

North Central Cancer Treatment Group

N04C2, An Exploratory, Randomized, Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR® Depot) for Symptomatic Ascites in Cancer Patients

Addendum 3 – November 23, 2007

Summary

- Kit information has been updated in Section 14.0.
- Section 15.2 has been corrected to reflect that placebo is no longer provided for this study as of addendum 2.
- Section 16.31 has been corrected to indicate that the Mayo Clinic Data Safety Monitoring Board will review (and has been reviewing) this protocol as opposed to the NCCTG Data Monitoring Committee (DMC).
- 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 3 and revised NCI version date.

Protocol Resources

Page 2: **Daniel Satele** replaces ~~Laura Denton~~ as the NCCTG *Research Base* Protocol Development Coordinator.

Section 14.0 **Translational/Pharmacologic Studies**

Page 19-20: The kit information has been updated as follows (section numbers have been renumbered accordingly):

14.11 Collection of specimens

14.111 Kits are required for this study.

14.1111 Kits will be supplied through MCLCT. Participating institutions may obtain kits by faxing the Supply Order Form (found in the Forms Packet) **to the number listed on the form.**

14.1112 The kit contains supplies and instructions for collecting, processing, and shipping specimens. Allow at least two weeks to receive the kits. ~~Kits will not be forwarded to you by express mail.~~

14.1113 Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Allow at least two weeks to receive the kits.

14.1114 Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number or alternate billing number for express service. NCCTG will not cover the cost for rush delivery of kits.

14.112 **ALL** sections of the form/specimen collection labels must be completed.

Section 15.0**Drug Information**

Page 20:

The last sentence in Section 15.111 has been revised as follows:

The saline will be obtained from the commercial drug supply at the NCCTG institution (see **Section 15.3**).

Page 22:

Per Addendum 2, the placebo is no longer being provided for this study. Therefore, Section 15.211 has been revised as follows:

~~15.211 Placebo for Sandostatin LAR Depot (octreotide acetate for injectable suspension) is supplied as 30 mg microparticles parenteral and 1 Sandostatin LAR microsphere 2 mL vehicle. Store the product at refrigerated temperatures between 2°C – 8°C (36°F – 46°F) and protect from light during storage. Placebo: An intramuscular injection of 2 mL of Sodium Chloride Injection USP will be administered for the placebo dose. The saline will be obtained from the commercial drug supply at the NCCTG institution (see Section 15.3).~~

The first sentence of Section 15.22 was revised to remove the reference to provided placebo. These revisions are editorial and reflect changes that were implemented with addendum 2.

Preparation and Mixing: Prepare the Sandostatin LAR Depot ~~and matching placebo~~ as instructed on a Novartis Instruction sheet, video, or CD.

Section 16.0**Statistical Considerations and Methodology**

Page 26:

As a result of this study being reviewed by the Mayo Clinic Data Safety Monitoring Board, the first paragraph in Section 16.31 has been revised as follows:

~~The NCCTG Data Monitoring Committee is responsible for modifications involving changes in patient accrual (including early termination) and timing of results reporting will meet twice a year (spring and fall) to review the data for accrual problems, unexpected toxicities, and/or differences in outcome between regimens.~~

This study will be monitored by the Mayo Clinic Data Safety Monitoring Board (DSMB). Reports containing patient characteristics, toxicity and administrative information will be provided to the DSMB every six months, with the first report due at the first reporting period after study initiation. Reports will be due January 31 and July 31 or April 30 and October 31, unless otherwise specified by the DSMB.