

North Central Cancer Treatment Group

**N0871, A Phase II Study of Carboplatin (CBDCA), Paclitaxel (TAXOL), and Everolimus (RAD001) in Previously Untreated Patients with Measurable Disease with Cancer of Unknown Primary (CUP)**

Addendum 8 – March 25, 2011

**Summary**

- An updated Investigators Brochure (IB) for Everolimus dated December 14, 2010 has been received. Therefore, the consent form has been updated accordingly.
- Administrative/editorial changes.

**Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.**

**Title Page** Addendum 8 has been added and the NCI version date has been revised.

**Protocol Resources**

Page 2: **Tamra Chomjak** replaces ~~Sara Braun~~ as the NCCTG Research Base Research Protocol Specialist.

**Appendix I** **Consent Form**

Pages 8-9: Due to the receipt of the updated IB for Everolimus, the risk section have been revised as follows:

Likely (*events occurring greater than 20% of the time*)

- Skin rash
- Mouth sores (stomatitis/mucositis). Inflammation and/or sores in the mouth that may make swallowing difficult and are painful. This usually appears within the first couple of weeks after starting therapy and may go away without any change in the dose. In some cases, a dose reduction may be necessary.
- Fatigue (feeling tired)
- Upset stomach (nausea)
- Weight loss or poor appetite (anorexia)
- Low blood platelets that may increase the risk of bleeding (thrombocytopenia)
- Low white blood cells that may increase the chance of a viral, bacterial, or fungal infection (neutropenia)
- Change in taste (dysgeusia)
- Diarrhea or loose bowel movements. This can usually be treated with pills such as Imodium®.
- Headache
- **Infections (such as a cold, sore throat (pharyngitis), bronchitis, sinus infection (rhinitis), or pneumonia) (*moved from Less likely*)**
- **Cough (*moved from Less likely*)**
- **Lowering of the red blood cells which could make you feel tired (anemia) and may require the need for blood transfusions (*moved from Less likely*)**
- **Increased amounts of lipids. This would include cholesterol and triglycerides in the blood.**

**(hyperlipidemia). You may need to be treated with a lipid lowering agent.** *(moved from Less likely)*

- **High blood sugar level (hyperglycemia)** *(moved from Less likely)*
- **Abnormal kidney function (Increased creatinine)** *(newly added)*
- **Loss of strength, weakness (Asthenia)** *(newly added)*

Less likely *(events occurring less than or equal to 20% of the time)*

- Itching (pruritis)
- Redness of the skin (erythema)
- Pimples on your skin (acne)
- ~~Infections (such as a cold, sore throat (pharyngitis), bronchitis, sinus infection (rhinitis), or pneumonia)~~ *(moved to Likely)*
- Poor wound healing
- High blood pressure (hypertension)
- Low blood pressure (hypotension)
- Swelling in your arms and legs (edema)
- Certain kind of infection of the liver which causes inflammation and can cause liver damage (hepatitis)
- Dizziness
- Yeast infection in the mouth and throat (thrush/oral candidiasis)
- Difficulty passing stool (constipation)
- Swelling of the belly area (abdominal distention)
- Abdominal pain
- ~~Cough~~ *(moved to Likely)*
- Fever (pyrexia)
- ~~Lowering of the red blood cells which could make you feel tired (anemia) and may require the need for blood transfusions~~ *(moved to Likely)*
- ~~Increased amounts of lipids. This would include cholesterol and triglycerides in the blood. (hyperlipidemia). You may need to be treated with a lipid lowering agent.~~ *(moved to Likely)*
- Throwing up (vomiting)
- Low blood glucose which could be severe (hypoglycemia)
- Impaired glucose tolerance (intermittently raised glucose levels of 140-199 after 2 hours)
- ~~High blood sugar level (hyperglycemia)~~ *(moved to Likely)*
- Change in blood electrolytes, low sodium (hyponatremia)
- Low potassium levels in the blood (hypokalemia)
- Small red or purple spots on your skin (petechia)
- Flu like symptoms (fever, aching joints)
- Difficulty falling or staying asleep (insomnia)
- Nervousness
- Changes in heart rhythm seen on electrocardiogram
- Inflammation of the foreskin and head of penis (balanitis)
- Inflammation of the urinary bladder (cystitis)
- Profuse bleeding (hemorrhage)