

Immunotherapy drug found safe in treating cancer patients with HIV

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Dr. Tom Uldrick of Fred Hutchinson Cancer Research Center led the study. Credit: Robert Hood / Fred Hutch

The results of a study led by physicians at Fred Hutchinson Cancer Research Center showed that patients living with HIV and one of a variety of potentially deadly cancers could be safely treated with the immunotherapy drug pembrolizumab, also known by its brand name, KEYTRUDA.

During an ASCO presentation concurrent with release of a study in *JAMA Oncology*, Fred Hutch researcher and lead author Dr. Tom Uldrick said that in nearly all cases it was safe to use the drug in [patients](#) with [cancer](#) and HIV. The "adverse events profile," a measure of the safety of the drug in the study, was not substantially different from prior studies that excluded such patients. The results, study authors said, are likely applicable to five similar drugs that block receptors known as PD-1 or PD-L1 on the surface T cells.

"Our conclusion is that anti-PD-1 therapy is appropriate for [cancer patients](#) with well-controlled HIV, and that patients with HIV and cancer can be treated with the drug and should be included in

future immunotherapy studies," Uldrick said.

The 30-patient trial studied only pembrolizumab, the anti-PD-1 therapy manufactured by Merck. Merck provided the study drug to the National Cancer Institute (NCI). The NCI sponsored the trial. HIV-positive patients with different cancers that might respond to the drug were included in the trial. Among the cancers treated were [lung cancer](#); Kaposi sarcoma, or KS; non-Hodgkin lymphoma; liver cancer; anal cancer and advanced squamous cell skin cancer.

Fred Hutch immunotherapy researcher Dr. Mac Cheever is director of the NCI-funded Cancer Immunotherapy Trials Network, which carried out the trial, and he is senior author of the *JAMA Oncology* paper. The study was conducted at seven different cancer centers across the United States, including the HIV and AIDS Malignancy Branch of the National Cancer Institute, in Bethesda, Maryland.

Overall, the safety profile of pembrolizumab in people with HIV and cancer was similar to that noted in clinical [trials](#) in the general population. Although the primary purpose of the study was to evaluate safety, it also provided a snapshot of the anti-cancer activity of the [drug](#) on these patients. One patient with lung cancer had a complete response to treatment, and activity was also noted in important HIV-associated cancers, including non-Hodgkin lymphoma, Kaposi sarcoma and liver cancer.

An unexpected death on study from a rare KSHV-associated B-cell lymphoproliferation was noted in one patient and while the association with therapy is still unclear, it has led to recommendations to use substantial caution if anti-PD-1 therapy is considered in the setting of KSHV-associated multicentric Castleman disease. The researchers concluded that anti-PD-1 therapy may be considered for FDA approved indications in patients

with HIV who are on antiretroviral therapy and have a CD4 count above a certain threshold (100 cells per microliter of blood). However, more research is needed as to its effectiveness in the setting of HIV infection.

The FDA, Friends of Cancer Research, and the American Society of Clinical Oncology have all recommended that HIV patients should be included in more clinical trials. The NCI has generally allowed patients with HIV to enroll on the immunology studies that it sponsors with PD-1 and PD-L1 inhibitors. However, this trial was one of only two trials sponsored by the NCI to focus exclusively on patients living with HIV, and it has been the first prospective trial to report its results.

"Exclusion of people with HIV in clinical trials is a longstanding problem that grew out of the poor outcomes of AIDS patients with cancer, before there were effective antiviral therapies for HIV," Uldrick said. In prior research, Uldrick surveyed 46 recent [clinical trials](#) that led to approval of cancer drugs, and found 30 contained explicit exclusions for patients with HIV, and nine others where an exclusion was implied.

More information: Thomas S. Uldrick et al, Assessment of the Safety of Pembrolizumab in Patients With HIV and Advanced Cancer—A Phase 1 Study, *JAMA Oncology* (2019). [DOI: 10.1001/jamaoncol.2019.2244](#)

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Dr. Uldrick reported the following disclosures: Merck & Co. during the conduct of the study, and Celgene and Roche outside the submitted work. In

addition, Dr. Uldrick had a patent to the NCI and Celgene issued. Dr. Cheever reported the following disclosures: grants from NIH, NCI during the conduct of the study; as well as others from Merck, Horizon, Dendreon and Celldex outside the submitted work.

Provided by Fred Hutchinson Cancer Research Center

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