

North Central Cancer Treatment Group

N0177: A Pilot and Phase II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Update 3 – July 6, 2007

**Summary**

- Inconsistencies in the IB and IC consent forms have been identified and corrected to coincide with the changes reflected in Addendum 12.

**Replacement pages are provided. Please incorporate into the protocol and keep this update with your protocol.**

**Title page** Updated to reflect Update 3 and revised NCI version date.

**Appendix IB Consent Form**

Pages 5-6: Due to inconsistencies between the consent forms and Addendum 12, the following corrections have been made to the risks sections for temozolomide:

Temozolomide (TMZ)

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

- ~~Headache~~ (has been deleted as this entry was a duplication)

Less Likely (events occurring less than or equal to 20% of the time):

- ~~Loss of appetite~~ (deleted as decrease in appetite was moved to “Likely”)

**Appendix IC Consent Form**

More common side effects **Likely (events occurring greater than 20% of the time):**

- **Decrease in appetite** (was moved from “Less Likely”)
- **Fever** (was moved from “Less Likely”)

Less common side effects **Less Likely (events occurring less than or equal to 20% of the time):**

- ~~Decrease in blood counts that may result in infection, bleeding or anemia~~ (this was broken into the following 3 separate entries)
- **Fall in the white blood cell counts that leads to a higher risk of infection**
- **Fall in the platelet count leading to a higher risk of bleeding**
- **Fall in the red blood cell count leading to anemia (feeling tired and low energy)**
- ~~Loss of appetite~~ (deleted as decrease in appetite was moved to “Likely”)
- ~~Fever~~ (was moved to “Likely”)
- ~~Weight loss and/or decrease in appetite~~ (was moved to “Likely”)
- **Numbness or tingling or burning in your arms or legs** (wording was expanded)
- **Change in liver function tests (tests that show how the liver is working)** (wording was expanded):  
Liver damage
- **Itchiness** (was newly added)
- **Dizziness** (was newly added)
- **Anxiety** (was newly added)
- **Depression** (was newly added)
- **Memory loss** (was newly added)
- **Muscle or joint pain** (was newly added)
- **Shortness of breath** (was newly added)
- **Cough** (was newly added)
- **Increased need to pass urine** (was newly added)

Rare side effects but serious (events occurring less than 2-3% of the time):

- **Myelodysplastic syndrome (problem with the bone marrow that causes decreased production of red cells, white cells, or platelets that can sometimes turn into blood cancer)** *(was newly added)*
- **Convulsions** *(was newly added)*
- **Weakness on one side of the body** *(was newly added)*
- **Abnormal coordination** *(was newly added)*
- **Paralysis** *(was newly added)*
- **Severe skin reaction** *(was newly added)*
- **Allergic reaction** *(was newly added)*