
Operations Office

Telephone (507) 266-3853



Date: May 12, 2009

To: NCCTG Primary CRAs, Primary PIs

From: Linda S. Long
Research Protocol Specialist III

Re: N0745, Phase I/II Randomized Trial of Sorafenib and Bevacizumab as First-Line Therapy in Patients with Locally Advanced or Metastatic Hepatocellular Carcinoma

This memo is in response to questions regarding how the drugs sorafenib and bevacizumab will be supplied for the above study. An upcoming amendment will include changes to the protocol to correct and clarify drug procurement, but meanwhile the information provided in this memo should be used.

Bevacizumab: Bevacizumab, although manufactured by Genentech, will be supplied through funding provided by Bayer/Onyx at no cost to the patient.

Sorafenib: Sorafenib is approved by the Food and Drug Administration for use in treating unresectable hepatocellular carcinoma, but it is not available through retail pharmacies. It is available only through specialty pharmacies. Counselors at Bayer's REACH[®] Program will assist in procuring sorafenib for this study. The counselors will contact the specialty pharmacies to order the drug following patient enrollment in the REACH[®] Program.

Please note the following corrections.

- Sorafenib is not being supplied by Bayer as currently noted in the consent forms. REACH[®] Program counselors will assist the patient in finding financial assistance for covering the cost of the drug. They will assist all patients who complete the enrollment whether the patient has commercial insurance, Medicare Part D, or no insurance.
- **The correct website address to find out more about the REACH[®] Program is www.nexavar-us.com.** An enrollment form is available there and must be completed for each patient.

Call the REACH[®] Program at 1-877-322-4448 and tell the counselor that you are calling with regards to the NCCTG study N0745. The counselors can then provide you with details about the program and instructions on completing the enrollment form. Please remind the counselor that the drug is to be sent to the physician's address and not to the patient as is stated on the enrollment form.

If you have any questions concerning this communication, please contact me at 507/266-3853.