Summer 2005

# Research Base

CCCWFU CCOP

Mile Stones

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- Study results will be presented at the Fifth Annual Meeting on September 29th, 2005.
- Learning Curve: New Eligibility Criteria for Protocols

## Research Base Completes First Ever Study of Donepezil (Aricept) in Irradiated Brain Tumor Patients

The Comprehensive Cancer Center of Wake Forest University (CCCWFU) Community Clinical Oncology Program (CCOP) Research Base has completed the first ever study of the FDA-approved Alzheimer's disease drug donepezil (Aricept) in long-term survivors of brain irradiation for primary or metastatic brain tumors. The study, led by Dr. Steve Rapp (Department of Psychiatry), Dr. Ed Shaw, and Robin Rosdhal, RN (both from the Department of Radiation Oncology) was presented at the 9th Annual Meeting of the Society of Neuro-Oncology held in Toronto last October and received the Society's prestigious Quality of Life Award. The Phase II open-label study enrolled 35 patients who were 6 month or longer survivors of partial or whole brain irradiation with stable (or absent) brain disease. Most patients enrolled had a low- or intermediate-grade glioma, or a meningioma. Nearly half to 80% of the patients had subjective complaints of fatigue, anxiety, slowed thinking, poor short-term memory, or word-finding problems at baseline.

*(Continued on page 2)*

## Fifth Annual Meeting: Sept. 29

The fifth annual Research Base annual meeting will be held on Thursday September 29, 2005. The venue will once again be the Grand Dunes Resort by Marriott in Myrtle Beach, SC. The meeting includes a morning session of round table discussions for research nurses, clinical research professionals, and physicians (medical, radiation, and surgical oncologists). The Round Table Sessions will cover a variety of subjects of interest to all participants. The afternoon session will include a Principal Investigator overview of all open Research Base clinical trials and clinical trials in development.

A block of rooms has been reserved until August 25, 2005. The rate for a single or double room garden view is $155 per night and oceanfront is $199 per night. For reservations call 1-800-644-2881 and request a group rate for the Piedmont Oncology Association.

If you have not completed a registration form, please complete the one on page 5 and fax it to Lisa Hawkins at 336-716-6275 by August 25, 2005.

# Donepezil Study Completes

*(Continued from page 1)*

The endpoints of the study were quality of life (measured by the FACT-Brain), mood (measured by the POMS), and cognition (measured by a battery of neurocognitive tests of thinking, memory, and language function). Patients were assessed prior to taking donepezil (dose 5-10mg/day), after 3 and 6 months of study drug, and then following 6 weeks off medication. The results demonstrated a significant improvement in quality of life, mood, and cognitive function with donepezil. The effects appeared to wear off when the patient discontinued donepezil at the end of 6 months. A manuscript on the study is under review by the Journal of Clinical Oncology. In addition, the investigators have submitted a R01 grant to the National Cancer Institute to perform a Phase III randomized placebo-controlled double-blind randomized trial with donepezil in the same study population. If funded, this would be a joint venture between the CCOP Research Bases of the CCCWFU and M.D. Anderson in Houston.

For more information, contact either:
Dr. Rapp (srapp@wfubmc.edu),
Dr. Shaw (eshaw@wfubmc.edu), or
Robin Rosdhal (rosdhal@wfubmc.edu).

Dr. Edward Shaw
Research Base PI

# Data Management

What's New? Query Schedule.

We know that you're busy but we need your data. Query letters are intended to be gentle reminders to get that data to us. We are serious about timely data submission. It's an integral part of good patient care. The new schedule for query letters is one month intervals. The first query letter will be sent to you requesting data when your data is one month overdue. In a month, if we don't get a response, a second query will be sent to you with a copy to your PI. If, after another month, we still don't get a response a third query is sent to you, your PI and Dr. Edward Shaw of the Research Base. Our goal is to have the best database anywhere and we need your help. Please call us with your questions!

Data Tip: Please remember to **grade** all symptoms and toxicities on MedWatch forms.

And lastly: For Outstanding Data Submission, the winners are:
Claudette Phinney of Greenville, SC
Sarah Bienvenu of LSU New Orleans, LA
Deana Mills, SCCC Danville, VA
Sharon Hubbard, SCCC Martinsville, VA
Mickey Wortman, SCCC Asheville, NC

Thank you for your astute attention to detail and wonderful attitudes. It's folks like you that make our jobs easier. We appreciate you!

And now for the swimsuit competition . . . .

# Just Getting Started

I know I am preaching to the choir but, I would like to talk about starting new trials at your sites. It can be a little daunting the first time you register someone on a newly opened trial. After you have been through it once and start the second registration, it gets easier. The more you work with a trial the more familiar it gets. It's like that first time you got on a bike…a little scary and now "No Big Deal". Just remember, there is a Research Base department full of people to answer your questions. No question is a dumb question. Don't be afraid to ask.

Margaret Crowley, LPN
*Clinical Studies Coordinator*

# The Learning Curve

With your help we are continually improving our protocols. We have now included several easy to read guidelines and tables. "Dummy" sheets with specific instructions for completing the PG-SGA and the RJL Cyprus system (BIA data) are available. We will provide these handouts at our annual meeting in September. If you would like "dummy" sheets prior to then, please let me know. Listed below are several of the most significant changes since our last newsletter:

*Protocol 60A02 Juice Plus/Placebo in Head and Neck Cancer*

- Patients may not have taken high dose vitamin supplementation in the last 2 months prior to study entry. New table with Vitamin A, C and E acceptable daily limits has been added.
- The **original** Food Questionnaire filled out by the patient must be mailed to Research Base Data Management. Please make sure all questions have been answered. A copy should be made and placed in the patient's chart at the participating site.
- Patient GI Questionnaires (telephone interview) should be performed at the completion of weeks 1,2,3,4, and 8 of patient taking study medication.

*Protocol 97102 Oxandrin/Megace in Patients Receiving Chemotherapy for Solid Tumors*

- Our Research Base computer specialist, Ping Tan, has written a program for the PG-SGA. You now only have to circle the answers without adding or subtracting the scores. When the Data managers enter the information into the computer system it will automatically calculate the totals.
- The BIA information is entered on a new RJL web site www.rjlsystems.com. After you have entered the required information, you will be able to print a very impressive computer generated report. A copy of this report should be mailed or faxed to the Data Management Center.
- Patients that are diabetic are allowed except for the drug classification of Sulfonyureas. A list of common diabetic medications in this category has been listed in the protocol as a helpful guide.

*Protocol 97202 COQ10 for Treatment Related Fatigue in Breast Cancer Patients*

- Due to a delay in lab results, patients may be registered within 24 hours of the first chemotherapy treatment if labs were drawn prior to first chemotherapy treatment. Statin drugs are not allowed on this protocol. A list of commonly used statin drugs has been added as a guide.

*Protocol 71103 Single agent Depsipeptide in Metastatic or Unresectable Soft Tissue Sarcomas and*
*Protocol 83403 Single agent Depsipeptide in Recurrent, Platinum Sensitive Adenocarcinoma of the Ovary and Peritoneum*

- Eligibility criteria now allows for patients to have a serum creatinine level of $\leq$ 1.5 X institutional normal limits upon study entry.
- Potassium and Magnesium levels within institutional normal limits are acceptable for study entry. Potassium level $\geq$ 4.0 and Magnesium level $\geq$ 2.0 are required prior to Depsipeptide administration. A table with acceptable Potassium and Magnesium supplementation guidelines has been inserted into section 4.2 of the protocol.

Happy Recruiting!
Robin Rosdhal RN, OCN

# Open Protocols

## Cancer Control and Prevention

**97202** A Phase III 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**

**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**

**97102** A Phase III Randomized Study Comparing the Effects of Oxandrolone (Oxandrin®)and Megestrol Acetate (Megace®) On Lean Body Mass, Weight, Body Fat, and Quality Of Life in Patients with Solid Tumors and Weight Loss Receiving Chemotherapy **Glenn Lesser, MD**

## Cancer Treatment

**91202** A Phase II Trial of Thalidomide and Procarbazine in Adult Patients with Recurrent or Progressive Malignant Gliomas **Glenn Lesser, MD**

**83403** Phase II Study of Single Agent Depsipeptide (FK228) in Recurrent, Platinum Sensitive Adeno-Carcinoma of the Ovary or Peritoneum **Brigitte Miller, MD**

**71103** Phase II Study of Single Agent Depsipeptide (FK228) in Metastatic or Unresectable Soft Tissue Sarcomas **Paul Savage, MD**

# Protocols Under Construction

## Cancer Control and Prevention

**97405** Phase II studies of Soy protein, Venlafaxine, and Soy protein + Venlafaxine on Vasomotor Symptoms of Men with Prostate Cancer **Mara Vitolins, PhD**

**98301** Phase II study of St. John's Wort for the Treatment of Hot Flashes in Women with a History of Breast Cancer **Michelle Naughton, PhD**

Phase III Study of Donepezil in Irradiated Brain **Steven Rapp, MD**

Phase III Double Blinded Randomized Study to Determine Whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors **Kathryn Greven, MD and Brigitte Miller, MD**

## Cancer Treatment

**30102B** Phase I/II Study of Weekly Docetaxel and Carboplatin in patients with Recurrent Squamous Carcinoma of the Cervix **Brigitte Miller, MD**

**83203** Phase II Study of Weekly Docetaxel and Capecitabine for Persistent or Recurrent Platinum Resistant Epithelial Carcinoma of the Ovary, Fallopian Tube or Peritoneum **Brigitte Miller, MD**

**23102** Phase II Study of GM-CSF in Patients with Chronic Phase Myeloid Leukemia (CP-CML) who are not in Complete Cytocenetic Remission after Initial Therapy **Istvan Molnar, MD**

A Phase I/II Trial of Sodium Gammalinolenic Acid (NaGLA), Gemcitabine, 5-Fluorouracil and Radiation for Patients with Locally Advanced (Non-Metastatic) Andenocarcinoma of the Pancreas **William Blackstock, MD**

# Annual Meeting Registration Form

**If you have not completed a registration form, please complete the one below and fax it to Lisa Hawkins at 336-716-6275 by August 25, 2005.**

- ☐ 8:00 am Continental Breakfast
- ☐ 8:30 am Round Table Session
- ☐ 11:15 am Business Meeting
- ☐ 12:00 pm Lunch (provided)
- ☐ 1:00 pm Protocol Review
- ☐ 7:00 pm Reception

*There are no registration fees associated with the Research Base Meeting.*

Name: _____

Guest Name(s): _____

Address/City/State/Zip:_____
_____

Email:_____

Credential(s): _____

Business Phone: _____

Last 4 digits of SS#/AMA#: _____

CCOP/Non-CCOP Name: _____

Hospital/Practice Name/Location:
_____
_____

Congratulations to Michael Farmer, MD for accruing the most patients of all the residents in the WFUBMC department of Radiation Oncology in the last quarter.

# Contact Information

*NEW PAGER NUMBERS: (336) 716-4220 + EXTENSION

| *Protocol Information Office* FAX: (336) 716-6275 | | | | |
|---|---|---|---|---|
| Gina Enevold, MSN, RN, GNP<br>Administrator<br>(336) 716-4035<br>genevold@wfubmc.edu<br>Pager extension: 6943* | June Fletcher-Steede, BS, RT (R)(T), CCRP<br>Site Coordinator<br>(336) 716-6733<br>jsteede@wfubmc.edu<br>Pager: (336) 806-6944 | Del Jones<br>Assistant Project Manager<br>Protocol Development<br>(336)716-3020<br>deljones@wfubmc.edu<br>Pager extension: 4280* | Megan Whelen, BS<br>Assistant Project Manager<br>Regulatory<br>(336)716-5992<br>mwhelen@wfubmc.edu<br>Pager extension: 4350* | Lisa Hawkins<br>Administrative Assistant<br>(336) 716-0891<br>lhawkins@wfubmc.edu<br>Pager extension: 1689* |
| *Data Management Center* FAX: (336) 713-6476 | | | | *Core Laboratory* |
| Cissy Yates, BS, MT<br>Assistant Project Manager<br>(336) 713-3172<br>Cyates@wfubmc.edu<br>Pager extension: 3104* | Rhonda Kimball<br>Protocol Specialist<br>(336)713-6531<br>rkimball@wfubmc.edu | Sharnita Duren, BS<br>Protocol Specialist<br>(336)713-6566<br>sduren@wfubmc.edu | | Andrea Rice, BS<br>Core Laboratory<br>(336) 716-2573<br>arice@wfubmc.edu<br>Pager: (336)716-7450 |
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## Inside Mile Stones


- Donepezil Study Results
- New Studies in Development
- Remember to fax in your Annual Meeting Registration Form by August 25th

## Out and About with June

The National Cancer Institute requires that all NCI funded CCOPs put patients on cancer prevention and control studies. With the closure of the STAR and SELECT studies, the CCCWFU Research Base is a wonderful source for prevention/control studies. We currently have three studies available for our sites to open and accrue patients to, which would assist you in meeting the requirements of NCI.

- 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
- 97102: A Phase III Randomized Study Comparing the Effects of Oxandrolone (Oxandrin) ® and Megestrol Acetate (Megace) ® On Lean Body Mass, Weight, Body Fat, and Quality Of Life in Patients with Solid Tumors and Weight Loss Receiving Chemotherapy
- 97202: A Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients

All details of the above protocols can be found on the CCCWFU Research Base website, www1. wfubmc.edu/cancer/ CCCWFU+CCOP+Research+Base/Open+Protocols .

As always if you have any questions, give me a call at 336-716-6733.

June Fletcher-Steele

## Welcome New Sites!

- Santa Rosa Memorial Santa Rosa, CA (CCOP)
- Virginia Mason Seattle, WA (CCOP)
- Hugh Chatham Elkin, NC (non-CCOP)