

North Central Cancer Treatment Group

N0572: A Phase I/II Trial of Sorafenib and CCI-779 in Patients with Recurrent Glioblastoma

Update 1 – June 27, 2008

**Summary**

- Clarification has been made regarding the dose level for the phase II portion of the study.
- Clarification has been made with regard to patient pre-registration accrual.
- Administrative/editorial

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

**Title page** Updated to reflect the addition of Update 1 and revised NCI version date.

**Protocol Resource**

Page 2: **Wanda DeKrey** replaces ~~Beverly Kowbe~~ and the NCCTG Member nurse protocol resource contact.

Helen Tollefson has been removed as a pathology protocol resource contact.

**Section 6.0** **Registration/Randomization Procedures**

Page 22: Throughout this section Randomization Center has been changed to Registration Office.

**Section 7.0** **Protocol Treatment**

Page 26: Section 7.211 now reads due to the clarification of the dose level for the phase II portion: The **starting** phase II dose will be CCI-779 25 mg and sorafenib 200 mg bid. **This is dose level 0 from the table in Section 7.12.** ....6 more patients will be enrolled at dose level -1 and evaluated. **If required, this (and any subsequent) phase II dose reduction will follow the dose levels in table in Section 7.12.....**

Section 7.2211 now reads due to the clarification of the dose level for the phase II portion:....CCI-779 at the **current** MTD level as defined in the phase I portion **and Section 7.21** of this study on Day 1....

Page 27: Due to the clarification of the dose level for the phase II portion of the study, Sections 7.2221 and 7.232 tables have been revised to refer to Section 7.21 for appropriate dose level.

**Section 8.0** **Dosage Modification Based on Adverse Events**

Page 30: CTC Category – Blood/Bone Marrow now reflects that the platelets are Grade 2 rather than Grade 3.

**Section 16.0**

Page 75:

**Statistical Considerations and Methodology**

The following statement has been added to the third paragraph of Section 16.35 for clarification:

**If the trial goes to full accrual, we anticipate pre-registering 145 patients to register a total of 96 patients necessary for the study design and allotted over accrual.**

**Appendix IB**

Page 13:

**Consent Form**

**What are the costs of tests and procedures?** The following has been removed from the 2<sup>nd</sup> paragraph, second sentence, because there is no testing being done on the blood cells: ~~and on your blood cells~~