



Concerns: Anal Cancer

The Food and Drug Administration approved Zynyz (retifanlimab), the first immunotherapy for people with advanced anal cancer.

August 11, 2025 By [Liz Highleyman](#)

In May, the Food and Drug Administration approved Zynyz (retifanlimab), the first immunotherapy for people with advanced anal cancer. It is approved for use with chemotherapy for initial treatment of adults with inoperable recurrent or metastatic anal cancer and alone for those who experience disease progression or can't tolerate chemo. Zynyz is a monoclonal antibody that blocks PD-1, an immune checkpoint protein on T cells. Some tumors can hijack PD-1 to turn off immune responses; checkpoint inhibitors restore T-cell activity. The FDA approval is supported by results from the Phase III POD1UM-303 study, which enrolled previously untreated anal cancer patients, including those living with HIV. Participants randomly assigned to receive Zynyz had a 37% lower risk of disease progression or death compared with placebo recipients, and the median duration of response was about twice as long. HIV-positive participants maintained viral suppression and did not experience more or worse side effects.

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