

May 2016 Northside Meeting

* * * * *

Business and Announcements

Nancy B. led the meeting and approximately 40 people attended. The group welcomed two new members. **Quaye** was diagnosed in 2012. She is taking Revlimid and is in a complete remission. She has not had a stem cell transplant. **Alicia B.** was diagnosed in March 2016. She is currently on a RVD regimen and preparing for a stem cell transplant. Thank you very much to **Dr. Harvey**, Associate Professor of Hematology and Medical Oncology at the Winship Cancer Institute of Emory University who spoke at the meeting and provided a wealth of information.

Dr. Harvey is a Board Certified Oncology Pharmacist and is the Director Phase 1 Clinical Trials (CT) at Emory. Approximately 30-40% of Dr. Harvey's CT patients have multiple myeloma (MM) and the rest have other types of hematologic cancers. The majority of his patients have exhausted their options with other treatments. During Phase 1 clinical trials (CT) drugs that have never before been administered to humans are tested on patients participating in the trial. Some examples of drugs that have been through his program include Ninlaro (ixazomib), Daratumumab, Elotuzumab, and Panobinostat.

There are a lot of options now for MM patients using monoclonal antibodies combined with standard drugs. Treatments that use 3-5 drugs combined are very popular due to the enhanced results achieved when combining drugs. Amazing differences have been realized with next generation drugs. Just small changes to drugs in the same realm have resulted in remarkable changes that benefit the patient. The FDA approved four new MM drugs in 2015. The new head of the FDA is less focused on safety and more focused on delivery to patients with unmet needs. Dr. Harvey answered many questions as follows:

Q: Are any CTs being conducted for newly diagnosed patients?

A: Not yet. One reason is because they purposely test with patients who have undergone previous treatments. The current standard of care, Rev/Vel/dex, works very well, so the need for new drugs is not so urgent as for those who are running out of options when the current drugs stop working.

Q: If you participate in a CT being conducted at a specific location, must you be present at that location?

A: Yes during treatment because the CT is very controlled and safety is very important. Some patients have been able to get their doctors to open a trial for them locally but not all centers are able to or want to provide CTs for their patients. With doctors at different locations, there is the potential for more errors without universal medical records connected.

Q: Do our doctors know what trials are open and applicable to us?

A: Yes, when trials are opened they must be published. Refer to <https://clinicaltrials.gov>. This is a complex site, so [search for open trials at the location you prefer.](#)

Q: Do Phase 1 studies have upper age limits?

A: No, general fitness is more important than age. It is also illegal to discriminate on age, race, and gender. The population in CT does not match the general population (CT average 7 years younger) and blacks are under-represented.

Q: Is it ever advantageous for a patient who is in a complete remission (CR) to participate in a CT?

A: Maybe, because a patient in a CR still has some MM cells in their body.

Q: Can the FDA approve drugs that have only been through Phase 1 CTs?

A: Yes, if the trial was set up from the beginning this way and it is a new type of drug to meet an unmet medical need. It is good news to see the new drugs get to patients quicker.

Q: How many patients participate in a Phase 1 CT?

A: Generally 20-30 patients.

Q: How long does it take after FDA approval for Insurance companies to begin approving drugs for patients?

A: Once the FDA approves a drug it gets a J-code and then Insurance companies should be ready to begin approving the drug for their customers. It takes a while for their systems to get updated.

Q: What can be done about the high cost of drugs?

A: That is a long discussion about the pharmaceutical companies, but there is a responsibility to get better drugs for patients.

Q: Why is Dexamethasone (Dex) so often prescribed with other MM drugs?

A: Dr. Harvey thinks of Dex as "bacon" in the sense that "it makes everything better". When Dex is combined with other MM drugs the other drugs work better. Also, Dex directly kills MM cells.

Q: What is the difference between Dex and Prednisone?

A: Both drugs are corticosteroid anti-inflammatory drugs that have similar activity but the strength is different. Dex is five times stronger than Prednisone. Our bodies naturally produce the equivalent of about 7.5 mg Prednisone in the form of cortisol on a daily basis. IV-administered Prednisone is the standard in Europe.

Q: How is Dex dosage determined?

A: Historical data is used for Dex dosing. In CT, different doses are tried and patient reactions monitored.

Q: Does Prednisone raise blood sugar like Dex does?

A: Yes at equivalent levels because cortisol and steroids in general product a fight or flight response, which is a natural, physiological response. The general response to these drugs is a rise in blood sugar, feelings of anxiousness and/or anger, and then a crash where patients generally feel bad.

Q: Is there anything else that can be prescribed for diabetics that will not raise blood sugar yet yield the same response as Dex or Prednisone?

A: No, so diabetics must be very closely monitored when taking these important drugs

Q: I am on maintenance drugs and there is no Dex prescribed – why?

A: It depends on the amount of MM present and other factors.

Q: I was on Revlimid pre and post stem cell transplant (SCT) and now for five years on maintenance with good results, but should I be concerned with secondary cancers?

A: The rates of getting a secondary cancer from taking Revlimid is about 1 in 25; and those secondary cancers are likely to be hematologic/bone marrow related cancers. Consider the long term effects of treatments and stay educated so that you ask the right questions. It is more important than ever for patients on Revlimid to be diligent and proactive about their general health and get regular checkups.

Q: If a patient is on maintenance and their MM becomes active, should they go on a drug that they've used in the past?

A: It depends on how well the old drug worked for them and the tolerability. Sometimes it's very reasonable to return to drugs that have worked well before.

Q: I've taken Carfilzomib, Pomalidomide, and Dex for a few months and now my M spike = 0. How long should I continue with this maintenance?

A: Generally, a patient can continue with the same regimen indefinitely until one of the following occurs: 1) intolerable side effects or 2) it stops working.

Q: If my M spike = 0 does this mean I'm in a CR?

A: Additional tests to be performed when determining remission levels include free light, immunofixation, bone marrow biopsy, and blood tests.

Q: How often should a MM patient get a bone marrow biopsy?

A: The bone marrow is the source of MM cells. Generally a bone marrow biopsy should be performed at diagnosis and for CR confirmation. A bone marrow biopsy is also required for baselining purposes when participating in a CT.

Q: I'm taking Dex, Pomalidomide, and Daratumumab. What does Pomalidomide do to make Daratumumab work better?

A: Pomalidomide boosts the population of natural killer cells and Daratumumab makes MM cells available to be killed.

Q: Do high doses of Vitamin A enhance the activity of Daratumumab?

A: Dr. Harvey did not know but commented that retinoids in general makes cells cycle faster and die.

Q: Please comment on CAR T-Cell therapy

A: CAR T-Cell therapy has been proven to be very effective but it is highly toxic and it is just in the beginning stages of testing for MM patients.

Southside Multiple Myeloma Support Group

May 2016

Doris led the group in a moment of silence. There were 10 members present--no new members.

Our **July 23rd meeting** speaker will be Shannon Reilly, MS, ACNP, Clinical Nurse Consultant for Celgene. The topic: **How to Navigate Your Lab Reports** - Please bring lab reports from your 3-4 last visits and specific questions.

On **June 18th** we will **celebrate our 10th anniversary** of our support group. The celebration will be sponsored by John Schwarz, Representative for Takeda Pharmaceuticals and held at Paschal Brothers Restaurant, 170 Northside Drive. This celebration will be held in lieu of our standard 4th Saturday meeting. Ten years ago after her MM diagnosis, Doris decided there should be an MM support group on the Southside of the city. With the assistance of Andy Lebkuecher (former IMF Southeastern Regional Director) and his wife Cathy (an MM patient), Doris submitted a proposal to the International Myeloma Foundation to add SSMMSG to the Atlanta Area MM Support Group, "and the rest is history".

Thank You Doris!!

Member Updates Doris and Kimberly reported they had telephoned a number of members. Kimberly has been sending out greeting cards to connect with those we have not been able to reach by phone or email. Doris had been in touch with Andrew, Harold, Mariam, Gary, Jameca, Mary, Marion, Elizabeth, and provided a report about each.

The group realized we have not been routinely collecting addresses and decided to add address to the sign-in sheet.

Business

While we were somewhat disappointed with the response from the Atlanta **Concerned Black Clergy** for the LLS Clergy Roundtable Luncheon, the group decided to continue to visit and present during their meetings 2-3 times each year. Vermell attends CBC routinely.

LLS Clergy Roundtable Report- Thirty attendees, as expected, were present for the lunch. Some of the outcomes included: **(1)** LLS was able to obtain responses to questions that will be helpful in the development of strategies to increase MM awareness in the African American community through faith-based organizations. **(2) Vermell** reported she provided a mini MM presentation to 24 members of her congregation at the request of her minister who also attended the luncheon. **(3)** Another attendee placed MM flyers in bags of 400 participants attending the Wilkerson Farm Spring Fest sponsored by her family.

Caregiver Appreciation Event – Gail reported that the June 11th date for CGA event has been postponed until the fall because we did not receive anticipated funds.

Shop for a Cause: Friday, August 26, 2016 through Sunday, August 28, 2016, Macy's will host its 11th annual Shop "For A Cause" benefiting charities nationwide. Since 2006, "Shop For A Cause" has raised more than \$47 Million for charities across the country. Macy's provides the savings passes at no cost to your organization, along with promotion tools to help you sell them. This is our opportunity to be part of the fundraising for our support group by selling the \$5 "Shop for a Cause" savings passes. If we sell 100 passes, that's \$500 for our support group. This is our only fund raiser; please plan to participate by selling at least 4-5 saving passes. Shopping pass discount of up to 25% throughout the store on an assortment of regular, sale and clearance merchandise. Savings passes are valid at all Macy's stores only on the event days. However they are not valid on macys.com. **Plus, at each Macy's store, customers who bring in their savings pass will be eligible to win a \$500 gift card, no purchase necessary.** We are hoping each member will be responsible for at least 4 tickets. This is a way to communicate with 3 other people about myeloma. Contact Paulette ([470-428-2988](tel:470-428-2988) or [email ppmneely@gmail.com](mailto:ppmneely@gmail.com)) to get your tickets.

Open Discussion

Members discussed their current status. One member shared her primary physician in another state diagnosed her with MM and referred her to an oncologist. She shared her diagnosis with her family. After years of biannual visits to the oncologist with no treatment, she was confused. The oncologist said your numbers are stable; "we will continue to watch the numbers". During a recent visit accompanied by a daughter, she was told she did not have myeloma-she had smoldering myeloma. That was her first time hearing "Smothering" Myeloma. This created some tension with family. There should be clear communication from providers to patients about their new diagnosis and what they should expect going forward.

What should you ask your doctor about multiple myeloma?

As we deal with cancer and the process of treatment, we need to have frank and open discussions with your cancer care team. Get answers to questions, no matter how minor they might seem. Have someone with you and take notes. Among the questions we might ask are:

- What's my stage of multiple myeloma? What does that mean?
- What are my treatment choices?
- What side effects can I expect from treatment?
- How long will it take me to recover from treatment?
- When can I go back to work or resume other activities after treatment?
- What are the chances that the cancer will come back after treatment?
- Does one type of treatment reduce the risk of recurrence more than another?
- What should I do to be ready for treatment?
- Should I get a second opinion?

There will no doubt be other questions about your personal situation. Be sure to write down your questions so that you remember to ask them during each visit with the cancer team. Also keep in mind that doctors are not the only ones who can give you information. Other health care professionals, such as nurses and social workers, may have the answers you seek. Go to reliable websites and get print materials to learn more about myeloma and your treatment regimen.

•**MM Vocabulary for today:** What is the other name for **Ixazomib**? **Answer: Ninlaro.**