

- Register today for the 8th Annual Meeting
  - New Study: Cold Fx
  - Spotlight on Connie Daniels
- Inside Mile Stones:**

Wake Forest University Baptist  
**MEDICAL CENTER**  
 Comprehensive Cancer Center

**Mile Stones**  
 CCCWFU CCOP Research Base

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 Winston Salem, NC 27157  
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 www.wfubmc.edu/cancer/researchbase



## CCCWFU CCOP Research Base Open Protocols

- 60A02** A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients **Steve Akman, MD, PI**
- 91105** Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients **Steven Rapp, PhD, PI**
- 97106** A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors **Kathryn Greven, MD, PI**
- 97202** A Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients **Glenn Lesser, MD, PI**
- 97405** Phase III Study of Soy, Venlafaxine (EffexorXR™), and Soy + Venlafaxine on Hot Flush Symptoms in Men with Prostate Cancer **Mara Vitolins, RD, PhD, PI**
- 98308** A Phase III Randomized, Double-Blind, Placebo Controlled Trial of North American Ginseng Extract (CVT-E002; COLD-fx®) to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia. *(opening soon)* **Kevin High, MD, PI**

# Mile Stones

## CCCWFU CCOP RESEARCH BASE

A Semi-annual Newsletter  
 Summer 2008 Volume 5 Issue 2

### Cold Fx Study Opening Soon by Kevin High, MD, PI

Chronic Lymphocytic Leukemia (CLL) is the most common adult leukemia in developed countries occurring at a rate of 20/100,000 population and accounting for 22-30% of all leukemias. Nearly all cases of CLL occur in older adults with a median age of diagnosis of 60-70 years. As the name implies, CLL is a chronic illness that may remain stable or progress very slowly over many years. Median survival time depends on stage at presentation. Overall median survival time is 4-5 years after initiation of treatment, but early stage patients often do not require treatment for many years after initial diagnosis. Even without treatment patients with CLL have an increased risk of infection, particularly acute respiratory infections (ARIs) due to a CLL-induced immune compromise. Infection is the most common complication of CLL, and most CLL patients are over the age of 60, an additional risk factor for infection. Though many ARIs are viral and antibiotics are therefore unnecessary, the risk of bacterial infection in CLL patients leads most practitioners to empirically treat many infectious episodes with antibiotics.

In recent studies, an extract of North American Ginseng, CVT-E002 (Cold-fx™/®, CV Technologies Inc.), has been shown to reduce the risk of (ARIs) in older adults. In some of these studies, serious influenza and respiratory syncytial virus (RSV) infections were reduced, even in debilitated elderly such as nursing home residents. No complementary/alternative therapy has ever been shown to reduce the risk of infection in CLL patients. We will be conducting a study in 280 untreated CLL patients to determine if CVT-E002 can reduce the risk and severity of ARIs, and reduce the need for systemic antibiotics during the winter respiratory season of 2008-2009. The study is a randomized, placebo-controlled trial that will be conducted through the CCOP Research Base. All patients will be enrolled between November 1 and December 31, 2008 and followed through the end of the winter respiratory season (April 30, 2009). The schema below indicates the major inclusion/exclusion criteria, stratification and randomi-

#### Inside this Issue:

- Cold Fx study to open soon 1
- Spotlight on Connie Daniels 2
- Out and About with June 2
- Annual Meeting 4
- The Learning Curve 5
- Protocol Listings 6

#### Register Today!

**8th Annual Meeting  
 September  
 25-27, 2008  
 Winston-Salem,  
 NC**



## Spotlight on: Connie Daniels

**Q:** How long have you worked in research/healthcare?

**A:** I have worked in healthcare for 27 years with a background in clinical lab and surgical pathology. I joined the staff at Danville Hematology and Oncology, Inc. as Study Coordinator ten years ago.

**Q:** What is your role with the CCCWFU CCOP Research Base?

**A:** I work for Dr. David Caldwell and Dr. Tim Brotherton as Study Coordinator. I also work with Lendy Cox who is a Data Manager. Danville Hematology and Oncology, Inc. is a private practice and the only medical oncology practice in the Danville, VA area.

**Q:** What effective methods have you found to accrue and retain patients on Research Base studies?

**A:** I try to review all new patient charts prior to their first visit in our office. Basic information is collected on each patient at that time (diagnosis, stage and any complicating factors, poor performance status or mental illness for example) and placed in a database. Both processes help identify potential patients.

**Q:** What are your hobbies?

**A:** I enjoy gardening and just being outside.

**Q:** Is there any other information you would like to share with our Milestone's readers?

**A:** I am a 9 year cancer survivor so I've had the experience of being on the receiving end of a cancer diagnosis. I know how the diagnosis turns your world upside down. And even though I only play a small part, I just really want to help cancer research move forward. Maybe one day our kids and grandkids won't have to deal with the diagnosis of cancer.



## Out and About with June

I am available to come to your site for certification, training or to update you on the status of the Research Base protocols. Just contact me at 336-716-6733 or [jsteede@wfubmc.edu](mailto:jsteede@wfubmc.edu) to make an appointment...and I will be out and about to you.

*June Fletcher-Steede*

For article ideas and comments, please contact Sarah Hahne at [shahne@wfubmc.edu](mailto:shahne@wfubmc.edu).



## The Learning Curve

A few updates in research life:

When new patients are registered remember to fax or mail in a copy of your baseline forms. This includes signed informed consent, on-line eligibility checklist/ registration form, initial flow sheet, pathology report, baseline scans and labs as required per protocol. This information is verification of patient eligibility.

### **60A02 A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients**

We only need 3 more patients to close the study. Please contact me if you have an eligible patient for registration and need a lab kit. It's also inventory time, so anyone that has Wal-mart or Shell Gas gift cards please call me at 336-713-6519.

### **97202 A Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients**

This protocol currently has accrued 211 patients. We are 25 patients away from reaching the accrual goal of 236.

### **97106 A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors**

Twenty seven minority patients are needed to reach the protocol goal of 156 patients. It is

by Robin Rosdhal RN, OCN

often difficult to remember what is included in minorities, Native American or Alaskan, African American, Asian, Native Hawaiian or Pacific Islander.

### **91105 Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients**

Please continue to mail patient protocol forms and neurocognitive booklets to data management. The brain MRI CD needs to be mailed separately to Gina Enevold at the address listed below. Please include a completed Appendix # 15 (BRAIN MRI CD SUBMISSION FORM) to receive your \$25.00 reimbursement.

Attn: Gina Enevold, MSN  
CCCWFU CCOP Research Base PIO  
2000 West First Street  
Suite 401  
Winston Salem, NC 27104

### **71103 A Phase II Study of Single Agent Depsipeptide (FK228) in Metastatic or Unresectable Soft Tissue Sarcomas**

Recently, Wake Forest we had an NCI audit conducted by Theradex. We are awaiting our official evaluation but the exit interview went well. It may be an unusual way to describe an audit but "it was a great learning experience."

The Research Base currently has several new and interesting protocols in the works. Hope to see you in Winston-Salem for our annual meeting so you can hear about these upcoming studies!

[www.wfubmc.edu/cancer/researchbase](http://www.wfubmc.edu/cancer/researchbase)

## Research Base Eighth Annual Meeting

This year's annual meeting will be held at Graylyn International Conference Center in Winston-Salem, NC. Meeting attendees will experience a unique blend of old world charm, innovative technology and a personal touch that would make the Gray family proud. Graylyn is listed in the National Register of Historic Places and is one of the finest examples of Norman Revival architecture in the country. A perfect combination of a modern, sophisticated conference facility and an enchanting, historic residence, Graylyn is sure to captivate from the moment you arrive at the estate gates.



In room amenities include such things as full-size desks, internet connectivity, irons and ironing boards, hair dryers, and Gilchrist and Soames® toiletries. Coffee service stations will be provided throughout the guest room wing each morning. During free time, you can explore the Estate. Stay indoors, curled up by one of the many fireplaces or in the Mediterranean-style sunroom. Enjoy the exercise room or billiards room. Retreat outside for tennis, or walking and running trails. Meeting attendees will enjoy extensive buffets during breakfast and lunch, while evening dining is leisurely with table service and specially designed menus. And ... they provide free Dove bars to all guests as a bedtime snack! You can call 1-800-472-9596 to make your reservations. Request the CCCWFU CCOP Research Base group rate (\$199 per night).

Shuttle service will be available from the Greensboro Airport to the Estate in Winston-Salem. Transportation will be provided by the Estate to Reynolda House, Reynolda Village, and the Wake Forest University Campus. The meeting dates are September 25-27, 2008. Registration is now open through our website [www.wfubmc.edu/cancer/researchbase](http://www.wfubmc.edu/cancer/researchbase) and there are no fees associated with registration.

Contact Lisa Hawkins at [lhawkins@wfubmc.edu](mailto:lhawkins@wfubmc.edu) or 336-716-0891 with any questions concerning registration.

## Cold Fx Study *(continued from page 1)*

zation protocol, and the treatment arms.

If you wish to enroll subjects in this study, it will be important to complete local IRB and other regulatory documents in a timely fashion, and then identify untreated CLL patients in your practice in the early fall of 2008. This will allow all subjects to be enrolled during the short enrollment period from November 1 to December 31, 2008. The protocol will be discussed in detail at this year's CCOP Annual Meeting in Winston-Salem, NC on September 25-27, 2008.

### Eligibility Determination:

#### Inclusion Criteria:

- Age  $\geq 18$  (note CLL is a disease that occurs almost exclusively in adults age 50 and over),
- Phenotypic evidence of CLL (i.e., flow cytometry or bone marrow biopsy),
- ECOG performance status  $\leq 2$  (Karnofsky score  $> 60\%$ ),
- Life expectancy  $> 12$  months,
- Able to provide informed consent

#### Exclusion criteria:

- HIV, cirrhosis, CVD, malignancy other than CLL
- Creat  $> 2.0$  mg/dl (or Cr clearance  $\leq 50$  ml/min if serum creat  $< 2.0$ )
- Serum aminotransferases  $> 2.5$  ULN
- Current or prior treatment with fludarabine, alemtuzumab, rituximab, IV, IVG, hematopoietic stem cell transplantation
- Current or recent (w/in 3 mos) therapy with chlorambucil
- Current treatment with corticosteroids  $\geq$  equivalent 20 mg/day prednisone
- Use of antibiotic prophylaxis other than TMP-SMX
- Current use of warfarin
- Allergy to ginseng products
- Current use of other herbal products (and unwilling to discontinue)

### Enrollment:

280 untreated CLL patients between Nov 1 and Dec 31, 2008

### Stratification:

Antibiotic prophylaxis with trimethoprim/sulfamethoxazole (TMP-SMX) yes/no  
Serum IgG ( $\leq 500$  mg/dL,  $> 500$  mg/dL)  
Influenza vaccine status - yes/no

### Randomization:

**Arm 1:** CVT-E002 (200 mg) administered orally twice daily  
**Arm 2:** Matching placebo (microcrystalline cellulose) administered orally twice daily

### Treatment Phase:

Treatment through April 30, 2009  
Symptom and medication diary kept throughout  
F/U visits at weeks 4, 10, EOS and phone F/U 4 weeks post-treatment