

North Central Cancer Treatment Group

N0775: A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or
ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV
Malignant Melanoma

Addendum 15 – May 27, 2011

Summary

- The Research Base Protocol Specialist has been revised
- Section 15.0 and the consent form revisions due to the review of Temozolomide Investigator Brochure dated December 3, 2010

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

Title Page Reflects the addition of Addendum 15 and a new NCI version date.

Protocol Resources

Page 2: **Tamra Chomjak** has replaced Sara Braun as the Research Base Protocol Specialist. The phone number and e-mail have been revised accordingly.

Section 15.0 Drug Information

Page 54: Section 15.49a has been revised due to the review of Temozolomide Investigator Brochure dated December 3, 2010. Changes are as follows:

Known potential adverse events: (Please see the temozolomide package insert for a comprehensive list of adverse events) Hematological: Thrombocytopenia, leukopenia, myelodysplastic syndrome, neutropenia, lymphopenia, anemia, aplastic anemia. Gastrointestinal: Nausea, vomiting, anorexia. Hepatic: Elevated liver enzymes (reversible) Skin: Rash (could be severe), psoriasis, **pruritus, severe skin rash (Stevens Johnson syndrome; erythema multiforme; epidermal necrolysis)**. Other: Constipation, diarrhea, stomatitis, fatigue, decreased performance status, headache, lack of interest in or ability to carry out daily activities, hemiparesis, pneumonitis, change in kidney function tests, **pyrexia, pain (including abdominal), myalgia, arthralgia, amnesia, depression, anxiety, asthenia, dizziness, tingling or burning in your arms or legs, dyspnea, cough, edema, urinary urgency, seizures, abnormal coordination, paralysis, allergic reaction (fever, chills, swelling of body, shortness of breath), later development of secondary leukemia, lymphoma, or other cancers**. Re-activation of hepatitis infection is possible.

Appendix I **Consent Form**

Pages 10/11: Based on review of Temozolomide Investigator Brochure dated December 3, 2011, the “Rare but serious risks of temozolomide have been revised, as follows:

Rare but serious risks of temozolomide (events occurring less than 2-3% of the time)

- Problem with the bone marrow that causes decreased production of red cells, white cells, or platelets that can sometimes turn into blood cancer called myelodysplastic syndrome
- Convulsions
- Weakness on one side of your body (Hemiparesis)
- Abnormal coordination
- Inability to move an arm or leg (paralysis)
- **Allergic reactions, including severe skin reaction rash or skin peeling as with a severe sunburn (Stevens Johnson syndrome; erythema multiforme; epidermal necrolysis)**
- **Fever, chills, swelling of body, shortness of breath** (Allergic reaction)
- Re-activation of hepatitis infection if you have previously been diagnosed with Hepatitis (a type of infection in the liver)
- A blood disorder in which the body’s bone marrow does not make enough new blood cells (Aplastic anemia)
- Inflammation in the lungs (Pneumonitis)
- Change in kidney function tests (tests that show the kidneys are working)
- **Later development of secondary leukemia, lymphoma or other cancers**