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Many of those living with HIV face a new life-threatening challenge: cancer

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As the world marks the 30-year anniversary of the first reporting of HIV/AIDS, now comes the realization of a new challenge for people with the incurable disease. For reasons not yet clear, people with HIV face a higher rate of cancers not usually associated with HIV. This increasing rate of "non-AIDS defining cancers" includes lung, head and neck, liver, kidney, and anal cancers, among others. The alarming uptick in cancer rates highlights the critical need to understand how to treat tumors in people taking highly active anti-retroviral therapy (HAART) for HIV. Given what is known about HAART drug interactions, can newer targeted cancer therapies be given safely to patients with HIV?

To explore potential interactions between HAART and the newer cancer drugs, the AIDS Malignancy Consortium (AMC), a National Cancer Institute (NCI)-supported clinical trials group founded in 1995 to support innovative trials for AIDS-related cancers, has conducted the first of a planned series of studies. John Deeken, M.D., a research physician at Georgetown Lombardi Comprehensive Cancer Center and national chairman of the study, presented the findings today during a poster session at the 2011 annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

He says these early results already have the potential to change the way that cancer is treated in HIV patients.

"Up to this point, oncologists have not had much information about treating cancer in people taking HAART," says Deeken. "We're basically

at square one because people with HIV usually are not included in cancer clinical trials. They're excluded because physicians are worried about causing further immune suppression in HIV patients, and because HAART drugs are notorious for causing drug-drug interactions and serious side effects."

The first drug being studied is sunitinib. Sunitinib (Sutent®) may stop the growth of cancer cells by blocking blood flow to the tumor and by blocking some of the enzymes needed for cell growth. However, agents in the HAART cocktail are thought to affect the same enzymes involved in sunitinib metabolism.

The AMC chose to study sunitinib because this oral medication was approved by the Food and Drug Administration to treat kidney cancer, which is occurring at an increasing rate among HIV patients, and the drug is being studied in other cancer types that also affect HIV patients, such as lung and liver cancers.

Safety was examined separately for two groups within the phase I study. Group one included those whose HAART combination did not include ritonavir, while patients in group two were taking a ritonavir-based protease inhibitor HAART cocktail.

Between August 2009 and April 2011, a total of 19 patients were enrolled, treated, and completed at least one cycle of therapy. Sunitinib (50mg/day) was well tolerated in patients in group one – those taking non-ritonavir based HAART regimens. Patients treated with sunitinib who were in group two, those taking the ritonavir-based therapy, experienced more side effects including higher rates of neutropenia (compared to those reported on phase III studies of sunitinib).

"Already, we have important information that can impact treatment," says Deeken. "When the trial is complete, we may have data to

recommend that patients take different dosages of sunitinib based on what HAART cocktail they are taking. We also found that patients could keep taking their HIV medications safely, and that sunitinib did not affect the HIV disease status of patients in either group."

"Our HIV disease is now frequently being well controlled with HAART medications, but we are still having multiple medical problems including getting cancer earlier and more frequently," says James Weihe, a community representative for the AIDS Malignancy Consortium. "I am 60 years old and have been diagnosed with 3 minor cancers and 2 major cancers within the last 2 years. Frequently we are rejected from clinical trials just because we are HIV positive. Dr. Deeken and the work his colleagues are doing give us new hope. Their research shows that we can be included in cancer research trials if the dosages of the medications are adjusted to avoid drug-drug interactions and other side effects."

"The NCI has called for clinical trials criteria to include people with HIV though the adoption of these criteria has been slow," says Deeken. "Here we are, years after many new and effective anti-cancer treatments have been identified and we know so little about using these drugs in people who are also on therapy for their HIV. While the need for caution is understandable, it may be scientifically unjustified as well as fundamentally unfair to exclude patients with HIV from clinical trials."

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