standard" treatment to which the three-drug combination of bortezomib, lenalidomide, and low-dose dexamethasone (VRd) is compared to. In elderly patients, lenalidomide plus low-dose dexamethasone is being tested as a replacement for melphalan-prednisone-thalidomide (MPT). These future trials will guide us on what role this regimen will play in long-term management of myeloma.

If myeloma patients can achieve 93% two-year survival with lenalidomide low-dose dexamethasone, why should they still consider transplantation?

Myeloma patients who are eligible for transplant should never give up this option, because it is still the standard of care, whether it's done early or late. The fact that lenalidomide low-dose dexamethasone as primary therapy gave us results in the same range as transplant was very surprising and very encouraging. But ours was not a randomized result. Many patients who were responding well to the therapy at the four-cycle time point just wanted to stay on it, so they're inherently a biased population. The ones who opted for transplant had slightly lower response rates at four cycles. The lenalidomide/dexamethasone hypothesis needs to be tested in a randomized comparison.

Were there other significant ASCO presentations dealing with newly diagnosed myeloma?

One interesting presentation, by Dr. Jean-Luc Harousseau (Hotel-Dieu Hospital, Nantes), updated data from Intergroup Francophone du Myelome (IFM) 2005/01 trial. The Phase III trial of bortezomib (VELCADE®) plus dexamethasone versus vincristine-doxorubicin-dexamethasone (VAD) as induction prior to autologous stem cell transplantation (ASCT) in previously untreated myeloma shows an increased response rate before ASCT. The patients are being followed and, at this point in time, there are no significant differences in survival between the two regimens.

If bortezomib/dexamethasone is showing improved response before transplant, why is there no difference in survival?

All the patients proceeded to transplant, which may be neutralizing the improved induction results. Additionally, as in the ECOG trial, follow up is too short to know one way or the other. But it is important for patients to know that this IFM trial, as well as the ECOG trial we just discussed, present two options for induction regimens that are both reasonably well established.

Dr. Paul Richardson (Dana-Farber Cancer Institute) presented data at ASCO on a Phase II trial combining these three drugs – VELCADE, REVLIMID, dexamethasone (VRd) – and he was able to show 100% response rates, with 70% of patients achieving either CR or very good partial response (VGPR). This was a smaller study of approximately 60 patients, and there was no control arm, so we have to be careful how we interpret these results. Those caveats notwithstanding, it is still very encouraging to see such a response rate. It will be interesting to see randomized trials of VRd versus lenalidomide/dexamethasone (SWOG trial) and VRd versus bortezomib/dexamethasone (ECOG trial), and I would encourage patients to consider entering these Phase III trials.

There were other promising combination induction regimens presented at ASCO, including the Phase II cytoxan-bortezomib-dexamethasone (CBD) study presented by the Mayo Clinic in Scottsdale, and the bortezomib-adriamycin-dexamethasone (PAD) regimen presented by Dr. Antonio Palumbo (University of Torino) on behalf of the Italian Multiple Myeloma Study Group.

What relapse studies presented at ASCO were of interest?

There were updates of lenalidomide trials in the relapsed setting, including a study presented by Dr. Richardson of long-term follow up with patients who had been on lenalidomide for more than four years. The promising message of this trial is that a subset of patients with advanced myeloma can sustain response for more than four years after starting salvage therapy.

CONTINUES ON PAGE 11

UPDATE FROM ASCO — continued from previous page

Dr. Kenneth Anderson (Dana-Farber Cancer Institute) presented encouraging results from a Phase II study of VELCADE, REVLIMID, and dexamethasone (VRd) in patients with relapsed/refractory myeloma.

Dr. Mohamad Hussein (H. Lee Moffitt Cancer Center) presented on a lenalidomide study that was done years ago. He found a 30% response rate among the relapsed/refractory myeloma patient population using lenalidomide as a single-agent. It is impressive that almost a third of the patients responded to treatment that included nothing but lenalidomide.

How does one compare results of studies using a single agent to trials using two, three, or four drugs?

Ideally, you can look at randomized trials that show a benefit at an endpoint that's meaningful. A study may show that three drugs get a better response rate than two drugs. That's not surprising – of course three active drugs are better than two! But once you use those three drugs, you no longer have them in your arsenal when the patient relapses. Patients who take two drugs will still have that third drug as an option in the future. What we really need to look at is OS, and at this time we have no such comparative studies. But we do have some clues from comparisons of some older trials, like VISTA and IFM, that showed not only improved response but also improved OS by adding a third agent early in the treatment course.

This raises a question regarding an issue you addressed at ASCO during both educational and oral sessions. You've said that the best indication of survival is survival. Isn't CR an indication of survival?

One controversy in the field of myeloma is whether we should treat patients until they reach the CR end point, or there is another end point to focus on. I believe CR is a good thing to achieve, and very desirable in myeloma. But some caveats must be kept in mind and additional research is needed:

- CR is not a consistent predictor of eventual OS. While there have been trials in which the arm that had the higher CR rate went on to be the arm that showed the better survival, there have also been trials in which the arm that had the better CR rate did NOT show better survival. Patients who achieve CR are likely to do well compared to patients who don't achieve CR. But there are many myeloma patients who get into a very good partial response (VGPR) and do just fine.
- Assessing CR is dependent on a subjective test – immunofixation – which is a lot like examining a photograph to see if you spot a mark on the image. Immunofixation is not performed by an infallible laboratory instrument. Instead, one looks at a gel for a "band" pattern. Sometimes, the band can be so faint that one person will think they see it while another will not. Thus this test can be very observer-dependent.
- To achieve CR we often intensify therapy, and this may be a double-edged sword. Intensified and/or prolonged therapy to achieve CR may result in higher toxicity and cost, and more side-effects impacting quality of life. And there is no good data that getting a CR at all costs improves survival. For patients who reach CR, its duration must also be taken into consideration. This can depend on a number of things that might happen after the CR is achieved – new drugs may become available, complications may occur, etc.
- Millions of Americans have small monoclonal proteins in their blood (MGUS), and those proteins are not a problem. It is possible for a myeloma patient to regress to a minimal residual disease or MGUS-like stage, where the small amount of M-protein does not cause problems. Such patients may be better off staying in the "MGUS-like" low disease burden state than trying to intensify therapy in an attempt to reduce minimal disease to zero.
- Finally, myeloma is not a single disease but likely a heterogeneous group of diseases with different genetic components and types. Dr. Bart Barlogie (University of Arkansas for Medical Sciences) has shown that if you look at the myeloma patient population, there is a small high-risk group (about 15%) that benefit greatly from achieving CR, but the vast majority of patients (about 85%) had the standard-risk type of myeloma where the long-term survival outcome was similar whether they reach CR or not.

As is said earlier, I am very much in favor of a goal that seeks high 100% CR rates in myeloma with effective therapy. But we need studies looking at better definitions of CR. To that end, the International Myeloma Working Group (IMWG) has come out with a more stringent definition of CR (termed "stringent CR"). We also encourage trials to report CR plus VGPR, which may be a more appropriate, reproducible, end point than CR. **MT**

DSMM — continued from Page 9

We also have a very close collaboration with the IMF, in part through Gregor Brozeit, Director of IMF Europe. US myeloma specialists have come to Germany to make presentations to our patient groups, and I have presented at meetings of two myeloma support groups in the US.

What is your outlook for the future?

The next generation of novel agents is forthcoming, and there are several promising new drugs that we are already testing at our center, including a histone deacetylase (HDAC) inhibitor, novel antibodies directed at the myeloma cells, two different heat shock protein (HSP) inhibitors, and an inhibitor of the Hedgehog signaling pathway. A new proteasome inhibitor, the next generation of bortezomib, is currently in Phase I and II trials, with Phase III trials slated to start before the end of this year.

I would also like to mention that we need to continue to work towards a greater collaboration with medical specialists in the areas where many myeloma patients encounter problems, such as orthopedics and radiology and so on. In addition, we need to continue to strengthen both pre-clinical and clinical myeloma research, and continue to collaborate and exchange information with colleagues in all parts of the world. **MT**

NLB ACTIVITIES UPDATE

Myeloma Today in conversation with Elizabeth Bilotti, MSN, APRN, BC, OCN

Elizabeth Bilotti, MSN, APRN, BC, OCN
Multiple Myeloma/
Transplant Program
St. Vincent's
Comprehensive Cancer Center
New York, NY

You are the leader of Long-Term Care Plan Taskforce of the Nurse Leadership Board (NLB). What is the basic aim of this task force?

The novel therapies that have become part of the treatment options available to today's multiple myeloma patients have had a positive impact on survivorship. Myeloma patients are living longer with their disease, and the medical professionals tending to their care must address long-term consequences of myeloma and its treatments, as well as other health maintenance issues that may not have been part of the overall picture a decade ago. The Long-Term Care Plan Taskforce was formed to identify and articulate these issues and to disseminate this information to the patient and the medical communities. All members of the NLB are working on this project.

Can you give us an example of issues that the taskforce is addressing?

The taskforce is focused on developing statements on bone health and bone disease, cardiovascular health, functional mobility and safety, renal complications, sexuality and sexual dysfunction, chronic pain and pain management, and health maintenance (e.g. PSA testing and colonoscopy, good exercise and nutrition habits, and monitoring the risks for developing comorbidities, or other illnesses).

Why is the taskforce focusing on health maintenance beyond myeloma treatment?

While the patients and their oncology teams are focused on addressing the myeloma diagnosis and treatment, it is very important not lose sight of a patient's overall health. Although we see many younger patients with myeloma, the average age of patients is in the upper decades of their life span. Wellness screening is something that every healthy person should undergo, and such screening is even more important to a person with myeloma.

Why is wellness screening of particular importance to myeloma patients?

Myeloma patients must pay attention to their overall health, because any complications that they might experience may hinder our ability to treat their myeloma. Treatment of additional health issues that a myeloma patient might face may cause increased toxicities and side effects from therapies.

How will the Long-Term Care Plan benefit the community?

NLB members saw a need to develop a Long-Term Care Plan for myeloma patients to provide access to essential information and to raise awareness about overall wellness from a primary healthcare standpoint. The NLB's Long-Term Care Plan will offer recommendations about immunizations and vaccinations, and explain how problems in various areas of health may impact side effects of myeloma treatments, as well as a patient's myeloma treatment options. This information will be of value to the patient community, as well as to healthcare professionals in clinical practice.

What progress has been made by this taskforce so far?

To aid the development of the NLB's Long-Term Care Plan, NLB members broke into four-person groups, each group focusing on a separate aspect of the plan – Bone Health and Bone Disease, Functional Mobility and Safety, Renal Complications and Disease, Sexuality and Sexual Dysfunction, and Health Maintenance (which includes wellness screenings recommended by the US Preventive Services Task Force). Chronic pain and pain management is a part of each category, as applicable. Each of these sub-groups is now in the process of developing a recommendations outline for their section of the Long-Term Care Plan.

How do you plan to disseminate the plan in the future?

The NLB taskforce will address how to best disseminate the information in the next phase of this project, but I would like to share with Myeloma Today readers the importance of this project. Effective interventions for reducing the incidence and severity of disease in the US are those that address the personal health practices of patients. To effectively address health practices, patients must understand why it is important for them to take actions to benefit their health in addition to what they must already do for their myeloma. This might seem like an added burden, but patients who understand the specific reasons why they should improve their personal health practices and lifestyle may be able to prevent unnecessary complications.

CONTINUES ON PAGE 14

GASTROINTESTINAL SIDE EFFECTS ASSOCIATED WITH MYELOMA THERAPIES

Myeloma Today in conversation with Page Bertolotti, RN, OCN

Please define gastrointestinal side effects as they relate to myeloma treatment.

Gastrointestinal (GI) side effects include constipation, diarrhea, nausea, and vomiting. GI side effects may occur as a result of any anti-cancer therapy, from conventional chemotherapy to treatments using novel agents such as lenalidomide (Revlimid®), thalidomide (Thalomid®), and bortezomib (Velcade®). GI side effects may be managed with appropriate medical interventions, thereby minimizing their impact on the patient's quality of life and adherence to therapy.

The side effects from conventional chemotherapy have been studied over the years, so the IMF's Nurse Leadership Board (NLB) focused on developing a consensus statement for assessing and managing GI side effects associated with novel therapies. The NLB recommendations are the result of evidence-based reviews, as well as a consensus of the experience of NLB members. These recommendations are applicable for managing GI side effects caused by any chemotherapeutic agent, novel or conventional.

Page Bertolotti, RN, BSN, OCN
Cedars Sinai Outpatient Cancer Center
at the Samuel Oschin
Comprehensive Cancer Institute
Los Angeles, CA

What impact might GI side effects have on a patient?

GI side effects can have a negative impact on a patient's quality of life and may even interfere with optimal therapy for that patient's myeloma. Adequate management of GI toxicities has been shown to increase adherence to the treatment regimen, decrease physiological impairment, improve quality of life, decrease psychological effects like anxiety and depression, and prevent adverse events that may lead to hospitalization, as well as other serious complications. Patients whose GI side effects are managed are also less likely to become socially isolated. It's important to remember that when patients experience a decreased quality of life, caregivers are also affected.

How are GI side effects assessed?

The National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) is used to identify, quantify, and monitor treatment-related side effects. NCI CTCAE measures toxicities as grades 1 through 5 (1 is mild, 2 is moderate, 3 is severe, 4 is life-threatening or disabling, and 5 defines death associated with the adverse event). Grading the toxicities also helps determine if there is a need for dosage modifications.

Are there management strategies for coping with GI side effects that you can share with our readers?

First, I'd like to make the point that all patients should report any GI side effects to their healthcare providers who can offer guidance for managing the adverse events. Then clinicians and patients should weigh the beneficial vs. the harmful effects of all interventions according to that patient's individual circumstances and priorities.

If a patient experiences fewer bowel movements than usual, this should be reported. If two or three days go by without a bowel movement, this should be reported immediately. Management of constipation may include increased oral fluid intake, increased fiber intake, increased physical activity, nutritional adjustments, stimulant laxatives, stool softeners, or pharmacologic measures. To counter potential opioid-induced constipation, a prophylactic regimen should be considered.

Patients with abnormally low levels of red blood cells, neutrophils (granulocytes), and/or platelets should avoid rectal agents and/or manipulation to manage their constipation.

Management of diarrhea may also include increasing hydration in the form of water, electrolyte replacement beverages, nutrition-rich sports drinks, diluted fruit juices, and broth, while avoiding alcoholic, caffeinated, carbonated, and high-sugar beverages. Patients with diarrhea may be advised against high fiber, high fat, and heavily spiced foods, as well as dairy products. If a patient experiences diarrhea while receiving anti-myeloma therapy that is not known to cause this side effect, a culture or other measures may have to be taken to ascertain the cause.

What are some management strategies for coping with nausea and vomiting?

Nausea is an uncomfortable or unpleasant sensation in the stomach or at the back of the throat. Nausea may or may not result in vomiting. Many patients worry that nausea is an inevitable result of cancer therapy, and the patients' expectation of nausea has been shown to correlate with its development during treatment, so prevention is key, especially early in therapy. If a patient has (or is at risk for) nausea, we recommend appropriate prophylactic and therapeutic interventions and an effective nausea management plan. Non-pharmacologic interventions can be used in conjunction with drug interventions. Patients may benefit from acupuncture, acupressure, guided imagery, music therapy, and progressive muscle relaxation. With anti-emetic therapy and care and advice, the incidence and severity of nausea can be reduced. It should be noted that some anti-nausea medications can cause constipation.

Patients may also experience anticipatory nausea, which occurs before receiving an anti-cancer treatment. Some patients begin experiencing this while they are at home getting dressed to go for their therapy. Anticipatory nausea is a conditioned response resulting from an aversion patients feel towards therapy. Anticipatory nausea requires preventative strategies that form the basis of management of therapy-associated nausea. A sedative taken in advance of the anti-myeloma treatment may reduce or eliminate the incidence of anticipatory nausea.

Vomiting is often confused with nausea but is, in fact, a separate phenomenon that may or may not occur in conjunction with nausea – sometimes vomiting is preceded by nausea and sometimes not. Vomiting is a mechanism by which the body attempts to expel toxins. Vomiting, along with nausea, is considered one of the most disturbing and feared side effects of cancer treatment, but vomiting can be one of the most manageable side effects of cancer treatment today.

In closing, is there anything else that you would like to share with our readers?

Gastrointestinal side effects such as constipation, diarrhea, nausea, and vomiting are some of the most manageable side effects of cancer therapy, and I encourage patients to promptly report their experiences to their

CONTINUES ON PAGE 14

IMF HOTLINE COORDINATORS ANSWER YOUR QUESTIONS

The IMF Hotline 800-452-CURE (2873) is staffed by Debbie Birns, Paul Hewitt, Nancy Baxter, Missy Klepetar.
The phone lines are open Monday through Friday, 8am to 4pm (Pacific Time).
To submit your question online, please email TheIMF@myeloma.org.

I had a stem cell transplant about four months ago and just got word that my myeloma is in remission. My bone marrow biopsy was normal and the doctor can't find the myeloma protein in my blood. I had hoped to enjoy my remission, but my doctor wants me to consider taking thalidomide as an "insurance policy" to keep the myeloma from coming back. What is your take on maintenance therapy?

Debbie Birns, Paul Hewitt, Nancy Baxter, and Missy Klepetar

Two caveats are in order. First, we are defining "maintenance therapy" narrowly to signify treatment given following stem cell transplant to "maintain" the gains made with high-dose therapy. The issue of maintenance therapy following induction or "frontline" therapy is a thorny and unresolved one, and there is simply not enough clinical trial data available to establish guidelines. Second, it is important to note that even in the context of ongoing therapy after autologous stem cell transplant, maintenance therapy is a controversial and much-discussed topic in myeloma, and we are far from having a definitive answer.

The first and simplest statement that can be made concerning maintenance therapy post transplant is: **for patients who are in complete remission (CR) or very good partial response (VGPR, or ≥90% reduction in monoclonal protein) after an autologous transplant, there are no data to indicate that further therapy is necessary and/or beneficial.**

"…because responses may occur with doses of 50 to 100 mg/day, maintenance therapy with these low doses should be proposed… thalidomide could benefit patients who do not have a very good partial response (VGPR) at time of randomization, but has a limited effect among patients already in VGPR at time of randomization. Thus, thalidomide may improve the survival by reducing the tumor mass after high-dose therapy rather than by a pure maintenance effect. This result also suggests that stopping thalidomide as soon as VGPR has been reached could be an effective strategy to reduce the side effects and to avoid thalidomide resistance at time of relapse."

If the response to auto transplant is less than VGPR, then we must turn to the results of a significant clinical trial conducted by the Intergroupe Francophone du Myelome (IFM), a large clinical trials consortium in France with a long history of expertise in autologous stem cell transplantation. The trial results were published in Blood in November 2006, with Dr. Michel Attal as chief author. The article is entitled "Maintenance therapy with thalidomide improves survival in patients with myeloma." Patients were randomized two months after stem cell transplant to receive no maintenance, pamidronate only, or thalidomide plus pamidronate, and were followed for four years. The authors' two major conclusions were: "Thalidomide is an effective maintenance therapy in patients with multiple myeloma," and "Maintenance treatment with pamidronate does not decrease the incidence of bone events."

However, examining more closely the conclusion that thalidomide is an effective maintenance therapy, one must look at the subset of patients for whom this statement was true. The authors summarized their findings as follows: It was true for patients who failed to achieve at least a VGPR. In other words, thalidomide was beneficial for the active treatment of residual disease (≥ 10% residual) after transplant.

The authors, thus, do not recommend ongoing thalidomide treatment for patients who are already in complete remission (i.e. those in whom no monoclonal protein can be measured). Much more research needs to be done on the issue of maintenance therapy both post transplant and in the non-transplant setting. Below are some of the areas that are under investigation:

- the role of corticosteroids added to thalidomide maintenance;
- the role of maintenance therapy in patients with high-risk myeloma;
- the role of Velcade® (bortezomib), Revlimid® (lenalidomide), and experimental agents that target cell-signaling cascades or surface receptors as maintenance therapy.

We encourage all myeloma patients to discuss the pros and cons of maintenance therapy in their own particular case with their oncologists and to consider participating in clinical trials that will help answer these important questions. **MT**

NLB UPDATE — continued from page 12

Is there one simple recommendation you can make that would help patients better tend to their overall health?

If you wouldn't want your internist treating your myeloma, why would you want your myeloma specialist treating your hypertension or diabetes? Doctors who keep up-to-date in their area of specialty may not be as current in new drugs or guidelines in other areas of medicine. Many patients travel long distances to see myeloma specialists but, to improve or maintain coordination of their overall health, they should also have a local internist looking after them. **MT**

GASTROINTESTINAL SIDE EFFECTS — continued from page 13

healthcare team. We understand that some patients feel embarrassed to talk about constipation and diarrhea. We understand that nausea and vomiting are sometimes not reported immediately because patients believe this is part of the treatment and they try to cope on their own. "I did not want to bother you," they say. But we are here to help our patients, and adequate management of side effects ensures a better outcome for them. **MT**

SPOTLIGHT ON ADVOCACY

Congress Busy with Myeloma Related Issues in 2008

By Christine Murphy, MA

While Congress focuses on issues such as the upcoming Presidential election, the economy, the housing crisis, and the War in Iraq, other issues such as those of importance to the myeloma community also received attention in the first half of 2008. This is a summary of cancer related issues that Congress worked on before adjourning for the Memorial Day Recess.

Christine K. Murphy, MA
Murphy Consulting LLC
Arlington, VA

Genetic Information Nondiscrimination Act Signed Into Law

Genetic information can no longer be used to deny someone health insurance or job opportunities under legislation passed by the US House of Representatives and the Senate in late April 2008 and signed into law by the President. Representative Louise Slaughter (D-NY) first introduced a genetic nondiscrimination bill 12 years ago. The Genetic Information Nondiscrimination Act makes it illegal for a health plan or insurer to deny coverage or charge higher premiums to a healthy person based solely on a genetic predisposition to a disease. Similarly, an employer cannot use genetic information in making hiring, firing or promotion decisions.

Kennedy and Hutchison Drafting Comprehensive Cancer Bill

Senators Ted Kennedy (D-MA) and Kay Bailey Hutchison (R-TX) are drafting legislation that would impact all aspects of cancer care. The overall objective of this legislation is to advance the continuum of cancer care, including research, education, prevention, detection, treatment, and survivorship issues. Senators Kennedy and Hutchison have been working with the cancer community in the development of this legislation. The Kennedy-Hutchison cancer bill is expected to be introduced in 2008.

Access to Cancer Clinical Trials Act of 2008 Introduced in the Senate

On May 8, Senators Sherrod Brown (D-OH), Arlen Specter (R-PA), and Sheldon Whitehouse (D-RI) introduced S 2999, the "Access to Cancer Clinical Trials Act of 2008," a companion bill to HR 2676, which was introduced by Representative Deborah Pryce (R-OH) in 2007. The purpose of S 2999 is to prohibit a group health plan from:

(1) denying an eligible participant or beneficiary participation in clinical trials related to the treatment of cancer that are federally funded or conducted under an investigational new drug application reviewed by the Food and Drug Administration (FDA);

(2) denying (or limiting or imposing additional conditions on) the coverage of routine patient costs* for items and services furnished in connection with such participation; or

(3) discriminating against an individual on the basis of such participation.

NIH Could Receive Extra $400 million in FY 2008

The Senate Committee on Appropriations included $400 million for the National Institutes of Health (NIH) in the fiscal year (FY) 2008 supplemental appropriations bill. With this increase to NIH, the National Cancer Institute (NCI) would receive an additional $65 million on top of the $4.8 billion already appropriated in FY 2008. The inclusion of these funds in a supplemental funding bill is extremely rare and illustrates the strength of support that cancer research has in Congress.

The funds for NIH are being added as part of a larger spending package for key domestic priorities. The full Senate considered the bill during the week of May 19. Because the President is opposed to the domestic spending, it is likely that the bill will be challenged by his supporters in the Senate necessitating a 60 vote majority to pass the Senate.

IMF Cosponsors Briefing on Improving Cancer Care

The International Myeloma Foundation, along with partners in the cancer community, cosponsored a briefing on the importance of cancer care plans and cancer treatment summaries in guaranteeing high quality cancer care. The briefing encouraged Congress to forward HR 1078/S 2790, the "Comprehensive Cancer Care Improvement Act". The Comprehensive Cancer Care Improvement Act improves the coordination of all elements of cancer care, including quality cancer treatment and appropriate symptom management. A core provision of this bill would establish a new Medicare service for cancer care planning which has been identified by the Institute of Medicine as an element of quality cancer care for cancer survivors.

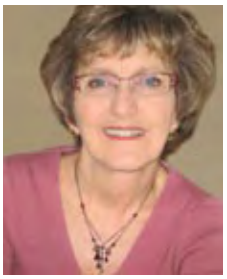
Congressional attention for cancer issues (other than funding for important cancer programs) will soon wane as the election draws closer. The IMF will continue to monitor these issues and push for Congress to take action on myeloma specific issues before adjournment of the 110th Congress. For more information on IMF's advocacy activities, please visit www.myeloma.org. **MT**

*Routine patient costs are all items and services provided in the clinical trial that are otherwise generally available to a qualified individual, with certain exceptions.

Imagine Moving Forward is the theme of the IMF's myeloma bracelet. Wear one in honor, celebration, or in memory of a loved one. When people ask you about it, you'll have a perfect opportunity to spread the word about multiple myeloma. These bracelets are only $1 each in sets of 10. Youth bracelets are now available, so everybody in your family who has been touched by myeloma can wear one! Order bracelets online at our website www.myeloma.org, or contact Suzanne Battaglia at SBattaglia@myeloma.org or 800-452-CURE (2873).

2008 IMF SUPPORT GROUP LEADERS' RETREAT

By Paula Van Riper



In August 1999, I thought I had a muscle strain in my right leg. Instead, as an orthopedist soon discovered, I had a large solitary plasmacytoma at the "neck" of my femur, where it meets the hip. I was in danger of fracturing my leg and having the myeloma cells enter my bloodstream. Within five days I was in the hospital having the tumor removed and my hip replaced.

A couple of days after my surgery, I found the IMF through the Internet. I called the Hotline and, in that moment, my life changed. I was no longer alone. The IMF became my source of information, inspiration, and education. The Foundation has been near and dear to me ever since, and I continue to embrace the IMF for taking me, and others like me, out of the darkness. With a positive attitude, I was walking within five days of the surgery, and I was soon back at work as Dean of Academic Services at Rutgers University.

Three years later, my IgG climbed to a level that required treatment. Due to chromosome 13 deletion, a single autologous transplant was unlikely to result in a durable remission, so I opted for an auto transplant followed by a series of mini-allogeneic transplants. It was after my first allo that I attended my first IMF Patient & Family Seminar, and it was then that I made a deal with myself – as soon as I felt better, I would start a myeloma support group in my area.

I approached the IMF for help with getting a group off the ground. Not only did I receive assistance but, even before my group was formed, I received an invitation to attend a Support Group Leaders Retreat. That wonderful experience gave me the huge confidence and the practical tools I needed to get my group started. I knew that I had a great organization backing me every step of the way in my new endeavor. The first meeting of the Central New Jersey Myeloma Support Group took place in July 2005, with four people sitting around my kitchen table. My support group has since grown to 40 active members, and I have now attended four IMF Support Group Leaders' Retreats.

The ninth annual IMF Support Group Leaders' Retreat took place April 11–13 in Tempe, AZ. The patient community had the largest representation ever, with 70 leaders and a total of 125 participants from groups across the US, Canada, and Europe.

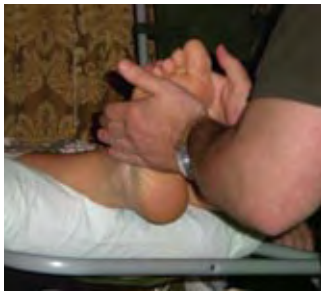
I remain in awe of how thoughtful and conscientious the IMF is in providing training and leadership for the myeloma patient and caregiver community. The IMF helps us to start groups and to maintain them, but what I find most remarkable is that the IMF listens to its membership with such sensitivity that it proactively anticipates our needs even before they arise.

Susie Novis and some of the audience of support group leaders

As at all the IMF events I have attended, the retreat's agenda was well thought out, giving participants an opportunity to learn from some of the most experienced people in the field of myeloma. Even when the IMF re-examines topics from previous years, the information is always updated and presented from a new perspective. It is always exciting to hear what is happening in myeloma research and what is new in the clinical setting. Dr. Brian Durie and Dr. Rafael Fonseca provided us with valuable insights into the scientific and clinical world of myeloma. Dr. Durie and Bonnie Jenkins, a nurse for more than 20 years and a member of the IMF's Nurse Leadership Board, held an open discussion about talking to your doctor. Teresa Miceli, another member of the IMF's Nurse Leadership Board, covered the complex issue of treatment side effects.

Dr. Durie and Bonnie Jenkins held an open discussion about how to talk to your doctor

David Girard gave a hands-on presentation of reflexology and as well as a discussion of complementary medicine. When he demonstrated the techniques of reflexology, many of the volunteers reported improvement in the way their feet and legs felt afterwards. Both of David's sessions were very informative, and I came away with a better understanding of these areas.



David Girard demonstrating reflexology

Debbie Exner and Maddie Hunter co-presented a session entitled "Patient NOT Passive"

Maddie Hunter and Debbie Exner co-presented a session entitled "Patient NOT Passive" to help the participants to be more fully engaged with their medical team. The session included demonstrations of effective interactions and evaluation of valuable phraseology that can be employed when dealing with medical professionals. It is possible to be polite while being persistent in pursuing the best possible medical care.

Continues on Next Page

SOUTHEASTERN VIRGINIA MULTIPLE MYELOMA SUPPORT GROUP

Jerry Walton was diagnosed with myeloma two years ago. His response to the diagnosis was to take action and, with help from the IMF, to launch the SouthEastern Virginia (SEVA) Multiple Myeloma Support Group. "I hoped that by coming together and supporting each other on a personal level, we would help each other become more educated," says Jerry. The group held the first of its monthly meetings in August 2007, and Jerry's vision quickly began to take shape. Group members exchange information, share experiences, participate in lively discussion, and provide support to one another. Some SEVA meetings feature guest speakers who give presentations on various topics of interest to the group. "Some people say they live to learn," adds Jerry, "As myeloma patients, we learn to live."

Since its inception, SEVA has been serving patients and caregivers in the Norfolk, Virginia Beach, and northeast North Carolina areas. Now, thanks to the Polycom voice conferencing system provided by the IMF, the group's horizon has expanded immensely. Polycom technology has made it possible for speakers to address the group via long-distance discussions. Group meetings have also started to include some members who are unable to be physically present. In one case, a group member was able to participate in a meeting while she was undergoing treatment out of town. In another, a member not ready to travel following a stem cell transplant joined the discussion from her home over 100 miles away. "It was a real treat to be able to connect and extend our group support across the miles," says Jerry. "We look forward with great excitement about this new tool to bringing myeloma experts and their knowledge into our midst, and to staying in touch with members who are receiving or recovering from treatment out of the local area. Thanks a million to the IMF for making the SEVA acronym stand for more than just SouthEasternVirginiA. It now also stands for Superbly Enhanced Vocal Access." **MT**

Editor's Note: This group meets the third Saturday of each month from 10am to noon at the Catholic Charities building in Virginia Beach, VA. For more information, please visit SEVA's website at www.seva.myeloma.org or contact Jerry Walton at jerryewalton@cox.net or 757-495-8432.

SGLR — continued from page 16

The retreat introduced three technology-based initiatives that I am very excited about. The Myeloma Manager™, a computer software tool, was developed by the IMF to help patients and caregivers navigate the seemingly unmanageable and complex information of various myeloma tests and treatment programs. It helps organize laboratory results and other medical information, and offers online support for this innovative tool. The Myeloma Manager is something that can benefit every patient. The vast majority of us are not medical professionals, but it is very important for each of us to track our status with our disease. With the Myeloma Manager, all one has to do is plug in the relevant numbers and see them converted into charts and graphs that plot the trend of your disease. Quite literally, the Myeloma Manager gives us a picture of where our disease is going. Most doctors don't have the time to do that kind of tracking on individual patients. The Myeloma Manager empowers patients to stay on top of the disease and to establish a more productive and dynamic dialogue with the doctors.

Another technology-driven tool that the IMF has now made available to us is to set up support group websites. Most of us have no idea how to create a website, and having a template and assistance with setting it up is most helpful. Some groups already have their own websites, but mine didn't, so I am happy to take advantage of this offer from the IMF.

The IMF has also created a web portal for support group leaders, which serves as a mechanism to post and to share helpful information, including programs that proved to be popular when presented to their groups. This online forum facilitates communication and offers a library of resources for group leaders. I am very excited about having access to information and ideas that may be new tome and my group that have already been tested and refined by other group leaders.

After five years of drug-free remission, last summer I developed a tumor in my spine. With the help of radiation and lenalidomide, I am back to feeling wonderful and I feel very blessed to be marking the eighth anniversary of my diagnosis this August. The IMF has been an important partner in my journey with myeloma. I have personally benefitted from the IMF's efforts to bring information and hope to patients. Now, as a support group leader, I am honored to serve as a conduit between the IMF and to the patient community.

Fluid education, information, new tools and techniques, and camaraderie are what the IMF Support Group Leaders' Retreat program is all about. As in previous years, I returned home energized and excited about sharing with my group what I learned at the retreat. I often say that myeloma is the best and the worst thing that has ever happened to me – it has complicated my life but it has also introduced me to the most wonderful people with whom I have developed amazing friendships that I would have never had if not for my diagnosis. There are people from all across the US, and some from Canada, who have become family to me. This is why instead of saying "Why me?" I now say "Thank you." I would like to encourage all myeloma group leaders to take part in the invaluable experience of the IMF Support Group Leaders' Retreat. You and your group will be glad you did. **MT**

Editor's Note: The 10th annual Support Group Leaders' Retreat will take place in Irving, TX, July 10–12, 2009. For more information, please contact the IMF at TheIMF@myeloma.org or 800-452-CURE (2873).

IMF EUROPE CONDUCTS MEETINGS IN SPAIN

The IMF hosted its 5th Patient & Family Seminar in Spain in Valencia on May 31, 2008. This was the first seminar held in Spain in a city other than Madrid or Barcelona. The goal of the IMF Europe program is to expand the reach of its seminars to patients in all parts of the country.

Dr. Javier de la Rubia (University Hospital La Fé, Spain) hosted the Valencia seminar. IMF Scientific Advisors Dr. Morie Gertz (Mayo Clinic, USA) and Dr. Joan Bladé (University Clinic of Barcelona, Sapin) also participated in the event. One hundred patients and family members from throughout western Spain attended the six-hour meeting.

Audience member asks question at the IMF Patient & Family Seminar in Valencia

The meeting was held at the Valencia Hilton and featured talks by each doctor covering a spectrum of topics, including an introduction to myeloma, when to begin treatment, and managing side effects. A panel discussion was followed by questions from the audience, then an hour of breakout sessions in which each doctor answered questions from attendees.

"My mother was diagnosed with myeloma four years ago, and from the first moment our main source of education was the IMF website. The scientific information was honest and easy to understand. It was great to have the opportunity to attend Valencia IMF Patient & Family Seminar."

– Pachi Clemente, attendee

Gregor Brozeit, Dr. Javier de la Rubia, Dr. Joan Bladé, Dr. Morie Gertz, and David Girard

"I found the patient reception very warm – they were enthusiastic & inquisitive. It was a privilege to present to such a committed group of patients."

– Dr. Morie A. Gertz

The IMF also hosted doctors' meetings in Barcelona and Pamplona for practicing hematologists and hematology residents. Dr. Bladé hosted a lecture in Barcelona at the University Hospital Clinic, which featured Dr. Gertz, and Dr. Felipe Prósper hosted a lecture in Pamplona at the University of Navarra Hospital Clinic, which featured Dr. Gertz, Dr. de la Rubia, and Dr. Maria-Victoria Mateos (University of Salamanca, Spain). The meetings offered comprehensive educational sessions covering the role of novel therapies in the treatment of myeloma and amyloidosis. **MT**

UPDATES FROM AROUND THE GLOBE

EMEA recommends new contraindication for Velcade®

The European Medicines Agency (EMEA) has recommended that Velcade® (bortezomib) should not be used in multiple myeloma patients who are diagnosed with either acute diffuse infiltrative pulmonary disease or pericardial disease. The EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded during its March 2008 meeting that the benefits of Velcade are greater than its risks, except in patients with acute diffuse infiltrative pulmonary and pericardial disease. The CHMP therefore recommended contraindicating the use of Velcade for these patients. The European Summary of Product Characteristics (SmPC) has been updated to reflect these two new contraindications. This change is limited to the European label only. The US Package Insert is not affected and does not contain a contraindication for acute infiltrative lung disease or pericardial disease. The only contraindication in the US label is for those patients with hypersensitivity to bortezomib, boron, or mannitol.

TGA approves a supplemental filing for thalidomide

The Australian Therapeutic Goods Administration (TGA) approved a supplemental filing granting Thalidomide Pharmion® marketing approval for use in combination with melphalan and prednisone for patients with untreated multiple myeloma ineligible for high-dose chemotherapy. Additionally, for the treatment of patients with untreated myeloma, marketing approval was granted for thalidomide in combination with dexamethasone for induction therapy prior to high-dose chemotherapy with autologous stem cell rescue. This marketing approval represents the first oral cancer therapy ever registered for newly diagnosed myeloma patients in Australia. **MT**

Editor's Note: The IMF continues to strive to find better ways to serve our community – wherever in the world it may be. If you have ideas to contribute to our continued growth and development, please feel free to contact us at TheIMF@myeloma.org or 800-452-CURE (2873).

E-PATIENTS: EQUIPPED, ENABLED, EMPOWERED, AND ENGAGED

By Joanna FitzPatrick

You never forget the day you're told. For me it was in the middle of the afternoon on November 4, 2003. My husband Jim walked into my office and said, "I have some bad news." The expression on his face revealed no news other than he was tired, which had been a recent complaint. But at age 60, wasn't he just getting older? "The lab tests from my physical show cancer cells in my blood! The doctor wants me to make an appointment with a hematologist-oncologist immediately."

Jim and Joanna FitzPatrick

"A what? And you have what?" Suddenly my literary vocabulary seemed very inadequate. I needed medical information. Before, I would have run to a library, but now I ran to the Internet. I had just become an e-patient. Jim, of course was the real patient; I became the caregiver. But just like e-mail and e-commerce, the information I started accessing was all on the Internet. I perched my hands over my laptop computer's keyboard and typed "multiple myeloma" into Google's search bar. Hundreds of files about this rare cancer appeared.

Fifteen minutes later I had to close my office door as I read through teary eyes: "A rare disease of malignant plasma cells that, in time, takes over the bone marrow. There is no cure." This was heartbreaking, but I returned to my online research knowing that only with knowledge could I gain some control over the situation. But then… how to sift through all this medical information? How to know what was reliable? Who were the real experts? Who were the quacks?

This is where the myeloma listserv came in. I needed anecdotal advice from people who personally knew about this disease, the patients themselves and their caregivers. An online myeloma support group I found through the Association of Cancer Online Resources (ACOR) was the answer. This website offers access to 159 mailing list communities called listservs that provide support and information to people affected by cancer and related disorders. I registered my name and password on the myeloma listserv of 1400 participants, becoming 1401.

At first I was shy like anyone joining a new community who doesn't know anyone. In the online listserv vernacular it's called "lurking." Then, too anxious to wait two weeks before our first oncologist consultation, I copied Jim's diagnostic lab reports into the listserv address and hit "SEND." Out it went to fourteen hundred strangers. An hour later I had received a dozen compassionate and knowledgeable responses from myeloma caregivers and patients! After reading these reassuring messages, many from cancer survivors who have defied the statistics, I felt a surge of hope.

At our first meeting, our oncologist told us that Jim's cancer was aggressive and needed immediate treatment. A decision had to be made. The oncologist gave us several options and, aided by the information I had garnered from the myeloma listserv, we chose to participate in a clinical trial. Jim started treatment that day. Eventually tandem stem cell transplants followed his induction therapy.

Jim and I had become what one of our listserv members called "e-patients: equipped, enabled, empowered, and engaged." The myeloma online support group became my virtual community. No one is identified by age, race, gender, income or educational level, but we all come together in a web of love, united in our fight against myeloma, and determined to find its cure.

Mike Katz, a myeloma patient himself, started this listserv in the mid-nineties with fellow myeloma patient, June Brazil. "It seemed like a logical extension to have a 24/7 online resource for people who needed help fighting their disease," he says. "The International Myeloma Foundation (IMF) was very involved from the beginning, hosting the listserv on its web server, providing the software and giving us input on medical issues." In 1998 the site became myeloma@listserv.acor. I will never forget what a difference it made for me the first time I connected to this virtual community and I am indebted to Mike, June, and the IMF for their generous contribution.

After I had a basic medical understanding of multiple myeloma from attending Jim's many doctor appointments and from my own online research, I felt confident to help others on the listserv, particularly the newly diagnosed. Online cancer communities also offer information on Medicare and disability coverage, prescription discounts, treatment choices, side effects from chemotherapy, and new clinical trials. I connected with my online community in a way I could never have connected with my family and friends. Online we discuss vivid details of disease that might make the uninitiated squeamish.

Yes, there is bliss in ignorance and sometimes I wish I knew less, but as Francis Bacon so aptly said, "knowledge is indeed power." Online cancer support groups are powerful and necessary forums for cancer patients and their families. An informed e-patient online group gives patients and families options that never existed before Internet access, and the emotional support of these groups makes the worse days tolerable and the best days a celebration for those of us who must live with cancer. **MT**

Editor's Note: If you are a myeloma patient or caregiver, and you would like to share your story with readers of *Myeloma Today*, please email Marya Kazakova at mkazakova@myeloma.org or write to the IMF at 12650 Riverside Drive, North Hollywood, CA 91607.

IMFers RAISE FUNDS TO BENEFIT MYELOMA COMMUNITY

By Suzanne Battaglia

Kallen Dahlke Cell Phone Drive

When Kallen Dahlke's mother was diagnosed with multiple myeloma the day after Thanksgiving 2007, a relative contacted the IMF to order InfoPacks for the entire family. The packet contained a leaflet with ideas for raising funds to support myeloma research and other IMF programs. Kallen chose to tackle cell phone collection as her project, but decided not to share this with her family right away. "I was worried about letting them down if the project didn't succeed, so I wanted to make sure I could pull this off," says Kallen. First, she contacted the school board for permission to place cell phone collection boxes in a local high school. Next, Kallen solicited prizes to be awarded as part of her drive, including a flat-screen television donated by Best Buy and gift certificates to a local hair salon. Then she brought her family and friends aboard.

Chris and Kallen Dahlke

In January, volunteers started collecting phones and distributing flyers about the project. Collection boxes were placed at the Port Huron Northern High School, where Kallen's father is the Principal, and several students took a personal interest in the project. Two weeks later, 727 cell phones had been collected.

"I am very proud of everyone who supported this project. It felt so good to know how many people cared," says Kallen. "My family and friends, the high school students, coworkers, and other members of the local community helped out tremendously. I am grateful for their participation, without which this project would not have been so successful. My aim was to find a way to benefit myeloma patients in honor of my mom but, unexpectedly, this experience has also become part of my family's healing process."

Meet the new Director of Member Events

Suzanne Battaglia has been promoted to the position of Director of Member Events. Suzanne joined the IMF in January 1997, bringing with her 20 years of experience in theatrical and event production. As Producer of Special Events, she spearheaded the IMF's first four Gala celebrations, as well as the Robert A. Kyle Lifetime Achievement Award dinners. Suzanne created the successful "Mail For The Cure" campaign, and has worked on a broad variety of fundraisers across the US. "For the last several years, I have focused on growing the program of grassroots events that are highly successful in raising public awareness, as well as funds for myeloma research and other IMF programs," says Suzanne. "I really enjoy my one-on-one relationships with IMFers, and I try to personally attend as many events as possible. It is very rewarding to see our members become empowered and, in turn, to empower others in their local communities." Please join us in thanking her for the many years of dedicated service to myeloma patients and caregivers. Suzanne can be reached at sbattaglia@myeloma.org.

Music Against Myeloma

On April 24, the third annual Music Against Myeloma event took place at the Cutting Room, a popular club in the heart of New York City. The event was conceived by Slava Rubin in memory of his father, Mark Rubin, who passed away in November of 1993. Music Against Myeloma is Slava's way to honor his dad while raising awareness and funds for myeloma research.


Thomas Ian Nicholas, Suzanne Battaglia, and Slava Rubin

Music Against Myeloma tickets were sold for $30 in advance and $50 dollars at the door, and offered the 200 attendees who gathered to support the event lots of value for the money.Thanks to Red Bull and Budweiser, drinks were free. Guests who wanted to keep their taste buds happy enjoyed delicious cupcakes baked by Sugar Sweet Sunshine and delectable assorted cheeses donated by Murray's. And there was live music all night long from performers including Lost in October, Holtz, Amanda Thorpe, Rachel Platten, Avi Wisnia, and Thomas Ian Nicholas. Tony Orlando was also on hand to sing a couple of favorites. Guests also had the opportunity to bid on incredible sports memorabilia presented by Grandstand Sports, and to buy comfy socks donated by Pralin.

This year, Mike Katz, IMF director and myeloma patient, attended the event and spoke to the crowd about the impressive progress that has been made in myeloma research and treatment since Mark Rubin's diagnosis. More advances in the field are forthcoming, and Music Against Myeloma is committed to helping facilitate this process.In its three years,the event has raised over $45,000 for myeloma research, thanks togenerous sponsors, incredible music talent, and a host of amazing people dedicated to its success. We all look forward to the day when Music Against Myeloma celebrates this disease becoming a thing of the past.

"JC" Golf Tournament

On May 17, the 9th annual "JC" Golf Tournament was held at the Wapicada Golf Course in St. Cloud, MN. The event honors the memory Janet "JC" Johnson. The five-person scramble format was enjoyed by 160 golfers, and was followed by tournament prizes, dinner, a silent auction, and a dance featuring the band "Canoise." Green Mill Restaurant and Short Stop Custom Catering returned as the event's major sponsors and provided dinner for all participants.

The winning team, comprised of five men from the Zins family, shot 16 under! The Zins family was instrumental to organizing the first the "JC" golf tournament 10 years ago, and Larry Zins, Bob Zins, and Mary Zins Klis, along with other board members, have kept things rolling ever since. "For us, this event is definitely a family affair, "says Mary Zins. "My parents and all non-golfing siblings and spouses attend the dinner, and the rest of us,

Continues on Next Page

IMF FORMS THE FOUNDERS' CIRCLE

Major donors recognized at inaugural Summit

By Heather Cooper Ortner

To recognize and thank the major donors who have had a significant impact on the activities of the IMF, the Foundation has formed donor recognition circles. This year, we also created a Summit to recognize those donors at the Founders' Circle level and above. All IMFers invited to join the Fouders' Circle Summit have made significant donations to support our mission of improving the quality of life of myeloma patients while working toward prevention and a cure.

Dr. Brian Van Ness

Participants in the inaugural Founders' Circle Summit have an exclusive and unique opportunity to get a behind-the-scenes look at what is happening in the world of myeloma research and where the new discoveries are likely to take us in the near future.

Dr. Brian Durie

During a full day of off-the-record briefings, participants were given an overview of the groundbreaking progress being made in research labs around the world.

The myeloma experts on hand included Dr. Brian Durie, Chairman of the IMF and member of its Scientific Advisory Board, Dr. Brian Van Ness, IMF Scientific Advisor and co-director of the Bank On A Cure® DNA research initiative, and Dr. Howard Urnovitz, an expert in the field of genomics and chronic disease and CEO and co-founder of Chronix Biomedical Inc.

Dr. Howard Urnovitz

The inaugural Founders' Circle Summit took place on June 20-21 in Los Angeles, CA. Twenty major donors from across the US attended in person, and several other members joined the meeting via telephone. Participants were treated to a delightful welcome dinner, followed the next day by intimate discussions about research supported by the IMF. The Summit concluded with a thank-you dinner.

The Founders' Circle Summit will become an annual IMF event, with the next meeting already scheduled tentatively for May 1–2, 2009. **MT**

MEMBER EVENTS — continued from page 20

The winning team: Larry Zins, Scott Zins, Jeff Zins, Jim Zins, and John Zins

including all the kids, are out on the golf course. Our aunts and uncles and cousins, plus all our friends, participate in some way. There are several other families with similar participation, which is why this tournament is so special to so many of us. It's about friends and family having a great time for a great cause."

To date, thanks to sponsors, donors, prize contributors, and volunteers, the tournament has raised over $152,000 to benefit IMF programs.

Join Us

We are grateful to all IMFers who contribute their time, imagination, and hard work to benefit the myeloma community. Our FUNdraising program provides you with the tools, assistance, and expertise to make your event a success. Choose an established event model or create your own – no idea is too large or too small. Join us in working together toward our common goal... a CURE. Please contact me, Suzanne Battaglia, at sbattaglia@myeloma.org or 800-452-CURE (2873). **MT**

UPCOMING MEMBER EVENTS

September 6, 2008 **"Heuer Golf Tournament"** – Caledonia, NY
Contact: Nancy Heuer, 585-538-4333 or nheuer@cob.rit.edu

September 26, 2008 **"Bertino Beer & Wine Tasting"** –
Huntingdon Valley, PA
Contact: Kathy Bertino, 610-905-0310

November 1, 2008 **"Evening 4 A Cure"** – Lancaster, NY
Cocktails, Chinese, Silent and Live Auctions, Dinner – Fox Valley Club
For details & info about attending, contact: Jerra Barit 716-741-9351

Staff Updates

Missy Klepetar

After several years working in education management at UCLA Medical Center and Pepperdine University School of Law, Missy Klepetar joined the IMF staff as a Development Assistant. Starting August 2006, she supported the day-to-day needs of the Development department and, in addition, managed all registrations for the IMF Patient & Family Seminar program. In May 2008, Missy made the transition to the IMF Hotline as the Hotline Associate. To prepare for her new role at the IMF – helping answer your questions about myeloma – she has received extensive training from Hotline Coordinators Debbie Birns, Nancy Baxter, and Paul Hewitt. To contact Missy, please email mklepetar@myeloma.org.

Rachael Coffey

Rachael Coffey holds a degree in Public Health Education. She has worked for the Northern Michigan Hospital Community Health Education Center and has served as an Executive Assistant in the Department of Medical Affairs at Aptium Oncology Inc. in Los Angeles. In July 2007, Rachael joined the IMF as an Administrative Assistant. She is in the office part-time as she is currently working on a Master's degree in Nursing at UCLA. At the IMF, Rachael assists David Girard with the Bank On A Cure® project by helping to manage the database, prepare weekly updates, perform survey intake, coordinate mailings, and answer questions from callers. She also works with Lisa Paik on submissions of manuscripts for publication. For the IMF Patient & Family Seminar program, Rachael prepares the attendee materials. To contact Rachael, please email rcoffey@myeloma.org.

Cell Phones for a Cure

Put your old cell phone to good use!

Donate your old cell phone and become part of finding the cure. The IMF has partnered with a cell phone recycling organization that makes a donation for every cell phone we turn in. Current cell phone models are worth up to $20 each. Many older models are worth $1 to $10.

You can help the IMF continue its research and programs. You can help our environment. You can provide cell phones to underserved communities. And it's as easy as sending us your old cell phones. For more information about how to turn your old cell phone into a contribution (or how to set up an IMF collection program at your business or school), call Kemo Lee at at 800-452-CURE (2873).

Or, you can mail your phones direct to the IMF:

International Myeloma Foundation
c/o **Cell Phones for a Cure**
12650 Riverside Drive, Suite 206
North Hollywood, CA 91607-3421.

2008/2009 IMF Calendar of Events

Aug 8–9	IMF Patient & Family Seminar – Short Hills, NJ
Aug 22–23	IMF Patient & Family Seminar – San Diego, CA
Sept 2	IMF Patient & Family Seminar – Berlin, GERMANY
Sept 6	CMG Annual Patient Day – Podebrady, CZECH REPUBLIC
Sept 12	Regional Community Workshop – Honolulu, HAWAII
Sept 18–19	Biennial – 5th Annual International Symposium on Clinical Applications of Serum Free Light Chain Analysis – Bath, UK
Oct 11	Regional Community Workshop – KC, MO area, KS
Oct 13*	Regional Community Workshop – St. Charles, MO *(date may change)*
Oct 10	IMF Patient & Family Seminar – Paris, FRANCE
Oct 17	IMF Patient & Family Seminar – Rome, ITALY
Oct 18	Regional Community Workshop – Longview/Gladewater, TX
Oct 20–26	Myeloma Awareness Week – NATIONWIDE
Oct 25	Regional Community Workshop – Twin Cities, MN
Oct 29–Nov 2	Southwest Oncology Group (SWOG) meeting – Chicago, IL
Nov 14–16	Eastern Cooperative Oncology Group (ECOG) meeting – Ft. Lauderdale, FL
Nov 22	4th Annual Southwest Symposium– Phoenix, AZ
Dec 6–9	American Society of Hematology (ASH) meeting – San Francisco, CA
– 2009 –	
April 17–18	IMF Patient & Family Seminar – San Francisco, CA
July 10–12	Support Group Leaders Retreat – Dallas, TX

Other events/meetings will be posted in later editions of *Myeloma Today* as dates are finalized.
For more information, please visit www.myeloma.org or call 800-452-CURE (2873).
IMF–Latin America, IMF–Japan and IMF–Israel events are not included above.

Honorary Co-Chairs
Irena & Mike Medavoy • Julie Chen & Leslie Moonves
Chair
Loraine Boyle
Honorary Committee
Kevin & James Abernathy
Alec Baldwin
Candice Bergen
Halle Berry
Lisa Birnbach
Ruth & Jake Bloom
Lorraine Bracco
Kim Cattrall
Blythe Danner
Lisa Doty & Stu Smiley
Caroline Ducrocq & Howard Hesseman
Andrea Eastman
Susie Essman
Marc Forster
Paula & Peter Gallagher
Ronda Gomez-Quinones & Howard Zieff
Carl Gottlieb
Robin Green & Mitchell Burgess
Deborah & Allen Grubman
Mariska Hargitay
Patricia Heaton & David Hunt
Michael Keaton
Robin Leach
Dr. Stuart Lerner
Alex Meneses
Jenny & Robert Morton
Annette O'Toole & Michael McKean
Diane Passage & Ken Starr
Chynna Phillips & William Baldwin
Doris Roberts
Anna & Ray Romano
Jane Rose
Janet & Marvin Rosen
Monica & Philip Rosenthal
Chrisann Verges & Ricky Jay
Mary & Fred Willard
Alfre Woodard & Roderick Spencer
Committee in formation as of July 15, 2008

Celgene & MILLENNIUM®
present

INTERNATIONAL MYELOMA FOUNDATION

2nd Annual Comedy Celebration

Benefiting the Peter Boyle Memorial Fund

Hosted by
RAY ROMANO
Featuring
JEFF GARLIN, PATRICIA HEATON, ROBERT KLEIN, DORIS ROBERTS & FRED WILLARD
Additional performances to be announced

Saturday, November 15, 2008 – 6:00pm
The Wilshire Ebell Theatre & Club – Los Angeles, California

For information about sponsorship opportunities, please call **(818) 487-7455** or email: **events@myeloma.org**

SAVE THE DATE!

International Myeloma Foundation
12650 Riverside Drive, Suite 206
North Hollywood, CA 91607-3421
U.S.A.
www.myeloma.org
(800) 452-CURE (2873)
Change Service Requested

"Until There is a Cure... There is the IMF."

NON-PROFIT ORGANIZATION U.S. POSTAGE PAID N. Hollywood, CA PERMIT NO. 665

Dedicated to improving the quality of life of myeloma patients while working towards prevention and a cure.