

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

Addendum 16 – July 24, 2009

Summary

- Due to updated information reflected in the most recent Investigator Brochure (IB) for erlotinib, the Drug Information section and consent forms have been revised accordingly.
- Editorial/administrative changes.

A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this addendum with your protocol

Title page Updated to reflect Addendum 16 and revised NCI version date.

Protocol Resources

Page 2: **Wanda L. DeKrey, R.N., OCN** replaces ~~Beverly L. Kowbel~~ as the NCCTG Member Nurse.

John M. Beranek (Jack) replaces ~~Janis Wobeschall~~ as the NCCTG *Research Base* Protocol Development Coordinator. Also, Jack's title has changed to reflect NCCTG *Research Base* **Research Protocol Specialist**.

~~Christine R. Maszk~~ has been removed as the NCCTG *Research Base* Pathology Coordinator.

Section 15.0 **Drug Information**

Page 46: In order to reflect current information listed in the most updated IB for erlotinib, the following risks have been added to the nursing guidelines:

15.169b A smoking study found that smoking is known to induce CYP1A1 and CYP1A2 and has been shown to reduce erlotinib exposure by 50 to 60%, therefore, patients should refrain from smoking while taking erlotinib.

15.169c Instruct patient to not consume grapefruit or grapefruit juice while participating in this study.

Due to the addition of Sections 15.169b and 15.169c, Section 15.169 has now become 15.169a.

Appendices IB-IC

Page 1: In order to reflect current information listed in the most updated IB for erlotinib, a new paragraph has been added to the section “What will happen in the study?” as follows:

It is recommended that you not smoke while taking OSI-774 as smoking can decrease the level of medication in your system and may decrease its effect. Also, do not consume grapefruit or grapefruit juice while taking OSI-774.

Appendix IC

Page 4 : Per Addendum 15, the risks section for OSI-774 was updated. The change for “Irritation of stomach...” was inadvertently missed and has now been updated as follows:

Less likely side effects (events that occur less than or equal to 20% of the time):

- Irritation **or sores in the lining somewhere in the digestive tract** of stomach or bowel which may lead to ulcers (~~lining breakdown~~) or bleeding (*reworded*)