AIDS MALIGNANCY CLINICAL TRIALS CONSORTIUM (AMC)

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PRESS RELEASE

ASSESSING THE SAFETY OF SUNITINIB IN HIV-INFECTED PERSONS WITH CANCER: AMC STUDY #061

Rockville, MD, July 2, 2014: A study investigating the safety and tolerability of Sunitinib involved 19 persons infected with HIV was recently completed and was conducted by the AIDS Malignancy Consortium. **Sunitinib** (marketed as **Sutent** by Pfizer,, and previously known as **SU11248**) is an oral chemotherapy drug that was approved by the FDA for the treatment of renal cell carcinoma and imatinib -resistant gastrointestinal stromal tumor on January 26, 2006. Sunitinib was the first cancer drug simultaneously approved for two different indications.

The purpose of the study was to determine the safety and tolerability of Sunitinib when given to individuals who were also taking HIV antiretroviral medications. Volunteers were stratified into 2 treatment arms based on whether they were receiving antiretroviral therapy with or without Ritonavir. Ritonavir is a widely prescribed medication to combat HIV infection and a potent inhibitor of **Cytochrome P450 3A4 (CYP3A4).** CYP3A4 is mainly found in the liver and in the intestine. Its purpose is to metabolize toxins or drugs, so that they can be removed from the body.

Volunteers who participated in this study received Sunitinib orally for 1 to 6 cycles of 28 days with medication followed by a 2 week period without medication. One of the 6 volunteers receiving the Ritonavir-based therapy at a Sunitinib dose of 37.5 mg/day experienced a dose-limiting toxicity (poor wound healing) and 60% of the volunteers who received this dose of Sunitinib experienced a significant lowering of white blood cells which can lead to a heightened risk of infection. Efavirenz, like Ritonavir, is an important backbone of a number of HIV antiretroviral regimens and has an opposite effect on CYP3A4 and resulted in an increased exposure of the main Sunitinib metabolite, whereas Ritonavir caused a decreased exposure of the Sunitinib metabolite. Volunteers on other antiretroviral regimens tolerated a Sunitinib dose of 50 mg/day and had no dose-limiting toxicities.

Although no volunteer in this study had their cancer shrink in size after beginning Sunitinib, 10 volunteers had stable disease, including 8 whose tumors remained stable for a prolonged period of time.

The information gained from this study will serve as an important step towards understanding how chemotherapy drugs and HIV medications interact and defining tolerable doses of anticancer drugs in HIV-positive persons with cancer.

Reference: Rudek MA, Moore PC, Mitsuyasu RT, *et al*. A phase 1/pharmacokinetic study of Sunitinib in combination with highly active antiretroviral therapy in human immunodeficiency virus-positive patients with cancer: AIDS Malignancy Consortium trial AMC 061. *Cancer*. 2014;120(8):1194-202. (Link to Abstract).

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AIDS Malignancy Consortium Trial # 061: Sunitinib Malate in Treating HIV-Positive Patients with Cancer Receiving Antiretroviral Therapy

For more information about HIV cancer malignancies, visit the AMC website at:

http://www.AIDSCancer.org