

North Central Cancer Treatment Group

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

Update 2 – May 29, 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 2 and revised NCI version date.

Protocol Resources

Page 2: **Helen J. Tollefson** replaces ~~Christine R. Maszk~~ as the NCCTG *Research Base* Pathology Coordinator.

Schema

Page 5: The Phase II Schema has been revised to provide clarification of Groups 1, 2, and 3. **“Patients NOT undergoing surgery with prior anti-VEGF treatment (Group 3)”** is newly added. “Patients NOT undergoing surgery” now reflects Group 1 rather than “Both group 1 and group 3.”

Section 7.0

Protocol Treatment

Page 26: For clarification purposes, the heading for Section 7.21 has been revised as follows:
~~Adverse Event Stopping Rule~~ **Additional Phase II MTD Determination**

For clarification purposes, Section 7.212 has been revised as follows:

As of Addendum 8, the Phase II dose is currently dose level -1 per section 7.12 (Sorafenib 200 mg bid, CCI-779 20 mg q-weekly). ~~The prior anti-VEGF treatment group 3 patients will start at the current group 1 Phase II dose as per Section 7.211~~ **Patients in group 1, 2, or 3 will start at this current group 1 Phase II dose as per Section 7.211.**

Page 27: The “Dose” column for CCI-779 in Sections 7.2221, 7.232, and new Section 7.241 have been corrected to reflect Section 7.212.

Pages 28: For clarification purposes, Section 7.24 is newly added.

Section 14.0 **Translational/Pharmacologic Studies**

Page 45: The second bullet in Section 14.11 has been updated as follows:

- Tumor tissue (Section 14.2 **or 14.3**)