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 June 16, 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. will join us in July. She will present information about the Freelite testing.
- Dr. Lori DuBenske, PhD UW Psychology will speak at our August 18th meeting.
- Tentative plans for Dr Natalie Callander to speak at the October meeting.
- Still waiting to hear from the UW Sleep Clinic. Hoping to get one of the doctors to come to present information about the importance of good sleep and being well.
- Have made contact with the UW Kidney clinic for a speaker. Still waiting to hear from them too.

Leukemia Lymphoma Society 13th Annual Multiple Myeloma Conference

Date: Saturday September 12, 2015
Location: Country Springs Hotel-Pewaukee, WI
Conference is free to attend and we welcome anyone impacted by a myeloma diagnosis: patients, caregivers & families, and healthcare professionals!

Register Here! For those folks without internet access, call 262-785-4274. More info to follow. This is a conference worth attending!

Dr Aric Hall, MD who spoke at our February 2015 meeting will be staying in Madison after all! Aric is a third year oncology fellow at the UW Carbone Cancer Center. He is currently working with Dr Natalie Callander.

Recently there have been several articles about precision treatment initiatives. Here is one that group member, Kay passed along.

NCI to begin nationwide trial to test treatments based on genetic mutations in patients' tumors.

In a 1,300-word story on its front page, the Washington Post (6/2, A1, Dennis, Bernstein) reports that "the National Cancer Institute's announcement Monday that it will soon begin a nationwide trial to test treatments based on the genetic mutations in patients' tumors, rather than on where the tumors occur in the body, highlights a profound shift taking place in the development of cancer" medications. In announcing the new initiative, James H. Doroshow, director of the division of cancer treatment and diagnosis at the NCI, said, "We are truly in a paradigm change." The Post adds that "the FDA in recent years has embraced an array of novel trial designs and shown a willingness to approve drugs rapidly if they show unmistakable benefits in early trials." The Post adds that "the American Society of Clinical Oncology...announced this week that it is starting a comparable project that will provide patients with drugs targeted at similar molecular abnormalities and collect the data from oncologists providing their care, to better understand the effectiveness of the treatments."

The Wall Street Journal (6/2, Winslow, Subscription Publication) reports that Doroshow said of the trial, called NCI-Match, "This is the largest and most rigorous precision oncology trial that has ever been attempted." The announcement was made at the American Society of Clinical Oncology annual meeting. ASCO's project is called TAPUR.

The Los Angeles Times (6/2, Healy) "Science Now" blog reports that "one of the TAPUR trial's key draws for participants will be its ability to make often prohibitively costly new drugs available to patients whose cancers are deemed likely to respond."

On the CURE website the following article appeared.

Patients to be Treated Based on Tumor Genomics, Not Disease Type, in ASCO's First Clinical Trial

Author: Lauren M. Green

The American Society of Clinical Oncology (ASCO) is testing what will happen if patients are treated according to the genomics of their tumors, rather than on the basis of their disease types, such as breast or colorectal cancers.

Through an ASCO clinical trial, physicians will have the option of prescribing oncology drugs that are approved by the U.S. Food and Drug Administration, but not in a patient's specific cancer type — as long as the genomics of the patient's tumor match the drug's target.

The trial — known as TAPUR, or Targeted Agent and Profiling Utilization Registry — is the first run by ASCO in its 50-year history. The study's aim is to simplify patient access to cancer treatments across many tumor types. ASCO unveiled the trial June 1 in a press briefing during its 2015 Annual Meeting of nearly 30,000 oncology professionals in Chicago.

The nonrandomized TAPUR trial will involve patients with any advanced solid tumor, multiple myeloma or non-Hodgkin lymphoma that has a genomic variation known to be the target of an existing approved drug.

The primary objectives of TAPUR are twofold, explained ASCO's chief medical officer, Richard L. Schilsky, at the press briefing: to improve access to potentially effective therapies for a much broader population than is typically enrolled in clinical trials, and to gather important information on the antitumor and toxicity of targeted drugs across multiple cancers.

"Increasingly, we find that patients with advanced cancer who no longer have any standard treatment options are having a genomic profiling test performed," noted Schilsky in explaining the rationale for the initiative. "These tests are now readily available…and sometimes what's known as 'a potentially actionable variant' is detected." Estimates in the literature are highly variable, he added, but about 40 percent to 70 percent of the time these tests are likely to turn up something that the doctor might be able to act on:

"The question that the doctor and the patient then face is, 'How do I get the drug that is suggested by my tumor's profile?'"

Although in some cases the drug will be investigational and thus best administered in the context of a conventional clinical trial, "in other cases, given the large number of targeted therapies that are now commercially available, the best option for the patient might be to receive a commercially available targeted drug, but one that would have to be prescribed outside of its

FDA-approved indication," a process that can be very complicated and burdensome.

Even when patients do get access to these agents, said Schilsky, "we have no mechanism right now to learn the experience of that patient — how the patient did, whether they responded or not, whether they had side effects. That information is never captured in any organized way that we as an oncology community can learn from."

A Collaborative Effort

Five pharmaceutical companies (AstraZeneca, Bristol-Myers Squibb, Eli Lilly and Company, Genentech and Pfizer) have signed on to provide their currently marketed targeted drugs at no charge to participants, and more are expected to join the effort, noted ASCO President Peter Paul Yu in a statement. He added that "at least 13 drugs that target more than 15 genomic variants will be provided by these companies."

Data analysis will be provided by two technology companies, Syapse, which will automate the study workflow, and NextBio, which will support and inform the case review.

Patient advocates also will be providing guidance and oversight support for TAPUR. Jane Perlmutter, a cancer survivor and nationally recognized patient advocate, will help coordinate patient advocate recruitment and training for the initiative.

"TAPUR has enormous potential to improve our understanding of the effectiveness of currently available therapies in treating cancers with genomic variations and to learn from patients who are treated with off-label drugs," said Perlmutter in an ASCO statement, adding that the program will be especially helpful "for those with advanced cancer for whom traditional therapies are no longer working.

ASCO also is collaborating with the Netherlands Center for Personalized Cancer Treatment, which is conducting a clinical trial using a study protocol very similar to TAPUR's.

Timetable and Protocol

Schilsky said that ASCO will submit its completed trial protocol and consent form to an institutional review board in July, and the organization hopes to begin patient enrollment by the end of this year.

He said the patient eligibility criteria are intentionally broader than those of a typical clinical trial. The study will enroll patients with advanced solid tumors, B-cell non-Hodgkin lymphoma and multiple myeloma who are not responding to standard anti-cancer treatment or for whom no acceptable treatment is available. Patients will be screened to determine if they have adequate organ function to participate based on broad inclusion/exclusion criteria.

Any genomic test that is available to the physician in clinical practice, as long as it is performed in a CLIA-certified/CAP-accredited laboratory, will be enough to qualify a patient to enter the study, Schilsky said.

If a patient meets the trial criteria, his or her physician can select a drug from among those available in the TAPUR study protocol that targets the genomic variation in the patient's tumor. Physicians can consult one of ASCO's three oversight committees set up for the initiative, the Molecular Tumor Board, for guidance on potential therapies on or off the study, if a relevant drug match is not described in the protocol. ASCO also will have a Steering Committee and a Data and Safety Monitoring Board to oversee the effort.

All patients who receive treatment through TAPUR will be monitored for standard toxicity and efficacy outcomes, including objective response rate per RECIST criteria — the study's primary endpoint — as well as time on treatment and progression-free and overall survival.

Schilsky explained that the unit of evaluation in the study will be a "tumor type genomic variant drug group." The plan is to

enroll eight patients per group; if no responses are observed, enrollment in that group will be stopped, but if there is at least one response, enrollment will be expanded up to a total of 24 patients.

"The idea here is to detect a signal of drug activity…we hope that signals of activity will result in pharmaceutical companies, the clinical oncology research community or others pursuing those signals," he continued.

TAPUR will be launched initially at three clinical sites — the Michigan Cancer Research Consortium, the Cancer Research Consortium of West Michigan and the Carolinas Health System — with the ultimate goal of expanding the effort nationally.

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