

Mary Crowley Quarterly

April 19, 2013—Vol. 3, Issue 2

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Silver Dollar at the Ranch, May 18, 2013

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TeamQuest Race 2013, September 28th

A full-disk multiwavelength extreme ultraviolet image of the sun taken by SDO on March 30, 2010. False colors trace different gas temperatures. Reds are relatively cool (about 60,000 Kelvin, or 107,540 F); blues and greens are hotter (greater than 1 million Kelvin, or 1,799,540 F). Credit: NASA/Goddard/SDO AIA Team

Melanoma: Where's Our Menelaus?

Most melanomas are black skin lesions due to pigment production and, although most of them (approximately 84%) are localized with a high probability of cure, the remaining ones have a short survival time and, until recently, have defied effective treatment. There have been two recent treatment breakthroughs: Yervoy™, which modulates the immune system, produces a 10% response rate and almost doubles the average survival rate (to 10 months) and Vemurafenib, a therapy inactivating the specific gene mutation occurring in 60% of melanomas, which has a high response rate but also a high recurrence rate. Why such problems? Melanoma is like Proteus, the wily shape shifter in Homer's *Odyssey* who could change from one shape to another. When one dominant mutant gene that controls growth signals is blocked (by Vemurafenib), melanoma cells can open up new detours and bypasses allowing for resumption of growth. Likewise, following immunotherapy, the cancer cells can produce immune inhibiting proteins, a tough defensive line. At Mary Crowley, we are devising ways to circumvent these shape shifting capabilities. Many of our targeted agents are directed at both the known abnormal growth signal pathway and the known and presumed detours and bypasses to try to block resistance from emerging. We are also investigating innovative immune approaches including the FANG™ vaccine, which incorporates a mechanism to block the cancer's ability to make immune suppressive proteins, allowing us to break through its defensive line. Basically, we are looking for a Menelaus, the Greek warrior who finally caught and controlled the slippery Proteus.

Written by Dr. Neil Senzer, Scientific
Director at Mary Crowley Cancer
Research Centers

Updates:



Upcoming Speaking Engagements

April 19th, 2013: Cook Children's Hospital; Dr. Maurizio Ghisoli—keynote speaker at Grand Rounds addressing Mary Crowley's focus on Ewing's Sarcoma for children.

April 25–28, 2013: Oncology Nursing Society 38th Annual Congress; Cindi Bedell RN, MSN, NP-C, Wanda Strange, RN, OCN, Kimberly Reed, RN, Tricia McCord RN, OCN, and Stefanie Walker, RN— three posters titled, "Personalized Vaccine Therapy: The Time is Now", "Biological Warfare: Preparing Nurses to Care for Patients Receiving Microorganisms to Fight Cancer", "Compassion Fatigue: Acknowledging Grief and Loss Inherent in the Oncology Nurse Role"; speech titled "Clinical Trials and Research Coverage: Differentiating Clinical Trial Research and Standard of Care Costs".

May 15, 2013: American Society of Gene & Cell Therapy (ASGCT) Conference; Dr. Nemunaitis— "Clinical Update of bi-shRNA furin/GMCSF DNA Transfected Autologous Tumor Vaccine (FANG) in Cancer Patients "; "Novel Approaches to Cancer Immunotherapy" symposium, and "Clinical Update of bi-shRNA Nanoplex Technology in Cancer" ; "Topical Review: Cancer Gene Therapy" educational program.

May 31, 2013: American Society of Clinical Oncology (ASCO); Dr. Nemunaitis— ECG Satellite Symposium titled, *Harnessing the Immune System in NSCLC: Implications of Emerging Data and Immunotherapeutic Strategies for Personalized Medicine* May 31st @ 6:30 pm.

June 4th, 2013: Young Texans Against Cancer, Dallas chapter— Dr. Nemunaitis— Mary Crowley's "one-two punch" approach to fighting cancer.

Mary Crowley *Moving Science Forward*



Melanoma Study Drug Advances: In March 2013 Amgen (NASDAQ:AMGN) announced top-line results from the Phase 3 trial in melanoma, which evaluated the efficacy and safety of talimogene laherparepvec for the treatment of unresected stage IIIB, IIIC or IV melanoma. The study met its primary endpoint of durable response rate (DRR), defined as the rate of complete or partial response lasting continuously for at least six months. "These are the first Phase 3 results of this novel approach to cancer therapy," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "A high unmet need exists in melanoma and we believe the innovative mechanism of action of talimogene laherparepvec may offer a promising approach for these patients." Mary Crowley was a leading site for early phase trials of this innovative investigational therapy, with Dr. Neil Senzer serving as Lead Principal Investigator. **Press Release: Thousand Oaks, Calif. (March 19, 2013)- Amgen**

Menelaus Goes To The "Street"



Advanced melanoma is still a deadly disease with limited therapeutic options. However with recent advances focused on targeted immune and molecular technology, melanoma survival has improved. So, to follow-up in the unique way of Dr. Senzer involving Greek mythology, we have discovered a weakness that Proteus is unaware of! Utilization of Vemurafenib then Yervoy™ provide an additive 1:2 punch of signal control (V600 mutation-directed) followed by targeted immune attack (Treg inhibition) WITHOUT the crippling effects of chemotherapy-induced immune suppression. This approach works and passes FDA's assessment. To temporarily get away from Greek mythology (Sorry Neil) and go to the streets of America, patients with melanoma progressing after Vemurafenib/Yervoy (or earlier if V600 "-") have an opportunity to participate in several other (potentially additive) melanoma experimental studies at Mary Crowley, (see below).

Study 11-26

CAVATAK™ uses coxsackievirus, an oncolytic virus similar to Oncovex™. The virus is designed to grow within the tumor (and not in healthy cells), break up and shrink the tumor, and reactivate the immune system to systemically fight cancer.

Study 11-14

INXN-2001 is designed to deliver genetic material into the tumor in order to make Interleukin 12 (IL-12). IL-12 is a cytokine that increases the ability of the immune system to kill tumor cells. The INXN 2001 is combined with INXN-1001, an Activator Ligand, which is a capsule that is taken by mouth. The INXN-1001 acts as a switch to release IL-12 from INXN-2001.

Study 12-06

IMCgp100 is an immune agent designed to bridge proteins that target peptides expressed in most melanomas. IMCgp100 is made up of two parts, a 'T cell receptor' and an 'anti-CD3 fragment'. This design will stimulate the immune system and control cancer growth.

In this effort, Mary Crowley is going to the street and adding "brass knuckles" to the boxing gloves of Menelaus (our physicians) in his effort to control Proteus (cancer).

"Think about research for your advanced melanoma patient"~ John Nemunaitis, MD, Executive Medical Director at Mary Crowley

Donors:

Silver Dollar For Cancer Research

Mary Crowley is privileged to partner with Speedway Children's Charities at Texas Motor Speedway as beneficiaries of the Silver Dollar At The Ranch event. Silver Dollar At The Ranch began in 2008 as a philanthropic event to help raise funds for cancer research and programs on both local and national levels. This 6th annual event will help raise funds to support the Ewing's Sarcoma research initiatives at Mary Crowley and patients like Carley Rutledge, who has participated in a clinical trial involving a *personalized* investigational vaccine. Carley said, "Having the treatment option of a vaccine therapy when my cancer recurred allowed me to have my freshman year of college and the hope of many more years to come." Carley will also serve as the honorary hero of the Silver Dollar event.

The event theme will be "Happy Trails...on a path to the cure!" Centered in North Texas, the outdoor "Party with a Purpose" has raised over \$1 million dollars in five years and there is little chance of it slowing down. Ranch owners, Mardi and Chip Ferrier, generously donate and host Silver Dollar at the Ranch year after year on their XO Ranch in Aubrey, Texas. This party in the pasture will be hosted by Brendan Higgins and Lee Anne Lockhen and features entertainers Chris Cagle and the Rankin Twins. Great food, spectacular auction items, and more will make this a not-to-be missed event. For more information and tickets, go to:

www.silverdollarattheranch.com.



Carley Rutledge with her horse Trigger

Million Dollar Round Table Foundation Supporting Mary Crowley

On February 28th, 2013, Allan W. Newberry, CLU, of Dallas, Texas, secured a \$10,000 grant from the MDRT Foundation on behalf of Mary Crowley. Newberry, a 41-year MDRT member, is an active supporter of Mary Crowley Cancer Research Centers. The MDRT Foundation grant will support the organization's Blessing Others Benevolence Program. This program provides aide to cancer patients who are experiencing financial hardship or unable to pay for: travel and medical expenses, including flights, gas, lodging, prescriptions for pain medications or co-pays for scans or x-rays. Without this type of support, many cancer patients would not be able to participate in a potentially beneficial cancer research trial.



Left to right: Shannon Cagnina, COO, Mary Crowley; John Nemunaitis, MD, Executive Medical Director, Mary Crowley; Allan Newberry, CLU, MDRT Representative; Ellen Dearman, Vice President of Development, Mary Crowley

Manuary Party Benefits Mary Crowley Cancer Research Centers

Charlotte and Rob Huthnance wanted to do something special to celebrate Charlotte's one year anniversary since being diagnosed with Ovarian Cancer. So, they gathered friends and family and asked them to help her fight cancer through a fundraising event called a "Stache Bash" on "Manuary" 26th! Entry to the party required a mustache, a donation, and a sense of humor. Can't grow one? Buy one at the door for \$250! A great time was had by all including an award ceremony for the various 'staches. This passionate group raised over \$37,000 for Mary Crowley Cancer Research Centers, where Charlotte is currently a patient.

Our deepest gratitude goes to these foundations. To further support our research, go to: www.marycrowley.org and click "Donate".



Charlotte and Rob Huthnance, Hosts of the 2013 Manuary 'Stache Bash.

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Donate Now!
www.marycrowley.org

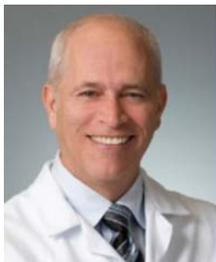
Mary Crowley Spotlight: New Trustees

Edwin Flores, PhD, JD



Edwin Flores, PhD, JD, is an Immunologist who trained at Washington University in St Louis before attending the University of Texas Law School and becoming a licensed patent attorney. He works specifically in the area of new biologic technologies and has successfully prosecuted multiple patents for RNA interference technologies. Dr. Flores also served for 9 years on the DISD School Board, several review committees of the NIH, as a scientific advisor to the Perot Museum, and on numerous other charitable boards. Mr. Flores is enthusiastic about Mary Crowley's expertise in rapidly translating laboratory discoveries to cancer patients, and looks forward to raising awareness and support for Mary Crowley and its vital mission in the pursuit of a cure.

Charles Brunicardi, MD



Dr. Chuck Brunicardi is the Vice Chair of surgery for David Geffen School of Medicine at UCLA and former DeBakey Chair of Surgery at the Baylor College of Medicine in Houston. Dr. Brunicardi is the editor of the Schwarz *Principles of Surgery* textbook, which serves as the main teaching text for surgery in American medical schools today. Dr. Brunicardi is also the discoverer of the pivotal PDX1 gene correlation to pancreatic and other cancers, as well as a collaborator of Mary Crowley in personalized molecular approaches to cancer treatment. Dr. Brunicardi stated that he has enjoyed working with Dr. John Nemunaitis, Mary Crowley's Executive Medical Director, to expand its personalized cancer research program and is looking forward to helping Mary Crowley achieve its mission.