

November 2009 Meeting News

New Members

The group welcomed **Dan** and his wife, **Bonnie**. Dan was diagnosed with myeloma in April 2009. He had a stem cell transplant at Emory 40 days ago and is doing well except for problems with neuropathy in his feet. **Hector** was diagnosed with myeloma in March 2009. Hector is currently getting Zometa treatments and is planning to harvest stems cells, and then proceed with a stem cell transplant early next year. It was also noted by some group members that Hector's family attended and raised a substantial amount of money for Atlanta's MMRF Race for Research in November! Also attending the meeting for the first time was **Vanessa** who was very recently diagnosed with myeloma on 10/29/2009. Vanessa is currently on a VDT-PACE regimen. Also joining the group this month was **Folami** who was diagnosed with myeloma in September 2008. Folami had a stem cell transplant in July and is doing well.

Business & Other Information

Nancy led the meeting. Approximately 45 members were present. This year's MMRF Race for Research in Atlanta was held on November 1, 2009, and was a big success! It was a beautiful day and approximately \$3,500 was raised by the TeamTogether group.

Guest Speakers

Special thanks are extended to two associates from Proteolix (now Onyx), Susan Demo Ph.D. and Mai Le, M.D. The presentation began with information about the company's history including the background of Carfilzomib's development and a general overview of how drugs are discovered. Drug development can be a long, slow, and expensive process. The phases it traverses include Research, Development, Clinical Trials, and New Drug Application (NDA) Filing/Food and Drug Administration (FDA) Approval. The majority of drugs never make it through all of the phases. New drugs are discovered in a variety of ways, including 1) Mutation targeting (example: "Gleevec"), which took 20 years to develop, 2) Blind testing agents (example: "Taxol"), which was found from tree bark, and 3) Drugs discovered for other targets (example: "Thalidomide"), initially used to prevent morning sickness in pregnancy, and since found to be effective for managing myeloma. Proteolix was founded in 2003, with the knowledge that 1) Velcade targets a cell's proteasome in multiple myeloma, and 2) Velcade showed that targeting the cell's proteasome is effective. Therefore, the intent for a next generation drug should include a way to block the proteasome in a different way from Velcade (i.e. a drug with a different structure than Velcade), and should be highly selective in blocking the cell's proteasome over other proteins. Thus, Carfilzomib is specifically designed to target only the cell's proteasome and does so with less toxicity. The FDA's four clinical trial phases are established as (roughly): Phase 1 - Discover safety in humans and proper dosage, Phase 2 - Determine efficacy (and where accelerated approval sometimes occurs), Phase 3 - Largest population study (and where FDA approval occurs), and Phase 4 - Continued research post FDA approval. Carfilzomib is currently in "Phase 2" clinical trials for relapsed myeloma patients and in the process of seeking accelerated approval, with plans to continue on with Phase 3. Some current trials are closed and some are still open. Carfilzomib is currently only available intravenously, but there are plans to try to restructure it to make it available orally in the future. Due to the trial phase that it is in, Carfilzomib is currently only being tested as a single agent, however combination trials are expected to open in 2010, where Carfilzomib

will be tested in conjunction with other agents including Revlimid, and Dexamethasone. The importance of participating in clinical trials to help enable the expedition of drug testing and market readiness was discussed. Despite the benefits for the patient of participating in clinical trials (including highly monitored care) there is only about a 3% enrollment rate. Associates from Proteolix (now Onyx) work closely with local doctors at Emory where clinical trials are offered in the Atlanta area. For clinical trial details, refer to <http://clinicaltrials.gov/> and/or discuss with your doctor.

Member Updates & Collaboration

With sadness the group acknowledged the passing of some of its members in October - **Carter** husband of **Julie**; and **George** father of **Shemeka**. The groups' condolences are extended to their loved ones.

Nancy completed tandem stem cell transplants at Northside (the second in May) and is doing well. Nancy was able to complete both transplants without ever being admitted into the hospital. **Dana** attended the meeting 105 days after a stem cell transplant and is doing well. Dana's advice to the group was to take things "one day at a time". **Virgil** mentioned that he has experienced neuropathy since being on Velcade and that an over-the-counter neuropathy relief product called "FreezIt" has helped him tremendously. **Karyn** and her husband, **Greg** will be moving to the Dallas, TX area soon – probably toward the end of this year. Karyn said that she is beginning maintenance therapy with Velcade.

Submitted by Wendy