Love Healing Support

Wisconsin Multiple Myeloma Support Group

"Providing an opportunity for multiple myeloma patients and their loved ones to come together to exchange information for mutual support, comfort, and friendship"

Meeting: **Tuesday March 17, 2015 3:30pm – 5:30pm**
451 Junction Road
UW West Clinic Room 1287
Enter the clinic… proceed left past the vending area… turn left again and conf. room 1287 is the last one on the left.

Information: Jayne Schwartz 608- 244-2120
schwartzdon@sbcglobal.net

Mailing Address: Wisconsin Multiple Myeloma Support Group
3309 Chicago Avenue
Madison, WI 53714-1815

More Information:

International Myeloma Foundation (IMF)	Multiple Myeloma Research Foundation (MMRF)
Phone: 800 - 452 - 2873	203 - 972 - 1250
Email: TheIMF@myeloma.org	info@themmrf.org
Website: www.myeloma.org	www.multiplemyeloma.org

Upcoming speakers

Debbie Boldt-Houle, Senior Director Scientific Affairs from the Binding Site, Inc needed to reschedule her presentation. She will join us in July. She will present information about the Freelite testing.

Donations

A big thank you to Al Kanner for his very generous donation to our support group. It is appreciated.

Our sincere condolences to the Enright family.

I am sorry to report that Rob Enright passed away February 14, 2015. Sue and Rob joined our group early on and when they moved, started a group in West Bend, WI. Rob was a positive supporter for many of his group members. He was a true fighter trying many new treatment paths. We will miss him. Sue Enright continues in her role of Midwest Regional Director of Support Groups for the IMF.

"Glossary of Myeloma Terms & Definitions" and "Guide to Myeloma Acronyms and Abbreviations"

Group member Mary passed along this helpful information. With so many new members, this guide is a great tool to keep all the terminology straight. The IMF has updated both sources. It is available on their website. myeloma.org -> Choose the tab "about myeloma" -> "newly diagnosed" -> "Learn the Vocabulary". You will find both the "Glossary of Myeloma Terms & Definitions" and "Guide to Myeloma Acronyms and Abbreviations". As with earlier versions, it can be printed or saved as text or pdf. For the new members, if you are confused by the terms… take it to your next clinic appointment.

Our own Dr Natalie Callander, UW Carbone Cancer Center is featured on this 50 minute presentation. As always, she has a great message to share.
http://videos.med.wisc.edu/videos/57974

The International Myeloma Foundation-Living Well with Myeloma Teleconference Series
Understanding the ImmuneSystem in Myeloma
Thursday, March 19, 2015
4PM Pacific / 5PM Mountain / 6PM Central / 7PM Eastern
Duration: 60 minutes (including Q&A)

Speaker: Brian G.M. Durie, MD

Pre-Register today! It's FREE.immunesystem.myeloma.org

Myeloma Beacon published: Feb 23, 2015 3:30 pm

The U.S. Food and Drug Administration (FDA) has approved panobinostat, which will be marketed under the brand name Farydak, for the treatment of relapsed and refractory multiple myeloma.

Farydak has been approved for use in combination with Velcade (bortezomib) and dexamethasone (Decadron) in patients with multiple myeloma who have received at least two prior standard therapies.

The two prior therapies must include Velcade and at least one treatment from the immunomodulatory class of drugs, which includes Revlimid (lenalidomide), thalidomide, and Pomalyst (pomalidomide, Imnovid).

The FDA approval of Farydak is the agency's third go-ahead for a new myeloma therapy in less than three years. Prior to Farydak, the agency approved Pomalyst in early 2013 and Kyprolis (carfilzomib) in the summer of 2012.

The FDA's decision was announced earlier this afternoon by the agency in a press release, which also noted that the drug's approved prescribing information will contain a so-called black box warning. Such warnings are intended to highlight important safety issues associated with a drug.

In the case of Farydak, the black box warning alerts "patients and health care professionals that severe diarrhea and severe and fatal cardiac events, arrhythmias and electrocardiogram (ECG) changes have occurred in patients receiving Farydak," according to the FDA press release.

An Eventful Road To Approval

The FDA's decision to approve Farydak is likely to come as a surprise to many people. The drug was reviewed during an FDA advisory committee meeting in early November last year, but failed to gain the support of the committee, which voted 5 to 2 against recommending the drug for FDA approval (see related Beacon news).

The FDA typically makes approval decisions that reflect the recommendations of its advisory committees. Thus, there was widespread pessimism about Farydak's chances for FDA approval following the early November advisory committee vote.

Some of that pessimism dissipated, however, when the FDA announced late in November that it was giving itself an extra three months to reach a decision on Farydak's approval application. Had it not taken that step, the agency would have had to announce its decision by the end of November (see related Beacon news).

There are many reasons why the FDA can decide to delay an approval decision. However, in this case, one reasonable interpretation was that the agency was unwilling to make a quick decision based on its advisory committee's recommendation.

There also was speculation at the time that one option the FDA might be considering was an approval of Farydak that was more restrictive than what Novartis requested in its approval application.

Novartis originally requested Farydak approval for use in myeloma patients who have had one previous therapy. The FDA approval announced today is more restrictive. It specifies that Farydak is to be used in patients with at least two prior therapies, and there are additional requirements as to what those previous therapies must be.

The FDA decision to approve Farydak caps a long, arduous effort by Novartis to develop the drug as a new cancer therapy. After initially testing Farydak in a wide range of different cancers, Novartis decided in 2009 to ask the FDA to approve the drug as a new treatment for Hodgkin's lymphoma. That new drug application, however, was turned down by the federal regulator after less than 60 days of review.

Following the FDA rejection of Farydak's lymphoma new drug application, Novartis shifted gears and focused development of the drug on its potential use as a myeloma therapy. The company initiated a number of different trials testing Farydak in multiple myeloma, including the trial that eventually served as the basis for the regulatory submission that led to today's approval announcement.

Novartis has not yet indicated when Farydak will be available in U.S. pharmacies, or what the drug's cost will be.

Farydak is an orally administered drug that belongs to a class of drugs called histone deacetylase (HDAC) inhibitors. These drugs work by increasing the production of proteins that slow cell division and cause cell death.

Other HDAC inhibitors have been, or are currently being, investigated as potential myeloma therapies, including Zolinza (vorinostat), Istodax (romidepsin), ricolinostat (ACY-1215), quisinostat, and CUDC-097.

The FDA's approval of Farydak is based on data from the Phase 3 clinical trial known as PANORAMA-1. The trial tested Farydak in combination with Velcade and dexamethasone in relapsed/refractory multiple myeloma patients who have failed at least one prior treatment.

The published results of the trial show that adding Farydak to treatment with Velcade and dexamethasone improved progression-free survival in trial participants by almost 4 months (from 8.1 months to 12 months). There also was a trend to improved overall survival.

In its press release today, however, the FDA described the progression-free survival of Farydak somewhat differently than in the previously published results, saying:

Study results showed participants receiving the Farydak combination saw a delay in their disease progression (progression-free survival) for about 10.6 months, compared to 5.8 months in participants treated with bortezomib and dexamethasone alone.

Participants in the PANORAMA-1 trial who were treated with Farydak also experienced frequent side effects. These included low blood cell counts, which often occur in patients being treated with anti-myeloma therapies, as well as significant gastrointestinal side effects.

The frequency and seriousness of these side effects are likely a key reason for the black-box safety warning the FDA has included in the drug's officially approved prescribing information.

Dates to Remember….
IMF San Francisco Patient & Family seminar- March 27-28, 2015.

IMF Info Line – If you or someone you care for has myeloma, you have questions. Probably, lots of them. You can search the Internet all you want, but other than asking your doctor, there is no better way to get your questions answered than to call the IMF Info Line. Debbie, Missy, Judy and Paul know their stuff and they want to share what they know with you. Just ask anyone who has called the IMF Info Line. Patients or caregivers are welcome to contact the Info Line staffed by trained specialists at 800-452-CURE (800-452-2873). The Info Line is staffed between 9am and 4pm Pacific Time, 11am to 6pm Central time or infoline@myeloma.org.

The **Trillium Fund** was established by our founding support group members to facilitate Multiple Myeloma research here in Madison at the Wisconsin Institute of Medical Research. If you or your family wish to donate or send a memorial to this program, checks can be made payable to the "UW Foundation – Trillium Fund".
Send to: Maureen Dembski, Director of Development
UW Carbone Cancer Center
University of Wisconsin Foundation
1848 University Avenue
Madison, WI 53726
maureen.dembski@supportuw.org