

April 2016 Northside Meeting

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Business and Announcements

Nancy B. led the meeting and approximately 35 people attended. Thanks to those who brought the refreshments, which are coordinated by Libba. A back-up is needed for refreshments in case Libba is unavailable. Please contact Nancy if you can help keep this going for the group. Tom L. announced that he has esophageal cancer and just got a port to start treatment.

Guest Speaker --

Charise Gleason from Emory Winship Cancer Institute was our guest. She has been at Emory since 1998 and appreciates the relationships with the Myeloma patients. Winship sees nearly 2000 MM patients per year. She was glad to visit our group and said that every talk provides an opportunity for the patients to get a new perspective to use with your Healthcare team. Charise began with a review of bone marrow and Myeloma. The normal function of plasma cells is to fight infection. When the abnormal Myeloma plasma cells crowd out the normal cells, the result is lots of infections. Cancers disrupt the normal function of the body. Also the treatment can impact the normal functions of the body, also leading to more infections.

The healthcare team is reminded that they are dealing with people who want good quality of life. The patient must keep focused on the total situation and work with the doctors on the best treatment decision. The cytogenetics of your MM is reading the genes of the abnormal plasma cells, not the normal cells in your bone marrow test. If the test shows missing chromosomes or translocations, then that tells the doctors how to treat the MM. For those with abnormal chromosomes, then the patient will need continuous treatment after transplant. The new mindset is that they are not able to take long breaks from treatment. With the chromosome criteria, high risk smoldering MM (SMM) will progress sooner and needs treatment to avoid progression and potential organ and bone damage. The ever-changing guidelines are driven by data and updated regularly. The current guideline for newly diagnosed MM patients is for Rev/Vel/dex (RVd) which gives a response in 100% of patients. This is wonderful news for patients. RVd was originally for relapsed MM, but after further trials, it was approved for newly diagnosed. At ASH this year, RVd was confirmed as the way to treat newly diagnosed MM. Now doctors are working on a 4-drug combination in a clinical trial that adds a monoclonal antibody to RVd. This is getting better results and data has shown that a deeper original response to treatment leads a long term survival, in most cases. Proteasome inhibitors (PI - Velcade) have new agents (Kyprolis and Ninlaro) that are getting better. If your MM progresses on one drug, the next generation works.

Q – Is Dex needed with PI?

A - Dex with the PI makes the plasma cell more available for cell kill.

Q – Can Kyprolis be taken alone?

A – Start with a multi-drug combination to get the best response up front. Then work with your doctor to reduce dosage to ease side effects and prevent long term damage. It is important for patients (and caregivers) to give feedback to the Healthcare team for setting the plan. The PI drugs cause lots of gastro problems, but there are meds to help with the effects.

The newest PI is Oprozomib and it is being tested against Ninlaro. Immunotherapy includes the monoclonal antibodies that target receptors on the cells for the immune system to kill the cancers cells. This includes Daratumumab (Dara) and Elotuzumab (Elo) along with new version in clinical trials. Other trials are testing vaccines.

Q – Are the vaccines to prevent or treat MM?

A – The vaccines contain antibodies to fight the disease and are being tested in SMM/MGUS at early stages to prevent advancement of the disease and organ/bone damage.

Q – Someone heard of a clinical trial of the vaccine right after transplant. Is this available at Emory?

A – Not at Emory, but Charise will check other centers and let Nancy know what is available.

Q – Are the treatment goals different now?

A – The primary goal is to get the disease knocked down as low as possible on the initial treatment. Early in the journey is the best time to get close to zero disease. At relapse, it is harder to get to zero, so the goal is to control the disease.

Q – Can the monoclonal antibodies be used as a single agent?

A – The other agents are used with the monoclonal antibodies to help the other agents work better and open up the immune system to attack the MM with the natural killer (NK) cells. Most drugs work with the immune system so Elotuzumab is used with Revlimid. Emory uses lots of monoclonal antibodies. Phase 3 trials are critical for FDA approval, but even after the drug is approved, some patients are still on the treatment.

Q – Is Elo used only with Rev and Dex?

A – At Emory the treatment starts that way but can be adjusted with other agents. There is a clinical trial with Dara given Sub Q and the early data looks good.

Q – What are the side effects for Dara Sub Q?

A – That trial is not at Emory yet, so we don't know the effects. Dara usually has low side effects after the first dose. Elo has a little more fevers and flu-like symptoms. Leg cramps come from the Rev included with this treatment. In a clinical trial, the patients are watched closely and all side effects are graded to go into the data collected. Grades 1 & 2 can be controlled, while grades 3 & 4 are more severe and may lead to reduction or termination of treatment. The researchers are tuned to the impact of side effects for the patient's quality of life. Note that we will be seeing more oral treatment for patients. New drugs are being offered at more Emory centers around Atlanta, so the team is getting lots of calls and offering varied support.

Q – What is Pyrexia?

A – A fever greater than 100.5 which is critical to notify your healthcare team.

Dara with Rev/dex is getting 89% response rate! If maintenance with Dara alone, dosage is once per month. If the patient progresses on this therapy, then other drugs are added and the Dara is given more frequently to get the MM under control. If a patient progresses on Pomalidomide (Pom) or Dara, then those are given together to get a response.

Q – The approach is that more is better, but can a patient start with one drug and increase as needed?

A – As proven in clinical trials, multi-drug programs are best for first treatment to get the deepest response. On relapse, some start with single Dara or Pom/dex to reduce side effects and get control of the disease.

Q – Can a patient get a quicker response with more than one drug?

A – Typically, yes, especially in newly diagnosed patients. The goal is to get the deepest response early which leads to more control over the long term. With multi-drugs, the dose is usually lower for less toxicity. As the MM relapses, a stronger program is needed with more toxicity.

Q – Once a new drug is approved, how long to get insurance coverage?

A – Usually a couple of months at Emory where we have staff working with the insurance companies. Dara and Elo got insurance approval pretty quick since they are given as infusion in the clinic.

Q – When looking at treatment, how should a patient consider side effects along with other health conditions such as high blood pressure and diabetes?

A – Looking at clinical trials, there are eligibility requirements, so the patient must look for other options. Dex has issues for diabetes. Other drugs may impact kidneys or heart.

After induction when the disease is knocked down, the cytogenetics and risk factors are used to determine maintenance treatment. Dara/Pom/dex is a good combination. Other clinical trials are also available: ARRY-520 is Filgrastim which is a new type and works differently, but it also suppresses blood counts. Another trial is with selinexor, which has lots of gastro issues, so the patient must be pro-active on medication to control problems.

Imaging is an important tool in tracking your MM. An X-ray needs 30% of bone loss to show up. Most patients get a skeletal survey (full body x-ray) at diagnosis. An MRI can show more detail, such as smaller lesions and soft tissue plasmacytoma.

Q – Do all MM patients get lesions?

A – 80% present with bone issues which are treated with Bisphosphonates.

If you are on a clinical trial, you will get a full set of tests. At Emory, SMM and MGUS get an MRI of the spine. Low dose, full body CT scans are a new approach and will be available at Emory soon. The Emory MM team is writing up care plans for the patients at all Emory sites. PET is done on all patients after transplant, which tells more about the response. PET measures the uptake of glucose and lights up to create “hot spots” of MM activity and some other issues. Emory will move to PET for all newly diagnosed MM patients. In addition to the entire test schedule, it is very important to tell your healthcare team about any new or increased pain. They do not take pain symptoms lightly. Only the patient knows if the pain is new or increased.

Q – Any limit on the length of Rev treatment? What about secondary cancers?

A – Secondary cancers occur more often when the patient has had an Alkylating agent (Melphalan). The risk of secondary cancer is lower than the risk of MM; the benefits outweigh the risks. It is important to get all regular testing done to monitor risks. How long to take Rev? It works as long as you take it! We don't know the limit, but if symptoms increase, then evaluate and watch closely.

Q – A patient said that he has been on Rev for 6 years. Should he do the MRD test and what to ask the doctor about going off Rev?

A – If something is working, why change? The clinic will learn with the patient and work to track the disease. We don't know all the answers. A drug holiday helps the system to rebound, but we do not want to build resistance to the Rev. The patient preference is part of the answer, so the patient must be educated on all options. Some patients do not get off Rev due to early cytogenetics.

Q – Any new options for peripheral neuropathy (PN)?

A – To reverse it, take away the treatment that caused it. Some patients have PN from previous treatments. Now there are compounds that help and are not totally absorbed to the whole body. Try physical therapy and keep moving. You can regenerate nerves and sometime that regeneration can increase pain temporarily.

Q – What is the safest pain medication?

A – Do not take NSAIDs – aspirin, ibuprofen (Advil, Motrin, etc), Naproxen (Aleve and others). If your liver is OK, you can take Tylenol. Call your clinic to get a prescription. They should evaluate conditions for each patient.

Submitted by Nancy B

Southside Multiple Myeloma Support Group April 2016

Doris led the group in a prayer. There were 16 present. Next month's meeting on May 28th will feature open discussion from members.

Business

Caregiver Appreciation Event - Plans are still being developed for the Caregiver Appreciation Event currently scheduled for June 11th. We are looking at other potential venues including the Georgian Terrace Inn across from the Fox. Only 30 members from the Southside and Northside support groups responded that they would attend. We are therefore, extending the attendance to all blood cancers; we are planning for 100 participants. We are still waiting to hear from additional sponsors including Celgene.

Speaker: Tricia Hernandez – Patient Access Manager, The Leukemia and Lymphoma Society, Georgia Chapter. She is a 13 year Hodgkin's Lymphoma survivor and has been with LLS for less than 2 years. Tricia described the vision and mission of LLS with passion and purpose.

The Leukemia & Lymphoma Society (LLS), founded in 1949, is the world's largest voluntary health organization dedicated to funding blood cancer research, education and patient services. LLS's mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and to improve the quality of life of patients and their families. LLS created the Information Resource Center (IRC) to provide accurate, current information about blood diseases and support for blood cancer patients, caregivers and families, their health professionals. **IRC** specialists are professional social workers, nurses and health educators. Tricia says the goal of the organization is to put itself out of business. A cure happens as the result of research. LLS brings all the players to the table –patients, pharma, academia, government (FDA), insurance and health. She said through work of LLS, Hodgins Lymphoma is now curable and survival rates for all blood cancers have improved including multiple myeloma. As a result of continuing research and successful clinical trials, four new or novel myeloma treatments have been approved in the last 12 months – Darzalex (Daratumumab), Emlucity (Elotuzumab), Farydak (Panobinostat), and Ninlaro (Ixazomib).

The Leukemia & Lymphoma Society – Georgia Chapter offers a variety of programs and services for people affected by blood cancer. All services are offered free of charge. Below are descriptions of some programs and services offered by LLS.

LLS Patient Access Programs

Information

- **Information Resource Center** – One-on-one support is available from 9 am to 9 pm (EST) from Information Specialists who are master's level oncology social workers, nurses and health educators. They can answer general questions, offer guidance and support and assist with clinical-trial searches. They can be reached at 1-800-955-4572, via email at infocenter@lls.org or online chat at www.lls.org/information-specialists .

Education

- **Education Programs** – LLS sponsors a range of free telephone and web education programs, videos, and local education programs for patients and caregivers about various disease, support and treatment topics.
- **Education Materials** - Available on a variety of different blood cancer topics and diagnoses. You may order publications to receive by mail by calling 1-800-955-4572 or view/print them as PDFs from our website at <http://www.lls.org/resource-center/download-or-order-free-publications>.

Support and Financial Assistance

- **Patti Robinson Kaufmann First Connection Program** - A peer mentor support program, connecting people who are newly diagnosed or having a new treatment with a trained peer volunteer who has gone through a similar experience. This program is available to patients, caregivers and family members. To be matched with a peer volunteer, please call 404-720-7838 or email tricia.hernandez@lls.org .

- **Family Support Groups** - An ideal place to talk with other people affected by blood cancers including patients, family members and caregivers. LLS support groups are professionally moderated and offered in person or by phone
- **Online Chats** - A friendly forum to share experiences and chat about a variety of topics. Each chat is moderated by an oncology social worker and is password protected.
- **Leukemia & Lymphoma Co-Pay Assistance Program** - Offers financial support toward the cost of insurance co-payments and/or insurance premium costs for prescription drugs. Patients must qualify both medically and financially for this program. To get more information or to apply for this program call 877-557-2672 or visit www.lls.org/copay . Funds are subject to availability.

Volunteering

- **Honored Hero** - Honored patients and families provide inspiration for our fundraising events, fueling efforts to raise funds that support research and help patients.
- **Other volunteer opportunities** – LLS offers various opportunities to become an advocate, volunteer at fundraising events or in the offices or to speak on behalf of LLS and share LLS resources in the community. Please contact tricia.hernandez@lls.org or call 404-720-7838 if interested in volunteering.

Tricia reminded us of the Light the Night fund raiser that occurs each year. Our Light the Night Walk will be held on Saturday **October 8, 2016 - 4:30 PM**, Centennial Olympic Park, 265 Park Avenue West NW, Atlanta, GA 30313.

Save The Dates – Tuesday, June 21, 2016 Myeloma Education Update 5:30 pm-7:30 pm UGA Center for Continuing Education 1197 South Lumpkin Street, Athens, GA 30602 and

LLS 2016 Blood Cancer Conference: Saturday, July 23 8am to 3pm at the Cobb Galleria. The conference is for survivors, caregivers and health professionals. Breakouts will include topics such as Integrative Medicine and specific Myeloma sessions. **LLS will be looking for volunteers to assist with registration and the like for this event.**

To register for one or both these workshops, contact Tricia at [404-720-7838](tel:404-720-7838) tricia.hernandez@lls.org

Patient Updates

Evelyn reports her blood work is good; doctors have said her counts are good. She is not on medication for MM but is in dialysis three times per week. **Patt** is still in remission and is taking 5 mgs of Revlimid; labs are taken quarterly and Zometa infusion quarterly. **Kimberly** is still in remission; she will go in June for an MRI to check the site of the original tumor. **Selina** is going once each month for labs; she is not currently on medication only pain meds. **Doris** is going monthly for Zometa and is on 25 mg Revlimid (14 days on 14 days off) and 2 ½ pills of Dexamethasone. Her numbers are down significantly. **Alma** has been off Zometa since preparation for oral surgery due to problems with her jaw. She is on Daratumumab / Pomalyst /Dexamethasone and goes weekly for lab tests. **Janet** says one day she is very well; the next day, not so much. She is on Dexamethasone and Pameidronate; she has some digestive discomforts. Janet says lab reports show no evidence of Myeloma. She will have a PET Scan next week. When **Geraldine** attended our support group meeting last year she was in crisis. She began treatment with the novel regimen and BMT was scheduled and cancelled twice. Her numbers are now good; she is off all medications except an over the counter liquid Calcium supplement. SCT is recommended; she is considering a second opinion. She has no family members in Georgia and it would be a challenge for her to receive SCT at Northside since they have an outpatient SCT procedure. She is a Kaiser patient. **Larry** says he is in a **complete stringent remission (CSR)**; he is on Duloxetine and aspirin for neuropathy and is receiving treatment with George Spinolo, MD, Hematologist with Cancer Care Specialists in Stockbridge and Dr. Kaufman at Emory.

Announcements/Resources/Upcoming Meetings

Stay Alert. While progress in treatment of myeloma is exciting, the respected Institute for Clinical and Economic Review (ICER) published an article challenging the cost-effectiveness of treating relapsed or refractory MM. Dr. Durie and other myeloma researchers were concerned that the analysis was flawed, error filled, "...spurious, and misleading with misleading results." These are harsh words. Risk: Insurance payers could use conclusions like this to set **policy on denying treatment. CMS (Centers for Medicare and Medicaid Services)** is included in payers that could limit treatment options based on faulty conclusions.

- Advocacy. Respond to efforts from LLS, IMF, and MMRF to help to control costs of cancer therapy.
- Recent Archived Webinars. IMF MMRF, and BMT (www.bmtinfony.org)
- IMF – 12 YouTube videos on different MM topics from the Boca Raton Patient & Family Seminar. They range from 24 minutes to 80 minutes in length. <https://www.youtube.com/playlist?list=PLAWij8qSJy6SxdyFzP5DEBmVtIjM7N2n>

- IMF - Smart Patients is an online peer-to-peer program – get daily emails from patients and caregivers regarding their MM treatment journey. They share experiences from preparation for SCT to hints on increasing energy to discussions on new medications, side effects, and more. <http://www.smartpatients.com/imf> .

Clinical Trials Definitions of phases

- Phase 1 - see if experimental medicine is safe
- Phase 2 - see if treatment is effective
- Phase 3 - see if treatment is safe and effective AND works better than currently available drugs

Cancer Care Connect - connect@cancercare.org

- Managing the Side Effects of Immuno-Therapy
Tuesday, May 10, 2016, 1:30 – 2:30 PM, ET
- Managing Symptoms and Treatment Side Effects of Multiple Myeloma
Thursday, May 26, 2016, 1:30 – 2:30 PM, ET

Clinical Trials - Updates (clinicaltrials.gov)

Multiple Myeloma Bone Study – Randomized Double Blind (the patient does not know what they are getting).
Denosumab versus Zoledronic Acid (Zometa) in newly diagnosed

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Smoldering Multiple Myeloma

- **A Study to Evaluate 3 Dose Schedules of Daratumumab in Participants with Smoldering Multiple Myeloma**
- **Lenalidomide or Observation in Treating Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma**
- **Daratumumab in Participants with Smoldering Multiple Myeloma**
- **ARROW- Phase III Clinical trial for relapsed or refractory MM. Carfilzomib (Kyprolis) and dexamethasone. Compare Kyprolis once a week versus twice weekly dosing.**

Selinexor (STORM) - For those heavily treated for MM (e.g., Velcade, Revlimid, Kyprolis, Pomalyst). Receive Selinexor (KPT-330) and Dex three times a week.

TOURMALINE MM1 – A phase 3, randomized study comparing Oral Ixazomib (**Ninlaro**) plus Lenalidomide (**Revlimid**) and Dexamethasone Vs. Placebo plus Lenalidomide and Dexamethasone in Adult Patients With Relapsed and/or Refractory Multiple Myeloma

MM Vocabulary for today: There are four classes of drugs Myeloma Therapies

1. **Proteasome Inhibitors** - Bortezomib/Velcade; Carfilzomib/Kyprolis; Ninlaro/Ixazomib
2. **Immunomodulating** - Thalidomide, Lenalidomide/Revlimid; Pomalidomide/Pomalyst
3. **Monoclonal Antibodies** - Daratumumab/Darzalex; Elotuzumab/Empliciti
4. **Histone Deacetylase** - Panobinostat/Farydak

*New agents - Farydak, Darzalex, Ninlaro, and Empliciti

Notes respectfully submitted by Paulette, Kimberly and Gail.