



Myeloma Today

A publication of the International Myeloma Foundation

IMWG tackles the rising cost of myeloma treatments PAGE 4



When hope collides with sky-high price tags

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IMF Executive Team

Chief Financial Officer
Jennifer Scarne
jscarne@myeloma.org

**Senior Vice President,
Strategic Planning**
Diane Moran
dmoran@myeloma.org

**Senior Vice President,
Clinical Education & Research Initiatives**
Lisa Paik
lpaik@myeloma.org

**Senior Vice President,
Global Affairs**
Daniel Navid
dnavid@myeloma.org

**Senior Vice President, Global Medical
Affairs & Strategic Partnerships**
Pierre Sayad
psayad@myeloma.org

IMF Staff

Database Manager
Sevag Abajian
sabajian@myeloma.org

Inventory Control Manager
Betty Arevalo
marevalo@myeloma.org

Director, Member Events
Suzanne Battaglia
sbattaglia@myeloma.org

Medical Editor
Debbie Birns
dbirns@myeloma.org

**Southeast Regional Director,
Support Groups**
Nancy Bruno
nbruno@myeloma.org

Senior Director of Advocacy
Meghan Buzby, MBA
mbuzby@myeloma.org

**Special Events and
Donor Relations Manager**
Sharon Chow
schow@myeloma.org

**Director, Support Groups &
Regional Community Workshops**
Kelly Cox
kcox@myeloma.org

Administrative Assistant
Elaine DeLasho
edelasho@myeloma.org

**Director, Europe &
the Middle East**
Nadia Elkebir
nelkebir@myeloma.org

**Midwest Regional Director,
Support Groups**
Sue Enright
senright@myeloma.org

Meeting Coordinator
Carmen Greene
cgreene@myeloma.org

InfoLine Coordinator
Paul Hewitt
phewitt@myeloma.org

Web Specialist
Kevin Huynh
khuynh@myeloma.org

Editor-in-Chief, Publications
Marya Kazakova
mkazakova@myeloma.org

Member Events Associate
Ilana Kenville
ikenville@myeloma.org

InfoLine Coordinator
Missy Klepetar
mklepetar@myeloma.org

Communications Associate
Sapna Kumar
skumar@myeloma.org

Medical Affairs Assistant
Xuan Lam
xlam@myeloma.org

Accountant
Phil Lange
plange@myeloma.org

Research Project Coordinator
Amirah Limayo
alimayo@myeloma.org

Director, Development
Randi Lovett
rlovett@myeloma.org

Publication Design
Jim Needham
jneedham@myeloma.org

**Florida Regional Director,
Support Groups**
Anne Pacowta
apacowta@myeloma.org

Director of Operations
Selma Plascencia
splascencia@myeloma.org

Director of Meetings
Annabel Reardon
areardon@myeloma.org

**Development &
Operations Assistant**
Joy Riznikove
jriznikove@myeloma.org

Web Producer
Miko Santos
msantos@myeloma.org

Director of Major Gifts
Elise Segar
esegar@myeloma.org

Distribution
Brando Sordoni
bsordoni@myeloma.org

Assistant to the President
Rafi Stephan
rstephan@myeloma.org

Advocacy Associate
Lindsey Trischler
ltrischler@myeloma.org

**Senior Director,
Support Groups**
Robin Tuohy
rtuohy@myeloma.org

InfoLine Coordinator
Judy Webb
jwebb@myeloma.org

Outreach
Jonathan Weitz
jweitz@myeloma.org

**Global Advocacy
Executive**
Ray Wezik
rwezik@myeloma.org

A Message from the President

Dear Reader,

In June, the IMF held the 7th annual IMWG (International Myeloma Working Group) Summit, and once again it was a huge success. For those of you who are new to the IMF, I'd like to take this opportunity to tell you about how the "working group" started and why it's so important.

Years ago, Dr. Durie and I were talking about what it would take to really move myeloma research forward and ultimately find the cure. Not a small "nut to crack" that's for sure. There were more and more people becoming interested in myeloma but there wasn't a lot of collaboration. If we were serious about finding a cure, we had to get these great minds to work together and, truthfully, at first it wasn't easy. We held the first meeting in 2004 at ASH in San Diego, CA, and maybe 6 or 7 people showed up. We were on our way! From that fledgling meeting, more and more people came on board and today the IMWG is comprised of 210 members from 34 countries. Over the years we've formed work groups based on the members' areas of interest and expertise. To date, IMWG members have published 46 papers in the most prestigious journals, with many more in progress. These papers are very important, as they provide guidelines covering all aspects of myeloma (e.g., diagnosis, treatment, relapse, maintenance).

The IMWG meets twice a year, at the annual meeting of ASH in December and at the annual two-day IMWG Summit held just prior to the annual meeting of EHA (European Hematology Association).

This year's IMWG Summit was held in Copenhagen, Denmark. The meeting agenda was very exciting and included plenary

sessions with Drs. Paul Richardson, Philippe Moreau, Antonio Palumbo, and Ola Landgren. Topics included screening for MGUS, role of MRD detection, optimal use of imaging methods, how best to use immune therapies, and can we cure myeloma, to name a few. There was a lively debate on early vs. delayed transplant in the era of novel therapies, and in-depth panel discussions on new issues, along with new combinations and how to use them. Work groups drilled down to discuss other important topics, such as cost and value in myeloma therapy, as well as optimal use of immune therapy.

As you can see we've come a long way and, for me, just hearing the word "cure" used has had a profound impact. I always believed we would get there, having my fingers crossed and saying a prayer, and now we're almost there.

It takes collaboration, tenacity, dedication, resources, and incredibly smart people. Please join the IMF as we march toward the finish line!

Warm regards,



Susie Novis Durie, President



The general session of the 2016 IMWG Summit utilized a double-screen format, allowing greater participation in the discussions by the 100+ people in attendance.

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Myeloma Experts of the IMWG Tackle Soaring Costs of Care



By **Brian G.M. Durie, MD**
IMF Chairman

The myeloma community is at a critical moment in its history. While we are pleased that four new myeloma drugs (Darzalex®, Empliciti®, Ninlaro®, and Farydak®) were approved in 2015 by the US

Food and Drug Administration, the annual price tag for some treatment combinations can climb well above six figures. Clearly, this is not a sustainable situation.

Recognizing our responsibility to lead the way in addressing costs effectively, members of the International Myeloma Working Group (IMWG), the research arm of the IMF, launched a plan of action at a special session of the June 2016 annual meeting held in Copenhagen this year.

“The discussion was very lively,” reported Prof. Jean-Luc Harousseau from France, who led the well-attended session. “Many are interested in this question. Are we [IMWG] able to have a significant impact on drug prices? Some were pessimistic. But others said we are a well-respected international group whose guidelines are followed around the world.”



Dr. Jean-Luc Harousseau

An urgent need

Given the current budget-conscious economic climate, the IMWG recognizes there is an urgent need for clear myeloma treatment guidelines which consider cost, but which also protect patients from processes that may limit or distort access.

In the past two years, overly complicated and imperfect treatment value assessment tools have been offered by, among others, the American Society for Clinical Oncology, Memorial Sloan Kettering Cancer Center, and the National Comprehensive Cancer Network. But none drew the outcry that erupted over the myeloma treatment value assessment effort published in April 2016 by the Boston-based Institute for Clinical Economic Review (ICER).

Critics of the draft report were extremely worried that the Centers for Medicare and Medicaid Services (CMS) would turn to ICER for guidance on its proposed overhaul of Medicare Part B, as CMS had done previously in examining costs in other diseases. IMF Senior



Robin and Michael Tuohy

Director of Support Groups Robin Tuohy provided compelling testimony at a May 26th public hearing on the report, explaining why restricting access to myeloma drugs would have threatened the life of her husband Michael Tuohy, a 16-year survivor.

After an onslaught of criticism from patients, doctors, drug makers, and patient advocates, ICER issued a final report in June which admitted that the institute lacked the expertise to adequately assess the complexities of new myeloma therapies. It conceded that a “Fail First” policy is a mistake for myeloma patients. The report’s authors also indicated that they have come to understand that each myeloma patient is unique and that all therapies will be required during the course of multiple relapses.



Dr. S. Vincent Rajkumar

ICER, in essence, deferred to the expertise of doctors who work with myeloma therapies every day and to the experience of patients who have expressed both their needs and their views as impassioned advocates for all patients.

Time to act

But such efforts to shave costs off lifesaving treatments cannot and will not go unchallenged by myeloma experts. And so, the stage is set. It is time for the IMWG to act on behalf of patients.

In the next two months, IMWG members will:

- Prepare access or cost-stratified guidelines for use of therapies throughout the course of the disease, from frontline to relapse. The need for such guidelines was noted in a letter written by Dr. Philippe Moreau and Dr. S. Vincent Rajkumar, and published in *The Lancet* in July. In the face of rapid therapeutic gains in myeloma, they write, patients may not profit due to an “absence of a coherent strategy to tackle the heterogeneity of the disease, paucity of strategic trials and high cost of treatment.” To address the latter, the authors call for “the development of clear guidelines and treatment pathways that take efficacy, safety, and cost into account.” Such guidelines, they write, “should not be an extensive list of all possible options but rather a limited menu of one or two options that are judged to be preferred standards of care.”
- Initiate meetings of all stakeholders, including, of course, patients, pharmaceutical companies, insurers, central pharmacies, hospitals and clinics, health economists, and regulators, who will ultimately need to change the cost and reimbursement landscape.

IMWG consensus statements and guidelines routinely seek the maximum input and feedback to incorporate all opinions and suggestions. We anticipate that useful guidelines developed by the IMWG will also spur desperately needed changes and will transform the cost/payer landscape.

We must develop a system in which treatment costs do not overwhelm the budgets of individuals and healthcare systems alike. **MT**

The Most Important Questions Facing Myeloma Experts in 2016



Congenial colleagues address the 2016 IMWG Summit in Copenhagen: Dr. Jesús San Miguel, Dr. Ola Landgren, Dr. Antonio Palumbo, and Dr. Shaji Kumar.

By Debbie Birns
IMF Medical Writer

Close to one hundred members of the International Myeloma Working Group (IMWG) gathered in Copenhagen from June 7th to 9th, just prior to the European Hematology Association (EHA) meeting, for the seventh annual IMWG Summit. This important and prestigious meeting allows myeloma experts from around the globe to discuss pressing issues and to set an agenda of publications, clinical trials, and advocacy efforts for the coming year.

The meeting began with lectures based on unanswered questions facing myeloma specialists in 2016. Each presentation was followed by a lively discussion. Break-out groups based on these questions followed the general session. Following are the questions under discussion, the sub-questions that must be addressed in order to answer the larger questions, and the steps that will be taken going forward.

Are we ready to screen the general population for MGUS?

Dr. Sigurdur Kristinsson

- Dr. Sigurdur Kristinsson is about to commence the Black Swan-funded iStopMM trial in Iceland, where everyone aged 40 or older will be screened for MGUS.
- The study will demonstrate if earlier detection leads to improved overall survival, if quality of life is improved or impaired, if mass screening is cost effective, and if it is possible to identify common genetic mutations among those who develop MGUS.
- Based on the results of Dr. Kristinsson's iStopMM trial, we will know if it's feasible and valuable to screen the general population for MGUS.

What is the role of MRD detection in myeloma?

Dr. Bruno Paiva

- CR (complete response) without MRD status is not predictive of remission duration or survival. Studies have clearly demonstrated that MRD testing is informative at all stages of treatment.
- Many questions remain: What is the exact definition of "MRD-negative?" How should it be used to guide therapy? Will it be used to help accelerate development of novel drug combinations? Should it be an endpoint in clinical trials? What are the optimal time points for serial measurement? How should patients who are MRD-positive be treated? Should patients who are MRD-positive but are in an MGUS state, with no active disease, be treated?
- These questions must be answered through clinical trials with sensitive MRD assays.
- New International Myeloma Working Group Consensus Criteria for Response and Minimal Residual Disease Assessment in Multiple Myeloma have been accepted for publication in *The Lancet Oncology*.

What are the optimal imaging methods for myeloma?

Dr. Elena Zamagni

- In lieu of whole-body x-rays, which are of limited value, whole-body low-dose CT (WBLDCT) is the proposed standard of care in Europe for staging and diagnostic work-up.
- Both PET/CT and whole-body MRI (WBMRI) are useful at diagnosis, especially combined with cytogenetics. MRI is best for detection of diffuse bone marrow involvement.
- For monitoring after therapy, PET/CT is best. Standard MRI is not good because of a high false-positive rate.

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SCENES FROM THE 2016 IMWG SUMMIT



1. IMF Chairman Dr. Brian Durie leads a discussion by Dr. Joseph Mikhael, Dr. Maria-Victoria Mateos, and Dr. Paul Richardson during live-stream broadcast, "Making Sense of Treatment."
2. IMF President Susie Novis Durie supports lively exchange by myeloma researchers at 2016 IMWG Summit in Copenhagen.
3. Dr. Paul Richardson asks a question and makes a point at the IMWG Summit Plenary session.
4. In a popular role-playing exercise, IMF's Lisa Paik portrays a patient perplexed by MRD test results, and Dr. Vincent Rajkumar, co-stars as her doctor.

5. Dr. Bruno Paiva (Spain) and Dr. Giampaolo Merlini (Italy)
6. Dr. Jae Hoon Lee (Korea)
7. Behind the scenes: IMWG Conference Series panelists prepare to debate the best myeloma treatment options in 2016, current controversies, and what's next.
8. Dr. Sonja Zweegman (The Netherlands)
9. Dr. Heinz Ludwig (Austria)
10. Dr. Elisabet E. Manasanch (US)

THE MOST IMPORTANT QUESTIONS – CONTINUED FROM PAGE 5

- To assess smoldering myeloma (SMM), MRI is the standard of care. A new Black Swan research project for SMM was proposed using diffusion-weighted-imaging (DWI) MRI administered every six months for two years.
- PET/CT must be standardized by lesion type, area, and number of lesions.
- An IMWG paper on PET/CT will be completed in the near future.

How do we best use new immune therapies in myeloma?

Dr. Joseph Mikhael

- At this time, we have many questions that must be addressed in clinical trials.
- Currently, the approved immunotherapies (Empliciti and Darzalex) are approved for use later in the disease course.
- In clinical trials Darzalex is demonstrating efficacy throughout the disease course and in all types of myeloma patients regardless of their risk status.
- We need to better define the role of Empliciti.
- The cost of these therapies in combination with other drugs is staggering.
- It's still too early to formally recommend CAR T-cell therapy for myeloma. Targets are still being explored, such as T cells, NK cells, SLAM F7, and B-cell maturation antigen (BCMA), combined with either auto or allo transplant.
- Checkpoint inhibitors (e.g., pembrolizumab, nivolumab) do not have single-agent activity, but are proving themselves in combination. Checkpoint inhibition is “a revolution in cancer treatment.”
- Remaining questions include:
 - Should immune therapies be used up front, in relapse, as maintenance, or throughout the disease course?
 - Which drugs are they best combined with?
 - Which patients will benefit from each type of therapy? Will there be “boutique” drugs that are effective in small classes of patients, such as venetoclax for patients with t(11;14) myeloma?
 - Could the immune therapies be more cost-effective if combined with cyclophosphamide?
 - Could immune therapy affect the host immune system adversely and make it harder to fight a relapse?

Can we cure myeloma?

Dr. Bruno Paiva and Dr. Shaji Kumar

Dr. Paiva presented for Dr. San Miguel, who was delayed coming from the ASCO meeting in Chicago.

- The Spanish researchers' approach to curative therapy for high-risk smoldering myeloma (HR SMM) uses six cycles of Kyprolis + Revlimid + dexamethasone (KRd) followed by high-dose therapy and autologous stem cell rescue (i.e. what is commonly called “autologous stem cell transplant” or ASCT), two cycles of consolidation therapy with KRd, and two years of maintenance therapy with Rd. (This is the CESAR trial, which is already accruing patients in Spain.)

- Mayo Clinic, Landgren at the NCI, and the Spanish group found that there is a survival benefit with early treatment of HR SMM.
- We now have the tools to achieve deep responses and to evaluate treatment efficacy: MRD assessment via PET/CT and immunophenotypic (next-generation flow cytometry) or molecular (next-generation sequencing of DNA) testing.
- High-risk patients as defined by cytogenetics, extramedullary disease, early relapse, and primary refractoriness should be identified and treated early and aggressively.
- Myeloma is the only cancer that is not routinely treated early.

Dr. Kumar presented the Black Swan Research “Cure Trial.”

- The IMF Black Swan Research Initiative's approach to cure for HR SMM is four cycles of KRd + Darzalex followed by either ASCT or four more cycles of KRd + Darzalex, followed by four cycles of KRd + Darzalex consolidation, and maintenance therapy for one year with Kyprolis, low-dose Revlimid, and Darzalex given every other month. (This is called the ASCENT trial, and it has not yet opened for patient accrual.)
- SMM might be the right time to cure myeloma before there is a high proportion of malignant plasma cells with significant genetic mutations.
- If we treat myeloma early and cure it, we will make it less expensive to treat myeloma.
- Unanswered questions are:
 - Are we striving to achieve complete clonal deletion or a return to the MGUS signature?
 - What is the risk of harm to the patients?
 - What is the cost of care?
 - What is the impact on quality of life?
 - Is there enough time to identify and treat high-risk SMM if the disease is aggressive?
 - How do we square treatment of asymptomatic disease with the treatment-associated risks of Kyprolis and stem cell transplant?
 - Should we be thinking about treating MGUS and not waiting for SMM?

How do we approach treatment of patients who are in complete response but are still MRD-positive?

Dr. Vincent Rajkumar

- About half of the patients in CR after stem cell transplant are MRD-positive.
- Is it right to provide the results of MRD testing without having answers to the question of what to do about it?
- Until clinical trials determine the best approach for a patient in CR who is MRD-positive, we should not do anything unless there is disease progression. We don't want to harm patients by over-treating them.
- With good immune recovery after treatment, many patients' immune systems will control reemergence of the remaining clone. A recent report from the PETHEMA group shows that evidence of normal plasma cell recovery and normal B cell maturation was associated with improved survival outcomes irrespective of MRD status.

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THE MOST IMPORTANT QUESTIONS – CONTINUED FROM PAGE 7

- Genomics can help determine the stability or instability of the remaining clone.
- There needs to be a consensus about how to counsel patients who are MRD positive so that they do not go from doctor to doctor trying to figure out if they need further treatment.

When should we use genome sequencing in myeloma? Does the genetic signature of HR SMM support early treatment?

Dr. Gareth Morgan and Dr. Ola Landgren

Dr. Morgan:

- Gene sequencing technology is robust and is cheaper, faster, and more accurate than FISH (fluorescence in situ hybridization) testing. Gene sequencing would enable creation of a more effective International Staging System than FISH currently does.
- We MUST segment myeloma into different sub-types using gene sequencing, and then find and target the driver mutations: KRAS, NRAS, and MYC.
- Gene copy number loss and loss of both alleles is most important in calculating risk.
- We need to form a consensus on the proper sequencing panel to use worldwide and then abandon FISH.

Dr. Landgren:

- The NF-kappa B pathway is implicated in the pathogenesis of myeloma. The more mutations in this pathway, the lower the level of complete response (CR).
- Up to 50 percent of HR SMM patients had mutations in NRAS and KRAS genes.
- The lack of significantly recurring mutations in patients with HR SMM is suggestive of treatment-responsive disease biology, and supports the notion of early treatment of HR SMM.
- Dr. Landgren is in the process of sequencing the DNA and RNA of another 100 patients with HR SMM, and there is Swedish data on 100 MGUS patients who developed MM and 100 who did not. He will explore the mutational landscapes of these patients.

Should we be doing transplant up front or delaying it until relapse in this era of novel therapies?

Debate between Drs. Sergio Giralt and Sagar Lonial

Pro: Dr. Giralt

- The magnitude of benefit with early transplant is 41 months of progression-free survival (PFS) versus 26 months in the IFM/DFCI trial that randomized patients to transplant or no transplant following induction therapy with VRD. The IFM data at 4 years of follow-up shows a survival benefit of 13 months for upfront transplant.
- There is, however, a three-fold increase in the rate of death from second primary malignancy in those who had transplant in this trial. Nine out of 100 patients died from transplant-related mortality, and anything over 1 percent is not acceptable.
- The symptom burden is cumulatively worse for patients who do not have early transplant.

Con: Dr. Lonial

- Not every patient must have an up-front transplant. Therapy should be tailored for each individual patient. The doctor must evaluate what is the best tool to give a patient at any given time.
- Don't ask a transplant doctor if patients should have upfront transplant.
- The IFM DFCI trial does not yet have overall survival data (only the IFM data is available at this time, and it still needs further follow-up).
- If you attained MRD with or without transplant, the IFM data tells us that survival thus far is the same.
- There is no data to demonstrate that patients who are MRD negative after induction therapy will benefit from transplant.
- We are seeing a signal for higher mortality in the transplant group in the IFM/DFCI trial.

And the results of the debate? Dr. Giralt won the case for early transplant by a large margin.

New combinations, new issues: how to use them, how to develop them?

Drs. Moreau, Durie, Palumbo, and Rajkumar

Statement of the problem:

- There are now six classes of agents to treat myeloma, with at least 30 combinations available. What is the optimal option for each patient? We don't know.
- We lack biomarkers to determine or predict efficacy.
- We do not have cost-effectiveness comparisons for various regimens.
- We currently have no well-defined surrogate markers of cure.
- There is a lack of funding for investigator-initiated clinical trials.
- Gene sequencing is not widely available.

We need to develop the following clinical trial strategies to:

- Prevent progression from SMM to MM.
- Define the best triplet therapy for relapse that is cost effective.
- Define molecular sub-types of myeloma that respond better to one drug than another.
- Determine if modifying therapy based on response or MRD detection will improve outcome.
- Establish MRD negativity as a surrogate for cure with either NGF or NGS and PET, sequentially performed and negative at several time points.
- Use MRD testing to figure out when to stop treating patients.
- Create new IMWG guidelines on safety, efficacy, and cost of treatment.
- Formally address quality of life (QOL) with a validated patient questionnaire.
- Involve patients in the design of clinical trials and a QOL assessment tool.
- Work with pharma and regulatory agencies to define optimal trials to answer strategic questions and get drugs approved.
- Create a global database about first relapse and treatment outcomes. **MT**

ASCO 2016: Excitement About Daratumumab, Concern Over Value and Cost of Myeloma Treatment



photo © 2016 copyright ASCO

By Brian G.M. Durie, MD
IMF Chairman

At the latest annual meeting of the American Society of Clinical Oncology (ASCO), held in Chicago June 3–7, 2016, far fewer myeloma-related abstracts were presented than will be presented at the annual meeting of the American Society of Hematology (ASH) in December. However, there was quite a bit of excitement about the results of the phase III CASTOR study, a randomized trial comparing daratumumab + bortezomib (Velcade® [V]) + dexamethasone [d] versus V+d alone. Beyond this study, the other interesting aspect of this year's ASCO meeting was the number of abstracts focused on treatment costs, quality of life, and value measures – 13 in all!

CASTOR study

The pre-planned interim analysis of the CASTOR study in March showed that the primary end point of improved progression-free survival (PFS) was reached at a statistical level $P \leq 0.0001$. This analysis was conducted by an Independent Data Monitoring Committee. It was recommended that the trial stop early and that patients receiving Vd alone be offered daratumumab following confirmed disease progression. Based upon the findings, the data will be discussed with authorities to prepare for regulatory filings for use of daratumumab in combination with Vd in relapsed patients. Without knowing the full details, the implication is that there was substantial improvement in PFS with the daratumumab + Vd combination.

This means that the range of options in the relapse setting continues to expand.

POLLUX study

The results of another (“twin”) daratumumab trial, the POLLUX study, were presented as a late-breaking abstract at the 2016 Congress of the European Hematology Association (EHA), which immediately followed the ASCO meeting in June. This showed that dara + Revlimid[R] + dexamethasone[d] was significantly better than Rd alone in a similar population to the CASTOR study.

At ASCO, results with ixazomib (Ninlaro®) + pomalidomide + dex and pembrolizumab + Rd were also presented, with encouraging results. In addition, the SAR compound (another anti-CD38 antibody) was evaluated with results in two abstracts: as a single agent and in combination with Rd.

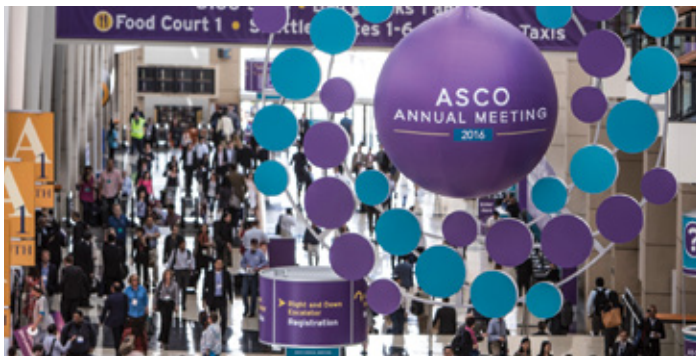
The role of ASCT, maintenance

At ASCO, upfront ASCT was evaluated in the EMN03/HO95 MM trial, which compared VMP without ASCT with CyBorD followed by high-dose melphalan. The upfront ASCT patients had superior outcomes. Thus, the value and costs of ASCT have to be considered versus the use of novel agents. Another helpful abstract presented the results of a meta-analysis of Revlimid maintenance after ASCT, evaluating the data from the CALGB and IFM trials. The conclusion is that maintenance does indeed improve overall survival (OS).

On a completely different note, the Memorial Sloan Kettering Cancer Center (MSKCC) team and collaborators identify recurrently mutated genes, identified by whole-genome (exosome) sequencing, that indicate a high risk of transition from high-risk smoldering

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ASCO 2016 – CONTINUED FROM PAGE 9



myeloma (HRSMM) to active MM and a need for treatment. This type of information can reset the “start clock” for the initiation of myeloma therapy.

ASCO abstracts concerned with “value” and “cost”

One ASCO study showed that routine management is still the most expensive part of myeloma care. Another study showed that triple therapy with KRd gives longer remissions versus the two-drug approach with Rd, and hereby reduces costs. The comparison of VRd versus CyBORd shows superior outcomes with VRd for high-risk patients. A comparison of carfilzomib-based therapies with pomalidomide-based therapies for relapsed patients showed superior benefit in time-to-next-treatment (TTNT) and lower monthly costs

with pomalidomide-based approaches. In another study, costs were lower with daratumumab and carfilzomib versus pomalidomide+dex therapy. Yet another study emphasized that the costs of treatment for therapy-related adverse events/toxicities can be expensive.

It is obvious that all of this will be truly complex, and to sort out all the conflicting perspectives and opinions with regard to costs will be challenging. Nonetheless, this is so important that IMWG (International Myeloma Working Group) members are up for the challenges and will produce comprehensive recommendations (see page 4). **MT**



Team members share the IMF’s extensive library of the latest myeloma educational materials and interview top myeloma experts at ASCO 2016.



IMF Videos Capture ASCO 2016 Highlights by Experts

Once again, the IMF team at ASCO 2016 filmed insightful and, in some cases, bilingual overviews of top myeloma news by the leading myeloma experts at the annual meeting of the American Society of Clinical Oncology in Chicago.

Dr. Katja Weisel (University of Tübingen) reported in both English and German about the CASTOR study. Also reporting in two languages, Dr. María-Victoria Mateos (University Hospital of Salamanca) provided an overview in Spanish of the top ASCO studies and then also reported in English about a study using pembrolizumab in combination with Revlimid (lenalidomide) and dexamethasone.

Dr. Paul Richardson (Dana-Farber Cancer Institute) said that the results of the CASTOR study bode “very well for the future of monoclonal antibodies with both proteasome inhibitors and immunomodulatory drugs, and is going to translate into additional benefit for our patients.”

Other highlights from ASCO were studies focused on the role of autologous stem cell transplant and where it belongs in the course of treatment. As Dr. Richardson pointed out, the role of ASCT is still unclear, however, the flexibility allows patients to “retain the ability to have choices.” Also in attendance at ASCO was Dr. Sagar Lonial (Winship Cancer Institute), who commented that recent studies of lenalidomide show shorter responses after relapse, but “there is a significant survival benefit associated with lenalidomide maintenance.”

Perhaps the most uplifting commentary on the research studies presented at ASCO 2016 was by Dr. Morie Gertz (Mayo Clinic), who said, “These reports are making it ever-increasingly clear that we are moving toward a cure for multiple myeloma.”

To watch IMF’s 2016 ASCO videos go to: <http://tinyurl.com/ASCO2016videos>. **MT**

IMF Honors Dr. S. Vincent Rajkumar

“This award is a reflection of Dr. Kyle’s leadership, vision, and guidance... The people who have won this award in the past are giants in the field, and I am very humbled.”

– Dr. S. Vincent Rajkumar



Music fills the historic Borsen Old Stock Exchange.

The International Myeloma Foundation (IMF) presented the 14th annual Robert A. Kyle Lifetime Achievement Award to Dr. S. Vincent Rajkumar during a ceremony in Copenhagen, Denmark on Wednesday evening, June 8, 2016. The award was given during the IMF’s annual International Myeloma Working Group (IMWG) Summit, and the event was held at the beautiful and historic Borsen Old Stock Exchange, which dates back to 1625.

The highlight of the evening occurred when Dr. Rajkumar surprised the audience with a guitar and vocal performance of Bob Dylan’s classic, “Knockin’ on Heaven’s Door,” accompanied by Dr. Philippe Moreau, also on guitar and vocals, and the IMF’s Pierre Sayad on keyboards. The song’s original lyrics were “doctored” to fit the occasion and poked good-natured fun at some of the well-known audience members.

Dr. Jesús San Miguel (University of Navarra, Pamplona, Spain) kicked off the program by praising Dr. Rajkumar, then he cited his friend and colleague’s one flaw – “Dr. Rajkumar is a fan of Barcelona football!” Dr. Antonio Palumbo then presented a slide show of Rajkumar family photos, including one of Dr. Rajkumar, age 5, already wearing a button-down shirt and tie. This was a sign that Dr. Rajkumar was destined to be “a Mayo man,” Dr. Palumbo teased.

Inspiration and tributes

High spirits were accompanied by emotional tributes to Dr. Rajkumar by his closest colleagues, including a moving video from Dr. Robert Kyle (Mayo Clinic, Rochester, Minnesota), the award’s namesake and a man who has served as a mentor to Dr. Rajkumar. Knee surgery prevented Dr. Kyle from making the journey from Rochester to Copenhagen for the event. Instead, Dr. Kyle recorded a video in which he praised Dr. Rajkumar for helping to foster the education and growth of young medical fellows, and for authoring hundreds of important myeloma research articles.



Dr. Vincent Rajkumar, with his wife, Dr. Priya Sampathkumar

Dr. Rajkumar, who is the Edward W. and Betty Knight Scripps Professor of Medicine at the Mayo Clinic in Rochester, Minnesota, has worked closely with Dr. Kyle for 20 years. “Bob Kyle is an inspiration,” said Dr. Rajkumar. “He is the person I want to be like, but simply cannot. This award is a reflection of Dr. Kyle’s leadership, vision, and guidance, more than anything I have done. The people who have won this award in the past are giants in the field, and I am very humbled.”

(continues on next page)

2016 KYLE LIFETIME ACHIEVEMENT AWARD – CONTINUED FROM PAGE 11

Dr. Rajkumar credited his parents' sacrifices as he described early frustrations pursuing a medical education in India. "I tried in 1982 to get into medical school and didn't get in. I tried again in 1984. I know how much my parents tried to help, and my family would have loved to be here."

He also thanked Mayo Clinic colleagues, Dr. Angela Dispenzieri, Dr. Morie Gertz, and Dr. Shaji Kumar. "I would have been in a boat back to India if it wasn't for Morie Gertz. He told me he would move heaven and earth to get the best people no matter where they're from."

And he paid homage to the IMF. "IMF President Susie Novis Durie and Chairman Dr. Brian Durie adopted me," said Dr. Rajkumar. "The IMF totally embraced me!"

Two decades of success

Dr. Rajkumar joined the Mayo Clinic in 1995 to train in hematology and medical oncology. He joined the staff in 1999, rising to professor in 2006. His research focuses on clinical, epidemiological, and laboratory research for myeloma and related disorders.

Dr. Rajkumar has led numerous phase I, II, and III clinical trials investigating the role of new agents in myeloma, including the pivotal trials that led to the approval of thalidomide in myeloma in the US, and has published more than 300 peer-reviewed papers primarily in the field of myeloma and related plasma cell disorders. Dr. Rajkumar was lead author on the 2014 IMWG Updated Criteria for the Diagnosis of Multiple Myeloma, considered to be a paradigm shift in the approach to multiple myeloma.

In addition to his stellar research credentials, Dr. Rajkumar excels at science communications, serving as Associate Editor for the *Mayo Clinic Proceedings*; Section Editor for the journal *Leukemia*; Associate Editor for the *European Journal of Haematology*; and Editor-in-Chief of *Blood Cancer Journal*. He is equally adept at sharing medical information through social media, as his thousands of Twitter followers can attest.

At the end of his remarks, Dr. Rajkumar brought the topic around to the central theme of his work. "We do this for the patients. We want to cure myeloma. Yelak Biru, who is a patient, said to me 'Now that you've won a lifetime achievement award, you cannot retire – you have to help us! Believe me, I'm not going anywhere. I'm going to be like Bob Kyle.'" **MT**



1. Robert A. Kyle Lifetime Achievement Award honoree Dr. Vincent Rajkumar, with IMF President Susie Novis Durie and Chairman Dr. Brian Durie
2. Dr. Rajkumar channels Bob Dylan, helped by Dr. Philippe Moreau, left, Pierre Sayad, center.



3. With fellow Kyle Award honoree (2012) Dr. Jesús San Miguel
4. Close friend and Mayo Clinic colleague, Dr. Manish Gandhi
5. Susie Novis Durie and Dr. Brian Durie
6. Eleven Kyle Award honorees in one place: Doctors Brian Durie, Pieter Sonneveld, Antonio Palumbo, Jean-Luc Harousseau, Heinz Ludwig, Vincent Rajkumar, Gösta Gahrton, Douglas Joshua, Jesús San Miguel, Joan Bladé, Mario Boccadoro.



ONS 2016 Satellite Symposium Updates in Multiple Myeloma: Case Studies in Collaborative Nursing and Patient Care

The IMF's Nurse Leadership Board

Founded in 2006, the IMF Nurse Leadership Board® (NLB) is a professional partnership representing nurse experts caring for multiple myeloma patients at leading medical centers. The NLB's primary mission is to improve the nursing care and self-care of patients with myeloma by educating nurses and patients via consensus publications, symposia, multimedia, and research.

Co-Chairs



Beth Faiman,
PhD, MSN, APRN-BC, AOCN
Taussig Cancer Institute
Cleveland Clinic



Joseph D. Tariman,
PhD, ANP-BC
DePaul University
Chicago, IL

Faculty



Donna D. Catamero,
ANP-BC, OCN, CCRC
Mount Sinai
Medical Center



Tiffany Richards,
RN, MS, ANP-BC
MD Anderson
Cancer Center

The IMF Nurse Leadership Board satellite symposium at the Oncology Nursing Society (ONS) annual conference attracted a record number of nearly a thousand nurses. Held on April 28, 2016 in San Antonio, Texas, the successful event was Standing Room Only! The IMF-sponsored symposium, titled "Updates in Multiple Myeloma: Case Studies in Collaborative Nursing and Patient Care," was presented by a panel that included members of the NLB. Co-chairs Beth Faiman and Joseph D. Tariman were joined by faculty members Donna D. Catamero and Tiffany Richards. The presentation highlighted myeloma patient case studies and the practice of shared decision-making between patients, caregivers, and healthcare providers.

As a result of this program, participants will be able to:

- Identify newly approved therapies and combination regimens in myeloma,
- Apply best practices in management of myeloma patients receiving newly approved therapies and combination regimens,
- Discuss survivorship care plans and practical tools for long-term management and care of myeloma patients, and
- Express the key role nurses play in advocating for patients and their caregivers.

Six case studies were presented, followed by a discussion of myeloma drugs in development and a Q&A session between faculty and participants. Case studies addressed how to apply the latest developments in the field of myeloma to a variety of real-world scenarios. Topics covered included newly diagnosed myeloma, diagnostic criteria, biomarkers and genomics, clonal evolution, the balancing act of treatment options at each point in the disease continuum, response, relapsed myeloma, bone health, renal health, immunotherapy, and minimal residual disease and MRD-negative. The collaborative practice of myeloma being treated by a multidisciplinary team, as well as patient preference being a key element of shared decision making were also discussed.

The symposium program was designed to meet the educational needs of oncology nurses in community or academic settings who are involved in the care of patients with myeloma. Resources from the NLB's 2016 ONS Satellite Symposium are available on the IMF website nurses.myloma.org, presented in a HIPAA-compliant context to protect patient privacy. Nurses are increasingly crucial in patient care and education of patients and, as always, the IMF is here to help. We invite you to take advantage of the full library of NLB materials, and to contact us for further information. **MT**

Page Bertolotti, RN, BSN, OCN
Samuel Oschin Cancer Center at
Cedars-Sinai Medical Center
Los Angeles, CA

Kevin Brigle, PhD, NP
VCUHS Massey Cancer Center
Richmond, VA

Donna D. Catamero, ANP-BC, OCN, CCRC
Mount Sinai Medical Center
New York, NY

Kathleen Colson, RN, BSN, BS
Dana-Farber Cancer Institute
Boston, MA

Hollie Devine, MSN, ANP-BC
James Cancer Hospital at
Ohio State University Medical Center
Columbus, OH

Deborah Doss, RN, OCN
Dana-Farber Cancer Institute
Boston, MA

Beth Faiman, PhD, MSN, APRN-BC, AOCN
Cleveland Clinic Taussig Cancer Institute
Cleveland, OH

Elizabeth Finley-Oliver, RN, BSN, OCN
H. Lee Moffitt Cancer Center
and Research Institute
Tampa, FL

Charise Gleason, MSN, NP-BC, AOCNP
Winship Cancer Institute of Emory University
Atlanta, GA

Patricia A. Mangan, RN, MSN, APRN-BC
Abramson Cancer Center at
The University of Pennsylvania
Philadelphia, PA

Ann McNeill, RN, MSN, APN
John Theurer Cancer Center at
Hackensack University Medical Center
Hackensack, NJ

Teresa Miceli, RN, BSN, OCN
Mayo Clinic - Rochester
Rochester, MN

Kimberly Noonan, RN, ANP, AOCN
Dana-Farber Cancer Institute
Boston, MA

Tiffany Richards, RN, MS, ANP-BC
MD Anderson Cancer Center
Houston, TX

Sandra Rome, RN, MN, AOCN, CNS
Cedars-Sinai Medical Center
Los Angeles, CA

Joseph Tariman, PhD, ANP-BC
School of Nursing/College of Science and Health
De Paul University
Chicago, IL

Daniel Verina, BS, BSN, MSN, ACNP-BC
Mount Sinai Medical Center
New York, NY

International Affiliates

Tracy King, RN, MN
Royal Prince Alfred Hospital
Institute of Haematology
Camperdown, Australia

Cindy Manchulenko, RN, BN, MSN
Leukemia/BMT Program of British Columbia
Hematology Research and Clinical Trials Unit
Vancouver, Canada

Reading Medical Journalism

The IMF InfoLine coordinators answer your questions

By Debbie Birns
IMF Medical Editor

The IMF InfoLine regularly fields calls and emails from patients and family members who are understandably excited about a story they've read in the newspaper or on the internet, heard on the radio, or seen on the TV news, usually about a drug in development or a patient who has been "cured" at a particular institution. All too often, it falls upon an InfoLine coordinator to temper the news with a dose of cautious skepticism. In many cases, facts must be separated from wishful thinking or outright hype.

Here are some tips for consumers of medical journalism that will help you root out what is important and relevant news, and what needs to be taken with a grain of salt. (A future InfoLine column will provide tips on reading actual journal articles with an eye to demystifying some of the medical jargon and statistics.)

1. Hidden variables

Many news stories do not make clear, or misstate, whether there is a direct cause-and-effect relationship between a healthcare intervention and an outcome, or only an association. A recent news story reported that increased physical activity reduces the risk of 13 cancers, among them myeloma. The results of this large observational study were reported by most news outlets as if there were a direct causal relationship between exercise ("physical activity") and cancer risk. Was it actually the physical activity that led to a decreased risk of cancer? Or were there hidden variables that could have led to this result? Perhaps the lower incidence of cancer was the result of a healthier diet. Or perhaps it was consistent aspirin consumption, or reduced smoking, or any number of other factors taken singly or jointly. Observational studies of big population groups like this one are generally based on patients' responses to questionnaires that they have been asked to complete, and are not designed to provide direct cause-and-effect evidence. Only large randomized clinical trials where one set of people is assigned a certain intervention and another set receives either no intervention or a different one can provide cause-and-effect data. Make sure you know which type of study was done before a headline is taken as fact.

2. Single case reports

One anecdote does not equal medical data. A story about a single myeloma patient who is "cured" after a particular intervention may be interesting and hopeful, but it is a human interest story, not medical data. As one medical commentator put it in his analysis of the potential for curing myeloma with an engineered measles virus, "one success story does not make a miracle cure."

3. Use of the word "cure"

While we all hope that the single patient who has been the subject of a "cure" story will indeed be cured, we don't yet have a real definition of cure for myeloma. The word "cure" is often misused in medical reporting. In myeloma, which is a remitting and relapsing disease, a patient can be in remission for years and then, unfortunately, relapse. The new methods of minimal residual disease (MRD) detection can



Paul Hewitt, Judy Webb, and Missy Klepetar

help predict long survival, but we really don't yet know at what time point, and by which test or tests, we can safely say a patient has been cured. The determination of cure is likely to require far longer than two years of MRD-negative status. If news stories had said that the patient had "responded completely and remains in remission after two years," the article would have presented a far more accurate picture, but have generated far less hype.

4. Bias

Always look for the source of the story for potential bias. Press releases from pharmaceutical manufacturers and medical institutions may be canted to make a drug in clinical trials or an institution conducting those trials look good. Physicians who have financial relationships with drug manufacturers may present data in such a way that the drug looks more effective and safer than it is. Although medical journals often disclose physician ties to the pharmaceutical industry, many news stories do not. Commentary from an expert who is not an investigator in the trial should be included in the news story to validate the report or to express reservations.

5. Side effects

Be wary if the news story mentions only the benefits of a particular therapy without mentioning the side effects ("adverse events" in medical-speak) and whether or not those side effects are reversible. While side effects rarely occur in every patient who receives a particular therapy, it's equally rare to find a treatment that doesn't cause any side effects at all.

6. Is the trial open?

Few news stories about a "promising new therapy" mention whether or not the treatment protocol in question is still open and available to patients. It seems irresponsible to raise hopes about the possibility of participating in exciting new research and yet fail to mention that the trial in question is closed or not yet open, but that is often the case. The reporter may state where the research is being conducted, causing a mass of patient inquiries at that institution (frustrating both those who answer the inquiries at the research facility and the patients who wish to participate in a closed study). Visit clinicaltrials.gov to check if a particular trial is open to accrual.

(continues on next page)

Los Angeles Patient & Family Seminar

Friday & Saturday – August 19-20, 2016



Register NOW for this seminar –
online LosAngeles2016.myeloma.org
telephone (800) 452-CURE (2873)

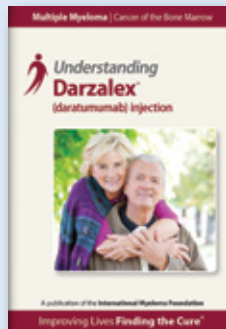
Become Empowered at an IMF Patient & Family Seminar

- **Education**
Up-to-date, vital information on myeloma.
- **Access to Experts**
One-on-one access to myeloma experts.
- **Camaraderie**
Share your experiences with other myeloma patients and caregivers.

New IMF Publications

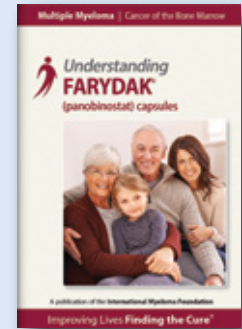
The IMF is pleased to announce four new educational publications of interest to patients, caregivers, and healthcare professionals.

The *Understanding Darzalex® (daratumumab) injection* booklet will inform you about a highly effective new medication to treat myeloma, which is a laboratory-made monoclonal antibody that targets a specific single protein on the surface of myeloma cells. Of the four new therapies for myeloma approved in 2015 by the US Food and Drug Administration (FDA), only Darzalex has single-agent activity and was approved with “break-through” status. Darzalex is approved for patients with myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory drug, or who are double-refractory to a proteasome inhibitor and



an immunomodulatory drug. The IMF also has a new tip card on Darzalex.

The *Understanding Farydak® (panobinostat) capsules* booklet will inform you about the first histone deacetylase (HDAC) inhibitor approved to treat myeloma. The FDA has approved Farydak to be used in combination with Velcade® (bortezomib) and the steroid dexamethasone for the treatment of patients with relapsed/refractory myeloma who have received at least two prior regimens. The IMF also has a new tip card on Farydak.



IMF publications are available on the website myeloma.org, where you will find a wealth of other valuable information, or by contacting us via 800-452-CURE (2873) or 818-487-7455 or TheIMF@myeloma.org. We look forward to hearing from you. **MT**

READING MEDICAL JOURNALISM – CONTINUED FROM PAGE 14

7. Preliminary results

You seldom read that a particular type of therapy or research is very promising, but that we'll just have to wait until more time has elapsed and the results are mature to judge the safety and efficacy of the therapy. (Reporters leave that for the InfoLine to say!) Instead, you will typically read about some new therapy that is curing patients relatively shortly after the therapy has been administered. One such example is the “news stories” (a.k.a. press releases) about a particular type of vaccine therapy that has been in early-phase post-transplant trials. Keep in mind that any time post-transplant therapy is involved, the timeline for the efficacy of therapy is very long, since the effects of the transplant itself are commonly in the two- to three-year range. To say that patients are benefiting from this therapy is premature.

Beware of results that may be promising but warrant a longer time frame for evaluation of efficacy than has currently elapsed. **MT**

Please visit myeloma.org for up-to-date information about myeloma, and contact the IMF with your myeloma-related questions and concerns. The IMF InfoLine consistently provides callers with the best information about myeloma in a caring and compassionate manner. The InfoLine is staffed by Paul Hewitt, Missy Klepetar, and Judy Webb. IMF InfoLine specialists can be reached at 800-452-CURE (2873) in the US and Canada, or 818-487-7455 worldwide. Phone lines are open Monday through Friday, 9 a.m. to 4 p.m. (Pacific). To submit your question electronically, please email InfoLine@myeloma.org.

Gaining a Global Perspective on Myeloma Patient Issues



The fourth annual summit of the IMF's Global Myeloma Action Network (GMAN) was held in Copenhagen, Denmark in June, immediately following the meeting of the International Myeloma

Working Group. The GMAN summit garnered an impressive level of participation, drawing 40 individuals representing 30 organizations and 25 countries from around the world. Members from as far as Australia, South Korea, and Brazil joined with their counterparts from Europe and North America to discuss issues that affect myeloma patients



Dr. Abonour giving his talk to our group on June 10th

on a global level. Three issues emerged from summit discussions that require clear next steps, which are detailed below.

Global awareness

During day one of the summit, members were divided into three small groups and each was given a different topic focused on global awareness. The topics were the result of the survey that was sent to each GMAN member prior to the summit asking to define "global awareness." After robust discussions, members agreed that as a priority, GMAN should select a day to celebrate Global Myeloma Awareness Day.



Chul Hwan Lee, Executive Director of the Korea Blood Cancer Association

EU policy initiative

Mait Raava of the Estonian Myeloma Society gave a presentation about the current system of treatment approvals within the European



Mait Raava of the Estonian Myeloma Society

Union (EU). He noted that once the European Medicines Agency (EMA) approves a new treatment for use, each individual member country then must approve the treatment for use and reimbursement within the state. However, each state often uses different criteria and formulas to determine the cost-to-benefit analysis, which results in varied treatment availability from country to country. Under Mait's leadership, GMAN

has proposed a cost-benefit formula that uses the same scientific inputs to be used by all EU members.

Patient charter

Steve Roach of Myeloma Australia presented a draft of the "International Charter for People with Myeloma." The patient charter outlines the rights and expectations of patients, caregivers, health providers, governments, and pharmaceutical companies. It is a comprehensive document that sets a standard across the globe, giving those who fall below the standard a tool to use in achieving their goals. Supported by 37 myeloma organizations from around the world, GMAN members can use all or parts of the charter to ultimately ensure the rights of patients everywhere.



Steve Roach of Myeloma Australia

We look forward to pursuing these next steps with our members and industry partners in the coming months. Thank you to those who came to Copenhagen and to our sponsors for allowing us to continue building this wonderful group of dedicated advocates. **MT**



IMF's Meghan Buzby and Ray Wezik



Dinner Cruise: Yelak Biru and Jack Aiello, then from the left going clockwise, Joan Bladé and Kyla Juett from Grupo de Pacientes y Familiares con Mieloma Múltiple in Spain, Mariola Grabarczyk and Emilia Demczur from the Carita Foundation in Poland.



Crystal A. Nuuttila of the Syopapotiilaat support group in Finland

Susie Novis Durie Educational Grants Awarded

The Susie Novis Durie Educational Grants, created to help member organizations of the IMF's Global Myeloma Action Network (GMAN) increase education, awareness, and access to treatment, were given to three nonprofits groups at the GMAN summit in Copenhagen. Recipients are: Mijelom CRO in Croatia, recipient of a \$10,000 Senior Grant; the Armenian Hematology Association (AHA), recipient of a \$5,000 Junior Grant; and the United Against Cancer Foundation (FUNCA-Fundación Unidos Contra el Cáncer) in Paraguay, recipient of a \$5,000 Junior Grant.

With the Susie Novis Durie grant award, Mijelom CRO will be able to work on several fronts to improve myeloma patients' lives and address current limited access to treatment in the region. For example, currently there are no support groups for myeloma patients in Croatia and the Republic of Bosnia and Herzegovina (BiH), and due to the region's impoverished state and complex health care system, patients are often unable to access the care they need. With the grant funding, Mijelom CRO will be able to translate educational leaflets into Croatian and Bosnian; create a social media campaign; work to end the practice of charging value-added taxes on donated myeloma drugs; and host a patient seminar.

The Armenian Hematology Association (AHA) will fund a 2016 Multiple Myeloma Awareness year with its grant, in order to encourage earlier diagnosis of the disease. According to Yervand Hakobyan, MD, PhD, who works in a hematology center and serves as secretary of the AHA, 75 percent of patients diagnosed with myeloma annually in Armenia are already in advanced stages of the disease. Many of these patients may already be suffering from severe bone lesions, anemia, renal insufficiency, and other later-stage damage. Awareness activities in the works include printing a book in Armenian for myeloma patients; mentoring



Susie Novis Durie and Dr. Yervand Hakobyan of the Armenian Hematology Association

regional doctors through teleconferences; conducting educational seminars for patients and caregivers; and co-hosting educational seminars for regional doctors alongside the Fund of Armenian Relief (FAR).

The second Junior Grant recipient, the United Against Cancer Foundation (FUNCA-Fundación Unidos Contra el Cáncer), will host a seminar for hematologists, patients, and their families with its award monies. The goal is to increase awareness so that myeloma patients can be diagnosed earlier and gain access to treatment; share best practices among doctors and patients; and to share how multiple myeloma patients can live with dignity. The keynote speaker for this seminar will be Dr. Lidiane Andino Neves (Paraguay's Central Hospital). As a multiple myeloma specialist, Dr. Neves is one of the main providers to myeloma patients in Paraguay. **MT**

Expert Meetings in China



Chinese Myeloma Committee's Dr. Wenming Chen (seated, second from left) with his team and guests (left to right) Daniel Navid, Prof. Jean-Luc Harousseau, and Lisa Paik at the Patient & Family Seminar held at the Beijing Chaoyang Hospital

By Daniel Navid
IMF Senior Vice President, Global Affairs



Dr. Wenming Chen

The IMF joined with the Chinese Myeloma Committee for a series of expert meetings on May 12-15 in Beijing organized by Dr. Wenming Chen. These included a training event for “Elite Young Chinese Myeloma Doctors,” the Chinese Myeloma Summit, and a Patient & Family Seminar at the Chaoyang Hospital. In addition, the IMF team had a meeting at China’s drug regulatory agency.

About 20 young doctors joined the training session, which involved expert presentations followed by case studies and discussion. Several participants were graduates of the IMF Master Class. Along with leading Chinese doctors, the IMF’s participating international experts included Prof. Jean-Luc Harousseau (France), Dr. Wee Joo Chng (Singapore) who addressed relapsed and refractory myeloma and the status



Dr. Wee Joo Chng

and directions for IMF’s work on minimal residual disease (MRD), and Dr. Juan Flores Morales (Spain) who reviewed lab work and the Next Generation Flow approach for determining MRD.

The next event, an IMF expert meeting for 200+ Chinese doctors, included Dr. Andrew Spencer (Australia) who spoke on MRD and monoclonal gammopathy of undetermined significance (MGUS)



Dr. Andrew Spencer



Dr. Heinz Ludwig

and smoldering multiple myeloma (SMM), and Dr. Heinz Ludwig (Austria) who spoke on the latest diagnostic criteria and treatment of newly diagnosed myeloma, and Prof. Harousseau who spoke on transplantation issues. Lisa Paik (IMF Senior Vice President, Clinical Education & Research

Initiatives) gave an opening address as did Dr. Chen.

The third event, the patient and family seminar, attracted 120 participants. Presentations on latest developments in myeloma research by Dr. Chen and Prof. Harousseau were followed by questions from the patients in attendance. It was well evident that the patients greatly appreciated the opportunity to meet and learn from Drs. Harousseau and Chen.



Dr. Haoyang Cai

Finally, the IMF team had a meeting at the Chinese drug approval agency for discussions about the approval process for myeloma treatments in China and how Chinese involvement in the IMF’s Asian Myeloma Network (AMN) clinical trials might be accelerated. The team was very well received and came away from that meeting with a positive impression about future cooperation.



Dr. Jin Lu

The IMF extends its most grateful appreciation to Dr. Chen and his colleagues for their efforts in organizing these events, and to our team of international experts for their invaluable input that ensures our success in Beijing. **MT**

Patient Meetings Across Europe

By **Nadia Elkebir**
IMF Director of Europe and the Middle East

The IMF's 2016 patient education program in Europe got underway in March with our first-ever meeting in Budapest, Hungary. That meeting also marked the beginning of a new partnership with the Hungarian patient group MOHA (Magyar Onkohematológiai betegekért Alapítvány) and Dr. Mikala Gabor (IMWG member and



Dr. Rafat Abonour of the United States with Dr. Mikala Gabor of Hungary during the first MOHA-IMF educational patient day in Budapest

head of hematology of St. Lazlo Hospital). Faculty included Drs. Nagy Zsolt, Judith Bildó, and Agnes Riskó, as well as special guest presenter Dr. Rafat Abonour of the United States. For more information about this meeting, please read the Spring 2016 edition of *Myeloma Today*. Since March, the IMF has participated in more meetings across Europe, adding other "first ever" milestones to our record.



Dr. Judith Bildó

Italy

On May 19, the first ever livestream of a conference for hematology-oncology professionals and patients with blood cancers in Italy was held in Rome. Organized by Prof. Mario Boccadoro (President, Conferenza Nazionale di Oncoematologia) and Luigi Parravicini, with support from the IMF, the conference connected 1,150 participants and four patient centers. Dr. Federico Mandelli (President, Italian patient association AIL) and Prof. Boccadoro gave an engaging welcome speech to the participants. Prestigious myeloma experts spoke about the latest trends in myeloma research in Italy and elsewhere.



Nadia Elkebir and newly diagnosed myeloma patient Simona Sallustio at the Rome conference

On June 4, the next patient meeting in partnership with AIL took place in Padova. This successful seminar was led by Prof. Gianpietro

Semenzato (Hematology Director, Azienda ospedaliera di Padova). The topics were numerous and informative, and covered both myeloma and lymphoma. Active Q&A with lots of inquiries from the participants followed each session. More than 150 patients and caregivers from Padova and neighboring regions were in attendance.



Prof. Gianpietro Semenzato



AIL billboard in the Rome subway

France

On June 18, the IMF hosted the 14th Annual Paris Patient & Family Seminar. Drs. Brian G.M. Durie, Jean-Luc Harousseau (Nantes), and Chantal Doyen (Belgium) presented the latest myeloma research and information. They spoke on the importance of clinical trials, myeloma



Bernard Delcour (President, AF3M), Thierry Barbieux (President, MYMU), Susie Novis Durie, and Nadia Elkebir



Catherine Filliol



During a Q&A session, a patient asks the faculty about the myeloma drugs of tomorrow

(continues on next page)

PATIENT MEETINGS ACROSS EUROPE – CONTINUED FROM PAGE 19



drugs of yesterday and today, and the IMF's Black Swan Research Initiative®. In addition to the engaging dialogue from these three extraordinary doctors from three different countries, the IMF was also pleased to host Thierry Barbieux (President, Belgian patient group MYMU) and Bernard Delcour (President, French patient group AF3M).

Austria

On June 25, the IMF returned to Vienna for a recurrent patient meeting that takes place thanks to a strong relationship with Myelom-Lymphom Austria. More than 100 participants were in attendance to learn from an esteemed panel that featured Prof. Dr. Heinz Ludwig and Dr. Jens Hillengass. What an exciting experience it was! Myeloma patient Andy Sninsky from the US, who is in remission,



Nadia Elkebir and Andy Sninsky

was present to share his inspiring story of living his life to the fullest despite myeloma. Andy flew from the US to Switzerland, then biked all the way to Vienna (and later Slovakia, Hungary, the Czech Republic, and the Ukraine). Andy was well received by the local patients, and he was also the subject of an article in a popular local newspaper.

More to come in 2016, 2017

Please see the meetings calendar below for dates and locations of remaining 2016 patient education events.

Looking toward 2017, the IMF continues to expand our programs in Europe, and we are proud to announce a new collaboration with the Belgian group MYMU (Association de patients atteints de Myélome). The first joint IMF-MYMU seminar will be held in the Spring of 2017 in La Hulpe, Belgium. The President of MYMU, Thierry Barbieux, will invite French- and Flemish-speaking Belgian patients to participate, as well as myeloma experts from both Belgium and France. Visit myelome.be for more information about the MYMU.

We are also making plans for our first joint patient seminar with Multiple Myeloma Ireland, to be held in 2017 in Dublin in collaboration with Dr. Patrick Hayden, clinical lead for myeloma at St. James Hospital in Dublin and President of the Irish myeloma patient association. Dr. Hayden will soon be joining the IMWG. Please visit multiplemyelomaireland.org for more information. **MT**



Dr. Patrick Hayden

Fall 2016 seminars to be held by the IMF and our partners in Europe

- Sept 9–10 IMF Patient & Family Seminar Lázně Bělhorad, Czech Republic
- Sept 23–25 IMF Patient & Family Seminar Heidelberg, Germany
- Oct 1 IMF Patient & Family Seminar Napoli, Italy
- Oct 7–8 IMF Patient & Family Seminar Liptovský Jan, Slovakia
- Oct 17 IMF Patient & Family Seminar Tromsø, Norway
- Oct 18 IMF Patient & Family Seminar Trondheim, Norway
- Oct 20 IMF Patient & Family Seminar Oslo, Norway
- Oct 24 IMF Patient & Family Seminar Reykjavík, Iceland
- Oct 27 IMF Patient & Family Seminar Korsør, Denmark

Advocates in the Spotlight: John Killip and Tom Hardy

By Lindsey Trischler
IMF Advocacy Associate

Two days before the much-anticipated May 26th ICER (Institute for Clinical and Economic Review) public meeting in St. Louis, IMF

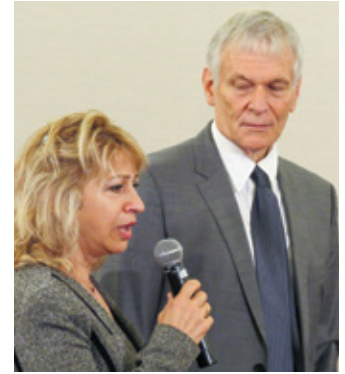


John Killip at podium

advocates John Killip of Kansas City and Tom Hardy of St. Louis participated in a briefing regarding the potential danger the report poses to patients. The briefing was hosted by Patients Rising and also featured speakers from the Center for Medicine in the Public Interest and the Alliance for the Adoptions of Innovations in Medicine (AIMED Alliance). The briefing stressed the negative repercussions ICER's report could have on patients' ability to access new and innovative drugs, the use of Quality-Adjusted Life Years (QALYs), and the impact on the overall survival rate of myeloma patients.

John Killip has been an active member of the IMF's ACTION Team and was integral to our efforts to get oral parity legislation passed in Missouri in 2014. He was enthusiastic about participating in the briefing to help amplify the voices of myeloma patients. John is a nine-year survivor of myeloma and said, "Where would I be if they based

the value of my treatment to a five-year survival? It is inappropriate that ICER or anyone challenge the value of that treatment to me and to my family, or my continued ability to generate income."



Tayebeh and Tom Hardy

Tom Hardy echoed John's sentiments, "When I was diagnosed with myeloma, I was given five years to live. Now I'm alive and feeling very well six years later. I outlived the prognosis thanks to multiple treatments."

Tom also expressed that, like many, getting his diagnosis changed his outlook on life. He feels that his life post-cancer is better and more fulfilling than ever before, and this is just another example of why the use of QALYs in ICER's report is extremely harmful.

Defining "value" of treatments continues to be a hot topic for policy makers as healthcare costs continue to become more and more unsustainable; however, it's imperative that value in care is defined by the patients themselves, not mathematic formulas. At the briefing, thoughtful comments from John and Tom did a wonderful job of representing myeloma patients and the IMF. We applaud them for using their voices as advocates to speak up against the many flaws in the ICER report.

If you would like to get more involved in the IMF's advocacy efforts, please email advocacy@myeloma.org.

Federal Oral Parity Bills Gain Momentum

By Meghan Buzby
IMF Senior Director of Advocacy

Over the past few months, the IMF and our colleagues from the Patients Equal Access Coalition (PEAC) have been working hard to secure co-sponsors for the Cancer Drug Coverage Parity Act in both the House and Senate. We now have more support from key players than ever before.

In the House, we have added 55 co-sponsors to the bill since the beginning of 2016, bringing the total number to 106. The co-sponsors are evenly divided between Republicans and Democrats, and include 20 members (11 Republicans and 9 Democrats) who sit on the House Committee on Energy and Commerce. This committee has jurisdiction over the bill. Additionally, we have secured the support of two members of House Republican Leadership, Rep. Greg Walden and Rep. Pete Sessions.

In the Senate, we have gained the support of 16 additional co-sponsors, bringing the total number to 20 (6 Republicans and 14 Democrats). Our co-sponsors include 9 of the 23 members who sit on the Health, Education, Labor, and Pensions (HELP) Committee,

which has jurisdiction over the bill. Last month, Sen. Chuck Schumer signed on as a co-sponsor. As the second-ranking Democrat in the Senate, his co-sponsorship will be very influential.

Compared to last Congress, we have increased co-sponsorship dramatically: from 2 to 16 Senate co-sponsors and almost tripling the Republican co-sponsorship in the House.

We understand the importance of advocating for research and innovation funding. We also firmly believe that removing barriers to access for newly developed treatments is equally important. Please join us and our PEAC coalition to advance this legislation to make sure that all cancer patients have affordable access to their medications. Visit advocacy.myeloma.org or email us at advocacy@myeloma.org for more information. **MT**



Rep. Pete Sessions



Senator Chuck Schumer

Yelak Biru: 20-Year Myeloma Survivor Shares His Story

IMF Board of Directors member Yelak Biru was diagnosed with myeloma in 1999 at the age of 25. Today he leads the North Texas Myeloma Support Group, attends the Annual Meeting of the American Society of Hematology with the IMF and a group of Support Group Leaders from across the US, and, in 2015, spoke on behalf of patients at the Annual Congress of the European Hematology Association. Yelak also moderates the Smart Patients message board. Like all patients, Yelak encounters massive amounts of myeloma research news. He shared with Myeloma Today his approach to understanding the myeloma research landscape.



When I was diagnosed 20 years ago, the options were extremely limited and the life expectancy of a myeloma patient was a couple of years, maybe three. With the approval of four new drugs in 2015 for myeloma in the US, the treatment approach is changing rapidly. But the challenges of uncertainty remain for both patients and healthcare providers – when to start treatment, when to stop treatment, what's the definition of a cure for myeloma,

and how do you accelerate innovations and development of drugs to achieve that.

With so much myeloma research going on now – and so many new drugs approved – how do you as a patient sort through it all?

You're right, the explosion of information for myeloma is astounding. There are hundreds of clinical trials and many drug combinations to choose from. The question really is how you weed through all that data to find information relevant to you. The first step for me is to decide the category of information I want. I care about translational research – research that's ready for prime time. When it comes to choosing drugs or a combination of drugs, obviously I rely on my myeloma expert and local hematologist.

I also have a set of treatment philosophies that I depend on: My first philosophy is being able to maximize quality of life: for me QOL is the ability to maximize living life. Spending less time at the doctor's office, continuing to work, continuing to travel and lead a somewhat balanced life. My second philosophy is to, as much as possible, ensure the drug I'm taking doesn't prevent me from taking other drugs in the future.

How do you follow research developments?

As a support group leader and a liaison for the Smart Patients myeloma community, I consider it my privilege and responsibility to keep up with the rapidly changing landscape for myeloma.

- Social media is one of the major ways I keep up with developments. I learned about the FDA's historic approval of the three drugs for our disease this past November through social media.
- I was lucky enough to attend the first American Society of Hematology (ASH) meeting the IMF brought patients to in 2006. Since then, I've been able to attend more than a half dozen of them.

- I'm a member of the IMF's Global Myeloma Action Network (GMAN), where I'm able to have a global view of the development in innovation as well as the challenges with access.
- I participate as a patient advisor for pharmaceutical companies that are doing an excellent job of innovating.
- I'm also an IMF board member.

As you can see, I've been able to build a holistic means of keeping up.

Do patients become intrigued by clinical trial reports – or bogged down?

Building on my categorization and compartmentalization philosophy, I look at information from the past, the present, and the future perspective. I appreciate the past, understand the present and am energized about the future. This allows me to be super-focused and allow for the focus to evolve over time.

I've also surrounded myself with great myeloma mentors, virtual and in real life, such as Peter Tischler, the founder of the North Texas Myeloma Support group, Mike Katz, THE [late] Mike Katz, and others that are patient advisors for SWOG and Alliance myeloma communities.

I also categorize data in two categories: data I consume and data I pass along. In the first category is what is relevant for me based on the history of my myeloma, previous treatments, how I responded, the side effects, and the quality of life potential certain trials promise. For the communities I support or participate in, I look for personalized and just-in-time information I can pass on.

Is it about trusting your sources?

I think it's about developing relationships. Information is a commodity. Like you buy your favorite clothing from your favorite retailer or go to a particular laundry because they know you by name, you go to a site, organization, and person you've established a personal relationship with to get your information. But that trust is built over time. Just like any relationship.

Do you grow elated or frustrated or both?

My frustration is with the fact that myeloma continues to be incurable and we lose too damn many friends to the disease! The C word used to be like the F word. You don't say it in public. But conservative and pragmatic practitioners who have and who are dedicating their lives to the treatment of myeloma patients are starting to use the word "cure." So my responsibility, my obligation, and my honor is to increase the means by which we can change myeloma patients' fear to hope. **MT**

2016 Mike Kubik Memorial Golf Tournament

Darla Kubik's husband, Michael Kubik, was diagnosed with multiple myeloma in 2011 at the age of 49. He thought he had sprained a rib while playing golf, but the radiologist found a bone lesion, and further testing confirmed the diagnosis of myeloma. He passed away two and a half years later in May 2013 from pneumonia complications.



Michael Kubik

Mike was an avid golfer and he played nearly every week, usually in the company of his closest friends. On the one-year anniversary of his passing, his buddies decided to honor his memory by playing a round of golf together. "I think a total of 16 people showed up to play that year," recalls Dwight Royall, a good friend and regular player in Mike's foursome. "Once we got to the 19th hole, we raised a few beers to Mike and talked about doing something to make a difference for other people with myeloma. Darla pointed us in the direction of the IMF, and we all made donations in Mike's memory. We also agreed to meet and play again the next year to keep Mike's memory alive."

In 2015, the group put more organization into the planning of a golf tournament to honor Mike, this time picking a date in March during Myeloma Awareness Month that also coincided with Mike's birthday. After being rained out in March, the golf tournament finally took place in April 2015. Although the delay caused several golfers to back out, approximately 40 people took part in the event. The IMF was one of the designated beneficiaries.

"In 2015, we reached out to the IMF, because our family had received so much support from the organization while Michael was ill," says Darla. "We were also very involved with the North Texas chapter of the IMF-affiliated myeloma support groups. We were hoping to raise enough money during our second golf tournament to give back to the two groups who had been there for our family. At that time, the IMF's Black Swan Research Initiative® was beginning to make significant strides forward in myeloma research; we found their work to be very exciting and we wanted to contribute to the progress being made. It was an ambitious undertaking but Dwight Royall, who was instrumental in getting the golf tournament off the ground, told me that he would do anything he could to help and, together with co-organizer Dr. John Coble, he has done just that."

The 2016 Mike Kubik Memorial Golf Tournament had 74 participants, including 62 golfers, one of whom was IMF Board of Directors member John O'Dwyer. "Most of our tournament supporters are there because they knew my husband," says Darla. "Most of our friends had never heard of myeloma before Michael's diagnosis, and the same can be said about members of our family. So it meant a lot to us that someone who is a key part of the IMF, the organization that's looking for a cure, attended our event. It is also meaningful that the tournament has grown enough that we can help raise myeloma awareness."

As the tournament expands from year to year, it includes more and more participants from the general public. Darla, who serves as the MC, sees this as an opportunity to carry on her husband's legacy of myeloma education. "This was very important to Michael, who made a point to share what he learned about his disease with our extended family and with others."

The Kubik Family includes two grown sons, Tyler and Mikale, and three granddaughters. Both sides of the family were well represented at the tournament, by Michael's brother and nephews, and by Darla's parents who traveled to Texas from North Dakota to serve as judges for the "hole-in-one." Other participants drove from East Texas to the Dallas area, and some players came from New Mexico and Louisiana.



Dr. John Coble, Darla Kubik, Ron Haney, and Dwight Royall

"Mike was a card, he loved practical jokes, and everyone who knew him enjoyed him," shares Dwight. "Mike's passing left a hole in our long-standing group of friends. So while we play the tournament, we share stories about Mike among ourselves and also with the people who didn't have the pleasure of knowing him."

For all the events, the major sponsor has been Cascade Health Services, the long-term care company that Michael was a partner in along with Ron Haney. Cascade Health Services donated \$5,000 in 2015 and \$10,000 in 2016, and Darla successfully brought in other donors from the local community. Over the past two years, the Mike Kubik Memorial Golf Tournament has raised nearly \$25,000 for the IMF and \$2,000 for the North Texas Myeloma Support Group. Next year's tournament is being planned for the Spring of 2017. **MT**

Fundraisers are taking place across the country as friends of the IMF help support essential myeloma research and patient programs while also raising awareness. Please contact Suzanne Battaglia, IMF Director of Member Events, at sbattaglia@myeloma.org or 800-452-CURE (2873), and join us in working together toward our common goal...a CURE.



Pierre Sayad
Senior Vice President,
Global Medical Affairs &
Strategic Partnerships

psayad@myeloma.org

Pierre S. Sayad has joined the IMF as Senior Vice President, Global Medical & Scientific Affairs. Pierre completed his graduate work in Molecular Physiology at Loma Linda University, School of Medicine. In 2003, he began his pharmaceutical career at Eli Lilly and Company, and held leadership roles across Commercial and Medical Affairs teams. During his ten-year tenure at Lilly, Pierre helped launch four blockbuster neuroscience medicines for various mental illnesses.

After Lilly, Pierre joined the management-consulting firm, Campbell Alliance. As a senior consultant managing projects in the Medical Affairs and Commercial practice areas, Pierre worked with clients at more than 25 pharmaceutical and biotech companies, including Pfizer, Genentech, Novartis, and GlaxoSmithKline. In 2012, he joined Onyx Pharmaceuticals as head of Global Strategy and Operations for the Medical and Scientific Affairs Organization. He ultimately formalized and launched Onyx's Global Strategic Partnerships program, and was heavily involved in Onyx's transition to Amgen.

Given his role at Onyx (a subsidiary of Amgen), Pierre has been very familiar with the IMF's Black Swan Research Initiative® and the organization's other innovative platforms aimed at curing myeloma. He currently works directly with the IMF President and the Chairman of the Board, and is committed to advancing myeloma treatment paradigms, ultimately improving the lives of patients.



Sevag Abajian
Database Manager

sabajian@myeloma.org

Sevag Abajian joined the IMF team in 2015, bringing with him extensive database experience acquired at several public service and non-profit organizations, including the American Heart Association and UCLA. Sevag now manages the IMF database and the IMF's online donation website. In addition, he helps prepare and launch the *Myeloma Minute* e-newsletter and a variety of e-mail blasts for several subscriber groups. Sevag earned a B.A. in Political Science at UCLA, where he also minored in Human Complex Systems. He is currently working on completing his Master's Degree in Public Administration. Sevag loves watching and attending sporting events, especially UCLA and professional football. **MT**

IMF Board Member Dr. Edith Mitchell Appointed to Cancer Moonshot Advisory Panel



The International Myeloma Foundation (IMF) congratulates Board Member Dr. Edith Mitchell on her appointment as a scientific advisor on Vice President Joe Biden's Cancer Moonshot Initiative. This initiative aims to eliminate cancer as we know it. Vice President Biden heads the Cancer Moonshot Task Force, which is charged to "make the most of federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care." The IMF could not be more honored to have one of our Board Members working across government channels toward this singular goal.



Dr. Mitchell is a Professor of Medical Oncology and a researcher at the Sidney Kimmel Cancer Center at Thomas Jefferson University, where she also serves as Director of the Center to Eliminate Cancer Disparities and Associate Director for Diversity Affairs. Not only is she a practicing oncologist, Dr. Mitchell is a retired Brigadier General. She has served as the Air National Guard Assistant to the Command Surgeon for US Transportation command and headquarters Air Mobility Command at the Scott Air Force Base in Illinois. In addition, in 2015, she was named president of the National Medical Association, the nation's longest-standing professional organization for African-American physicians.

We are certain in her new role in advising as part of the Cancer Moonshot Initiative, Dr. Mitchell will continue to work tirelessly for the cancer community. "Minorities, especially African Americans, suffer a disproportionate share of the burden of cancer in the United States, with higher incidence rates and poorer survival when compared to other racial and ethnic populations," she said. "Therefore, the Moonshot Initiative may define prevention, diagnostic, and interventional strategies leading to cancer healthcare equity." We wish Dr. Mitchell well on this important effort! **MT**

Meet the Researchers: Drs. Mateos and Hillengass

The IMF is proud to spotlight two outstanding researchers – Dr. María-Victoria Mateos and Dr. Jens Hillengass. Both are members of the International Myeloma Working Group (IMWG), which consists of nearly 200 leading myeloma experts.



Dr. María-Victoria Mateos

A physician and Associate Professor of Medicine, Dr. María V. Mateos is the director of the Myeloma Program and coordinates the Clinical Trials Unit in the Haematology Department at the University of Salamanca, Spain. She also serves as coordinator of GEM (Spanish Myeloma Group), with direct involvement in the design and development of clinical trials.

Dr. Mateos is also a member of the International Myeloma Society (IMS),

the European Hematology Association (EHA), and the American Society of Hematology (ASH).

Dr. Mateos met the IMF and IMF Chairman, Dr. Brian Durie, in 2008, when she was invited to become a member of the IMWG. “Since that moment, I am proud to have been involved in many activities supported by the IMF/IMWG, to be the author of some relevant IMWG guidelines, and to actively participate in its annual Summit meeting.”

“Finally, and this represents a key support, the Intergroupe Francophone du Myélome (IFM) is closely working with our group, through the Black Swan Research Initiative®, to standardize one highly sensitive flow cytometry method for the detection of minimal residual disease (MRD) in myeloma. We are testing MRD detection as primary objective in a trial for asymptomatic myeloma patients at

high risk of progression and it will help us to find the cure of some myeloma patients.”

Sharing Dr. Mateos’s enthusiasm about the IMWG and Black Swan Research Initiative, Dr. Jens Hillengass commented, “The BSRI and IMWG meetings inspire me – I hear about new ideas, can discuss with more experienced researchers, and can present my own work and let it be reflected by other experts. I love to treat and educate patients and, together with Nadia Elkebir, [IMF Director of Europe & the Middle East] I have had the opportunity to do so in and outside Germany.”



Dr. Jens Hillengass

Having studied at the University of Heidelberg medical school, Dr. Hillengass began his research career in 1999 as a medical student in the lab for angiogenesis research of Thomas Moehler. Since 2002, Dr. Hillengass has worked in the Department of Hematology, Oncology, and Rheumatology at the University of Heidelberg, first as a resident, and currently as an attending physician in the Myeloma and Autologous Transplant Outpatient Department.

Dr. Hillengass came to the US in 2012 as a visiting researcher at the National Cancer Institute (NCI). He became a postdoctoral lecturer in 2013, and in 2016 earned an assistant professorship. He specializes in internal medicine, and hematology and oncology, and also teaches at the medical school of the University of Heidelberg. He has been published in *JCO*, *Leukemia*, and *Clinical Cancer Research*, in studies on the prognostic and pathophysiologic impact of imaging findings in monoclonal plasma cell disorders. **MT**

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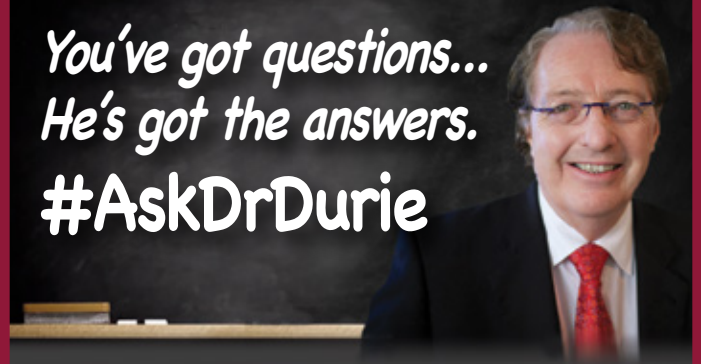
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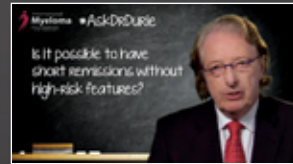
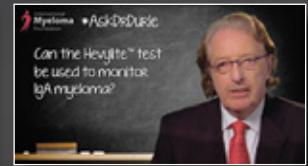


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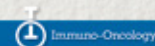
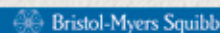
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2016 IMF Calendar of Events

Aug 19–20	IMF Patient & Family Seminar – Los Angeles, CA	Oct 17	IMF Patient & Family Seminar – Tromsø, Norway
Sept 9–10	IMF Patient & Family Seminar – Lázně Běłhorad, Czech Republic	Oct 18	IMF Patient & Family Seminar – Trondheim, Norway
Sept 10	IMF Regional Community Workshop – Kansas, MO	Oct 20	IMF Patient & Family Seminar – Oslo, Norway
Sept 17	IMF Regional Community Workshop – Sacramento, CA	Oct 24	IMF Patient & Family Seminar – Reykjavík, Iceland
Sept 23–25	IMF Patient & Family Seminar – Heidelberg, Germany	Oct 27	IMF Patient & Family Seminar – Korsør, Denmark
Oct 1	IMF Regional Community Workshop – Charlotte, NC	Nov 5	10th Annual Comedy Celebration – Los Angeles, CA
Oct 1	IMF Patient & Family Seminar – Napoli, Italy	Dec 2–5	58 th American Society of Hematology (ASH) Annual Meeting and Exposition – San Diego, CA
Oct 7–8	IMF Patient & Family Seminar – Liptovský Jan, Slovakia		

*The IMF is proud to work with our global partners. We thank them for supporting our international meetings.
For more information about upcoming events, please visit calendar.myeloma.org or call 800-452-CURE (2873).*

For information on activities in Australia, Canada, Israel, Japan, or Latin America, please visit:

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