

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 13 – October 26, 2007

**Summary**

- The 11<sup>th</sup> edition of the Investigator Brochure for erlotinib (OSI-774) dated February 15, 2007 was received. The Drug Information section (Section 15.0) and consent forms have been updated accordingly. Consent for Study 1 will not be updated as patients are no longer receiving treatment.
- Administrative/editorial changes.

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

**Title page** Updated to reflect Addendum 13 and revised NCI version date.

**Section 14.0** **Translational/Pharmacologic Studies**

Page 41: The address for Dr. Maihle's laboratory has been updated in Section 14.232 as follows:  
At the end of the study, or upon request, Dr. Uhm will forward the specimens to Dr. Maihle's Laboratory, Yale University – School of Medicine, 300 George Street, Suite 8400 770, New Haven, CT 06511 for sEGFR determination.

**Section 15.0** **Drug Information**

Page 44: Due to the updated Investigator Brochure for OSI-774, the following has been added to Section 15.15:  
**Per updated OSI-774 Investigator Brochure, Edition #11, dated February 15, 2007, the following adverse event has been reported:**  
Heart attack.

**Appendices** **Consent Form**  
**IB, IC**

Page 5: Under the risk section for OSI-774, the "Rare but serious" section has been updated as follows due to the receipt of an updated Investigator Brochure dated February 15, 2007:

**Rare but serious side effects (events that occur less than 2-3% of the time):**

- Lung irritation (this may be life threatening)
- Skin sores/ulcers
- Irritation of stomach or bowel, which may lead to ulcers (lining breakdown) or bleeding
- Increased risk of bleeding in patients who have low platelet count, are taking blood thinners, or are taking certain drugs for pain called NSAIDS (aspirin or ibuprofen)
- Changes in liver function tests, which may indicate liver damage, this may be life threatening
- Decreased kidney function
- Damage to the front of the eye, which may lead to changes in vision
- Infection, which may be life threatening
- **Heart attack**