

North Central Cancer Treatment Group

N0272: Phase I/II Trial of Imatinib Mesylate; (Gleevec; STI571) in Treatment of Recurrent Oligodendroglioma and Mixed Oligoastrocytoma

Addendum 15 – December 23, 2011

Summary

- This addendum is in response to a Request for Amendment (RA) from the National Cancer Institute (NCI) dated November 16, 2011 concerning Imatinib Mesylate (STI571). The Drug Information section and the Phase II consent form have been updated accordingly.
- Administrative changes.

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

Title page Revised to reflect Addendum 15 and updated NCI version date.

Protocol Resources

Page 2: **Sanna L. McKinzie** replaces ~~John M. (Jack) Beranek~~ as the NCCTG Research Base Protocol Specialist.

Section 15.0 Drug Information

Pages 43-46: Due to the receipt of the RA from NCI for Imatinib Mesylate, Section 15.42 has been replaced in its entirety.

Appendix IB Consent Form

Page 6: Due to the receipt of the RA from NCI for Imatinib Mesylate, the Less Likely risk section has been updated as follows:

Less Likely (events occurring less than or equal to 20% of the time)

- Build-up of fluid around your heart and/or infection in the lining around your heart
- Chills, shivering
- Increased sweating
- Weight gain
- Hair loss or thinning
- Darkening or lightening of the skin
- Itching
- Severe reaction of the skin and gut lining that may include rash, shedding, or death of skin tissue and could cause you to be hospitalized for treatment (necrosis)
- Loss of appetite
- Build up of fluid in the belly/abdomen (Ascites)
- Constipation
- Loss of body fluids (dehydration – which may require fluids into a vein)
- Excess passing of gas (Flatulence)
- Heartburn or indigestion
- Irritation or sores somewhere in the digestive tract
- **Irritation or sores in the lining of the anus (newly added)**

- **Irritation or sores in the lining of the mouth** (*newly added*)
- **Irritation or sores in the lining of the rectum** (*newly added*)
- **Irritation or sores in the lining of the small bowel** (*newly added*)
- **Irritation or sores in the lining of the voice box** (*newly added*)
- **Irritation or sores in the lining of the throat** (*newly added*)
- **Irritation or sores in the lining of the windpipe** (*newly added*)
- Bleeding in some organ(s) of the digestive tract
- Bleeding within a tumor
- Swelling of the head and neck area
- Swelling of the outer layers of an organ
- Abnormal liver or bone enzyme level (alkaline phosphatase)
- Increased level of a liver enzyme (ALT/SGPT)
- Increased level of a liver enzyme (AST/SGOT)
- Elevation of a liver pigment (bilirubin) in the blood indicative of liver dysfunction
- Increased blood level of creatinine, as substance normally eliminated by the kidneys into the urine
- Decreased blood phosphate level
- Decreased blood potassium level
- Decreased blood sodium level
- Arthritis/joint swelling (damage to your joints)
- Dizziness (sensation of lightheadedness, unsteadiness, giddiness, spinning or rocking)
- Head pain/Headache
- Cough
- Excess fluid that accumulates in the pleural cavity, the fluid-filled space that surrounds the lungs
- Pain in the lining of the chest cavity and lungs
- Shortness of breath
- Joint pain
- Decreased number of a type of white blood cell (lymphocyte)
- **Bleeding with a decreased number of blood cells (platelets) that help to clot blood (may increase risk of bleeding)** (*wording expanded*)
- Fever
- Muscle cramps
- Infection somewhere in the body associated with or without dangerously low levels of a type of white blood cell (neutrophils)