

North Central Cancer Treatment Group

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

Addendum 14 – July 9, 2010

Summary

- An updated Comprehensive Adverse Events and Potential Risks (CAEPR) for Bevacizumab (Avastin) (version 2.1, dated May 4, 2010) has been received from the National Cancer Institute (NCI). Therefore, the Drug Information section and consent form have been updated accordingly.

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

Title page Updated to reflect the addition of Addendum 14 and revised NCI version date.

Section 15.0 Drug Information

Pages 49-53: Due to the receipt of the updated Bevacizumab (Avastin) CAEPR from NCI, Section 15.231 has been replaced in its entirety.

Pages 49-66: Due to the inclusion of the updated Sorafenib CAEPR repagination has occurred.

Appendix I Consent Form

Pages 8-10 Due to the receipt of the updated Bevacizumab (Avastin) CAEPR from NCI, the risks sections have been replaced in their entirety.

Please note specific changes as follows:

Added New Risk:

- Less Likely: Abnormal changes in the growth plate that may affect the growth of long bones in very young children. This side effect appeared to be reversible after the treatment was stopped but has not been assessed with long-term use of the bevacizumab drug.; Blood in the urine
- Rare But Serious: Damage of or clots in small blood vessels in the kidney that can cause complications, some of which are serious including abnormal destruction of red blood cells (hemolysis) or platelets (that help to clot blood) and kidney failure

Increase in Risk Attribution:

- Changed to Less Likely from Reported But Undetermined: Infection (collection of pus) around the rectum; Fainting