



May 2008

## CINJ Clinical Trials News

Dear Colleague:

This issue of *Clinical Trials News* is dedicated to The Cancer Institute of New Jersey Oncology Group (CINJOG), a network of physicians, nurses and researchers that perform multi-center cancer research in New Jersey. The network combines the strengths and skills of our state's expert providers to improve research, education and cancer prevention throughout the state. To inquire more information about CINJOG and the trials listed in this issue, please call Marianne Balay, MS, RN, Associate Director of CINJOG at 732-235-7150.

A common denominator running throughout several of the exciting trials that will be added to the CINJOG trial menu this spring is the use of hydroxychloroquine to inhibit autophagy, a tumor resistance mechanism. Autophagy is a process by which tumor cells survive during times of starvation or injury induced by various agents such as angiogenesis inhibitors. These studies will be added to our CINJOG menu book coming out in May 2008.

### **CINJ Oncology Group #040804: Phase I/II Study of Ixabepilone in Combination with the Autophagy Inhibitor Hydroxychloroquine for the Treatment of Patients with Metastatic Breast Cancer**

Principal Investigator: Vassiliki Karantza-Wadsworth, MD, PhD 732-235-5337  
Research Nurse Clinician: Lien Huzzy, RN, BSN, OCN 732-235-8962

#### Target Population:

The study population will consist of women with histologically or cytologically confirmed breast cancer. Histologic or cytologic elements can be established on metastatic tumor aspirate or biopsy. Patients must have received at least two, but no more than three, prior chemotherapy regimens for metastatic breast cancer. Patients must also have anthracycline-resistant (or must have been treated with minimum cumulative doxorubicin dose of 240 mg/m<sup>2</sup> or epirubicin dose of 360 mg/m<sup>2</sup>) and taxane-resistant metastatic breast cancer.

#### Objectives:

The primary objective of this study is to assess the antitumor activity, as measured by tumor response rate, in patients with metastatic breast cancer who receive ixabepilone plus hydroxychloroquine combination therapy as a third-line treatment. The primary endpoint is to determine the recommended Phase II dose of ixabepilone and hydroxychloroquine in patients with metastatic breast cancer.

### **CINJ Oncology Group # 030801: Modulation of autophagy with hydroxychloroquine in combination with carboplatin, paclitaxel and bevacizumab in patients with advanced/recurrent non-small cell lung cancer – a Phase I/II study**

Principal Investigator: Mika Sovak, MD, PhD 732-235-9873  
Research Nurse Clinician: Lisa Guensch, R.N., BSN 732-235-8939

Target Population:

The study population will consist of patients with histologically or cytologically confirmed non-small cell lung cancer EXCEPT squamous cell carcinoma. Mixed tumors will be categorized by the predominant cell type unless small cell elements are present, in which case the patient is ineligible. Cytologic or histologic elements can be established on metastatic tumor aspirate or biopsy. Sputum cytology alone is not sufficient. Patients with advanced stage NSCLC (stage IIIB with malignant pleural effusion, or stage IV, or recurrent disease).

Objectives:

The objectives of this study are to assess the antitumor activity and determine the phase II dose of paclitaxel, carboplatin, bevacizumab in combination with hydroxychloroquine in patients with advanced or recurrent NSCLC cancer.

**CINJ Oncology Group # 080805: A Phase II Study of Docetaxel and Modulation of Autophagy with Hydroxychloroquine for Metastatic Hormone Refractory Prostate Cancer**

Principal Investigator: Robert DiPaola, MD 732-235-7414

Research Nurse Clinician: Dorinda Metzger, RN, MSN, OCN 732-235- 6363

Target Population:

The study population will consist of patients with histologically proven prostate cancer with metastatic disease, and progression after initial hormonal therapy will be eligible for this study. Patients with prostate cancer in whom bicalutamide or flutamide has been recently withdrawn, must demonstrate progression of disease and be at least 6 weeks and 4 weeks respectively beyond the discontinuation of such agents. LHRH agonists will be continued.

Objectives:

The primary objective of this study is to assess the antitumor activity, as measured by tumor response rate of docetaxel in combination with hydroxychloroquine on metastatic hormone refractory, chemotherapy naïve prostate cancer patients.

**CINJ Oncology Group #080803: Autophagic Cell Death in Patients with Hormone-Dependent Prostate-Specific Antigen Progression After Local Therapy for Prostate Cancer**

Principal Investigator: Mark N. Stein, MD 732-235-6777

Research Nurse Clinician: Dorinda Metzger, RN, MSN, OCN 732-235-6363

Target Population:

The study population will consist of patients with histologically proven stage D0 prostate cancer (i.e., tumor originally diagnosed as being limited to the prostate, and now having a rising PSA value after definitive local therapy). Patients must have undergone local treatment via prostatectomy or radiation therapy. Patients must have PSA progression after local treatment.

Objectives:

The objectives of this study are: to determine the effect on the biological activity of hydroxychloroquine in prostate cancer -“biological activity” will be assessed by PSA response; to determine the effect on peripheral blood mononuclear cell (PBMC) LC3-II expression by the use of

hydroxychloroquine; to determine the expression of Beclin-1 in a population of patients having undergone local treatment with prostatectomy; and to determine the feasibility and safety of administering hydroxychloroquine in this population of patients.

Also featured in this issue of CTNews is a **Quality of Life** trial written by one of our community physicians, Dr. Michael Gruber, studying Stereotactic Radiosurgery for the Treatment of 1-3 Brain Metastases in Non-Small Cell Lung Cancer.

**CINJ Oncology Group # 030601: Phase II Study of Stereotactic Radiosurgery, Temozolomide and Erlotinib Chemotherapy for the Treatment of 1-3 Brain Metastases in Non-Small Cell Lung Cancer**

<u>Principal Investigator:</u>	Molly Gabel, MD	732-235-6777
<u>Lead Network Investigator:</u>	Michael L. Gruber, MD	212-263-6267
<u>Nurse Contact:</u>	Marianne Balay, MS, RN	732-235-7150

Target Population:

The study population will consist of patients who have histologically confirmed NSCLC and 1-3 brain metastases.

Objectives:

To evaluate the effect of sequential stereotactic radiosurgery and combination chemotherapy with erlotinib and temozolomide on cognitive function and to evaluate the feasibility and safety of sequential stereotactic radiosurgery (SRS) with temozolomide and erlotinib as first line therapy for one to three brain metastases in NSCLC patients.

Lastly, the Spring/Summer edition of the CINJOG Trial Menu will be sent soon. Please consider opening a few of the trials in it at your site. Should you have any questions about how to do that, please call Marianne Balay at 732-235-7150. Thank you for your commitment to the fight against cancer, and please save the evening of October 16, 2008 for the next CINJOG Research Meeting.

Sincerely,

Robert DiPaola, MD  
 Director, CINJ Oncology Group  
 Chief of Medical Oncology, The Cancer Institute of New Jersey  
 Professor of Medicine, UMDNJ-Robert Wood Johnson Medical School