

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 19 – May 14, 2010

Summary

An updated Comprehensive Adverse Events and Potential Risks (CAEPR) list for Erlotinib (version 2.3, dated March 29, 2010) has been received from the National Cancer Institute (NCI). Therefore, the Drug Information section and consent forms have been updated accordingly.

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

Title page Updated to reflect Addendum 19 and revised NCI version date.

Section 14.0 **Translational/Pharmacologic Studies**
Page 42: Section 14.234 has been updated as follows:

Ship samples Monday through ~~Friday~~ **Thursday** ONLY. Do not send samples on weekends or holidays or the day before a holiday.

Section 15.0 **Drug Information**
Pages 43-45: Due to the receipt of the updated CAEPR for Erlotinib from NCI, The CAEPR has been replaced in its entirety in Section 15.15.

Appendices IB-IC **Consent Forms**
Pages 4-5 Due to the receipt of the updated CAEPR for Erlotinib from NCI, the risks sections have been updated as follows:

Likely side effects (events that occur greater than 20% of the time):

- Diarrhea
- ~~Rash/flaking or shedding of outer layer of skin~~ **Skin rash with the presence of macules (flat discolored area) and papules (raised bump) (reworded)**
- Vomiting
- Loss of appetite
- Tiredness or fatigue

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

- Mouth dryness
- Headache **or head pain** (*wording expanded*)
- Hair loss or thinning
- Heartburn, gas, or upset stomach
- Taste changes
- Dry, red, irritated eyes
- ~~Damage to the front of the eye, which may lead to changes in vision~~ **Inflammation (swelling and redness) of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids). Commonly called “pink eye.”** (*reworded*)
- Stomach pain
- Nose bleeds
- Increased level of a liver enzyme (ALT/SGPT; AST/SGOT)
- Abnormal liver or bone enzyme level (alkaline phosphatase)
- Elevation of a liver pigment (bilirubin) in the blood indicative of liver dysfunction
- Acne; pimples
- Cough
- Shortness of breath
- Dry skin
- ~~Nail changes~~ **Loss of some or all of the finger or toenails** (*reworded*)
- Itching
- ~~Irritation or sores in the lining somewhere in the digestive tract~~ (*deleted*)
- ~~Infections somewhere in the body associated with dangerously low levels of a type of white blood cell count (neutrophils)~~ (*deleted*)
- Nausea, the urge to vomit
- A condition in which your body does not have as much water and fluid as it should (dehydration, which can be caused by severe diarrhea and/or vomiting)
- In-grown eyelashes/thickening of eyelashes
- Inflammation of the lungs (pneumonitis, which can rarely be life-threatening or fatal)
- Bleeding in some organ(s) of the digestive tract
- **Irritation or sores in the lining of the mouth** (*newly added*)
- **Infection of the skin** (*newly added*)

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

- Severe skin and gut lining reaction that may include rash and peeling or death of tissue
- Painful redness or peeling of the skin on the palms of the hands and soles of the feet
- Liver failure that can be life threatening or fatal, particularly in patients with underlying impairment of the liver function
- A hole in a part(s) of the digestive of the digestive tract (which commonly requires surgery and can be life-threatening or fatal)
- Bleeding in the brain or spinal cord
- Inflammation of the cornea of the eye
- A hole or sore in the outer layer of the eye (caused by severe inflammation or dry eye syndrome)