

North Central Cancer Treatment Group

N0776: Phase II Trial of Avastin® in Combination with Sorafenib in Recurrent Glioblastoma Multiforme

Update 1 – January 22, 2009

Summary

Administrative/editorial changes.

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.

Section 1.0 **Background**
Page 4: As reflected in Addendum 4, the protocol was revised due to the responses seen in patients who received the reduced Sorafenib dose of Cycle 1. Therefore, the treatment section of the Schema has been revised as follows:

Active Treatment – Cycle 1⁺

Sorafenib BID days 1 through 5 and 8 through 12 (of cycle 1) plus Avastin® (day 1 of cycle 1)

Active Treatment Cycles 2⁺

~~If patient does not experience grade 3 or 4 treatment related adverse event:~~

~~Sorafenib BID (days 1 through 14 of each cycle) plus Avastin® (day 1 of each cycle)~~

~~If patient does experience grade 3 or 4 treatment related adverse event:~~

~~Sorafenib BID days 1 through 5 and 8 through 12 (of each cycle) plus Avastin® (day 1 of each cycle)~~

Appendix I **Consent Form**

Page 3: As reflected in Addendum 4, the protocol was revised due to the responses seen in patients who received the reduced Sorafenib dose of Cycle 1. Therefore, the third paragraph under “During the study” has now been revised as follows:

~~For cycle 1, you will take sorafenib, one tablet by mouth twice a day on days 1 through 5 and 8 through 12. If you do not have any bad side effects during cycle 1, you will take sorafenib, one tablet by mouth twice a day every day. If you do have any bad side effects but they are not bad enough for you to stop treatment, you will continue to take the sorafenib days 1 through 5 and 8 through 12 during each cycle of treatment. A cycle of treatment covers a 14-day period of time. The treatment will continue until your disease gets worse.~~